PHARMACY & THERAPEUTICS COMMITTEE

Tuesday, September 15th, 2026
5:00pm – 7:00pm

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

Location: Microsoft Teams
Meeting ID: 241 706 711 768 12
Password: Uw2dt9dU

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,,149528944# 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 COMMMITTEE 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** *Donna Carey, MD, Chief Medical Officer – Alameda Alliance* • Agenda Overview	2 min	-
II)	**Informational Updates** *Donna Carey, MD, Chief Medical Officer – Alameda Alliance* *Luke Lim R.Ph., Senior Pharmacy Director – Alameda Alliance* • MedImpact P&T 2027 • PBM Oversight • Medical UIS • P&T Committee guest expansion	15 min	-
III)	**Pharmacy Utilization Reports (Quarter 2, 2026)** *Luke Lim R.Ph., Senior Pharmacy Director – Alameda Alliance* • 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: 9/15/2026*** *(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

(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
Chelating agents Class Review	• No changes
Hepatitis B agents Class Review	• No changes
Intranasal steroids Class Review	• No changes
Pancreatic Enzymes Class Review	• No changes
Pneumococcal Vaccines Class Review	• No changes
Respiratory Aids and Devices 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
Quantity Limit Exception	• No changes
Antibiotic Eye Medications	• No changes
Antiemetics	• No changes
Nuedexta (dextromethorphan/quinidine)	• No changes
Cartilaginous Repair Agents	• No changes
Memantine ER (Namenda XR)	• No changes
Ophthalmic Anti-inflammatory Immunomodulators	• No changes
Penicillamine (Depen, Cuprimine), Trientine HCl (Syprine) for Wilson's disease	• No changes
Iron-chelating Agents	• Change naming convention to show generic availability of Ferriprox tablet
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
Lidocaine Patch	• No changes
Mesalamine	• No changes
Corticosteroids for Ulcerative Colitis and Crohn's disease	• No changes
Atovaquone-proguanil (Malarone)	• No changes
Intranasal Steroids	• No changes
Scabicides and Pediculicides	• No changes
Rifamycin Antibiotics	• No changes

10 min EV

Topical Acne Agents	• No changes
Alosetron (Lotronex)	• No changes
Viberzi (eluxadoline)	• No changes
Hepatitis C Medications	• Remove Peg-Intron and Viekira pak from criteria as they have been discontinued
Rifabutin (Mycobutin)	• No changes
Tranexamic acid (Lysteda)	• No changes
Moxifloxacin Oral Tablet	• No changes
Santyl Ointment	• No changes
Topical Antibiotics	• No changes
Vowst	• No changes
Rho Kinase Inhibitors	• No changes
Xolremdi	• No changes
Anti-Parkinson's Agents for OFF Episodes	• No changes
Ctexli	• No changes
Vykat XR	• No changes
Physician Administered Drug (PAD) Guidelines	**Changes**
Exondys 51	• No changes
Erythropoiesis-Stimulating Agents	• No changes
B-Cell Maturation Antigen (BCMA) Directed Chimeric Antigen Receptor (CAR) T-Cell Therapy	• No changes
Fecal microbiota	• No changes
Qalsody (tofersen)	• No changes
Lamzede	• No changes
Enzyme Replacement Therapies for Fabry Disease	• No changes
Enzyme replacement therapy for acid sphingomyelinase deficiency (ASMD)	• No changes
Rytelo (imetelstat)	• No changes
Anti-Parkinson's Agents for OFF Episodes	• No changes
Encelto	• No changes
Nulibry	• No changes
Zevaskyn	• No changes
Interim Formulary Updates	
• See p. 183 in packet	
Summary of Physician Administered Drug (PAD) Updates	
• See p. 184 in packet	
Pharmacy Policy & Procedure Updates	
• RX-017 Investigational Drug Review and Coverage Determination Policy	• New
DSNP Policy & Procedure Updates	
• RX-D-001 Part D Transition Process	• New- MedImpact
• RX-D-010 Medicare Part D Daily Claims Review	• Procedure process language update. See redlines.

• RX-D-021 Medicare Part D Best Available Evidence (BAE)	• MedImpact BAE SOP LIS override information and duration included. See redlines.
ED Oversight	
• There was one finding in Q2 ED oversight report. We are working with our PBM to resolve.	
P&T Meeting Minutes	
• P&T Meeting Minutes Q2, June 16th, 2026	

V) New Business

Iryna Makukh, PharmD, Pharmacist – PerformRx

New MRG

- Hepcludex monograph and MRG criteria

New PAD

- Mucopolysaccharidosis II (Hunter Syndrome) Agents
- Cartilaginous Repair Agents

VI) Class Reviews, Monographs, and Recommendations

Iryna Makukh, PharmD, Pharmacist – PerformRx

- None

VII) Medication Request Guidelines

Rahel Negash, PharmD, Pharmacist – Alameda Alliance

1. Dronabinol
2. White Blood Cell Stimulators
3. Constipation agents
4. Immunizations
5. Medications for the treatment of Multi-Drug Resistant Tuberculosis
6. Palforzia
7. Duvyzat
8. Anti-Obesity Medications
9. Injectable/Infusible Bone-Modifying Agents for Oncology Indications
10. Injectable/Infusible Agents for Osteoporosis and Paget's Disease
11. Pulmonary Biologics for Respiratory and Eosinophilic Conditions
12. Agents for Primary Biliary Cholangitis

45 min V

VIII) Physician Administered Drug (PAD) Policies

Iryna Makukh, PharmD, Pharmacist – PerformRx

1. Ophthalmic indications for bevacizumab
2. White Blood Cell Stimulators
3. Iron-containing Products
4. Tepezza
5. Gene Therapy for Hemophilia B
6. Omisirge
7. Elevidys
8. Injectable/Infusible Bone-Modifying Agents for Oncology Indications
9. Injectable/Infusible Agents for Osteoporosis and Paget's Disease

10 min V

IX) Informational Updates on New Developments in Pharmacy
Iryna Makukh, PharmD, Pharmacist – PerformRx
- New Product Review

2 min V

X) Old Business
- N/A

2 min -

RECONVENE IN OPEN SESSION

XI) Public Comment

XII) Adjournment
-

ACTION / FOLLOW-UP ITEMS

ITEM	DUE DATE	RESPONSIBLE

FUTURE P&T MEETINGS

NEXT MEETING	2026 P&T MEETINGS
December 15, 2026	

PHARMACY & THERAPEUTICS COMMITTEE

Tuesday, September 15th, 2026
5:00pm – 7:00pm

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 Luke Lim at 510-995-4781 lulim@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 the 2nd Quarter 2026

- The top 50 drugs accounted for **1,515 claims** for **760 members** and cost **$1,898,679**, which is an increase of $278,957 in spend from the previous quarter.
- Biktarvy remains at number one with 41 claims for 16 members. There was an increase of 2 claims since the previous quarter.
- Ozempic is at numbers 2, 5, and 6, with 293 total claims for 129 members. There was an increase of 25 claims and 11 members from the previous quarter.
- Vemlidy remains at number 3 with 49 claims for 23 members. There was an increase of 1 claim 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.
- Kisqali is up at numbers 4 and 9 with 9 claims for 3 members. There was an increase of 4 claims and 1 member from the previous quarter. The medication is managed via the Oral and Injectable Oncology Medications MRG.

Rank	DDID	Label Name	Claims	Unique Members	Total Cost
1	201625	Biktarvy Oral Tablet 50-200-25 MG	41	16	$165,466.94
2	218338	Ozempic (2 MG/DOSE) Subcutaneous Solution Pen-injector 8 MG/3ML	131	52	$127,937.99
3	195609	Vemlidy Oral Tablet 25 MG	49	23	$98,734.85
4	206142	Kisqali (600 MG Dose) Oral Tablet Therapy Pack 200 MG	5	2	$93,028.51
5	209911	Ozempic (1 MG/DOSE) Subcutaneous Solution Pen-injector 4 MG/3ML	83	34	$80,923.14
6	221271	Ozempic (0.25 or 0.5 MG/DOSE) Subcutaneous Solution Pen-injector 2 MG/3ML	79	43	$76,767.25
7	214809	Skyrizi Pen Subcutaneous Solution Auto-injector 150 MG/ML	3	2	$70,296.00
8	199758	Verzenio Oral Tablet 100 MG	4	1	$66,744.24
9	206141	Kisqali (400 MG Dose) Oral Tablet Therapy Pack 200 MG	4	1	$59,681.56
10	229056	Dupixent Subcutaneous Solution Auto-injector 300 MG/2ML	14	8	$57,905.40
11	229072	Mounjaro Subcutaneous Solution Auto-injector 5 MG/0.5ML	52	28	$55,094.35
12	223809	Cosentyx UnoReady Subcutaneous Solution Auto-injector 300 MG/2ML	6	2	$49,635.75
13	219135	Skyrizi Subcutaneous Solution Cartridge 360 MG/2.4ML	2	1	$46,854.00
14	212379	Cabenuva Intramuscular Suspension Extended Release 600 & 900 MG/3ML	6	4	$41,278.56

Rank	DDID	Label Name	Claims	Unique Members	Total Cost
15	182336	Farxiga Oral Tablet 10 MG	123	59	$41,123.05
16	99674	Lenalidomide Oral Capsule 5 MG	4	1	$41,069.66
17	207962	Rybelsus Oral Tablet 14 MG	42	17	$40,877.58
18	229071	Mounjaro Subcutaneous Solution Auto-injector 2.5 MG/0.5ML	36	22	$38,224.42
19	228573	Livdelzi Oral Capsule 10 MG	3	1	$35,127.24
20	229078	Mounjaro Subcutaneous Solution Auto-injector 7.5 MG/0.5ML	33	17	$34,968.94
21	229076	Mounjaro Subcutaneous Solution Auto-injector 10 MG/0.5ML	32	16	$33,802.84
22	213515	Lupkynis Oral Capsule 7.9 MG	2	1	$33,286.80
23	215133	Wegovy Subcutaneous Solution Auto-injector 2.4 MG/0.75ML	23	9	$29,562.42
24	207961	Rybelsus Oral Tablet 7 MG	30	16	$29,296.32
25	229073	Mounjaro Subcutaneous Solution Auto-injector 15 MG/0.5ML	27	12	$28,561.75
26	177191	Eliquis Oral Tablet 5 MG	84	40	$26,241.05
27	218349	Bimzelx Subcutaneous Solution Auto-injector 160 MG/ML	3	1	$24,081.78
28	192096	Odefsey Oral Tablet 200-25-25 MG	6	2	$23,118.18
29	182335	Farxiga Oral Tablet 5 MG	62	31	$19,769.86
30	225062	Xphozah Oral Tablet 30 MG	6	2	$19,710.72
31	234345	cycloSPORINE (PF) Ophthalmic Emulsion 0.05 %	44	27	$19,228.86
32	201117	Steglatro Oral Tablet 15 MG	54	21	$17,935.56
33	229075	Mounjaro Subcutaneous Solution Auto-injector 12.5 MG/0.5ML	17	8	$17,885.14
34	122702	Januvia Oral Tablet 100 MG	60	27	$17,834.67
35	184849	Jardiance Oral Tablet 25 MG	58	25	$17,666.30

Rank	DDID	Label Name	Claims	Unique Members	Total Cost
36	120500	Dasatinib Oral Tablet 20 MG	2	1	$17,291.62
37	190802	Genvoya Oral Tablet 150-150-200-10 MG	4	2	$17,041.96
38	218613	Camzyos Oral Capsule 5 MG	2	1	$16,684.14
39	185612	Enbrel SureClick Subcutaneous Solution Auto-injector 50 MG/ML	2	1	$16,621.30
40	189014	Tolvaptan Oral Tablet Therapy Pack 45 & 15 MG	1	1	$16,275.00
41	215136	Wegovy Subcutaneous Solution Auto-injector 1.7 MG/0.75ML	12	7	$15,652.61
42	186088	Ofev Oral Capsule 150 MG	1	1	$14,378.35
43	181560	Actemra Subcutaneous Solution Prefilled Syringe 162 MG/0.9ML	3	1	$14,334.66
44	234699	Shingrix Intramuscular Suspension Prefilled Syringe 50 MCG/0.5ML	52	50	$14,315.22
45	186069	Nintedanib Esylate Oral Capsule 150 MG	2	1	$13,018.12
46	228549	Nemluvio Subcutaneous Auto-injector 30 MG	3	1	$12,937.02
47	215132	Wegovy Subcutaneous Solution Auto-injector 1 MG/0.5ML	10	5	$12,780.61
48	170142	Xarelto Oral Tablet 20 MG	22	11	$12,631.58
49	127437	FreeStyle Lite Test In Vitro Strip	169	104	$12,551.84
50	226896	Cimzia (2 Syringe) Subcutaneous Prefilled Syringe Kit 200 MG/ML	2	1	$12,442.82
TOTAL			**1,515**	**760**	**$1,898,678.53**

Medi-Cal Top 50 Drugs by Cost for 2nd Quarter 2026

- Top 50 drugs accounted for 28,204 claims for 24,391 members and cost $59,216,109. Compared with 1Q2026: 25,128 claims for 21,808 members and cost $55,189,600. We see more claims, more members, and more spend.
- Biktarvy compare 852/704 vs 873/739 (decline)
- Skyrizi compare 162/151 vs 144/135 (increase)
- Ozempic utilization very stable, other GLP1 users are not migrating after 1/1/26 change.

Rank	GCN	Label Name	Claims	Unique Members	Total Cost
1	44426	BIKTARVY 50-200-25 MG TABLET	852	704	$6,711,843.21
2	49591	SKYRIZI 150 MG/ML PEN	162	151	$4,255,262.67
3	48277	DUPIXENT 300 MG/2 ML PEN	334	267	$2,674,171.80
4	53536	OZEMPIC 0.25-0.5 MG/DOSE PEN	1845	1458	$2,426,039.76
5	52125	OZEMPIC 2 MG/DOSE (8 MG/3 ML)	1328	1020	$2,325,920.91
6	36723	JARDIANCE 25 MG TABLET	2432	2227	$1,983,834.14
7	36716	JARDIANCE 10 MG TABLET	2431	2162	$1,857,196.56
8	48208	OZEMPIC 1 MG/DOSE (4 MG/3 ML)	1174	942	$1,837,535.79
9	42624	VEMLIDY 25 MG TABLET	488	398	$1,678,400.61
10	49099	CABENUVA ER 600 MG-900 MG SUSP	202	171	$1,636,569.17
11	27418	INVEGA SUSTENNA 234 MG/1.5 ML	240	164	$1,518,943.22
12	49468	COSENTYX UNOREADY 300 MG PEN	73	57	$1,501,100.61
13	43506	HUMIRA(CF) PEN 40 MG/0.4 ML	117	89	$1,483,187.27
14	52337	MOUNJARO 5 MG/0.5 ML PEN	729	611	$1,164,756.67
15	94200	DEXCOM G7 SENSOR	989	843	$1,128,764.40
16	52336	MOUNJARO 2.5 MG/0.5 ML PEN	777	663	$1,060,132.65

Rank	GCN	Label Name	Claims	Unique Members	Total Cost
17	40133	TAGRISSO 80 MG TABLET	31	25	$1,041,003.78
18	97724	ENBREL 50 MG/ML SURECLICK	74	57	$993,209.30
19	47136	TRIKAFTA 100-50-75 MG/150 MG	15	12	$895,901.38
20	58471	YEZTUGO 463.5 MG/1.5 ML VIAL	63	62	$859,459.63
21	33935	ELIQUIS 5 MG TABLET	1300	1072	$850,776.29
22	97472	ZINC SULFATE POWDER	428	242	$850,663.97
23	46966	RYBELSUS 14 MG TABLET	355	326	$848,704.47
24	57037	RYBELSUS 7 MG TABLET	388	344	$824,638.27
25	34394	FARXIGA 10 MG TABLET	849	741	$769,160.61
26	40953	DESCOVY 200-25 MG TABLET	191	167	$765,401.61
27	37682	ABILIFY MAINTENA ER 400 MG SYR	140	106	$764,968.60
28	43968	SYMTUZA 800-150-200-10 MG TAB	100	77	$761,084.98
29	44014	HUMIRA(CF) PEN 80 MG/0.8 ML	26	21	$734,628.24
30	52338	MOUNJARO 7.5 MG/0.5 ML PEN	465	381	$727,703.29
31	19216	RESTASIS 0.05% EYE EMULSION	741	691	$721,971.73
32	25200	FREESTYLE LITE TEST STRIP	4155	3997	$714,221.35
33	54456	FERRIPROX 1,000 MG TAB(2X/DAY)	13	9	$713,895.63
34	49487	APRETUDE ER 600 MG/3 ML VIAL	138	118	$709,408.54
35	43222	DUPIXENT 300 MG/2 ML SYRINGE	88	74	$686,660.02
36	49748	WEGOVY 0.25 MG/0.5 ML PEN	497	458	$684,424.27
37	56136	NEMLUVIO 30 MG PEN	71	59	$655,644.15

Rank	GCN	Label Name	Claims	Unique Members	Total Cost
38	38702	INVEGA TRINZA 819 MG/2.63 ML	57	55	$651,476.37
39	24147	NORDITROPIN FLEXPRO 15 MG/1.5	50	37	$629,723.46
40	46822	RINVOQ ER 15 MG TABLET	50	44	$629,275.50
41	47586	TEPEZZA 500 MG VIAL	3	3	$617,947.77
42	52333	MOUNJARO 10 MG/0.5 ML PEN	372	304	$609,642.77
43	97400	JANUVIA 100 MG TABLET	698	653	$591,994.70
44	98637	BASAGLAR 100 UNIT/ML KWIKPEN	1145	986	$556,931.83
45	52335	MOUNJARO 15 MG/0.5 ML PEN	254	202	$536,013.50
46	52475	SKYRIZI 360 MG/2.4 ML ON-BODY	25	22	$526,256.27
47	36003	VELPHORO 500 MG CHEWABLE TAB	85	68	$525,252.88
48	36172	OTEZLA 30 MG TABLET	46	39	$522,869.21
49	36398	MYALEPT 11.3 MG (5 MG/ML) VIAL	2	2	$502,234.80
50	94200	FREESTYLE LIBRE 3 SENSOR PLUS	1116	1010	$499,300.89
TOTAL			**28,204**	**24,391**	**$59,216,109.50**

636 IHSS Top 50 Prior Authorization Requests by Volume for the 2nd Quarter 2026

- Top 50 PA requests = 260. There were 438 total PA requests for quarter 2.
  - 81 requests (31%) were approved. This approval rate is 6% lower than was observed last quarter.
  - 179 requests (69%) were denied or partially approved.
- Lidocaine 5% patch is at number 1 with 30 requests and 9 approvals (30%).
  - Lidocaine requires a diagnosis of neuropathic pain and trial and failure of gabapentin or pregabalin and one other formulary alternative (e.g., duloxetine, venlafaxine, nortriptyline, amitriptyline, etc.) or morphine MME ≧ 50/day for 3 months.
- Wegovy injection solution is at numbers 2, 10, 14 & 31 with 32 total requests and 6 approvals (19%).
  - 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.
  - Wegovy for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) requires a diagnosis of MASH with moderate to advanced liver fibrosis and prescriber attestation on lifestyle counseling on nutrition and exercise and avoidance of excess alcohol intake.
- Jardiance is at numbers 3 & 6 with 28 total requests and 6 approvals (21%).
  - 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.
- Vemlidy is at number 4 with 14 requests and 7 approvals (50%).
  - Vemlidy requires a diagnosis of hepatitis B and trial and failure of, intolerance to, or inability to use entecavir.
- Zepbound is at numbers 5 & 24 with 15 total requests and 5 approvals (33%).
  - 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 and trial and failure or inability to use PAP therapy.

RANK	DRUGS	Total	Approved		Denied		Partially Approved	
1	LIDOCAINE Patch 5%	30	9	30.00%	20	66.67%	1	3.33%
2	WEGOVY Soln Auto-inj 0.25MG/0.5ML	18	2	11.11%	16	88.89%	0	0.00%
3	JARDIANCE Tablet 10MG	17	1	5.88%	13	76.47%	3	17.65%
4	VEMLIDY Tablet 25MG	14	7	50.00%	4	28.57%	3	21.43%
5	ZEPBOUND Soln Auto-inj 2.5MG/0.5ML	11	3	27.27%	8	72.73%	0	0.00%
6	JARDIANCE Tablet 25MG	11	5	45.45%	5	45.45%	1	9.09%
7	REPATHA SURECLICK Soln Auto-inj 140MG/ML	8	4	50.00%	1	12.50%	3	37.50%
8	WEGOVY Tablet 4MG	7	1	14.29%	6	85.71%	0	0.00%
9	TACROLIMUS Ointment 0.1%	6	4	66.67%	0	0.00%	2	33.33%
10	WEGOVY Soln Auto-inj 2.4MG/0.75ML	6	2	33.33%	3	50.00%	1	16.67%
11	OPZELURA Cream 1.5%	6	0	0.00%	6	100.00%	0	0.00%
12	TRETINOIN Cream 0.025%	5	1	20.00%	4	80.00%	0	0.00%
13	WEGOVY Tablet 1.5MG	5	0	0.00%	5	100.00%	0	0.00%
14	WEGOVY Soln Auto-inj 1MG/0.5ML	5	2	40.00%	3	60.00%	0	0.00%
15	NURTEC Tablet Disintegrating 75MG	5	1	20.00%	2	40.00%	2	40.00%
16	XIFAXAN Tablet 550MG	5	1	20.00%	4	80.00%	0	0.00%
17	KERENDIA Tablet 10MG	4	2	50.00%	2	50.00%	0	0.00%
18	MIRABEGRON ER Tablet ER 24HR 25MG	4	2	50.00%	2	50.00%	0	0.00%
19	TRANEXAMIC ACID Tablet 650MG	4	3	75.00%	1	25.00%	0	0.00%
20	MIEBO Solution 1.338GM/ML	4	2	50.00%	2	50.00%	0	0.00%
21	UBRELVY Tablet 50MG	4	1	25.00%	3	75.00%	0	0.00%
22	PHENTERMINE HCL Tablet 37.5MG	4	2	50.00%	2	50.00%	0	0.00%
23	ZORYVE Cream 0.15%	4	0	0.00%	4	100.00%	0	0.00%
24	ZEPBOUND Soln Auto-inj 5MG/0.5ML	4	2	50.00%	2	50.00%	0	0.00%
25	OZEMPIC (0.25 OR 0.5 MG/DOSE) Soln Pen-inj 2MG/3ML	4	3	75.00%	0	0.00%	1	25.00%
26	SCOPOLAMINE Patch 72HR 1MG/3DAYS	4	0	0.00%	3	75.00%	1	25.00%
27	PROLIA Soln Pref Syr 60MG/ML	3	0	0.00%	3	100.00%	0	0.00%
28	ESTRING Ring 7.5MCG/24HR	3	1	33.33%	2	66.67%	0	0.00%
29	TADALAFIL Tablet 20MG	3	0	0.00%	3	100.00%	0	0.00%
30	LINZESS Capsule 145MCG	3	0	0.00%	2	66.67%	1	33.33%
31	WEGOVY Soln Auto-inj 0.5MG/0.5ML	3	0	0.00%	3	100.00%	0	0.00%
32	TRETINOIN Cream 0.05%	3	0	0.00%	3	100.00%	0	0.00%
33	FEBUXOSTAT Tablet 40MG	3	0	0.00%	3	100.00%	0	0.00%
34	UBRELVY Tablet 100MG	3	1	33.33%	2	66.67%	0	0.00%

RANK	DRUGS	Total	Approved		Denied		Partially Approved	
35	XIIDRA Solution 5%	3	2	66.67%	1	33.33%	0	0.00%
36	LINZESS Capsule 290MCG	3	3	100.00%	0	0.00%	0	0.00%
37	OXYCODONE HCL Tablet 5MG	3	2	66.67%	1	33.33%	0	0.00%
38	CYCLOSPORINE (PF) Emulsion 0.05%	3	3	100.00%	0	0.00%	0	0.00%
39	RYBELSUS Tablet 3MG	3	2	66.67%	1	33.33%	0	0.00%
40	VTAMA Cream 1%	2	0	0.00%	2	100.00%	0	0.00%
41	FLUTICASONE-SALMETEROL Aerosol 115/21/MCG/ACT	2	0	0.00%	2	100.00%	0	0.00%
42	DEXLANSOPRAZOLE Capsule DR 60MG	2	0	0.00%	2	100.00%	0	0.00%
43	SKYRIZI PEN Soln Auto-inj 150MG/ML	2	0	0.00%	1	50.00%	1	50.00%
44	LINZESS Capsule 72MCG	2	0	0.00%	2	100.00%	0	0.00%
45	CEQUA Solution 0.09%	2	1	50.00%	1	50.00%	0	0.00%
46	BILDYOS Soln Pref Syr 60MG/ML	2	2	100.00%	0	0.00%	0	0.00%
47	LISDEXAMFETAMINE DIMESYLATE Capsule 30MG	2	0	0.00%	2	100.00%	0	0.00%
48	DUPIXENT Soln Auto-inj 300MG/2ML	2	1	50.00%	0	0.00%	1	50.00%
49	TALICIA Capsule DR 250/12.5/10/MG	2	1	50.00%	1	50.00%	0	0.00%
50	CARISOPRODOL Tablet 350MG	2	2	100.00%	0	0.00%	0	0.00%
TOTAL		**260**	**81**	**31%**	**158**	**61%**	**21**	**8%**

Medi-Cal Top 50 Prior Authorization Requests by Volume for 2nd Quarter 2026

- Unsure why Vitamin D3 is suddenly top on the PA list, it was not present 2Q2026
- Wegovy is #2 volume. It has 71% approval due to indications like CV-risk reduction and NASH
- Zepbound has 46% approval rate due to indications like OSA
- Freestyle and Dexcom CGMs still in top 10
- Ozempic approvals 33/119 (28%) vs 1Q2026 21/117 (18%)
- Mounjaro approval rate and volume steady (1Q2026 42/111 [38%])

Rank	Drug Name	Total	Approved		Denied	
1	VITAMIN D3	890	706	79.3%	184	20.7%
2	WEGOVY	640	454	70.9%	186	29.1%
3	ZEPBOUND	443	203	45.8%	240	54.2%
4	SYSTANE BALANCE	376	229	60.9%	147	39.1%
5	FEXOFENADINE HCL	300	187	62.3%	113	37.7%
6	FREESTYLE LIBRE 3 PLUS SENSOR	273	205	75.1%	68	24.9%
7	OPZELURA	158	129	81.6%	29	18.4%
8	DEXCOM G7 SENSOR	152	119	78.3%	33	21.7%
9	OZEMPIC	119	33	27.7%	86	72.3%
10	MOUNJARO	111	45	40.5%	66	59.5%
11	SYSTANE COMPLETE	105	49	46.7%	56	53.3%
12	ALLERGY RELIEF	100	69	69.0%	31	31.0%
13	OMNIPOD 5 DEXG7G6 PODS (GEN 5)	98	94	95.9%	4	4.1%
14	SILDENAFIL CITRATE	94	3	3.2%	91	96.8%
15	SOD SULF-POTASS SULF-MAG SULF	91	47	51.6%	44	48.4%
16	ALPRAZOLAM	85	61	71.8%	24	28.2%

Rank	Drug Name	Total	Approved		Denied	
17	CARBOXYMETHYLCELLULOSE SODIUM	82	38	46.3%	44	53.7%
18	DUPIXENT PEN	72	69	95.8%	3	4.2%
19	TADALAFIL	71	11	15.5%	60	84.5%
20	NOVASOURCE RENAL 2 CAL	70	63	90.0%	7	10.0%
21	VOQUEZNA	70	46	65.7%	24	34.3%
22	ENSURE ORIGINAL	65	50	76.9%	15	23.1%
23	ASSURE LANCE	62	62	100.0%	0	0.0%
24	XIFAXAN	62	36	58.1%	26	41.9%
25	PHENTERMINE HCL	58	54	93.1%	4	6.9%
26	POLYETHYLENE GLYCOL 3350	58	0	0.0%	58	100.0%
27	DOXEPIN HCL	52	25	48.1%	27	51.9%
28	OXYCODONE HCL	52	48	92.3%	4	7.7%
29	REFRESH TEARS	52	21	40.4%	31	59.6%
30	TERBINAFINE	52	28	53.8%	24	46.2%
31	SCOPOLAMINE	51	38	74.5%	13	25.5%
32	DEXCOM G7 RECEIVER	50	32	64.0%	18	36.0%
33	CETIRIZINE HCL	49	33	67.3%	16	32.7%
34	ESTRADIOL VALERATE	47	47	100.0%	0	0.0%
35	TESTOSTERONE	47	39	83.0%	8	17.0%
36	FREESTYLE LIBRE 2 PLUS SENSOR	46	32	69.6%	14	30.4%
37	SKYRIZI PEN	45	41	91.1%	4	8.9%

Rank	Drug Name	Total	Approved		Denied	
38	FREESTYLE LIBRE 3 READER	44	28	63.6%	16	36.4%
39	BELBUCA	43	35	81.4%	8	18.6%
40	NURTEC ODT	41	25	61.0%	16	39.0%
41	FINASTERIDE	39	9	23.1%	30	76.9%
42	OXYCONTIN	38	32	84.2%	6	15.8%
43	TRELEGY ELLIPTA	38	24	63.2%	14	36.8%
44	METRONIDAZOLE	37	13	35.1%	24	64.9%
45	TRIAMCINOLONE ACETONIDE	37	31	83.8%	6	16.2%
46	BOOST	36	32	88.9%	4	11.1%
47	HYDROCODONE-ACETAMINOPHEN	35	27	77.1%	8	22.9%
48	COSENTYX UNOREADY PEN	34	30	88.2%	4	11.8%
49	HUMIRA(CF) PEN	33	31	93.9%	2	6.1%
50	MELATONIN	31	17	54.8%	14	45.2%
	TOTAL	**5734**	**3780**	**65.9%**	**1954**	**34.10%**

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

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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.

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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

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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) Lead poisoning Mercury poisoning (off-label)	10 mg/kg orally 3 times daily for 5 days followed by 10 mg/kg orally twice daily for 14 days
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/m^2/day or 50 to 75 mg/kg/day IM or IV for 5 days • Lead encephalopathy: ○ 1000 to 1500 mg/m^2/day or 25 to 75 mg/kg/day IM or IV for 5 days • Lead nephropathy: ○ SCr 2 to 3 mg/dL: 500 mg/m^2 IM or IV every 24 hours for 5 days ○ SCr 3 to 4 mg/dL: 500 mg/m^2 IM or IV every 48 hours for 3 doses ○ SCr >4 mg/dL: 500 mg/m^2 IM or IV once weekly

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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/mm^3 • Hypersensitivity
Deferiprone (Ferriprox®)	**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

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Medication	Boxed Warnings	Contraindications
Calcium Disodium Versenate	**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

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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

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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

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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

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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.

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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.

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Thalassemia

Taher AT, Farmakis D, Porter JB, et al. Guidelines for the Management of Transfusion-Dependent β-Thalassaemia (TDT). 5th edition. Nicosia, Cyprus: Thalassaemia International Federation; 2025.

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 (Grade C, Class I).
- Chelation therapy at the correct doses and frequency can balance iron excretion with iron accumulation from transfusion (Grade A, Class I).
- 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 (Grade B, Class I).
- Response to chelation is dependent on the dose applied and the duration of exposure (Grade A, Class I).
- Response to chelation is affected by the rate of blood transfusion (Grade B, Class II).
- Chelation therapy removes myocardial storage iron slowly (months or years) (Grade A, Class I).
- Chelation can reverse iron-mediated cardiac dysfunction rapidly (within weeks) by rapid chelation of labile iron, if 24-hour chelation cover is achieved (Grade B, Class IIa).
- The optimal chelation regimen and dosing depend on approved local indications and prescribing information of individual chelators, must be tailored for the individual, and will vary based on current clinical situation and iron overload profile (Grade A, Class I).
- 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 deferoxamine) (Grade B, Class I).
- Patients receiving iron chelation should be closely monitored for unwanted adverse effects and their management including dose modifications/interruptions according to local prescribing information (Grade A, Class I).
- Chelation therapy will not be effective if it is not taken regularly – a key aspect of chelation management is to work with patients and their families to optimize adherence (Grade B, Class I)

Recommendation Definitions

Level of Evidence	Definition
Grade A	Data derived from multiple randomized clinical trials or meta-analyses.
Grade B	Data derived from a single randomized clinical trial or large non-randomized studies.
Grade C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.
Class of Recommendation	**Definition**
Class I	There is evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.
Class IIa	There is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure. The weight of evidence is in favor of usefulness/efficacy and therefore should be considered.
Class IIb	There is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure. The usefulness/efficacy is less well established by evidence/opinion and therefore may be considered.

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Level of Evidence	Definition
Class III	There is evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.

Taher A, Musallam K, Cappellini MD. Guidelines for the Management of Non-Transfusion Dependent β-Thalassaemia (NTDT). 3rd edition. Nicosia (Cyprus): Thalassaemia International Federation; 2023.

Iron Overload

- Iron chelation therapy with deferasirox should be initiated in non-transfusion dependent thalassemia patients ≥10 years of age if any of the below is evident:
  - Liver iron concentration ≥5 mg Fe/g dry weight
  - Serum ferritin level ≥800 ng/mL
  - Serum ferritin level >300 to <800 ng/mL (liver iron concentration measurement is not possible) and other clinical or laboratory measures indicative of iron overload
- Deferasirox therapy should be discontinued when patients reach a liver iron concentration value of 3 mg Fe/g dry weight or serum ferritin level 300 ng/mL and patients should continue to be monitored for iron overload as indicated earlier
- The use of other iron chelators cannot be recommended until larger, randomized studies evaluating effects on liver iron concentration are available
- Tea consumption should be encouraged in non-transfusion dependent thalassemia patients, as it may have some benefit in decreasing iron absorption from the gut
- Patients with non-transfusion dependent thalassemia who require long-term regular blood transfusions should be managed for secondary iron overload similar as per guidelines for patients with transfusion-dependent thalassemia

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 µg/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 µg/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 µg/dL

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  - For a non-pregnant adolescent girl or woman of child-bearing age who has a blood lead concentration of 45 to 70 µg/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 µg/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 µg/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 µg/dL
  - For a non-pregnant adolescent or an adult with a blood lead concentration >70 to 100 µg/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 µg/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 µg/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.

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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; Tau^2 0.47; I^2 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-		

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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
Appenenzeller-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 x 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

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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

	Median		**75th Percentile**		**90th 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 × 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 × 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.

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Formulary Placement, Utilization and Cost Experience (04-01-2026 to 06-30-2026)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Copper Chelators								
trientine hydrochloride (Syprine®) 250 mg capsule	0	0	0	0	0	0 (0%)	F-PA-AL(min 21)	No change
Cuvrior™ (trientine tetrahydrochloride) 300 mg tablet	0	0	0	0	0	0 (0%)	NF	No change
penicillamine (Cuprimine®) 250 mg capsule	0	0	0	0	0	0 (0%)	F-PA	No change
penicillamine (Depen® Titratabs) 250 mg tablet	0	0	0	0	0	0 (0%)	F-PA	No change
Galzin® (zinc acetate) 25 mg, 50 mg capsule	0	0	0	0	0	0 (0%)	NF	No change
Iron Chelators								
deferoxamine (Desferal®) 500 mg, 2 g solution for injection	0	0	0	0	0	0 (0%)	F	No change
deferasirox (Exjade®) 125 mg, 250 mg, 500 mg dispersible tablet	0	0	0	0	0	0 (0%)	F-PA-AL(min 21)	No change
deferasirox (Jadenu®) 90 mg, 180 mg, 360 mg tablet	0	0	0	0	0	0 (0%)	F-PA	No change
deferasirox (Jadenu® Sprinkle) 90 mg, 180 mg, 360 mg oral granules in packet	0	0	0	0	0	0 (0%)	F-PA	No change
deferiprone (Ferriprox™) 500, 1000 mg tablet	0	0	0	0	0	0 (0%)	NF	No change
Ferriprox™ (deferiprone) 100 mg/mL oral solution	0	0	0	0	0	0 (0%)	NF	No change
Lead (and Other) Chelators								
Chemet® (succimer) 100 mg capsule	0	0	0	0	0	0 (0%)	NF	No change
Calcium Disodium Versenate 200 mg/mL injection solution	0	0	0	0	0	0 (0%)	NF	No change
TOTAL	**0**	**0**	**0**	**0**	**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

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Prior Authorization Criteria

Recommendation: No changes

Penicillamine (Depen, Cuprimine), Trientine HCl (Syprine) for Wilson's disease	
Therapeutic Classes (AHFS)	Heavy Metal Antagonists
Medications	Formulary, PA required Penicillamine (Depen Titratabs) tablet Trientine (Syprine) Penicillamine (Cuprimine) capsule Non-Formulary 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	~~9/2025~~9/2026

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Recommendation: No changes

Iron-chelating Agents	
Therapeutic Classes (AHFS)	Heavy Metal Antagonists
Medications	Formulary, PA required Deferasirox (Jadenu) tablet -PREFERRED Deferasirox (Jadenu) granules Deferasirox (Exjade) tablet Non-Formulary 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	**INITIAL CRITERIA FOR CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS FOR DEFERASIROX**
	• 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

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	REAUTHORIZATION CRITERIA FOR CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS FOR DEFERASIROX
	• 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

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	• 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	~~9/2025~~9/2026

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Hepatitis B

Executive Summary

CLASS OVERVIEW

Hepatitis B is a liver infection caused by the hepatitis B virus (HBV), a double-stranded DNA virus belonging to the family of hepadnaviruses. HBV infection is transmitted by sexual contact, injection drug use, infected mothers to newborn infants, contact with blood or open sores, needle sticks, and other sharing of items such as toothbrushes or razors. Although initiatives for universal HBV infection prevention through vaccination have been successful, HBV continues to generate significant disease burden. It is estimated that there are more than 250 million persons with chronic HBV infection in the world, with men having a slightly increased risk. Patients infected with HBV may be asymptomatic, develop nonspecific symptoms such as fatigue and anorexia, or experience acute symptoms such as jaundice and right upper quadrant discomfort. While acute HBV can be cleared, some patients may develop a chronic infection. Chronic hepatitis B (CHB), if left unmanaged, can result in complications such as necroinflammatory liver damage and hepatocellular carcinoma, and approximately 1.1 million people die annually from HBV-related liver disease. This review covers all oral and injectable medications indicated and approved for the treatment of CHB. This includes Baraclude® (entecavir) oral tablet and solution, Epivir® HBV (lamivudine) oral tablet, Hepsera® (adefovir), Viread® (tenofovir disoproxil fumarate), and the newest oral medication, Vemlidy® (tenofovir alafenamide), as well as injectable Pegasys® (peginterferon alfa-2a).

UTILIZATION FINDINGS

There were 98 claims for 61 members, for a total cost of $103,672.65, and an average cost per claim of $1,057.88. The most highly utilized medication was Vemlidy tablet with 49 claims, followed by entecavir tablet with 31 claims. There were 14 prior authorization requests with 10 approvals (71%).

RECOMMENDATIONS

- No changes

CLINICAL SUMMARY

Hepatitis B is a liver infection caused by the hepatitis B virus (HBV), a double-stranded DNA virus belonging to the family of hepadnaviruses. HBV infection is transmitted by sexual contact, injection drug use, infected mothers to newborn infants, contact with blood or open sores, needle sticks, and other sharing of items such as toothbrushes or razors. Although initiatives for universal HBV infection prevention through vaccination have been successful, HBV continues to generate significant disease burden. It is estimated that there are more than 250 million persons with chronic HBV infection in the world, with men having a slightly increased risk. Patients infected with HBV may be asymptomatic, develop nonspecific symptoms such as fatigue and anorexia, or experience acute symptoms such as jaundice and right upper quadrant discomfort. While acute HBV can be cleared, some patients may develop a chronic infection. Chronic hepatitis B (CHB), if left unmanaged, can result in complications such as necroinflammatory liver damage and hepatocellular carcinoma, and approximately 1.1 million people die annually from HBV-related liver disease. However, with antiviral treatment, HBV can be well-managed.

