

Alameda Alliance for Health
1240 South Loop Road
Alameda, CA 94502

Location: Microsoft Teams
Meeting ID: 243 002 854 421
Password: wCH5kt
Phone conference ID: 979 692 650#

YOU MAY SUBMIT COMMENTS ON ANY AGENDA ITEM OR ON ANY ITEM NOT ON THE AGENDA, IN WRITING VIA MAIL TO “ATTN: ALLIANCE PHARMACEUTICAL AND THERAPEUTICS COMMITTEE” 1240 SOUTH LOOP ROAD, ALAMEDA, CA 94502; OR THROUGH E-COMMENT AT bochoa@alamedaalliance.org. YOU MAY WATCH THE MEETING LIVE BY LOGGING IN VIA COMPUTER AT THE FOLLOWING LINK: [Microsoft Teams Meeting](#) OR MAY LISTEN TO THE MEETING BY CALLING IN TO THE FOLLOWING TELEPHONE NUMBER+1 510-210-0967,,979692650#. IF YOU USE THE LINK AND PARTICIPATE VIA COMPUTER, YOU MAY, THROUGH THE USE OF THE CHAT FUNCTION, REQUEST AN OPPORTUNITY TO SPEAK ON ANY AGENDIZED ITEM, INCLUDING GENERAL PUBLIC COMMENT. YOUR REQUEST TO SPEAK MUST BE RECEIVED BEFORE THE ITEM IS CALLED ON THE AGENDA. IF YOU PARTICIPATE BY TELEPHONE, YOU MAY SUBMIT ANY COMMENTS VIA THE E-COMMENT EMAIL ADDRESS DESCRIBED ABOVE OR PROVIDE COMMENT [DURING THE MEETING AT THE END OF EACH TOPIC](#).

PLEASE NOTE: THE ALAMEDA ALLIANCE FOR HEALTH IS MAKING EVERY EFFORT TO FOLLOW THE SPIRIT AND INTENT OF THE BROWN ACT AND OTHER APPLICABLE LAWS REGULATING THE CONDUCT OF PUBLIC MEETINGS, IN ORDER TO MAXIMIZE TRANSPARENCY AND PUBLIC ACCESS. DURING EACH AGENDA ITEM, YOU WILL BE PROVIDED A REASONABLE AMOUNT OF TIME TO PROVIDE PUBLIC COMMENT. THE COMMITTEE WOULD APPRECIATE, HOWEVER, IF COMMUNICATIONS OF PUBLIC COMMENTS RELATED TO ITEMS ON THE AGENDA, OR ITEMS NOT ON THE AGENDA, ARE PROVIDED PRIOR TO THE COMMENCEMENT OF THE MEETING.

AGENDA

ITEM VOTE	DESCRIPTION	TIME
I)	Call to order <i>Donna Carey, MD, Chief Medical Officer – Alameda Alliance</i> Agenda Overview	2 min -
II)	Informational Updates <i>Donna Carey, MD, Chief Medical Officer – Alameda Alliance</i> <i>Luke Lim, R.Ph., Senior Pharmacy Director – Alameda Alliance</i> - Stipend update - NCQA audit - DSNP policies wrapping up	15 min -
III)	Pharmacy Utilization Reports (Quarter 2, 2025) <i>Luke Lim, R.Ph. Senior Pharmacy Director – Alameda Alliance</i> - Top 50 Drugs by Cost - Top 50 PA Reviewed Drugs	2 min -

ADJOURN TO CLOSED SESSION (Pursuant to California Government Code Title 5, §54954.5(h))

Discussion will Concern: Review and Recommendations to changes to the AAH Formulary and utilization management for selected drug classes

Estimated Date of Public Disclosure: 09/16/2025 (formulary changes only; no trade secrets will be disclosed)

IV) E-Voting Material/Consent Agenda

The following items have been sent to the voting committee for review via E-voting

Luke Lim, R.Ph., Senior Pharmacy Director – Alameda Alliance

Benita Ochoa, CPhT, Lead Pharmacy Technician – Alameda Alliance

(All matters listed on the Consent Calendar are to be approved with one motion unless a member of the P&T Committee removes an item for separate action. Any consent calendar item for which separate action is requested shall be heard as the next Agenda item in closed session.)

Monographs/Class Reviews	Changes
Bowel Prep Agents Class Review	• No changes
Chelating Agents Class Review	• No changes
Fluoroquinolones (oral) Class Review	• No changes
Hepatitis C Agents Class Review	• No changes
Respiratory Aids and Devices Class Review	• No changes
Rho Immune Globulins Class Review	• No changes
VEGF Inhibitors Class Review	• No changes
Medication Request Guidelines	Changes
Physician Administered Medication (PAD)/ Medical Benefit Guidelines	• No changes
Off-label uses	• No changes
Safety Edit Exception	• No changes
Nuedexta (dextromethorphan/quinidine)	• No changes
Cartilaginous Repair Agents	• No changes
Memantine ER (Namenda XR)	• No changes
Vancomycin	• No changes
Multaq (dronedarone)	• No changes
Erythropoiesis-Stimulating Agents	• No changes
Drugs for Gender Dysphoria For Less Than 21 Years Old	• No changes
Drugs for Gender Dysphoria For At Least 21 Years Old	• No changes
Corticosteroids for Ulcerative Colitis and Crohn's disease	• No changes
Atovaquone-proguanil (Malarone)	• No changes
Intranasal Steroids	• No changes
Topical Acne Agents	• No changes

10 min EV

Injectable/Infusible Bone-Modifying Agents for Oncology Indications	• No changes
Alosetron (Lotronex)	• No changes
Viberzi (eluxadoline)	• No changes
Rifabutin (Mycobutin)	• No changes
Tranexamic acid (Lysteda)	• No changes
Santyl Ointment	• No changes
Topical Antibiotics	• No changes
Injectable/Infusible Agents for Osteoporosis and Paget's Disease	• No changes
Vowst	• No changes
Duvyzat	• No changes
Rho Kinase Inhibitors	• No changes
Xolremdi	• No changes
Anti-obesity medications	• Update naming conventions to show the availability of generic Qsymia
Physician Administered Drug (PAD) Guidelines	Changes
Adakveo	• No changes
Injectable/Infusible Agents for Osteoporosis and Paget's Disease	• No changes
Exondys 51	• No changes
Erythropoiesis-Stimulating Agents	• No changes
Iron-containing Products	• No changes
Tepezza	• No changes
B-Cell Maturation Antigen (BCMA) Directed Chimeric Antigen Receptor (CAR) T-Cell Therapy	• No changes
Gene Therapy for Hemophilia B	• No changes
Fecal microbiota	• No changes
Omisirge	• No changes
Qalsody (tofersen)	• No changes
Lamzede	• No changes
Enzyme Replacement Therapies for Fabry Disease	• No changes
Roctavian	• No changes
Enzyme replacement therapy for acid sphingomyelinase deficiency (ASMD)	• No changes

Rytelo (imetelstat)	• No changes
Interim Formulary Updates	
• See p. 210 in packet	
Summary of Physician Administered Drug (PAD) Updates	
• See P. 213 in packet	
Pharmacy Policy & Procedure Updates	
• RX-007 Pharmaceutical Patient Safety, Drug Recalls, Quality Assurance	
DSNP Policy & Procedure Updates	
• RX-D 008 Part D Coverage	• RX-D 11 Medicare Part D End Stage Renal Disease
• RX-D 026 Medicare Part D Annual Reporting	• RX-D-028 Medicare Part D Coordination of Benefits (COB)
• RX-D 027 Pharmacy Network Access Contracting	• RX-D 031 Medicare Part D Emergency Preparedness
• RX-D 029 Medicare Part D Low Income Subsidy	• RX-D-034 Medicare Part D Negative Formulary Change Notification
• RX-D 032 Medicare Part D Early Prescription Refill	
ED Oversight	
• None	
90 Day Maintenance List updates	
• Minor updates & Add HIV PreP	
P&T Meeting Minutes	
• P&T Meeting Minutes Q2 June 17, 2025	

V) New Business

Iryna Makukh, PharmD, Pharmacist – PerformRx

New MRG

- QL recommendations
- Vykat XR
- Immunoglobulin A (IgA) Nephropathy Agents

New PAD

- Encelto
- Nulibry
- Zevaskyn
- Amvuttra

VI) Class Reviews, Monographs, and Recommendations

Iryna Makukh, PharmD, Pharmacist – PerformRx

1. Ophthalmic Antibiotics and Antibiotic-Corticosteroid Combinations Class Review
2. Ctexli Monograph and new MRG criteria

45
min

V

VII) Medication Request Guidelines

Rahel Negash, PharmD, Pharmacist – Alameda Alliance

1. Quantity Limit Exception

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2. Antiemetics
 3. Ophthalmic Anti-inflammatory Immunomodulators
 4. Dronabinol
 5. White Blood Cell Stimulators
 6. Constipation agents
 7. Mesalamine
 8. Scabicides and Pediculicides
 9. Rifamycin Antibiotics
 10. Medications for the treatment of Multi-Drug Resistant Tuberculosis
 11. Palforzia
 12. Specialty Biologic Agents
 13. Immunizations
 14. Vyalev
 15. Antifibrotic Respiratory Tract Agents
 16. Filspari
-

VIII) Physician Administered Drug (PAD) Policies

Iryna Makukh, PharmD, Pharmacist – PerformRx

1. White Blood Cell Stimulators	10	
2. Elevidys	min	V
3. Vyalev		
-

IX) Informational Updates on New Developments in Pharmacy

Iryna Makukh, PharmD, Pharmacist – PerformRx

• New Product Review	2	
	min	V
-

X) Old Business

• MRG criteria review for Lidocaine patch, Alprazolam (Xanax), and Diuretics	2	
• New Product Review from Q2 2025	min	-
• Pharmacy strategy update (Dr. Carey)		
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RECONVENE IN OPEN SESSION

XI) Public Comment

XII) Adjournment

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ACTION / FOLLOW-UP ITEMS

PHARMACY & THERAPEUTICS COMMITTEE

Tuesday, September 16th, 2025
5:00pm – 7:00pm

ITEM	DUE DATE	RESPONSIBLE

FUTURE P&T MEETINGS	
NEXT MEETING	2025 P&T MEETINGS
December 16 2025	

The Alameda Alliance for Health Pharmacy & Therapeutics Committee welcomes you to its meetings and your interest is appreciated. If you wish to speak on a matter on the agenda, you will have the opportunity to do so in the order determined by the Chair. If you wish to speak on a matter not on the agenda, please wait until the Chair asks for public comments at the end of the regular agenda. Please be brief and limit your comments to the specific subject under discussion.

Note: Only matters within the jurisdiction of the Alameda Alliance for Health Pharmacy & Therapeutics Committee may be addressed. If necessary, the Chair may limit the total time to be devoted to public comment on any item, and the time allotted to individual speakers, to ensure sufficient time for the consideration of all matters on the agenda.

This meeting is wheelchair accessible. Please contact Rahel Negash at 510-747-6108 rnegash@alamedaalliance.org at least 72 hours before the meeting to request agenda materials in an alternative format, or any other reasonable disability-related accommodations or services that may be necessary for you to participate in and enjoy the benefits of the meeting.

636 IHSS Top 50 Drugs by Cost for 2nd Quarter 2025

- The top 50 drugs accounted for **1,374 claims** for **683 members** and cost **\$1,624,476**, which is an increase of \$160,509 in spend from the previous quarter.
- Biktarvy remains at number one, claims having gone up by 1, and there is one additional member since the previous quarter.
- Ozempic is at numbers 2, 4, and 5, with 278 total claims for 131 members. There was an increase of 4 claims and 4 members from the previous quarter.
- Vemlidy is up to number 3 with 55 claims for 22 members. There was an increase of 1 claim for 22 members from the previous quarter. This medication is managed via the Hepatitis B MRG, which requires trial and failure of, intolerance to, or reason not to use, entecavir.
- Nerlynx is up at number 6 with 7 claims for 1 member. There was an increase of 2 claims for one member from the previous quarter. This medication is managed via the Oncology MRG.

Rank	DDID	Label Name	Claims	Unique Members	Total Cost
1	201625	Biktarvy Oral Tablet 50-200-25 MG	35	15	\$142,132.78
2	218338	Ozempic (2 MG/DOSE) Subcutaneous Solution Pen-injector 8 MG/3ML	110	44	\$104,459.36
3	195609	Vemlidy Oral Tablet 25 MG	55	22	\$90,885.63
4	209911	Ozempic (1 MG/DOSE) Subcutaneous Solution Pen-injector 4 MG/3ML	84	41	\$79,464.90
5	221271	Ozempic (0.25 or 0.5 MG/DOSE) Subcutaneous Solution Pen-injector 2 MG/3ML	84	46	\$79,307.04
6	198848	Nerlynx Oral Tablet 40 MG	7	1	\$67,461.80
7	202548	Humira (2 Syringe) Subcutaneous Prefilled Syringe Kit 40 MG/0.4ML	4	1	\$53,770.28
8	223809	Cosentyx UnoReady Subcutaneous Solution Auto-injector 300 MG/2ML	7	2	\$52,135.34
9	199758	Verzenio Oral Tablet 100 MG	3	1	\$47,222.25
10	215133	Wegovy Subcutaneous Solution Auto-injector 2.4 MG/0.75ML	36	15	\$46,834.70
11	177191	Eliquis Oral Tablet 5 MG	82	37	\$46,589.51
12	214809	Skyrizi Pen Subcutaneous Solution Auto-injector 150 MG/ML	2	2	\$43,990.72
13	219135	Skyrizi Subcutaneous Solution Cartridge 360 MG/2.4ML	2	1	\$43,990.72
14	207961	Rybelsus Oral Tablet 7 MG	42	17	\$39,744.72

Rank	DDID	Label Name	Claims	Unique Members	Total Cost
15	193034	Ocaliva Oral Tablet 5 MG	2	1	\$38,895.98
16	182336	Farxiga Oral Tablet 10 MG	69	31	\$38,688.95
17	215132	Wegovy Subcutaneous Solution Auto-injector 1 MG/0.5ML	24	15	\$31,027.26
18	184849	Jardiance Oral Tablet 25 MG	52	21	\$29,923.12
19	190802	Genvoya Oral Tablet 150-150-200-10 MG	7	3	\$28,387.58
20	207962	Rybelsus Oral Tablet 14 MG	30	14	\$28,341.60
21	229056	Dupixent Subcutaneous Solution Auto-injector 300 MG/2ML	6	2	\$23,630.52
22	184045	Erlotinib HCl Oral Tablet 25 MG	3	1	\$22,717.68
23	197146	Cosentyx Sensoready (300 MG) Subcutaneous Solution Auto-injector 150 MG/ML	3	1	\$22,482.39
24	192096	Odefsey Oral Tablet 200-25-25 MG	6	2	\$22,089.90
25	201117	Steglatro Oral Tablet 15 MG	66	29	\$21,798.67
26	228549	Nemludio Subcutaneous Auto-injector 30 MG	4	1	\$20,804.80
27	229071	Mounjaro Subcutaneous Solution Auto-injector 2.5 MG/0.5ML	20	13	\$20,460.34
28	219459	Paxlovid (300/100) Oral Tablet Therapy Pack 20 x 150 MG & 10 x 100MG	14	14	\$20,257.93
29	206142	Kisqali (600 MG Dose) Oral Tablet Therapy Pack 200 MG	1	1	\$19,180.70
30	205122	Actemra ACTPen Subcutaneous Solution Auto-injector 162 MG/0.9ML	4	1	\$19,112.88
31	226896	Cimzia (2 Syringe) Subcutaneous Prefilled Syringe Kit 200 MG/ML	3	1	\$17,773.32
32	182335	Farxiga Oral Tablet 5 MG	31	16	\$17,514.25
33	120500	Dasatinib Oral Tablet 20 MG	2	1	\$17,291.62

Rank	DDID	Label Name	Claims	Unique Members	Total Cost
34	215135	Wegovy Subcutaneous Solution Auto-injector 0.25 MG/0.5ML	13	8	\$16,662.80
35	189098	Entresto Oral Tablet 24-26 MG	28	12	\$16,412.95
36	201116	Steglatro Oral Tablet 5 MG	37	16	\$15,288.62
37	218737	Radicava ORS Oral Suspension 105 MG/5ML	1	1	\$15,008.56
38	122702	Januvia Oral Tablet 100 MG	47	21	\$14,242.41
39	215134	Wegovy Subcutaneous Solution Auto-injector 0.5 MG/0.5ML	11	9	\$14,212.75
40	229051	Trulicity Subcutaneous Solution Auto-injector 1.5 MG/0.5ML	15	5	\$14,095.40
41	212379	Cabenuva Intramuscular Suspension Extended Release 600 & 900 MG/3ML	2	2	\$13,136.80
42	204204	Shingrix Intramuscular Suspension Reconstituted 50 MCG/0.5ML	55	51	\$12,964.75
43	184848	Jardiance Oral Tablet 10 MG	20	11	\$12,444.65
44	170142	Xarelto Oral Tablet 20 MG	22	10	\$12,396.51
45	229072	Mounjaro Subcutaneous Solution Auto-injector 5 MG/0.5ML	12	6	\$12,309.64
46	215136	Wegovy Subcutaneous Solution Auto-injector 1.7 MG/0.75ML	9	7	\$11,659.81
47	189100	Entresto Oral Tablet 49-51 MG	18	8	\$11,431.41
48	225121	Zepbound Subcutaneous Solution Auto-injector 10 MG/0.5ML	11	5	\$11,343.17
49	225120	Zepbound Subcutaneous Solution Auto-injector 7.5 MG/0.5ML	11	5	\$11,341.87
50	127437	FreeStyle Lite Test In Vitro Strip	162	93	\$11,155.00
TOTAL			1,374	683	\$1,624,476.34

Medi-Cal Top 50 Drugs by Cost for 2nd Quarter 2025

- The top 50 drugs accounted for 29,741 claims for 25,468 members and cost \$62,950,490 which is an increase of \$2,543,207 in spend from 1Q2025.
- Claims increased 5.7% compared with 1Q2025.
- Unique utilizers increased 6.1% compared with 1Q2025.
- Spend increased 4.2% compared with 1Q2025.
- Biktarvy down 41 claims.
- Jardiance each up about 100 claims.
- Ozempic 0.25mg 2085->2039 claims
- Wegovy 2.4mg 1004->1183 claims
- Wegovy 0.5mg 996->1149 claims
- Ozempic 2mg 1137->1242 claims
- Ozempic 1mg 1281->1305 claims
- Pursuant to 2025-2026 State Budget, effective January 1, 2026: Drugs used for weight loss and weight loss-related-indications will be excluded from Medi-Cal Rx coverage for all Medi-Cal members.

Rank	GCN	Label Name	Claims	Unique Members	Total Cost
1	44426	BIKTARVY 50-200-25 MG TABLET	928	734	\$7,065,099.59
2	36723	JARDIANCE 25 MG TABLET	2200	2023	\$3,045,229.34
3	36716	JARDIANCE 10 MG TABLET	2204	1965	\$2,897,052.49
4	49591	SKYRIZI 150 MG/ML PEN	119	110	\$2,880,802.74
5	53536	OZEMPIC 0.25-0.5 MG/DOSE PEN	2039	1594	\$2,551,427.10
6	49754	WEGOVY 2.4 MG/0.75 ML PEN	1183	855	\$2,466,291.07
7	52125	OZEMPIC 2 MG/DOSE (8 MG/3 ML)	1242	954	\$2,027,052.55
8	48208	OZEMPIC 1 MG/DOSE (4 MG/3 ML)	1305	1053	\$2,015,158.61
9	49749	WEGOVY 0.5 MG/0.5 ML PEN	1149	1000	\$1,786,054.15
10	49748	WEGOVY 0.25 MG/0.5 ML PEN	1204	1084	\$1,764,044.85
11	49752	WEGOVY 1 MG/0.5 ML PEN	1065	898	\$1,687,994.38
12	43506	HUMIRA(CF) PEN 40 MG/0.4 ML	124	101	\$1,671,181.09

Rank	GCN	Label Name	Claims	Unique Members	Total Cost
13	48277	DUPIXENT 300 MG/2 ML PEN	221	192	\$1,569,767.70
14	42624	VEMLIDY 25 MG TABLET	496	391	\$1,562,693.27
15	27418	INVEGA SUSTENNA 234 MG/1.5 ML	265	174	\$1,553,161.42
16	49753	WEGOVY 1.7 MG/0.75 ML PEN	854	686	\$1,505,365.87
17	49099	CABENUVA ER 600 MG-900 MG SUSP	184	164	\$1,496,201.24
18	33935	ELIQUIS 5 MG TABLET	1113	908	\$1,273,111.30
19	47136	TRIKAFTA 100-50-75 MG/150 MG	22	18	\$1,063,928.83
20	28159	STELARA 90 MG/ML SYRINGE	27	25	\$1,056,193.77
21	34394	FARXIGA 10 MG TABLET	751	663	\$1,052,552.20
22	40953	DESCOVY 200-25 MG TABLET	275	216	\$977,074.14
23	40133	TAGRISSO 80 MG TABLET	32	24	\$941,726.68
24	94200	DEXCOM G7 SENSOR	768	663	\$859,885.56
25	46965	RYBELSUS 7 MG TABLET	410	366	\$825,996.32
26	46966	RYBELSUS 14 MG TABLET	381	338	\$822,007.46
27	44014	HUMIRA(CF) PEN 80 MG/0.8 ML	24	18	\$809,657.37
28	97724	ENBREL 50 MG/ML SURECLICK	60	53	\$802,252.41
29	54988	ZEPBOUND 2.5 MG/0.5 ML PEN	639	581	\$787,488.53
30	43968	SYM TUZA 800-150-200-10 MG TAB	102	73	\$777,041.35
31	49487	APRETUDE ER 600 MG/3 ML VIAL	160	142	\$742,814.80
32	98637	BASAGLAR 100 UNIT/ML KWIKPEN	1477	1225	\$730,826.30
33	54989	ZEPBOUND 5 MG/0.5 ML PEN	543	456	\$723,701.96

Rank	GCN	Label Name	Claims	Unique Members	Total Cost
34	49468	COSENTYX UNOREADY 300 MG PEN	35	30	\$723,631.20
35	25200	FREESTYLE LITE TEST STRIP	4080	3914	\$698,827.70
36	37682	ABILIFY MAINTENA ER 400 MG SYR	133	94	\$661,281.33
37	97400	JANUVIA 100 MG TABLET	806	733	\$646,965.82
38	38702	INVEGA TRINZA 819 MG/2.63 ML	55	55	\$614,860.50
39	40092	GENVOYA TABLET	68	57	\$578,201.22
40	54991	ZEPBOUND 7.5 MG/0.5 ML PEN	380	315	\$540,433.45
41	54456	FERRIPROX 1,000 MG TAB(2X/DAY)	11	8	\$508,461.15
42	52475	SKYRIZI 360 MG/2.4 ML ON-BODY	26	21	\$487,889.40
43	30819	XARELTO 20 MG TABLET	404	355	\$486,239.84
44	43699	MAVYRET 100-40 MG TABLET	29	27	\$477,301.04
45	36398	MYALEPT 11.3 MG (5 MG/ML) VIAL	5	2	\$476,492.71
46	43148	ILARIS 150 MG/ML VIAL	8	6	\$474,825.29
47	43222	DUPIXENT 300 MG/2 ML SYRINGE	66	55	\$458,679.86
48	46822	RINVOQ ER 15 MG TABLET	42	28	\$445,777.38
49	48456	EVRYSDI 60 MG/80 ML(0.75MG/ML)	6	6	\$444,381.06
50	40848	TALTZ 80 MG/ML AUTOINJECTOR	21	15	\$435,405.53
TOTAL			29,741	25,468	\$62,950,490.92

Top 50 Prior Authorization Requests by Volume for the 2nd Quarter 2025

- Top 50 PA requests = 247. There were 378 total PA requests for quarter 2.
 - 64 requests (26%) were approved. This approval rate is lower by 2% than it was observed last quarter.
 - 183 requests (74%) were denied or partially approved.
- Wegovy is at numbers 1, 4, 12, 16 and 22 with 53 total requests and 11 approvals (21%).
 - Wegovy to reduce excess body weight requires a diagnosis of class III/severe obesity (BMI ≥ 40) and trial and failure or inability to use Qsymia and Contrave.
 - Wegovy to reduce the risk of major adverse cardiovascular events requires a documentation that the patient is obese or has BMI ≥ 27 , has an established cardiovascular disease (prior myocardial infarction, stroke or symptomatic peripheral arterial disease), patient is on standard of care treatment for CVD and does not have diabetes.
- Jardiance is at numbers 2 & 6 with 29 total requests and 3 approvals (10%).
 - Jardiance requires trial and failure of one of the following: metformin, branded/generic drug containing metformin, branded angiotensin receptor/neprilysin inhibitor (ARNi), generic angiotensin-converting enzyme inhibitor (ACEi), generic angiotensin receptor blocker (ARB), generic mineralocorticoid receptor antagonist (MRA), or generic beta blocker AND documentation of trial and failure, intolerance, contraindication or inability to use one preferred formulary step therapy medication.
- Zepbound is at numbers 3, 20, & 26 with 24 total requests and 7 approvals (29%).
 - Zepbound to reduce excess body weight requires a diagnosis of class III/severe obesity (BMI ≥ 40) and trial and failure or inability to use Qsymia and Contrave.
 - Zepbound for moderate to severe obstructive sleep apnea requires trial and failure regarding lifestyle changes and behavioral modifications to reach BMI $< 30 \text{ kg/m}^2$ and trial and failure or inability to use PAP therapy.
- Lidocaine 5% patch is at number 5 with 12 requests and 0 approvals (0%).
 - Lidocaine requires a diagnosis of neuropathic pain and a trial and failure of gabapentin or pregabalin and one other formulary alternative (e.g., duloxetine, venlafaxine, amitriptyline) used for neuropathic pain or morphine MME $\geq 50/\text{day}$ for 3 months.
- Vemlidy is at number 7 with 11 requests. There were 6 approvals (55%).
 - Vemlidy requires a diagnosis of Hepatitis B and trial and failure of, intolerance to, or inability to use entecavir tablets.

RANK	DRUGS	Total	Approved		Denied		Partially Approved	
1	WEGOVY Soln Auto-inj 0.25MG/0.5ML	24	3	12.50%	20	83.33%	1	4.17%

RANK	DRUGS	Total	Approved		Denied		Partially Approved	
2	JARDIANCE Tablet 10MG	18	1	5.56%	13	72.22%	4	22.22%
3	ZEPBOUND Soln Auto-inj 2.5MG/0.5ML	18	3	16.67%	13	72.22%	2	11.11%
4	WEGOVY Soln Auto-inj 2.4MG/0.75ML	16	5	31.25%	8	50.00%	3	18.75%
5	LIDOCAINE Patch 5%	12	0	0.00%	11	91.67%	1	8.33%
6	JARDIANCE Tablet 25MG	11	2	18.18%	6	54.55%	3	27.27%
7	VEMLIDY Tablet 25MG	11	6	54.55%	4	36.36%	1	9.09%
8	XIIDRA Solution 5%	8	1	12.50%	6	75.00%	1	12.50%
9	OZEMPIC (0.25 OR 0.5 MG/DOSE) Soln Pen-inj 2MG/3ML	8	3	37.50%	4	50.00%	1	12.50%
10	CONTRACE Tablet ER 12HR 8;90MG	7	2	28.57%	4	57.14%	1	14.29%
11	REPATHA SURECLICK Soln Auto-inj 140MG/ML	7	3	42.86%	3	42.86%	1	14.29%
12	WEGOVY Soln Auto-inj 1MG/0.5ML	6	2	33.33%	3	50.00%	1	16.67%
13	OXYCODONE HCL Tablet 5MG	6	6	100.00%	0	0.00%	0	0.00%
14	MOUNJARO Soln Auto-inj 2.5MG/0.5ML	5	5	100.00%	0	0.00%	0	0.00%
15	PROLIA Soln Pref Syr 60MG/ML	4	1	25.00%	3	75.00%	0	0.00%
16	WEGOVY Soln Auto-inj 0.5MG/0.5ML	4	0	0.00%	4	100.00%	0	0.00%
17	ZTLIDO Patch 1.8%	4	0	0.00%	4	100.00%	0	0.00%
18	SKYRIZI PEN Soln Auto-inj 150MG/ML	3	1	33.33%	2	66.67%	0	0.00%
19	FINASTERIDE Tablet 1MG	3	0	0.00%	3	100.00%	0	0.00%
20	ZEPBOUND Soln Auto-inj 7.5MG/0.5ML	3	1	33.33%	1	33.33%	1	33.33%
21	FARXIGA Tablet 10MG	3	2	66.67%	0	0.00%	1	33.33%
22	WEGOVY Soln Auto-inj 1.7MG/0.75ML	3	1	33.33%	2	66.67%	0	0.00%
23	NURTEC Tablet Disintegrating 75MG	3	0	0.00%	2	66.67%	1	33.33%
24	CEQUA Solution 0.09%	3	1	33.33%	1	33.33%	1	33.33%
25	TACROLIMUS Ointment 0.1%	3	1	33.33%	1	33.33%	1	33.33%
26	ZEPBOUND Soln Auto-inj 10MG/0.5ML	3	3	100.00%	0	0.00%	0	0.00%
27	TOUJEO MAX SOLOSTAR Soln Pen-inj 300UNIT/ML	3	0	0.00%	1	33.33%	2	66.67%
28	LINZESS Capsule 72MCG	3	0	0.00%	3	100.00%	0	0.00%
29	MIRABEGRON ER Tablet ER 24HR 25MG	3	1	33.33%	1	33.33%	1	33.33%
30	RAMELTEON Tablet 8MG	2	0	0.00%	1	50.00%	1	50.00%
31	BASAGLAR KWIKPEN Soln Pen-inj 100UNIT/ML	2	1	50.00%	1	50.00%	0	0.00%
32	TERIPARATIDE Soln Pen-inj 620MCG/2.48ML	2	0	0.00%	2	100.00%	0	0.00%
33	CYCLOSPORINE Emulsion 0.05%	2	1	50.00%	0	0.00%	1	50.00%
34	PHENTERMINE HCL Capsule 15MG	2	0	0.00%	1	50.00%	1	50.00%
35	DICLOFENAC SODIUM Gel 3%	2	0	0.00%	2	100.00%	0	0.00%
36	BUDESONIDE Suspension 0.5MG/2ML	2	1	50.00%	1	50.00%	0	0.00%

RANK	DRUGS	Total	Approved		Denied		Partially Approved	
37	DIFLUPREDNATE Emulsion 0.05%	2	0	0.00%	2	100.00%	0	0.00%
38	TRELEGY ELLIPTA Aero Pow Br Act 200;62.5;25MCG/ACT	2	0	0.00%	2	100.00%	0	0.00%
39	EZETIMIBE Tablet 10MG	2	1	50.00%	1	50.00%	0	0.00%
40	CICLOPIROX OLAMINE Cream 0.77%	2	0	0.00%	2	100.00%	0	0.00%
41	ADBRY Soln Pref Syr 150MG/ML	2	1	50.00%	1	50.00%	0	0.00%
42	QSYMIA Capsule ER 24HR 3.75;23MG	2	0	0.00%	2	100.00%	0	0.00%
43	FEBUXOSTAT Tablet 40MG	2	0	0.00%	1	50.00%	1	50.00%
44	ROCKLATAN Solution 0.02;0.005%	2	1	50.00%	1	50.00%	0	0.00%
45	HUMALOG KWIKPEN Soln Pen-inj 100UNIT/ML	2	1	50.00%	0	0.00%	1	50.00%
46	SYNTHROID Tablet 75MCG	2	1	50.00%	1	50.00%	0	0.00%
47	INSULIN DEGLUDEC FLEXTOUCH Soln Pen-inj 100UNIT/ML	2	1	50.00%	1	50.00%	0	0.00%
48	TRANEXAMIC ACID Tablet 650MG	2	1	50.00%	1	50.00%	0	0.00%
49	LINZESS Capsule 145MCG	2	0	0.00%	1	50.00%	1	50.00%
50	TRETINOIN Cream 0.025%	2	0	0.00%	2	100.00%	0	0.00%
TOTAL		247	64	26%	149	60%	34	14%

Medi-Cal Top 50 Claims by Volume for 2nd Quarter 2025

- The top 50 drugs accounted for 224,703 claims for 201,794 members at a cost of \$4,993,486. This is a 1256 claim increase (+0.5%) from 2Q2025 and cost increase of \$143,867 (+3%).
- Chronic condition drugs appear as #4, and not again until #9.
- Analgesics occupy #1 (diclofenac), #3 (ibuprofen), #5 (APAP) of the top 10
- Allergies occupy #2 (fluticasone), #6 (cetirizine), #8 (loratadine)

Rank	GCN	Label Name	Claims	Unique Members	Total Cost
1	45680	DICLOFENAC SODIUM 1% GEL	11295	9563	\$330,935.34
2	62263	FLUTICASONE PROP 50 MCG SPRAY	10840	9813	\$243,522.18
3	35742	IBUPROFEN 600 MG TABLET	10120	9129	\$144,774.71
4	00161	ASPIRIN EC 81 MG TABLET	9027	8373	\$102,161.17
5	16965	ACETAMINOPHEN 500 MG CAPLET	8623	7817	\$112,494.95
6	49291	CETIRIZINE HCL 10 MG TABLET	8552	7888	\$130,667.76
7	22913	ALBUTEROL HFA 90 MCG INHALER	7228	5943	\$258,430.12
8	60563	LORATADINE 10 MG TABLET	7113	6344	\$111,678.13
9	43721	ATORVASTATIN 20 MG TABLET	6260	5837	\$96,851.24
10	02683	AMLODIPINE BESYLATE 5 MG TAB	5949	5241	\$111,657.30
11	43722	ATORVASTATIN 40 MG TABLET	5829	5353	\$98,517.83
12	02682	AMLODIPINE BESYLATE 10 MG TAB	5378	4757	\$104,413.47
13	86212	POLYETHYLENE GLYCOL 3350 POWD	5057	4606	\$128,129.03
14	10857	METFORMIN HCL 1,000 MG TABLET	5047	4628	\$86,372.89
15	22913	VENTOLIN HFA 90 MCG INHALER	4957	4317	\$283,370.73
16	10810	METFORMIN HCL 500 MG TABLET	4583	4017	\$71,705.18

Rank	GCN	Label Name	Claims	Unique Members	Total Cost
17	46430	FAMOTIDINE 20 MG TABLET	4576	4018	\$67,985.86
18	00781	GABAPENTIN 300 MG CAPSULE	4487	3645	\$79,780.55
19	00223	VITAMIN D3 25 MCG TABLET	4271	4064	\$52,581.05
20	04348	OMEPRazole DR 20 MG CAPSULE	4161	3622	\$65,501.13
21	25200	FREESTYLE LITE TEST STRIP	4080	3914	\$698,827.70
22	94422	VITAMIN D2 1.25MG(50,000 UNIT)	3965	3649	\$60,576.51
23	43720	ATORVASTATIN 10 MG TABLET	3847	3546	\$57,960.42
24	40120	PANTOPRAZOLE SOD DR 40 MG TAB	3804	3210	\$60,328.48
25	20045	ONDANSETRON ODT 4 MG TABLET	3755	3415	\$55,831.13
26	16965	ACETAMINOPHEN 500 MG TABLET	3735	3384	\$34,067.09
27	99882	VITAMIN D3 50 MCG SOFTGEL	3700	3583	\$45,099.52
28	09101	DOCUSATE SODIUM 100 MG SOFTGEL	3305	2901	\$41,277.33
29	97503	FERROUS GLUCONATE 324 MG TAB	3285	2974	\$46,651.89
30	39661	AMOXICILLIN 500 MG CAPSULE	3194	2950	\$43,263.06
31	50272	LIDOCAINE 5% PATCH	3191	2797	\$275,042.46
32	14851	LOSARTAN POTASSIUM 50 MG TAB	3056	2739	\$63,299.30
33	94781	FOLIC ACID 1 MG TABLET	2948	2594	\$49,934.73
34	48191	TAMSULOSIN HCL 0.4 MG CAPSULE	2932	2566	\$49,678.28
35	35793	NAPROXEN 500 MG TABLET	2929	2596	\$48,236.23
36	29189	SYSTANE BALANCE 0.6% EYE DROP	2910	2732	\$102,800.89
37	14850	LOSARTAN POTASSIUM 25 MG TAB	2856	2566	\$54,584.19

Rank	GCN	Label Name	Claims	Unique Members	Total Cost
38	35744	IBUPROFEN 800 MG TABLET	2817	2463	\$44,116.02
39	94444	MONTELUKAST SOD 10 MG TABLET	2767	2503	\$47,045.66
40	39802	CEPHALEXIN 500 MG CAPSULE	2703	2536	\$39,220.56
41	16391	TRAZODONE 50 MG TABLET	2685	2096	\$44,483.62
42	35741	IBUPROFEN 400 MG TABLET	2650	2526	\$36,581.92
43	16964	ACETAMINOPHEN 325 MG TABLET	2633	2486	\$26,275.52
44	13943	HYDROXYZINE HCL 25 MG TABLET	2604	2054	\$42,325.77
45	30370	CLOTRIMAZOLE 1% TOPICAL CREAM	2600	2400	\$41,062.93
46	94200	FREESTYLE 28G LANCETS	2593	2539	\$46,260.63
47	43032	METRONIDAZOLE 500 MG TABLET	2590	2411	\$34,722.40
48	31242	TRIAMCINOLONE 0.1% OINTMENT	2523	2328	\$54,517.60
49	23323	CALCIUM 600 MG-VIT D3 10MCG TB	2350	2230	\$34,043.49
50	29840	BENZONATATE 100 MG CAPSULE	2343	2131	\$33,840.66
TOTAL			224,703	201,794	\$4,993,486.61

Bowel Prep Agents

Executive Summary

Class Overview

Bowel preparation (“prep”) regimens are most commonly used in the setting of colonoscopy but also prior to planned elective colon resection, procedures with the potential to injure the bowel (e.g. advanced endometriosis, staging for gynecologic malignancies), and barium enema x-ray examinations. The purpose of bowel prep in the setting of colonoscopy is clear visualization and accurate diagnosis; in the surgical setting, bowel prep is used to reduce the risk of resultant infection. There are various formulations available on the market, most of which are orally administered solutions for reconstitution or dilution – hypertonic [e.g. Suprep (sodium, potassium and magnesium sulfates)]; isotonic [e.g. polyethylene glycol-electrolyte (PEG-ES) solutions]; hypotonic [e.g. over-the-counter Miralax (PEG-3350) + bisacodyl + magnesium citrate, this regimen is not Food and Drug Administration (FDA) approved]. One regimen (Sutab) is in tablet form with instructions to drink with large volumes of clear liquid. Additionally, sodium phosphate (Fleet) enemas are commonly used as a preparation for sigmoidoscopy.

A multi-society task force including the American Society for Gastrointestinal Endoscopy (ASGE), American College of Gastroenterology (ACG), and the American Gastroenterological Association (AGA) collaborate on recommendations for optimizing adequacy of bowel cleansing for colonoscopy, with a recent update to guidelines in 2025. The task force asserts no clear first-line choice of agent; selection of a bowel preparation regimen that considers the individual's medical history, medications, and, when available, the adequacy of bowel preparation reported from prior colonoscopies is recommended. Lower volume preps are suggested for most patients, and those at risk for volume overload or electrolyte disturbances should avoid hyperosmotic regimens. Split-dose regimens (typically half of the laxative product consumed the day prior to the procedure and the other half on the day of procedure) are recommended for most patients as well.

Specific to the pediatric population, the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) guideline was last updated in 2014, and offers best practices for cleanout regimens which include an osmotic laxative agent (PEG or non-PEG based), usually combined with the stimulant laxative bisacodyl. A preference of agents or single vs split dose regimens is not outlined.

There are no bowel prep products in the pipeline anticipated to be approved within the next 6 months. Many products in this class are available generically.

Utilization Findings

There were 70 claims for 69 members, for a total cost of \$1,737.91 and an average cost per claim of \$24.83. The most highly utilized medication was PEG-ES (Na₂SO₄, NaHCO₃, NaCl, KCl) (Golytely®) 236 g powder for reconstitution, with 56 claims, followed by Peg-electrolyte (NaCl, NaHCO₃, KCl) (NuLYTELY®) 420 g oral solution with 9 claims. There were 2 prior authorization requests with 1 approval (50%).

Recommendations

- No changes

Clinical Summary

Bowel preparation (“prep”) regimens are most commonly used in the setting of colonoscopy but also prior to planned elective colon resection, procedures with the potential to injure the bowel (e.g. advanced endometriosis, staging for gynecologic malignancies), and barium enema x-ray examinations. The purpose of bowel prep in the setting of colonoscopy is clear visualization and accurate diagnosis; in the surgical setting, bowel prep is used to reduce the risk of resultant infection. There are various formulations available on the market, most of which are orally administered solutions for reconstitution or dilution – hypertonic [e.g. Suprep (sodium, potassium and magnesium sulfates)]; isotonic [e.g. polyethylene glycol-electrolyte (PEG-ES) solutions]; hypotonic [e.g. over-the-counter Miralax (PEG-3350) + bisacodyl + magnesium citrate, this regimen is not Food and Drug Administration (FDA) approved]. One regimen (Sutab) is in tablet form with instructions to drink with large volumes of clear liquid. Additionally, sodium phosphate (Fleet) enemas are commonly used as a preparation for sigmoidoscopy.

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Practice Guidelines

Jacobson BC, Anderson JC, Burke CA, et al. Optimizing bowel preparation quality for colonoscopy: consensus recommendations by the US Multi-Society Task Force on Colorectal Cancer. *Gastrointest Endosc.* 2025;101(4):702-732. doi:10.1016/j.gie.2025.02.010.

- We do not recommend one bowel preparation purgative as superior to others about bowel preparation adequacy for ambulatory patients at low risk for inadequate bowel preparation (strong recommendation, high-quality evidence).
- We suggest 2 L bowel preparation regimens instead of 4 L regimen preparation (weak recommendation, moderate-quality evidence).
- We recommend the selection of a bowel preparation regimen that considers the individual's medical history, medications, and, when available, the adequacy of bowel preparation reported from prior colonoscopies (strong recommendation, moderate-quality evidence).
- We recommend against the use of hyperosmotic regimens in individuals at risk for volume overload or electrolyte disturbances (strong recommendation, high-quality evidence).
- We recommend a split-dose administration of bowel preparation purgatives for all patients, regardless of high-volume or low-volume preparation (strong recommendation, high-quality evidence).
- We recommend that a same-day regimen is an acceptable alternative to split dosing for individuals undergoing an afternoon colonoscopy (strong recommendation, high-quality evidence).
- We suggest that a same-day regimen is an inferior alternative to split dosing for individuals undergoing a morning colonoscopy (weak recommendation, low-quality evidence).
- For individuals using a split-dose regimen for colonoscopy preparation, we recommend the consumption of the second portion begin 4–6 hr before the time of colonoscopy and be completed at least 2 hr before the procedure start (strong recommendation, moderate-quality evidence).
- We suggest the adjunctive use of oral simethicone for bowel preparation before colonoscopy (weak recommendation, moderate-quality evidence).
- We suggest against the routine use of non simethicone adjuncts for bowel preparation before colonoscopy (weak recommendation, low-quality evidence).
- When patients report incomplete adherence to the bowel preparation regimen or offer statements suggesting that their bowel preparation may not be adequate (e.g., dark bowel effluent), we suggest insertion of the colonoscope to the sigmoid colon to confirm inadequacy before aborting the procedure (weak recommendation, low-quality evidence).
- We recommend bowel preparation quality be assessed only after all washing and suctioning have been completed, using reliably understood descriptors that communicate the adequacy of the preparation (strong recommendation, moderate-quality evidence).
- We recommend the term “adequate bowel preparation” be used to indicate that standard screening or surveillance intervals can be assigned based on the findings of the colonoscopy (strong recommendation, moderate-quality evidence).
- We suggest the routine use of irrigation pumps to assist with bowel preparation during colonoscopy (weak recommendation, very low-quality evidence).
- We suggest the use of same-day salvage maneuvers when feasible for inadequate bowel preparations (weak recommendation, moderate-quality evidence).
- We recommend routine tracking of the rate of adequate bowel preparations at the level of individual endoscopists and at the level of the endoscopy unit (strong recommendation, moderate-quality evidence).

- We recommend an endoscopy unit-level and individual endoscopist-level bowel preparation adequacy rate of $\geq 90\%$ (strong recommendation, moderate-quality evidence).
- When the bowel preparation is deemed inadequate to allow assigning standard screening or surveillance intervals, we recommend rescheduling a colonoscopy within 12 mo for screening or surveillance colonoscopies, and as soon as possible (i.e. generally within 3 mo) for those performed for an abnormal non colonoscopic colorectal cancer screening test (strong recommendation, moderate-quality evidence).
- In the setting of a previous inadequate bowel preparation, we recommend modifications to bowel preparation instructions to include 1 or more of the following: increased attention to communicating the bowel preparation regimen instructions; increased use of patient navigation; restricting the intake of vegetables and legumes for 2 to 3 d before colonoscopy; allowing only clear liquids on the day before colonoscopy; the addition of promotility agents; treatment of underlying constipation; temporary cessation of anticholinergic, opioid, or other constipating medications; and/or the use of high-volume bowel preparation regimens (strong recommendation, moderate-quality evidence).
- We recommend individuals at high risk for inadequate bowel preparation quality be managed like individuals with a prior inadequate bowel preparation, with modifications to their bowel preparation regimen as previously described (strong recommendation, moderate-quality evidence).
- We suggest the following bowel preparation regimen for individuals at high risk for inadequate bowel preparation quality: split-dose 4 L polyethylene glycol-electrolyte lavage solution + 15 mg bisacodyl the afternoon before the colonoscopy and a low-residue diet 3 and 2 d before colonoscopy changing to clear-liquid diet the day before colonoscopy (weak recommendation, low-quality evidence).

Recommendation Definitions

Recommendation Strength	Definition
Strong	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted. The less values and preferences vary, or the lesser the uncertainty in values and preferences, the higher the likelihood that a strong recommendation is warranted. The lower the costs of an intervention, the higher the likelihood that a strong recommendation is warranted.
Weak	The narrower the gradient between the desirable and undesirable effects, the higher the likelihood that a weak recommendation is warranted. The lower the quality of evidence, the higher the likelihood that a weak recommendation is warranted. The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted. The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted.

Quality of Evidence	Definition
High	Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low	Any estimate of effect is very uncertain

Pall H, Zacur GM, Kramer RE, et al. Bowel Preparation for Pediatric Colonoscopy: Report of the NASPGHAN Endoscopy and Procedures Committee. J Pediatr Gastroenterol Nutr. 2014 Sep;59(3):409-16. doi: 10.1097/MPG.0000000000000447.

NASPGHAN best practices cleanout regimens

Option 1: PEG-3350, 1-day cleanout	<50 kg = $4 \text{ g} \cdot \text{kg}^{-1} \cdot \text{day}^{-1}$ * + bisacodyl 5 mg >50 kg = 238 g in 1.5 L sports drink* + bisacodyl 10 mg
Option 2: PEG-3350, 2-day cleanout	<50 kg = $2 \text{ g} \cdot \text{kg}^{-1} \cdot \text{day}^{-1}$ * + bisacodyl 5 mg >50 kg = $2 \text{ g} \cdot \text{kg}^{-1} \cdot \text{day}^{-1}$ * + bisacodyl 10 mg
Option 3: NG cleanout	PEG-ELS: $25 \text{ mL} \cdot \text{kg}^{-1} \cdot \text{h}^{-1}$, maximum 450 mL/h [†] Sulfate-free PEG-ELS: $25 \text{ mL} \cdot \text{kg}^{-1} \cdot \text{h}^{-1}$, maximum 450 mL/h [†]
Option 4: non- PEG cleanout	Magnesium citrate $4\text{--}6 \text{ mL} \cdot \text{kg}^{-1} \cdot \text{day}^{-1}$ + bisacodyl 5–10 mg

The vast majority (>90%) of children should not need NG cleanout and inpatient stay unless persistent vomiting or history of failed procedure because of poor bowel preparation. Patients with significant stool burden may benefit from modified regimen, that is, doubling duration of cleanout in option 1. NG = nasogastric tube; PEG = polyethylene glycol; PEG-3350 = a specific polyethylene glycol product; PEG-ELS = PEG with electrolytes.

*Should be administered for 4 to 6 hours.

[†]Until effluent is clear or up to 4 L and then reassess.

Formulary Placement, Utilization and Cost Experience (04-01-2025 to 06-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Bowel Prep Agents-Rx								
peg-electrolyte (NaCl, NaHCO ₃ , KCl) (NuLYTELY®) solution 420 gram oral solution	9	9	\$284.64	\$31.63	0	0 (0%)	F	No change
PEG-Prep [PEG-ES (NaCl, NaHCO ₃ , KCl, Bisac)](Halflytely® with bisacodyl and flavor pack) 5 mg-210 gram oral kit†	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Sodium, potassium and magnesium sulfates (Suprep®) Bowel Prep Kit 17.5 gram-3.13 gram-1.6 gram oral solution	0	0	\$0.00	\$0.00	1	0 (0%)	NF	No change
Clenpiq™ (sodium picosulfate, magnesium oxide, ascorbic acid) 10 mg-3.5 g-12 g/175 mL solution	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Plenvu® [PEG-ES (Na ₂ SO ₄ , NaCl, KCl, sodium ascorbate, ascorbic acid)] 140 gram-9 gram-5.2 gram powder pack	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Sutab® (sodium sulfate, potassium chloride, and magnesium sulfate) 1.479-0.188-0.225 gram tablet	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
[PEG-ES (Na ₂ SO ₄ , NaCl, KCl; ascorbic acid, sodium ascorbate)] (MoviPrep®) 100 g powder for reconstitution	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
PEG-ES (Na ₂ SO ₄ , NaHCO ₃ , NaCl, KCl) (Golytely®) 236 g powder for reconstitution	56	55	\$1,148.46	\$20.51	0	0 (0%)	F (1 fill per 90 days)	No change
PEG-ES ((Na ₂ SO ₄ , NaHCO ₃ , NaCl, KCl) (Colyte® w/Flavor packs)) 240 g powder for reconstitution	3	3	\$56.37	\$18.79	0	0 (0%)	F (1 fill per 90 days)	No change
Suflave™ powder (PEG 3350-KCl-NaCl-NaSulf-MgSul) Oral Solution Reconstituted 178.7 GM	2	2	\$248.44	\$124.22	1	1 (100%)	NF	No change
TOTAL	70	69	\$1,737.91	\$24.83	2	1 (50%)		

Key (as applicable) F = Formulary, no restrictions; F-QL = Formulary, quantity limit applies; F-AL = Formulary, age limit applies; F-ST = Formulary, step therapy applies; F-PA = Formulary, PA required; NF = Non-formulary; X = Excluded

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Chelators

Executive Summary

Class Overview

Chelating agents are medications that form chelates within the body to help remove excess metals including copper (Cu), iron (Fe), and lead (Pb). A chelate is a chemical compound formed between a metal ion and the chelating agent. Chelators can form several bonds to a single metal ion. The resulting chelates can be excreted from the body, making these medications useful in treating Wilson disease, iron overload, and lead poisoning. Wilson disease is a rare genetic disorder that prevents the liver from properly eliminating copper resulting in its accumulation in the liver, brain and eyes. Although liver transplantation is the only curative measure for this disease, chelating medications such as trientine (Syprine®, Cuvrior™), penicillamine (Depen®, Cuprimine®), and Galzin® (zinc acetate) are mainstays of therapy to reduce copper levels and improve patient quality of life. Deferasirox (Exjade®, Jadenu®), Ferriprox™ (deferiprone), and deferoxamine (Desferal®) all have FDA indications for the treatment of iron overload. Iron overload is caused by increased iron intake (e.g., from blood transfusions) or increased iron absorption (e.g., hereditary hemochromatosis [HH], ineffective erythropoiesis that occurs in certain inherited anemias, and liver disease). Excessive iron stores must be treated to prevent end organ damage. Important in the treatment of severe, symptomatic lead toxicity are Chemet® (succimer) and Calcium Disodium Versenate (edetate calcium disodium). Asymptomatic cases of lead toxicity are treated with remediation and removal of the source of lead exposure. The scope of this class review will only be on chelating agents for the treatment of Wilson disease, thalassemia, HH, and lead poisoning.

Utilization Findings

There were no claims and no prior authorization requests.

Recommendations

- No changes

Clinical Summary

Chelating agents are medications that form chelates within the body to help remove excess metals including copper (Cu), iron (Fe), and lead (Pb). A chelate is a chemical compound formed between a metal ion and the chelating agent. Chelators can form several bonds to a single metal ion. The resulting chelates can be excreted from the body, making these medications useful in treating Wilson disease, iron overload, and lead poisoning.

Wilson disease is an inherited autosomal recessive disorder occurring in 1 in 30,000 live births and leads to impaired function of the intracellular copper transporter, ATP7B. Copper build-up occurs primarily in the liver, brain, and cornea and over time, the liver becomes cirrhotic. Neurologic manifestations may also occur including dysarthria, gait abnormalities, dystonia, drooling, and tremor. Some patients may also experience psychiatric manifestations including depression, personality changes, impulsiveness, and in severe cases, psychosis. Although liver transplantation is the only curative measure for this disease, chelating medications such as trientine (Syprine®), penicillamine (Depen®, Cuprimine®), and Galzin® (zinc acetate) are mainstays of therapy to reduce copper levels and improve patient quality of life. Penicillamine or trientine should be used as initial treatment for acute, symptomatic patients with Wilson disease. Presymptomatic patients should be treated with zinc acetate, penicillamine, or trientine. Cuvrior™ (trientine tetrahydrochloride), an alternative salt version comparable to the existing hydrochloride salt version, was approved in April 2022 for the treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine.

Iron overload is caused by increased iron intake (e.g., from blood transfusions) or increased iron absorption (e.g., HH, ineffective erythropoiesis that occurs in certain inherited anemias, and liver disease). Excessive iron stores must be treated to prevent end organ damage. Chelation therapy is recommended in iron-overloaded, transfusion-dependent patients (e.g., beta thalassemia major [TM], severe beta thalassemia intermedia, sickle cell anemia, myelodysplasia, aplastic anemia, Diamond-Blackfan anemia) and patients with hemochromatosis and unstable hemodynamic status because phlebotomy cannot be used in these patient populations. In patients with hemochromatosis eligible for phlebotomy, this is preferred due to high efficacy, avoidance of side effects, and paucity of clinical data for chelators in this setting. Chelation therapy is also recommended in non-transfusion dependent thalassemia (NTDT) as well as other iron-overloaded conditions. Deferasirox (Exjade®, Jadenu®), Ferriprox™ (deferiprone), and deferoxamine (Desferal®) all have FDA indications for the treatment of iron overload. Deferoxamine must be given by continuous infusion, either subcutaneously (SQ) or intravenously (IV), while deferiprone and deferasirox are orally active. Each has its own benefits, toxicities, and requirements for monitoring of side effects.

Acute lead poisoning can occur due to occupational or environmental exposure. Chemet® (succimer) is labeled for use in pediatric patients with lead poisoning and retains an off-label use for adults. Dimercaprol and calcium disodium versenate are indicated to treat lead poisoning in pediatric patients as well as adults. Lead chelation therapy is only ever used for symptomatic patients or those with severely high blood lead levels. Rather, asymptomatic lead-exposed patients with low to moderate blood lead levels are treated by removing the source of lead exposure.

There are currently no drugs in phase III or later development for the treatment of Wilson disease, iron overload, or lead poisoning. No existing agents are under investigation for a label expansion and no new agents are up for approval within the upcoming year.

Indications, Dosing and Administration

Medication	Indications	Dosing/Administration
Copper Chelators		
Trientine hydrochloride (Syprine®) 250, 500 mg oral capsule	Wilson disease in patients who are intolerant of penicillamine	- Adult: 750 mg to 1250 mg/day orally given in divided doses 2 to 4 times daily (max: 2g/day) - Pediatric: 20 mg/kg/day orally in 2 to 3 divided doses (max: 1500 mg/day)
Cuvrior™ (trientine tetrahydrochloride) 300 mg oral tablet	Wilson disease in patients who are de-coppered and tolerant to penicillamine	300 to 3000 mg/day orally in 2 equally divided doses based on penicillamine total daily dose
Penicillamine (Cuprimine®) 250 mg oral capsule Penicillamine (Depen® Titratabs) 250 mg oral tablet	Cystinuria	- Adult: 1 to 4 g/day orally in 4 divided doses - Pediatric: 20 to 40 mg/kg/day orally in 4 divided doses (max: 1200 mg/day)
	Wilson disease	- Adult: 750 mg to 1500 mg/day orally in divided doses (max: 2g/day) - Pediatric: 20 mg/kg/day orally in 2 to 3 divided doses
Galzin® (zinc acetate) 25 mg, 50 mg oral capsule	Wilson disease, maintenance treatment following chelation therapy	- Adult: 50 mg orally 3 times daily - Pediatric (≥ 10 years): 25 mg to 50 mg orally 3 times daily
Iron Chelators		
Deferoxamine (Desferal®) 500 mg, 2 g solution for injection	Acute iron toxicity	1g, either IM or IV, may be followed by 500 mg every 4 hours for 2 doses (max: 6 g/day)
	Chronic iron overload	- IM: 500 mg to 1 g/day (max: 1 g/day) - IV: 40 to 50 mg/kg/day (max: 60 mg/kg/day) over 8 to 12 hours for 5 to 7 days per week - SQ: 1 g to 2 g/day or 20 to 40 mg/kg/day (max: 60 mg/kg/day) over 8 to 12 hours for 5 to 7 days per week
Deferasirox (Exjade®) 125 mg, 250 mg, 500 mg oral dispersible tablet	- Chronic iron overload due to transfusions - Chronic iron overload in non-transfusion-dependent thalassemia syndromes	- Chronic iron overload due to transfusions: 20 to 40 mg/kg orally once daily - Chronic iron overload in non-transfusion-dependent thalassemia syndromes: 10 to 20 mg/kg orally once daily
Deferasirox (Jadenu®) 90 mg oral tablet Deferasirox (Jadenu® Sprinkle) 90 mg oral granules in packet		- Chronic iron overload due to transfusions: 14 to 28 mg/kg once daily - Chronic iron overload in non-transfusion-dependent thalassemia syndromes: 7 to 14 mg/kg orally once daily
Deferiprone (Ferriprox™) 500, 1,000 mg tablet	Transfusional iron overload	75 mg/kg/day orally in 2 divided doses (using 1000 mg twice-a-day tablet formulation only) or 3 divided doses

Medication	Indications	Dosing/Administration
Ferriprox™ (deferiprone) 100 mg/mL oral solution		(using oral solution, 500 mg tablet, or 1,000 mg 3-times-a-day tablet formulation) (max: 99 mg/kg/day)
Lead (and Other) Chelators		
Chemet® (succimer) 100 mg oral capsule	Arsenic poisoning (off-label)	10 mg/kg orally 3 times daily for 5 days followed by 10 mg/kg orally twice daily for 14 days
	Lead poisoning	
	Mercury poisoning (off-label)	
Calcium Disodium Versenate 200 mg/mL injection solution	Lead poisoning (acute and chronic), lead encephalopathy, lead nephropathy	• Symptomatic patients or patients whose blood lead level (BLL) is >100 mcg/dL: ○ 1500 mg/m²/day or 50 to 75 mg/kg/day IM or IV for 5 days • Lead encephalopathy: ○ 1000 to 1500 mg/m²/day or 25 to 75 mg/kg/day IM or IV for 5 days • Lead nephropathy: ○ SCr 2 to 3 mg/dL: 500 mg/m² IM or IV every 24 hours for 5 days ○ SCr 3 to 4 mg/dL: 500 mg/m² IM or IV every 48 hours for 3 doses ○ SCr >4 mg/dL: 500 mg/m² IM or IV once weekly

Boxed Warnings and Contraindications

Medication	Boxed Warnings	Contraindications
Copper Chelators		
Trientine (Syprine®, Cuvrior™)	None	Hypersensitivity
Penicillamine (Cuprimine®, Depen® Titratabs)	Experienced physician: Should be administered under close supervision of a physician familiar with dosage and toxicity considerations Toxicity symptoms: Warn patients to promptly report any symptoms suggesting toxicity (fever, sore throat, chills, bruising, bleeding)	• Renal insufficiency (in rheumatoid arthritis [RA] patients) • Breast-feeding • Pregnancy (in RA patients) • Previous penicillamine-related aplastic anemia or agranulocytosis
Galzin® (zinc acetate)	None	Hypersensitivity
Iron Chelators		
Deferoxamine (Desferal®)	None	• Hypersensitivity • Severe renal disease • Anuria
Deferasirox (Exjade®, Jadenu®)	Gastrointestinal (GI) hemorrhage: GI hemorrhages, which may be fatal, can occur and more likely in elderly patients with advanced hematologic malignancies or low platelet counts Hepatic failure: Hepatic injury and failure may occur. Avoid use in patients with severe hepatic impairment and reduce dose with moderate hepatic impairment Renal failure: Acute renal failure and death can occur, particularly in patients with comorbidities and those who are in the advanced stages of their hematologic disorders. Consider dose reductions or interruptions in therapy if increases occur or in patients with preexisting renal disease	• CrCl <40 mL/min • Poor performance status • High-risk myelodysplastic syndromes • Advanced malignancies • Platelet counts less than 50,000/mm³ • Hypersensitivity
Deferiprone (Feriprox™)	Agranulocytosis/Neutropenia: Can cause agranulocytosis that can lead to serious infections and death. Monitor absolute neutrophil count (ANC) prior to treatment and weekly during therapy. Interrupt treatment if neutropenia or infection develops	Hypersensitivity
Lead (and Other) Chelators		
Chemet® (succimer)	None	Hypersensitivity

Medication	Boxed Warnings	Contraindications
Calcium Disodium Versenate	Fatal Toxicity/Cerebral edema: Capable of producing toxic effects that can be fatal. Patients with lead encephalopathy and cerebral edema may experience a lethal increase in intracranial pressure following IV infusion; the IM route is preferred for these patients	• Anuria • Active renal disease • Hepatitis

Warnings/Precautions

Medication	Warnings/Precautions
Copper Chelators	
Trientine (Syprine®, Cuvrior™)	Concerns related to adverse effects: Copper deficiency, neurologic worsening, hypersensitivity, iron deficiency
Penicillamine (Cuprimine®, Depen® Titratabs)	Concerns related to adverse effects: Allergic reactions, anti-glomerular basement membrane (GBM) disease (Goodpasture syndrome) bronchiolitis obliterans, dermatologic concerns, drug fever, taste alteration, agranulocytosis, aplastic anemia, thrombocytopenia, hepatotoxicity, lupus-like syndrome, proteinuria, pemphigus, hematuria, myasthenic syndrome, penicillin cross-sensitivity, toxicity symptoms Disease-related concerns: Cystinuria, lead poisoning, Wilson disease Concurrent drug therapy issues: Hematopoietic-depressant drugs Special populations: Elderly patients may be more susceptible to skin rash and/or taste alterations Other: Should be administered under the close supervision of a physician familiar with the toxicity and dosage considerations
Galzin® (zinc acetate)	Concerns related to adverse effects: Neurological deterioration, gastric irritation/upset, copper deficiency Other: Not recommended in symptomatic patients, hepatic copper levels should not be used to manage therapy
Iron Chelators	
Deferoxamine (Desferal®)	Concerns related to adverse effects: Acute respiratory distress syndrome (ARDS), auditory effects, growth retardation, infection, infusion reactions, mucormycosis, ocular effects, renal effects, urine discoloration Disease-related concerns: Aluminum toxicity, hemochromatosis, myasthenia gravis Concurrent drug therapy issues: Combination treatment with ascorbic acid (>500 mg/day in adults) may impair cardiac function
Deferasirox (Exjade®, Jadenu®)	Concerns related to adverse effects: Auditory disturbances, bone marrow suppression, dermatologic toxicity, GI reactions, hepatic failure, hypersensitivity, ocular disturbances, renal failure Special population: Elderly patients have higher risk of toxicity and fatal events; associated with serious and fatal adverse events in pediatric population, usually associated with volume depletion or continued doses of 20 to 40 mg/kg/day (Exjade®) or 14 to 28 mg/kg/day (Jadenu®) Dosage form specific issues: Some formulations may contain lactose Other: Overchelation of iron may increase development of renal toxicity with doses >25 mg/kg/day (Exjade®) or >17.5 mg/kg/day (Jadenu®) while serum ferritin values <1,000 mcg/L; may cause variable decreases in the serum concentration of zinc and copper
Deferiprone (Ferriprox™)	Concerns related to adverse effects: Agranulocytosis/neutropenia, hepatotoxicity, hypersensitivity, zinc deficiency Dosage form specific issues: Available in 2 different 1000 mg oral tablet formulations (twice-a-day and 3-times-a-day formulation)
Lead (and Other) Chelators	
Chemet® (succimer)	Concerns related to adverse effects: Neutropenia, hepatic effects, hypersensitivity reactions Disease-related concerns: Encephalopathy, lead poisoning, liver impairment, renal impairment

Medication	Warnings/Precautions
	Other: Adequate hydration should be maintained during therapy
Calcium Disodium Versenate	Concerns related to adverse effects: Arrhythmia, ECG changes during IV therapy, nephrotoxicity Disease related concerns: Investigate, identify, and remove sources of lead exposure; consultation with a clinical toxicologist or an expert in the treatment of heavy metal poisoning is highly recommended before use; caution in renal impairment; extreme caution in patients with lead encephalopathy and cerebral edema. Other: Name confusion with edetate disodium (not commercially available in the U.S.) which should never be used to treat lead poisoning

Practice Guidelines

Wilson Disease

Schilsky ML, Roberts EA, Bronstein JM, et al. A Multidisciplinary Approach to the Diagnosis and Management of Wilson Disease: 2022 Practice Guidance on Wilson Disease from the American Association for the Study of Liver Diseases (AASLD). Hepatology. Published online December 7, 2022.

- All patients with a newly established diagnosis of Wilson disease should be initiated on lifelong medical therapy for Wilson disease. Timing of treatment in children who are less than 3 years-old should be individualized to the degree of organ damage.
- Initial treatment for symptomatic patients with Wilson disease should include a chelating agent (D-penicillamine or trientine). Trientine may be better tolerated.
- Treatment of asymptomatic patients with Wilson disease can be a chelating agent (D-penicillamine or trientine at a lower dose than for initial therapy) or zinc.
- The suitability for transition to maintenance therapy for Wilson disease includes time on therapy (generally more than 1 year) and favorable clinical and biochemical response to therapy. Maintenance therapy may be a lower dose of chelating agent (D-penicillamine or trientine) or full-dose zinc.

European Association for the Study of the Liver (EASL). EASL-European Reference Network (ERN) Clinical Practice Guidelines on Wilson's Disease. J Hepatol. Published online February 22, 2025:S0168-8278(24)02706-5.

- Chelators should be the primary choice in patients with significant liver disease, e.g. features of significant fibrosis and cirrhosis, liver failure, and haemolysis (Level of evidence 3, strong recommendation, strong consensus).
- Either zinc or chelators should be used in patients with a neurological presentation (Level of evidence 2, strong recommendation, consensus)
- A 'start low, go slow' treatment regimen is recommended for chelators, especially in patients with a neurological presentation (Level of evidence 3, strong recommendation, strong consensus).
- Either zinc or chelators may be used in asymptomatic patients without signs of significant liver involvement (Level of evidence 4, weak recommendation, consensus).
- Once treatment response is achieved, a change of treatment (lowering chelator dose, switching to zinc) can be considered for medium and long-term safety reasons (Level of evidence 4, weak recommendation, strong consensus).
- When patients do not achieve sufficient treatment response, adherence should be checked in detail based on copper balance, laboratory investigations and clinical symptoms (Level of evidence 2, strong recommendation, strong consensus).
- In patients with Wilson's disease who do not achieve sufficient treatment response on first-line therapy despite a good adherence to treatment and a 24-hour urinary copper excretion in the target range, or side effects, switching treatment should be considered (D-penicillamine to trientine and vice versa or zinc to chelators) (Level of evidence 2, strong recommendation, strong consensus).
- In patients with Wilson's disease who develop paradoxical neurological worsening on first-line therapy, decreasing the dose of chelators and slowing the increase of doses or changing the Wilson's disease treatment

should be considered (chelators to zinc or zinc to chelators) (Level of evidence 2, strong recommendation, consensus).

- Liver transplantation should be considered on a case-to-case basis in patients with a continuous worsening of neurological symptoms despite at least 6 months of optimized medical treatment (Level of evidence 2, strong recommendation, consensus).
- Liver transplantation should be considered in patients with decompensated cirrhosis despite adequate medical treatment (Level of evidence 2, strong recommendation, strong consensus).
- Patients with decompensated cirrhosis in Wilson's disease may respond to medical therapy, usually after >3 months of treatment, but they should be concomitantly evaluated for liver transplantation (Level of evidence 3, strong recommendation, strong consensus).
- Any anti-copper therapy should be maintained during pregnancy and breastfeeding (Level of evidence 4, weak recommendation, consensus).
- Specific treatment for Wilson's disease (chelators and zinc salts) enables improvement of neurological and neuropsychiatric symptoms but may be insufficient to control symptoms, in which case symptomatic treatments should be considered (Level of evidence 2, strong recommendation, strong consensus).
- Symptomatic treatments of neurological symptoms should be based on pharmacotherapy, botulinum toxin injections, physiotherapy, speech therapy and rarely neurosurgery (Level of evidence 2, strong recommendation, strong consensus).
- Neuropsychiatric symptoms can be treated by psychotropic medications (mood stabilizers, antidepressants, anxiolytics) and/or psychotherapy. Neuroleptics should be avoided (except quetiapine or clozapine) as they could worsen neurological symptoms (Level of evidence 2, strong recommendation, strong consensus).
- Anti-copper therapy is not indicated after liver transplantation (Level of evidence 4, strong recommendation, strong consensus)

Recommendation Definitions

Level of Evidence	Criteria	Definition
1	Systematic reviews (with homogeneity) of randomized controlled trials	Further research is unlikely to change confidence in the estimate of benefit and risk
2	Randomized controlled trials or observational studies with dramatic effects; systematic review of lower quality studies (i.e., non-randomized, retrospective)	
3	Non-randomized controlled cohort/follow-up study/control arm of randomized trial (systematic review is generally better than an individual study)	Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate
4	Case-series, case-control, or historically controlled studies (systematic review is generally better than an individual study)	
5	Expert opinion (mechanism-based reasoning)	Any estimate of effect is uncertain

Strength of Recommendation	Wording	Definition
Strong	Shall, should, is recommended. Shall not, should not, is not recommended.	Factors influencing the strength of the recommendation included the quality of the evidence, presumed patient-important outcomes, and cost.

Strength of Recommendation	Wording	Definition
Weak	Can, may, is suggested. May not, is not suggested.	Variability in preferences and values, or more uncertainty. Recommendation is made with less certainty, or higher cost or resource consumption.

Consensus Strength	Definition
Strong Consensus	>95% agreement,
Consensus	>75-95% agreement
Majority Agreement	>50-75% agreement
No Consensus	<50% agreement

Hereditary Hemochromatosis

Kowdley KV, Brown KE, Ahn J, Sundaram V. American College of Gastroenterology Clinical Guideline: Hereditary Hemochromatosis. Am J Gastroenterol. 2019 Aug;114(8):1202-1218.

- We recommend that phlebotomy be used as the first-line treatment in patients diagnosed with HH as determined by C282Y homozygosity or C282Y/H63D compound heterozygosity (Strong recommendation, moderate quality of evidence).
- We recommend against chelation as the first-line therapy for HH, given the effectiveness of phlebotomy, the associated side effects of chelation including hepatic and renal toxicity, and the relatively small sample size of clinical trials supporting chelation (Strong recommendation, low quality of evidence).
- We recommend the use of iron chelation for the treatment of HH in the patient who is intolerant or refractory to phlebotomy or when phlebotomy has the potential for harm such as in patients with severe anemia or congestive heart failure (Strong recommendation, low quality of evidence).
- We recommend against the routine use of proton pump inhibitors (PPIs) as the primary treatment of HH (Strong recommendation, low quality of evidence).

Recommendation Definitions

Strength of Recommendation	Definition
Strong	Factors influencing the strength of the recommendation included the quality of the evidence, presumed patient-important outcomes, and cost.
Weak	Variability in preferences and values, or more uncertainty. Recommendation is made with less certainty, or higher cost or resource consumption.

Quality of Evidence	Definition
High	Further research is unlikely to change confidence in the estimate of the clinical effect.
Moderate	Further research may change confidence in the estimate of the clinical effect.
Low	Further research is very likely to affect the confidence on the estimate of clinical effect.
Very low	Any estimate of the effect is very certain.

Thalassemia

Cappellini M, Cohen A, Porter J, Taher A, Vprakasit V, eds. Guidelines for the Management of Transfusion Dependent Thalassemia (TDT) [Internet]. 4th edition. Thalassaemia International Federation; 2021. Available at: <https://www.thalassemia.org/boduw/wp-content/uploads/2021/06/TIF-2021-Guidelines-for-Mgmt-of-TDT.pdf>.

Iron Overload and Chelation

- Chelation therapy is an effective treatment modality in improving survival, decreasing the risk of heart failure and decreasing morbidities from transfusion-induced iron overload (A).
- Chelation therapy at the correct doses and frequency can balance iron excretion with iron accumulation from transfusion (A).
- Absolute change in total body iron in response to chelation can be calculated from change in LIC (B).
- Direction of change in body iron in response to transfusion and chelation can usually but not always be estimated from the trend in serum ferritin (B).
- Prevention of iron accumulation using chelation therapy is preferable to rescue treatment because iron-mediated damage is often irreversible, and removal of storage iron by chelation is slow - particularly after it has escaped the liver (B).
- Response to chelation is dependent on the dose applied and the duration of exposure (A).
- Response to chelation is affected by the rate of blood transfusion (B).
- Chelation can reverse iron-mediated cardiac dysfunction rapidly (within weeks) by rapid chelation of labile iron, if 24-hour chelation cover is achieved (A).
- Chelation therapy removes myocardial storage iron slowly (months or years) (A).
- Over-chelation increases side effects from chelation therapy, and doses should therefore be decreased as serum ferritin or liver iron levels fall (demonstrated most clearly with DFO) (B).
- The optimal chelation regime must be tailored for the individual and will vary with their current clinical situation. (not a graded recommendation)
- Chelation therapy will not be effective if it is not taken regularly – a key aspect of chelation management is to work with patients to optimize adherence (B).

Cardiac Complications in Thalassemia Major

- Combined therapy with deferoxamine and deferiprone represent the best available intensive chelation for thalassemia major patients with severe cardiac iron overload, with or without overt cardiac dysfunction or heart failure (B).

Liver Disease

- Deferoxamine, deferiprone and deferasirox are effective in decreasing total body iron burden as well as LIC (A).

Infections

- As a measure, temporary discontinuation of deferoxamine during a febrile illness until establishing whether the episode is caused by a pathogen that can use deferoxamine as siderophore or taken under control is strongly advised (B).

- Deferasirox or deferiprone can be continued during febrile episodes (C).

Endocrine Disease

- Short Stature and Retarded Growth
 - Prevention and Treatment of growth abnormalities in patients with TM should include:
 - Use of new iron-chelators with lower toxicity on the skeleton and with better patient compliance. (not a graded recommendation)
- Hypothyroidism
 - If subclinical hypothyroidism is detected, chelation should be intensified and the patient carefully monitored
- Impaired Glucose Tolerance (IGT) and Diabetes Mellitus (DM)
- Intensive chelation therapy is effective to normalize β -cell function and may improve insulin secretion and glucose tolerance and reduce liver iron deposition (*not a graded recommendation*).
- Summary
 - Endocrine complications, growth and pubertal delay are common manifestations of iron overloading in TM and carry significant morbidity. As such, patients with TM need regular monitoring for signs and symptoms of endocrine complications. Prevention remains the priority, and there are limited data to support a role for chelation therapy in this. Once endocrine complications have developed, management should focus on halting the progression of such complications and treating associated symptoms (*not a graded recommendation*).
 - Normalization of total body iron load with very intensive combined chelation (deferoxamine plus deferiprone) reverses cardiac and endocrine complications of TM (B).

Osteoporosis

- Adequate iron chelation may prevent iron toxicity in the bone and sufficient blood transfusions may help prevent and treat early bone loss (*not a graded recommendation*).

Psychological Support

- Patient-reported health outcome shows that oral chelation therapy has a beneficial impact, relative to parenteral chelation (B).
- Benefits of psychological support have been suggested using a variety of approaches (C) which include:
 - Targeting changes in institutional organization practices
 - Patient group sessions
 - Family therapy
 - Patient chelation camps

Recommendation Definitions

Quality of Evidence	Definition
A	Data derived from multiple randomized clinical trials or meta-analyses.
B	Data derived from a single randomized clinical trial or large non-randomized studies.
C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

Lead Poisoning

WHO Guideline for Clinical Management of Exposure to Lead. World Health Organization; 2021. Available at: <https://www.who.int/publications/i/item/9789240037045>.

Chelation therapy in individuals exposed to lead

- Children ≤ 10 years of age
 - For a child (≤ 10 years) with a blood lead concentration ≥ 45 $\mu\text{g}/\text{dL}$, oral or parenteral chelation therapy is recommended (Strong recommendation, very low-certainty evidence).
 - For a child (≤ 10 years) with a blood lead concentration of 40 to 44 $\mu\text{g}/\text{dL}$, when there is doubt about the accuracy of the measurement, a persistently elevated blood lead concentration in spite of measures to stop exposure or significant clinical features of lead poisoning, oral chelation therapy should be considered (Conditional recommendation, very low-certainty evidence).
 - For a child (≤ 10 years) with lead encephalopathy, urgent hospital admission and parenteral chelation therapy are recommended (Strong recommendation, very low-certainty evidence).
- Non-pregnant adolescents (11–18 years) and adults (≥ 19 years) with blood lead concentration 45 to 70 $\mu\text{g}/\text{dL}$
 - For a non-pregnant adolescent girl or woman of child-bearing age who has a blood lead concentration of 45 to 70 $\mu\text{g}/\text{dL}$ but who does not show clinical features of lead poisoning, oral chelation therapy should be considered (Conditional recommendation, very low-certainty evidence).
 - For a male patient aged ≥ 11 years or a woman who is no longer of child-bearing age who has a blood lead concentration of 45 to 70 $\mu\text{g}/\text{dL}$ but who does not show clinical features of lead poisoning, chelation therapy is not indicated. The patient should, however, be re-evaluated within 2–4 weeks to ensure that the blood lead concentration is decreasing and the patient remains well (Conditional recommendation, very low-certainty evidence).
 - For a non-pregnant adolescent or adult with a blood lead concentration of 45 to 70 $\mu\text{g}/\text{dL}$ and who has mild–moderate clinical features of lead poisoning (such as abdominal pain, constipation, arthralgia, headache, lethargy), chelation therapy is suggested (Conditional recommendation, very low-certainty evidence).
- Non-pregnant adolescents (11–18 years) and adults (≥ 19 years) with blood lead concentrations of >70 to 100 $\mu\text{g}/\text{dL}$
 - For a non-pregnant adolescent or an adult with a blood lead concentration >70 to 100 $\mu\text{g}/\text{dL}$ but who does not show significant neurological features of toxicity, chelation therapy is suggested (Conditional recommendation, very low-certainty evidence).
 - For a non-pregnant adolescent or adult with a blood lead concentration >70 to 100 $\mu\text{g}/\text{dL}$ and with significant neurological features of lead toxicity (e.g., irritability, drowsiness, ataxia, convulsions, coma) or lead encephalopathy, urgent parenteral chelation therapy is recommended (Strong recommendation, very low-certainty evidence).
- Pregnant women
 - For a pregnant woman with lead encephalopathy, regardless of trimester, urgent chelation therapy is recommended. The preferred chelating agent depends on the stage of the pregnancy and available data on safety of use in pregnancy (Strong recommendation, very low-certainty evidence).
 - For a pregnant woman with a blood lead concentration ≥ 45 $\mu\text{g}/\text{dL}$, with or without clinical features of lead poisoning, but without lead encephalopathy:
 - In the first trimester: the guideline development group could not make a recommendation because of an uncertain balance of risks and benefits (No recommendation).

- In the second or third trimester: chelation therapy is recommended (Strong recommendation, very low-certainty evidence).

Recommendation Definitions

Strength of Recommendation	Definition
Strong	The group is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects.
Weak	The group concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects but is not confident of this interpretation.

Quality of Evidence	Definition
High	Further research is unlikely to change confidence in the estimate of the clinical effect.
Moderate	Further research may change confidence in the estimate of the clinical effect.
Low	Further research is very likely to affect the confidence on the estimate of clinical effect.
Very low	Any estimate of the effect is very certain.

Clinical Trials/Systematic Reviews/Meta-Analyses

Citation	Design	Endpoints
Schilsky ML, Czlonkowska A, Zuin M, et al. Trientine tetrahydrochloride versus penicillamine for maintenance therapy in Wilson disease (Chelate): a randomized, open-label, non-inferiority, phase 3 trial. Lancet Gastroenterol Hepatol. 2022;7(12):1092-1102.	Randomized, open-label, non-inferiority, phase 3 trial comparing penicillamine with trientine tetrahydrochloride for maintenance therapy in patients with Wilson disease. N=53 Arms: Patients were randomly assigned (1:1) to continue receiving oral penicillamine or switched to oral trientine tetrahydrochloride Inclusion criteria: Patients aged 18-75 years with stable Wilson disease who were treated for at least 1 year with penicillamine Exclusion criteria: None listed	- Primary endpoint: Serum non-caeruloplasmin-bound copper (NCC) levels at 24 weeks - Secondary endpoint: Urinary copper excretion at 24 weeks, side effects
Results: After 24 weeks, the mean difference in serum NCC between the penicillamine group and trientine tetrahydrochloride group was -9.1 µg/L (95% confidence interval [CI], -24.2 to 6.1), with the lower limit of the 95% CI within the defined non-inferiority margin. At 24 weeks, urinary copper excretion was lower with trientine tetrahydrochloride than with penicillamine (mean difference, 238 µg/24 h [99% CI, 116 to 360]). At 48 weeks, trientine tetrahydrochloride remained non-inferior to penicillamine in terms of NCC (mean difference NCC, -15.5 µg/L [95% CI, -34.5 to 3.6]). Urinary copper excretion at 48 weeks remained in the expected range for well treated patients in both study groups, and the mean difference (125 µg/24 h [99% CI, -37.6 to 287]) was not significantly different. The most common treatment-emergent adverse events were headache for penicillamine (19% vs. 8%) and abdominal pain for trientine tetrahydrochloride (4% vs. 15%); all treatment-emergent adverse events resolved and were mild to moderate. Conclusion: The efficacy of trientine tetrahydrochloride as oral maintenance therapy was non-inferior to penicillamine and well tolerated in adults with Wilson disease.		
Citation	Design	Endpoints
Bollig C, et al. Deferasirox for managing iron overload in people with thalassaemia. Cochrane Database Syst Rev. 2017 Aug 15;8:CD007476.	Systematic review and meta-analysis of randomized controlled trials (RCTs) of trials through August 2016 of deferasirox versus no therapy, placebo or another iron-chelating treatment in patients with transfusion-dependent thalassemia or NTDT. N=16 studies; 1,807 participants	- Primary endpoint: Overall mortality measured at any point in time - Secondary endpoints: Reduced end-organ damage, measures of iron overload, measures of iron excretion
Results: There did not appear to be a clear difference in the risks of immunization when women who received anti-D at 28 and 34 weeks' gestation were compared with women who were not given antenatal anti-D: risk ratio (RR) for incidence of RhD alloimmunization during pregnancy was 0.42 (95% confidence interval [CI] 0.15 to 1.17); at birth of a RhD-positive infant the RR was 0.42 (95% CI 0.15 to 1.17); and within 12 months after birth of a RhD-positive infant the average RR was 0.39 (95% CI 0.10 to 1.62; Tau² 0.47; I² 39%). Neither of the trials reported on incidence of RhD alloimmunization in subsequent pregnancies. Considering secondary outcomes, in one trial, women receiving anti-D during pregnancy were shown to be less likely to register a positive Kleihauer test in pregnancy (RR 0.60, 95% CI 0.41 to 0.88) and at the birth of a RhD-		

positive infant (RR 0.60, 95% CI 0.46 to 0.79). No clear differences were seen for neonatal jaundice (RR 0.26, 95% CI 0.03 to 2.30). Neither of the trials reported on adverse effects associated with anti-D treatment.

Conclusion: Existing studies do not provide conclusive evidence that the use of anti-D during pregnancy benefits either mother or baby in terms of incidence of RhD alloimmunization during the pregnancy or postpartum, or the incidence of neonatal morbidity. However, women receiving anti-D may be less likely to register a positive Kleihauer test in pregnancy and at the birth of an RhD-positive infant. Fewer women who receive anti-D during pregnancy may have RhD antibodies in a subsequent pregnancy, with benefits for the baby, however this needs to be tested in studies of robust design.

Citation	Design	Endpoints
Appenzeller-Herzog C, Mathes T, Heeres MLS, Heinz Weiss K, Houwen RHJ, Ewald H. Comparative effectiveness of common therapies for Wilson disease: A systematic review and meta-analysis of controlled studies. Liver Int. 2019 Nov;39(11):2136-2152.	Systematic review and meta-analysis of prospective and retrospective, randomized and non-randomized, controlled studies and comparative observational trials through January 2019 of patients with Wilson disease (any age or stage) mostly comparing D-penicillamine to no treatment, zinc, trientine or succimer. N=23 studies; 2,055 participants	- Primary endpoint: Mortality and asymptomatic/improved - Secondary endpoints: Side effects, early neurological deterioration, treatment discontinuation and orthotopic liver transplantation (OLT)

Results:

D-penicillamine vs. no treatment

- Mortality – Odds ratio (OR), 0.013 (95% CI, 0.0010 to 0.17; $I^2 = 31\%$)
- Remaining or becoming asymptomatic – OR, 22.3 (95% CI, 0.40 to 1.2×10^3 ; $I^2 = 86\%$)
- Other outcomes were not reported for this comparison

D-penicillamine vs. zinc salts

- Mortality – OR, 0.73 (95% CI, 0.16 to 3.40; $I^2 = 37\%$)
- Asymptomatic/improved – OR, 0.84 (95% CI, 0.48 to 1.48; $I^2 = 0\%$)
- Side effects – OR, 3.28 (95% CI, 0.542 to 19.9; $I^2 = 24\%$)
- Neurological deterioration – OR, 3.71 (95% CI, 0.42 to 32.7; $I^2 = 10\%$)
- Treatment discontinuation – OR, 2.96 (95% CI, 1.14 to 7.66; $I^2 = 48\%$)
- OLT – OR, 1.74 (95% CI, 0.066 to 46.0; $I^2 = 37\%$)

Other comparisons

- Not enough studies comparing other drug combinations to perform meta-analysis.

Conclusion: There are some indications that zinc is safer than D-penicillamine therapy while being similarly effective in preventing or reducing hepatic or neurological Wilson Disease symptoms. Study quality was low warranting cautious interpretation of our findings.

Citation	Design	Endpoints

Cao Y, Chen A, Bottai M, Caldwell KL, Rogan WJ. The impact of succimer chelation on blood cadmium in children with background exposures: a randomized trial. J Pediatr. 2013 Aug; 163(2):598-600.	Randomized, double-blind, placebo-controlled trial utilizing cadmium, a toxic metal with known detrimental effects including renal toxicity, hypertension, and skeletal disorders, to investigate the use of the drug in lead poisoning. N=780 Arms: Children received up to three 26-day courses of succimer or placebo Inclusion criteria: Children between 12 and 33 months of age, who had a confirmed blood lead concentration between 20 and 44 µg/dL, and who lived in a residence suitable for lead dust reduction Exclusion criteria: None listed	Primary endpoint: Blood cadmium levels after 1-week of treatment																					
Results: There was almost no difference in blood cadmium levels when measured after one week. The 90th percentile group receiving succimer actually saw a slight increase in blood cadmium levels when measured after one week. Between Group Difference of Blood Cadmium Level (µ/L) After Treatment <table><tr><td></td><td colspan="2">Median</td><td colspan="2">75th Percentile</td><td colspan="2">90th Percentile</td></tr><tr><td></td><td>Difference (95% CI)</td><td>P-value</td><td>Difference (95%CI)</td><td>P value</td><td>Difference (95%CI)</td><td>P value</td></tr><tr><td>Adjusted</td><td>0.00 (-0.01 to 0.01)</td><td>0.98</td><td>0.00 (-0.01 to 0.01)</td><td>0.69</td><td>0.01 (-0.01 to 0.02)</td><td>0.42</td></tr></table>				Median		75 th Percentile		90 th Percentile			Difference (95% CI)	P-value	Difference (95%CI)	P value	Difference (95%CI)	P value	Adjusted	0.00 (-0.01 to 0.01)	0.98	0.00 (-0.01 to 0.01)	0.69	0.01 (-0.01 to 0.02)	0.42
	Median		75 th Percentile		90 th Percentile																		
	Difference (95% CI)	P-value	Difference (95%CI)	P value	Difference (95%CI)	P value																	
Adjusted	0.00 (-0.01 to 0.01)	0.98	0.00 (-0.01 to 0.01)	0.69	0.01 (-0.01 to 0.02)	0.42																	
Conclusion: Succimer has shown efficacy in animals diminishing GI absorption and cadmium tissue retention, however there is no evidence for therapeutic efficacy following chronic cadmium exposure. This trial specifically finds that succimer has no effect on background blood cadmium concentrations resulting from background exposure in U.S. children. Succimer may not reduce cadmium because succimer is mainly distributed in extracellular space while cadmium is mostly bound intracellularly to metallothionein. However it is approved for the treatment of pediatric lead poisoning as of 1991.Results: Anti-D was significantly inferior to IVIG at increasing platelet counts, both for thresholds of >20 × 10⁹/L at 24 to 72 hours (response rate ratio for anti-D vs. IVIG: 0.85, 95% CI 0.78 to 0.94) and >50 × 10⁹/L at 24 to 72 hours (response rate ratio for anti-D vs. IVIG: 0.75, 95% CI 0.61 to 0.92). Bleeding response was assessed in 4 studies, but some heterogeneity in reporting leads to unclear conclusion. General symptoms after anti-D infusion were less frequent than after IVIG (odds ratio [OR] 0.39, 95% CI 0.25 to 0.62). Hemolysis was more frequent after anti-D. The overall quality of the studies was low.																							

Formulary Placement, Utilization and Cost Experience (04-01-2025 to 06-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbbs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Copper Chelators								
trientine hydrochloride (Syprine®) 250 mg capsule	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA AL >21yrs	No change
Cuvrior™ (trientine tetrahydrochloride) 300 mg tablet	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
penicillamine (Cuprimine®) 250 mg capsule	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA	No change
penicillamine (Depen® Titratabs) 250 mg tablet	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA	No change
Galzin® (zinc acetate) 25 mg, 50 mg capsule	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Iron Chelators								
deferoxamine (Desferal®) 500 mg, 2 g solution for injection	0	0	\$0.00	\$0.00	0	0 (0%)	F	No change
deferasirox (Exjade®) 125 mg, 250 mg, 500 mg dispersible tablet	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA AL >21yrs	No change
deferasirox (Jadenu®) 90 mg tablet	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA	No change
deferasirox (Jadenu® Sprinkle) 90 mg oral granules in packet	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA	No change
deferiprone (Ferriprox™) 500, 1000 mg tablet	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Ferriprox™ (deferiprone) 100 mg/mL oral solution	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Lead (and Other) Chelators								
Chemet® (succimer) 100 mg capsule	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Calcium Disodium Versenate 200 mg/mL injection solution	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
TOTAL	0	0	\$0.00	\$0.00	0	0 (0%)		

Key (as applicable) F = Formulary, no restrictions; F-QL = Formulary, quantity limit applies; F-AL = Formulary, age limit applies; F-ST = Formulary, step therapy applies; F-PA = Formulary, PA required; NF = Non-formulary; X = Excluded

Prior Authorization Criteria

No changes

Penicillamine (Depen, Cuprimine), Trientine HCl (Syprine) for Wilson's disease	
Therapeutic Classes (AHFS)	Heavy Metal Antagonists
Medications	<u>Formulary, PA required</u> Penicillamine (Depen Titratabs) tablet Trientine (Syprine) Penicillamine (Cuprimine) capsule <u>Non-Formulary</u> Cuvrior (trientine tetrahydrochloride)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	N/A
Coverage Duration	Initial If all criteria are met, approve for up to a 6 month duration; if all of the criteria are not met, the request is referred to a clinical reviewer for medical necessity review. Reauthorization If all criteria are met, approve for up to a 12 month duration; if all of the criteria are not met, the request is referred to a clinical reviewer for medical necessity review.
PA Review Criteria	Criteria for initial approval: • Documented confirmed diagnosis of Wilson's disease • For penicillamine (Depen, Cuprimine), documented adequate trial (at least 3 months) and failure of, or intolerance to, due to significant side effects/toxicity, or a contraindication to therapy with trientine (Syprine) • For Cuvrior (trientine tetrahydrochloride), documented adequate trial (at least 3 months) and failure of, or intolerance to, due to significant side effects/toxicity, or a contraindication to therapy with BOTH trientine (Syprine) and penicillamine Criteria for re-authorization: • Documentation of positive clinical response.
Criteria Statement	Penicillamine (Depen, Cuprimine) are reserved for members who have used (or cannot/should not use) trientine (Syprine). Cuvrior (trientine tetrahydrochloride) is reserved for members who have used (or cannot/should not use) both trientine (Syprine) and penicillamine.
Last P&T Review Date	9/20249/2025

Iron-chelating Agents	
Therapeutic Classes (AHFS)	Heavy Metal Antagonists
Medications	Formulary, PA required Deferasirox (Jadenu) tablet -PREFERRED Deferasirox (Jadenu) granules Deferasirox (Exjade) tablet <u>Non-Formulary</u> Ferriprox (deferiprone) tablet Ferriprox (2 times a day) (deferiprone) 1,000 mg tablet Ferriprox (deferiprone) solution
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Physician must be a hematologist.
Coverage Duration	Initial/Re-Approval If all conditions are met, the request will be approved for up to 6 months. If all criteria are not met, the request is referred to Clinical Reviewer for medical necessity review.
PA Review Criteria	<u>INITIAL CRITERIA FOR CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS FOR DEFERASIROX</u> • Patient must be ≥ 2 years old. (check AAH active CCS cases for members < 21 years of age) • Diagnosis of chronic iron overload due to blood transfusions • Patient receiving blood transfusions on a regular basis/participating in blood transfusion program • Serum ferritin concentration consistently greater than 1000mcg/L. ◦ If serum ferritin falls to <1,000 mcg/L at 2 consecutive visits, consider dose reduction (especially if dose is >17.5 mg/kg/day) ◦ (If the serum ferritin levels fall below 500 mcg/L on any one monitoring visit, deferasirox therapy discontinued). • Documented treatment failure, contraindication, or significant intolerance to deferoxamine (Desferal) treatment. • If the request is for deferasirox (Exjade) tablet, member must have tried and failed deferoxamine (Desferal) AND deferasirox (Jadenu) tablet OR a medical reason why member is unable to use (e.g. intolerance, contraindication, etc.) deferoxamine (Desferal) AND deferasirox (Jadenu) tablet must be provided. • If the request is for deferasirox (Jadenu) granules, member must meet the criteria above and have tried and failed deferoxamine (Desferal) AND deferasirox (Exjade) tablet AND (Jadenu) tablet OR a medical reason why member is unable to use (e.g. intolerance, contraindication, etc.) deferoxamine (Desferal) AND deferasirox (Exjade) tablet AND deferasirox (Jadenu) tablet must be provided <u>REAUTHORIZATION CRITERIA FOR CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS FOR DEFERASIROX</u>

- If the request is for deferasirox (Exjade) tablet, member must have tried and failed deferoxamine (Desferal) AND deferasirox (Jadenu) tablet OR a medical reason why member is unable to use (e.g. intolerance, contraindication, etc.) deferoxamine (Desferal) AND deferasirox (Jadenu) tablet must be provided.
- Serum ferritin concentration consistently greater than 1000 mcg/L.
 - If serum ferritin falls to <1,000 mcg/L at 2 consecutive visits, consider dose reduction (especially if dose is >17.5 mg/kg/day)
 - If the serum ferritin levels fall consistently below 500 mcg/L on any one monitoring visit, deferasirox therapy must be discontinued

INITIAL CRITERIA FOR CHRONIC IRON OVERLOAD IN NON-TRANSFUSION DEPENDENT THALASSEMIA SYNDROMES FOR DEFERASIROX

- Patient must be ≥ 10 years old (check AAH active CCS cases for members < 21 years of age)
- Diagnosis of thalassemia syndrome
- Liver iron content (LIC) by liver biopsy of ≥ 5 mg Fe/g dry weight
- Serum ferritin level on ≥ 2 measurements at least one month apart of >300 mcg/L
- If the request is for deferasirox (Exjade) tablet, member must have tried and failed deferasirox (Jadenu) tablet OR a medical reason why member is unable to use (e.g. intolerance, contraindication, etc.) deferasirox (Jadenu) tablet must be provided.
- If the request is for deferasirox (Jadenu) granules, member must meet the criteria above and have tried and failed deferasirox (Exjade) tablet AND deferasirox (Jadenu) tablet OR a medical reason why member is unable to use (e.g. intolerance, contraindication, etc.) deferasirox (Exjade) tablet AND deferasirox (Jadenu) tablet must be provided

REAUTHORIZATION CRITERIA FOR CHRONIC IRON OVERLOAD IN NON-TRANSFUSION DEPENDENT THALASSEMIA SYNDROMES FOR DEFERASIROX

- If the request is for deferasirox (Exjade) tablet, member must have tried and failed deferasirox (Jadenu) tablet OR a medical reason why member is unable to use (e.g. intolerance, contraindication, etc.) deferasirox (Jadenu) tablet must be provided.
- Serum ferritin consistently > 300 mcg/L.
- If serum ferritin < 300 mcg/L, LIC must be obtained. If LIC < 3 mg Fe/g, treatment should be discontinued.