Different stages of HBV infection are characterized by the presence of HBV-specific antibodies or antigens. Hepatitis B surface antigen (HBsAg) is detected within 1 to 9 weeks of a new acute infection. A majority of patients will have detectable levels after one month from exposure to HBV, indicating that the patient is infectious. Fifteen weeks from the first symptoms, about 50% of those infected will test negative for HBsAg and HBV DNA. Hepatitis B surface antibody (HBsAb) becomes detectable after HBsAg disappears in patients who recover from the virus and avoid a chronic infection. Generally, the presence of serum HBsAb indicates recovery and immunity from HBV. The hepatitis B core antibody (HBcAb) remains in the blood indefinitely, regardless of acute or chronic infection status. Similarly, IgG anti-HBc will also remain in the blood indefinitely. Hepatitis B e-antigen (HBeAg) is generally detectable in patients with a new acute infection and is associated with higher HBV DNA levels. Along with HBeAg, IgM anti-HBc also indicates a new acute infection. In particular, IgM anti-HBc can indicate an acute exacerbation in a chronically infected patient. Table 1 summarizes key HBV serology information.

Table 1: HBV Serology and Interpretation for HBV Infection Serology

Serologic Marker	Abbreviation	Interpretation
Hepatitis B surface antigen	HBsAg	HBsAg is detected in high levels in serum during acute or chronic hepatitis B virus infection. The presence of HBsAg indicates that the person is infectious.
Hepatitis B surface antibody	HBsAb	As part of the normal immune response to infection, the body produces antibodies to HBsAg. The presence of anti-HBs generally indicates recovery and immunity from hepatitis B virus infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B.
Hepatitis B core antibody	HBcAb	HBcAb appears at the onset of symptoms in acute hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus in an undefined time frame.
Hepatitis B e antigen	HBeAg	HBeAg indicates that the virus is replicating and the patient has high levels of HBV.
IgM antibody to hepatitis B core antigen	IgM HBcAb	IgM HBcAb indicates recent infection with HBV. Its presence indicates acute infection.

Adapted from Mast EE et al. CDC Morbidity and Mortality Weekly Report. 2005; 54(RR-16):1-31.

CHB is defined as having HBsAg ≥6 months and is classified in four stages: immune tolerance, immune active/clearance, inactive carrier, and reactivation. In children and less commonly in adults, CHB begins with an immune-tolerant phase, high-level viremia, and minimal liver inflammation. As the virus interacts with the host immune system and viral co-infections, CHB progresses to an immune active/clearance phase with active liver disease and viral replication followed by an inactive carrier phase with low viral replication and minimal liver inflammation. In patients with inactive or resolved hepatitis B or in the setting of immunosuppression, reactivation may occur spontaneously, and manifests as increases in

serum hepatitis B DNA and HBeAg. In order to prevent potentially fatal hepatitis and liver failure due to hepatitis B reactivation, hepatitis B serology should be identified prior to beginning immunosuppressive agents or chemotherapy, and preemptive antiviral therapy may be warranted. The specific criteria and laboratory characteristics for the different classifications of CHB are summarized in Table 2.

Table 2: Chronic Hepatitis B (CHB) Immune Stages: Laboratory Characteristics					
	HBsAg	**HBeAg**	**HBcAg**	**HBV DNA**	**ALT**
Immune-tolerant CHB	+	+	+	+++	-
Immune-active CHB	+	+/-	+	+++	+
Inactive CHB	+	-	+	+/-	-

Adapted from: McMahon BJ et al. The Medscape Journal of Medicine. 2008; 10(4):91; Table 1

The American Association for the Study of Liver Diseases and the European Association for the Study of the Liver recommend pegylated-interferon (Peg-IFN)-alfa-2a or Peg-IFN-alfa-2b, entecavir (ETV, Baraclude®), or tenofovir disoproxil fumarate (TDF, Viread®) or tenofovir alafenamide (TAF, Vemlidy®) as preferred initial therapy for adults with immune-active CHB to decrease the risk of liver-related complications. Tenofovir alafenamide (TAF, Vemlidy®) received a new indication in 03/2024 for treatment of chronic hepatitis B virus infection in adults and pediatric patients ≥6 years of age and weighing ≥25 kg with compensated liver disease. However, no current guidelines reflect its use in pediatric populations. The World Health Organization offers similar recommendations for the nucleot(s)ide analogs (NAs; e.g. ETV, TDF/TAF) but excludes immunomodulators (e.g. Peg-IFN) as they have fallen out of favor in clinical practice due to their extensive adverse effect profiles. Peg-IFN-alfa-2b has been permanently discontinued and therefore, Peg-IFN-alfa-2a is the only interferon product indicated for CHB that is readily available. Head-to-head comparisons of antiviral therapies fail to show superiority of one therapy over another in achieving risk reduction in liver-related complications. However, in recommending Peg-IFN, TDF/TAF, and ETV as preferred therapies, the most important factor to consider is the lack of resistance with long-term use. Aside from antiviral resistance, patient-specific factors that must be considered when choosing between Peg-IFN, ETV, and TDF/TAF including the:

- Desire for finite therapy
- Anticipated tolerability of treatment side effects
- Comorbidities: Peg-IFN is contraindicated in persons with autoimmune disease, uncontrolled psychiatric disease, cytopenias, severe cardiac disease, uncontrolled seizures, and decompensated cirrhosis.
- Previous history of lamivudine resistance (entecavir is not preferred in this setting).
- Family planning: A finite therapy with Peg-IFN pre-pregnancy or use of oral antiviral that is safe in pregnancy is best.
- HBV genotype: A and B genotypes are more likely to achieve HBeAg and HBsAg loss with Peg-IFN than non-A/B genotypes.
- Medication costs.

TAF (Vemlidy®), the novel prodrug of TDF (Viread®), was added to the list of preferred agents in the most recent updates of all three practice guidelines. This drug was noted for its lower incidence of bone and renal toxicity compared to TDF, but is not preferred over TDF. Both drugs are currently priced similarly, however, the highest dose of TDF (300 mg) is now available generically at significantly reduced costs. Lamivudine (LAM, Epivir® HBV) and adefovir (ADV, Hepsera®) are also available generically but are non-preferred NAs. The duration of therapy for NA-based therapy is variable and influenced by HBeAg status, duration of HBV DNA suppression, and the presence of cirrhosis/decompensation. All NAs require dose adjustment in persons with creatinine clearance <50 mL/min. Clinical studies indicate that patients taking TAF have better renal laboratory tests and less bone mineral density decreases when compared to TDF and that switching from TDF to TAF preserves efficacy while maintaining these renal and bone benefits.

INDICATIONS, DOSING and ADMINISTRATION*

Medication	Indications	Dosing/Administration
	Oral Agents	
Tenofovir disoproxil fumarate (Viread®)	• Chronic hepatitis B in adults and pediatric patients 12 years of age and older	• Chronic hepatitis B: 300 mg once daily Treatment duration (AASLD practice guidelines): • Patients not achieving <2 log decrease in serum HBV DNA after at least 6 months of therapy should either receive additional treatment or be switched to an alternative therapy. • Hepatitis Be antigen (HBeAg) positive chronic hepatitis: Treat ≥1 year until HBeAg seroconversion and undetectable serum HBV DNA; continue therapy for ≥6 months after HBeAg seroconversion • HBeAg negative chronic hepatitis: Treat >1 year until hepatitis B surface antigen (HBsAg) clearance • Decompensated liver disease: Lifelong treatment is recommended
Vemlidy® (tenofovir alafenamide fumarate)	• Chronic hepatitis B virus infection in adults and pediatric patients ≥6 years of age and weighing ≥25 kg with compensated liver disease	• Chronic hepatitis B: Oral: 25 mg once daily
Adefovir (Hepsera®)	• Chronic hepatitis B (adults and children ≥12 yo) with evidence of active viral replication (based on persistent elevation of ALT/AST or histologic evidence), including patients with lamivudine-resistant hepatitis B	• Chronic hepatitis B: Oral: 10 mg once daily Treatment duration (AASLD practice guidelines): • Hepatitis Be antigen (HBeAg) positive chronic hepatitis: Treat ≥1 year until HBeAg seroconversion and undetectable serum HBV DNA; continue therapy for ≥6 months after HBeAg seroconversion • HBeAg negative chronic hepatitis: Treat >1 year until hepatitis B surface antigen (HBsAg) clearance • Patients not achieving a <2 log decrease in serum HBV DNA after at least 6 months of therapy should either receive additional treatment or be switched to an alternative therapy.
Entecavir (Baraclude®)	• Chronic hepatitis B virus (HBV) infection in adults and pediatric patients 2 years and older with evidence of active viral replication and either evidence of persistent transaminase elevations or histologically-active disease. • HBV reinfection prophylaxis, post liver transplant (off-label) • HIV/HBV coinfection (off-label) • Note: In adults, indication is based on data in patients with compensated and	• Chronic hepatitis B virus (HBV) infection, treatment: Oral: ○ Nucleoside treatment naive: 0.5 mg once daily ○ Lamivudine-refractory or -resistant viremia (or known lamivudine- or telbivudine-resistant mutations): 1 mg once daily ○ Decompensated liver disease: 1 mg once daily

Medication	Indications	Dosing/Administration
	decompensated liver disease; in children, indication is based on data in patients with compensated liver disease.	Treatment duration (AASLD Practice Guidelines): • Hepatitis Be antigen (HBeAg) positive chronic hepatitis: Treat ≥1 year until HBeAg seroconversion and undetectable serum HBV DNA; continue therapy for ≥6 months after HBeAg seroconversion • HBeAg negative chronic hepatitis: Treat >1 year until hepatitis B surface antigen (HBsAg) clearance • Decompensated liver disease: Lifelong treatment is recommended. • Patients not achieving a primary response (<2 log decrease in serum HBV DNA) after at least 6 months of therapy should either receive additional treatment or be switched to an alternative therapy.
Lamivudine (Epivir® HBV) tablet	• Chronic hepatitis B associated with evidence of hepatitis B viral replication and active liver inflammation. • Limitations of use: Use only when an alternative antiviral agent with a higher genetic barrier to resistance is not available or appropriate; has not been evaluated in patients with HBV-HIV-1 coinfection, hepatitis C virus or hepatitis delta virus; has also not been evaluated in patients with chronic HBV infection with decompensated liver disease or in liver transplant recipients. • Not a preferred agent due to high rates of resistance.	• Chronic hepatitis B: Oral: 100 mg once daily Treatment duration (AASLD practice guidelines): • Hepatitis Be antigen (HBeAg) positive chronic hepatitis: Treat ≥1 year until HBeAg seroconversion and undetectable serum HBV DNA; continue therapy for ≥6 months after HBeAg seroconversion • HBeAg negative chronic hepatitis: Treat >1 year until hepatitis B surface antigen (HBsAg) clearance • Patients not achieving <2 log decrease in serum HBV DNA after at least 6 months of therapy should either receive additional treatment or be switched to an alternative therapy
Injectable Agents		
Pegasys® (peginterferon alfa-2a) 180 mcg/0.5 mL SQ syringe, solution	• Adult Patients: Adults with HBeAg-positive and HBeAgnegative chronic hepatitis B (CHB) infection who have compensated liver disease and evidence of viral replication and liver inflammation • Pediatric Patients: Non-cirrhotic pediatric patients 3 years of age and older with HBeAg-positive CHB and evidence of viral replication and elevations in serum alanine aminotransferase (ALT)	• Chronic hepatitis B: SubQ: 180 mcg once weekly for 48 weeks.

*****Non-HBV indications for these agents and pediatric dosing are not included in this chart.

BOXED WARNINGS and CONTRAINDICATIONS

Medication	Boxed Warnings	Contraindications
Oral Agents		
Tenofovir disoproxil fumarate (Viread®) Vemlidy® (tenofovir alafenamide fumarate)	• Severe acute exacerbations of hepatitis B have been reported in patients who discontinue therapy	None
Adefovir (Hepsera®)	• Severe acute exacerbations of hepatitis B have been reported in patients who discontinue therapy • Therapy with entecavir is not recommended for HIV/HBV coinfected patients who are not also receiving antiretroviral therapy. • Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported • Long term administration may result in nephrotoxicity in patents at risk of or with underlying renal dysfunction	
Entecavir (Baraclude®) Lamivudine (Epivir® HBV) tablet	• Severe acute exacerbations of hepatitis B have been reported in patients who discontinue therapy • Therapy with entecavir is not recommended for HIV/HBV coinfected patients who are not also receiving antiretroviral therapy. • Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported	
Injectable Agents		
Pegasys® (peginterferon alfa-2a) SQ syringe, solution	• Risk of serious disorders: Peginterferon alfa-2a may cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Monitor patients closely with periodic clinical and laboratory evaluations. Withdraw therapy in patients with persistently severe or worsening signs or symptoms of these conditions. In many, but not all, cases, these disorders resolve after stopping peginterferon alfa-2a therapy.	• Hypersensitivity reactions (eg, urticaria, angioedema, bronchoconstriction, anaphylaxis, Stevens-Johnson syndrome) to peginterferon alfa-2a, other alfa interferons, or any component of the formulation; autoimmune hepatitis; hepatic decompensation in cirrhotic patients (Child-Pugh score >6, class B and C) before treatment; hepatic decompensation with Child-Pugh score ≥6 in cirrhotic CHC coinfected with HIV before treatment; neonates and infants (due to benzyl alcohol component) • Combination therapy with peginterferon alfa-2a and ribavirin is also contraindicated in pregnancy; men whose female partners are pregnant; patients with

Medication	Boxed Warnings	Contraindications
		hemoglobinopathies (ie, thalassemia major, sickle cell disease); coadministration with didanosine

WARNINGS/PRECAUTIONS

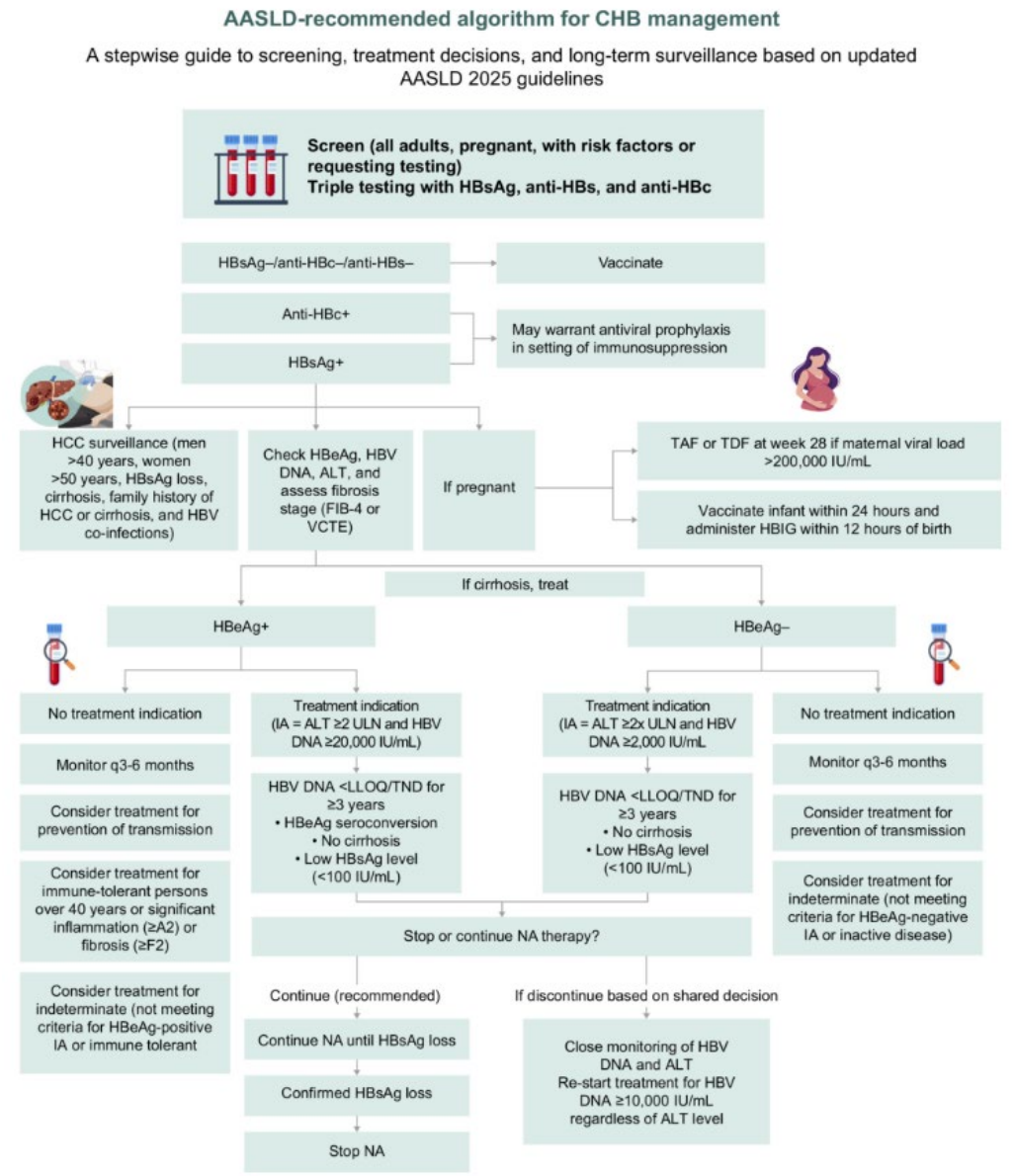
Medication	Warnings/Precautions
Oral Agents	
Tenofovir disoproxil fumarate (Viread®)	**Concerns related to adverse effects:** • Decrease bone mineral density, immune reconstitution syndrome, lactic acidosis/hepatomegaly, osteomalacia, renal dysfunction, renal toxicity **Disease related concerns:** • Use caution in patients with hepatic impairment, there is limited data supporting treatment of chronic hepatitis B in patients with decompensated liver disease, dosage adjustment is required in renal impairment CrCl < 50 mL/min, IDSA guidelines recommend avoiding tenofovir in HIV patients with preexisting kidney disease and not on hemodialysis when other options exist. **Concerns related to concurrent drug therapy**: • Do not use in combination with other adefovir or other tenofovir containing products.
Vemlidy® (tenofovir alafenamide fumarate)	**Concerns related to adverse effects:** • Lactic acidosis/hepatomegaly **Disease related concerns:** • Use is not recommended in patients with Child Pugh class B or C hepatic impairment, should not be used as a single treatment for HIV-1 due to risk of developing resistance, use is not recommended in CrCl < 15 mL/min, acute renal failure, Fanconi syndrome, or renal toxicity have been reported
Adefovir (Hepsera®)	**Concerns related to concurrent drug therapy:** • Do not use concurrently with any product containing tenofovir
Entecavir (Baraclude®)	**Concerns related to adverse effects:** • See boxed warnings **Disease related concerns:** • Observe patients with hepatic impairment for increased adverse reactions, use caution in patients with renal impairment, dosage adjusted recommended for CrCl < 50 mL/min
Lamivudine (Epivir® HBV) tablet	**Concerns related to adverse effects:** • May cause fat redistribution, patients may develop immune reconstitution syndrome, discontinue treatment if signs/symptoms of pancreatitis occur **Disease related concerns:** • Use caution in patients with renal impairment, dosage reduction is recommended, patients treated with lamivudine-HBV with YMDD-mutant HBV showed diminished treatment response
Injectable Agents	
Pegasys® (peginterferon alfa-2a) SQ syringe, solution	**Concerns related to adverse effects:** • Bone marrow suppression, CNS depression, dermatologic effects, gastrointestinal effects, hepatic effects, hypersensitivity reactions, neuropsychiatric disorders: [US Boxed Warning], ophthalmic effects (decreased or loss of vision and retinopathy, including macular edema, optic neuritis, papilledema, retinal hemorrhages, retinal detachment (serous), cotton wool spots, and retinal artery or vein thrombosis), pancreatitis, pulmonary effects **Disease-related concerns:**

Medication	Warnings/Precautions
	• Autoimmune disease: [US Boxed Warning], cardiovascular disease, diabetes, hepatitis B flares, infectious disorders: [US Boxed Warning], ischemic disorders: [US Boxed Warning], renal impairment, seizure disorders, thyroid disorders **Special populations:** • Use with caution in the elderly; certain adverse effects (eg, neuropsychiatric, cardiac, flu-like reactions) may be more severe. • Growth velocity (height and weight) was decreased in children with or without combination treatment with ribavirin, during the length of treatment **Other warnings/precautions:** • Appropriate use: Hepatitis B: Hepatitis B genotypes A and B are more likely to achieve HBeAg and HBsAg loss with peg-interferon than non-A/B genotypes. For patients with hepatitis B coinfected with hepatitis delta virus, pegylated interferon is the only effective therapy.

AASLD IDSA Practice Guideline on Treatment of Chronic Hepatitis B (2026)

Ghany, Marc G., Pan, Calvin Q., Lok, Anna S., et al. AASLD IDSA Practice Guideline on treatment of chronic hepatitis B. Hepatology 83(4):p 974-997, April 2026.

- For pregnant persons with HBV DNA levels greater than 200,000 IU/mL at any time point during pregnancy, regardless of HBeAg status, AASLD recommends initiating tenofovir disoproxil fumarate or tenofovir alafenamide at gestational week 28 to prevent mother-to-child transmission. Tenofovir disoproxil fumarate has a more extensive safety record in pregnancy than tenofovir alafenamide.
- For persons who are HBsAg-positive with viremia not meeting disease-specific treatment indications and who are in high-risk scenarios for transmission to others, AASLD suggests a shared decision-making approach regarding antiviral treatment.
- For persons in the immune-tolerant phase (defined as HBeAg-positive, HBV DNA >107 IU/mL, and normal ALT levels), AASLD suggests antiviral therapy for those over age 40 years or with significant liver inflammation (grade 2 or higher) or fibrosis (F2 or greater) on liver biopsy or noninvasive tests. For persons under age 40 years who are interested in starting treatment earlier, AASLD suggests shared decision-making with consideration of risk factors as well as the benefits and risks of treatment.
- In adults with HBsAg-positive, HBeAg-negative chronic HBV infection without cirrhosis and in the indeterminate phase, AASLD suggests antiviral therapy using a shared decision-making approach by assessing risks and benefits and to reevaluate that decision at each follow-up visit if treatment has not been initiated.
- In adults with chronic hepatitis B, who are HBeAg-negative without cirrhosis, with sustained undetectable HBV DNA on nucleos(t)ide analogue therapy, AASLD suggests not withdrawing nucleos(t)ide analogue therapy until HBsAg loss.
- In persons who achieved HBsAg loss, AASLD suggests continued HCC surveillance for those with cirrhosis, with family history of HCC, men who experienced HBsAg loss after age 40, and women who experienced HBsAg loss after age 50 years.
- In persons with HBV-HDV co-infection, AASLD suggests HCC surveillance of adults independent of cirrhosis status. The decision to undertake surveillance in children should be individualized due to the risk of HCC being unknown in this population.
- In persons with HBV-HIV co-infection, AASLD suggests HCC surveillance for men ≥18 years of age and women ≥40 years of age.
- In persons with HBV-HCV co-infection, AASLD recommends treatment for HCV and suggests HCC surveillance as per criteria for HBV mono-infection.



Update to AASLD Hepatitis B Guidelines (2018)

Terrault NA, Bzowej NH, Chang KM, et al. Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B. Hepatology. 2018; 67(4): 1560-1599.

In the 2018 hepatitis B guidance, AASLD added evidence pertaining to tenofovir alafenamide (TAF)'s place in therapy. However, there were no clinically significant changes in hepatitis B treatment recommendations. The following is a summary of major points from the 2018 AASLD hepatitis B update:

- TAF was added to the list of preferred antivirals (tenofovir disoproxil fumarate [TDF], entecavir [ETV], PEG-interferon [IFN]-alfa-2a, and IFN-alfa-2b) because it was noted for its high barrier to resistance, and decreased bone and renal toxicity compared to TDF. However, it is not preferred over TDF or any other preferred agent. Further, TAF is not recommended in pregnancy or children due to insufficient data.
- Lamivudine (LAM) and adefovir (ADV) are treatment options, but are not preferred.
- In certain scenarios, the AASLD recommends against antiviral therapy: in immune-tolerant CHB; for prevention of HBV perinatal transmission when HBV DNA ≤ 200,000 IU/mL in pregnant women; and in HBeAg-positive children with normal ALT levels.
- AASLD recommends antiviral therapy indefinitely for patients with decompensated cirrhosis. Patients who seroconvert can consider treatment discontinuation while immune-active patients should remain on treatment

indefinitely. Upon treatment failure, the guidelines suggest switching, not adding on, within the preferred agents.

European Association for the Study of the Liver (EASL) Clinical Practice Guidelines on the Management of Hepatitis B Virus Infection (2017)

EASL 2017 Clinical Practice Guidelines on the management of hepatitis B virus infection. Journal of Hepatology. 2017; 67(2): 370-398.

- The preferred treatment options are identical to the AASLD preferred treatment options: ETV, TDF, or TAF, which all have a high barrier to resistance. PEG-IFN can be considered in mild-to-moderate CHB but must be avoided in acute hepatitis B infections. Upon treatment failure, the guidelines suggest switching, not adding on, within the preferred agents. Combination therapies are not generally recommended.

AASLD Hepatitis B Guidelines (2016)

Terrault NA, Bzowej NH, Chang KM, et al. AASLD Guidelines for Treatment of Chronic Hepatitis B. Hepatology. 2016; 63(1): 261-83.

Treatment of Persons with Immune-Active CHB

- Recommends antiviral therapy for adults with immune-active CHB (HBeAg negative or positive) to decrease the risk of liver-related complications (Level 1)
- Recommends PEG-IFN-alfa-2a, IFN-alfa-2b, ETV, or tenofovir (TDF or TAF) as preferred initial therapy for adults with immune-active CHB (Level 1)

Treatment of immune-tolerant adults with hepatitis B

- The AASLD recommends against antiviral therapy for adults with immune-tolerant CHB (Level 1).
- Suggests that ALT levels be tested at least every 6 months for adults with immune tolerant CHB to monitor for potential transition to immune-active or immune-inactive CHB (Level 2)
- Suggests antiviral therapy in the select group of adults >40 years of age with normal ALT and elevated HBV DNA (1,000,000 IU/mL) and liver biopsy specimen showing significant necroinflammation or fibrosis (Level 2)

Treatment of HBeAg-positive, immune-active persons with chronic hepatitis who seroconvert to anti-HBe on NA therapy

- Suggests that HBeAg-positive adults without cirrhosis but with CHB who seroconvert to anti-HBe on therapy discontinue NAs after a period of treatment consolidation (Level 2)
- Suggests indefinite antiviral therapy for HBeAg-positive adults with cirrhosis and CHB who seroconvert to anti-HBe on NA therapy, based on concerns for potential clinical decompensation and death, unless there is a strong competing rationale for treatment discontinuation (Level 2)

Duration of treatment in persons with HBeAg-negative, immune-active CHB

- Suggests indefinite antiviral therapy for adults with HBeAg-negative, immune-active CHB unless there is a compelling rationale for treatment discontinuation (Level 2)

Renal and bone disease in persons on NA therapy

- Suggests no preference between ETV or TDF regarding potential long-term risks of renal and bone complications (Level 2)

Management of persons with persistent low-level viremia on NA therapy

- Suggests that persons with persistent low-level viremia (<2,000 IU/mL) on ETV or TDF monotherapy continue monotherapy, regardless of ALT (Level 2)
- Suggests 1 of 2 strategies in persons with virological breakthrough on ETV or TDF monotherapy: either switch to another antiviral monotherapy with a high barrier to resistance or add a second antiviral drug that lacks cross-resistance (Level 2)

Management of adults with cirrhosis and low-level viremia

- Suggests that adults with compensated cirrhosis and low-level viremia (<2,000 IU/mL) be treated with antiviral therapy to reduce the risk of decompensation, regardless of ALT level (Level 2)
- Recommends that HBsAg-positive adults with decompensated cirrhosis be treated with antiviral therapy indefinitely regardless of HBV DNA level, HBeAg status, or ALT level to decrease risk of worsening liver-related complications (Level 1)

Management of chronic hepatitis b in pregnancy

- Suggests antiviral therapy to reduce the risk of perinatal transmission of HBV in HBsAg-positive pregnant women with an HBV DNA level >200,000 IU/mL (Level 2)
- Recommends against the use of antiviral therapy to reduce the risk of perinatal transmission of HBV in HBsAg-positive pregnant women with an HBV-DNA level ≤ 200,000 IU/mL (Level 1)

Treatment of CHB in children

- Suggests antiviral therapy in HBeAg-positive children (ages 2 to <18 years) with both elevated ALT and measurable HBV-DNA levels, with the goal of achieving sustained HBeAg seroconversion (Level 2)
- Recommends against the use of antiviral therapy in HBeAg-positive children (ages 2 to <18 years) with persistently normal ALT, regardless of HBV-DNA level (Level 1)

AASLD Levels of Evidence

Level of Evidence	Description
Level 1	"We recommend"; Most patients should receive the recommended course of action; The recommendation can be adopted as policy in most situations
Level 2	"We suggest"; Different choices will be appropriate for different patients; The recommendation is likely to require debate and involvement of stakeholders

WHO Hepatitis B Guidelines (2015)

Abraham P, Aghokeng A, Andrieux-Meyer I, et al. Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection. World Health Organization. 2015; 1-166.

Recommendations: First-line antiviral therapies for chronic hepatitis B

- In all adults, adolescents and children aged 12 years or older in whom antiviral therapy is indicated, the nucleos(t)ide analogues (NAs) which have a high barrier to drug resistance (TDF/TAF or ETV) are recommended. Entecavir is recommended in children aged 2–11 years. (Strong recommendation, moderate quality of evidence)
- NAs with a low barrier to resistance (LAM, adefovir or telbivudine) can lead to drug resistance and are not recommended. (Strong recommendation, moderate quality of evidence)

Recommendations: Second-line antiviral therapies for management of treatment failure

- In persons with confirmed or suspected antiviral resistance (i.e. history of prior exposure or primary non-response) to lamivudine, ETV, adefovir or telbivudine, a switch to TDF/TAF is recommended. (Strong recommendation, low quality of evidence)
    - Treatment adherence should be reinforced
    - For adefovir resistance, a switch to either TDF/TAF or ETV can be considered
    - To date, there has been no reported resistance with TDF/TAF. If there is primary non-response, then treatment adherence should be reinforced and monitored. At present, there is therefore no indication to switch to an alternative drug regimen

Recommendations: When to stop treatment

- Lifelong NA therapy: All persons with cirrhosis based on clinical evidence (or APRI score >2 in adults) require lifelong treatment with NAs, and should not discontinue antiviral therapy because of the risk of reactivation, which can cause severe acute-on-chronic liver injury. (Strong recommendation, low quality of evidence)
- Discontinuation: Discontinuation of NA therapy may be considered exceptionally in:
    - persons without clinical evidence of cirrhosis (or based on APRI score ≤2 in adults);
    - and who can be followed carefully long term for reactivation;
    - and if there is evidence of HBeAg loss and seroconversion to anti-HBe (in persons initially HBeAg-positive) and after completion of at least one additional year of treatment;
    - and in association with persistently normal ALT levels and persistently undetectable HBV DNA levels (where testing is available).
        - Where HBV DNA testing is not available: Discontinuation of NA therapy may be considered in persons who have evidence of persistent HBsAg loss and after completion of at least one additional year of treatment, regardless of prior HBeAg status. (Conditional recommendation, low quality of evidence)
- Retreatment: Relapse may occur after stopping therapy with NAs. Retreatment is recommended if there are consistent signs of reactivation (HBsAg or HBeAg becomes positive, ALT levels increase, or HBV DNA becomes detectable again) (where HBV DNA testing is available) (Strong recommendation, low quality of evidence)

WHO Level of Evidence

Level of Evidence	Description
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 effect.
Low	Further research is very likely to have an estimate of effect and is likely to change the estimate.
Very Low	Any estimate of effect is very uncertain.

CLINICAL TRIALS/SYSTEMATIC REVIEWS/META-ANALYSES

Citation	Design	Endpoints
Biomedtracker. A Phase 3, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Switching From Tenofovir Disoproxil Fumarate 300 mg QD to Tenofovir Alafenamide 25mg QD in Subjects With Chronic Hepatitis B Who Are Virologically Suppressed (NCT02979613). Informa Business Intelligence Inc. https://www.biomedtracker.com	Randomized, double-blind, parallel assignment, phase III trial enrolled 488 participants with chronic hepatitis B (CHB) who were assigned to receive tenofovir alafenamide (TAF) 25 mg (n=233) or tenofovir disoproxil fumarate (TDF) 300 mg daily (n=232) for 48 weeks and then switched to the other therapy for 48 more weeks. Inclusion criteria: Must have the ability to understand and sign a written informed consent form; consent must be obtained prior to initiation of study procedures; Adult male and non-pregnant, non-lactating females; Documented evidence of chronic HBV infection previously; Maintained on TDF 300 mg QD for at least 48 weeks, and as monotherapy for chronic hepatitis B for at least 24 weeks with viral suppression (HBV DNA < LLOQ) for a minimum of 12 weeks prior to screening; Adequate renal function; Normal ECG	• Primary endpoints: Proportion of Participants with hepatitis B virus (HBV) DNA ≥ 20 IU/mL at Week 24, as Determined by the Modified US FDA-Defined Snapshot Algorithm (virologic suppression) • Secondary endpoints: Alanine aminotransferase (ALT) normalization; bone and renal safety parameters
Results: Virologically suppressed patients who were switched from TDF to TAF displayed non-inferior rates of viral suppression (96.3% in both arms) after 48 weeks of treatment compared to patients who remained on TDF; TAF demonstrated significant improvements in renal and bone safety parameters compared to TDF, with TAF-treated patients displaying mean changes of +0.66g/cm^2 and +1.74g/cm^2 in hip and spine bone mineral density, respectively, versus declines of -0.51g/cm^2 and -0.11g/cm^2 in TDF-treated patients; TAF-treated patients displayed a small median recovery in estimated glomerular filtration rate (+0.99 mL/min) after 48 weeks of treatment, versus continued declines in TDF-treated patients (-2.74 mL/min); rates of ALT normalization were increased in both groups. **Conclusion**: TAF was non-inferior to TDF in the treatment of patients with CHB, having comparable viral suppression and increases in ALT normalization. However, TAF had significant improvements in bone and renal safety parameters when compared to TDF.		
Citation	**Design**	**Endpoints**
Han Y, Zeng A, Liao H, et al. The efficacy and safety comparison between tenofovir and entecavir in treatment of chronic hepatitis B and HBV related cirrhosis: A systematic review and Meta-analysis. International Immunopharmacology. 2017; 42: 168-175. DOI: 10.1016/j.intimp.2016.11.022	Meta-analysis assessing the efficacy and safety between tenofovir disoproxil fumarate (TDF) and entecavir (ETV) in the treatment of chronic hepatitis B (CHB) and HBV related cirrhosis. PubMed, the Cochrane Library, Nature, CNKI and WanFang data were searched for the keywords “tenofovir,” “entecavir,” “chronic hepatitis B,” or “CHB”.	• Primary endpoints: Differences in undetectable HBV-DNA, ALT normalization; eGFR levels; and hypophosphatemia incidence.
Results: There was a significant difference of ALT normalization in the short-term period of 3 months (RR=1.43, 95%CI: 1.06-1.94, P<0.017) and 6 months (RR=0.89, 95%CI: 0.81-0.97, P<0.017), and significant difference of undetectable HBV-DNA only in 3 month follow-up period (RR=1.59, 95%CI: 1.04-2.42, P<0.017) between TDF and ETV, but no significant difference in the long-term period. There was a significant difference between TDF and ETV in eGFR level (RR=1.601, 95%CI: 1.035-2.478, P=0.0034) and hypophosphatemia incidence (RR=4.008, 95%CI: 1.485-10.820, P=0.006). **Conclusion:** TDF had better efficacy than ETV in the short-term (3 months) but this normalized and viral suppression and liver function improvement, including HBV-related liver cirrhosis, was similar after 6 months. TDF and ETV may influence renal function but TDF may increase the risk of renal damage and hypophosphatemia.		

Citation	Design	Endpoints
Jun DW, Ahn SB, Kim TY, et al. Efficacy of Pegylated Interferon Monotherapy versus Sequential Therapy of Entecavir and Pegylated Interferon in Hepatitis B e Antigen-Positive Hepatitis B Patients: A Randomized, Multicenter, Phase IIIb Open-Label Study (POTENT Study). Chinese Medical Journal. 2018; 131(14): 1645-1651.	Randomized, multicenter, open-label, phase IIIb study evaluating the efficacy of pegylated interferon (Peg-IFN) monotherapy versus sequential therapy of entecavir (ETV) and pegylated interferon in 162 hepatitis B e-antigen (HBeAg)-positive HBV patients (POTENT study). HBeAg-positive patients received Peg-IFN (mono-treatment group, n=81) for 48 weeks or ETV for 12 weeks with a 48 week course of Peg-IFN starting at week 5 of ETV therapy (sequential treatment group, n=81). Inclusion criteria: Chronic HBV (HBeAg-positive); Elevated ALT (>2x upper limit of normal)	• Primary endpoint: HBeAg seroconversion at week 24 • Secondary endpoints: HBeAg seroclearance at week 24; HBV DNA levels at week 24
Results: HBeAg seroconversion rate in PEG-IFN vs. ETV then PEG-IFN (18.2% vs 18.2%; p = 1.000); HBeAg seroclearance rate in PEG-IFN vs. ETV then PEG-IFN (19.7% vs 19.7%; p = 1.000); HBV DNA levels in PEG-IFN vs. ETV then PEG-IFN (28.8% vs 28.8%; p = 1.000); Adverse event profiles were similar between the two arms, although the PEG-IFN monotherapy arm had a slightly more hepatotoxicity. **Conclusion**: There were no differences in the HBeAg seroconversion and seroclearance rate, and HBV DNA levels. Slightly more hepatotoxicity was observed in the PEG-IFN monotherapy arm but overall, the safety profiles between the two regimens were similar. The increased risk of hepatotoxicity may be associated with the longer duration of PEG-IFN therapy but this is unclear given the limited sample size.		
Citation	**Design**	**Endpoints**
Su YC, Lin PC, Yu HC et al. Antiviral prophylaxis during chemotherapy or immunosuppressive drug therapy to prevent HBV reactivation in patients with resolved HBV infection: a systematic review and meta-analysis. European Journal of Clinical Pharmacology. 2018; 74(9): 1111-1119.	Systematic review and meta-analysis comparing the efficacy of antiviral prophylaxis versus that of non-prophylaxis in resolved HBV-infected patients undergoing chemotherapy or immunotherapy. Pubmed, the Cochrane library, and clinicaltrials.gov were searched and included studies evaluating patients with resolved HBV who received chemotherapy or immunosuppressive therapy and adults using LAM, ETV, telbivudine (TBV), and TDF. A total of 13 studies of 1,210 patients were included.	• Primary endpoint: Relative risk of HBV reactivation • Secondary endpoints: Hepatitis rates; liver failure rates
Results: Risk of HBV reactivation in antiviral prophylaxis vs placebo: RR = 0.47 (95% CI: [0.13, 1.69]); Hepatitis rates in antiviral prophylaxis vs placebo: RR = 1.19 (95% CI: [0.4, 3.57]); Liver failure rates in antiviral prophylaxis vs placebo: RR = 2.74 (95% CI: [0.26, 29.05]); There were no differences in safety between the two groups. Adverse events included disease- or immunosuppression-related complications. **Conclusion**: This meta-analysis did not demonstrate a clear difference in risk of HBV reactivation, hepatitis rates, or liver failure rates. Clinicians may consider prophylaxis given comparable safety profiles between the prophylaxis and placebo groups.		
Citation	**Design**	**Endpoints**
Wu J, Yin F, Zhou X et al. Efficacy of nucleoside analogues for hepatitis B virus-related liver failure: A network meta-analysis. Acta Pharmaceutica. 2018; 68(1): 19-30.	Meta-analysis to compare the efficacy of nucleos(t)ide analogs (NAs) in the treatment of HBV-related liver failure. A total of 1,660 patients from 12 studies about the efficacy of LAM (n=563), ETV (n=520), TBV (n=105), and TDF (n=14) in HBV-related liver failure or comparing several NAs with regards to mortality, survival, HBV DNA, or model for end-stage liver disease (MELD) score were included (non-NA, n=458).	Primary endpoints: Mortality; Three-month survival rate; HBV DNA levels; MELD score reduction

Results: Mortality of the TDF group was found to be the lowest. However, there were no significant differences compared to the ETV group (OR: 0.39; 95% CI [0.02, 5.02]), LAM group (OR: 0.43; 95% CI [0.03, 5.17]), TBV group (OR: 0.75; 95% CI [0.03, 15.74]) and non-NAs group (OR: 0.11; 95% CI [0.01, 1.13]); The three month survival rate of the TDF group was the highest and the difference was significant compared to the non-NAs group (OR: 8.30; 95% CI [1.31, 69.38]). However, the differences compared with the other NAs, including the ETV group (OR: 3.94; 95 % CI [0.57–33.21]), LAM group (OR: 3.09; 95% CI [0.46, 25.94]), and TBV group (OR: 4.18; 95% CI, [0.51, 39.41]) were not significant; The HBV DNA in the ETV group was lowest and the mean difference (MD) was significant compared to the non-NAs group (MD: -2.66, 95% CI [-5.19, -0.16]). However, there were no significant differences between the ETV group and the other two NA groups, including the LAM group (MD: -0.33; 95% CI [-1.91, 1.25]) and TBV group (MD: -0.25; 95% CI [-4.73 to 4.08]); The TDF group had the lowest MELD score. There was also a significant difference between the TDF group and the non-NAs group (MD: -7.85, 95% CI [-13.27, -2.20]) while the differences between the TDF group and the other NA groups, including ETV group (MD: -3.79; 95% CI [-10.08, 2.80]), LAM group (MD: -4.47; 95% CI [-10.93, 2.25) and TBV group (MD: -2.59; 95% CI: [-10.48, 5.61]), were not significant; No new safety signals were detected.
Conclusion: TDF demonstrated the lowest mortality rate, highest survival rate, and largest MELD score reduction compared to other NAs, and ETV the largest in HBV DNA level reductions. However, the TDF group only had a sample size of 14 subjects. All of the reviewed NAs were shown to be clinically comparable and no new safety signals were detected.

FORMULARY PLACEMENT, UTILIZATION AND COST EXPERIENCE (04-01-2026 to 06-30-2026)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Oral Agents								
Tenofovir disoproxil fumarate (Viread®) 300 mg oral tablet	18	15	$1,852.40	$102.91	0	0 (0%)	F	No change
Viread® (tenofovir disoproxil fumarate) 150, 200, 250 mg oral tablet	0	0	$0.00	$0.00	0	0 (0%)	F-PA	No change
Viread® (tenofovir disoproxil fumarate) 40 mg/gram oral powder	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Vemlidy® (tenofovir alafenamide) 25 mg oral tablet	49	23	$99,693.95	$2,034.57	14	10 (71%)	F-PA-QL (30/30)	No change
Adefovir (Hepsera®) 10 mg oral tablet	0	0	$0.00	$0.00	0	0 (0%)	F-PA	No change
Entecavir (Baraclude®) 0.5, 1 mg oral tablet	31	23	$2,126.30	$68.59	0	0 (0%)	F-QL (30/30)	No change
Baraclude® (entecavir) 0.05 mg/mL oral solution	0	0	$0.00	$0.00	0	0 (0%)	F-PA	No change
Lamivudine (Epivir® HBV) 100 mg oral tablet	0	0	$0.00	$0.00	0	0 (0%)	F-PA	No change
Injectable Agents								
Pegasys® (peginterferon alfa-2a) 180 mcg/0.5 mL SQ syringe	0	0	$0.00	$0.00	0	0 (0%)	F-PA	No change
Pegasys® (peginterferon alfa-2a) 180 mcg/0.5 mL SQ solution	0	0	$0.00	$0.00	0	0 (0%)	F-PA	No change
TOTAL	**98**	**61**	**$103,672.65**	**$1,057.88**	**14**	**10 (71%)**		

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

Recommendation: No changes

Hepatitis B Drugs		
Therapeutic Classes (AHFS)	Various	
Medications	Formulary Tenofovir disoproxil fumarate (Viread) 300 mg tablet Entecavir (Baraclude) 0.5, 1 mg tablets Formulary - PA required Baraclude (entecavir) 0.05 mg/ml solution Adefovir (Hepsera) 10 mg tablet Lamivudine (Epivir HBV) 100 mg tablet Lamivudine (Epivir HBV) 25 mg/5 ml solution Viread 150mg, 200mg, 250mg tablet Vemlidy (tenofovir alafenamide fumarate) 25 mg tablet Non-formulary Viread (Tenofovir disoproxil fumarate) 40mg/gm oral powder **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 Approval**	For pregnant patients taking prophylaxis therapy for reduction of perinatal transmission of HBV: 6 months All other INITIAL requests: 12 months: Requests can be approved for up to a 90 day supply
	Later Approvals	For RENEWAL requests for patients undergoing chemotherapy: HBV prophylactic treatment is only approved for up to an additional 12 months upon completion of chemotherapy. For RENEWAL requests for patients requiring prophylaxis against HBV reactivation due to high-risk therapies: non-chemotherapy related agents may be approved for an additional 6 months after discontinuation of the high-risk therapy; or 12 months after discontinuation of b-cell depleting agents. Otherwise, RENEWAL requests for patients continuing use of high-risk therapies may be approved for 12 months. RENEWAL requests will not be considered for perinatal prophylaxis after 3 months postpartum All other RENEWAL requests:12 months Requests can be approved for up to a 90 day supply Partial approvals - For situations where lab values required for later approvals/ renewals are missing either in full or in part should be granted for 3 months.

	*If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	**INITIAL CRITERIA for adult population:** • Diagnosis of Hepatitis B; AND • Medication is being prescribed at an appropriate FDA approved dose (for age and weight); AND • Requests for Vemlidy require trial and failure of, intolerance to, or inability to use entecavir (Baraclude) tablet AND • **For Immune-Active chronic hepatitis B (CHB)**: Elevation of ALT ≥2 ULN (above 50 U/L for females or 66 U/L for males) OR evidence of significant histological disease (significant inflammation and/or fibrosis); AND A) Elevated HBV DNA ≥ 2000 IU/mL (HBeAg negative); OR B) Elevated HBV DNA > 20,000 IU/mL (HBeAg positive). • **For Compensated or Decompensated Cirrhosis:** Presence of compensated or decompensated cirrhosis and detectable serum HBV DNA. • **Prophylaxis for Transplant Recipients with Hepatitis B:** A) Patient is HBsAg-positive and undergoing liver transplantation, regardless of HBeAg status or HBV-DNA level pre-transplant; OR B) Patient is HBsAg-negative and received a HBsAg-negative but anti-HBc–positive graft; OR C) Patient has received a HBsAg-positive (non-liver) organ transplant. • **Pregnant Women (for perinatal transmission prophylaxis only; patient does not meet other eligibility categories):** A) Patient is HBsAg-positive pregnant women with an HBV DNA level >200,000 IU/mL; AND B) Patient is in the third trimester of pregnancy • **Undergoing Chemotherapy or Will Be Initiating Cytotoxic Chemotherapy**: A) Patient is HBsAg-positive, anti-HBc–positive regardless of baseline serum HBV DNA levels; OR B) Patient is HBsAg-negative, anti-HBc–positive; AND 1) Receiving anti-CD20 antibody therapy (e.g., rituximab); OR 2) Undergoing stem cell transplantation. • **Acute Symptomatic Hepatitis B** Patient has acute hepatitis B with acute liver failure OR has a protracted, severe course, as indicated by total bilirubin >3 mg/dL (or direct bilirubin >1.5 mg/dL), international normalized ratio >1.5, encephalopathy, or ascites. • **Prophylaxis for Individuals at High Risk of Hepatitis B Reactivation:** A) Patient is HBsAg negative, anti-HBc positive and receiving B cell-depleting agents; OR B) Patient is HBsAg positive and receiving any of the following: anthracycline derivatives, anti-TNF therapy, anti-IL-6 therapy, B cell-depleting agents, CAR-t cell therapy, cytokine/integrin inhibitors, transcatheter arterial chemoembolization, tyrosine kinase inhibitors, janus kinase inhibitors, HCV co-infection undergoing

	direct-acting antivirals therapy, corticosteroid therapy of moderate-high dose and duration of ≥4 weeks. ***For adults, if request is for adefovir (Hepsera) or lamivudine (Epivir HBV), documentation of treatment failure or contraindication to entecavir (Baraclude) tablet AND tenofovir disoproxil fumarate (Viread) 300 mg tablet must be provided.** ***If request is for oral solution/oral powder, medical justification for use (i.e. difficulty swallowing) must be provided.** **INITIAL CRITERIA for Treatment of CHB in children (ages 2 to <18 years):** • Diagnosis of Hepatitis B; AND • Medication is being prescribed at an appropriate FDA approved dose (for age and weight); AND • Patient is HBeAg-positive with both: A) elevated ALT; AND B) measurable HBV-DNA levels ***For children, if request is for adefovir (Hepsera) or lamivudine (Epivir HBV), documentation of treatment failure or contraindication to entecavir (Baraclude) tablet or disoproxil fumarate (Viread) 300 mg tablet must be provided.** **For requests for Viread 150mg, 200mg, or 250mg tablet, documentation of weight required as rationale supporting why tenofovir disoproxil fumarate (Viread) 300 mg tablet cannot be used.** ***If request is for oral solution/oral powder, medical justification for use (i.e. difficulty swallowing) must be provided.** **RENEWAL CRITERIA** • Documented response to treatment shown by reduced HBV DNA levels. • If all other criteria are met but the necessary lab values have not been provided, a partial approval for 3 months may be granted. The partial approval should indicate what information is needed for ongoing approval. OR • Patient continues to require prophylaxis for Hepatitis B reactivation due to continuation of high risk therapies, or recent discontinuation of high risk therapies (see Coverage Duration section above)
Criteria Statement	N/A
Last P&T Review Date	~~6/2026~~9/2026

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Intranasal Corticosteroids

Executive Summary

CLASS OVERVIEW

Allergic rhinitis, also known as allergic rhinosinusitis, is an inflammatory immunoglobulin E (IgE)-mediated disease characterized by nasal congestion, rhinorrhea, sneezing, and/or nasal itching that occurs from the inflammation of the inside lining of the nose when a person inhales an allergen like animal dander or pollen. Allergic rhinitis is common, affecting roughly 10-30% of individuals in the US. There are several pharmacotherapy options for allergic rhinitis, many of which are available over-the-counter (OTC). Treatments include intranasal corticosteroids (INS), oral antihistamines, oral leukotriene receptor antagonists (LTRAs), immunotherapy, as well as dual combination therapy of the previous drug classes. Consensus exists among clinical practice guidelines for allergic rhinitis, which recommend INS over oral antihistamines and LTRAs, as they are the most effective single maintenance therapy for allergic rhinitis and cause few side effects. FDA approved INS for allergic rhinitis include: beclomethasone, budesonide, ciclesonide, flunisolide, fluticasone, mometasone, and triamcinolone. No single INS product is recommended over another per clinical practice guidelines.

UTILIZATION FINDINGS

There were 217 claims for 166 members, for a total cost of $2,626.19, and an average cost per claim of $12.10. The most highly utilized medication was fluticasone nasal spray with 217 claims. There were no prior authorization requests.

RECOMMENDATIONS

- No changes

CLINICAL SUMMARY

Allergic rhinitis is the chronic inflammation of the inside lining of the nose due to the inhalation of an allergen and is thought to be conducted by IgE mediated hyper inflammatory pathways. Symptoms include nasal congestion, rhinorrhea, sneezing, and/or nasal itching. Allergic rhinitis is common, affecting roughly 10-30% of individuals in the US. Proposed or identified risk factors for allergic rhinitis include family history of atopy, birth during pollen season, maternal smoking exposure in the first year of life, exposure to indoor allergens, and presence of allergen-specific IgE.

The mechanism of allergic rhinitis is as follows. Upon exposure to an allergen, atopic individuals respond by producing allergen-specific IgE. IgE antibodies bind to IgE receptors on mast cells in the respiratory mucosa. When the same allergen is subsequently inhaled, IgE antibodies are bridged on the cell surface by allergen, resulting in activation of the cell. Mast cells in the nasal tissues release preformed and granule-associated chemical mediators, which cause the symptoms of allergic rhinitis.

There are several pharmacotherapy options for allergic rhinitis, many of which are available over-the-counter. Treatments include INS, oral antihistamines, oral LTRAs, immunotherapy, as well as combination therapy. Clinical practice guidelines for allergic rhinitis recommend INS as first-line therapy in the treatment of allergic rhinitis. INS are recommended over oral antihistamines and LTRAs as they are the most effective single maintenance therapy for allergic rhinitis and cause few side effects. FDA approved INS for allergic rhinitis include: beclomethasone, budesonide, ciclesonide, flunisolide, fluticasone, mometasone, and triamcinolone. No single INS product is recommended over another.

INDICATIONS, DOSING and ADMINISTRATION

Medication	Indications	Dosing/Administration
Intranasal Steroid & Antihistamine Combination		
Azelastine/fluticasone (Dymista®)	Seasonal allergic rhinitis	1 spray (137 mcg azelastine/50 mcg fluticasone) per nostril twice daily
Ryaltris® (olopatadine/mometasone)		2 sprays (olopatadine 1,330 mcg/mometasone 50 mcg) in each nostril twice daily
Intranasal Steroids		
Beconase AQ® (beclomethasone dipropionate)	Nasal Polyps, postsurgical prophylaxis Allergic rhinitis Non-allergic (vasomotor) rhinitis	1 or 2 sprays (42 or 84 mcg) in each nostril twice daily
Qnasl® (beclomethasone dipropionate)	Allergic rhinitis	2 sprays (160 mcg) in each nostril once daily
Budesonide	Allergic rhinitis Upper respiratory symptoms	2 sprays (64 mcg) in each nostril once daily; once symptoms improve, reduce to 1 spray (32 mcg) in each nostril once daily
Omnaris® (ciclesonide)	Seasonal and perennial allergic rhinitis	2 sprays (100 mcg) per nostril once daily
Zetonna® (ciclesonide)		1 spray (37 mcg) per nostril once daily
Flunisolide	Rhinitis	2 sprays (50 mcg) in each nostril twice daily; may increase to 2 sprays in each nostril 3 times daily; max 400 mcg/day
Fluticasone propionate	Non-allergic rhinitis	2 sprays (100 mcg) in each nostril once daily or 1 spray in each nostril twice daily; once symptoms are controlled after 1 week, consider reducing to 1 (50 mg) spray in each nostril once daily
Fluticasone propionate (Flonase® Allergy Relief)	Upper respiratory allergies	
Flonase® Sensimist (fluticasone furoate)		2 sprays (55 mcg) in each nostril once daily; once symptoms are controlled after 1 week, consider reducing to 1 (27 mg) spray in each nostril once daily
Xhance® (fluticasone propionate) 93 mcg nasal spray	Nasal polyps	1 spray (93 mcg) per nostril twice daily; some patients may require 2 sprays (186 mcg) per nostril twice daily; max 744 mcg/day
Mometasone furoate (Nasonex®)	Allergic rhinitis Nasal polyps Seasonal allergic rhinitis prophylaxis	2 sprays (100 mcg) in each nostril once daily
Sinuva® (mometasone furoate)	Nasal polyps	1 implant (1,350 mcg) placed in the ethmoid sinus under endoscopic visualization for up to 90 days
Triamcinolone acetonide (Nasacort®)	Allergic rhinitis Upper respiratory allergies	2 sprays (110 mcg) in each nostril once daily; once symptoms are controlled, reduce to 1 spray (55 mcg) in each nostril once daily

BOXED WARNINGS and CONTRAINDICATIONS

Medication	Boxed Warnings	Contraindications
Aazelastine/fluticasone (Dymista®)	None	Hypersensitivity to azelastine, fluticasone, or any component of the formulation
Ryaltris® (olopatadine/mometasone)		Hypersensitivity to olopatadine, mometasone, or any component of the formulation
Beconase AQ®, Qnasl® (beclomethasone dipropionate)		Hypersensitivity to beclomethasone or any component of the formulation
Budesonide		Hypersensitivity to budesonide or any component of the formulation; children <6 years of age when used for self-medication (OTC)
Omnaris®, Zetonna® (ciclesonide)		Hypersensitivity to ciclesonide or any component of the formulation
Flunisolide		Hypersensitivity to flunisolide or any component of the formulation
Fluticasone propionate (Flonase® Allergy Relief, Xhance®)		Hypersensitivity to fluticasone or any component of the formulation; children <4 years of age when used for self-medication (OTC)
Flonase® Sensimist (fluticasone furoate)		Hypersensitivity to fluticasone or any component of the formulation; children <2 years of age when used for self-medication (OTC)
Mometasone furoate (Nasonex®, Sinuva®)		Hypersensitivity to mometasone or any component of the formulation
Triamcinolone acetonide (Nasacort®)		Hypersensitivity to triamcinolone or any component of the formulation; children <2 years of age when used for self-medication (OTC)

WARNINGS/PRECAUTIONS

Medication	Warnings/Precautions
Azelastine/fluticasone (Dymista®)	**Concerns related to adverse effects:** - Adrenal suppression - CNS depression - Delayed wound healing: Avoid use in patients with recent nasal septal ulcers, nasal surgery, or nasal trauma until healing has occurred - Immunosuppression - Infections - Local nasal effects: Nasal septal perforation, nasal ulceration, epistaxis, and localized *Candida albicans* infections of the nose and/or pharynx may occur - Ocular disease: Increased intraocular pressure, open-angle glaucoma, and cataracts have occurred with intranasal corticosteroid use **Special Populations:** - Pediatric: Avoid using higher than recommended dosages in pediatric patients
Ryaltris® (olopatadine/mometasone)	**Concerns related to adverse effects:** - Adrenal suppression - CNS depression - Delayed wound healing: Avoid use in patients with recent nasal septal ulcers, nasal surgery, or nasal trauma until healing has occurred - Immunosuppression - Infections - Local nasal effects: May cause epistaxis, nasal ulceration, or septal perforation **Disease-related concerns:** - Infections: Local *Candida* infections of the nose and throat have occurred from nasal administration of mometasone

Medication	Warnings/Precautions
	- Ocular disease: Increased intraocular pressure, glaucoma, and cataracts have occurred with prolonged use of mometasone **Special Populations:** - Pediatric: Avoid using higher than recommended dosages in pediatric patients
Beclonase AQ®, Qnasl® (beclomethasone)	**Concerns related to adverse effects:** - Adrenal suppression - Delayed wound healing: Avoid use in patients with recent nasal septal ulcers, nasal surgery, or nasal trauma until healing has occurred - Hypersensitivity reactions - Immunosuppression - Local nasal effects: Nasal septal perforation, nasal ulceration, epistaxis, and localized *Candida albicans* infections of the nose and/or pharynx may occur - Ocular disease: Increased intraocular pressure, open-angle glaucoma, and cataracts have occurred with intranasal corticosteroid use **Special populations:** - Pediatric: Avoid using higher than recommended dosages in pediatric patients **Other warnings/precautions:** - Do not use in presence of untreated localized infection of nasal mucosa - Treatment may need to be continued for several weeks or more before therapeutic results can be assessed in treatment of nasal polyps
Budesonide	**Concerns related to adverse effects:** - Adrenal suppression - Delayed wound healing: Avoid use in patients with recent nasal septal ulcers, nasal surgery or nasal trauma until healing has occurred - Hypersensitivity - Immunosuppression - Local nasal effects: Nasal septal perforation, nasal ulceration, epistaxis, and localized *Candida albicans* infections of the nose and/or pharynx may occur **Disease-related concerns:** - Ocular disease: Use with caution in patients with cataracts and/or glaucoma **Special populations:** - Pediatric: Avoid using higher than recommended dosages in pediatric patients
Omnaris®, Zetonna® (ciclesonide)	**Concerns related to adverse effects:** - Adrenal suppression - Delayed wound healing: Avoid use in patients with recent nasal septal ulcers, nasal surgery or nasal trauma until healing has occurred - Immunosuppression - Local nasal effects: Nasal septal perforation, nasal ulceration, epistaxis, and localized *Candida albicans* infections of the nose and/or pharynx may occur - Ocular disease: Increased intraocular pressure, open-angle glaucoma, and cataracts have occurred with intranasal corticosteroid use **Special populations:** - Pediatric: Avoid using higher than recommended dosages in pediatric patients
Flunisolide	**Concerns related to adverse effects:** - Adrenal suppression

Medication	Warnings/Precautions
	- Delayed wound healing: Avoid use in patients with recent nasal septal ulcers, nasal surgery or nasal trauma until healing has occurred - Immunosuppression - Local nasal effects: Nasal septal perforation, nasal ulceration, epistaxis, and localized *Candida albicans* infections of the nose and/or pharynx may occur **Special populations:** - Pediatric: Avoid using higher than recommended dosages in pediatric patients **Other warnings/precautions:** - Withdrawal: Symptoms of corticosteroid withdrawal (e.g., joint pain, muscle pain, lassitude, depression) may occur when transferring from a systemic corticosteroid to a topical corticosteroid
Fluticasone (Flonase® Allergy Relief, Flonase® Sensimist, Xhance®)	**Concerns related to adverse effects:** - Adrenal suppression - Delayed wound healing: Avoid use in patients with recent nasal septal ulcers, nasal surgery, or nasal trauma until healing has occurred - Hypersensitivity - Immunosuppression - Local nasal effects: Nasal septal perforation, nasal ulceration, nasal erosion, epistaxis, and localized *Candida albicans* infections of the nose and/or pharynx may occur **Disease-related concerns:** - Hepatic impairment: Accumulation may occur - Infections: Use caution or avoid use in patients with active or quiescent tuberculosis infections of the respiratory tract, systemic fungal, bacterial, viral, or parasitic infections, or ocular herpes simplex - Ocular disease: Use with caution in patients with cataracts and/or glaucoma **Special populations:** - Pediatric: Avoid using higher than recommended dosages in pediatric patients **Other warnings/precautions:** - Withdrawal: Symptoms of corticosteroid withdrawal (e.g., joint pain, muscle pain, lassitude, depression) may occur when transferring from a systemic corticosteroid to a topical corticosteroid
Mometasone (Nasonex®, Sinuva®)	**Concerns related to adverse effects:** - Adrenal suppression - Delayed wound healing: Avoid use in patients with recent nasal septal ulcers, nasal surgery, or nasal trauma until healing has occurred - Hypersensitivity reactions - Immunosuppression - Local nasal effects: Nasal septum perforation, epistaxis, irritation, and infection of the nose and/or pharynx may occur **Disease-related concerns:** - Hepatic impairment: Drug accumulation may increase with severity of hepatic impairment - Infections: Use with caution or avoid use in patients with active or latent tuberculosis infection of the respiratory tract, untreated systemic fungal, bacterial, viral, or parasitic infections, or ocular herpes simplex - Ocular disease: Use with caution in patients with cataracts and/or glaucoma

Medication	Warnings/Precautions
	Special populations: - Pediatric: Avoid using higher than recommended dosages in pediatric patients **Other warnings/precautions:** - For Sinuva® implant, insertion should only be done by health care providers trained in otolaryngology
Triamcinolone (Nasacort®)	**Concerns related to adverse effects:** - Adrenal suppression - Delayed wound healing: Avoid use in patients with recent nasal septal ulcers, nasal surgery, or nasal trauma until healing has occurred - Immunosuppression - Local nasal effects: Nasal septal perforation, nasal ulceration, epistaxis, and localized *Candida albicans* infections of the nose and/or pharynx may occur **Disease-related concerns:** - Infections: Use caution or avoid in patients with ocular herpes simplex, latent tuberculosis (TB), and/or TB reactivity, or in patients with untreated fungal, viral, or bacterial infections - Ocular disease: Use with caution in patients with cataracts and/or glaucoma **Special populations:** - Pediatric: Avoid using higher than recommended dosages in pediatric patients

PRACTICE GUIDELINES

Seidman MD, Gurgel RK, Lin SY, et al. Clinical practice guideline: Allergic rhinitis. Otolaryngol Head Neck Surg. 2015;152(1 Suppl):S1-43.

- Intranasal Steroids
  - Clinicians should recommend intranasal steroids for patients with a clinical diagnosis of allergic rhinitis who symptoms affect their quality of life (Strong recommendation, high confidence in evidence)
    - No intranasal corticosteroid is recommended over another
- Combination therapy
  - Clinicians may offer combination pharmacologic therapy in patients with AR who have inadequate response to pharmacologic therapy (Option, high confidence in evidence)
    - When initial therapy with an intranasal steroid does not lead to adequate control of allergic nasal symptoms or the patient cannot tolerate INS, the practitioner may choose combination therapies of which the most effective additive to an intranasal steroid is an intranasal antihistamine

Dykewicz MS, Wallace DV, Baroody F, et al. Treatment of seasonal allergic rhinitis: An evidence-based focused 2017 guideline update. Ann Allergy Asthma Immunol. 2017;119(6):489-511.

- For initial treatment of seasonal allergic rhinitis in persons aged 12 or older, routinely prescribe monotherapy with an intranasal corticosteroid rather than an intranasal corticosteroid in combination with an oral antihistamine (Strong recommendation, moderate certainty of evidence)
- For initial treatment of seasonal allergic rhinitis in persons aged 15 years or older, recommend an intranasal corticosteroid over a leukotriene receptor antagonist (Strong recommendation, high certainty of evidence)
- For treatment of moderate to severe seasonal allergic rhinitis in persons aged 12 or older, consider combination of an intranasal corticosteroid and an intranasal antihistamine for initial treatment (Weak recommendation, high certainty of evidence)

Recommendation Definitions

Strength of Recommendation	Definition
Strong	Benefits of the recommended approach clearly exceed the harms and that the quality of supporting evidence is excellent.
Weak	Benefits exceed the harms but evidence is not as strong.
Option	Either the quality of evidence that exists is suspect or that well-done studies show little clear advantage to one approach over another.
No recommendation	There is both a lack of pertinent evidence and an unclear balance between benefits and harms.
Certainty of Evidence	**Definition**
High	High confidence that the true effect lies close to the estimate of the effect.
Moderate	Moderate confidence in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
Very low	Very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

Dykewicz MS, Wallace DV, Amrol DJ, et al. Rhinitis 2020: A practice parameter update. J Allergy Clin Immunol. 2020;146(4):721-767.

- We recommend that when choosing monotherapy for persistent allergic rhinitis, intranasal corticosteroids be the preferred medication (Strong recommendation, high certainty of evidence)
- We recommend that for the initial treatment of moderate/severe severe allergic rhinitis in patients ≥15 years of age, the clinician use an intranasal corticosteroid over a leukotriene receptor antagonist (Strong recommendation, high certainty of evidence)

- We suggest that the clinician consider the combination of an intranasal corticosteroid and an intranasal antihistamine for the initial treatment of moderate/severe nasal symptoms of severe allergic rhinitis in patients ≥12 years old (Conditional recommendation, high certainty of evidence)
- We suggest that the clinician consider the combination of an intranasal corticosteroid and an intranasal antihistamine for moderate/severe severe allergic rhinitis and perennial allergic rhinitis that is resistant to pharmacologic monotherapy (Conditional recommendation, moderate certainty of evidence)
- We suggest that the clinician consider the combination of an intranasal corticosteroid and an intranasal antihistamine for moderate/severe non-allergic rhinitis that is resistant to pharmacologic monotherapy (Conditional recommendation, low certainty of evidence)
- We suggest that for patients taking an intranasal corticosteroid who have persistent rhinorrhea, the clinician may consider the addition of intranasal ipratropium (Conditional recommendation, moderate certainty of evidence)
- We suggest that patients with persistent nasal congestion unresponsive to an intranasal corticosteroid or to an intranasal corticosteroid-intranasal antihistamine combination be offered combination therapy with addition of an intranasal decongestant for up to 4 weeks (Conditional recommendation, low certainty of evidence)
- We recommend that the clinician not prescribe, as initial treatment, a combination of an oral antihistamine and an intranasal corticosteroid in preference to monotherapy with an intranasal corticosteroid in patients ≥12 years of age with symptoms of severe allergic rhinitis (Strong recommendation, moderate certainty of evidence)
- We suggest that the clinician not prescribe the combination of an oral antihistamine and an intranasal corticosteroid in preference to monotherapy with an intranasal corticosteroid in all patients with severe allergic rhinitis and perennial allergic rhinitis (Conditional recommendation, very low certainty of evidence)
- We suggest against the addition of the oral leukotriene receptor antagonist montelukast to an intranasal corticosteroid for allergic rhinitis, due to the lack of adequate evidence of improved efficacy and concerns for serious neuropsychiatric events from montelukast (Conditional recommendation, very low certainty of evidence)
- We suggest that the clinician offer an intranasal corticosteroid as a first-line therapy for non-allergic rhinitis (Conditional recommendation, low certainty of evidence)

Recommendation Definitions

Strength of Recommendation	Definition
Strong	The work group and Joint Task Force on Practice Parameters (JTFPP) are confident that the desirable effects of adherence to the statement outweigh the undesirable effects. This recommendation may be appropriate to be used as a practice standard indicator. A strong recommendation is worded as ‘‘We recommend,’’ implying that the clinician ‘‘should’’ follow the recommendation.
Conditional	The work group and JTFPP reach a decision that the desirable effects of adherence to the statement probably outweigh the undesirable effect. A conditional recommendation worded as ‘‘We suggest,’’ implying that the clinician ‘‘may’’ follow the recommendation.
Certainty of Evidence	**Definition**
High	Further research is very unlikely to change confidence in the estimate of effect. The recommendation is based on high-quality evidence, such as multiple highly rated randomized controlled trials, systematic reviews, or meta-analyses.
Moderate	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate. The recommendation would likely be based on somewhat limited evidence, such as reduced number or quality of randomized controlled trials or controlled trials without randomization.
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate. The recommendation would likely be based on very weak evidence, such as non-experimental studies, registries, or comparative studies.
Very low	Any estimate of effect is very uncertain. The recommendation is based largely on very low quality studies and/or on expert opinion.

CLINICAL TRIALS/SYSTEMATIC REVIEWS/META-ANALYSES

Citation	Design	Endpoints
Sousa-Pinto B, Vieira RJ, Bognanni A, et al. Efficacy and safety of intranasal medications for allergic rhinitis: Network meta-analysis. Allergy. 2025;80(1):94-105.	Systematic review and network meta-analysis to compare the use of intranasal antihistamines, INS, and intranasal antihistamine + INS in adults with seasonal or perennial allergic rhinitis. Primary literature was searched up to September 2023. Included studies were randomized controlled trials that compared intranasal medications as well as those comparing active intranasal medications with placebo. The network meta-analysis included 165 primary studies.	• Change in total nasal symptoms score • Change in total ocular symptom score
Results: Among individual medications, azelastine/fluticasone, and fluticasone furoate were the most frequently highest-ranked interventions for efficacy outcomes, being regularly associated with clinically meaningful larger improvements when compared to other active treatments. Considering drug classes, intranasal antihistamine + INS were the highest-ranked interventions for all outcomes in which they were assessed, followed in most cases by INS. **Conclusion:** Intranasal medications for allergic rhinitis display clinically relevant differences in their efficacy, but all show a good safety profile. To our knowledge, this is the first network meta-analysis comparing intranasal antihistamine, INS, and intranasal antihistamine + INS in allergic rhinitis, providing relevant evidence for guideline developers and practicing physicians on the most efficacious treatments.		
Citation	**Design**	**Endpoints**
Gross GN, Berman G, Amar NJ, Caracta CF, Tantry SK. Efficacy and safety of olopatadine-mometasone combination nasal spray for the treatment of seasonal allergic rhinitis. Ann Allergy Asthma Immunol. 2019;122(6):630-638.	Phase 3 study to compare the efficacy of olopatadine 1,330 mcg/mometasone 50 mcg nasal spray twice daily to olopatadine (1330 mcg), mometasone (50 mcg), and placebo in patients with seasonal allergic rhinitis. A total of 1,176 patients ≥ 12 years old with seasonal allergic rhinitis were randomized into a double-blind, placebo controlled, parallel group trial.	• Change from baseline in reflective total nasal symptom score (rTNSS) • Change from baseline in instantaneous TNSS (iTNSS) • Change from baseline in individual symptom scores (i.e., nasal obstruction, rhinorrhea, nasal itching, sneezing, ocular symptoms)
Results: Intranasal olopatadine/mometasone provided statistically significant and clinically meaningful rTNSS improvements vs. placebo (least squares mean difference, -1.09; 95% confidence interval [CI], -1.49 to -0.69; P<0.001) and vs. olopatadine (P=0.03) and mometasone (P=0.02). Similar significant improvements in iTNSS were also observed with intranasal olopatadine/mometasone (P<0.05 for all). Furthermore, intranasal olopatadine/mometasone significantly improved overall ocular symptoms, individual nasal and ocular symptoms, and quality of life vs. placebo (P≤0.001 for all). **Conclusion:** Intranasal olopatadine/mometasone is efficacious and well tolerated vs placebo for treating seasonal allergic rhinitis-associated nasal and ocular symptoms, with a rapid onset of action of 15 minutes in adult and adolescent patients 12 years and older.		
Citation	**Design**	**Endpoints**
Juel-Berg N, Darling P, Bolvig J, et al. Intranasal corticosteroids compared with oral antihistamines in allergic rhinitis: A systematic review and meta-analysis. Am J Rhinol Allergy. 2017;31(1):19-28.	Systematic review and meta-analysis to compare INS with non-sedating oral antihistamines as treatments for allergic rhinitis. Primary literature was searched up to January 22, 2015. Included studies were randomized controlled trials that compared the efficacy and/or adverse effects of INS and oral antihistamines in patients with allergic rhinitis. The meta-analysis included five randomized controlled trials with a total of 990 patients.	• Change in total nasal symptoms score • Change in individual symptom scores (i.e., nasal obstruction, rhinorrhea, nasal itching, sneezing, ocular symptoms)

Results: INS were superior to oral antihistamines in improving total nasal symptoms score (standard mean difference [SMD] -0.70 [95% CI, -0.93 to -0.47]) and in relieving the following: nasal obstruction (SMD -0.56 [95% CI, -0.82 to -0.29]), rhinorrhea (SMD -0.47 [95% CI, -1.00 to 0.05]), nasal itching (SMD -0.42 [95% CI, -0.65 to -0.18]), sneezing (SMD -0.52 [95% CI, -0.73 to -0.32]), and quality of life (SMD -0.90 [95% CI, -1.18 to -0.62]). There was no difference in relief of ocular symptoms (SMD -0.08 [95% CI, -0.23 to 0.08]). **Conclusion:** INS were superior to oral antihistamines in improving nasal symptoms and quality of life in patients with allergic rhinitis.		
Citation	**Design**	**Endpoints**
Carr WW, Ratner P, Munzel U, et al. Comparison of intranasal azelastine to intranasal fluticasone propionate for symptom control in moderate-to-severe seasonal allergic rhinitis. Allergy Asthma Proc. 2012;33(6):450-8.	Compare the efficacy of azelastine 137 mcg/spray 1 spray per nostril twice daily to fluticasone 50 mcg/spray 1 spray per nostril twice daily in patients with seasonal allergic rhinitis via a post hoc analysis of data from a previously published direct-comparison study. A total of 610 moderate to severe seasonal allergic rhinitis patients ≥ 12 years old were randomized into a double-blind, placebo controlled, parallel group trial.	• Change from baseline in rTNSS (morning and evening) over 14 days
Results: Fluticasone was superior to azelastine in alleviating rhinorrhea (fluticasone change from baseline: -1.17 ± 1.47, azelastine change from baseline: -0.82 ± 1.23, P=0.0433) but azelastine showed comparable efficacy for all other nasal and ocular symptoms. There was no clinically or statically significant difference between azelastine and fluticasone for reduction in the overall rhinitis quality of life questionnaire. **Conclusion:** Intranasal azelastine and fluticasone for 14 days have efficacy of comparable magnitude with patients with moderate to severe seasonal allergic rhinitis.		

FORMULARY PLACEMENT, UTILIZATION AND COST EXPERIENCE (04-01-2026 to 06-30-2026)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Intranasal Steroid & Antihistamine Combination								
Azelastine/fluticasone (Dymista®) 137 mcg-50 mcg nasal spray	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Ryaltris® (olopatadine/mometasone) 665 mcg-25 mcg nasal spray	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Intranasal Steroids								
Qnasl®(beclomethasone dipropionate) 40 mcg, 80 mcg nasal spray	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Beconase AQ®(beclomethasone dipropionate) 42 mcg nasal spray	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Budesonide 32 mcg nasal spray	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Omnaris® (ciclesonide) 50 mcg nasal spray	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Zetonna® (ciclesonide) 37 mcg nasal spray	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Flunisolide 25 mcg (0.025 %) nasal spray	0	0	$0.00	$0.00	0	0 (0%)	F-ST	No change
Fluticasone propionate (Flonase® Allergy Relief) 50 mcg nasal spray	217	166	$2,626.19	$12.10	0	0 (0%)	F	No change
Flonase® Sensimist (fluticasone furoate) 27.5 mcg nasal spray	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Xhance® (fluticasone propionate) 93 mcg nasal spray	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Mometasone furoate (Nasonex®) 50 mcg nasal spray	0	0	$0.00	$0.00	0	0 (0%)	F-ST; QL(17/30)	No change
Sinuva® (mometasone furoate) 1,350 mcg sinus implant	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Triamcinolone acetonide (Nasacort®) 55 mcg nasal spray	0	0	$0.00	$0.00	0	0 (0%)	F	No change
TOTAL	**217**	**166**	**$2,626.19**	**$12.10**	**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

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	~~9/2025~~9/2026

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PERFORMRx℠

Pancreatic Enzymes

Executive Summary

CLASS OVERVIEW

Pancreatic enzyme replacement therapy (PERT) is the mainstay of therapy for pancreatic insufficiency. Current marketed products approved by the FDA include Creon, Zenpep, Viokace, Pancreaze and Pertzye. All products are indicated for treatment of pancreatic insufficiency secondary to "other conditions"; Creon and Viokace are the only agents indicated in patients with pancreatectomy; Viokace is the only agent without an indication for use in cystic fibrosis patients. The guidelines for management of cystic fibrosis briefly discuss the use of PERT and do not deem one product preferable over another. Each agent used for PERT consists of amylase, protease and lipase. Among these three, lipase plays the most important role, and all the products are dosed according to lipase content. Viokace is the only agent which is not formulated with an enteric coating, and therefore is subject to rapid degradation in the duodenum due to low pH. To prevent such degradation, it is recommended to be administered concomitantly with H2 receptor antagonist or proton pump inhibitor to transiently raise the pH. Viokace may have modest benefit in alleviating pain associated with chronic pancreatitis in a specific subgroup of patients based on results of a single trial. This benefit has not been observed with the enteric coated formulations. Pertzye is a coated formulation which consists of bicarbonate, which may confer a theoretical benefit of not requiring other concomitant acid suppressants. All PERT agents are recommended to be administered with meals to help with fat absorption and to primarily act in the duodenum. All these agents are not interchangeable as they differ in amount of amylase, bioequivalence and dissolution rates, as evident in in-vitro studies. No near-term products were noted to be in development in the PERT class.

UTILIZATION FINDINGS

There were 20 claims for 8 members, for a total cost of $16,642.35, and an average cost per claim of $832.12. The most highly utilized medication was Creon capsule with 18 claims, followed by Zenpep capsule with 2 claims. There were no prior authorization requests.

RECOMMENDATIONS

- No changes

CLINICAL SUMMARY

Pancreatic exocrine insufficiency (PEI) can be found in a multitude of patient populations. It is commonly observed in patients with cystic fibrosis, post-pancreatic procedures, chronic pancreatitis due to other conditions, such as celiac disease, and pancreatic malignancy. Pancreatic steatorrhea is the most common symptom of PEI but can be absent in some patients. The most practical test, and most commonly used for diagnosis of pancreatic insufficiency is 72-hour stool test, which measures amylase concentration in the stool; however, it can be unreliable in patients with mild disease or those who have diarrhea. Non-pharmacologic recommendations include reduction in fat intake; however, this is not recommended once PERT is initiated, and in patients with cystic fibrosis, fat intake has been associated with positive pulmonary outcomes. In patients with a compelling condition which is highly associated with PEI, once common symptoms appear, PERT should be initiated, and improvement in symptoms would be confirmatory of the diagnosis. The degree of fat malabsorption is indicative of the degree of PEI, hence early initiation of PERT is beneficial. Goal of PERT is to minimize malabsorption of fat, improve quality of life and extend prognosis. Initial doses for all agents, are based on similar weight-based dosing. Doses exceeding 6000units/kg/meal should be carefully increased and may warrant a 72-hour stool test, as higher doses have been associated with colonic strictures. Currently there are not direct comparator trials demonstrating superiority of any one product over another; however, the enteric coated formulations are generally preferred for management of PEI, whereas the non-coated formulation (Viokace) is preferred for management of abdominal pain associated with chronic pancreatic insufficiency.