INITIAL CRITERIA FOR TRANSFUSIONAL IRON OVERLOAD DUE TO THALASSEMIA SYNDROMES OR SICKLE CELL DISEASE AND OTHER ANEMIAS FOR FERRIPROX (DEFERIPRONE)

- Patient must be ≥ 3 years old for oral solution OR ≥ 8 years old for tablets (check AAH active CCS cases for members < 21 years of age)
- Diagnosis of thalassemia syndrome, or sickle cell disease, or other anemia
- Patient receiving blood transfusions on a regular basis/participating in blood transfusion program
- Serum ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, Ferriprox must be discontinued
- Documentation that the patient is unable to use deferoxamine (Desferal) parenterally
- Documented trial and failure of deferasirox (Exjade, Jadenu) or medical reason why deferasirox cannot be used

	- Brand Ferriprox (2 times a day) 1000mg tablets and Ferriprox liquid will be approved with documentation of trial and failure, contraindication, or intolerance to generic deferiprone tablets REAUTHORIZATION CRITERIA FOR TRANSFUSIONAL IRON OVERLOAD DUE TO THALASSEMIA SYNDROMES OR SICKLE CELL DISEASE AND OTHER ANEMIAS FOR FERRIPROX (DEFERIPRONE) - Patient continues to receive blood transfusions on a regular basis/ or participates in a blood transfusion program - Serum ferritin concentration is consistently > 1000 mcg/L. If the serum ferritin levels fall consistently below 500 mcg/L, Ferriprox must be discontinued - If the request is for brand Ferriprox (2 times a day) 1000mg tablets or Ferriprox liquid, documentation of trial and failure, contraindication, or intolerance to generic deferiprone tablets
Criteria Statement	For chronic iron overload due to blood transfusions deferasirox (Jadenu) tablet is reserved for members who have used (or cannot/should not use) deferoxamine. Deferasirox (Exjade) tablet is reserved for members who have used (or cannot/should not use) deferoxamine AND (Jadenu) tablet. Deferasirox (Jadenu) granules are reserved for members who have used (or cannot/should not use) deferoxamine AND deferasirox (Jadenu) tablet AND deferasirox (Exjade) tablet. For chronic iron overload in non-transfusion dependent thalassemia syndromes deferasirox (Exjade) tablet is reserved for members who have used (or cannot/should not use) deferasirox (Jadenu) tablet. Deferasirox (Jadenu) granules are reserved for members who have used (or cannot/should not use) deferasirox (Jadenu) tablet AND deferasirox (Exjade) tablet. For transfusional iron overload due to thalassemia syndromes or sickle cell disease and other anemias, deferiprone (Ferriprox) tablet is reserved for members who are receiving blood transfusions who have used (or cannot/should not use) deferoxamine (Desferal) and deferasirox (Exjade, Jadenu). Brand Ferriprox (2 times a day) 1000mg tablets and Ferriprox liquid are reserved for members who have used (or cannot/should not use) generic deferiprone tablets.
Last P&T Review Date	9/2024/2025

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Fluoroquinolones (Oral)

Executive Summary

Class Overview

The fluoroquinolones (FQs) are a family of broad spectrum, systemic antibacterial agents. They are active against a wide range of aerobic gram-positive and gram-negative organisms and have indications for a variety of infections including urinary tract, lower respiratory tract, infectious diarrhea, skin and skin structure, intra-abdominal, sexually transmitted, bacterial prostatitis and sinusitis. In the early 2000s, the FQs became the most prescribed class of antibiotics in the United States. However, with increased use came a better understanding of the rare, but serious, side effects of this drug class. For treatment of most common infections, such as community-acquired pneumonia, skin and soft tissue infection, urinary tract infection, and osteomyelitis, guidelines recommend FQs as alternative agents. Due to their class-wide black boxed warning of potentially irreversible side effects involving the tendons, muscles, and central nervous system, FQs should be limited to patients with no other treatment options when used specifically as treatment for acute sinusitis, acute bronchitis and uncomplicated urinary tract infections. In 2018, the FDA strengthened their warnings regarding mental health side effects including delirium and disturbances in attention, disorientation, agitation, nervousness, memory impairment, as well as significant hypoglycemia that can lead to coma. In 2019, the FDA issued new safety warnings for FQs in patients with known aortic aneurysms or those with risk factors for aneurysm such as Marfan's syndrome, Ehlers-Danlos syndrome, peripheral atherosclerotic vascular diseases, hypertension, and/or advanced age.

FQs can be further classified into four generations based on their antimicrobial activity. First-generation agents are no longer on the market. The second-generation FQs, which includes ciprofloxacin and ofloxacin, have expanded gram-negative activity and moderately improved gram-positive coverage. Levofloxacin is a third-generation quinolone; the third-generation quinolones have an improved spectrum of activity for gram-positive bacteria compared to the second-generation quinolones, particularly for *S. pneumoniae*. Fourth generation FQs, such as moxifloxacin, have superior coverage against pneumococci and anaerobes. Baxdela® (delafloxacin), the most recently approved FQ, has an even broader spectrum of antibiotic activity and is commonly referred to as the "next generation" FQ. Although FQs can be utilized for some off-label indications and are available in alternate dosage forms, only labeled indications for oral FQs are discussed in this review.

Utilization Findings

There were 46 claims for 42 members, for a total cost of \$96.23 and an average cost per claim of \$2.09. The most highly utilized medication was ciprofloxacin tablet, with 29 claims, followed by levofloxacin tablet with 17 claims. There were no prior authorization requests.

Recommendations

- No changes

Clinical Summary

The fluoroquinolones (FQs) have been a popular class of antibiotics for use in a variety of infections. They inhibit two bacterial enzymes, DNA gyrase and topoisomerase IV, which have essential and distinct roles in DNA replication. The quinolones bind to the complex of each of these enzymes with DNA; the resulting complexes, including the drug, block progress of the DNA replication enzyme complex. Ultimately, this action results in damage to bacterial DNA and bacterial cell death.

FQs are active against a wide range of aerobic gram-positive and gram-negative organisms and have indications for a variety of infections including urinary tract, lower respiratory tract, infectious diarrhea, skin and skin structure, intra-abdominal, and sexually transmitted as well as bacterial prostatitis and sinusitis. Guidelines recommend that oral fluoroquinolones are first line treatment for prostatitis, inhalation anthrax and certain types of infectious diarrhea. For treatment of community-acquired pneumonia, skin and soft tissue infection, urinary tract infection, and osteomyelitis, guidelines recommend FQs as alternative agents. Resistance is of concern for any antibiotic and proper antimicrobial stewardship should be employed. Mutations that encode subunits of DNA gyrase and topoisomerase IV or regulate the expression of cytoplasmic membrane efflux pumps or proteins that constitute outer membrane diffusion channels will directly affect the activity of FQs. Newer drugs in this class have been developed with less resistance and a broader spectrum of activity including better coverage of gram-positive organisms and, for some FQs, anaerobes.

FQs have box warnings for severe adverse reactions including tendinitis and tendon rupture, peripheral neuropathy, CNS effects, and exacerbation of muscle weakness in patients with myasthenia gravis. In July 2018, the FDA strengthened FQ warnings regarding mental health side effects including delirium and disturbances in attention, disorientation, agitation, nervousness, memory impairment, as well as significant hypoglycemia that can lead to coma. The FDA issued a new safety warning in December 2019 citing observational studies that suggested an association between FQ use and aortic aneurysm. Experts recommend avoiding FQs in patients with known aortic aneurysms or those with risk factors for aneurysm such as Marfan's syndrome, Ehlers-Danlos syndrome, peripheral atherosclerotic vascular diseases, hypertension, and/or advanced age. No causative role has been determined and the absolute risk of these events is low.

There are currently a few fluoroquinolones in the pipeline including injectable, oral, and inhaled formulations. NeuroSense Therapeutics/Biogen is seeking approval of oral PrimeC (celecoxib/ciprofloxacin) which is in Phase II of development. Raptor Pharmaceuticals/Amgen is seeking approval of inhaled Quinsair (levofloxacin hemihydrate) which is in phase III of development.

Indications, Dosing and Administration

Medication	Indications	Dosing/Administration
Levofloxacin	• Treatment of nosocomial pneumonia • Treatment of community-acquired pneumonia • Treatment of complicated skin and skin structure infections • Treatment of uncomplicated skin and skin structure infections (mild to moderate) including abscesses, cellulitis, furuncles, impetigo, pyoderma, wound infections • Treatment of chronic bacterial prostatitis • Inhalational anthrax (post-exposure) to reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis • Treatment of plague, including pneumonic and septicemic plague, due to Yersinia pestis (Y. pestis) and prophylaxis for plague in adults and pediatric patients, 6 months of age and older • Treatment of complicated urinary tract infections • Treatment of acute pyelonephritis caused by Escherichia coli, including cases with concurrent bacteremia • Treatment of uncomplicated urinary tract infections (mild to moderate) due to Escherichia coli, Klebsiella pneumoniae, or Staphylococcus saprophyticus • Treatment of acute bacterial exacerbation of chronic bronchitis (ABECB) • Treatment of acute bacterial sinusitis (ABS)	• Nosocomial pneumonia – 750mg every 24 hours for 7-14 days • Community acquired pneumonia – 500mg every 24 hours for 7-14 days[†] • Community acquired pneumonia – 750mg every 24 hours for 5 days[†] • Complicated skin and skin structure infections – 750mg every 24 hours for 7-14 days • Uncomplicated SSSI - 500mg every 24 hours for 7-10 days • Chronic bacterial prostatitis – 500mg every 24 hours for 28 days • Inhalation anthrax (post-exposure), adult and pediatric patients >50 kg – 500mg every 24 hours for 60 days ○ Pediatric patients ≥6 months and <50kg – 8mg/kg (not to exceed 250 mg per dose) every 12 hours for 60 days • Plague, adult and pediatric patients >50kg – 500mg every 24 hours for 10-14 days ○ Pediatric patients ≥6 months and <50kg – 8mg/kg (not to exceed 250 mg per dose) every 12 hours for 10-14 days • Complicated Urinary tract infection or acute pyelonephritis – 750mg every 24 hours for 5 days[#] • Complicated Urinary tract infection or acute pyelonephritis – 250mg every 24 hours for 10 days[“] • Uncomplicated urinary tract infection – 250 mg every 24 hours for 3 days • Acute bacterial exacerbation of chronic bronchitis – 500mg every 24 hours for 7 days • Acute bacterial sinusitis – 750mg every 24 hours for 5 days OR 500mg every 24 hours for 10-14 days
Ciprofloxacin (Cipro®)	• Treatment of skin and skin structure infections • Treatment of bone and joint infections	• Skin and Skin structure – 500-750mg every 12 hours for 7-14 days • Bone and joint – 500-750 mg every 12 hours for 4-8 weeks

	• Treatment of complicated intra-abdominal infections (used in combination with metronidazole) • Treatment of infectious diarrhea • Treatment of typhoid fever (enteric fever) caused by Salmonella typhi • Treatment of uncomplicated cervical and urethral gonorrhea • Adult and pediatric patients from birth to 17 years of age for inhalational anthrax (post-exposure) to reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis • Treatment of plague, including pneumonic and septicemic plague, due to Yersinia pestis (Y. pestis) and prophylaxis for plague in adults and pediatric patients from birth to 17 years of age • Treatment of chronic bacterial prostatitis • Treatment of lower respiratory tract infections • Treatment of acute exacerbations of chronic bronchitis (AECB) caused by Moraxella catarrhalis • Treatment of urinary tract infections • Treatment of acute uncomplicated cystitis • Pediatric patients aged one to 17 years of age for treatment of complicated urinary tract infections (cUTI) and pyelonephritis due to Escherichia coli • Treatment of acute sinusitis	• Complicated intra-abdominal – 500 mg every 12 hours for 7-14 days • Infectious diarrhea – 500mg every 12 hours for 5-7 days • Typhoid fever – 500mg every 12 hours for 10 days • Uncomplicated urethral and cervical gonococcal infections – 250mg single dose • Inhalational anthrax (post-exposure) – 500mg every 12 hours for 60 days ○ Pediatric patients – 15mg/kg (maximum 500mg per dose) every 12 hours for 60 days • Plague – 500-750mg every 12 hours for 14 days ○ 15mg/kg (maximum 500mg per dose) every 8 to 12 hours for 10-21 days • Chronic bacterial prostatitis – 500mg every 12 hours for 28 days • Lower respiratory tract infections – 500-750mg every 12 hours for 7-14 days • Urinary tract infections – 250-500mg every 12 hours for 7-14 days ○ Complicated urinary tract or pyelonephritis (patients 1-17 years of age) – 10mg/kg to 20mg/kg maximum 750mg per dose, not to be exceeded in patients weighing more than 51kg; every 12 hours for 10-21 days • Acute uncomplicated cystitis – 250mg every 12 hours for 3 days • Acute sinusitis – 500mg every 12 hours for 10 days
Moxifloxacin	• Treatment of Community Acquired Pneumonia • Treatment of Uncomplicated Skin and Skin Structure Infections • Treatment of Complicated Skin and Skin Structure • Treatment of Complicated Intra-Abdominal Infections including	• CAP – 400mg every 24 hours for 7-14 days • Uncomplicated SSSI – 400mg every 24 hours for 7 days • Complicated SSSI – 400mg every 24 hours for 7-21 days

	polymicrobial infections such as abscess • Treatment of plague, including pneumonic and septicemic plague, due to susceptible isolates of <i>Yersinia pestis</i> and prophylaxis of plague • Treatment of ABS · Treatment of ABECB	• Complicated intra-abdominal infections – 400mg every 24 hours for 5-14 days • Plague – 400mg every 24 hours for 10-14 days • ABS – 400mg every 24 hours for 10 days • ABECB – 400mg every 24 hours for 5 days
Baxdela® (delafloxacin)	• Treatment of acute bacterial skin and skin structure infections (ABSSSI) • Treatment of community-acquired bacterial pneumonia (CABP)	• ABSSSI: 450 mg every 12 hours for 5-14 days • CABP: 450 mg every 12 hours for 5-10 days
Ofloxacin	• Treatment of ABECB • Treatment of CAP • Treatment of uncomplicated SSSI • Treatment of acute, uncomplicated urethral and cervical gonorrhea • Treatment of nongonococcal cervicitis/urethritis • Treatment of mixed infections of the urethra and cervix • Treatment of acute pelvic inflammatory disease • Treatment of uncomplicated cystitis • Treatment of complicated UTI's • Treatment of prostatitis	• ABECB – 400 mg every 12 hours for 10 days · CAP – 400 mg every 12 hours for 10 days • Uncomplicated SSSI – 400mg every 12 hours for 10 days • Acute, uncomplicated urethral and cervical gonorrhea – 400 mg as a single dose • Nongonococcal cervicitis/urethritis due to <i>C. trachomatis</i> – 300mg every 12 hours for 7 days • Mixed infection of the urethra and cervix due to <i>C. trachomatis</i> and <i>N. gonorrhoeae</i> – 300mg every 12 hours for 7 days • Acute pelvic inflammatory disease – 400 mg every 12 hours for 10-14 days • Uncomplicated cystitis due to <i>E. coli</i> or <i>K. pneumoniae</i> – 200 mg every 12 hours for 3 days • Uncomplicated cystitis due to other approved pathogens – 200mg every 12 hours for 7 days • Complicated UTI's – 200mg every 12 hours for 10 days • Prostatitis due to <i>E. coli</i> – 300mg every 12 hours for 6 weeks

†Due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae* (including multi-drug-resistant isolates [MDRSP]), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae*

‡Due to *Streptococcus pneumoniae* (excluding multi-drug-resistant isolates [MDRSP]), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Mycoplasma pneumoniae*, or *Chlamydia pneumoniae*

#This regimen is indicated for cUTI due to *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis* and AP due to *E. coli*, including cases with concurrent bacteremia

«This regimen is indicated for cUTI due to *Enterococcus faecalis*, *Enterococcus cloacae*, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*; and for AP due to *E. coli*

ØMulti-drug resistant *Streptococcus pneumoniae*, includes isolates previously known as PRSP (penicillin-resistant *Streptococcus pneumoniae*), and are strains resistant to two or more of the following antibiotics: penicillin (MIC 2 µg/mL), 2nd generation cephalosporins (e.g., cefuroxime), macrolides, tetracyclines and trimethoprim/sulfamethoxazole

Boxed Warnings and Contraindications

Medication	Boxed Warnings	Contraindications
Levofloxacin Ciprofloxacin (Cipro®) Moxifloxacin Baxdela® (delafloxacin) Ofloxacin	- Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together including: - Tendinitis and tendon rupture - Peripheral neuropathy - Central nervous system effects - Reserve use of levofloxacin for treatment of acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, or uncomplicated urinary tract infection for patients who have no alternative treatment options because of the risk of disabling and potentially serious adverse reactions - Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis	- Known hypersensitivity to specific agent (levofloxacin, ciprofloxacin, moxifloxacin, delafloxacin, ofloxacin) or other quinolone antibacterials - Ciprofloxacin only: Concomitant administration with tizanidine

Warnings/Precautions

Medication	Warnings/Precautions
Levofloxacin Ciprofloxacin (Cipro®) Moxifloxacin Baxdela® (delafloxacin) Ofloxacin	Concerns related to adverse events: [US Boxed Warning]: Fluoroquinolones are associated with disabling and potentially irreversible serious adverse reactions that may occur together, including tendinitis and tendon rupture, peripheral neuropathy, and CNS effects. - Peripheral neuropathy - Central nervous system (CNS) effects, including convulsions, toxic psychoses, and increased intracranial pressure - May increase the risk of aortic dissections or ruptures and should not be used in patients with an aortic aneurysm or those at increased risk, including patients with peripheral atherosclerotic vascular diseases, hypertension, genetic disorders involving blood vessel changes (eg, Marfan syndrome, Ehlers-Danlos syndrome), and the

	elderly, unless no other treatment options are available. Longer treatment duration (eg, >14 days) may increase risk. • Serious and occasionally fatal hypersensitivity and/or anaphylactic reactions • Moderate to severe photosensitivity/phototoxicity reactions after sun or UV light exposure • Prolongation of the QT interval on the ECG and infrequent cases of arrhythmia reports of severe hepatotoxicity have been received for patients treated with levofloxacin • Prolonged use may result in fungal or bacterial superinfection, including Clostridioides (formerly Clostridium) difficile-associated diarrhea (CDAD) and pseudomembranous colitis; CDAD has been observed >2 months post antibiotic treatment • Increased incidence of musculoskeletal disorders • Disturbances of blood glucose, including symptomatic hyper and hypoglycemia have been reported, usually in diabetic patients receiving concomitant treatment with an oral hypoglycemic agent or with insulin • Cipro only: Rarely, crystalluria has occurred; urine alkalinity may increase the risk. Ensure adequate hydration during therapy Disease related concerns: • Fluoroquinolones have neuromuscular blocking activity and may exacerbate muscle weakness in patients with myasthenia gravis • Use with caution in patients with renal impairment; dosage adjustment required. May increase risk of tendon rupture • Use with caution in patients with rheumatoid arthritis; may increase risk of tendon rupture • Ciprofloxacin and ofloxacin only: Since ciprofloxacin is ineffective in the treatment of syphilis and may mask symptoms, all patients should be tested for syphilis at the time of gonorrheal diagnosis and 3 months later • Moxifloxacin only: Use with caution in patients with significant bradycardia or acute myocardial ischemia • Moxifloxacin only: Use with caution in patients with diabetes mellitus; glucose regulation may be altered • Ofloxacin only: Use with caution in individuals at risk of seizures (CNS disorders or concurrent therapy with medications which may lower seizure threshold). Potential for seizures, although very rare, may be increased with concomitant NSAID therapy Concurrent drug therapy issues: • Potentially significant interactions may exist, requiring dose or frequency adjustment, additional monitoring, and/or selection of alternative therapy Special Populations: • Adverse effects (eg, hepatotoxicity, tendon rupture, QT changes, aortic dissection) may be increased in the elderly • Levofloxacin, moxifloxacin, & ofloxacin only: Hemolytic reactions may (rarely) occur with quinolone use in patients with latent or actual G6PD deficiency • Levofloxacin, ciprofloxacin, & moxifloxacin only: Safety of use in pediatric patients for >14 days of therapy has not been studied; increased incidence of musculoskeletal disorders (eg, arthralgia, tendon rupture) has been observed in children

	Dosage form specific issues: - Levofloxacin only: Some dosage forms may contain benzyl alcohol; large amounts of benzyl alcohol (≥ 99 mg/kg/day) have been associated with a potentially fatal toxicity ("gasping syndrome") in neonates; the "gasping syndrome" consists of metabolic acidosis, respiratory distress, gasping respirations, CNS dysfunction (including convulsions, intracranial hemorrhage), hypotension, and cardiovascular collapse - Delafloxacin only: Avoid use of IV formulation in patients with end-stage renal disease (eGFR < 15 mL/minute/1.73 m²); injection contains excipient cyclodextrin (sulfobutylether-beta-cyclodextrin [SBECD]), which may accumulate Other warnings/precautions: [US Boxed Warning]: Reserve use of fluoroquinolone for treatment of acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, or uncomplicated urinary tract infection for patients who have no alternative treatment options because of the risk of disabling and potentially serious adverse reactions (eg, tendinitis and tendon rupture, peripheral neuropathy, CNS effects).

Practice Guidelines

Bower WA, Yu Y, Person MK, et al. CDC Guidelines for the Prevention and Treatment of Anthrax, 2023. MMWR Recomm Rep 2023;72(No. RR-6):1–47.

- In Vivo PEPAbx and Treatment of Anthrax
 - PEP: Meta-analyses and most individual animal studies that could not be combined into any of the meta-analyses found a survival benefit for PEPAbx compared with no PEPAbx for amoxicillin, amoxicillin/clavulanate (two of three studies), ciprofloxacin, dalbavancin, daptomycin, doxycycline, imipenem, minocycline, ofloxacin, omadacycline, oritavancin, and tetracycline.
 - Treatment: The in vivo meta-analyses and studies that could not be combined into any of the meta-analyses demonstrated a survival benefit for monotherapy compared with no treatment for amoxicillin/clavulanate, ciprofloxacin, clindamycin, dalbavancin, doxycycline, eravacycline, imipenem, omadacycline, oritavancin, penicillin, and vancomycin. Clarithromycin, levofloxacin, linezolid, and rifampin did not demonstrate a statistically significant survival benefit when compared with no treatment.

Metlay JP, Waterer GW, et al. Diagnosis and Treatment of Adults with Community-acquired Pneumonia. An Official Clinical Practice Guideline of the American Thoracic Society and Infectious Diseases Society of America. Am J Respir Crit Care Med. 2019 Oct 1;200(7):e45-e67.

- For outpatient adults with comorbidities such as chronic heart, lung, liver, or renal disease; diabetes mellitus; alcoholism; malignancy; or asplenia we recommend: monotherapy with a respiratory fluoroquinolone (levofloxacin 750 mg daily, moxifloxacin 400 mg daily, or gemifloxacin 320 mg daily) (strong recommendation, moderate quality of evidence).
- In inpatient adults with nonsevere CAP without risk factors for MRSA or *P. aeruginosa* (see Recommendation 11), we recommend the following empiric treatment regimen: monotherapy with a respiratory fluoroquinolone (levofloxacin 750 mg daily, moxifloxacin 400 mg daily) (strong recommendation, high quality of evidence).

Shane AL, Mody RK, Crump JA et al. 2017 Infectious diseases society of America clinical practice guidelines for the diagnosis and management of infectious diarrhea. Clin Inf Dis. 2017.

- For the empiric management of infectious diarrhea, the recommended empiric antimicrobial therapy should be either a fluoroquinolone such as ciprofloxacin, depending on the local susceptibility patterns and travel history (strong, moderate).
- Ciprofloxacin is first line treatment for diarrhea caused by *Salmonella enterica* Typhi or Paratyphi, and *Shigella*.
- Clinicians treating people with shigellosis for whom antibiotic treatment is indicated should avoid prescribing fluoroquinolones if the ciprofloxacin MIC is 0.12 µg/mL or higher even if the laboratory report identifies the isolate as susceptible.
- The choice of antimicrobial agent may change due to evolving resistance patterns. Fluoroquinolone resistance in US and Canadian patients without international travel remains low.

Berbari EF, Kanj SS, Kowalski TJ, et al. 2015 Infectious Diseases Society of America (IDSA) Clinical Practice Guidelines for the Diagnosis and Treatment of Native Vertebral Osteomyelitis in Adults. Clin Infect Dis. 2015 September:e26-46.

- For native vertebral osteomyelitis (NVO) caused by enterobacteriaceae and *Pseudomonas aeruginosa* ciprofloxacin is alternative treatment. For enterobacteriaceae, recommends ciprofloxacin 500–750 mg PO q12 h

or 400 mg IV q12 hours and for pseudomonas aeruginosa recommends ciprofloxacin 750 mg PO q12 h (or 400 mg IV q8 h) for 6 weeks duration.

- For native vertebral osteomyelitis (NVO) caused by Pseudomonas aeruginosa, double coverage may be considered of β -lactam and ciprofloxacin.
- Moxifloxacin, levofloxacin and ciprofloxacin are not recommended for staphylococcal NVO, but may be used in patients in patients with NVO due to Enterobacteriaceae and other susceptible aerobic gram-negative organisms.

Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 update by the Infectious Diseases Society of America. Clin Infect Dis. 2014;59(2):e10-52.

- For Cutaneous Anthrax, an appropriate treatment is Ciprofloxacin 500 mg by mouth (po) twice a day or levofloxacin 500 mg intravenously (IV)/po every 24 hours $\times$ 60 days is recommended for bioterrorism cases because of presumed aerosol exposure (strong, low).
- Recommended therapy for infections following animal bites, includes fluoroquinolones such as ciprofloxacin, levofloxacin or moxifloxacin which have good activity against P. multocida and some anaerobes (strong, moderate).

Clinical Trials/Systematic Reviews/Meta-Analyses

Citation	Design	Endpoints
Mittmann N, Jivarj F, Wong A, Yoon A. Oral fluoroquinolones in the treatment of pneumonia, bronchitis and sinusitis. Can J Infect Dis. 2002;13(5):293-300.	Systematic review of literature for 37 clinical trials of antibiotics used in the treatment of CAP, AECB and sinusitis. Comparative and single arm meta-analyses were conducted. Inclusion criteria: original study, random allocation to treatment groups, treatment with one of the following oral antibiotics – moxifloxacin, levofloxacin, ciprofloxacin and gatifloxacin, controlled by either placebo or active comparator medication, double-blind, single-blind or open-label treatment, 18 years of age and older, diagnosis of mild to moderate CAP, AECB or sinusitis, and treatment duration of at least 3 days Exclusion criteria: epidemiological studies, abstracts, non-comparator studies, dose-finding studies, pharmacokinetic studies and single doses studies were excluded from the analysis	- Clinical success rate was primary outcome variable in the analysis - Success rate was defined as the proportion of patients who had a successful outcome (improvement in symptoms and were cured after at least 3 days of therapy) and/or responded to treatment - Safety endpoint was evaluated by examining adverse events and study dropouts
Results: -The comparative meta-analysis of moxifloxacin and clarithromycin for the treatment of CAP resulted in no significant differences in outcome. - For AECB, there was no statistically significant difference in the outcome between ciprofloxacin or moxifloxacin and clarithromycin or between levofloxacin and cefuroxime; clinical success and failure rates differed by 7.8% ($p=0.06$) and 11.7%, ($p<0.001$), respectively. - For SIN, no statistically significant differences in outcome rates were found between comparators, clinical success and failure rates for levofloxacin versus clarithromycin differed by 1.6% ($p=0.50$) and 1.6% ($p=0.5$), respectively. For ciprofloxacin versus cefuroxime, and moxifloxacin and cefuroxime, clinical success rates differed by 2.5% ($p=0.18$) and 0.7% ($p=0.50$), respectively. The single-arm meta-analysis for CAP, clinical success was 95.0% (no 95% CI was available for one study) for gatifloxacin, followed by levofloxacin (94.3%, 95% CI 91.7% to 97%). The different treatments were considered to be equivalent. - For AECB, the analysis found that the treatments were equivalent in moxifloxacin (94.2%, 95% CI 92.8% to 95.6%), ciprofloxacin (90.8%, 95% CI 75.5% to 94.1%), gatifloxacin (89%, 95% CI 85.9% to 92.1%), and levofloxacin (84.8%, 95% CI 75.5% to 94.1%). - Lastly, for treatment of sinusitis, gatifloxacin had a clinical success rate of 93.0% (no 95% CI was available for one study), levofloxacin (92.7%, 95% CI 88.0% to 97.5%), moxifloxacin (90.1%, 95% CI 87.7% to 92.4%) and ciprofloxacin (88.2%, 95% CI 84.5% to 91.9%); no significant differences were found between the treatment groups. Overall dropout rate and adverse events were similar. Conclusion: In general, fluoroquinolones that were studied had similar efficacy, safety and dropout rates.		

Citation	Design	Endpoints
Lee JH, Kim SW, Kim JH, Ryu YJ, Chang JH. High-dose levofloxacin in community-acquired pneumonia: a randomized, open-label study. Clin Drug Investig. 2012;32(9):569-76.	Phase 4, prospective, open-label trial that enrolled 40 patients who were randomized to receive levofloxacin 750mg IV once daily, followed by the same dose of oral levofloxacin at discharge or ceftriaxone 2g IV plus oral azithromycin	- Primary endpoint: clinical success rate - Safety endpoint: adverse events
Results: The clinical success rate was 94% in the levofloxacin group and 84% in the control group of ceftriaxone plus azithromycin ($p>0.05$). The overall adverse events were similar in both groups. Conclusion: High dose levofloxacin treatment exhibited clinical, microbiological efficacy with similar safety profile comparable to that of ceftriaxone and azithromycin therapy. However, large-scale clinical trials are needed to verify these results and conclusion.		
Citation	Design	Endpoints
O'riordan W, Mcmanus A, Teras J, et al. A comparison of the efficacy and safety of intravenous followed by oral delafloxacin with vancomycin plus aztreonam for the treatment of acute bacterial skin and skin structure infections: a phase 3, multinational, double-blind, randomized study. Clin Infect Dis. 2018.	Phase 3, multicenter, double-blind, stratified trial randomized 850 patients with ABSSSI to receive either delafloxacin 300mg IV every 12 hours for 3 days with a switch to 450mg oral delafloxacin, or vancomycin 15mg/kg IV with aztreonam for 5-14 days. Inclusion criteria: diagnosis of ABSSI defined as cellulitis/erysipelas, wound infection, major cutaneous abscess, or burn infection that was characterized by $\geq 75\text{cm}^2$ of erythema and ≥ 2 signs of systemic infection Exclusion criteria: Patients with infection types including diabetic foot infection, osteomyelitis and decubitus ulcer, and less serious skin infections such as impetigo and minor cutaneous abscess.	- Primary endpoint - objective response (OR) at 48-72 hours after initiation of treatment based on $\geq 20\%$ decrease in lesion size - Secondary endpoint – investigator-assessed response based on resolution of signs and symptoms at follow up (day 14) - Treatment emergent adverse events (TEAEs) was the safety endpoint
Results: The OR was reportedly 83.7% in the delafloxacin arm and 80.6% in the vancomycin plus aztreonam arm. Regarding the investigator-assessed success, it was similar at follow up with 87.2% versus 84.4%, respectively. The frequency of TEAEs was similar between the groups – TEAEs leading to discontinuation was higher in the vancomycin plus aztreonam arm (1.2% vs 2.4%) Conclusion: Delafloxacin monotherapy was noninferior to IV vancomycin/aztreonam combination therapy in terms of efficacy. It was also well tolerated. Transitioning from IV formulation to oral still resulted in comparable efficacy as compared to vancomycin and aztreonam. Ultimately, delafloxacin, available as both IV and oral formulations, provide a treatment option for ABSSSI due to gram-positive which includes MRSA and gram-negative bacteria.		

Citation	Design	Endpoints
Bundrick W, Heron SP, Ray P et al. Levofloxacin versus ciprofloxacin in the treatment of chronic bacterial prostatitis: a randomized double-blind multicenter study. Urology. 2003; 62(3):537-41.	In a multicenter, double-blind, active control trial, 377 men with were randomized to treatment with levofloxacin 500mg once daily or ciprofloxacin 500mg twice daily for 28 days for the treatment of chronic bacterial prostatitis Inclusion criteria: clinical diagnosis of chronic bacterial prostatitis as evidenced by a history of chronic bacterial prostatitis, current clinical signs and symptoms of prostatitis, and laboratory evidence of prostatitis Exclusion criteria: not listed	- Primary endpoint – microbiologic efficacy in the microbiologically assessable population as defined by clinical success rate and microbiologic eradication rate - Safety endpoint was treatment emergent adverse events (TEAEs)
Results: Clinical success was achieved at post-therapy visit in 75% of the microbiologically assessable levofloxacin patients and 72.8% of the ciprofloxacin patients. For the end of drug treatment, 75.0% and 76.8% experienced eradication of all pathogens present at study entry for levofloxacin and ciprofloxacin, respectively. 44.2% vs 37.2% (levofloxacin vs ciprofloxacin) experienced at least one TEAE. Conclusion: Levofloxacin is equivalent clinically and microbiologically to ciprofloxacin for the treatment of chronic bacterial prostatitis, with similar safety profiles.		

Formulary Placement, Utilization and Cost Experience (04-01-2025 to 06-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Fluoroquinolones (Oral)								
Ciprofloxacin (Cipro®) 250mg/5ml, 500mg/5ml oral suspension	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Ciprofloxacin (Cipro®) 250mg, 500mg, 750mg oral tablet	29	26	\$59.69	\$2.06	0	0 (0%)	F- QL (60/30)	No change
Baxdela® (delafloxacin) 450 mg oral tablet	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Levofloxacin oral solution 25mg/ml	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Levofloxacin 250mg, 500mg, 750mg oral tablet	17	16	\$36.54	\$2.15	0	0 (0%)	F	No change
Moxifloxacin 400mg oral tablet	0	0	\$0.00	\$0.00	0	0 (0%)	F-ST (Prior use of isoniazid, rifampin, pyrazinamide, or ethambutol is required)	No change
Ofloxacin 300mg, 400mg oral tablet	0	0	\$0.00	\$0.00	0	0 (0%)	F	No change
TOTAL	46	42	\$96.23	\$2.09	0	0 (0%)		

Key (as applicable) F = Formulary, no restrictions; F-QL = Formulary, quantity limit applies; F-AL = Formulary, age limit applies; F-ST = Formulary, step therapy applies; F-PA = Formulary, PA required; NF = Non-formulary; X = Excluded

Prior Authorization Criteria

No changes

Moxifloxacin Oral Tablet	
Therapeutic Classes (AHFS)	Quinolone antibiotics
Medications	<u>Formulary, Step Therapy</u> Moxifloxacin 400mg tablet **Please Note: If the request is for moxifloxacin for the treatment of multi-drug resistant tuberculosis, refer to criteria for medications for the treatment of multi-drug resistant tuberculosis ***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial/Re-Approval If all of the criteria are met, approve 1 fill up to FDA approved maximum dosing If the criteria is not met, the request will be referred to a clinical reviewer for medical necessity review.
PA Review Criteria	Criteria for approval: • Appropriate diagnosis/indication AND • Appropriate dose of medication based on age (i.e. pediatric and elderly populations) and indication AND • Documented trial and failure or intolerance to up to two formulary antibiotics that are used to treat the documented diagnosis OR • No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia. OR • Based on culture and sensitivity data, moxifloxacin is the only treatment option.
Criteria Statement	Moxifloxacin tablet is reserved for members who have used (or cannot/should not use) up to two formulary antibiotic medications (if available) that are used to treat the documented diagnosis or when moxifloxacin is the only treatment option, based on culture and sensitivity data.
Last P&T Review Date	9/20249/2025

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Hepatitis C

Executive Summary

Class Overview

Hepatitis C virus (HCV) infection is the most common bloodborne pathogen in the United States with transmission commonly occurring via the shared use of injection drug equipment. HCV infection is associated with high morbidity and mortality and remains a significant public health concern in the United States, with chronic infections possibly leading to severe liver complications including cirrhosis and hepatocellular carcinoma. In 2024, the World Health Organization (WHO) reported that approximately 50 million people had chronic HCV infection, and approximately 1 million new infections occurred each year. There are six distinct genotypes of HCV (numbered 1-6), with genotype 1 being the most common. Rates of acute HCV infection are highest among persons aged 30-39 years, non-Hispanic American Indian/Alaskan Native persons, and males.

Guidelines published in 2023 by the American Association for the Study of Liver Diseases (AASLD) and in 2024 by the Infectious Diseases Society of America (IDSA) emphasize prevention, early detection, and treatment with direct-acting antiviral therapy as being essential to reduce the burden of HCV-related morbidity and mortality. Both organizations recommend treatment for all patients with acute or chronic HCV infection, except those with a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy, with a goal to achieve a virologic cure evidenced by a sustained virological response (SVR). Selection of the ideal initial treatment regimen may need to be individualized based on patient- and disease-specific factors.

All current direct acting antivirals fall into one of three categories: NS3/4A protease inhibitors (medication name ending in -previr), NS5A inhibitors (medication name ending in -asvir), and polymerase inhibitors (medication name ending in -buvir). Both AASLD and IDSA guidelines recommend Mavyret® (glecaprevir-pibrentasvir) and Epclusa® (sofosbuvir-velpatasvir) as first-line initial treatment agents regardless of HCV genotype if noncirrhotic or if with compensated cirrhosis. Epclusa® is also recommended for use with weight-based ribavirin in patients with decompensated cirrhosis, regardless of HCV genotype. The utilization of Harvoni® (ledipasvir-sofosbuvir) and Zepatier® (elbasvir-grazoprevir) is limited by HCV genotype, comorbid conditions (ie. cirrhosis, HIV), and HCV resistance. The use of Vosevi® (sofosbuvir-velpatasvir-voxilaprevir) is mainly recommended in treatment experienced patients who are undergoing retreatment, regardless of HCV genotype. Pegasys® (peginterferon alfa-2a) was traditionally used in combination with ribavirin for the treatment of HCV, but has not been routinely recommended for use since the creation of highly effective direct acting antiviral therapy. Ribavirin is still used in combination with certain direct-acting antiviral therapy for specific indications, but is not recommended for use as a monotherapy for treatment of HCV.

Utilization Findings

There was no utilization and no prior authorization requests.

Recommendations

- No changes

Clinical Summary

Hepatitis C virus (HCV) infection is the most common bloodborne pathogen in the United States with transmission commonly occurring via the shared use of injection drug equipment. HCV infection is associated with high morbidity and mortality and remains a significant public health concern in the United States, with chronic infections possibly leading to severe liver complications including cirrhosis and hepatocellular carcinoma. In 2024, the World Health Organization (WHO) reported that approximately 50 million people had chronic HCV infection, and approximately 1 million new infections occurred each year. There are six distinct genotypes of HCV (numbered 1-6), with genotype 1 being the most common. Rates of acute HCV infection are highest among persons aged 30-39 years, non-Hispanic American Indian/Alaskan Native persons, and males.

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A new direct-acting antiviral, bemnifosbuvir-ruzasvir, is currently in being studied in a phase 3, randomized, controlled, open-label study compared to sofosbuvir-velpatasvir to compare efficacy and safety in treatment of adults with chronic HCV and either no cirrhosis or compensated liver cirrhosis (NCT06868264). The study is actively recruiting and is anticipated to enroll 800 patients with an anticipated completion date of December 2026.



Indications, Dosing and Administration

Medication	Indications	Dosing/Administration
Pegasys 180 mcg/mL vial Pegasys 180 mcg/0.5 mL syringe	The treatment of chronic HCV in patients 5 years of age and older with compensated liver disease not previously treated with interferon alpha, in patients with histological evidence of cirrhosis and compensated liver disease, and in adults with CHC/HIV coinfection and CD4 count greater than 100 cells/mm³ - Combination therapy with Copegus is recommended unless patient has contraindication to or significant intolerance to Copegus Pegasys monotherapy is indicated for: - Treatment of adult patients with HBeAg positive and HBeAg negative chronic hepatitis B infection who have compensated liver disease and evidence of viral replication and liver inflammation	Pegasys is administered by subcutaneous injection in the abdomen or thigh. <u>Pegasys Monotherapy:</u> The recommended dose of PEGASYS monotherapy for chronic hepatitis C is 180 mcg (1 mL vial, 0.5 mL prefilled syringe or 0.5 mL disposable autoinjector) once weekly for 48 weeks. <u>Pegasys/Copegus Combination:</u> Genotypes 1, 4 – 180 mcg once weekly with 1000 mg (<75kg) or 1200 mg (≥75 kg) Copegus for 48 weeks Genotypes 2, 3 – 180 mcg once weekly with 800 mg Copegus for 24 weeks
Ribavirin 200 mg capsule Ribavirin 200 mg tablet	Copegus is a nucleoside analogue indicated for the treatment of chronic hepatitis C (CHC) virus infection in combination with Pegasys in patients 5 years of age and older with compensated liver disease not previously treated with interferon alpha, and in adult CHC patients coinfecting with HIV.	<u>Pegasys/Copegus Combination:</u> Genotypes 1, 4 – 180 mcg once weekly with 1000 mg (<75kg) or 1200 mg (≥75 kg) Copegus for 48 weeks Genotypes 2, 3 – 180 mcg once weekly with 800 mg Copegus for 24 weeks
Vosevi 400-100-100 mg tablet	Vosevi is a fixed-dose combination of sofosbuvir, HCV nucleotide analog NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor, and is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have: - genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor. - genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.	The recommended dosage of Vosevi is one tablet, taken orally, once daily with food. All genotypes and without cirrhosis or with Child-Pugh A compensated cirrhosis, and treatment experienced with an NS5A inhibitor: Vosevi for 12 weeks Genotypes 1a or 3 and without cirrhosis or with Child-Pugh A compensated cirrhosis, and treatment experienced with sofosbuvir without an NS5A inhibitor: Vosevi for 12 weeks

Sovaldi 200, 400 mg tablet Sovaldi 150, 200 mg pellet packet	Sovaldi is an HCV nucleotide analog NS5B polymerase inhibitor indicated for the treatment of: • Adult patients with genotype 1, 2, 3 or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen. • Pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.	The recommended dosage of SOVALDI is one 400 mg tablet, taken orally, once daily with or without food. Taken in combination with ribavirin or in combination with pegylated interferon and ribavirin for the treatment of HCV. Genotype 1 or 4 and treatment naïve with Child-Pugh A compensated cirrhosis or without cirrhosis: Sovaldi + peginterferon alfa + ribavirin for 12 weeks Genotype 2 and treatment naïve or experienced interferon-based regimen with or without ribavirin and without cirrhosis or with Child-Pugh A compensated cirrhosis: Sovaldi + ribavirin for 12 weeks Genotype 3 and treatment naïve or experienced interferon-based regimen with or without ribavirin and without cirrhosis or with Child-Pugh A compensated cirrhosis: Sovaldi + ribavirin for 24 weeks
Epclusa 200-50, 400-100 mg tablet Epclusa 150-37.5, 200-50 mg pellet packet Sofosbuvir-velpatasvir 400-100 mg tablet	Epclusa is a fixed-dose combination of sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection: • without cirrhosis or with compensated cirrhosis with decompensated cirrhosis for use in combination with ribavirin	Recommended dosage in adults: One tablet (400 mg of sofosbuvir and 100 mg of velpatasvir) taken orally once daily with or without food Any genotype and treatment naïve or treatment experienced with peginterferon alfa/ribavirin with or without an HCV NS3/4A protease inhibitor and without cirrhosis or Child-Pugh A compensated cirrhosis: Epclusa for 12 weeks Any genotype and treatment naïve or treatment experienced with peginterferon alfa/ribavirin with or without an HCV NS3/4A protease inhibitor and with Child-Pugh B or C decompensated cirrhosis: Epclusa + ribavirin for 12 weeks

Zepatier 50-100 mg tablet	Zepatier is a fixed-dose combination product containing elbasvir, a HCV NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor, and is indicated for treatment of chronic HCV genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg. Zepatier is indicated for use with ribavirin in certain patient populations.	Testing patients with HCV genotype 1a infection for the presence of virus with NS5A resistance associated polymorphisms is recommended prior to initiation of treatment with Zepatier to determine dosage regimen and duration. Zepatier is a two-drug, fixed-dose combination product containing 50 mg of elbasvir and 100 mg of grazoprevir in a single tablet. The recommended dosage of Zepatier is one tablet taken orally once daily with or without food. Genotype 1a + treatment naïve or PegIFN/RBV-experienced without baseline NS5A polymorphisms: Zepatier for 12 weeks Genotype 1a + treatment naïve or PegIFN/RBV-experienced with baseline NS5A polymorphisms: Zepatier + ribavirin for 16 weeks Genotype 1b + treatment naïve or PegIFN/RBV-experienced: Zepatier for 12 weeks Genotype 1a or 1b + PegIFN/RBV/PI-experienced: Zepatier + ribavirin for 12 weeks Genotype 4 + treatment naïve: Zepatier for 12 weeks Genotype 4 + PegIFN/RBV-experienced: Zepatier + ribavirin for 16 weeks

Mavyret 100-40 mg tablet Mavyret 50-20 mg pellet packet	Mavyret is a fixed-dose combination of glecaprevir, a HCV NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adult and pediatric patients 3 years and older with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). Mavyret is indicated for the treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.	Mavyret tablets are a fixed combination drug product containing glecaprevir 100 mg and pibrentasvir 40 mg in each tablet. The recommended oral dosage of Mavyret in adults is 3 tablets taken at the same time once daily with food (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg) Genotype 1-6 and treatment naïve, without cirrhosis or with Child-Pugh A compensated cirrhosis: Mavyret for 8 weeks Genotype 1-6 and treatment experienced with peginterferon, ribavirin, and/or sofosbuvir, without cirrhosis: Mavyret for 8 weeks • If with Child-Pugh A compensated cirrhosis: Mavyret for 12 weeks Genotype 1 and treatment experienced with an NS4/4A protease inhibitor without prior treatment with an NS5A inhibitor and without cirrhosis or with Child-Pugh A compensated cirrhosis: Mavyret for 12 weeks Genotype 1 and treatment experienced with an NS5A inhibitor without prior treatment with an NS4/4A protease inhibitor and without cirrhosis or with Child-Pugh A compensated cirrhosis: Mavyret for 16 weeks Genotype 3 and treatment experienced with peginterferon, ribavirin, and/or sofosbuvir, without cirrhosis or with Child-Pugh A compensated cirrhosis: Mavyret for 16 weeks

Harvoni 45-200, 90-400 mg tablet Harvoni 33.75-150, 45-200 mg pellet packet Ledipasvir-sofosbuvir 90-400 mg tablet	Harvoni is a fixed-dose combination of ledipasvir, HCV NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic HCV in adults and pediatric patients 3 years of age and older: • Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis. • Genotype 1 infection with decompensated cirrhosis, in combination with ribavirin. • Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin.	The recommended dosage of HARVONI in adults with genotype 1, 4, 5, or 6 HCV is one tablet (90 mg ledipasvir and 400 mg sofosbuvir) taken orally once daily with or without food. Genotype 1 and treatment-naïve without cirrhosis or with Child-Pugh A compensated cirrhosis, or if treatment experienced with peginterferon alfa ± ribavirin based regimen with or without an HCV protease inhibitor and without cirrhosis: Harvoni for 12 weeks Genotype 1 and treatment experienced with peginterferon alfa + ribavirin based regimen with or without an HCV protease inhibitor and with Child-Pugh A compensated cirrhosis: Harvoni for 24 weeks Genotype 1 and treatment-naïve or treatment experienced with peginterferon alfa + ribavirin based regimen with or without an HCV protease inhibitor and with Child-Pugh B or C decompensated cirrhosis: Harvoni + ribavirin for 12 weeks. Genotype 1 or 4 and treatment-naïve or treatment experienced with peginterferon alfa ± ribavirin based regimen with or without an HCV protease inhibitor liver transplant recipients without cirrhosis or with Child-Pugh A compensated cirrhosis: Harvoni + ribavirin for 12 weeks Genotype 4, 5, or 6 and treatment-naïve or treatment experienced with peginterferon alfa ± ribavirin based regimen with or without an HCV protease inhibitor and without cirrhosis or with Child-Pugh A compensated cirrhosis: Harvoni for 12 weeks



Boxed Warnings and Contraindications

Medication	Boxed Warnings	Contraindications
Pegasys 180 mcg/mL vial Pegasys 180 mcg/0.5 mL syringe	Risk of serious disorders and ribavirin-associated effects. May cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Monitor closely and withdraw therapy with persistently severe or worsening signs or symptoms of the above disorders. Use with ribavirin: Ribavirin may cause birth defects and fetal death; avoid pregnancy in female patients and female partners of male patients	Autoimmune hepatitis Hepatic decompensation in patients with cirrhosis Use in neonates/infants Known hypersensitivity reactions such as urticaria, angioedema, bronchoconstriction and anaphylaxis to alpha interferons or any component of the product <u>Additional contraindications with ribavirin:</u> Pregnant women and men whose female partners are pregnant Hemoglobinopathies (e.g., thalassemia major, sickle cell disease) Coadministration with didanosine
Ribavirin 200 mg capsule Ribavirin 200 mg tablet	Risk of serious disorders and ribavirin associated effects Ribavirin monotherapy, including Copegus, is not effective for the treatment of chronic HCV infection The hemolytic anemia associated with ribavirin therapy may result in worsening of cardiac disease and lead to fatal and nonfatal myocardial infarctions. Patients with a history of significant or unstable cardiac disease should not be treated with Copegus Significant teratogenic and embryocidal effects have been demonstrated in all animal species exposed to ribavirin. Therefore, Copegus is contraindicated in women who are pregnant and in the male partners of women who are pregnant. Extreme care must be taken to avoid pregnancy during therapy and for 6 months after completion of treatment in both female patients and in female partners of male patients who are taking Copegus therapy.	Pregnant women and men whose female partners are pregnant Hemoglobinopathies Coadministration with didanosine <u>Additional contraindications with Pegasys:</u> Autoimmune hepatitis Hepatic decompensation in cirrhotic patients
Vosevi 400-100-100 mg tablet	Risk of hepatitis B virus reactivation in patients coinfecting with HCV and HBV	Coadministration with rifampin
Sovaldi 200, 400 mg tablet Sovaldi 150, 200 mg pellet packet	Risk of hepatitis B virus reactivation in patients coinfecting with HCV and HBV	When used in combination with peginterferon alfa/ribavirin or ribavirin alone, all contraindications to peginterferon alfa and/or ribavirin also apply to SOVALDI combination therapy

Epclusa 200-50, 400-100 mg tablet Epclusa 150-37.5, 200-50 mg pellet packet Sofosbuvir-velpatasvir 400-100 mg tablet	Risk of hepatitis B virus reactivation in patients coinfecting with HCV and HBV	EPCLUSA and ribavirin combination regimen is contraindicated in patients for whom ribavirin is contraindicated
Zepatier 50-100 mg tablet	Risk of hepatitis B virus reactivation in patients coinfecting with HCV and HBV	Patients with moderate or severe hepatic impairment (Child-Pugh B or C) OATP1B1/3 inhibitors that are known or expected to significantly increase grazoprevir plasma concentrations, strong CYP3A inducers, and efavirenz. If Zepatier is administered with ribavirin, the contraindications to ribavirin also apply.
Mavyret 100-40 mg tablet Mavyret 50-20 mg pellet packet	Risk of hepatitis B virus reactivation in patients coinfecting with HCV and HBV	Patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation. Coadministration with atazanavir or rifampin
Harvoni 45-200, 90-400 mg tablet Harvoni 33.75-150, 45-200 mg pellet packet Ledipasvir-sofosbuvir 90-400 mg tablet	Risk of hepatitis B virus reactivation in patients coinfecting with HCV and HBV	If used in combination with ribavirin, all contraindications to ribavirin also apply to Harvoni combination therapy.



Warnings/Precautions

Medication	Warnings/Precautions
Pegasys 180 mcg/mL vial Pegasys 180 mcg/0.5 mL syringe	Use with Ribavirin • Birth defects and fetal death: patients must have a negative pregnancy test prior to therapy, use 2 or more forms of contraception, and have monthly pregnancy tests • Hemolytic anemia • History of significant or unstable cardiac disease Patients exhibiting the following events should be closely monitored and may require dose reduction or discontinuation of therapy: • Neuropsychiatric events • Autoimmune and endocrine disorders (including thyroid disorders; hyperglycemia) • Ophthalmologic disorders • Cerebrovascular disorders • Hepatic decompensation in cirrhotic patients. Exacerbation of hepatitis during hepatitis B treatment • Pulmonary disorders • Infections (bacterial, viral, fungal) • Bone marrow suppression • Colitis and pancreatitis • Hypersensitivity and serious skin reactions including Stevens-Johnson syndrome • Growth impairment with combination therapy in pediatric patients • Peripheral neuropathy when used in combination with telbivudine
Ribavirin 200 mg capsule Ribavirin 200 mg tablet	Birth defects and fetal death with ribavirin: • Do not use in pregnancy and for 6 months after treatment. Patients must have a negative pregnancy test prior to therapy, use at least 2 forms of contraception and undergo monthly pregnancy tests. Pegasys/Copegus: Patients exhibiting the following conditions should be closely monitored and may require dose reduction or discontinuation of therapy: • Hemolytic anemia may occur with a significant initial drop in hemoglobin. This may result in worsening cardiac disease leading to fatal or nonfatal myocardial infarctions. • Risk of hepatic failure and death: Monitor hepatic function during treatment and discontinue treatment for hepatic decompensation • Severe hypersensitivity reactions including urticaria, angioedema, bronchoconstriction, and anaphylaxis, and serious skin reactions such as Stevens-Johnson Syndrome • Pulmonary disorders, including pulmonary function impairment and pneumonitis, including fatal cases of pneumonia • Severe depression and suicidal ideation, autoimmune and infectious disorders, suppression of bone marrow function, pancreatitis, and diabetes • Bone marrow suppression with azathioprine coadministration • Growth impairment with combination therapy in pediatric patients

Vosevi 400-100-100 mg tablet	Risk of Hepatitis B Virus Reactivation: - Test all patients for evidence of current or prior HBV infection before initiation of HCV treatment. Monitor HCV/HBV coinfecting patients for HBV reactivation and hepatitis flare during HCV treatment and post-treatment followup. Initiate appropriate patient management for HBV infection as clinically indicated. Risk of Hepatic Decompensation/Failure in Patients with Evidence of Advanced Liver Disease: - Hepatic decompensation/failure, including fatal outcomes, have been reported mostly in patients with cirrhosis and baseline moderate or severe liver impairment (Child-Pugh B or C) treated with HCV NS3/4A protease inhibitor-containing regimens. Monitor for clinical and laboratory evidence of hepatic decompensation. Discontinue Vosevi in patients who develop evidence of hepatic decompensation/failure. Bradycardia with Amiodarone Coadministration: - Serious symptomatic bradycardia may occur in patients taking amiodarone with Vosevi, a sofosbuvir-containing regimen, particularly in patients also receiving beta blockers, or those with underlying cardiac comorbidities and/or advanced liver disease. Coadministration of amiodarone with Vosevi is not recommended. In patients without alternative viable treatment options, cardiac monitoring is recommended.
Sovaldi 200, 400 mg tablet Sovaldi 150, 200 mg pellet packet	Risk of Hepatitis B Virus Reactivation: - Test all patients for evidence of current or prior HBV infection before initiation of HCV treatment. Monitor HCV/HBV coinfecting patients for HBV reactivation and hepatitis flare during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated. Bradycardia with amiodarone coadministration: - Serious symptomatic bradycardia may occur in patients taking amiodarone with a sofosbuvir-containing regimen, particularly in patients also receiving beta blockers, or those with underlying cardiac comorbidities and/or advanced liver disease. Coadministration of amiodarone with Sovaldi is not recommended. In patients without alternative, viable treatment options, cardiac monitoring is recommended.
Epclusa 200-50, 400-100 mg tablet Epclusa 150-37.5, 200-50 mg pellet packet Sofosbuvir-velpatasvir 400-100 mg tablet	Risk of Hepatitis B Virus Reactivation: - Test all patients for evidence of current or prior HBV infection before initiation of HCV treatment. Monitor HCV/HBV coinfecting patients for HBV reactivation and hepatitis flare during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated. Bradycardia with amiodarone coadministration: - Serious symptomatic bradycardia may occur in patients taking amiodarone, particularly in patients also receiving beta blockers, or those with underlying cardiac comorbidities and/or advanced liver disease. Coadministration of amiodarone with Epclusa is not recommended. In patients without alternative viable treatment options, cardiac monitoring is recommended.

Zepatier 50-100 mg tablet	Risk of Hepatitis B Virus Reactivation: - Test all patients for evidence of current or prior HBV infection before initiation of HCV treatment. Monitor HCV/HBV coinfecting patients for HBV reactivation and hepatitis flare during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated. ALT Elevations: - Perform hepatic laboratory testing prior to therapy, at treatment week 8, and as clinically indicated. For patients receiving 16 weeks of therapy, perform additional hepatic laboratory testing at treatment week 12. For ALT elevations on Zepatier, follow recommendations in full prescribing information. Risk of Hepatic Decompensation/Failure in Patients with Evidence of Advanced Liver Disease: - Hepatic decompensation/failure, including fatal outcomes, have been reported mostly in patients with cirrhosis and baseline moderate or severe liver impairment (Child-Pugh B or C) treated with HCV NS3/4A protease inhibitor-containing regimens. Monitor for clinical and laboratory evidence of hepatic decompensation. Discontinue Zepatier in patients who develop evidence of hepatic decompensation/failure. Risk Associated with Ribavirin Combination Treatment: - If Zepatier is administered with ribavirin, the warnings and precautions for ribavirin also apply
Mavyret 100-40 mg tablet Mavyret 50-20 mg pellet packet	Risk of Hepatitis B Virus Reactivation: - Test all patients for evidence of current or prior HBV infection before initiation of HCV treatment. Monitor HCV/HBV coinfecting patients for HBV reactivation and hepatitis flare during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated. Risk of Hepatic Decompensation/Failure in Patients with Evidence of Advanced Liver Disease: - Hepatic decompensation/failure, including fatal outcomes, have been reported mostly in patients with cirrhosis and baseline moderate or severe liver impairment (Child-Pugh B or C). Monitor for clinical and laboratory evidence of hepatic decompensation. Discontinue Mavyret in patients who develop evidence of hepatic decompensation/failure
Harvoni 45-200, 90-400 mg tablet Harvoni 33.75-150, 45-200 mg pellet packet Ledipasvir-sofosbuvir 90-400 mg tablet	Risk of Hepatitis B Virus Reactivation: - Test all patients for evidence of current or prior HBV infection before initiation of HCV treatment. Monitor HCV/HBV coinfecting patients for HBV reactivation and hepatitis flare during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated. Bradycardia with amiodarone coadministration: - Serious symptomatic bradycardia may occur in patients taking amiodarone, particularly in patients also receiving beta blockers, or those with underlying cardiac comorbidities and/or advanced liver disease. Coadministration of amiodarone with Harvoni is not recommended. In patients without alternative, viable treatment options, cardiac monitoring is recommended.

Practice Guidelines

Bhattacharya D, Aronsohn A, Price J, Lo Re V; AASLD-IDSA HCV Guidance Panel. Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Clin Infect Dis. 2023 May 25:ciad319.

The following charts reflects the 2023 updates to recommendations for initial treatment of HCV infected adults and retreatment of HCV infected adults:

Table 1. Recommendations for Initial Treatment of Hepatitis C Virus–Infected Adults

Regimen	Genotype	Classification	Duration	Rating	Caveats and Other Considerations
Treatment-naïve without cirrhosis or with compensated cirrhosis Glecaprevir/pibrentasvir	1–6	Recommended	8 wk	I, A ^a	
Sofosbuvir/velpatasvir	1–6	Recommended	12 wk	I, A ^b	For genotype 3 infection with compensated cirrhosis, NS5A RAS testing is recommended. If baseline NS5A RAS Y93H is present, add weight-based ribavirin or choose another recommended regimen.
Ledipasvir/sofosbuvir	1, 4, 5, 6	Recommended	12 wk	I, A ^c	Not recommended for genotype 6e infection if subtype is known.
	1 without cirrhosis	Recommended	8 wk	I, B	Applicable to patients without cirrhosis who are not living with human immunodeficiency virus and whose HCV RNA is <6 million IU/mL.
Elbasvir/grazoprevir	1b, 4	Recommended	12 wk	I, A ^d	
	1a	Alternative	12 wk	I, A	For genotype 1a infection, NS5A RAS testing is recommended. If baseline RASs are present (ie, substitutions at amino acid positions 28, 30, 31, or 93), another recommended regimen should be used.
Sofosbuvir/velpatasvir + weight-based ribavirin	3	Alternative	12 wk	Ila, A	Applicable to genotype 3 infection with compensated cirrhosis and baseline NS5a Y93 RAS.
Sofosbuvir/velpatasvir/voxilaprevir		Alternative	12 wk	Ila, B	Applicable to genotype 3 infection with compensated cirrhosis and baseline NS5a Y93 RAS.
Treatment-naïve with decompensated cirrhosis					
Sofosbuvir/velpatasvir + weight-based ribavirin	1–6	Recommended	12 wk	I, A ^e	Low initial dose of ribavirin (600 mg) is recommended for patients with CTP class C cirrhosis; increase as tolerated.
Sofosbuvir/velpatasvir	1–6	Recommended	24 wk	I, A ^e	Applicable to patients who are ribavirin ineligible.
Ledipasvir/sofosbuvir + weight-based ribavirin	1, 4, 5, 6	Recommended	12 wk	I, A ^f	Low initial dose of ribavirin (600 mg) is recommended for patients with CTP class C cirrhosis; increase as tolerated.
Ledipasvir/sofosbuvir	1, 4, 5, 6	Recommended	24 wk	I, A ^f	Applicable to patients who are ribavirin ineligible.

Recommendations are listed by recommended vs alternative and by genotypic activity, evidence level, and alphabetically.

Abbreviations: CTP, Child–Turcotte–Pugh score; HCV, hepatitis C virus; NS5A, hepatitis C virus nonstructural protein 5A; RAS, resistance-associated substitution.

^aThe level of evidence rating is I, B for persons with compensated cirrhosis.

^bThe level of evidence rating is I, B for persons with genotype 5 or 6 infection.

^cThe level of evidence rating is Ila, B for persons with genotype 5 or 6 infection and those with genotype 4 infection and compensated cirrhosis.

^dThe level of evidence rating is Ila, B for persons with genotype 4 infection and compensated cirrhosis.

^eOnly available data for genotype 6 infection are in persons with compensated cirrhosis.

^fOnly available data for genotypes 5 or 6 infection are in a small number of persons with compensated cirrhosis.

Table 2. Recommendations for Retreatment of Hepatitis C Virus–Infected Adults by Prior Exposure

Regimen	Genotype	Classification	Duration	Rating	Caveats and Other Considerations
Sofosbuvir-based treatment failure without cirrhosis or with compensated cirrhosis					
Sofosbuvir/velpatasvir/ voxilaprevir	1–6	Recommended	12 wk	I, A	For genotype 3 infection with compensated cirrhosis, add weight-based ribavirin if there are no contraindications.
Glecaprevir/pibrentasvir	1, 2, 4, 5, 6	Alternative	16 wk	I, A	Not recommended for patients with prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (eg, elbasvir/grazoprevir).
Glecaprevir/pibrentasvir treatment failure without cirrhosis or with compensated cirrhosis					
Glecaprevir/pibrentasvir + sofosbuvir + weight-based ribavirin	1–6	Recommended	16 wk	IIa, B	
Sofosbuvir/velpatasvir/ voxilaprevir	1–6	Recommended	12 wk	IIa, B	For patients with compensated cirrhosis, addition of weight-based ribavirin is recommended (rating IIa, C).
Sofosbuvir/velpatasvir/voxilaprevir or sofosbuvir + glecaprevir/pibrentasvir treatment failure without cirrhosis or with compensated cirrhosis					
Glecaprevir/pibrentasvir + sofosbuvir + weight-based ribavirin	1–6	Recommended	16 wk	IIa, B	Extension to 24 wk should be considered in extremely difficult cases (eg, genotype 3 infection with compensated cirrhosis) or failure following sofosbuvir + glecaprevir/pibrentasvir therapy.
Sofosbuvir/velpatasvir/ voxilaprevir + weight-based ribavirin	1–6	Recommended	24 wk	IIa, B	
Sofosbuvir- or NS5A inhibitor–based treatment failure with decompensated cirrhosis					
Sofosbuvir/velpatasvir + weight-based ribavirin	1–6	Recommended	24 wk	II, C ^a	Low initial dose of ribavirin (600 mg) is recommended for patients with CTP class C cirrhosis; increase as tolerated.
Ledipasvir/sofosbuvir + weight-based ribavirin	1, 4, 5, 6	Recommended	24 wk	II, C ^b	Low initial dose of ribavirin (600 mg) is recommended for patients with CTP class C cirrhosis; increase as tolerated.

Recommendations are listed by recommended vs alternative and by genotypic activity, evidence level, and alphabetically.

Abbreviations: CTP, Child–Turcotte–Pugh score; NS3/4A, hepatitis C virus nonstructural protein 3–4A; NS5A, hepatitis C virus nonstructural protein 5A.

^aOnly available data for genotypes 5 or 6 infection are in a small number of persons with compensated cirrhosis.

^bOnly available data for genotype 6 infection are in persons with compensated cirrhosis.

Recommendation Definitions

Class/Level	Definition
I	Evidence and/or general agreement that a given diagnostic evaluation, procedure, or treatment is beneficial, useful, and effective
II	Conflicting evidence and/or a divergence of opinion about the usefulness and efficacy of a diagnostic evaluation, procedure, or treatment
IIa	Weight of evidence and/or opinion is in favor of usefulness and efficacy
IIb	Usefulness and efficacy are less well established by evidence and/or opinion
III	Conditions for which there is evidence and/or general agreement that a diagnostic evaluation, procedure, or treatment is not useful and effective or if it in some cases may be harmful
A	Data derived from multiple randomized clinical trials, meta-analyses, or equivalent
B	Data derived from a single randomized trial, nonrandomized studies, or equivalent
C	Consensus opinion of experts, case studies, or standard of care

Clinical Trials/Systematic Reviews/Meta-Analyses

Citation	Design	Endpoints
Pegasys (peginterferon alfa-2a) [package insert]. Hoffmann-La Roche Inc., Nutley, NJ; Sep 2011.	Randomized, open-label, active-controlled trial N=630 Roferon-A (interferon alfa-2a) 3 MIU 3x weekly (N=207), Pegasys 135 mcg once weekly, Pegasys 180 mcg once weekly (N=208) Compensated liver disease, detectable HCV, liver biopsy diagnosis of chronic hepatitis, previously untreated with interferon	Sustained response (undetectable HCV RNA on or after study week 68)
Results: Sustained virologic response: Roferon-A 3 MIU vs. Pegasys 180 mcg [11% vs 26%; 15 percent difference (95% CI: 8 – 23)] Conclusion: Pegasys 180 mcg resulted in significantly more subjects who experienced sustained response compared to Roferon-A.		
Citation	Design	Endpoints
Fried MW, Shiffman ML, Reddy KR, et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection. N Engl J Med. 2002;347(13):975-982. doi:10.1056/NEJMoa020047.	Randomized (2:2:1), double-blind, placebo and active-controlled trial N=1121 180 ug peginterferon alfa-2a once weekly plus daily ribavirin 1000-1200 mg (based on body weight) (n=453), 180 ug peginterferon alfa-2a plus daily placebo (N=224), 3 million units interferon alfa-2b three times weekly plus daily ribavirin x 48 weeks (N=444) Adult patients, never received interferon, > 2000 copies of HCV RNA/mL, liver biopsy consistent with diagnosis of chronic hepatitis C were included. Patients were excluded if neutropenic, thrombocytopenic, anemic, HIV+, decompensated liver disease.	Sustained virologic response (absence of HCV RNA at end of follow-up of at least > 20 weeks)
Results: Sustained virologic response: - Peginterferon alfa-2a + ribavirin vs interferon alfa-2b plus ribavirin (56% vs. 44%, P<0.001) - Peginterferon alfa-2a + ribavirin vs. peginterferon alfa-2a plus placebo (56% vs 29%, P<0.001) Conclusion: Peginterferon alfa-2a plus ribavirin was significantly more effective than interferon alfa-2b plus ribavirin or peginterferon alfa-2a alone for the treatment of chronic hepatitis C.		

Citation	Design	Endpoints
Bourlière M, Gordon SC, Flamm SL, et al. Sofosbuvir, Velpatasvir, and Voxilaprevir for Previously Treated HCV Infection. <i>N Engl J Med</i>. 2017;376(22):2134-2146. doi:10.1056/NEJMoa1613512	Two phase 3 trials • POLARIS-1: Randomized, double-blind, placebo-controlled • POLARIS-4: Randomized, open-label, active-controlled POLARIS-1 (N=415), POLARIS-4 (N=333) POLARIS-1: sofosbuvir-velpatasvir-voxilaprevir (any genotype) (N=263) vs. placebo (only genotype 1) (N=152) x 12 weeks POLARIS-4: sofosbuvir-velpatasvir-voxilaprevir (any genotype) (N=182) vs. sofosbuvir-velpatasvir (genotype 1, 2, 3) (N=151) x 12 weeks Criteria: adult patients with elevated HCV RNA at screening and chronic HCV infection, with virologic failure after completing previous treatment of at least 4 weeks duration • POLARIS-1: previous treatment included NS5A inhibitor • POLARIS-4: previous treatment with any DAA regimen not including NS5A inhibitor, except those who received only a protease inhibitor with peginterferon and ribavirin	Sustained virologic response (HCV RNA < 15 IU/mL 12 weeks after end of treatment and received at least one dose of active treatment or placebo)
Results: POLARIS-1: Vast majority of enrolled patients were genotype 1 (N=300), followed by genotype 3 (N=78), then genotype 4 (N=22) • Overall sustained virologic response: sofosbuvir-velpatasvir-voxilaprevir group = 96% (95% CI: 93-98%) [N=253] ○ N=249 returned for 24 week post-treatment visit, 100% experienced SVR • SVR by genotype: 1a (96% [95% CI: 90-99%]); 1b (100% [95% CI: 92-100%]); 2 (100% [95% CI: 48-100%]); 3 (95% [95% CI: 87-99%]); 4 (91% [95% CI: 71-99%]); 5 (100% [95% CI: 54-100%]) POLARIS-4: Vast majority of enrolled patients were genotype 1 (N=144), followed by genotype 3 (N=106), then genotype 2 (N=64) • Overall sustained virologic response: sofosbuvir-velpatasvir-voxilaprevir group = 98% (95% CI: 95-99%) [N=177] ○ Sofosbuvir-velpatasvir group = 90% (95% CI: 84-94%) [N=136] ○ 173 patients (sofosbuvir-velpatasvir-voxilaprevir) and 133 patients (sofosbuvir-velpatasvir) returned at 24 weeks post treatment with 100% SVR Conclusion: 12 weeks of treatment with sofosbuvir–velpatasvir–voxilaprevir resulted in high rates of sustained virologic response among patients with and patients without compensated cirrhosis who had HCV of any genotype and who had not had a sustained virologic response after previous treatment with regimens containing DAAs, including NS5A inhibitors.		

Citation	Design	Endpoints
Lawitz E, Mangia A, Wyles D, et al. Sofosbuvir for previously untreated chronic hepatitis C infection. <i>N Engl J Med</i> . 2013;368(20):1878-1887. doi:10.1056/NEJMoa1214853	Two phase 3 studies (NEUTRINO and FISSION) NEUTRINO – single arm, open-label study (N=327) - Sofosbuvir plus peginterferon alfa-2a + ribavirin (genotype 1, 4, 5, or 6) FISSION – randomized, open-label, active control, noninferiority study (N=499) - Sofosbuvir + ribavirin vs. peginterferon alfa-2a + ribavirin (genotype 2 or 3) Criteria: adult males and females with confirmed chronic HCV infection, either with or without liver cirrhosis and no prior treatment with interferon or ribavirin	Sustained virologic response at 12 weeks after the end of therapy
Results: NEUTRINO: majority had HCV genotype 1 (89%), followed by genotype 4 (9%), then the remaining 2% had genotype 5 (N=1) or 6 (N=5). - SVR at 12 weeks: 90% (95% CI: 87% – 93%); SVR by genotype: 1a (92%); 1b (82%); 4 (96%); 5 (100%); 6 (100%) - SVR without cirrhosis: 92% (95% CI: 89% - 95%); SVR with cirrhosis: 80% (95% CI: 67% to 89%) FISSION: majority had HCV genotype 3 (72%), and remaining 28% had genotype 2 - SVR at 12 weeks following sofosbuvir-ribavirin for 12 weeks: 67%; SVR at 12 weeks following peginterferon-ribavirin for 24 weeks: 67% - Absolute difference between groups: 0.3 percentage points (95% CI: -7.5 – 8); Noninferiority test: P < 0.001 Conclusion: Sofosbuvir, peginterferon, and ribavirin in previously untreated patients with HCV infection, most of whom had genotype 1 or 4 infection, demonstrated an SVR at 12 weeks in 90% of patients. Sofosbuvir + ribavirin for 12 weeks was noninferior to peginterferon alfa-2a + ribavirin for 24 for SVR at 12 weeks.		
Citation	Design	Endpoints
Feld JJ, Jacobson IM, Hézode C, et al. Sofosbuvir and Velpatasvir for HCV Genotype 1, 2, 4, 5, and 6 Infection. <i>N Engl J Med</i> . 2015;373(27):2599-2607. doi:10.1056/NEJMoa1512610	Phase 3, randomized (5:1) double-blind, placebo controlled study N=741 Sofosbuvir-velpatasvir once daily (genotype 1, 2, 4, 5, 6) [N=624] vs. matching placebo (genotype 1, 2, 4, 6) [N=116] Criteria: adult patients with chronic HCV infection of genotypes 1, 2, 4, 5, or 6, 20% of patients would have been treatment experienced with interferon, 20% of patients would have evidence of cirrhosis.	Sustained virologic response (HCV RNA < 15 IU/mL) at 12 weeks after end of treatment
Results: In the sofosbuvir-velpatasvir group, majority had genotype 1a (34%), then 1b (19%) and 4 (19%), followed by 2 (17%), then 6 (7%), and 5 (6%). - SVR at 12 weeks for sofosbuvir-velpatasvir: 99% (95% CI: 98% - > 99%); none of the patients in the placebo group experienced SVR - Rate of SVR similar regardless of HCV genotype - SVR at 12 weeks for patients with cirrhosis (N=121): 99% [N=120] (95% CI: 95% - > 99%) - SVR at 12 weeks for treatment-experienced (N=201): 99% [N=200] (95% CI: 97% - 100%) Conclusion: treatment with sofosbuvir–velpatasvir for 12 weeks resulted in high rates of sustained virologic response in patients with HCV genotype 1, 2, 4, 5, or 6, including those with cirrhosis and those who had received previous treatment and those who had not been treated.		

Citation	Design	Endpoints
Foster GR, Afdhal N, Roberts SK, et al. Sofosbuvir and Velpatasvir for HCV Genotype 2 and 3 Infection. <i>N Engl J Med.</i> 2015;373(27):2608-2617. doi:10.1056/NEJMoa1512612	Two randomized, phase 3, open-label studies (ASTRAL-2 and ASTRAL-3) ASTRAL-2 (N=266) enrolled patients with genotype 2 - Sofosbuvir-velpatasvir for 12 weeks vs sofosbuvir plus weight based ribavirin for 12 weeks ASTRAL-3 (N=552) enrolled patients with genotype 3 - Sofosbuvir-velpatasvir for 12 weeks vs sofosbuvir plus weight based ribavirin for 24 weeks Criteria: adults with at least 6 month history of HCV infection, with 20% of patients being treatment experienced with interferon-containing regimen and 20% of patients with compensated cirrhosis.	Sustained virologic response (HCV RNA < 15 IU/mL) at 12 weeks after end of treatment
Results: ASTRAL-2 - SVR at 12 weeks sofosbuvir-velpatasvir: 99% (95% CI: 96% - 100%) - SVR at 12 weeks sofosbuvir-ribavirin: 94% (95% CI: 88% to 97%) - Strata-adjusted absolute difference: 5.2 percentage points (95% CI: 0.2 – 10.3, P = 0.02) ASTRAL-3 - SVR at 12 weeks sofosbuvir-velpatasvir: 95% (95% CI: 92% - 98%) - SVR at 12 weeks sofosbuvir-ribavirin: 80% (95% CI: 75% to 85%) - Strata-adjusted absolute difference: 14.8 percentage points (95% CI: 9.6 – 20.0, P < 0.001) Conclusion: rates of sustained virologic response at 12 weeks with fixed-dose combination of sofosbuvir–velpatasvir once daily were superior to those among patients who received standard treatment with sofosbuvir–ribavirin for patients with HCV genotype 2 or 3.		
Citation	Design	Endpoints
Zepatier (elbasvir and grazoprevir) [package insert]. Merck & Co., Inc., Whitehouse Station, NJ; 2021.	Randomized (3:1), double-blind, placebo-controlled study (C-EDGE TN) N=408 Elbasvir and grazoprevir for 12 weeks (N= 306) vs. matching placebo for 12 weeks (N=102) Criteria: treatment naïve subject with genotype 1 or 4 with or without cirrhosis.	Sustained virologic response at 12 weeks after the end of treatment
Results: - SVR Genotype 1 (N=288): 95%; SVR Genotype 1 + Cirrhosis (N=68): 97% - SVT Genotype 4 (Pooled N=66 from C-SCAPE, C-EDGE TN, C-EDGE COINFECTION): 97% (64/66)		

Citation	Design	Endpoints
Zeuzem S, Foster GR, Wang S, et al. Glecaprevir-Pibrentasvir for 8 or 12 Weeks in HCV Genotype 1 or 3 Infection. N Engl J Med. 2018;378(4):354-369. doi:10.1056/NEJMoa1702417	Two phase 3, randomized, open-label studies ENDURANCE-1 (genotype 1): - Glecaprevir-pibrentasvir for 8 weeks (N=351) - Glecaprevir-pibrentasvir for 12 weeks (N=352) ENDURANCE-3 (genotype 3): - Glecaprevir-pibrentasvir for 12 weeks (N=233) - Sofosbuvir-daclatasvir for 12 weeks (N=115) Criteria: adult patients with confirmed chronic HCV, ENDURANCE-1 enrolled treatment naïve or treatment experienced with interferon or pegylated interferon with or without ribavirin or treatment with sofosbuvir plus ribavirin with or without pegylated interferon. ENDURANCE-3 enrolled only treatment naïve patients.	Sustained virologic response at week 12 after treatment
Results: ENDURANCE-1: - SVR at 12 weeks in the 8 week treatment group: 99.1% (95% CI: 98-100%) - SVR at 12 weeks in the 12 week treatment group: 99.7% (95% CI: 99-100%) ENDURANCE-3: - SVR at 12 weeks in glecaprevir-pibrentasvir group: 95% (95% CI: 93-98%) - SVR at 12 weeks in Sofosbuvir-daclatasvir group: 97% (95% CI: 93-99.9%) - Rate difference for noninferiority: -1.2 percentage points (95% CI: -5.6 to 3.1) Conclusion: 8 weeks of treatment with glecaprevir–pibrentasvir resulted in high rates of sustained virologic response at 12 weeks among patients without cirrhosis who had HCV genotype 1 infection or genotype 3 infection.		
Citation	Design	Endpoints
Asselah T, Kowdley KV, Zadeikis N, et al. Efficacy of Glecaprevir/Pibrentasvir for 8 or 12 Weeks in Patients With Hepatitis C Virus Genotype 2, 4, 5, or 6 Infection Without Cirrhosis. Clin Gastroenterol Hepatol.	2 open-label, single arm studies (SURVEYOR-II Part 4, ENDURANCE-4); and 1 randomized, double-blind, placebo-controlled study (ENDURANCE-2) ENDURANCE-2: glecaprevir-pibrentasvir (N=202) vs placebo (N=100) for 12 weeks (genotype 2) ENDURANCE-4: glecaprevir-pibrentasvir (N=121) for 12 weeks (genotype 4, 5, 6) SURVEYOR-II Part 4: glecaprevir-pibrentasvir (N=203) for 8 weeks (genotypes 2, 4, 5, 6) Criteria: Adult patients with at least 6 month history of HCV infection with genotypes 2, 4, 5, or 6, and either treatment naïve or experienced, and absence of cirrhosis.	Percentage of patients achieving sustained virologic response at 12 weeks

2018;16(3):417-426. doi:10.1016/j.cgh.2017.09.027		
Results: • Genotype 2 SVR at 12 weeks with 8 weeks of treatment: 98% • Genotype 2 SVR at 12 weeks with 12 weeks of treatment: 99% • Genotype 4-6 SVR at 12 weeks with 8 weeks of treatment: 93% • Genotype 4-6 SVR at 12 weeks with 12 weeks of treatment: 99% Conclusion: 8-week treatment with glecaprevir-pibrentasvir in non-cirrhotic patients with HCV genotypes 2, 4, 5, or 6 infection yielded high SVR12 rates similar to those observed with 12-week treatment		
Citation	Design	Endpoints
Kowdley KV, Gordon SC, Reddy KR, et al. Ledipasvir and sofosbuvir for 8 or 12 weeks for chronic HCV without cirrhosis. <i>N Engl J Med</i> . 2014;370(20):1879-1888. doi:10.1056/NEJMoa1402355	Phase 3, randomized, open-label study N = 647 Ledipasvir-sofosbuvir for 8 weeks (N=215) vs. ledipasvir-sofosbuvir + ribavirin for 8 weeks (N=216) vs. ledipasvir-sofosbuvir for 12 weeks (N=216) Criteria: adults with treatment naïve chronic HCV genotype 1 infections without cirrhosis	Sustained virologic response (HCV RNA < 25 IU/mL) at 12 weeks after the end of therapy
Results: • SVR at 12 weeks for ledipasvir-sofosbuvir for 8 weeks: 94% (95% CI: 90-97%) • SVR at 12 weeks for ledipasvir-sofosbuvir + ribavirin for 8 weeks: 93% (95% CI: 89-96%) • SVR at 12 weeks for ledipasvir-sofosbuvir for 12 weeks: 95% (95% CI: 92-98%) Conclusion: All three groups of previously untreated patients with HCV genotype 1 infection without cirrhosis who received treatment with ledipasvir–sofosbuvir had rates of sustained virologic response that were higher than 90%.		



Formulary Placement, Utilization and Cost Experience (04-01-2025 to 06-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Pegasys® (peginterferon alfa 2a) 180 mcg/ml vial	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA	No change
Pegasys® (peginterferon alfa 2a) 180 mcg/0.5 ml syringe	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA	No change
Ribavirin 200 mg capsule	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Ribavirin 200 mg tablet	0	0	\$0.00	\$0.00	0	0 (0%)	F	No change
Sovaldi® (sofosbuvir) 200 mg, 400 mg tablets	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA NF-400mg	No change
Sovaldi® (sofosbuvir) 150 mg, 200 mg pellet packets	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Zepatier® (elbasvir-grazoprevir) 50-100 mg tablet	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA	No change
Mavyret® (glecaprevir-pibrentasvir) 100-40 mg tablet	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA	No change
Mavyret® (glecaprevir-pibrentasvir) 50-20 mg pellet packet	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA	No change
Harvoni® (ledipasvir-sofosbuvir) 45-200 mg, 90-400 mg tablets	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA	No change
Harvoni® (ledipasvir-sofosbuvir) 33.75-150 mg, 45-200 mg pellet packets	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Epclusa® (sofosbuvir-velpatasvir) 200-50 mg, 400-100 mg tablets	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA *400mg-100mg NF-200mg-50mg	No change
Epclusa® (sofosbuvir-velpatasvir) 150-37.5 mg, 200-50 mg pellet packets	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Vosevi® (sofosbuvir-velpatasvir-voxilaprevir) 400-100-100 mg tablet	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
TOTAL	0	0	\$0.00	\$0.00	0	0 (0%)		

Key (as applicable) F = Formulary, no restrictions; F-QL = Formulary, quantity limit applies; F-AL = Formulary, age limit applies; F-ST = Formulary, step therapy applies; F-PA = Formulary, PA required; NF = Non-formulary; X = Excluded



Prior Authorization Criteria

No changes

Hepatitis C Medications: All requests must be reviewed by a clinical pharmacist first and then forwarded to AAH for review

MAVYRET (glecaprevir/ pibrentasvir) - PREFERRED AGENT
SOFOSBUVIR /VELPATASVIR (GENERIC EPCLUSA)-PREFERRED AGENT
LEDIPASVIR /SOFOSBUVIR (GENERIC HARVONI)-PREFERRED AGENT

ZEPATIER (elbasvir/ grazoprevir)
VOSEVI (sofosbuvir/ velpatasvir/ voxilaprevir)
EPCLUSA (sofosbuvir/velpatasvir)
HARVONI (ledipasvir/ sofosbuvir)
SOVALDI (sofosbuvir)
PEG-INTRON (peginterferon alfa-2b) PEGASYS (peginterferon alfa-2a)
RIBAVIRIN
VIEKIRA PAK (ombitasvir, paritaprevir, ritonavir and dasabuvir)
ANY OTHER NEWLY MARKETING AGENT for treatment of Hepatitis C

NOTE: Where applicable and appropriate: MAVYRET (glecaprevir/pibrentasvir), SOFOSBUVIR/VELPATASVIR (GENERIC EPCLUSA), or LEDIPASVIR/SOFOSBUVIR (GENERIC HARVONI) are the PREFERRED AGENTS for Hepatitis C requests unless a documented medical reason has been provided (intolerance, hypersensitivity, contraindication, etc.) why the member is not able to use Mavyret, sofosbuvir/velpatasvir (generic Epclusa), or ledipasvir/sofosbuvir (generic Harvoni).

All initial requests MUST meet the following requirements:

1. Life expectancy $\geq$ 12 months.
2. Lab testing required before starting treatment (copy of results required) if required for treatment selection per AASLD guidelines
 - Genotype must be provided if:
 - Genotype testing required for all who are not going to receive Mavyret or generic Epclusa
 - Genotype testing required for generic Epclusa in treatment naive patients with compensated cirrhosis
 - Genotype testing required for patients who do not qualify for simplified treatment (treatment-experienced, have or had decompensated cirrhosis (Child-Pugh B and C), have ESRD, are HIV positive, have current HBV infection (positive for HbsAg), are pregnant, have known or suspected hepatocellular carcinoma, or have had a liver transplant)
2. Provider has addressed all potential drug interactions with Hepatitis C regimen (including discontinuation of the interacting drug, dose reduction, or counseling of the patient of the risks associated with the use of both medications), AND

3. **Dose and Duration of Therapy: (SEE TREATMENT SUMMARY THAT FOLLOWS):** Approvals of requests will be consistent with package labeling or current guidelines, at FDA approved dosing. These regimens are subject to change as newly marketed agents become available. Pediatric patients will be limited to one tablet/packet per day. Medications must be dose consolidated to 1 tablet/packet daily, as appropriate. **ALL regimens are for 28 day supply per fill.**

Hepatitis C Treatment Summary

*****For all charts, sofosbuvir/velpatasvir (generic Epclusa) and ledipasvir/sofosbuvir (generic Harvoni) refer to their generic formulations*****

Treatment Naïve			
Genotype	Treatment Option	Duration	
		No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
All	Mavyret	8 weeks	8 weeks
All [^]	sofosbuvir/velpatasvir (generic Epclusa)	12 weeks	12 weeks

[^]Genotype testing required; for genotype 3 with compensated cirrhosis, only use sofosbuvir-velpatasvir (generic Epclusa) if no Y93H resistance

Treatment Experienced, with and without compensated cirrhosis		
Genotype	Prior Treatment	Preferred Regimen
All	Sofosbuvir-based and Zepatier treatment failures, including: Sovaldi + ribavirin ± interferon Harvoni Epclusa Zepatier	12 weeks Vosevi (± ribavirin) [^]
	Mavyret treatment failures Mavyret only	16 weeks Mavyret + Sovaldi + ribavirin 12 weeks Vosevi (± ribavirin) ^a
	Multiple DAA treatment failures, including: Vosevi Sovaldi + Mavyret	16 weeks Mavyret + Sovaldi + ribavirin* 24 weeks Vosevi + ribavirin

^Add ribavirin for 12 weeks in patients with genotype 3 and cirrhosis, if no contraindications

^a Add ribavirin if the patient has compensated cirrhosis

*Extension of treatment to 24 weeks should be considered in extremely difficult cases (eg, genotype 3 with cirrhosis) or failure following Sovaldi + Mavyret.

Unique patient populations Refer to current AASLD guidelines @ <http://www.hcvguidelines.org/>

For all unique and key populations: NOTE: If Mavyret, sofosbuvir/velpatasvir (generic Epclusa), or ledipasvir/sofosbuvir (generic Harvoni) are recommended treatment options, they are preferred unless medical reason provided that member is unable to use Mavyret, sofosbuvir/velpatasvir (generic Epclusa), or ledipasvir/sofosbuvir (generic Harvoni).

HIV/HCV Coinfection

Decompensated Cirrhosis (Child-Pugh B or C)

Recurrent HCV Infection Post-Transplant

HCV-Uninfected Transplant Recipients Receiving Organs From HCV-Viremic Donors

Renal Impairment

Kidney Transplant

Pregnancy

Pediatrics *Medications should be dose consolidated to no more than one tablet/packet daily if possible.

Last Review/Revision Date: 6/9/2025

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Respiratory Aids, Devices, and Equipment

Executive Summary

Class Overview

The following review includes a variety of devices and equipment used for the treatment of respiratory conditions such as Chronic Obstructive Pulmonary Disease (COPD) and asthma. Commonly, patients may experience difficulty with proper inhaler technique for a variety of reasons, leading to deposition of the inhaled medication to the oral mucosa or upper airways rather than the lungs. This can result in sub-optimal therapeutic results and in some cases (such as with inhaled corticosteroids) adverse drug reactions such as fungal infections of the mouth.

Devices such as spacers and nebulizers are designed to assist in delivery of the respective medication more efficiently to the lungs. Spacers and valved-holding chambers are devices which are attached to the mouthpiece of the inhaler and reduce the particle size of the plume released, and can allow more time for a slower inhale or alleviate some of the coordination issues some patients may have with actuation and inhalation. Nebulizers, while there are several different types of devices, all function to atomize liquid medication into a mist, which is then inhaled by the patient through a mouthpiece or mask over several minutes time. There is no need to coordinate actuation and breath with a nebulizer, and they can be used in special circumstances such as mechanically ventilated patients or in patients with a tracheostomy.

Peak flow meters are devices used to measure the maximum expiratory rate of a patient over a short and forceful exhale. This measurement reasonably correlates to a patient's percent predicted value for the forced expiratory volume in one second (FEV₁), which indicates the degree of airflow limitation being experienced by the patient and is helpful in monitoring asthma symptoms and severity.

There are a wide variety of products available in this category, and device selection is driven by multiple variables such as patient preferences, condition and severity, choice of pharmacotherapy, provider experience, availability, and cost. Many of these products require prescription, but over the counter (OTC) options also exist.

Utilization Findings

There were 9 claims for 9 members, for a total cost of \$185.30 and an average cost per claim of \$20.59. The most highly utilized products were compact space chamber and optichamber diamond vhc with 3 claims each. There were no prior authorization requests.

Recommendations

- No changes

Formulary Placement, Utilization and Cost Experience (04-01-2025 to 06-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Spacers and Accessories								
Aerobika Oscillating Pep Systm	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Quake Vibratory Pep Device	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Ombra Compressor System	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Pari Trek S Combo Pack	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
In-Check Nasal With Mask	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
In-Check Dial Training Device	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Threshold Pep Device	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Ebase Controller W-Conn Cord	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Ace Aerosol Cloud Enhancer	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Aerotrach Holding Chamber	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Comfortseal Medium Mask	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Comfortseal Small Mask	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Comfortseal Large Mask	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Litetouch Small Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Litetouch Medium Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Litetouch Large Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Pediatric Mouthpiece	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Optichamber Adult Mask-Large	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Sidestream Pediatric Face Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Silicone Mask-Infant	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Silicone Mask-Pediatric	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Altera Nebulizer Handset	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change

Pflex Inspiratory Trainer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Threshold Int Trainer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Windmill Trainer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
One Way Valved Mouthpiece	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
One Way Valved Mouthpiece	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Aerochamber Mechanical Vent	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Aerochamber Mini	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Aerochamber Mv Hold Chamber	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Aerochamber Plus Flow-Vu	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Aerochamber Plus Flow-Vu	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Aerochamber Z-Stat Plus W-Flow	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Aerochamber Z-Stat Plus W-Flow	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Aerovent Plus Holding Chamber	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Breatherite Mdi Spacer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Breathrite Valved Mdi Chamber	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Compact Space Chamber	3	3	\$47.36	\$15.79	0	0 (0%)	F-QL (2/365)	No change
Easivent Holding Chamber	1	1	\$40.65	\$40.65	0	0 (0%)	F-QL (2/365)	No change
Flexichamber	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Microchamber	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Microchamber	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Microspacer For Aerosol Device	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Optichamber Diamond Vhc	3	3	\$48.66	\$16.22	0	0 (0%)	F-QL (2/365)	No change

Pocket Chamber	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Prochamber Holding Chamber	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Riteflo Spacer	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Eq Space Chamber	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Vortex Holding Chamber	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Aerochamber Plus Flow-Vu Small	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Aerochamber Plus Flow-Vu Small	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Aerochamber Z-Stat Plus-Small	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Breatherite Spacer-Infant Mask	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Breatherite Spacer-Infant Mask	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Breatherite Spacer-Neonate Msk	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Breatherite Spacer-Sm Chld Msk	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Clever Choice Chamber-Sm Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Compact Space Chamber-Sm Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Optichamber Diamond W-Sml Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Pro Comfort Spacer-Child Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Pro Comfort Spacer-Infant Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Eq Space Chamber-Small Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Vortex Vhc Ladybug Toddler Msk	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Easivent Mask-Small	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Easivent Mask-Medium	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Easivent Mask-Large	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Aerochamber Plus Flow-Vu Large	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change

Aerochamber Plus Flow-Vu Large	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Aerochamber Z-Stat Plus Large	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Breatherite Spacer-Adult Mask	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Compact Space Chamber-Lrg Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Optichamber Diamond W-Lrg Mask	2	2	\$48.63	\$24.32	0	0 (0%)	F-QL (2/365)	No change
Pro Comfort Spacer-Adult Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Procure Spacer With Adult Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Pure Comfort Spacer-Adult Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Eq Space Chamber-Large Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Aerochamber Plus Flow-Vu Med	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Aerochamber Plus Flow-Vu Med	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Aerochamber Plus Flow-Vu Med	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Aerochamber Z-Stat Plus-Med	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Breatherite Spacer-Lg Chld Msk	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Compact Space Chamber-Med Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Optichamber Diamond W-Med Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Procure Spacer With Child Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Eq Space Chamber-Medium Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Vortex Vhc Frog Child Mask	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Flexichamber-Sm Child Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Flexichamber-Lg Child Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change

Flexichamber-Sm Adult Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Panda Mask Small	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Panda Mask Medium	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Panda Mask Large	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Pediatric Panda Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Vortex Adult Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Pediatric Small Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Pediatric Medium Mask	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Nebulizers and Supplies								
Airs Disposable Nebulizer Kit	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change
Sidestream Custom Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Sidestream Nebulizer Pediatric	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Sami The Seal Compressor Nebul	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change
Aeroeclipse li Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change
Aeroeclipse li Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Aeroeclipse xl Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Aeroneb Go Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Aeroneb Go Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Altera Nebulizer System	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Aura Portaneb Mesh Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Innospire Go Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Pari Lc Plus Nebulizer Set	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change
Pari Lc Plus Nebulizer Set	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Lc Plus Nebulizer-Ped Mask	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Pari Lc Sprint Nebulizer Set	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Mc 300 Nebulizer W-Mouthpiece	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change

Mc 300 Nebulizer-Unvrsl Tubing	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Mini Plus Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Ultrasonic Mini Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Pari Lc Sprint Sinus Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Prodigy Mini-Mist Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Sidestream Dispos Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Sidestream Reusable Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Sidestream Plus Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Sootheneb Mesh Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Clever Choice Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Clever Choice Whisper Aire Ped	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Comp-Air Nebulizer System	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Compressor Nebulizer System	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Easy Air Compressor Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Easy Neb Compressor Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Home Nebulizer Plus Sidestream	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Innospire Deluxe Compres Neb	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Innospire Elegance Compres Neb	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change
Innospire Essence Compres Neb	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change
Innospire Mini Compressor Neb	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Neb200 Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Pediatric Bear Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Pediatric Comp-Air Compres Neb	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Procure Compressor Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Procure Pediatric Neb Dog	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Procure Pediatric Neb Bear	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Procure Pediatric Neb Eagle	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Proneb Max Compressor-Lc Plus	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Proneb Max Compressr-Lc Sprint	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Pulmoneb Lt Compressor Nebul	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Pureair Mini Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Smartneb Compressor Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Sootheneb Compressor Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Pari Trek S Compact Compressor	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Vios Aerosol Delivery System	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change

Vios Aerosol Delivery System	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Vios Aerosol Delivery System	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change
Vios Aerosol Delivery System	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change
Vios Aerosol Delivery System	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Willis The Whale Compressr Neb	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Sinustar Reusable Nebulizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Peak Flower Meters								
Airzone Peak Flow Meter	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change
Asthma Check Peak Flow Mtr	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Clever Choice Peak Flow Meter	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Microlife Peak Flow Meter	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Mini Wright Peak Flow Meter	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change
Peak-Air Peak Flow Meter	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change
Personal Best Peak Flow Mtr	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2/365)	No change
Personal Best Peak Flow Mtr	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Piko 1 Flow Meter	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Pocket Peak Flow Meter	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change
Purecomfort Peak Flow Mtr Adlt	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Purecomfort Peak Flow Mtr Chld	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Strive Peak Flow Meter	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Truzone Peak Flow Meter	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (1/365)	No change
Aerogear Asthma Action Kit	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Asthmapack Children's Care Kit	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Nasal Strips, Humidifiers, Vaporizers								
Cool Mist Humidifier	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
CVS Cool Mist Humidifier	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Cool Mist Humidifier	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Cool Mist Humidifier	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Ultrasonic Humidifier	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Cool Moisture Humidifier	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change

Procare Humidifier	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Pure Comfort Humidifier	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Vaporizer 1.2 Gallon	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Vaporizer 1.2 Gallon	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
CVS Warm Steam Vaporizer	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Breathe Right Nasal Strips	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Breathe Right Nasal Strips	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Breathe Right Vapor Strips	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Breathe Right Nasal Strips	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Ra Nasal Strips Large	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Rest Easy Nasal Strips Large	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Rest Easy Nasal Strips Sm-Med	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Provent Nasal Device	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Provent Starter Kit	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Total	9	9	\$185.30	\$20.59	0	0 (0%)		

Key (as applicable) F = Formulary, no restrictions; F-QL = Formulary, quantity limit applies; F-AL = Formulary, age limit applies; F-ST = Formulary, step therapy applies; F-PA = Formulary, PA required; NF = Non-formulary; X = Excluded

References

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3. Gerald L, Carr T. Peak expiratory flow monitoring in asthma. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com>. Accessed on April 14, 2025.



Rho Immune Globulins

Executive Summary

Class Overview

Rho(D) immune globulins, also known as anti-D immunoglobulins, are human plasma–derived products consisting of immunoglobulin G (IgG) antibodies to the RhD antigen. It is primarily used to prevent anti-D antibodies from forming during pregnancy when a mother has RhD-negative blood and the baby is RhD-positive. Prevention of anti-D antibodies, also known as RhD alloimmunization or RhD isoimmunization, in RhD-negative women who deliver an RhD-positive baby is important as it can cause severe, potentially fatal, hemolytic disease of the fetus and newborn. Current recommendations from the American College of Obstetricians and Gynecologists (ACOG), supported by strong scientific evidence, advocate that prophylactic anti-D immunoglobulins be offered to RhD-negative women at 28 weeks of gestation.

There are currently four Rho(D) immune globulin products available on the market, HyperRHO® S/D, RhoGAM® Ultra-Filtered PLUS, Rhophylac®, and WinRho® SDF, all of which are indicated in the prevention of RhD alloimmunization in an RhD-incompatible pregnancy. These products can also be used in the prevention or suppression of RhD alloimmunization in RhD-negative individuals who have been transfused with RhD-positive blood products, including red blood cells or blood components containing red blood cells (including platelet concentrates or granulocyte concentrates). Rhophylac® and WinRho® SDF also have additional indications to be used to treat immune thrombocytopenic purpura (ITP) in patients with Rh-positive blood. ITP, also known as idiopathic thrombocytopenic purpura, is an autoimmune disorder characterized by the destruction of platelets in response to unknown stimulus. Rho(D) immune globulins are typically used as an alternative in the setting of ITP, and according to the latest American Society of Hematology (ASH) guidelines for ITP, are only recommended to be used in children with newly diagnosed ITP.

Utilization Findings

There was no utilization and no prior authorization requests.

Recommendations

- No changes

Clinical Summary

Rho(D) immune globulins, also known as anti-D immunoglobulins, are human plasma–derived products consisting of IgG antibodies to the RhD antigen. They are used primarily to prevent RhD antibodies, also known as anti-D antibodies, from forming during pregnancy when a mother has RhD-negative blood and the fetus is RhD-positive. RhD is a blood group antigen and is one of a variety of red blood cell antigen systems found in humans, with the ABO system being the main blood group factor system. When a patient is RhD-negative, it means they do not have the RhD antigen present on their red blood cells, whereas if an individual is RhD-positive, the antigen is present. Maternal RhD antibodies develop as a result of maternal immune system exposure to RhD-positive red blood cells. This is also known as RhD alloimmunization or RhD isoimmunization. Once antibodies are present in the mother’s circulation, they can cross the placenta and opsonize fetal red blood cells, which are then phagocytized by macrophages in the fetal spleen.

Events that can cause maternal RhD alloimmunization include transplacental fetomaternal bleeding, injection with needles contaminated by RhD-positive blood, inadvertent transfusion of Rh-positive blood, and RhD-mismatched allogeneic hematopoietic stem cell transplantation. Transplacental fetomaternal bleeding account for virtually all cases of maternal RhD alloimmunization, as it has been shown tiny quantities of fetal red blood cells gain access to the maternal circulation in nearly all pregnancies. The frequency and volume of spontaneous fetomaternal bleeding increase with advancing gestational age and are highest at delivery. Fetomaternal bleeding can also be associated with miscarriage, abortion, ectopic pregnancy, invasive in-utero procedures, maternal abdominal trauma, and antepartum maternal hemorrhage. RhD alloimmunization can be effectively prevented by administration of anti-D immunoglobulins to women exposed or at high risk of being exposed to RhD-positive red blood cells. Prevention of RhD alloimmunization is vital as it can cause severe, potentially fatal, hemolytic disease of the fetus and newborn (HDFN). HDFN, also known as Rhesus disease or Rh disease, occurs when the anti-D antibodies that are formed by the mother cross the placenta and destroy her baby's red blood cells. This may result in the fetus or newborn to become anemic and develop jaundice. Antibodies can also continue attacking the baby's red blood cells for a few months after birth.

Current recommendations from ACOG recommend that RhD-negative women with a negative anti-D antibody screen who are carrying a fetus that is, or may be, RhD-positive receive Rho(D) immune globulins at 28 weeks of gestation, after delivery of an RhD-positive newborn, and after an antepartum event associated with an increased risk of fetomaternal bleeding. RhD-negative women who screen positive for anti-D antibodies should not receive anti-D immune globulin as it is not effective once alloimmunization to the RhD antigen has occurred and will not prevent a rise in maternal titer. Interventions are available for predicting the risk for HDFN as well as diagnosing and treating severe fetal anemia in newborns. RhD-negative women who are carrying an RhD-negative fetus do not benefit from Rho(D) immune globulins.

The mechanism of action as to how Rho(D) immune globulins prevents RhD alloimmunization is unproven. Possibilities include rapid macrophage-mediated clearance of anti-D-coated red cells and/or down-regulation of antigen-specific B cells before an immune response occurs. Rho(D) immune globulins are available as both intravenous (IV) and intramuscular (IM) injections, both of which are equally effective. There are currently four Rho(D) immune globulin products available on the market, HyperRHO® S/D, RhoGAM® Ultra-Filtered PLUS, Rhophylac®, and WinRho® SDF, all of which are indicated in the prevention of RhD alloimmunization in an RhD-incompatible pregnancy. These products can also be used in the prevention or suppression of RhD alloimmunization in RhD-negative individuals who have been transfused with RhD-positive blood products, including red blood cells or blood components containing red blood cells.

(including platelet concentrates or granulocyte concentrates). MICRhoGAM® Ultra-Filtered PLUS was another Rho(D) immune globulin that was also available, however, as of early 2025 it has been discontinued in the US.

Rhophylac® and WinRho® SDF also have additional indications to be used to treat ITP in patients with Rh-positive blood. ITP, also known as idiopathic thrombocytopenic purpura, is an autoimmune disorder characterized by the destruction of platelets in response to unknown stimulus. ITP is one of the more common causes of thrombocytopenia with an estimated prevalence in the United States of about 8 per 100,000 children and 12 per 100,000 adults. There are two types of ITP: acute and chronic. Acute ITP is the most common type and usually occurs in children after a viral infection. It generally lasts less than 6 months. Chronic ITP mostly affects adults and lasts 6 months or longer. Primary ITP refers to an acquired condition in which the immune system produces autoantibodies against platelets, leading to their destruction or underproduction. Secondary ITP is caused by underlying conditions such as HIV, hepatitis C, systemic lupus erythematosus (SLE) and chronic lymphocytic leukemia (CLL). Patients with ITP are usually asymptomatic, however, if symptoms do occur, patients primarily experience bleeding, with some also reporting fatigue. Rho(D) immune globulins are typically used as an alternative in the setting of ITP, and according to the most recent 2019 ASH guidelines for ITP, are only recommended to be used as alternative to corticosteroids in children with newly diagnosed ITP. While there is also evidence that suggests intravenous immunoglobulin (IVIG) is more efficacious than Rho(D) immune globulins in the setting of ITP, current guideline recommendations do not provide a preference between the two.

Indications, Dosing and Administration

Medication	Indications	Dosing/Administration
HyperRHO® S/D (Rho[D] immune globulin [human])	Prevention of RhD isoimmunization in an RhD-incompatible pregnancy: Antepartum and postpartum RhD prophylaxis for the prevention of hemolytic disease of the newborn; RhD prophylaxis following spontaneous or induced abortion, ruptured tubal pregnancy, amniocentesis or abdominal trauma; RhD prophylaxis following spontaneous or induced abortion up to 12 weeks' gestation	Antepartum prophylaxis: 1500 units (300 mcg) IM at 28 weeks gestation Postpartum prophylaxis: 1500 units IM Abdominal trauma: 1500 units IM following abdominal trauma in the second or third trimester Aminocentesis: 1500 units IM at 15 to 18 weeks' gestation or during the third trimester Ectopic Pregnancy: 1500 units IM for complications occurring at ≥13 weeks' gestation Termination of pregnancy: 250 units IM 3 hours or as soon as possible following spontaneous or induced abortion occurring <13 weeks' gestation; 1500 units IM following miscarriage or abortion occurring ≥13 weeks' gestation Threatened pregnancy loss with continuation of pregnancy: 1500 units IM following threatened loss at any time during pregnancy
	Transfusion: Prevention or suppression of RhD isoimmunization in RhD-negative individuals who have been transfused with RhD-positive blood products, including red blood cells or blood components containing red blood cells (including platelet concentrates or granulocyte concentrates)	Multiply the volume of RhD-positive whole blood administered by the hematocrit of the donor unit to equal the volume of RBCs transfused. The volume of RBCs is then divided by 15 mL, providing the number of 1500 unit syringes to administer. Administer as soon as possible and within 72 hours after an incompatible transfusion.
RhoGAM® Ultra-Filtered PLUS (Rho[D] immune globulin [human])	Prevention of RhD isoimmunization in an RhD-incompatible pregnancy: Antepartum RhD prophylaxis; Postpartum RhD prophylaxis following delivery of an RhD-positive baby; RhD prophylaxis following amniocentesis, chorionic villus sampling (CVS), percutaneous umbilical blood sampling (PUBS), abdominal trauma or obstetrical manipulation, placenta previa, ectopic pregnancy, threatened pregnancy loss after 12 weeks' gestation, pregnancy	Antepartum prophylaxis: 1500 units (300 mcg) IM at 26 to 28 weeks' gestation; if delivery does not occur within 12 weeks after the dose, a second 1500 unit dose is recommended Postpartum prophylaxis: 1500 units IM Abdominal trauma: 1500 units IM within 72 hours following abdominal trauma or obstetrical manipulation occurring at ≥13 weeks' gestation

Medication	Indications	Dosing/Administration
	termination (spontaneous or induced) after 12 weeks' gestation	Aminocentesis: 1500 units IM within 72 hours of a procedure occurring at ≥ 13 weeks' gestation Ectopic Pregnancy: 1500 units IM within 72 hours of complications occurring at ≥ 13 weeks' gestation Termination of pregnancy: 1500 units IM within 72 hours following spontaneous or induced termination occurring ≥ 13 weeks' gestation Threatened pregnancy loss with continuation of pregnancy: 1500 units IM within 72 hours following threatened loss ≥ 13 weeks' gestation. Additional invasive/manipulative procedures or obstetric complications: 1500 units IM within 72 hours of chorionic villus sampling or percutaneous umbilical blood sampling ≥ 13 weeks gestation
	Transfusion: Prevention or suppression of RhD isoimmunization in RhD-negative individuals who have been transfused with RhD-positive blood products, including red blood cells or blood components containing red blood cells (including platelet concentrates or granulocyte concentrates)	2.5 to 15 mL RhD-positive red blood cell exposure: 1500 units IM within 72 hours after an incompatible transfusion >15 mL RhD-positive red blood cell exposure: 100 units/mL of RhD-positive red blood cell exposure; multiple doses may be given at the same time or spaced at intervals; total dose must be given within 72 hours of exposure
Rhophylac® (Rho[D] immune globulin [human])	Immune thrombocytopenic purpura: To increase platelet counts in RhD-positive nonsplenectomized adults with chronic ITP	250 units/kg IV
	Prevention of RhD isoimmunization in an RhD-incompatible pregnancy: Routine antepartum and postpartum RhD prophylaxis; RhD prophylaxis in cases of obstetric complications including miscarriage, abortion, threatened abortion, ectopic pregnancy or hydatiform mole, transplacental hemorrhage resulting from antepartum hemorrhage; RhD prophylaxis following invasive procedures during pregnancy including amniocentesis,	Antepartum prophylaxis: 1500 units (300 mcg) IM or IV at 28 to 30 weeks gestation Postpartum prophylaxis: 1500 units IM or IV Abdominal trauma: 1500 units IM or IV within 72 hours of complication Aminocentesis: 1500 units IM or IV within 72 hours of procedure

Medication	Indications	Dosing/Administration
	chorionic biopsy, or obstetric manipulative procedures such as external version or abdominal trauma	Ectopic Pregnancy: 1500 units IM or IV within 72 hours of complication Termination of pregnancy: 1500 units IM or IV within 72 hours of miscarriage or abortion Threatened pregnancy loss with continuation of pregnancy: 1500 units IM or IV within 72 hours of threatened abortion Additional invasive/manipulative procedures or obstetric complications: 1500 units IM or IV within 72 hours of procedures such as chorionic biopsy or external version, or within 72 hours of complications such as hydatidiform mole, or transplacental hemorrhage resulting from antepartum hemorrhage
	Transfusion: Prevention or suppression of RhD isoimmunization in RhD-negative individuals who have been transfused with RhD-positive blood products, including red blood cells or blood components containing red blood cells (including platelet concentrates or granulocyte concentrates)	100 units/2 mL transfused blood or 100 units/mL erythrocyte concentrate IV or IM within 72 hours after an incompatible transfusion
WinRho® SDF (Rho[D] immune globulin [human])	Immune thrombocytopenic purpura: To raise platelet counts in RhD-positive nonsplenectomized patients with the following conditions: - Children with chronic or acute ITP - Adults with chronic ITP - Children and adults with ITP secondary to HIV infection	Initial: - Hemoglobin ≥ 10 g/dL: 250 units/kg IV as a single injection, or can be given as 2 divided doses on separate days - Hemoglobin 8 to <10 g/dL: 125 to 200 units/kg IV, as a single injection, or can be given as 2 divided doses on separate days - Hemoglobin <8 g/dL: Alternative treatment should be used Maintenance: Dosing frequency determined by clinical response in platelet counts, RBC, hemoglobin, and reticulocyte levels: - Hemoglobin ≥ 10 g/dL: 250 to 300 units/kg IV - Hemoglobin 8 to <10 g/dL: 125 to 200 units/kg IV - Hemoglobin <8 g/dL: Alternative treatment should be used

Medication	Indications	Dosing/Administration
	Prevention of RhD isoimmunization in an RhD-incompatible pregnancy: Routine antepartum and postpartum RhD prophylaxis; RhD prophylaxis in cases of obstetric complications including miscarriage, abortion, threatened abortion, ectopic pregnancy or hydatiform mole, transplacental hemorrhage resulting from antepartum hemorrhage; RhD prophylaxis following invasive procedures during pregnancy including amniocentesis, chorionic biopsy, or obstetric manipulative procedures such as external version or abdominal trauma	Antepartum prophylaxis: 1500 units (300 mcg) IM or IV at 28 weeks gestation Postpartum prophylaxis: 600 units IV or IM; dose should be administered within 72 hours of delivery but may be given up to 28 days after delivery Aminocentesis: 1500 units IM or IV immediately after amniocentesis occurring before 34 weeks gestation; repeat dose every 12 weeks during pregnancy; administer 600 units within 72 hours of amniocentesis occurring after 34 weeks gestation Termination of pregnancy: 600 units IM or IV within 72 hours of abortion occurring after 34 weeks gestation Threatened pregnancy loss with continuation of pregnancy: 1500 units IM or IV immediately following a threatened abortion occurring any time during pregnancy Additional invasive/manipulative procedures or obstetric complications: 1500 units IM or IV after chorionic villus sampling before 34 weeks gestation; repeat dose every 12 weeks during pregnancy; administer 600 units within 72 hours of manipulation occurring after 34 weeks gestation
	Transfusion: Prevention or suppression of RhD isoimmunization in RhD-negative individuals who have been transfused with RhD-positive blood products, including red blood cells or blood components containing red blood cells (including platelet concentrates or granulocyte concentrates)	Administer within 72 hours after exposure of incompatible blood transfusion: - IV: Calculate dose as follows; administer 3000 units every 8 hours until the total dose is administered: • Exposure to RhD-positive whole blood: 9 mcg/mL blood • Exposure to RhD-positive red blood cells: 18 mcg/mL cell - IM: Calculate dose as follows; administer 6000 units every 12 hours until the total dose is administered: • Exposure to RhD-positive whole blood: 12 mcg/mL blood



Medication	Indications	Dosing/Administration
		Exposure to RhD-positive red blood cells: 24 mcg/mL cell

Boxed Warnings and Contraindications

Medication	Boxed Warnings	Contraindications
HyperRHO® S/D	None	None
RhoGAM® Ultra-Filtered PLUS		- Anaphylactic or severe systemic reaction to a previous dose of human immune globulin - Use in RhD-positive individuals
Rhophylac®	Intravascular Hemolysis: Intravascular hemolysis leading to death has been reported in patients treated with Rho(D) immune globulin for ITP. Intravascular hemolysis can lead to clinically compromising anemia and multisystem organ failure, including acute respiratory distress syndrome. Serious complications, including severe anemia, acute renal insufficiency, renal failure, and disseminated intravascular coagulation, have also been reported. Patients treated with Rho(D) immune globulin for ITP should be closely monitored in a health care setting for at least 8 hours after administration. A dipstick urinalysis to monitor for hematuria and hemoglobinuria is to be performed at baseline and then after administration at 2 hours, 4 hours, and prior to the end of the monitoring period. Alert patients and monitor the signs and symptoms of intravascular hemolysis, including back pain, shaking chills, fever, and discolored urine or hemoglobinuria. Absence of these signs and/or symptoms within 8 hours does not indicate intravascular hemolysis cannot occur subsequently. If signs and/or symptoms of intravascular hemolysis are present or suspected after Rho(D) immune globulin administration, posttreatment laboratory tests should be performed, including plasma hemoglobin, haptoglobin, lactate dehydrogenase, and plasma bilirubin (direct and indirect). If ITP patients are to be transfused after receiving Rho(D) immune globulin, use Rho(D)-negative red blood	- Anaphylactic or severe systemic reaction to a previous dose of human immune globulin - Use in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity - Administration to the neonate of a mother who received Rhophylac® postpartum
WinRho® SDF		- Hypersensitivity to Rho(D) immune globulin or any component of the formulation - Known anaphylactic or severe systemic reaction to a previous dose of human immune globulin - Use in IgA-deficient patients with antibodies to IgA - Autoimmune hemolytic anemia with preexisting hemolysis or at high risk for hemolysis - Suppression of RhD isoimmunization in infants

Warnings/Precautions

Medication	Warnings/Precautions
Rho(D) immune globulin (HyperRHO® S/D, RhoGAM® Ultra-Filtered PLUS, Rhophylac®, WinRho® SDF)	Concerns related to adverse effects: - Anaphylactoid/hypersensitivity reactions - Anaphylaxis: May contain trace amounts of IgA; patients with antibodies to IgA have a greater risk of developing potentially anaphylactic reactions - Intravascular hemolysis (<i>Rhophylac® and WinRho® SDF only</i>): Intravascular hemolysis may result in clinically compromising anemia and multiorgan system failure including acute respiratory distress syndrome; patients should be closely monitored, and alternative therapies should be used in patients with preexisting hemolysis or a high risk of hemolysis (e.g., positive direct antiglobulin test, elevated reticulocyte count) - Pulmonary edema - Renal effects: Use with caution in patients with renal impairment or at risk for renal disease (e.g., diabetes mellitus, >65 years of age, volume depletion, sepsis, paraproteinemia, concomitant use of nephrotoxic medications) - Thrombotic events: Use with caution in patients with a history of atherosclerosis, known/suspected hyperviscosity, advanced age, impaired cardiac output, prolonged immobilization, coagulation disorders, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, or multiple cardiovascular risk factors Disease-related concerns: - Bleeding disorders: Bleeding/hematoma may occur from IM administration - Immune thrombocytopenia - RhD suppression: For use in the mother; if RhD antibodies are already present in the mother, use of the Rho(D) immune globulin is not beneficial; if paternity is certain and the father is confirmed to be RhD-negative, administration of the immune globulin is not needed Dosage form specific issues: - Human plasma: May potentially contain infectious agents which could transmit disease - Maltose: Some products may contain maltose, which may result in falsely elevated blood glucose readings; avoid use in patients with an allergy to corn - Polysorbate 80: Some dosage forms may contain polysorbate 80 (also known as Tweens); hypersensitivity reactions, usually a delayed reaction, have been reported following exposure to pharmaceutical products containing polysorbate 80 in certain individuals; thrombocytopenia, ascites, pulmonary deterioration, and renal and hepatic failure have been reported in premature neonates after receiving parenteral products containing polysorbate 80

Practice Guidelines

American College of Obstetricians and Gynecologists: Practice Bulletin No. 181: Prevention of Rh D Alloimmunization. Obstet Gynecol. 2017;130(2):e57-e70.

Level A. The following recommendations are based on good and consistent scientific evidence:

- Prophylactic anti-D immune globulin should be offered to unsensitized RhD-negative women at 28 weeks of gestation. Following birth, if the infant is confirmed to be RhD-positive, all RhD-negative women who are not known to be sensitized should receive anti-D immune globulin within 72 hours of delivery.

Level B. The following recommendations are based on limited or inconsistent scientific evidence:

- Administration of anti-D immune globulin is recommended with all invasive diagnostic procedures such as chorionic villus sampling or amniocentesis in RhD-negative women when the fetuses could be RhD-positive.

Level C. The following recommendations are based primarily on consensus and expert opinion:

- External cephalic version (regardless of success) is associated with a 2-6% risk of fetal-maternal hemorrhage, and anti-D immune globulin is indicated for unsensitized RhD-negative patient.
- It is reasonable to administer anti-D immune globulin to RhD-negative women who are suspected of molar pregnancy and who undergo uterine evacuation.
- Although the risk of alloimmunization is low, the consequences can be significant, and administration of anti-D immune globulin should be considered in cases of spontaneous first-trimester miscarriage, especially those that are later in the first trimester.
- Because of the higher risk of alloimmunization, RhD-negative women who have instrumentation for their miscarriage should receive anti-D immune globulin prophylaxis.
- Anti-D immune globulin should be given to RhD-negative women who have pregnancy termination, either medical or surgical.
- Administration of anti-D immune globulin for all cases of ectopic pregnancy in RhD-negative women is recommended.
- Anti-D immune globulin is recommended for RhD-negative women who experience antenatal hemorrhage after 20 weeks of gestation.
- Anti-D immune globulin should be administered to RhD-negative women who have experienced abdominal trauma.
- Anti-D immune globulin should be administered to RhD-negative women who experience fetal death in the second or third trimester.

Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Adv. 2019;3(23):3829-3866.

Management of adult patients with newly diagnosed ITP

- In adults with newly diagnosed ITP and a platelet count of $<30 \times 10^9/L$ who are asymptomatic or have minor mucocutaneous bleeding, the ASH guideline panel *suggests* corticosteroids rather than management with observation (Conditional recommendation based on very low certainty in the evidence of effects).
- In adults with newly diagnosed ITP and a platelet count of $\geq 30 \times 10^9/L$ who are asymptomatic or have minor mucocutaneous bleeding, the ASH guideline panel *recommends against* corticosteroids and in favor of management with observation (Strong recommendation based on very low certainty in the evidence of effects).

- In adults with newly diagnosed ITP, the ASH guideline panel *suggests* either prednisone (0.5-2.0 mg/kg per day) or dexamethasone (40 mg per day for 4 days) as the type of corticosteroid for initial therapy (Conditional recommendation based on very low certainty in the evidence of effects).
- In adults with newly diagnosed ITP, the ASH guideline panel *suggests* corticosteroids alone rather than rituximab and corticosteroids for initial therapy (Conditional recommendation based on very low certainty in the evidence of effects).

Management of adults with ITP who are corticosteroid-dependent or do not have a response to corticosteroids

- In adults with ITP for ≥ 3 months who are corticosteroid-dependent or unresponsive to corticosteroids and are going to be treated with a TPO-RA, the ASH guideline panel *suggests* either eltrombopag or romiplostim (Conditional recommendation based on very low certainty in the evidence of effects).
- In adults with ITP lasting ≥ 3 months who are corticosteroid-dependent or have no response to corticosteroids, the ASH guideline panel *suggests* either splenectomy or a TPO-RA (Conditional recommendation based on very low certainty in the evidence of effects).
- In adults with ITP lasting ≥ 3 months who are corticosteroid-dependent or have no response to corticosteroids, the ASH guideline panel *suggests* rituximab rather than splenectomy (Conditional recommendation based on very low certainty in the evidence of effects).
- In adults with ITP lasting ≥ 3 months who are corticosteroid-dependent or have no response to corticosteroids, the ASH guideline panel *suggests* a TPO-RA rather than rituximab (Conditional recommendation based on very low certainty in the evidence of effects).

Management of children with newly diagnosed ITP

- In children with newly diagnosed ITP who have no or minor bleeding, the ASH guideline panel *suggests* observation rather than corticosteroids (Conditional recommendation based on very low certainty in the evidence of effects).
- In children with newly diagnosed ITP who have no or minor bleeding, the ASH guideline panel *recommends* observation rather than IV immunoglobulin (IVIG) (Strong recommendation based on moderate certainty in the evidence of effects).
- In children with newly diagnosed ITP who have no or minor bleeding, the ASH guideline panel *recommends* observation rather than anti-D immunoglobulin (Strong recommendation based on moderate certainty in the evidence of effects).
- In children with newly diagnosed ITP who have non-life-threatening mucosal bleeding and/or diminished health-related quality of life (HRQoL), the ASH guideline panel *suggests* prednisone (2-4 mg/kg per day; maximum 120 mg daily for 5-7 days) rather than dexamethasone (0.6 mg/kg per day; maximum 40 mg per day for 4 days) (Conditional recommendation based on very low certainty in the evidence of effects).
- In children with newly diagnosed ITP who have non-life-threatening mucosal bleeding and/or diminished HRQoL, the ASH guideline panel *suggests* corticosteroids rather than anti-D immunoglobulin (Conditional recommendation based on low certainty in the evidence of effects).
- In children with newly diagnosed ITP who have non-life-threatening mucosal bleeding and/or diminished HRQoL, the ASH guideline panel *suggests* either anti-D immunoglobulin or IVIG (Conditional recommendation based on low certainty in the evidence of effects).
- In children with newly diagnosed ITP who have non-life-threatening mucosal bleeding and/or diminished HRQoL, the ASH guideline panel *suggests* corticosteroids rather than IVIG (Conditional recommendation based on low certainty in the evidence of effects).

Management of children with ITP who do not have a response to first-line treatment

- In children with ITP who have non–life-threatening mucosal bleeding and/or diminished HRQoL and do not respond to first-line treatment, the ASH guideline panel *suggests* the use of TPO-RAs rather than rituximab (Conditional recommendation based on very low certainty in the evidence of effects).
- In children with ITP who have non–life-threatening mucosal bleeding and/or diminished HRQoL and do not respond to first-line treatment, the ASH guideline panel *suggests* TPO-RAs rather than splenectomy (Conditional recommendation based on very low certainty in the evidence of effects).
- In children with ITP who have non–life-threatening mucosal bleeding and/or diminished HRQoL and do not respond to first-line treatment, the ASH guideline panel *suggests* rituximab rather than splenectomy (Conditional recommendation based on very low certainty in the evidence of effects).

Recommendation Definitions

Strength of Recommendation	Wording in the Guideline	Definition
Strong	“The guideline panel recommends...”	Most individuals should follow the recommended course of action. Formal decision aids are not likely to be needed to help individual patients make decisions consistent with their values and preferences. The recommendation can be adopted as policy in most situations. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator. The recommendation is supported by credible research or other convincing judgments that make additional research unlikely to alter the recommendation.
Conditional	“The guideline panel suggests...”	Recognize that different choices will be appropriate for individual patients and that you must help each patient arrive at a management decision consistent with the patient’s values and preferences. Decision aids may be useful in helping individuals to make decisions consistent with their individual risks, values, and preferences. Policy-making will require substantial debate and involvement of various stakeholders. Performance measures about the suggested course of action should focus on whether an appropriate decision-making process is duly documented. The recommendation is likely to be strengthened (for future updates or adaptation) by additional research.
Level of Certainty	Definition	
High	The guideline panel has a lot of confidence that the true effect is similar to the estimated effect.	
Moderate	The guideline panel believes that the true effect is probably close to the estimated effect.	
Low	The true effect might be markedly different from the estimated effect.	
Very Low	The true effect is probably markedly different from the estimated effect.	

Clinical Trials/Systematic Reviews/Meta-Analyses

Citation	Design	Endpoints
Okwundu CI, Afolabi BB. Intramuscular versus intravenous anti-D for preventing Rhesus alloimmunization during pregnancy. Cochrane Database Syst Rev. 2013;(1):CD007885.	Systematic review conducted by searching the Cochrane Pregnancy and Childbirth Group's Trials Register for studies up to September 2012 to compare the efficacy of IM versus IV anti-D immunoglobulin in preventing RhD alloimmunization in RhD-negative pregnant women. A total of 2 studies were included, involving 447 RhD negative women.	- Primary endpoint: Incidence of RhD alloimmunization - Secondary endpoint: Maternal serum anti-D concentration, neonatal morbidity (e.g. jaundice, anemia)
Results: There was no incidence of RhD alloimmunization in either of the studies, as the sample size was insufficient for meaningful comparison of this uncommon outcome. One of the studies found that the mean anti-D immunoglobulin concentrations after IV and IM administration differed up to 7 days (36.1 ng/mL IV; 19.8 ng/mL IM on day seven). However, from two to three weeks post-administration, the concentrations were similar for both routes of administration. None of the women involved in the studies developed antibodies against the RhD antigen. Conclusion: IM and IV administration of anti-D are equally effective. The number of included studies and the number of participants are not enough to assess whether there are any differences. The choice of IM or IV route of administration will depend on the available preparations, the dose to be administered and also on the patients' preferences. This review found insufficient information upon which to guide practice due to the limited number of included studies, small sample sizes and methodological limitations.		
Citation	Design	Endpoints
Mcbain RD, Crowther CA, Middleton P. Anti-D administration in pregnancy for preventing Rhesus alloimmunisation. Cochrane Database Syst Rev. 2015;(9):CD000020.	Systematic review conducted by searching the Cochrane Pregnancy and Childbirth Group's Trials Register for studies up to May 2015 to assess the effects of antenatal anti-D immunoglobulin on the incidence of RhD alloimmunization when given to Rh-negative women without anti-D antibodies. A total of 2 studies were included, involving 4,500 women.	- Primary endpoint: Incidence of RhD alloimmunization (during pregnancy, postpartum, and in subsequent pregnancies) - Secondary endpoints: Incidence of positive Kleihauer test (test that detects fetal cells in the maternal blood), neonatal morbidity (e.g. jaundice, anemia), and adverse events
Results: There did not appear to be a clear difference in the risks of immunization when women who received anti-D at 28 and 34 weeks' gestation were compared with women who were not given antenatal anti-D: risk ratio (RR) for incidence of RhD alloimmunization during pregnancy was 0.42 (95% confidence interval [CI] 0.15 to 1.17); at birth of a RhD-positive infant the RR was 0.42 (95% CI 0.15 to 1.17); and within 12 months after birth of a RhD-positive infant the average RR was 0.39 (95% CI 0.10 to 1.62; Tau² 0.47; I² 39%). Neither of the trials reported on incidence of RhD alloimmunization in subsequent pregnancies. Considering secondary outcomes, in one trial, women receiving anti-D during pregnancy were shown to be less likely to register a positive Kleihauer test in pregnancy (RR 0.60, 95% CI 0.41 to 0.88) and at the birth of a RhD-		

positive infant (RR 0.60, 95% CI 0.46 to 0.79). No clear differences were seen for neonatal jaundice (RR 0.26, 95% CI 0.03 to 2.30). Neither of the trials reported on adverse effects associated with anti-D treatment.

Conclusion: Existing studies do not provide conclusive evidence that the use of anti-D during pregnancy benefits either mother or baby in terms of incidence of RhD alloimmunization during the pregnancy or postpartum, or the incidence of neonatal morbidity. However, women receiving anti-D may be less likely to register a positive Kleihauer test in pregnancy and at the birth of an RhD-positive infant. Fewer women who receive anti-D during pregnancy may have RhD antibodies in a subsequent pregnancy, with benefits for the baby, however this needs to be tested in studies of robust design.

Citation	Design	Endpoints
Xie X, Fu Q, Bao Z, Zhang Y, Zhou D. Clinical value of different anti-D immunoglobulin strategies for preventing Rh hemolytic disease of the fetus and newborn: A network meta-analysis. PLoS ONE. 2020;15(3):e0230073.	Network meta-analysis conducted by searching the Web of Science, PubMed, EMBASE, China National Knowledge Infrastructure (CNKI) and Wanfang databases for studies that evaluated the value of different anti-D immunoglobulin strategies in preventing the incidence of RhD alloimmunization. Studies that were included were randomized controlled studies with RhD-positive fetuses in intrauterine pregnancies of Rh-negative pregnant women. Studies were also required to have reported dose and frequency of anti-D immunoglobulin injections and reported positive incidence of anti-D antibody in postpartum mothers. Duplications, reviews, case reports, conference abstracts, and studies without useful data were excluded. A total of 24 studies were included, involving 64,860 patients.	Primary endpoint: Incidence of RhD alloimmunization

Results: Among all therapeutic measures, injecting 300 mcg anti-D immunoglobulin at 28 and 34 gestational weeks appeared to be the most effective measure for preventing alloimmunization (surface under the cumulative ranking curve [SUCRA] = 96.8%), while a single injection at 28 gestational weeks (SUCRA = 89.2%) was the second most effective. Administering no injection or a placebo (SUCRA = 0.0%) was the least effective intervention measure.

Conclusion: Among the therapeutic measures, administration of 300 mcg anti-D immunoglobulin at 28 and 34 gestational weeks appeared to be the best method for reducing the positive incidence of anti-D antibodies in the maternal serum. Therefore, it may be the most effective treatment for preventing fetal hemolytic disease.

Citation	Design	Endpoints
Lioger B, Maillot F, Ternant D, Passot C, Pintaud G, Bejan-angoulvant T. Efficacy and Safety of Anti-D Immunoglobulins versus Intravenous Immunoglobulins for Immune Thrombocytopenia in Children: Systematic Review and Meta-analysis of Randomized	Systematic review and meta-analysis conducted by searching Medline, Embase, and CENTRAL Cochrane library database for studies up to October 2016 to assess the efficacy and safety of anti-D and IVIG in children with ITP. Studies that were included were randomized controlled studies that enrolled children under age 18 years with ITP and evaluated the effect of anti-D compared with IVIG. Secondary ITP related to HIV, hepatitis B or C infections, autoimmune diseases, or immune deficiency syndromes was excluded. Studies that included a third arm of treatment, such as a glucocorticoid regimen were not excluded. Uncontrolled or nonrandomized studies were not considered for this review. A total of 11 studies with 558 children were included.	- Primary endpoint: Platelet response (as defined in each included study) and bleeding - Secondary outcomes: Adverse drug reactions

Controlled Trials. J Pediatr. 2019;204:225-233.e8.		
Results: Anti-D was significantly inferior to IVIG at increasing platelet counts, both for thresholds of $>20 \times 10^9/L$ at 24 to 72 hours (response rate ratio for anti-D vs. IVIG: 0.85, 95% CI 0.78 to 0.94) and $>50 \times 10^9/L$ at 24 to 72 hours (response rate ratio for anti-D vs. IVIG: 0.75, 95% CI 0.61 to 0.92). Bleeding response was assessed in 4 studies, but some heterogeneity in reporting leads to unclear conclusion. General symptoms after anti-D infusion were less frequent than after IVIG (odds ratio [OR] 0.39, 95% CI 0.25 to 0.62). Hemolysis was more frequent after anti-D. The overall quality of the studies was low. Conclusion: Compared with anti-D, IVIG led to a better response in terms of platelet count and may be preferred as a first-line treatment of ITP in children with acute hemorrhagic symptoms. However, the clinical significance of IVIG superiority on platelet count remains unclear.		

Formulary Placement, Utilization and Cost Experience (04-01-2025 to 06-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Rho(D) Immune Globulins								
HyperRHO® S/D (Rho[d] immune globulin [human]) 250, 1500 unit intramuscular syringes	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
RhoGAM® Ultra-Filtered PLUS (Rho[d] immune globulin [human]) 1,500 unit intramuscular syringe	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Rhophylac® (Rho[d] immune globulin [human]) 1,500 unit/2 mL injection syringe	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
WinRho® SDF (Rho[d] immune globulin [human]) 1500 unit/1.3 mL, 2500 unit/2.2 mL, 5000 unit/4.4 mL, 15,000 unit/13 mL injection solution	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
TOTAL	0	0	\$0.00	\$0.00	0	0 (0%)		

Key (as applicable) F = Formulary, no restrictions; F-QL = Formulary, quantity limit applies; F-AL = Formulary, age limit applies; F-ST = Formulary, step therapy applies; F-PA = Formulary, PA required; NF = Non-formulary; X = Excluded

References

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11. Xie X, Fu Q, Bao Z, Zhang Y, Zhou D. Clinical value of different anti-D immunoglobulin strategies for preventing Rh hemolytic disease of the fetus and newborn: A network meta-analysis. PLoS ONE. 2020;15(3):e0230073.
12. Lioger B, Maillot F, Ternant D, Passot C, Paintaud G, Bejan-angoulvant T. Efficacy and Safety of Anti-D Immunoglobulins versus Intravenous Immunoglobulins for Immune Thrombocytopenia in Children: Systematic Review and Meta-analysis of Randomized Controlled Trials. J Pediatr. 2019;204:225-233.e8.



VEGF Inhibitors

Executive Summary

Class Overview

This review focuses on the ophthalmic agents classified as vascular endothelial growth factor (VEGF) inhibitors. Angiogenesis as stimulated by growth factors such as VEGF contributes to the destructive nature of ocular disorders such as age-related macular degeneration (AMD), diabetic macular edema (DME), diabetic retinopathy (DR), and retinal vein occlusion (RVO), and is implicated as a key cause of tumor growth in cancer. VEGF inhibitors reduce leakage from blood vessels, prevent the proliferation of new abnormal vessels, decrease swelling of the retina, and improve visual acuity in patients with neovascular (wet) AMD, DR, and DME. Most patients with AMD and many with DR and DME will receive treatment with intravitreal VEGF inhibitors.

Ophthalmic agents Vabysmo™ (faricimab-svoa), Eylea® (aflibercept), Beovu® (brolucizumab-dbl), and Lucentis® (ranibizumab) are all FDA-approved for ocular use. Avastin® (bevacizumab), however, has a long history of established off-label use for these conditions (and compounded to a concentration far less than systemic oncology doses). Overall the use of Avastin® off-label has a lower cost than other single source anti-VEGF products and currently in the United States it has more than 50% of the total VEGF ophthalmic market share in AMD and diabetic eye disease (DR and DME). Biosimilar agents have also been approved and launched in the last few years for several of these agents, including Eylea®, Lucentis®, and Avastin®. Class-related adverse reactions include increased retinal vasculitis, intraocular pressure, endophthalmitis, retinal detachment, thromboembolic events and injection-related discomfort.

Utilization Findings

There was no utilization and no prior authorization requests.

Recommendations

- No changes

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Clinical Summary

Age-related macular degeneration

AMD is the leading cause of severe visual impairment and blindness and is a common health problem that significantly impacts the function and quality of life for affected individuals. Advancing age, northern European ancestry, and genetics are main risk factors, as well as smoking. It is classified as dry (atrophic or nonexudative), or wet (neovascular or exudative). Dry AMD is characterized by subretinal drusen deposits, atrophy or detachment of the retinal pigment epithelium, and subretinal pigment epithelial clumping. Wet AMD is characterized by growth of abnormal vessels into the subretinal space that may leak, leading to fluid beneath the retina. Dry AMD may progress to wet AMD. Wet AMD is much less common than dry AMD (only 10-15 % of patients with AMD is classified as wet AMD), but accounts for over 80% of blindness in AMD patients. Objectives for best outcomes consist of identifying at-risk populations, education on prevention and modifiable risk factors (ie smoking cessation), and minimizing or reversing loss of vision through treatment and follow up. For intermediate and more advanced dry AMD, ocular vitamin and mineral supplements are recommended to reduce/slow the risk of disease progression. VEGF Inhibitors are considered first-line treatment for wet AMD, and the choice of agent, according to guidelines, should be individualized. Ocular vitamin and mineral formulation supplements are also recommended.

Lucentis®, Eylea®, and Avastin® are all used commonly for anti-VEGF therapy and have comparable efficacy for treatment of wet AMD. Comparative trials between Avastin® and Lucentis® had similar outcomes on visual acuity (the CATT and IVAN trials). Eylea® and Lucentis® have been directly compared as well (in the VIEW 1 and VIEW 2 trials), with visual acuity outcomes similar between Eylea® given monthly or bi-monthly and Lucentis® dosed monthly. The newest agent, Beovu®, demonstrated in head-to-head HAWK and HARRIER trials that every 12-week dosing was non-inferior to every 8-week dosing with Lucentis® in terms of best-corrected visual acuity at 48 weeks. However, there were a large proportion of the patients (almost 50%) who, based presence of disease activity at defined monitoring periods, required reducing the dosing interval from 12 weeks to 8 weeks. This proportion declined even further during the second year of these studies (45% in HAWK and 39% in HARRIER maintained a Q 12 week dosing regimen through week 96). Recent reports of potentially sight-threatening retinal vasculitis may further disadvantage this product over other class competitors.

Macular edema (ME) from retinal vein occlusion (RVO)

Retinal vein occlusion is a consequence of cardiovascular disease with artery hardening and the formation of clots of the retinal veins. RVO can be classified as central or branch retinal vein occlusion depending on the location. These clots or “strokes” in the eye can quickly blur or cause loss of vision. RVO can then lead to capillary leakage, macular edema (when fluids leak into the macula and surrounding tissues), and retinal neovascularization. The main risk factor is advanced age, with RVO being uncommon in patients under 40 years of age. There is not a known treatment which unblocks retinal vein occlusion, so treatment is focused on targeting the macular edema and neovascularization, and management of the underlying disease (hypertension, diabetes, etc.). VEGF inhibitors are considered first-line therapy for treatment of ME, and intravitreal glucocorticoids can be used for refractory patients. Avastin® (off-label), Eylea® and Lucentis® are commonly used, with comparative data on these agents lacking in this condition. Retinal laser photocoagulation is first-line therapy for the neovascularization occurring as a result of RVO, with VEGF inhibitors

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playing a more limited role here to improve the effectiveness of the laser treatment. “Treat and extend” and “treat and observe” approaches to treatment interval are practiced in this setting as well.

Diabetic retinopathy (DR) with and without diabetic macular edema (DME)

Diabetic retinopathy is caused by poor blood sugar control which damages the blood vessels of the retina, leading to vision loss. Not surprisingly, loss of vision associated with DR is the most common cause of vision loss in 20-75 year olds. DR can occur with or without diabetic macular edema. DR can be proliferative (meaning neovascularization in the back of the eye) or non-proliferative, and these vessels are prone to hemorrhages that can temporarily or permanently impair vision. Blood sugar and blood pressure control are modifiable risk factors which can be controlled to reduce the incidence and further progression of DR. Early detection and intervention is key to sight preservation. Medical treatment is based on severity of DR as well as whether there is DME and if it affects the center of the macula (center-involved) or is noncenter-involved. First-line therapy for center-involved DME is anti-VEGF therapy, with laser treatments possible for persistent edema as second-line. Noncenter-involved DME is treated with laser photocoagulation therapy first-line. Proliferative diabetic retinopathy is treated with pan-retinal photocoagulation (PRP) surgery. Anti-VEGF therapy can also be used for proliferative diabetic retinopathy but is not considered first-line by the current guidelines of the American Ophthalmic Association.

Eylea® and Lucentis® are FDA approved for DME, with Avastin® off-label also commonly used. One comparative trial (the DRCR.net Protocol T trial) demonstrated no significant differences in improved visual acuity between the three agents after 1 year in patients with mild vision loss, but in patients with baseline visual acuity of 20/50 or worse, Eylea® demonstrated significantly better improvements than both Lucentis® and Avastin®. However after 2 years, the Eylea® advantage over Lucentis® was no longer demonstrated, but was still statistically superior to Avastin®. Reducing the burden of frequent injections with “treat and extend” and “treat and observe” techniques are used. One trial (TRES-DME) showed “treat and extend” dosing with ranibizumab to be comparable to monthly dosing in terms of visual and anatomic results in patients with center-involved DME at 2 years.

Current anti-vascular endothelial growth factor (anti-VEGF) therapies have become the standard of care due to their ability to maintain or prevent progression of vision loss in the majority of patients with AMD. These therapies, however, require life-long intraocular injections, typically repeated every 4 to 16 weeks in frequency, to maintain efficacy. Due to the burden of these treatments, patients often experience a decline in vision with reduced frequency of treatment over time. A study (NCT04704921) with an estimated completion date of May 2026, will evaluate the efficacy and safety of ABBV-RGX-314 gene therapy in participants with AMD. The study will evaluate 2 dose levels of ABBV-RGX-314 administered once, relative to an active comparator (Ranibizumab) administered every 28 days. The primary endpoint of this study is the mean change from baseline in best-corrected visual acuity (BCVA) of ABBV-RGX-314 relative to ranibizumab at Week 54.

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Indications, Dosing and Administration

Medication	Indications	Dosing/Administration
Avastin® (bevacizumab) 100 mg/4 ml vial Bevacizumab 1.25 mg/0.05 ml, 2 mg/0.08 mg, 2.5 mg/0.1 ml, 2.75 mg/0.11 ml, 3.25 mg/0.13 ml intravitreal solution prefilled syringes Vegzelma™ (bevacizumab-adcd) 100 mg/4 ml vial Mvasi® (bevacizumab-awwb) 100 mg/4 ml vial Zirabev™ (bevacizumab-bvzr) 100 mg/4 ml vial Alymsys® (bevacizumab-maly) 100 mg/4 ml vial	Age-related macular degeneration Diabetic macular edema	Intravitreal: AMD: 1.25 mg monthly for 3 months, then may be given scheduled (monthly) or as needed based on monthly ophthalmologic assessment DME: 1.25 mg initially; repeat every 4 weeks depending on ophthalmologic response
Vabysmo™ (faricimab-svoa) 6 mg/0.05 ml vial Vabysmo™ (faricimab-svoa) 6 mg/0.05 ml intravitreal solution prefilled syringe	Age-related macular degeneration, neovascular Diabetic macular edema Macular edema following retinal vein occlusion	Intravitreal: AMD: - Initial: 6 mg once every 4 weeks for 4 doses - Every 8-week regimen: 6 mg on weeks 20, 28, 36, and 44 - Every 12-week regimen: 6 mg on weeks 24, 36, and 48 - Every 16-week regimen: 6 mg on weeks 28 and 44 DME: - Fixed interval regimen: 6 mg once every 4 weeks for 6 doses, followed by 6 mg once every 8 weeks - Variable interval regimen: 6 mg once every 4 weeks for at least 4 doses, followed by 6 mg every 4 to 16 weeks RVO: 6 mg once every 4 weeks for 6 months
Eylea® (aflibercept) 2 mg/0.05 ml vial Eylea® (aflibercept) 2 mg/0.05 ml intravitreal solution prefilled syringe Eylea HD® (aflibercept) 8 mg/0.07 ml vial Pavblu™ (aflibercept-ayyh) 2 mg/0.05 ml vial	Age-related macular degeneration Diabetic macular edema Diabetic retinopathy Macular edema following retinal vein occlusion	Intravitreal: AMD: - Eylea and aflibercept biosimilar Pavblu: 2 mg once every 4 weeks for the first 12 weeks, followed by 2 mg once every 8 weeks - Eylea HD: 8 mg once every 4 weeks every 21 to 35 days for the first 3 doses, followed by 8 mg once every 8 to 16 weeks

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Pavblu™ (aflibercept-ayyh) 2 mg/0.05 ml intravitreal solution prefilled syringe		DME: - Eylea and aflibercept biosimilar Pavblu: 2 mg once every 4 weeks for the first 5 injections, followed by 2 mg once every 8 weeks - Eylea HD: 8 mg once every 4 weeks for the first 3 doses, followed by 8 mg once every 8 to 16 weeks Diabetic retinopathy: - Eylea and aflibercept biosimilar Pavblu: 2 mg once every 4 weeks for the first 5 injections, followed by 2 mg once every 8 weeks - Eylea HD: 8 mg once every 4 weeks for the first 3 doses, followed by 8 mg once every 8 to 12 weeks RVO: - Eylea and aflibercept biosimilar Pavblu: 2 mg once every 4 weeks
Beovu® (brolucizumab-dblI) 6 mg/0.05 ml intravitreal solution prefilled syringe	Age-related macular degeneration, neovascular Diabetic macular edema	Intravitreal: AMD: 6 mg once per month for 3 months, followed by 6 mg once every 8 to 12 weeks DME: 6 mg every 6 weeks for 5 doses, followed by 6 mg once every 8 to 12 weeks
Lucentis® (ranibizumab) 0.3 mg/0.05 ml vial Lucentis® (ranibizumab) 0.3 mg/0.05 ml, 0.5 mg/0.05 ml intravitreal solution prefilled syringes Susvimo™ (ranibizumab) 10 mg/0.1 ml (implant 1st fill) intravitreal solution kit Susvimo™ (ranibizumab) 10 mg/0.1 ml (implant refill) intravitreal solution vial Cimerli® (ranibizumab-eqrn) 0.3 mg/0.05 ml, 0.5mg/0.05 ml vials Byooviz™ (ranibizumab-nuna) 0.5 mg/0.05 ml vial	Age-related macular degeneration, neovascular Diabetic macular edema Diabetic retinopathy Macular edema following retinal vein occlusion Myopic choroidal neovascularization	Intravitreal: AMD: - Lucentis and ranibizumab biosimilars: 0.5 mg once a month. After 3 or 4 consecutive monthly doses, dosing interval may be extended - Susvimo: 2 mg delivered continuously with refills administered every 24 weeks. Supplemental injections of 0.5 mg may be administered to the affected eye while implant is in place, if needed DME: - Lucentis and Cimerli: 0.3 mg once a month. After 3 consecutive monthly does, dosing interval may be extended - Susvimo: 2 mg delivered continuously with refills administered every 24 weeks. Supplemental injections of 0.5 mg may be administered to the affected eye while implant is in place, if needed Diabetic retinopathy: - Lucentis and Cimerli only: 0.3 mg once a month

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		RVO: • Lucentis and ranibizumab biosimilars: 0.5 mg once a month. After 3 consecutive monthly doses, dosing interval may be extended Myopic choroidal neovascularization: • Lucentis and ranibizumab biosimilars: 0.5 mg once a month for up to 3 months; may retreat if necessary

Boxed Warnings and Contraindications

Medication	Boxed Warnings	Contraindications
Avastin® (bevacizumab) 100 mg/4 ml vial Bevacizumab 1.25 mg/0.05 ml, 2 mg/0.08 mg, 2.5 mg/0.1 ml, 2.75 mg/0.11 ml, 3.25 mg/0.13 ml intravitreal solution prefilled syringes Vegzelma™ (bevacizumab-adcd) 100 mg/4 ml vial Mvasi® (bevacizumab-awwb) 100 mg/4 ml vial Zirabev™ (bevacizumab-bvzr) 100 mg/4 ml vial AlymSYS® (bevacizumab-maly) 100 mg/4 ml vial	None	None
Vabysmo™ (faricimab-svoa) 6 mg/0.05 ml vial Vabysmo™ (faricimab-svoa) 6 mg/0.05 ml intravitreal solution prefilled syringe	None	Hypersensitivity to faricimab or any component of the formulation Ocular or periocular infections Active intraocular inflammation
Eylea® (aflibercept) 2 mg/0.05 ml vial Eylea® (aflibercept) 2 mg/0.05 ml intravitreal solution prefilled syringe Eylea HD® (aflibercept) 8 mg/0.07 ml vial Pavblu™ (aflibercept-ayyh) 2 mg/0.05 ml vial Pavblu™ (aflibercept-ayyh) 2 mg/0.05 ml intravitreal solution prefilled syringe	None	Hypersensitivity to aflibercept or any component of the formulation Current ocular or periocular infection Active intraocular inflammation
Beovu® (brolucizumab-dbli) 6 mg/0.05 ml intravitreal solution prefilled syringe	None	Hypersensitivity to brolucizumab or any component of the formulation Ocular or periocular infections Active intraocular inflammation
Lucentis® (ranibizumab) 0.3 mg/0.05 ml vial Lucentis® (ranibizumab) 0.3 mg/0.05 ml, 0.5 mg/0.05 ml intravitreal solution prefilled syringes	Endophthalmitis (implant): the implant has been associated with an up to 3-fold higher rate of endophthalmitis than monthly intravitreal injections of ranibizumab. Many of these events were associated with conjunctival retractions or erosions.	Hypersensitivity to ranibizumab or any component of the formulation Ocular or periocular infection Active intraocular inflammation

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Susvimo™ (ranibizumab) 10 mg/0.1 ml (implant 1st fill) intravitreal solution kit Susvimo™ (ranibizumab) 10 mg/0.1 ml (implant refill) intravitreal solution vial Cimerli® (ranibizumab-eqrn) 0.3 mg/0.05 ml, 0.5mg/0.05 ml vials Byooviz™ (ranibizumab-nuna) 0.5 mg/0.05 ml vial		

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Warnings/Precautions

Medication	Warnings/Precautions
Avastin® (bevacizumab) 100 mg/4 ml vial Bevacizumab 1.25 mg/0.05 ml, 2 mg/0.08 mg, 2.5 mg/0.1 ml, 2.75 mg/0.11 ml, 3.25 mg/0.13 ml intravitreal solution prefilled syringes Vegzelma™ (bevacizumab-adcd) 100 mg/4 ml vial Mvasi® (bevacizumab-awwb) 100 mg/4 ml vial Zirabev™ (bevacizumab-bvzr) 100 mg/4 ml vial Alymsys® (bevacizumab-maly) 100 mg/4 ml vial	Concerns related to adverse effects • GI perforation/fistula • Heart failure • Hemorrhage • Hypertension • Infusion reactions • Mortality • Necrotizing fasciitis • Ocular adverse events • Osteonecrosis of the jaw • Posterior reversible encephalopathy syndrome • Proteinuria / nephrotic syndrome • Thromboembolism • Wound healing complications Disease-related concerns • Renal impairment: increase in blood pressures were noted in a retrospective review of patients with renal insufficiency (CrCl < 60) Special populations: • Older adult: patients > 65 years of age have an increased incidence of arterial thrombotic events
Vabysmo™ (faricimab-svoa) 6 mg/0.05 ml vial Vabysmo™ (faricimab-svoa) 6 mg/0.05 ml intravitreal solution prefilled syringe	Concerns related to adverse effects: • Endophthalmitis and retinal detachment • Increase in intraocular pressure • Thromboembolic events • Retinal vasculitis and/or retinal vascular occlusion • Immunogenicity
Eylea® (aflibercept) 2 mg/0.05 ml vial Eylea® (aflibercept) 2 mg/0.05 ml intravitreal solution prefilled syringe Eylea HD® (aflibercept) 8 mg/0.07 ml vial Pavblu™ (aflibercept-ayyh) 2 mg/0.05 ml vial Pavblu™ (aflibercept-ayyh) 2 mg/0.05 ml intravitreal solution prefilled syringe	Concerns related to adverse effects: • Endophthalmitis / retinal detachment / retinal vasculitis • Hypersensitivity reactions • Increased intraocular pressure • Thromboembolic events Disease-related concerns • Retinopathy of prematurity: following intravitreal injection, abnormal angiogenesis and tortuosity may recur
Beovu® (brolucizumab-dbli) 6 mg/0.05 ml intravitreal solution prefilled syringe	Concerns related to adverse effects: • Endophthalmitis and retinal detachment • Increased intraocular pressure

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	• Retinal vasculitis/retinal vascular occlusion • Thromboembolic events
Lucentis® (ranibizumab) 0.3 mg/0.05 ml vial Lucentis® (ranibizumab) 0.3 mg/0.05 ml, 0.5 mg/0.05 ml intravitreal solution prefilled syringes Susvimo™ (ranibizumab) 10 mg/0.1 ml (implant 1st fill) intravitreal solution kit Susvimo™ (ranibizumab) 10 mg/0.1 ml (implant refill) intravitreal solution vial Cimerli® (ranibizumab-eqrn) 0.3 mg/0.05 ml, 0.5mg/0.05 ml vials Byooviz™ (ranibizumab-nuna) 0.5 mg/0.05 ml vial	Concerns related to adverse effects: • Conjunctival effects • Endophthalmitis / retinal detachment • Hypersensitivity reactions • Increased intraocular pressure • Retinal vasculitis • Septum dislodgement • Thromboembolic events • Visual acuity • Vitreous hemorrhage Disease-related concerns: • Diabetic macular edema and diabetic retinopathy: higher incidence of fatal events

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Practice Guidelines

Age-Related Macular Degeneration Preferred Practice Pattern. American Academy of Ophthalmology (2024).

- Although an estimated 80% of patients with age-related macular degeneration (AMD) have non-neovascular or atrophic AMD, the neovascular form is responsible for most of the severe vision loss associated with AMD.
- Risk factors for the development of advanced AMD include smoking, increasing age, northern European ancestry, and genetic factors. Cigarette smoking has been identified as the primary modifiable risk factor in numerous studies on advanced AMD. It is strongly recommended to advise patients with AMD or those at risk for AMD to stop smoking. Routine genetic testing is not currently recommended.
- In light of all of the available information on aspirin use and AMD, the current preferred practice for patients who have been instructed by their physician that long-term aspirin is appropriate and beneficial is to continue with aspirin therapy as prescribed.
- There is no evidence-based treatment for early AMD.
- According to the Age-Related Eye Disease Study (AREDS2), antioxidant vitamin and mineral supplementation should be considered in patients with intermediate AMD or geographic atrophy (GA) in one or both eyes and other advanced AMD in one eye. There is no evidence to support the use of these supplements for patients who have less than intermediate AMD and no evidence of any prophylactic value for family members without signs of AMD. A Mediterranean diet is associated with a reduced risk of developing AMD and of existing AMD becoming worse.
- Early detection and prompt treatment of active neovascular AMD improves visual outcomes. Intravitreal injection therapy using anti-vascular endothelial growth factor (VEGF) agents, which may or may not target other factors such as placental growth factor or angiopoietin-2, is the most effective way to manage neovascular AMD and is the first-line treatment. Symptoms suggestive of post-injection endophthalmitis or retinal detachment require prompt evaluation.
- The choice of biologic product (reference, biosimilar, or interchangeable) should be that of the treating ophthalmologist and the patient whenever possible.

Clinical Trials/Systematic Reviews/Meta-Analyses

Citation	Design	Endpoints
Ricci F, Bandello F, Navarra P, Staurenghi G, Stumpp M, Zarbin M. Neovascular Age-Related Macular Degeneration: Therapeutic Management and New-Upcoming Approaches. Int J Mol Sci. 2020 Nov 3;21(21):8242. doi: 10.3390/ijms21218242. PMID: 33153227; PMCID: PMC7662479.	A Phase III, Multicenter, Randomized, Double Masked, Sham Injection-Controlled Study N = 716 Ranibizumab 0.3 mg (N = 238), 0.5 mg (N = 240) and sham injection (N = 238). Inclusion: Age > 50 years; Active primary or recurrent subfoveal choroidal neovascularization (CNV) lesions secondary to age-related macular degeneration (AMD) in the study eye; Lesions with occult CNV or with some classic CNV component are permissible. However, if classic CNV (well-demarcated hyperfluorescence boundaries in the early phase of the fluorescein angiogram) is present, the area of classic CNV must be <50% of the total lesion size; The total area of CNV (including both classic and occult components) encompassed within the lesion must be ≥50% of the total lesion area; The total lesion area must be ≤12 disc areas (DA) in size; Best corrected visual acuity, using Early Treatment of Diabetic Retinopathy Study (ETDRS) charts, of 20/40 to 20/320 (Snellen equivalent) in the study eye	- Primary Endpoint: proportion of patients losing fewer than 15 letters from baseline visual acuity at 12 months. - Secondary Endpoints: Visual acuity improving by 15 or more letters, mean increases in visual acuity, visual acuity maintained at 24 months
Results: At 12 months, 94.5% of the group given 0.3 mg of ranibizumab and 94.6% of those given 0.5 mg lost fewer than 15 letters, as compared with 62.2% of patients receiving sham injections (P<0.001 for both comparisons). Visual acuity improved by 15 or more letters in 24.8% of the 0.3-mg group and 33.8% of the 0.5-mg group, as compared with 5.0% of the sham-injection group (P<0.001 for both doses). Mean increases in visual acuity were 6.5 letters in the 0.3-mg group and 7.2 letters in the 0.5-mg group, as compared with a decrease of 10.4 letters in the sham-injection group (P<0.001 for both comparisons). The benefit in visual acuity was maintained at 24 months. During the 24 months, presumed endophthalmitis was identified in five patients (1.0%) and serious uveitis in six patients (1.3%) given ranibizumab. Conclusion: Intravitreal administration of ranibizumab for 2 years prevented vision loss and improved mean visual acuity, with low rates of serious adverse events, in patients with minimally classic or occult choroidal neovascularization secondary to age-related macular degeneration.		
Citation	Design	Endpoints
Liberski S, Wichrowska M, Kocięcki J. Aflibercept versus Faricimab in the Treatment of Neovascular Age-Related Macular Degeneration and Diabetic Macular Edema: A	A multicenter, single-blind, noninferiority trial N = 1208 Ranibizumab monthly (N = 301), Bevacizumab monthly (N = 286), Ranibizumab as needed (N = 298), Bevacizumab as needed (N = 300)	Primary Endpoint: mean change in visual acuity at 1 year, with a noninferiority limit of 5 letters on the eye chart

Review. Int J Mol Sci. 2022 Aug 20;23(16):9424. doi: 10.3390/ijms23169424. PMID: 36012690; PMCID: PMC9409486.	Inclusion Criteria: Active, subfoveal choroidal neovascularization (CNV); Fibrosis < 50% of total lesion area; Visual acuity (VA) 20/25-20/320; Age ≥ 50 yrs; At least 1 drusen (>63μ) in either eye or late AMD in fellow eye Exclusion Criteria: Previous treatment for CNV in study eye; Other progressive retinal disease likely to compromise VA; Contraindications to injections with Lucentis or Avastin	Secondary Endpoints: mean decrease in central retinal thickness, average cost, visual acuity score at 1 year
Results: Bevacizumab administered monthly was equivalent to ranibizumab administered monthly, with 8.0 and 8.5 letters gained, respectively. Bevacizumab administered as needed was equivalent to ranibizumab as needed, with 5.9 and 6.8 letters gained, respectively. The mean decrease in central retinal thickness was greater in the ranibizumab-monthly group (196 μm) than in the other groups (152 to 168 μm, P=0.03 by analysis of variance). Rates of death, myocardial infarction, and stroke were similar for patients receiving either bevacizumab or ranibizumab (P>0.20). The proportion of patients with serious systemic adverse events (primarily hospitalizations) was higher with bevacizumab than with ranibizumab (24.1% vs. 19.0%; risk ratio, 1.29; 95% confidence interval, 1.01 to 1.66). Conclusion: At 1 year, bevacizumab and ranibizumab had equivalent effects on visual acuity when administered according to the same schedule. Ranibizumab given as needed with monthly evaluation had effects on vision that were equivalent to those of ranibizumab administered monthly.		
Citation	Design	Endpoints
Heier JS, Brown DM, Chong V, Korobelnik JF, Kaiser PK, Nguyen QD, Kirchhof B, Ho A, Ogura Y, Yancopoulos GD, Stahl N, Vitti R, Berliner AJ, Soo Y, Anderesi M, Groetzbach G, Sommerauer B, Sandbrink R, Simader C, Schmidt-Erfurth U; VIEW 1 and VIEW 2 Study Groups. Intravitreal aflibercept (VEGF trap-eye) in wet age-related macular degeneration. Ophthalmology. 2012 Dec;119(12):2537-48. doi: 10.1016/j.ophtha.2012.09.006. Epub 2012 Oct 17. Erratum in:	A phase III, double-masked, randomized study N = 1240 Eylea 2 mg Q8 weeks (N = 306), Eylea 2 mg Q4 weeks (N = 309), Ranibizumab 0.5 mg Q4 weeks (N = 291) Inclusion: Men and women ≥50 years of age; Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by Fluorescein angiography (FA) in the study eye; ETDRS Best-Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters; Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures; Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.	- Primary Endpoint: percentage of patients who maintained visual acuity, defined as loss of fewer than 15 letters of best corrected visual acuity (BCVA) on the ETDRS chart (3 lines), at 52 weeks. - Secondary Endpoints: Mean Change from Baseline in Best Corrected Visual Acuity (BCVA), Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score,

Ophthalmology. 2013 Jan;120(1):209-10.		
PMID: 23084240.		

Results:						
Table 2: Efficacy Outcomes at Week 52 (Full Analysis Set with LOCF) in VIEW1 and VIEW2 Studies						
	VIEW1			VIEW2		
	EYLEA 2 mg Q8 weeks ^a	EYLEA 2 mg Q4 weeks	ranibizu- mab 0.5 mg Q4 weeks	EYLEA 2 mg Q8 weeks ^a	EYLEA 2 mg Q4 weeks	ranibizu- mab 0.5 mg Q4 weeks
Full Analysis Set	N=301	N=304	N=304	N=306	N=309	N=291
Efficacy Outcomes						
Proportion of patients who maintained visual acuity (%) (<15 letters of BCVA loss)	94%	95%	94%	95%	95%	95%
Difference ^b (%) (95.1% CI)	0.6 (-3.2, 4.4)	1.3 (-2.4, 5.0)		0.6 (-2.9, 4.0)	-0.3 (-4.0, 3.3)	
Mean change in BCVA as measured by ETDRS letter score from Baseline	7.9	10.9	8.1	8.9	7.6	9.4
Difference ^b in LS mean (95.1% CI)	0.3 (-2.0, 2.5)	3.2 (0.9, 5.4)		-0.9 (-3.1, 1.3)	-2.0 (-4.1, 0.2)	
Number of patients who gained at least 15 letters of vision from Baseline (%)	92 (31%)	114 (38%)	94 (31%)	96 (31%)	91 (29%)	99 (34%)
Difference ^b (%) (95.1% CI)	-0.4 (-7.7, 7.0)	6.6 (-1.0, 14.1)		-2.6 (-10.2, 4.9)	-4.6 (-12.1, 2.9)	
BCVA = Best Corrected Visual Acuity; CI = Confidence Interval; ETDRS = Early Treatment Diabetic Retinopathy Study; LOCF = Last Observation Carried Forward (baseline values are not carried forward); 95.1% confidence intervals were presented to adjust for safety assessment conducted during the study. ^a After treatment initiation with 3 monthly doses ^b EYLEA group minus the ranibizumab group						

Conclusion: Eylea 2 mg Q8 weeks and Eylea 2 mg Q4 weeks groups were shown to have efficacy that was clinically equivalent to the ranibizumab 0.5 mg Q4 group. A generally favorable safety profile was observed for both EYLEA and ranibizumab. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies.

Citation	Design	Endpoints
Low A, Faridi A, Bhavsar KV, Cockerham GC, Freeman M, Fu R, Paynter R, Kondo K, Kansagara D. Comparative effectiveness and harms of intravitreal anti-vascular endothelial growth factor agents for three retinal conditions: a systematic review and meta-analysis. Br J Ophthalmol. 2019 Apr;103(4):442-451. doi: 10.1136/bjophthalmol-2018-312691. Epub 2018 Nov 8. PMID: 30409915	A systematic review/meta-analysis (SR/MA) comparing aflibercept, bevacizumab and ranibizumab efficacy and safety in neovascular AMD, diabetic macular edema, and central or branch retinal vein occlusion. Data from published and unpublished randomized, controlled trial, cohort or modeling studies searched through February 2017.	• Best-corrected visual acuity changes • Quality of life • Ocular or systemic adverse effects

Results: Of 17 included trials, none reported a clinically important difference (≥ 5 letters) in gained best visual acuity. Nine trials provide high-strength evidence of no difference between bevacizumab and ranibizumab for NVAMD. Three trials provide moderate-strength evidence of no difference between bevacizumab and ranibizumab for DME. There was low-strength evidence of similar effects between aflibercept and ranibizumab for NVAMD, aflibercept and bevacizumab for RVO and all three agents for DME. There was insufficient evidence to compare bevacizumab and ranibizumab for RVO. Rates of ocular adverse events were low, and systemic harms were generally similar between groups, although 1 DME trial reported more arterial thrombotic events with ranibizumab versus aflibercept.

Conclusion: This SR/MA failed to find significant differences in the most commonly used anti-VEGF agents in terms of efficacy or safety.

Citation	Design	Endpoints
Ohji M, Lanzetta P, Korobelnik JF, Wojciechowski P, Taieb V, Deschaseaux C, Janer D, Tuckmantel C. Efficacy and Treatment Burden of Intravitreal Aflibercept Versus Intravitreal Ranibizumab Treat-and-Extend Regimens at 2 Years: Network Meta-Analysis Incorporating Individual Patient Data	A SR/MA comparing visual outcomes and treatment burden between treat-and-extend (T&E) regimens of aflibercept and ranibizumab in wet AMD after 2 years Trials were searched to October 2018 Six RCTs were included (ALTAIR, VIEW 1 and 2, CATT, CANTREAT, and TREX)	• Mean change in Early Treatment Diabetic Retinopathy Study [ETDRS] letters vs baseline • Treatment burden (mean number of injections)

Meta-Regression and Matching-Adjusted Indirect Comparison. Adv Ther. 2020 Mar 28. doi: 10.1007/s12325-020-01298-x. [Epub ahead of print]. PMID: 32222903		
Results: At 2 years, the median difference (95% credibility interval) between aflibercept T&E and ranibizumab T&E regarding the numbers of Early Treatment Diabetic Retinopathy Study (ETDRS) letters gained was not significant. Aflibercept T&E was associated with significantly fewer injections than ranibizumab (on average 6 fewer injections at 2 years). Conclusion: The authors found aflibercept may be superior to ranibizumab when both are used in a treat and extend fashion for wet AMD, as it required fewer injections to maintain similar vision outcomes when assessed over 2 years.		
Citation	Design	Endpoints
Solomon SD, Lindsley K, Vedula SS, Krzystolik MG, Hawkins BS. Anti-vascular endothelial growth factor for neovascular age-related macular degeneration. Cochrane Database Syst Rev. 2019 Mar 4;3:CD005139. doi: 10.1002/14651858.CD005139.pub4. PMID: 30834517	Cochrane SR/MA of RCTs evaluating pegaptanib, ranibizumab, and bevacizumab against placebo/photodynamic laser control or each other, with at least 1 year follow-up for neovascular AMD. Multiple registry sources searched for trials; latest date was through 11/28/2018. Included 16 RCT (6347 participants) with neovascular AMD: 6 trials compared vs a control 10 trials compared ranibizumab to bevacizumab	- Measures of ocular and systemic effects - Quality of life
Results: The overall assessment was risk of bias was low, and overall moderate-high certainty evidence. For trials comparing pegaptanib, ranibizumab, and bevacizumab against placebo/photodynamic laser control, more patients: - who received intravitreal injection of any of the three anti-VEGF agents had gained 15 letters or more of visual acuity (risk ratio [RR] 4.19, 95% confidence interval [CI] 2.32 to 7.55) - lost fewer than 15 letters of visual acuity (RR 1.40, 95% CI 1.27 to 1.55) - showed mean improvement in visual acuity (mean difference 6.7 letters, 95% CI 4.4 to 9.0 in one pegaptanib trial; mean difference 17.8 letters, 95% CI 16.0 to 19.7 in three ranibizumab trials) after one year of follow-up - showed improvement in morphologic outcomes (e.g. size of CNV, central retinal thickness) compared with participants not treated with anti-VEGF agents (moderate-certainty evidence).		

Pegaptanib was not directly compared to any of the other anti-VEGF treatments, however controlled data showed ranibizumab and bevacizumab each yielded larger improvements in visual acuity outcomes.

When trials compared bevacizumab and ranibizumab with same regimens:

- Visual acuity outcomes after bevacizumab and ranibizumab were similar with respect to gain of 15 or more letters of visual acuity (RR 0.95, 95% CI 0.81 to 1.12) and loss of fewer than 15 letters of visual acuity (RR 1.00, 95% CI 0.98 to 1.02)
- Results showed similar mean improvement in visual acuity (mean difference [MD] -0.5 letters, 95% CI -1.5 to 0.5) after one year of follow-up, despite the substantially lower cost of bevacizumab compared with ranibizumab.
- Reduction in central retinal thickness was less among bevacizumab-treated participants than among ranibizumab-treated participants after one year (MD -11.6 μ m, 95% CI -21.6 to -1.7) but the researchers did not interpret it to be clinically meaningful.

In terms of safety, ocular inflammations and increased intraocular pressure were the side effects reported most. Endophthalmitis was reported in less than 1% of anti-VEGF patients, but not among control patients. Serious adverse event rates were similar across groups but since event numbers/trial participants were low this may have not been enough to adequately show a measure a meaningful difference.

Conclusion: All three anti-VEGF agents were effective in treating neovascular AMD. Bevacizumab and ranibizumab were similarly effective on visual acuity measures when compared directly. Safety data for rare events may have been not adequately tested for due to small trial sizes.

Citation	Design	Endpoints
Dugel PU, Koh A, Ogura Y, Jaffe GJ, Schmidt-Erfurth U, Brown DM, Gomes AV, Warburton J, Weichselberger A, Holz FG; HAWK and HARRIER Study Investigators. HAWK and HARRIER: Phase 3, Multicenter, Randomized, Double-Masked Trials of Brolucizumab for Neovascular Age-Related Macular Degeneration. Ophthalmology . 2020 Jan;127(1):72-84. doi: 10.1016/j.ophtha.2019.04.017. Epub 2019 Apr 12. PMID: 30986442	Two double-blind, active-controlled randomized trials (HAWK and HARRIER) comparing brolucizumab and aflibercept in patients with untreated, active neovascular AMD. N=1,817 patients <u>Arms:</u> after initial monthly loading doses in all arms, patients received either: HAWK: brolucizumab 3mg Q 12/8 wk, brolucizumab 6mg Q 12/8 wk, aflibercept 2mg Q 8 wk HARRIER: brolucizumab 6mg Q 12/8 wk, aflibercept 2mg Q 8 wk *brolucizumab regimens were 12 weeks, with optional adjustment to every 8 weeks if needed based on disease activity.	• Primary: noninferiority in mean best-corrected visual acuity (BCVA) change from baseline to Week 48 (margin: 4 letters) • Select secondary: percentage of patients who maintained q12w dosing through Week 48, anatomic outcomes

Results:

- At Week 48, each brolucizumab arm demonstrated noninferiority to aflibercept in BCVA change from baseline (least squares [LS] mean, +6.6 [6 mg] and +6.1 [3 mg] letters with brolucizumab vs. +6.8 letters with aflibercept [HAWK]; +6.9 [brolucizumab 6 mg] vs. +7.6 [aflibercept] letters [HARRIER]; $P < 0.001$ for each comparison).
- Greater than 50% of brolucizumab 6 mg-treated eyes were maintained on q12w dosing through Week 48 (56% [HAWK] and 51% [HARRIER]).
- At Week 16, after identical treatment exposure, fewer brolucizumab 6 mg-treated eyes had disease activity versus aflibercept in HAWK (24.0% vs. 34.5%; $P = 0.001$) and HARRIER (22.7% vs. 32.2%; $P = 0.002$).
- Greater central subfield thickness reductions from baseline to Week 48 were observed with brolucizumab 6 mg versus aflibercept in HAWK (LS mean -172.8 μm vs. -143.7 μm ; $P = 0.001$) and HARRIER (LS mean -193.8 μm vs. -143.9 μm ; $P < 0.001$).
- Anatomic retinal fluid outcomes favored brolucizumab over aflibercept.
- Overall, adverse event rates were generally similar with brolucizumab and aflibercept.

Conclusion: The authors concluded brolucizumab was noninferior to aflibercept in BCVA at Week 48. Slightly more than 50% of brolucizumab 6 mg-treated eyes were able to stay on q12w dosing through the treatment period. Anatomic outcomes favored brolucizumab over aflibercept. Adverse events/safety was similar between products.

Citation	Design	Endpoints
Virgili G, Parravano M, Evans JR, Gordon I, Lucenteforte E. Anti-vascular endothelial growth factor for diabetic macular edema: a network meta-analysis. Cochrane Database Syst Rev. 2018 Oct 16;10:CD007419. doi: 10.1002/14651858.CD007419.pub6. PMID: 30325017	Cochrane SR/MA of RCTs evaluating aflibercept, ranibizumab, and bevacizumab directly against each other, another treatment (such as laser), sham or no treatment in people with diabetic macular edema (DME). Multiple registry sources searched for trials; latest date was through 4/26/2017. Included 24 studies (6007 participants)	• Three efficacy outcomes: gain of 15 or more Early Treatment Diabetic Retinopathy Study (ETDRS) letters; mean change in best-corrected visual acuity (BCVA); mean change in central retinal thickness (CRT) • Three safety outcomes: all severe systemic adverse events (SSAEs); all-cause death; arterial thromboembolic events • Quality of life

Results (select):

- Aflibercept, bevacizumab and ranibizumab were all more effective than laser for improving vision by 3 or more lines after one year.
- People receiving ranibizumab were less likely to gain 3 or more lines of VA at one year compared with aflibercept: RR 0.75 (95% CI 0.60 to 0.94). For every 1000 people treated with aflibercept, 92 fewer would gain 3 or more lines of VA at one year if treated with ranibizumab (22 to 148 fewer). On average people receiving ranibizumab had worse VA at one year (MD 0.08 logMAR units, 95% CI 0.05 to 0.11), and higher CRT (MD 39 μm , 95% CI 2 μm to 76 μm).
- Ranibizumab and bevacizumab were comparable with respect to aflibercept and did not differ in terms of VA: RR of gain of 3 or more lines of VA at one year 1.11 (95% CI 0.87 to 1.43), and difference in change in VA was 0.00 (95% CI -0.02 to 0.03) logMAR. CRT reduction favored ranibizumab by -29 μm (95% CI -58 μm to -1 μm).
- The previous version of this review found moderate-certainty evidence of good safety of antiangiogenic drugs versus control. This update used data at the longest available follow-up (one or two years) and found that aflibercept, ranibizumab and bevacizumab do not differ regarding systemic serious adverse events (SSAEs). However, risk of bias was variable, loop inconsistency could be found and estimates were not precise enough on relative safety regarding less frequent events such

as arterial thromboembolic events or death. Two-year data were available and reported in only four RCTs in this review. Most industry-sponsored studies were open-label after one year. One large publicly-funded study compared the three drugs at two years and found no difference.

Conclusion: The authors concluded anti-VEGF agents were effective at improving vision in people with DME with three to four in every 10 people likely to experience an improvement of 3 or more lines VA at one year. There was a small advantage in VA and CRT shown with aflibercept over ranibizumab and bevacizumab, but the results were only shown over short-term (one year) and longer term data is needed to determine if these effects are durable. Other concerns noted real-world effects not likely being the same as those in a highly-controlled experimental environment and the need for longer than two-year data comparing agents. Adverse effects were similar between drugs but authors has some concerns about certainty of that data in regards to arterial thromboembolic events and death of any cause.

Citation	Design	Endpoints
Maloney MH, Schilz SR, Herrin J, Sangaralingham LR, Shah ND, Barkmeier AJ. Risk of Systemic Adverse Events Associated with Intravitreal Anti-VEGF Therapy for Diabetic Macular Edema in Routine Clinical Practice. Ophthalmology . 2019 Jul;126(7):1007-1015. doi: 10.1016/j.ophtha.2018.09.040. Epub 2018 Oct 4. NCT 30292542	A retrospective cohort study of claims databases (private and Medicare advantage) of patients treated with anti-VEGF therapy vs. control (laser or intravitreal corticosteroid) for DME. Claims searched between 1/1/2006-12/31/2015 Total of 23,348 patients receiving treatment for DME met inclusion criteria; 13,365 received macular laser, 9,219 received intravitreal anti-VEGF, and 764 received intravitreal corticosteroid as initial treatment	Risk of cerebrovascular disease, myocardial infarction, major bleeding, and all-cause hospitalization occurring within 6 months of initial DME treatment

Results: Anti-VEGF pharmacotherapy was not associated with an increased hazard of cerebrovascular disease (HR, 0.96; 95% CI, 0.65-1.41; P = 0.83), major bleeding (HR, 1.23; 95% CI, 0.76-1.99; P = 0.41), or myocardial infarction (HR, 1.03; 95% CI, 0.73-1.44; P = 0.88) when compared with macular laser for DME; however, there was an increased hazard of post-treatment all-cause hospital admission (HR, 1.17; 95% CI, 1.05-1.30; P = 0.01). The rates of all primary systemic serious adverse events outcomes were similar after treatment with anti-VEGF versus corticosteroid (P > 0.05 for all).

Conclusion: Authors concluded no increased risks associated with anti-VEGF treatment in DME patients compared to those using laser or intravitreal corticosteroid therapy in CVD, major bleeding, or MI, but potential increase in all cause hospitalization.

Citation	Design	Endpoints
Hykin P, Prevost AT, Vasconcelos JC, Murphy C, Kelly J, Ramu J, Hounscome B, Yang Y, Harding SP, Lotery A, Chakravarthy U, Sivaprasad S; LEAVO Study Group. Clinical Effectiveness of Intravitreal Therapy	A prospective, 3-arm, double-masked, randomized noninferiority trial (Lucentis, Eylea, Avastin in Vein Occlusion [LEAVO] Study). Patients randomized to ranibizumab, aflibercept, or bevacizumab for 100 weeks. Patients received injections at 4, 8, and 12 weeks, and thereafter injected if certain follow up criteria were met	Adjusted mean change in BCVA in the study eye at 100 weeks

With Ranibizumab vs Aflibercept vs Bevacizumab for Macular Edema Secondary to Central Retinal Vein Occlusion: A Randomized Clinical Trial. JAMA Ophthalmol. 2019 Aug 29. PMID: 31465100	Inclusion criteria: 18 years or older, visual impairment due to CRVO-related macular edema of less than 12 months, best-corrected visual acuity (BCVA) Early Treatment Diabetic Retinopathy Study letter score (approximate Snellen equivalent) in the study eye between 19 (20/400) and 78 (20/32), and spectral domain optical coherence tomography imaging central subfield thickness of 320 μm or greater. N=463 participants; mean age 69 years, 57% male	
Results: The mean (SD) gain in BCVA letter score at 100 weeks: ○ 12.5 (21.1) for ranibizumab ○ 15.1 (18.7) for aflibercept ○ 9.8 (21.4) for bevacizumab • Aflibercept was noninferior to ranibizumab (intention-to-treat-adjusted mean BCVA difference, 2.23 letters; 95% CI, -2.17 to 6.63 letters; P < .001). • Bevacizumab was <i>not noninferior</i> to ranibizumab (intention-to-treat-adjusted mean BCVA difference, -1.73 letters; 95% CI, -6.12 to 2.67 letters; P = .07). • Fewer mean injections were given in the aflibercept group (10.0) than in the ranibizumab (11.8) group (mean difference at 100 weeks, -1.9; 95% CI, -2.9 to -0.8). Conclusion: The authors concluded aflibercept was non-inferior to ranibizumab (but also not superior) on BCVA at 100 weeks, but could not make a definitive conclusion with bevacizumab (i.e. may possibly be inferior) for treatment of macular edema secondary to RVO.		

Formulary Placement, Utilization and Cost Experience (04-01-2025 to 06-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
*note, bevacizumab biosimilars are not currently available in vial sizes that would be used in ophthalmic indications but they are used off-label for this purpose and have been included in the class review								
Avastin® (bevacizumab) 100 mg/4 ml vial	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Bevacizumab 1.25 mg/0.05 ml, 2 mg/0.08 mg, 2.5 mg/0.1 ml, 2.75 mg/0.11 ml, 3.25 mg/0.13 ml intravitreal solution prefilled syringes	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Vegzelma™ (bevacizumab-adcd) 100 mg/4 ml vial	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Mvasi® (bevacizumab-awwb) 100 mg/4 ml vial	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Zirabev™ (bevacizumab-bvzr) 100 mg/4 ml vial	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Alymsys® (bevacizumab-maly) 100 mg/4 ml vial	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Vabysmo™ (faricimab-svoa) 6 mg/0.05 ml vial	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Vabysmo™ (faricimab-svoa) 6 mg/0.05 ml intravitreal solution prefilled syringe	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Eylea® (aflibercept) 2 mg/0.05 ml vial	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Eylea® (aflibercept) 2 mg/0.05 ml intravitreal solution prefilled syringe	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Pavblu™ (aflibercept-ayyh) 2 mg/0.05 ml vial	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Pavblu™ (aflibercept-ayyh) 2 mg/0.05 ml intravitreal solution prefilled syringe	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Eylea HD® (aflibercept) 8 mg/0.07 ml vial	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Beovu® (brolucizumab-dbli) 6 mg/0.05 ml intravitreal solution prefilled syringe	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Lucentis® (ranibizumab) 0.3 mg/0.05 ml vial	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Lucentis® (ranibizumab) 0.3 mg/0.05 ml, 0.5 mg/0.05 ml intravitreal solution prefilled syringes	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Susvimo™ (ranibizumab) 10 mg/0.1 ml (implant 1st fill) intravitreal solution kit	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Susvimo™ (ranibizumab) 10 mg/0.1 ml (implant refill) intravitreal solution vial	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change



Cimerli® (ranibizumab-eqrn) 0.3 mg/0.05 ml, 0.5mg/0.05 ml vials	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Byooviz™ (ranibizumab-nuna) 0.5 mg/0.05 ml vial	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
TOTAL	0	0	\$0.00	\$0.00	0	0 (0%)		

Key (as applicable) F = Formulary, no restrictions; F-QL = Formulary, quantity limit applies; F-AL = Formulary, age limit applies; F-ST = Formulary, step therapy applies; F-PA = Formulary, PA required; NF = Non-formulary; X = Excluded

Prior Authorization Criteria

No changes

Ophthalmic indications for bevacizumab	
Medications	Avastin (bevacizumab) Mvasi (bevacizumab-awwb) - biosimilar Zirabev (bevacizumab-bvzr) - biosimilar
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "Other Criteria" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age for MCAL
Prescriber Restrictions	Prescriber must be an ophthalmologist
Coverage Duration	A 3 month duration for initial approval and 12 months for renewal
Maximum Billable Units	Variable
Other Criteria	- Member must have a diagnosis for an ophthalmic indication accepted in a nationally recognized compendia - Age related macular degeneration - Choroidal retinal neovascularization - Branch retinal vein occlusion with macular edema - Central retinal vein occlusion with macular edema - Choroidal retinal neovascularization, secondary to pathologic myopia - Macular edema due to diabetes mellitus - Retinopathy due to diabetes mellitus - Retinopathy of prematurity - Must be prescribed at a dose that is consistent with nationally recognized compendia If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review
Last Review Date	3/20259/2025

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Alameda MRGs for review Q3 2025 P&T Consent Agenda

Recommendation: No changes

Physician Administered Medication (PAD)/ Medical Benefit Guidelines	
Therapeutic Classes (AHFS)	N/A
Medications	Physician Administered Medications (PAD) under the medical benefit
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval Up to a 6 month duration depending upon the diagnosis and usual treatment therapies Later Approvals Up to a 12 month duration depending upon the diagnosis and usual treatment therapies If criteria is not met, request will be sent to a clinical reviewer for medical necessity review.
PA Review Criteria	**Medications falling under the physician administered drug/ medical benefit will be reviewed by AAH. Forward requests to AAH for review** <u>Initial Authorization:</u> • Approve if: ○ Medication or product is administered by a healthcare professional AND ○ The medication will be provided via the Medical Benefit AND ○ Appropriate diagnosis/indication for requested medication or meets criteria below AND ▪ Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Diagnosis section above) OR ▪ Requested use can be supported by at least two published peer reviewed clinical studies which must be submitted along with request ○ Requested quantity does not exceed FDA approved or standard off-label dose - OR • Member is new to the plan (within the last 6 months) and the request is for continuation of therapy. Approve if: ○ Continuation of therapy is clinically appropriate AND ○ Medication or product is administered by a healthcare professional AND ○ Prescriber attests that member has been on this medication continuously before joining AAH AND ○ Request is for generic or single source brand AND ○ The diagnosis and dosage provided meets FDA labeling and/or drug-specific criteria or off-label criteria <u>Reauthorization:</u> • Continuation of therapy is clinically appropriate AND • Medication or product is administered by a healthcare professional under the Medical Benefit
Criteria Statement	N/A

Last P&T Review Date	~~9/2024~~ 9/2025

Recommendation: No changes

Off-label uses	
Therapeutic Classes (AHFS)	N/A
Medications	Formulary, Formulary PA required, Formulary, ST required, or Non-formulary medications with off-label uses
Covered Uses	Off-Label indications (medically accepted indications are defined using the following sources: American Hospital Formulary Service-Drug Information (AHFS-DI), Truven Health Analytics Micromedex DrugDEX (DrugDEX), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology and/or positive results from two peer-reviewed published studies.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval 12 months Later Approvals 12 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	Initial criteria for approval: - One of the following: - Patient has had a documented trial and or intolerance with up to two preferred medications used to treat the documented diagnosis, or for medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated. - No other formulary medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND - One of the following: - Medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources (as noted in Covered Uses section above) - Requested use can be supported by at least two published peer reviewed clinical studies which must be submitted along with request AND - Medication is being requested at an appropriate dose per literature Reauthorization criteria for approval: - Patient is stable and continuing the medication AND - Medication is used for appropriate indication and at appropriate dose
Criteria Statement	Medications for off-label use are reserved for members who have a medication being requested at an appropriate dose per the medical literature AND have used (or cannot should not use) up to two preferred medications to treat the diagnosis, or where there is no other formulary medication with a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia available AND the medication is being requested for an accepted off-label use and is listed in the standard clinical decision support resources or requested use can be supported by at least two published peer reviewed clinical studies.
Last P&T Review Date	9/20249/2025

Recommendation: No changes

Safety Edit Exception	
Therapeutic Classes (AHFS)	N/A
Medications	Formulary drugs and non-formulary drugs (non-formulary and formulary drug criteria must also be met): - Exceeding the Food and Drug Administration (FDA) or compendia max dose recommendations - Exceeding the FDA dosing or compendia administration frequency recommendations - Exceeding the FDA or compendia duration of therapy recommendations - Duplication of therapy error at Point of Service (POS) - Age Restriction error at POS - Day Supply Limit error at POS
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert.
Exclusion Criteria	See "PA Review Criteria"
Required Clinical Information	See "PA Review Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval One month approval for duplication of therapy when transitioning from one agent to another and day supply limit due to a dose increase . All other scenarios: 12 months Later Approvals 12 months If criteria is not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review.
PA Review Criteria	Exceeding the Food and Drug Administration (FDA) or compendia maximum dose, administration frequency or duration of therapy recommendations. - The member must have a documented treatment failure with the drug at the maximum tolerated dose or maximum dose (whichever is the lesser dose), administration frequency or duration of therapy. AND - The provider must submit a medical reason why the maximum dose, administration frequency or duration of therapy needs to be exceeded based on the member's condition or treatment history. Duplication of therapy <u>Transition from one agent to another</u> - If a provider has outlined a plan to transition a member to a similar drug or provided a dose titration schedule, the requested drug is approved for one month*. <u>Concurrent Therapy with two similar agents</u> - The provider must submit a medical reason why treatment with more than one drug in the same class is required based on the member's condition and treatment history. OR - The provider must submit disease state specific standard of care guidelines supporting concurrent therapy. Age Restriction

	- The provider must submit a medical reason why the drug is needed for a member whose age is outside of the plan's minimum or maximum age limit. AND - The indication and dose requested is supported by the Medical Compendia or current treatment guidelines. Day Supply Limit - An additional fill exceeding the day supply limit is needed based on a dose increase or is needed to achieve a total daily dose OR - The provider must submit a medical reason why an additional fill is needed outside of the plan's day supply limit. AND - The indication and dose requested is supported by the Medical Compendia or current treatment guidelines.
Criteria Statement	N/A
Last P&T Review Date	~~9/2024~~ 9/2025

Recommendation: No changes

Nuedexta (dextromethorphan/quinidine)	
Therapeutic Classes (AHFS)	Central nervous system agents, miscellaneous
Medications	Formulary, PA required Nuedexta (dextromethorphan/quinidine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a neurologist or psychiatrist
Coverage Duration	Initial Approval 6 months Later Approvals 12 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	All requests must be reviewed by a clinical pharmacist first and then forwarded to AAH for review Criteria for initial authorization: • For a diagnosis of Pseudobulbar Affect (PBA) approve • For all other diagnoses, use off label criteria Criteria for re-authorization: • Patient is stable and continuing the medication AND • Medication is used for appropriate indication and at appropriate dose
Criteria Statement	Nuedexta is reserved for members who have a diagnosis of pseudobulbar affect.
Last P&T Review Date	~~9/2024~~ 9/2025

Recommendation: No changes

Cartilaginous Repair Agents	
Therapeutic Classes (AHFS)	Anti-inflammatory/antiarthritic agents, misc; devices
Medications	<u>Formulary, PA required</u> Euflexxa (hyaluronate sodium) – preferred agent <u>Non-formulary (non-preferred agents)</u> Hyalgan (hyaluronate sodium) Durolane Genvisc 850 Trivisc Synvisc Synvisc-One Orthovisc Monovisc Gel-One Visco-3 Hymovis Triluron Gelsyn-3 Supartz FX Any other hyaluronic acid/cartilaginous repair agent product
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See “PA Review Criteria” below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval One complete course of treatment (based on the FDA labeled dose of the drug requested). Later approvals One complete course of treatment (based on the FDA labeled dose of the drug requested).
PA Review Criteria	All requests must be reviewed by a clinical pharmacist first and then forwarded to AAH for review Initial authorization: • Diagnosis of osteoarthritis (OA)/degenerative joint disease (DJD) of the knee • Documentation (by either attestation or claims data) the patient recently (over the past 4 months) has had adequate trials on simple analgesics (acetaminophen containing products) AND NSAIDs (including 2 different prescription strength NSAIDs) on a continuous basis for 3 months without success or has a medical reason (intolerance, hypersensitivity, contraindication, etc.) for not being able to utilize simple analgesic products and NSAIDs. • Documentation patient has recently (within past 12 months) tried at least ONE steroid injection without success, per affected knee or has a medical reason for not being able to utilize steroid injections. • Documentation of at least one course of physical therapy for knee osteoarthritis

	• Attestation confirming that the patient has no contraindications to the injections (active joint infection, bleeding disorder) • If the medication request is for hyaluronic acid derivative (HAD) product other than Euflexxa, the patient has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) for not taking Euflexxa to treat their medical condition. Re-authorization • Documentation was submitted that the patient had an objective response to the treated knee(s) (e.g. decreased joint pain or stiffness, improved knee range of motion, etc) that lasted for ≥ 6 months to previous HAD therapy. • Documentation was submitted that the member has a return of symptoms of osteoarthritis that has not responded to analgesics or NSAIDs, or has a medical reason (intolerance, hypersensitivity, contraindication, etc) for not being able to utilize these therapies. • If the medication request is for hyaluronic acid derivative (HAD) product other than Euflexxa, the patient has a documented medical reason (intolerance, hypersensitivity, contraindication, etc) for not taking Euflexxa to treat their medical condition.
Criteria Statement	For osteoarthritis (OA)/degenerative joint disease (DJD) of the knee, Euflexxa is reserved for members who have used (or cannot/should not use) acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs) and steroids, and have had physical therapy for knee osteoarthritis. For osteoarthritis (OA)/degenerative joint disease (DJD) of the knee, other hyaluronic acid derivative products are reserved for members who have used (or cannot/should not use) Euflexxa.
Last P&T Review Date	<u>9/2024</u> 9/2025

Recommendation: No changes

Memantine ER (Namenda XR)	
Therapeutic Classes (AHFS)	Central Nervous System Agents, Misc
Medications	Formulary, step therapy required memantine ER (Namenda XR)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See " PA Review Criteria " below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial/Re-Approval If all conditions are met, the request will be approved for up to 12 months. If all criteria are not met, the request is referred to Clinical Reviewer for medical necessity review.
PA Review Criteria	Criteria for approval - Documented trial and failure, intolerance, or contraindication to use donepezil AND memantine IR - OR - Documentation member unable to adhere to twice daily dosing due to caregiver limitations
Criteria Statement	Memantine ER is reserved for members who have used (or cannot/should not use) donepezil AND memantine IR or for members unable to comply with twice daily dosing due to caregiver limitations.
Last P&T Review Date	9/20249/2025

Recommendation: No changes

Vancomycin	
Therapeutic Classes (AHFS)	Antibacterials, miscellaneous
Medications	<u>Formulary, with quantity limit</u> Vancomycin 125, 250 mg capsules Firvanq 25, 50 mg/ml solution <u>Non-Formulary</u> Vancomycin 250mg/5ml (50mg/ml) oral solution
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial/Re-Approval Durations exceeding 10 days are approvable if vancomycin was used for initial episode of Clostridium (or Clostridioides) difficile infection (CDI) and now pulsed-tapered regimen required. If all criteria are not met, the request is referred to Clinical Reviewer for medical necessity review.
PA Review Criteria	Requests for formulary agents above the quantity limit will be approved if: - Dosing requested is appropriate based on dosing guidelines AND - Treatment with vancomycin capsules or Firvanq is being requested for treatment of a first recurrence when vancomycin capsules or Firvanq was used for initial treatment and pulsed-tapered regimen is required OR - Treatment with vancomycin capsules or Firvanq is being requested for treatment of a second or subsequent recurrence and pulsed-tapered regimen is required Requests for vancomycin 250mg/5ml (50mg/ml) oral solution will be approved if: - Dose is appropriate per label or supported by compendia/standard of care guidelines for initial treatment OR first, second, or subsequent recurrence and pulsed-tapered regimen is required AND - The patient has tried and failed both formulary dosage forms, and/or has another documented medical reason (intolerance, hypersensitivity, contraindication, etc.) for not utilizing these medications to treat their medical condition.
Criteria Statement	Vancomycin capsules or Firvanq above the quantity limits are reserved for members with a first recurrence of Clostridium (or Clostridioides) difficile infection (CDI) after initial treatment with vancomycin capsules or Firvanq or members with a second recurrence in which pulsed-tapered regimen is required. Vancomycin 250mg/5ml (50mg/ml) oral solution is reserved for members who have used (or cannot/should not use) formulary vancomycin capsules and Firvanq.
Last P&T Review Date	9/20249/2025

Recommendation: No changes

Multaq (dronedarone)	
Therapeutic Classes (AHFS)	Antiarrhythmic agents
Medications	Formulary, PA required Multaq (dronedarone)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See " PA Review Criteria " below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	N/A
Coverage Duration	Initial/Re-Approval If all conditions are met, the request will be approved for up to 12 months. If all criteria are not met, the request is referred to Clinical Reviewer for medical necessity review.
PA Review Criteria	<u>CRITERIA FOR APPROVAL</u> • Diagnosis of paroxysmal or persistent atrial fibrillation (AF) or atrial flutter. • Attestation that the patient does not have NYHA (New York Heart Association) Class III or IV heart failure or symptomatic heart failure with recent decompensation in the last 4 weeks requiring hospitalization. • Attestation that the patient does not have permanent atrial fibrillation (AF) that will not or cannot be cardioverted or restored to normal sinus rhythm.
Criteria Statement	Multaq is reserved for members who have paroxysmal or persistent atrial fibrillation or atrial flutter without NYHA (New York Heart Association) class III or IV heart failure or symptomatic heart failure with recent decompensation in the last 4 weeks requiring hospitalization. Members must also not have permanent atrial fibrillation that cannot be cardioverted to normal sinus rhythm.
Last P&T Review Date	9/20249/2025

Recommendation: No changes

Erythropoiesis-Stimulating Agents	
Therapeutic Classes (AHFS)	Erythropoiesis-Stimulating Agents
Medications	<u>Formulary, PA required</u> Retacrit (epoetin alfa-epbx) - PREFERRED Aranesp (darbepoetin alfa) Procrit (epoetin alfa) Epogen (epoetin alfa) <u>Non-formulary</u> Mircera (methoxy polyethylene glycol-epoetin beta)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval If criteria are met, the request will be approved as follows: 1 month if the patient is deficient in iron, vitamin B12 or folate, and in the perisurgical setting 3 months for all other requests. If the provider attests that the preferred medication is for a chronic or long-term condition, reauthorization will be approved for 12 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	<u>Criteria for authorization of existing epoetin users who are NEW to the plan:</u> • Documentation of current dose • Documentation of hemoglobin level results within 30 days or member has responded to therapy (≥ 1-2 g/dL increase in hemoglobin (Hgb) or decrease in transfusion requirements) <u>Requests for Initial Therapy:</u> • All lab results submitted must have been drawn within 30 days of request: • The following lab values – hemoglobin (Hgb) and hematocrit (HCT) • Normal lab results or, if abnormally low, appropriate supplementation as follows: ○ serum ferritin level (normal is > 100 ng/mL) ○ transferrin saturation (TSAT) (normal is > 20%) ○ vitamin B12 level(> 223 pg/mL) ○ folate level (> 3.1 ng/mL) • For requests for non-preferred ESAs, documentation must be provided as to why preferred are not medically appropriate for the member. • For anemia of CKD: ○ Hgb < 10 g/dL • For anemia related to cancer: ○ Receiving myelosuppressive therapy for palliative treatment (members receiving myelosuppressive therapy with <u>curative intent</u> should <u>not</u> receive ESAs) AND documented <u>symptomatic</u> anemia with Hgb <10 g/dL

Erythropoiesis-Stimulating Agents	
	OR ○ The member has symptomatic anemia related to myelodysplastic syndrome AND documented serum erythropoietin level ≤ 500 mU/mL • For zidovudine-related anemia in members with HIV: ○ The member must currently be receiving zidovudine-containing highly active antiretroviral therapy (HAART) (zidovudine ≤ 4200 mg/week) ○ Erythropoietin level ≤ 500 mU/mL • For ribavirin-induced anemia: ○ Documented attempt to reduce dose was made ○ HgB < 12 g/dL • For members undergoing surgery to reduce the need for allogenic blood transfusion: ○ Perioperative hemoglobin must be < 13 g/dL and > 10 g/dL. ○ The member is scheduled for an elective, non-cardiac, nonvascular surgery. Reauthorization: • Repeat normal labs within 30 days from date of request, or appropriate supplementation as follows: ○ serum ferritin level (> 100 ng/mL) ○ TSAT ($> 20\%$) ○ vitamin B12 level (> 223 pg/mL) ○ folate level (> 3.1 ng/mL) • For anemia of CKD: HgB ≤ 11 g/dL • For anemia related to cancer: HgB ≤ 12 g/dL • For zidovudine-related anemia in members with HIV: HgB ≤ 12 g/dL • For ribavirin-induced anemia: HgB ≤ 12 g/dL • An increase in dose has not occurred more than once every 4 weeks • If the request is a non-preferred agent, documentation must be provided as to why preferred medications are not medically appropriate for the member
Criteria Statement	Mircera, Procrit, Epogen, or Aranesp are reserved for members who have used (or cannot/should not use) Retacrit.
Last P&T Review Date	<u>9/2024</u> 9/2025

Recommendation: No changes

Drugs for Gender Dysphoria For Less Than 21 Years Old	
Therapeutic Classes (AHFS)	Androgens; Antineoplastic Agents; Estrogens; Gonadotropins; Mineralocorticoid (Aldosterone) Antagonists; 5-Alpha-Reductase Inhibitors; Progestins
Medications	Anti-androgens and progestins (Adjunct) <u>Formulary</u> • Spironolactone (Aldactone) 25, 50, 100mg tablet • Finasteride (Proscar) 5mg tablet • Dutasteride (Avodart) 0.5mg capsule • Progesterone (Prometrium) 100, 200mg capsule • Medroxyprogesterone 2.5, 5mg tablet • Medroxyprogesterone acetate intramuscular (Depo-Provera) 150mg/mL <u>Non-formulary:</u> • Depo-Provera 400mg/mL injectable suspension • Progesterone 50mg/mL oil solution
	Estrogen Agents for Male-to-Female (MTF) <u>Formulary</u> • Estradiol (Estrace) 0.5, 1, 2mg tablet • Premarin 0.3, 0.45, 0.625, 0.9, 1.25mg tablet • Estradiol-<i>once-weekly</i> 0.025, 0.0375, 0.05, 0.06, 0.075, 0.1mg patch: QL of #12 per 84 days • Estradiol-<i>twice-weekly</i> 0.025, 0.05, 0.075, 0.1mg patch: QL of #24 per 84 days • Estradiol valerate 20mg/mL, 40mg/mL vial: 1 vial per 30 days <u>Non-formulary</u> • Depo-Estradiol (estradiol cypionate) 5mg/mL
	Testosterone Agents for Female-to-Male (FTM) <u>Formulary (first-line)</u> • Testosterone cypionate 100mg/mL (QL #10 ml/30 days), 200mg/mL intramuscular oil (QL #5 ml/30 days) • Testosterone (Vogelxo) 1% gel pump (QL #300gm/30 days) • Testosterone (Androgel) 1.62% gel pump (QL #300gm/30 days) <u>Formulary, PA required (second-line)</u> • Testosterone (Androgel) 1% 50 mg packets • Testosterone (Androgel) 1% 25 mg packets • Testosterone (Testim) 1% gel tube • Testosterone (Axiron) 30mg/1.5ml solution pump • Testosterone enanthate 200mg/mL intramuscular oil (QL #5 ml/30 days)
	<u>Non-formulary</u> • Testosterone (Fortesta) 2% gel pump • Testosterone (Androgel) 1.62% gel packets • Androderm (testosterone transdermal patch) 2mg/24 hours, 4mg/24 hours • Aveed 750mg/3mL vial • Testopel pellet implant • Testosterone implant pellet • Methyltestosterone (Testred) oral capsules • Methitest (methyltestosterone) oral tablets • Testone CIK (testosterone cypionate) intramuscular injection kit • Natesto (testosterone) nasal gel pump

Drugs for Gender Dysphoria For Less Than 21 Years Old	
	• Xyosted (testosterone enanthate) subcutaneous auto-injector • Jatenzo (testosterone undecanoate) oral capsules Gonadotropin-Releasing Hormone Receptor Agonists (GnRHa) <u>Formulary, PA required</u> • Lupron Depot-Ped 1-Month (leuprolide) 7.5, 11.25, 15, 30 mg syringe kit (for less than 18 years) • Lupron Depot (leuprolide) 3.75, 7.5, 11.25, 22.5, 30, 45mg syringe kit • Leuprolide acetate 1mg/0.2mL solution kit <u>Non-formulary</u> • Trelstar (triptorelin) 3.75, 11.25, 22.5 mg Mixject suspension • Eligard (leuprolide acetate) 7.5, 22.5, 30, 45mg subQ • Zoladex (goserelin acetate) 3.6, 10.8mg subQ implant • Supprelin LA (histrelin) 50mg subQ implant kit • Triptodur 6-month (triptorelin) 22.5mg • Fensolvi (leuprolide acetate) syringe kit Any other newly marketed agent to treat gender dysphoria *Requests for greater than indicated quantity or age limits will be reviewed on a case by case basis
Covered Uses	Medically accepted indications are defined using the following disease specific guidelines: Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline; World Professional Association for Transgender Health (WPATH) Standards of care for the health of transgender and gender diverse people; American College of Obstetrician and Gynecologists (ACOG): Committee opinion on health care for transgender and gender diverse individuals: the TransActive Education and Advocacy Group; the World Health Organization (WHO)
Exclusion Criteria	Contraindications to any of the medications listed above
Required Clinical Information	See “PA Review Criteria” below
Age Restrictions	See “PA Review Criteria” below
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval 12 months Later Approvals 24 months Exception Approval 3 months if requested labs are outside of recommended range or not provided; further approval requires requested labs and/or action plan submitted
PA Review Criteria	**Cosmetic medications used to treat gender dysphoria, mental health, or substance use disorder ARE approved as appropriately indicated (e.g. FDA approval, compendia supported, etc.).** All requests must be reviewed by a clinical pharmacist first and then forwarded to AAH for review INITIAL CRITERIA to start treatment for non-preferred drugs and preferred drugs that require PA, the following must be met: • Clinic notes or consult detailing the diagnosis of gender dysphoria / gender identity disorder (GID) per DSM-V diagnostic criteria made by a qualified mental health professional • Documentation of patient readiness to start GnRHa and/or cross-sex hormone therapy • Must meet the class specific criteria outlined below

Drugs for Gender Dysphoria For Less Than 21 Years Old

- Dosage prescribed based on recommendations from medical compendia and/or the Food And Drug Administration (FDA) as appropriate
- For formulary agents with prior authorization, approve for 12 months if meet ALL of the initial criteria to start treatment; for non-formulary agents, must have documentation showing trial and failure, contraindication, intolerance and/or side effects to formulary agents, as outlined in the individual sections below

Estrogen Agents (for Male-to-Female):

INITIAL CRITERIA to start treatment:

- Documentation member is at least 16 years of age AND at least in Tanner stage 2
- Documentation member does NOT have: history of DVT/PE, thromboembolic disease, stroke and/or MI within the last 12 months; known or suspected breast cancer
- If requesting estradiol cypionate injection, documentation trial and failure, contraindication, intolerance and/or side effects to one formulary oral estrogen agent and estradiol valerate injection
- If requesting transdermal estrogen patch, documentation of trial and failure, contraindication, intolerance and/or side effects to formulary oral **and** injectable estrogen agents
- If any labs are out of recommended range or not provided, follow Exception Approval process (see "Coverage Duration")

RENEWAL CRITERIA:

- Documentation of estradiol levels (less than 200 pg/ml) and testosterone levels (less than 55 ng/dL)
- Documentation member does NOT have: history of DVT/PE, thromboembolic disease, stroke and/or MI within the last 12 months; known or suspected breast cancer
- If any labs are out of recommended range or not provided, follow Exception Approval process (see "Coverage Duration" for approval limit)

Testosterone Agents (for Female-to-Male):

INITIAL CRITERIA to start treatment:

- Documentation member is at least 16 years of age **and** at least in Tanner stage 2
- No evidence of known or suspected breast cancer and/or pregnancy
- If requesting formulary-prior authorization required testosterone agents, documentation trial and failure, contraindication, intolerance and/or side effects to one first-line formulary injectable testosterone agent AND one first-line formulary topical testosterone agent
- If requesting non-formulary testosterone agents, documentation trial and failure, contraindication, intolerance and/or side effects to one first-line formulary injectable testosterone agent AND one first-line formulary topical testosterone agent AND at least one formulary PA-required, (second-line) testosterone agent
- If any labs are out of recommended range or not provided, follow Exception Approval process (see "Coverage Duration")

RENEWAL CRITERIA:

- Documentation of hematocrit less than 50%
- Documentation of testosterone levels; discontinue or reduce dose if greater than 1000 ng/dL
- No evidence of known or suspected breast cancer and/or pregnancy

Drugs for Gender Dysphoria For Less Than 21 Years Old

- If any labs are out of recommended range or not provided, follow Exception Approval process (see “Coverage Duration”)

Antiandrogens and Progesterone Agents (Adjunct):

INITIAL CRITERIA for non-formulary agents:

- Documentation member is at least 18 years of age
- Require documentation of trial and failure, intolerance, contraindication, or inability to use spironolactone, dutasteride, finasteride, medroxyprogesterone acetate tablet and medroxyprogesterone acetate IM.
- Documentation member does NOT have known or suspected pregnancy
- For medroxyprogesterone: documentation member does NOT have history of DVT/PE, thromboembolic disease, stroke and/or MI within the last 12 months and/or severe liver disease
- If any labs are out of recommended range or not provided, follow Exception Approval process (see “Coverage Duration”)

RENEWAL CRITERIA for non-formulary agents:

- No evidence that member is currently pregnant
- For medroxyprogesterone: documentation member does NOT have history of DVT/PE, thromboembolic disease, stroke and/or MI within the last 12 months and/or severe liver disease
- If any labs are out of recommended range or not provided, follow Exception Approval process (see “Coverage Duration”)

GnRHa:

INITIAL CRITERIA to start treatment:

- Documentation of baseline labs for LH, FSH, estradiol and testosterone levels at pubertal levels AND at least in Tanner stage 2
- Documentation of weight
- Members less than 18 years old: Lupron Depot-Ped 1-Month and leuprolide acetate solution are preferred agents
- Members greater than or equal to 18 years old: Lupron Depot (1-, 3-, 4-, and 6)-Month and leuprolide acetate solution are preferred agents
- If any labs are out of recommended range or not provided, follow Exception Approval process (see “Coverage Duration”)

RENEWAL CRITERIA:

- Members less than 16 years of age: Documentation of bone age on x-ray of left hand AND bone density on x-ray absorptiometry
- Documentation there is a continual need to delay puberty until at least 21 years of age (i.e. extreme short stature)

For requests over the quantity limit:

- The member must have a documented treatment failure with the drug prescribed at the health plan’s quantity limit **OR** the member requires a dose within prescribing guidelines that exceeds the plan’s quantity limit **AND**
- The provider has submitted a medical reason why the plan’s quantity limit will be inadequate based on the member’s condition and treatment history **AND**
- The dose requested is supported by the Medical Compendia or current treatment guidelines.