INDICATIONS, DOSING and ADMINISTRATION

Medication	Indications	Dosing/Administration
Creon®	Treatment of exocrine pancreatic insufficiency in adult and pediatric patients	Age based dosing for Creon, Zenpep, Pertzye & Pancreaze for pancreatic insufficiency **0 to 12 months** –Zenpep and Creon 3000U/120mL of breast milk or formula. For Pertzye, use 4,000U/120mL. For Pancreaze use 2600U /120mL) **1 to 4 years** – 1000U/kg/meal, max 2500U/meal or 10000U/day or 4000U/g of fat ingested/day **4years or older** – 500U/kg/meal, max 2500U/meal or 10000U/day or 4,000U/1g of fat ingested/day Capsules can be opened & contents sprinkled on applesauce for administration. Contents should not be mixed with breast milk or formula but should rather be given before or after their administration. For snacks, doses are generally half of what patient is using for their meals.
Zenpep®	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.	
Pancreaze®		
Pertzye®		
Viokace®	Viokace (pancrelipase) tablets, in combination with a proton pump inhibitor, are indicated in adults for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy.	For adult patients with pancreatic insufficiency secondary to chronic pancreatitis or pancreatectomy - 500U/kg/meal, max 2,500U/meal or 10,000U/day or 4,000U/1g of fat ingested/day with a proton pump inhibitor or H2-receptor antagonist.

BOXED WARNINGS and CONTRAINDICATIONS

Medication	Boxed Warnings	Contraindications
Creon®	None	None
Zenpep®		
Pancreaze®		
Pertzye®		
Viokace®		

WARNINGS/PRECAUTIONS

Medication	Warnings/Precautions
Creon®	**Fibrosing Colonopathy** – A rare and very serious side effect, it typically occurs in pediatric patients consuming doses higher than 6,000u/kg/meal for a prolonged period time. Benefit of such high doses should be justified by obtaining results from a 72hour fecal test **Potential for Irritation to Oral Mucosa** – retention of pancreatic enzyme products in the oral cavity may lead to mucosal irritation and enzymatic inactivity **Potential for Risk of Hyperuricemia** – all pancreatic enzymes are derived from porcine tissue and therefore contain purines, which have potential for increasing serum uric acid concentrations. Caution should be exercised in patients with underlying gout or hyperuricemia at baseline. **Potential Viral Exposure from the Product Source** –derived from porcine tissue, and therefore carry a theoretical risk of transmission of novel or unknown viruses that are not tested for in manufacturing process **Allergic Reactions** – patients who have history of severe allergies or anaphylaxis from porcine products may have such reactions from consumption of pancreatic enzymes. **Potential for Exacerbation of Symptoms of Lactose Intolerance** (Viokace only) **–** contain lactose monohydrate, patients with lactose intolerance may not be able to tolerate Viokace.
Zenpep®	
Pancreaze®	
Pertzye®	
Viokace®	

PRACTICE GUIDELINES

American Gastroenterological Association (AGA) Clinical Practice Update on the Epidemiology, Evaluation, and Management of Exocrine Pancreatic Insufficiency: Expert Review (2023). Available at: https://gastro.org/clinical-guidance/epidemiology-evaluation-management-exocrine-pancreatic-insufficiency/

Best practice advice

1. EPI should be suspected in patients with high-risk clinical conditions, such as chronic pancreatitis, relapsing acute pancreatitis, pancreatic ductal adenocarcinoma, cystic fibrosis, and previous pancreatic surgery.
2. EPI should be considered in patients with moderate-risk clinical conditions, such as duodenal diseases, including celiac and Crohn's disease; previous intestinal surgery; longstanding diabetes mellitus; and hypersecretory states (eg, Zollinger–Ellison syndrome).
3. Clinical features of EPI include steatorrhea with or without diarrhea, weight loss, bloating, excessive flatulence, fat-soluble vitamin deficiencies, and protein-calorie malnutrition.
4. Fecal elastase test is the most appropriate initial test and must be performed on a semi-solid or solid stool specimen. A fecal elastase level <100 µg/g of stool provides good evidence of EPI, and levels of 100–200 µg/g are indeterminate for EPI.
5. Fecal elastase testing can be performed while on pancreatic enzyme replacement therapy.
6. Fecal fat testing is rarely needed and must be performed when on a high-fat diet. Quantitative testing is generally not practical for routine clinical use.
7. Response to a therapeutic trial of pancreatic enzymes is unreliable for EPI diagnosis.
8. Cross-sectional imaging methods (computed tomography scan, magnetic resonance imaging, and endoscopic ultrasound) cannot identify EPI, although they play an important role in the diagnosis of benign and malignant pancreatic disease.
9. Breath tests and direct pancreatic function tests hold promise, but are not widely available in the United States.
10. Once EPI is diagnosed, treatment with pancreatic enzyme replacement therapy (PERT) is required. If EPI is left untreated, it will result in complications related to fat malabsorption and malnutrition, having a negative impact on quality of life.
11. PERT formulations are all derived from porcine sources and are equally effective at equivalent doses. There is a need for H2 or proton pump inhibitor therapy with non–enteric-coated preparations.
12. PERT should be taken during the meal, with the initial treatment of at least 40,000 USP units of lipase during each meal in adults and one-half of that with snacks. The subsequent dosage can be adjusted based on the meal size and fat content.
13. Routine supplementation and monitoring of fat-soluble vitamin levels are appropriate. Dietary modifications include a low-moderate fat diet with frequent smaller meals and avoiding very-low-fat diets.
14. Measures of successful treatment with PERT include reduction in steatorrhea and associated gastrointestinal symptoms; a gain of weight, muscle mass, and muscle function; and improvement in fat-soluble vitamin levels.
15. EPI should be monitored and baseline measurements of nutritional status should be obtained (body mass index, quality-of-life measure, and fat-soluble vitamin levels). A baseline dual-energy x-ray absorptiometry scan should be obtained and repeated every 1–2 years.

Pancreatic Enzymes Clinical Care Guidelines. Cystic Fibrosis Foundation (2019). Available at: https://www.cff.org/pancreatic-enzymes-clinical-care-guidelines#pancreatic-enzyme-replacement-therapy-recommendations.

Recommendations	Evaluation of the Evidence
1. Pancreatic insufficient patients should consume a high-calorie diet with unrestricted fat that is appropriate to age and clinical status. Such diets have been shown superior to low-fat diets in promoting growth and lung function.	Consensus
2. A nutritional assessment should be performed regularly as a component of routine care in patients with CF. Additional assessment should occur when dosing of PERT is altered.	Consensus
3. Enzyme dosing may be done either by grams of fat ingested or by weight. Dosing by grams of fat is more likely to mimic the normal pancreatic response to a meal, although weight-based dosing may be simpler and more convenient, particularly in older children and adults.	Consensus
4. Infants generally require 450-900 lipase units/g of fat, OR 2,000–4,000 lipase units per 120 ml of formula or when breastfeeding. Infants generally ingest a higher amount of fat/kg of body weight than do adults.	Consensus
5. Older children and adults generally require 500–4,000 lipase units per gram of fat ingested (mean, 1,800 lipase units/g of fat), OR 500-2,500 lipase units/kg/meal, 250-1,250 lipase units/kg/snack, with three meals and two to three snacks per day. It is suggested that initial dosing be in the lower range and titrated up as needed to treat malabsorption.	Consensus
6. Doses of enzyme exceeding 2,500 lipase units/kg/meal, or 4,000 lipase units/g of fat warrant further investigation. Doses of enzyme >6,000 lipase units/kg/meal have been associated with fibrosing colonopathy. It is not clear if doses >2,500 lipase units/kg/meal or >4,000 lipase units/g of fat are safe. It is also unlikely that higher enzyme doses will improve clinical condition in patients with CF and poor growth or gastrointestinal symptoms, thus it is recommended not to exceed these doses and that patients on higher doses be titrated down to a lower dosing range.	Consensus
7. Patients should receive only the product brands prescribed by their CF care center. Enteric-coated microencapsulated enzymes are the most effective treatment for PI in CF. Patients should not use health food store enzymes or enzymes without an enteric coating unless directed to do so by their CF physician.	Consensus
8. Enzyme capsules may be opened and the contents mixed with a small quantity of applesauce or another non-alkaline food, but they should not be crushed or allowed to sit in food. Enzymes may be inactivated by exposure to alkaline environments or prolonged contact with a moist environment.	Consensus
9. Enzymes should be stored in a cool, dry place and checked regularly for expiration dates.	Consensus
10. Signs and symptoms of poor response to enzyme therapy include abdominal complaints (bloating, flatus, abdominal pain, and loose, frequent stools or overt diarrhea) along with symptomatic steatorrhea (bulky, oily, foul stools) and/or poor growth. These symptoms may also be seen with other conditions. Before increasing enzymes as a result of symptoms, consider dietary factors, adherence issues, intestinal hyperacidity, abnormal intestinal motility, and liver disease with low intestinal bile salt content, as well as non-CF gastrointestinal disease.	Consensus
11. Fibrosing colonopathy should be considered in patients with CF who have evidence of obstruction, bloody diarrhea, or chylous ascites, or who have a combination of abdominal pain, ongoing diarrhea, and/or poor weight gain. Fibrosing colonopathy is characterized by colonic strictures. Its cause is unclear, but it has been associated with high doses of pancreatic enzyme supplements. Patients at highest risk include children younger than 12 years, patients taking >6,000 lipase units/kg/meal for more than 6 months, history of meconium ileus in infancy or distal intestinal obstruction syndrome, and history of previous intestinal surgery. Diagnosis is generally made by imaging or histopathology. Fibrosing colonopathy may respond to reduction of enzyme dose, particularly in the early stages, but in later stages colectomy may be required.	Consensus

Medical Management of Chronic Pancreatitis in Children: A Position Paper by the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition Pancreas Committee (2021). Available at: https://naspghan.org/wp-content/uploads/2021/02/Medical_Management_of_Chronic_Pancreatitis_in.30.pdf

Nutrition and endocrine

1. Patients with CP are at risk for macro- and micronutrient deficiencies. Patients should be monitored for growth and pubertal delay, dietary intake, and fat-soluble vitamin deficiencies. Growth and intake should be reviewed at every clinic visit, a minimum of every 6 to 12 months. Fat-soluble vitamin laboratory analysis should occur every 12 to 18 months or as clinically indicated. 1B
2. A multidisciplinary approach that includes a clinical pediatric dietitian is needed to adequately monitor nutritional status, evaluate nutrient intake and provide education and recommendations to help prevent both malnutrition and obesity. 1C
3. There is a clear role for PERT in children with CP who have EPI with steatorrhea, poor growth and/or nutritional deficiencies. PERT dosing for CP-associated EPI is similar to that used in patients with CF. 1B
4. Children with CP should be screened yearly for pancreatogenic DM with a fasting glucose and HbA1c level. 1C
5. Consider OGTT if pre-diabetes is present based on abnormal fasting glucose (100–125 mg/dL) and/or HbA1c level (5.7%–6.4%). OGTT should be performed annually once a patient is considered to have pre-diabetes. 1C
6. Chronic pancreatitis patients with diabetes should be referred to a pediatric endocrinologist to optimize glucose management and determine if evaluation for other forms of DM should be considered. 1B
7. It is important to address clinical symptoms of malabsorption and PERT in children with CP and DM to improve glycemic control. 1C
8. Insufficient data exists to recommend the use of antioxidants as a treatment to prevent EPI or other disease progression in children with CP. 2C

Pain management

9. Treatment of pain in pediatric CP requires a multidisciplinary approach, ideally involving a pediatric pain physician, pediatric gastroenterologist, psychologist, nurse, and physical therapist. 1B
10. Cognitive behavioral Therapy (CBT) should be considered in management of pediatric CP pain. 1B
11. Physical therapy may be considered as an adjunct therapy for pain management in children with CP. 2B
12. There is insufficient data to recommend PERT as therapy for pain in children without EPI. 1B
13. There is insufficient data to recommend antioxidants, steroids, leukotriene antagonists, or somatostatins in the management of pain for children with CP. 2C
14. Analgesic pain management in CP should follow an ‘‘analgesic ladder’’ that incorporates the layering of non-opioid and opioid medications. Ideally this should be directed by a pain specialist working in partnership with a pancreatologist or gastroenterologist. 1B
15. Neuromodulators may be effective in treating pain in children with CP as part of a multidisciplinary approach. 1C
16. Celiac plexus block for pain has not been shown to be effective in children with CP and cannot be recommended. 1C
17. Children with CP suffering from pain refractory to standard medical management should be evaluated at a center with pediatric experience in pain management. 1C

Lifestyle modifications

18. On the basis of long-term adult data, providers should caution patients about the acute and chronic negative effects of alcohol abuse on pancreatic health. 1B
19. Health-care providers should caution patients about the dose-dependent response of tobacco smoking on the development and progression of CP among adult patients and should advise against smoking. 1A
20. Data are limited regarding the impact of weight and BMI on CP outcomes, as such, providers should counsel patients and parents about a balanced healthy diet and lifestyle. 1C
21. Administering a survey tool to assess QOL and/or functional assessment among pediatric patients to assess degree of impairment and drive targeted interventions indicated. 2C

Sequelae of disease

22. The majority of pancreatic fluid collections will resolve spontaneously with supportive care. Intervention is reserved for complications from mass-effect, infection/necrosis or if spontaneous regression of the collection is thought to be unlikely. 1B
23. Children with CP that continue to exhibit abdominal pain, bloating or other GI concerns deserve an appropriate GI workup to evaluate for other etiologies that may explain their symptoms. 1C

CP = chronic pancreatitis; DM = diabetes mellitus; EPI = exocrine pancreatic insufficiency; GI = gastrointestinal, OGTT = oral glucose tolerance test; PERT = pancreatic enzyme replacement therapy; QOL = quality of life.

GRADE level definitions

Class/Level	Definition
1	Strong recommendation
2	Weak recommendation
A	High quality of evidence
B	Moderate quality of evidence
C	Low quality of evidence
GPP	Good practice point

CLINICAL TRIALS/SYSTEMATIC REVIEWS/META-ANALYSES

Citation	Design	Endpoints
Shafiq N, Rana S, Bhasin D. Pancreatic enzymes for chronic pancreatitis. Cochrane Database Syst Rev. 2009 Oct 7;(4):CD006302.	Cochrane review which evaluated the efficacy of various pancreatic enzyme formulations for use in chronic pancreatitis. Main objective was to evaluate results of trial with PERT vs. placebo, comparing different types of PERT, comparison of different doses of PERT. Published and unpublished data were collected, and both randomized and non-randomized trials, as well as blinded and non-blinded trials were assessed. Ten trials were identified and evaluated	Multiple outcomes were assessed across heterogeneous trials. These included: change in frequency of abdominal pain, duration of pain episodes, intensity of pain, weight loss, steatorrhea, fecal fat content and quality of life.
Results: Due to small sample sizes and significant heterogeneity among the trials overall results were difficult to pool, and therefore were inconclusive. **Conclusion**: The authors concluded that despite inability to pool different trials for specific primary endpoint, each trial showed benefit in various endpoints and manifestations associated with chronic pancreatitis and improvement in quality of life when PERT was used.		

Citation	Design	Endpoints
Whitcomb DC, Lehman GA, Vasileva G, et al. Pancrelipase delayed-release capsules (CREON) for exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatic surgery: A double-blind randomized trial. Am J Gastroenterol. 2010 Oct;105(10):2276-86.	This was a double-blind, randomized, multi-country, placebo-controlled, parallel-group trial enrolling patients ≥18 years old with confirmed exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatic surgery conducted in clinical research centers or hospitals. After a 5-day placebo run-in period (baseline), patients were randomized to pancrelipase (CREON) (72,000 lipase units per meal; 36,000 per snack) or placebo for 7 days. All patients received an individually designed diet to provide at least 100 g of fat per day. Primary efficacy endpoint was analyzed using non-parametric analysis of covariance.	• The primary efficacy measure was the change in coefficient of fat absorption (CFA) from baseline to end of the double-blind period • Secondary outcomes included: the coefficient of nitrogen absorption (CNA), clinical symptoms, and safety parameters.
Results: In total, 25 patients (median age of 54 years, 76% male) received pancrelipase (CREON) and 29 patients (median age of 50 years, 69% male) received placebo. The mean standard deviation change from baseline in coefficient of fat absorption was significantly greater with pancrelipase vs. placebo: 31.9 ± 18.6 vs. 8.7 ± 12.4 % (P <0.0001) [corrected]. Similarly, the mean standard deviation change from baseline in coefficient of nitrogen absorption was greater for pancrelipase vs. placebo: 35.2 ± 29.1 vs. 8.9 ± 28.0 % (= 0.0005) [corrected].Greater improvements from baseline in stool frequency, stool consistency, abdominal pain, and flatulence were observed with CREON vs. placebo. Treatment-emergent adverse events were reported in five patients (20.0%) in the CREON group and in six (20.7%) in the placebo group; the most common were gastrointestinal (GI) events and metabolism/nutrition disorders. There were no treatment discontinuations due to adverse events secondary to he treatment. **Conclusion**: The authors concluded that CREON 12,000-lipase unit capsules were effective in treating fat and nitrogen maldigestion with an adverse event rate similar to that of placebo in patients with EPI due to chronic pancreatitis or pancreatic surgery		

Citation	Design	Endpoints
Toskes PP, Secci A, Thieroff-Ekerdt R; ZENPEP Study Group. Efficacy of a novel pancreatic enzyme product, EUR-1008 (Zenpep), in patients with exocrine pancreatic insufficiency due to chronic pancreatitis. Pancreas. 2011 Apr;40(3):376-82.	This was a randomized, double-blind, dose-response, crossover study with a run-in phase with placebo of 7 to 9 days and two treatment periods of 9 to 11 days, which consisted of a high dose treatment (seven capsules of 20,000 units of lipase per day) and a low-dose treatment (defined as seven capsules of 5,000units of lipase per day). Patients in each arm were monitored in hospital during baseline run in period, or one of the two cross over periods for the high or low dose, respectively. Inclusion criteria: age over 18 years old, women of childbearing potential must be using birth control throughout the duration of the study, documented diagnosis of	• Primary endpoint was comparison of coefficient of fat absorption between placebo, high dose and low dose groups. • Secondary endpoints include change from placebo baseline in coefficient of fat absorption in high dose and low dose groups during hospital treatment;

	chronic pancreatitis, mean coefficient of fat absorption is less than 20% and documented diagnosis of PEI exists and informed consent Exclusion criteria: unable to give informed consent, participation in another clinical trial within 30 days of enrollment, diagnosis of cystic fibrosis, excessive alcohol consumption, known drug abuse, uncontrolled diabetes mellitus, pregnancy or lactation, evidence of gastric or duodenal ulcer, presence of HIV infection, presence of hyperuricemia, presence of chronic inflammatory bowel disease, presence of acute biliary disease, known pork allergy, known fat absorption secondary to metabolic disease or surgery not leading to PEI, presence of viral hepatitis, known severe atopic predispositions.	change from placebo baseline in coefficient of nitrogen absorption during hospital treatment; change from placebo baseline in weight at end of each treatment period; change from placebo baseline in body mass index at the end of treatment
Results: Mean CFA was significantly higher with low- (88.9%) and high-dose (89.9%) ZENPEP versus placebo run-in (82%; P < 0.001; n = 72) with no difference between doses (P = 0.228, primary end point). In patients with baseline CFA less than 90% (n = 33), the high dose was significantly more effective (CFA: 84.1%) than the low dose (CFA: 81.1%; P < 0.001). Post hoc analysis revealed an increase in treatment effect with more severe PEI. Coefficient of nitrogen absorption (P < 0.001), body weight (P ≤ 0.021), and body mass index (P ≤ 0.020) also increased significantly with both doses compared with baseline. Percentage of days with EPI symptoms decreased with both doses. **Conclusion**: The trial demonstrates clear benefit of Zenpep over placebo. Patients with more severe baseline PEI tended to benefit more from the use of Zenpep and warranted higher dosing.		

Citation	Design	Endpoints
Colombo C, Fredella C, Russo MC, et al. Efficacy and tolerability of Creon for Children in infants and toddlers with pancreatic exocrine insufficiency caused by cystic fibrosis: an open-label, single-arm, multicenter study. Pancreas. 2009 Aug;38(6):693-9.	Open label study in infants below the age of 24 months. Subjects had confirmed diagnosis of cystic fibrosis with exocrine pancreatic insufficiency and coefficient of fat absorption of greater than 70%. Study sample size was N=12 and study duration was 8 weeks.	• Primary endpoint was change in the coefficient of fat absorption after two weeks of treatment. • Secondary endpoints were not well defined, but loss in mean stool fat and mean fecal energy loss were also reported.
Results: After two weeks of treatment with pancrelipase (CREON), there was a statistically significant increase in the mean CFA from baseline (84.7 vs 58.0%; P=0.0013). There was a statistically significant reduction in mean stool fat (from 13.3 to 5.3 g/d; P=0.001) and mean fecal energy loss (from 238.5 to 137.9 kJ/d; P=0.018) after two weeks of pancrelipase treatment. Dietary fat intake did not change, whereas an improvement was observed in stool frequency and characteristics. Patient weight and height increased over eight weeks of treatment with pancrelipase. No serious adverse event was reported. **Conclusion**: The authors concluded that CREON significantly reduced fat malabsorption in patients when compared with placebo and was well tolerated. This trial supports the use of CREON in pediatric patients, especially in infants, however the very small sample size enables confounding and provides lesser representation of various patient characteristics.		

Citation	Design	Endpoints
Trapnell BC1, Strausbaugh SD, Woo MS, Tong SY, Silber SA, Mulberg AE, Leitz G. Efficacy and safety of PANCREAZE® for treatment of exocrine pancreatic insufficiency due	This study had multiple phases. Initially, there was a screening phase for 7 days, followed by an open label, run-in phase, which was 14 days or shorter, followed by less than or equal to 7 days of placebo-controlled withdrawal phase. During the screening phase, patient's current PERT was discontinued, high fat meals were provided, and based on overall lipase requirements, PANCREAZE was initiated to a dose of maximum 10,000 lipase units/kg/day. Patients who achieved a coefficient of	• The primary efficacy endpoint was change in percent CFA between the 72-hour stool collections at the end of the open-label phase and double-blind phase. Fat intake (dietary fat) and fat excretion (fecal fat) data were used to

to cystic fibrosis. J Cyst Fibros. 2011 Sep;10(5):350-6	fat absorption of greater than 80% were randomized to receive placebo or PANCREAZE and were assessed based on their 72-hour stool test. This randomization was conducted during the double-blind phase. The study was conducted in US only across 11 different centers in patients ranging in age from 7 years old to 60 years old. Inclusion criteria: confirmed diagnosis of cystic fibrosis by either genetic testing or sweat test. Confirmed pancreatic exocrine insufficiency based on 72-hour stool test. Achieving coefficient of fat absorption greater than 80% to continue to the randomized, double blinded phase. Exclusion criteria: extreme cachexia, defined as BMI less than 10th percentile, severe/acute pulmonary disease unrelated to complications of cystic fibrosis; exacerbation of CF pulmonary disease≤1 month before screening; congenital anomalies of gastrointestinal tract; distal intestinal obstruction syndrome≤6 months of screening or requirement of surgical management to treat; hypersensitivity to porcine products; clinically significant gastrointestinal symptoms (e.g., vomiting, constipation); or disease or disorder that could interfere with assessment of study drug. Participants were excluded if they were taking drugs affecting blood uric acid concentrations or prokinetic agents (e.g., metoclopramide, cisapride,)≤30 days of screening; concurrent supplemental enteral nutrition; immunosuppressant agents for organ transplantation; or systemic steroid therapy. Females were excluded if pregnant, planning to become pregnant, or nursing.	calculate fecal fat excretion per 24 h, which was determined from the 72-hour stool collection. Percent CFA was calculated as: Percent CFA={[Fat intake (grams)−Fat excretion (grams)]/Fat intake (grams)}×100. • A key secondary variable was change in coefficient of nitrogen absorption (CNA), a surrogate for protein absorption, from the open-label phase to the double-blind phase. The ingested nitrogen was determined from diet records, and nitrogen excretion measurements comprised total nitrogen (fecal, in grams) for each 72-hour stool collection period. Percent CNA was calculated as: Percent CNA={[nitrogen intake (grams)−nitrogen excretion (grams)]/nitrogen intake (grams)}×100. • Another key secondary variable was prevention of the clinical signs and symptoms of EPI (abdominal pain, bloating, diarrhea, greasy stools, vomiting) during the double-blind phase. Overall improvement in health from the open-label phase to the double-blind phase was assessed using a self-reported global assessment of change (GAC) scale (0=worse, 1=same, 2=better, and 3=excellent).
Results: The mean CFA was similar in PANCREAZE® and placebo groups at baseline but was markedly higher in the PANCREAZE® group than the placebo group in the double-blind withdrawal phase. The CFA between open-label and double-blind phases (primary endpoint) was similar for the PANCREAZE® group but was markedly lower in the placebo group. The change in CFA for individual participants ranged from +8% to −16% in the PANCREAZE® group and from 0% to −75% in the placebo group. The primary endpoint results were similar for pediatric and adult patients. **Conclusion**: The study demonstrated effectiveness of PANCREAZE® in treatment of exocrine pancreatic insufficiency in cystic fibrosis patients, both children and adults, with minimal adverse events, which were not significantly different from those experienced within the placebo group.		
Citation	**Design**	**Endpoints**

Taylor CJ, Thieroff-Ekerdt R, Shiff S. Comparison of two pancreatic enzyme products for exocrine insufficiency in patients with cystic fibrosis. J Cyst Fibros. 2016 Sep;15(5):675-80.	This was a randomized, double blind, active-controlled, cross-over, multinational, non-inferiority trial which compared Creon with Zenpep. Sample size was n=96. Patients were enrolled on a maintained baseline PERT regimen. Once enrolled, they initiated a diet that consisted of 100g/day of fat. Patients were assigned to either a Creon group or a Zenpep group. Without a washout, the patient was switched to the respective group, with the treatment dose being as close as possible to baseline PERT dose. After 28 days of treatment, patients were switched to the other group for another 28 day time period. Inclusion criteria: Confirmation of cystic fibrosis with a genotype test in addition to presence of a clinical feature, or with a sweat test. Documentation of pancreatic exocrine insufficiency with a 72-hour stool test. Adequate nutritional status, defined as a BMI of at least 19kg/m^2 for adults or BMI greater than or equal to 10th percentile for pediatric patients. Exclusion criteria were presence of one or more severe cardiac, renal, metabolic or gastrointestinal comorbidities.	• The primary efficacy endpoint was coefficient of fat absorption over 72-hour period • Secondary endpoints included change in body weight, coefficient of nitrogen absorption, signs and symptoms of exocrine pancreatic insufficiency, as noted in patient's self-recorded diary, as well as overall impact on overall health, activities of daily living, etc. as recorded in Cystic Fibrosis Questionnaire – Revised
Results: Overall patient characteristics and distributions were similar across both Creon and Zenpep groups. Overall, mean age was 19.2 years and males represented approximately 60% of the sample size. For the primary efficacy endpoint (coefficient of fat absorption over 72 hours), Zenpep demonstrated equivalence to Creon. Their mean coefficients of absorptions were 84.1% (SE 1.1) and 85.3 (SE 1.1), respectively. Difference in least squared means was 1.3% (95% CI: -3.6 to 1.1, p=0.297). This was well within the pre-defined non-inferiority margin of -5% to 5%. Secondary endpoints were similar as well. Coefficients of nitrogen absorption for Creon and Zenpep were 82.0 (SE 1.2) and 80.9 (SE 1.2), respectively. The LS mean difference between the two CNA was -1.1 (95% CI: -3.3 to 1.2, p=0.334). The average number of stools per day was also similar between the two groups, 1.5(SE 0.1) for Zenpep and 1.5(SE 0.1) for Creon. There were no statistically significant differences between Zenpep and Creon groups when comparing treatment emergent adverse events.		
Citation	**Design**	**Endpoints**
Konstan MW, Accurso FJ, Nasr SZ, Ahrens RC, Graff GR. Efficacy and safety of a unique enteric-coated bicarbonate-buffered pancreatic enzyme replacement therapy in children and adults with cystic fibrosis. Clinical investigation. 2013;3(8):723-729.	This was a randomized, double blind, placebo-controlled, cross-over study. There were six well defined disparate periods during the study: A 4-day screening period (to determine eligibility), a 7 to 10 days of dose stabilization period (allowing optimal dosing of PERT), two separate 6 to 8 days of treatment periods (buffered pancrelipase and placebo cross-over) which were separated by 7 to 10 days of washout and dose stabilization periods. The dose optimization phases were open labeled. **Inclusion criteria**: age 7 years or above; confirmed diagnosis of cystic fibrosis, confirmed diagnosis of EPI; patients must currently be using PERT to manage EPI; adequate nutritional status (defined as BMI greater than or equal to fifth percentile for patients 7 years to 20 years old; for patients above the age of 20 years, BMI greater than 16.0 for females, and BMI greater than 16.5 for males. Patients received controlled, high-fat diet, with fat content calculated as 2g of fat/kg/day. 72-hour stool assessment was used to calculate the coefficients of fat and nitrogen absorption	• Primary endpoint: absolute mean difference between the coefficients of fat and nitrogen absorption. The authors determined that an overall sample size of 20 would allow for 90% power while evaluating these endpoints. • Secondary endpoint was treatment emergent adverse events.
Results: 21 subjects completed the study. Mean lipase doses during different study phases were as follows: 1406 units during dose stabilization, 1557 during washout and restabilization period, and 1565 during treatment period. A mixed-model analyses was conducted with fixed effects for age group, treatment sequence, treatment group,		

period, age × sequence interaction, age × treatment interaction and a random effect for subject within age × sequence. Mean fat intake was 109 ± 30 and 114 ± 39 g/day ± SD during active and placebo treatment, respectively (p = 0.23). Mean protein intake was 109 ± 33 and 107 ± 31 g/day ± SD during active and placebo treatment, respectively (p = 0.54), finding no statistically significant difference between the two treatment groups. Overall, there was a statistically significant improvement in both fat and nitrogen absorption for active treatment over placebo treatment. Mean CFA was 82.5% during active treatment versus 46.3% during placebo treatment, an absolute difference of 36.2 representing a 78.2% improvement for active treatment over placebo (p < 0.001). Mean CNA was 79.0% during active treatment versus 47.2% during placebo treatment, an absolute difference of 31.8%, representing a 67.4% relative improvement for active treatment over placebo (p < 0.001). Differences in CFA and CNA in favor of active treatment over placebo remained significant when comparing treatments within age subgroups. Subjects experienced statistically significant decreases in mean stool frequency (bowel movements) and mean stool weight over the 72-h stool collection period during active treatment compared with placebo treatment. Overall, the number of bowel movements decreased 40% (p < 0.001) and mean stool weight decreased by 50%. Incidence of treatment emergent adverse events was similar between the two groups. Patients within the placebo group complained more frequently of gastrointestinal symptoms.

Conclusion: Despite similar intake of fat and protein between the placebo and buffered pancrelipase groups, the coefficients of fat and nitrogen absorption were statistically significantly different between the two groups, favoring active treatment group.

Citation	Design	Endpoints
Anthera. A Phase 3, Randomized, Open-Label, Assessor-Blind, Non-Inferiority, Active-Comparator Study Evaluating the Efficacy and Safety of Liprotamase in Subjects With Cystic Fibrosis-Related Exocrine Pancreatic Insufficiency. Available from:https://clinicaltrials.gov/ct2/show/NCT03051490. NLM identifier: NCT03051490. Accessed March 8, 2018 Duffy, S. Sollpura Falls Short in Exocrine Pancreatic Insufficiency Trial. eMPR. U S A. In press March 13, 2018	This was a phase 2, randomized, open-label, assessor-blind, non-inferiority, active controlled trial comparing effectiveness of liprotamase with that of porcine pancrelipase (Pancreaze). Sample size was 140 participants. **Inclusion Criteria:** Confirmed diagnoses of cystic fibrosis and pancreatic exocrine insufficiency; good disease control with PERT prior to enrollment and good nutritional status. **Exclusion Criteria:** History of fibrosing colonopathy, distal intestinal obstruction syndrome in 6 months prior to screening, use of enteral tube feedings, chronic diarrhea unrelated to PEI, liver function test anomalies, history of liver or lung transplant, or significant bowel resection, FEV1<30%	• Primary endpoint was non-inferiority of coefficient of fat absorption between the two treatment groups. • Secondary endpoints were non-inferiority of coefficient of nitrogen absorption and treatment emergent adverse events between the two groups.

Results: The results are currently unpublished on clinicaltrials.gov and are not published in literature; however, a press release from Anthera pharmaceuticals confirms that liprotamase failed to meet both primary endpoint and one of the key secondary endpoints (i.e. coefficient of nitrogen absorption)

Conclusion: Liprotamase is inferior to Pancreaze when coefficients of fat and nitrogen absorption are compared between the two groups.

Citation	Design	Endpoints
Phillip P. Toskes, Grazyna Rydzewska, Jean-René Basque, Valérie Ratheau, Ivan T. Shaw. M1387 Safety and Efficacy of Immediate-Release Pancrelipase, Viokase®16, With Proton Pump Inhibitor Therapy for Correction of Steatorrhea in Patients With Chronic Pancreatitis With Exocrine Pancreatic Insufficiency. Gastroenterology. 2010:May;Vol. 138, Issue 5, S-394	This was a randomized, double blind, placebo controlled, parallel study which evaluated the efficacy of Viokace in comparison to placebo while treating EPI associated with chronic pancreatitis. Patients were randomized at 2:1 ratio for Viokace and placebo groups, respectively. All patients were enrolled with a baseline proton pump inhibitor (PPI) or were initiated on omeprazole 20mg per day. All subjects were confirmed to have pancreatic insufficiency by both the pancreatic elastase test and coefficient of fat absorption	• Primary endpoint was the difference between coefficients of fat absorption between placebo and Viokace • Secondary endpoints included stool frequency and safety assessments

Results: The mean CFA for subjects on VIOKASE®16 was 85.5% ± 8.9 and 58.0% ± 24.2 for subjects on Placebo (p<0.0001). Mean CFA during the washout phase was 47.6% ± 24.1 in the Viokace group and 56.6% ± 22.2 for Placebo. The change in CFA from washout phase to treatment phase for subjects on Viokace was 38.0% ± 25.4 compared to 1.4% ± 13.3 for subjects on Placebo. Viokace was superior to Placebo for improving stool frequency (1.93 ± 0.99 daily movements for Viokace and 2.33 ± 0.95 for Placebo; p=0.0083)

Conclusion: Viokace was more effective compared to placebo in the primary efficacy endpoint.

FORMULARY PLACEMENT, UTILIZATION AND COST EXPERIENCE (04-01-2026 to 06-30-2026)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Enteric Coated Formulations								
Creon® 3k-9.5k-15k, 6k-19k-30k, 12k-38k-60k, 24k-76k-120k, 36k-114k-180k capsule	18	7	$14,599.13	$811.06	0	0 (0%)	F-AL (min 21)	No change
Pertzye® 4k-14375, 8k-28.75k, 16k-57.5k, 24k-86.25k capsule	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Pancreaze® 4.2k-14.2k, 10.5k-35.5k, 16.8k-56.8k, 21k-54.7k, 2.6k-8.8k, 37k-97.3k capsule	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Zenpep® 20k-63-84k, 40k-126k-168k, 5k-17k-24k, 25k-79k-105k, 10-32-42k, 15-47-63k, 3-10-14k, 60k-189,600-252,600 capsule	2	1	$2,043.22	$1,021.61	0	0 (0%)	F-AL (min 21)	No change
Non-Enteric Coated Formulation								
Viokace® 10.4k-39.15k, 20.88k-78.3k tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
TOTAL	**20**	**8**	**$16,642.35**	**$832.12**	**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

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Pneumococcal Vaccines

Proprietary Name	Non-proprietary Name
Capvaxive®	pneumococcal 21-valent conjugate vaccine
Prevnar 20®	pneumococcal 20-valent conjugate vaccine
Pneumovax-23®	pneumococcal vaccine polyvalent
Vaxneuvance®	pneumococcal 15-valent conjugate vaccine

Utilization Findings

There were 25 claims for 25 members, for a total cost of $7,160.28, and an average cost per claim of $286.41. The most highly utilized medication was Capvaxive with 13 claims, followed by Prevnar 20 with 12 claims. There were no prior authorization requests.

Recommendations

- No changes

Clinical Summary

Pharmacologic Classification

For prevention of pneumococcal disease, either pneumococcal polysaccharide (PPSV) or conjugate-type (PCV) vaccines are currently available. These inactivated bacterial vaccines stimulate an immune response to the polysaccharide capsular "shell" of the bacteria. PPSV contains partially purified pneumococcal capsular polysaccharides only, whereas PCV contains capsular polysaccharides attached to a protein very similar to diphtheria toxin. Generally, PCV vaccines produce a more robust and durable immune response. The PCV form is more appropriate for young children (under 2 years of age) because their immature immune systems do not recognize and build immunity to the capsular polysaccharides when presented alone, and the protein-conjugate helps elicit a T cell-dependent memory response. Currently PCV products Prevnar and Vaxneuvance are FDA-approved for use in children, and PPSV (Pneumovax 23) is approved for children 2 years of age and older. Prevnar 20 has FDA approval in pediatric populations for prevention of pneumococcal disease in patients 6 weeks and older, and for the prevention of otitis media in patients 6 weeks through 5 years old. Capvaxive, the newest available PCV vaccine, is currently indicated only in adults.

Disease and Treatment Overview

Streptococcus pneumoniae infection can cause severe disease in both adult and pediatric populations and is the leading cause of bacterial pneumonia in the world. Other serious complications include meningitis, bacteremia, and otitis media. Elderly individuals, young children, those with certain chronic conditions, and the immune-compromised are especially at risk. More than 90 pneumococcal serotypes are known, and vaccine developers focus efforts on including serotypes in the vaccines most commonly causing invasive or drug-resistant disease. CDC recommends routine vaccination against pneumococcal disease for all children under 5 years of age, and adults 50 years and older. Older children and adults

deemed at higher risk for pneumococcal disease should also be vaccinated, and complete recommendations can be found on the CDC's website.

The most recent ACIP recommended vaccination schedule for children under 18 years was updated to include a choice of either Prevnar 20 or Vaxneuvance where vaccination with a pneumococcal conjugate vaccine was recommended, with no preference given to the choice of agent. Pneumococcal conjugate vaccines are recommended as a series of four doses for all children younger than 5 years old, beginning at 2 months of age. Prevnar 13 has recently been discontinued, and guidelines state children who started vaccination series with this agent can finish with Prevnar 20 or Vaxneuvance without starting over. Additional vaccination recommendations for children with certain medical conditions are also available.

The CDC approved updates to guidelines and recommendations for pneumococcal vaccine use for the adult population most recently in October 2024 based off ACIP recommendations, which address the use of newer product Capvaxive. Adult recommendations were expanded to include those 50 years of age or older who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown. These individuals should receive a pneumococcal conjugate vaccine [either PCV 21 (Capvaxive), PCV 20 (Prevnar 20) or PCV 15 (Vaxneuvance)]. If PCV 15 is used, this should be followed by a dose of Merck's PPSV 23 (Pneumovax-23) ≥ 1 year later. Adults with immunocompromising conditions, cochlear implant, or CSF leak might benefit from shorter intervals such as ≥8 weeks. Recommendations for PCVs among adults aged 19–49 years with risk conditions and PCV13-vaccinated adults have not changed from previous recommendations.