Continuation of therapy for NEW members from another health plan:

- If criteria are met for initial authorization, coverage duration is 12 months
- If criteria are not met for initial authorization and/or requested labs are outside of recommended range **or** not provided, allow one-time coverage duration of 3 months until all of requested labs and clinic notes are received

Drugs for Gender Dysphoria For Less Than 21 Years Old	
Criteria Statement	Estradiol cypionate injection: For use in gender dysphoria, estradiol cypionate injection is reserved for members who have previously used (or cannot/should not take) formulary oral estradiol or Premarin tablet <u>and</u> estradiol valerate injection Estrogen patch: For use in gender dysphoria, estradiol patches are reserved for members who have previously used (or cannot/should not take) oral estradiol or Premarin tablet <u>and</u> estradiol injection or members who have had a history of cardiovascular events. Testosterone 1% packet or tube, testosterone 30mg/1.5ml solution pump or testosterone enanthate 200mg/mL intramuscular oil For use in gender dysphoria, [Formulary, PA required (second-line) medications] <INSERT: testosterone packets/tube/solution pump or testosterone enanthate 200mg/mL intramuscular oil> are reserved for members who have previously used (or cannot/should not take) testosterone cypionate injection AND testosterone 1% gel pump or testosterone (Androgel) 1.62% gel pump. For use in gender dysphoria, non-formulary testosterone products are reserved for members who have used (or cannot/should not use) testosterone cypionate AND testosterone (Vogelxo) 1% gel pump or testosterone (Androgel) 1.62% gel pump AND testosterone 1% gel packets, tube, or testosterone 30mg/1.5ml solution pump or testosterone enanthate 200mg/mL intramuscular oil. Quantity Limits: Requests for quantities over the quantity or fill limit are reserved for members who have a documented medical need for quantities in excess of the limits. Exception approval: The criteria for approval has not been met. The Alliance cannot cover xxDRUGxx as requested because insufficient information was received from your doctor to approve this medication as requested. The Alliance uses the Gender Dysphoria Drug Coverage Guidelines to determine what information is needed. Specifically, information required that has not yet been received includes: [1] Clinic notes that describe the diagnosis and treatment plan; and [2] Lab results showing [enter required labs]. We recommend that you talk with your provider about the needed information before we can approve for the full duration as requested. We will instead approve a 3-month supply of xxDRUGxx from [enter dates of approval].
Last P&T Review Date	9/20249/2025

Recommendation: No changes

Drugs for Gender Dysphoria For At Least 21 Years Old	
Therapeutic Classes (AHFS)	Androgens; Antineoplastic Agents; Estrogens; Gonadotropins; Mineralocorticoid (Aldosterone) Antagonists; 5-Alpha-Reductase Inhibitors; Progestins
Medications	Anti-androgens and progestins (Adjunct) <u>Formulary</u> • Spironolactone (Aldactone) 25, 50, 100mg tablet • Finasteride (Proscar) 5mg tablet • Dutasteride (Avodart) 0.5mg capsule • Progesterone (Prometrium) 100, 200mg capsule • Medroxyprogesterone 2.5, 5, 10mg tablet • Medroxyprogesterone acetate intramuscular (Depo-Provera) 150mg/mL <u>Non-formulary:</u> • Depo-Provera 400mg/mL injectable suspension • Progesterone 50mg/mL oil solution
	Estrogen Agents for Male-to-Female (MTF) <u>Formulary:</u> • Estradiol (Estrace) 0.5, 1, 2mg tablet • Premarin 0.3, 0.45, 0.625, 0.9, 1.25mg tablet • Estradiol-once-weekly 0.025, 0.0375, 0.05, 0.06, 0.075, 0.1mg patch: QL of #12 per 84 days • Estradiol-twice-weekly 0.025, 0.05, 0.075, 0.1mg patch: QL of #24 per 84 days • Estradiol valerate 20mg/mL, 40mg/mL vial: 1 vial per 30 days <u>Non-formulary</u> • Depo-Estradiol (Estradiol cypionate) 5mg/mL
	Testosterone Agents for Female-to-Male (FTM) <u>Formulary (first-line)</u> • Testosterone cypionate 100mg/mL (QL #10 ml/30 days), 200mg/mL intramuscular oil (QL #5 ml/30 days) • Testosterone (Vogelxo) 1% gel pump (QL #300gm/30 days) • Testosterone (Androgel) 1.62% gel pump (QL #150gm/30 days) <u>Formulary, PA required (second-line)</u> • Testosterone (Androgel) 1% 50 mg packets • Testosterone (Androgel) 1% 25 mg packets • Testosterone (Testim) 1% gel tube • Testosterone (Axiron) 30mg/1.5ml solution pump • Testosterone enanthate 200mg/mL intramuscular oil (quantity limit #5 ml/30 days)
	<u>Non-formulary</u> • Testosterone (Fortesta) 2% gel pump • Testosterone (Androgel) 1.62% gel packets • Androderm (testosterone transdermal patch) 2mg/24 hours, 4mg/24 hours • Aveed 750mg/3mL vial • Testopel pellet implant • Testosterone implant pellet • Methyltestosterone (Testred) oral capsules • Methitest (methyltestosterone) oral tablets • Testone CIK (testosterone cypionate) intramuscular injection kit

Drugs for Gender Dysphoria For At Least 21 Years Old	
	- Natesto (testosterone) nasal gel pump - Xyosted (testosterone enanthate) subcutaneous auto-injector - Jatenzo (testosterone undecanoate) oral capsules Gonadotropin-Releasing Hormone Receptor Agonists (GnRHa) <u>Formulary, PA required</u> - Lupron Depot-Ped 1-Month (leuprolide) 7.5, 11.25, 15, 30 mg syringe kit (for less than 18 years) - Lupron Depot (leuprolide) 3.75, 7.5, 11.25, 22.5, 30, 45mg syringe kit - Leuprolide acetate 1mg/0.2mL solution kit <u>Non-formulary</u> - Trelstar (triptorelin) 3.75, 11.25, 22.5 mg Mixject suspension - Eligard (leuprolide acetate) 7.5, 22.5, 30, 45mg subQ - Zoladex (goserelin acetate) 3.6, 10.8mg subQ implant - Supprelin LA (histrelin) 50mg subQ implant kit - Triptodur 6-month (triptorelin) 22.5mg - Fensolvi (leuprolide acetate) syringe kit Any other newly marketed agent to treat gender dysphoria *Requests for greater than indicated quantity or age limits will be reviewed on a case by case basis
Covered Uses	Medically accepted indications are defined using the following disease specific guidelines: Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline; World Professional Association for Transgender Health (WPATH): Standards of care for the health of transgender and gender diverse people); American College of Obstetrician and Gynecologists (ACOG): Committee opinion on health care for transgender and gender diverse individuals; the TransActive Education and Advocacy Group; the World Health Organization (WHO)
Exclusion Criteria	Contraindications to any of the medications listed above
Required Clinical Information	See “PA Review Criteria” below
Age Restrictions	See “PA Review Criteria” below
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval 12 months Later Approvals 24 months Exception Approval 3 months if requested labs are outside of recommended range or not provided; further approval requires requested labs and/or physician attestation they have educated the member and explained the risks
PA Review Criteria	**Cosmetic medications used to treat gender dysphoria, mental health, or substance use disorder ARE approved as appropriately indicated (e.g. FDA approval, compendia supported, etc.).** All requests must be reviewed by a clinical pharmacist first and then forwarded to AAH for review INITIAL CRITERIA to start treatment for non-preferred drugs and preferred drugs that require PA, the following must be met: - Clinic notes or consult detailing the diagnosis of gender dysphoria / gender identity disorder (GID) per DSM-V diagnostic criteria made by a qualified mental health professional - Documentation of patient readiness to start GnRHa and/or cross-sex hormone therapy

Drugs for Gender Dysphoria For At Least 21 Years Old

- Must also meet the class specific criteria outlined below
- Dosage prescribed based on recommendations from medical compendia and/or the Food And Drug Administration (FDA) as appropriate
- For formulary agents with prior authorization, approve for 12 months if meet ALL of the initial criteria to start treatment; for non-formulary agents, must have documentation showing trial and failure, contraindication, intolerance and/or side effects to formulary agents, as outlined in the individual sections below

Estrogen Agents (for Male-to-Female):

INITIAL CRITERIA to start treatment:

- Documentation member does NOT have: history of DVT/PE, thromboembolic disease, stroke and/or MI within the last 12 months; known or suspected breast cancer
- If requesting estradiol cypionate injection, documentation trial and failure, contraindication, intolerance and/or side effects to one formulary oral estrogen agent [or estradiol patches] and estradiol valerate injection
- If requesting transdermal estrogen patch, documentation trial and failure, contraindication, intolerance and/or side effects to formulary oral **and** injectable estrogen agents
- If any labs are out of recommended range or not provided, follow Exception Approval process (see "Coverage Duration")

RENEWAL CRITERIA:

- Documentation of estradiol levels (less than 200 pg/ml) and testosterone levels (less than 55 ng/dL)
- Documentation member does NOT have: history of DVT/PE, thromboembolic disease, stroke and/or MI within the last 12 months; known or suspected breast cancer
- If any labs are out of recommended range or not provided, follow Exception Approval process (see "Coverage Duration")

Testosterone Agents (for Female-to-Male):

INITIAL CRITERIA to start treatment:

- No evidence of known or suspected breast cancer and/or pregnancy
- If requesting formulary-prior authorization required testosterone agents, documentation trial and failure, contraindication, intolerance and/or side effects to one first-line formulary injectable testosterone agent AND one first-line formulary topical testosterone agent
- If requesting non-formulary testosterone agents, documentation trial and failure, contraindication, intolerance and/or side effects to one first-line formulary injectable testosterone agent AND one first-line formulary topical testosterone agent AND at least one formulary PA-required, (second-line) testosterone agent
- If any labs are out of recommended range or not provided, follow Exception Approval process (see "Coverage Duration")

RENEWAL CRITERIA:

- Documentation of hematocrit less than 50%
- Documentation of testosterone levels; discontinue or reduce dose if greater than 1000 ng/dL
- No evidence of known or suspected breast cancer and/or pregnancy

Antiandrogens and Progesterone Agents (Adjunct use):

INITIAL CRITERIA for non-formulary agents:

Drugs for Gender Dysphoria For At Least 21 Years Old	
	- Require documentation of trial and failure, intolerance, contraindication, or inability to use spironolactone, dutasteride, finasteride, medroxyprogesterone acetate tablet <u>and</u> medroxyprogesterone acetate IM - No evidence of known or suspected pregnancy - For medroxyprogesterone: documentation member does NOT have history of DVT/PE, thromboembolic disease, stroke and/or MI within the last 12 months and/or severe liver disease - If any labs are out of recommended range or not provided, follow Exception Approval process (see "Coverage Duration") RENEWAL CRITERIA for non-formulary agents: - Documentation member does NOT have known or suspected pregnancy - For medroxyprogesterone: documentation member does NOT have history of DVT/PE, thromboembolic disease, stroke and/or MI within the last 12 months and/or severe liver disease - If any labs are out of recommended range or not provided, follow Exception Approval process (see "Coverage Duration") <u>GnRHa (Adjunct use):</u> INITIAL CRITERIA to start treatment: - Require documentation of trial and failure, intolerance, contraindication, or inability to use spironolactone, dutasteride, finasteride, medroxyprogesterone acetate tablet <u>and</u> medroxyprogesterone acetate IM - Documentation of baseline labs for LH, FSH, estradiol and testosterone levels - Documentation member is on CONCOMITANT hormone replacement therapy (as verified by claims history) - No evidence of known or suspected pregnancy (if Female-to-Male transition) - If any labs are out of recommended range or not provided, follow Exception Approval process (see "Coverage Duration") RENEWAL CRITERIA: - Documentation of estradiol and testosterone levels - If any labs are out of recommended range or not provided, follow Exception Approval process (see "Coverage Duration") <u>For requests over the quantity limit:</u> - The member must have a documented treatment failure with the drug prescribed at the health plan's quantity limit OR the member requires a dose within prescribing guidelines that exceeds the plan's quantity limit AND - The provider has submitted a medical reason why the plan's quantity limit will be inadequate based on the member's condition and treatment history AND - The dose requested is supported by the Medical Compendia or current treatment guidelines. <u>Continuation of therapy for NEW members from another health plan:</u> - If criteria are met for initial authorization, coverage duration is 12 months - If criteria are not met for initial authorization and/or requested labs are outside of recommended range <u>or</u> not provided, allow one-time coverage duration of 3 months until all of requested labs and clinic notes are received
Criteria Statement	Estradiol cypionate injection: For use in gender dysphoria, estradiol cypionate injection is reserved for members who have previously used (or cannot/should not take) formulary oral estradiol or Premarin tablets or estradiol patches <u>and</u> estradiol valerate injection. Estrogen patch:

Drugs for Gender Dysphoria For At Least 21 Years Old	
	For use in gender dysphoria, estradiol patch is reserved for members who have previously used (or cannot/should not take) oral estradiol or Premarin tablets <u>and</u> estradiol valerate injection or have a history of cardiovascular disease. Testosterone 1% packet or tube, testosterone 30mg/1.5ml solution pump or testosterone enanthate 200mg/mL intramuscular oil For use in gender dysphoria, [Formulary, PA required (second-line) medications] <INSERT: testosterone packets/tube/solution pump or testosterone enanthate 200mg/mL intramuscular oil> are reserved for members who have previously used (or cannot/should not take) testosterone cypionate injection AND testosterone 1% gel pump or testosterone (Androgel) 1.62% gel pump. For use in gender dysphoria, non-formulary testosterone products are reserved for members who have used (or cannot/should not use) testosterone cypionate AND testosterone (Vogelxo) 1% gel pump or testosterone (Androgel) 1.62% gel pump AND testosterone 1% gel packets, tube, or testosterone 30mg/1.5ml solution pump or testosterone enanthate 200mg/mL intramuscular oil. Quantity Limits: Requests for quantities over the quantity or fill limit are reserved for members who have a documented medical need for quantities in excess of the limits. <u>Any GnRHa:</u> For use in gender dysphoria, GnRHa products are reserved for members with ALL of the following: 1) have previously used (or cannot/should not take) ALL of the following: spironolactone, dutasteride, finasteride, medroxyprogesterone; AND 2) records showing you are currently using hormone therapy. <u>Exception approval:</u> The criteria for approval has not been met. The Alliance cannot cover xxDRUGxx as requested because insufficient information was received from your doctor to approve this medication as requested. The Alliance uses the Gender Dysphoria Drug Coverage Guidelines to determine what information is needed. Specifically, information required that has not yet been received includes: [1] Clinic notes that describe the diagnosis and treatment plan; and [2] Lab results showing [enter required labs]. We recommend that you talk with your provider about the needed information before we can approve for the full duration as requested. We will instead approve a 3-month supply of xxDRUGxx from [enter dates of approval].
Last P&T Review Date	9/2024/9/2025

Recommendation: No changes

Corticosteroids for Ulcerative Colitis and Crohn's disease	
Therapeutic Classes (AHFS)	Corticosteroids, Adrenals
Medications	<u>Formulary</u> budesonide (Entocort EC) capsule (QL 540/365) Hydrocortisone (Cortenema) rectal enema <u>Formulary, Prior Authorization Required</u> budesonide (Uceris) tablet Cortifoam (hydrocortisone acetate) foam Budesonide (Uceris) 2mg foam Ortikos (budesonide) capsule Any other corticosteroid for ulcerative colitis or Crohn's disease
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	N/A
Coverage Duration	Initial/Re-Approval Budesonide (Uceris) foam, Cortifoam, Ortikos capsule or Budesonide tablet (Uceris) If the criteria are met, the request will be approved for up to a 2 month duration Approval to Exceed 3 months QL: If criteria are not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review.
PA Review Criteria	<u>Criteria for Authorization</u> Budesonide (Uceris) tablet is approved when all of the following criteria are met: • Documentation of a diagnosis of mild to moderate ulcerative colitis and failed remission • Documentation of trial and failure, contraindication, intolerance, or inability to use maximum tolerated and therapeutic dose of oral aminosalicylates (i.e. sulfasalazine or balsalazide) for 8 weeks AND rectal mesalamine for up to 6 weeks Budesonide (Uceris) foam and Cortifoam are approved when all of the following criteria are met: • Documentation of a diagnosis of ulcerative colitis. • Documentation of a trial and failure, intolerance, contraindication, or inability to formulary rectal mesalamine and formulary rectal corticosteroids. <u>Ortikos is approved when all of the following criteria are met:</u> • <u>Documentation of a diagnosis of mild to moderate Crohn's disease involving the ileum and/or the ascending colon</u> • <u>Documentation of trial and failure, contraindication, intolerance, or inability to use budesonide (Entocort EC) capsule</u> <u>Requests for exceeding quantity limit of 540 capsules per 365 days for budesonide (Entocort EC) capsule</u>

	• The member must have a documented treatment failure with the drug prescribed at the health plan's quantity limit OR the member requires a dose within prescribing guidelines that exceeds the plan's quantity limit. AND • The provider has submitted a medical reason why the plan's quantity limit will be inadequate based on the member's condition and treatment history. AND • The dose requested is supported by the Medical Compendia or current treatment guidelines.
Criteria Statement	Budesonide (Uceris) tablet is reserved for members who have mild to moderate ulcerative colitis and have used (or cannot/should not use) the maximum tolerated and therapeutic dose of oral aminosalicylates (sulfasalazine or balsalazide) for 8 weeks AND rectal mesalamine for up to 6 weeks Budesonide (Uceris) foam or Cortifoam are reserved for members who have ulcerative colitis and have used (or cannot/should not use) formulary rectal mesalamine and formulary rectal corticosteroids. Ortikos is reserved for members who have mild to moderate Crohn's disease involving the ileum and have used (or cannot/should not use) budesonide (Entocort EC) capsule. Requests for budesonide (Entocort EC) capsule above the quantity limit are reserved for members who have used (or cannot/should not use) this medication in doses under the quantity limit and whose prescriber has a reason why the quantity limit is inadequate.
Last P&T Review Date	<u>9/2024</u> 9/2025

Recommendation: No changes

Atovaquone-proguanil (Malarone)	
Therapeutic Classes (AHFS)	Antimalarials
Medications	Formulary, PA required: Atovaquone-proguanil (Malarone) 62.5-25 mg tablet Atovaquone-proguanil (Malarone) 250-100 mg tablet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage duration	<u>For prophylaxis:</u> If all of the conditions are met, the request will be approved for up to 3 months. If all of the criteria are not met, the request is referred to a clinical reviewer for medical necessity review. <u>For treatment:</u> If all of the conditions are met, the request will be approved for one time fill. If all of the criteria are not met, the request is referred to a clinical reviewer for medical necessity review.
PA Review Criteria	<u>CRITERIA FOR THE USE OF ATOVAQUONE/PROGUANIL FOR MALARIA PROPHYLAXIS</u> • The medication is being prescribed at a dose that is within FDA approved guidelines. • Member is traveling to a country with mefloquine resistant malaria (see CDC website at http://www.cdc.gov/malaria/travelers/country_table/a.html) OR • Member is traveling to a country with known malaria risk and due to time constraints is unable to start prophylaxis with preferred agents 1-2 weeks prior to departure OR • Member has underlying neuropsychiatric conditions (as shown through clinical notes and/or claims history) such as: active and/or recent history of depression, chronic anxiety disorders, psychosis, and/or schizophrenia. <u>CRITERIA FOR THE USE OF ATOVAQUONE/PROGUANIL FOR MALARIA TREATMENT</u> • Diagnosis of malaria
Criteria Statement	For prophylaxis, atovaquone-proguanil is reserved for members traveling to a country with mefloquine resistance, member is unable to start therapy 1 to 2 weeks prior to travel departure, or member has condition such as depression, anxiety, psychosis, or schizophrenia.
Last P&T Review Date	~~9/2024~~ 9/2025

Recommendation: No changes

Intranasal Steroids	
Therapeutic Classes (AHFS)	Corticosteroids, nasal
Medications	Formulary, step therapy required Flunisolide 0.025% spray Mometasone 50 mcg actuation nasal suspension spray (quantity limit)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval 12 months Later Approvals 12 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	Flunisolide or mometasone nasal spray are approved when the following criteria are met: - Documentation of a trial and failure, contraindication, or inability to use (nasal burning, headache, etc.) fluticasone nasal spray OR Flonase Sensimist OR triamcinolone nasal spray OR budesonide 32mcg nasal suspension Non-formulary intranasal steroids are approved when the following criteria are met: - Documentation of a trial and failure, contraindication, or inability to use (nasal burning, headache, etc.) fluticasone nasal spray OR Flonase Sensimist OR triamcinolone nasal spray OR budesonide 32mcg nasal suspension AND - Documentation of a trial and failure, contraindication, or inability to use (nasal burning, headache, etc.) flunisolide 0.025% spray OR mometasone 50 mcg nasal spray For requests above the quantity limit - The member must have a documented treatment failure with the drug prescribed at the health plan's quantity limit OR the member requires a dose within prescribing guidelines that exceeds the plan's quantity limit. AND - The provider has submitted a medical reason why the plan's quantity limit will be inadequate based on the member's condition and treatment history. AND - The dose requested is supported by the Medical Compendia or current treatment guidelines.
Criteria Statement	Flunisolide nasal spray or mometasone nasal spray are reserved for members who have used (or cannot/should not use) fluticasone nasal spray OR Flonase Sensimist OR triamcinolone nasal spray OR budesonide 32mcg nasal suspension. Non-formulary steroidal nasal sprays are reserved for members who have used (or cannot/should not use) fluticasone nasal spray or Flonase Sensimist or triamcinolone nasal spray or budesonide 32mcg nasal suspension AND flunisolide nasal spray or mometasone nasal spray.
Last P&T Review Date	<u>9/2024</u> 9/2025

Recommendation: No changes

Topical Acne Agents	
Therapeutic Classes (AHFS)	Cell stimulants and proliferants
Medications	Formulary restricted to members ≤ 21 years and quantity limit #45 g/30 days; prior authorization required for members > 21 years Tretinoin (Retin-A) 0.01%, 0.025%, 0.05% gel Tretinoin (Retin-A) 0.1%, 0.025%, 0.05% cream
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval 12 months Later Approvals 12 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	<u>Tretinoin criteria for approval:</u> For members ≤ 21 years of age: - Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to Differin 0.1% gel OTC For members > 21 years of age - Diagnosis of acne vulgaris - Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to Differin 0.1% gel OTC AND topical antibiotics
Criteria Statement	For members ≤ 21 years of age, tretinoin gel or cream are reserved for members who have used (or cannot/should not use) Differin 0.1% OTC gel. For members > 21 years of age, tretinoin gel or cream are reserved for members who have acne, who have used (or cannot/should not use) Differin 0.1% OTC gel and topical antibiotics.
Last P&T Review Date	<u>9/2024</u> /2025

Recommendation: No changes

Injectable/Infusible Bone-Modifying Agents for Oncology Indications	
Therapeutic Classes (AHFS)	Bone resorption inhibitors
Medications	<u>Preferred Agent, prior authorization required</u> Pamidronate disodium: 3mg/ml, 6 mg/ml, 9 mg/ml liquid in 10 ml vials, 30 mg, 90 mg vials Zoledronic Acid 4 mg/5 ml vial <u>Non-preferred Agents, prior authorization required</u> Xgeva (denosumab) Prolia (denosumab)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an oncologist or endocrinologist
Coverage Duration	Initial/Re-Approval If all conditions are met, the request will be approved for up to for 6 months or as recommended per FDA approved indications and/or as defined by the medical compendium as defined above and/or per the NCCN, ASCO, NOF or NIH standard of care guidelines; if all of the above criteria are not met then, the request is referred to Clinical Reviewer for medical necessity review.
PA Review Criteria	CRITERIA FOR APPROVAL: • Prescribed dosing of medication is within FDA approved indications or is supported by the medical compendium as defined by the Social Security Act or per the NCCN, ASCO, or NIH standard of care guidelines. • If the request is for Xgeva (denosumab) for any of the indications below, the patient must have a documented trial and failure of pamidronate OR zoledronic acid or has a documented medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc) for not utilizing one of these agents to manage the medical condition ○ bone metastases from solid tumors ○ hypercalcemia of malignancy ○ multiple myeloma osteolytic lesions • If the medication request is for Xgeva (denosumab) for treating Giant Cell Tumor of Bone, the patient has documentation submitted that the giant cell tumor of bone is unresectable, that surgical resection is likely to result in severe morbidity (e.g. denosumab is being used to aid in resection by shrinking the tumor), or that disease has recurred. • If the request is for Prolia (denosumab) for breast cancer, the patient has a documented trial and failure of pamidronate OR zoledronic acid that is consistent with claims history, or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc) for not utilizing one of these agents to manage their medical condition • If the request is for Prolia (denosumab) for prostate cancer, approve.
Criteria Statement	Xgeva is reserved for treating Giant Cell Tumor of Bone in members who are not able to have surgery or who are not candidates for surgery, or in members where disease has recurred.

	Xgeva is reserved for members with cancer indications who have used (or cannot/should not use) pamidronate or zoledronic acid. Prolia is reserved for members with cancer indications who have used (or cannot/should not use) pamidronate or zoledronic acid.
Last P&T Review Date	<u>9/2024</u> <u>9/2025</u>

Recommendation: No changes

Alosetron (Lotronex)	
Therapeutic Classes (AHFS)	Anti-Inflammatory Agents (GI Drugs)
Medications	Alosetron (Lotronex)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert.
Exclusion Criteria	N/A
Required Clinical Information	See “ PA Review Criteria ” below
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Initial Approval If the criteria are met, approve up to #2 tablets/day for 3 months initially. Later Approvals If patient is tolerating and responding to treatment after 3 months, subsequent requests may be approved for #2 tablets/day for 12 months. If criteria is not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review.
PA Review Criteria	<u>Criteria for Approval</u> • Patient has diagnosis of severe chronic diarrhea-predominant irritable bowel syndrome (IBS-D) and has had anatomic or biochemical GI abnormalities excluded and has symptoms that have lasted 6 months or longer (includes one or more of the following: frequent and severe abdominal pain/discomfort; frequent bowel urgency or fecal incontinence; disability or restriction of daily activities due to IBS) • Documented trial and failure, contraindication, or intolerance to a tricyclic antidepressant (TCA) (e.g., amitriptyline)
Criteria Statement	Alosetron is reserved for women who have severe chronic diarrhea-predominant irritable bowel syndrome (IBS-D) who have used (or cannot/should not use) a tricyclic antidepressant (TCA) (e.g., amitriptyline).
Last P&T Review Date	~~9/2024~~ 9/2025

Recommendation: No changes

Viberzi (eluxadoline)	
Therapeutic Classes (AHFS)	GI Drugs, Miscellaneous
Medications	Viberzi (eluxadoline)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert.
Exclusion Criteria	Viberzi is contraindicated in patients with sphincter of Oddi spasms.
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval If the criteria are met, approve up to #2 tablets/day for 3 months initially. Later Approvals If patient is tolerating and responding to treatment after 3 months, subsequent requests may be approved for #2 tablets/day for 12 months. If criteria is not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review.
PA Review Criteria	<u>Criteria for Approval</u> • Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) • Provider attestation that the member has a gallbladder and does not drink more than 3 alcoholic beverages per day. • Documented trial and failure, contraindication, or intolerance to a tricyclic antidepressant (TCA) (e.g., amitriptyline).
Criteria Statement	Viberzi (eluxadoline) is reserved for members who have diagnosis of irritable bowel syndrome with diarrhea (IBS-D) who have a gallbladder, and do not drink more than 3 alcoholic beverages per day and have used (or cannot/should not use) a tricyclic antidepressant (TCA) (e.g. amitriptyline).
Last P&T Review Date	9/20249/2025

Recommendation: No changes

Rifabutin (Mycobutin)	
Therapeutic Classes (AHFS)	Antitubercular agents
Medications	Formulary, PA required Rifabutin (Mycobutin) 150 mg capsule
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See “PA Review Criteria” below
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is an infectious disease specialist or working in consultation with infectious disease specialist
Coverage Duration	Initial Approval Diagnosis of tuberculosis If all of the conditions are met, the request will be approved for up to 26 weeks. If all of the criteria are not met, the request is referred to a clinical reviewer for medical necessity review. Prophylaxis of disseminated mycobacterium avium complex (MAC) disease If all of the conditions are met, the request will be approved for up to a 12 month duration. If all of the criteria are not met, the request is referred to a clinical reviewer for medical necessity review.
PA Review Criteria	For prophylaxis of disseminated mycobacterium avium complex (MAC) disease, approve if: • Documentation of advanced HIV • Documentation that the patient does not have active tuberculosis • Documented trial and failure, contraindication, intolerance, or inability to use azithromycin or clarithromycin • Requested dose is within recommended dosing guidelines For diagnosis of tuberculosis, approve if: • Documented contraindication, intolerance, or inability to use rifampin. • Requested dose is within recommended dosing guidelines
Criteria Statement	For prophylaxis of disseminated mycobacterium avium complex (MAC) disease, rifabutin is reserved for members who have used (or cannot/should not use) azithromycin or clarithromycin and do not have active tuberculosis. For tuberculosis, rifabutin is reserved for members who have used (or cannot/should not use) rifampin
Last P&T Review Date	~~9/2024~~ 9/2025

Recommendation: No changes

Tranexamic acid (Lysteda)	
Therapeutic Classes (AHFS)	Hemostatics
Medications	PA required, quantity limit (30/5), fill limit (1 fill per 28 days) Tranexamic acid (Lysteda) 650mg tablet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	Patients who are pregnant
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	None
Coverage Duration	Initial Approval 6 months Later Approvals 12 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	Criteria for initial authorization: • Diagnosis of cyclic heavy menstrual bleeding (HMB) • The medication is used at the FDA-approved dose of 1,300 mg 3 times daily (3,900 mg/day) for a maximum of 5 days during monthly menstruation • Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to a formulary combined oral estrogen-progestin contraceptive OR an oral progestin only contraceptive AND a non-steroidal anti-inflammatory agent. Criteria for re-authorization: • Patient is stable and has a reduction of heavy menstrual bleeding Criteria for Quantities and Fills Greater Than Allowed: If the patient requires doses greater than the set limits after meeting approval the following conditions must be met: • The provider has submitted a medical reason why the plan's quantity or fill limit will be inadequate based on the member's condition and treatment history
Criteria Statement	Tranexamic acid (Lysteda) is reserved for members who are experiencing heavy menstrual bleeding and have tried and failed or are unable to take oral contraceptives and non-steroidal anti-inflammatory agents (NSAIDs). Requests for quantities over the quantity or fill limit are reserved for members who have a documented medical need for quantities in excess of the limits.
Last P&T Review Date	9/20249/2025

Recommendation: No changes

Santyl Ointment	
Therapeutic Classes (AHFS)	Collagenase (enzymatic debriding ointment)
Medications	<u>Formulary, PA required</u> Santyl ointment
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See “ PA Review Criteria ” below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval 3 months Later Approvals 3 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	Criteria for initial approval of Santyl ointment - Santyl ointment requests may be approved for up to 3 months - For requests greater than 3 months, the provider must submit a medical reason of necessity - Type of wound is one of the following: - Wounds to be debrided, severe burns, or chronic dermal ulcers - Verification that the requested amount does not exceed the amount on the Santyl dosing calculator: https://www.santyl.com/hcp/dosing - Dimension of wound and duration of treatment required for calculation of dose and amount Criteria for reauthorization: - Documentation submitted indicates a clinical benefit was observed (e.g., reduction in wound size, decrease in wound-related pain, etc.) - Duration of time requested as therapy extension - Verification that the requested amount does not exceed the amount on the Santyl dosing calculator: https://www.santyl.com/hcp/dosing - Dimension of wound and duration of treatment required for calculation of dose and amount
Criteria Statement	Santyl ointment is reserved for members who are undergoing wound care treatment requiring enzymatic debridement therapy.
Last P&T Review Date	<u>9/2024/2025</u>

Recommendation: No changes

Topical Antibiotics	
Therapeutic Classes (AHFS)	ANTIBACTERIALS (SKIN, MUCOUS MEMBRANE)
Medications	<u>Formulary, with quantity limits</u> clindamycin phosphate topical gel 1% (60/30, 6 fills per 12 months) clindamycin phosphate (Cleocin T) topical lotion 1% (6 fills per 12 months) clindamycin phosphate (Cleocin T) topical solution 1% (6 fills per 12 months) clindamycin phosphate topical swab 1% (6 fills per 12 months) erythromycin-benzoyl peroxide (Benzamycin) topical gel 3-5% (6 fills per 12 months) Ery Pads (erythromycin) topical swab 2% (6 fills per 12 months) erythromycin with ethanol (Erygel) topical gel 2% (6 fills per 12 months) erythromycin with ethanol topical solution 2% (6 fills per 12 months) gentamicin topical cream 0.1% (2 fills per 12 months) gentamicin topical ointment 0.1% (2 fills per 12 months) A quantity limit is defined as a limitation in the amount of medication per fill or time period and/or limitation in the amount of fills per calendar year or other time period.
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert.
Exclusion Criteria	See "PA Review Criteria"
Required Clinical Information	See "PA Review Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval 3 months (request for more than 6 fills in 12 months, or 2 fills in 12 months for gentamicin) Later Approvals 6 months If criteria is not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review.
PA Review Criteria	<u>Formulary step therapy required topical antibiotic criteria for approval:</u> - Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to topical benzoyl peroxide <u>Initial Approval: Topical antibiotic request for exceeding quantity or fill limit</u> - The member must have a documented clinical benefit and need to continue the drug prescribed over the health plan's quantity or fill limit - OR - The member requires a dose within prescribing guidelines that exceeds the plan's quantity or fill limit. <u>Later Approval: Topical antibiotic request: continues to exceed quantity or fill limit</u> - Documentation that condition has improved or stabilized with therapy and the prescriber recommends continuation of therapy
Criteria Statement	Formulary topical antibiotic <insert drug> is reserved for members who have used (or cannot/should not use) topical benzoyl peroxide. Formulary topical antibiotic <insert drug> is reserved for members who have used (or cannot/should not use) quantities within the quantity and/or fill limits.
Last P&T Review Date	9/20249/2025

Recommendation: No changes

Injectable/Infusible Agents for Osteoporosis and Paget's Disease	
Therapeutic Classes (AHFS)	Bone resorption inhibitors; Parathyroid agents
Medications	ibandronate (Boniva) injection zoledronic acid (Reclast) Prolia (denosumab) teriparatide (Forteo)--PREFERRED Tymlos (abaloparatide)--PREFERRED Evenity (romosozumab-aqqg) pamidronate
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial/Re-Approval If all conditions are met, the request will be approved for up to 12 months. ***FORTEO/TERIPARATIDE/TYMLOS REQUESTS WILL ONLY BE APPROVED FOR A TOTAL DURATION OF 24 MONTHS*** *** EVENITY WILL ONLY BE APPROVED FOR A TOTAL OF 12 MONTHS*** If all criteria are not met, the request is referred to Clinical Reviewer for medical necessity review.
PA Review Criteria	CRITERIA FOR APPROVAL FOR ALL REQUESTS: - Documentation (by either attestation or claims data) the member is taking adequate calcium and vitamin D supplementation - The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate POSTMENOPAUSAL OR MALE OSTEOPOROSIS: - If the request is for very high risk postmenopausal osteoporosis or postmenopausal osteoporosis, with prior fractures, a documented trial and failure of an oral bisphosphonate will not be required. - Very high risk is defined as having one or more of the following: - History of fracture in the past 12 months - Multiple fractures - Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids) - Very low T scores (< -3.0) - High risk for falls - History of injurious falls - Very high fracture probability as determined by fracture risk assessment tool (FRAX) (e.g. major osteoporosis fracture >30%, hip fracture > 4.5%) - Documentation was submitted indicating the member is a postmenopausal woman or a male over 50 years of age and one of the following: - A bone mineral density (BMD) value consistent with osteoporosis (i.e., T-scores equal to or less than -2.5)

- Has had an osteoporotic fracture
- A T-score between -1 and -2.5 at the femoral neck or spine and a 10 year hip fracture probability >3% or a 10 year major osteoporosis-related fracture probability >20% based on the US-adapted WHO absolute fracture risk model.
- If the request is for Forteo (teriparatide), Teriparatide, Evenity (romosozumab), or Tymlos (abaloparatide), one of the following applies to the member:
 - Documented trial and failure of ibandronate (Boniva) or zoledronic acid (Reclast) AND Prolia (denosumab) or has a medical reason (e.g. intolerance, contraindication, etc.) why these therapies are not suitable to be used
 - Has severe osteoporosis (T-Score -3.5 or below, or T-Score of -2.5 or below plus a fragility fracture)
- If the request is for Forteo or Evenity, a medical reason why the member is unable to use Tymlos or teriparatide, if appropriate, based on the diagnosis.
 - Requests for brand Forteo (teriparatide) also require a medical reason why the member is unable to use Teriparatide
- If the request is for Evenity, the member does not have a history of a heart attack or stroke within the preceding year

GLUCOCORTICOID-INDUCED OSTEOPOROSIS:

- For members ≥ 40 years of age on long-term glucocorticoid therapy:
 - Documentation that the member is currently utilizing glucocorticoid therapy for a minimum of 3 months
 - Dosage of the glucocorticoid therapy is greater than 2.5 mg of prednisone daily or its equivalent
 - Member has a moderate to very high risk of fracture based on ONE of the following:
 - History of osteoporotic fracture
 - BMD less than or equal to -1 at the hip or spine
 - FRAX 10-year probability of hip or combined major osteoporotic fracture of ≥1 and 10 percent (with glucocorticoid adjustment), respectively
- For adult members (all ages) receiving HIGH dose glucocorticoid therapy:
 - Member has a moderate to very high risk of fracture based on ONE of the following:
 - History of prior fracture
 - Glucocorticoid dose ≥ 30 mg/day or cumulative ≥ 5 grams/year of prednisone or its equivalent
 - Continuing glucocorticoid treatment ≥ 7.5 mg/day of prednisone or its equivalent for ≥ 6 months AND BMD Z score < -3 OR significant BMD loss (> least significant change of DXA)
- If the request is for Forteo (teriparatide), Teriparatide or Tymlos (abaloparatide), the member has a documented trial and failure of zoledronic acid (Reclast) or Prolia (denosumab) or a medical reason (e.g. intolerance, contraindication, etc.) as to why the member is unable to use these medications is provided:
 - Requests for brand Forteo (teriparatide) also require a medical reason why the member is unable to use Teriparatide

PAGET'S DISEASE:

- Documentation of a confirmed diagnosis of Paget's disease.
- Documentation (from within 60 days of the request) that the member has a serum alkaline phosphatase level of ≥ two times the upper limit of normal OR

	the member is symptomatic OR the member is at risk for complication from Paget's disease CRITERIA FOR REAPPROVAL: The member has documentation of clinical benefit from the medication
Criteria Statement	Ibandronate (Boniva) Injection, Prolia, or zoledronic acid (Reclast) are reserved for members with a diagnosis of postmenopausal or male osteoporosis who have used (or cannot/should not use) oral bisphosphonates, unless the member has very high risk osteoporosis, an oral bisphosphonate is not required. Forteo, teriparatide, Evenity, or Tymlos are reserved for members with a diagnosis of postmenopausal or male osteoporosis who have used (or cannot/should not use) ibandronate (Boniva) or zoledronic acid (Reclast) AND Prolia. Additionally, Forteo and Evenity are reserved for members who have used (or cannot/should not use) Tymlos or teriparatide. Forteo is reserved for members who have used (or cannot/should not use) teriparatide. Tymlos, Forteo, Teriparatide, Prolia or zoledronic acid (Reclast) are reserved for members with glucocorticoid-induced osteoporosis who are 40 years of age or older on long-term glucocorticoid therapy or are on high dose glucocorticoid therapy regardless of age, and have a moderate to very high risk of fracture, and have used (or cannot/should not use) oral bisphosphonates. Forteo, Teriparatide, or Tymlos are reserved for members with glucocorticoid-induced osteoporosis who have used (or cannot/should not use) zoledronic acid (Reclast) or Prolia. Additionally, Forteo is reserved for members who have used (or cannot/should not use) Teriparatide, Zoledronic acid (Reclast) and pamidronate are reserved for members with Paget's disease who have used (or cannot/should not use) oral bisphosphonates.
Last P&T Review Date	<u>9/20249/2025</u>

Recommendation: No changes

Vowst	
Therapeutic Classes (AHFS)	OTHER MISCELLANEOUS THERAPEUTIC AGENTS
Medications	Vowst (fecal microbiota spores, live-brpk)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	Treatment of Clostridioides difficile infection (CDI)
Required Clinical Information	See “ PA Review Criteria ” below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	N/A
Coverage Duration	If all the criteria are met, the request will be approved for 1 treatment course.
PA Review Criteria	<u>Initial Authorization:</u> • Medication is prescribed at an FDA approved dose • Diagnosis of at least 1 recurrent episode of CDI (≥2 total CDI episodes) • Current episode of CDI must be controlled (<3 unformed/loose stools/day for 2 consecutive days) • Positive stool test for C. difficile within 30 days before prior authorization request • Administration will occur 24–72 hours following completion of antibiotic course for CDI treatment • Confirmation patient will bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst *Vowst is limited to 1 treatment course*
Criteria Statement	Vowst is reserved for members who have a diagnosis of at least 1 recurrent episode of CDI (≥2 total CDI episodes), with the current episode of CDI being controlled (<3 unformed/loose stools/day for 2 consecutive days) and a positive stool test for C. difficile within 30 days before prior authorization request. Administration must be 24–72 hours following completion of antibiotic course for CDI treatment and the member must bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst.
Last P&T Review Date	9/20249/2025

Recommendation: No changes

Duvyzat	
Therapeutic Classes (AHFS)	Other Miscellaneous Therapeutic Agents
Medications	Duvyzat (givinostat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See “ PA Review Criteria ” below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age According to package insert
Prescriber Restrictions	Prescribed by a neurologist or provider or specializes in the treatment of Duchenne Muscular Dystrophy (DMD)
Coverage Duration	If all the criteria are met, the initial request will be approved for 12 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a clinical reviewer for medical necessity review
PA Review Criteria	<u>Initial Authorization:</u> • Medication is prescribed at an FDA approved dose according to body weight • Genetically confirmed diagnosis of Duchenne Muscular Dystrophy (DMD) and copies of testing were submitted with request • Patient has been stable on baseline corticosteroids for at least 6 months • Patient is ambulatory <u>Re-Authorization:</u> • Documentation or provider attestation of positive clinical response (such as improved muscle function, muscle strength, or disease stabilization) • Patient is on concurrent corticosteroid treatment • Patient is ambulatory • Medication is prescribed at an FDA approved dose according to body weight
Criteria Statement	Duvyzat is reserved for members who have a diagnosis of DMD, who are ambulatory and have been stable on baseline corticosteroids for at least 6 months.
Last P&T Review Date	9/20249/2025

Recommendation: No changes

Rho Kinase Inhibitors	
Therapeutic Classes (AHFS)	Rho Kinase Inhibitors
Medications	Rhopressa (netarsudil) Rocklatan (netarsudil/latanoprost)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See “ PA Review Criteria ” below
Age Restrictions	Member must be ≥ 18 years old
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval: 12 months Later Approvals: 12 months If the conditions are not met, the request will be sent to a clinical reviewer for medical necessity review
PA Review Criteria	<u>Initial Authorization:</u> • Diagnosis of ocular hypertension or open-angle glaucoma • Documented trial and failure of a prostaglandin inhibitor or beta-adrenergic antagonist • Member has not had: ◦ Previous glaucoma intraocular surgery or glaucoma laser procedure in the affected eye; OR ◦ Ocular surgery or laser treatment within three months prior to initiation • Member does not currently have any of the following: ◦ Ocular infection ◦ Inflammation ◦ Blepharitis ◦ Conjunctivitis ◦ Ocular disease <u>Re-Authorization:</u> • Member must continue to meet above criteria • Member has demonstrated efficacy (e.g. reduction in intraocular pressure)
Criteria Statement	Rhopressa and Rocklatan are reserved for members who have a diagnosis of ocular hypertension or open-angle glaucoma and have tried and failed a prostaglandin inhibitor or beta-adrenergic antagonist.
Last P&T Review Date	9/20249/2025

Recommendation: No changes

Xolremdi	
Therapeutic Classes (AHFS)	Hematopoietic Agents
Medications	Xolremdi (mavorixafor)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See “ PA Review Criteria ” below
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescriber must be an immunologist or a hematologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a clinical reviewer for medical necessity review
PA Review Criteria	<u>Initial Authorization:</u> • Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome confirmed by genotype variant of chemokine receptor 4 (CXCR4) and absolute neutrophil count (ANC) of ≤ 400 cells/μL • Documentation of baseline ANC and absolute lymphocyte count (ALC) • Documentation of member weight • Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> • Documentation or provider attestation of positive clinical response (i.e. improvement from baseline in ANC and/or ALC) • Documentation of member weight • Medication is prescribed at an FDA approved dose
Criteria Statement	Xolremdi is reserved for members who have a confirmed diagnosis of WHIM syndrome with documented member weight and baseline ANC and ALC.
Last P&T Review Date	9/20249/2025

Recommendation: Update naming conventions to show the availability of generic Qsymia as phentermine/topiramate

Anti-Obesity Medications	
Therapeutic Classes (AHFS)	GI drugs, miscellaneous; anorexigenic agents
Medications	Alli (orlistat) Xenical (orlistat) Phentermine (phentermine hcl) (Adipex-P) Phentermine (phentermine hcl) (Lomaira) ~~Phentermine/topiramate (Qsymia)~~ (~~phentermine/topiramate~~) Contrave (naltrexone/bupropion) Saxenda (liraglutide) Wegovy (semaglutide) Zepbound (tirzepatide) Any other newly marketed agent **Please Note: If the request is for Wegovy to reduce the risk of major adverse cardiovascular events please refer to the Wegovy criteria***
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	N/A
Coverage Duration	Initial/Re-Approval If all conditions are met, the request will be approved for up to 6 months. If all criteria are not met, the request is referred to Clinical Reviewer for medical necessity review.
PA Review Criteria	<u>INITIAL CRITERIA FOR APPROVAL</u> <u>Phentermine HCL (Adipex-P)</u> • Diagnosis of class III/severe obesity (including documentation of BMI ≥ 40) • For phentermine (Lomaira): trial and failure or medical reason for not using generic phentermine (Adipex-P) <u>Alli</u> • Diagnosis of class III/severe obesity (including documentation of BMI ≥ 40) <u>Phentermine/topiramate (Qsymia)</u> • For adults: Diagnosis of class III/severe obesity (including documentation of BMI ≥ 40) OR ◦ For pediatrics: BMI of 120% of the 95th percentile standardized for age and sex or ≥35 kg/m² ▪ https://www.cdc.gov/healthyweight/bmi/calculator.html • Documented trial and failure, contraindication, or intolerance to use phentermine HCL (Adipex-P) and topiramate as separate ingredients <u>Contrave</u> • Diagnosis of class III/severe obesity (including documentation of BMI ≥ 40) • Documented trial and failure, contraindication, or intolerance to use <u>phentermine/topiramate (Qsymia)</u> <u>Saxenda, Wegovy, and Zepbound</u>

	• Diagnosis of class III/severe obesity (including documentation of BMI ≥ 40) • Documented trial and failure, contraindication, or intolerance to use phentermine/topiramate (Qsymia) AND Contrave <u>Xenical:</u> • Diagnosis of class III/severe obesity (including documentation of BMI ≥ 40) • Documented trial and failure, contraindication, or intolerance to Alli dosed at 120 mg (2 capsules) three times daily. <u>REAUTHORIZATION CRITERIA FOR APPROVAL</u> • Documented weight loss of 5% of body weight or more, compared with baseline
Criteria Statement	Phentermine is reserved for members who have a diagnosis of class III/severe obesity with body mass index of ≥ 40. Generic Lomaira is reserved for members who have used (or cannot/should not use) generic Adipex-P. Alli is reserved for members who have a diagnosis of class III/severe obesity with a body mass index of ≥ 40. Phentermine/topiramate (Qsymia) is reserved for adult members who have a diagnosis of class III/severe obesity with a body mass index of ≥ 40 or pediatric members who are obese with a BMI of 120% of the 95th percentile standardized for age and sex or ≥ 35 kg/m² and who have used (or cannot/should not use) phentermine and topiramate as separate ingredients. Contrave is reserved for members who have a diagnosis of class III/severe obesity with a body mass index of ≥ 40 and who have used (or cannot/should not use) phentermine/topiramate (Qsymia). Saxenda, Wegovy, and Zepbound are reserved for members who have a diagnosis of class III/severe obesity with a body mass index of ≥ 40 and who have used (or cannot/should not use) phentermine/topiramate (Qsymia) and Contrave. Xenical is reserved for members who have a diagnosis of class III/severe obesity with a body mass index of ≥ 40 and who have used (or cannot/should not use) Alli.
Last P&T Review Date	6/20259/2025

Alameda PADs for review Q3 2025 P&T Consent Agenda

Recommendation: No changes

Adakveo	
Medications	Adakveo (crizanlizumab-tmca)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "other criteria"
Age Restrictions	Check AAH active CCS cases for members < 21 years of age for MCAL Member must be 16 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If the criteria are met, the initial request will be approved for up to a 12 month duration; reauthorization requests will be approved for up to 12 months.
Maximum Billable Units	Variable
Other Criteria	Initial Authorization: • Member has a confirmed diagnosis of sickle cell disease • Documentation was provided that the member has had 2 or more pain crises in the last 12 months • Documentation was provided that the member has been taking hydroxyurea at the maximum tolerated dose and has been compliant within the last 6 months (or a medical reason was provided why the patient is unable to use hydroxyurea) • Documentation of the member's current weight • Request is for an FDA-approved dose Reauthorization: • Documentation has been submitted that the member has demonstrated or maintained ONE of the following changes from baseline: ○ Reduction in pain crises ○ Increased time between crises ○ Decrease in days hospitalized • Documentation of the member's current weight • Request is for an FDA-approved dose If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last Review Date	9/20249/2025

Recommendation: No changes

Injectable/Infusible Agents for Osteoporosis and Paget's Disease	
Medications	ibandronate (Boniva) injection zoledronic acid (Reclast) Prolia (denosumab) teriparatide (Forteo) Tymlos (abaloparatide) Evenity (romosozumab-aqqg) Pamidronate Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "other criteria"
Age Restrictions	Check AAH active CCS cases for members < 21 years of age for MCAL
Prescriber Restrictions	N/A
Coverage Duration	If all conditions are met, the request will be approved for up to 12 months. ***FORTEO/TERIPARATIDE/TYMLOS REQUESTS WILL ONLY BE APPROVED FOR A TOTAL DURATION OF 24 MONTHS*** *** EVENITY WILL ONLY BE APPROVED FOR A TOTAL OF 12 MONTHS*** reauthorization requests will be approved for up to 12 months.
Maximum Billable Units	Variable
Other Criteria	CRITERIA FOR APPROVAL FOR ALL REQUESTS: • Dose is appropriate per label or supported by compendia/standard of care guidelines • The member is taking adequate calcium and vitamin D supplementation • The member has a documented (consistent with pharmacy claims) adequate trial of an oral bisphosphonate or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using an oral bisphosphonate POSTMENOPAUSAL OR MALE OSTEOPOROSIS: • If the request is for very high risk postmenopausal osteoporosis or postmenopausal osteoporosis, with prior fractures, a documented trial and failure of an oral bisphosphonate will not be required. ○ Very high risk is defined as having one or more of the following: ▪ History of fracture in the past 12 months ▪ Multiple fractures ▪ Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids) ▪ Very low T scores (< -3.0) ▪ High risk for falls ▪ History of injurious falls ▪ Very high fracture probability as determined by fracture risk assessment tool (FRAX) (e.g. major osteoporosis fracture >30%, hip fracture > 4.5%) • Documentation was submitted indicating the member is a postmenopausal woman or a male over 50 years of age and one of the following: ○ A bone mineral density (BMD) value consistent with osteoporosis (i.e., T-scores equal to or less than -2.5) ○ Has had an osteoporotic fracture

- A T-score between -1 and -2.5 at the femoral neck or spine and a 10 year hip fracture probability >3% or a 10 year major osteoporosis-related fracture probability >20% based on the US-adapted WHO absolute fracture risk model.
- If the request is for Forteo (teriparatide), Teriparatide, Evenity (romosozumab), or Tymlos (abaloparatide), one of the following applies to the member:
 - Documented trial and failure of ibandronate (Boniva) or zoledronic acid (Reclast) AND Prolia (denosumab) or has a medical reason (e.g. intolerance, contraindication, etc.) why these therapies are not suitable to be used
 - Has severe osteoporosis (T-Score -3.5 or below, or T-Score of -2.5 or below plus a fragility fracture)
- If the request is for Forteo or Evenity, a medical reason why member is unable to use Tymlos or teriparatide, if appropriate, based on the diagnosis.
 - Requests for brand Forteo (teriparatide) also require a medical reason why the member is unable to use Teriparatide
- If the request is for Evenity, the member does not have a history of a heart attack or stroke within the preceding year

GLUCOCORTICOID-INDUCED OSTEOPOROSIS THERAPY:

- For members ≥ 40 years of age on long-term glucocorticoid therapy:
 - Documentation that the member is currently utilizing glucocorticoid therapy for a minimum of 3 months
 - Dosage of the glucocorticoid therapy is greater than 2.5 mg of prednisone daily or its equivalent
 - Member has a moderate to very high risk of fracture based on ONE of the following:
 - History of osteoporotic fracture
 - BMD less than or equal to -1 at the hip or spine
 - FRAX 10-year probability of hip or combined major osteoporotic fracture of ≥1 and 10 percent (with glucocorticoid adjustment), respectively
- For adult members (all ages) receiving HIGH dose glucocorticoid therapy:
 - Member has a moderate to very high risk of fracture based on ONE of the following:
 - History of prior fracture
 - Glucocorticoid dose ≥ 30 mg/day or cumulative ≥ 5 grams/year of prednisone or its equivalent
 - Continuing glucocorticoid treatment ≥ 7.5 mg/day of prednisone or its equivalent for ≥ 6 months AND BMD Z score < -3 OR significant BMD loss (> least significant change of DXA)
- If the request is for Forteo (teriparatide), Teriparatide, or Tymlos (abaloparatide), the member has a documented trial and failure of zoledronic acid (Reclast) or Prolia (denosumab) or a medical reason (e.g. intolerance, contraindication, etc.) as to why the member is unable to use these medications is provided:
 - Requests for brand Forteo (teriparatide) also require a medical reason why the member is unable to use Teriparatide

PAGET'S DISEASE:

- Documentation of a confirmed diagnosis of Paget's disease.
- Documentation (from within 60 days of the request) that the member has a serum alkaline phosphatase level of ≥ two times the upper limit of normal OR the member is symptomatic OR the patient is at risk for complication from Paget's disease

	CRITERIA FOR REAPPROVAL: The member has documentation of clinical benefit from the medication
Last Review Date	~~9/2024~~ 9/2025

Recommendation: No changes

Exondys 51	
Medications	Exondys 51 (eteplirsén) injection
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "other criteria"
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescribed by neurologist or provider who specializes in the treatment of DMD
Coverage Duration	If the criteria are met, the initial request will be approved for a maximum 6 month duration. Further authorizations will be for 6 months.
Maximum Billable Units	Variable
Other Criteria	Initial Authorization: Exondys 51 is approved when all of the following criteria are met: • Documentation of a diagnosis of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping • Dose is within FDA approved dosing • Member has been on a stable dose of corticosteroids for at least 6 months • Baseline dystrophin levels are provided • Results of motor function tests are provided [e.g. 6-Minute Walk Test (6MWT), Time to Stand Test (TTSTAND), Time to Run/Walk Test (TTRW), North Star Ambulatory Assessment (NSAA), Time to Climb 4 Steps Test (TTCLIMB)] • The member is ambulatory (e.g. able to walk with or without assistance, and not wheelchair dependent) Criteria for Re-Authorization: Documentation of all of the following: • The member is ambulatory • Improvement or stabilization demonstrated by scores of motor function tests [e.g. 6-Minute Walk Test (6MWT), Time to Stand Test (TTSTAND), Time to Run/Walk Test (TTRW), North Star Ambulatory Assessment (NSAA), or Time to Climb 4 Steps Test (TTCLIMB)] • Improvement in dystrophin level from baseline • Documentation of tolerability • Dose is within FDA approved dosing If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last Review Date	9/20249/2025

Recommendation: No changes

Erythropoiesis-Stimulating Agents	
Medications	Retacrit (epoetin alfa-epbx) - biosimilar Procrit (epoetin alfa) Epogen (epoetin alfa) Mircera (methoxy polyethylene glycol-epoetin beta) Aranesp (darbepoetin alfa) Any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See “ Other Criteria ” below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	N/A
Maximum Billable Units	variable
Coverage Duration	Initial Approval If criteria are met, the request will be approved as follows: 1 month if the patient is deficient in iron, vitamin B12 or folate, and in the perisurgical setting 3 months for all other requests. If the provider attests that the preferred medication is for a chronic or long-term condition, reauthorization will be approved for 12 months
Other Criteria	** When this biosimilar is indicated, and available, the member must have documented dates of trial and failure, intolerance, inability to use, or contraindication to the biosimilar medication prior to the brand medication approval, OR the currently available biosimilar product does not have the same appropriate use (per the references outlined in “Covered Uses”) as the reference biologic drug being requested, in addition to meeting all applicable criteria below. <u>Criteria for authorization of existing epoetin users who are NEW to the plan:</u> • Documentation of current dose • Documentation of hemoglobin level results within 30 days or member has responded to therapy (≥1-2 g/dL increase in hemoglobin (HgB) or decrease in transfusion requirements) <u>Requests for Initial Therapy:</u> • All lab results submitted must have been drawn within 30 days of request: • The following lab values – hemoglobin (HgB) and hematocrit (HCT) • Normal lab results or, if abnormally low, appropriate supplementation as follows: ○ serum ferritin level (normal is > 100 ng/mL) ○ transferrin saturation (TSAT) (normal is > 20%) ○ vitamin B12 level(> 223 pg/mL) ○ folate level (> 3.1 ng/mL) • For anemia of CKD: ○ HgB < 10 g/dL

Erythropoiesis-Stimulating Agents	
	• For anemia related to cancer: ○ Receiving myelosuppressive therapy for palliative treatment (members receiving myelosuppressive therapy with <u>curative intent</u> should <u>not</u> receive ESAs) AND documented <u>symptomatic</u> anemia with HgB <10 g/dL OR ○ The member has symptomatic anemia related to myelodysplastic syndrome AND documented serum erythropoietin level ≤ 500 mU/mL • For zidovudine-related anemia in members with HIV: ○ The member must currently be receiving zidovudine-containing highly active antiretroviral therapy (HAART) (zidovudine ≤ 4200 mg/week) ○ Erythropoietin level ≤ 500 mU/mL • For ribavirin-induced anemia: ○ Documented attempt to reduce dose was made ○ HgB < 12 g/dL • For members undergoing surgery to reduce the need for allogenic blood transfusion: ○ Perioperative hemoglobin must be < 13 g/dL and > 10 g/dL. ○ The member is scheduled for an elective, non-cardiac, nonvascular surgery. Reauthorization: • Repeat normal labs within 30 days from date of request, or appropriate supplementation as follows: ○ serum ferritin level (> 100 ng/mL) ○ TSAT (> 20%) ○ vitamin B12 level (> 223 pg/mL) ○ folate level (> 3.1 ng/mL) • For anemia of CKD: HgB ≤ 11 g/dL • For anemia related to cancer: HgB ≤ 12 g/dL • For zidovudine-related anemia in members with HIV: HgB ≤ 12 g/dL • For ribavirin-induced anemia: HgB ≤ 12 g/dL • An increase in dose has not occurred more than once every 4 weeks • Dose continues to be appropriate per label or supported by compendia/standard of care guidelines If all of the above criteria are not met for initial or re-authorization, the request is referred to a Clinical Reviewer for medical necessity review
Last Review Date	9/20249/2025

Recommendation: No changes

Iron-containing Products	
Medications	Injectafer (ferric carboxymaltose) injection, solution Ferumoxytol (Feraheme) Monoferric (ferric derisomaltose)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "other criteria"
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, request may be approved for: - Injectafer: two (2) doses of up to 750mg maximum at least seven (7) days apart, or 1 dose of up to 1000mg maximum once. May reapprove for recurrent anemia - Ferumoxytol (Feraheme): 2 doses of 510mg maximum at least 3-8 days apart. May re-approve for persistent or recurrent anemia - Monoferric (ferric derisomaltose): 1 dose of up to 1000mg maximum once. May re-approve for recurrent anemia
Maximum Billable Units	Variable
Other Criteria	Initial Authorization: - Diagnosis of iron deficiency anemia - Members who have intolerance to oral iron or have tried and failed oral iron, or - Members for whom initiation of oral iron would be medically contraindicated (such as malabsorption syndromes, severe blood loss, etc.) or - Members is a dialysis patient - Medication is being prescribed at an age appropriate FDA approved dose or is supported by compendia or standard of care guidelines - The member has tried and failed, has an intolerance, or inability to use one of the following: iron dextran (Infed), iron sucrose (Venofer), or sodium ferric gluconate complex (Ferrlecit) OR - Diagnosis of iron deficiency in adult patients with heart failure and New York Heart Association class II/III (Injectafer only) Re-authorization: - Medication is being prescribed at an FDA approved dose or is supported by compendia or standard of care guidelines - Documentation provided that member had a positive response to therapy (as evidenced by improved lab values such as hemoglobin, ferritin, transferrin saturation) but continues to have iron deficiency or iron deficiency anemia If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last Review Date	9/20249/2025

Recommendation: No changes

Tepezza	
Medications	Tepezza (teprotumumab-trbw)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "other criteria"
Age Restrictions	Member must be 18 years age or older
Prescriber Restrictions	Prescriber must be an ophthalmologist or endocrinologist
Coverage Duration	If all of the criteria are met, the request will be approved for up to 24 weeks of treatment (8 total infusions). Retreatment requests will not be allowed beyond the 8 dose limit.
Maximum Billable Units	Variable
Other Criteria	Initial Authorization: Tepezza is approved when all of the following are met: • Dosing does not exceed dosing guidelines as outlined in the package insert • Member has a confirmed diagnosis of Graves' disease • Documentation of moderate-severe thyroid eye disease as evidenced by one or more of the following: ○ Lid retraction of >2mm ○ Moderate or severe soft-tissue involvement ○ Proptosis ≥3mm above normal values for race and sex ○ Periodic or constant diplopia • Member must be euthyroid or thyroxine and free triiodothyronine levels are less than 50% above or below normal limits (submit laboratory results with request) • Members of reproductive potential: attestation the member is not pregnant, and appropriate contraception methods will be used before, during, and 6 months after the last infusion • Member has had a trial and therapy failure of, or contraindication to: ○ For active disease: oral or IV glucocorticoids ○ For chronic/inactive disease: rehabilitative surgery Re-authorization: • Retreatment or renewal requests beyond a total of 24 weeks of treatment (8 total infusions) will not be allowed. If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last Review Date	9/20249/2025

Recommendation: No changes

B-Cell Maturation Antigen (BCMA) Directed Chimeric Antigen Receptor (CAR) T-Cell Therapy	
Medications	Abecma (idecabtagene vicleucel), Carvykti (ciltacabtagene autoleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "Other Criteria" below
Age Restrictions	Member must be 18 years or older Check AAH active CCS cases for members < 21 years of age for MCAL
Prescriber Restrictions	Prescriber must be an oncologist, hematologist or other appropriate specialist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one –time infusion per lifetime.
Maximum Billable Units	Variable
Other Criteria	<u>Initial Authorization</u> - Member has a diagnosis of relapsed or refractory multiple myeloma (RRMM) - For Abecma, member must have also received at least 2 prior lines of therapy including: - An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide) - A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib) - An anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab) - For Carvykti, member must also be refractory to lenalidomide AND have received at least 1 prior line of therapy including: - An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide) - A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib) - Member does not have an active infection or inflammatory disorder - Member will be screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines - Member will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment - Member has not previously received a BCMA CAR-T therapy <u>Re-authorization:</u> - Treatment exceeding 1 dose per lifetime will not be authorized. If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last Review Date	~~9/2024~~ 9/2025

Recommendation: No changes

Gene Therapy for Hemophilia B	
Medications	Hemgenix (etranacogene dezaparvovec), Beqvez (fidanacogene elaparvovec-dzkt)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	Patient has previously received treatment with Hemgenix or Beqvez
Required Clinical Information	See “Other Criteria” below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age for MCAL Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment for one gene therapy agent for Hemophilia B
Maximum Billable Units	Variable
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of Hemophilia B (congenital Factor IX deficiency) with ONE of the following: ○ Currently using Factor IX prophylaxis therapy ○ Has current or historical life-threatening hemorrhage ○ Has repeated, serious spontaneous bleeding episodes • Documentation that patient has $\leq 2\%$ of normal circulating Factor IX) • Prescriber attests they have performed liver health assessments, including enzyme testing and hepatic ultrasound and elastography • Documented Factor IX inhibitor titer test showing the patient is negative for Factor IX inhibitors • For Beqvez: Patient does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test • Patient’s weight • Medication is prescribed at an FDA approved dose and for FDA indication The safety and effectiveness of repeat administration of Hemgenix or Beqvez have not been evaluated and will not be approved. If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last Review Date	9/20249/2025

Recommendation: No changes

Fecal microbiota	
Medications	Rebyota (fecal microbiota, live-jslm) Vowst (fecal microbiota spores, live-brpk)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for Healthcare Professional (USP DI), and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	Treatment of Clostridioides difficile infection (CDI)
Required Clinical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	N/A
Coverage Duration	If all the criteria are met, the request will be approved for 1 treatment course
Maximum Billable Units	Variable
Other Criteria	<u>Initial Authorization:</u> - Medication is prescribed at an FDA approved dose - Diagnosis of at least 1 recurrent episode of CDI (≥ 2 total CDI episodes) - Current episode of CDI must be controlled (< 3 unformed/loose stools/day for 2 consecutive days) - Positive stool test for C. difficile within 30 days before prior authorization request - Administration will occur 24–72 hours following completion of antibiotic course for CDI treatment - For Vowst only: confirmation patient will bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst *Rebyota and Vowst are limited to 1 treatment course* If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review
Last Review Date	9/20249/2025

Recommendation: No changes

Omisirge	
Medications	Omisirge (omidubicel-onlv)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patient has previously received this medication
Required Clinical Information	See "other criteria"
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescribed by an oncologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment.
Maximum Billable Units	Variable
Other Criteria	Initial Authorization: • Patient has a hematologic malignancy planned for umbilical cord blood transplantation (UCBT) following myeloablative conditioning • Prescriber attests that the patient is eligible for myeloablative allogeneic hematopoietic stem cell transplantation (HSCT) AND does not have a readily available matched related donor, matched unrelated donor, mismatched unrelated donor, or haploidentical donor • Patient has not received a prior allogeneic HSCT • Patient does not have known allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material The safety and effectiveness of repeat administration of Omisirge have not been evaluated and will not be approved. If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last Review Date	9/20249/2025

Recommendation: No changes

Qalsody (tofersen)	
Medications	Qalsody (tofersen)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	See "other criteria"
Required Clinical Information	See "other criteria"
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescribed by a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS)
Coverage Duration	If the criteria are met, the initial request will be approved for up to a 6 month duration; reauthorization requests will be approved for up to 6 months.
Maximum Billable Units	Variable
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of ALS • Documentation of genetic test confirming a mutation in the superoxide dismutase 1 (SOD1) gene • Member is not dependent on invasive ventilation or tracheostomy • Documentation of slow vital capacity (SVC) $\geq 50\%$ • Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> • Documentation or provider attestation of positive clinical response (e.g., reduction in the mean concentration of neurofilament light [NfL] chains in the plasma, reduction in concentration of SOD1 in cerebrospinal fluid (CSF), or improvement in the Revised ALS Functional Rating Scale (ALSFRS-R) total score) • Member is not dependent on invasive ventilation or tracheostomy • Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last Review Date	9/20249/2025

Recommendation: No changes

Lamzede	
Medications	Lamzede (velmanase alfa-tycv)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "other criteria"
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescribed by a specialist in the treatment of alpha-mannosidosis or other lysosomal storage disorders
Coverage Duration	If all of the criteria are met, the request will be approved for 12 months.
Maximum Billable Units	Variable
Other Criteria	Initial Authorization - Diagnosis of alpha-mannosidosis as confirmed by one of the following: - Deficiency in alpha-mannosidase enzyme levels or activity in blood leukocytes - DNA testing - Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis - Prescriber attests patient can walk without support - Patient's weight - Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines Reauthorization - Patient has demonstrated a clinical response (i.e., reduction in serum oligosaccharide concentrations, stabilization or improvement in 3-minute stair climbing test [3MSCT], 6-minute walking test [6-MWT], forced vital capacity [FVC], etc.) - Prescriber attests that medication will only be used to treat non- central nervous system manifestations of alpha-mannosidosis - Prescriber attests patient can walk without support - Patient's weight - Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last Review Date	9/20249/2025

Recommendation: No changes

Enzyme Replacement Therapies for Fabry Disease	
Medications	Fabrazyme (agalsidase beta) Elfabrio (pegunigalsidase alfa)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "other criteria"
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescribed by a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease
Coverage Duration	If the criteria are met, the initial request will be approved for up to a 6 month duration; reauthorization requests will be approved for up to 12 months.
Maximum Billable Units	Variable
Other Criteria	Initial Authorization: - Male members must have a documented diagnosis of Fabry disease confirmed by <u>one</u> of the following: - An undetectable (<1%) alpha galactosidase A (alpha-Gal-A) activity level OR - A deficient alpha-Gal-A activity level AND a documented detection of pathogenic mutations in the galactosidase alpha (GLA) gene by molecular genetic testing - Female members must have a documented diagnosis of Fabry disease confirmed by detection of pathogenic mutations in the GLA gene by molecular genetic testing AND evidence of clinical manifestation of the disease (e.g. kidney, neurologic, cardiovascular, gastrointestinal) - Member must not be using concurrently with Galafold (migalastat) - Documentation of the member's current weight - Request is for an FDA-approved dose Re-Authorization: - Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function, or has remained asymptomatic - Member must not be using concurrently with Galafold (migalastat) - Documentation of the member's current weight - Request is for an FDA-approved dose If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last Review Date	9/20249/2025

Recommendation: No changes

Roctavian	
Medications	Roctavian (valoctocogene roxaparvovec-rvox)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Prior use of gene therapy for Hemophilia A
Required Clinical Information	See "other criteria"
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescriber must be a hematologist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment
Maximum Billable Units	Variable
Other Criteria	<u>Initial Authorization:</u> • Diagnosis of severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) • Documentation of a current prophylactic regimen of Factor VIII infusions or bispecific monoclonal antibodies (i.e. Hemlibra) • Documented FDA-approved anti-AAV5 antibody test showing the patient is negative for anti-AAV5 antibodies • Documented Factor VIII inhibitor titer test showing the patient is negative for Factor VIII inhibitors • Prescriber attestation of performed liver health assessments • Patient weight • Medication is prescribed at an FDA approved dose The safety and effectiveness of repeat administration of Roctavian has not been evaluated and will not be approved. If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last Review Date	9/20249/2025

Recommendation: No changes

Enzyme replacement therapy for acid sphingomyelinase deficiency (ASMD)	
Medications	Xenpozyme (olipudase alfa-rpcp)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "other criteria"
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Specialists experienced in the treatment of ASMD
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Maximum Billable Units	Variable
Other Criteria	<u>Initial Authorization:</u> - Medication is prescribed at an FDA approved dose - Member has a diagnosis of ASMD confirmed by one of the following: - Deficiency in acid sphingomyelinase (ASM) enzyme activity (as measured by peripheral blood leukocytes, cultured skin fibroblasts, or dried blood spots) - Sphingomyelin phosphodiesterase-1 (SMPD1) gene mutation - Member has a clinical presentation consistent with ASMD type B or type A/B - Documentation of members height and weight - Documentation of baseline ALT and AST within 1 month prior to initiation of treatment <u>Re-Authorization:</u> - Documentation or provider attestation of positive clinical response (i.e. improvement in splenomegaly, hepatomegaly, pulmonary function, etc.) - Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last P&T Review Date	9/20249/2025

Recommendation: No changes

Rytelo (imetelstat)	
Medications	Rytelo (imetelstat)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "Other Criteria" below
Age Restrictions	Member must be 18 years of age or older Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescriber must be a hematologist or oncologist
Coverage Duration	Initial requests will be approved for 6 months. Reauthorization requests will be approved for 6 months.
Maximum Billable Units	Variable
Other Criteria	Criteria for initial approval: • Diagnosis of myelodysplastic syndromes (MDS) with transfusion-dependent anemia • Myelodysplastic Syndrome Revised International Prognostic Scoring System (IPSS-R) categorization as low or intermediate-1 risk of progression • Member has transfusion burden of 4 or more red blood cell (RBC) units within an 8 week period over the last 4 months • Prescriber attestation that complete blood cell count (CBC) will be obtained prior to initiation, weekly for first two cycles, and prior to each cycle thereafter • Member's weight has been provided with request • Medication is prescribed at an FDA approved dose Reauthorization: • Documentation or provider attestation of reduction in RBC transfusion burden as compared with baseline • Provider attestation that patient is tolerating the medication and is not experiencing any serious adverse reactions • Member's weight has been provided with request • Medication is prescribed at an FDA approved dose If all of the above criteria are not met for initial or re-authorization, the request is referred to a Clinical Reviewer for medical necessity review
Last Review Date	9/20249/2025

Alameda Alliance for Health (IHSS)

Q3 2025 INTERIM FORMULARY UPDATES

These changes have been made to the Alliance's formulary recently. The changes were necessary to enhance the formulary.

Medication	Formulary Change
Embecta Pen Needle U/F Miscellaneous 31G X 5 MM	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 31G X 5/16" 0.5 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 31G X 5/16" 1 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 31G X 15/64" 0.5 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 31G X 15/64" 1 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U-100 Miscellaneous 27G X 5/8" 1 ML	NF to F-QL (200 EA per 30 days)
Embecta Pen Needle U/F Miscellaneous 31G X 8 MM	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 31G X 5/16" 0.3 ML	NF to F-QL (200 EA per 30 days)
Embecta Ins Syr U/F 1/2 Unit Miscellaneous 31G X 5/16" 0.3 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U-100 Miscellaneous 28G X 1/2" 1 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe Miscellaneous 28G X 1/2" 1 ML	NF to F-QL (200 EA per 30 days)
Embecta Pen Needle U/F Miscellaneous 32G X 6 MM	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 31G X 15/64" 0.3 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 30G X 1/2" 0.5 ML	NF to F-QL (200 EA per 30 days)
Embecta Pen Needle U/F Miscellaneous 29G X 12.7MM	NF to F-QL (200 EA per 30 days)
Embecta Ins Syr U/F 1/2 Unit Miscellaneous 31G X 15/64" 0.3 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe Miscellaneous 28G X 1/2" 0.5 ML	NF to F-QL (200 EA per 30 days)
Embecta Pen Needle Nano 2 Gen Miscellaneous 32G X 4 MM	NF to F-QL (200 EA per 30 days)
Embecta Pen Needle Nano Miscellaneous 32G X 4 MM	NF to F-QL (200 EA per 30 days)
Embecta AutoShield Duo Miscellaneous 30G X 5 MM	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 30G X 1/2" 1 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 30G X 1/2" 0.3 ML	NF to F-QL (200 EA per 30 days)
Eltrombopag Olamine Oral Tablet 12.5 MG	NF to F-PA
Eltrombopag Olamine Oral Tablet 50 MG	NF to F-PA
Eltrombopag Olamine Oral Tablet 75 MG	NF to F-PA
Eltrombopag Olamine Oral Tablet 25 MG	NF to F-PA
Promacta Oral Tablet 12.5 MG	F-PA to NF
Promacta Oral Tablet 50 MG	F-PA to NF
Promacta Oral Tablet 75 MG	F-PA to NF
Promacta Oral Tablet 25 MG	F-PA to NF
Phentermine-Topiramate Oral Capsule Extended Release 24 Hour 3.75-23 MG	NF to F-PA

Medication	Formulary Change
Phentermine-Topiramate Oral Capsule Extended Release 24 Hour 7.5-46 MG	NF to F-PA
Phentermine-Topiramate Oral Capsule Extended Release 24 Hour 11.25-69 MG	NF to F-PA
Phentermine-Topiramate Oral Capsule Extended Release 24 Hour 15-92 MG	NF to F-PA
Qsymia Oral Capsule Extended Release 24 Hour 3.75-23 MG	F-PA to NF
Qsymia Oral Capsule Extended Release 24 Hour 7.5-46 MG	F-PA to NF
Qsymia Oral Capsule Extended Release 24 Hour 11.25-69 MG	F-PA to NF
Qsymia Oral Capsule Extended Release 24 Hour 15-92 MG	F-PA to NF
Edurant PED Oral Tablet Soluble 2.5 MG	NF to F
Emtricitab-Rilpivir-Tenofovir DF Oral Tablet 200-25-300 MG	NF to F
Complera Oral Tablet 200-25-300 MG	F to NF
Yeztugo Subcutaneous Solution 463.5 MG/1.5ML	NF to F
Yeztugo Oral Tablet 300 MG	NF to F
Afluria Intramuscular Suspension	NF to F-QL-AL (1 fill per 270 days, 12 years and above)
Afluria Preservative Free Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 12 years and above)
Fluad Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 65 years and above)
Fluarix Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 12 years and above)
Flublok Intramuscular Solution Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 12 years and above)
Flucelvax Intramuscular Suspension	NF to F-QL-AL (1 fill per 270 days, 12 years and above)
Flucelvax Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 12 years and above)
Flulaval Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 12 years and above)
FluMist Nasal Liquid	NF to F-QL-AL (1 fill per 270 days, 12 - 49 years)
Fluzone High-Dose Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 65 years and above)
Fluzone Intramuscular Suspension	NF to F-QL-AL (1 fill per 270 days, 12 years and above)
Fluzone Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 12 years and above)
PenmenVyr Intramuscular Suspension Reconstituted	NF to F-QL-AL (1 vial per 1 fill, 2 fills per lifetime, 10-25 years)
mNexspike Intramuscular Suspension Prefilled Syringe 10 MCG/0.2ML	NF to F

Medication	Formulary Change
mNexspike Intramuscular Suspension Prefilled Syringe 10 MCG/0.2ML	NF to F
mNexspike Intramuscular Suspension Prefilled Syringe 10 MCG/0.2ML	NF to F

Alameda Alliance for Health Q3 2025 PAD Updates

This list only includes summary of changes to prior authorization (PA) for physician administered drugs for quarter 3 2025 and is not comprehensive.

HCPCS Code	HCPCS Description	Action
Q5154	OMLYCLO (OMALIZUMAB-IGEC)	Add PA
Q5159	OSPOMYV AND XBRYK (DENOSUMAB-DSSB)	Add PA
Q5158	BOMYNTRAV AND CONEXXENCE (DENOSUMAB-BNHT)	Add PA
Q5157	STOBOCLO AND OSEVELT (DENOSUMAB-BMWO)	Add PA
Q5155	YESAFILI (AFLIBERCEPT-JBVF)	Add Pa
Q5156	AVTOZMA (TOCILIZUMAB-ANOH)	Add PA
J3402	RYONCIL (REMESTEMCEL-L-RKND)	Add PA
J7173	ALHEMO (CONCIZUMAB-MTCI)	Add PA
J3403	ENCELTO (REVAKINAGENE TARORETCEL-LWEY)	Add PA
J7174	QFITLIA (FITUSIRAN)	Add PA
J9011	DATROWAY (DATOPOTAMAB DERUXTECAN)	Add PA
J0614	GRAFAPEX (TREOSULFAN)	Add PA
J1809	NULIBRY (FOSDENOPTERIN)	Add PA
J9045	CARBOPLATIN (PARAPLATIN)	Remove PA
J9060	CISPLATIN (PLATINOL)	Remove PA
J9171	DOCETAXEL (TAXOTERE)	Remove PA
J9201	GEMCITABINE HCL (GEMZAR)	Remove PA
J9263	OXALIPLATIN (ELOXATIN)	Remove PA
J9267	PACLITAXEL (TAXOL)	Remove PA
J9035	BEVACIZUMAB (AVASTIN)	Remove PA



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POLICY AND PROCEDURE

Policy Number	RX-007
Policy Name	Pharmaceutical Patient Safety, Drug Recalls, Quality Assurance
Department Name	Pharmacy Services
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy Services
Line(s) of Business	Medi-Cal, D-SNP, IHSS
Effective Date	05/01/2012
Administrative Oversight Committee Approval Date	5/21/2025

POLICY STATEMENT

This policy documents Alameda Alliance for Health (Alliance) Pharmacy Department patient safety procedures and functions.

The Alliance works closely with its Pharmacy Benefit Manager (PBM) to ensure proper patient safety protocols are available and practiced to prevent patient safety issues related to pharmaceutical services.

The Alliance has adapted The National Coordinating Council for Medication Error Reporting and Prevention's (NCC MERP) definition of "medication error," which is:

"A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use."

PROCEDURE

Pharmacy Benefit Drug Recalls and Withdrawals Procedure

- A. The Food and Drug Administration (FDA) has three (3) different types of recalls, based on the potential severity of harm to the public.
 - 1. Class I: dangerous or defective products that may cause serious health problems or even death
 - 2. Class II: less dangerous products than Class I, that may cause only temporary health problems
 - 3. Class III: products for which use or exposure is not likely to cause adverse health consequences
- B. Market withdrawal or voluntary recall is a removal of a marketed product that FDA considers to be in violation of the laws it administers and against which it would initiate legal action (e.g., seizure).
- C. Alliance's PBM checks FDA drug recall notifications and generates member impact reports using claims data. The reports contain the member and prescriber mailing information, describe the withdrawal, recommend contacts for further information, and instruct how to dispose of remaining recalled product.
- D. Drug recall notifications are sent to impacted members and prescribers. Alliance will notify members within 48 hours for Class I and within 30 days for Class II recalls/withdrawals. Class III recalls are not acted upon. The Alliance will not act on limited FDA withdrawal impacting specific lots of products. The PBM does not collect product lot numbers and it is not possible to identify utilization by members.
- E. The process for market withdrawal involves the following formulary management actions:
 - 1. PBM provides the Alliance with a supplemental drug update, which is a specific communication regarding a change to the FDA status of a medication. This recall notice must be received within 48 business hours of initial notice from FDA.
 - 2. All records in National Drug Data File (NDDF) are terminated by setting the recall/withdrawal flag.
 - 3. Product is terminated from Alliance formularies.
 - 4. Product is terminated from all applicable drug management programs.
 - 5. Prior Authorizations for affected product are terminated.

Medical Benefit Drug Recalls and Withdrawals Procedure

- A. Pharmacy Technicians check shared email inbox < D4@alamedaalliance.org > for FDA Recall Alerts. Lot specific recalls are not acted upon because the Alliance does not know which members and providers may have encountered a specific lot. Class III recalls are not acted upon.
- B. The Pharmacy Department works with the Analytics Department to identify members and prescribing providers impacted for recalls classified as Class I, Class II and Market Withdrawals recall.
 - i. Impacted members are those who have a medical claim for the recalled physician administered drug within 180 days prior to the recall.
 - ii. Impacted prescribing providers are those who submitted a medical claim for the recalled physician administered drug within 180 days prior to the recall on a medical claim.
- C. Using the results from the Analytics Department, the Pharmacy Department sends the impacted member and prescriber lists to Provider Services and Communications & Outreach to ensure impacted members and providers will be notified by letter. The letter will contain the summary details of the recall, including drug name, strength, manufacturer, NDC number(s), whom to contact with further concerns, and how to dispose of remaining recalled product (if applicable).
 - a. For Class I recalls, Alliance will notify impacted members and prescribers by letter within 15 calendar days or less of the FDA notice.
 - b. For Class II recalls or Market Withdrawals, Alliance will notify impacted members and prescribers by letter within 30 days or less of the FDA notice.

Communicating Drug Recalls and Withdrawals

- A. In addition to notifying members via letter or phone, as detailed above, the Alliance shall make public all drug recall and withdrawal information on the member plan website. The content can be located under “Safety Resources” within the “Pharmacy & Drug Benefits” section.
- B. The Pharmacy Department will forward recall notices and impact reports to Alliance departments such Provider Services, Member Services, Utilization Management and Claims Department.

Medication Error Identification and Reduction (MEIR)

- A. The Alliance may receive reports of medication errors from network pharmacies, prescribers, internal staff, and/or members.
- B. The Alliance internal staff may include but are not limited to:
 - 1. Clinicians involved in review of prior authorization requests or appeals request
 - 2. Appeals and Grievances staff
 - 3. Member service representatives
 - 4. Quality Improvement Staff
 - 5. Pharmacy Staff
- C. The Alliance staff will be trained to identify potential reportable medication errors and understand how to evaluate, resolve, document, and, if necessary, report to the appropriate authority.
- D. A report of all received medication errors is presented quarterly to the UM Committee for the purpose of documenting medication errors, identifying trends and patterns, and to determine if further action is necessary (i.e. reporting the medication error to the FDA and/or relevant State Board(s) of Pharmacy).
- E. When appropriate, reported medication errors are shared and discussed with downstream providers at the point of dispensing to ensure that corrective actions are implemented and future errors are prevented. These notifications shall be sent by mail with the option to discuss over the phone. This process shall comply with the medication error identification and reduction reporting requirements defined by Centers for Medicare and Medicaid Services (CMS), Utilization Review Accreditation Commission (URAC) and other regulatory and accreditation agencies.

Annual Patient Part D Safety Reports

CMS releases Annual Patient Safety Reports on the Patient Safety Analysis Web Portal each April. Alameda Medicare Operations will designate additional users of the Patient Safety Analysis Web Portal.

The report is updated monthly and contains an annual set of Patient Safety measures. These measure packages include a summary contract-level report for each measure and additional beneficiary-level files.

- Alliance downloads and reviews measure packages to compare performance to benchmark averages and monitor progress in improving measure rates.
- Alliance will identify members and prescribers needing outreach using the Patient Safety reports and internal analytics.

All measures are calculated based on Pharmacy Quality Alliance (PQA) measure specifications and Value Sets, which include NDCs. The PQA updates their Value Sets biannually, usually in February and July. The April year of service (YOS) reports use the most recent updated PQA NDC lists and the ICD-10 diagnoses codes for both current and prior year data. Between NDC list updates, Alliance may observe differences between their internal monitoring reports and the Patient Safety reports, especially if applying more real-time NDC changes or capturing PDE data not yet submitted to or processed by CMS.

The Patient Safety Analysis Web Portal facilitates communication between CMS, Part D plan sponsors, and Acumen, LLC. Alliance can view “at-a-glance” Rate Summary and Performance Graphs for each measure and respond directly to outlier notices. Alliance may review their underlying measure data in the reports and alert CMS if potential errors or anomalies are identified in the rate calculations per the measure specifications. For questions regarding rate calculations, diagnosis codes, exclusions, or underlying data, Alliance may contact PatientSafety@AcumenLLC.com.

Overutilization Monitoring System / Drug Management Program Policy Statement on Drug Management Programs (DMPs):

In accordance with CMS regulations and the 2025 Part D DMP Guidance, Alliance shall implement a Drug Management Program to identify and manage beneficiaries at risk for misuse or abuse of frequently abused drugs (FADs), specifically opioids and benzodiazepines. Alliance will utilize CMS’s Overutilization Monitoring System (OMS) criteria to identify Potential At-Risk Beneficiaries (PARBs) and, through the delegated PBM, conduct thorough case management to determine At-Risk Beneficiaries (ARBs). Case management will include clinical outreach to prescribers, verification of risk, and documentation of prescriber agreement when applicable. Beneficiaries identified as ARBs may be subject to coverage limitations, including point-of-sale (POS) claim edits, prescriber limitations, and/or pharmacy limitations, with consideration for beneficiary preferences and reasonable access.

Operational Requirements and Compliance:

Alliance or its delegated PBM will ensure that all DMP activities are supported by written policies and procedures, approved by the appropriate clinical oversight committee, and executed by licensed clinical staff. The plan will comply with all notification requirements, including timely issuance of Initial and Second Notices, and will provide beneficiaries with appeal rights as outlined in 42 CFR § 423.580. Exempted beneficiaries—such as those receiving hospice care, cancer-related pain treatment, or residing in long-term care facilities—will be excluded from DMPs upon reliable identification. The plan will report all relevant data to CMS via OMS and MARx systems within required timeframes and will coordinate with other sponsors to ensure continuity of care for beneficiaries transitioning between plans.