Prescribing Information

INDICATIONS, DOSING and ADMINISTRATION

Medication	Indications	Dosing/Administration
Capvaxive® (pneumococcal 21-valent conjugate vaccine)	In adults 18 years of age and older, Capvaxive is indicated for: • active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B • active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B The indication for the prevention of pneumonia caused by S. pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.	Intramuscular: Adults 18 years and older: a single 0.5 mL dose
Prevnar 20® (pneumococcal 20-valent conjugate vaccine)	In individuals 6 weeks of age and older Prevnar 20 is a vaccine indicated for: • active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F In individuals 6 weeks through 5 years of age, Prevnar 20 is a vaccine indicated for: • active immunization for the prevention of otitis media caused by S. pneumoniae serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F In individuals 18 years of age and older, Prevnar 20 is a vaccine indicated for: • active immunization for the prevention of pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F **This indication for the prevention of pneumonia caused by S. pneumoniae serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F in*	Intramuscular: Children: 0.5 mL as a 4-dose immunization series at 2, 4, 6, and 12 through 15 months of age Adults 18 years of age and older: 0.5 mL as a single dose

	individuals 18 years of age and older is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA) assay. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.	
Pneumovax-23® (pneumococcal vaccine polyvalent)	In persons 50 years of age or older and persons aged ≥2 years who are at increased risk for pneumococcal disease, Pneumovax 23 is a vaccine indicated for: • active immunization for the prevention of pneumococcal disease caused by the 23 serotypes contained in the vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F)	Intramuscular or subcutaneous: Adults: 0.5 mL as a single dose Children aged ≥2 years who are at increased risk for pneumococcal disease: 0.5 mL as a single dose
Vaxneuvance® (pneumococcal 15-valent conjugate vaccine)	In individuals 6 weeks of age and older, Vaxneuvance is indicated for: • active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F	Intramuscular: Children: a 4-dose series at 2, 4, 6 and 12 through 15 months of age (and at least 2 months after the third dose) Adults: 0.5 mL as a single dose

BOXED WARNINGS and CONTRAINDICATIONS

Medication	Boxed Warnings	Contraindications
Capvaxive® (pneumococcal 21-valent conjugate vaccine)	N/A	Severe allergic reaction (eg, anaphylaxis) to pneumococcal vaccine, any component of the formulation, or any diphtheria toxoid-containing vaccine
Prevnar 20® (pneumococcal 20-valent conjugate vaccine)		
Pneumovax-23® (pneumococcal vaccine polyvalent)		Severe allergic reaction (eg, anaphylactic/ anaphylactoid reaction) to pneumococcal vaccine or any component of the formulation
Vaxneuvance® (pneumococcal 15-valent conjugate vaccine)		Severe hypersensitivity (eg, anaphylaxis) to pneumococcal conjugate vaccine, any component of the formulation, or to diphtheria toxoid.

WARNINGS/PRECAUTIONS

Medication	Warnings/Precautions
Capvaxive® (pneumococcal 21-valent conjugate vaccine)	***Concerns related to adverse effects:*** • Anaphylactoid/hypersensitivity reactions: Immediate treatment (including epinephrine 1 mg/mL) for anaphylactoid and/or hypersensitivity reactions should be available during vaccine use • Vaccine administration that is too high on the upper arm may cause shoulder injury (eg, shoulder bursitis, tendinopathy) resulting in shoulder pain and reduced range of motion following injection • Syncope has been reported with use of injectable vaccines and may result in serious secondary injury (eg, skull fracture, cerebral hemorrhage); typically reported in adolescents and young adults and within 15 minutes after vaccination

	Disease-related concerns: • Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever) • Use with caution in patients with bleeding disorders (including thrombocytopenia); bleeding/hematoma may occur from IM administration ***Concurrent drug therapy issues:*** • Use with caution in patients receiving anticoagulant therapy; bleeding/hematoma may occur from IM administration • To maximize vaccination rates, the Advisory Committee on Immunization Practices (ACIP) recommends simultaneous administration (ie, >1 vaccine on the same day at different anatomic sites) of all age-appropriate vaccines (live or inactivated) for which a person is eligible at a single clinic visit, unless contraindications exist ***Special populations:*** • Consider deferring vaccination during periods of severe immunosuppression (eg, patients receiving chemo-/radiation therapy or other immunosuppressive therapy including high-dose corticosteroids); may have a reduced response to vaccination • Antibody responses were lower in older adults >65 years compared to adults 50 to 59 years
Prevnar 20® (pneumococcal 20-valent conjugate vaccine)	***Concerns related to adverse effects:*** • Vaccine administration that is too high on the upper arm may cause shoulder injury (eg, shoulder bursitis, tendinopathy) resulting in shoulder pain and reduced range of motion following injection • Syncope has been reported with use of injectable vaccines and may result in serious secondary injury (eg, skull fracture, cerebral hemorrhage); typically reported in adolescents and young adults and within 15 minutes after vaccination ***Disease-related concerns:*** • Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever) • Use with caution in patients with bleeding disorders (including thrombocytopenia); bleeding/hematoma may occur from IM administration ***Concurrent drug therapy issues:*** • Use with caution in patients receiving anticoagulant therapy; bleeding/hematoma may occur from IM administration • Receipt of PPSV23 1 to 5 years prior to pneumococcal conjugate vaccine (PCV20) diminishes response to PCV20 when compared to response in PPSV23 naive individuals • To maximize vaccination rates, the Advisory Committee on Immunization Practices (ACIP) recommends simultaneous administration (ie, >1 vaccine on the same day at different anatomic sites) of all age-appropriate vaccines (live or inactivated) for which a person is eligible at a single clinic visit, unless contraindications exist ***Special populations:*** • Consider deferring immunization during periods of severe immunosuppression (eg, patients receiving chemo-/radiation therapy or other immunosuppressive therapy including high-dose corticosteroids); may have a reduced response to vaccination • Antibody responses were lower in adults ≥70 years of age compared to adults 18 to 64 years of age

	Dosage form specific issues: • 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
Pneumovax-23® (pneumococcal vaccine polyvalent)	***Concerns related to adverse effects:*** • Anaphylactoid/hypersensitivity reactions: Immediate treatment (including epinephrine 1 mg/mL) for anaphylactoid and/or hypersensitivity reactions should be available during vaccine use • Vaccine administration that is too high on the upper arm may cause shoulder injury (eg, shoulder bursitis, tendinopathy) resulting in shoulder pain and reduced range of motion following injection • Syncope has been reported with use of injectable vaccines and may result in serious secondary injury (eg, skull fracture, cerebral hemorrhage); typically reported in adolescents and young adults and within 15 minutes after vaccination ***Disease-related concerns:*** • Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness • Use with caution in patients with bleeding disorders (including thrombocytopenia); bleeding/hematoma may occur from IM administration • Use with caution in patients with severely compromised cardiovascular function where a systemic reaction may pose a significant risk • Patients with HIV should be vaccinated as soon as possible following confirmation of the diagnosis • Vaccination may not be as effective in patients with chronic CSF leaks due to congenital lesions, skull fractures, or neurosurgical procedures • Use with caution in patients with severe pulmonary disease where a systemic reaction may pose a significant risk • Patients who will undergo splenectomy should also be vaccinated at least 2 weeks prior to surgery, if possible • May cause relapse in patients with stable idiopathic thrombocytopenia purpura ***Concurrent drug therapy issues:*** • Use with caution in patients receiving anticoagulant therapy; bleeding/hematoma may occur from IM administration • To maximize vaccination rates, the Advisory Committee on Immunization Practices (ACIP) recommends simultaneous administration (ie, >1 vaccine on the same day at different anatomic sites) of all age-appropriate vaccines (live or inactivated) for which a person is eligible at a single clinic visit, unless contraindications exist • This vaccine does not replace the need for penicillin (or other antibiotic) prophylaxis against pneumococcal infection. In persons who require penicillin (or other antibiotic) prophylaxis against pneumococcal infection, such prophylaxis should not be discontinued after vaccination with pneumococcal vaccine ***Special populations:*** • Consider deferring immunization during periods of severe immunosuppression (eg, patients receiving chemo/radiation therapy or other immunosuppressive therapy [including high-dose corticosteroids]); may have a reduced response to vaccination • Pneumococcal vaccine is not approved for use in children <2 years. Children in this age group do not develop an effective immune response to the capsular types contained in this polysaccharide vaccine

	• Patients who will undergo cochlear implant placement should be vaccinated at least 2 weeks prior to surgery, if possible • Postmarketing reports of adverse effects in elderly patients, especially those with comorbidities, have been significant enough to require hospitalization
Vaxneuvance® (pneumococcal 15-valent conjugate vaccine)	***Concerns related to adverse effects:*** • Vaccine administration that is too high on the upper arm may cause shoulder injury (eg, shoulder bursitis, tendinopathy) resulting in shoulder pain and reduced range of motion following injection • Syncope has been reported with use of injectable vaccines and may result in serious secondary injury (eg, skull fracture, cerebral hemorrhage); typically reported in adolescents and young adults and within 15 minutes after vaccination ***Disease-related concerns:*** • Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever) • Use with caution in patients with bleeding disorders (including thrombocytopenia); bleeding/hematoma may occur from IM administration ***Concurrent drug therapy issues:*** • Use with caution in patients receiving anticoagulant therapy; bleeding/hematoma may occur from IM administration • To maximize vaccination rates, the Advisory Committee on Immunization Practices (ACIP) recommends simultaneous administration (ie, >1 vaccine on the same day at different anatomic sites) of all age-appropriate vaccines (live or inactivated) for which a person is eligible at a single clinic visit, unless contraindications exist ***Special populations:*** • Consider deferring vaccination during periods of severe immunosuppression (eg, patients receiving chemo-/radiation therapy or other immunosuppressive therapy including high-dose corticosteroids); may have a reduced response to vaccination

Price

	Capvaxive®	Prevnar 20®	Pneumovax-23®	Vaxneuvance®
Formulary Status	F-QL-AL	F-QL	F-QL	F-QL
Price Per Dose^	$302	$309	$117	$241

^Proprietary drug pricing is based on wholesale acquisition cost (WAC) and non-proprietary drug pricing is based on National Average Drug Acquisition Cost (NADAC) for 1 month supply unless otherwise noted.

Pneumococcal Serotypes in FDA-Approved Vaccines

Serotype	Capvaxive®	Prevnar 20®	Pneumovax 23®	Vaxneuvance®
1		X	X	X
2			X	
3	X	X	X	X
4		X	X	X
5		X	X	X
6A	X	X		X
6B		X	X	X
7F	X	X	X	X
8	X	X	X	
9N	X		X	
9V		X	X	X
10A	X	X	X	
11A	X	X	X	
12F	X	X	X	
14		X	X	X
15A	X			
15B	X	X	X	
15C	X			
16F	X			
17F	X		X	
18C		X	X	X
19F		X	X	X
19A	X	X	X	X
20			X	
20A	X			
22F	X	X	X	X
23A	X			
23B	X			
23F		X	X	X
24F	X			
31	X			
33F	X	X	X	X
35B	X			

Formulary Placement, Utilization and Cost Experience (04-01-2026 to 06-30-2026)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	**Rx**	**Mbrs**	**Total**	**Avg/Rx**	**Total**	**Approved (%)**	**Current**	**Recommend**
Pneumococcal Vaccines								
Capvaxive® (pneumococcal 21-valent conjugate vaccine) (PF) 0.5 mL intramuscular syringe	13	13	$3,723.35	$286.41	0	0 (0%)	F-QL (0.5mL/1 lifetime); AL(≥18)	No change
Prevnar 20® (pneumococcal 20-valent conjugate vaccine) (PF) 0.5 mL intramuscular syringe	12	12	$3,436.93	$286.41	0	0 (0%)	F-QL (0.5mL/1 dose; 1 fill per lifetime)	No change
Pneumovax-23® (pneumococcal vaccine polyvalent) 25 mcg/0.5 mL injection syringe	0	0	$0.00	$0.00	0	0 (0%)	F-QL (0.5mL/1 dose; 2 fills per lifetime)	No change
Vaxneuvance® (pneumococcal 15-valent conjugate vaccine crm197 protein adsorbed)/0.5 mL injection suspension	0	0	$0.00	$0.00	0	0 (0%)	F-QL (0.5mL/1 dose; 1 fill per lifetime)	No change
TOTAL	**25**	**25**	**$7,160.28**	**$286.41**	**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

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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 (FEV_1), 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 11 claims for 11 members, for a total cost of $223.32, and an average cost per claim of $20.30. The most highly utilized was Optichamber Diamond Vhc with 5 claims, followed by Optichamber Diamond W-Lrg Mask with 3 claims. There were no prior authorization requests.

Recommendations

- No changes

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Formulary Placement, Utilization and Cost Experience (04-01-2026 to 06-30-2026)

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 Imt 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

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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
Breathrite Valved Mdi Chamber	0	0	$0.00	$0.00	0	0 (0%)	F-QL(2/365)	No change
Compact Space Chamber	2	2	$33.74	$16.87	0	0 (0%)	F-QL(2/365)	No change
Easivent Holding Chamber	0	0	$0.00	$0.00	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	5	5	$80.14	$16.03	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
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
Compact Space Chamber-Lrg Mask	0	0	$0.00	$0.00	0	0 (0%)	F-QL(2/365)	No change

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Optichamber Diamond W-Lrg Mask	3	3	$70.97	$23.66	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
Procare 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
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
Procare 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
Vortex Vhc Pediatric Med 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 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 II Nebulizer	0	0	$0.00	$0.00	0	0 (0%)	F-QL(1/365)	No change
Aeroeclipse II 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
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

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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
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 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
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
Procare Compressor Nebulizer	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Procare Pediatric Neb Dog	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Procare Pediatric Neb Bear	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Procare 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

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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	1	1	$38.47	$38.47	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 Flow Meters								
Airzone Peak Flow Meter	0	0	$0.00	$0.00	0	0 (0%)	F-QL(1/365)	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(1/365)	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
Nasal Strips, Humidifers, 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

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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
TOTAL	**11**	**11**	**$223.32**	**$20.30**	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

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Alameda MRGs for review Q3 2026 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**** **Initial Authorization:** • 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 **Reauthorization:** • 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	~~9/2025~~9/2026

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	~~9/2025~~9/2026

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	~~9/2025~~9/2026

Recommendation: No changes

Quantity Limit Exception	
Therapeutic Classes (AHFS)	N/A
Medications	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. In addition, a quantity limit may require a member to use an optimized dose and strength.
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	~~9/2025~~9/2026

Recommendation: 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
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	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	~~9/2025~~9/2026

Recommendation: No changes

Antiemetics	
Therapeutic Classes (AHFS)	5-HT3 Receptor Antagonists, Neurokinin-1 receptor antagonists
Medications	Formulary ondansetron (Zofran) tablet 4mg, 8mg (quantity limit) ondansetron (Zofran) ODT (quantity limit) Formulary, Prior Authorization Required 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 Non-Formulary 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 Focinvez (fosaprepitant) IV solution 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 **For reference, please consult the most recent NCCN guidelines for Antiemesis*

	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	~~9/2025~~9/2026

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	~~9/2025~~9/2026

Recommendation: No changes

Cartilaginous Repair Agents	
Therapeutic Classes (AHFS)	Anti-inflammatory/antiarthritic agents, misc; devices
Medications	Formulary, PA required Euflexxa (hyaluronate sodium) – preferred agent Non-formulary (non-preferred agents) 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	~~9/2025~~9/2026

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	~~9/2025~~9/2026

Recommendation: No changes

Ophthalmic Anti-inflammatory Immunomodulators	
Therapeutic Classes (AHFS)	EENT anti-inflammatory agents, miscellaneous.
Medications	**Formulary, step therapy required** Cyclosporine (Restasis) 0.05% dropperette **Formulary PA (prior authorization required)** 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) Tryptyr (acoltremon) 0.003 % ophthalmic solution 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, Tryptyr, 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	~~9/2025~~9/2026

Recommendation: No changes

Penicillamine (Depen, Cuprimine), Trientine HCl (Syprine) for Wilson's disease	
Therapeutic Classes (AHFS)	Heavy Metal Antagonists
Medications	Formulary, PA required Penicillamine (Depen Titratabs) tablet Trientine (Syprine) Penicillamine (Cuprimine) capsule Non-Formulary 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	~~9/2025~~9/2026

Recommendation: Change naming convention to show generic availability of Ferriprox tablet

Iron-chelating Agents	
Therapeutic Classes (AHFS)	Heavy Metal Antagonists
Medications	Formulary, PA required Deferasirox (Jadenu) tablet -PREFERRED Deferasirox (Jadenu) granules Deferasirox (Exjade) tablet Non-Formulary Deferiprone (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	**INITIAL CRITERIA FOR CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS FOR DEFERASIROX**
	• 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
	REAUTHORIZATION CRITERIA FOR CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS FOR DEFERASIROX
	• 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	~~9/2025~~9/2026

Recommendation: No changes

Vancomycin	
Therapeutic Classes (AHFS)	Antibacterials, miscellaneous
Medications	Formulary, with quantity limit Vancomycin 125, 250 mg capsules Firvanq 25, 50 mg/ml solution Non-Formulary 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	~~9/2025~~9/2026

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	**CRITERIA FOR APPROVAL** • 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	~~9/2025~~9/2026

Recommendation: No changes

Erythropoiesis-Stimulating Agents	
Therapeutic Classes (AHFS)	Erythropoiesis-Stimulating Agents
Medications	Formulary, PA required Retacrit (epoetin alfa-epbx) - **PREFERRED** Aranesp (darbepoetin alfa) Procrit (epoetin alfa) Epogen (epoetin alfa) Non-formulary 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	**Criteria for authorization of existing epoetin users who are NEW to the plan:** • 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) **Requests for Initial Therapy:** • 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: o serum ferritin level (normal is > 100 ng/mL) o transferrin saturation (TSAT) (normal is > 20%) o vitamin B12 level(> 223 pg/mL) o 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:** o HgB < 10 g/dL • **For anemia related to cancer:** o Receiving myelosuppressive therapy for palliative treatment (members receiving myelosuppressive therapy with curative intent should not receive ESAs) **AND** documented symptomatic 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	~~9/2025~~9/2026

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)** Formulary • 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 Non-formulary: • Depo-Provera 400mg/mL injectable suspension • Progesterone 50mg/mL oil solution **Estrogen Agents for Male-to-Female (MTF)** Formulary • 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 Non-formulary • Depo-Estradiol (estradiol cypionate) 5mg/mL **Testosterone Agents for Female-to-Male (FTM)** Formulary (first-line) • 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) Formulary, PA required (second-line) • 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) Non-formulary • 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 and 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 and 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	~~9/2025~~9/2026

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)** Formulary • 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 Non-formulary: • Depo-Provera 400mg/mL injectable suspension • Progesterone 50mg/mL oil solution **Estrogen Agents for Male-to-Female (MTF)** Formulary: • 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 Non-formulary • Depo-Estradiol (Estradiol cypionate) 5mg/mL **Testosterone Agents for Female-to-Male (FTM)** Formulary (first-line) • 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) Formulary, PA required (second-line) • 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) Non-formulary • 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 and 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") **GnRHa (Adjunct use):** INITIAL CRITERIA to start treatment: • Require documentation of trial and failure, intolerance, contraindication, or inability to use spironolactone, dutasteride, finasteride, medroxyprogesterone acetate tablet and 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") **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
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 and 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 and 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. **Any GnRHa:** 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. **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	~~9/2025~~9/2026

Recommendation: No changes

Lidocaine Patch	
Therapeutic Classes (AHFS)	ANTIPRURITICS AND LOCAL ANESTHETICS
Medications	Formulary-PA Lidocaine (Lidoderm) 5% transdermal patch Non-Formulary 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	**CRITERIA FOR AUTHORIZATION for lidocaine 5% patch** • 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, any tricyclic antidepressant (TCA), such as: nortriptyline, amitriptyline, desipramine, etc.) in the last 365 days OR • Member is using over 50 mg morphine equivalence/day for 3 months. **CRITERIA FOR AUTHORIZATION for non-formulary patches** • 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, any TCA). 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, any TCA) AND who have used (or cannot/should not use) lidocaine 5% patches.
Last P&T Review Date	~~9/2025~~9/2026

Recommendation: No changes

Mesalamine	
Therapeutic Classes (AHFS)	Anti-Inflammatory Agents (GI Drugs)
Medications	Formulary Mesalamine (Canasa) suppository Mesalamine (Rowasa) rectal enema Mesalamine (SFRowasa) rectal enema Formulary, Step Therapy Mesalamine DR (Delzicol DR) capsule Mesalamine ER (Apriso) capsule Mesalamine DR (Lialda) tablet Formulary, PA Required Mesalamine ER (Pentasa) 500mg capsule Pentasa (mesalamine ER) 250mg capsule Mesalamine DR (Asacol HD) 800mg tablet 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	Criteria for Authorization 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 Mesalamine DR (Asacol HD), mesalamine ER (Pentasa) or Pentasa (mesalamine ER) 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. Mesalamine DR (Asacol HD), mesalamine ER (Pentasa), Pentasa (mesalamine ER) 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	~~9/2025~~9/2026

Recommendation: No changes

Corticosteroids for Ulcerative Colitis and Crohn's disease	
Therapeutic Classes (AHFS)	Corticosteroids, Adrenals
Medications	Formulary budesonide (Entocort EC) capsule (QL 540/365) Hydrocortisone (Cortenema) rectal enema Formulary, Prior Authorization Required 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 QL:** 3 months If criteria are not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review.
PA Review Criteria	Criteria for Authorization 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. Ortikos is approved when all of the following criteria are met: • Documentation of a diagnosis of mild to moderate Crohn's disease involving the ileum and/or the ascending colon • Documentation of trial and failure, contraindication, intolerance, or inability to use budesonide (Entocort EC) capsule Requests for exceeding quantity limit of 540 capsules per 365 days for budesonide (Entocort EC) capsule

	• 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	~~9/2025~~9/2026

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	For prophylaxis: 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. For treatment: 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	CRITERIA FOR THE USE OF ATOVAQUONE/PROGUANIL FOR MALARIA PROPHYLAXIS • 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. **CRITERIA FOR THE USE OF ATOVAQUONE/PROGUANIL FOR MALARIA TREATMENT** • 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	~~9/2025~~9/2026

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	~~9/2025~~9/2026

Recommendation: No changes

Scabicides and Pediculicides	
Therapeutic Classes (AHFS)	Scabicides and pediculicides
Medications	Formulary, Step therapy required Malathion (Ovide) 0.5% lotion Spinosad (Natroba) 0.9% suspension Ivermectin (Sklice) 0.5% lotion Non-Formulary Crotan (crotamiton) 10% lotion Pruradik (crotamiton) 10% lotion 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: **Head Lice:** 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 **Scabies:** For the approval of the formulary-step therapy required medications: • Diagnosis of scabies (Sarcoptes scabiei) • 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, Pruradik 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, Pruradik 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	~~9/2025~~9/2026

Recommendation: No changes

Rifamycin Antibiotics	
Therapeutic Classes (AHFS)	Rifamycin Antibiotics
Medications	Formulary Prior Authorization Required Xifaxan (rifaximin)
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:** If all of the criteria are met, approve up 1 fill up to FDA approved maximum dosing. **IBS-D:** 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:** 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	Criteria for Authorization For all diagnoses **:** • Drug is being prescribed at FDA approved dose (including patient age) For diagnosis of traveler's diarrhea **:** • 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**:** • 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)**:** • 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 is 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	~~9/2025~~9/2026

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	Tretinoin criteria for approval: 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	~~9/2025~~9/2026

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	Criteria for Approval • 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	~~9/2025~~9/2026

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	Criteria for Approval • 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	~~9/2025~~9/2026

Recommendation: Remove Peg-Intron and Viekira pak from criteria as they have been discontinued

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 MARKETED 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 ≥ 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: ~~9/2025~~9/2026

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	~~9/2025~~9/2026

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	~~9/2025~~9/2026

Recommendation: No changes

Moxifloxacin Oral Tablet	
Therapeutic Classes (AHFS)	Quinolone antibiotics
Medications	Formulary, Step Therapy 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	~~9/2025~~9/2026

Recommendation: No changes

Santyl Ointment	
Therapeutic Classes (AHFS)	Collagenase (enzymatic debriding ointment)
Medications	**Formulary, PA required** 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	~~9/2025~~9/2026

Recommendation: No changes

Topical Antibiotics	
Therapeutic Classes (AHFS)	ANTIBACTERIALS (SKIN, MUCOUS MEMBRANE)
Medications	Formulary, with quantity limits 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** (request for more than 6 fills in 12 months, or 2 fills in 12 months for gentamicin) 3 months **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	Initial Approval: Topical antibiotic request for exceeding quantity or fill limit • 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. Later Approval: Topical antibiotic request: continues to exceed quantity or fill limit • 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) quantities within the quantity and/or fill limits.
Last P&T Review Date	~~9/2025~~9/2026

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	**Initial Authorization:** • 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 be24–72 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	~~9/2025~~9/2026

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	**Initial Authorization:**
	• 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
	
	Re-Authorization:
	• 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	~~9/2025~~9/2026

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	**Initial Authorization:** • 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 **Re-Authorization:** • 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	~~9/2025~~9/2026

Recommendation: No changes

Anti-Parkinson's Agents for OFF Episodes	
Therapeutic Classes (AHFS)	Dopamine Precursors
Medications	Vyalev (foscarbidopa 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	Vyalev: Concurrent use with a nonselective monoamine oxidase (MAO) inhibitor (such as phenelzine or tranylcypromine) Onapgo: Concurrent use with 5HT3 antagonists, including antiemetics (e.g. ondansetron, granisetron, dolasetron, palonosetron) and alosetron Concurrent use of Vyalev and Onapgo
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 requests will be approved for up to a 6 month duration 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)
	• For Vyalev: patient is taking ≥400 mg of levodopa/day
	• For Onapgo: patient is currently taking and will continue to take carbidopa/levodopa
	• 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 and Onapgo are reserved for members who have a diagnosis of advanced Parkinson's disease, who experience persistent motor fluctuations despite optimized carbidopa/levodopa therapy, 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	~~9/2025~~9/2026

Recommendation: No changes

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	**Initial Authorization:** • 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) **Re-Authorization:** • 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~~9/2026

Recommendation: No changes

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	**Initial Authorization:** • 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.) **Re-Authorization:** • 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~~9/2026

Alameda PADs for review Q3 2026 P&T Consent Agenda

Recommendation: No changes

Exondys 51	
Medications	Exondys 51 (eteplirsen) 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	~~9/2025~~9/2026

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
	
	• **For anemia related to cancer:**

Erythropoiesis-Stimulating Agents	
	○ Receiving myelosuppressive therapy for palliative treatment (members receiving myelosuppressive therapy with curative intent should not receive ESAs) **AND** documented symptomatic 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	~~9/2025~~9/2026

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	**Initial Authorization**
	• 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
	Re-authorization:
	• 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	~~9/2025~~9/2026

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	**Initial Authorization:** • 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	~~9/2025~~9/2026

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	**Initial Authorization:** • 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) ≥ 50% • Medication is prescribed at an FDA approved dose **Re-Authorization:** • 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	~~9/2025~~9/2026

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	~~9/2025~~9/2026

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 one of the following: 1. An undetectable (<1%) alpha galactosidase A (alpha-Gal-A) activity level OR 2. 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	~~9/2025~~9/2026

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	**Initial Authorization:**
	• 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
	
	Re-Authorization:
	• 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	~~9/20259~~/2026

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	~~9/2025~~9/2026

Recommendation: No changes

Anti-Parkinson's Agents for OFF Episodes	
Medications	Vyalev (foscarbidopa 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	Vyalev: Concurrent use with a nonselective monoamine oxidase (MAO) inhibitor (such as phenelzine or tranylcypromine) Onapgo: Concurrent use with 5HT3 antagonists, including antiemetics (e.g. ondansetron, granisetron, dolasetron, palonosetron) and alosetron Concurrent use of Vyalev and Onapgo
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 requests will be approved for up to a 6 month duration and reauthorization requests will be approved for 12 months.
Maximum Billable Units	Variable

Other 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)
	• For Vyalev: patient is taking ≥400 mg of levodopa/day
	• For Onapgo: patient is currently taking and will continue to take carbidopa/levodopa
	• 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)
	
	Reauthorization
	• 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	~~9/2025~~9/2026

Recommendation: No changes

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	**Initial Authorization** • 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 mm^2 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	~~9/20259~~/2026

Recommendation: No changes

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	**Initial Authorization:**
	• 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
	
	Re-Authorization:
	• 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~~9/2026

Recommendation: No changes

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	**Initial Authorization**
	• 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 cm^2
	• 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~~9/2026

Alameda Alliance for Health (IHSS)

Q3 2026 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
Ozempic Oral Tablet 1.5 mg	NF to F-ST-QL (ST: prior use of metformin containing product is required; QL: 30 tabs/30 days)
Ozempic Oral Tablet 4 mg	NF to F-ST-QL (ST: prior use of metformin containing product is required; QL: 30 tabs/30 days)
Ozempic Oral Tablet 9 mg	NF to F-ST-QL (ST: prior use of metformin containing product is required; QL: 30 tabs/30 days)
Rybelsus (Formulation R2) Oral Tablet 1.5 MG	F-ST-QL to NF
Rybelsus (Formulation R2) Oral Tablet 4 MG	F-ST-QL to NF
Rybelsus (Formulation R2) Oral Tablet 9 MG	F-ST-QL to NF
Macitentan Oral Tablet 10 MG	NF to F-PA-QL (QL: 30 each/30 days)
Opsumit Oral Tablet 10 MG	F-PA-QL to NF
Mirabegron ER Oral Suspension Reconstituted ER 8 MG/ML	NF to F-PA
Myrbetriq Oral Suspension Reconstituted ER 8 MG/ML	F-PA to NF
Breztri Aerosphere Inhalation Aerosol 160-18-4.8 MCG/ACT	NF to F-PA-QL (QL: 10.7 GM per 30 days)
FluMist Nasal Liquid	NF to F-QL-AL (QL: 1 fill/270 days; AL: 12-49 years)
Fluzone Intramuscular Suspension	NF to F-QL-AL (QL: 1 fill/270 days; AL: 12 years and above)
Fluarix Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (QL: 1 fill/270 days; AL: 12 years and above)
Fluzone High-Dose Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (QL: 1 fill/270 days; AL: 65 years and above)
Fluad Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (QL: 1 fill/270 days; AL: 65 years and above)
Flucelvax Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (QL: 1 fill/270 days; AL: 12 years and above)
Flulaval Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (QL: 1 fill/270 days; AL: 12 years and above)
Flublok Intramuscular Solution Prefilled Syringe 0.5 ML	NF to F-QL-AL (QL: 1 fill/270 days; AL: 12 years and above)
Fluzone Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (QL: 1 fill/270 days; AL: 12 years and above)

Summary of PAD Prior Authorization Changes P&T Q3 2026

HCPCS Code	HCPCS Description	Prior Authorization Action
J2504	ADAGEN (PEGADEMASE BOVINE)	Remove PA
J9181	ETOPOSIDE (TOPOSAR)	Remove PA
J9352	TRABECTEDIN (YONDELIS)	Remove PA
Q5173	DENOSUMAB-ADET (PONLIMSI) BIOSIMILAR	Add PA
J1757	TIVIDENOFUSP ALFA-EKNM (AVLAYAH)	Add PA
J3406	OMIDUBICEL-ONLV (OMISIRGE)	Add PA
J1818	PEGZILARGINASE-NBLN (LOARGYS)	Add PA
Q5172	FILGRASTIM-LAHA (FILKRI) BIOSIMILAR	Add PA

POLICY AND PROCEDURE

Policy Number	RX-017
Policy Name	Investigational Drug Review and Coverage Determination Policy
Department Name	Pharmacy
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy
Line(s) of Business	MCAL, DSNP, IHSS
Effective Date	TBD
Administrative Oversight Committee Approval Date	TBD

Commented [TT1]: Should we include other LOB as well?

POLICY STATEMENT

Purpose

To establish criteria and procedures for reviewing drug requests submitted as investigational and for determining coverage when a member is participating in a clinical trial. This policy is intended to align with California Welfare & Institutions Code §14132.98 and Medi-Cal Clinical Trials Policy requirements. This policy is intended to align with CMS National Coverage Determination (NCD) Routine Costs in Clinical Trails (310.1). This policy is intended to align with California Code, Health and Safety Code - HSC § 1370.4.

Scope

This policy applies to all medical drug and pharmacy drug benefit reviews involving:

- Investigational drugs, biologics, or medical products.
- Requests associated with clinical trial participation.
- Requests in which a drug is determined to be the investigational item or service under a qualifying clinical trial.

Definitions

Investigational Drug

A drug, biologic, or product that has not received FDA approval for the requested indication, dosage form, route of administration, or intended use, or is otherwise designated as investigational within a clinical trial protocol.

Qualifying Clinical Trial

A clinical trial conducted for the prevention, detection, or treatment of a serious or life-threatening disease or condition, as defined under applicable federal and state law.

Routine Patient Care Costs

Items and services provided to a member participating in a qualifying clinical trial that would otherwise be covered or that are necessary to monitor, diagnose, mitigate, or treat complications arising from participation in the clinical trial. Routine patient care costs may include:
Services that would otherwise be covered outside of the clinical trial;
Services required for administration of the investigational item or service;
Services used to prevent, diagnose, monitor, or treat complications related to trial participation.

Non-Covered Clinical Trial Costs

The following are not covered:

- The investigational drug, biologic, device, product, or service that is the subject of the qualifying clinical trial;
- Services otherwise excluded from coverage under applicable benefit programs;
- Travel, lodging, companion expenses, and other non-clinical expenses;
- Services provided solely for research data collection or analysis.

PROCEDURE

A. Coverage of Routine Clinical Trial Costs

The Plan may cover routine patient care costs associated with a qualifying clinical trial when all applicable statutory, regulatory, and benefit requirements are met. Coverage determinations shall not be based solely on the geographic location of the clinical trial site or the network status of the treating provider or principal investigator.

B. Non-Coverage of Investigational Drugs Under Clinical Trials

The investigational drug, biologic, device, or product that is the subject of a qualifying clinical trial is not a covered benefit and shall be denied coverage.
When a reviewer determines that the requested drug is being supplied, administered, studied, evaluated, or otherwise serves as the investigational item or service under a clinical trial protocol, the request shall be denied as non-covered because it is the investigational item or service that is the subject of the clinical trial.

C. Identification of Clinical Trial Participation

A request may be considered associated with a clinical trial when any of the following are identified:

- Documentation references a clinical trial, research protocol, investigational study, IND protocol, or study sponsor.
- Documentation includes a ClinicalTrials.gov identification number (8-digit National Clinical Trial, NCT number).
- The prescriber, facility, or supporting records indicate enrollment or anticipated enrollment in a clinical trial.
- The requested drug is being provided pursuant to a study protocol.

D. Reviewer Outreach Requirements

If available documentation indicates the member is participating in a clinical trial but does not clearly identify whether the requested drug is the investigational item or service:

1. The reviewer may conduct outreach to the requesting provider, study investigator, facility, or authorized representative.
2. The reviewer shall request clarification regarding:
    - The name of the investigational drug or product;
    - Whether the requested drug is the study drug;
    - Whether the requested drug is being supplied by the study sponsor;
    - The member's participation status in the clinical trial.
3. Coverage determination may be based on information received through outreach and available clinical documentation.

E. Inability to Verify Investigational Status

If, after reasonable efforts, sufficient information is not provided to determine whether the requested drug is the investigational item or service, the reviewer may deny the request for insufficient information, consistent with applicable utilization management procedures.

F. Documentation Requirements

The case record should include, when available:

- Clinical trial title;
- ClinicalTrials.gov identifier (8-digit National Clinical Trial, NCT number);
- Protocol name or study identifier;
- Identification of the investigational drug or service;
- Documentation supporting the coverage determination;
- Records of outreach and responses received.

Suggested Denial Rationale Language

Clinical Trial Investigational Drug Denial

Medi-Cal and Medicare line of business:

"The requested drug is identified as the investigational drug/item that is the subject of a clinical trial. Under applicable Medi-Cal and CMS Medicare clinical trial coverage requirements and California Welfare & Institutions Code §14132.98, routine patient care costs associated with a qualifying clinical trial may be covered; however, the investigational drug or service that is the subject of the clinical trial is not a covered benefit. Therefore, coverage for the requested drug is denied."

Group Care IHSS Commercial line of business:

The requested drug is the investigational product that is the subject of an ongoing clinical trial and has been requested for use in the investigational setting. Based on the information submitted, the requested drug is considered experimental or investigational under the terms of the member's health plan coverage and is therefore not a covered benefit at this time. Accordingly, coverage for the requested drug is denied.
Pursuant to California Health & Safety Code §1370.4, members who are denied coverage for a therapy on the basis that it is experimental or investigational may request review through the Department of Managed Health Care's Independent Medical Review program if the applicable statutory requirements are met.

Information regarding the IMR process and application rights will be provided with this determination as required by California law.

AFFECTED DEPARTMENTS/PARTIES

Pharmacy
UM

RELATED POLICIES AND PROCEDURES

None

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

None

REVISION APPROVAL HISTORY

New Policy: 07/2026

REFERENCES

California Welfare & Institutions Code §14132.98
Medi-Cal Clinical Trials Policy
CMS National Coverage Determination (NCD) Routine Costs in Clinical Trials (310.1)
California Health and Safety Code - HSC § 1370.4

MONITORING

POLICY AND PROCEDURE

Policy Number	RX-D-001
Policy Name	Part D Transition Process
Department Name	Pharmacy
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy
Line(s) of Business	D-SNP
Effective Date	TBD
Administrative Oversight Committee Approval Date	TBD

POLICY STATEMENT

The purpose of this policy is to describe the Alameda Alliance for Health (the Alliance) Pharmacy Benefit Manager's (PBM's) process for transition and ensure that continued drug coverage is provided to new and current Part D members. The transition process allows for a temporary supply of drugs and sufficient time for members to work with their health care providers to select a therapeutically appropriate formulary alternative, or to request a formulary exception based on medical necessity. Transition processes will be administered by Alliance PBM in a manner that is timely, accurate and compliant with all relevant CMS guidance and requirements as per 42 CFR §423.120(b)(3).

This policy is necessary with respect to:

(1) New enrollees into prescription drug plans following the annual coordinated election period;
(2) Newly eligible Medicare beneficiaries from other coverage;
(3) Enrollees who switch from one plan to another after the start of a contract year;
(4) Current enrollees affected by negative formulary changes across contract years,
(5) Enrollees residing in long-term care (LTC) facilities.

Applicable personnel in the Alameda Alliance for Health (the Alliance) Health Care Services and Operations departments follow this policy. This document is intended to describe processes necessary to meet regulatory requirements as of the effective date above.

PROCEDURE

1 Policy

1.1 Overview
Alliance PBM supports the Alliance in administering a transition process that is in compliance with the established CMS transition requirements.

This policy is necessary with respect to:
(1) New enrollees into prescription drug plans following the annual coordinated election period;
(2) Newly eligible Medicare beneficiaries from other coverage;
(3) Enrollees who switch from one plan to another after the start of a contract year;
(4) Current enrollees affected by negative formulary changes across contract years; and
(5) Enrollees residing in long-term care (LTC) facilities.

Alliance PBM will ensure that its transition policy will apply to non-formulary drugs, meaning both (1) Part D drugs that are not on the Alliance's formulary, and (2) Part D drugs that are on the Alliance's formulary but require prior authorization or step therapy, or that have an approved QL lower than the beneficiary's current dose, under the Alliance's utilization management rules. Alliance PBM will ensure that its policy addresses procedures for medical review of non-formulary drug requests, and when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

Also in accordance with CMS requirements, Alliance PBM ensures that drugs excluded from Part D coverage due to Medicare statute are not eligible to be filled through the transition process. However, to the extent that the Alliance covers certain excluded drugs under an Enhanced benefit, those drugs should be treated the same as Part D drugs for the purposes of the transition process.

1.2 Transition Population
Alliance PBM will maintain an appropriate transition process consistent with 42 CFR §423.120(b)(3) that includes a written description of how, for enrollees whose current drug therapies may not be included in their new Part D plan's formulary, it will effectuate a meaningful transition for: (1) new enrollees into prescription drug plans following the annual coordinated election period, (2) newly eligible Medicare beneficiaries from other coverage, (3) enrollees who switch from one plan to another after the start of a contract year, (4) current enrollees affected by negative formulary changes across contract years, (5) enrollees residing in long-term care (LTC) facilities.

1.3 Transition Period
Alliance PBM allows the Alliance to choose the number of transition days offered under their transition policy. CMS requires a minimum of 90 days from the start of coverage under a new plan. The 90 days are calculated from the Alliance start

date. Alliance PBM will extend its transition policy across contract years should a beneficiary enroll in the Alliance with an effective enrollment date of either November 1 or December 1 and need access to a transition supply. The Alliance may choose to enhance the transition policy to provide coverage beyond the CMS minimum requirements.

With the exception of Alliance PBM's "Transition Across Calendar Years" processes described later in this policy, the Alliance has two options for setting the member's transition start date; utilizing Alliance PBM's system default logic or continue populating Segment Code 05 of the Type 24 file.

Alliance PBM's default process for setting the transition start date will work with Alliance PBM's Type 23 (member record layout) file, or equivalent file type if the Alliance does not utilize the Type 23. Whenever the Type 23 loads or its equivalent file loads, the transition start date default process will run simultaneously and analyze the member's group number assignment and the member's effective date within that group.

- For members that are new to the Alliance or that are re-enrolling but had a break in coverage, Alliance PBM's default process will set the transition start date to match the member's effective date within the group.
- For existing (non-new) members that are assigned to a new group within the Alliance, Alliance PBM's default process will analyze the change in group number assignment to determine if it results in a new CMS contract and/or plan assignment.
    - If the change in group number resulted in a new CMS contract assignment, the member's transition start date will be updated to mirror the effective date of the group change.
    - If the change in group number did not result in a new CMS contract assignment, the member's transition start date will remain as is and will not be updated.
    - If the change in group number resulted in a new plan assignment and new formulary ID, the member's transition start date will be updated to mirror the effective date of the group change.
    - If the change in group number did not result in a new plan assignment or new formulary ID, the member's transition start date will remain as is and will not be updated.

Alliance PBM's default logic aligns with guidance issued by CMS stating the Alliance must effectuate transition for members that change either CMS contract or plan, irrespective of whether or not the change resulted in a new Part D formulary assignment.

If the Alliance continues to utilize Segment Code 05 of the Type 24 for setting member's transition start date, the Alliance is ultimately responsible for indicating which of their members should be in a transition period. The Alliance must place their members into a transition period by populating the appropriate Member plan Part D Start Date in Segment Code 05 of the Type 24 File (Member Attribute Load File). The transition period (90-day minimum) is then calculated from the Member plan Part D Start Date with the Alliance.

Alliance PBM will ensure that it will apply all transition processes to a brand-new prescription for a non-formulary drug if it cannot make the distinction between a brand-new prescription for a nonformulary drug and an ongoing prescription for a non-formulary drug at the point-of-sale.

1.4 Implementation Statement

a) Claims Adjudication System: Alliance PBM has systems capabilities that allow Alliance PBM to provide a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as to allow the Alliance and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.

b) Pharmacy Notification at Point-Of-Sale: Alliance PBM utilizes the current NCPDP
Telecommunication Standard to provide POS messaging. Alliance PBM reviews NCPDP reject and approval codes developed during the External Codes List (ECL) process. Pharmacy messages are modified based on industry standards.

c) Edits During Transition: Alliance PBM will only apply the following utilization management edits during transition at point-of-sale: edits to determine Part A or B versus Part D coverage, edits to prevent coverage of non-Part D drugs, and edits to promote safe utilization of a Part D drug. Step therapy and prior authorization edits must be resolved at point-of-sale.

Alliance PBM will ensure that the transition policy provides refills for transition prescriptions dispensed for less than the written amount due to quantity limit safety edits or drug utilization edits that are based on approved product labeling.

As outlined in 42 CFR §423.153(b), Alliance PBM has implemented Point-of-Sale (POS) PA edits to determine whether a drug is covered under Medicare Parts A or B as prescribed and administered, is being used for a Part D medically accepted indication or is a drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D (Transmucosal Immediate Release Fentanyl (TIRF) and Cialis drugs as an example).

d) Pharmacy Overrides at Point-Of-Sale: During the member's transition period, all edits (with the exception of those outlined in section 1.4(c)) associated with non-formulary drugs are automatically overridden at the point-of-sale. Pharmacies can also contact Alliance PBM's Pharmacy Help Desk directly for immediate assistance with point-of-sale overrides. Alliance PBM can also accommodate overrides at point-of-sale for emergency fills as described in section 1.7. Please see section 1.10 for specific information for the processing of non-formulary drugs in the Six Classes of Clinical Concern.

1.5 Transition Fills for New Members in the Outpatient (Retail) Setting
Alliance PBM will ensure that in the retail setting, the transition policy provides for a one time temporary fill of at least a month's supply of medication (unless the enrollee presents with a prescription written for less than a month's supply in which case the Alliance must allow multiple fills to provide up to a total of a month's supply of medication) anytime during the first 90 days of a beneficiary's enrollment in the Alliance, beginning on the enrollee's effective date of coverage. If a brand medication is being filled under transition, the previous claim must also be brand (based on Comprehensive NDC SPL Data Elements File [NSDE] marketing status). If a generic medication is being filled under transition, the previous claim can be either brand or generic (based on NSDE marketing status).

1.6 Transition Fills for New Members in the LTC Setting
Alliance PBM will ensure that in the long-term care setting: (1) the transition policy provides for a one time temporary fill of at least a month's supply (unless the enrollee presents with a prescription written for less) which should be dispensed incrementally as applicable under 42 CFR §423.154 and with multiple fills provided if needed during the first 90 days of a beneficiary's enrollment in the Alliance, beginning on the enrollee's effective date of coverage (2) after the transition period has expired, the transition policy provides for a 31-day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days) while an exception or prior authorization is requested and (3) for enrollees being admitted to or discharged from a LTC facility, early refill edits are not used to limit appropriate and necessary access to their Part D benefit, and such enrollees are allowed to access a refill upon admission or discharge.

1.7 Emergency Supplies and Level of Care Changes for Current Members
An Emergency Supply is defined by CMS as a one-time fill of a non-formulary drug that is necessary with respect to current members in the LTC setting. Current members that are in need of a one-time Emergency Fill or that are prescribed a non-formulary drug as a result of a level of care change can be placed in transition via an NCPDP pharmacy submission clarification code. Alliance PBM can also accommodate a one-time fill in these scenarios via a manual override at point-of-sale.

Upon receiving an LTC claim transaction where the pharmacy submitted a Submission Clarification Code (SCC) value of "18", which indicates that the claim transaction is for a new dispensing of medication due to the patient's admission or readmission into an LTC facility, Alliance PBM's claims adjudication system will recognize the current member as being eligible to receive transition supplies and will only apply the point-of-sale edits described in section 1.4(c) of this policy. In this instance, the Alliance does not need to enter a point-of-sale override.

For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, the Alliance will effectuate a meaningful transition by either: (1) providing a transition process at the start of the new contract year or (2) effectuating a transition prior to the start of the new contract year.

POS logic is able to accommodate option 1 by allowing current members to access transition supplies at the point-of-sale when their claims history from the previous calendar year contains an approved claim for the same drug that the member is attempting to fill through transition and the drug is considered a negative change from one plan year to the next. To accomplish this, POS looks for Part D claims in the member's claim history that were approved prior to January 1 of the new plan year, and that have the same HICL value as the transition claim. Additionally, if a brand medication is being filled under transition, the previous claim must also be brand (based on NSDE marketing status). If a generic medication is being filled under transition, the previous claim can be either brand or generic (based on NSDE marketing status).

Negative changes are changes to a formulary that result in a potential reduction in benefit to members. These changes can be associated to removing the covered Part D drug from the formulary, changing its preferred or tiered cost-sharing status, or adding utilization management. The transition across contract year process is applicable to all drugs associated to mid-year and across plan-year negative changes.

1.8 Transition Extension

The Alliance will make arrangements to continue to provide necessary Part D drugs to enrollees via an extension of the transition period, on a case-by-case basis, to the extent that their exception requests or appeals have not been processed by the end of the minimum transition period and until such time as a transition has been made (either through a switch to an appropriate formulary drug or a decision on an exception request). On a case-by-case basis, point-of-sale overrides can also be entered by the Alliance or by Alliance PBM (if authorized by the Alliance to do so) in order to provide continued coverage of the transition drug(s).

1.9 Cost-sharing for Transition Supplies

Alliance PBM will ensure that cost-sharing for a temporary supply of drugs provided under its transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees. For non-LIS enrollees, the Alliance must charge the same cost sharing for non-formulary Part D drugs provided during the transition that would apply for nonformulary drugs approved through a formulary exception in accordance with 42 CFR §423.578(b) and the same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply if the utilization management criteria are met.

1.10 Six Classes of Clinical Concern

Per CMS guidance, members transitioning to the Alliance while taking a drug within the six classes of clinical concern must be granted continued coverage of therapy for the duration of treatment, up to the full duration of active enrollment in the Alliance as long as the drug remains on formulary. Utilization management restrictions (PA and/or Step Therapy), which may apply to new members naïve to therapy, are not applied to those members transitioning to the Medicare Part D plan on agents within these key categories. The six classes include:

1) Antidepressant;
2) Antipsychotic;
3) Anticonvulsant;
4) Antineoplastic;
5) Antiretroviral; and
6) Immunosuppressant (for prophylaxis of organ transplant rejection).

For new members, protected class drug logic will always override transition logic to process the claim. Additionally for new members, a 120-day transition period from their member start date is provided.

1.11 Member Notification

Alliance PBM provides the Alliance (via FTP) with two daily files called the Transition Notification “All” File and the Transition Notification “Print” file. The Transition Notification “All” File, which contains claims data and other member information, provides the Alliance with all of the information needed to contact members and providers regarding transition fills. The Transition Notification “Print” File includes necessary member and claims data needed to produce member notices. This file was created to allow the ability to produce one transition notice per member within a 100 day period where the drug, transition type and applicable drug restrictions are the same.

The Alliance will send written notice consistent with CMS transition requirements via U.S. first class mail to enrollee within three business days of adjudication of the temporary transition fill. If the enrollee completes his or her transition supply in several fills, the Alliance is required to send notice with the first transition fill only. The notice must include:

(1) an explanation of the temporary nature of the transition supply an enrollee has received;
(2) instructions for working with the Alliance and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the Alliance's formulary;
(3) an explanation of the enrollee's right to request a formulary exception; and
(4) a description of the procedures for requesting a formulary exception.

For long-term care residents dispensed multiple supplies of a Part D drug in increments of 14-days-or-less, consistent with the requirements under 42 CFR 423.154(a)(1)(i), the written notice must be provided within 3 business days after adjudication of the first temporary fill. The Alliance will use the CMS model Transition Notice via the file-and-use process or submit a non-model Transition Notice to CMS for marketing review subject to a 45-day review. The Alliance will ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice.

Providing written notification to the member and/or provider in accordance with CMS requirements is ultimately the responsibility of the Alliance. The Alliance also has the option to contract with Alliance PBM's print vendor to receive the Transition of Care Notification File and facilitate the fulfillment process of member notification on the Alliance's behalf.

Alliance PBM and Alliance PBM's print vendor adhere to all CMS Marketing Guidelines as set forth in Chapter 2 of the Medicare Prescription Drug Benefit Manual.

The Alliance will make their transition policy available to enrollees via link from Medicare Prescription Drug Plan Finder to the Alliance web site and include in pre-and post-enrollment marketing materials as directed by CMS.

Alliance PBM provides the Alliance (via FTP) with a file to assist in producing a Prescriber Transition Notification letter to be mailed to the prescriber at the same time the transition letter is mailed to the member. This information is obtained from the existing Transition Notification Files that are sent to the Alliance daily, as described above. The file/letter includes the following:

- Prescriber information
- Member information
- Transition claim details

The Alliance is given the option to use Alliance PBM's preferred print vendor to mail the Prescriber Transition letters or to mail the notification on their own. Alliance PBM has created a Prescriber Transition Notification letter template and a File Specification document for the Alliance to utilize. The letter template provides physicians with formulary alternatives.

1.12 PDE Reporting

Since this is a CMS required process, any drugs dispensed that qualify under the transition period are reported as covered Part D drugs with appropriate Alliance and member cost sharing amounts on the Prescription Drug Event (PDE).

1.13 CMS Submission

The Alliance will submit a copy of its transition process policy to CMS.

1.14 Pharmacy and Therapeutics Committee Role

The Alliances uses the Alliance PBM Pharmacy and Therapeutics Committee (P&T) which maintains a role in the transition process in the following areas:

1) The Alliance PBM P&T committee reviews and recommends all formulary step therapy and prior authorization guidelines for clinical considerations; and

2) The Alliance PBM P&T committee reviews and recommends procedures for medical review of non-formulary drug requests, including the exception process.

1.15 Exception Process

Alliance PBM follows an overall transition plan for Medicare Part D members; a component of which includes the exception process. Alliance PBM's exception process integrates with the overall transition plan for these members in the following areas:

1) Alliance PBM's exception process complements other processes and strategies to support the overall transition plan. The exception process follows the guidelines set forth by the transition plan when applicable.

2) When evaluating an exception request for transitioning members, the Alliance's exception evaluation process considers the clinical aspects of the drug, including any risks involved in switching, when evaluating an exception request for transitioning members.

3) The exception policy includes a process for switching new Medicare Part D plan members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

The Alliance will make available prior authorization or exceptions request forms upon request to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on plan web sites.

DEFINITIONS / ACRONYMS

CMS – Centers for Medicare and Medicaid Services – The agency within the US Federal Government that is charged with the execution and maintenance of the law defining the prescription drug program for senior citizens, the disabled, and the infirm.

Emergency Supply – An Emergency Supply is defined by CMS as a one-time transition fill that is necessary with respect to members that are outside of their initial 90-day transition period and that are in the LTC setting.

FTP File Transfer Protocol – One of the methods used by Alliance PBM and its clients to transfer electronic files via the Internet. The first two bits of the file indicate the type of file. HICL An First Data Bank (FDB) data warehouse term that is an alpha-numeric code used to describe drugs ingredients. The HICL codes have been sequenced according to an ingredient sequence table. The HICL sequence table establishes relative importance to each ingredient, relative to other ingredients. The relative importance of an ingredient is based on its clinical and therapeutic use. The most important ingredients are sequenced first and the least significant are sequenced last.

Level of Care Changes – Level of care changes include the following changes from one treatment setting to another:

- Enter LTC facility from hospitals or other settings;
- Leave LTC facility and return to the community;
- Discharge from a hospital to a home;
- End a skilled nursing facility stay covered under Medicare Part A (including pharmacy
charges), and revert to coverage under Part D;
- Revert from hospice status to standard Medicare Part A and B benefits; and
- Discharge from a psychiatric hospital with medication regimens that are highly individualized.

LTC – Long Term Care

NSDE – The FDA's Comprehensive NDC Structured Product Labeling Data Elements file. This file is used to provide structured product labeling of Brand and Generic drugs.

PA – Prior Authorization - The process undertaken to make a benefit determination that is made prior to the intended delivery of the healthcare service, treatment or supply under review (e.g., a Pre-Service Claim). Prior Authorization includes requests for coverage determination for medications that are designated on the client part D formulary as "Prior Authorization Required", "Step Therapy", "Quantity Restrictions" or for requests for exception for non-formulary medications or co-insurance amount.

PDE – Prescription Drug Event. File that reports all claims transactions to CMS for inclusion in the annual financial reconciliation between CMS and the Plans.

Plan – Medicare Part D Plan Sponsors who are Alliance PBM clients.

POS – The acronym given to Alliance PBM's point-of-sale prescription transaction processing computer system. Also indicates that the actual retail transaction occurs when the claim is

submitted electronically by the pharmacy.

P&T Committee – Pharmacy & Therapeutics Committee – An independent group of external & internal health care practitioners that are responsible for evaluating the efficacy, safety and cost effectiveness of medications to determine potential additions, subtractions and other changes to a formulary.

UM – Utilization Management – A set of guidelines that can be applied independently or jointly that otherwise restrict access to the dispensing or consumption of prescription drugs. The four basic restrictions are prior authorization (PA), quantity limits (QL), step therapy (ST) and tier placement. UM is a tool used by health plans to ensure safe, efficacious and cost-effective use of medication by members.

AFFECTED DEPARTMENTS/PARTIES

Health Care Services
Pharmacy
Operations

RELATED POLICIES AND PROCEDURES

None

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

None

REVISION APPROVAL HISTORY

New Policy: 4/16/2025
Updated: 6/30/2026

REFERENCES

Federal Register, Vol. 76, No. 73, Part II, 42 CFR, §423.120(b)(3), §423.153(b), §423.154
Chapter 6 Medicare Prescription Drug Benefit Manual
Medicare Marketing Guidelines
Transition of Care Notification File
Implementation Questionnaire (IQ)
Medicare Part D Coverage Determinations

MONITORING

In addition to daily rejected claims review, Alliance staff will perform transition sample reviews to ensure compliance with CMS regulations and Alliance policies and procedures. The results of these internal audits will be provided to Alliance Compliance Department.

POLICY AND PROCEDURE

Policy Number	RX-D-010
Policy Name	Medicare Part D Daily ~~Rejected~~ Claims Review
Department Name	Pharmacy Services
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy Services
Line(s) of Business	Medicare Advantage DSNP
Effective Date	1/1/2026
Administrative Oversight Committee Approval Date	~~8/20/2025~~

POLICY STATEMENT

~~Review~~Plan sponsor undergoes review of the daily ~~rejected~~ pharmacy claims, including denied and approved claims, to ensure compliance with the Centers for Medicare and Medicaid Services (CMS) ~~guidance~~requirements for Medicare Part D sponsors. Alameda Alliance for Health (Alliance) will perform oversight of its Pharmacy Benefit Manager (PBM) to ensure the beneficiaries' pharmacy benefit is being administered accurately. Identified issues will be resolved expeditiously and appropriate outreach performed to ensure beneficiary medication access.

PROCEDURE

1 Access Daily ~~Reject~~Claims Report from PBM

1.1 Link to location of PBM Daily ~~rejected~~ claims report and instructions on how to retrieve ~~[will be~~is detailed and expanded upon in SOP~~]~~

~~1.2 Directions where to store original report~~

~~1.3 Directions on where to store edited/reviewed copy.~~

~~2 Rejected claims research is to validate that each rejected claim is compliant with CMS rules and regulations.~~

~~2.1 Determine that rejection is appropriate. Research is required – common research:~~

- What is the source of the reject (e.g., Medicare D exclusions, BvsD, Prior Authorization (PA), Step Therapy (ST) etc.)?
- Is PBM coding functioning as intended (e.g., step therapy, grandfathering etc.)?
- Does the member have a history of paid claims for the drug in question?
- Is the messaging appropriate for the reject code?
- Product Not on Formulary (Reject MR;569)
- B vs D (Reject 75;569;)
- This Product May Be Covered Under Hospice – Medicare Part A (Reject A3;569)
- This Product May Be Covered Under Medicare Part B Bundled Payment to an End-Stage Renal Disease (ESRD) Dialysis Facility (Reject A4;569)
- PROTECTED CLASS (YES)
    - Immunosuppressant (for prophylaxis of organ transplant rejection)
    - Antidepressant
    - Antipsychotic
    - Anticonvulsant
    - Antiretroviral
    - Antineoplastic classes
- TRANSITION ELIGIBLE (TRANSD3)
- Coordination of Benefits (COB) (Reject 41)
- Refill Too Soon (RTS) (79) – sample review
- Plan Limitation Exceeded (Maximum Daily Dose) (Reject 76)
- Step Therapy (Reject 608;569;)
- Quantity Dispensed Exceeds Maximum Allowed (Reject 9G;569;)
- Prior Authorization (Reject 75;569;)
- DUR Reject Error (Reject 88;569;) – sample review
- Initial Fill Days' Supply Exceeds Limits (Reject 925;569;88;) – sample review
- Product/Service Not Covered -Plan/Benefit Exclusion - Compound Drug (Reject 70;) – sample review
- Days' Supply Exceeds Plan Limitation (Reject 7X;569) – sample review
- Not Covered Under Part D Law (Column H – Reject A5) – sample review

Point of Sale (POS) or administrative rejects (e.g. Reject 04 M/I PCN, 09 M/I DOB) can be filtered out of the manual review process but should be monitored for trends overall and per NCPCP.

2.2 Validating Rejected Claims

2.2.1 Retrieve most current CMS approved formulary for plan located at: https://alamedaalliance.org/

2.2.2 Identification of potentially inappropriate rejections which may require verification against the current CMS approved formulary/utilization management criteria and requirements by using data filter on rejection codes.

2.2.3 Priority review is needed for B vs D rejections; CMS expectations are that B vs D rejections should be able to be resolved at point of sale, otherwise, the claim should be resolved and the medication dispensed to the beneficiary within 24 hours.

2.2.4 Filter for reject 79 and complete refill threshold calculations on a sample which includes retail (75%) and ophthalmic (70%) claims.

3. Transition Fill (TF)

CMS requires that all Part D sponsors have an appropriate transition process in place for new and renewing beneficiaries to assure continuity of care and avoid interruptions in drug therapy until a switch to a therapeutically equivalent medication or approved coverage determination has occurred.

Rejected claims should be reviewed to determine if the claim should have paid as a TF. The following factors must be considered.

- Is member within transition window (e.g., first 90 days of enrollment)
  - Is member considered a new or renewing member?
  - What is the current transition policy for renewing members (e.g., is ANOC applicable or do current members follow new member logic etc.)?
- If outside of transition window, is member transition eligible due to level of care change or in need of emergency supply?
- Is drug transition eligible?
  - Negative formulary changes across plan years (if applicable per transition policy/logic)
- Location (LTC vs. retail)
- Minimum day supply (retail = 30 days, LTC = 98 days except limited day supply = 14 days and package size exceptions)
- Package size exceptions may allow for greater than 30 or 98-day supply if drug is supplied in an unbreakable package (e.g., inhaler, ophthalmic solutions, syringe, vial etc.).

The following are scenarios and drug types which are excluded from the automated TF logic at point of sale.

- B versus D drugs- TF does not apply to Part B drugs. Determinations must be completed, and assessment of TF eligibility of any determination made as Part D.
- Part B Drugs
- Drugs on a specific transition exclusions list that require indication validation (e.g., Transmucosal Fentanyl etc.)
- Non-Med D/excluded drugs (e.g., drugs used for cosmetic purposes etc.)
- Over The Counter (OTC) drugs (except insulins)
- ESRD drugs- TF does not apply to drugs determined to be bundled under the ESRD benefit. Determinations must be completed, and assessment of TF eligibility of any determination made as 'D'

- ~~Safety edits (FDA approved maximum dose) - If a claim is rejected for safety purposes evaluation is required to ensure plan provides refills for transition prescriptions dispensed for less than the written amount due to quantity limits for safety purposes or drug utilization edits that are based on approved product labeling. The reference source of truth for maximum daily dose is the FDA labeling for the medication. (Labeling verbiage states Maximum Daily Dose = xxxx).~~

~~Claims that are identified as a transition eligible must have transition eligibility confirmed by verifying member eligibility and/or other parameters which determine member to be TF eligible (e.g., Level of Care , Emergency Supply). Claims determined to be TF eligible with reject codes of 70, 75, 9G, 7x, 608 and MR will be targeted for manual review.~~

~~4. Transition Fill (TF) Eligibility~~

~~A member is defined as new when 1 or more of the following criteria is met:~~

- ~~A new enrollee following the annual election period~~
- ~~Transition of newly eligible Medicare member from other coverage~~
- ~~Transition from one plan to another after the start of the contract year~~
- ~~Current enrollees affected by a negative formulary change across contract years~~
- ~~Enrolled residing in LTC facilities~~

~~Renewing members within the same plan at the start of the contract are allowed a transition if there is history of a paid claim within **180 day look back**. Year over year evaluation of transition fill logic is required to determine how renewing members' transition fill eligibility will be handled. If renewing members are only allowed transition supplies for drugs on the ANOC, this must be considered in assessing a beneficiary's transition eligibility.~~

2 Report is filtered on rejected claims. Each rejection type is reviewed for appropriateness of denial. Clinical denials, such as Prior Authorization required or Quantity Limit, are reviewed for appropriateness of denial by comparing the claim to the formulary print and the ASCII formulary file.

2.1 Directions on how to review each rejection type is detailed in SOP.

2.2 Compare clinical rejection types (PA, QL, etc) against the formulary print and the ASCII file that is submitted to CMS. Anytime claims adjudication does not match the formulary print or the formulary ASCII file, the claim or discrepancy needs escalation.

3 Administrative rejects (such as M/I PCN or M/I DOB) are monitored for trends, with an emphasis placed on systemic processing errors that lead to member access issues.

4 When it is determined that a member has a claim denying (appropriately) for over 7 days, there may be a member access issue. The plan performs outreach to the prescriber, member, and/or pharmacy to help initiate a coverage determination, provide information on formulary alternatives, or otherwise help the member receive treatment.

5 When a B versus D determination rejected claim has not been resolved by the following business day at the pharmacy, plan outreaches to member, prescriber, and/or pharmacy to obtain diagnosis and enter an operational prior authorization to allow the claim to process under Part D or Part B.

Commented [TB1]: We may decide we don't need to do this process. If so, language can be removed.

6 As a part of the daily claims review, plan will ensure that eligible members are given transition fills. This includes new members to the plan who are within their 90 day transition period, members who have experienced a negative formulary change across plan years, and members who have experienced a level of care change or are in need of an emergency supply.

DEFINITIONS / ACRONYMS

~~ANOC- Annual Notice of Change~~
CMS- Centers for Medicare and Medicaid Services
~~COB- Coordination of Benefits~~
DUR-Drug Utilization Review
ESRD- End-Stage Renal Disease
FDA- Federal Drug Administration
LTC- Long Term Care
OTC- Over the Counter (medication not requiring a prescription)
PA- Prior Authorization
PBM- Pharmacy Benefit Manager
~~POS- Point of Sale~~
~~RTS- Refill too Soon~~
ST- Step Therapy
~~TF- Transitional Fill~~

AFFECTED DEPARTMENTS/PARTIES

Pharmacy Services
PBM

RELATED POLICIES AND PROCEDURES

None

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

SOP-D-010 Medicare Part D Daily Rejected Claims Review

REVISION HISTORY

New Policy: 8/20/2025, 08/2026

REFERENCES

42 CFR §423.120(b)(3) Part D Transition requirements

Prescription Drug Benefit Manual, Ch. 6: Part D Drugs and Formulary Requirements, Rev. 18, 01-05-16

HPMS Memo - Part D Transition Monitoring Analysis (TMPA), January 17, 2018

HPMS Memo – Job Aids Replace the Common Conditions, Best Practice Audit Memos, April 20, 2016

HPMS Memo – Common Conditions, Improvement Strategies, and Best Practices based on 2013 Program Audit Reviews, August 27, 2014

HPMS Memo – Best Practices and Common Findings Memo #2 from 2012 Program Audits, July 30, 2013

HPMS Memo – Best Practices and Common Findings from 2012 Program Audits, September 10, 2012

HPMS Memo – 2011 Program Audit Findings and Best Practices, January 20, 2012

MONITORING

The If/Then Tables below are designed to provide an overview of each reject code, potential research required, and the action based on the outcome of the research. Research required may vary based on unique claim scenarios and are not comprehensive.

Reject Code	Messaging	Research Points	If	Then
MR	Non-Formulary	✓Is the member transition eligible	If member is transition eligible	Refer to Transition Table
		✓Verify if drug filed on CMS approved formulary for specific plan	If drug is not on approved formulary	Valid
			If drug is on approved formulary	Send for research and provide override if deemed appropriate

		✓ If member has an active MPA on file for the drug	If member has a formulary exception	Send for research and provide override if deemed appropriate
			If member does not have an active formulary exception	Valid
75	Prior Authorization Required	✓Is the member transition eligible?	If member is transition eligible	Refer to Transition Table
		✓Verify drug filed on CMS approved formulary as PA Required (PA=1 or 2)	If drug is not listed with PA required on CMS approved formulary	Send for research and provide override if deemed appropriate
		✓If drug is PA=2, verify if member has prior use within defined lookback period	If no prior use	Valid
			If history of paid claim within lookback period	Send for research and provide override if deemed appropriate
		✓Verify if there is an active PA on file for the drug	If active PA on for drug is on file	Send for research and provide override if deemed appropriate
			If drug does require PA and no active PA on file	Valid
		✓Verify if the drug has previously paid	If drug has previously paid	Validate how claim paid (e.g., Negative formulary change, expired PA)
75	Prior Authorization Required- BvsD	✓Verify drug filed on CMS approved formulary as PA Required-BvsD (PA=3)	If drug is on CMS approved formulary as BvsD	Valid- Send for BvsD review
			If drug is not BvsD	Send for research and provide override if deemed appropriate
		✓Verify if drug utilizes autologic based on location	If autologic applies drug should pay D	Send for research and provide

		code (LTC or retail claim) to determine payment	without determination	override if deemed appropriate
608	Step Therapy	✓Is the member transition eligible	If member is transition eligible	Refer to Transition Table
		✓Verify drug filed on CMS approved formulary as Step Therapy (Step=1 or 2)	If drug is not filed with Step on CMS approved formulary	Send for research and provide override if deemed appropriate
		✓Verify if there is an active MPA on file for the drug	If active MPA on for drug is on file	Send for research and provide override if deemed appropriate
		✓If step=2, verify if member has prior use within defined 365 lookback period	If member has history of drug within lookback period	Send for research and provide override if deemed appropriate
			Drug has ST requirements, no active PA or drug history which satisfies Step	Valid
AC	Product Not Covered Non-Participating Manufacturer	✓Verify if manufacturer is on current CMS Labeler Code File http://cms.gov/Medicare/Prescription-DrugCoverage/PrescriptionDrugCovGenIn/Pharma.html	For brand drugs if manufacturer is not listed	Valid
			For brand drugs if manufacturer is listed on CMS Labeler File	Send for research and provide override if deemed appropriate
A3	This Product May be Covered Under Hospice - Part A	✓ Verify member is active hospice status in PBM claims system and MARx	If member is not in active hospice	Send for research and provide override if deemed appropriate

			If member has active hospice status and drug is on hospice list	Valid
		✓Verify if there is an active PA on file for the drug to document drug is not for terminal illness	If active PA on for drug is on file	Send for research and provide override if deemed appropriate
A4	This Product May be Covered Under the Medicare Part B Bundled Payment to an ESRD Dialysis Facility	✓ Verify member has active ESRD status in PBM claims system and/or MArx	If member is not on active dialysis status	Send for research and provide override if deemed appropriate
		✓Verify if there is an active PA on file for the drug to document drug is not related to treatment of ESRD	If active PA on for drug is on file	Send for research and provide override if deemed appropriate
A5	Not Covered Under Part D Law	✓ Verify drug is Med D excluded (e.g., agents used for cosmetic, weight loss, purposes, bulk powders, drugs used for sexual dysfunction etc.)	If drug is Med D excluded	Valid
			If drug is not Med D excluded	Send for research and provide override if deemed appropriate
		✓ Verify if drug is eligible for coverage as part of administrative cost (e.g., OTC) for specific plan benefit	If drug is eligible for payment as part of benefit	Send for research and provide override if deemed appropriate
A6	This Product/Service May Be Covered Under Medicare Part B	✓ Verify claim processed on Part B if applicable to plan benefit	If drug is Med B and processed on Part B benefit	Valid
		✓ Verify drug/supply is Med B covered (e.g., diabetic testing supplies)	If drug/supply is not Med B	

				Send for Further Research--Evaluate if override is needed
9G	Plan Limits Exceeded	✓Verify drug filed on CMS approved formulary as having a quantity limit	If drug does have days' supply limits and claims exceeds approved limit	Valid
			If drug was not filed with a quantity limit	Send for further research and evaluate if override is needed
		✓Verify drug the quantity rejection matches what is on file with CMS	If quantity limit reject differs from CMS approved limit	Send for further research and evaluate if override is needed
		✓Verify quantity submitted exceeds CMS approved limit ✓Verify quantity is coded appropriately as a daily dose or quantity versus time to assess if limit was exceeded	If claim exceeds approved amount without an MPA	Valid
		✓Verify if there is an active MPA on file for the drug	If active MPA on for drug is on file which overrides QL	Send for further research and evaluate if override is needed
			If no active PA on file	Valid
79	Refill Too Soon	✓ Determine if pharmacy is mail or retail/LTC ✓ Verify projected refill date based on the following thresholds Retail – 75% LTC – 85%.	If refillable date is outside of expected threshold	Send for further research and evaluate if override is needed
			If refillable date threshold is exceeded	Valid

		Ophthalmic 70%		
7x	Days' Supply Exceeds Plan Limitation	✓ Verify if drug has special limits based on overarching plan limits (e.g., Extended days' supply network, High Cost or Specialty Tier)	Did claim exceed 90 days' supply?	Valid
			If drug is on not on tier which limits days' supply	Send for Further Research--Evaluate if override is needed
		✓ Verify if drug is dispensed in an unbreakable package (e.g., Copaxone)	If drug is dispensed in unbreakable package and is dispensed in smallest package size	Send for Further Research--Evaluate if override is needed
70	Compounds	✓ Verify if compound contains any Part B or BvsD payable drug	If Part B drug is in compound-whole compound should pay Part B; verify if claim paid on Part B based on benefit	Valid
		✓ Verify if compound contains at least 1 Med D payable drug	If drug has Part D payable ingredient and SCC 08 assumed	Send for Further Research--Evaluate if override is needed
			If SCC not assumed; verify SCC 08 not submitted	Valid
88/925	DUR Reject			
	Drug Safety Alert (e.g., drug interaction)	Evaluate rejection message and validate DUR reason	If rejection cannot be validated (e.g., no interacting drug present in history)	Send for Further Research--Evaluate if override is needed
			DUR rejection reason validated	Valid
76	Max Dose	✓ Verify FDA labelled max dose is exceeded	If claim exceeds FDA labelled maximum dose	Valid
			If drug does not have FDA labelled maximum dose or	Send for further research and

			max dose is not exceeded	evaluate if override is needed
42-45	Prescriber ID rejections	✓Prescriber validation rejection resolved within 24 hours	Rejection resolved and claim paid within 24 hours	Valid
			Rejection not resolved within 24 hours	Send for Further Research--Evaluate if override is needed
Yes	Protected Class			
	Refill Too Soon – select a few samples	✓ Determine if pharmacy is mail or retail/LTC ✓ Verify projected refill date based on the following thresholds Retail – 85% LTC – 75%	If refillable date is outside of expected threshold or if quantity and day supply has changed	Contact the pharmacy and confirm if the member is needing an override due to a change in dose. Enter a Dose Increase override to allow the claim to pay.
			If refillable date threshold is exceeded	Valid

POLICY AND PROCEDURE

Policy Number	RX-D-021
Policy Name	Medicare Part D Best Available Evidence (BAE)
Department Name	Pharmacy Services
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy Services
Line(s) of Business	DSNP
Effective Date	1/1/2026
Administrative Oversight Committee Approval Date	~~8/20/2025~~

POLICY STATEMENT

Alameda Alliance for Health (Alliance) will provide its enrollees access to Part D drugs at the correct LIS cost-sharing when presented with evidence of LIS eligibility, even if Alliance and MARx system do not yet reflect their eligibility. If institutional status is verified, zero cost-sharing applies.

PROCEDURE

1 ~~Alliance/~~PBM ~~p~~Pharmacy H~~h~~elp ~~d~~Desk or PBM Member Services Call Center will refer enrollees to contact Alliance Member Services. Alliance Member Services will collect as much information and documentation as possible to ~~will be staffed with trained individuals prepared to assist pharmacists and enrollees to receive the documentation (e.g. by fax or email) so that system changes to correct cost-sharing levels can be implemented as soon as possible.~~ establish correct LIS subsidy and request assistance from Alliance Pharmacy Department.

2 Alliance Pharmacy will update PBM claims processing system with LIS subsidy information. Follow attachment for SOP to update claims processing system. Suggested temporary LIS level duration is 60 days as recommended by CMS.

3 -Alliance Pharmacy or ~~/~~PBM will notify the pharmacy when LIS status changes have been made so pharmacy can reprocess claims.

~~1 if they cannot make necessary system changes immediately upon confirming and/or receiving the appropriate documentation.~~

~~2 Generally the PBM will accept BAE from members, providers, and member's representative. If someone with documentation contacts the PerformRx Customer Care Center, they will update a member's LIS status in Darwin.~~

~~3 Alliance/PBM will notify the pharmacy when changes have been made immediately upon confirming and/or receiving the appropriate documentation.~~

4 Alliance Pharmacy ~~PBM will notify~~will request LIS research from -Alliance Enrollment by ~~securely~~ emailing whenever manually updating a member's LIS level.

4.1 distgrpEnrollment@AlamedaAlliance.org
4.2 DeptAAWMemberSupport@alamedaalliance.org
~~4.1 Subject line: "Alameda Alliance 820 DSNP member LIS level adjustment"~~
~~4.2 Provide summary of memberID, new information supplied (plus images if available), and actions taken.~~
4.3 distgrpPharmacy@alamedaalliance.org
~~4.41.1 DeptAAWMemberSupport@alamedaalliance.org~~
4.4 Subject line: "DSNP member manual LIS adjustment"
4.5 Provide summary of memberID, any documentation supplied or obtained, and actions taken.
~~5.01.1 distgrpEnrollment@AlamedaAlliance.org~~

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~~6~~5 Acceptable BAE Documentation

~~6.1~~5.1 Medicaid card with name and eligibility date.
~~6.2~~5.2 State documents confirming active Medicaid status.
~~6.3~~5.3 State Medicaid electronic enrollment file printout.
~~6.4~~5.4 State Medicaid system screen print.
~~6.5~~5.5 Other state documentation showing Medicaid status.
~~6.6~~5.6 SSA award letter for LIS applicants.
~~6.7~~5.7 For institutionalized beneficiaries: remittance from facility, state confirmation of Medicaid payment, or state system screen print.

~~7~~6 Eligibility System Updates

~~7.1~~6.1 Alliance Enrollment will update internal eligibility system within 48-72 hours of receiving BAE documentation~~. This is accomplished through emailing member name, ID#, documentation updated to distgrpEnrollment@AlamedaAlliance.org~~.
~~7.2~~6.2 ~~Submit~~ Alliance Enrollment to submit LIS correction requests to CMS pursuant to IT-D-003 D-SNP Low Income Subsidy (LIS) Processing Enrollment policy.

~~8 Submitting Correction Requests to CMS~~

~~8.1 Complete CMS BAE Assistance Worksheet (Columns A–F).~~
~~8.1.1 Best Available Evidence (BAE) | CMS~~
~~8.2 Determine urgency based on medication supply (Immediate vs. Non-Immediate).~~
~~8.3 Email encrypted worksheet to CMS Regional Office within **1 business day**.~~
~~8.3.1 DEPARTMENT OF HEALTH & HUMAN SERVICES~~
~~8.4 Record case in **CTM** (Complaint Tracking Module).~~
~~8.5 Notify beneficiary of results within **1 business day**; up to 4 attempts, last in writing using CMS Model Notices.~~
~~8.6 Provide correct cost-sharing immediately upon confirmation.~~
~~8.7 Close case in CTM under "Beneficiary Needs Assistance with Acquiring Medicaid Eligibility Information."~~

~~**Complaint Tracking Module** (CMS, Chapter 13 70.5.3)~~

~~https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/chapter-13-premium-and-cost-sharing-subsidies-for-low-income-individuals-v09-14-2018.pdf~~

~~When BAE is not available the CTM (Complaint Tracking Module) is another method that may be used to substantiate a Subsidy Level Request on behalf of the beneficiary. To provide expedited service on behalf of Medicare beneficiaries. Alliance will enter BAE assistance requests into the CTM on behalf of the enrollee.~~

~~CMS reviews and completes a resolution section indicating LIS level and effective dates. After receiving the CTM case, CMS will attempt to confirm with the appropriate state Medicaid agency whether the beneficiary is~~

eligible for LIS. The CMS Account Manager reports findings to the plan. Alliance submits those findings to RPC so that appropriate subsidy levels can be updated in ELMO.