PARB Identification Criteria

Minimum OMS Criteria

- Opioid use >90 MME/day from multiple prescribers/pharmacies.
- History of opioid-related overdose + recent opioid prescription.

Supplemental OMS Criteria

- Use of opioids from ≥ 7 prescribers or pharmacies, regardless of MME.

Exemptions

Beneficiaries are **exempt** from DMPs if they:

- Are treated for cancer-related pain.
- Receive hospice or palliative care.
- Reside in LTC facilities with single-pharmacy contracts.
- Have sickle cell disease.

Case Management Requirements

- Clinical staff must contact prescribers to verify risk and discuss limitations.
- Sponsors must document outreach and prescriber responses.
- If prescribers are unresponsive after 3 attempts in 10 business days, sponsors may proceed with POS edits.

Beneficiary Notices

1. **Initial Notice:** Sent after case management, outlines intended limitations.
2. **Second Notice:** Sent if limitation is implemented.
3. **Alternate Second Notice:** Sent if no limitation is imposed or beneficiary is exempt.

Coverage Limitations

Sponsors may impose:

1. **POS Claim Edits:** Limit drug types or dosages.
2. **Prescriber Limitations:** Restrict to selected prescribers.
3. **Pharmacy Limitations:** Restrict to selected pharmacies.

Prescriber/Pharmacy Selection

- Beneficiary preferences are prioritized unless they conflict with network policies or risk mitigation.
- Sponsors must ensure **reasonable access** based on geography, health needs, and usage patterns.

Appeals and Extensions

- Beneficiaries may appeal within 60 days of the Second Notice.
- Coverage limitations may be extended for up to 2 years with clinical justification and prescriber agreement.
- Alliance's PBM is delegated for ARB Appeals

Data Reporting

- Sponsors must report case management and coverage decisions to CMS via OMS and MARx.
- Timely data sharing between sponsors is required when beneficiaries change plans.

DEFINITIONS / ACRONYMS

ARBs (At-Risk Beneficiaries): Confirmed through case management and subject to coverage limitations.

CMS: Centers for Medicare and Medicaid Services

DMP: Drug Management Program

FAD(s): Frequently Abused Drugs

FDA: Food and Drug Administration
MARx: Medicare Advantage and Prescription Drug system used by the Centers for Medicare & Medicaid Services (CMS)
MME: Morphine Milligram Equivalents
NCC MERP: National Coordinating Council for Medication Error Reporting and Prevention.
NCQA: National Committee on Quality Assurance
NDC: National Drug Code
NDDF: National Drug Data File
OMS: Overutilization Monitoring System
PARBs (Potential At-Risk Beneficiaries): Identified via CMS's Overutilization Monitoring System (OMS) or prior plan data.
PBM: Pharmacy Benefit Manager (Currently, PerformRx)
POS: Point of Service
URAC: Utilization Review Accreditation Commission

AFFECTED DEPARTMENTS/PARTIES

Pharmacy Department
Pharmacy Benefit Manager (PerformRx)
Provider Relations
Quality Improvement
Member Services
Analytics
Communications & Outreach

RELATED POLICIES AND PROCEDURES

P&T Charter

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

REVISION APPROVAL HISTORY

5/1/2012, 5/19/2016, 12/11/2018, 11/13/2020, 3/16/2021, 6/21/2022, 3/28/2023, 4/10/2024, 5/21/2025, 9/3/2025

REFERENCES

- CMS Part D Manual, Chapter 7 – Prescription Drug Benefit Manual, section 20.5 – Medication Error Identification and Reduction (MEIR)
- PerformRx Policy, DRUM-1-02 - Internal Medication Error Identification and Reduction Systems
- NCQA 2026, UMA 4, Element I
- DHCS All Plan Letter 20-020 Governor's Executive Order N-01-19, regarding Transitioning Medi-Cal Pharmacy Benefit from Managed Care to Medi-CalRx
- DMHC APL 20-035 (OPL): Medi-Cal Pharmacy Benefit Carve Out – Medi-Cal Rx
- Food and Drug Administration (FDA) Recalls, Corrections and Removals
- <https://www.cms.gov/files/document/2025-patient-safety-memo-202504.pdf>
- 42 CFR§ 423.153(f)(2) - requirements for case management, clinical contact, and prescriber verification for the purposes of DMPs

MONITORING

This policy will be reviewed annually to ensure effectiveness by P&T Committee.



POLICY AND PROCEDURE

Policy Number	RX-D-008
Policy Name	Part D Coverage Determinations
Department Name	Pharmacy Services
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy Services
Line(s) of Business	D-SNP
Effective Date	TBD
Subcommittee Name	Pharmacy and Therapeutics Committee
Subcommittee Approval Date	TBD
Administrative Oversight Committee Approval Date	TBD

POLICY STATEMENT

The purpose of this document is to describe Medicare Part D coverage determination and exceptions policy and procedures for Alameda Alliance for Health (the “Alliance”) Pharmacy staff to help ensure compliance with all applicable federal and state laws and CMS requirements.

The Medicare Part D coverage determination and exceptions process adheres to specific CMS requirements to ensure the protection of Medicare beneficiary rights and establish a standard for addressing and responding timely to coverage determination requests.

PROCEDURE

The Alliance and/or its contracted PBM has established and maintains procedures for accepting oral, written, faxed and electronic coverage determination requests; review, processing, provider outreach, appropriate decision making and member/provider notification in accordance with current CMS requirements.

1. Types of coverage determinations (CDs):
 - a. A decision about whether to provide or pay for a drug, including a decision related to:

- i. A medication that is not on the Alliance/PBM formulary (non-formulary);
 - ii. A medication determined not to be medically necessary;
 - iii. A medication furnished by an out-of-network pharmacy (reimbursement request); or
 - b. A decision on cost share for a drug (tiering request);
 - c. Decision regarding satisfaction of utilization management (UM) requirements including prior authorization (PA), step-therapy (ST), or quantity limits (QL);
2. Exception requests are when the enrollee requests the plan waive requirements. If the Alliance/PBM is unable to determine if an enrollee or prescriber is asking for an exception to criteria, the case will be treated as an attempt to satisfy UM criteria. Types of exception requests include:
- i. A decision regarding a tiering exception request;
 - ii. A decision regarding a formulary exception request;
3. Who can make a request for a coverage determination?
- a. An enrollee;
 - b. A prescribing physician (or other prescriber); or
 - c. An enrollee's appointed representative;
4. The duration of the approval for an exception is one year from the decision date and the duration of approval of satisfying a UM requirement is dictated by the duration submitted to CMS.
5. Once an adverse coverage determination has been made, the appeals (redetermination) process may be triggered. If a Part D member disputes an adverse coverage determination, the case is handled according to the Medicare appeals process. If a member complains about any other aspect of the Alliance operations (e.g., the manner in which a benefit was provided), the Alliance addresses the issue through the grievance process.
6. When the Alliance/PBM decides not to provide or pay for a requested benefit, in whole or in part, the decision is an adverse coverage determination. If the Alliance makes an adverse coverage determination, a written denial notice that includes appeal rights must be provided to the member.
7. The Alliance does not treat the presentation of a prescription at the pharmacy counter as a request for a coverage determination. The Alliance/PBM will never extend the applicable adjudication timeframe by dispensing a temporary supply of the requested medication. For example, if the Alliance receives a request outside of its normal business hours, it cannot approve a temporary 72-hour supply of the requested

medication and defer issuing a decision for 72 hours; a determination will always be made within the appropriate timeframe.

8. The Alliance/PBM can accept coverage determination requests from members and prescribers via phone, fax, or electronically 24 hours a day, 7 days a week, including holidays.
9. Alliance' PBM is delegated to approve, modify, and deny coverage determination requests. The PBM operates 7-days a week with clinical pharmacists available to decide coverage determination requests within the turnaround time.

4.1 PROCEDURES FOR STANDARD COVERAGE DETERMINATION

1. The turnaround timeframe for a standard coverage determination is 72 hours beginning with the date and time the coverage determination request is received by the Alliance/PBM. The Alliance/PBM works within this time frame for a standard coverage determination. Procedures and timeframes related to coverage determinations for direct member reimbursement are discussed in Section 4.4 Procedures for Reimbursement Requests.
2. The Alliance/PBM will make a total of three (3) attempts within the first 48 hrs hours from the time the request was received from the member, provider or other prescriber, by phone or facsimile, to collect additional information needed to make a decision from the prescriber; each outreach is entered in the PBM's Coverage Determination tracking system. The Alliance/PBM may use a CMS model request form to request the information.
3. Requests- A member, member's authorized representative, or member's prescribing physician or other prescriber may request a standard coverage determination by phone or in writing. If the drug has a UM edit, the coverage determination request for the drug needs medical documentation to support the request. Request should include:
 - a. Member information, such as name, member ID, and date of birth;
 - b. Requesting prescriber name, telephone and fax numbers;
 - c. The pharmacy where the claim was denied: pharmacy name, telephone and fax numbers;
 - d. Drug(s) requested with dispensing information, dosage and frequency, drug strength, quantity, duration, and number of refills if needed; and
 - e. Diagnosis and history including formulary medications tried and medical justification for the use of drug(s) requested.
4. The Alliance/PBM makes available on its website a medication request form should the prescriber choose to use it for a coverage determination request; however, the Alliance/PBM does not require a coverage determination request to be made on a specific form. Members calling into the Alliance/PBM member call center will have their request for a coverage determination documented as to time and date.

5. Upon receipt of the request by the Alliance Pharmacy Operations/PBM, a pharmacist or pharmacy technician reviews the submitted information and attempts to collect necessary information to determine if the submitted information is insufficient for a coverage determination. The pharmacist or pharmacy technician adheres to the timeline for a standard coverage determination beginning with the date and timestamp when the request was initially received.
6. The Alliance will place at least one outbound call to a member or a member's appointed representative (if applicable), before a coverage determination decision is made. Outbound calls to members or member's appointed representative by a pharmacy technician or a pharmacist are documented in the PBM Coverage Determination tracking system with date and timestamp and a brief description of the call content.
7. Notification Considered Delivered by health plan
 - a. Verbal notification is considered delivered on the date and time an Alliance/PBM representative speaks to or leaves a voicemail for the enrollee or their representative.
 - b. If verbal notification was successfully provided, the plan must send written notification within three (3) calendar days of the verbal notice. If unable to provide verbal notification, then written notice must be provided within the standard timeframe of 72 hrs. from receipt of request.
 - i. Written notification is also sent via fax to the prescriber concurrently with the member written notification.
 - ii. If applicable, written notification is also sent electronically to the prescriber through the electronic Prior Authorization platform.
8. Approvals-All favorable coverage determinations are entered into the PBM claim system with an override and duration of therapy to effectuate the approval. A test claim should be run to ensure the approved medication will process as expected.
 - a. The Alliance/PBM uses the CMS approved coverage determination notice. The approval letter clearly informs the member of the duration of therapy, conditions of the approval, if any, and coverage rules pertaining to subsequent refills, if applicable.
 - b. An approval letter is generated and sent to the member within the coverage determination timeframe. Outbound calls to members are placed to ensure compliance with the timeframe for a standard coverage determination.
 - c. The approval letter is addressed to the member with a facsimile copy provided to his/her appointed representative and the prescriber requesting the coverage determination.
9. Denials-All adverse or denied coverage determination decisions are entered into PBM coverage determination tracking system for documentation.

- a. The Alliance/PBM uses the CMS approved model letter for denial. A denial letter is generated and sent to the member or their authorized representative within the coverage determination timeframe. Outbound calls to members are placed within the 72 hour timeframes to ensure compliance.
- b. The denial letter is sent to the requesting prescriber.
- c. The denial letter includes:
 - i. The specific reason for the denial taking into account the member's present medical condition, disabilities, and special language requirements, if any.
 - ii. Information regarding the right to appeal or appoint a representative to file an appeal on the member's behalf.
 - iii. A description of any applicable Medicare coverage rule or any other applicable Part D plan policy upon which the denial decision was based, including any specific formulary criteria that must be satisfied for approval.
 - iv. A description of both the standard and expedited redetermination processes and time frames, including conditions for obtaining an expedited reconsideration, and the rest of the appeals process.
- d. All communications related to coverage determination should be documented with dates and times in the PBM coverage determination system.

4.2 PROCEDURES FOR EXPEDITED COVERAGE DETERMINATION

1. A member, member's authorized representative, or member's prescribing physician or other prescriber may request an expedited coverage determination by phone or in writing.
2. The Alliance/PBM treats any request marked as "urgent, stat, ASAP or expedited" as an expedited coverage determination.
3. The Alliance/PBM treats any request as an expedited coverage determination if the member or prescriber indicates, either orally or in writing, that applying the standard timeframe for making a coverage determination may seriously jeopardize the life or health of the member or the member's ability to regain maximum function.
4. The turnaround timeframe for an expedited coverage determination is 24 hours beginning with the time the request for coverage determination is received by the Alliance/PBM.
5. To meet the timeframe, the Alliance Pharmacy Operations/PBM may place one (1) outbound call to the requesting prescriber if additional information is needed to make a decision.
 - a. Outbound calls to prescribers by a pharmacist or a pharmacy technician are documented with date and timestamp and a brief description of the call content.

6. Notification Considered Delivered by health plan for expedited coverage determinations.
 - a. Verbal notification is considered delivered on the date and time an Alliance/PBM representative speaks to or leaves a voicemail for the enrollee or their representative.
 - b. If verbal notification was successfully provided, the plan must send written notification within three (3) calendar days of the verbal notice. If unable to provide verbal notification, then written notice must be provided within the expedited timeframe of 24 hrs. from receipt of request.
 - i. Written notification is also sent via fax to the prescriber concurrently with the member written notification.
 - ii. If applicable, written notification is also sent electronically to the prescriber through the electronic Prior Authorization platform.
7. Approvals-All favorable expedited coverage determinations are entered in the PBM claims adjudication system with an override and duration of therapy to effectuate the approval.
8. The Alliance uses the CMS approved coverage determination notice. The approval letter clearly informs the member of the duration of therapy, conditions of the approval, if any, and coverage rules pertaining to subsequent refills, if applicable.
9. An approval letter is generated and sent to the member with a copy provided to his/her appointed representative within the coverage determination timeframe. Outbound calls to members are placed to ensure compliance with the 24 hour timeframe for an expedited coverage determination.
10. The approval letter is sent to the prescriber requesting the PA.
11. Denials-All adverse or denied expedited coverage determination decisions are entered into the PBM Coverage Determination tracking system for documentation.
 - a. The Alliance/PBM uses the CMS approved model letter for denial. A denial letter is generated and sent to the member within the coverage determination timeframe. Outbound calls to members are placed within the 24 hour timeframes to ensure compliance.
 - b. The denial notice is sent to both the member or his/her authorized representative and the requesting prescriber.
 - c. The denial notice includes:
 - i. The specific reason for the denial taking into account the member's present medical condition, disabilities, and special language requirements, if any;
 - ii. Information regarding the right to appeal or appoint a representative to file an appeal on the member's behalf;

- iii. A description of any applicable Medicare coverage rule or any other applicable Part D plan policy upon which the denial decision was based, including any specific formulary criteria that must be satisfied for approval
- iv. A description of both the standard and expedited redetermination processes and time frames, including conditions for obtaining an expedited reconsideration, and the rest of the appeals process
- d. All communications related to coverage determination should be documented with dates and times in the PBM Coverage Determination tracking system.

4.3 PROCEDURES FOR EXCEPTION REQUESTS

1. Exception requests are coverage determination requests for non-formulary medication, tiering exceptions, and requests for exceptions to utilization management (UM) criteria.
 - a. A tiering exception is prohibited for a non-formulary drug approved under the formulary exception process.
 - b. However, an approved UM exception request for a medication may also have a tiering exception request because it is for a formulary medication.
2. Exception requests can be either standard (decision and notification within 72 hours) or expedited (decision and notification within 24 hours).
 - a. The adjudication timeframe may be tolled up to 14 (fourteen) days pending receipt of the prescriber's supporting statement. Upon receiving the initial supporting statement the Alliance/PBM must obtain any additional information, make its decision, and notify the enrollee and prescriber, as appropriate within the following timeframes:
 - i. If prescriber's supporting statement is received, the plan must make notification 24 (expedited) or 72 (standard) hours after receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first. *Refer to 40.5.4 Adjudication Timeframes for Coverage Determinations Involving an Exception.*
 - i. If the prescriber's supporting statement is not received by the end of the 14 calendar days, then notification must occur not later than 24 (expedited) or 72 (standard) hours from the end of the 14 calendar days from receipt of the exception request.
3. Non-formulary exception requests and requests for Exceptions to Prior Authorization criteria require the submission of supporting documentation which indicates that the requested medication should be approved because:
 - a. All covered Part D drugs on any tier of a plan's formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects;

- b. The number of doses available under a dose restriction for the prescription drug:
 - i. Has been ineffective in the treatment of the enrollee's disease or medical condition or;
 - ii. Based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or
 - c. The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements:
 - i. Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or
 - ii. Has caused or based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee.
 - 4. Tiering exceptions are limited to applicable cost-sharing tiers containing the same type of alternative drug(s) to treat the enrollee's condition.
 - a. Plans are not required to offer tiering exceptions for brand name drugs or biological products at a cost sharing level of alternative drugs, where the alternatives include only generic or authorized generic drugs. (This would be tier 1 – generic tier.)
 - b. Tiering Exception requests require the submission of supporting documentation which indicates that the drug in the lower cost-sharing tier for the treatment of the enrollee's condition.
 - i. Would not be as effective as the requested drug in the higher cost-sharing tier; and/or
 - ii. Would have adverse effects.
 - 5. Exception Approvals- If an exception request is approved; members or members' representatives are notified verbally within 24 hours for an expedited coverage determination and within 72 hours for a standard coverage determination.
 - a. Tiering Exception approval
 - i. When the Alliance/PBM approves a tiering exception, the Alliance/PBM will provide coverage for the drug in the higher cost-

sharing tier at the cost-sharing level that applies to the drug in the applicable lower cost-sharing tier.

- ii. Tiering exceptions cost sharing is based on Part D sponsor bid submissions: the Alliance is not required to approve a tiering exception for a drug in a higher cost-sharing tier at the generic tier cost-sharing level if the Alliance/PBM maintains a separate tier that only includes generic drugs (only medications with an FDA ANDA designation). The Alliance/PBM maintains a formulary tier which includes very high cost and unique medications designated on the specialty tier. The medications placed in the specialty tier are not eligible for a tiering exception.

b. Non-formulary Exception approval

- i. Approved formulary exceptions are granted through at least the remainder of the plan year (or 12 months) without requiring additional justification for refills or new prescriptions.
- c. The written notification of an exception request approval will be written in a manner that is understandable to the enrollee and provides the conditions of approval which would include the following:
 - i. The duration of an approval;
 - ii. Limitations associated with an approval; and/or
 - iii. Any coverage rules applicable to subsequent refills.

6. Exception Denials- The Alliance/PBM will use the standard CMS denial notice when issuing denials for coverage determination requests. The denial rationale provided in the notice will be specific to each individual case and the reason for the denial using language the enrollee can understand. The denial notice will include the following:

- a. The specific reason for the denial that considers the enrollee's presenting medical condition, disabilities, and special language requirements, if any;
- b. A description of the specific formulary criteria that must be satisfied for approval. The denial notice must explicitly state the need for a prescriber's supporting statement and clearly state the type of information that needs to be submitted when seeking a formulary or tiering exception.
 - i. For example, if the drug is subject to step therapy, the denial notice must clearly explain the step criteria and indicate that if the enrollee can't take the step drug(s), the enrollee's prescriber must submit a supporting statement explaining why the enrollee can't tolerate the step drug(s).
- c. A list of relevant formulary alternatives that the member's prescriber should consider for the member (formulary alternatives should only include medications that have the FDA labeled indication to treat the member's

condition and are in the same drug class, same dosage form and/or have the same mechanism of action).

- d. Information regarding the right to appoint a representative to file an appeal (redetermination) on the enrollee's behalf;
- e. For coverage denials, a description of both the standard and expedited redetermination processes and time frames, including conditions for obtaining an expedited reconsideration, and the rest of the appeals process; and
- f. The denial rationale must be specific to each individual case and written in language that an enrollee can understand.

7. Medical Necessity

- a. If the Alliance/PBM expects to issue a partially or fully adverse medical necessity decision based on the initial review of the request, the coverage determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the Part D plan sponsor issues the coverage determination decision.
- b. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. A pharmacist would generally be considered an appropriate health care professional for purposes of meeting this requirement.
- c. A decision to deny based on a determination that the clinical documentation supporting the coverage request is unavailable or insufficient (i.e., there is unmet criteria) is generally considered a denial based on the lack of medical necessity.
- a. The Alliance employs a medical director(s) who is responsible for ensuring the clinical accuracy of all coverage determinations and redeterminations involving Medical Necessity.

4.4 PROCEDURES FOR REIMBURSEMENT REQUESTS

Member reimbursement requests for Part D drugs purchased out of pocket must be resolved within fourteen (14) days. There is no tolling for reimbursement requests.

- 1. Alliance members may request reimbursement for Part D drugs purchased out of pocket under the following circumstances:
 - a. Drugs or vaccine medications purchased at a retail pharmacy;
 - b. Drugs received while in an observation stay at a hospital or other out-patient facility

Members will need to present their request with a list of drugs purchased and a receipt of payment. The Alliance/PBM will then consider each drug for reimbursement under the coverage determination process. Out of Network claims are limited to a thirty (30) day

supply and will be reimbursed at the Alliance/PBM's standard pharmacy reimbursement rate. The member may not be reimbursed for the full amount they paid at the pharmacy and reimbursement will be minus any required cost share or copay.

4.4.1. Requests for Reimbursement for Drugs or Vaccine Medications Purchased at a Retail Pharmacy:

A member may mail or call in a request for reimbursement for drugs they paid out of pocket for at a retail pharmacy.

- a. Before the Alliance/PBM considers reimbursement under the coverage determination process, a printout from the pharmacy with the member's name, drug and what they paid for the drug is required.
- b. If the reimbursement request is called or mailed in and the receipt and/or list of drugs is still needed, a maximum of 1 phone call attempts will be made to the member to attain this information. These attempts are call-tracked.
- c. Once the Alliance/PBM has the list of drug(s) and proof of payment, the clock starts and a reimbursement coverage determination may be started.
 - i. If the member insists that a coverage determination be started even before they have the proof of payment and itemized list to present to the Alliance/PBM, then a case will be started and reviewed based on the request alone.
 - ii. If the 14 day time limit comes before the member has provided the necessary information, the case will be decided at that time and the necessary notifications will be made. If denied, the member would need to appeal to have the case reviewed again.
- d. If the drug is approved for reimbursement, the amount owed to the member (minus any deductible and/or copay/coinsurance) will be mailed to the member via check from PBM per the next available payment cycle. The Alliance/PBM representative will process a claim in the PBM online system for the drug.
- e. A decision letter is mailed to the member.
- f. The reimbursement case is closed in the internal case documentation system.

4.4.2 Requests for Reimbursement for Self-Administered Drugs (SADs):

When a member has a stay in the hospital (or other out-patient facility) that is considered an observation stay and the hospital provides the medications, some medications may not be covered under the Part C benefit. The member submit the medication bill to the Alliance for reimbursement.

- a. Member may mail or call in a request for reimbursement for drugs they were provided at the hospital during an observation stay (not inpatient), or other outpatient facility.
- b. Before the Alliance/PBM considers reimbursement under the coverage determination process, the member must show proof of payment from the hospital or other outpatient facility via a receipt or printout. Along with the proof of payment the member must present an itemized list of drugs that they paid for with the date(s) of service.
 - i. It is possible that the member may state the amount of money they owe for their drugs is beyond what they can pay on their own.

Hardship cases will be reviewed on a case by case basis, taking into consideration the member's circumstances at that time.

- c. If the receipt and/or list of drugs is still needed, the request will be treated as an inquiry and a maximum of 1 phone call attempt will be made to the member to attain this information. These attempts are call-tracked.
- d. Once the Alliance/PBM has this information the clock starts and a redetermination coverage determination may be started.
 - i. If the member insists that a coverage determination be started even before they have the proof of payment and itemized list to present to the Alliance, then a case will be started and reviewed based on the request alone.
 - ii. If the fourteen (14) day time limit comes before the member has provided the necessary information, the case will be decided at that time and the necessary notifications will be made. If denied, the member would need to appeal to have the case reviewed again.
- e. If the drug is approved for reimbursement, the Alliance/PBM representative will process a claim in the PBM claims system for the drug(s). The amount owed to the member (minus any deductible and/or copay/coinsurance) will be mailed to the member via check from PBM per the available payment cycle.
- f. A decision letter is also mailed to the member.
- g. The reimbursement case is closed in the internal case documentation system.

4.4.3 Requests for Reimbursement with a Formulary Edit:

There will be times when a Reimbursement Request is presented for reimbursement and the medication is either non-formulary (NF) or has a formulary edit (Prior Authorization (PA), Step Therapy (ST), or Quantity Limit (QL) exception).

- a. A case is opened in the Alliance/PBM coverage determination tracking system.
- b. The receipt of the NDCs and other pertinent information specific to the case will be requested as well as receipt date and time of the exception request. A supporting statement from the prescriber must be obtained per the exception process.
- c. Once all information received is entered, the drug is sent for review by the Alliance/PBM clinical pharmacist.
- d. This decision must be made in exactly 72 hours as it will be processed under the standard coverage determination timeframe.
- e. If approved, the duration of the override follows the same process as a regular coverage determination.
- f. The request for reimbursement for this drug must then be processed and paid within the original 14 day timeframe from when the request was received.

4.4.4. Processing a Direct Member Reimbursement (DMR) Request for a Days' Supply of an Opioid Longer than 7 days:

A request for payment for any drug the enrollee believes may be covered by the plan must be processed as a coverage determination, including opioids.

- a. If the enrollee making the request was not opioid naïve, the plan should not apply the 7 day supply limit and process the request based on any other applicable plan rules and the facts and circumstances of the case.
- b. If the enrollee was opioid naïve, the Alliance/PBM will process the member reimbursement as an exception request, and request a supporting statement from the prescriber (verbal or written) attesting that the longer days' supply was medically necessary.
- c. If there are no other plan limitations on coverage, even if the longer days' supply is denied, the Alliance/PBM will cover up to a 7 days' supply, consistent with state and federal law.

4.5 PROCEDURES FOR WITHDRAWALS, DISMISSALS

Please refer to Medicare Parts C & D Enrollee Grievances, Organization /Coverage Determinations, and Appeals Guidance in its entirety for specific guidance if a request for a reopening is received from the member or if the plan sponsor decides to reopen a case.

4.5.1 Withdrawals

The party that submits the request for an initial determination may voluntarily withdraw the request verbally at any time before the decision is issued. The Alliance/PBM will clearly document the date and the reason for the withdrawal and issue the written notice.

- b. A dismissal notification is required indicating the reason as “withdrawal” to the entity requesting the withdrawal.

4.5.2 Dismissals

CMS 4190-F2, effective January 1, 2022, updated dismissal requirements.

A dismissal of a request is when a plan decides to stop consideration of a request before issuing a decision.

- c. A plan may dismiss a request when any of the following apply:
 - i. The entity making the request is not permitted to make a coverage determination request;
 - ii. The entity making the request failed to make a valid request for a coverage determination;
 - iii. The enrollee dies while the request is pending;
 - iv. The entity making the request submits a timely written request for a withdrawal of their coverage determination;
- d. Written notice of dismissal must be provided to the entity who made the request. The notice must include information as appropriate, including applicable appeal rights.

- e. A dismissal of a coverage determination is binding unless it is modified or reversed by the plan or vacated.
 - i. A dismissal may be vacated by the entity that issued the dismissal (plan or IRE), if good cause for doing so is established within six (6) months of the date of the dismissal.

4.6 FAILURE TO MEET THE COVERAGE DETERMINATION TIMEFRAME

- a. If the Alliance/PBM does not provide notice of its standard or expedited coverage determination within the required time frame, the complete case file will be forwarded by the Alliance/PBM to the IRE within 24 hours of the expiration of the adjudication time frame.
 - i. If the Alliance/PBM makes a completely favorable decision soon after the adjudication timeframe expires (i.e., within 24 hours) and notifies the member of the decision, the Alliance/PBM does not forward the case file to the IRE. This process should only happen rarely. Effectuation should also be completed to avoid delay for the member to access the drug. Written notification of approval should also be sent to the member.
 - ii. For cases forwarded to the IRE, the plan must make reasonable and diligent efforts to gather and forward all pertinent information for the IRE.
- b. The Alliance/PBM will notify the enrollee that it has forwarded his or her request to the IRE for review.
 - i. The Alliance/PBM will send the CMS Notice of Case Status within 24 hours of the expiration of the adjudication time frame.
 - ii. The notice will advise the enrollee of his/her right to submit additional evidence that may be pertinent to the enrollee's case, if the enrollee chooses, and direct the enrollee to submit such evidence to the IRE, and include information on how to contact the IRE.
- c. Upon receipt of the decision from the IRE, the Alliance/PBM effectuates the decision within 24 hours of the IRE decision unless the case is dismissed which may be the case when a coverage determination is completely favorable shortly after expiration of the adjudication timeframe.
- d. Effectuation pursuant to an IRE decision except for dismissal includes the Alliance/PBM providing oral and written notification to the member of the IRE decision. All outcomes of the IRE decision are logged into the PBM Coverage Determination tracking system.
- e. The Alliance/PBM notifies the IRE of effectuation within 14 days of receipt of the IRE decision in the manner dictated in the IRE notification. Notice of effectuation copy is entered into the case file.

5.0 Oversight and Monitoring of Coverage Determinations

Audits are done on a regular basis (monthly) to ensure accuracy of cases that have been completed. All denials are audited and up to 100% of all approvals are audited. When temporary help is needed, “real-time” audits are conducted to assure that errors are caught in a timely manner.

Monitoring for Timeliness

The PBM Coverage Determination system will monitor the coverage determination and exception cases for timeliness; however, the Alliance Pharmacy Operations will have to monitor the PBM system.

Effectuation Timeliness

Upon approval of a coverage determination, the coverage determination specialist enters the appropriate override for the medication in the claims adjudication system. The date stamp of when the override was entered is tracked in the system to show effectuation of the approval*. If this is a request for a new drug, the override is entered with an effective date of when the request was made and to term the end of the calendar year unless in the last quarter as stated in the policy and procedure. If the request is due to the denial of a claim at the pharmacy, the override is entered to allow for coverage of the last denied claim and to term the end of the calendar year unless in the last quarter as stated in the policy and procedure. Please refer to “Length of Approvals” above for additional timeframes.

*Please note: The time stamped on effectuation shown may be different than the time zone of the PBM. The Alliance will ensure that time change differences are accounted for in the processing of coverage determinations. The actual effectuation time in the case will reflect the time zone where the decision was rendered and entered into the PBM system.

DEFINITIONS / ACRONYMS

Appointed Representative - An individual either named by an enrollee including his/her prescribing physician or authorized under State or other applicable law to act on behalf of the enrollee. The Appointed Representative form is found on the Alliance website.

Centers for Medicare & Medicaid Services (CMS) - refers to the federal agency within the Department of Health and Human Services that administers the Medicare program and oversees all Medicare Advantage Organizations.

Coverage Determination - refers to any decision (i.e., an approval or denial for a prescription drug) made by The Alliance or its Pharmacy Benefit Manager (PBM), regarding

payment or benefits to which a member believes he or she is entitled. Presentation of a prescription at the pharmacy counter is not a coverage determination.

Dismissal - A decision not to review a request for an initial determination because it is considered invalid or does not otherwise meet Medicare Part D requirements.

Effectuation - refers to payment of a claim, authorization or provision of a benefit The Alliance has approved. For the purpose of this policy, effectuate is intended to include oral and written notification to the member, written notification to the prescriber and override entry in PBM claims payment system so that a claim is paid.

Exceptions - refer to requests for a non-formulary Part D covered drug, changing the tier copay ("tiering exception") or waiver of Prior Authorization requirements.

Formulary - refers to the list of Part D drugs covered by The Alliance for members enrolled in its plans/ The Formulary is a continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis and/or treatment of disease and promotion of health.

Independent Review Entity (IRE) - An independent entity contracted by CMS to review adverse level 1 (redetermination) appeal decisions made by the plan. The current contractor is C2C Innovative Solutions Inc. (C2C).

Low Income Cost-share Subsidy (LICS) - refers to the Medicare subsidy specific to Part D for qualified beneficiaries in the form of reduced co-payments.

Pharmacy Benefits Manager (PBM) - Perform Rx is The Alliance's PBM and provides the POS claims processing system for pharmacy claims.

Part D drug - A drug that may be dispensed only upon a prescription, is being used for medically-accepted indication as defined by section 1927(k)(6) of the Social Security Act, and is one of the following:

- A drug that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;
- A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;
- Insulin described in section 1927(k)(2)(C) of the Act;
- Medical supplies associated with the delivery of insulin;
- A vaccine licensed under section 351 of the Public Health Service Act and its administration.

Prior Authorization (PA) - An evaluation of the drug's prescribed use against a predetermined set of CMS approved criteria in order to determine whether the drug/drug class will be covered by the beneficiary's insurance plan.

Provider Supporting Statement - refers to the reasons provided by the prescriber when a drug being requested is not on the Formulary or the prescriber requests a waiver of the UM requirements. The statement has to indicate reasons why the member cannot use a Formulary drug, a Formulary drug with no UM edits or a lower-cost sharing drug.

Quantity Limits (QL) - refers to a dose restriction, including the number and/or dosage form, that causes a particular Part D drug not to be covered for the number of doses and/or dosage form prescribed

Step Therapy (ST) - refers to a particular Part D drug not to be covered until the requirements of the plan's coverage policy are met, which requirements are approved by CMS

Redetermination - Level 1 Part D appeal which reviews an adverse coverage determination, including the findings upon which the decision was based and any other submitted evidence.

Reopening - A remedial action taken to change a binding determination or decision even though the determination or decision may have been correct at the time it was made.

Tolling - The start of the timeframe for a standard or expedited exception request if the sponsor is waiting to receive the prescriber's supporting statement. A plan may toll a request for up to 14 (fourteen) days. Reimbursement requests are not eligible for tolling.

Utilization Management (UM) edits - refer to the requirements for the approval of a drug which can be one of the following: prior authorization (PA), step therapy (ST), or a quantity limit (QL).

Withdrawal - A verbal or written request to rescind or cancel an initial determination.

AFFECTED DEPARTMENTS/PARTIES

Pharmacy Department
PerformRx PBM

RELATED POLICIES AND PROCEDURES

RX-D 17-Part D Delegation Oversight and Monitoring
RX-D 009-Part D Appeals (Redeterminations)

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

None

REVISION HISTORY

New Policy

REFERENCES

42 CFR §423.560

Part C&D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (01.01.2020), Section 50 – Reconsiderations and Redeterminations (Level 1 Appeals), Section 60 – Reconsiderations by the Independent Review Entity (Level 2 Appeal), Sections 70, 80 and 90, and Appendix 2 – Medicare Prescription Drug (Part D) Appeals Process Overview.

Collaboration



POLICY AND PROCEDURE TEMPLATE

Policy Number	RX-D-011
Policy Name	Medicare Part D End Stage Renal Disease (ESRD)
Department Name	Pharmacy Services
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy Services
Line(s) of Business	D-SNP
Effective Date	1/1/2026
Subcommittee Name	Pharmacy and Therapeutics Committee
Subcommittee Approval Date	12/17/2024
Administrative Oversight Committee Approval Date	TBD

POLICY STATEMENT

It is the policy of Alameda Alliance for Health (Alliance) to ensure proper payment of End Stage Renal Disease (ESRD) medications under pharmacy Part D benefit. Drugs and biologics, except “oral only” drugs, included in the Part B bundled payment to an ESRD dialysis facility are not covered under Part D. Immunosuppressive therapy for a beneficiary who has received a Medicare covered kidney or non-renal transplant are not payable under Part D.

PROCEDURE

1. The Pharmacy Benefit Manager (PBM), on behalf of Alliance has established procedures (attached) for:
 - a. Rejections coded for ESRD members
 - i. Alliance’s PBM will process claims according to the following rules: if the member does not have a Part B covered transplant indicator, the claim will direct to Part D and process according to the Part D formulary status. If the member has a Part B covered transplant indicator, the claim will pay under Part B.
 - ii. Upon receiving an ESRD Transaction Reply Code (TRC) for the beneficiary via the Daily Transaction Reply Report (DTRR), plan sponsors may then utilize segment 08 within the Type 24 file to indicate that the member has one of the following ESRD attributes. Kidney transplants for beneficiaries are conveyed through CMS’ MARx system. In similar fashion, the ABII portal can be used to convey Medicare-covered non-renal transplants for beneficiaries.

- b. Beneficiary level Prior Authorization POS requirements for CMS classified ‘always’ ESRD medications and ‘maybe’ ESRD medications.
 - i. ESRD ‘always’ medications include those used for:
 - 1) Access Management
 - 2) Anemia management
 - 3) Bone and Mineral metabolism
 - 4) Cellular Management.
 - ii. ESRD ‘maybe’ medications include:
 - 1) Antiemetics
 - 2) Anti-infectives
 - 3) Antipruritics
 - 4) Anxiolytics,
 - 5) Excess fluid management
 - 6) Fluid and Electrolyte Management including volume expanders
 - 7) Pain Management.
 - iii. Retrospectively reviewing ESRD claims identified based on the Transaction Reply Codes (TRCs) provided by CMS on the daily Transaction Reply Reports (TRR) and providing a report monthly to Alliance.
 - 2. With the FDA approval of injectable Parsabiv (etelcalcetide) under the bone and mineral metabolism category it was included in the ESRD PPS as of January 1, 2018. Therefore Sensipar (cinacalcet) is also included in the ESRD PPS and is not payable under Part D.
 - 3. The inclusion in the ESRD PPS of oral-only ESRD drugs and biologicals.
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PROCESS

- 1. Alliance will perform a retrospective review of Part D claims paid after the ESRD/Dialysis start date period for CMS classified drugs as ‘always’ and/or ‘maybe related to ESRD treatment for the purpose of determining if the drugs were related to the beneficiary’s ESRD treatment:
 - a. Determining if the drugs were unrelated to the ESRD beneficiary’s dialysis treatment. As needed, Alliance will conduct outreach to the ESRD facility or prescriber to determine payment responsibility of the drug.
 - b. In the 2019 Final Call letter CMS announced the launch of a web portal called Additional Beneficiary Information Initiatives (ABII, pronounced ‘Abby’). The portal will be part of the group of Acumen web portals to which all Part D contracts already have access. As part of this initiative CMS will begin populating ABII with Medicare-covered transplant data derived from Medicare fee-for-service claims.
 - c. Alliance will notify the PBM if a paid claim during the election period is determined to be either an ESRD facility liability or a beneficiary liability (such as when a member requests a non-formulary drug and agrees to assume financial liability). The PBM establishes and maintains a process to reverse the claim, negate the PDE and adjust the beneficiaries TrOOP and total drug spend.
 - d. Alliance will have processes in place to handle payment resolution directly with the ESRD facility. In the case of beneficiary liability, Alliance will send a recovery notice directly to the beneficiary. In both scenarios, payment resolution will be

- accomplished without requiring the retail pharmacy to reverse and rebill the original claim.
4. The Alliance will perform a retrospective review of claims for ESRD members to determine proper coverage.
 - a. Daily reject reviews
 - b. Monthly retrospective reviews.
 - i. PBM generates the ESRD Report on a monthly basis so that Part D plan sponsors may regularly review claims approved under the Part D benefit that are associated with their beneficiaries receiving dialysis treatment. Plan sponsors may use the report to:
 - ii. Identify claims for prescriptions that should have been covered under Part B instead of Part D and then work with the dialysis facility to recover any inappropriate payments; and or any claims that paid inappropriately under Part D, work with PBM to exclude the PDE record.
 - iii. PBM's ESRD Report includes both the "ESRD Always" drugs in addition to the "ESRD Maybe" drugs. Consistent with the CMS memo dated November 14, 2014, titled "Part D Payment for Drugs for Beneficiaries Receiving Renal Dialysis Services," drugs in the "ESRD Always" seven categories may be used for the treatment of ESRD. Alliance may use the report to:
 - a. Identify claims for prescriptions that should have been covered under Part B instead of Part D, and then work with the dialysis facility to recover any inappropriate payments; and
 - b. For any claims that paid inappropriately under Part D, work with PBM to exclude the PDE record.
 3. Drugs in the "ESRD Maybe" category of seven (7) drugs may be used for the treatment of ESRD.
 - i. For drugs in the "Maybe" category, if the drug was used for the treatment of ESRD, it should be covered under the bundled payment to the facility and plan sponsors should work the facility to recover the Part D payment.
 - ii. PBM utilizes two different PPDLs to support ESRD and Transplant processes.
 - CMS ESRD Always for the four (4) categories always covered by ESRD.
 - CMS Kidney Transplant (KTRANS) lists the immunosuppressants used for transplants.
 - iii. If the NDC submitted on the claim is not found on either list OR if the drug is a compound, normal processing rules apply. Each compound represents a unique drug entity and PBM is unable to determine at the point of sale the medical condition for which the compound was prescribed.
 4. Payment Recovery
Alliance will work with the dialysis facility to recover the Part D payment. Beneficiaries should also be directed to the dialysis facility to recover any cost sharing incurred on the claim.

DEFINITIONS / ACRONYMS

ABII – Additional Beneficiary Information Initiatives (ABII portal)

Coverage Determination – A decision made by or on behalf of a Part D plan sponsor

Daily Transaction Reply Reporting (DTRR) – The file will be transmitted daily in reply to any action that initiates or impacts a beneficiary’s status or its enrollment. It also will communicate changes affecting a beneficiary throughout all enrollment periods and accordingly, all affected Plans will receive a notification on a TRR. This is especially valuable regarding retroactive enrollments.

End State Renal Disease r(ESRD) – resulting in permanent kidney failure that requires a regular course of dialysis or a kidney transplant.

HPMS – Health Plan Management System

PBM – Pharmacy Benefit Manager

Point of Sale (POS)- A capability of retail pharmacies to electronically access plan design and eligibility information to process and transmit drug claims data at the time of purchase.

Prescription Drug Event (PDE) – is a summary record submitted to CMS. The PDE data is not the same as individual drug claim transactions but are summary extracts using CMS defined standard fields.

Prior Authorization (PA) – A process whereby certain designated preferred drugs must meet established before the prescription can be covered.

Prospective Payment System (PPS) – is a method of reimbursement in which Medicare payment is made based on a predetermined, fixed amount.

Transaction Reply Code (TRC) – Codes used to explain what action MARx took in response to new information from CMS systems or in response to input from Plans, CMS or other users.

Transaction Reply Report (TRR) – A report that CMS provides to Part D sponsors containing details of the rejected and accepted enrollment transactions that CMS has processed for a Part D sponsor’s contract(s) over a specified period of time.

PPS – Prospective Payment System

AFFECTED DEPARTMENTS/PARTIES

Pharmacy Services
PBM

RELATED POLICIES AND PROCEDURES

PerformRx PBM Medicare BvsD List Management DTP for AAH

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

None

REVISION HISTORY

New – 12/17/2024

REFERENCES

HPMS Memo – Sensipar (cinacalcet) Furnished for the Treatment of ESRD Moving from Part D to ESRD PPS, Effective January 1, 2018 – published August 18, 2017.

HPMS Memo - Part D Payment for Drugs for Beneficiaries Receiving Renal Dialysis Services, November 14, 2014.

HPMS Memo – Two Updates Pertaining to End-Stage Renal Disease (ESRD) Related Drugs, May 12, 2015.

The calendar year 2011 ESRD PPS final rule (CMS-1418-F), which appeared in the Federal Register on August 12, 2010, requires the inclusion in the ESRD PPS payment bundle of all drugs and biologicals used in the treatment of ESRD, effective January 1, 2011.
42 C.F.R. § 413.174(f)(6), effective January 1, 2025

MONITORING

Alliance Pharmacy Department Staff will include results of ongoing monitoring in monthly Delegated Function Oversight/Monitoring statistics.



POLICY AND PROCEDURE TEMPLATE

Policy Number	RX-D-026
Policy Name	Medicare Part D Annual Reporting
Department Name	Pharmacy Services
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy Services
Line(s) of Business	D-SNP
Effective Date	TBD
Subcommittee Name	Pharmacy and Therapeutics Committee
Subcommittee Approval Date	TBD
Administrative Oversight Committee Approval Date	TBD

POLICY STATEMENT

Alameda Alliance for Health (Alliance) is in compliance with 42 CFR §423.514(a) which requires each Part D sponsor to develop, compile, evaluate and report to the Centers for Medicare and Medicaid Services (CMS) and to the public, at the times and in the manner that CMS requires, statistics indicating the following:

- 1) The cost of its operations.
- 2) The patterns of utilization of its services.
- 3) The availability, accessibility, and acceptability of its services.
- 4) Information demonstrating that the Part D sponsor has a fiscally sound operation.
- 5) Pharmacy performance measures.
- 6) Other matters that CMS may require.

PROCEDURE

This document lists reporting timeframes, deadlines and required levels of reporting. Reporting deadlines may occur in the subsequent calendar year. Data elements may be reported at the Plan (PBP) level, or the individual Contract level. The following criteria were used in selecting reporting requirements:

- 1) Minimal administrative burden on Part D sponsors.
- 2) Legislative and regulatory authority;
- 3) Validity, reliability, and utility of data elements requested; and
- 4) Wide acceptance and current utilization within the industry. Unless otherwise specified, drug utilization data should include all covered* Part D drugs, including compounded drugs.

PROCESS

1.0 Level of Data to be Reported

Alliance will report in HPMS at the level of reporting for each reporting section as specified in the reporting requirements and within each reporting section.

1.1 A summary of the reporting level required for each reporting section is below.

REPORTING REQUIREMENT SECTION LEVEL OF REPORTING

Enrollment and Disenrollment- Contract

Medication Therapy Management (MTM) Programs -Contract

Grievances- Contract

Improving Drug Utilization Review Controls- Contract

Coverage Determinations and Redeterminations - Contract

Medicare Prescription Payment Plan - Contract & Plan

2.0 Timely Submission of Data

2.1 Data submissions are due by 11:59 p.m. Pacific time on the date of the reporting deadline.

2.2 Only data that reflect a good faith effort by Alliance to provide accurate responses to Part D Reporting Requirements will count as data submitted in a timely manner.

2.3 Alliance must report all data based on the most current Technical Specifications as of the reporting deadline.

2.3.1 Sponsors should not submit “placeholder” data.

2.3.2 HPMS will not allow the resubmission of data that are identical to the original data submission.

2.4 In order to accommodate data validation activities, with the exception of the Medicare Prescription Payment Plan section, data corrections must be submitted prior to 11:59 p.m. Pacific time on March 31st, or if March 31st falls on a weekend or federal holiday, prior to 11:59 p.m. Pacific time on the preceding business day.

2.5 Data corrections for the Medicare Prescription Payment Plan section must be submitted prior to 11:59 p.m. Pacific time on May 31st, or if May 31st falls on a weekend or federal holiday, prior to 11:59 p.m. Pacific time on the preceding business day.

2.6 The following steps must be followed by a Part D sponsor to request resubmission:

a. Click the Resubmission Request link on the HPMS Part D Plan Reporting Start Page.

b. Select/complete the following:

- Reporting section (e.g., Redeterminations);
- Time period (e.g., 1st quarter 2025);
- Contracts or plans, depending on reporting level; and
- Reason for the resubmission request.

2.7 Alliance should report data based on the interpretation of these documents and retain documentation supporting their HPMS data submissions.

2.8 The Sponsoring Organization (SO) must retain this complete archive for the 10-year retention period required per federal regulations and be prepared to provide the archive to CMS upon request.

2.9 Alliance will reference Medicare Part D Reporting Requirements, Effective as of January 1, 2025, for data element definitions.

3.0 General Data Entry Rules

3.1 HPMS will allow the entry of a zero.

3.2 HPMS will not allow the entry of the following:

- a negative;
- a greater than sign (>);
- a less than sign (<);
- a semi-colon (;) or
- decimals

4.0 Exclusions from Reporting

4.1 The Part D Reporting Requirements apply to Part D sponsors offering the Part D benefit.

4.2 Data relating to Part B claims are excluded from these Part D reports unless otherwise specified (e.g., Coverage Determinations and Redeterminations reporting).

4.3 Terminations:

4.3.1 If a contract terminates before July 1 in the following year after the contract year (CY) reporting period, the contract is not required to report any data for the respective two years – the CY reporting period, and the following year.

- Example: Contract terminates June 2025. The contract will not report CY 2024 (“contract year reporting period”) or CY 2025 data (“following year”).

4.3.2 If a PBP (Plan) under a contract terminates at any time in the CY reporting period and the contract remains active through July 1 of the following year, the contact must still report data for all PBPs, including the terminated PBP.

5.0 Reporting Sections Required

5.1 Enrollment and Disenrollment – See Attachment I for HPMS layout and templates for more information.

- A. Data elements definitions
- B. QA checks/Thresholds
- C. Edits and Validation Checks
- D Analysis
- E. Notes

5.1.1 Reporting at Contract level, Bi-annually, Reporting Periods 1/1/2025- 6/30/2025 (data due last Monday of August) and 7/1/2025-12/31/2025 (data due last Monday of February)

5.1.2 No validation required.

5.2 Medication Therapy Management (MTM) Program – See Attachment II -for the information that will be collected for each beneficiary identified as being eligible for the Part D MTM program, whether based on CMS’ specifications or other plan-specific expanded targeting criteria within the reporting period.

- A. Data elements definitions
- B. QA checks/Thresholds
- C. Edits and Validation Checks
- D Analysis
- E. Notes – Alliance should refer to the annual MTM Program Guidance and Submission memo for information about the Part D MTM program requirements and

definitions. It is posted on the CMS MTM web page at www.cms.gov > Medicare > Prescription Drug Coverage Contracting > Medication Therapy Management and webpage www.cms.gov>Medicare>Coverage>Prescription Drug Coverage Contracting>Part D Reporting .
E. Reporting Period January 1 – December 31 (due last Monday of February)

5.3 Grievances – See Attachment III - for HPMS layout and templates for more information.

- A. Data elements definitions
- B. QA checks/Thresholds
- C. Edits and Validation Checks
- D Analysis
- E. Notes
- F. Reporting quarterly data on an annual basis at the contract level. Data files to be uploaded through the HPMS at the Contract level, following templates provided in HPMS.
- G. Reporting January 1- March 31, April 1-June 30, July 1 – September 30, and October 1-December 31 (All quarters due the first Monday of February.)

5.4 Improving Drug Utilization Review Controls – Attachment IV - for HPMS layout and templates for more information.

- A. Data elements definitions
- B. QA checks/Thresholds
- C. Edits and Validation Checks
- D Analysis
- E. Notes – See Medicare Part D Reporting Requirements: Technical Specifications Document Contract Year 2025 for General notes, Opioid Care Coordination edits, and Hard MME edit/opioid naïve days supply safety edits. Reporting is at contract level, quarterly: accumulation January 1- March 31, January 1- June 30, January 1 - September 30, and January 1 – December 31 (all due the last Monday of February).

5.5 Coverage Determinations, Redeterminations (including At-Risk Redeterminations under a Drug Management Program), and Reopenings – Attachment V - for HPMS layout and templates for more information.

- A. Data elements definitions
- B. QA checks/Thresholds
- C. Edits and Validation Checks
- D Analysis
- E. Notes - See Medicare Part D Reporting Requirements: Technical Specifications Document Contract Year 2025 for General Notes. Coverage Determinations (including exceptions), Disposition- Coverage Determinations (non-exceptions), Disposition- Utilization Management Exceptions, Disposition- Formulary Exceptions, Disposition- Tiering Exceptions, Redeterminations (including exceptions and at-risk redeterminations), Disposition- Utilization Management Exception Redeterminations, Disposition- Formulary Exception Redeterminations, Disposition- Tiering Exception Redeterminations, Disposition- At-Risk Redeterminations and Reopenings.
- F. Reporting is at contract level, quarterly: January 1- March 31, January 1- June 30, January 1 -September 30, and January 1 – December 31 (all due the last Monday of February).

5.6 Medicare Prescription Payment Plan – Attachment VI—Reporting at the contract – PBP level- CMS collects beneficiary-level data on the Medicare Prescription Payment Plan through the Medicare Prescription Drug (MARx) System.

A. Data elements definitions

B. QA checks/Thresholds

C. Edits and Validation Checks

D Analysis

E. Notes – Refer to Medication Prescription Payment Guidance for additional information.

F. To be reported at the PBP level for yearly period January 1 – December 31 (Last Monday of April)

DEFINITIONS / ACRONYMS

CMS – Center for Medicare and Medicaid Services

CY – Coverage Year

HPMS - Health Plan Management System

MA – Medicare Advantage

MA-PD – Medicare Advantage Prescription Drug

MTM – Medication Therapy Management

OOP – Out-of-Pocket

PBP – Plan Benefit Package

PDP – Prescription Drug Plan

QA- Quality Analysis

SO- Sponsoring Organization

AFFECTED DEPARTMENTS/PARTIES

Pharmacy Services

Pharmacy Benefit Manager (Currently – PerformRx)

Enrollment

Grievances & Appeals

RELATED POLICIES AND PROCEDURES

RX-D 015 Medicare Part D Medication Therapy Management (MTM)

RX-D 008 Part D Coverage Determinations

RX-D 017 Part D or PBM Delegated Function Oversight and Monitoring

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

Attachment I – VII

REVISION HISTORY

New Policy

REFERENCES

Medicare Part D Reporting Requirements: Technical Specifications Document Contract Year 2025, Effective January 1, 2025

MONITORING

Alliance Pharmacy Department Staff will include results of ongoing monitoring in monthly Delegated Function Oversight/Monitoring statistics.

Collaboration

Attachment I

1. Enrollment:

- A. The total number of enrollment requests (initiated by the beneficiary or his/her authorized legal representative) received in the reporting period. Do not include auto/facilitated or passive enrollments, rollover transactions, or other enrollments effectuated by CMS
- B. Of the total reported in A, the number of enrollment requests complete at the time of initial receipt.
- C. Of the total reported in A, the number of enrollment requests that were not complete at the time of initial receipt and for which the sponsor was required to request additional information from the applicant (or his/her representative).
- D. Of the total reported in A, the number of enrollment requests denied due to the sponsor's determination that the applicant was not eligible for an election period.
- E. Of the total reported in C, the number of enrollment requests received that are incomplete upon initial receipt and completed within established timeframes.
- F. Of the total reported in C, the number of enrollment requests denied due to the applicant or his/her authorized legal representative not providing the information required to complete the enrollment request within established timeframes.
- G. Of the total reported in A, the number of paper enrollment requests received.
- H. Of the total reported in A, the number of telephonic enrollment requests received (if sponsor offers this mechanism).
- I. Of the total reported in A, the number of electronic enrollment requests received via an electronic device or secure internet website (if sponsor offers this mechanism).
- J. Of the total reported in A, the number of Medicare Online Enrollment Center (OEC) enrollment requests received.
- K. Of the total reported in A, the number of enrollment requests received from an applicant through an agent or broker.

2. Disenrollment:

- A. The total number of voluntary disenrollment requests received in the reporting period. Do not include disenrollments resulting from an individual's enrollment in another plan.
- B. Of the total reported in A, the number of disenrollment requests was complete at the time of initial receipt.
- C. Of the total reported in A, the number of disenrollment requests that were not complete at the time of initial receipt.
- D. Of the total reported in A, the number of disenrollment requests denied due to the sponsor's determination that the enrollee was not eligible for an election period.
- E. Of the total reported in C, the number of disenrollment requests received that are incomplete upon initial receipt and completed within established timeframes.
- F. Of the total reported in C, the number of disenrollment requests denied due to the enrollee or his/her authorized legal representative not providing information required to complete the disenrollment request within established timeframes.
- G. The total number of involuntary disenrollments for failure to pay plan premium in the reporting period.
- H. Of the total reported in G, the number of disenrolled individuals who submitted a timely request for reinstatement for Good Cause.
- I. Of the total reported in H, the number of favorable Good Cause determinations.
- J. Of the total reported in I, the number of individuals reinstated.

collaboration

Attachment II

The following information will be collected for each beneficiary identified as being eligible for the Part D MTM program, whether based on CMS' specifications or other plan-specific expanded targeting criteria within the reporting period. Regardless of this designation, the corresponding MTM services delivered to each beneficiary (such as targeted medication review or comprehensive medication review) must meet CMS definitions. The reported beneficiaries must receive MTM services that meet or exceed **CMS' MTM program requirements.**

- A. Contract Number.
- B. MBI Number.
- C. Beneficiary first name.
- D. Beneficiary last name.
- E. Beneficiary date of birth.
- F. Beneficiary identified as cognitively impaired at time of comprehensive medication review (CMR) offer or delivery of CMR. (Y (yes), N (no), or U (unknown)).
- G. Beneficiary in a long-term care facility at the time of the first CMR offer or delivery of CMR? (Y (yes), N (no), or U (unknown)).
- H. Date of MTM program enrollment.
- I. Targeting criteria met. Required if met the specified targeting criteria per CMS – Part D requirements in § 423.153(d)(2). (Multiple chronic diseases/multiple Part D drugs/cost threshold; Drug management program at-risk beneficiary; Both; None).
- J. Date met the specified targeting criteria per CMS – Part D requirements in § 423.153(d)(2). Required if met the specified targeting criteria per CMS – Part D requirements. (May be same as Date of MTM program enrollment).
- K. Date of MTM program opt-out, if applicable.
- L. Reason participant opted-out of MTM program (Death; Disenrollment from Plan; Request by beneficiary; or Other). Required if Date of MTM program opt-out is applicable.
- M. Offered annual CMR. (Y (yes) or N (no)). Required if met the specified targeting criteria per CMS – Part D requirements.
- N. If offered a CMR, date of (initial) offer.
- O. Received annual CMR with written summary in CMS standardized format. (Y (yes) or N (no)). Required if offered annual CMR.
- P. Date(s) of CMR(s). (If more than 1 CMR is received, report the date of the initial CMR.) Required if received annual CMR.
- Q. Date CMR written summary in CMS standardized format was provided or sent. (If more than 1 CMR was performed, report the date the initial CMR written summary was provided or sent.).
- R. Method of delivery for the annual CMR. (In-Person; Synchronous Telehealth – telephone; Synchronous Telehealth – video conferencing; Other real-time method). (If more than 1 CMR is received, report the method of delivery for the initial CMR). Required if received annual CMR.
- S. Qualified Provider who performed the initial CMR. (Physician; Registered Nurse; Licensed Practical Nurse; Nurse Practitioner; Physician's Assistant; Local Pharmacist; LTC Consultant Pharmacist; Plan Sponsor Pharmacist; Plan Benefit

Manager (PBM) Pharmacist; MTM Vendor Local Pharmacist; MTM Vendor Inhouse Pharmacist; Hospital Pharmacist; Pharmacist – Other; Supervised Pharmacy Intern; or Other). Required if received annual CMR.

T. Recipient of initial CMR. (Beneficiary, Beneficiary's prescriber; Caregiver; or Other authorized individual). Required if received annual CMR.

U. Number of targeted medication reviews. Required if met the specified targeting criteria per CMS – Part D requirements.

V. Date the first TMR was performed.

W. Number of medication therapy problem recommendations made to beneficiary's prescriber(s) as a result of MTM services.

X. Number of medication therapy problem resolutions resulting from recommendations made to beneficiary's prescriber(s) as a result of MTM recommendations.

Y. Number of communications sent to beneficiary regarding safe disposal of medications. Required if met the specific targeting criteria per CMS – Part D requirements.

Z. Method of delivery for information regarding safe disposal of medications (CMR; TMR; Welcome Letter; Other). If more than one communication is sent, report the method of initial communication.

Attachment III

Title 42, Part 423, Subpart M describes Part D sponsors requirements for grievances, including timeframes for standard and expedited requests.

Sponsors should:

- Report data based on when the enrollee/enrollee representative is notified (orally or written) of the grievance decision.
- Track multiple grievances by a single complainant and report as separate grievances.

Sponsors should not:

- Include CTM data when reporting grievances.
- Report general inquiries or questions that do not include a complaint as grievances.
- Include grievances filed by prospective enrollees.
- Report withdrawn grievances.

Data elements should be uploaded to HPMS at the Contract level:

- A. Number of Total Grievances
- B. Number of Total Grievances in which timely notification was given
- C. Number of Expedited Grievances
- D. Number of Expedited Grievances in which timely notification was given
- E. Number of Dismissed Grievances

Attachment IV

1. Opioid Care Coordination Safety Edit at 90 MME

- A. The prescriber count criterion used, if applicable.
- B. The pharmacy count criterion used, if applicable.
- C. The number of claims rejected due to the care coordination edit.
- D. Of the total reported in element C, the number of claim rejections overridden by the pharmacy.

Of the total reported in element D:

- E. The number of claim rejections overridden by the pharmacy within 24 hours of the initial claim rejection.
- F. The number of claim rejections overridden by the pharmacy due to an exemption.
- G. Of the total not in element F, the number of claim rejections overridden by the pharmacy as a result of prescriber consultation.
- H. The number of unique beneficiaries with at least one claim rejected due to the care coordination edit.

Of the total reported in element H:

- I. The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy.
- J. The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy within 24 hours of the initial claim rejection.
- K. The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy due to an exemption.
- L. Of the total not in element K, the number of unique beneficiaries with at least one claim rejection overridden by the pharmacy as a result of prescriber consultation.

2. Hard MME Safety Edit

- M. Did the plan have a hard MME edit in place during the time period above? (Y (yes) or N (no)).

If yes to element M:

- N. The cumulative MME threshold used.
- O. The prescriber count criterion used, if applicable.
- P. The pharmacy count criterion used, if applicable.
- Q. The number of claims rejected due to the hard MME edit.
- R. The number of unique beneficiaries with at least one claim rejected due to the hard MME edit.
- S. Of the total reported in element R, the number of unique beneficiaries with at least one claim rejection overridden by the pharmacy due to an exemption.
- T. Of the total reported in element R and not in element S, the number of unique beneficiaries who requested a coverage determination for the prescription(s) subject to the edit.
- U. Of the total reported in element T, the number of unique beneficiaries that had a favorable (either full or partial) coverage determination for the prescription(s) subject to the edit.

3. Opioid Naïve Days Supply Safety Edit

V. The look-back period used to identify an initial opioid prescription fill for the treatment of acute pain for the opioid naïve days' supply edit.

W. The number of claims rejected due to the opioid naïve days' supply edit.

Of the total reported in element W:

X. The number of rejected claims overridden by the pharmacy due to an exemption.

Y. The number of rejected claims overridden by the pharmacy because the beneficiary was not opioid naïve.

Z. Of the total not in elements X or Y, the number of rejected claims for which up to a 7-day supply (covered by the plan) was dispensed by the pharmacy.

AA. The number of unique beneficiaries with at least one claim rejected due to the opioid naïve days' supply edit.

Of the total reported in element AA:

BB. The number of unique beneficiaries with at least one rejected claim overridden by the pharmacy due to an exemption.

CC. The number of unique beneficiaries with at least one rejected claim overridden by the pharmacy because the beneficiary was not opioid naïve.

DD. The number of unique beneficiaries for whom up to a 7 day supply (covered by the plan) was dispensed by the pharmacy.

EE. The number of unique beneficiaries with an opioid naïve days supply edit claim rejection who requested a coverage determination for the prescription(s) subject to the edit.

FF. Of the total in element EE, the number of unique beneficiaries with an opioid naïve days' supply edit claim rejection who had a favorable (either full or partial) coverage determination for the prescription(s) subject to the edit.

Attachment V

1. Coverage Determinations (including exceptions)

- A. Total Number of Coverage Determinations Processed (including exceptions)
- B. Total Number of Withdrawn Coverage Determinations
- C. Total Number of Dismissed Coverage Determinations

Disposition – Coverage Determinations (non-exceptions)

- D. The total number of fully favorable decisions.
- E. The total number of partially favorable decisions.
- F. The total number of adverse decisions.

Disposition – Utilization Management Exceptions

- G. The number of utilization management exceptions.
- H. The number of fully favorable decisions.
- I. The number of partially favorable decisions.
- J. The number of adverse decisions.

Disposition – Formulary Exceptions

- K. The number of formulary exceptions.
- L. The number of fully favorable decisions.
- M. The number of partially favorable decisions.
- N. The number of adverse decisions.

Disposition – Tiering Exceptions

- O. The number of tiering exceptions.
- P. The number of fully favorable decisions.
- Q. The number of partially favorable decisions.
- R. The number of adverse decisions.

2. Redeterminations (including exceptions and at-risk redeterminations)

- A. Total Number of Redeterminations Processed (including exceptions and at-risk)
- B. Total Number of Withdrawn Redeterminations
- C. Total Number of Dismissed Redeterminations

Disposition – Redeterminations (non-exceptions)

- D. The number of fully favorable decisions.
- E. The number of partially favorable decisions.
- F. The number of adverse decisions.

Disposition – Utilization Management Exception Redeterminations

- G. The number of utilization management exceptions.
- H. The number of fully favorable decisions.
- I. The number of partially favorable decisions.
- J. The number of adverse decisions.

Disposition – Formulary Exception Redeterminations

- K. The number of formulary exceptions.
- L. The number of fully favorable decisions.
- M. The number of partially favorable decisions.
- N. The number of adverse decisions.

Disposition – Tiering Exception Redeterminations

- O. The number of tiering exceptions.
- P. The number of fully favorable decisions.
- Q. The number of partially favorable decisions.
- R. The number of adverse decisions.

Disposition – At-Risk Redeterminations

- S. The number of at-risk redeterminations.
- T. The number of fully favorable decisions.
- U. The number of partially favorable decisions.
- V. The number of adverse decisions.

3. Reopening's

- A. The total number of reopened (revised) decisions, for any reason, in the time period above.
- B. For each case that was reopened, the following information will be uploaded in a data file:
 - 1. Contract Number.
 - 2. Case ID.
 - 3. Case level (Coverage Determination or Redetermination);
 - 4. Date of original disposition.
 - 5. Original disposition (Fully Favorable; Partially Favorable or Adverse).
 - 6. Was case processed under expedited timeframe (Y/N).
 - 7. Case type (Pre-service; Payment).
 - 8. Date case was reopened.
 - 9. Reason(s) for reopening (Clerical Error, Other Error, New and Material Evidence, Fraud or Similar Fault, or Other);
 - 10. Date of reopening disposition (revised decision).
 - 11. Reopening disposition (Fully Favorable; Partially Favorable, Adverse, or Pending).

Attachment VI

Data file to be uploaded through the HPMS at the Plan (PBP) level:

Likely to benefit identification:

A. The total number of individuals identified as likely to benefit from the Medicare Prescription Payment Plan during the reporting period through any of the following methods: prior to plan year criteria; during the plan year criteria; POS criteria (unique beneficiaries, including those who did not elect to participate in the Medicare Prescription Payment Plan).

B. The total number of individuals identified as likely to benefit from the Medicare Prescription Payment Plan during the reporting period based on prior to plan year criteria (unique beneficiaries, including those who did not elect to participate in the Medicare Prescription Payment Plan).

C. The total number of individuals identified as likely to benefit from the Medicare Prescription Payment Plan during the reporting period based on during the plan year criteria (unique beneficiaries, including those who did not elect to participate in the Medicare Prescription Payment Plan).

D. The total number of individuals identified as likely to benefit from the Medicare Prescription Payment Plan during the reporting period based on POS criteria (unique beneficiaries, including those who did not elect to participate in the Medicare Prescription Payment Plan).

E. Among individuals identified in element A, the total number of those individuals who submitted an election request to participate in the Medicare Prescription Payment Plan during the reporting period.

Election request processing:

F. The total number of Medicare Prescription Payment Plan election requests received during the reporting period.

G. Of the total reported in element F, the number of election requests that were accepted during the reporting period.

H. Of the total reported in element F, the number of election requests that were not complete at the time of initial receipt and for which the sponsor was required to request additional information from the applicant (or his/her representative).

I. Of the total reported in element H, the number of election requests received that were able to be completed within established timeframes.

J. Of the total reported in element H, the number of election requests denied due to the applicant or his/her authorized legal representative not providing the information required to complete the election request within established timeframes.

K. Of the total reported in element F, the number of election requests that were denied during the reporting period.

Unsettled balances:

L. The collected Medicare Prescription Payment Plan amounts from the reporting period.

M. The uncollected Medicare Prescription Payment Plan balances from the reporting period.

N. Number of program participants with uncollected Medicare Prescription Payment Plan balances from the reporting period.

O. Number of individuals precluded from opting into the Medicare Prescription Payment Plan (in the subsequent year).

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POLICY AND PROCEDURE TEMPLATE

Policy Number	RX-D-027
Policy Name	Pharmacy Network Access/Contracting
Department Name	Pharmacy Services
Department Officer	Chief Medical Officer
Policy Owner	Senior Director-Pharmacy Services
Line(s) of Business	D-SNP
Effective Date	1/1/2026
Subcommittee Name	Pharmacy and Therapeutics (P&T) Committee
Subcommittee Approval Date	TBD
Administrative Oversight Committee Approval Date	TBD

POLICY STATEMENT

To ensure that Alliance and its delegate are in compliance with applicable CMS regulations governing the process for establishing and contracting a pharmacy network for Alliance's Medicare Part D business.

To identify Alliance and its delegate's pharmacy network access standards and provide written documentation for the CMS required access standards, defined in 42 CFR § 423.120(a), for each of the following types of pharmacies:

- Retail Pharmacy Network
- Long Term Care (LTC)
- Home Infusion (HI)
- Indian Health Services, Indian Tribes and Tribal organizations and Urban Indian Organization (I/T/U)

Pharmacy access standards are addressed by Alliance and its delegate in completing a CMS Solicitation for Application, implementing pharmacy network management programs and CMS required reporting. This document does not address access standards for physician offices.

PROCEDURE

1 CMS Requirements

RX-D-027 Pharmacy Network Access/Contracting

1.1 Any Willing Provider

1.1.1 In accordance with Any Willing Provider requirements, Alliance and its delegate requires will contract with any pharmacy that meets the plan PBM's standard terms and conditions. Contracted pharmacies in the network are not required to accept insurance risk as a condition of participation. The Alliance will not prohibit a pharmacy from, nor penalize a pharmacy for, informing a Part D plan enrollee of the availability at that pharmacy of a prescribed medication at a cash price that is below the amount that the enrollee would be charged to obtain the same medication through the Alliance Part D plan.

1.2 Level Playing Field between Network Pharmacies and Mail Order Pharmacies

1.2.1 Alliance and its delegate will ensure that if mail order pharmacy services will be provided, that the enrollees have reasonable access to the same benefits at retail pharmacies, such as an extended supply (90-day supply) of covered Part D drugs as they do at mail.

2 Network pharmacies

2.1 Includes retail pharmacies, mail-order pharmacies, Long Term Care/institutional (LTC) pharmacies, Home Infusion (HI) and Indian Health Services, and Indian tribe or tribal organization, or urban Indian organization (I/T/U) pharmacies. Alliance and its delegate provide adequate access to home infusion pharmacies based on the number of enrollees in the plan's service areas and the geographic distribution and capacity of home infusion pharmacies in those service areas. Alliance and its delegate offer standard terms and conditions to all similarly situated network pharmacies in the service area.

2.2 Home Infusion Contracting

2.2.1 Alliance and its delegate ensure that all home infusion pharmacies provide home infusion drugs in a usable form, provide the full range of home infusion Part D drugs including home infusion drugs for both short term acute care and long term chronic care, provide assurances that ancillary services are in place before dispensing home infusion drugs and provide covered home infusion drugs within 24 hours of discharge from an acute setting, unless the next required dose, as prescribed, is required to be administered later than 24 hours after discharge.

2.3 Long Term Care Pharmacy Contracting

2.3.1 Alliance and its delegate contracts with any willing long-term care pharmacies in the plan's service areas that accept Alliance and its delegate's standard terms and conditions. Alliance and its delegate will ensure that the long-term care pharmacy network meets the convenient access standards through an assessment of number of enrollees in the service areas and in an LTC facility, geographic distribution of long-term care pharmacies relative to number of enrollees, capacity of long-term pharmacies in the service areas, and contracting

relationships with long term care facilities of long-term care pharmacies in the service areas.

2.3.2 Contractual arrangements with long-term care pharmacies will include terms and conditions that require the disclosure of any and all discount and rebate arrangements with drug manufacturers or other parties that is designed to or likely to directly influence or impact utilization of Part D drugs. Any LTC rebates disclosed to Alliance and its delegate will be reported to CMS in accordance with Part D LTC rebate reporting instructions.

2.3.3 LTC facilities participating in Medicare Part D must dispense all brand oral solid drugs for Part D patients in 14-day or less increments.

2.4 I/T/U Network Contracting

2.4.1 Alliance and its delegate offer standard contracting terms and conditions conforming to the model CMS addendum for all Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies in its Part D Plan service area.

3 Geographic Access

3.1 As part of a systematic review of pharmacy network access, Alliance and its delegate initiate a geographic assessment at least yearly.

3.2 Access Standards

3.2.1 Alliance and its delegate's pharmacy network meets the following criteria as stated in 42 CFR Sec. 423.120 (a):

- a. at least 90% of enrollees, on average, in urban areas served by Alliance's Part D plan live within two (2) miles of a network retail pharmacy or I/T/U pharmacy.
- b. at least 90% of enrollees, on average, in suburban areas served by Alliance's Part D plan live within five (5) miles of a network retail pharmacy or I/T/U pharmacy
- c. at least 70% of enrollees, on average, in rural areas served by Alliance's Part D plan live within fifteen (15) miles of a network retail pharmacy or I/T/U pharmacy.

3.3 If a retail pharmacy is removed or ceases to be a part of the Alliance and its delegate pharmacy network, continuing geographic access will be analyzed by a disruption analysis against previous claims or by a zip code analysis of the leaving pharmacy. If there is a disruption in geographic access, Alliance and its delegate will recruit sufficient Medicare network retail pharmacies to achieve the designated geographic access parameters.

4 Mail order pharmacy network

4.1 Alliance and its delegate utilize its own mail order pharmacy which is considered to be a "preferred" pharmacy provider. In accordance with Any Willing Provider requirements, Alliance and its delegate contracts with any mail order pharmacy that meets Alliance and its delegate's standard terms and conditions.

- 4.2 In accordance with Level Playing Field requirements, enrollees in the Alliance plan may receive equivalent benefits to the mail order pharmacy benefit, including a 90-day supply of covered Part D drugs, at any Alliance and its delegate network retail pharmacy which contracts to participate.
 - 4.3 On an annual basis, Alliance and its delegate will calculate the percentage of extended supply prescriptions filled at retail pharmacies vs. mail order pharmacy.
 - 4.4 Alliance and its delegate must obtain explicit prior approval from a beneficiary for the utilization of mail-order pharmacy services. Alliance and its delegate should require their network retail and mail order pharmacies to obtain patient consent to deliver a prescription, new or refill, prior to each delivery.
- 5 Access in Physician Office
 - 5.1 Alliance and its delegate provide adequate access to covered Part D drugs that are appropriately dispensed and administered by a physician in a physician's office.
- 6 Pharmacy Network Directory
 - 6.1 The pharmacy network directory will be updated on a regular basis, at least quarterly and be available on the Alliance website.
- 7 Pharmacy Network Credentialing and Monitoring
 - 7.1 Refer to specific PerformRx Network Pharmacy Credentialing and Monitoring Policy.
- 8 Network Pharmacy Record Keeping
 - 8.1 Alliance and its delegate will ensure that network pharmacies will maintain for 10 years, books, documents and other evidence of accounting procedures and practices consistent with CMS regulations.
 - 8.2 Network pharmacies will maintain prescription records in their original format for the greater of 3 years or the period required by State law and allow those records to be transferred to an electronic format that replicated the original prescription for the remaining 7 years of the 10-year record retention requirement.
 - 8.3 Alliance and its delegate will assure that they maintain the records for the pharmacy network including contracts and accreditation forms.
- 9 Pharmacy Access during a Federal Disaster or Other Public Health Emergency
 - 9.1 Alliance and its delegate ensure that the Pharmacy Network will guarantee immediate refills of Part D medications to any beneficiary located in an "emergency area," defined as the area in which the President has declared a major disaster, or the Secretary of the Department of Health and Human Services (DHHS) has declared a public health emergency. For those enrollees residing in the emergency area all "refill too soon" edits will be removed for the period of the emergency declaration through the use of an override code at Point of Sale.
 - 9.2 Because the following conditions might exist during an emergency: a limited number of operational pharmacies, limitations on transportation and travel, and the disruption of U.S. mail – Alliance and its delegate's Pharmacy Network

will allow an affected enrollee to obtain the maximum extended day supply, if requested and available at the time of refill.

- 9.3 Alliance and its delegate will continuously monitor the Federal Emergency Management Agency (FEMA) Web site (<http://www.fema.gov/news/disasters.fema>) for issuance of Presidential major disaster declarations and the DHHS Web site (<http://www.dhhs.gov/>) for public health emergency declarations.
- 9.4 In advance of an impending disaster, Alliance and its delegate's Pharmacy Network may remove refill too soon edits for those enrollees whose primary residence is located in the geographic area identified in the declarations, regardless of the location at which they are attempting to obtain a refill. At the end of the emergency declaration or at the closure of the disaster incident period, as specified in the aforementioned Web sites or 30 days from the initial Presidential declaration, Alliance and its delegate's Pharmacy Network should re-implement their edits and continue to work closely with enrollees who are displaced or otherwise impacted by the disaster and need access to their Part D benefits. This may include continuing to guarantee out-of-network (OON) pharmacy access to those enrollees who cannot reasonably access a network pharmacy (i.e., the locality is so badly impacted by the disaster that prescription drugs are only available through a severely limited distribution chain).

10 Out of Network Pharmacy Access (OON)

- 10.1 Alliance and its delegate ensure that enrollees have access to medically necessary and appropriate prescription drugs when a network pharmacy may not be available or accessible.
- 10.2 Alliance and its delegate will pay claims for covered prescription drugs obtained at pharmacies not in the plan's national/ regional Pharmacy Network under the following conditions:
 - a. The enrollee could not be reasonably expected to obtain the drug at a network pharmacy.
 - b. The enrollee does not obtain prescription drugs at non-network pharmacies on a routine basis.
- 10.3 Alliance and its delegate may charge enrollees the difference between the OON's usual and customary charge and the plan's allowance. (Refer to Alliance and its delegate's DMR policy).
 - 10.3.1 The following tools are available to assist enrollees in locating a plan pharmacy:
 - a. All enrollees receive a Membership Card along with their fulfillment packet. The Membership Card contains a toll-free Customer Service phone number, which is operational 8 AM to 8 PM PST, and instructions to contact customer Service to find the nearest plan pharmacy.
 - b. Enrollees can locate Plan pharmacies directly by accessing Alliance and its delegate's web site.
 - 10.3.2 Alliance and its delegate may approve claims for covered drugs obtained at a pharmacy and administered by a physician in an office setting, and not covered under Medicare Part B, such as Part D-covered vaccines.

10.4 If an enrollee cannot locate a plan pharmacy, and must therefore seek services at an OON pharmacy, the following procedures are in place:

10.4.1 The OON pharmacy attempts to fill the prescription and receives a “pharmacy not contracted with plan” error message. Three possible courses of action will follow:

- a. The pharmacy calls the toll-free Customer Service number located on the enrollee’s prescription card. If during normal business hours, Monday through Friday, the pharmacy can immediately become a contracted Alliance and its delegate’s Network Pharmacy, thus enabling the pharmacy to fill the enrollee’s prescription as a Plan Network Pharmacy.
- b. The pharmacy calls the toll-free Customer Service number located on the enrollee’s prescription card. If NOT during normal business hours, Monday through Friday, or if the pharmacy does NOT want to become a contracted Alliance and its delegate’s Network Pharmacy, the Customer Service operator advises the pharmacy representative of the closest Plan Pharmacy for referral of the enrollee.
- c. The enrollee elects to have the OON pharmacy fill his/her prescription(s) and pays the OON pharmacy out of pocket. The OON pharmacy will charge the enrollee the full usual and customary price for the drug. That price may be higher than the plan’s contracted rate for the same drug had it been filled in an Alliance and its delegate’s Network pharmacy.

10.4.2 If the enrollee elects to have the OON pharmacy fill his/her prescription(s), he/she completes a Direct Member Reimbursement (DMR) form to receive reimbursement from Alliance and its delegate.

- a. This form is provided in the enrollee’s Fulfillment packet and is also available for printing from the Alliance/its delegate’s web site.
- b. Direct Member Reimbursement requests are considered to be coverage determinations. DMR instructions specifically state that DMR must be received by Alliance and its delegate .
- c. The DMR form requires the enrollee to provide the following information:
 - i. Enrollee name, address, and phone number
 - ii. Name and address of the ONN pharmacy
 - iii. Receipt received from OON pharmacy for completed payment
- d. The DMR form contains instructions for mailing the completed form to Alliance and its delegate for processing the enrollee reimbursement. Incomplete DMR forms will not be processed and will instead be returned to the enrollee with instructions to complete and resubmit.
- e. The Alliance and its delegate’s Data Entry department receives all DMR forms. DMR forms that do not meet the less than 90-day requirement are returned to the enrollee and do not get processed by the Alliance and its delegate.

- f. The time frames for Direct Member Reimbursement requests are the following:
 - i. If a plan sponsor is issuing an unfavorable reimbursement decision, it must make the decision and provide notice of the decision no later than fourteen (14) calendar days after receiving the reimbursement request.
 - ii. If a plan sponsor is issuing a favorable reimbursement decision, it must make the decision, provide notice of the decision, and make payment no later than fourteen (14) calendar days after receiving the reimbursement request.
- g. Data Entry enters the information from the DMR form into Alliance and its delegate's claims system and an on-line claim is electronically processed. Two possible courses of action will follow:
 - i. The drug(s) are part of the Alliance formulary. The claim is successfully adjudicated on-line at the plan's "contracted rate", which provides reimbursement to the enrollee based on Alliance and its delegate's plan allowance for the Part D drug; once adjudicated, the applicable amount is added to the patient's TrOOP balance.
 - ii. The drug(s) are not part of the Alliance formulary (i.e. not a covered Part D drug) and therefore require a provider's supporting statement per normal coverage determination processes. Alliance and its delegate will then determine whether the request is approved or denied, and provider and member notices are provided.
- h. Claims (DMR requests) that are approved are electronically forwarded to Finance. Finance cuts checks every Friday (usually taking at least one week to process the current week's checks) and mails enrollee reimbursement checks to the address the enrollee provided on their DMR form.

DEFINITIONS/ACRONYMS

DMR: Direct Member Reimbursement is utilized by members to seek reimbursement for prescription payments necessitated by utilization of an out of network pharmacy.

GeoAccess: A specific reporting program utilized by Alliance and its delegate.

HI: Home Infusion (HI) pharmacy networks are not expected to provide or pay for HI supplies, equipment, or professional services, however, must provide professional services and the supplies necessary for HI services.

I/T/U: A pharmacy operated by the Indian Health Services, an Indian tribe or tribal organization, or urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 USC 1603.

LTC: Long term care pharmacies are owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Mail Order: Remote pharmacies offering prescription drug services. The inclusion of mail-order pharmacies in Part D plan networks is optional and network mail-order pharmacies will not count toward meeting the retail pharmacy access requirements specified in section 50.1. *Since network inclusion of mail-order pharmacies is optional, sponsors may designate a subset of formulary drugs (e.g., particular tiers or "maintenance drugs" only) for availability via network mail-order pharmacies. As described in section 50.10, to the extent that a Part D plan offers benefits, including extended supplies of drugs (e.g., 90-day supplies), through network mail-order pharmacies, the plan must ensure that enrollees have reasonable access to the same benefits at network retail pharmacies.*

Out of Service Area: Pharmacies outside a Plan Sponsor's Covered Service Area. Although CMS uses the term Out of Network (OON) for these pharmacies; they could still be contracted as part of The Health Plan's national pharmacy network.

Retail Pharmacy: Any licensed pharmacy that is not a Mail Order pharmacy from which Part D Beneficiaries could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.

RHC: Rural Health Center.

Rural: The five-digit Zip Codes in which the population density is less than 1,000 persons per square mile.

Suburban: The five-digit Zip Codes in which the population density is between 1,000 and 3,000 persons per square mile.

Urban: The five-digit Zip Codes in which the population density is greater than 3,000 persons per square mile.

AFFECTED DEPARTMENTS/PARTIES

Pharmacy Services
Pharmacy Benefit Manager (Currently PerformRx)
Finance

RELATED POLICIES AND PROCEDURES

None

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

None

REVISION HISTORY

New Policy

REFERENCES

42 CFR §423.120 (a) - Access to covered Part D drugs
Prescription Drug Benefit Manual, Chapter 5: Benefits and Beneficiary Protections, 50 – Access to Covered Part D Drugs, 50.5 - Long-Term Care (LTC) Pharmacy Access
42 CFR §423.154 Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA-PD plans.
42 CFR §423.505 - Contract provisions
Pharmacy Directory, Prescription Drug Coverage Download - [Table of Contents](#)
Medicare Prescription Drug Benefit Manual, Chapter 14 – Coordination of Benefits
Medicare Prescription Drug Benefit Manual, Chapter 18 – Part C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals

MONITORING

Alliance Pharmacy Department will assure that its delegate is performing all activities related to Access to Part D drugs including network pharmacy GeoAccess requirements, contracting provisions, credentialing and appropriate monitoring.



POLICY AND PROCEDURE TEMPLATE

Policy Number	RX-D-028
Policy Name	Medicare Part D Coordination of Benefits (COB)
Department Name	Pharmacy Services
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy Services
Line(s) of Business	D-SNP
Effective Date	TBD
Subcommittee Name	Pharmacy and Therapeutics Committee
Subcommittee Approval Date	TBD
Administrative Oversight Committee Approval Date	TBD

POLICY STATEMENT

Alameda Alliance for Health (the Alliance) is committed to maintaining enrollees' Personal Health Information (PHI), supporting the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule), and to establish the order of payment rules established by the Centers for Medicare and Medicaid Services (CMS) for Coordination of Benefits (COB).

PROCEDURE

This policy ensures specifically that the COB at the Point of Sale (POS) includes:

- The primary, secondary, or tertiary payers are correctly determined, and the pharmacy claims are routed to the payers in the correct order.
- True Out of Pocket (TrOOP) expenses are calculated correctly, and Prescription Drug Events (PDEs) are reported accurately.

PROCESS

CMS requires Part D plan sponsors, in this case the Alliance, to coordinate benefits with State Pharmaceutical Assistance Programs (SPAPs) and other providers of prescription drug coverage with regards to payment of premiums and coverage, as well as supplementing Part D benefits.

1. Receipt of COB Information:

Members' COB information can come from various sources as listed below. The Alliance's enrollment department ensures that the information is collected, verified, and eligibility records are updated and shared with the Pharmacy Benefit Manager (PBM).

- New member Enrollment – information provided by the member on the application form
- Daily COB file received from CMS.
- Member Services call center

CMS requires the Alliance to coordinate benefits with supplemental payers when:

- Supplemental payers send electronic eligibility data for Part D eligible beneficiaries that are in their plan to CMS.
- The 4Rx on the claim paid by the supplemental plan matches the 4Rx on the eligibility information the supplemental payer has sent to CMS.
- The Part D Sponsor has paid for the Part D drug and the supplemental payment transaction information (N transaction) can be matched to the Other Health Insurance (OHI) information on record and the covered Part D claim.
- When coordinating benefits, only supplemental coverage of Part D covered drugs must follow COB Rules as only Part D covered drugs count towards the beneficiary's TrOOP accumulation. The drug must meet the CMS definition of a Part D drug.

2. Nx Transactions

The Transaction Facilitator sends record of payment from payers supplemental to Part D plan (in the form of an N transaction) for purposes of tracking TrOOP in real time. Part D plans are to process N Transactions real-time and appropriately apply the information to TrOOP. Where necessary, Part D Plans are to adjust claims when record of payment is delayed.

- N1 Refers to an original other payer transaction that informs the primary Medicare payer of patient liability reduction.
- N2 Refers to a reversal of the original other payer transaction.
- N3 Refers to a reverse and resubmit of the original other payer transaction.

The PBM receives the Nx transactions from the Part D facilitator via the Alliance and validates the information against the eligibility file and reprocesses the claims as appropriate. (Refer to PBM policy):

The Alliance Pharmacy Department will monitor the following:

- Nx Performance Reports which include all rejected Nx transactions: these cumulative detail and summary reports are created on the 1st and 15th day of each month and contain all rejected Nx transactions for the current calendar year as of the day prior to issuance.
- Timely adjustment of claims and issuance of refunds or recovery notices based on the Payment Reports provided by the PBM.

- Member Appeals and Grievances related to the application of COB process to ensure accuracy and correct application of the primary payer.

DEFINITIONS / ACRONYMS

COB: Coordination of Benefits refers to the process used by insurance plans when a person is covered by more than one plan. It is used to identify the order of benefit determination, i.e., which plan pays first (the [primary payer](#)), which plan pays second (the [secondary payer](#)), and in some cases which plan pays third (the tertiary payer) to avoid overpayment or duplicate payments..

COBC: Coordination of Benefits Contractor is the CMS contractor that consolidates the activities that support the collection, management, and reporting of other insurance coverage for Medicare members.

MSP – Medicare Secondary Payer

N Transactions: Supplemental Payment Transactions

PDE: Prescription Drug Event is a specific format of claim reporting that has financial, beneficiary, provider and dispensing information fields. PDEs are a CMS requirement for Part D as the source of truth for member prescription drug dispensing events.

TrOOP: True out-of-pocket (TrOOP) refers to the maximum amount that the beneficiary (or other entities on beneficiary's behalf) must pay before the beneficiary reaches the "catastrophic" level of coverage. The TrOOP amount changes annually. In 2025, the amount is \$2,000.

AFFECTED DEPARTMENTS/PARTIES

Pharmacy Services

Enrollment

Pharmacy Benefit Manager (Currently PerformRx)

RELATED POLICIES AND PROCEDURES

RX-D 002 Prescription Drug Event (PDE) Submission, Rejection, Monitoring and Resolution

RX- D 33 Medicare TrOOp, FIR, and NX Transactions

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

None

REVISION HISTORY

New Policy

REFERENCES

RX-D-028 Medicare Part D Coordination of Benefits (COB)

Medicare Part D Benefits Manual Chapter 14, Section 20
Coordination of Benefits-Other Health Insurance (COB-OHI) Record Updates, July 30, 2024
<https://www.cms.gov/medicare/coordination-benefits-recovery/overview/secondary-payer>
<https://www.cms.gov/medicare/coordination-benefits-recovery/overview/coordination-benefits>

MONITORING

Alliance Pharmacy Department Staff will include results of ongoing monitoring in monthly Delegated Function Oversight/Monitoring statistics.



POLICY AND PROCEDURE

Policy Number	RX-D-029
Policy Name	Medicare Part D Low Income Subsidy
Department Name	Pharmacy
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy Services
Line(s) of Business	D-SNP
Effective Date	TBD
Subcommittee Name	Pharmacy and Therapeutics Committee, Peer Review and Credentialing Committee
Subcommittee Approval Date	TBD
Administrative Oversight Committee Approval Date	TBD

POLICY STATEMENT

Alameda Alliance for Health (Alliance) is contracted with the Centers for Medicare and Medicaid Services (CMS) to provide Part D benefits to its enrollees who qualify for Medicare Extra Help (or Low-Income Subsidy).

PROCEDURE

Alliance Medicare Part D provides drug coverage to those who qualify for Extra Help (or low-income subsidy). The Extra Help program is a federal assistance program that subsidizes enrollee costs including annual deductibles, prescription copays, and monthly Part D premiums. CMS releases income limit guidance for Low Income Subsidy eligibility.

PROCESS

To establish the correct premium, cost sharing, and deductible levels with the correct effective dates for current, prior, and prospective enrollees, Part D sponsors should refer to the Daily Transaction Reply Report (DTRR).

The DTRRs provide full replacement LIS profiles to Plans in response to any LIS change that impacts a Part D enrollment period. When there is a new enrollment or a LIS Status change, Part D sponsors will receive a TRC for every LIS period that overlaps the new enrollment (including PDP changes). Therefore, the DTRR is the definitive source of LIS eligibility information. It is important to note that unlike much of the data provided in the DTRR, LIS

eligibility information is not based on Current Calendar Month (CCM) reporting. Other relevant files, codes and LIS verification sources for the plan:

LIS/Part D Premium File (1st and 3rd Sunday of every month)

LIS History (LISHIST) (monthly – history period of LIS not to exceed 36 months)

Loss of Subsidy File (twice yearly- September/December)

MA Full dual Auto Assignment Notification File (3rd of each month)

Transaction Codes (TRC) to identify LIS:

TRC 121- LIS Period Status

TRC 223- LIS Removed

Medicare Advantage Prescription Drug (MARx) UI screens-

M232- Beneficiary Eligibility

M203-Beneficiary Snapshot

M231-Premium View

M256-Status Activity

M257-Status Detail-Medicaid

Coverage Year (CY) 2026 Maximum LIS Beneficiary Cost-Sharing Table

Low-Income Subsidy Category	LIS Category	Deductible	Copayment up to Out-of-Pocket Threshold ^a	
			Generic	Brand
Full-Benefit Dual Eligible Beneficiaries Institutionalized or Receiving Home and Community-Based Services	3	\$0	\$0	\$0
Full-Benefit Dual Eligible Beneficiaries with income ≤ 100% FPL	2	\$0	\$1.60	\$4.90
Full-Benefit Dual Eligible Beneficiaries with income between 100% and 150% FPL	1	\$0	\$5.10	\$12.65
Non-Full Benefit Dual Eligible Beneficiaries Applied or are eligible for Medicare Savings Program (QMB-only, SLMB-only, or QI); or Supplemental Security Income (but not Medicaid)	1	\$0	\$5.10	\$12.65
Non-Full Benefit Dual Eligible Beneficiaries Applied and with income ≤ 150% FPL for 2024 and resources ≤ \$17,600 (\$35,130 if married) ^b	1	\$0	\$5.10	\$12.65

Notes. —

- a. The out-of-pocket threshold is \$2,100 for 2026. Beginning in CY 2024, under section 1860D-2(b)(4)(A)(i) of the Act, as amended by section 11201(a) of the IRA, there is no cost-sharing for covered Part D drugs above the annual out-of-pocket (OOP) threshold, as defined at section 1860D-2(b)(4)(B) of the Act, for any Part D beneficiaries, including LIS-eligible beneficiaries.
- b. The resource limits displayed include \$1,500 per person for burial expenses. For beneficiaries that did not notify SSA that they expect to use some of their resources for burial expenses, the applicable resource limit is \$16,100 (\$32,130 if married).

DEFINITIONS / ACRONYMS

Daily Transaction Reply Report (DTRR) - A CMS-generated file that provides responses to enrollment and eligibility transactions submitted by states or plans, indicating whether each record was accepted or rejected and detailing any required actions or errors. AAH will use the Daily Transaction Reply Report (DTRR) to reconcile its beneficiary records with the Monthly Membership Report (MMR), which is beneficiary specific.

Extra Help - Medicare program that helps people with limited incomes and resources reduce Medicare Part D prescription drug costs, such as premiums, deductibles, and copays. Extra Help is also called the “Low-Income Subsidy”, or “LIS”.

LICS – Low Income Cost Sharing – Equal to the difference between the plan benefit for cost-sharing, and the low-income cost-sharing charged to a member based on their low-income cost sharing level. For example, if the plan benefit is \$25 cost-share for a drug, and a low-income member’s cost-share is \$1, the difference of \$24 is LICS. CMS reconciles LICS dollar for dollar.

Low Income Subsidy (LIS) - Refers to the Medicare subsidy specific to Part D for qualified beneficiaries in the form of reduced co-payments. Also referred to as Extra Help.

Medicare Advantage Prescription Drug System (MARx) - The primary CMS online and batch system that provides access to information about Medicare enrollment, payment, premium withhold, for beneficiaries.

Prescription Drug Event (PDE) – Part D encounter data submitted to CMS to reconcile Part D spend to the CMS Part D benefit.

Prescription Drug Plan (PDP) – Payer-sponsored CMS approved Part D prescription drug plan

Transaction Reply Code (TRC) – TRCs are used by CMS to communicate LIS status and changes to Medicare plans.

AFFECTED DEPARTMENTS/PARTIES

Pharmacy Services

Enrollment

Member Services

Pharmacy Benefit Manager (Currently PerformRx)

RELATED POLICIES AND PROCEDURES

FIN-D-111 Enrollment/Payment Reconciliation and Attestation Submission

FIN-D-909 Part D Reconciliation
Medicare Part D Best Available Evidence
RX-D-002 Prescription Drug Event (PDE) Submission, Rejection, Monitoring and Resolution
RX-D-006 Claim Adjudication

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

None

REVISION APPROVAL HISTORY

New Policy

REFERENCES

Centers for Medicare & Medicaid Services. (2024, October 31). *Calendar Year (CY) 2025 resource and cost-sharing limits for low-income subsidy (LIS)*. U.S. Department of Health & Human Services.

<https://www.cms.gov/files/document/calendaryear2025resourceandcostsharinglimitsforlowincome subsidy.pdf>

Centers for Medicare & Medicaid Services. (2024). *Low Income Subsidy (LIS)*. U.S. Department of Health & Human Services. <https://www.cms.gov/training-education/partner-outreach-resources/low-income-subsidy-lis>

Centers for Medicare & Medicaid Services. (2024, November 27). *Plan Communication User Guide (PCUG), version 18.2*. U.S. Department of Health & Human Services.

<https://www.cms.gov/mapd-helpdesk>

United States Congress. (2022). Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11201(a), 136 Stat. 1818. <https://www.congress.gov/bill/117th-congress/house-bill/5376>

MONITORING

Alliance Pharmacy Department Staff will include results of ongoing monitoring in monthly Delegated Function Oversight/Monitoring statistics.



POLICY AND PROCEDURE TEMPLATE

Policy Number	RX-D-031
Policy Name	Medicare Part D Emergency Preparedness
Department Name	Pharmacy Services
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy Services
Line(s) of Business	D-SNP
Effective Date	[Original date policy was approved by committee - MM/DD/YYYY – TBD for new policies]
Subcommittee Name	Pharmacy and Therapeutics Committee
Subcommittee Approval Date	TBD
Administrative Oversight Committee Approval Date	TBD

POLICY STATEMENT

Alameda Alliance for Health (Alliance) is committed to its enrollees in times of disaster or public health emergency to obtain emergency supply of medication until the end of the emergency.

PROCEDURE

In the event that a Disaster or Public Health Emergency has been declared by Presidential declaration, the Secretary of DHHS or the State Governors Office, emergency procedures will apply. Affected Emergency or Disaster Areas are identified by monitoring the FEMA, DHHS, and CMS websites.

PROCESS

1.0 Pharmacy Access

Alliance will lift their “refill-too-soon” (RTS) edits for affected areas with assistance from the contracted PBM through the termination of the emergency or upon the expiration of the 90-day period beginning from the initial declaration, whichever occurs first.

Alliance may exercise some operational discretion as to how these edits are lifted during a disaster or emergency as long as access to Part D drugs is provided at the point-of-sale.

For major disasters declared by the President of the United States, Part D sponsors should pay particular attention to the closure of disaster incident periods listed in the Disaster Federal Register Notice section on Federal Emergency Management Agency's (FEMA's) Web site <http://www.fema.gov/news/disasters.fema>, noting that in circumstances in which the incident period has not officially closed 30 days from the initial Presidential declaration.