Submitting to the CTM

1. The plan will record a CTM entry.
Lead: CMS
Category: Premiums and Costs
Subcategory: Beneficiary needs assistance with acquiring Medicaid eligibility information (EX)
Absent unusual circumstances, plans are to enter cases within one business day of being notified that the beneficiary claims to be subsidy eligible but cannot provide the plan with acceptable Best Available Evidence (BAE).
When entering, include all the following information in the "Complaint Summary":
• Medicare Beneficiary Identifier (MBI)
• Beneficiary's First and Last Name
• Beneficiary's Address
• Beneficiary's Date of Birth
• Issue Level: Immediate Need, Urgent, No Issue Level.
• Any additional information germane to the beneficiary's matter.

These cases will be reflected as "1.50" in the plan data extract.
2. After receiving the CTM case, CMS will:

a. Attempt to confirm with the appropriate state Medicaid agency whether the beneficiary is eligible for the low-income subsidy (LIS).

b. If CMS can confirm, the case will be changed to "Plan Lead" and re-categorized as "Premiums and Costs – Beneficiary needs assistance with acquiring Medicaid eligibility
information (EX)" category/subcategory for plan review/action. These cases will be reflected as "2.50" in the plan data extract. Additional information will be placed in the "Comments" section of the case and will include as applicable:

• Resolution
• Start of Medicaid/ Medicaid Institutional Status (MM/CCYY)
• Dual Eligible Status (Full/Partial)
• Institutional Status (Yes/No/ Unknown)
• LIS Co-Pay Level
• Any additional information germane to the beneficiary's matter.

c. If CMS cannot confirm, the case will be changed to "Plan Lead" and re-categorized to 2.50. The "comments section" will note the following: CMS has been unable to confirm LIS status with Name/State. Refer the beneficiary to Medicaid.gov and educate them on how to navigate the website to select About Us > Get Help with Medicaid & CHIP > Select State in which they reside. Then, they can obtain information on eligibility, enrollment, or check the status of an existing application.

3. When updates are provided, the plan will ensure its internal systems to reflect LIS status if appropriate and submit a request for correction to CMS' contractor in accordance with the procedures outlined in Chapter 13, Section 70.5.4 of the CMS Prescription Drug Benefit Manual. If CMS determines the beneficiary ineligible for LIS, no system updates are to be initiated.

4. As soon as the plan receives confirmation from CMS that a beneficiary is subsidy eligible (consistent with the direction in Chapter 13, Section 70.5.3 of the CMS Prescription Drug Benefit Manual), plans are to:

a. **Provide Drug Coverage at Correct Cost-Share:** Must immediately provide the beneficiary access to covered Part D drugs at a reduced cost-sharing level no greater than the higher of the LIS cost-sharing levels for full subsidy eligibles, or at zero cost-sharing if CMS also verifies the beneficiary's institutional status.

b. **Contact Beneficiary:** Attempt to notify the beneficiary of the results of the CMS review within one business day of receiving those results. If a plan is unable to reach the beneficiary as a result of this initial attempt, it must attempt to notify the beneficiary until it succeeds or until it has attempted to do so a total of four times. The fourth attempt, if necessary, shall be in writing, using one of two CMS Model Notices listed in Chapter 13 of the CMS Prescription Drug Benefit Manual.

i. If a request for a subsidy was made on the beneficiary's behalf by an advocate or authorized representative, it shall be sufficient for the plan to contact that advocate or representative. If, however, the only request made on the beneficiary's behalf was by a pharmacist, the plan must also contact the beneficiary directly. After informing the beneficiary, or their representative, of the outcome, the plan is to close the case. After informing the beneficiary, or their representative, of the outcome, the plan is to close the case.

c. **Notice of Eligibility:** If CMS determines that the beneficiary is LIS eligible, plans are to send the "Determination of LIS Eligibility" Model Notice provided as Attachment A. If CMS determines that the beneficiary is not LIS eligible, or is unable to confirm the beneficiary's LIS status, plans are to use the "Determination of LIS Ineligibility" Model Notice provided as Attachment B. See the February 17, 2017 HPMS Memorandum, "Best Available Evidence Process Update" for attachments.

d. **Disagreement with Decision:** Should the beneficiary disagree with the outcome, the plan should submit a Plan Request to refer the matter back to CMS with appropriate CTM notes. A CMS caseworker will attempt to contact the beneficiary, affirm the outcome, and close the case.

NOTE:

- This process is not intended to serve as a general alternative to the subsidy eligibility confirmation process. Thus, it does not permit pharmacies or any other parties to send beneficiary records directly to the plan for research in the absence of a request for assistance from the beneficiary (or other individual on the beneficiary's behalf) or in lieu of making reasonable efforts to acquire the documentation from, or on behalf of, the beneficiary.

- In rare circumstances, a beneficiary's record may be incorrect in CMS' systems after they have applied for and been awarded the Part D extra help through the Social Security Administration. In these instances, make certain the beneficiary is able to access their Part D plan benefit. You may use this process to advise CMS when our systems need to be updated since corrections cannot be submitted to the RPC for processing.

Necessary Elements of a CTM

- Complaint Tracking ID#
- CMS Account Manager name
- Beneficiary
- Start of Medicaid/Medicaid Institutional Status (Effective Date)
- Dual Eligible Status (Full/Partial)

- ~~Institutional Status (Yes/No/Unknown)~~
- ~~LIS Co-Pay Level~~

~~Compliance with LIS Standard Operating Procedure~~ ~~(SOP)~~

~~The guidelines for Alliance submitting documentation requesting a change in a beneficiary's Low-Income Subsidy (LIS) level are written in accordance with CMS Chapter 13. The Best Available Evidence (BAE) section is written specifically in accordance with Chapter 13 70.5.2 and 70.5.3.~~

~~These guidelines are intended to assist Alliance in their compliance with RPC's Submission Procedure. Any transactions submitted by Alliance that do not comply with the guidelines may not be accepted. Careful adherence to these guidelines will ensure that transactions submitted to the RPC can be processed timely and as requested.~~

~~Low-Income Subsidy (LIS) Overview~~

- ~~The Medicare Modernization Act (MMA) allows beneficiaries to receive "Extra Help" (subsidy) with Part D prescription drug costs.~~
- ~~This extra help takes the form of subsidies paid by the Federal Government to the drug plan in which the Medicare beneficiary enrolls.~~
- ~~The subsidy provides assistance with the premium, deductible, and co-payments of the program.~~
- ~~When a beneficiary's deemed status is not accurate in CMS' systems, Part D sponsors are required to submit their LIS Deeming request to the Retroactive Processing Contractor (Reed & Associates).~~
- ~~Alliance must submit all valid manual LIS deeming requests to the RPC following the guidance contained in this SOP.~~

Timing of Manual LIS Status Correction

As described in Chapter 13 70.5.4 (Transmitting and Timing of Manual LIS Status Correction), ~~prior to submitting a manual correction request to the RPC,~~ CMS recommends allowing a reasonable time for updated LIS information to be ~~automatically~~ entered into CMS' systems and reported to Alliance. The recommended delay is a minimum of 30 days and a maximum of 60 days, as it is likely that a significant portion of those who qualify under BAE policy in one month will be deemed for LIS via the normal process within the next several weeks. If the LIS Status Correction has not been performed after 60 days, IT should follow IT-D-003 D-SNP Low Income Subsidy (LIS) Processing Enrollment policy.

~~follow the procedure below under "Instructions for Submission to RPC".~~

~~Instructions for Submission to RPC~~

~~Effective August 3, 2007, Reed & Associates, CPAs (Reed) was designated by the Centers for Medicare & Medicaid Services (CMS) as the national contractor responsible for processing retroactive transactions for all Medicare Advantage Organizations, Part D Sponsors, Cost-based Plans, PACE Organizations, and Medicare-Medicaid Plans (MMPs). Under the terms of this contract, Reed validates and processes all retroactive transactions involving enrollment including those covered by this Standard Operating Procedure (SOP). All transactions submitted by Organizations must be in accordance with the processes outlined in this SOP as well as the latest CMS Guidance.~~

Alliance must submit all manual LIS deeming update transactions to the RPC following the specific guidance contained in this SOP. If Alliance has questions regarding the submission of transactions, they should contact the RPC's Client Services Department (clientservices@reedassociates.org).

Alliance should expect that transactions are processed and reported in the order received by the RPC. The general process is noted below:

A. Alliance submit the following to the RPC:
    a. A cover letter;
    b. The RPC submission spreadsheet; and
    c. BAE for each beneficiary identified in the retroactive transactions.
B. The RPC will import the transactions from the eRPT system into the RPC tracking system and, if necessary, issue error reports to Alliance within five (5) calendar days.
C. The RPC will review the transactions and, if applicable, make changes in CMS' systems within 35 days of the receipt date. A final disposition report (FDR) will be issued to Alliance communicating the results of RPC's review. Alliance should carefully monitor CMS' systems, RPC FDRs, Transaction Reply Reports (TRRs) and Monthly Membership Reports (MMRs) to ensure that all requested transactions have been processed.
D. Alliance must resubmit transactions to the RPC within 45 days of the issuance of the FDR if the original request was not processed as requested.
E. If Alliance believes that a transaction has not been processed within the 35-day timeframe, they should contact the RPC's Client Services Department to make a Transaction Inquiry. Instructions for transaction inquiries can be found in the section titled *Transaction Inquiries by Organization*. (Attachment I)

Submissions that meet all the requirements explained in this SOP should be sent via a "Submission Package" in the Electronic Retroactive Processing Transmission (eRPT) system (https://portal.cms.gov/) .
Alliance should ensure that all Submission Packages sent to the RPC have been reviewed for accuracy and completeness. Any packages received by the RPC that do not adhere to the guidelines in this SOP will not be processed.

Submission Packaging Instructions:

a. Cover Letter

A cover letter must accompany all transactions submitted to the RPC. This letter should, at a minimum, contain the applicable contract number(s) (i.e., H#, S#, R#, E#) and a Certification Statement signed by an official representing the Organization. Below is an example of appropriate language for the Certification Statement:

*"I certify, as an authorized representative of the Organization, that the information submitted to the Retroactive Processing Contractor on <**date**> is accurate and complete. Supporting documentation is being maintained at the Organization for each request."*

Alliance must retain the original supporting documentation for the requested transactions as they may be required to produce it during a CMS audit.

The cover letter should also include any special circumstances or instructions Alliance believes may be necessary to assist the RPC in processing the submitted transactions timely and accurately. For example, if the submission contains transactions that require RO Approval or special handling instructions from an Account Manager, this information should be stated in the cover letter for the RPC to immediately identify.

b. Submission Spreadsheet

Retroactive transactions must be listed by Alliance on the Excel submission spreadsheet template. The completed spreadsheet must be saved in an "xls" or an "xlsx" file format and sent via a "Submission Package" in order to be uploaded into the eRPT system (https://portal.cms.gov/) .

The submission spreadsheet template is available on the RPC's website at (https://www.reedassociates.org/rpe-submission-toolkit/).

The formatting of the submission spreadsheet template, including tab names, column headers, column order, cell placement and cell formatting, must not be changed or altered in any way, or the spreadsheet may not import properly. Additionally, Alliance should note that there are drop-down menus for several of the columns which require very specific responses.

If Alliance automates the spreadsheet completion process, the RPC suggests that you review all spreadsheet components carefully (especially the required responses for the drop-down menus) to avoid errors in importing the spreadsheets and reviewing the transactions. The RPC cannot import transactions that do not meet the formatting requirements of the submission spreadsheet.

Specific instructions for how to complete each column of the spreadsheet are included on the spreadsheet itself. Basic instructions are listed below the column headers.

Please utilize the following table to provide the RPC with the correct information in the *Dual Eligible Status* and *Institutional Status* columns as it relates to the LIS status level being requested:

Dual Eligible Status (Medicaid Status Level)	Institutional or HCBS Status	LIS Level	Co-Payment Amount
Partial	No/Unknown	Level 1	High
Full	No/Unknown	Level 2	Low
Full	Yes	Level 3	None

Table 1 - LIS Deeming Copayment Levels

Please contact the RPC's Client Services Department with additional questions on how to complete the spreadsheet.

c. Documentation Required

- Retroactive transactions covered by this SOP are not subject to the Enrollment Data Validation review process.
- All Organizations must electronically submit the supporting documentation for each transaction covered by this SOP to the RPC as PDF files via a "Submission Package" in the eRPT system (https://portal.cms.gov/) .
- Alliance should only submit documentation that is required for processing. Documentation which has not been approved by CMS will not facilitate processing.
- In order for the electronic documentation to be accurately matched to the request listed on the submission spreadsheet, the documentation for each request must be sent in individual PDF files. Each request must include the RPC LIS Documentation Worksheet along with the specific documents required for manual LIS Deeming updates. The worksheet can be found on the RPC's website at https://www.reedassociates.org/rpe-submission-toolkit/.

- ~~In order to process the deeming request as submitted, RPC must receive documentation that includes all of the necessary elements of a CTM as listed below. These elements must support the request in order to be processed as requested.~~
  - ~~Complaint Tracking ID#~~
  - ~~CMS Account Manager name~~
  - ~~Beneficiary~~
  - ~~Start of Medicaid/Medicaid Institutional Status (Effective Date)~~
  - ~~Dual Eligible Status (Full/Partial)~~
  - ~~Institutional Status (Yes/No/Unknown)~~
  - ~~LIS Co-Pay Level~~

Enrollees with Best Available Evidence (BAE) Documentation

All documents listed below are valid for the purpose of establishing the correct cost-sharing and effective date for individuals who should be deemed eligible for LIS. ~~They are the only documents permissible for submission to the Retroactive Processing Contractor (Reed) for an LIS deeming update.~~

Level 1 Partial/No and Level 2 Full/No (CMS PDBM Chapter 13, 70.5.2)

~~Acceptable BAE pertaining to Level 1 P/N (CMS Chapter 13 70.5.2)~~

- A copy of the beneficiary's Medicaid card that includes the beneficiary's name and eligibility date during a month after June of the previous calendar year
- A copy of a state document that confirms active Medicaid status during a month after June of the previous calendar year
- A print-out from the State electronic enrollment file showing Medicaid status during a month after June of the previous calendar year
- A screen print from the State's Medicaid systems showing Medicaid status during a month after June of the previous calendar year
- Other documentation provided by the state showing Medicaid status during a month after June of the previous calendar year
- A letter from the Social Security Administration (SSA) showing that the individual receives Supplemental Security Income (SSI) (CMS Chapter 13 70.6, 70.6.1, 70.6.2)
- An application filed by Deemed Eligible confirming the beneficiary is "automatically eligible for extra help." (SSA publication HI03094.605)

~~Alliance may also prepare a report of contact as evidence of a beneficiary's status as a full benefit dual eligible individual, institutionalized individual, and/or Home & Community Based Services (HBCS) recipient when Alliance makes a verification call to the State Medicaid Agency. The report of contact must include the date of the verification call and the name, title, and telephone number of the state staff person who verified the Medicaid status for a month after June of the previous calendar year.~~

- ~~If for some reason none of the above is available, Alliance can submit a CTM (Complaint Tracking Module). If that is submitted, proceed to that section for processing instructions.~~

~~To substantiate P/N LIS Level 1~~

~~BAE Documentation must reflect one or all of bullet's a-c (below) during a month after June of the previous calendar year (as defined by CMS Chapter 13 70.5.2):~~

~~a) Indicates Medicaid benefits as Limited; and/or~~

~~b) Member is eligible for SSI; and/or~~

~~c) Medicare Savings Program (QMB, SLMB, QI/QI1, QDWI)~~

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~~**Level 2 Full/No**~~

~~Acceptable BAE pertaining to Level 2 F/N (CMS Chapter 13 70.5.2)~~

- ~~A copy of the beneficiary's Medicaid card that includes the beneficiary's name and eligibility date for a month after June of the previous calendar year~~
- ~~A copy of a state document that confirms active Medicaid status during a month after June of the previous calendar year~~
- ~~A print-out from the State electronic enrollment file showing Medicaid status during a month after June of the previous calendar year~~
- ~~A screen print from the State's Medicaid systems showing Medicaid status during a month after June of the previous calendar year~~
- ~~Other documentation provided by the state showing Medicaid status during a month after June of the previous calendar year~~
- ~~A letter from SSA showing that the individual receives SSI (CMS Chapter 13 70.6, 70.6.1, 70.6.2)~~
- ~~An application filed by Deemed Eligible confirming the beneficiary is "automatically eligible for extra help." (SSA publication HI03094.605)~~
- ~~Alliance may also prepare a report of contact as evidence of a beneficiary's status as a full benefit dual eligible individual, institutionalized individual, and/or HCBS recipient when the sponsor makes a verification call to the State Medicaid Agency. The report of contact must include the date of the verification call and the name, title, and telephone number of the state staff person who verified the Medicaid status for a month after June of the previous calendar year.~~
- ~~If for some reason none of the above is available, sponsors/plans can submit a CTM. If that is submitted, proceed to that section for processing instructions.~~

~~To substantiate F/N Level 2 BAE Documentation must demonstrate Full Comprehensive Medicaid Eligibility during a month after June of the previous calendar year (as defined by CMS Chapter 13 70.5.2).~~

~~NOTE: QMB PLUS and SLMB PLUS are Full Comprehensive Medicaid, therefore LIS 2.~~

LIS 3 Full~~/~~Yes

~~Acceptable BAE pertaining to Level 3 F/Y (CMS Chapter 13 70.5.2)~~

~~(~~For LIS Level 3 Full/Yes, the beneficiary must be Full Comprehensive Medicaid (Full) AND Institutionalized ~~or~~ OR receiving Home and Community Based Services [HCBS]~~(Yes,)~~

- Remittance from the facility showing Medicaid payment on behalf of the beneficiary for a full calendar month after June of the previous calendar year.
- Copy of a state document that confirms Medicaid payment on behalf of the individual to the facility for a full calendar month after June of the previous calendar year
- Screen print from the State's Medicaid systems showing the individual's institutional status based on at least a full calendar month stay for Medicaid payment purposes for a month after June of the previous calendar year.
- Effective as of a date specified by the Secretary, but no earlier than January 1, 2017, a copy of:
- State-issued Notice of Action, Notice of Determination, or Notice of Enrollment that includes the beneficiary's name and HCBS eligibility date during a month after June of the previous calendar year;
- State -approved HCBS Service Plan that includes the beneficiary's name and effective date beginning a month after June of the previous calendar year;
- State-issued prior authorization approval letter for HCBS that includes the beneficiary's name and effective date beginning during a month after June of the previous calendar year;
- Other documentation provided by the State showing HCBS eligibility status during a month after June of the previous calendar year; or,
- A state-issued document, such as remittance advice, confirming payment for HCBS, including the beneficiary's name and the dates of HCBS.
- State-issued document, such as remittance advice, confirming payment for HCBS, including the beneficiary's name and the dates of HCBS.

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- -The sponsor may also prepare a report of contact as evidence of a beneficiary's status as a full benefit dual eligible individual, institutionalized individual, and/or HCBS recipient when Alliance makes a verification call to the State Medicaid Agency. The report of contact must include the date of the verification call and the name, title, and telephone number of the state staff person who verified the Medicaid status for a month after June of the previous calendar year.
- ~~If for some reason none of the above is available, sponsors/plans can submit a CTM. If that is submitted, proceed to that section for processing instructions.~~

~~**RPC Importing Transactions & Error Reports**~~

~~The RPC will import the transactions into the tracking system and update the status of the Submission Package in eRPT to "In Process" within five (5) calendar days. Any errors that are noted during the importation process will also be communicated to Alliance via eRPT as a "Response Document" at that time.~~

~~The status of the Submission Package in eRPT and the error report(s) uploaded to the Submission Package should be carefully monitored by Alliance to ensure that all of the transactions are received by the RPC and imported properly.~~

~~A Final Disposition Report (FDR) will not be issued for the transactions that receive an error message during the importation process. Transactions that cause an error message and are subsequently resubmitted to the RPC are not considered to be resubmissions because they were never processed due to importation errors.~~

~~**RPC Issuance of Final Disposition Reports (FDRs)**~~

~~Valid retroactive transactions will be processed by the contractor within 35 days of receipt. If the RPC determines that it *should* and *can* make the requested changes, the retroactive change will be made in CMS' systems. Payment adjustments will be made accordingly as CMS processes the changes. Note that payment adjustments are not directly handled by the RPC.~~

~~After processing the adjustments, the RPC will provide Alliance with a Final Disposition Report (FDR) via eRPT to the Organization. The FDR communicates the disposition of the requests to Alliance. The disposition codes used by the RPC are available on the RPC's website (https://www.reedassociates.org/rpe-submission-toolkit/).~~

~~Alliance must have ongoing membership reconciliation processes that include data comparisons of Alliance information to all relevant CMS/RPC files and reports including Final Disposition Reports (FDRs), Transaction Reply Reports (TRRs) and Monthly Membership Reports (MMRs).~~

~~If the request cannot be processed for any reason, the materials submitted to the RPC will not be returned to Alliance; however, the disposition code provided by the RPC on the FDR will indicate why the submission, in whole or in part, could not be completed. The disposition code descriptions should be read very carefully to ensure that each transaction can be properly resubmitted and processed by the RPC. Instructions for resubmissions are detailed in the section *Resubmissions by Organizations*.~~

~~If Alliance has concerns or questions regarding the determination made by the RPC, they should first contact the RPC's Client Services Department by using the Transaction Inquiry form described in the section Transaction Inquiries by Organization (Attachment 1). If a transaction is found to have been processed incorrectly by the RPC, then Reed's Quality Assurance Department will work with the RPC Processing team to~~

correct the transaction. For transactions or other matters that cannot be resolved by the RPC, Alliance should contact their local Account Manager for further assistance.

Resubmissions by Alliance

Following the issuance of the Final Disposition Report (FDR), Alliance may determine (by reviewing the disposition codes provided on the FDRs) that transactions were not processed by the RPC. Once the error is identified and resolved, Alliance may file a resubmission request for previously denied retroactive transactions.

Please note a FDR is not issued for records that are not successfully imported by the RPC. Therefore, the second submission of those transactions to the RPC would not be considered a resubmission transaction. Alliance should submit those transactions following the normal procedures since they were never originally entered into the system as a valid transaction.

In general, all the steps outlined in section A of the *Instructions for Submission to the RPC* must be followed for a resubmission (including all documentation which supports the request). Additional requirements for resubmissions to be imported and processed are listed below.

A. Resubmission transactions must be sent to the RPC within 45 days of receiving the original FDR for the request. It is highly recommended that Alliance reconcile the FDRs to CMS' Systems prior to resubmitting transactions. Alliance can then submit a master submission for all discrepant retroactive transactions.
B. Resubmission transactions must be listed on the Excel submission spreadsheet template following the standard submission process described in Section A.

C. On the documentation worksheet, Alliance should clearly state that the transaction is a resubmission and is not a duplicate transaction. Not stating this in the documentation worksheet could delay or negate the RPC's review of the requested transaction.

D. Documentation requirements for resubmissions are identical to the documentation requirements detailed above; however, if a transaction was not processed due to a missing document, Alliance must submit the documentation from the first request plus the requested documentation to ensure that the transaction is processed.

If the resubmission has been denied multiple times, it is strongly recommended that the Alliance contact the responsible Account Manager for additional guidance and/or a case- specific approval.

Transaction Inquiries by Organization

To follow up on specific previously submitted adjustment transactions, an inquiry may be submitted by email to clientservices@reedassociates.org, via "Transaction Inquiry" in eRPT, or telephone to our Client Services Department: (402) 315-3660. For inquiries sent via eRPT, Alliance is advised to complete the RPC Transaction Inquiry Excel template as instructed below.

Note: Alliance should not submit duplicate transactions unless the RPC specifically requests that duplicate information be submitted. All other general processing inquiries that are not case specific can be made via e-mail or by phone.

RPC's Client Services Department:

Reed & Associates, CPAs – CMS RPC

~~Attn: Client Services Department~~
~~11717 Burt Street, Suite 103~~
~~Omaha, NE 68154~~
~~Phone: (402) 315-3660~~
~~Email: clientservices@reedassociates.org~~

~~Furthermore, all system issues and questions regarding the eRPT application should be forwarded to the MAPD Help Desk (email: MAPDHelp@cms.hhs.gov; phone: 1-800-927-8069). Although the RPC relies heavily on the eRPT application, its development and maintenance is managed by another CMS contractor. Therefore, the RPC can only provide limited support regarding the application.~~

Note: Alliance member services, pharmacy services and/or PBM may carry out needed support and tasks included in this policy.

DEFINITIONS / ACRONYMS

BAE - Best Available Evidence
CMS - The Centers for Medicare and Medicaid
~~**CTM** - complaint tracking Module~~
~~**eRPT** - Electronic Retroactive Processing Transmission~~
~~**FDR** - Final Disposition Report~~
LIS - Low-Income Subsidy
MARx -Medicare Advantage and Prescription Drug system
~~**MMR** - Monthly Membership Report~~
PBM – Pharmacy Benefit Manager
~~**RPC** - Retroactive Processing contractor~~
~~**TRC** - Transaction Reply Code~~
~~**TRR** - Transaction Reply Report~~

AFFECTED DEPARTMENTS/PARTIES

Pharmacy PBM ~~(PerformRx)~~
Pharmacy Services
Member Services
IT Department

RELATED POLICIES AND PROCEDURES

~~PerformRx P&P PHDC 3-05 Best Available Evidence~~

IT-D-003 D-SNP Low Income Subsidy (LIS) Processing Enrollment

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

None

REVISION HISTORY

New Policy: 8/20/2025
Updated: 12/2025, 8/2026

REFERENCES

Medicare Prescription Drug Benefit Manual Chapter 13 - Premium and Cost-Sharing Subsidies for Low-Income Individuals, October 1, 2018
~~Reed & Associates, CPA: CMS Retroactive Enrollment & Payment Validation, Retroactive Processing Contractor RPC, March 1, 2021~~MedImpact Best Available Evidence BAE Program Description document (attached)

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~~[List references such as regulatory citations]~~

MONITORING

Alliance Pharmacy Department Staff will ~~include~~ follow and monitor individual members whose LIS status requires updating through the Best Available Evidence process.~~results of ongoing monitoring in monthly Delegated Function Oversight/Monitoring statistics.~~

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~~**Attachment I**~~

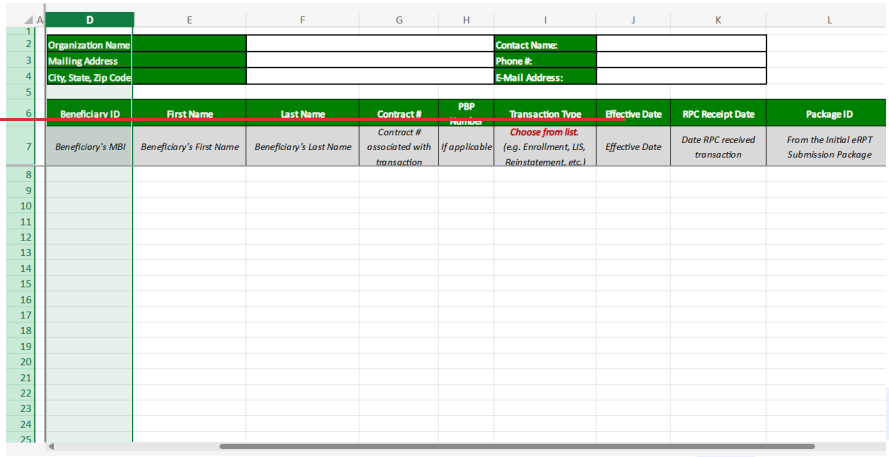
~~To follow up on specific previously submitted adjustment transactions, an inquiry may be submitted by email to clientservices@reedassociates.org, via "Transaction Inquiry" in eRPT, or telephone to our Client Services Department: (402) 315-3660. For inquiries sent via eRPT, Alliance is advised to complete the RPC Transaction Inquiry Excel template as instructed below.~~

~~**Completing the RPC Transaction Inquiry Excel Template:**~~

~~A. Input the following information associated with the submitted transaction:~~
~~a. Inquiry Type (select the type of inquiry for this transaction)~~
~~b. Explanation (If you selected "Question on Rejection" or "Other," please include a brief explanation on your inquiry)~~
~~c. Beneficiary ID (beneficiary's Beneficiary ID)~~
~~d. First Name (beneficiary's first name)~~
~~e. Last Name (beneficiary's last name)~~
~~f. Contract Number (contract number associated with the transaction)~~
~~g. PBP Number (if appropriate)~~
~~h. Transaction type (e.g. Enrollment, LIS, Reinstatement, etc...)~~
~~i. Effective Date~~
~~j. RPC Receipt Date (the day eRPT provided the notification the RPC downloaded the package)~~
~~k. The eRPT Package ID for the Submission Package~~

Draft

B. Create a Transaction Inquiry package in eRPT, upload the completed RPC Transaction Inquiry, and select "Submit" to send it to the RPC for review.



Organization Name					Contact Name:			
Mailing Address					Phone #:			
City, State, Zip Code					E-Mail Address:			

Beneficiary ID	First Name	Last Name	Contract #	PBP Number	Transaction Type	Effective Date	RPC Receipt Date	Package ID
Beneficiary's MBI	*Beneficiary's First Name*	*Beneficiary's Last Name*	*Contract # associated with transaction*	*If applicable*	*Choose from list. (e.g. Enrollment, LIS, Reinstatement, etc.)*	*Effective Date*	*Date RPC received transaction*	*From the Initial eRPT Submission Package*

The RPC Transaction Inquiry Template is available on the RPC's website (http://www.reedassociates.org/) in the **RPC Client Services** section.

draft

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

PHARMACY & THERAPEUTICS COMMITTEE

Record of Committee Meeting Minutes

Tuesday, June 16, 2026 | 5:00pm – 7:00pm

Status	Voting Committee Members	Organization	Initials	Officer / Notes
A	Donna Carey, MD	Chief Medical Officer-Alliance	DC	Chairman
P	Luke Lim, R.Ph.	Senior Director of Pharmacy Services – Alliance	LL	Co-Chair
A	Rahel Negash, Pharm D	Pharmacy Services Supervisor – Alliance	RN	
P	Aaron Basrai, PharmD	Haller's Pharmacy	AB	BOG
A	Paul Bayard, MD	La Clinica de la Raza (CHCN)	PB	
P	Ivan Lee, MD	Private Practice	IL	
A	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
P	Pat DeHoratius	PerformRx	PD	Manager Formulary/DUR
A	Barrie Cheung	PerformRx	BC	Regional Pharmacy Director
P	Ramon Tran Tang, PharmD	Alameda Alliance	RT	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
A	Bibek Sandhu, PharmD, MBA	PillarRX	SB	Consulting Pharmacist

Other Guests	

Follow-up Items:

Clerk of the Committee: Benita Ochoa

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Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
I) Call to Order	L. Lim	• Agenda Overview	Call to order at: 5:06PM	
II) Informational Updates	L. Lim	Informational Update • PBM Update The Alliance has selected MedImpact as its new Pharmacy Benefit Manager (PBM), effective January 1, 2027, replacing PerformRx. MedImpact will provide delegated PBM services for both the Group Care/IHSS line of business and the DSNP (Dual Eligible Special Needs Plan) line of business. The implementation project is already underway, with Alliance and MedImpact teams collaborating over the past several weeks. Current workstreams include formulary development and printing, as well as IT connectivity and system integration efforts needed to establish PBM operations and ensure readiness for the 2027 transition. • New Medicare Pharmacist The Alliance has hired a new Medicare Pharmacist, Tara Benson. Tara brings approximately 20 years of pharmacist experience, including 14–15 years focused on Medicare pharmacy work at MedImpact. Her hiring is especially noteworthy given that MedImpact has also been selected as the Alliance's new PBM beginning January 1, 2027. While coincidental, her extensive Medicare and MedImpact experience is expected to be an asset to the organization. • Future PAD Directions The committee previously reviewed and approved the Rx-005 Pharmacy and Therapeutics (P&T) Committee Policy and Procedure. Updates were made to explicitly clarify that the P&T Committee has oversight of PAD drugs across all lines of business, including: ○ Medi-Cal ○ Group Care/IHSS ○ DSNP, where PAD drugs are categorized as Part B benefits The policy also reaffirms the committee's responsibility for oversight of the Group Care pharmacy benefit program. Looking ahead, the health plan and the committee will need to determine the best approach for managing PAD drugs across all lines of business. Currently, PerformRx supports PAD drug development and review, but only for the IHSS/Group Care line of business, highlighting the need for a broader strategy as oversight expands.		

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Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		Questions:		

III) **Pharmacy Utilization Reports (Quarter 1,2026)**	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 1,442 claims for 720 members and cost $1,619,721, which is a decrease of $101,621 in spend from the previous quarter.
		• Biktarvy remains at number one with 39 claims for 16 members. There was an increase of 2 claims and 1 member since the previous quarter.
		• Ozempic is at numbers 2, 4, and 5, with 268 total claims for 118 members. There was an increase of 9 claims from the previous quarter.
		• Vemlidy remains at number 3 with 49 claims for 22 members. There was a decrease of 6 claims and a decrease of 1 member 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.
		• Kisqali is up at numbers 6 and 18 with 5 claims for 2 members. There was an increase of 2 claims and 1 member from the previous quarter. The medication is managed via the Oral and Injectable Oncology Medications MRG.
		
		Top 50 Drugs by Cost (Medi-Cal)
		• The top 50 drugs accounted for 25,128 claims for 21,808 members and cost $55,189,600. Compared with 34,940 claims for 29,605 members and cost $67,521,651 in 4Q2025. This represents decreases of 9,812 claims and 7,797 members and $12,332,051 spend from 4Q2025.
		• Biktarvy 873/739 claims/members versus 921/761 claims/members 4Q2025.
		• Jardiance both strengths holding steady
		• Skyrizi utilization 144/135 compared to 131/125 4Q2025
		  ○ Wegovy and Zepbound utilization no longer listed in top 50 GLP1 for weight loss has been discontinued by Medi-Cal Rx starting 1/1/2026
		  ○ Ozempic utilization holding steady, suggesting Wegovy/Zepbound members not migrating
		  ○ Dupixent now 324/253 from 301/246		

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Agenda Item	Discussion Leader	Discussion Summary	Action	Notes

		Top 50 PA Reviewed Drugs by Volume (IHSS)
		• Top 50 PA requests = 278. There were 421 total PA requests for quarter 1.
		  ○ 102 requests (37%) were approved. This approval rate is 10% higher than was observed last quarter.
		  ○ 176 requests (63%) were denied or partially approved.
		• Lidocaine 5% patch is at number 1 with 26 requests and 8 approvals (31%).
		  ○ Lidocaine requires a diagnosis of neuropathic pain and trial and failure of gabapentin or pregabalin and one other formulary alternative (e.g., duloxetine, venlafaxine, nortriptyline, amitriptyline, etc.) or morphine MME ≥ 50/day for 3 months.
		• Jardiance is at numbers 2 & 4 with 40 total requests and 5 approvals (13%).
		  ○ 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.
		• Mounjaro is at numbers 3 & 41 with 18 total requests and 12 approvals (67%).
		  ○ Mounjaro requires trial and failure of a metformin containing product.
		• Zepbound is at numbers 5 & 39 with 17 total requests and 2 approvals (12%).
		  ○ 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 Contrives.
		  ○ Zepbound for moderate to severe obstructive sleep apnea requires trial and failure regarding lifestyle changes and behavioral modifications to reach BMI <30 kg/m^2 and trial and failure or inability to use PAP therapy.
		• Ozempic is at numbers 6, 21 & 23 with 19 total requests and 11 approvals (58%).
		  ○ Ozempic requires trial and failure of a metformin containing product.
		
		Top 50 PA Reviewed Drugs by Volume (Medi-Cal)
		• The top 50 PA requests = 4,435 (compared 4Q25 2,848)
		• Most requested items are Wegovy (973/331 approve, 34% approval rate) and Zepbound (731/137 approve, 19% approval rate)
		• Freestyle Libre CGM Sensor dropped to #3, 287/220 approve, 77% approval rate
		• #5 Dexcom G7 Sensor is also CGM item
		• #4 Opzelura no movement
		• Sildenafil – ED indication, 100% denial rate
		• Tadalafil – PAH indication so approval rate is higher at 13%
		• Top approval rates: Novasource Renal 2 Cal (nutritional formula), Estradiol valerate, Lomaira (phentermine tab), Cosentyx (plaque psoriasis, autoimmune), Boost (nutritional formula)
		• Ozempic has sixth-lowest approval rate at 18%		

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Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
IV) E-Voting Material/Consent Agenda	L. Lim	**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* *(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.)*	Approved via e-voting: Yes: 4 No: 0 Abstained: 3	

Monographs/Class Reviews	**Changes**
Benzodiazepines Class Review	• No changes
Contraceptive Foams and Devices Class Review	• No changes
Diuretics Class Review	• No changes
Gaucher Disease Agents 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, minor grammatical correction
Non-formulary and prior authorization required oral liquid formulations	• No changes
Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention	• No changes
Cholinesterase Inhibitors	• Remove Adlarity patch as it has been discontinued
Roflumilast (Daliresp)	• No changes
febuxostat (Uloric)	• No changes
Hepatitis B Drugs	• No changes
Injectable Atypical Antipsychotic Medications	• No changes
Lamotrigine ER	• No changes
Levalbuterol (Xopenex/Xopenex HFA)	• No changes
Potassium-removing agents	• No changes
Fenofibrates	• No changes
Nutritional formulas, infant formulas	• No changes
Lipotropics	• No changes

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Agenda Item	Discussion Leader	Discussion Summary		Action	Notes
		Opioid Use Disorder (OUD) Agents	• No changes		
		Long acting opioids	• No changes		
		Pregabalin (Lyrica and Lyrica CR)	• No changes		
		Rufinamide (Banzel)	• No changes		
		Vigabatrin (Sabril)	• No changes		
		Sedative Hypnotics	• No changes		
		Epidiolex (cannabidiol)	• No changes		
		Tiagabine (Gabitril)	• No changes		
		Topiramate (Topamax) sprinkles	• No changes, minor grammatical correction		
		Phosphate Binders	• No changes		
		Short acting opioid containing products	• No changes		
		Subcutaneous Treatments for Hemophilia	• No changes		
		Spravato (esketamine) Intranasal	• No changes		
		Aptiom (eslicarbazepine)	• No changes		
		Rectiv (nitroglycerin) ointment	• No changes		
		Acute Migraine Treatments	• No changes		
		Sleep Disorder Therapy	• No changes		
		Adenosine Triphosphate-Citrate Lyase (ACL) inhibitors	• No changes		
		Gonadotropin Releasing Hormone Antagonists	• No changes		
		Lupkynis	• No changes		
		Vaginal Progesterone	• No changes		
		Fertility Agents	• Change naming convention to show generic availability of Cetrotide		
		Radicava ORS (edaravone)	• No changes		
		Joenja	• No changes		
		Skyclarys (omaveloxolone)	• No changes		
		Vyjuvek	• No changes		
		Filsuvez	• No changes		
		Eohilia	• No changes		
		Crenessity	• No changes		
		MEK Inhibitors for Neurofibromatosis Type	• No changes		
		H. Pylori Treatment Medications	• No changes		

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Agenda Item	Discussion Leader	Discussion Summary	Action	Notes

Physician Administered Drug (PAD) Guidelines	**Changes**
Naglazyme	• No changes
Calcitonin Gene-Related Peptide (CGRP) Antagonists for Headache Prevention	• No changes
Radicava (edaravone)	• No changes
Vyjuvek	• No changes
Generalized Pustular Psoriasis (GPP) Agents	• No changes
Bleeding Disorder Products	• No changes
Amtagvi	• No changes
Lenmeldy	• No changes
Kisunla	• No changes
Kebilidi	• No changes
Agents for graft versus host disease	• No changes
Fertility Agents	• Change naming convention to show generic availability of Cetrotide
Interim Formulary Updates	
• See p. 195 in packet	
Summary of Physician Administered Drug (PAD) Updates	
• See p. 197 in packet	
Pharmacy Policy & Procedure Updates	
• RX-005 P&T Committee Roles and Scope	
• **ED Oversight**	
• **None**	
P&T Meeting Minutes	
• P&T Meeting Minutes Q1 March 17,2026	

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Agenda Item	Discussion Leader	Discussion Summary	Action	Notes

Question/Comment:
CR: The mental health field is increasingly moving away from the term "treatment-resistant depression" (TRD) because it can imply that the patient is responsible for not responding to treatment. Instead, there is a preference for terminology that focuses on the illness itself, such as "difficult-to-treat depression" (DTD). Other medical conditions are generally not described as "treatment resistant," making DTD a more patient-centered and less stigmatizing term.