In the absence of a Presidential major disaster or emergency declaration or a public health emergency, Alliance may consider lifting the edits -- for instance, in advance of an impending disaster -- if they determine it is appropriate to do so to ensure pharmacy access. However, at all times, and especially in disaster and/or public health emergency situations, Alliance must ensure, consistent with *Prescription Drug Benefit Manual (PDBM) Chapter 5: Benefits and Beneficiary Protections, September 30, 2011*, that their enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy, and when such access is not routine.

2.0 Emergency Access to Benefit (EAB) Set-up

Alliance should set up emergency prescription dispensing procedures with the PBM proactively as part of the benefit design. Four possible solutions are:

- 1) None. If the emergency prescription dispensing procedures are not implemented, PBM will follow normal procedures if a member requests replacement medication.
- 2) Standing. Allows a specified number of refill overrides within a defined timeframe.
- 3) Zip Code. Allows unlimited refills for members within the zip codes defined in the Disaster Declaration.
- 4) Zip Code & Standing. Allows unlimited refills for members within the zip codes defined in the Disaster Declaration; but if the member resides outside of the zip code, then a refill override is allowed if the member hasn't exceeded the number allowed within the timeframe.

3.0 Member Access to Covered Drugs

3.1 PBM will ensure that enrollees whose residential address by zip code, that are in emergency area will receive RTS overrides of the covered Part D medications for emergency/disaster duration, regardless of the location at which they are attempting to obtain the medication so long as the pharmacy is in network.

3.2 If a member from the Emergency or Disaster Area attempts to fill a prescription for lost or damaged medication and the claim rejects with a client selected reject code, the pharmacy has the ability to enter Submission Clarification Code (SCC) disaster override code 13 in NCPDP vD.0 field 420-DK "Submission Clarification Code". Claims that adjudicate using the override code are flagged and reportable.

3.3 During a time of Disaster, the PBM will allow members to obtain the maximum days' supply allowable within benefit and pharmacy contract limits, if available at the time of refill.

4.0 Monitoring of Government websites

Alliance and PBM will monitor FEMA, DHHS, CMS, state and local websites as appropriate to determine disaster no longer exists or upon the expiration of the ninety (90)-day period beginning from the initial declaration by DHHS, whichever occurs first. Unless otherwise specified, the initial expiration date will be ninety (90) days from the declaration date.

4.1 After reinstatement of the RTS edits, Alliance and PBM will continue to work closely with enrollees who indicate that they are still displaced or otherwise impacted by the disaster

or emergency. Enrollees that are serviced by mail-order or specialty pharmacy can specify an alternate shipping address if they are displaced by the Disaster or emergency. This will be a case-by-case basis.

DEFINITIONS / ACRONYMS

CMS – Centers for Medicare and Medicaid Services

DHHS – Department of Health and Human Services

FEMA - Federal Emergency Management Agency

PBM- Pharmacy Benefit Manager

RTS – Refill too Soon

SCC - Submission Clarification Code

AFFECTED DEPARTMENTS/PARTIES

Pharmacy Services

Pharmacy Benefit Manager (Currently – PerformRx)

RELATED POLICIES AND PROCEDURES

RX-D 017 Part D or PBM Delegated Function Oversight and Monitoring

RX-D 032 Medicare Part D Early Prescription Refill

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

None

REVISION HISTORY

New Policy

REFERENCES

Prescription Drug Benefit Manual (PDBM) Chapter 5: Benefits and Beneficiary Protections, September 30, 2011

MONITORING

Alliance Pharmacy Department Staff will include results of ongoing monitoring in monthly Delegated Function Oversight/Monitoring statistics.



POLICY AND PROCEDURE TEMPLATE

Policy Number	RX-D-032
Policy Name	Medicare Part D Early Prescription Refill
Department Name	Pharmacy Services
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy Services
Line(s) of Business	D-SNP
Effective Date	[Original date policy was approved by committee - MM/DD/YYYY – TBD for new policies]
Subcommittee Name	Pharmacy and Therapeutics Committee
Subcommittee Approval Date	TBD
Administrative Oversight Committee Approval Date	TBD

POLICY STATEMENT

Alameda Alliance for Health (Alliance) with this policy is documenting the process for prescription early refill in accordance with the Centers of Medicare & Medicaid Services (CMS) regulations and guidelines. An early refill edit is a utilization management tool used to promote compliance and to prevent waste. An early refill edit cannot be used to limit appropriate and necessary access to an enrollee's Part D benefit.

PROCESS

1.0 CMS Requirement

1.1 CMS considers safety edits to prevent dispensing of unsafe dosing of drugs to be part of the concurrent Drug Utilization Review (DUR) requirements for all Part D drugs. CMS does not require Part D sponsors to submit POS safety related edits as part of their HPMS formulary submission, even if they are implemented as hard edits (with the exception of opioid specific edits, as defined in Chapter 6 – Part D Drugs and Formulary Requirements, section 30.2.2.1). These edits are typically applied at point-of-sale (POS) and assist the pharmacist in identifying and/or preventing inappropriate drug therapy.

2.0 Refill Criteria

2.1 To comply with pharmacy best practice standards and regulatory requirements the following criteria is used to determine when a prescription can be refilled:

- 2.1.1 At least 85 percent of the medication must be used, based on the quantity of the previously filled prescription.
- 2.1.2 An excess amount of the medication must not have been accumulated over the past 180 days.

Note: The prescription refill review will occur whether the refill is ordered at a participating retail pharmacy or via PerformRx member website or calling the pharmacy number on the back of the member's benefit card.

for 2.1.3 The Plan's refill guideline "look back" period is 180 days. A member can receive a refill when 85 percent of the medication on hand is used. However, if the patient regularly refills prescriptions a little early each month, those early fill quantities will be accumulated when determining whether they are eligible refill.

2.1.4 These early refill guidelines are designed to minimize the excessive use, waste and stockpiling of prescription medications. No more than a 30-day supply of medication can remain on hand for a refill to be approved.

2.2 If enrollee regularly orders medication when only 85 percent of the quantity has been used, they will accumulate an excess supply, and the refill date may be adjusted.

2.3 To avoid having a refill delayed, the following guidelines apply:

2.2.1 For a 30-day retail prescription, order a refill when they have no more than a 4-day supply remaining. (For a 30-day mail order prescription, they may order the refill no more than 7 days earlier, to ensure you receive the refill before the medication on hand is used.)

2.2.2 For a 90-day retail or mail order prescription, request the refill when they have no more than a 13-day supply remaining.

2.4 If a prescription reflects a change in dosage, it is treated like a new prescription and the look back period starts over from zero. However, if a new prescription is identical to the previous one, the system will continue to look back 180 days to determine if the refill can be approved.

2.5 If enrollee orders a refill at a participating retail pharmacy too early, they will be asked to wait until the allowable refill date. If they order the refill through the mail order pharmacy, the pharmacy may hold the refill until the allowable date.

2.6 Exceptions to this refill policy can be made under certain circumstances.

2.6.1 If enrollee is traveling outside of the United States 90 days or more, you may request an extended day supply of medication by completing the *Request for Medicare Prescription Drug Coverage Determination* form 30 days prior to the scheduled departure date.

2.7 Early Refill Edits on Topical Ophthalmic Products

2.7.1 To assist Alliance and its PBM in determining proper edits to protect beneficiary access CMS recommends allowing the following for topical ophthalmic products:

- Permit refills at 70% of the predicted days of use. By way of an example, for a prescribed medication with an expected duration of 30 days of use, the refills would be permitted at day 21.
- Ensure that the refill allowances are the same regardless of purchase through retail or mail-order sources.
- Permit physicians to authorize earlier refills than 70% days of use for particular beneficiaries who continue to have difficulty with inadvertent wastage.

2.8 Exceptions to Refill too Soon rejects:

- Vacation Supply

- 30 day supply allowed for vacation supply 1 time per medication per year
- Vacation supply DOES NOT include controlled medications
- Lost/Stolen/Spilled/Damaged
 - 30 day supply allowed for vacation supply 1 time per medication per year
 - Lost/Stolen/Spilled/Damaged overrides include controlled medications
 - Stolen controlled medications require Police Report ID#

DEFINITIONS / ACRONYMS

CMS – Centers for Medicare & Medicaid Services

DUR – Drug Utilization Review

POS – Point of Sale

PBM – Pharmacy Benefit Manager

AFFECTED DEPARTMENTS/PARTIES

Pharmacy Services

RELATED POLICIES AND PROCEDURES

RX-D Medicare Part D Emergency Preparedness

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

None

REVISION HISTORY

New Policy

REFERENCES

Chapter 6 – Part D Drugs and Formulary Requirements

HPMS memo - Early Refill Edits on Topical Ophthalmic Products, June 2, 2010

MONITORING

Alliance Pharmacy Department Staff will include results of ongoing monitoring in monthly Delegated Function Oversight/Monitoring statistics.



POLICY AND PROCEDURE

Policy Number	RX- D-034
Policy Name	Medicare Part D Negative Formulary Change Notification
Department Name	Pharmacy Services
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy Services
Line(s) of Business	D-SNP
Effective Date	TBD
Subcommittee Name	Pharmacy and Therapeutics Committee
Subcommittee Approval Date	TBD
Administrative Oversight Committee Approval Date	TBD

POLICY STATEMENT

Alameda Alliance for Health (Alliance) and its contracted PBM will follow the Centers for Medicare and Medicaid Services (CMS) guidelines for limiting changes to Part D formularies during the contract year. Negative formulary changes will adhere to request, approval and notification requirements as set forth by CMS, in accordance with 42 CFR 423.120(e).

PROCEDURE

1.0 Part D Formulary Changes

- Alliance utilizes the Pharmacy Benefit Manager's (PBM) Standard Formulary, with all formulary development and maintenance functions delegated. Except as described below, prior to implementing a negative formulary change, Alliance must submit to CMS a negative formulary change request. Once CMS approves the formulary to be used for the benefit year (around September of the year preceding the benefit year), CMS does not allow the removal of a covered part D drug from the formulary with the exception of:

1.1 Immediate Negative Formulary Change

Immediate negative formulary changes may be implemented at any time and are not restricted by the prohibition on negative changes during the period from the start of

the annual coordinated election period to 60 days after the beginning of the contract year associated with that annual coordinated election period.

Immediate negative formulary changes can be implemented, provided that Alliance has given prior general notice to CMS as well as current and prospective enrollees, in accordance with 42 CFR 423.120(f)(2). Immediate negative formulary change means an immediate substitution or market withdrawal that meets the requirements of §423.120(e)(2)(i) or (ii) including:

- Removal of a brand name drug, a reference product, or a brand name biological product within 30 days of adding a corresponding drug to its formulary on the same or lower cost sharing tier and with the same or less restrictive utilization management requirements, so long as Alliance previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval because such drug was not yet available on the market.
- Immediately removing a Part D drug withdrawn from sale by the manufacturer or that the Food and Drug Administration (FDA) determines to be withdrawn for safety or effectiveness reasons.

1.2 Formulary Maintenance Changes

Negative change requests for maintenance changes are considered to be approved after 30 days unless otherwise notified by CMS. Maintenance change means one of the following:

- Removal or placement in a less preferred tier of a brand name drug upon the availability and addition of an A-rated generic or multi-source brand name equivalent, at a tier with lower cost to the beneficiary (other than immediate substitutions that meet the requirements of § 423.120(e)(2)(i)).
- Removal of a non-Part D drug inadvertently included on the formulary.
- Addition of utilization management tools based upon a new FDA boxed warning.
- Removal of a drug based upon a new FDA market withdrawal notice.
- Removal of a drug based on long term shortage and market availability.
- Removal or placement in a less preferred tier based upon new clinical guidelines or information recognized by CMS.
- Removal or placement of a reference product within 90 days of adding a biosimilar biological product other than an interchangeable biological product of that reference product to the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements.
- Making negative formulary changes based upon new clinical guidelines or information or to promote safe utilization.
- Adding PA to help determine Part B versus Part D coverage.
- When an ACIP recommendation is narrowed and no PA is in place for that vaccine, the plan must submit a negative formulary change request to add a PA requirement that aligns with the newly narrowed recommendation, consistent with §423.120(e)(1). (Note: If ACIP withdraws a recommendation for a previously recommended vaccine such that the vaccine no longer meets the definition of an ACIP-recommended adult vaccine, Part D sponsors are not required to submit a negative change request.)

1.3 Non-maintenance (Other) Changes

Non-maintenance changes must not be implemented until the plan receives notice of approval from CMS. Affected enrollees are exempt from non-maintenance changes for

the remainder of the contract year. PBM shall not implement any Other Formulary Changes, or issue any beneficiary notices of such changes, prior to receiving explicit CMS approval.

Non-maintenance type of changes include:

- Changing of formulary drugs from preferred to non-preferred.
- Adding utilization management (not defined under maintenance change).
- Increasing cost sharing on preferred drugs (unrelated to the reasons stated above).
- Removing dosage forms.
- Exchanging therapeutic alternatives (either by formulary addition/removal or tier exchanges).

2.0 Submitting proposed formulary changes

2.1 PBM as delegated, will submit all proposed negative formulary changes to CMS for approval via the Negative Formulary Change Request Template within the required timeframe based on the type of proposed negative formulary change.

2.2 For the removal or tier change of a brand name medication and addition of newly approved generics rated therapeutically equivalent by the FDA, PBM is not required to submit a Negative Change Request (NCR) prior to effectuation if the generic could not have been included with the initial plan year's formulary. PBM will include the generic substitution in the next available formulary submission to CMS. Additionally, PBM will still submit a NCR notifying CMS of the change as soon as the decision to implement this change is made. The effective date of the NCR submission for expedited substitutions that are implemented immediately will reflect the date of implementation even if the date is prior to the NCR submission date.

2.3 Submission of proposed negative formulary changes other than the removal or tier change of a brand name medication and addition of newly approved generics rated therapeutically equivalent by the FDA at least 30-days prior to the effective date of the change.

2.4 For all changes other than the removal or tier change of a brand name medication and addition of newly approved generics, upon explicit approval from CMS, PBM submits the change as part of the monthly formulary updates one month prior to the intended effective date.

3.0 Notice of Formulary Changes

3.1 Unless otherwise stated, all negative formulary changes must be sent to Entities, Providers, Pharmacies, and affected enrollees. Notice requirements are dependent on the type of negative formulary change implemented. For negative changes other than the removal or tier change of a brand name medication and addition of newly approved generics rated therapeutically equivalent by the FDA, PBM provides notice at least 30 days prior to the effective date of a change in the formulary.

3.1.1 Notice to Entities: Alliance provides an annual notice with information on the website where entities can verify the formulary status of particular drugs.

3.1.2 Notice to Enrollees: PBM provides direct written notice to affected enrollees at least 30 days prior to the effective date of change.

3.1.3 Alliance/PBM website provides notice to current and prospective enrollees to include both negative and positive changes.

3.1.4 Alliance/PBM updates the formulary on the website monthly to include both negative and positive changes.

3.2 No Prior Notice Required: PBM may change its plan formulary without providing prior written notice when:

3.2.1 PBM expands its formulary through Formulary Enhancement.

3.2.2 PBM immediately removes drugs that are deemed unsafe by the FDA or that are removed from the market by the manufacturer.

3.2.3 PBM may immediately remove or change the tier of a brand name medication and add its generic equivalent.

3.3 Retrospective Notice: When the PBM removes covered Part D drugs pursuant to an FDA action or a manufacturer withdrawal from the market, PBM provides retrospective notice of such formulary changes to affected enrollees.

3.3.1 In the event PBM removes or changes the tier of a brand name medication and adds its generic equivalent, retrospective beneficiary notice as required by CMS occurs generally within one month.

DEFINITIONS / ACRONYMS

CMS – Centers for Medicare and Medicaid

EOB – Explanation of Benefits

EOC -Evidence of Coverage

FDA – Food and Drug Administration

HPMS – Health Plan Management System

NCR- Negative Change Request

PBM – Pharmacy Benefit Management

SPAP – State Pharmaceutical Assistance Plan

UM – Utilization Management

AFFECTED DEPARTMENTS/PARTIES

Pharmacy Services

Pharmacy Benefit Manager (Currently PerformRx)

RELATED POLICIES AND PROCEDURES

PerformRx PBM Policy PTFD 3-03

RX-D 013 Explanation of Benefits (EOB)

RX-D 020 Part D Delegation Oversight Auditing (PBM)

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

None

REVISION HISTORY

New

REFERENCES

Medicare Prescription Drug Manual – Chapter 6- Part D Drugs and Formulary Requirements- January 15, 2016, Sectio 30.3

Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4208-F)

42 CFR 423.4

42 CFR 423.100

MONITORING

Alliance Pharmacy Department Staff will include results of ongoing monitoring in monthly Delegated Function Oversight/Monitoring statistics.

Collaboration



Alameda Alliance for Health
1240 South Loop Road
Alameda, CA 94502
Phone Number: **1.510.747.4567**
Toll-Free: **1.877.932.2738**

People with hearing and speaking impairmentsIf you cannot hear or speak well (CRS/TTY):
711/1.800.735.2929

www.alamedaalliance.org

90-Day Supply on Maintenance Medications

Medications are available for Alameda Alliance for Health (Alliance) Group Care ~~Members~~ through their choice of in-network retail pharmacies or the Walgreens Mail Service pharmacy. Prescriptions are filled with generic versions, when available and medically necessary. Certain medications are subject to prior authorization (PA) review by Alameda Alliance for Health (the Alliance).

This list may not include all 90-day maintenance medications as product updates are being made periodically. Questions about drugs not included on this list should be directed to the Alliance Pharmacy Services Department at **1.510.747.4541**.

Products in **red** are new additions to the list.

Asthma & COPD

Arnuity Ellipta
Atrovent HFA
Combivent
Flovent Diskus
Flovent HFA
Fluticasone/Salmeterol blister w/device
Fluticasone/Salmeterol ~~Respiclick~~RespiClick
Montelukast
~~Qvar~~QVAR ReditHaler
Spiriva HandiHaler
Spiriva Respimat
Stiolto Respimat
Theophylline

Tudorza Pressair

Blood Pressure & Heart Health

Acetazolamide
Aliskiren
Aliskiren/Amlodipine
Amiloride
Amiodarone
Amlodipine/Benazepril
Aspirin/Dipyridamole
Atenolol
Atenolol/Chlorthalidone
Azilsartan
Benazepril
Benazepril/HCTZ

Bisoprolol Bisoprolol/HCTZ

Bumetanide
Blood Pressure & Heart Health (cont.)
Candesartan
Captopril
Carvedilol
Chlorthalidone
Cilostazol
Clonidine
Clopidogrel
Digoxin
Diltiazem
Dipyridamole
Dronedarone

Commented [TZ1]: Is it possessive? Walgreens' Mail Service pharmacy.?

Commented [KV2R1]: Correct as is.

Commented [TZ3]: Looks like we do a space after the end of each grouping, like with 'Gout'. It looks good with the markup off

Enalapril
 Enalapril/HCTZ
 Eprosartan
Blood Pressure & Heart Health (cont.)
 Eprosartan/HCTZ
 Felodipine
 Flecainide
 Fosinopril
 Furosemide
 Guanfacine
 Hydralazine
 Hydrochlorothiazide
 Indapamide
 Irbesartan
 Irbesartan/HCTZ
 Isoproterenol
 Isosorbide Dinitrate
 Isosorbide Mononitrate
 Labetalol
 Lisinopril
 Lisinopril/HCTZ
 Methyldopa
 Methyldopa/HCTZ
 Metolazone
 Metoprolol Succinate
 Metoprolol Tartrate
 Mexiletine
 Midodrine
~~Minoxidil~~ Minoxidil
 Nadolol
 Niacin
 Nicardipine

Nifedipine
 Nitroglycerin
 Olmesartan
Blood Pressure & Heart Health (cont.)
 Pentoxifylline
 Pindolol
 Prazosin
 Propafenone
 Propranolol
 Propranolol/HCTZ
 Quinidine gluconate
 Quinidine sulfate
 Ramipril
 Reserpine
 Sotalol
 Spironolactone
 Spironolactone/HCTZ
 Telmisartan
 Telmisartan/HCTZ
 Terazosin
 Triamterene/HCTZ
 Valsartan/HCTZ
 Verapamil
 Warfarin

Diabetes
 Chlorpropamide
 Glimepiride
 Glipizide
 Glyburide
 Glyburide, micronized
 Glyburide/Metformin

Metformin
 Nateglinide
 Pioglitazone/~~le~~ Metformin

Diabetes (cont.)
 Pioglitazone/~~le~~ Metformin
 Rosiglitazone
 Rosiglitazone/Metformin
 Tolazamide
 Tolbutamide

Gastrointestinal Health
 Balsalazide
~~Sulfasalazine~~ Sulfasalazine
 Ursodiol

Gout
 Allopurinol
 Probenecid

High Cholesterol
 Atorvastatin
 Cholestyramine/Aspartame
 Colestipol
~~Docosahexaenoic~~ Docosahexaenoic Acid/EPA
 Ezetimibe/Simvastatin
 Fenofibrate
 Fenofibrate, nanocrystallized
 Fluvastatin
 Gemfibrozil
 Lovastatin
 Omega-3 Fatty Acids/Fish Oil
 Omega-3 Fatty Acids/Vitamin E

Simvastatin

Human Immunodeficiency Virus (HIV)

Emtricitabine-Tenofovir

Descovy

Liver Disease

Adefovir

Baraclude solution

Entecavir

~~Lamivudine~~Lamivudine

Tenofovir 300_mg tablets

Vemlidy

Viread

Men's Health

Alfuzosin

Doxazosin

Finasteride

Tamsulosin

Terazosin

Mental Health

Bupropion

Duloxetine

Escitalopram

Fluoxetine

Mirtazapine

Paroxetine

Sertraline

Trazodone

Miscellaneous

Cabergoline

Fludrocortisone

Hydroxychloroquine

Hydroxyurea

Leflunomide

Methazolamide

Miscellaneous

Methotrexate

Methylsulfate

Neostigmine

Myasthenia Gravis

Edrophonium Chloride

Physostigmine Salicylate

Pyridostigmine Bromide

Osteoporosis & Paget's Disease

Alendronate

Calcitonin (Salmon)

Raloxifene

Parkinson's & Alzheimer's

Bromocriptine

Carbidopa/Levodopa

Donepezil

Entacapone

Pramipexole

Ropinirole

Seizures & Epilepsy

Carbamazepine

Clobazam

Clonazepam

Divalproex sodium

Ethosuximide

Ezogabine

Gabapentin

Levetiracetam

Levetiracetam NaCl

Seizures & Epilepsy

Phenobarbital

Phenytoin

Primidone

Rufinamide

Tiagabine

Topiramate

Valproic Acid

Zonisamide

Thyroid Conditions

Armour Thyroid

Levothyroxine

Liothyronine

Methimazole

Propylthiouracil

Transplant

Azathioprine

Mycophenolate Mofetil

Mycophenolate Sodium

Tacrolimus

Urinary Incontinence & Retention

Bethanechol
Desmopressin

~~Oxybutinin~~Oxybutynin

Vitamins & Nutritional Health

Calcium Carbonate/Vitamin D2
Calcium Carbonate/Vitamin D3
Calcium Citrate/Vitamin D2
Calcium Citrate/Vitamin D3
Calcium Glubionate
Calcium Gluconate
Calcium Lactate
Calcium Phosphate/Vitamin D3
Cholecalciferol (Vitamin D3)
Cyanocobalamin (Vitamin B-12)
Ferrous Sulfate
Folic Acid
Folic Acid with Multivitamins
Magnesium Oxide
Multivitamins
Potassium Bicarbonate
Potassium Chloride
Pyridoxine
Thiamine

Women's Health

Estradiol
Estrogens, Conjugated
Estrogens, Conjugated/Medroxyprogesterone Acetate
Estrogens, Esterified
Estrogens, Esterified/Methyltestosterone
Norethindrone Acetate/Ethinyl Estradiol

Vitamins & Nutritional Health

B Complex with Vitamin C
Calcitriol

Calcium Acetate 667 mg
Calcium Carbonate



Up to 365-Day Supply on Contraceptives

Generic products are listed under **LABEL NAME** by their ingredient components.

LABEL NAME	GENERIC NAME	STRENGTH	DOSAGE FORM
ALYACEN 1/35	NORETHINDRONE & ETHINYL ESTRADIOL	1 MG-35MCG	TABLET
ALYACEN 7/7/7	NORETHINDRONE & ETHINYL ESTRADIOL	0.5MG/0.75MG/1MG- 35MCG	TABLET
AMETHIA	LEVONORGESTREL & ETHINYL ESTRADIOL & ETHINYL STRADIOL	0.15MG-30MCG/10MCG 3 MONTH DOSE PACK	TABLET
AMETHIA LO	LEVONORGESTREL/ETHINYL ESTRADIOL & ETHINYL ESTRADIOL	0.10MG-20MCG/10MCG 3 MONTH DOSE PACK	TABLET
AMETHYST	ETHINYL ESTRADIOL & LEVONORGESTREL	90MCG-20MCG	TABLET
APRI	ETHINYL ESTRADIOL & DESOGESTREL	0.15MG-0.03MG	TABLET
BALZIVA	ETHINYL ESTRADIOL & NORETHINDRONE	0.4MG-35MCG	TABLET
BEYAZ	DROSPIRENONE/ ETHINYL ESTRADIOL/ LEVOMEFOLATE CALCIUM	3MG-0.02MG-0.45MG	TABLET
BRIELLYN	ETHINYL ESTRADIOL & NORETHINDRONE	0.4MG-35MCG	TABLET
CAMRESE	LEVONORGESTREL/ETHINYL ESTRADIOL & ETHINYL ESTRADIOL	0.15MG-30MCG 3 MONTH DOSE PACK	TABLET
CAMRESE LO	ETHINYL ESTRADIOL & LEVONORGESTREL	0.10MG-20MCG 3 MONTH DOSE PACK	TABLET
CONCEPTROL	NONOXYNOL 9	4%	VAGINAL GEL
CONDOMS	CONDOMS, LATEX, LUBRICATED	N/A	TOPICAL
DROSPIRENONE-ETHINYL ESTRADIOL	DROSPIRENONE-ETHINYL ESTRADIOL	3MG-0.03MG	TABLET
ELLA	ULIPRISTAL	30MG	TABLET
ENSKYCE	DESOGESTREL & ETHINYL ESTRADIOL	0.15MG-0.03MG	TABLET
GENERESS FE	NORETHINDRONE & ETHINYL ESTRADIOL & FERROUS FUMARATE	0.8MG-25MCG/75MG	TABLET
GIANVI	DROSPIRENONE & ETHINYL ESTRADIOL	3MG-20MCG	TABLET

LABEL NAME	GENERIC NAME	STRENGTH	DOSAGE FORM
GILDESS 1.5/30	NORETHINDRONE & ETHINYL ESTRADIOL	1.5MG-30MCG	TABLET
GILDESS 1/20	NORETHINDRONE & ETHINYL ESTRADIOL	1MG-20MCG	TABLET
GILDESS FE 1/20	NORETHINDRONE ACETATE & ETHINYL ESTRADIOL & FERROUS FUMARATE	1MG-20MCG/75MG	TABLET
GILDESS FE 1.5/30	NORETHINDRONE ACETATE & ETHINYL ESTRADIOL & FERROUS FUMARATE	1.5MG-30MCG/ 75MG	TABLET
GYNOL II	NONOXYNOL 9	3%	VAGINAL GEL
INTROVALE	LEVONORGESTREL & ETHINYL ESTRADIOL	0.15MG-30MCG	TABLET
JOLESSA	LEVONORGESTREL & ETHINYL ESTRADIOL	0.15MG-30MCG	TABLET
JUNEL 1.5/30	NORETHINDRONE ACETATE & ETHINYL ESTRADIOL	1.5-0.03MG	TABLET
JUNEL 1/20	NORETHINDRONE ACETATE & ETHINYL ESTRADIOL	1MG-20MCG	TABLET
JUNEL FE 1.5/30	NORETHINDRONE ACETATE & ETHINYL ESTRADIOL & FERROUS FUMARATE	1.5-0.03MG	TABLET
JUNEL FE 1/20	NORETHINDRONE ACETATE & ETHINYL ESTRADIOL & FERROUS FUMARATE	1MG-20MCG	TABLET
KARIVA	DESOGESTREL-ETHINYL ESTRADIOL	0.15MG/0.02MG-0.01MG	TABLET
LEVONORGESTREL-ETHINYL ESTRADIOL	LEVONORGESTREL-ETHINYL ESTRADIOL	0.1MG-20MCG (84)/10MCG (7) 3 MONTH PACK	TABLET
LEVONORGESTREL-ETHINYL ESTRADIOL	LEVONORGESTREL-ETHINYL ESTRADIOL	0.1MG-20MCG	TABLET
LEVONORGESTREL-ETHINYL ESTRADIOL	LEVONORGESTREL-ETHINYL ESTRADIOL	0.15MG-30MCG 3 MONTH PACK	TABLET
LEVONORGESTREL	LEVONORGESTREL	0.75 MG	TABLET
LEVONORGESTREL	LEVONORGESTREL	1.5 MG	TABLET
LO LOESTRIN FE	NORETHINDRONE & ETHINYL ESTRADIOL (FERROUS FUMARATE)	1MG-10MCG/75MG	TABLET
LOMEDIA 24 FE	NORETHINDRONE & ETHINYL ESTRADIOL (FERROUS FUMARATE)	1MG-20MCG/75MG	TABLET
LORYNA	DROSPIRENONE & ETHINYL ESTRADIOL	3MG-20MCG	TABLET
LOW-OGESTREL	NORGESTREL & ETHINYL ESTRADIOL	0.3MG-30MCG	TABLET
LUTERA	LEVONORGESTREL & ETHINYL ESTRADIOL	0.1MG-20MCG	TABLET
MARLISSA	LEVONORGESTREL & ETHINYL ESTRADIOL	0.15MG-30MCG	TABLET

7/9

LABEL NAME	GENERIC NAME	STRENGTH	DOSAGE FORM
MICROGESTIN 1.5/30	NORETHINDRONE & ETHINYL ESTRADIOL	1.5MG-30MCG	TABLET
MICROGESTIN 1/20	NORETHINDRONE & ETHINYL ESTRADIOL	1MG-20MCG	TABLET
MICROGESTIN FE 1.5/30	NORETHINDRONE & ETHINYL ESTRADIOL (FERROUS FUMARATE)	1.5MG-30MCG/ 75MG	TABLET
MICROGESTIN FE 1/20	NORETHINDRONE & ETHINYL ESTRADIOL (FERROUS FUMARATE)	1MG-20MCG/75MG	TABLET
MINASTRIN 24 FE	NORETHINDRONE & ETHINYL ESTRADIOL (FERROUS FUMARATE)	1MG-20MCG/75MG	TABLET
NATAZIA	DIENOGEST & ESTRADIOL VALERATE	3MG/2MG-2MG/ 2MG-3MG-1MG	TABLET
NECON 0.5/35	NORETHINDRONE & ETHINYL ESTRADIOL	0.5MG-35MCG	TABLET
NECON 1/35	NORETHINDRONE & ETHINYL ESTRADIOL	1MG-35MCG	TABLET
NECON 1/50	NORETHINDRONE-MESTRANOL	1MG-50MCG	TABLET
NECON 10/11	NORETHINDRONE & ETHINYL ESTRADIOL	0.5MG-35MCG/ 1MG-35MCG	TABLET
NECON 7/7/7	NORETHINDRONE & ETHINYL ESTRADIOL	0.5MG/0.75MG/1MG-35MCG	TABLET
NEXPLANON	ETONOGESTREL	68MG	SUBDERMAL
NORETHINDRONE	NORETHINDRONE	0.35MG	TABLET
NORGESTIMATE-ETHINYL ESTRADIOL	NORGESTIMATE-ETHINYL ESTRADIOL	0.25MG-35MCG	TABLET
NORGESTIMATE-ETHINYL ESTRADIOL	NORGESTIMATE-ETHINYL ESTRADIOL	0.18MG/0.215MG/ 0.25MG-25MCG	TABLET
NORGESTIMATE-ETHINYL ESTRADIOL	NORGESTIMATE-ETHINYL ESTRADIOL	0.18MG/0.215MG/ 0.25MG-35MCG	TABLET
NORINYL 1+50	NORETHINDRONE-MESTRANOL	1MG-50MCG	TABLET
NORTREL 1/35	NORETHINDRONE & ETHINYL ESTRADIOL	1 MG-35MCG	TABLET
NORTREL 7/7/7	NORETHINDRONE & ETHINYL ESTRADIOL	0.5MG/0.75MG/ 1MG-35MCG	TABLET
NUVARING	ETONOGESTREL/ETHINYL ESTRADIOL	0.12MG-0.015MG	VAGINAL RING
OGESTREL	NORGESTREL & ETHINYL ESTRADIOL	0.5MG-50MCG	TABLET
PORTIA	LEVONORGESTREL-ETHINYL ESTRADIOL	0.15MG-0.03MG	TABLET
QUARTETTE	LEVONORGESTREL-ETHINYL ESTRADIOL	0.15MG-20MCG/ 0.15MG-25MCG 3 MONTH DOSE PACK	TABLET
QUASENSE	LEVONORGESTREL-ETHINYL ESTRADIOL	0.15MG-30MCG 3 MONTH DOSE PACK	TABLET
RECLIPSEN	DESOGESTREL-ETHINYL ESTRADIOL	0.15MG-0.03MG	TABLET

LABEL NAME	GENERIC NAME	STRENGTH	DOSAGE FORM
SAFYRAL	DROSPIRENONE-ETHINYL ESTRADIOL- LEVOMEFOLATE	3MG-0.03MG-0.451MG	TABLET
TILIA FE	NORETHINDRONE & ETHINYL ESTRADIOL (FERROUS FUMARATE)	1MG/20MCG-30MCG-35MCG (75MG)	TABLET
TODAY CONTRACEPTIVE SPONGE	NONOXYNOL 9	1000MG	VAGINAL SPONGE
TRI-LEGEST FE	NORETHINDRONE & ETHINYL ESTRADIOL (FERROUS FUMARATE)	1MG/20MCG-30MCG-35MCG (75MG)	TABLET
TRI-NORINYL	NORETHINDRONE & ETHINYL ESTRADIOL	0.5MG/1MG/0.5MG-35MCG	TABLET
TRI-LO-SPRINTEC	NORGESTIMATE-ETHINYL ESTRADIOL	0.18MG/0.215MG/ 0.25MG-25MCG	TABLET
TRIVORA	LEVONORGESTREL/ETHINYL ESTRADIOL	0.05MG-0.075MG-0.125MG/ 0.03MG-0.04MG-0.03MG	TABLET
VAGINAL CONTRACEPTIVE FILM	NONOXYNOL 9	28%	VAGINAL FILM
VAGINAL CONTRACEPTIVE FOAM	NONOXYNOL 9	12.5%	VAGINAL FOAM
VELIVET TRIPHASIC REGIMEN	DESOGESTREL/ETHINYL ESTRADIOL	0.1MG-0.125MG-0.15MG/25MCG	TABLET
VESTURA	DROSPIRENONE-ETHINYL ESTRADIOL	3MG-20MCG	TABLET
XULANE	NORELGESTROMIN-ETHINYL ESTRADIOL	4.86MG-0.53MG	TRANSDERMAL PATCH
ZENCHENT FE	NORGESTIMATE-ETHINYL ESTRADIOL (FERROUS FUMARATE)	0.4MG-35MCG/75MG	TABLET
ZOVIA 1/35E	ETHYNODIOL DIACETATE-ETHINYL ESTRADIOL	1MG-35MCG	TABLET
ZOVIA 1/50E	ETHYNODIOL DIACETATE-ETHINYL ESTRADIOL	1 MG-50MCG	TABLET

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Nếu quý vị cần giúp đỡ đọc tài liệu này hoặc muốn một định dạng khác, vui lòng gọi cho Ban Dịch vụ Hội viên Alliance theo số **1.510.747.4567**.

Kung kailangan mo ng tulong sa pagbasa ng dokumentong ito o kung gusto mo ng ibang format, mangyaring tumawag sa Alliance Member Services Department sa **1.510.747.4567**.

P&T Committee Meeting
Minutes
March 18, 2025



Alameda Alliance for Health
1240 South Loop Road
Alameda, CA 94502

PHARMACY & THERAPEUTICS COMMITTEE
Record of Committee Meeting Minutes
Tuesday, June 17, 2025 | 5:00pm – 7:00pm

Status	Voting Committee Members	Organization	Initials	Officer / Notes
P	Donna Carey, MD	Chief Medical Officer-Alliance	DC	Chairman
P	Luke Lim, R.Ph.	Senior Director of Pharmacy Services – Alliance	NT	Co-Chair
P	Rahel Negash, Pharm D	Pharmacy Services Supervisor – Alliance	RN	
A	Aaron Basrai, PharmD	Haller's Pharmacy	AB	BOG
P	Paul Bayard, MD	La Clinica de la Raza (CHCN)	PB	
P	Ivan Lee, MD	Private Practice	IL	
P	Bao Dao, MD	Epic Care	BD	
P	Charles Raynor, PharmD	Alameda County Behavioral Health Dept.	CR	

P=Present; PH=Call-in; A=Absent; CMO = Chief Medical Officer; DOPS=Director of Pharmacy Services; BOG = Board of Governors Representative

Status	Regular Guests	Organization	Initials	Role / Department
P	Iryna Makukh	PerformRx	IM	Pharmacy Formulary Management.
P	Liza Rosendale	PerformRx	LR	Clinical Program Manager
A	Pat DeHoratius	PerformRx	PD	Manager Formulary/DUR
P	Lauren Megargell	PerformRx	LM	Formulary Director
P	Barrie Cheung	PerformRx	BC	Regional Pharmacy Director
P	Ramon Tran Tang, PharmD	Alameda Alliance	RT	Clinical Pharmacist
P	Jefferey Bencini, Pharm D	Alameda Alliance	JB	Clinical Pharmacist
P	Timothy Tong, Pharm D	Alameda Alliance	TT	Clinical Pharmacist
A	Beverly Juan, MD	Alameda Alliance	BJ	Medical Director
A	Darryl Crowder	Alameda Alliance	DC	Provider Relations
P	Bibek Sandhu, PharmD, MBA	PillarRX	SB	Consulting Pharmacist

Other Guests	

Follow-up Items:

Clerk of the Committee: Benita Ochoa

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
I) Call to Order	D. Carey	- Agenda Overview	Call to order at: 5:07PM	
II) Informational Updates	D. Carey L. Lim	Informational Update New Senior Director of Pharmacy – Luke Lim DC: I'm going to call the meeting to order. Once again, thanks everyone for being here. I know it's late. Probably have already had a really long day, so really appreciate this extra time that you're giving us to go through the things for our committee today. I'm going to start with just some brief informational updates. I believe this is. Luke, this is your first meeting, correct? LL: Yes, hello everyone. This is my first Alameda alliance pharmacy and Therapeutics Committee meeting. DC: Great. So, I'll let you introduce yourself, but I want to introduce our new senior Director of Pharmacy, Luke Lim. We're so excited to have him join the Alliance team. So, Luke, do you want to introduce yourself and tell a little bit more about your background? LL: Sure. Thanks so much, Doctor Carey. Hello and good evening, everybody. Thanks so much for attending and being present at our pharmacy and Therapeutics Committee meeting. My name is Luke Lim. I'm the new senior director of Pharmacy for Alameda Alliance. I've been a pharmacist for 26 years. The 1st 13 years were in various dispensing environments, chain and independence and the most recent thirteen years was in a variety of managed care roles, most recently with Anthem Blue Cross. I was the PBM account manager. For their Nevada Medicaid health plan. So happy to be here and looking forward to working with all of you. Thank you. DC: Awesome. Thank you, Luke. Once again, really excited that you've joined the Alliance team. Already making some great progress and some movement in the pharmacy side and so really happy that you're here. The only other update that I have. Is around just continuing to do recruitment on the alliance side. So, we still have a couple of medical director positions that are open. But we did just fill our medical director of utilization management. And so, his name is Doctor Parag Sharma. As you know, our UM team does work really closely in pharmacy team for utilization management. So really excited to have Doctor Sharma join our team. We're still interviewing for a medical director of quality, so we're in the process of interviewing for that position. The only other piece I will give in terms of information is our DSNP. We are moving. Along with our DSNP implementation. Lots of work is happening. As you know, we've had P&PS come to this committee for D SNP. We are on target for starting January 1, 2026. We've submitted our bid earlier this month. Our model of care was approved by CMS. We had a score of around 96 percent, so anything above 90 means that 90% means that we are approved for three years. We don't have to do any more work around our model of care for the next three years.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		P&T Stipend DC: For committees, not just P&T, but for all of our committees and through that process kind of got a sense of what our sister plans were providing. Looking at our committees, we have that provides stipends. And we came up with the decision that we would pay our providers essentially about a, you know, 100 at the equivalent of \$150.00 per hour for attending. The meetings, so that is standard across the alliance, came with the 300. Per committee meeting. I know that for this particular committee, there were questions around, you know, how did we come up with that? There's extra work that's happening, and it's difficult to compare, you know, committee to committee because some committees, you know, we're pooling people from their work in the middle of the day. Other committees have work that's required outside of the committee, and other committees are all of the work done within the committee. But taking everything into consideration, it was standardized across the board for all committees for attending the committee meeting to get a stipend of about \$300. So, I'm going to pause there and see if there's any questions and comments. PB: Yeah. So, but yeah, as someone who's been expressing about this, first of all, this is something that you all knew in the March meeting and didn't mention so because I think it was voted on in December 2nd of all, as I've stated at least twice, we have the E voting, which is essentially the equivalent of another meeting, right? And that's why the original stipend was 300 and then increased to 600. Because of the E voting OK and I've been on this committee almost since the inception, if not the inception itself, I've been on it in a very long time. That was the rationale. Because the E voting is essentially another meeting. And if you look at the items for E voting, there's actually I believe there's more for E voting than there is for the two. What we will be covering in this committee, so we are essentially we're not getting paid 150 an hour where we're when I put in the hours that I put in. I think I'm getting at what you're saying. \$300.00, you're paying me more like 50 to \$60. So that is a really big difference. The E voting part of this meeting compared to other committees, OK, if I'd be so it's really two meetings. It's not one meeting and that's the difference and so. DC: Yeah. So thank you for that. And you know, I took your, you know, your emails and your kind of objections and kind of comment about it because of it. It does make sense. And so, I did put in a proposal. For E voting I don't have a resolution of that for today. But I did submit a proposal for there to be an additional stipend for the amount of time that you put in to, you know, prior to this meeting. So I do appreciate that that is an extensive amount of time. And so, I have put in a proposal to have additional funding for the E voting. But again, I haven't had. Any response yet? So I can't say if that's moving forward. So, I can't say if that's moving forward. But I did want to make sure that you were aware that I did put in a request for additional funding for the EVOTE. So unfortunately, I don't have a resolution tonight on whether that's been approved, but it is a proposal that is, you know, being reviewed and I will hopefully be able to have some response and will again provide that information via e-mail because I don't want to wait until. Our next P&T committee meeting. So I really appreciate you raising that issue and appreciate you, you know, recognizing the work that you all do on this committee. The importance of this committee. And the requirement to have the extra time that it takes. Excuse me for doing the work on this committee and I would absolutely want to value your time and value the work that you're doing. So again, there's a proposal out. Hopefully it's accepted, and I will come back as soon as I hear about the proposal. And make sure to let the		



Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		committee know. Any other questions, comments about the stipend? OK, great. I again. I will circle back as soon as I hear regarding the proposal. All right. Thank you, Luke. You can go ahead with the utilization reports. <u>Questions:</u> <u>Comments:</u>		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
III) Pharmacy Utilization Reports (Quarter 1, 2025)	L. Lim	(All matters listed on the Consent Calendar are to be approved with one motion unless a member of the P&T Committee removes an item for separate action. Any consent calendar item for which separate action is requested shall be heard as the next Agenda item in closed session.) Top 50 Drugs by Cost (IHSS) - The top 50 drugs accounted for 1,268 claims for 649 members and cost \$1,463,967, which is a decrease of \$125,484 in spend from the previous quarter. - Biktarvy remains at number one, claims having gone up by 2, and there are two additional members since the previous quarter. - Ozempic is at numbers 2, 3 and 5, with 274 total claims for 127 members. There was an increase of 2 claims and a decrease of 10 members from the previous quarter. - Vemlidy is down to number 4 with 54 claims for 23 members. There was a decrease of 1 claim for 23 members from the previous quarter. This medication is managed via the Hepatitis B MRG, which requires trial and failure of, intolerance to, or reason not to use, entecavir. - Verzenio is up at number 6 with 3 claims for 1 member. There was an increase of one claim for one member from the previous quarter. This medication is managed via the Oncology MRG. <u>Questions:</u> Top 50 Drugs by Cost (Medi-Cal) - The top 50 drugs accounted for 28,126 claims for 24,001 members and cost \$60,407,283 which is an increase of \$2,289,907 in spend from 4Q2024. - The drug mix has changed from 4Q2024 because during that quarter the top 50 drugs accounted for 42,049 claims for 36,406 members and cost \$58,117,376.51. 1Q2025 represents 66.8% of the claims volume and 65% of the member count and yet \$2.2M increased spending. - Biktarvy remains at the number 1 spot with 969 claims for 725 members. An increase of 80 claims but 2 less members from last quarter. I am unsure if we have days' supply per claim, but we should hope these are 90–100-day supplies. - Jardiance is in positions #2 and #3, Jardiance 25mg tab with 2092 claims for 1928 members and Jardiance 10mg with 2108 claims for 1869 members. This increased utilization reflects the expanded indication for Jardiance (Type 2 diabetes, prophylaxis heart failure in diabetes and non-diabetes patients and reduction of risk of GFR decline in ESRD patients). 169 more members are using Jardiance 25mg relative to the previous quarter and 121 more members are using Jardiance 10mg relative to the previous quarter. - Ozempic moves to #4 with 2085 claims for 1625 members. This reflects a decrease of 33 claims and increase of 24 members from 4Q2024.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Skyrizi remains #5 spot with 110 claims for 104 members, compared to 102 claims for 94 members during 4Q2024. - Wegovy, a GLP-1 drug indicated for weight-loss and risk-reduction of cardiovascular events is at #6 and over \$2M in spending. DHCS has proposed excluding this drug from the 2026 Medi-Cal Rx, citing a need to reduce prescription spending. I'll note that with this drug, DHCS has proposed excluding Wegovy from the 2026 Medical RX benefit, citing a need to reduce prescription spending. Again, this is only for weight loss. Weight loss indication. Questions: PB: Would the same be applied as Zepbound LL: I would think that Zepbound, yeah, I think Zepbound would be the same unless it gets an expanded indication, which I believe they're seeking for. It's either obstructive sleep apnea or the mash indication. Top 50 PA Reviewed Drugs by Volume (IHSS) - Top 50 PA requests = 261. There were 378 total PA requests for quarter 1. - o 74 requests (28%) were approved. This approval rate is lower by 11% than was observed last quarter. - o 187 requests (72%) were denied or partially approved. - Wegovy is at numbers 1, 7, 11, 12 and 42 with 61 total requests and 10 approvals (16%). - o Wegovy to reduce excess body weight requires a diagnosis of obesity or BMI ≥ 27 and at least one weight-related comorbidity (diabetes, hypertension, hyperlipidemia) or history of heart attack, despite diet and exercise, and trial and failure or inability to use Qsymia and Contrave. - o Wegovy to reduce the risk of major adverse cardiovascular events requires a documentation that the patient is obese or has BMI ≥ 27, has an established cardiovascular disease (prior myocardial infarction, stroke or symptomatic peripheral arterial disease), patient is on standard of care treatment for CVD and does not have diabetes. - Lidocaine 5% patch is at number 2 with 25 requests and 5 approvals (20%). - o Lidocaine requires a diagnosis of neuropathic pain and a trial and failure of gabapentin or pregabalin and one other formulary alternative (e.g., duloxetine, venlafaxine, amitriptyline) used for neuropathic pain or morphine MME ≥ 50/day for 3 months. - Jardiance is at numbers 3 & 6 with 33 total requests and 7 approvals (21%). - o Jardiance requires trial and failure of one of the following: metformin, branded/generic drug containing metformin, branded angiotensin receptor/neprilysin inhibitor (ARNi), generic angiotensin-converting enzyme inhibitor (ACEi), generic angiotensin receptor blocker (ARB), generic		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		mineralocorticoid receptor antagonist (MRA), or generic beta blocker AND documentation of trial and failure, intolerance, contraindication or inability to use one preferred formulary step therapy medication. - Zepbound is at numbers 4 & 9 with 19 total requests and 2 approvals (11%). - o Zepbound to reduce excess body weight requires a diagnosis of obesity or BMI ≥ 27 and at least one weight-related comorbidity (diabetes, hypertension, hyperlipidemia) or history of heart attack, despite diet and exercise, and trial and failure or inability to use Qsymia and Contrave. - o Zepbound for moderate to severe obstructive sleep apnea requires trial and failure regarding lifestyle changes and behavioral modifications to reach BMI $<30 \text{ kg/m}^2$ and trial and failure or inability to use PAP therapy. - Vemlidy is at number 5 with 11 requests. There were 8 approvals (73%). - o Vemlidy requires a diagnosis of Hepatitis B, and trial and failure of, intolerance to, or inability to use entecavir tablets. <u>Questions:</u> Top 50 PA Reviewed Drugs by Volume (Medi-Cal) - The top 50 drugs accounted for 223,447 claims for 200,737 members at a cost of \$4,849,619.33. This is a decrease of 11,493 claims (5.4%) from 1Q2025 and decrease cost of \$298,478 (-5.8%). - Diclofenac 1% gel has risen to #1 with 10,513 claims (17.2%) for 8962 members (16.2%). This product rose from 5th to 1st place over the last 3 consecutive quarters. - Ibuprofen 600mg tab remains at #2 with 10,405 claims for 9456 members. This compares to 1Q2025 with 9,573 claims for 8,656 members. This is an increase of 832 claims (8.7%) - Albuterol was #1 in claims utilization during 1Q2025 but has fallen to #6 with 8215 claims (-33.3%) for 6843 members (-32.2%). This is a numerical decrease of 4108 claims. - APAP 500mg caplets is at #3 with 9168 claims and 8188 members. - Fluticasone has risen from #5 to #4 with 9008 (11.5%) claims for 8157 (13.1%) members. - No drug for a chronic condition appears until #8, atorvastatin 20mg tablet. <u>Questions:</u>		

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IV) E-Voting Material/Consent Agenda	L. Lim B. Ochoa	E-Voting Material/Consent Agenda The following items have been sent to the voting committee for review via E-voting <i>Luke Lim, R.Ph., Senior Pharmacy Director – Alameda Alliance</i> <i>Benita Ochoa, CPhT, Lead Pharmacy Technician – Alameda Alliance</i> <i>(All matters listed on the Consent Calendar are to be approved with one motion unless a member of the P&T Committee removes an item for separate action. Any consent calendar item for which separate action is requested shall be heard as the next Agenda item in closed session.)</i>	Approved via e-voting: Yes: 5 No: 0 Abstained: 2																																						
		Monographs/Class Reviews			Changes	Anticonvulsants Class Review	No changes	Contraceptives, Foams and Devices Class Review	No changes	Parkinson’s Disease Agents Class Review	No changes	Potassium Removing Agents Class Review	No changes	Potassium Supplements Class Review	No changes	Luxturna Monograph	No changes	Provenge Monograph	No changes	Ridaura Monograph	No changes	Sucraid Monograph	No changes	Medication Request Guidelines	Changes	Formulary, step therapy required *For drugs without specific criteria	No changes	Non-formulary and prior authorization required oral liquid formulations	No changes	Medications for Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy	No changes	Roflumilast (Daliresp)	No changes	febuxostat (Uloric)	No changes	Levalbuterol (Xopenex/Xopenex HFA)	No changes	Lidocaine Patch	No changes	Fenofibrates	No changes
		Monographs/Class Reviews			Changes																																				
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		Lidocaine Patch			No changes																																				
		Fenofibrates			No changes																																				

Agenda Item	Discussion Leader	Discussion Summary		Action	Notes
		Nutritional formulas, infant formulas	• No changes		
		Lipotropics	• No changes		
		Long acting opioids	• No changes		
		Serotonin Receptor Agonists (Tryptans)	• No changes		
		Pregabalin (Lyrica and Lyrica CR)	• No changes		
		Sedative Hypnotics	• No changes, minor correction in the criteria statement		
		Hepatitis C Medications	• No changes		
		Phosphate Binders	• No changes		
		Xolair (omalizumab) for Asthma, Urticaria, and IgE-Mediated Food Allergy	• No changes		
		Short acting opioid containing products	• No changes		
		Alprazolam (Xanax)	• No changes		
		Diuretics	• No changes		
		Rectiv (nitroglycerin) ointment	• No changes		
		Acute Migraine Treatments	• No changes		
		Adenosine Triphosphate-Citrate Lyase (ACL) inhibitors	• No changes		
		Gonadotropin Releasing Hormone Antagonists	• No changes		
		Hereditary Angioedema (HAE)	• No changes		
		Lupkynis	• No changes		
		Radicava ORS (edaravone)	• No changes		
		Daybue (trofinetide)	• No changes		
		Filspari	• No changes		
		Joenja	• No changes		
		Skyclarys (omaveloxolone)	• No changes		
		Vyjuvek	• No changes		

Agenda Item	Discussion Leader	Discussion Summary		Action	Notes
		Filsuvez	No changes, minor addition that the tube is for single use for clarity		
		Wegovy	No changes		
		Rezdiffra	No changes		
		Physician Administered Drug (PAD) Guidelines	Changes		
		SMN2 Splicing Modifiers for the Treatment of Spinal Muscular Atrophy (SMA)	No changes		
		Naglazyme	No changes		
		Leqembi	No changes		
		Radicava (edaravone)	No changes		
		Vyjuvek	No changes		
		Generalized Pustular Psoriasis (GPP) Agents	No changes		
		Amtagvi	No changes		
		Lenmeldy	No changes		
		Interim Formulary Updates			
		See p. 275 in packet			
		Summary of Physician Administered Drug (PAD) Updates			
		See p. 276 in packet			
		Pharmacy Policy & Procedure Updates			
		RX-001 Pharmaceutical Operating Processes Summary	Removed lost, stolen language AB 118		
		RX-003 Exception Review Process	Removed lost, stolen language AB 118		
		RX-004 Formulary Management	AB 118 exclusions & SB 729		
		DSNP Policy & Procedures (7 NEW)			
		RX-D-012 Medicare Part D Fraud, Waste and Abuse (FWA)	RX-D-021 Medicare Part D Best Available Evidence (BAE)		
		RX-D-013 Explanation of Benefits (EOB) Oversight and Monitoring	RX-D-022 Medicare Part D Complaint Tracking Module (CTM)		
		RX-D-019 Medicare Prescription Payment Plan (M3P) Process, Monitoring and Oversight	RX-D-025 Appointment of Representative (AOR)		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		RX-D-020 Part D Delegation Oversight Auditing (PBM)		
		ED Oversight 1 finding: tadalafil (Cialis) 20mg tablet – pending SIU review		
		90 Day Maintenance List updates None		
		P&T Meeting Minutes P&T Meeting Minutes Q1 March 18, 2025		
		Questions/Comments: PB: There was a question on Lidocaine patch and. I'm not sure that was resolved because I think that as I recall you're wanting. Amitriptyline among the issues is you want amitriptyline in there, which is more anticholinergic and. You know, we often prescribe nortriptyline to elderly patients, not necessarily amitriptyline. And so that's that was one issue that I think I didn't see. Addressed and I would also add that as we've gotten people off opiates, which has been a good thing, one of the ways we've done that is Lidocaine patch, the diclofenac gel as well. So that's something that's been helpful now. IM: Sorry, so I saw your question about the lidocaine patch, and I was I was going to include other examples of Tca's in the criteria as well and I'm planning to bring it as an old business for the next quarter meeting if that's OK. PB: Ok, Great. And then I think you answered the question about the Doxepin concentrate menthol liquid and that's available. That's excellent. And I think I believe Doctor Raynor, we both had questions about alprazolam because you're wanting us to try and failure I a short acting benzo. But then also clonazepam and diazepam, which are long-acting benzos and that doesn't really make sense. You know, if I understand, we all want to limit benzos and we want to limit alprazolam. So, I would, I would suggest a guideline that really aims at limiting the use of it rather than saying we have to try a longer acting benzo like clonazepam. Diazepam again, which is not really recommended for elderly patients. So, you know. Insisting on trying and failing lorazepam and clonazepam and diazepam. Doesn't make sense. IM: Yeah, that makes sense. Doctor Bayard, I will work on that criteria and I will bring it to the next quarter, I think which is going to be limited to one lorazepam. The short acting benzo, just like you suggested. But I just want to bring it back to my team and review it and we can review it in more detail next quarter. PB: Yeah, and quantity limits sound fine. And you know, I historically have heard alprazolam is more addicting. It is relatively more addictive. I don't know if that's still the case, but because I understand you know, putting limits on it for sure are, are there quantity limits on it now? IM: Yeah, I believe there are quantity limits. DC: So, I want to make sure that we've gotten the three medications. So the lidocaine patch was. Would you like that to be pulled or moved forward with the E vote? OK. So pulling the lidocaine patch and then the furosemide, and alprazolam. So if we can note that in our minutes that we will bring those back for discussion at the next P&T.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes																										
		<u>Interim Formulary Changes</u> These changes have been made to the Alliance’s formulary recently. The changes were necessary to enhance the formulary. <table><tr><th>Medication</th><th>Formulary Change</th></tr><tr><td>Topiramate Oral Capsule Sprinkle 50 MG</td><td>NF to F-PA</td></tr><tr><td>Simlandi (2 Syringe) Subcutaneous Prefilled Syringe Kit 20 MG/0.2ML</td><td>NF to F-QL (maintenance: 4 syringes per 28 days; loading dose: should use 40mg strength for loading)</td></tr><tr><td>Simlandi (1 Syringe) Subcutaneous Prefilled Syringe Kit 80 MG/0.8ML</td><td>NF to F-QL (maintenance: 2 syringes per 28 days; loading dose: 4 syringes)</td></tr><tr><td>Liraglutide Subcutaneous Solution Pen-injector 18 MG/3ML</td><td>NF to F-PA</td></tr><tr><td>Victoza Subcutaneous Solution Pen-injector 18 MG/3ML</td><td>F-PA to NF</td></tr><tr><td>Rybelsus Oral Tablet 4 MG</td><td>NF to F-ST-QL (ST: requires trial and failure of a metformin containing product; QL:30 tablets/30 days)</td></tr><tr><td>Rybelsus Oral Tablet 9 MG</td><td>NF to F-ST-QL (ST: requires trial and failure of a metformin containing product; QL:30 tablets/30 days)</td></tr><tr><td>Rybelsus Oral Tablet 1.5 MG</td><td>NF to F-ST-QL (ST: requires trial and failure of a metformin containing product; QL:30 tablets/30 days)</td></tr><tr><td>Simlandi (1 Pen) Subcutaneous Auto-injector Kit 80 MG/0.8ML</td><td>NF to F-QL (maintenance: 2 pens per 28 days; loading dose: 4 pens)</td></tr><tr><td>Purified Cortrophin Gel Subcutaneous Prefilled Syringe 80 UNIT/ML</td><td>NF to F-PA</td></tr><tr><td>Purified Cortrophin Gel Subcutaneous Prefilled Syringe 40 UNIT/0.5ML</td><td>NF to F-PA</td></tr><tr><td>Ferric Citrate Oral Tablet 1 GM 210 MG(Fe)</td><td>NF to F-PA</td></tr></table>	Medication	Formulary Change	Topiramate Oral Capsule Sprinkle 50 MG	NF to F-PA	Simlandi (2 Syringe) Subcutaneous Prefilled Syringe Kit 20 MG/0.2ML	NF to F-QL (maintenance: 4 syringes per 28 days; loading dose: should use 40mg strength for loading)	Simlandi (1 Syringe) Subcutaneous Prefilled Syringe Kit 80 MG/0.8ML	NF to F-QL (maintenance: 2 syringes per 28 days; loading dose: 4 syringes)	Liraglutide Subcutaneous Solution Pen-injector 18 MG/3ML	NF to F-PA	Victoza Subcutaneous Solution Pen-injector 18 MG/3ML	F-PA to NF	Rybelsus Oral Tablet 4 MG	NF to F-ST-QL (ST: requires trial and failure of a metformin containing product; QL:30 tablets/30 days)	Rybelsus Oral Tablet 9 MG	NF to F-ST-QL (ST: requires trial and failure of a metformin containing product; QL:30 tablets/30 days)	Rybelsus Oral Tablet 1.5 MG	NF to F-ST-QL (ST: requires trial and failure of a metformin containing product; QL:30 tablets/30 days)	Simlandi (1 Pen) Subcutaneous Auto-injector Kit 80 MG/0.8ML	NF to F-QL (maintenance: 2 pens per 28 days; loading dose: 4 pens)	Purified Cortrophin Gel Subcutaneous Prefilled Syringe 80 UNIT/ML	NF to F-PA	Purified Cortrophin Gel Subcutaneous Prefilled Syringe 40 UNIT/0.5ML	NF to F-PA	Ferric Citrate Oral Tablet 1 GM 210 MG(Fe)	NF to F-PA		
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Ferric Citrate Oral Tablet 1 GM 210 MG(Fe)	NF to F-PA																													



Agenda Item	Discussion Leader	Discussion Summary		Action	Notes
		Auryxia Oral Tablet 1 GM 210 MG(Fe)	F-PA to NF		
		Sunlenca Oral Tablet 300 MG	NF to F		
		Paxlovid Oral Tablet Therapy Pack 6 x 150 MG & 5 x 100MG	NF to F-QL-AL (QL: 11 tabs/180 days, AL: 12 years and older)		
		Ticagrelor Oral Tablet 90 MG	NF to F-PA		
		Brilinta Oral Tablet 90 MG	F-PA to NF		
		Amnesteem Oral Capsule 30 MG	NF to F-PA		
		Adalimumab-aaty CD/UC/HS Start Subcutaneous auto-injector kit 80 mg/0.8ml	NF to F-QL (loading dose: 4 pens)		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes																																																									
		The following changes have been made to the Alliance ‘s PAD PA list recently. These changes were necessary to evaluate medical necessity based on medical guidelines, utilization, and other information. <u>Physician Administered Drug (PAD) Prior authorization (PA) list Updates</u> <table><tr><th>HCPSC Code</th><th>HCPSC Description</th><th>Action</th></tr><tr><td>J0139</td><td>ADALIMUMAB</td><td>Add PA Requirement</td></tr><tr><td>J0177</td><td>AFLIBERCEPT HD</td><td>Add PA Requirement</td></tr><tr><td>J0725</td><td>CHORIONIC GONADOTROPIN</td><td>Add PA Requirement</td></tr><tr><td>J1299</td><td>ECULIZUMAB</td><td>Add PA Requirement</td></tr><tr><td>J1326</td><td>ZOLBETUXIMAB-CLZB (VYLOY)</td><td>Add PA Requirement</td></tr><tr><td>J2351</td><td>OCRELIZUMAB, 1 MG AND HYALURONIDASE-OCSQ</td><td>Add PA Requirement</td></tr><tr><td>J3391</td><td>ATIDARSAGENE AUTOTEMCEL (LENMELDY)</td><td>Add PA Requirement</td></tr><tr><td>J7172</td><td>MARSTACIMAB-HNCQ (HYMPAVZI)</td><td>Add PA Requirement</td></tr><tr><td>J9024</td><td>ATEZOLIZUMAB, 5 MG AND HYALURONIDASE-TQJS (TECENTRIQ HYBREZA)</td><td>Add PA Requirement</td></tr><tr><td>J9037</td><td>BELANTAMAB MAFODOTIN-BLMF (BLENREP)</td><td>Add PA Requirement</td></tr><tr><td>J9038</td><td>NIKTIMVO (AXATILIMAB-CSFR)</td><td>Add PA Requirement</td></tr><tr><td>J9054</td><td>BORTEZOMIB (BORUZU)</td><td>Add PA Requirement</td></tr><tr><td>J9161</td><td>DENILEUKIN DIFTITOX-CXDL</td><td>Add PA Requirement</td></tr><tr><td>J9174</td><td>DOCETAXEL (BEIZRAY)</td><td>Add PA Requirement</td></tr><tr><td>J9275</td><td>COSIBELIMAB-IPDL (UNLOXCYT)</td><td>Add PA Requirement</td></tr><tr><td>J9276</td><td>ZANIDATAMAB-HRII (ZIIHERA)</td><td>Add PA Requirement</td></tr><tr><td>J9289</td><td>NIVOLUMAB, 2 MG AND HYALURONIDASENVHY (OPDIVO QVANTIG)</td><td>Add PA Requirement</td></tr><tr><td>J9341</td><td>THIOTEPA (TEPYLUTE)</td><td>Add PA Requirement</td></tr></table>	HCPSC Code	HCPSC Description	Action	J0139	ADALIMUMAB	Add PA Requirement	J0177	AFLIBERCEPT HD	Add PA Requirement	J0725	CHORIONIC GONADOTROPIN	Add PA Requirement	J1299	ECULIZUMAB	Add PA Requirement	J1326	ZOLBETUXIMAB-CLZB (VYLOY)	Add PA Requirement	J2351	OCRELIZUMAB, 1 MG AND HYALURONIDASE-OCSQ	Add PA Requirement	J3391	ATIDARSAGENE AUTOTEMCEL (LENMELDY)	Add PA Requirement	J7172	MARSTACIMAB-HNCQ (HYMPAVZI)	Add PA Requirement	J9024	ATEZOLIZUMAB, 5 MG AND HYALURONIDASE-TQJS (TECENTRIQ HYBREZA)	Add PA Requirement	J9037	BELANTAMAB MAFODOTIN-BLMF (BLENREP)	Add PA Requirement	J9038	NIKTIMVO (AXATILIMAB-CSFR)	Add PA Requirement	J9054	BORTEZOMIB (BORUZU)	Add PA Requirement	J9161	DENILEUKIN DIFTITOX-CXDL	Add PA Requirement	J9174	DOCETAXEL (BEIZRAY)	Add PA Requirement	J9275	COSIBELIMAB-IPDL (UNLOXCYT)	Add PA Requirement	J9276	ZANIDATAMAB-HRII (ZIIHERA)	Add PA Requirement	J9289	NIVOLUMAB, 2 MG AND HYALURONIDASENVHY (OPDIVO QVANTIG)	Add PA Requirement	J9341	THIOTEPA (TEPYLUTE)	Add PA Requirement		
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		J9342	THIOTEPA, NOT OTHERWISE SPECIFIED	Add PA Requirement		
		J9382	ZENOCUTUZUMAB-ZBCO	Add PA Requirement		
		Q2058	OBECABTAGENE AUTOLEUCEL (AUCATZYL)	Add PA Requirement		
		Q5098	USTEKINUMAB-SRLF (IMLDOSA)	Add PA Requirement		
		Q5099	USTEKINUMAB-STBA (STEQEYMA)	Add PA Requirement		
		Q5100	USTEKINUMAB-KFCE (YESINTEK)	Add PA Requirement		
		Q5139	ECULIZUMAB-AEEB (BKEMV)	Add PA Requirement		
		Q5140	ADALIMUMAB-FKJP (HULIO)	Add PA Requirement		
		Q5141	ADALIMUMAB-AATY (YUFLYMA)	Add PA Requirement		
		Q5142	ADALIMUMAB-RYVK (SIMLANDI)	Add PA Requirement		
		Q5143	ADALIMUMAB-ADBM (CYLTEZO)	Add PA Requirement		
		Q5144	ADALIMUMAB-AACF (IDACIO)	Add PA Requirement		
		Q5145	ADALIMUMAB-AFZB (ABRILADA)	Add PA Requirement		
		Q5146	TRASTUZUMAB-STRF (HERCESSI)	Add PA Requirement		
		Q5147	AFLIBERCEPT-AYYH (PAVBLU)	Add PA Requirement		
		Q5148	FILGRASTIM-TXID (NYPOZI)	Add PA Requirement		
		Q5149	AFLIBERCEPT-ABZV (ENZEEVU)	Add PA Requirement		
		Q5150	AFLIBERCEPT-MRBB (AHZANTIVE)	Add PA Requirement		
		Q5151	ECULIZUMAB-AAGH (EPYSQLI)	Add PA Requirement		
		Q5152	ECULIZUMAB-AEEB (BKEMV)	Add PA Requirement		
		Q5153	AFLIBERCEPT-YSZY (OPUVIZ)	Add PA Requirement		

Agenda Item	Discussion Leader	Discussion Summary			Action	Notes
		Q9996	USTEKINUMAB-TTWE (PYZCHIVA), SUBCUTANEOUS,	Add PA Requirement		
		Q9997	USTEKINUMAB-TTWE (PYZCHIVA), INTRAVENOUS	Add PA Requirement		
		Q9998	USTEKINUMAB-AEKN (SELARSDI)	Add PA Requirement		
		Q9999	USTEKINUMAB-AAUZ (OTULFI)	Add PA Requirement		
		S0122	MENOTROPINS	Add PA Requirement		
		S0126	FOLLITROPIN ALFA	Add PA Requirement		
		S0128	FOLLITROPIN BETA	Add PA Requirement		
		S0132	GANIRELIX ACETATE	Add PA Requirement		
		J1300	ECULIZUMAB (SOLIRIS)	Add PA Requirement		
		S0122	MENOTROPINS	Add PA Requirement		
		S0126	FOLLITROPIN ALFA	Add PA Requirement		
		S0128	FOLLITROPIN BETA	Add PA Requirement		
		S0132	GANIRELIX ACETATE	Add PA Requirement		
		J1300	ECULIZUMAB (SOLIRIS)	Remove from PA		
		V) New Business	Iryna Makukh	<u>New MRG</u>		
Tryngolza - Drug Overview: - Tryngolza is an apolipoprotein C3-directed antisense oligonucleotide. - Indication: Adjunct to diet for adults with Familial Chylomicronemia Syndrome (FCS). - Mechanism: Binds to APOC3 mRNA → degradation → ↓ APOC3 protein → ↑ triglyceride clearance. - About FCS: - Rare genetic disorder (~3,000 U.S. cases). - Characterized by severe hypertriglyceridemia (>880 mg/dL). - Caused by LPL deficiency or mutations in related genes. - Symptoms: Abdominal pain, pancreatitis, dyspnea, hepatosplenomegaly, memory loss. - Clinical Data: - Phase 3 trial (66 patients, 12 months): - ↓ Triglycerides by 42.5% at 6 months, 57% at 12 months vs. placebo. - ↓ Incidence of acute pancreatitis. - Administration & Cost:						

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Dosage: 80 mg subcutaneous injection, monthly. - Cost: \$62,000/month (WAC). - Coverage duration: Initial approval: 6 months - Renewal: 12 months with documentation of clinical benefit - The approval of tranquilizer was based on randomized double-blind placebo-controlled Phase 3, 12 Month study in 66 patients who received either Tryngolza or placebo, the primary end. - Cost: \$62,000/month (WAC). - Prescriber: Must be an endocrinologist, lipidologist, or cardiologist experienced in FCS. - Initial Coverage: 6 months; Renewal: 12 months. - Initial Authorization Criteria: - Triglyceride Level: ≥ 880 mg/dL (based on clinical trial inclusion). - Refractory to Standard Therapies: e.g., statins, fibrates. - Genetic Testing: - Pathogenic mutation in FCS-related genes, or - Inconclusive results + clinical evidence (e.g., NAFCS score ≥ 45, FCS score ≥ 10, history of pancreatitis or recurrent abdominal pain). - FDA-Approved Dose: Must be prescribed. - Diet: Prescriber must attest to adherence to a low-fat diet. - Renewal Criteria: - Evidence of clinical benefit (e.g., reduced triglycerides or fewer pancreatitis episodes). - Continued adherence to FDA-approved dose and low-fat diet. - For re authorization, we ask for documentation of the positive clinical benefit such as reduction in fasting triglyceride level from baseline. Or fewer acute pancreatitis events. And these were primary and secondary endpoints in the clinical trial. - Also, medication is prescribed at an FDA approved dose and the prescriber test. - The Member will continue to follow a low-fat diet and that's all for this new criteria for Tryngolza. <u>Questions/Comments:</u> <u>Crenessity</u> - Crenessity is indicated as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients four years of age and older with classic congenital adrenal hyperplasia. - Cost: \$639 per capsule or per mL (oral solution). - Monthly cost: \$38,000–\$76,000 depending on formulation and dose. - Prescriber: Specialist required. - Diagnosis: Medically confirmed classic CAH due to 21-hydroxylase deficiency. - Current Therapy: On stable supraphysiologic glucocorticoid dose: - Adults: >13 mg/m²/day (hydrocortisone equivalent). - Pediatrics (4–17 yrs): ≥ 12 mg/day. - Indication: Adjunct to glucocorticoid therapy for classic congenital adrenal hyperplasia (CAH) in patients aged ≥ 4 years.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Mechanism: A CRF1 receptor antagonist that reduces adrenal androgen production, allowing for lower glucocorticoid doses. - Disease Background: Classic CAH is a rare genetic disorder (1 in 15,000 births) caused by 21-hydroxylase deficiency. Leads to excess androgen production, causing early puberty, growth issues, and short stature. - Clinical Trials: Phase 3 studies in adults and children showed reduced glucocorticoid doses and lower androgen levels. - Formulation: Oral capsule and oral solution; dosed twice daily. - Cost: \$38,000–\$76,000/month depending on formulation and dose - Initial Approval: 6 months; Renewal: 12 months. - Requirements: Confirmed classic CAH due to 21-hydroxylase deficiency. On supraphysiologic glucocorticoid dose (≥ 13 mg/m²/day for adults; ≥ 12 mg/day for children). - Weight-based dosing; dose adjustments for CYP3A4 inducers. - Capsule formulation preferred unless medically necessary to use oral solution (cost containment). - No dose stacking (e.g., using multiple lower-strength capsules when higher strength is available). - Cost Control: Use the most cost-effective dosing forms and regimens. - Capsules are preferred over oral solutions unless medically necessary. - Avoid using multiple lower-strength capsules when a higher-strength option is available. - Reauthorization Criteria: Must show reduction in glucocorticoid dosage from baseline, as the drug is intended to be glucocorticoid sparing. If no reduction is achieved, treatment should be discontinued. - Medication must continue to be prescribed at an FDA-approved dose per package insert. <u>Questions/Comments:</u> <u>H. Pylori Treatment Medications</u> - H. pylori is a common infection linked to dyspepsia, peptic ulcers, and gastric cancer. - Rising antibiotic resistance, especially to clarithromycin, has led to updated treatment recommendations. - Preferred Regimens: Treatment-naïve patients (unknown antibiotic susceptibility): - Bismuth quadruple therapy (BQT) for 14 days is preferred. - Rifabutin triple therapy or amoxicillin dual therapy (if no penicillin allergy) are acceptable alternatives. - Treatment-experienced patients: Optimized BQT for 14 days if not previously used. - If previously treated with optimized BQT, use rifabutin triple therapy or vonoprazan-based regimens. - Clarithromycin or levofloxacin regimens only if susceptibility is confirmed. - Coverage Criteria: Prescriber: Must be a gastroenterologist, infectious disease specialist, or other H. pylori expert. - Approved for up to 14 days, per guideline-recommended treatment length. - Confirmed H. pylori-positive infection. - Trial and failure of a generic, guideline-recommended first-line regimen, such as BQT (PPI + bismuth + tetracycline + metronidazole). - Medical Exceptions: Allowed if a valid medical reason is provided for not using first-line therapy.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Dosing: Must be appropriate per FDA labeling. - Renewals: Not approved — treatment is intended as a single course. If infection persists, a different regimen must be used. - Overall: Criteria are straightforward, focused on appropriate use, cost-effective prescribing, and alignment with clinical guidelines. <u>Questions/Comments:</u> PB: I have a question on the 1st on the Talicia you know, I see that at least up to date it's pretty expensive and we don't cover pylera because the individual components are cheaper, right? IM: Yeah, I looked into that. But the dosing of rifabutin in this dose in the talicia it's not available separately. And that's why we wouldn't be able to break it down. And that's the only reason why we did it this way. PB: Yeah, I think the others, the ones with the, the vonoprazin are going to be expensive as well because that's a new medication. IM: Yeah, they're similar in price. PB: All right. OK. Thank you. <u>MEK inhibitors for Neurofibromatosis Type 1 (NF1)</u> - MEK Inhibitor Criteria for NF1 - Drug: Gomekli – a newly approved MEK inhibitor. - Indication: For adults and children (≥ 2 years) with NF1 who have symptomatic plexiform neurofibromas (PNs) that cannot be completely surgically removed. - Background: NF1 is a rare, autosomal dominant genetic disorder caused by mutations in a tumor suppressor gene on chromosome 17. Affects skin, bones, and nervous systems. - Prevalence estimates range from 1 in 2,000 to 1 in 4,000 individuals. - Significance: Gomekli is the first FDA-approved treatment for NF1-related PNs in adults. Koselugo (approved in 2020) was previously available only for pediatric patients ≥ 2 years. - NF1 Overview: - A rare genetic disorder with variable presentation; some individuals remain undiagnosed, complicating prevalence estimates. - Common signs: café-au-lait spots, neurofibromas, and freckling in armpits/groin. - ~30–50% develop plexiform neurofibromas (PNs), which can cause pain, disfigurement, motor and airway dysfunction. - PNs often begin in early childhood and can reduce life expectancy by 15–20 years. - Treatment Background: - Historically, surgery was the main option but had high recurrence and morbidity. - Gomekli is the first FDA-approved treatment for NF1-related PNs in adults. - Approved based on a Phase 2 trial (114 patients, ages ≥ 2) showing tumor shrinkage and durable response at 24 months. - Long-term treatment duration guidance is still pending. - Dosing & Cost:		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Form: Capsules and tablets. - Dose: 2 mg/m² orally twice daily for 21 days of a 28-day cycle. - Cost: ~\$34,650/month for adults with BSA ≥1.5 m² (WAC-based). - Pediatric MEK Inhibitor: Approved only for children with NF1-related plexiform neurofibromas (PNs). - Available as oral capsules. - Cost: ~\$22,000/month at maximum pediatric dose. - Coverage Criteria Highlights: - Prior use of a MEK inhibitor is an exclusion criterion, based on the clinical trial design. - Concurrent use of multiple MEK inhibitors is not supported by safety or efficacy data. - Age restrictions apply as per FDA labeling. - Drug Approvals: - Gomekli: Approved for adults and children ≥2 years. - Koselugo: Approved for pediatric patients only. - Prescriber Guidance: - No prescriber restrictions are recommended. - NF1 with PN is typically managed by a multidisciplinary team, which may include: Primary care, neurologists, oncologists, geneticists, surgeons, and eye specialists. - Specialist involvement depends on tumor location and symptoms. - Coverage Duration: Initial: 6 months. Renewal: 12 months. - Based on clinical trial data showing disease progression slowing by 6 months. - Initial Authorization Requirements: Confirmed diagnosis of NF1 with symptomatic PN not amenable to complete resection. Monotherapy only: Use of more than one MEK inhibitor is not appropriate. - Dosing: Medication must be prescribed at an FDA-approved dose. - Reauthorization Requirements: Provider attestation or documentation of a positive clinical response. At minimum: no evidence of disease progression. Ideal outcome: ~20% reduction in plexiform neurofibroma (PN) volume, which was the primary endpoint in clinical trials. <u>Questions/Comments:</u> <u>New PAD</u> <u>Kebilidi</u> - Indication: One-time in vivo gene therapy for Aromatic L-Amino Acid Decarboxylase (AADC) deficiency in adults and children ≥2 years. - Disease Background: Extremely rare genetic disorder (fewer than 350 cases globally). - Caused by mutations in the DDC gene, leading to neurotransmitter deficiency (dopamine, serotonin, epinephrine). Symptoms begin in infancy; common signs include truncal hypotonia and oculogyric crises. - No current curative treatment management is symptomatic. - Mechanism: Uses AAV2-based gene therapy to deliver a functional DDC gene directly into the brain.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Promotes dopamine production in the putamen. First FDA-approved treatment for AADC deficiency and first gene therapy delivered directly into the brain. - Cost: \$3.95 million (one-time treatment). - Coverage Criteria: Must be prescribed by a neurologist or geneticist. - Prescriber: Must be a neurologist or geneticist, as diagnosis and treatment are typically initiated by these specialists. - Exclusion: Prior gene therapy is an exclusion, since Kebilidi is a one-time treatment. - Coverage Duration: Approved for one-time use per lifetime, consisting of 4 infusions in a single neurosurgical procedure. - Initial Authorization Requirements: FDA-approved dose. Genetically confirmed diagnosis of AADC deficiency, with mutations in the DDC gene. - Prescribing Information-Based Requirements: Skull maturity must be confirmed by neuroimaging. This was a key inclusion criterion in clinical trials. - Lack of skull maturity is a contraindication per prescribing information. Patients must exhibit classic AADC deficiency symptoms: Oculogyric crises Truncal hypotonia Developmental delay - Symptoms must be poorly managed by symptomatic therapies, as there are no curative treatments for AADC deficiency. <u>Questions/Comments:</u> <u>Agents for graft versus host disease</u> - Niktimvo - Type: Monoclonal antibody. - Indication: For chronic GVHD in adults and pediatric patients ≥ 20 kg after failure of ≥ 2 prior systemic therapies. - Coverage Criteria: Prescriber: Hematologist, oncologist, or transplant specialist. - Initial Approval: 3 months (based on 12-week trial endpoint). Renewal: 6 months (treatment continued up to 9 months in trials). - Dosing: Every 2 weeks until disease progression or unacceptable toxicity. - Ryoncil - Type: Allogeneic bone marrow–derived mesenchymal stromal cell therapy. - Indication: For steroid-refractory acute GVHD in pediatric patients ≥ 2 months. - Prescriber: Same as above. - Initial Approval: 2 months (covers 12 infusions). - Renewal: 1 month. - 1. Nicktimbo (for Chronic GVHD) - Indication: For adults and pediatric patients ≥ 20 kg with chronic GVHD after failure of ≥ 2 prior systemic therapies, including a systemic corticosteroid (or documented reason for not using one). - Prescriber: Hematologist, oncologist, or transplant specialist. - Dosing: Every 2 weeks until disease progression or toxicity. - Coverage Duration: - Initial: 3 months (based on 12-week trial endpoint).		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Renewal: 6 months (treatment continued up to 9 months in trials). - Requirements: Diagnosis of chronic GVHD. - FDA-approved dose. - Patient weight documented (≥ 20 kg). - Clinical benefit required for renewal (e.g., symptom improvement, reduced steroid use). - 2. Ryoncil (for Acute GVHD) - Indication: For pediatric patients ≥ 2 months with steroid-refractory acute GVHD. - Prescriber: Same as above. - Dosing: Initial: 8 infusions (2x/week for 4 weeks). If partial/mixed response: 4 more infusions (1x/week for 4 weeks). If GVHD recurs: 8 additional infusions (2x/week for 4 weeks). - Coverage Duration: Initial: 2 months (up to 12 infusions). Renewal: 1 month. - Requirements: Diagnosis of acute GVHD. Failure or contraindication to systemic corticosteroids. FDA-approved dose and weight-based dosing. Clinical benefit required for renewal (e.g., symptom improvement, reduced steroid use). For re-treatment: documentation of GVHD recurrence after initial complete response. <u>Questions/Comments:</u> <u>Fertility Agents</u> - Based on SB 729, which mandates coverage for infertility treatment, including up to three completed oocyte (egg) retrievals for IVF - Applies to fully insured health plans in California, effective January 1, 2026 (delayed from July 2025) - Prescriber Requirement: Must be an OB/GYN, fertility specialist, or endocrinologist experienced in fertility care. - Exclusion: Pregnancy is the only exclusion criterion. - Coverage Duration: General fertility treatment: Approved for 12 months. - IVF: Approved for up to 3 cycles, per the bill. - Initial Authorization Requirements: Medication is prescribed for an FDA-approved indication for infertility. Dose and duration are FDA-supported. - For Novarel and Ovidrel: Must show trial and failure of Pregnyl (cost-based). - For Cetrotide: Must show trial and failure or intolerance to Ganirelix (cost-based). <u>Questions/Comments:</u> <u>Tryngolza</u> - An MRG policy was created for Tryngolza and also included as a PD document, in case it's used in a clinical setting. The PD criteria match the MRG exactly. - No changes or additions were needed. <u>Questions/Comments:</u>		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
VI) Class Reviews, Monographs, and Recommendations-	Iryna Makukh	1. <u>Alzheimer's Disease Agents Class Review</u> - Utilization Overview (Page 418): 5 total claims for 4 members. - Total cost: \$79.93; average cost per claim: \$15.99. - Only medications were used: Donepezil (3 claims) and Memantine (2 claims). - No prior authorization (PA) requests. - Formulary Status: Alameda covers the most cost-effective products. - No changes recommended to the formulary. - PA Criteria Update (Page 419): A new cholinesterase inhibitor (a prodrug of Galantamine) was introduced. It's a delayed-release tablet designed to improve tolerability. - Cost: \$749/month for 15 mg twice daily. - Recommended to be added as a non-formulary PA-required agent. - Reserved for members who have used or cannot use Rivastigmine or Donepezil. - The only change is the addition of the new agent to PA criteria. - No other changes or recommendations for this drug class. <u>Questions/Comments:</u> PB: Is so this is supposed to be better tolerated than galantamine. Is that right? So, would you also consider the trial failure of Rivastigmine, Donepezil, or Galantamine? IM: Yes, Galantamine is on one formulary, but with PA request so in order to get galantamine you would still have to try rivastigmine or Donepezil. If you add galantamine as well, you would basically have to go through the donepezil, rivastigmine and galantamine. Do you think that would be a better alternative? Not on formulary, it's on formulary, but with PA criteria like PA required. But the other two, the Donepezil and the rivastigmine, they are, they would just go at point of sale. PB: Right, right. Right. With the same criteria, just because it's OK, so it's more expensive. IM: Yeah. Yeah, it's a lot more expensive. Yeah. And also, it would be better tolerated for GI side effects. So, if they have, you know, GI side effects with the donepezil or rivastigmine, they could have the same GI side effects with galantamine, but this would actually be helpful, yeah. Alright, so you're keeping a non-form because of cost and that's the main. That's why you're moving it down. All right. Thank you. IM: Yes.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		2. <u>Stelara biosimilars review</u> Overview (Page 425): - Several Stelara biosimilars launched last quarter. - All biosimilars share the same indications as Stelara: plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. - Most offer prefilled syringes and 130 mg single-dose vials; some lack the 45 mg/0.5 mL vial option. - Pricing & Recommendations (Page 426–427): Yesintek and Otulfi are the most cost-effective options at \$3,000 and \$3,620 respectively. Recommended to add both to the formulary with PA (prior authorization) required status. These two will be Step 2 preferred agents. All other Stelara biosimilars to be listed as Step 3 agents in the drug list (Page 428). - Criteria Update: Added language to include Stelara as a reference biologic with available biosimilars. Only changes are formulary additions and updates to PA criteria to reflect new biosimilars. <u>Questions/Comments:</u>		
VII) Medication Request Guidelines	R. Negash	The committee has reviewed and discussed the following updates and additions to the Medication Review Guidelines (MRG) Guideline (Changes): 1. <u>Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention</u> - The update involves a minor change in the peer review criteria section. - Specifically, Nortriptyline and Duloxetine are being removed as examples of preferred TCAs. - No other changes are being made to the policy. <u>Comments:</u> PB: Is that just simplified? So, you're just saying examples? As long as they've tried to Tri cyclic, you don't care which one, and as long as they've tried an SNRI, you don't care which one is that. RN: Correct. PB: A simplification issue then. That is fine. RN: As long as they've tried to Tri cyclic, you don't care which one, and as long as they've tried an SNRI, you don't care which one is that. Guideline (Changes): 2. <u>Hepatitis B Drugs</u> - Coverage Duration Section: Three approval durations were added for renewal requests based on therapy type - 4 or 12 months for patients continuing high-risk therapy. - Additional 6 months if high-risk non-chemotherapy is discontinued. - 12 months if B-cell depleting therapy is discontinued. - PA Review Criteria Section: - Consolidated criteria for compensated and decompensated cirrhosis:	Move to approve: 1st: BD 2nd: PB	

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		Now allows approval if detectable serum HBV DNA is present. Removes previous threshold of >2000 IU/mL for compensated cirrhosis. - Initial Request Criteria for High-Risk Patients - Approval granted under two scenarios: HBsAg-negative and anti-HBc positive, receiving B-cell depleting agents. HBsAg-positive and receiving any of the following: - o Anti-TNF agents - o IL-6 inhibitors - o B-cell depleting agents - o CAR-T therapy - o Anthracycline derivatives - o Integrase inhibitors - o Tyrosine kinase inhibitors - o JAK inhibitors - o Direct-acting antivirals for HCV - o Moderate/high-dose corticosteroids (≥4 weeks) - Renewal Criteria Section: Added language to support continued prophylaxis if: The patient is still on high-risk therapy or recently discontinued such therapy. - All updates are based on current guideline recommendations. - No other changes were made to the policy. <u>Comments:</u> Guideline (Changes): <u>3. Injectable Atypical Antipsychotic Medications</u> - Market Availability Updates: - Removed: Zyprexa and Perseris — discontinued and no longer available. - Added: Erzofri (paliperidone palmitate ER) a new extended-release injectable for schizophrenia. - No other changes on this policy, since the specific drugs are not mentioned in the PA review criteria. <u>Comments:</u> PB: Is that the same as Invega sustenna right? Is that monthly injectable? IM: It is the same. The only difference is in initiation dosing. Erzofri is designed for like single dose initiation versus Sustenna. PB: I assume the new one is more expensive, correct? IM: Yes CR: Were there any reports done to see if anybody is currently utilizing Perseris? RN: I don't believe we ran utilization, but since it was removed from market.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		CR: What I was informed was it wasn't completely removed. They're not marketing it anymore. And there would still be some available. IM: Let me check really quick utilization and I'll get back to you on that. CR: Yeah. If we don't have anybody in the last two or three months, then great. But if you have somebody on it. We might want to do a transition off and have people have prescribers notified so that they can start transitioning, but not just completely remove it. RN: Thank you for the feedback. Guideline (Changes): 4. Opioid Use Disorder (OUD) Agents - AB 1842 mandates that health plans must cover at least one FDA-approved medication in each of the following categories without prior authorization (PA), step therapy, or utilization review - Opioid overdose reversal (e.g., naloxone) - Daily oral buprenorphine for detox/maintenance - Long-acting buprenorphine (e.g., Sublocade) - Long-acting injectable naltrexone (e.g., Vivitrol) - Added to formulary: - Subutex (sublingual tablet – buprenorphine) - Sublocade (subcutaneous injection – long-acting buprenorphine) - Vivitrol (intramuscular injection – long-acting naltrexone) - Removed from: Formulary quantity limits and Non-formulary PA status to complete alignment - PA review criteria section language remove because it no longer requires a PA. <u>Comments:</u> Guideline (Changes): 5. Sleep Disorder Therapy - 1. Medication Section - Added: Generic sodium oxybate (Xyrem) to formulary with PA. - Removed: Generic sodium oxybate from non-formulary section. - Added: Lumryz (sodium oxybate extended-release oral suspension) indicated for pediatric patients aged 7+. - 2. Coverage Duration Section - Lumryz added to ensure its approval duration is clearly defined. - 3. PA Review Criteria Section - New language added for Lumryz: - Requires treatment failure of generic sodium oxybate before approval. - These updates ensure appropriate access to newer therapies while maintaining step therapy protocols. - No other changes were made to the policy. <u>Comments:</u>		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		Guideline (Changes): 6. <u>Transthyretin-mediated Amyloidosis Agents</u> - Medication Section. Added to Preferred: Attruby (acoramidis) – due to comparable pricing. - Removed: Tegsedi – discontinued per Axia Pharmaceuticals. - Added to non-preferred: - Ambutra – for cardiomyopathy; requires trial/failure of preferred agents (Vyndamax, Vyndaqel, Attruby). - Peer Review Criteria – New criteria for patients with mixed phenotypes (polyneuropathy + cardiomyopathy): - Allows concurrent use of multiple agents with different mechanisms of action. - Removed previous restriction on concurrent therapy. - Clarified titles for “Polyneuropathy Type” and “Cardiomyopathy Type” - Reauthorization Section – Reiterated allowance for multiple agents in mixed phenotype cases. - Updates reflect new product availability, discontinuations, and clinical practice changes for treating mixed ATTR phenotypes. - No other changes were made to the policy. <u>Comments:</u> Guideline (Changes): 7. <u>Eohilia</u> - Updated example medications in the guideline reference section: - Removed: ciclosonide and Mometasone as examples. - This aligns with the guidelines listed examples, similar to how TCAs and SNRIs are referenced. - This is a minor clarification to better reflect current guideline language. - No other changes were made to the policy. <u>Comments:</u> Guideline (Changes): 8. <u>Spravato</u> - Covers use Spravato for treatment-resistant depression (TRD) and major depressive disorder (MDD) with acute suicidal ideation. - PA Review Criteria - Monotherapy now allowed for TRD: - Spravato can be used without an oral antidepressant. - For MDD with acute suicidal ideation: - Spravato must still be used with an oral antidepressant. - These updates align with the latest package insert indications. - Reauthorization Criteria - Updated to reflect the same distinction between TRD and MDD with suicidal ideation. - No other changes were made to the policy. <u>Comments:</u> Guideline (Changes): 9. <u>Hemlibra (emicizumab-kxwh)</u>		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Expanded Therapy Inclusion - First update to include therapies beyond Hemlibra. - Added Hemophilia B and Factor IX products throughout the policy for: - Diagnosis - Preferred therapies tried - 2. PA Review Criteria Updates - Requests must now include: - Appropriate dose, limits, and indication - Trial of Hemlibra before initiating newer agents like Qfitlia - 3. Safety Monitoring Requirements - For Qfitlia, providers must submit an attestation confirming: - Monitoring of antithrombin levels - Observation for signs of thrombotic events - Monitoring for acute or recurrent gallbladder disease - These requirements are based on the drug's black box warning. - These updates ensure safe, guideline-aligned use of newer hemophilia therapies while maintaining Hemlibra as the first-line treatment. - No other changes were made to the policy. <u>Comments:</u> Guideline (Changes): <u>10. Anti-Obesity Medications</u> - Updates made in response to California Assembly Bill (AB) 114, which proposes benefit exclusions and coverage criteria for anti-obesity medications. - Diagnosis Criteria – For adults: Must have Class 3 or severe obesity, defined as BMI ≥ 40. For pediatric patients (e.g., when requesting Qsymia): - BMI must be $\geq 120\%$ of the 95th percentile for age and sex, or BMI ≥ 35 kg/m². - These BMI-based criteria are now reflected throughout the policy - In the Reauthorization Criteria section - These updates align with regulatory guidance and ensure consistent application of clinical thresholds for anti-obesity treatment eligibility. - No other changes were made to the policy. <u>Comments:</u> PB: Yes. Can you tell me? Tell us about AB 114? RN: Well, the DMHC provided some suggestions for plan exclusions on coverage and for anti-obesity medications. The diagnosis of Class 3 and severe obesity was. one of the suggestions for exclusion, so in that filing that we sent to the state, this was something that we were in agreement on. PB: So then, because I think Class 3 obesity is BMI greater than 40 or greater than 35 and comorbidity. I'm not sure if I could. I think you're wanting to limit the numbers of prescriptions, correct? RN: We want to make sure that we're reviewing, you know, course appropriately. And you know, in consideration of cost, efficacy and there's also a potential for having some kind of coverage or weight loss programs.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		That's something that's also been in discussion. But it sounds like you're thinking of a proposal here to include the BMI. for 35 or higher they have a comorbidity or? PB: yeah. I'm not sure I'm making a proposal. I don't want us to get into trouble using the phrase Class 3 severe obesity. When I checked, it was greater than 40 or greater than 35 with the comorbidity. I mean, I don't use a lot of these drugs myself, but I just. I think if you I just want to be sure that that's an OK statement to make. We define Class 3 obesity as great BMI greater than 40. Stop rather than or because at least one definition is or you know, as I said, greater than 40 or greater than 35 with comorbidity. IM: Looking at CDC website right now with BMI categories for adults and class 3 obesity or severe obesity, they just have BMI 40 or greater. PB: Thank you. Yeah, unless you think you know, I forget a utilization. relatively high, right? So, as I do, you think we'll get complaints? RN: That's a good point. So, you know the strategy here would be for new members not continuing. PB: That sounds good. Thank you. Guideline (Changes): <u>11. Erectile Dysfunction Medications</u> - Based on guidance from the California Department of Managed Health Care (DMHC) and the template received, the policy is being retired. - This is due to a benefit exclusion for sexual dysfunction treatments, as outlined in AB 114 and related regulatory interpretations - The MRG for ED medications will be retired in alignment with state-level exclusions for sexual dysfunction treatments. <u>Comments:</u> Guideline (Changes): <u>12. Vaginal Progesterone</u> - Updates made in response to California Senate Bill (SB) 729, which expands infertility coverage requirements. - 1. Coverage Duration - Updated to allow up to three cycle approvals for vaginal progesterone therapy, in alignment with SB 729 requirements. - 2. Eligibility Criteria - Removed the requirement for iatrogenic infertility (infertility caused by medical treatment). - Now allows coverage for any form of infertility, broadening access. - These updates reflect expanded infertility coverage under SB 729, effective July 1, 2025 (though implementation may be delayed to January 1, 2026, per recent budget legislation - No other changes were made to the policy. <u>Comments:</u> Guideline (Changes): <u>13. Fertility Agents</u> - Updates to fertility agent coverage in response to California Senate Bill (SB) 729.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Coverage Duration Updated to allow up to three cycles of therapy, in alignment with SB 729. - Eligibility Criteria Removed the requirement for iatrogenic infertility. - Now allows coverage for any form of infertility, expanding access. - SB 729 mandates expanded infertility coverage for large-group health plans in California, including IVF and broader definitions of infertility. - Implementation has been delayed from July 1, 2025, to January 1, 2026, per the state budget agreement - These updates reflect regulatory compliance and broaden access to fertility treatments. - No other changes were made to the policy. <u>Comments:</u> Guideline (Changes): <u>14. Complement Inhibitors for the Treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH)</u> - Treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH). - New Soliris biosimilars have been introduced. - These biosimilars are now listed throughout the policy to reflect their availability and ensure alignment with current treatment options. <u>Comments:</u> PB: I think the first two are not exactly biosimilars, right? They're slightly different. They're complement inhibitors, but they have a different mode of action. and those are capsules PO the tablet and I think the Soliris is IV correct. and it's different. When I think about biosimilar, I tend to think they would have the same generic name. and those are different. RN: BKEMV has the same biosimilar name with ravulizumab PB: Yeah, BKEMV and then, yeah, this is. But for this one, this has the fabhalta and the voydeya correct. BD: I don't even call them biosimilar because. They manufacture cell lines very differently. I think they are acting on the same mechanism, but it's completely different, I think products. IM: So Fabhalta and Voydeya, they are not biosimilars to Fabhalta Voydeya. We can be and Epysqli are biosimilars to Soliris. And Soliris is IV, and so is Bkerv and Epysqli. They're interchangeable. Biosimilars to Soliris, but we're just including them in this policy because we have. You know some other conditions for fabhalta and voydeya to go through Soliris first and just including those biosimilars, since they're available like in the language. RN: So yes, so to reiterate, if we would get a request for voydeya, then we would want to see that there on either the Solaris, the Bkerv or Epysqli for six, six months or Ultomoris. As an example. OK.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		Guideline (Changes): <u>15. Complement Inhibitors for the Treatment of Myasthenia Gravis</u> - If there's other questions there, the next policy has the same change essentially. So, for the Soliris, Bkerv, Epysqli are on the policy. And there's no other changes here. <u>Comments:</u> PB: So, this is just a similar to Soliris in terms of being a complement inhibitor to different medication, but the similar guidelines. OK BD: Yeah, I think they are similar to other biosimilar for rituximab and some other. I think chemotherapy, they talk about the Bkerv and Epysqli. RN: Yes PB: And is there a cost difference between because this is a daily injectable? And then Soliris is an infusion. I mean, this is a daily sq I think. RN: Cost. Do we have that available? Perhaps someone at perform might have easier access to the cost. Or maybe we can come back. IM: It's a little bit different. It's different pricing depending on the condition. So Soliris' prices for Mycena gravis is around \$52,000 and Bkerv is \$47,000 at Epysqli would be 36,500. So it is substantially cheaper for Epysqli biosimilar versus Solaris. PB: What about the one run now Zilbrysq? IM: Yeah, Zilbrysq is cheaper. It depends on the weight as well, but the weight ranges from like 22,000 to up to 44,000 for like 70 kilograms. PB: OK. Good. So, it's a cheaper option that people can inject at home. That's great. OK. Thank you. BD: I have a question about this one? Are these biosimilars only approved for neurological and rheumatology, or are they also approved for P&H? IM: They are approved for P&H, Ajus and Myseno Gravis, but my mysenia gravis only in adults, not in Pediatrics. IM: I just had a comment about Perseris as well. Perseris is was there was no utilization in the last year, but we just checked for the news articles, and the latest one says that they are not taking it off market. They have just stopped conducting marketing activities. So, I think we should keep that drug in the criteria for now and you know, revisit when it's actually taken off or. When there is more news available. If that's OK.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
VIII) Physician Administered Drug (PAD) Policies	Iryna Makukh	Guideline (Changes): 1. Anti-CD19 CAR-T Immunotherapies - Recommendation: - Add new drug Aucatzyl—CD 19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia. - Add coverage duration for Aucatzyl and update coverage duration section for more clarity, since one treatment regimen of Aucatzyl includes 2 infusions. - Update Acute Lymphoblastic Leukemia (ALL) section with the new agent per indication and timeframe for post-transplant relapsed/refractory disease. - Update Follicular Lymphoma (FL) and Mantle Cell Lymphoma (MCL) sections with Breyanzi that received an expanded indication for FL and MCL treatment, supported by NCCN guidelines as a third line agent. - Correct miswording for Large B-cell Lymphoma section and formatting throughout the policy. - Update Re-authorization section with Aucatzyl. <u>Comments:</u> Guideline (Changes): 2. Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention - Remove nortriptyline and duloxetine from the list of trial and failure agents because they are not in the guidelines, and only amitriptyline and venlafaxine are specifically mentioned in the guidelines <u>Comments:</u> Guideline (Changes): 3. Complement Inhibitors - Recommendation: - Add newly launched biosimilars for Soliris: BKEMV and Epysqli to policy - Add trial and failure of Epysqli before Soliris or BKEMV for cost containment <u>Comments:</u> Guideline (Changes): 4. Myasthenia Gravis Agents Recommendation: - Add newly launched biosimilars for Soliris--BKEMV and Epysqli to policy	Approved 1 st :BD 2 nd : IL	

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Add age restriction exception for Soliris, since it received an approval in pediatric patients 6 years of age and above - Add requirements for pediatric patients for Soliris based on pediatric study protocol - Add trial and failure of Epysqli before Soliris or BKEMV for cost containment <u>Comments:</u> Guideline (Changes): 5. Bleeding Disorder Products - Recommendation: Add new bleeding disorder products to policy: Alhemo, Hymfavzi, and Qfitlia <u>Comments:</u>		
IX) Informational Updates on New Developments in Pharmacy	Iryna Makukh	<u>New Product Review</u> • New Products will be discussed at Q32025 P&T Committee Meeting.		

			BRAND NAME	GENERIC NAME/DOSAGE FORM	RECOMMENDATION			
			Prevymis	Letermovir oral packet 120mg, 20mg	Non-formulary			
			Jivi	antihemophilic factor (recombinant), PEGylated-aucI intravenous solution reconstituted 4000 unit	Non-formulary			
			Fenopron	Fenoprofen oral capsule 300mg	Non-formulary			
			Alhemo	concizumab-mtci pen-injector 60mg/1.5ml, 150 mg/1.5ml	Non-formulary (see updated MRG policy)			
			Steqeyma	ustekinumab-stba subcutaneous solution prefilled syringe 45 mg/0.5ml, 90mg/ml	Non-formulary (see updated MRG policy)			
			Datroway	Datopotamab deruxtecan-dlnk intravenous solution reconstituted 100 mg	Non-formulary			
			Adalimumab-adaz	Adalimumab-adaz Subcutaneous Solution Prefilled Syringe 20 MG/0.2ML	Non-formulary			
			Esperoct	Antihemophilic Factor (recombinant) glycopegylated-exei 4,000 unit	Non-formulary			
			Simlandi	adalimumab-ryvk subcutaneous prefilled syringe kit	F-QL (already added via CRF) (QL: 80mg/0.8mL: 2 syringes/28 days,			

				20 mg/0.2ml, 80mg/0.8ml	LD: 4 syringes; 20mg/0.2mL: 4 syringes/28 days, LD: use 40mg strength)			
			Fulvicin P/G	Griseofulvin oral tablet 165mg	Non-formulary			
			Steqeyma	ustekinumab-stba intravenous solution 130 mg/26ml	Non-formulary (see updated MRG policy)			
			Yesintek	Ustekinumab-kfce subcutaneous solution/ prefilled syringe 45 MG/0.5ML, 90 MG/ML	Add to F-PA (see updated MRG policy)			
			Niktimvo	Axatilimab-csfr intravenous solution 9mg/0.18ml, 22mg/0.44ml	Non-formulary (see new PAD policy)			
			Metformin#	Metformin HCl oral tablet 750mg	Non-formulary			
			Frindovyx	Cyclophosphamide intravenous solution 500mg/ml, 1g/2ml, 2g/4ml	Non-formulary			
			Griseofulvin	Griseofulvin ultramicrosize oral tablet 165 mg	Non-formulary			
			Halcinonide	Halcinonide External Solution 0.1%	Non-formulary			
			Ustekinumab-ttwe	Ustekinumab-ttwe subcutaneous solution prefilled syringe 45 mg/0.5ml, 90mg/ml	Non-formulary (see updated MRG policy)			

				Ustekinumab-ttwe intravenous solution 130 mg/26ml				
			Journavx	Suzetrigine 50mg oral tablet	Non-formulary			
			Feirza 1.5/30	ethinyl estradiol and norethindrone oral tablet 1.5-30 mg-mcg	Add to F			
			Valtva 1/50	ethynodiol diacetate and ethinyl estradiol oral tablet 1-50 mg-mcg	Add to F			
			Rybelsus	Semaglutide oral tablet 1.5mg, 4mg, 9mg	F-ST-QL (Already added via CRF) ST: Requires a previous trial with a metformin-containing product. QL: 30 tabs/30 days			
			Palforzia	Peanut allergen powder - initial dose 1-3yrs oral capsule sprinkle therapy pack 0.5 & 1 & 1.5 & 3 mg - initial dose 4-17yrs oral capsule sprinkle therapy pack 0.5 & 1 & 1.5 & 3 & 6 mg - oral capsule sprinkle	Non-formulary			

				therapy pack 1 x 1 mg				
			Evrysdi	Risdiplam 5mg oral tablet	Non-formulary			
			Selarsdi	Ustekinumab-aekn subcutaneous solution prefilled syringe 45 mg/0.5ml, 90mg/ml	Non-formulary (see updated MRG policy)			
			Gomekli	Mirdametinib oral capsule 1mg, 2mg Mirdametinib oral tablet soluble 1mg	Non-formulary (see new MRG policy)			
			Grafapex	Treosulfan IV solution reconstituted 1gm, 5m	Non-formulary			
			Zepbound	Tirzepatide subcutaneous solution 7.5mg/0.5ml, 10mg/0.5ml	Non-formulary			
			Omvoh (300mg dose)	Mirikizumab- mrkz (300 mg dose) subcutaneous solution auto-injector and prefilled syringe 100 mg/ml & 200 mg/2ml	Non-formulary			
			Onapgo	Apomorphine hydrochloride subcutaneous solution cartridge 98 mg/20ml	Non-formulary			
			Ivra	Melphalan intravenous solution 90 mg/ml	Non-formulary			

			Xromi	Hydroxyurea oral solution 100 mg/ml	Non-formulary			
			Metaxalone	Metaxalone oral tablet 640 mg	Non-formulary			
			Zunveyl	Benzgalantamine oral tablet delayed release 5 mg, 15mg	Non-formulary (see updated MRG policy)			
			Feirza 1/20	ethinyl estradiol and norethindrone oral tablet 1-20 mg-mcg	Add to F			
			Promethazine	Promethazine hcl oral solution 12.5 mg/10ml	Non-formulary			
			Valtoco	Diazepam 15 mg dose nasal liquid therapy pack 2 x 7.5 mg/0.1ml Diazepam 20 mg dose nasal liquid therapy pack 2 x 10 mg/0.1ml	Non-formulary			
			Pyzchiva	Ustekinumab-ttwe subcutaneous solution prefilled syringe 45mg/0.5ml and 90 mg/ml Ustekinumab-ttwe Intravenous Solution 130 MG/26ML	Non-formulary (see updated MRG policy)			
			Alhemo	Concizumab-mtci subcutaneous solution pen-injector 300 mg/3ml	Non-formulary (see updated MRG policy)			

			Raldesy	Trazodone oral solution 10 mg/ml	Non-formulary			
			Vimkunya	Chikungunya vaccine, recombinant intramuscular suspension prefilled syringe 40 mcg/0.8ml	Non-formulary			
			BKEMV	Ecilizumab-aeeb intravenous solution 300 mg/30ml	Non-formulary (see updated MRG and PAD policies)			
			Otulfi	Ustekinumab-aaaz subcutaneous solution prefilled syringe 45 mg/0.5ml Ustekinumab-aaaz subcutaneous solution prefilled syringe 90 mg/ml Ustekinumab-aaaz intravenous solution 130 mg/26ml	Add to F-PA (see updated MRG policy)			
			Romvimza	Vimseltinib oral capsule 14, 20, 30 mg	Non-formulary			
			Zunveyl	Benzgalantamine oral tablet delayed release 10 mg	Non-formulary (see updated MRG policy)			
			Lidocaine HCl	Lidocaine HCl urethral/mucosal external gel 2 %	Non-formulary			
			Epysqli	Ecilizumab-aagh intravenous solution 300 mg/30ml	Non-formulary (see updated MRG and PAD policies)			

			Purified Cortrophin Gel	Corticotropin subcutaneous prefilled syringe 40 unit/0.5ml, 80 unit/ml	F-PA (Already added via CRF)			
			Inzirqo	hydrochlorothiazide oral suspension 10mg/ml	Non-formulary			
			Xpovio (40 MG Once Weekly)	Selinexor (40 mg once weekly) oral tablet therapy pack 10 mg	Non-formulary			
			Ryoncil	remestemcel-L various intravenous kit sizes	Non-formulary (see new PAD policy)			
			Abirtega	Abiraterone acetate oral tablet 250mg	Non-formulary			
			Emend BiPack	Aprepitant oral capsule 80mg	Non-formulary			
			BAC (Butalbital-Acetamin-Caff)	Butalbital-acetaminophen-caff oral tablet 50-325-40mg	Non-formulary			
			cefazolin sodium-dextrose	cefazolin sodium-dextrose intravenous solution reconstituted 3-2 gm-% (50ml)	Non-formulary			
			Simlandi	Adalimumab-ryvk (1 pen) subcutaneous auto-injector kit 80 mg/0.8ml	F-QL (Already added via CRF) (QL: 2 pens/28 days; LD: 4 pens)			
			Sevenfact	coagulation factor viia-jncw intravenous solution reconstituted 2 mg	Non-formulary			

			Ivermectin	ivermectin oral tablet 6 mg	Non-formulary			
			Revuforj	Revumenib oral tablet 25 mg	Non-formulary			
			Rapiblyk	Landiolol intravenous solution reconstituted 280 mg	Non-formulary			
			Ctexli	Chenodiol 250 mg tablets	Non-formulary			
			Baclofen Refill Kit- SynchroMed	Baclofen intrathecal kit 40 mg/20ml	Non-formulary			
			Selarsdi	Ustekinumab-aekn intravenous solution 130 mg/26ml	Non-formulary (see updated MRG policy)			
			Encelto	revakinagene tarorectel-lwey intravitreal implant 200000 cells	Non-formulary			
			Acyclovir	Acyclovir Oral Suspension 800 MG/20ML	Non-formulary			
			Octreotide	SandoSTATIN LAR depot intramuscular kit 10 mg	Non-formulary			
			Qfitlia	Fitusiran subcutaneous solution 20 mg/0.2ml, subcutaneous solution auto-injector 50 mg/0.5ml	Non-formulary (see updated MRG policy)			
			Combogesic	Ibuprofen- acetaminophen oral tablet 325-97.5mg	Non-formulary			

			Tremfya Pen	Guselkumab pen subcutaneous solution auto-injector 100 mg/ml	Non-formulary			
			Vyloy	Zolbetuximab-clzb intravenous solution reconstituted 300 mg	Non-formulary			
			Tezruly	Terazosin oral solution 1 mg/ml	Non-formulary			
			Lutrate Depot	Leuprolide acetate intramuscular injectable 22.5 mg	Non-formulary			
			Xelria Fe	Norethin-eth estradiol-fe oral tablet chewable 0.4-35 mg-mcg	Add to F			
			Lamivudine	Lamivudine oral solution 300 mg/30ml	Non-formulary			
			Albuterol	Albuterol sulfate oral syrup 8 mg/20ml	Non-formulary			
			Paxlovid	Nirmatrelvir & ritonavir oral tablet therapy pack 6 x 150 mg & 5 x 100mg	F-QL-AL (Already added via CRF) (QL: 11 tabs/180 days, AL: 12 years and older)			
			Sunlenca	Lenacapavir 300mg oral tablet	F (Already added via CRF)			
			Zevtera	Ceftobiprole medocaril intravenous solution reconstituted 500 mg	Non-formulary			

Agenda Item	Discussion Leader	Discussion Summary					Action	Notes
			Vyvgart Hytrulo	Efgartigimod alfa-Hyalur-qvfc subcutaneous solution prefilled syringe 1000-10000 mg-unt/5ml	Non-formulary			
			Neffy	Epinephrine nasal solution 1 mg/0.1ml	Non-formulary			
			Amnesteem	Isotretinoin oral capsule 30 mg	F-PA (Already added via CRF)			
			Morphine sulfate	Morphine sulfate intravenous solution 2 mg/ml	Non-formulary			
			Adrenalin	Epinephrine in sodium chloride intravenous solution 5-0.9 mg/250ml-%	Non-formulary			
			Marcaine	Bupivacaine hydrochloride preservative free injection solution 0.75 %	Non-formulary			
			Adalimumab-aaty	Adalimumab-aaty CD/UC/HS Start Subcutaneous auto-injector kit 80 mg/0.8ml	F-QL (Already added via CRF) (QL: 2 pens/28 days, LD: 4 pens)			
X) Old Business		Pharmacists to prescribe Naloxone at POS						
		<u>Comments:</u>						
XI) Public Comment	D. Carey	No comment						
Adjournment	D. Carey	Meeting adjourned at 7:02PM					None	

P&T Committee Meeting Minutes
June 17, 2025



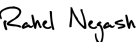
Signed by:

x Luke W. Lim, RPh
Pharmacy Director
D19D528D20E5408

Luke Lim, Rph
Senior Director, Pharmacy Services
Alameda Alliance for Health

09/02/2025 | 11:43 AM PDT

Date

DocuSigned by:

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Supervisor, Pharmacy Services
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Date

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09/02/2025 | 7:12 PM PDT

Date

Drug Name	Strength	Dose	QL recommended	Utilizers	Claims	Plan Cost
BIKTARVY	50-200-25 MG	1 qd	30/30	17	163	\$ 530,810.45
	30-120-15 MG	1 qd	30/30			
WEGOVY	1 MG/0.5ML	1 mg once a week	2mL/28 days	50	421	\$ 382,707.85
	2.4 MG/0.75ML	2.4 mg once a week	3ml/28 days			
	0.5 MG/0.5ML	0.5 mg once a week	2mL/28 days			
	0.25 MG/0.5ML	0.25 mg once a week	2mL/28 days			
	1.7 MG/0.75ML	1.7 mg once a week	3ml/28 days			
VEMLIDY	25 MG	1 qd	30/30	31	285	\$ 346,737.41
COSENTYX		300 mg qweek x 5 weeks 300 mg q4 weeks OR 150 mg subQ at weeks 0, 1, 2, 3, and 4 and then some patients may only need 150 mg q4weeks for some indications	Initial dose: 10mL per 35 days; Maintenance: 2mL per 28 days	3	52	\$ 292,972.43
	Cosentyx Sensoready (300 MG) Subcutaneous Solution Auto-injector 150 MG/ML		Initial dose: 10mL per 35 days; Maintenance: 2mL per 28 days			
	Cosentyx UnoReady Subcutaneous Solution Auto-injector 300 MG/2ML		Initial dose: 10mL per 35 days; Maintenance: 2mL per 28 days			
	Cosentyx Subcutaneous Solution Prefilled Syringe 150 MG/ML		Initial dose: 10mL per 35 days; Maintenance: 2mL per 28 days			
	Cosentyx Sensoready Pen Subcutaneous Solution Auto-injector 150 MG/ML		Initial dose: 10mL per 35 days; Maintenance: 2 mL per 28 days			
	Cosentyx (300 MG Dose) Subcutaneous Solution Prefilled Syringe 150 MG/ML		Initial dose: 10mL per 35 days; Maintenance: 2 mL per 28 days			
	Cosentyx Subcutaneous Solution Prefilled Syringe 75 MG/0.5ML		Initial dose: 5mL per 35 days; Maintenance: 1 mL per 28 days			
SKYRIZI	Skyrizi Pen Subcutaneous Solution Auto-injector 150 MG/ML	150 mg x 1 on wk 0 + 4 150 mg q12 week	Initial dose: 2mL/28 days; Maintenance: 1mL/84 days	4	19	\$ 254,609.36
	Skyrizi Subcutaneous Solution Prefilled Syringe 150 MG/ML	150 mg x 1 on wk 0 + 4 150 mg q12 week	Initial dose: 2mL/28 days; Maintenance: 1mL/84 days			
	Skyrizi Pen Subcutaneous Solution Auto-injector 150 MG/ML	150 mg x 1 on wk 0 + 4 150 mg q12 week	Initial dose: 2mL/28 days; Maintenance: 1mL/84 days			
	Skyrizi Subcutaneous Solution Cartridge 360 MG/2.4ML	180 or 360 mg q8 week	2.4 mL per 56 days			
	Skyrizi Subcutaneous Solution Cartridge 180 MG/1.2ML	180 or 360 mg q8 week	1.2 mL per 56 days			
REZUROCK	200 MG	1 qd	30/30	1	7	\$ 229,089.21
ZEJULA	100 MG		30/30	1	6	\$ 176,964.75
	200 MG	200 mg orally once daily	30/30			
	300 MG	300 mg orally once daily	30/30			
JARDIANCE	10 MG	10 mg orally once daily	30/30	51	392	\$ 175,385.20
	25 MG	10 mg orally once daily; may increase to 25 mg orally once daily	30/30			
FARXIGA	5 MG	1 qd	30/30	72	388	\$ 155,401.14
	10 MG	1 qd	30/30			
TRULICITY	0.75 MG/0.5ML	0.75 mg once a week	2mL/28 days	22	214	\$ 153,568.14
	1.5 MG/0.5ML	1.5 mg once a week	2mL/28 days			
	4.5 MG/0.5ML	4.5 mg once a week	2mL/28 days			

	3 MG/0.5ML	3 mg once a week	2mL/28 days			
STEGLATRO	5 MG	1 qd	30/30	62	553	\$ 152,762.56
	15 MG	1 qd	30/30			
JANUVIA	50 MG	1 qd	30/30	47	399	\$ 144,411.89
	25 MG	1 qd	30/30			
	100 MG	1 qd	30/30			
VERZENIO	50 MG	150 mg orally twice daily to 200 mg orally twice daily	60/30	2	10	\$ 138,079.07
	100 MG		60/30			
	150 MG		60/30			
	200 MG		60/30			
NERLYNX	40 MG	240 mg (six 40-mg tablets) orally once daily	180/30	1	18	\$ 126,591.48
OCALIVA	5 MG	5 mg orally once daily for the first 3 months; may increase to MAX of 10 mg once daily	30/30	1	22	\$ 123,356.73
	10 MG		30/30			
HUMIRA	Humira (2 Syringe) Subcutaneous Prefilled Syringe Kit 40 MG/0.4ML	160 mg x 1 day1, 80 mg x1 day 15 + 29 40 mg SC q wk	Initial dose: 8 syringes per 28 days; Maintenance: 4 syringes per 28 days	1	12	\$ 120,983.13
	Humira (2 Syringe) Subcutaneous Prefilled Syringe Kit 20 MG/0.2ML	160 mg x 1 day1, 80 mg x1 day 15 + 29 40 mg SC q wk	Initial dose: should use 40mg strength for loading. Maintenance: 4 syringes per 28 days			
	Humira (2 Syringe) Subcutaneous Prefilled Syringe Kit 10 MG/0.1ML	160 mg x 1 day1, 80 mg x1 day 15 + 29 40 mg SC q wk Pediatric dose:10 mg subQ every other week	Initial dose: should use 40mg strength for loading. Maintenance: 2 syringes per 28 days			
	Humira (2 Syringe) Subcutaneous Prefilled Syringe Kit 40 MG/0.8ML	160 mg x 1 day1, 80 mg x1 day 15 + 29 40 mg SC q wk	Initial dose: 8 syringes per 28 days; Maintenance: 4 syringes per 28 days			
	Humira-CD/UC/HS Starter Subcutaneous Auto-injector Kit 80 MG/0.8ML	160 mg x 1 day1, 80 mg x1 day 15 + 29 40 mg SC q wk or 80 mg every other week	1 each per 28 days			
	Humira-Psoriasis/Uveit Starter Subcutaneous Auto-injector Kit 80 MG/0.8ML & 40MG/0.4ML	160 mg x 1 day1, 80 mg x1 day 15 + 29 40 mg SC q wk or 80 mg every other week	1 each per 28 days			
	Humira (2 Pen) Subcutaneous Auto-injector Kit 40 MG/0.4ML	160 mg x 1 day1, 80 mg x1 day 15 + 29 40 mg SC q wk	Initial dose: 8 pens per 28 days; Maintenance: 4 pens per 28 days			
	Humira (2 Pen) Subcutaneous Auto-injector Kit 80 MG/0.8ML	160 mg x 1 day1, 80 mg x1 day 15 + 29 40 mg SC q wk or 80 mg every other week	Initial dose: 4 pens per 28 days; Maintenance: 2 pens per 28 days			

	Humira (2 Pen) Subcutaneous Auto-injector Kit 40 MG/0.8ML	160 mg x 1 day1, 80 mg x1 day 15 + 29 40 mg SC q wk or 80 mg every other week	Initial dose: 8 pens per 28 days; Maintenance: 4 pens per 28 days			
	Humira (1 Pen) Subcutaneous Auto-injector Kit 80 MG/0.8ML	160 mg x 1 day1, 80 mg x1 day 15 + 29 40 mg SC q wk or 80 mg every other week	Initial dose: 4 pens per 28 days; Maintenance: 2 pens per 28 days			
DUPIXENT	Dupixent Subcutaneous Solution Prefilled Syringe 300 MG/2ML	400 mg SUBQ once followed by 200 mg every 2 weeks OR 600 mg SUBQ once followed by 300 mg every 2 weeks	Initial dose: 4mL; Maintenance: 4mL per 28 days	5	40	\$ 107,781.59
	Dupixent Subcutaneous Solution Prefilled Syringe 200 MG/1.14ML		Initial dose: 2.28 mL; Maintenance: 2.28 mL per 28 days			
	Dupixent Subcutaneous Solution Auto-injector 200 MG/1.14ML		Initial dose: 2.28 mL; Maintenance: 2.28 mL per 28 days			
	Dupixent Subcutaneous Solution Auto-injector 300 MG/2ML		Initial dose: 4mL; Maintenance: 4mL per 28 days			
GENVOYA	150-150-200-10 MG	1 qd	30/30	4	42	\$ 107,241.53
JAKAFI	Jakafi Oral Tablet 5 MG	Initial, 5 mg orally twice daily; may increase to 10 mg twice daily	60/30	1	10	\$ 100,895.64
	Jakafi Oral Tablet 10 MG	twice daily	60/30			
	Jakafi Oral Tablet 15 MG	twice daily	60/30			
	Jakafi Oral Tablet 20 MG	twice daily	60/30			
	Jakafi Oral Tablet 25 MG	MAX 25 mg twice daily	60/30			
ZEPBOUND	2.5 MG/0.5ML	0.5mL once a week	2mL/28 days	17	160	\$ 99,797.03
	5 MG/0.5ML		2mL/28 days			
	7.5 MG/0.5ML		2mL/28 days			
	10 MG/0.5ML		2mL/28 days			
	12.5 MG/0.5ML		2mL/28 days			
	15 MG/0.5ML		2mL/28 days			
RADICAVA ORS	Radicava ORS Oral Suspension 105 MG/5ML	5mL once daily for 14 days, then 14 days off	100mL per 34 days (per 50ml bottle size)	1	10	\$ 76,649.37
	Radicava ORS Starter Kit Oral Suspension 105 MG/5ML	5mL once daily for 14 days, then 14 days off	70 mL per 28 days (35 mL bottle size)			
ACTEMRA	Actemra ACTPen Subcutaneous Solution Auto-injector 162 MG/0.9ML	162 MG/week	3.6 mL/28 days	2	32	\$ 70,369.98
	Actemra Subcutaneous Solution Prefilled Syringe 162 MG/0.9ML		3.6 mL/28 days			
ODEFSEY	200-25-25 MG	1 qd	30/30	3	29	\$ 68,450.19
DASATINIB	20 MG		60/30	1	8	\$ 65,774.47
	50 MG		60/30			
	70 MG		60/30			
	80 MG	once daily	30/30			

	100 MG	100 mg orally once daily, dose escalation to 140 mg/day was allowed	30/30			
	140 MG	140 mg orally once a day with or without food; dose escalation to 180 mg/day was allowed	30/30			
SPRYCEL	20 MG		60/30	1	5	\$ 59,710.64
	50 MG		60/30			
	70 MG		60/30			
	80 MG	once daily	30/30			
	100 MG	100 mg orally once daily, dose escalation to 140 mg/day was allowed	30/30			
	140 MG	140 mg orally once a day with or without food; dose escalation to 180 mg/day was allowed	30/30			
CABENUVA	400 & 600 MG/2ML	once a month	4mL/28 days	2	11	\$ 52,284.21
	600 & 900 MG/3ML	once every 2 months after 1st 2 monthly initiation injections	6mL/28 days			
GLATIRAMER ACETATE	Glatiramer Acetate Subcutaneous Solution Prefilled Syringe 20 MG/ML	20 mg subQ once daily	30mL/30 days	1	10	\$ 42,702.64
	Glatiramer Acetate Subcutaneous Solution Prefilled Syringe 40 MG/ML	40 mg subQ 3 times a week	12mL/30days			
APRETUDE	600 MG/3ML	600 mg IM on month 1 and 2, then every 2 months thereafter	3mL/28 days	3	16	\$ 42,209.49
CIMZIA	Cimzia-Starter Subcutaneous Prefilled Syringe Kit 200 MG/ML	400 mg x 1 on wk 0, 2, 4 400 mg q2 week	Initial dose: 2 each (6 syringes)	1	9	\$ 41,486.08
	Cimzia (2 Syringe) Subcutaneous Prefilled Syringe Kit 200 MG/ML	400 mg x 1 on wk 0, 2, 4 400 mg q2 week	Initial dose: 3 each (6 syringes); Maintenance: 2 each (4 syringes) per 28 days			
	Cimzia Subcutaneous Kit 2 X 200 MG	400 mg x 1 on wk 0, 2, 4 400 mg q2 week	Initial dose: 3 each (6 syringes); Maintenance: 2 each (4 syringes) per 28 days			
SYMTUZA	800-150-200-10 MG	1 qd	30/30	1	10	\$ 36,621.28
DESCOVY	200-25 MG	1 qd	30/30	4	32	\$ 34,010.72
	120-15 MG	1 qd	30/30			
VUMERITY	231 MG	Initial, 231 mg orally twice daily for 7 days, then increase to 462 mg (as two 231-mg capsules) twice daily.	120/30	1	4	\$ 33,501.77
TARPEYO	4 MG	16 mg orally once daily for a duration of 9 months	120/30	1	2	\$ 31,936.26

ADBRY	Adbry Subcutaneous Solution Prefilled Syringe 150 MG/ML	Initial, 600 mg subQ (four 150-mg injections OR two 300-mg injections) followed by 300 mg subQ (two 150-mg injections OR one 300-mg injection) every other week	Initial dose: 4 mL per 28 days ; Maintenance: 4 mL per 28 days	2	14	\$ 30,670.56
	Adbry Subcutaneous Solution Auto-injector 300 MG/2ML		Initial dose: 4 mL per 28 days ; Maintenance: 4 mL per 28 days			
XIFAXAN	550 MG	550 mg orally 3 times daily	90/30	3	15	\$ 28,921.21
	200 MG	200 mg orally 3 times daily for 3 days, 1200 mg/day divided in 3 doses (off-label for HE)	90/30			
LINZESS	Liness Oral Capsule 72 MCG	once daily	30/30	9	62	\$ 27,485.28
	Liness Oral Capsule 145 MCG	once daily	30/30			
	Liness Oral Capsule 290 MCG	once daily	30/30			
ERLOTINIB HCL	25 MG		30/30	1	17	\$ 25,591.01
	100 MG	100 mg orally 1 hour before or 2 hours after ingestion of food once daily	30/30			
	150 MG	150 mg orally 1 hour before or 2 hours after ingestion of food once daily	30/30			
BUDESONIDE-FORMOTEROL FU	80-4.5 MCG/ACT	2 inhalations twice daily	30.6gm/30	60	275	\$ 25,516.30
	160-4.5 MCG/ACT	2 inhalations twice daily	30.6gm/30			
MAVYRET	50-20 MG	Glecaprevir 300 mg/pibrentasvir 120 mg (three 100 mg/40 mg tablets) orally once daily with food for 12 weeks	84/28	1	6	\$ 25,377.36
	100-40 MG	Glecaprevir 250 mg/pibrentasvir 100 mg (five 50 mg/20 mg packets of pellets) orally once daily with food for 12 weeks	140/28			
CRESEMBA	74.5 MG	Loading dose: 372 mg orally (two 186-mg or five 74.5-mg capsules) every 8 hours for 6 doses; Maintenance dosage: 372 mg orally (two 186-mg or five 74.5-mg capsules) once daily	Initial dose: 30 caps; Maintenance: 150 caps/30 days	1	5	\$ 24,555.03
	186 MG		Initial dose: 12 caps; Maintenance: 60 caps/30 days			
CYCLOSPORINE	Ophthalmic Emulsion 0.05 %	1 drop in each eye twice daily	60/30	20	108	\$ 23,544.46
SOFOBUIR-VELPATASVIR	400-100 MG	Sofosbuvir 400 mg/velpatasvir 100 mg (one 400 mg/100 mg tablet) orally once daily	28/28	1	3	\$ 23,154.00

XPHOZAH	20 MG		60/30	1	9	\$ 22,825.92
	30 MG	30 mg orally twice daily	60/30			
WIXELA INHUB	100-50 MCG/ACT	1 oral inhalation of fluticasone 100, 250, or 500 mcg/salmeterol 50 mcg twice daily	60/30	54	243	\$ 21,652.49
	250-50 MCG/ACT		60/30			
	500-50 MCG/ACT		60/30			
QVAR REDHALER	40 MCG/ACT	40 to 80 mcg oral inhalation twice daily	10.6 gm/30 days	38	115	\$ 19,504.06
	80 MCG/ACT		10.6 gm/30 days			
TYMLOS	3120 MCG/1.56ML	80 mcg subQ once daily, tx for more than 2 years during pt's lifetime is not recommended	1.56mL/30 days	1	14	\$ 18,384.31
ISENTRESS HD	Isentress HD Oral Tablet 600 MG	1200 mg once daily	60/30	1	14	\$ 17,758.60
	Isentress Oral Packet 100 MG	100 mg twice daily--pediatric	60/30			
	Isentress Oral Tablet 400 MG	400 mg orally twice daily	60/30			
	Isentress Oral Tablet Chewable 100 MG	variable	180/30			
	Isentress Oral Tablet Chewable 25 MG	variable	180/30			
NEMLUVIO	Nemludio Subcutaneous Auto-injector 30 MG	Initial, 60 mg (two 30-mg injections) subQ once, followed by 30 mg subQ every 4 weeks OR for 90 kg or greater: same initial, maintenance: 60 mg subQ every 4 weeks	Initial dose: 2 Each (2 pens); Maintenance: 2 Each (2 pens)/30 days	1	4	\$ 16,646.64
TAGRISSE	40 MG	80 mg orally or via nasogastric tube once daily	30/30	2	2	\$ 15,706.50
	80 MG	80 mg orally or via nasogastric tube once daily	30/30			
REPATHA	Repatha Subcutaneous Solution Prefilled Syringe 140 MG/ML	140 mg SUBQ every 2 weeks or 420 mg SUBQ monthly; FH: Initial, 420 mg SUBQ once monthly; may increase to 420 mg once every 2 weeks	6 mL/28 days	4	33	\$ 15,252.50
	Repatha SureClick Subcutaneous Solution Auto-injector 140 MG/ML	140 mg SUBQ every 2 weeks or 420 mg SUBQ monthly; FH: Initial, 420 mg SUBQ once monthly; may increase to 420 mg once every 2 weeks	6 mL/28 days			
	Repatha Pushtronex System Subcutaneous Solution Cartridge 420 MG/3.5ML	140 mg SUBQ every 2 weeks or 420 mg SUBQ monthly; FH: Initial, 420 mg SUBQ once monthly; may increase to 420 mg once every 2 weeks	7 mL/28 days			
ENTECAVIR	0.5 MG	0.5 mg orally once daily	30/30	31	160	\$ 15,121.80
	1 MG	1 mg orally once daily	30/30			

JANUMET	50-1000 MG	MAX sitagliptin 100 mg and metformin 2000 mg per day	60/30	4	39	\$ 13,083.83
	50-500 MG	MAX sitagliptin 100 mg and metformin 2000 mg per day	60/30			
	Janumet XR 100-1000 MG	MAX sitagliptin 100 mg and metformin 2000 mg per day	30/30			
	Janumet XR 50-1000 MG	MAX sitagliptin 100 mg and metformin 2000 mg per day	60/30			
	Janumet XR 50-500 MG	MAX sitagliptin 100 mg and metformin 2000 mg per day	60/30			
EMGALITY	Emgality (300 MG Dose) Subcutaneous Solution Prefilled Syringe 100 MG/ML	300 mg subQ (3 consecutive subQ injections of 100 mg each) at the onset of the cluster period, and then monthly	3 mL/30 days	4	37	\$ 12,862.56
	Emgality Subcutaneous Solution Auto-injector 120 MG/ML	240 mg subQ (2 consecutive 120-mg doses) once as a loading dose, followed by 120 mg once monthly	Initial dose: 2 mL; Maintenance: 1mL/30 days			
	Emgality Subcutaneous Solution Prefilled Syringe 120 MG/ML	240 mg subQ (2 consecutive 120-mg doses) once as a loading dose, followed by 120 mg once monthly	Initial dose: 2 mL; Maintenance: 1mL/30 days			
TRELEGY ELLIPTA	100-62.5-25 MCG/ACT	1 oral inhalation of fluticasone furoate 100 mcg/umeclidinium 62.5 mcg/vilanterol 25 mcg or fluticasone furoate 200 mcg/umeclidinium 62.5 mcg/vilanterol 25 mcg once daily	60 EA (1 inhaler)/30days	3	21	\$ 12,686.34
	200-62.5-25 MCG/ACT	1 oral inhalation of fluticasone furoate 100 mcg/umeclidinium 62.5 mcg/vilanterol 25 mcg or fluticasone furoate 200 mcg/umeclidinium 62.5 mcg/vilanterol 25 mcg once daily	60 EA (1 inhaler)/30days			
ALOGLIPTIN	12.5 MG	orally once daily	30/30	16	103	\$ 11,464.87
	25 MG	25 mg orally once daily	30/30			
	6.25 MG	orally once daily	30/30			
	Alogliptin-metFORMIN HCl Oral Tablet 12.5-1000 MG		60/30			
	Alogliptin-metFORMIN HCl Oral Tablet 12.5-500 MG		60/30			
	Alogliptin-Pioglitazone Oral Tablet 12.5-30 MG	Alogliptin: 25 mg qd; Pioglitazone:15 to 45 mg orally once daily	60/30			

	Alogliptin-Pioglitazone Oral Tablet 25-15 MG		30/30			
	Alogliptin-Pioglitazone Oral Tablet 25-30 MG		30/30			
	Alogliptin-Pioglitazone Oral Tablet 25-45 MG		30/30			
KERENDIA	10 mg	10 mg orally once daily	30/30	3	19	\$ 11,314.31
	20 mg	20 mg orally once daily	30/30			
ORENCIA	Orencia ClickJect Subcutaneous Solution Auto-injector 125 MG/ML	125 mg subQ once weekly	4 mL/28 days	1	6	\$ 11,171.46
	Orencia Subcutaneous Solution Prefilled Syringe 125 MG/ML	125 mg subQ once weekly	4 mL/28 days			
	Orencia Subcutaneous Solution Prefilled Syringe 50 MG/0.4ML	pediatric: 50 mg subQ once weekly	1.6 mL/28 days			
	Orencia Subcutaneous Solution Prefilled Syringe 87.5 MG/0.7ML	pediatric: 87.5 mg subQ once weekly	2.8 mL/28 days			
FLUTICASONE-SALMETEROL	Fluticasone-Salmeterol Inhalation Aerosol Powder Breath Activated 250-50 MCG/ACT	via oral inhalation twice daily	60/30	54	155	\$ 11,053.28
	Fluticasone-Salmeterol Inhalation Aerosol Powder Breath Activated 500-50 MCG/ACT	via oral inhalation twice daily	60/30			
	Fluticasone-Salmeterol Inhalation Aerosol Powder Breath Activated 100-50 MCG/ACT	via oral inhalation twice daily	60/30			
	Fluticasone-Salmeterol Inhalation Aerosol Powder Breath Activated 113-14 MCG/ACT	Fluticasone 113 mcg/salmeterol 14 mcg OR fluticasone 232 mcg/salmeterol 14 mcg via oral inhalation twice daily	1 inhaler/30 days			
	Fluticasone-Salmeterol Inhalation Aerosol Powder Breath Activated 232-14 MCG/ACT	Fluticasone 113 mcg/salmeterol 14 mcg OR fluticasone 232 mcg/salmeterol 14 mcg via oral inhalation twice daily	1 inhaler/30 days			
	Fluticasone-Salmeterol Inhalation Aerosol Powder Breath Activated 55-14 MCG/ACT	Fluticasone 55 mcg/salmeterol 14 mcg, fluticasone 113 mcg/salmeterol 14 mcg, or fluticasone 232 mcg/salmeterol 14 mcg via oral inhalation twice daily	1 inhaler/30 days			
	Fluticasone-Salmeterol Inhalation Aerosol 115-21 MCG/ACT	2 oral inhalations of fluticasone 45 mcg/salmeterol 21 mcg, fluticasone 115 mcg/salmeterol 21 mcg, or fluticasone 230 mcg/salmeterol 21 mcg twice daily	12 gm/30 days			
	Fluticasone-Salmeterol Inhalation Aerosol 230-21 MCG/ACT	2 oral inhalations of fluticasone 45 mcg/salmeterol 21 mcg, fluticasone 115 mcg/salmeterol 21 mcg, or fluticasone 230 mcg/salmeterol 21 mcg twice daily	12 gm/30 days			

	Fluticasone-Salmeterol Inhalation Aerosol 45-21 MCG/ACT	2 oral inhalations of fluticasone 45 mcg/salmeterol 21 mcg, fluticasone 115 mcg/salmeterol 21 mcg, or fluticasone 230 mcg/salmeterol 21 mcg twice daily	12 gm/30 days			
LENALIDOMIDE	2.5 MG	5-25 mg once daily (for 21 days of every 28-day cycle or 10-15 mg for 28 days for mult myeloma)	28/28	1	1	\$ 10,830.01
	5 MG	once daily	28/28			
	10 MG	once daily	28/28			
	15 MG	once daily	21/28			
	20 MG	once daily	21/28			
	25 MG	once daily	21/28			
OTEZLA	20 MG	Initial titration over 5 days: Day 1, 10 mg orally in AM; Day 2, 10 mg twice daily; Day 3, 10 mg in AM, 20 mg in PM; Day 4, 20 mg twice daily; Day 5, 20 mg in AM, 30 mg in PM; Maintenance: Day 6 and thereafter, 30 mg orally twice daily	60/30	2	5	\$ 9,609.60
	30 MG	Pediatric Maintenance (20 to less than 50 kg): Day 6 and thereafter, 20 mg orally twice daily	60/30			
	Otezla Oral Tablet Therapy Pack 10 & 20 & 30 MG		55/28			
	Otezla Oral Tablet Therapy Pack 4 x 10 & 51 x20 MG		55/28			
ZORYVE	Zoryve External Cream 0.3 %	Apply to affected areas topically once daily (Plaque psoriasis)	60 gm/30	7	18	\$ 8,745.81
	Zoryve External Foam 0.3 %	Apply a thin layer topically once daily to affected areas of body and/or scalp when they are not wet (plaque psoriasis/seborrheic dermatitis)	60 gm/30			
	Zoryve External Cream 0.15 %	Apply to affected areas topically once daily (atopic dermatitis)	60 gm/30			
FLUTICASONE PROPIONATE HFA	Fluticasone Propionate HFA Inhalation Aerosol 110 MCG/ACT	Initial, 88 mcg via oral inhalation twice daily; MAX 880 mcg twice daily	12 gm/30 days	32	79	\$ 8,370.87

	Fluticasone Propionate HFA Inhalation Aerosol 220 MCG/ACT	MAX 880 mcg twice daily (FDA dosage)	24 gm/30 days			
	Fluticasone Propionate HFA Inhalation Aerosol 44 MCG/ACT	88 mcg via oral inhalation twice daily	10.6 gm/30 days			
SAXENDA	Saxenda Subcutaneous Solution Pen-injector 18 MG/3ML	Initial dosage and titration, 0.6 mg SUBQ once daily for 1 week; increase weekly in increments of 0.6 mg/day until maintenance dosage is reached; Maintenance, 3 mg SUBQ once daily	15 mL/30 days	1	10	\$ 8,140.49
XIIDRA	Xiidra Ophthalmic Solution 5 %	1 drop instilled into each eye twice daily	60 each/30	7	21	\$ 8,110.56
MIRABEGRON ER	25 MG	Initial, 25 mg orally once daily with or without food; may increase to MAX 50 mg orally once daily	30/30	6	40	\$ 7,953.42
	50 MG		30/30			
INVOKANA	100 MG	100 mg orally once daily, taken before the first meal of the day; may increase to 300 mg once daily	30/30	2	18	\$ 7,935.39
	300 MG		30/30			
Crenessity	Capsule 50 MG	Pediatric: 25 mg-100mg twice daily	60/30			
	Capsule 100 MG	100 mg orally twice daily (double dose if strong CYP3A4 inducer)	120/30			
	Capsule 25 MG	Pediatric: 25 mg-100mg twice daily	60/30			
	Oral Solution 50 MG/ML		240 mL/30 days			
Advair	Advair HFA Inhalation Aerosol 45-21 MCG/ACT	2 oral inhalations of fluticasone 45 mcg/salmeterol 21 mcg, fluticasone 115 mcg/salmeterol 21 mcg, or fluticasone 230 mcg/salmeterol 21 mcg twice daily	12 gm/30 days			
	Advair HFA Inhalation Aerosol 115-21 MCG/ACT	2 oral inhalations of fluticasone 45 mcg/salmeterol 21 mcg, fluticasone 115 mcg/salmeterol 21 mcg, or fluticasone 230 mcg/salmeterol 21 mcg twice daily	12 gm/30 days			

		2 oral inhalations of fluticasone 45 mcg/salmeterol 21 mcg, fluticasone 115 mcg/salmeterol 21 mcg, or fluticasone 230 mcg/salmeterol 21 mcg twice daily	12 gm/30 days			
	Advair HFA Inhalation Aerosol 230-21 MCG/ACT					
	Advair Diskus Inhalation Aerosol Powder Breath Activated 100-50 MCG/ACT	via oral inhalation twice daily	60/30			
	Advair Diskus Inhalation Aerosol Powder Breath Activated 250-50 MCG/ACT	via oral inhalation twice daily	60/30			
	Advair Diskus Inhalation Aerosol Powder Breath Activated 500-50 MCG/ACT	via oral inhalation twice daily	60/30			
		Initial, 75 mg SUBQ once every 2 weeks; if LDL-C response is inadequate, may adjust to 150 mg every 2 weeks OR Initial, 300 mg SUBQ once every 4 weeks; if LDL-C response inadequate just prior to next scheduled dose, may adjust to 150 mg every 2 weeks				
Praluent	Praluent Subcutaneous Solution Auto-injector 75 MG/ML		2 mL/28 days			
	Praluent Subcutaneous Solution Auto-injector 150 MG/ML		2 mL/28 days			
		(Delzicol(R) delayed-release capsule) 800 mg (two 400-mg capsules) orally 3 times daily for 6 weeks-Short term tx courses (6-8 weeks) for Active UC; For Chronic: (Delzicol(TM) delayed-release capsules) 1.6 g/day orally in 2 to 4 divided doses with or without food;				
Mesalamine	Mesalamine Oral Capsule Delayed Release 400 MG	(Lialda(R) delayed-release tablet) 2.4 or 4.8 g (two to four 1.2-g tablets) orally once daily with a meal for up to 8 weeks; (Lialda(R) delayed-release tablet) 2.4 g (two 1.2-g tablets) orally once daily with a meal	180/30			
	Mesalamine Oral Tablet Delayed Release 1.2 GM	(Asacol(R) HD delayed-release tablet) 1600 mg (two 800-mg tablets) orally 3 times daily for 6 weeks	120/30			
	Mesalamine Oral Tablet Delayed Release 800 MG		180/30			
		(Apriso(TM) extended-release capsule) 1.5 g orally once daily in the morning for UC maintenance				
	Mesalamine ER Oral Capsule Extended Release 24 Hour 0.375 GM		120/30			

New

Vykat XR	
Therapeutic Classes (AHFS)	Anorexigenic Agents and Stimulants, miscellaneous
Medications	Vykat XR (diazoxide choline)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See “ PA Review Criteria ” below
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, psychiatrist, or other physician with expertise in the treatment of Prader-Willi syndrome (PWS)
Coverage Duration	If all the criteria are met, the initial and reauthorization requests will be approved for 6 months. If the conditions are not met, the request will be sent to a clinical reviewer for medical necessity review
PA Review Criteria	<u>Initial Authorization:</u> • Medication is prescribed at an FDA approved dose • Documentation of patient’s body weight • Diagnosis of PWS confirmed by genetic testing (copies of test must be submitted with request) • Documentation patient experiences symptoms of hyperphagia related to PWS (e.g. food-seeking behaviors, food aggression, etc.) <u>Re-Authorization:</u> • Documentation of positive clinical response in hyperphagic symptoms (i.e. decrease in food-related aggression or food-seeking behavior, etc.) • Medication is prescribed at an FDA approved dose • Documentation of patient’s body weight
Criteria Statement	Vykat XR is reserved for members who have a confirmed diagnosis of PWS and experience symptoms of hyperphagia related to PWS.
Last P&T Review Date	9/2025

New

Immunoglobulin A (IgA) Nephropathy Agents	
Therapeutic Classes (AHFS)	Endothelin Receptor Antagonists, Miscellaneous Therapeutic Agents
Medications	Fabhalta (iptacopan), Filspari (sparsentan), Tarpeyo (budesonide), Vanrafia (atrasentan)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	For Filspari and Vanrafia only: pregnancy
Required Clinical Information	See “PA Review Criteria” below
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	If all of the criteria are met, it will be approved as follows: - Initial requests: Fabhalta: 6 months; Filspari, Tarpeyo, Vanrafia: 9 months - Reauthorization: Fabhalta, Filspari, Vanrafia: 12 months; Reauthorization requests for Tarpeyo will not be allowed as the safety and efficacy of subsequent courses have not been established If the conditions are not met, the request will be sent to a clinical reviewer for medical necessity review
PA Review Criteria	<u>Initial Authorization:</u> - Diagnosis of primary IgA nephropathy verified by biopsy - Member is on an ACE inhibitor or ARB at a maximally tolerated dose OR there is a medical reason that they cannot be on one - Member has proteinuria (defined as total urine protein ≥ 1 g/day) - Member has an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m² - Medication is prescribed at an FDA approved dose - For Fabhalta: - Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria - Member is at risk for disease progression as defined by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g - For Filspari: - Documentation of baseline liver function - Attestation that member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists, and/or aliskiren upon initiation of Filspari - For Vanrafia: - Member is at risk for disease progression as defined by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g <u>Re-Authorization:</u> - Documentation of positive clinical response (e.g. decrease in UPCR, stabilization of eGFR) - Medication is prescribed at an FDA approved dose - For Filspari: - Documentation of liver function ***Reauthorization requests for Tarpeyo will not be allowed as the safety and efficacy of subsequent courses have not been established***

Criteria Statement	Fabhalta, Filspari, Tarpeyo, and Vanrafia are reserved for members who have a diagnosis of IgA nephropathy, are on ACE inhibitor or ARB, have proteinuria and eGFR ≥ 30 mL/min/1.73 m ² . Additionally, for Fabhalta and Vanrafia members are at risk for disease progression, and for Filspari members will discontinue use of RAAS inhibitors/aliskiren upon initiation of Filspari.
Last P&T Review Date	9/2025

New

Encelto	
Medications	Encelto (revakinagene taroretcel-lwey)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "Other Criteria" below
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be an ophthalmologist or specialist in the treatment of macular telangiectasia (MacTel) type 2
Coverage Duration	If all criteria are met, the request will be approved for a single implant per eye per lifetime
Maximum Billable Units	Variable
Other Criteria	<u>Initial Authorization</u> • Confirmed diagnosis of idiopathic MacTel type 2 • Inner segment (IS)/outer segment (OS) photoreceptor (PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm² measured by spectral domain-optical coherence tomography (SD-OCT) • Best corrected visual acuity (BCVA) score of 54 letters or better (20/80 or better Snellen equivalent) measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart • Prescriber attests that member has no evidence of neovascular MacTel type 2 • Member has not previously received an Encelto implant for treated eye ***Reauthorizations are not permitted, as members are limited to a single implant per eye per lifetime*** If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review
Last Review Date	9/2025

New

Nulibry	
Medications	Nulibry (fosdenopterin)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "Other Criteria" below
Age Restrictions	According to package insert Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescriber must be a specialist in the treatment of enzyme or metabolic disorders
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.
Maximum Billable Units	Variable
Other Criteria	<u>Initial Authorization:</u> - Member has a diagnosis of molybdenum cofactor deficiency (MoCD) type A confirmed by genetic testing OR - Member has a presumptive diagnosis of MoCD type A with BOTH of the following: - Genetic test results are pending, AND - Member has clinical signs and symptoms associated with MoCD Type A (e.g. severe encephalopathy, intractable seizures, feeding difficulties) - Medication is prescribed at an FDA approved dose <u>Re-Authorization:</u> - For members whose initial authorization was under a presumptive diagnosis only: - Documentation of confirmed diagnosis of MoCD type A by genetic testing - Documentation or provider attestation of positive clinical response (e.g. improvement in neurologic function, reduction in concentrations of s-sulfocysteine [SSC]) - Medication is prescribed at an FDA approved dose If all of the above criteria are not met for initial or re-authorization, the request is referred to a Clinical Reviewer for medical necessity review
Last Review Date	9/2025

New

Zevaskyn	
Medications	Zevaskyn (prademagene zamikeracel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	Receipt of any prior chemical or biologic product for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), including Vyjuvek and Filsuvez
Required Clinical Information	See "Other Criteria" below
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a specialist experienced in the treatment of epidermolysis bullosa
Coverage Duration	If all of the criteria are met, the request will be approved for one treatment cycle only
Maximum Billable Units	Variable
Other Criteria	<u>Initial Authorization</u> • Patient has a diagnosis of RDEB with genetic testing confirming mutations in both COL7A1 genes • Presence of RDEB wounds with ALL of the following characteristics: ○ Open chronically for ≥6 months ○ Categorized as Stage 2 (partial-thickness) ○ Have an area of ≥20 cm² • Documentation is provided that there is no evidence of, or history of squamous cell carcinoma in the wound(s) to be treated • Medication is prescribed at an FDA approved dose The safety and effectiveness of repeat administration of Zevaskyn to the same treatment site have not been evaluated and will not be approved. If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review
Last Review Date	9/2025

New PAD policy based on approved MRG policy

Amvuttra	
Medications	Amvuttra (vutrisiran)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be neurologist, cardiologist, or specialist in the treatment of amyloidosis
Coverage Duration	If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 6 months.
Maximum Billable Units	Variable
Other Criteria	Initial Authorization: - Regimen does not exceed FDA-approved dose/frequency - Patient has not undergone a liver or heart transplant If the request is for Polyneuropathy Type: - Patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by documented transthyretin variant by genotyping - One of the following: - Patient has baseline polyneuropathy disability (PND) score $\leq$ IIIb - Patient has a baseline Familial Amyloid Polyneuropathy (FAP) Stage 1 or 2 - Patient has baseline neuropathy impairment (NIS) score $\geq$ 5 and $\leq$ 130 - Patient has clinical signs/symptoms of neuropathy If the request is for Cardiomyopathy Type: - Patient has a confirmed diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis - Documented amyloid deposit by biopsy or positive technetium 99m pyrophosphate (Tc 99m PYP) cardiac imaging - Patient has New York Heart Association (NYHA) functional class I, II, or III heart failure symptoms - Patient has contraindication to/or previous trial and failure or continued clinical progression with use of Vyndaqel, Vyndamax or Attriby Re-authorization: - Patient's regimen does not exceed FDA-approved dose/frequency for the agent - Patient has not undergone a liver or heart transplant - Documented positive clinical response to therapy from baseline (stabilization/slowing of disease progression, improved neurological impairment, motor functions, improved NIS score, stabilization/reduced rate of decline in 6 minute walk test, etc.) - Patient has continued NYHA functional class I, II, or III heart failure symptoms If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.

Last Review Date	9/2025



Ophthalmic Antibiotic and Antibiotic-Corticosteroid Combinations

Executive Summary

Class Overview

This review covers antibiotic products for ophthalmic use, with and without a corticosteroid. These preparations are only available as a prescription, and are used for various infectious and inflammatory indications involving the eye. Antibiotic preparations are typically selected empirically depending on the suspected causative bacterial organism. An ophthalmic antibiotic agent may also be used in ocular conditions or after procedures or injury where risk of bacterial infection is present. Judicious use of products containing ocular corticosteroids are generally recommended due to risks related to excessive exposure, such as cataracts and glaucoma. Preparations include as drops or ophthalmic ointments, and many agents in this category are available as generic.

Utilization Findings

There were 59 claims for 52 members, for a total cost of \$801.75 and an average cost per claim of \$13.59. The most highly utilized medication was Ofloxacin eye drops, with 15 claims, followed by Erythromycin eye ointment with 11 claims. There were no prior authorization requests.

Recommendations

- Change Tobradex 0.3-0.1% eye ointment to F-PA to align with MRG PA Criteria and for cost containment.



Clinical Summary

This review covers antibiotic products for ophthalmic use, with and without a corticosteroid. These preparations are only available as a prescription, and are used for various infectious and inflammatory conditions involving the eye. Antibiotic preparations are typically selected empirically depending on the suspected causative bacterial organism. An ophthalmic antibiotic agent may also be used in ocular conditions or after procedures or injury where risk of bacterial infection is present. Judicious use of products containing ocular corticosteroids are generally recommended due to risks related to excessive exposure, such as cataracts and glaucoma. Preparations include as drops or ophthalmic ointments, and many agents in this category are available as generic.

Practice Guidelines

American Academy of Ophthalmology Preferred Practice Pattern – Conjunctivitis (2023)

<https://www.aao.org/education/preferred-practice-pattern/conjunctivitis-ppp-2023>

HIGHLIGHTED FINDINGS AND RECOMMENDATIONS FOR CARE

- Conjunctivitis rarely causes permanent visual loss or structural damage, but the economic impact of conjunctivitis is considerable and largely due to lost work or school time and the cost of medical visits, testing, and treatment.
- Chronic and/or recalcitrant conjunctivitis may be indicative of an underlying malignancy such as sebaceous carcinoma, lymphoma, or squamous cell carcinoma; or an underlying inflammatory condition, such as mucous membrane pemphigoid; or a chronic infection such as chlamydia.
- The ophthalmologist plays a critical role in breaking the chain of transmission of epidemic adenoviral conjunctivitis, primarily by educating the patient and family about proper hygiene. Infected individuals should be counseled to wash hands frequently, to use a separate towel and pillow, and to avoid close contact with others during the period of contagion, which is usually 10 to 14 days from onset.
- Tonometers that are inadequately disinfected can transmit infection. Dilute bleach soak (sodium hypochlorite) at 1:10 concentration is an effective disinfectant for tonometers. 70% isopropyl alcohol (e.g., alcohol wipes), 3% hydrogen peroxide, and ethyl alcohol are no longer recommended. Tonometers that utilize single-use disposable tips can circumvent the issue of sterilization.
- Indiscriminate use of topical antibiotics or corticosteroids should be avoided. Viral conjunctivitis will not respond to antibacterial agents, and mild bacterial conjunctivitis is likely to be self-limited. For acute exacerbations of vernal conjunctivitis, topical corticosteroids are usually necessary to control severe symptoms and signs. No evidence exists demonstrating the superiority of any topical antibiotic agent.
- Gonococcal conjunctivitis is a hyperacute, vision-threatening infectious condition that requires immediate systemic therapy. Single-use tubes of ophthalmic ointment containing 0.5% erythromycin are used as the standard prophylactic agent to prevent ophthalmia neonatorum.
- Conjunctivitis can be associated with systemic diseases. Diagnosis of superior limbic keratoconjunctivitis may lead to further investigations that reveal a thyroid disorder. Diagnosis of floppy eyelid syndrome should prompt a sleep study to rule out sleep apnea.
- Herpes zoster can cause conjunctivitis, keratitis, and ocular inflammation in multiple tissues of the eye. Herpes zoster vaccination is strongly recommended in patients 50 years or older and patients 19 years or older who are immunocompromised.

American Academy of Ophthalmology Preferred Practice Pattern – Blepharitis (2023)

<https://www.aao.org/education/preferred-practice-pattern/new-preferredpracticepatternguideline-4>

HIGHLIGHTED FINDINGS AND RECOMMENDATIONS FOR CARE

- In the management of ocular surface disease, it is helpful to distinguish anterior and posterior (meibomian gland dysfunction [MGD]) blepharitis from aqueous deficient dry eye. Anterior blepharitis affects the lash line and includes posterior blepharitis, which is defined as meibomian gland involvement. Worsening of symptoms in the morning is typical of blepharitis, whereas worsening of the symptoms later in the day are typical of aqueous deficient dry eye.

- Blepharitis is typically a chronic condition that cannot be permanently cured. It is important for patients to understand that successful management depends on their compliance with a treatment regimen.
- Topical antibiotic drops or ointments with or without corticosteroids and/or oral antibiotics can be effective in the treatment of blepharitis. Although azithromycin is used as a treatment for blepharitis, it may produce cardiac arrhythmias when used orally in patients with cardiovascular problems.
- In-office procedures targeting the meibomian glands have shown efficacy in some studies, but there is a lack of independent, randomized controlled studies demonstrating superiority of any one of these treatments over another.
- In patients with blepharitis who do not respond to therapy, the possibility of carcinoma or immune-mediated diseases should be considered, particularly if the blepharitis is associated with loss of eyelashes and/or conjunctival cicatricial changes. Early diagnosis and appropriate treatment can prevent vision loss and disfigurement, and it may be lifesaving.

American Academy of Ophthalmology Preferred Practice Pattern – Bacterial Keratitis (2023)

<https://www.aao.org/education/preferred-practice-pattern/bacterial-keratitis-ppp-2023>

HIGHLIGHTED FINDINGS AND RECOMMENDATIONS FOR CARE

- The majority of community-acquired cases of bacterial keratitis that are small noncentral ulcers resolve with topical empiric therapy. However, smears and/or cultures are specifically indicated in certain circumstances.
- Contact lens wear is the number-one risk factor for microbial keratitis in the United States. Overnight wear (including orthokeratology) is a major risk factor for infection. In many other parts of the world trauma is the leading risk factor for bacterial keratitis.
- Topical antibiotics should be prescribed to prevent acute infection in patients with a corneal abrasion who wear contact lenses or suffered trauma. In these patients, patching the eye early on is not advised because these increase the risk of secondary bacterial keratitis.
- When treating microbial keratitis, corticosteroids may be considered after 48 hours of antibiotic therapy when the causative organism is identified and/or the infection has responded to therapy. Corticosteroids should be avoided in cases of suspected Acanthamoeba, Nocardia, or fungus. The efficacy of the therapeutic regimen is judged primarily by the clinical response. In Pseudomonas and other gram-negative keratitis, there may be increased inflammatory signs during the first 24 to 48 hours despite appropriate therapy.
- From 2005 to 2015 there was increased resistance of methicillin-resistant Staphylococcus aureus (MRSA) and Pseudomonas aeruginosa to topical fluoroquinolones.

Formulary Placement, Utilization and Cost Experience (04-01-2025 to 06-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Ophthalmic Antibiotic & Glucocorticoid Combinations								
Neomycin-bacitracin-polymyxin B-hydrocortisone (Neo Polycin HC®) 3.5 mg-400-10,000 unit/g-1 % eye ointment	0	0	\$0.00	\$0.00	0	0 (0%)	F	No change
Neomycin -polymyxin B-dexamethasone (Maxitrol®) 3.5 mg/g-10,000 unit/g-0.1 % eye oint	9	8	\$164.15	\$18.24	0	0 (0%)	F	No change
Neomycin-polymyxin-dexamethasone (Maxitrol®) 3.5 mg/mL-10,000 unit/mL-0.1% eye drops	7	7	\$108.33	\$15.48	0	0 (0%)	F	No change
Zylet® (tobramycin-loteprednol etabonate) 0.3 %-0.5 % eye drops, suspension	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Tobradex ST® (tobramycin / dexamethasone) 0.3 %-0.05 % eye drops, suspension	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Sulfacetamide-prednisolone (Vascocidin®) 10 %-0.23 % (0.25 %) eye drops	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Neomycin-polymyxin-hydrocortisone (Cortisporin®) 3.5 mg-10,000 unit-10mg/mL eye drop,susp	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
TobraDex® (tobramycin-dexamethasone) 0.3 %-0.1 % eye ointment	0	0	\$0.00	\$0.00	0	0 (0%)	F-QL (2 fills per 12 months)	→F-PA (2 fills per 12 months)
Tobramycin-dexamethasone (TobraDex®) 0.3%-0.1% eye drops, suspension	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Ophthalmic Antibiotics								
Sulfacetamide sodium (Sodium Sulamyd®) 10 % eye ointment	0	0	\$0.00	\$0.00	0	0 (0%)	F	No change
Sulfacetamide sodium (Sodium Sulamyd®) 10 % eye drops	0	0	\$0.00	\$0.00	0	0 (0%)	F	No change
Ciloxan® (ciprofloxacin hcl) 0.3 % eye ointment	0	0	\$0.00	\$0.00	0	0 (0%)	F-ST (Requires prior use of ciprofloxacin 0.3% eye drops, ofloxacin eye drops, or moxifloxacin 0.5% eye drops)	No change
Tobrex® (tobramycin) 0.3 % eye ointment	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change



Tobramycin (Tobrex®) 0.3 % eye drops	2	2	\$9.13	\$4.57	0	0 (0%)	F	No change
Neomycin-bacitracin-polymyxn (Neosporin®) 3.5 mg-400 unit-10,000 unit/gram eye oint	0	0	\$0.00	\$0.00	0	0 (0%)	F	No change
Polymyxin B sulfate-trimethoprim (Polytrim®) 10,000 unit-1 mg/mL eye drops	2	2	\$13.68	\$6.84	0	0 (0%)	F	No change
Moxifloxacin (Vigamox®) 0.5 % eye drops	5	4	\$118.30	\$23.66	0	0 (0%)	F	No change
Besivance® (besifloxacin hcl) 0.6 % eye drops, suspension	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Bacitracin-polymyxin B (Polysporin®) 500 unit-10,000 unit/gram eye ointment	0	0	\$0.00	\$0.00	0	0 (0%)	F	No change
Gatifloxacin (Zymaxid®) 0.5 % eye drops	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA	No change
Moxifloxacin (Moxeza®) 0.5 % viscous eye drops	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA	No change
Erythromycin (Ilotycin®) 5 mg/gram (0.5 %) eye ointment	11	11	\$142.11	\$12.92	0	0 (0%)	F	No change
Ciprofloxacin (Ciloxan®) 0.3 % eye drops	6	5	\$59.75	\$9.96	0	0 (0%)	F	No change
Gentamicin (Garamycin®) 0.3 % eye drops	2	2	\$10.78	\$5.39	0	0 (0%)	F	No change
Bacitracin (Baciguent®) 500 unit/gram eye ointment	0	0	\$0.00	\$0.00	0	0 (0%)	F	No change
Ofloxacin (Ocuflox®) 0.3 % eye drops	15	11	\$175.52	\$11.70	0	0 (0%)	F	No change
Neomycin 1.75 mg-polymyxin 10,000 unit-gramicidin 0.025mg/mL (Neosporin®) eye drops	0	0	\$0.00	\$0.00	0	0 (0%)	F	No change
Azasite® (azithromycin) 1 % eye drops	0	0	\$0.00	\$0.00	0	0 (0%)	F-PA	No change
Levofloxacin 1.5 % eye drops	0	0	\$0.00	\$0.00	0	0 (0%)	NF	No change
Total	59	52	\$801.75	\$13.59	0	0 (0%)		

Key (as applicable) F = Formulary, no restrictions; F-QL = Formulary, quantity limit applies; F-AL = Formulary, age limit applies; F-ST = Formulary, step therapy applies; F-PA = Formulary, PA required; NF = Non-formulary; X = Excluded

Prior Authorization Criteria

No changes

Antibiotic Eye Medications	
Therapeutic Classes (AHFS)	Antibacterials (EENT)
Medications	Formulary - Ciprofloxacin 0.3% eye drops - Ofloxacin 0.3% eye drops - Moxifloxacin (Vigamox) 0.5% eye drops - Neomycin-bacitracin-polymyxin B-hydrocortisone (Neo Polycin HC) 3.5 mg-400-10,000 unit/g-1 % eye ointment - Neomycin -polymyxin B-dexamethasone (Maxitrol®) 3.5 mg/g-10,000 unit/g-0.1 % eye oint
	Formulary, Step Therapy Required Ciloxan (ciprofloxacin) 0.3% eye ointment
	Formulary, PA required - Gatifloxacin (Zymaxid) - Moxifloxacin (Moxeza) - Azasite (azithromycin) - TobraDex (tobramycin-dexamethasone) 0.3 %-0.1 % eye ointment
	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert.
Covered Uses	
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	None.
Coverage Duration	Initial Approval If the conditions are met, the request will be approved for 1 fill with a quantity limit of 1 bottle/tube.
	Later Approvals If criteria are not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review.
PA Review Criteria	For the formulary, step therapy required medication Ciloxan (ciprofloxacin) 0.3% eye ointment - Documented contraindication to or trial and failure of one of the preferred antibiotic eye drops: ciprofloxacin, moxifloxacin (Vigamox), or ofloxacin For gatifloxacin (Zymaxid) all of the following criteria must be met: - For use after cataract surgery AND - Documented contraindication to or trial and failure of one of the preferred antibiotic eye drops: ciprofloxacin, moxifloxacin (Vigamox), or ofloxacin For Azasite and moxifloxacin (Moxeza) all of the following criteria must be met:

	• For use after cataract surgery AND • Documented contraindication to or trial and failure of one of the preferred antibiotic eye drops: ciprofloxacin, moxifloxacin (Vigamox), or ofloxacin AND • Documented contraindication to or trial and failure of gatifloxacin (Zymaxid) For TobraDex (tobramycin-dexamethasone) 0.3 %-0.1 % eye ointment all of the following criteria must be met: • Documented contraindication to or trial and failure of one of the preferred ophthalmic antibiotic & glucocorticoid combination eye ointments: neomycin-bacitracin-polymyxin B-hydrocortisone (Neo Polycin HC) eye ointment or neomycin -polymyxin B-dexamethasone (Maxitrol) eye ointment
Criteria Statement	Ciloxan (ciprofloxacin) eye ointment is reserved for members who cannot/should not take ciprofloxacin, moxifloxacin (Vigamox), or ofloxacin eye drops. Gatifloxacin (Zymaxid) is reserved for members who have had cataract surgery and who cannot/should not take ciprofloxacin, moxifloxacin (Vigamox), or ofloxacin eye drops. Azasite or moxifloxacin (Moxeza) are reserved for members who have had cataract surgery and who cannot/should not take ciprofloxacin, moxifloxacin (Vigamox), or ofloxacin eye drops AND gatifloxacin (Zymaxid) eye drops. TobraDex (tobramycin-dexamethasone) eye ointment is reserved for members who cannot/should not take neomycin-bacitracin-polymyxin B-hydrocortisone (Neo Polycin HC) eye ointment or neomycin -polymyxin B-dexamethasone (Maxitrol) eye ointment.
Last P&T Review Date	<u>9/20249/2025</u>

References

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Drug Name: Ctexli (chenodiol)**Manufacturer:** Mirum Pharmaceuticals**Approval Date:** 2/21/2025**Marketing Date:** 3/14/2025

Recommendation

Implement new Prior Authorization Criteria with no changes to formulary status.

Prescribing Information

Indication

Ctexli™ is indicated for the treatment of cerebrotendinous xanthomatosis (CTX) in adults.

Mechanism of Action

Endogenous chenodiol (chenodeoxycholic acid) is a primary bile acid, synthesized from cholesterol in the liver. In CTX, the major bile acid synthesis pathways are disrupted due to partial or total deficiency in sterol 27-hydroxylase encoded by the CYP27A1 gene.

Ctexli™ may act to replace deficient levels of the endogenous bile acid chenodeoxycholic acid in patients with CTX. Increased chenodiol levels in the enterohepatic bile acid pool restore the activation of farnesoid X receptor (FXR) and downregulate CYP7A1 leading to suppression and reduction of atypical bile acids and bile alcohols including cholestanol and 23S-pentol.

Dosage and Administration

The recommended dosage of Ctexli™ is 250 mg administered orally three times daily.

Black Box Warning

None

Adverse Reactions

Most common: diarrhea, headache, abdominal pain, constipation, hypertension, muscular weakness, and upper respiratory tract infection

Serious: hepatotoxicity

Use in Specific Populations, Pregnancy

Available data from published case reports over decades of use with chenodiol during pregnancy have not identified an increased risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Serious hepatic, renal and adrenal lesions occurred in fetuses of female Rhesus monkeys treated at doses 1 to 2 times the recommended human dose based on body surface area (mg/m²). Hepatic lesions also occurred at doses comparable to the human dose based on body surface area in neonatal baboons born to mothers administered chenodiol during pregnancy. The animal study findings have not been demonstrated with human use.

Drug Interactions

- Bile acid sequestering agents and aluminum-based antacids: Avoid concomitant use with Ctexli™.
- Coumarin and its derivatives: Monitor prothrombin time and adjust dosage accordingly.

How Supplied

250mg tablets

Price

\$53,730

(Per month, based on WAC.)

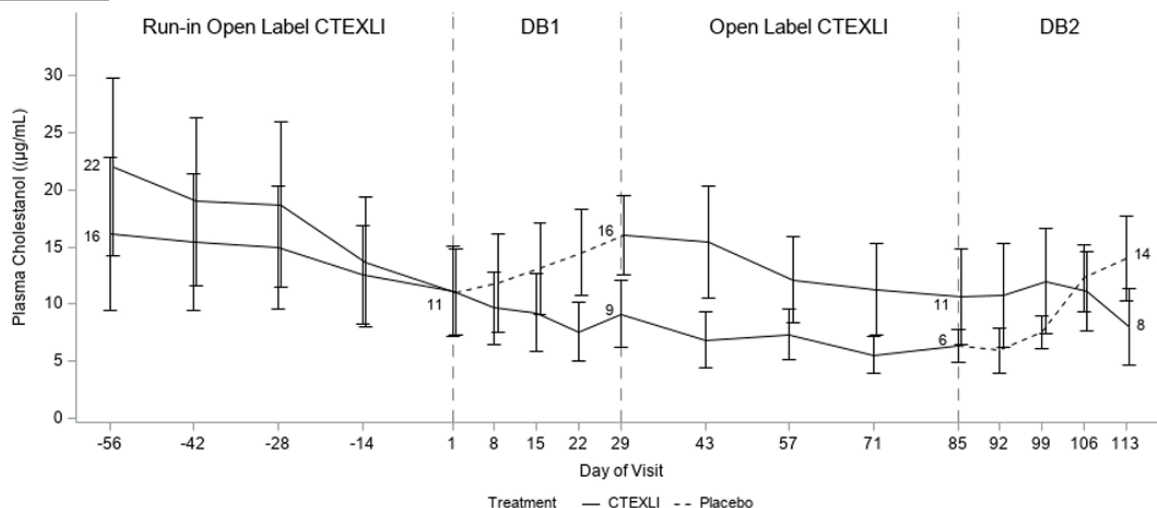
Clinical Studies

Completed

Title	Study to Evaluate Patients With Cerebrotendinous Xanthomatosis (RESTORE) NCT: 04270682
Design	Phase 3, randomized, double-blind, placebo controlled, 2-period with 2-treatment crossover trial in patients ≥16 years of age.
Population	N = 13 62% were male and 39% were female. The baseline median age was 42 years (16-55) and median age at diagnosis was 35 years (15-55). Ctexli is not approved for use in pediatric patients. The patient population consisted of 62% White, 15% Asian, and 23% Other (In the Other racial group, there was one patient who reported both White and Black). Ethnicity consisted of 15% Hispanic or Latino, 54% not Hispanic or Latino, and 31% unknown.
Arms	• Treatment in a crossover withdrawal design to receive either Ctexli™ 250 mg or placebo orally three times daily for 4 weeks during 2 double-blind treatment periods.

	- The study also included treatment with Ctexli™ 250 mg three times daily during an 8 week run-in period and an 8-week open label period in between the 2 double-blind withdrawal periods. - The total duration of study treatment was 24 weeks.
Endpoint(s)	Primary: Change from baseline in bile alcohols (urine 23s-pentol) during the two double-blind periods.
Inclusion Criteria	- Male or female at least 1 month or older at screening. - Clinical diagnosis of CTX with biochemical confirmation. - Women of childbearing potential must agree to the use of one highly reliable method of contraception during the study, plus one additional barrier method during sexual activity.
Exclusion Criteria	- Malabsorption disorder or confounding inflammatory gastrointestinal condition (for example, irritable bowel syndrome). - Documented history of heart failure. - Treatment with medications which impact bile acid absorption such as bile acid sequestering agents (eg, cholestyramine, colestipol, aluminum-based antacids). - Treatment with cholic acid medication. - Pregnancy.
Results	Primary:

Figure 1: Mean (SE) of Observed Plasma Cholestanol by Treatment Sequence (All Randomized Patients)



DB = double-blind. Solid line represents treatment with CTEXLI and dashed line represents treatment with placebo. The mean values of plasma cholestanol at baselines and end of each DB period are annotated in the figure.

Table 1: Summary Results for Plasma Cholestanol and Urine 23S Pentol

	Mean (SD)	CTEXLI (N = 13)	Placebo (N = 13)
Plasma Cholestanol (µg/mL)	Baseline	10.8 (10.0)	8.8 (7.8)
	Day 29	8.5 (7.0)	15.1 (8.8)
	Change from Baseline at Day 29	-2.3 (3.9)	6.2 (5.6)
	Treatment Difference	-8.5 (95% CI: -13.2, -3.9)	
Urine 23S-Pentol (ng/mL)	Baseline	1811 (1693)	1773 (1940)
	Day 29	1996 (1341)	31279 (27595)
	Change from Baseline at Day 29	185 (1479)	29506 (27257)
	Treatment Difference	-29321 (95% CI: -45701, -12941)	

For each study treatment (placebo or CTEXLI), the mean value at Baseline was calculated as the mean of the measurements obtained prior to receiving the study treatment during the double-blind study duration; and the mean value at Day 29 was calculated as the mean of the measurements at Day 29 at the end of the study treatment.

For each patient at each visit, the measurement of urine 23S-pentol was calculated as the geometric mean of first 3 morning void urine samples collected within 5 days prior to the visit.

Conclusion Results from the RESTORE study demonstrated that treatment with Ctexli™ not only improved urine bile alcohol levels but also serum cholestanol levels. Additionally, a greater proportion of patients receiving placebo required blinded rescue therapy, demonstrating the robustness of the effect.

Interpretation The RESTORE trial demonstrated significant reductions in plasma cholestanol and urine 23S-pentol levels. While Ctexli™ offers a promising treatment option, it carries a warning for potential liver toxicity, especially in individuals with pre-existing liver conditions or bile duct abnormalities. One

major limitation of this study is the small sample size. However, a larger sample size would be difficult to include given the rarity of this disease state.

Guidelines

National Organization for Rare Disorders (NORD). Cerebrotendinous Xanthomatosis [CTX](#). Last updated 2/2025.

Standard Therapies: Treatment

- Because oral bile acid replacement therapy can halt disease progression or prevent symptoms from occurring in asymptomatic individuals, early diagnosis and treatment of CTX is extremely important to prevent disease complications. Researchers have recently shown that CTX patients who started treatment later (after the age of 25 years) had a worse outcome and were significantly more limited in ambulation and more cognitively impaired than those that started treatment earlier (before the age of 25 years).
- Successful long-term treatment of a number of affected individuals who were asymptomatic in childhood has been reported in the literature.
- Treatment with chenodeoxycholic acid normalizes the production of cholestanol. The efficacy of treatment with chenodeoxycholic acid can be monitored using biochemical testing to confirm a decrease in blood cholestanol. Treatment can prevent symptoms in asymptomatic individuals and stop the progression of disease symptoms in affected individuals. After significant disease progression, treatment does not readily reverse the neurological deficits that have already occurred.
- It may be effective to give a drug that inhibits HMG-CoA reductase (an enzyme that plays a role in the creation of cholesterol in the liver) in conjunction with chenodeoxycholic acid. There are concerns that treatment with HMG-CoA reductase inhibitors (better known as statins) could boost the activity of receptors for low-density lipoprotein (LDL) cholesterol, thereby increasing cholesterol uptake and potentially worsening CTX. HMG-CoA reductase inhibitors can also cause muscle damage.
- In 2009, the U.S. Food and Drug Administration (FDA) re-approved an artificially made (synthetic) form of chenodeoxycholic acid known as Chenodal as a treatment for gallstones. This drug is also used as a first-line therapy to treat individuals with CTX.
- In 2025, the FDA approved chenodiol (Ctexli) to treat adults with CTX.
- Cholic acid, another bile acid, has also been used to treat young children with CTX. Although chenodeoxycholic acid is considered as a first-line therapy to treat CTX, cholic acid lacks the potential toxic effects on the liver (hepatotoxicity) sometimes associated with chenodeoxycholic acid.
- Additional treatment is symptomatic and supportive. For example, cataract surgery may be necessary before 50 years of age.
- Genetic counseling is recommended for affected families and individuals.

Clinical Opinions

Cerebrotendinous xanthomatosis (CTX) is a rare autosomal recessive genetic disorder caused by an abnormality in the *CYP27A1* gene, which results in a deficiency of the mitochondrial enzyme sterol 27-hydroxylase. The lack of enzyme prevents cholesterol from being converted into a bile acid called chenodeoxycholic acid. Deposits of cholesterol and a related compound called cholestanol accumulate in the nerve cells and membranes potentially causing damage to the brain, spinal cord, tendons, lens of the eye and arteries. The presentation of CTX varies between patients and is associated with a wide range of abnormalities. Most often, systemic symptoms develop earlier than neurologic symptoms. The first symptom for some patients may be chronic diarrhea in infancy. In the first decades of life, juvenile cataracts are often seen as an initial symptom of CTX. Tendinous xanthomas (fatty tumors) may appear in the second or third decade of life. Most affected individuals experience a decline in mental function beginning at puberty, but some show impairment beginning in childhood. CTX is often diagnosed through neurological symptoms of the disease that will continue to get worse without treatment. Patients are diagnosed through clinical evaluation, a detailed patient and family history, identification of characteristic clinical findings, and genetic testing.

Until the approval of Ctexli[™] (chenodiol), there were no FDA approved treatments for CTX. Chenodeoxycholic acid (CDCA) is often used as a first line treatment option, which works to normalize the body's ability to break down cholesterol. HMG-CoA reductase inhibitors may be prescribed to help lower cholesterol levels. Although Ctexli[™] is the first approved treatment option, Chenodal (chenodiol), containing the same active ingredient, was approved in 2009 and is indicated for the treatment of radiolucent stones in the bladder, but has been used off-label to treat CTX for several years.

Ctexli[™] approval was based on results from the Phase 3 RESTORE trial, which evaluated the safety and efficacy of Ctexli in 13 patients. The primary endpoint in the trial was the reduction in bile alcohols (urine 23S-pentol). At the end of the double-blind withdrawal period, urine 23S-pentol levels showed a 20-fold difference between placebo and Ctexli-treated patients.

Given the rarity of this disease state and steep cost, payers will likely opt to utilize management such as prior authorization for the management of Ctexli[™].

Alternatives

None

PA Criteria

Ctexli	
Therapeutic Classes (AHFS)	Cholelitholytic Agents
Medications	Ctexli (chenodiol)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	Concurrent use with Cholbam (cholic acid)
Required Clinical Information	See “ PA Review Criteria ” below
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, endocrinologist, or specialist in metabolic disorders
Coverage Duration	If all of the criteria are met, the request will be approved for 6 months for initial requests, and 12 months for renewal requests. If the conditions are not met, the request will be sent to a clinical reviewer for medical necessity review
PA Review Criteria	<u>Initial Authorization:</u> - Medication is prescribed at an FDA approved dose - Diagnosis of cerebrotendinous xanthomatosis (CTX) confirmed by genetic testing that detects variants in the CYP27A1 gene (copies of test must be submitted with request) <u>Re-Authorization:</u> - Documentation or provider attestation of positive clinical response (i.e. stabilization of cognitive development, improvement in laboratory abnormalities [i.e. urine 23S-pentol and plasma cholestanol], etc.) - Medication is prescribed at an FDA approved dose
Criteria Statement	Ctexli is reserved for members who have a diagnosis of CTX confirmed by genetic testing.
Last P&T Review Date	9/2025

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Alameda MRGs for review Q3 2025 P&T

Recommendation:

- Add language on requiring members to use an optimized dose and strength of a medication
- Policy will now include formulary and non-formulary medications that exceed published quantity limits

Quantity Limit Exception	
Therapeutic Classes (AHFS)	N/A
Medications	~~Formulary-d~~Drugs exceeding the Alameda Alliance's published quantity limits A quantity limit is defined as a limitation in the amount of medication per fill or time period and/or limitation in the amount of fills per calendar year or other time period. <u>In addition, a quantity limit may require a member to use an optimized dose and strength.</u>
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert.
Exclusion Criteria	See "PA Review Criteria"
Required Clinical Information	See "PA Review Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval 12 months Later Approvals 12 months If criteria is not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review.
PA Review Criteria	• The provider has submitted justification for the approval of doubling (or higher) of the number of tablets/capsules per prescription for a medication that has a higher strength tablet/capsule available, stating why that higher dose tablet/capsule cannot be used (e.g. two lorazepam 0.5mg tablets to equal the dose of lorazepam 1mg, when lorazepam 1mg tablet exists). AND • The dose requested is supported by the Medical Compendia or current treatment guidelines. OR • The member must have a documented treatment failure with the drug prescribed at the health plan's quantity limit OR the member requires a dose within prescribing guidelines that exceeds the plan's quantity limit. AND • The provider has submitted a medical reason why the plan's quantity limit will be inadequate based on the member's condition and treatment history. AND • The dose requested is supported by the Medical Compendia or current treatment guidelines.
Criteria Statement	N/A
Last P&T Review Date	<u>9/2024/2025</u>

Recommendation: Add new product Focinvez—new IV formulation of fosaprepitant

Antiemetics	
Therapeutic Classes (AHFS)	5-HT3 Receptor Antagonists, Neurokinin-1 receptor antagonists
Medications	<u>Formulary</u> ondansetron (Zofran) tablet 4mg, 8mg (quantity limit) ondansetron (Zofran) ODT (quantity limit) <u>Formulary, Prior Authorization Required</u> ondansetron (Zofran) tablet 24mg (quantity limit) palonosetron (Aloxi) IV solution 0.25mg/5ml vial palonosetron (Aloxi) IV solution 0.25mg/2ml vial, 0.25mg/5ml syringe granisetron (Kytril) oral tablet, IV solution aprepitant (Emend) capsule <u>Non-Formulary</u> ondansetron (Zofran) oral solution, IV solution, injection (IV/SQ) solution Anzemet (dolasetron) tablet Sustol (granisetron ER) SQ injection Sancuso (granisetron ER) transdermal patch fosaprepitant (Emend) IV emulsion Emend (fosaprepitant) powder packet Cinvanti (aprepitant) IV emulsion Varubi (rolapitant) oral capsule Akynzeo (fosnetupitant/palonosetron) capsule, IV solution <u>Focinvez (fosaprepitant) IV solution</u> Any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See “PA Review Criteria” below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	N/A
Coverage Duration	Initial/Re-Approval If all of the conditions are met, the request will be approved for up to a 6 month duration, as per chemotherapy cycle, or as recommended per FDA approved indications and/or defined medical compendium and/or per the NCCN, ASCO, NCI, or MASCC standard of care guidelines. If all of the criteria are not met, the request is referred to a clinical reviewer for medical necessity review.
PA Review Criteria	Criteria for approval (Pediatric Population): - Check AAH active CCS cases for members < 21 years of age Criteria for approval (Adult Population): - Prescribed dosing is within FDA approved indications and limitations and/or supported by medical compendium and NCCN, ASCO, NCI, or MASCC standard of care guidelines, and is within quantity limits, if applicable. - Patients receiving an antineoplastic agent = HIGH or MODERATE emetic risk per the NCCN Practice guidelines can receive palonosetron hydrochloride (Aloxi) and aprepitant (Emend) capsule, as first line antiemetic agents <i>*For reference, please consult the most recent NCCN guidelines for Antiemesis</i>

	which can be located under NCCN Guidelines for Supportive Care: Antiemesis @ https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf - For all other patients, if the request is for a formulary, prior authorization required or non-formulary agent, the patient has a documented treatment failure after receiving an adequate trial of formulary 5HT-3 RA (ondansetron) and/or has another documented medical reason (intolerance, hypersensitivity, contraindication, etc.) for not utilizing these medications to treat their medical condition. - The medication is recommended and prescribed by a specialist in the field to treat the patient's respective medical condition. For requests above the quantity limit - The provider has submitted a medical reason why the plan's quantity limit will be inadequate based on the member's condition and treatment history.
Criteria Statement	Antiemetics other than ondansetron tablets and ODT are reserved for members who have used (or cannot/should not use) oral ondansetron 4mg or 8 mg oral tablets or oral disintegrating tablets for the respective mechanism of action requested. Palonosetron (Aloxi) or aprepitant (Emend) capsule are reserved for members who are using a high or moderate emetic risk antineoplastic.
Last P&T Review Date	9/29/2025

Recommendation: Add new product Tryptyr indicated for the treatment of signs and symptoms of dry eye disease in adults.

Ophthalmic Anti-inflammatory Immunomodulators	
Therapeutic Classes (AHFS)	EENT anti-inflammatory agents, miscellaneous.
Medications	<u>Formulary, step therapy required</u> Cyclosporine (Restasis) 0.05% dropperette <u>Formulary PA (prior authorization required)</u> Restasis multidose (cyclosporine) 0.05% drops Xiidra (lifitegrast) 5% dropperette Cequa (cyclosporine) 0.09% ophthalmic dropperette Tyrvaya (varenicline) 0.03mg nasal spray Miebo (perfluorohexyloctane) 100% drops (1.338 gm/ml) <u>Tryptyr (acoltremon) 0.003 % ophthalmic solution</u> Any other newly approved agents
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval 12 months Later Approvals 12 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	The following criteria must be met for cyclosporine (Restasis) 0.05% dropperette: • Diagnosis of dry eye syndrome (decreased tear production) whose lack of tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, dry eye, or treatment of the signs and symptoms of dry eye disease. AND • Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to at least 30-day trials each of two different artificial tear products, one of which must be high viscosity artificial tears (e.g. methylcellulose, polyvinyl alcohol, polyethylene glycol, or oil containing) The following criteria must be met for formulary prior authorization required medications: • Diagnosis of dry eye syndrome (decreased tear production) whose lack of tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, dry eye, or treatment of the signs and symptoms of dry eye disease AND • Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to at least 30-day trials each of two different artificial tear products, one of which must be high viscosity artificial tears (e.g. methylcellulose, polyvinyl alcohol, polyethylene glycol, or oil containing) AND • Documentation of trial and failure, contraindication, or intolerance to cyclosporine (Restasis) 0.05% dropperette
Criteria Statement	For dry eye syndrome, cyclosporine (Restasis) 0.05% dropperette is reserved for members who have previously used (or cannot/should not use) artificial tears. Restasis Multidose, Xiidra, Cequa, Miebo, <u>Tryptyr</u> , or Tyrvaya are reserved for members who have previously used (or cannot/should not use) artificial tears and cyclosporine (Restasis) 0.05% dropperette.

Last P&T Review Date	9/20249/2025

Recommendation: Expand language on aprepitant to allow other NK1 receptor antagonists such as fosaprepitant

Dronabinol	
Therapeutic Classes (AHFS)	Antiemetics, Miscellaneous
Medications	<u>Formulary, PA required</u> Dronabinol (Marinol): pays at point of sale for members with diagnosis of HIV ICD 10 B20, for all other diagnoses, prior authorization is required <u>Non-formulary</u> Syndros oral solution
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval 12 months Later Approvals 12 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	Criteria for approval: • Patient has anorexia or weight loss associated with AIDS/HIV OR • Patient has nausea or vomiting due to chemotherapy AND documentation of trial and failure, contraindication, or intolerance to at least two of the following: ○ 5-HT3 antagonists (ondansetron up to 8mg BID, granisetron) ○ Dopamine receptor antagonists (e.g. prochlorperazine, promethazine, or metoclopramide) ○ <u>NK1 receptor antagonist (Aprepitant, fosaprepitant)</u> ○ Dexamethasone • OR Patient has anorexia or weight loss associated with cancer AND documentation of trial and failure, contraindication, or intolerance to megestrol or cyproheptadine. • If request is for Syndros, above criteria must be met AND documentation provided of inability to swallow dronabinol capsules must be provided
Criteria Statement	Dronabinol is reserved for members that have AIDS/HIV. For nausea or vomiting due to chemotherapy, dronabinol is reserved for members who have used (or cannot/should not use) ondansetron, granisetron, dexamethasone, or prochlorperazine. For weight loss due to cancer, dronabinol is reserved for members who have used (or cannot/should not use) megestrol or cyproheptadine.
Last P&T Review Date	<u>9/2024/9/2025</u>

Recommendation:

- Add new filgrastim biosimilar Nypozi (filgrastim-txid) to criteria and to F-PA as it is cost-effective
- Add Udenyca Onbody as it is missing from the policy
- Reorganize drug list for more clarity
- Add new long-acting CSF Ryzneuta (efbemalenograstim alfa-vuxw) to policy for completeness
- Add Flyneta to the acute hematopoietic radiation injury syndrome for pegfilgrastim products section, since it also has this indication
- Add treatment failure requirement with biosimilars Zarxio and Releuko to acute hematopoietic radiation injury syndrome section for filgrastim products, since both of these filgrastim biosimilars have this indication

White Blood Cell Stimulators	
Therapeutic Classes (AHFS)	Hematopoietic agents
Medications	<u>Formulary, PA required</u> plerixafor (Mozobil) Leukine (sargramostim) Ziextenzo (pegfilgrastim-bmez) Fulphila (pegfilgrastim-jmdb) –PREFERRED AGENT Udenyca (pegfilgrastim-cbqv) Udenyca Onbody (pegfilgrastim-cbqv) Stimufend (pegfilgrastim-fpgk) Flyneta (pegfilgrastim-pbbk) Ziextenzo (pegfilgrastim-bmez)
	Nivestym (filgrastim-aafi) – PREFERRED AGENT Zarxio (filgrastim-sndz) Releuko (filgrastim-ayow) Nypozi (filgrastim-txid)
	<u>Non-formulary</u> Nyvepria (pegfilgrastim-apgf) Neulasta (pegfilgrastim) Neulasta (pegfilgrastim) Onpro
	Neupogen (filgrastim) Granix (filgrastim-aafi)
	Rolvedon (eflapegastim-xnst) Ryzneuta (efbemalenograstim alfa-vuxw)
	Aphexda (motixafortide) plerixafor (Mozobil) Leukine (sargramostim)
	Any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See “PA Review Criteria” below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescriber must be a hematologist/oncologist.

Coverage Duration	Initial Approval 12 weeks or as recommended per FDA approved indications and/or as defined by the medical compendium as defined above and/or per the NCCN or ASCO standard of care guidelines If conditions are not met, the request will be sent to a clinical reviewer. Later Approval For all indications except chronic neutropenia: 12 weeks. For chronic neutropenia: 24 weeks. If all of the criteria are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	For approval: • Drug is being used for an FDA-approved indication at an FDA approved dose. AND • If the request is for Leukine: Documentation is submitted of the patient's current diagnosis, current bodyweight, body surface area and absolute neutrophil count (within 30 days of the request). • If the request is for a pegfilgrastim formulation, ~~or~~ Rolvedon, <u>or Ryzneuta</u>: ○ The patient has a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with the use of the preferred agent: Fulphila and/or has another documented medical reason (intolerance, hypersensitivity, etc.) for not using Fulphila to treat their medical condition. ○ If the request is for acute hematopoietic radiation injury syndrome, the patient has documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with the use of a biosimilar such as Ziextenzo, Udenyca, <u>Fylmetra</u> or Stimufend, and/or has another documented medical reason (intolerance, hypersensitivity, etc.) for not using a biosimilar indicated for acute hematopoietic radiation injury syndrome. • If the request is for a filgrastim formulation: ○ The patient has a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with the use of the preferred agent: Nivestym and/or has another documented medical reason (intolerance, hypersensitivity, etc.) for not using Nivestym. ○ If the request is for acute hematopoietic radiation injury syndrome, <u>the patient has documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with the use of a biosimilar such as Zarxio or Releuko and/or has another documented medical reason (intolerance, hypersensitivity, etc.) for not using a biosimilar indicated for acute hematopoietic radiation injury syndrome. Neupogen can be approved without prior use of Nivestym or medical reason for not using Nivestym.</u> • If the request is for plerixafor or Aphexda: ○ Documentation is submitted of the patient's current diagnosis, current body weight, and that the patient is using product in combination with a granulocyte-colony stimulating factor (G-CSF) agent (i.e. Zarxio or Fulphila) ○ If the request is for Aphexda, the patient has a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with the use of plerixafor and/or has another documented medical reason (intolerance, hypersensitivity, etc.) for not using plerixafor.

Criteria Statement	Neupogen, Zarxio, Releuko, Nypozi and Granix are reserved for members who have used (or cannot/should not use) Nivestym. Neulasta, Ziextenzo, Nyvepria, Stimufend, Fylnetra, Rolvedon, Ryzneuta and Udenyca are reserved for members who have used (or cannot/should not use) Fulphila. Plerixafor is reserved for members who are using plerixafor in combination with a granulocyte-colony stimulating factor (G-CSF) agent (i.e. Zarxio or Fulphila). Aphexda is reserved for members who have used (or cannot/should not use) plerixafor in combination with a G-CSF agent.
Last P&T Review Date	9/20249/2025

Recommendation: Update criteria with newly available generic for Motegrity as it is more cost-effective and update on formulary to F-PA

Constipation agents	
Therapeutic Classes (AHFS)	N/A
Medications	<u>Formulary, Prior Authorization Required</u> Linzess (linaclotide) capsule lubiprostone (Amitiza) Movantik (naloxegol) Relistor (methylnaltrexone) Symproic (naldemedine) ~~prucalopride~~ (Motegrity) (~~prucalopride~~) Trulance (plecanatide) Ibsrela (tenapanor)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria"
Age Restrictions	Patient must be ≥ 18 years of age Linzess: functional constipation in pediatric patients 6 to 17 years old
Prescriber Restrictions	None
Coverage Duration	Initial Approval 6 months Later Approvals 12 months If criteria is not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review.
PA Review Criteria	INITIAL AUTHORIZATION for irritable bowel syndrome with constipation predominate (IBS-C): - The patient has a clinical diagnosis of irritable bowel syndrome constipation predominate (IBS-C) - Medication is prescribed at an FDA approved dosage - Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to a soluble fiber (e.g. psyllium) within the last 90 days - If the above criteria are met, for requests for Linzess, Trulance, or lubiprostone (Amitiza): approve. OR - For requests for other formulary, prior authorization required medications, the above criteria must be met, AND documentation of trial and failure, contraindication, or intolerance of Linzess, Trulance, or lubiprostone (Amitiza) within the last 90 days is required. INITIAL AUTHORIZATION for chronic idiopathic constipation (CIC): - The patient has a clinical diagnosis of chronic idiopathic constipation (CIC) - Medication is prescribed at an FDA approved dosage - Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to use a soluble fiber (e.g. psyllium) within the last 90 days

- Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance, to at least 2 laxatives (example: milk of magnesia, polyethylene glycol, docusate sodium, senna) within the last 90 days
 - If the above criteria are met, for requests for Linzess, Trulance, [prucalopride](#) (Motegrity), or lubiprostone (Amitiza): approve.
- OR**
- For requests for other formulary, prior authorization required medications, the above criteria must be met, AND documentation of trial and failure, contraindication, or intolerance to Linzess, Trulance, [prucalopride](#) (Motegrity), or lubiprostone (Amitiza) within the last 90 days is required

INITIAL AUTHORIZATION FOR DIAGNOSIS OPIOID-INDUCED CONSTIPATION (OIC) with chronic non-cancer pain:

- The patient has a clinical diagnosis of opioid-induced constipation with chronic non-cancer pain
 - Medication is being prescribed at an FDA approved dosage
 - Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to at least 2 laxatives (example: milk of magnesia, polyethylene glycol, docusate sodium, senna) within the last 90 days
 - If the above criteria are met, for requests for Movantik, Symproic, or lubiprostone (Amitiza): approve
- OR**
- For requests for other formulary, prior authorization required medications, the above criteria must be met, AND documentation of trial and failure, contraindication, or intolerance to Movantik, Symproic, or lubiprostone (Amitiza) within the last 90 days is required

INITIAL AUTHORIZATION FOR DIAGNOSIS OPIOID-INDUCED CONSTIPATION (OIC) with advanced illness:

- The patient has a clinical diagnosis of opioid-induced constipation with advanced illness
 - Medication is being prescribed at an FDA approved dosage
 - Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to at least 2 laxatives (example: milk of magnesia, polyethylene glycol, docusate sodium, senna) within the last 90 days
 - If the above criteria are met, for requests for Relistor injectable (e.g. vial or syringe) approve.
- OR**
- For requests for other formulary, prior authorization required medications, the above criteria must be met, AND documentation of trial and failure, contraindication, or intolerance to Relistor injectable (e.g. vial or syringe) within the last 90 days is required

INITIAL AUTHORIZATION for functional constipation in pediatric patients (Linzess only):

- The patient has a clinical diagnosis of functional constipation (FC)
- Medication is being prescribed at an FDA approved dosage
- Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to at least 2 laxatives (example: polyethylene glycol, lactulose, milk of magnesia, docusate sodium, senna) within the last 90 days

	PA CRITERIA FOR REAUTHORIZATION (IBS-C, CIC, opioid-induced constipation, FC): • Documentation of continued clinical benefit from treatment. • Medication is being prescribed at an FDA approved dosage
Criteria Statement	For the diagnosis of irritable bowel syndrome with constipation, lubiprostone (Amitiza), Linzess, and Trulance are reserved for members who have used (or cannot/should not use) a soluble fiber (example: psyllium) within the last 90 days. Ibsrela is reserved for members who have also used lubiprostone (Amitiza), Linzess, or Trulance within the last 90 days. For the diagnosis of chronic idiopathic constipation, lubiprostone (Amitiza), Linzess, prucalopride (Motegrity), and Trulance are reserved for members who have used (or cannot/should not use) a soluble fiber (example: psyllium) AND at least 2 laxatives (example: milk of magnesia, polyethylene glycol, docusate sodium, senna) within the last 90 days. For the diagnosis of opioid-induced constipation with chronic non-cancer pain, lubiprostone (Amitiza), Symproic, and Movantik are reserved for members who have used (or cannot/should not use) at least 2 laxatives (example: milk of magnesia, polyethylene glycol, docusate sodium, senna) within the last 90 days. Relistor is reserved for members who have also used lubiprostone (Amitiza), Symproic, or Movantik within the last 90 days. For the diagnosis of opioid-induced constipation with advanced illness, Relistor injectable is reserved for members who have used (or cannot/should not use) at least 2 laxatives (example: milk of magnesia, polyethylene glycol, docusate sodium, senna) within the last 90 days. For the diagnosis of functional constipation in pediatric patients, Linzess is reserved for members who have used (or cannot/should not use) at least 2 laxatives (example: polyethylene glycol, lactulose, milk of magnesia, docusate sodium, senna) within the last 90 days.
Last P&T Review Date	9/2024/2025

Recommendation: Add mesalamine DR (Asacol HD) as it is missing from the policy

Mesalamine	
Therapeutic Classes (AHFS)	Anti-Inflammatory Agents (GI Drugs)
Medications	<u>Formulary</u> Mesalamine (Canasa) suppository Mesalamine (Rowasa) rectal enema Mesalamine (SFRowasa) rectal enema <u>Formulary, Step Therapy</u> Mesalamine DR (Delzicol DR) capsule Mesalamine ER (Apriso) capsule Mesalamine DR (Lialda) tablet <u>Formulary, PA Required</u> Mesalamine ER (Pentasa) 500mg capsule Pentasa (mesalamine <u>ER</u>) 250mg capsule <u>Mesalamine DR (Asacol HD) 800mg tablet</u> Any other mesalamine product
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval 12 months Later Approvals 12 months If criteria are not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review.
PA Review Criteria	<u>Criteria for Authorization</u> Mesalamine DR (Delzicol DR), mesalamine ER (Apriso), or mesalamine DR (Lialda) are approved when all of the following criteria are met: - Documentation of a diagnosis of ulcerative colitis - Documentation of a trial and failure or contraindication to sulfasalazine or balsalazide <u>Mesalamine DR (Asacol HD), Mesalamine ER (Pentasa) or Pentasa (mesalamine ER)</u> are approved when all of the following criteria are met: - Documentation of a diagnosis of ulcerative colitis - Documentation of a trial and failure or contraindication to sulfasalazine or balsalazide AND mesalamine DR (Lialda) or mesalamine DR (Delzicol DR) or mesalamine ER (Apriso)
Criteria Statement	Mesalamine DR (Lialda) tablet, mesalamine DR (Delzicol) or mesalamine ER (Apriso) are reserved for members who have ulcerative colitis and have used (or cannot/should not use) sulfasalazine or balsalazide. <u>Mesalamine DR (Asacol HD), Mesalamine ER (Pentasa), Pentasa (mesalamine ER)</u> are reserved for members with ulcerative colitis who have used (or cannot/should not use) sulfasalazine or balsalazide AND mesalamine DR (Lialda) tablet, mesalamine DR (Delzicol), or mesalamine ER (Apriso).
Last P&T Review Date	9/2024/2025

Recommendation: Add new product Pruradik (crotamiton) lotion indicated for eradication of scabies for completeness.

Scabicides and Pediculicides	
Therapeutic Classes (AHFS)	Scabicides and pediculicides
Medications	<u>Formulary, Step therapy required</u> Malathion (Ovide) 0.5% lotion Spinosad (Natroba) 0.9% suspension Ivermectin (Sklice) 0.5% lotion <u>Non-Formulary</u> Crotan (crotamiton) 10% lotion <u>Pruradik (crotamiton) 10% lotion</u> Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See “PA Review Criteria” below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial If all conditions are met, the request will be approved for up to 1 treatment. Re-approval If conditions are met, the request will be approved for a maximum of 2 treatments in a 30 day period. If all criteria are not met, the request is referred to Clinical Reviewer for medical necessity review.
PA Review Criteria	INITIAL: <u>Head Lice:</u> For the approval of the formulary-step therapy required medications: • Diagnosis of pediculosis capitis (head lice and its eggs). • Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to permethrin 1% OTC or pyrethrins/piperonyl butoxide OTC OR • Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to permethrin 1% OTC or pyrethrins/piperonyl butoxide OTC, within the previous 45 days, but no earlier than 7 days after the original fill. For the approval of the non-formulary medication: • All criteria above must be met AND documented trial and failure, intolerance, or reason not to use two of the following formulary medications: malathion (Ovide) 0.5% lotion or spinosad (Natroba) 0.9% suspension or ivermectin (Sklice) 0.5% lotion <u>Scabies:</u> For the approval of the formulary-step therapy required medications: • Diagnosis of scabies (<i>Sarcoptes scabiei</i>) • Documented trial and failure, intolerance, or hypersensitivity to the first line agent: permethrin 5% topical cream For the approval of the non-formulary medication:

	- All criteria above must be met AND documented trial and failure of: spinosad (Natroba) 0.9% suspension RENEWAL: - For head lice: spinosad can be approved for a second treatment if live lice are present 7 days after the initial treatment. - For head lice: malathion can be approved for a second treatment if live lice are present 7-9 days after the initial treatment. - For scabies: Crotan, <u>Pruradik</u> can be approved for a second treatment if itching still present or if new burrows or lesions continue to appear 2-4 weeks after the initial treatment & also the 2nd application 24 hours later
Criteria Statement	For the treatment of head lice, malathion (Ovide) 0.5% lotion, spinosad (Natroba) 0.9% suspension, and ivermectin (Sklice) 0.5% lotion are reserved for members who have used (or cannot/should not use) permethrin 1% OTC or pyrethrins/piperonyl butoxide OTC. For the treatment of scabies, spinosad (Natroba) 0.9% suspension is reserved for members who have used (or cannot/should not use) permethrin 5% topical cream. For the treatment of scabies, Crotan, <u>Pruradik</u> lotion is reserved for members who have used (or cannot/should not use) permethrin 5% topical cream AND spinosad (Natroba) 0.9% suspension.
Last P&T Review Date	<u>9/2024</u> <u>9/2025</u>

Recommendation: Remove Aemcolo (rifamycin) as it has been discontinued.

Rifamycin Antibiotics	
Therapeutic Classes (AHFS)	Rifamycin Antibiotics
Medications	<u>Formulary Prior Authorization Required</u> Xifaxan (rifaximin) ~~Aemcolo DR (rifamycin)~~
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial/Re-Approval Traveler's diarrhea (~~Xifaxan and Aemcolo~~): If all of the criteria are met, approve up to 1 fill up to FDA approved maximum dosing. IBS-D (~~Xifaxan~~): If all of the criteria are met, the request will be approved for up to #42/14 days for 3 fills for 1 year. Hepatic encephalopathy (~~Xifaxan~~): If all of the criteria are met, the initial request will be approved for up to 6 months. For re-approvals if all criteria are met, the request will be approved for up to 12 months. If criteria is not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review.
PA Review Criteria	<u>Criteria for Authorization</u> For all diagnoses (~~Xifaxan and Aemcolo~~): - Drug is being prescribed at FDA approved dose (including patient age) For diagnosis of traveler's diarrhea (~~Xifaxan and Aemcolo~~): - Documented trial and failure, contraindication, or intolerance to a fluoroquinolone (e.g. ciprofloxacin) OR azithromycin For reduction of overt hepatic encephalopathy recurrence or treatment of hepatic encephalopathy (~~Xifaxan~~): - Documented trial and failure, contraindication, or intolerance to lactulose in previous 30 days OR - Patient will be using lactulose concurrently For treatment of irritable bowel syndrome – diarrhea predominant (IBS-D) (~~Xifaxan~~): - Patient has diagnosis of moderate to severe disease (includes one or more of the following: frequent and severe abdominal pain/discomfort; frequent bowel urgency or fecal incontinence; disability or restriction of daily activities due to IBS) AND - Documented trial and failure, contraindication, or intolerance to a tricyclic antidepressant (TCA) (e.g. amitriptyline)

Criteria Statement	For traveler's diarrhea, Xifaxan ~~and Aemcolo-DR are~~ reserved for members who have used (or cannot/should not use) a fluoroquinolone (e.g. ciprofloxacin) or azithromycin. For hepatic encephalopathy, Xifaxan is reserved for members who have used (or cannot/should not use) lactulose in the prior 30 days or are concurrently using lactulose. For irritable bowel syndrome –diarrhea predominant, Xifaxan is reserved for members who have used (or cannot/should not use) a tricyclic antidepressant (TCA) (e.g. amitriptyline).
Last P&T Review Date	9/20249/2025

Recommendation:

- Change coverage duration for Sirturo to 12 months to match current guideline recommendations
- Remove “short course” and “long course” language from Sirturo section to align with clinical practice guideline updates that now recommend the use of a 6-month treatment rather than the 15-month or longer for regimens containing bedaquiline
- Remove resistance to fluoroquinolones (FQ) requirement from Sirturo and Pretomanid sections, since per guideline updates BPaLM or BPaL regimens are now recommended regardless of FQ resistance.

Medications for the treatment of Multi-Drug Resistant Tuberculosis	
Therapeutic Classes (AHFS)	Antitubercular agents
Medications	<u>Formulary, Step Therapy required</u> Cycloserine (Seromycin) 250 mg capsule Trecator (ethionamide) 250 mg tablet Moxifloxacin (Avelox) 400 mg tablet Linezolid (Zyvox) 600 mg tablet and 100 mg/5 ml suspension <u>Formulary PA required</u> Sirturo (bedaquiline fumarate) tablet Pretomanid tablet
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	Diagnosis of latent tuberculosis or drug-susceptible tuberculosis
Required Clinical Information	See “PA Review Criteria” below
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is an infectious disease specialist or working in consultation with infectious disease specialist
Coverage Duration	Initial Approval Trecator, Cycloserine, Moxifloxacin, Linezolid: Up to 20 months Sirturo: ~~24-12~~ months Pretomanid: 9 months
PA Review Criteria	Formulary, Step Therapy required medications criteria for approval: • Documentation member has intolerance, contraindication, or inability to use at least one first-line treatment: isoniazid, ethambutol, rifampin, OR pyrazinamide Formulary PA required medications criteria for approval: Sirturo (bedaquiline) <u>One of the following:</u> • ~~Diagnosis is laboratory confirmed pulmonary multidrug-resistant tuberculosis (MDR-TB) or rifampicin-resistant tuberculosis (RR-TB) with an isolate showing genotypic or phenotypic resistance to rifampin (RIF) AND one of the following:~~ ~~1. Short-course (generally 9-12 months)~~ ~~• Resistance to fluoroquinolones (FQ) has been ruled out~~ ~~Is being prescribed in combination with other TB medications~~ ~~2. Long-course (generally 15-24 months)~~ 1. Is being prescribed in combination with other TB medications • Is being used in combination with Pretomanid as below <u>Pretomanid</u> • Diagnosis is laboratory confirmed pulmonary extensively drug resistant (XDR)-

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	TB or treatment-intolerant or non-responsive MDR-TB or RR-TB with an isolate showing genotypic or phenotypic resistance to RIF. • ~~Documented FQ resistance~~ • Is being used in combination with Sirturo (bedaquiline) and linezolid • Medical reason why other guideline-recommended regimens cannot be used For requests for therapy to continue beyond the coverage duration initial approval time period, approve if medical justification provided (e.g. extensively drug resistant [XDR]-TB) for continuation of therapy **For moxifloxacin and linezolid requests for diagnoses other than MDRTB, see the drug-specific criteria for each.
Criteria Statement	For multi-drug resistant tuberculosis, Trecator, Cycloserine, moxifloxacin, or linezolid are reserved for members who have used (or cannot/should not use) isoniazid, ethambutol, rifampin, or pyrazinamide Pretomanid tablet is reserved for members with a diagnosis of multi-drug resistant or rifampin resistant tuberculosis, ~~with documented fluoroquinolone resistance~~, when used as part of a 3-drug ~~or~~ regimen. Sirturo tablet is reserved for members with a diagnosis of multi-drug resistant or rifampin resistant tuberculosis, when used in combination with Pretomanid and other medications to treat tuberculosis.
Last P&T Review Date	9/20249/2025

Recommendation: Revise language on the initial dose escalation tolerance requirement in re-authorization section.

Palforzia	
Therapeutic Classes (AHFS)	ALLERGENIC EXTRACTS (THERAPEUTIC)
Medications	Non-Formulary Palforzia (peanut [Arachis hypogaea] allergen powder-dnfp)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See “PA Review Criteria” below
Age Restrictions	- Initiation: Patient is age 1-17 years. - Up dosing and maintenance: Patient is age ≥ 1 years
Prescriber Restrictions	Prescriber is a specialist in the area of allergy/immunology
Coverage Duration	Initial Approval If the criteria are met, the initial request may be approved for up to a 6-month duration. Reauthorization Reauthorization requests may be approved for 6 months. If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	Initial Authorization: Palforzia is approved when all of the following criteria are met: - Patient has a confirmed diagnosis of peanut allergy - For patients starting initial dose escalation (new to therapy) - Patient has not had severe or life-threatening anaphylaxis within the previous 60 days - Patient will follow a peanut-avoidant diet - Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine - No history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease - Patient does not have uncontrolled asthma Criteria for Re-Authorization: Palforzia is approved for re-authorization when all of the following criteria are met - Patient will follow a peanut-avoidant diet - Patient is able to tolerate <u>the initial dose escalation per the prescribing information at least the 3 mg dose daily</u> - Patient is able to comply with the daily dosing requirements - Patient does not have recurrent asthma exacerbations or persistent loss of asthma control - Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine
Criteria Statement	Palforzia is reserved for members with an allergy to peanuts, who will follow a peanut-avoidant diet, who have not experienced anaphylaxis in the previous 60 days, don't have uncontrolled asthma, and have been prescribed injectable epinephrine.
Last P&T Review Date	9/2024/2025

Recommendation: Add new product Imuldosa—new cost-effective Stelara biosimilar

Specialty Biologic Agents	
Therapeutic Classes (AHFS)	Disease-Modifying Antirheumatic Agents
Medications	<u>Step 1: Preferred (pays at point-of-sale)</u> Hadlima (adalimumab-bwwd) Adalimumab-fkjp (Hulio) Adalimumab-aaty (Yuflyma)-- 80mg/0.8mL dose formulation available Simlandi (adalimumab-ryvk)
	<u>Step 2: Preferred (PA required)</u> Enbrel (etanercept) Simponi, Simponi Aria (golimumab) Infliximab Inflectra (infliximab-dyyb) Avsola (infliximab-axxq) Renflexis (infliximab-abda) Oencia (abatacept) Xeljanz, Xeljanz XR (tofacitinib) Kineret (anakinra) Otezla (Apremilast) Siliq (brodalumab) Kevzara (sarilumab) Tyenne (tocilizumab-aazg) Tofidence (tocilizumab-bavi) Olumiant (baricitinib) Entyvio (vedolizumab) Otulfi (ustekinumab-aaaz) Yesintek (ustekinumab-kfce) <u>Imuldosa (ustekinumab-srff)</u>
	<u>Step 3: Non-Preferred (PA required)</u> Humira (adalimumab) Stelara (ustekinumab) Skyrizi (risankizumab) Actemra (tocilizumab) Arcalyst (rilonacept) Ilaris (canakinumab) Tremfya (guselkumab) Remicade (infliximab) Cosentyx (secukinumab) Zeposia (ozanimod) Taltz (ixekizumab) Tysabri (natalizumab) Cimzia (certolizumab) Rinvoq (upadacitinib) Ilumya (tildrakizumab-asmn) Sotyktu (deucravacitinib) Bimzelx (bimekizumab) Omvoh (mirikizumab) Zymfentra (infliximab) All adalimumab biosimilar agents not listed in step 1(ex. Amjevita, Cyltezo, Hyrimoz, Yuflyma, etc.) Litfulo (ritlecininib) All Stelara biosimilars not listed in step 2 (ex. Steqeyma, Selarsdi, etc.)

	Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines. ** Non-FDA approved (i.e. off-label) uses; refer to the “Off-Label Use” policy**
Exclusion Criteria	N/A
Required Clinical Information	See “PA Review Criteria” below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescribed by a specialist in the field to treat the member’s respective medical condition
Coverage Duration	If all of the conditions are met, requests will be approved for 12 months.
PA Review Criteria	<u>Initial Authorization:</u> - The drug is being requested for an appropriate use (per the references outlined in “Covered Uses”) - The dose requested is appropriate for the requested use (per the references outlined in “Covered Uses”) - If the request is for a preferred Step 2 agent, documentation has been provided that the member has tried and failed or has a medical reason why (e.g. intolerance, contraindication) they cannot use a preferred Step 1 agent appropriate for the requested use (per the references outlined in “Covered Uses”) - If the request is for a non-preferred Step 3 agent, documentation has been provided that the member has tried and failed or has a medical reason why (e.g. intolerance, contraindication) they cannot use one preferred step 1 agent and one preferred step 2 agent appropriate for the requested use (per the references outlined in covered uses) AND: - If the request is for a reference biologic drug with a biosimilar or interchangeable biologic drug (ex. Humira, Remicade, Stelara), documentation of one of the following: - The provider has verbally, or in writing, submitted a member-specific reason why the reference biologic is required based on the member’s condition or treatment history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic, the provider has completed and submitted an FDA MedWatch form to justify the member’s need to avoid these drugs. MedWatch form must also be included with the prior authorization request. Form FDA 3500 – Voluntary Reporting - The currently available biosimilar product does not have the same appropriate use (per the references outlined in “Covered Uses”) as the reference biologic drug being requested *NOTE: - Requests for 80mg/0.8mL dose presentations of Humira or non-preferred biosimilar adalimumab agents, preferred biosimilar adalimumab-aaty 80mg/0.8mL should be used - Requests for Humira 10 mg/0.1 mL in pediatric patients may be approved without a trial of a step 1 or step 2 agent, when requested for an appropriate use (per the references outlined in “Covered Uses”) <u>Reauthorization:</u> - Documentation submitted indicates that the member has obtained clinical benefit from the medication.

	The drug is being requested for an appropriate use and dose (per the references outlined in "Covered Uses")
Criteria Statement	Step 2 preferred prior authorization required medications are reserved for members with an appropriate indication and dose, who have used (or cannot/should not use) a preferred step 1 medication. Step 3 non-preferred prior authorization required medications are reserved for members with an appropriate indication and dose, who have used (or cannot/should not use) a preferred step 1 medication and a step 2 preferred prior authorization required medication.
Last P&T Review Date	<u>6/2025</u>

Recommendation:

- Update the age limit for MResvia from 60 years and older to 18 years and older to account for the updated indication for individuals 18 through 59 years of age who are at increased risk for lower respiratory tract disease (LRTD) caused by RSV.
- Add new meningococcal vaccination Penmenvry to criteria to align with other meningococcal vaccinations on formulary

Immunizations	
Therapeutic Classes (AHFS)	Toxoids;vaccines
Medications	<u>Formulary, 1st line (fill limits indicated if applicable)</u> Influenza vaccine (only most recent strain is on formulary) – 1 fill per 270 days ActHib (Haemophilus influenzae type b) – 3 fills per lifetime Hiberix (Haemophilus influenzae type b) – 3 fills per lifetime Havrix, Vaqta (Hepatitis A) – 2 fills per lifetime Twinrix (Hepatitis A and B) – 4 fills per lifetime; age minimum 18 years Engerix-B (Hepatitis B) – 4 fills per lifetime Recombivax HB (Hepatitis B) – 3 fills per lifetime Hepilisav-B (Hepatitis B) – 2 fills per lifetime; age minimum 18 years PreHevrio (Hepatitis B trivalent) - 3 fills per lifetime; age minimum 18 years Gardasil-9 (HPV) – 3 fills per lifetime; age maximum 45 years I POL (Polio) – 5 fills per lifetime M-M-R II (Measles, Mumps, Rubella) – 2 fills per lifetime Proquad (Measles, Mumps, Rubella) – 2 fills per lifetime Priorix (Measles, Mumps, Rubella) – 2 fills per lifetime Menactra, Menveo A-C-Y-W (Meningococcal) – 2 fills per lifetime; age maximum 55 years MenQuadfi (Meningococcal) – 2 fills per lifetime Penbraya (Meningococcal) – 2 fills per lifetime; age maximum 25 years <u>Penmenvry (Meningococcal)—2 fills per lifetime; age limit: 10-25 years</u> Bexsero (Meningococcal) – 2 fills per lifetime; age maximum 25 years Trumenba (Meningococcal) – 3 fills per lifetime; age maximum 25 years Prenvar-13 (Pneumococcal) – 1 fill per lifetime Prenvar 20 (Pneumococcal) – 1 fill per lifetime Pneumovax 23 (Pneumococcal) – 2 fills per lifetime Vaxneuvance (Pneumococcal) – 1 fill per lifetime Capvaxive (Pneumococcal) – 1 fill per lifetime, age minimum 18 years Imovax Rabies and Rabavert (Rabies) Tenivac, TDVax (Tetanus/diphtheria) Boostrix and Adacel (Tetanus, diphtheria, pertussis) Pentacel (Tetanus, diphtheria, pertussis, polio, Haemophilus influenzae type b) – 4 fills per lifetime Vaxelis (Tetanus, diphtheria, pertussis, polio, Haemophilus influenzae type b) – 3 fills per lifetime Varivax (Chicken pox) – 2 fills per lifetime Shingrix (Shingles) – 2 fills per lifetime; age minimum 18 years Vivotif oral capsules (Typhoid) – 4 capsules per 1 fill; age 6 years and older Abrysvo (RSV) – 1 fill per lifetime Arexvy (RSV) – 1 fill per lifetime MResvia (RSV) – 1 fill per lifetime, age ~~60~~18 years and older
	<u>Non-Formulary, with PA required</u> Biothrax (Anthrax) Ixiaro (Japanese encephalitis) Typhim Vi (Typhoid)

Immunizations	
	YF-Vax (Yellow Fever) Dengvaxia (dengue) Ticovac (tick-borne encephalitis) Ixchiq (chikungunya) Any other newly marketed vaccine
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	See "Medication/Fill limits" above
Coverage Duration	Initial Approval As defined based on guidelines for covered uses Later Approvals As defined based on guidelines for covered uses If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	For Biothrax, Ixiaro, Typhim Vi, Dengvaxia, Ticovac, Ixchiq, and YF-Vax, approve if: - Documentation showing destination of travel where vaccines are recommended per ACIP and CDC: ACIP Vaccine Recommendations and CDC Travel Vaccine Recommendations - Documentation showing departure and return dates of travel. - Dosage and frequency are appropriate according to the FDA and manufacturer package inserts For formulary vaccines above the fill limit, approve if: Dosage and frequency are appropriate according to the FDA and manufacturer package inserts For all other non-formulary vaccines, approve if: - Documentation of trial and failure, inability to use, contraindication, or intolerance to formulary alternatives. - Dosage and frequency are appropriate according to the FDA and manufacturer package inserts.
Criteria Statement	Biothrax, Ixiaro, Typhim Vi, Dengvaxia, Ixchiq, Ticovac, and YF-Vax are reserved for members who are traveling to destinations that require vaccines recommended by the CDC and/or ACIP.
Last P&T Review Date	~~12/2024~~ 9/2025

Recommendation:

- Add new medication Onapgo and change the name of the policy to encompass all drugs. Onapgo is a subcutaneous apomorphine infusion device for the treatment of motor fluctuations in adults with advanced Parkinson's disease.
- Add exclusion criteria for Onapgo per contraindication in the PI
- Change coverage duration to 6 months for initial requests to better match safety and efficacy evaluations in clinical trials

VyalevAnti-Parkinson's Agents for OFF Episodes	
Therapeutic Classes (AHFS)	Dopamine Precursors
Medications	Vyalev (foscarnidopa and foslevodopa) Onapgo (apomorphine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	<u>Vyalev</u> : Concurrent use with a nonselective monoamine oxidase (MAO) inhibitor (such as phenelzine or tranylcypromine) <u>Onapgo</u> : <u>Concurrent use with 5HT3 antagonists, including antiemetics (e.g., ondansetron, granisetron, dolasetron, palonosetron) and alosetron</u> <u>Concurrent use of Vyalev and Onapgo</u>
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a neurologist or in consultation with a neurologist
Coverage Duration	If all of the criteria are met, the initial <u>requests will be approved for up to a 6 month duration</u> and reauthorization requests will be approved for 12 months. If the conditions are not met, the request will be sent to a clinical reviewer for medical necessity review
PA Review Criteria	Initial Authorization: • Diagnosis of advanced Parkinson's Disease • Medication is prescribed at an FDA approved dose • Prescriber attestation or documentation that the patient is experiencing persistent motor fluctuations despite optimized carbidopa/levodopa therapy (including a minimum of 2.5 hours of "off" time per day) • <u>For Vyalev: Patient is taking ≥400 mg of levodopa/day</u> • <u>For Onapgo: patient is currently taking and will continue to take carbidopa/levodopa</u> • Documented trial and failure (or contraindication) to at least two of the following adjunctive medication classes: ◦ COMT-inhibitors (e.g., entacapone) ◦ Dopamine agonists (e.g., ropinirole, pramipexole) ◦ MAO-B inhibitors (e.g., rasagiline, selegiline) Re-Authorization: • Documentation or provider attestation of positive clinical response (i.e. increase in "on" time without troublesome dyskinesia, decreased "off" time) • Medication is prescribed at an FDA approved dose
Criteria Statement	Vyalev <u>and Onapgo</u> <u>is/are</u> reserved for members who have a diagnosis of advanced Parkinson's disease, who experience persistent motor fluctuations despite optimized carbidopa/levodopa therapy, <u>are taking at least 400 mg of levodopa per day</u> , and who have used (or cannot/should not use) at least two of the following medication classes: COMT-inhibitors, dopamine agonists, and MAO-B inhibitors.
Last P&T Review Date	<u>3/2025</u> <u>9/2025</u>

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Recommendation: Remove attestation on drug interactions requirement

Antifibrotic Respiratory Tract Agents	
Therapeutic Classes (AHFS)	Antifibrotic Agents
Medications	Formulary, PA required Ofev (nintedanib) pirfenidone (Esbriet)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is a pulmonologist or lung transplant specialist
Coverage Duration	Initial Approval 6 months Later Approval 6 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	INITIAL CRITERIA FOR ALL DIAGNOSES: • Patient is 18 years of age or older • ~~Provider attests that they have reviewed the patient's other medications, and addressed all potential drug interactions~~ • Documentation has been provided that the patient does not smoke INITIAL CRITERIA FOR IDIOPATHIC PULMONARY FIBROSIS: • Confirmed diagnosis of Idiopathic Pulmonary Fibrosis attested to by prescriber • Pulmonary function test indicate patient has Forced Vital Capacity (FVC) greater than or equal to 50% within 30 days of request INITIAL CRITERIA FOR SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (ILD) (SSc-ILD): • The request is for Ofev (nintedanib). • Confirmed diagnosis of SSc-ILD attested to by prescriber • FVC $\geq$ 40% within 30 days of request • Trial and failure of mycophenolate mofetil (MMF), cyclophosphamide or azathioprine. INITIAL CRITERIA FOR CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE (ILDs) WITH A PROGRESSIVE PHENOTYPE: • The request is for Ofev (nintedanib). • Diagnosis of chronic fibrosing ILD (e.g. connective tissue disease [CTD]-associated ILD, chronic fibrosing hypersensitivity pneumonitis [HP], idiopathic non-specific interstitial pneumonia [INSIP], unclassifiable idiopathic interstitial pneumonia [IIP], environmental/occupational lung disease or sarcoidosis) with a progressive phenotype attested to by prescriber • Recent (12 month) history of treatment with at least one medication to treat ILDs (e.g. a corticosteroid, azathioprine, mycophenolate mofetil (MMF), n-acetylcysteine (NAC), rituximab, cyclophosphamide, cyclosporine, or tacrolimus) • FVC $\geq$ 45% predicted within 30 days of request REAUTHORIZATION CRITERIA: • Documentation submitted indicates that the member has obtained clinical benefit from the medication

	Documentation has been provided that the patient does not smoke
Criteria Statement	Ofev and pirfenidone are reserved for members with a diagnosis of pulmonary fibrosis have pulmonary function tests with FVC over 50%, and have documentation of non-smoking status. Ofev is reserved for members with a diagnosis of systemic sclerosis-associated interstitial lung disease, pulmonary function tests with FVC greater than or equal to 40%, and who has used (or cannot/should not use) mycophenolate mofetil, cyclophosphamide, or azathioprine, and have documentation of non-smoking status. Ofev is reserved for members with a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype, pulmonary function tests with FVC greater than or equal to 45% predicted, who has used (or cannot/should not use)) at least one medication to treat ILDs (e.g. a corticosteroid, azathioprine, mycophenolate mofetil, n-acetylcysteine (NAC), rituximab, cyclophosphamide, cyclosporine, or tacrolimus), and have documentation of non-smoking status.
Last P&T Review Date	<u>3/20259/2025</u>

Recommendation: Retire criteria as Filspari is included in the new Immunoglobulin A (IgA) Nephropathy Agents policy

Filspari	
Therapeutic Classes (AHFS)	OTHER MISCELLANEOUS THERAPEUTIC AGENTS
Medications	Filspari (sparsentan)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	- Pregnancy - Coadministration with renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists, or aliskiren
Required Clinical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a nephrologist
Coverage Duration	Initial Approval 9 months Later Approvals 12 months If criteria are not met, request will be sent to a clinical reviewer for medical necessity review.
PA Review Criteria	<u>Initial Authorization:</u> - Medication is prescribed at an FDA approved dose - Diagnosis of primary immunoglobulin A nephropathy (IgAN) verified by biopsy - Total urine protein ≥ 1.0 g/day - eGFR ≥ 30 mL/min/1.73 m² - Trial and failure with a maximized stable dose of ACE inhibitor or ARB <u>Re-Authorization:</u> - Documentation of positive clinical response as evidenced by a decrease in urine protein-to-creatinine ratio (UPCR) - Medication is prescribed at an FDA approved dose
Criteria Statement	Filspari is reserved for members with a diagnosis of primary immunoglobulin A nephropathy (IgAN) verified by biopsy, with a total urine protein ≥ 1.0 g/day and eGFR ≥ 30 mL/min/1.73 m ² , who have used (or cannot/should not use) a maximized stable dose of angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) medication.
Last P&T Review Date	6/2025

Alameda Q3 2025 PADs for Review Changes

Recommendation:

- Add new filgrastim biosimilar Nypozi (filgrastim-txid)
- Add Udenyca Onbody as it is missing from the policy
- Add new long-acting CSF Ryzneuta (efbemalenograstim alfa-vuxw)
- Remove acute hematopoietic radiation injury section for filgrastim products, since there are two Neupogen biosimilars that have an indication for acute hematopoietic radiation injury syndrome (Zarxio and Releuko)

White Blood Cell Stimulators	
Medications	plerixafor (Mozobil) Aphexda (motixafortide) Leukine (sargramostim) Long acting-CSF Neulasta (pegfilgrastim) Neulasta (pegfilgrastim) Onpro Fulphila (pegfilgrastim-jmdb) - biosimilar Udenyca (pegfilgrastim-cbqv) - biosimilar Udenyca Onbody (pegfilgrastim-cbqv) - biosimilar Ziextenzo (pegfilgrastim-bmez) - biosimilar Nyvepria (pegfilgrastim-apgf) – biosimilar Fylmetra (pegfilgrastim-pbbk) – biosimilar Stimufend (pegfilgrastim-fpgk) – biosimilar Rolvedon (eflapeggrastim-xnst) Ryzneuta (efbemalenograstim alfa-vuxw) Short acting-CSF Neupogen (filgrastim) Zarxio (filgrastim-sndz) - biosimilar Nivestym (filgrastim-aafi) - biosimilar Granix (tbo-filgrastim) – biosimilar Releuko (filgrastim-ayow) - biosimilar Nypozi (filgrastim-txid) - biosimilar Any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See “Other Criteria” below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age for MCAL
Prescriber Restrictions	Prescriber must be a hematologist/oncologist.
Maximum Billable Units	variable
Coverage Duration	Initial Approval 12 weeks or as recommended per FDA approved indications and/or as defined by the medical compendium as defined above and/or per the NCCN or ASCO standard of care guidelines

	Later Approval For all indications except chronic neutropenia: 12 weeks. For chronic neutropenia: 24 weeks.
Other Criteria	** When ~~the~~is biosimilar is indicated, the member must have documented dates of trial and failure, intolerance, inability to use, or contraindication to the biosimilar medication prior to the brand medication approval, OR the currently available biosimilar product does not have the same appropriate use (per the references outlined in “Covered Uses”) as the reference biologic drug being requested, in addition to meeting all applicable criteria below. For approval: • If the request is for Leukine: ◦ Documentation is submitted of the patient's current diagnosis, current bodyweight, body surface area and absolute neutrophil count (within 30 days of the request) • If the request is for plerixafor or Aphexda: ◦ Documentation is submitted of the patient's current diagnosis, current bodyweight, and that the patient is using product in combination with a granulocyte-colony stimulating factor (G-CSF) agent (i.e. Zarxio or Fulphila) ◦ If the request is for Aphexda, the patient has a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with the use of plerixafor and/or has another documented medical reason (intolerance, hypersensitivity, etc.) for not using plerixafor • If the request is for a pegfilgrastim formulation ~~, or~~ Rolvedon ~~, or Ryzneuta:~~ ◦ The patient has a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with the use of a biosimilar and/or has another documented medical reason (intolerance, hypersensitivity, etc.) for not using a biosimilar. • If the request is for a filgrastim formulation: ◦ The patient has a documented treatment failure (i.e. failure to reach and/or maintain target ANC, prolonged febrile neutropenia or infection requiring prolonged anti-infection use) with the use of a biosimilar and/or has another documented medical reason (intolerance, hypersensitivity, etc.) for not using a biosimilar. ◦ ~~If the request is for acute hematopoietic radiation injury syndrome, Neupogen can be approved without prior use of a biosimilar or medical reason for not using a biosimilar.~~ If all of the above criteria are not met for initial or re-authorization, the request is referred to a Clinical Reviewer for medical necessity review
Last Review Date	9/20249/2025

Recommendation: No changes

Sarepta Therapeutics had to suspend shipments of Elevidys on 7/22/2025 as there have been two deaths in the last few months. As of July 28, 2025 the FDA recommended removal of the voluntary hold for ambulatory patients who may now receive Elevidys. The investigation has concluded that the death was unrelated to the gene therapy product itself. The FDA continues to work with the manufacturer regarding non ambulatory patients, which remains subject to a voluntary hold.

Elevidys	
Medications	Elevidys (delandistrogene moxeparvovec-rokl)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	- Any deletion in exon 8 and/or exon 9 in the Duchenne muscular dystrophy (DMD) gene - Concurrent use with an exon skipping drugs (such as Exondys 51, Amondys 45, Vyondys 53, Viltepso)
Required Clinical Information	See "other criteria"
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescribed by neurologist or provider who specializes in the treatment of DMD
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment.
Maximum Billable Units	Variable
Other Criteria	<u>Initial Authorization:</u> - Medication is prescribed at an FDA approved dose - Documentation of weight - Genetically confirmed diagnosis of DMD and copies of testing were submitted with request - Member has been on a stable dose of corticosteroids for at least 3 months - Attestation patient has anti-recombinant adeno-associated virus serotype rh74 (anti-AAVrh74) total binding antibody titers of less than 1:400 - Attestation prescriber has assessed patient's liver function, platelet counts, and troponin-I before treatment If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last Review Date	9/20249/2025

Recommendation:

- Add new medication Onapgo and change the name of the policy to encompass all drugs. Onapgo is a subcutaneous apomorphine infusion device for the treatment of motor fluctuations in adults with advanced Parkinson's disease.
- Add exclusion criteria for Onapgo per contraindication in the PI
- Change coverage duration to 6 months for initial requests to better match safety and efficacy evaluations in clinical trials

VyalevAnti-Parkinson's Agents for OFF Episodes	
Medications	Vyalev (foscarnidopa and foslevodopa) Onapgo (apomorphine)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	<u>Vyalev</u> : Concurrent use with a nonselective monoamine oxidase (MAO) inhibitor (such as phenelzine or tranylcypromine) <u>Onapgo</u> : <u>Concurrent use with 5HT3 antagonists, including antiemetics (e.g. ondansetron, granisetron, dolasetron, palonosetron) and alosetron</u> <u>Concurrent use of Vyalev and Onapgo</u>
Required Clinical Information	See "Other Criteria" below
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a neurologist or in consultation with a neurologist
Coverage Duration	If all of the criteria are met, the initial <u>requests will be approved for up to a 6 month duration</u> and reauthorization requests will be approved for 12 months.
Maximum Billable Units	Variable
Other Criteria	<u>Initial Authorization</u> • Diagnosis of advanced Parkinson's Disease • Medication is prescribed at an FDA approved dose • Prescriber attestation or documentation that the patient is experiencing persistent motor fluctuations despite optimized carbidopa/levodopa therapy (including a minimum of 2.5 hours of "off" time per day) • <u>For Vyalev: Patient is taking ≥400 mg of levodopa/day</u> • <u>For Onapgo: patient is currently taking and will continue to take carbidopa/levodopa</u> • Documented trial and failure (or contraindication) to at least two of the following adjunctive medication classes: ◦ COMT-inhibitors (e.g., entacapone) ◦ Dopamine agonists (e.g., ropinirole, pramipexole) ◦ MAO-B inhibitors (e.g., rasagiline, selegiline) <u>Reauthorization</u> • Documentation or provider attestation of positive clinical response (i.e. increase in "on" time without troublesome dyskinesia, decreased "off" time) • Medication is prescribed at an FDA approved dose If all of the above criteria are not met for initial or re-authorization, the request is referred to a Clinical Reviewer for medical necessity review
Last Review Date	<u>3/20259/2025</u>

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BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Vykat XR	diazoxide choline oral tablet extended release 24 hour 25mg, 75mg, 150mg	Soleno Therapeutics	For the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS)	\$40,000 (for weight 40 to <65 kg) (note price varies greatly based on weight)	None	Non-formulary (see new MRG criteria)
Vanrafia	Atrasentan oral tablet 0.75 mg	Novartis Pharmaceuticals	- Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to creatinine ratio (UPCR) ≥ 1.5 g/g. - This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether VANRAFIA slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.	\$13,356	Filspari	Non-formulary (see new MRG criteria)
dilTIAZem HCl-Sodium Chloride	dilTIAZem HCl-sodium chloride intravenous solution 100-0.72 mg/100ml-%	WG Critical Care, LLC	- Temporary control of rapid ventricular rate in atrial fibrillation or atrial flutter. - Rapid conversion of paroxysmal supraventricular tachycardias (PSVT) to sinus rhythm.	\$38 per IV bag	Calcium channel blockers	Non-formulary
Bisoprolol Fumarate	Bisoprolol fumarate oral tablet 2.5 mg	TruPharma	Use in the management of hypertension. It may be used alone or in combination with other antihypertensive agents.	\$77	Beta blockers	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Dolobid	Diflunisal oral tablet 375 mg	Ina Pharmaceuticals	- Acute or long-term use for symptomatic treatment of the following: - Mild to moderate pain - Osteoarthritis - Rheumatoid arthritis	\$7,500 (max dose of 1.5g per day)	NSAIDs	Non-formulary
Symbravo	Meloxicam-rizatriptan oral tablet 20-10 mg	Axsome Therapeutics	- For the acute treatment of migraine with or without aura in adults Limitations of Use: - Symbravo should only be used where a clear diagnosis of migraine has been established - Symbravo is not indicated for the preventive treatment of migraine - Symbravo is not indicated for the treatment of cluster headache	\$1,150 (for 9 per month)	Triptans, Nurtec, Ubrelvy, etc.	Non-formulary
Lurbipr	Flurbiprofen oral tablet 100 mg	New HeightSRX	- For relief of the signs and symptoms of rheumatoid arthritis - For relief of the signs and symptoms of osteoarthritis.	\$270 (max dose 300mg/day)	NSAIDs	Non-formulary
Clemasz	Clemastine fumarate oral tablet 2.68 mg	New HeightSRX	For the relief of symptoms associated with allergic rhinitis such as sneezing, rhinorrhea, pruritus, and lacrimation. Also indicated for the relief of mild, uncomplicated allergic skin manifestations of urticaria and angioedema. It should be noted that clemastine fumarate is indicated for the dermatologic indications at the 2.68 mg dosage level only.	\$95 (for 2.68mg daily, dose varies per response)	Antihistamines	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Ustekinumab	Ustekinumab intravenous solution 130mg/26ml, subcutaneous solution 45mg/0.5ml, subcutaneous solution prefilled syringe 45mg/0.5ml, 90mg/ml	Janssen Biotech	Adult patients with: • moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy • active psoriatic arthritis (PsA) • moderately to severely active Crohn's disease (CD) • moderately to severely active ulcerative colitis Pediatric patients 6 years of age and older with: • moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy • active psoriatic arthritis (PsA)	\$7,288 every 3 months (for 90mg dose for adults)	Stelara and biosimilars	Non-formulary
Hemiclor	Chlorthalidone oral tablet 12.5 mg	Ingenus Pharmaceuticals	• For the treatment of hypertension in adults, to lower blood pressure.	\$30 per month (for dose of 12.5mg daily)	Thiazide diuretics (ie. HCTZ)	Non-formulary
Imaavy	Nipocalimab-aahu intravenous solution 1200 mg/6.5ml	Janssen Biotech	• For the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive	\$24,960 (maintenance dose for ~70kg patient)	Vyvgart, Vyvgart Hytrulo, Rystiggo	Non-formulary
Tepylute	Thiotepa intravenous solution 15 mg/1.5ml, 100 mg/10ml	Shorla Oncology	• For treatment of adenocarcinoma of the breast or ovary	\$1,114 per dose (for 70kg patient, doses given at 1-to-4-week intervals)	Alkylating agents (cisplatin, cyclophosphamide, etc.)	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Ustekinumab-aekn	Ustekinumab-aekn subcutaneous solution prefilled syringe 45 mg/0.5ml, 90 mg/ml	Teva Pharmaceuticals	Treatment of adult patients with: • moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy • active psoriatic arthritis (PsA) • moderately to severely active Crohn's disease (CD) • moderately to severely active ulcerative colitis Treatment of pediatric patients 6 years and older with: • moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy active psoriatic arthritis (PsA)	\$4,176 every 12 weeks (for 90mg dose).	Stelara biosimilars (Wezlana, Selarsdi, etc.)	Non-formulary
Escitalopram	Escitalopram oxalate oral solution 10 mg/10ml	Chartwell Rx	• Treatment of major depressive disorder (MDD) in adults and pediatric patients 12 years of age and older • Treatment of generalized anxiety disorder (GAD) in adults	\$54 (for dose of 10mg daily)	Fluoxetine, sertraline, paroxetine, etc.	Non-formulary
Wyost	Denosumab-bbdz subcutaneous solution 120 mg/1.7ml	Sandoz	• Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors • Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity • Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy	\$3,208 per dose - depends on indication (ranges from once a week to every 4 weeks)	Xgeva	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Jubbonti	Denosumab-bbdz subcutaneous solution prefilled syringe 60 mg/ml	Sandoz	For the treatment: • of postmenopausal women with osteoporosis at high risk for fracture • to increase bone mass in men with osteoporosis at high risk for fracture • of glucocorticoid-induced osteoporosis in men and women at high risk for fracture • to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer • to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer	\$1,604 per dose (given every 6 months for osteoporosis)	Prolia	Non-formulary
Livmarli	Maralixibat oral tablet 10mg, 15mg, 20mg, 30mg	Mirum Pharmaceuticals	• The treatment of cholestatic pruritus in patients 3 months of age and older with Alagille syndrome (ALGS) • The treatment of cholestatic pruritus in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC) Limitations of Use: Livmarli is not recommended in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in nonfunctional or complete absence of bile salt export pump (BSEP) protein.	\$238,230 (max dose of 40 mg daily)	Bylvay	Non-formulary
Miudella	Intrauterine Copper Device	Sebela Women’s Health	• For prevention of pregnancy in females of reproductive potential for up to 3 years	\$1,139 per device	Paragard IUD	Add to F

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Midazolam-Sodium Chloride	Midazolam-Sodium Chloride (PF) intravenous solution 50-0.9 mg/50ml-% and 100-0.9 mg/100ml-% intravenous solution	Sagent Pharmaceuticals	For sedation of intubated and mechanically ventilated adult, pediatric, and neonatal patients as a component of anesthesia or during treatment in a critical care setting.	\$30 per 100ml bag	Diazepam, lorazepam	Non-formulary
Edurant PED	Rilpivirine Oral Tablet Soluble 2.5 MG	Janssen Products	In combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve patients 2 years of age and older and weighing at least 14 kg with HIV-1 RNA less than or equal to 100,000 copies/mL.	\$2,460 (max dose of 25mg daily)	NNRTIs (efavirenz, nevirapine, etc.)	F (already added via CRF)
Avmapki Fakzynja Co-Pack	Avutometinib & Defactinib co-pack oral therapy pack 0.8 & 200 mg	Verastem	For the treatment of adult patients with KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) who have received prior systemic therapy. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.	\$48,500	None	Non-formulary
Ryzneuta	Efbemalenograstim alfa-vuxw subcutaneous solution prefilled syringe 20 mg/ml	Acrotech Biopharma Inc a	To decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use Ryzneuta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.	\$4,600 per dose (given once per chemo cycle)	Aranesp, Rolvedon, Granix, Neupogen, etc.	Non-formulary (see updated MRG & PAD criteria)

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Emrelis	Telisotuzumab vedotin-tllv 20mg, 100mg intravenous solution reconstituted	Abbvie	For the treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression [≥50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy. This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).	\$33,552 (for 60kg patient)	None	Non-formulary
EPINEPHrine Bitartrate- NaCl	EPINEPHrine Bitartrate- NaCl intravenous solution 16-0.9 mg/250ml-%	Baxter Healthcare	To increase mean arterial blood pressure in adult patients with hypotension associated with septic shock	\$145 per IV bag	Vasopressors	Non-formulary
Bucapsol	Buspirone 7.5mg, 10mg, 15mg oral capsules	Pangea Pharmaceuticals	For the management of anxiety disorders or the short-term relief of the symptoms of anxiety	\$2,982 (for dose of 20 mg/day)	Other anxiolytics (SSRIs, benzodiazepines, etc.)	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Emblaveo	Aztreonam-Avibactam Sodium Intravenous Solution Reconstituted 1.5-0.5 GM	Abbvie	When used in combination with metronidazole, is indicated in patients 18 years and older who have limited or no alternative options for the treatment of complicated intra-abdominal infections (cIAI) including those caused by the following susceptible gram-negative microorganisms: Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca, Enterobacter cloacae complex, Citrobacter freundii complex, and Serratia marcescens. Approval of this indication is based on limited clinical safety and efficacy data for Emblaveo. Usage to Reduce Development of Drug-Resistant Bacteria: To reduce the development of drug-resistant bacteria and maintain the effectiveness of Emblaveo and other antibacterial drugs, Emblaveo should be used only to treat infections that are proven or strongly suspected to be caused by bacteria	\$327 per vial	None	Non-formulary
Khindivi	Hydrocortisone oral solution 1 mg/ml	Eton Pharmaceuticals	Replacement therapy in pediatric patients five years of age and older with adrenocortical insufficiency.	\$11,422 per bottle	Alkindi Sprinkle, Cortef,	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Yutrepia	Treprostinil inhalation capsule 26.5mcg, 53mcg, 79.5mcg, 106mcg	Liquidia Technologies, Inc.	- Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%). - Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).	\$6,090 per box (dose depends on previous treatment)	Tyvaso DPI	Non-formulary
Rosyrah	levonorgestrel and ethinyl estradiol and ethinyl estradiol oral tablet 42-21-21-7 days	Xiromed	For use by females of reproductive potential to prevent pregnancy	\$332 per pack	Quartette, Fayosim, Rivelisa	Non-formulary
Merilog Merilog SoloStar	Insulin Aspart-szjj subcutaneous solution 100 unit/ml Insulin Aspart-szjj subcutaneous solution pen-injector 100 unit/ml	Sanofi	To improve glycemic control in adults and pediatric patients with diabetes mellitus	\$70 per vial \$27 per 3ml pen	NovoLog	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Glassia	Alpha1-proteinase inhibitor 4gm/200ml, 5gm/250ml intravenous solution	Baxalta	- For chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of Alpha -PI (alpha -antitrypsin deficiency). Limitations of Use: - The effect of augmentation therapy with any Alpha -PI, including GLASSIA, on pulmonary exacerbations and on the progression of emphysema in alpha - antitrypsin deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. - Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with Glassia are not available. - Glassia is not indicated as therapy for lung disease in patients in whom severe Alpha -PI deficiency has not been established.	4 GM - \$2,640/vial 5 GM - \$3,300/vial	Prolastin-C, Zemaira, Aralast NP	Non-formulary
Leqselvi	Deuruxolitinib 8mg oral tablet	Sun Pharmaceuticals	For the treatment of adults with severe alopecia areata. Limitation of Use: Leqselvi is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.	\$4,564	Litfulo, Olumiant	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Stoboclo	Denosumab-bmwo Subcutaneous Solution Prefilled Syringe 60 MG/ML	Celltrion USA	For the treatment: • of postmenopausal women with osteoporosis at high risk for fracture • to increase bone mass in men with osteoporosis at high risk for fracture • of glucocorticoid-induced osteoporosis in men and women at high risk for fracture • to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer • to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer	\$1,782 per dose	Prolia, Jubbonti	Non-formulary
Osenvelt	Denosumab-bmwo subcutaneous solution 120 mg/1.7ml	Celltrion USA	• Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors • Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity • Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy	\$3,277 per dose	Xgeva, Wyost	Non-formulary
Ensacove	ensartinib 25mg, 100mg oral capsules	Xcovery Holdings, Inc.	• For the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not previously received an ALK-inhibitor	\$20,960	Xalkori	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Arbli	Losartan oral suspension 10 mg/ml	Scienture	• Treatment of hypertension, to lower blood pressure in adults and children greater than 6 years old. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. • Reduction of the risk of stroke in patients with hypertension and left ventricular hypertrophy. There is evidence that this benefit does not apply to Black patients. • Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes and a history of hypertension	\$594 per 165ml bottle	ARBs	Non-formulary
Zelsuvmi	Berdazimer external gel 10.3 %	LNHC, Inc.	• For the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older	\$1,949 per box	Ycanth	Non-formulary
Zevaskyn	Prademagene zamikeracel external sheet	Abeona Therapeutics	• For the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB)	\$3.1 million per treatment	None	Non-formulary (see new PAD criteria)

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Bonsity	Teriparatide subcutaneous solution pen-injector 560 mcg/2.24ml	Alvogen	• Treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy • Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy • Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy	\$2,598 per pen	Forteo	Non-formulary
Meleya	Norethindrone Oral Tablet 0.35 MG	Xiromed	• For the prevention of pregnancy.	\$4 per pack	Camila, Ortho Micronor, Jolivette, Heather, etc.	Non-formulary
Galbriela	Ethinyl estradiol and norethindrone oral tablet chewable 0.8-25 mg-mcg	Xiromed	• For use by females of reproductive potential to prevent pregnancy	\$97 per pack	Generess, Layolis, Kaitlib, etc.	Add to F
Pruradik	Crotamiton external lotion 10 %	Trifluent Pharma	• For eradication of scabies (Sarcoptes scabiei) and for symptomatic treatment of pruritic skin.	\$1,588 per bottle	Crotan	Non-formulary (see updated MRG criteria)
hydrocodone-acetaminophen	HYDROcodone-Acetaminophen Oral Solution 10-300 MG/15ML	Hikma Pharmaceuticals	• For the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.	\$190 per 473ml bottle	Opioids, NSAIDs, acetaminophen, etc.	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Enflonsia	clesrovimab-cfor 105 mg/0.7 mL prefilled syringe	Merck Sharp & Dohme LLC	For the prevention of RSV lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season	\$556 per dose	Beyfortus	Non-formulary
Nilotinib D-Tartrate	Nilotinib D-Tartrate 50mg, 150mg, 200mg oral capsule	Cipla	- Adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. - Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib.	\$21,960 per month (for dose of 300mg twice daily)	Tasigna, Danziten	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Promethazine	Promethazine HCl oral syrup 6.25 mg/5ml	Xttrium	• Perennial and seasonal allergic rhinitis. Vasomotor rhinitis. • Allergic conjunctivitis due to inhalant allergens and foods. • Mild, uncomplicated allergic skin manifestations of urticaria and angioedema. • Amelioration of allergic reactions to blood or plasma. • Dermographism. • Anaphylactic reactions, as adjunctive therapy to epinephrine and other standard measures, after the acute manifestations have been controlled. • Preoperative, postoperative, or obstetric sedation. • Prevention and control of nausea and vomiting associated with certain types of anesthesia and surgery. • Therapy adjunctive to meperidine or other analgesics for control of post-operative pain. • Sedation in both children and adults, as well as relief of apprehension and production of light sleep from which the patient can be easily aroused. • Active and prophylactic treatment of motion sickness. • Antiemetic therapy in postoperative patients.	\$7 per bottle	Prochlorperazine, ondansetron, diphenhydramine, doxylamine, meclizine, etc.	Add to F

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Zepbound	tirzepatide subcutaneous solution 12.5 mg/0.5mL, 15 mg/0.5 mL	Eli Lilly and Company	A glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated in combination with a reduced-calorie diet and increased physical activity: - to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition. - to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.	\$1,019-\$1,259 (AWP price for 4 vials)	Wegovy, Saxenda	Non-formulary, remove Zepbound 2.5mg/0.5ml and 5mg/0.5ml single dose vials from formulary
Xifyrm	meloxicam intravenous solution 30 mg/mL	Azurity Pharmaceuticals	For use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics	\$30 (per 30 mg dose)	Other oral or IV NSAIDs	Non-formulary
Gonal-f RFF	follitropin alfa rediject subcutaneous solution pen-injector 900 unit/1.44 mL	Serono	- Induction of ovulation and pregnancy in oligoanovulatory women in whom the cause of infertility is functional and not due to primary ovarian failure. - Development of multiple follicles in ovulatory women as part of an Assisted Reproductive Technology (ART) cycle.	\$2,898 (per 900 unit device)	Follistim AQ	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Imuldosa	ustekinumab-srlf subcutaneous solution prefilled syringe 45 mg/0.5 mL, 90 mg/mL, intravenous solution 130 mg/26 mL	Golden State Medical Supply	Adult patients with: • moderate to severe plaque psoriasis (PsO)who are candidates for phototherapy or systemic therapy. • active psoriatic arthritis (PsA). • moderately to severely active Crohn’s disease (CD). • moderately to severely active ulcerative colitis. Pediatric patients 6 years and older with: • moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy. • active psoriatic arthritis (PsA).	\$2,332 (every 12 weeks, 90mg dose)	Other ustekinumab biosimilars (Selarsdi, Pyzchiva, etc.)	Add to F-PA (see updated MRG criteria)
Crenessity	crinecerfont oral capsule 25 mg	Neurocrine Biosciences	• An adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH)	\$19,166 (per 30 days)	None	Non-formulary
Zusduri	mitomycin intravesical solution reconstituted 40 mg, 80 mg	Urogen Pharma	• Treatment of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC)	\$129,000 (6-week course of therapy)	None	Non-formulary
Averi	desogestrel-ethinyl estradiol oral tablet 0.15-0.03 mg	Avion Pharmaceuticals	• For the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception	\$207 (per 28-day pack)	Other oral contraceptives	Add to F
Ibtrozi	taletrectinib adipate oral capsule 200 mg	Nuvation Bio	• Treatment of adult patients with locally advanced or metastatic <i>ROS1</i>-positive non-small cell lung cancer (NSCLC)	\$29,487 (per month)	Rozlytrek, Xalkori	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Yeztugo	lenacapavir subcutaneous solution 463.5 mg/1.5 mL, oral tablet 300 mg	Gilead	For pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition	\$14,109 (subcutaneous maintenance dosing every 6 months)	Descovy, emtricitabine-tenofovir disoproxil fumarate	F (already added via CRF)
Abigale Lo	estradiol-norethindrone	Xiromed	- Treatment of Moderate to Severe Vasomotor Symptoms due to Menopause - Treatment of Moderate to Severe Symptoms of Vulvar and Vaginal Atrophy due to Menopause Limitation of Use: When prescribing solely for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause, first consider the use of topical vaginal products. - Prevention of Postmenopausal Osteoporosis Limitation of Use: When prescribing solely for the prevention of postmenopausal osteoporosis, first consider the use of non-estrogen medications. Consider estrogen therapy only for women at significant risk of osteoporosis.	\$17 (per 28-day pack)	Menopause hormone therapy (Activella, Mimvey Lo)	Non-formulary
GNP Naloxone (OTC)	naloxone nasal liquid 4 mg/0.1 mL	Amerisource Bergen	Emergency treatment of opioid overdose	\$28 (box of 2)	Naloxone injection, Kloxxado, Opvee	Add to F

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
COVID-19 Flu A+B Antigen Test In Vitro Kit	COVID-19 Flu A+B Antigen Test In Vitro Kit	Walgreens	OTC item; COVID and flu test kit	\$23 (AWP pricing; box of 2)	Other OTC test kits for COVID-19 and/or influenza, provider-based testing	Non-formulary
Insupen32G Extr3me	Insulin pen needles 32G X 6 mm	HTL-STREFA	OTC item; insulin pen needles	\$68 (box of 100)	Other pen needle brands (BD, Novo Nordisk) and sizes	Non-formulary
Tryptyr	acoltremon ophthalmic solution 0.003 %	Alcon	Treatment of the signs and symptoms of dry eye disease	\$879	Cyclosporine, Xiidra	Add to F-PA (see updated PA criteria)
Lopressor	metoprolol oral solution 10 mg/mL	Validus	- For the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions - In the long-term treatment of angina pectoris - In the treatment of hemodynamically stable patients with definite or suspected myocardial infarction, to reduce the risk of cardiovascular mortality when used in conjunction with intravenous metoprolol therapy	\$375	Beta blockers (metoprolol, bisoprolol, labetalol)	Non-formulary
Fanapt	iloperidone titration pack C oral miscellaneous 1 & 2 & 6 mg, titration pack B oral miscellaneous 1 & 2 & 6 & 8 mg	Vanda	- Treatment of schizophrenia in adults - Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults	\$246	Atypical antipsychotics (risperidone, lurasidone, quetiapine)	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Pyzchiva	ustekinumab-ttwe subcutaneous solution 45 mg/0.5 mL	Sandoz	Treatment of adult patients with: • moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy • active psoriatic arthritis (PsA) • moderately to severely active Crohn's disease (CD) • moderately to severely active ulcerative colitis Treatment of pediatric patients 6 years and older with: • moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy active psoriatic arthritis (PsA)	\$4,176 every 12 weeks (for 45 mg dose)	Stelara, Skyrizi, Tremfya, Ilumya, Wezlana, Yesintek, Steqeyma, & other Stelara biosimilars	Non-formulary
Conexence	denosumab-bnht subcutaneous solution prefilled syringe 60 mg/mL	Fresenius Kabi	• Treatment of postmenopausal women with osteoporosis at high risk for fracture • To increase bone mass in men with osteoporosis at high risk for fracture • Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture • To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer • To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer	\$1,819 (60 mg dose administered every 6 months)	Jubbonti, Stoboclo	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Bomyntra	denosumab-bnht subcutaneous solution Prefilled Syringe 120 mg/1.7 mL, vial 120 mg/1.7 mL	Fresenius Kabi	- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors - Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity - Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy	\$3,346	Wyost, Osenvelt	Non-formulary
Abigale	estradiol-norethindrone oral tablet 1-0.5 mg	Xiromed	- Treatment of moderate to severe vasomotor symptoms due to menopause - Treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause - Prevention of postmenopausal osteoporosis	\$16	Menopause hormone therapy (Activella)	Non-formulary
Aerochamber2GO	aerochamber 2go anti-static device	Monaghan Medical	OTC item; spacer device for use with inhaler	\$38 (per each)	Other spacer brands and models	Non-formulary
Fanapt	iloperidone titration pack C oral miscellaneous 1 & 2 & 4 & 6 mg, titration pack A	Vanda	- Treatment of schizophrenia in adults - Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults	\$246	Atypical antipsychotics (risperidone, lurasidone, quetiapine)	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Lynozyfic	linvoseltamab-gcpt 5 mg/2.5ml, 200 mg/10ml intravenous solution	Regeneron	- For the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. - This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).	\$18,880 per week (given once weekly from Week 4 to Week 13 for 10 treatment doses)	Tecvayli, Elrexfio, Talvey	Non-formulary
Carbzah	Carbinoxamine 4 mg/5ml oral solution	IPG Pharmaceuticals	- Seasonal and perennial allergic rhinitis. - Vasomotor rhinitis. - Allergic conjunctivitis due to inhalant allergens and foods. - Mild, uncomplicated allergic skin manifestations of urticaria and angioedema. - Dermatographism. - As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled. - Amelioration of the severity of allergic reactions to blood or plasma.	\$2,484 per bottle	Antihistamines	Non-formulary

*	Pricing reflects Wholesale Acquisition Cost (WAC) per month unless otherwise noted.
^	The recommendation may be affected by state specific requirements including carve out lists and individual state mandates.
†	Pricing based on standard twice-monthly dosing for most indications.
‡	Pricing is per each kit on items listed as a kit.

#	Re-activation of previously discontinued product (i.e., other available NDCs now inactive)

Alameda Old Business MRG Criteria Review

Recommendation: include trial and failure of any tricyclic antidepressant (TCA)

Lidocaine Patch	
Therapeutic Classes (AHFS)	ANTIPRURITICS AND LOCAL ANESTHETICS
Medications	<u>Formulary-PA</u> Lidocaine (Lidoderm) 5% transdermal patch <u>Non-Formulary</u> ZTlido (lidocaine) 1.8% patch Lidocaine 4% patch Lidaflex (lidocaine) 4% patch Any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval 12 months (for up to a maximum of #90 patches per 30 days) Later Approvals 12 months (for up to a maximum of #90 patches per 30 days) If criteria is not met, request will be sent to a clinical reviewer for medical necessity review.
PA Review Criteria	<u>CRITERIA FOR AUTHORIZATION for lidocaine 5% patch</u> • Diagnosis of neuropathic pain AND • Documented trial and failure or intolerance to gabapentin at least 1800mg per day for 90 days in the last 365 days OR documented trial and failure or intolerance to pregabalin at least 300mg per day for 90 days in the last 365 days AND • Documented trial of a therapeutic dose and duration of one other formulary alternative (e.g., duloxetine, venlafaxine, <u>any tricyclic antidepressant (TCA), such as: nortriptyline, amitriptyline, desipramine, etc.</u>) in the last 365 days OR • Member is using over 50 mg morphine equivalence/day for 3 months. <u>CRITERIA FOR AUTHORIZATION for non-formulary patches</u> • The member meets the criteria for lidocaine 5% patch, as outlined in the section above AND • Documented trial and failure or intolerance to lidocaine 5% patch
Criteria Statement	Lidocaine 5% patches are reserved for members with neuropathic pain who have used (or cannot/should not use) gabapentin 1800 mg (or more) OR pregabalin 300mg (or more) AND one other formulary alternative (e.g., duloxetine, venlafaxine, <u>any TCA amitriptyline</u>). Non-formulary patches are reserved for members with neuropathic pain who have used (or cannot/should not use) gabapentin 1800 mg (or more) OR pregabalin 300mg (or more) AND one other formulary alternative (e.g., duloxetine, venlafaxine, <u>any</u>

	~~TCA~~ ~~amitriptyline~~) AND who have used (or cannot/should not use) lidocaine 5% patches.
Last P&T Review Date	~~6/2024~~ <u>9/2025</u>

Recommendation: change trial and failure agents to just lorazepam, since it's also a short-acting benzodiazepine versus longer-acting agents (clonazepam/diazepam).

Alprazolam (Xanax)	
Therapeutic Classes (AHFS)	BENZODIAZEPINES (ANXIOLYTIC, SEDATIVE/HYPNOTIC)
Medications	Non-formulary Alprazolam oral tablets (0.25mg, 0.5mg, 1mg and 2mg) Alprazolam oral ER tablets (0.5mg, 1mg, 2mg and 3mg) Alprazolam oral disintegrating tablets (0.25mg, 0.5mg, 1mg and 2mg)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Psychiatry
Coverage Duration	Initial Approval 3 months Later Approvals 3 months If criteria is not met, request will be sent to a clinical reviewer for medical necessity review.
PA Review Criteria	<u>CRITERIA FOR AUTHORIZATION</u> - Request is for alprazolam oral tablets: - Diagnosis of anxiety or panic disorders - Clinic notes to show trial and failure/<u>contraindication/intolerance</u> of <u>lorazepam at least 3 formulary benzodiazepines for at least 2 weeks (14 days) of therapy each (for example — clonazepam, diazepam and lorazepam)</u> - Request is for alprazolam oral disintegrating (ODT) tablets: - Diagnosis of anxiety or panic disorder - Clinic notes to show trial and failure/<u>contraindication/intolerance</u> of <u>lorazepam at least 3 formulary benzodiazepines for at least 2 weeks (14 days) of therapy each</u> - AND - Inability to swallow or another medical reason why alprazolam oral tablets cannot be used - Request is for alprazolam oral ER tablets: - Diagnosis of panic disorder - Clinic notes to show trial and failure/<u>contraindication/intolerance</u> of <u>lorazepam at least 3 formulary benzodiazepines for at least 2 weeks (14 days) of therapy each</u> - AND - Trial and failure of alprazolam oral tablets <u>RE-AUTHORIZATION</u> Documentation of clinical benefit and/or titration schedule for discontinuation (if applicable). Treatment plan should also be given for those on long term treatment (more than 3 months of therapy).
	Alprazolam oral tablets are reserved for members who have used (or cannot/should not use) <u>lorazepam. 3 formulary benzodiazepines for at least 2 weeks (14 days) of therapy each.</u> Alprazolam oral disintegrating (ODT) tablets are reserved for members who have used (or cannot/should not use) <u>lorazepam 3 formulary benzodiazepines for at least 2 weeks (14 days) of therapy each</u> AND who cannot/should not use alprazolam oral

	tablets or cannot swallow. Alprazolam ER tablets are reserved for members who have used (or cannot/should not use) <u>lorazepam</u> ~~3 formulary benzodiazepines for at least 2 weeks (14 days) of therapy each~~ AND who cannot/should not use alprazolam oral tablets.
Last P&T Review Date	<u>6/2024</u> <u>9/2025</u>

Recommendation: Add language to initial authorization to allow coverage for patients who started bumetanide in a hospital as a hospital discharge medication.

Diuretics	
Therapeutic Classes (AHFS)	Loop Diuretics, Thiazide-like Diuretics
Medications	Formulary, step therapy required Bumetanide tablet Metolazone tablet (quantity limit 30/30)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial Approval 12 months Reauthorization 12 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	Bumetanide step therapy criteria: - Documentation of a trial and failure or intolerance to torsemide 100 mg or furosemide 80 mg required OR <u>The medication was started in the hospital and member will continue on it outpatient-</u> Metolazone step therapy criteria: - Documentation of a trial and failure or intolerance to hydrochlorothiazide AND furosemide required.
	Bumetanide is reserved for members who have used (or cannot/should not use) torsemide 100 mg or furosemide 80 mg. <u>In addition, it is reserved for members who started the medication in the hospital and will continue on it outpatient-</u> Metolazone is reserved for members who have used (or cannot/should not use) hydrochlorothiazide AND furosemide.
Last P&T Review Date	<u>6/2024/2025</u>

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Prevymis	Letermovir oral packet 120mg, 20mg	Merck Sharp & Dohme LLC	- Prophylaxis of cytomegalovirus (CMV) infection and disease in adult and pediatric patients 6 months of age and older and weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) - Prophylaxis of CMV disease in adult and pediatric patients 12 years of age and older and weighing at least 40 kg who are kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])	\$342 – \$2,058 per box (dosing is body weight and indication specific in pediatric patients)	Ganciclovir, Foscavir, Valcyte	Non-formulary
Jivi	antihemophilic factor (recombinant), PEGylated-aucI intravenous solution reconstituted 4000 unit	Bayer	- On-demand treatment and control of bleeding episodes - Perioperative management of bleeding - Routine prophylaxis to reduce the frequency of bleeding episodes	\$3 per vial	Advate, Adynovate, Eloctate, Hemlibra, Novoeight, Recombinate, etc.	Non-formulary
Fenopron	Fenoprofen oral capsule 300mg	Galt Pharmaceuticals, LLC	- Relief of mild to moderate pain in adults - Relief of the signs and symptoms of rheumatoid arthritis - Relief of the signs and symptoms of osteoarthritis	\$22 per capsule (dose varies from 200mg – 600mg every 4 to 6 hours as needed)	Nalfon, ibuprofen, ketoprofen, diclofenac, etodolac, etc.	Non-formulary
Alhemo	concizumab-mtci pen-injector 60mg/1.5ml, 150 mg/1.5ml	Novo Nordisk Inc.	For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with: - hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors - hemophilia B (congenital factor IX deficiency) with FIX inhibitors	\$51,600 per month (cost of two 150mg pens per month) (maintenance dose varies based on concentration post loading dose)	Hypnavzi	Non-formulary (see updated MRG policy)

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Steqeyma	ustekinumab-stba subcutaneous solution prefilled syringe 45 mg/0.5ml, 90mg/ml	Celltrion USA, Inc.	Treatment of adult patients with: • moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy • active psoriatic arthritis (PsA) • moderately to severely active Crohn's disease (CD) • moderately to severely active ulcerative colitis Treatment of pediatric patients 6 years and older with: • moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy • active psoriatic arthritis (PsA)	\$4,176 every 12 weeks (for 90mg dose)	Stelara, Skyrizi, Tremfya, Ilumya, Wezlana & other Stelara biosimilars (once they launch)	Non-formulary (see updated MRG policy)
Datroway	Datopotamab deruxtecandlnk intravenous solution reconstituted 100 mg	Daiichi Sankyo, Inc.	For the treatment of adult patients with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.	\$19,564 every 3 weeks (dose is weight specific)	Trodelvy	Non-formulary
Adalimumab-adaz	Adalimumab-adaz Subcutaneous Solution Prefilled Syringe 20 MG/0.2ML	Sandoz	• Rheumatoid Arthritis • Juvenile Idiopathic Arthritis • Psoriatic Arthritis • Ankylosing Spondylitis • Crohn's Disease • Ulcerative Colitis • Plaque Psoriasis • Hidradenitis Suppurativa • Uveitis <i>Note: Adalimumab-adaz has many approved indications. See full prescribing information for details of each indication.</i>	\$657 per syringe	Humira, Amjevita, Idacio, Cyltezo, Hyrimoz, Yusimry, Yuflyma, Hadlima and other biosimilars	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Esperoct	Antihemophilic Factor (recombinant) glycopegylated-exei 4,000 unit	Novo Nordisk	For use in adults and children with hemophilia A for: - On-demand treatment and control of bleeding episodes - Perioperative management of bleeding - Routine prophylaxis to reduce the frequency of bleeding episodes Limitations of use: Esperoct is not indicated for the treatment of von Willebrand disease.	\$3 per vial	Advate, Jivi, Adynovate, Eloctate, Hemlibra, Novoeight, Recombinate, etc	Non-formulary
Simlandi	adalimumab-ryvk subcutaneous prefilled syringe kit 20 mg/0.2ml, 80mg/0.8ml	Teva Pharmaceuticals	Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn’s Disease, Ulcerative Colitis, Plaque Psoriasis, Hidradenitis Suppurativa, Uveitis	\$519 per dose (20mg syringe) \$1,038 per dose (80mg syringe)	Humira, Amjevita, Idacio, Cyltezo, Hyrimoz, Yusimry, Yuflyma, Hadlima and other biosimilars	F-QL (already added via CRF) (QL: 80mg/0.8mL: 2 syringes/28 days, LD: 4 syringes; 20mg/0.2mL: 4 syringes/28 days, LD: use 40mg strength)
Fulvicin P/G	Griseofulvin oral tablet 165mg	Solubiomix LLC	Fungal infections (see PI for full details)	\$5,184 per month (for twice daily dosing, dose is weight and indication specific)	Terbinafine, itraconazole, fluconazole, etc.	Non-formulary
Steqeyma	ustekinumab-stba intravenous solution 130 mg/26ml	Celltrion USA, Inc.	Treatment of adult patients with: - moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy - active psoriatic arthritis (PsA) - moderately to severely active Crohn's disease (CD) - moderately to severely active ulcerative colitis Treatment of pediatric patients 6 years and older with: - moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy - active psoriatic arthritis (PsA)	\$911 single infusion for UC or CD (for patients weighing 55 kg to 85 kg)	Stelara, Skyrizi, Tremfya, Ilumya, Wezlana, Yesintek, &other Stelara biosimilars (once they launch)	Non-formulary (see updated MRG policy)

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Yesintek	Ustekinumab-kfce subcutaneous solution/ prefilled syringe 45 MG/0.5ML, 90 MG/ML	Biocon Biologics	Treatment of adult patients with: • moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy • active psoriatic arthritis (PsA) • moderately to severely active Crohn's disease (CD) • moderately to severely active ulcerative colitis Treatment of pediatric patients 6 years and older with: • moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy active psoriatic arthritis (PsA)	\$3,000 every 12 weeks (for 90mg dose)	Stelara, Skyrizi, Tremfya, Ilumya, Wezlana, Steqeyma, & other Stelara biosimilars (once they launch)	Add to F-PA (see updated MRG policy)
Niktimvo	Axatilimab-csfr intravenous solution 9mg/0.18ml, 22mg/0.44ml	Incyte	• For the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg	\$23,100 per month (for 70kg patient)	Rezuorck, Imbruvica	Non-formulary (see new PAD policy)
Metformin [#]	Metformin HCl oral tablet 750mg	Lifsa Drugs	• As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus	\$33 per tablet (based on WAC, NADAC and MAC pricing not available)	DPP4 inhibitors, GLP1 agonists, sulfonylureas, thiazolidinediones, etc.	Non-formulary
Frindovyx	Cyclophosphamide intravenous solution 500mg/ml, 1g/2ml, 2g/4ml	Avyxa Pharma	• For treatment of adults and pediatric patients with malignant diseases: malignant lymphomas: Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma; multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of ovary, retinoblastoma, breast carcinoma	\$875 per ml (dose depends on regimen and body weight)	Bendamustine, ifosfamide (and other antineoplastic alkylating agents)	Non-formulary
Griseofulvin	Griseofulvin ultramicrosize oral tablet 165 mg	Ayurax	• Fungal infections (see PI for full details)	\$33 per tablet (based on WAC, NADAC and MAC pricing not available)	Terbinafine, itraconazole, fluconazole, etc.	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Halcinonide	Halcinonide External Solution 0.1%	Ina Pharmaceuticals	For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses	\$624 per bottle	High potency steroids – fluocinonide, betamethasone dipropionate, clobetasol propionate, etc.	Non-formulary
Ustekinumab-ttwe	Ustekinumab-ttwe subcutaneous solution prefilled syringe 45 mg/0.5ml, 90mg/ml Ustekinumab-ttwe intravenous solution 130 mg/26ml	Quallent Pharmaceuticals	Treatment of adult patients with: - moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy - active psoriatic arthritis (PsA) - moderately to severely active Crohn's disease (CD) - moderately to severely active ulcerative colitis Treatment of pediatric patients 6 years and older with: - moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy - active psoriatic arthritis (PsA)	\$15,742 every 12 weeks (for 90mg dose)	Yesintek, Stelara, Skyrizi, Tremfya, Ilumya, Wezlana, Steqeyma, & other Stelara biosimilars (once they launch)	Non-formulary (see updated MRG policy)
Journavx	Suzetrigine 50mg oral tablet	Vertex Pharmaceuticals	For the treatment of moderate to severe acute pain in adults	\$434 for 14 days of treatment	Opioids	Non-formulary
Feirza 1.5/30	ethinyl estradiol and norethindrone oral tablet 1.5-30 mg-mcg	Xiromed	For the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception	\$8 per pack	Loestrin, Microgestin, Larin, Junel, etc.	Add to F
Valtya 1/50	ethynodiol diacetate and ethinyl estradiol oral tablet 1-50 mg-mcg	Xiromed	For the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception	\$24 per pack	Kelnor 1/50	Add to F
Rybelsus	Semaglutide oral tablet 1.5mg, 4mg, 9mg	Novo Nordisk	An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	\$997 (max dose of 9mg/day)	Ozempic, Trulicity, etc.	F-ST-QL (Already added via CRF) ST: Requires a previous trial with a metformin-containing product. QL: 30 tabs/30 days

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Palforzia	Peanut allergen powder - initial dose 1-3yrs oral capsule sprinkle therapy pack 0.5 & 1 & 1.5 & 3 mg - initial dose 4-17yrs oral capsule sprinkle therapy pack 0.5 & 1 & 1.5 & 3 & 6 mg - oral capsule sprinkle therapy pack 1 x 1 mg	Greer Laboratories	For the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. Palforzia is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 years of age and older. Palforiza is to be used in conjunction with a peanut-avoidant diet. Limitation of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.	\$960 per pack	Xolair	Non-formulary
Evrysdi	Risdiplam 5mg oral tablet	Genentech	For the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients	\$33,660	Spinraza, Zolgensma	Non-formulary
Selarsdi	Ustekinumab-aekn subcutaneous solution prefilled syringe 45 mg/0.5ml, 90mg/ml	Teva Pharmaceuticals	Treatment of adult patients with: - moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy - active psoriatic arthritis (PsA) - moderately to severely active Crohn's disease (CD) - moderately to severely active ulcerative colitis Treatment of pediatric patients 6 years and older with: - moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy - active psoriatic arthritis (PsA)	\$4,176 every 12 weeks (for 90mg dose)	Stelara, Skyrizi, Tremfya, Ilumya, Wezlana, Yesintek, Steqeyma, & other Stelara biosimilars (once they launch)	Non-formulary (see updated MRG policy)

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Gomekli	Mirdametinib oral capsule 1mg, 2mg Mirdametinib oral tablet soluble 1mg	Springwork Therapeutics	For the treatment of adult and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection	\$34,650 (for average adult BSA)	Koselugo	Non-formulary (see new MRG policy)
Grafapex	Treosulfan IV solution reconstituted 1gm, 5m	Medexus Pharma	- Use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (alloHSCT) in adult and pediatric patients 1 year of age and older with acute myeloid leukemia (AML) - Use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation in adult and pediatric patients 1 year of age and older with myelodysplastic syndrome (MDS)	\$610 per gram	Melphalan, busulfan	Non-formulary
Zepbound	Tirzepatide subcutaneous solution 7.5mg/0.5ml, 10mg/0.5ml	Eli Lilly	Indicated in combination with a reduced-calorie diet and increased physical activity: - to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition - to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity Limitations of use: Coadministration with other tirzepatide-containing products or with any GLP-1 receptor agonist is not recommended	\$838 (per month for 10mg dose)	Wegovy, Saxenda	Non-formulary
OmvoH (300mg dose)	Mirikizumab-mrkz (300 mg dose) subcutaneous solution auto-injector and prefilled syringe 100 mg/ml & 200 mg/2ml	Eli Lilly	- Treatment of moderately to severely active ulcerative colitis in adults - Treatment of moderately to severely active Crohn's disease in adults	\$10,878	Humira, Infliximab, Rinvoq, Stelara, Entyvio	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Onapgo	Apomorphine hydrochloride subcutaneous solution cartridge 98 mg/20ml	Supernus Pharmaceuticals	For the treatment of motor fluctuations in adults with advanced Parkinson's disease	\$8,628	Vyalev, Apokyn	Non-formulary
Ivra	Melphalan intravenous solution 90 mg/ml	Apotex	For palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate	\$5,500 per vial	Bendamustine, cyclophosphamide (both off label)	Non-formulary
Xromi	Hydroxyurea oral solution 100 mg/ml	Rare Disease Therapeutics	To reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients 6 months of age and older with sickle cell anemia with recurrent moderate to severe painful crises	\$760 per bottle	Droxia, Siklos	Non-formulary
Metaxalone	Metaxalone oral tablet 640 mg	Ina Pharmaceuticals	Muscle relaxant indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions in adult and pediatric patients 13 years of age and older	\$ 4,510 (per month for max dose)	Flexeril, Zanaflex, NSAIDs	Non-formulary
Zunveyl	Benzgalantamine oral tablet delayed release 5 mg, 15mg	Alpha Cognition Inc.	For the treatment of mild to moderate dementia of the Alzheimer's type in adults	\$749 (per month for max dose)	Adlarity, Aricept, galantamine, Namzaric, Exelon	Non-formulary (see updated MRG policy)
Feirza 1/20	ethinyl estradiol and norethindrone oral tablet 1-20 mg-mcg	Xiromed	For the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception	\$8 per pack	Loestrin, Microgestin, Larin, Junel, etc.	Add to F
Promethazine	Promethazine hcl oral solution 12.5 mg/10ml	Chartwell Rx	Antihistamine with multiple approved indications such as seasonal allergic rhinitis, motion sickness, and nausea/vomiting. See full PI for details.	\$100.5 per unit dose cup (10mL)	Zyrtec, Claritin, Benadryl, etc.	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Valtoco	Diazepam 15 mg dose nasal liquid therapy pack 2 x 7.5 mg/0.1ml Diazepam 20 mg dose nasal liquid therapy pack 2 x 10 mg/0.1ml	Neurelis	For the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older	\$1,830 per box	Nayzilam	Non-formulary
Pyzchiva	Ustekinumab-ttwe subcutaneous solution prefilled syringe 45mg/0.5ml and 90 mg/ml Ustekinumab-ttwe Intravenous Solution 130 MG/26ML	Sandoz	Treatment of adult patients with: - moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy - active psoriatic arthritis (PsA) - moderately to severely active Crohn's disease (CD) - moderately to severely active ulcerative colitis Treatment of pediatric patients 6 years and older with: - moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy - active psoriatic arthritis (PsA)	\$5,830 every 12 weeks (for 90mg dose)	Stelara, Skyrizi, Tremfya, Ilumya, Wezlana, Yesintek, Steqeyma, & other Stelara biosimilars (once they launch)	Non-formulary (see updated MRG policy)
Alhemo	Concizumab-mtci subcutaneous solution pen-injector 300 mg/3ml	Novo Nordisk	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with: - hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors - hemophilia B (congenital factor IX deficiency) with FIX inhibitors	\$51,600 per month (for one 300mg pen per month)	Hympavzi	Non-formulary (see updated MRG policy)
Raldesy	Trazodone oral solution 10 mg/ml	Validus Pharmaceuticals	For the treatment of major depressive disorder (MDD) in adults	\$1,944 per month (for a dose of 400mg per day)	Vilazodone, Vortioxetine, SSRIs, atypical agents, SNRIs, tricyclic/tetracyclic antidepressants, MAOis	Non-formulary
Vimkunya	Chikungunya vaccine, recombinant intramuscular suspension prefilled syringe 40 mcg/0.8ml	Bavarian Nordic	For the prevention of disease caused by chikungunya virus (CHIKV) in individuals 12 years of age and older	\$275 per dose	Ixchiq	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
BKEMV	Eculizumab-aeeb intravenous solution 300 mg/30ml	Amgen	- Treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis - Treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy Limitation of Use: BKEMV is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)	\$5,870/300 mg vial	Soliris, Epysqli, & other Soliris biosimilars (once they launch)	Non-formulary (see updated MRG and PAD policies)
Otufi	Ustekinumab-aaaz subcutaneous solution prefilled syringe 45 mg/0.5ml Ustekinumab-aaaz subcutaneous solution prefilled syringe 90 mg/ml Ustekinumab-aaaz intravenous solution 130 mg/26ml	Fresenius Kabi	Treatment of adult patients with: - moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy - active psoriatic arthritis (PsA) - moderately to severely active Crohn’s disease (CD) - moderately to severely active ulcerative colitis Treatment of pediatric patients 6 years and older with: - moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy - active psoriatic arthritis (PsA)	\$3,619 every 12 weeks (for 90 mg dose)	Stelara, Skyrizi, Tremfya, Ilumya, Wezlana, Yesintek, Steqeyma, & other Stelara biosimilars (once they launch)	Add to F-PA (see updated MRG policy)
Romvimza	Vimseltinib oral capsule 14, 20, 30 mg	Deciphera Pharmaceuticals	For the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity	\$26,128 per month	Turalio	Non-formulary
Zunveyl	Benzgalantamine oral tablet delayed release 10 mg	Alpha Cognition USA	For the treatment of mild to moderate dementia of the Alzheimer's type in adults	\$749 per month (for max dose of 15mg twice daily)	Adlarity, Aricept, galantamine, Namzaric, Exelon	Non-formulary (see updated MRG policy)
Lidocaine HCl	Lidocaine HCl urethral/mucosal external gel 2 %	Armas Pharmaceuticals	For prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal)	\$247 for max dose of 30 ml in a 12 hour period	Xylocaine, Jelcaine Sterile	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Epysqli	Eculizumab-aagh intravenous solution 300 mg/30ml	Teva Pharmaceuticals	- The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. - The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complementmediated thrombotic microangiopathy.	\$4,566 per 300mg vial	Soliris, BKEMV	Non-formulary (see updated MRG and PAD policies)
Purified Cortrophin Gel	Corticotropin subcutaneous prefilled syringe 40 unit/0.5ml, 80 unit/ml	ANI Pharmaceuticals	Rheumatic disorders, Collagen diseases, Dermatologic diseases, Allergic states, Ophthalmic diseases, Symptomatic sarcoidosis, Nephrotic syndrome and Multiple Sclerosis	\$7,421 per 1ml syringe	Cortrophin, Acthar	F-PA (Already added via CRF)
Inzirqo	hydrochlorothiazide oral suspension 10mg/ml	ANI Pharmaceuticals	- The treatment of hypertension in adult and pediatric patients alone or in combination with other antihypertensive agents, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarction. - The treatment of edema associated with congestive heart failure, hepatic cirrhosis and renal disease including the nephrotic syndrome in adult and pediatric patients.	\$702 per month (for dose of 50mg daily)	Thiazide diruetics	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Xpovio (40 MG Once Weekly)	Selinexor (40 mg once weekly) oral tablet therapy pack 10 mg	Karyopharm Therapeutics	- In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy, - In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody - For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).	\$8,196 per week	Velcade, Kyprolis, Ninlaro, Revlimid	Non-formulary
Ryoncil	remestemcel-L various intravenous kit sizes	Mesoblast	Indicated for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older	\$194k per infusion	Rezurock, Imbruvica, Niktimvo	Non-formulary (see new PAD policy)
Abirtega	Abiraterone acetate oral tablet 250mg	Civicascript	Indicated in combination with prednisone for the treatment of patients with: - metastatic castration-resistant prostate cancer (CRPC) - metastatic high-risk castration-sensitive prostate cancer	\$120 per pack of 120 tablets	Zytiga, Yonsa	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Emend BiPack	Aprepitant oral capsule 80mg	Merck Sharp & Dohme	In combination with other antiemetic agents, in patients 12 years of age and older for prevention of: - acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin - nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC)	\$438 per pack (pack of 2)	Aponvie, Cinvanti, Zofran, Focinvez	Non-formulary
BAC (Butalbital- Acetamin-Caff)	Butalbital-acetaminophen- caff oral tablet 50-325- 40mg	Mikart	For the relief of the symptom complex of tension (or muscle contraction) headache	\$367 per month (for max dose of 6 per day)	Esgic, Fioricet	Non-formulary
cefazolin sodium- dextrose	cefazolin sodium-dextrose intravenous solution reconstituted 3-2 gm-% (50ml)	B. Braun Medical	- Treatment of the following infections caused by susceptible isolates of the designated microorganisms in adult and pediatric patients for whom appropriate dosing with this formulation can be achieved: - Respiratory tract infections - Urinary tract infections - Skin and skin structure infections - Biliary tract infections - Bone and joint infections - Genital infections - Septicemia - Endocarditis - Perioperative prophylaxis in adults and pediatric patients aged 10 to 17 years old for whom appropriate dosing with this formulation can be achieved	\$15 per bag	Other cephalosporins and antibacterials	Non-formulary
Simlandi	Adalimumab-ryvk (1 pen) subcutaneous auto- injector kit 80 mg/0.8ml	Teva Pharmaceuticals	Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis, Hidradenitis Suppurativa, Uveitis	\$1,038 per kit	Humira, Amjevita, Idacio, Cyltezo, Hyrimoz, Yusimry, Yuflyma, Hadlima and other biosimilars	F-QL (Already added via CRF) (QL: 2 pens/28 days; LD: 4 pens)

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Sevenfact	coagulation factor viia-jncw intravenous solution reconstituted 2 mg	Hema Biologics	For the treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors Limitation of Use: Sevenfact is not indicated for treatment of congenital factor VII deficiency	\$2.66 per vial	NovoSeven RT, Advate, Recombinate, etc.	Non-formulary
Ivermectin	ivermectin oral tablet 6 mg	Advagen Pharma	- Strongyloidiasis of the intestinal tract - Onchocerciasis	\$11 per tablet	Moxidectin	Non-formulary
Revuforj	Revumenib oral tablet 25 mg	Syndax Pharmaceuticals	For the treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year and older	\$333 per tablet (25mg tablets used for BSA dosing in patients weighing less than 40kg)	Venflexta	Non-formulary
Rapiblyk	Landiolol intravenous solution reconstituted 280 mg	AOP Orphan Pharmaceuticals	For the short-term reduction of ventricular rate in adults with supraventricular tachycardia including atrial fibrillation and atrial flutter	\$850 per vial	Adenosine, amiodarone, metoprolol, etc.	Non-formulary
Ctexli	Chenodiol 250 mg tablets	Mirum Pharmaceuticals	For treatment of cerebrotendinous xanthomatosis (CTX) in adults	\$53,730	None	Non-formulary
Baclofen Refill Kit-SynchroMed	Baclofen intrathecal kit 40 mg/20ml	Nexus	For use in the management of severe spasticity	\$640 per kit	Zanaflex, Botox, Dysport	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Selarsdi	Ustekinumab-aekn intravenous solution 130 mg/26ml	Teva Pharmaceuticals	Treatment of adult patients with: • moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy • active psoriatic arthritis (PsA) • moderately to severely active Crohn's disease (CD) • moderately to severely active ulcerative colitis Treatment of pediatric patients 6 years and older with: • moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy • active psoriatic arthritis (PsA)	\$1,530 per vial	Stelara, Skyrizi, Tremfya, Ilumya, Wezlana, Yesintek, Steqeyma, & other Stelara biosimilars	Non-formulary (see updated MRG policy)
Encelto	revakinagene taroretcel-lwey intravitreal implant 200000 cells	Neurotech Pharmaceuticals	• For the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel)	\$250,000 per implant	None	Non-formulary
Acyclovir	Acyclovir Oral Suspension 800 MG/20ML	Chartwell Rx	• Herpes zoster infections • Genital herpes • Chickenpox	\$96 per cup	Valtrex	Non-formulary
Tremfya	Guselkumab crohns induction subcutaneous solution auto-injector 200 mg/2ml	Janssen BioTech, Inc.	• Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy • Active psoriatic arthritis • Moderately to severely active ulcerative colitis • Moderately to severely active Crohn's disease	\$14,566 (per month for maintenance dosing)	Stelara, Skyrizi, Humira, Cosentyx, Taltz, etc.	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Octreotide	SandoSTATIN LAR depot intramuscular kit 10 mg	Teva Pharmaceuticals	- Treatment in patients who have responded to and tolerated octreotide acetate injection subcutaneous injection for: - Acromegaly - Severe diarrhea/flushing episodes associated with metastatic carcinoid tumors - Profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors	\$3,044 per kit	Signifor, Somatuline Depot	Non-formulary
Qfitlia	Fitusiran subcutaneous solution 20 mg/0.2ml, subcutaneous solution auto-injector 50 mg/0.5ml	Genzyme Corporation	For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors.	\$64,560 (per month for dose of 20mg a month) (note prices varies by antithrombin activity levels)	Hemlibra, Hympavzi, Alhemo	Non-formulary (see updated MRG policy)
Combogesic	Ibuprofen-acetaminophen oral tablet 325-97.5mg	AFT Pharmaceuticals	For the short term management of mild to moderate acute pain	\$936 (for max dose)	NSAIDs, Tylenol, opioids etc.	Non-formulary
Tremfya Pen	Guselkumab pen subcutaneous solution auto-injector 100 mg/ml	Janssen BioTech, Inc.	- Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy - Active psoriatic arthritis - Moderately to severely active ulcerative colitis - Moderately to severely active Crohn’s disease	\$14,566 every 8 weeks (maintenance dosing)	Stelara, Skyrizi, Humira, Cosentyx, Taltz, etc.	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Vyloy	Zolbetuximab-clzb intravenous solution reconstituted 300 mg	Astellas Pharma	Indicated in combination with fluoropyrimidine and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive as determined by an FDA-approved test	\$19,200 every 3 weeks (BSA of 2)	Keytruda, Opdivo	Non-formulary
Tezruly	Terazosin oral solution 1 mg/ml	ANI Pharmaceuticals	- The treatment of signs and symptoms of benign prostatic hyperplasia (BPH) - The treatment of hypertension alone or with other antihypertensive agents, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarction	\$474 per bottle	Doxazosin, prazosin	Non-formulary
Lutrate Depot	Leuprolide acetate intramuscular injectable 22.5 mg	Avyxa Pharma, LLC	Treatment of advanced prostate cancer	\$2,000 every 3 months	Lupron, Eligard, Camcevi	Non-formulary
Xelria Fe	Norethin-eth estradiol-fe oral tablet chewable 0.4-35 mg-mcg	Xiromed	Indicated for use by females of reproductive potential to prevent pregnancy	\$25 per pack	Finzala, Mibelas 24 Fe, Wymzya Fe, etc.	Add to F
Lamivudine	Lamivudine oral solution 300 mg/30ml	Chartwell Rx	Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. Limitations of Use: The dosage of this product is for HIV-1 and not for HBV	\$2,970	Epivir, Ziagen, Emtriva, stavudine, etc.	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Albuterol	Albuterol sulfate oral syrup 8 mg/20ml	Chartwell Rx	For the relief of bronchospasm in adults and children 2 years of age and older with reversible obstructive airway disease	\$0.8 per cup (based on MAC)	Levalbuterol, formoterol, budesonide, etc.	Non-formulary
Paxlovid	Nirmatrelvir & ritonavir oral tablet therapy pack 6 x 150 mg & 5 x 100mg	Pfizer	For the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death	\$1,496 per pack	Lagevrio, Veklury	F-QL-AL (Already added via CRF) (QL: 11 tabs/180 days, AL: 12 years and older)
Sunlenca	Lenacapavir 300mg oral tablet	Gilead Sciences	For the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 whose current antiretroviral regimen is failing due to resistance, intolerance, or safety considerations	\$813 per tablet (dosing depends on initiation schedule)		F (Already added via CRF)
Zevtera	Ceftobiprole medocaril intravenous solution reconstituted 500 mg	LA Jolla Pharmaceuticals	- Treatment of adult patients with Staphylococcus aureus bloodstream infections (bacteremia) (SAB), including those with right-sided infective endocarditis - Treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) - Treatment of adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia (CABP)	\$235 per vial	vancomycin and other antibiotics with activity against MRSA	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Vyvgart Hytrulo	Efgartigimod alfa-Hyalur- qvfc subcutaneous solution prefilled syringe 1000-10000 mg-unt/5ml	Argenx US	Adult patients with: - generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive - chronic inflammatory demyelinating polyneuropathy (CIDP)	\$66,920 every 4 weeks	Soliris, Ultomiris, Rystiggo, Vyvgart, Zilbrysq	Non-formulary
Neffy	Epinephrine nasal solution 1 mg/0.1ml	ARS Pharmaceutical Operations	For emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients 4 years of age and older who weigh 15 kg or greater	\$355 per dose	EpiPen	Non-formulary
Amnesteem	Isotretinoin oral capsule 30 mg	Mylan	Severe recalcitrant nodular acne	\$414 per month (initial dosing for 60kg patient)	Accutane, Claravis, Zenatane	F-PA (Already added via CRF)
Morphine sulfate	Morphine sulfate intravenous solution 2 mg/ml	Hikma Pharmaceuticals USA	- For adult and pediatric patients for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Morphine Sulfate Injection for use in patients for whom alternative treatment options [e.g., non-opioid analgesics or opioid combination products]: - Have not been tolerated, or are not expected to be tolerated - Have not provided adequate analgesia, or are not expected to provide adequate analgesia	\$2.58 per syringe	Opioids	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURE R	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Adrenalin	Epinephrine in sodium chloride intravenous solution 5-0.9 mg/250ml-%	Endo USA	Used to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock	\$50 per bag	Vasopressors	Non-formulary
Marcaine	Bupivacaine hydrochloride preservative free injection solution 0.75 %	Hospira	For the production of local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures	\$8 per 30ml vial	Local anesthetics (lidocaine, mepivacaine, etc.)	Non-formulary
Adalimumab-aaty	Adalimumab-aaty CD/UC/HS Start Subcutaneous auto-injector kit 80 mg/0.8ml	Celltrion USA	- Rheumatoid Arthritis - Juvenile Idiopathic Arthritis - Psoriatic Arthritis - Ankylosing Spondylitis - Crohn’s Disease - Ulcerative Colitis - Plaque Psoriasis - Hidradenitis Suppurativa - Uveitis <i>Note: Adalimumab-aaty has many approved indications. See full prescribing information for details of each indication.</i>	\$519 per kit	Humira, Amjevita, Idacio, Cyltezo, Hyrimoz, Yusimry, Hadlima and other biosimilars	F-QL (Already added via CRF) (QL: 2 pens/28 days, LD: 4 pens)

*	Pricing reflects Wholesale Acquisition Cost (WAC) per month unless otherwise noted.
^	The recommendation may be affected by state specific requirements including carve out lists and individual state mandates.
†	Pricing based on standard twice-monthly dosing for most indications.
‡	Pricing is per each kit on items listed as a kit.
#	Re-activation of previously discontinued product (i.e., other available NDCs now inactive)