AB**:** In response, it is suggested that both terms could be included in the criteria and treated as equivalent terminology. This would allow providers to use either treatment-resistant depression or difficult-to-treat depression when submitting authorization requests, while maintaining consistency and clarity in the criteria.

IM: Treatment-Resistant vs. Difficult-to-Treat Depression
The team reviewed whether to use "treatment-resistant depression (TRD)" or "difficult-to-treat depression (DTD)" in the criteria. After reviewing the literature, it was determined that the two terms are related but not interchangeable.
Because the criteria are based primarily on the FDA-approved labeling and package insert for Spravato, which specifically references treatment-resistant depression, the preference is to retain that terminology. TRD is a more narrowly defined concept that focuses on the trial and failure of pharmacologic therapies, making it more appropriate for coverage criteria.
In contrast, difficult-to-treat depression is considered a broader term that may encompass a wider range of clinical circumstances beyond medication treatment failure. To maintain consistency with FDA labeling and established coverage standards, the recommendation is to continue using treatment-resistant depression. Both terms could be included in the criteria with appropriate wording to improve clarity based on the committee's suggestion.

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

Medication	Formulary Change
Pomalidomide Oral Capsule 1 MG	NF to F-PA
Pomalidomide Oral Capsule 3 MG	NF to F-PA
Pomalidomide Oral Capsule 4 MG	NF to F-PA
Pomalidomide Oral Capsule 2 MG	NF to F-PA
Pomalyst Oral Capsule 1 MG	F-PA to NF
Pomalyst Oral Capsule 3 MG	F-PA to NF
Pomalyst Oral Capsule 4 MG	F-PA to NF
Pomalyst Oral Capsule 2 MG	F-PA to NF
Orladeyo Oral Packet 72 MG	NF to F-PA
Orladeyo Oral Packet 96 MG	NF to F-PA
Orladeyo Oral Packet 108 MG	NF to F-PA
Orladeyo Oral Packet 132 MG	NF to F-PA

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Agenda Item	Discussion Leader	Discussion Summary		Action	Notes
		Avtozma Subcutaneous Solution Prefilled Syringe 162 MG/0.9ML	NF to F-PA		
		Avtozma Subcutaneous Solution Auto-injector 162 MG/0.9ML	NF to F-PA		
		Milnacipran HCl Oral Tablet 25 MG	NF to F-ST-QL (60 tabs/30 days)		
		Milnacipran HCl Oral Tablet 12.5 MG	NF to F-ST-QL (60 tabs/30 days)		
		Milnacipran HCl Oral Tablet 50 MG	NF to F-ST-QL (60 tabs/30 days)		
		Milnacipran HCl Oral Tablet 100 MG	NF to F-ST-QL (60 tabs/30 days)		
		Milnacipran HCl Oral Miscellaneous 12.5 & 25 & 50 MG	NF to F-ST-QL (55 EA/28 days)		
		Savella Oral Tablet 25 MG	F-ST-QL to NF		
		Savella Oral Tablet 12.5 MG	F-ST-QL to NF		
		Savella Oral Tablet 50 MG	F-ST-QL to NF		
		Savella Oral Tablet 100 MG	F-ST-QL to NF		
		Savella Titration Pack Oral Miscellaneous 12.5 & 25 & 50 MG	F-ST-QL to NF		
		Arexvy Intramuscular Suspension Reconstituted 120 MCG/0.5ML	F-QL-AL 50+ to F-QL-AL 18+ (0.5 ml per dose)		
		Wegovy HD Subcutaneous Solution Auto-injector 7.2 MG/0.75ML	NF to F-PA-QL (3 ML per 28 days)		
		Nintedanib Esylate Oral Capsule 100 MG	NF to F-PA-QL (60 caps/30 days)		
		Nintedanib Esylate Oral Capsule 150 MG	NF to F-PA-QL (60 caps/30 days)		
		Ofev Oral Capsule 100 MG	F-PA-QL to NF		
		Ofev Oral Capsule 150 MG	F-PA-QL to NF		
		Zepbound KwikPen Subcutaneous Solution Pen-injector 15 MG/0.6ML	NF to F-PA-QL (2.4 ML per 28 days)		
		Zepbound KwikPen Subcutaneous Solution Pen-injector 12.5 MG/0.6ML	NF to F-PA-QL (2.4 ML per 28 days)		
		Zepbound KwikPen Subcutaneous Solution Pen-injector 10 MG/0.6ML	NF to F-PA-QL (2.4 ML per 28 days)		
		Zepbound KwikPen Subcutaneous Solution Pen-injector 7.5 MG/0.6ML	NF to F-PA-QL (2.4 ML per 28 days)		
		Zepbound KwikPen Subcutaneous Solution Pen-injector 5 MG/0.6ML	NF to F-PA-QL (2.4 ML per 28 days)		
		Zepbound KwikPen Subcutaneous Solution Pen-injector 2.5 MG/0.6ML	NF to F-PA-QL (2.4 ML per 28 days)		

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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.

Physician Administered Drug (PAD) Prior authorization (PA) list Updates

HCPCS Code	HCPCS Description	Action
J1577	Immune globulin (QIVIGY)	Add PA
J3405	Onasemnogene abeparvovec-brve (ITVISMA)	Add PA
J3386	Etuvetidigene autotemcel (WASKYRA)	Add PA
J1289	Narsoplimab-wuug (YARTEMLEA)	Add PA
J2361	Depemokimab-ulaa (Exdensur)	Add PA
J9053	Belantamab mafodotin-blmf (Blenrep)	Add PA
J9062	Amivantamab + hyaluronidase-lpuj (RYBREVANT FASPRO)	Add PA
J7176	Human fibrinogen-chmt (FESILTY)	Add PA
Q5168	Ranibizumab-leyk (NUFYMCO)	Add PA
Q5171	Denosumab-mobz (Boncresa)	Add PA
Q5165	Denosumab-mobz (Oziltus)	Add PA
Q5170	Aflibercept-boav (EYDENZELT)	Add PA
Q5166	Denosumab-desu (Osvyrti / Jubereq)	Add PA
Q5167	Denosumab-qbde (Enoby / Xtrenbo)	Add PA
Q5169	Pegfilgrastim-unne (Armlupeg)	Add PA
Q5164	Ustekinumab-hmny (Starjemza)	Add PA
J0851	Cytomegalovirus immune globulin (human), 50 mg	Add PA
J1461	Immune globulin (Privigen), 200 mg	Add PA
J1578	Immune globulin (Alyglo), 100 mg	Add PA
J1579	Immune globulin (Asceniv), 100 mg	Add PA
J1581	Immune globulin (Bivigam), 100 mg	Add PA
J1582	Immune globulin (Gammaplex), 100 mg	Add PA
J1583	Immune globulin (Gamunex-C / Gammaked), 200 mg	Add PA
J1584	Immune globulin, IV lyophilized (unspecified), 100 mg	Add PA
J1585	Immune globulin (Octagam), 200 mg	Add PA

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<tr><th>Agenda Item</th><th>Discussion Leader</th><th>Discussion Summary</th><th>Action</th><th>Notes</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>J1586</td><td>Immune globulin (Gammagard Liquid / ERC), 200 mg</td><td>Add PA</td></tr>
<tr><td>J1587</td><td>Immune globulin (Flebogamma / Flebogamma DIF), 100 mg</td><td>Add PA</td></tr>
<tr><td>J1588</td><td>Immune globulin (Panzyga), 200 mg</td><td>Add PA</td></tr>
<tr><td>J1589</td><td>Immune globulin, non-lyophilized (unspecified), 200 mg</td><td>Add PA</td></tr>
<tr><td>J1569</td><td>Immune globulin (Gammagard Liquid / Gammagard Liquid ERC)</td><td>Remove PA</td></tr>
<tr><td>J1459</td><td>Immune globulin (Privigen), 500 mg</td><td>Remove PA</td></tr>
<tr><td>J1556</td><td>Immune globulin (Bivigam), 500 mg</td><td>Remove PA</td></tr>
<tr><td>J1557</td><td>Immune globulin (Gammaplex), 500 mg</td><td>Remove PA</td></tr>
<tr><td>J1561</td><td>Immune globulin (Gamunex-C / Gammaked), 500 mg</td><td>Remove PA</td></tr>
<tr><td>J1566</td><td>Immune globulin, IV lyophilized (unspecified), 500 mg</td><td>Remove PA</td></tr>
<tr><td>J1568</td><td>Immune globulin (Octagam), 500 mg</td><td>Remove PA</td></tr>
<tr><td>J1569</td><td>Immune globulin (Gammagard Liquid / ERC), 500 mg</td><td>Remove PA</td></tr>
<tr><td>J1572</td><td>Immune globulin (Flebogamma / Flebogamma DIF), 500 mg</td><td>Remove PA</td></tr>
<tr><td>J1599</td><td>Immune globulin IV, non-lyophilized, not otherwise specified, 500 mg</td><td>Remove PA</td></tr>
<tr><td>J0013</td><td>Esketamine</td><td>Remove PA</td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td>V) New Business</td><td>Iryna Makukh</td><td><u>New MRG</u>

<u>Voquezna</u>
- A new prior authorization policy was presented for Voquezna (vonoprazan) 10 mg and 20 mg tablets for erosive esophagitis (EE) and non-erosive GERD (NERD). H. pylori treatment remains covered under a separate policy.
- Key criteria include:
○ Prescribed by or in consultation with a gastroenterologist or other relevant specialist.
○ EE: Endoscopy-confirmed diagnosis, H. pylori negative, and failure of two formulary PPIs at optimized dosing (or medical justification).</td><td>Move to approve:
1st:
2nd:</td><td></td></tr>
</table>

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Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		○ NERD: Symptomatic GERD with heartburn as the main symptom, symptoms for at least 6 months, no esophageal erosions on endoscopy, H. pylori negative, lifestyle modification counseling, and failure of two optimized PPIs. - Coverage durations follow FDA labeling: ○ EE healing: Up to 8 weeks ○ EE maintenance: Up to 6 months ○ NERD heartburn: Up to 4 weeks - Requests exceeding these durations will not be approved due to limited evidence and package insert recommendations. **Aqvesme** - Aqvesme, a newly approved oral pyruvate kinase activator indicated for the treatment of anemia in adults with alpha or beta thalassemia. It is the first FDA-approved therapy for both conditions and has an estimated cost of approximately $34,939 per month. - Initial authorization (6 months) requires: ○ Genetically confirmed beta thalassemia (including hemoglobin E/beta thalassemia) or alpha thalassemia with hemoglobin H disease. ○ Hemoglobin <10 g/dL or a need for regular red blood cell transfusions. ○ No cirrhosis, with baseline and ongoing liver function monitoring due to the risk of serious liver injury. ○ No prior gene therapy, bone marrow transplant, or stem cell transplant. ○ Use at an FDA-approved dose. - Reauthorization (12 months) requires documentation of clinical benefit, demonstrated by either: ○ A hemoglobin increase of at least 1 g/dL over 12 weeks, or ○ At least a 50% reduction in transfused red blood cells (with a reduction of at least two units) over 12 weeks. - Patients must also remain free of cirrhosis or hepatocellular injury and continue treatment at an FDA-approved dose. **Zycubo** - The committee reviewed criteria for Zycubo, the first FDA-approved copper replacement therapy for Menkes disease, a rare pediatric genetic disorder that causes severe copper deficiency and progressive neurologic deterioration. The medication is administered by subcutaneous injection and has an estimated cost of $56,000–$112,000 per month. - Initial authorization (6 months) requires: ○ Diagnosis of Menkes disease confirmed by biochemical or genetic testing. ○ Presence of a severe ATP7A mutation consistent with the clinical trial population. ○ Member is under 18 years of age. ○ Baseline monitoring of copper levels, electrolytes, kidney and liver function, and blood counts. ○ Prescription by, or in consultation with, a neurologist or Menkes disease specialist. ○ Use at an FDA-approved dose.		

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		- Reauthorization (12 months) requires:
		  o Documentation of clinical benefits, such as improved survival, developmental progress, physical gains, or normalization of copper-related biomarkers.
		  o Ongoing monitoring of copper levels, kidney and liver function, and other safety parameters.
		  o Continued use at an FDA-approved dose.
		- The criteria are based on clinical trial evidence demonstrating improved survival in patients with severe ATP7A mutations and safety monitoring recommendations in the prescribing information.
		
		Kygevvi
		- Kygevvi, the first FDA-approved treatment for thymidine kinase 2 deficiency (TK2D), an ultra-rare inherited mitochondrial disorder that causes progressive muscle weakness and respiratory failure. The therapy is approved for adults and pediatric patients whose symptoms began at 12 years of age or younger and has an estimated cost of $131,500 per month for a 40-kg patient.
		- Initial authorization (6 months) requires:
		  o Genetic confirmation of TK2D through TK2 gene mutations.
		  o Symptom onset at 12 years of age or younger.
		  o Baseline liver function testing (transaminases and bilirubin).
		  o Prescription by, or in consultation with, a neurologist or other TK2D specialist.
		  o Use at an FDA-approved dose.
		- Reauthorization (12 months) requires:
		  o Documentation of clinical benefits, such as stabilization or improvement in motor function, respiratory function, or other disease symptoms.
		  o Continued liver function monitoring.
		  o Continued use at an FDA-approved dose.
		- The criteria are based on the approved indication, clinical trial population, and prescribing information recommendations for monitoring potential liver toxicity.
		
		New PAD
		
		Injectable/Infusible Bone-Modifying Agents for Oncology Indications
		- the Injectable and Infusible Bone-Modifying Agents for Oncology Indications policy. This is not a new criterion; it is an existing MRG policy being included in the physician-administered drug (PAD) policy packet. The policy was last reviewed by the P&T Committee in Q4 2025.
		- The only updates since the last review were the addition of new biosimilars:
		  o Xgeva biosimilars: Xtrenbo and Aukelso
		  o Prolia biosimilars: Enoby and Bosaya
		- No other changes were made, and the existing coverage criteria remain unchanged.
		
		Loargys
		- Criteria for Loargys, the first FDA-approved enzyme replacement therapy for arginase 1 deficiency (ARG1-D), an ultra-rare inherited metabolic disorder that causes elevated arginine levels and		

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		neurologic symptoms such as seizures, developmental delays, and movement difficulties. Treatment is administered as a weekly IV infusion and may cost approximately $1.2–$2.1 million annually, depending on patient weight and dosing. - Initial authorization (6 months) requires: o Diagnosis of ARG1-D confirmed by genetic testing, elevated plasma arginine levels, or reduced arginase activity. o Prescription by, or in consultation with, a metabolic disease or urea cycle disorder specialist. o Documentation of patient weight. o Use in conjunction with a protein-restricted diet. o Baseline plasma arginine level documentation. o Use at an FDA-approved dose. - Reauthorization (12 months) requires: o Evidence of clinical response, including improvement or normalization of plasma arginine levels. o Updated patient weight documentation. o Continued use at an FDA-approved dose. - The criteria are based on clinical trial endpoints evaluating reductions in plasma arginine levels and treatment response at 24 weeks. **Questions/Comments:**		
VI) Class Reviews, Monographs, and Recommendations-	Iryna Makukh	**1. Anaphylaxis Agents Class Review** - Formulary status of anaphylaxis agents, noting that epinephrine remains the first-line treatment for anaphylaxis and is most administered via autoinjector. - 9 claims for 9 members were submitted, with a total cost of $2,272 and an average cost of $252.53 per claim. - The most utilized products were: o Generic Adrena click epinephrine auto-injector (6 claims) o Generic EpiPen epinephrine auto-injector (3 claims) o No prior authorization requests were received. - Formulary Recommendation: o Add the generic Adrena click 0.15 mg autoinjector to the formulary for consistency, as the 0.3 mg strength is already covered and both strengths are similarly priced. o Generic EpiPen and Adrena click products were considered cost-effective and clinically equivalent, differing mainly in device design and instructions for use. - No other formulary changes were recommended, as higher-cost branded products such as Auvi-Q, Symjepi, and Neffy remain non-formulary.		
		2. Yartemlea Monograph and new PAD criteria - Yartemlea the first FDA-approved treatment for hematopoietic stem cell transplant–associated thrombotic microangiopathy (TA-TMA), a rare and potentially fatal complication of stem cell		

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		transplantation. Yartemlea is a monoclonal antibody administered intravenously and costs approximately $147,220 per month with weekly dosing.
		- Initial authorization (6 months) requires:
		  o Diagnosis of TA-TMA following hematopoietic stem cell transplantation.
		  o Evidence of persistent TA-TMA, including low platelet count, microangiopathic hemolysis, and renal dysfunction.
		  o No eculizumab use within the previous 3 months.
		  o No active infection, positive direct Coombs test, or Shiga toxin-producing E. coli-associated hemolytic uremic syndrome.
		  o Prescription by, or in consultation with, a hematologist or transplant specialist.
		  o Use at an FDA-approved dose.
		- Reauthorization (12 months) requires:
		  o Documentation of positive clinical response, such as improvement in TA-TMA laboratory markers, organ function, or reduced transfusion needs.
		  o Continued use at an FDA-approved dose.
		- The criteria are based on the patient population and efficacy outcomes from the clinical trials that supported FDA approval.
		
		Comments:		

VII) Medication Request Guidelines	Iryna Makukh	The committee has reviewed and discussed the following updates and additions to the Medication Review Guidelines (MRG) Guideline (Changes): **1. Medications for Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy** - Reviewed criteria for medications used to treat ADHD and narcolepsy. - Recommendation is to add Arynta (lisdexamfetamine oral solution) to both the clinical criteria and formulary with prior authorization (PA) requirements. - Arynta is a brand oral solution formulation of lisdexamfetamine (Vyvanse®), providing an alternative dosage form for patients who may have difficulty swallowing capsules. - Cost analysis indicates it is comparably priced to generic lisdexamfetamine capsules. - Based on clinical and cost considerations, the recommendation is to add Arinta to the formulary PA drug list. **Comments:** Guideline (Changes): **2. Serotonin Receptor Agonists (Triptans)** - Reviewed criteria for serotonin receptor agonists. - Recommendation is to add Symbravo® (meloxicam/rizatriptan tablets) to the policy and place it on the non-formulary prior authorization (PA) required drug list. - Symbravo is a combination product containing meloxicam and rizatriptan. - For cost-containment purposes, members will be directed to use the two individual agents separately, as this approach is more cost-effective than the combination product.	Move to approve: 1st: LL 2nd: AB	

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		- Recommendation is to maintain non-formulary status with PA requirements and encourage use of separate meloxicam and rizatriptan therapies. **Comments:** Guideline (Changes): **3. Xolair (omalizumab) for Asthma, Urticaria, and IgE-Mediated Food Allergy** - Reviewed Xolair® (omalizumab) criteria for asthma, chronic idiopathic/spontaneous urticaria, and IgE-mediated food allergy. - Recommendation is to remove the corticosteroid requirement from the chronic urticaria section, as current guidelines do not recommend corticosteroids for routine management of chronic urticaria and reserve their use for acute exacerbations only. - Additionally, the reauthorization language is being updated to ensure it applies consistently across all approved indications. - These are the proposed updates to the Xolair criteria. **Comments:** Guideline (Changes): **4. Daybue (trofinetide)** - Reviewed Daybue criteria. - Recommendation is to add Daybue Stix, a new powder formulation that provides patients with greater dosing flexibility. - Add geneticists as eligible prescribers, recognizing that the condition may be managed by this specialty. - Remove the RTT Clinical Severity Scale rating requirement because it is not commonly used in clinical practice. - These changes are intended to improve patient access and align the criteria with current practice patterns. **Comments:** Guideline (Changes): **5. Transthyretin-mediated Amyloidosis Agents** - Reviewed criteria for transthyretin-mediated amyloidosis (ATTR) therapies. - Recommendation is to remove Vyndaqel from the criteria due to its discontinuation. - Also recommended is the removal of the exclusion for patients who have undergone liver or heart transplantation from both the initial authorization and reauthorization sections. - This change is supported by emerging evidence demonstrating potential benefit and use of ATTR therapies in post-transplant patients. - These are the proposed updates to the ATTR amyloidosis treatment criteria. **Comments:** Guideline (Changes): **6. Specialty Biologic Agents** - Reviewed criteria for specialty biologic agents. - Recommendation is to add Icotyde (Icotrokinra) to Step 3 of the drug list as a non-preferred agent.		

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		- Icotyde is a newly approved oral tablet indicated for moderate to severe plaque psoriasis in adults and pediatric patients aged 12 years and older who weigh at least 40 kg and are candidates for systemic therapy or phototherapy. - Due to its high cost (approximately $8,285 per month), it is being placed among the non-preferred agents. - Add a requirement for initial authorization that members use Cosentyx 150 mg double-pack before the single-pack formulation. - This change is being made for cost-containment purposes, as the single-pack and double-pack are priced similarly, making the double-pack the more cost-effective option. **Comments:** Guideline (Changes): **7. Anti-Obesity Medications** - Recommendation is to add the new Zepbound kwikpens formulation to the anti-obesity medication criteria. - The initial authorization criteria are being updated to require a medical justification for not using the Zepbound kwikpens before approving the Zepbound autoinjector. - This change is intended to support cost containment, as the kwikpens is a multi-dose pen and costs approximately $400 less per month than the autoinjector formulation. - These updates incorporate the new formulation while encouraging use of the more cost-effective option when clinically appropriate. **Comments:** Guideline (Changes): **8. GLP1 Receptor Agonists (Wegovy/Zepbound) for Non-Weight Loss** - Recommendation is to add the new Zepbound kwikpens formulation to the criteria. - Update the initial authorization requirements to require a medical reason for not using the Zepbound kwikpens before the autoinjector formulation. - This change supports cost containment, as the kwikpens is a lower-cost option compared to the autoinjector. - Additionally, the tirzepatide (Zepbound) request criteria are being revised to clarify the requirements for lifestyle changes and behavioral modification trials. - The update removes potentially confusing language related to the BMI threshold of 30 kg/m² that appeared in multiple sections, improving clarity and easing interpretation of the criteria. - These changes align this policy with the corresponding updates made to other Zepbound-related criteria. **Comments:** Guideline (Changes): **9. Familial Chylomicronemia Syndrome Agents** - Recommend removing the trial-and-failure requirement for Redemplo from the familial chylomicronemia syndrome (FCS) criteria before coverage of Tryngolxa. Tryngolxa recently underwent a significant price reduction following Redemplo' s market entry, resulting in more		

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		comparable pricing between the two agents. Given the reduced cost differential, the rationale for step therapy is diminished, and the requirement is no longer considered necessary. Guideline (Changes**):** **10. Injectable/Infusible Bone-Modifying Agents for Oncology Indications** - Recommend updating the injectable and infusible bone-modifying agent criteria for oncology indications by adding the new Xgeva biosimilars, Xtrenbo and Aukelso, and the new Prolia biosimilars, Enoby and Bosava, to the drug list. Additionally, add a requirement for trial and failure of Xtrenbo and Enoby as preferred biosimilar options prior to coverage of Xgeva and Prolia, respectively. This change is recommended for cost containment, as these newly launched biosimilars are competitively priced and offer a lower-cost treatment alternative. **Comments:** Guideline (Changes): **11. Injectable/Infusible Agents for Osteoporosis and Paget's Disease** - Recommend updating the injectable and infusible agent criteria for osteoporosis and Paget's disease by adding the new Prolia biosimilars, Enoby and Bosaya, to the drug list. Additionally, add a requirement for trial and failure of Enoby as a preferred biosimilar prior to coverage of Prolia. This change supports cost containment by promoting use of a newly available, competitively priced biosimilar. **Comments:** Guideline (Changes): **12. PCSK-9 Monoclonal Antibodies (mAbs)** - Recommend updating the PCSK9 monoclonal antibody criteria by adding Lerochol to the drug list and formulary with prior authorization (PA). Lerochol is indicated as an adjunct to diet and exercise to reduce LDL-C in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia. Because its pricing is comparable to Repatha and Praluent, it is recommended for formulary inclusion with PA. No additional criteria changes are recommended. **Comments:** Guideline (Changes): **13. SGLT2 Inhibitors and Combinations** - Recommend updating the SGLT2 inhibitor and combination product criteria to reflect the availability of new lower-cost generic dapagliflozin products. For cost savings, add the generic dapagliflozin products as preferred agents and remove the corresponding brand products from formulary coverage. The criteria changes are limited to updating the drug lists to reflect preferred generic coverage and non-preferred brand coverage. **Comments:** No changes recommended at this time. No further discussion.		

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VIII) Physician Administered Drug (PAD) Policies	Iryna Makukh	Guideline (Changes): **1. Anti-CD19 CAR-T Immunotherapies** - Recommend updating exclusion criteria since Yescarta, Tecartus, and Aucatzyl now don't have the exclusion for primary CNS lymphoma - Add new indication of Marginal Zone Lymphoma (MZL) for Breyanzi **Comments:** Guideline (Changes): **2. Leqembi** - Recommendation: Add Leqembi IQLIK to policy with the same requirements as IV Leqembi but with an addition that patient has been established on IV Leqembi for at least 18 months per PI. **Comments:** Guideline (Changes): **3. Roctavian** - Recommendation: Retire criteria as Roctavian was voluntarily removed from the market. The removal was not due to efficacy or safety concerns. **Comments:** Guideline (Changes): **4. Immunoglobulin Therapy (IVIG)(SMA)** - Recommendation: Add Qivigy to policy—new IV immune globulin product indicated for the treatment of adults with primary humoral immunodeficiency - Add Gammagard ERC to policy as a new formulation of Gammagard **Comments:** Guideline (Changes): **5. Amvuttra** - Recommendation: Remove exclusion of patients who have undergone liver or heart transplant from the initial and reauthorization sections since there is new evidence for use in patients after transplantation **Comments:** Guideline (Changes): **6. Familial Chylomicronemia Syndrome Agents** - Recommendation: Remove trial and failure of Redemplo requirement, since Tryngolza recently experienced a significant price drop in response to Redemplo becoming available as a competitor. **Comments:** Guideline (Changes): **7. Injectable/Infusible Agents for Osteoporosis and Paget's Disease)** - Recommendation: Add new Prolia biosimilar Enoby to the drug list **Comments:**	Approved 1st: LL 2nd: AB	
IX) Informational Updates on New Developments in Pharmacy	Iryna Makukh	New Product Review • New Products discussed.	Approved 1st: LL 2nd: CR	

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BRAND NAME	GENERIC NAME/DOSAGE FORM	RECOMMENDATION
Aqvesme	mitapivat oral tablet 100 mg	Non-formulary (see new MRG criteria)
Cefixime	cefixime oral tablet 400 mg	Non-formulary
Enoby	denosumab-qbde subcutaneous solution prefilled syringe 60 mg/mM	Add to F-PA (see updated criteria)
Xtrenbo	denosumab-qbde subcutaneous solution 120 mg/1.7 mL	Add to F-PA (see updated criteria)
Daybue Stix	trofinetide oral packet 5000 mg, 6000 mg, 8000 mg	Non-formulary (see updated MRG criteria)
Metoprolol Tartrate	metoprolol tartrate oral tablet 12.5 mg	Non-formulary
Corphena	dexchlorpheniramine maleate oral solution 2 mg/5 mL	Non-formulary
Edex	alprostadil (2 cartridge) intracavernosal kit 10 mcg, 20 mcg, 40 mcg; (6 cartridge) intracavernosal kit 10 mcg, 20 mcg, 40 mcg	Non-formulary
Opdivo Qvantig	nivolumab and hyaluronidase-nvhy subcutaneous	Non-formulary

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				solution 300-5000 mg -ut/2.5 mL				
			Shingrix	zoster vaccine recombinant intramuscular suspension prefilled syringe 50 mcg/0.5 mL	F-QL-AL (Already added via CRF; QL: 1 syringe/one fill; AL: 18 years and above)			
			Yartemlea	narsoplimab-wuug intravenous solution 370 mg/2 mL	Non-formulary (see new PAD criteria)			
			Gammagard ERC	immune globulin infusion- human injection solution 5 gm/50 mL, 10 gm/100 mL	Non-formulary (see updated PAD criteria)			
			Orudis	ketoprofen oral capsule 75 mg	Non-formulary			
			Diskets	methadone oral tablet soluble 40 mg	Non-formulary			
			Pivya	pivmecillinam oral tablet 185 mg	Non-formulary			
			Myqorzo	aficamten oral tablet 5 mg, 10 mg, 15 mg, 20 mg	Non-formulary			
			Sdamlo	amlodipine oral solution reconstituted 2.5 mg, 5 mg, 10 mg	Non-formulary			
			Lopressor	metoprolol tartrate oral tablet 12.5 mg	Non-formulary			

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			Rocuronium	rocuronium bromide +RFID intravenous solution 50 mg/5 mL	Non-formulary			
			Zybic	meloxicam oral suspension 7.5 mg/5 mL	Non-formulary			
			Zepbound KwikPen	tirzepatide subcutaneous solution pen-injector 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg/0.6 mL	F-PA-QL (Already added via CRF; QL: 2.4mL/28 days)			
			Zycubo	copper histidinate subcutaneous solution reconstituted 2.9 mg	Non-formulary (see new MRG criteria)			
			Lunsumio Velo	mosunetuzumab subcutaneous solution 5 mg/0.5 mL, 45 mg/mL	Non-formulary			
			Levetiracetam	levetiracetam oral tablet disintegrating soluble 500 mg	Non-formulary			
			Magnesium Sulfate	magnesium sulfate intravenous solution 3 gm/100 mL	Non-formulary			
			Pokonza	potassium chloride oral solution 10 mEq/15 mL (5%)	Non-formulary			
			Ontralfy	tizanidine oral solution 2 mg/5 mL	Non-formulary			
			Vykoura	leucovorin calcium injection solution 50 mg/5 mL, 350 mg/35 mL, 500 mg/50 mL	Non-formulary			

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			Ustekinumab-ttwe	ustekinumab-ttwe subcutaneous solution 45 mg/0.5 mL	Non-formulary			
			Tizanidine	tizanidine hcl oral capsule 8 mg	Non-formulary			
			Rybrevant Faspro	amivantamab and hyaluronidase-lpuj subcutaneous solution 2400-30000 mg-UT/15 mL, 3520-44000 mg-UT/22 mL	Non-formulary			
			Vabrinty	leuprolide acetate subcutaneous kit 22.5 mg	Non-formulary			
			Vybrique	sildenafil citrate oral film 25 mg, 50 mg, 75 mg, 100 mg	Non-formulary			
			Avtozma	tocilizumab-anoh subcutaneous solution prefilled syringe 162 mg/0.9 mL, auto-injector 162 mg/0.9 mL	F-PA (Already added via CRF)			
			Orladeyo	berotralstat oral packet 72 mg, 96 mg, 108 mg, 132 mg	F-PA (Already added via CRF)			
			Qivigy	immune globulin intravenous, human-kthm intravenous solution 5 gm/50 mL, 10 gm/100 mL	Non-formulary (see updated PAD criteria)			
			Loargys	pegzilarginase-nbln injection solution 2 mg/0.4 mL	Non-formulary (see new PAD criteria)			

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			Bosaya	denosumab-kyqq subcutaneous solution prefilled syringe 60 mg/mL	Non-formulary (see updated MRG and PAD criteria)			
			Aukelso	denosumab-kyqq subcutaneous solution 120 mg/1.7 mL	Non-formulary (see updated MRG and PAD criteria)			
			Pralatrexate	pralatrexate intravenous solution 20 mg/mL, 40 mg/2 mL	Non-formulary			
			Desmoda	desmopressin oral solution 0.05 mg/mL	Non-formulary			
			Yuviwel	navepegritide subcutaneous solution reconstituted 1.3 mg, 2.8 mg, 5.5 mg	Non-formulary			
			Rezenopy	naloxone hydrochloride nasal liquid 10 mg/0.11mL	Add to F			
			Yuvezzi*	carbachol and brimonidine tartrate ophthalmic solution 2.75-0.1 %	Non-formulary			
			Dexmedetom-idine HCl in NaCl	dexmedetomidine HCl in NaCl intravenous solution 1000 mcg/250mL	Non-formulary			
			Hydroxyzine	hydroxyzine hcl oral syrup 25 mg/12.5 mL	Non-formulary			
			Lacosamide	lacosamide oral solution 150 mg/15 mL, 200 mg/20 mL	Non-formulary			

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			Arynta	lisdexamfetamine dimesylate oral solution 10 mg/mL	Add to F-PA (see updated MRG criteria)			
			Kygevvi	doxecitine-doxribtimine oral packet 2-2 gm	Non-formulary (see new MRG criteria)			
			Lerochol	lerodalcibep subcutaneous solution prefilled syringe 300 mg/1.2 mL	Add to F-PA-QL (see updated MRG criteria; QL: 1.2 mL/30 days)			
			Neulasta	pegfilgrastim subcutaneous solution 4 mg/0.4mL	Non-formulary			
			Icotyde	icotrokinra oral tablet 200 mg	Non-formulary (see updated MRG criteria)			
			Contepo	fosfomycin sodium intravenous solution reconstituted 6 gm	Non-formulary			
			Wegovy HD	semaglutide subcutaneous solution auto-injector 7.2 mg/0.75mL	F-PA-QL (Already added via CRF; QL: 3mL/28 days)			
			Relgaabi	gabapentin oral capsule 200 mg	Non-formulary			
			Spinraza	nusinersen intrathecal solution 28 mg/5 mL, 50 mg/5 mL	Non-formulary			
			Atmeksi	methocarbamol oral suspension 750 mg/5 mL	Non-formulary			
			Steqeyma	ustekinumab-stba subcutaneous solution 45 mg/0.5 mL	Non-formulary			

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		Lifyorli	relacorilant (125 mg dose) oral capsule therapy pack 1 x 25 mg & 1 x 100 mg, (150 mg dose) oral capsule therapy pack 2 x 25 mg & 1 x 100 mg	Non-formulary		
		Avlayah	tividenofusp alfa-eknm intravenous solution reconstituted 150 mg	Non-formulary		
		Tolectin DS	tolmetin oral capsule 400 mg	Non-formulary		
		Ephedrine	ephedrine sulf (pressors)+RFID intravenous solution prefilled syringe 25 mg/5 mL, 50 mg/10 mL	Non-formulary		
		Glycopyrrolate	glycopyrrolate +RFID injection solution 0.2 mg/mL vial glycopyrrolate pf +RFID injection solution prefilled syringe 0.6 mg/3 mL	Non-formulary		
		Diprivan	diprivan +RFID intravenous emulsion 200 mg/20 mL	Non-formulary		
X) Old Business		None **Comments:**				
XI) Public Comment	L. Lim	• No comment				

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Adjournment	L. Lim	Meeting adjourned at 6:17PM	None	

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Signed by:
Luke W. Lim, R.Ph.
Pharmacy Director
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Luke Lim, R.Ph.
Senior Director, Pharmacy Services
Alameda Alliance for Health

07/15/2026 | 3:08 PM PDT
Date

Drug Name: Hepcludex (bulevirtide-gmod)

Manufacturer: Gilead Sciences

Approval Date: 5/22/2026

Marketing Date: 5/28/2026

Recommendation

Implement new Prior Authorization Criteria with no changes to formulary status.

Prescribing Information

Indication

Treatment of chronic hepatitis D virus (HDV) infection in adults without cirrhosis or with compensated cirrhosis.

This indication is approved under accelerated approval based on participants who achieved a decrease in HDV ribonucleic acid (RNA) and alanine aminotransferase (ALT) normalization. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Mechanism of Action

Hepcludex® is a synthetic 47-amino acid lipopeptide with a myristoylated N-terminus and an amidated C-terminus derived from amino acids 13-59 of the L-HBsAg preS1 domain from a hepatitis B virus (HBV) genotype (GT)-C consensus sequence (corresponding to GT-D preS1 amino acids 2-48).

Hepcludex® inhibits HDV infection by binding to the HDV receptor sodium taurocholate co-transporting polypeptide (NTCP) on the plasma membrane of hepatocytes, blocking HDV attachment to NTCP.

Dosage and Administration

8.5 mg once daily by subcutaneous (SQ) injection

Hepcludex® should be continued as long as it is associated with a response to treatment. The optimal treatment duration is unknown.

Black Box Warning

Posttreatment Severe Acute Exacerbation of Hepatitis D and B: Severe acute exacerbations of hepatitis D and hepatitis B may occur after Hepcludex® is discontinued, especially in patients with cirrhosis, who may be at increased risk of more severe flares or progression to hepatic decompensation. Monitor hepatic function closely with both clinical and

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laboratory follow-up, including HBV deoxyribonucleic acid (DNA) and HDV RNA viral load, for at least six months in patients who discontinue Hepcludex®. Resumption of antiviral therapy may be warranted.

Adverse Reactions

Most common (incidence ≥10%, all grades): Injection site reactions, headache, abdominal pain, fatigue, and pruritus

Serious: Exacerbation of hepatitis D and B after discontinuation of treatment and hypersensitivity reactions including anaphylaxis

Use in Specific Populations, Pregnancy

There is insufficient human data on the use of Hepcludex® during pregnancy to inform a drug-associated risk of birth defects and miscarriage. In nonclinical reproductive toxicity studies, Hepcludex® demonstrated no adverse effect on embryofetal development when administered to pregnant rats and rabbits at systemic exposures 4- and 37-fold relative to exposure in humans at the recommended human dose.

Drug Interactions

No CYP enzyme or transporter mediated inhibition or induction by Hepcludex® is anticipated at clinically relevant concentrations.

Due to peptide catabolism of Hepcludex®, the drug-drug interaction potential of other drugs to impact Hepcludex® pharmacokinetics, via CYP enzymes, is low.

How Supplied

8.5 mg SQ vial

Price

$23,286

(Per month, based on WAC.)

Clinical Studies

Completed

Title	A Phase 3, Randomized Trial of Bulevirtide in Chronic Hepatitis D (MYR 301) NCT: 03852719

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	PMID: 37345876
Design	Phase 3, multi-center, randomized, open-label, parallel-arm study to determine the effectiveness of bulevirtide in adults with chronic HDV infection without cirrhosis or with compensated cirrhosis
Population	N=101 The mean age was 41 years; 55% were male, 82% were White, 17% were Asian, and 1% were Black or African American. Forty-eight percent had compensated liver cirrhosis, 98% had HDV genotype 1, and 87% had HBV genotype D. Fifty-seven percent of participants had received previous interferon therapy and 59% were receiving nucleos(t)ide analog reverse transcriptase inhibitors for chronic hepatitis B.
Arms	Participants were randomly assigned in a 1:1 ratio to receive bulevirtide 8.5 mg subcutaneously once daily for 144 weeks or delayed treatment for 48 weeks followed by bulevirtide 8.5 mg subcutaneously once daily for 96 weeks (control group)
Endpoint(s)	Primary: • Combined response, defined as undetectable HDV RNA or ≥2 $\log_{10}$ IU/mL decline from baseline and ALT normalization at week 48 Secondary: • Undetectable HDV RNA level at week 48 • Safety & adverse events
Inclusion Criteria	• Positive serum anti-HDV antibody results or polymerase chain reaction (PCR) results for serum/plasma HDV RNA ≥6 months before screening • ALT >1 × upper limit normal (ULN), but <10 × ULN • Serum albumin >28 g/L • Negative urine pregnancy test (for females of childbearing potential)
Exclusion Criteria	• Child-Pugh hepatic insufficiency score >7 points • Hepatitis C virus (HCV) or uncontrolled human immunodeficiency virus (HIV) co-infection • Creatinine clearance (CrCl) <60 mL/min • Total bilirubin ≥34.2 µmol/L • Current or previous (<last 2 years) decompensated liver disease, including coagulopathy, hepatic encephalopathy, and esophageal varices hemorrhage • ≥1 additional known primary or secondary causes of liver disease other than HBV • White blood cell (WBC) count <3000 cells/mm^3 (<1500 if African individuals) • Absolute neutrophil count (ANC) <1500 cells/mm^3 (<1000 if African individuals) • Platelet count <60,000 cells/mm^3

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	• Use of interferon <6 months before screening
Results	**Table 4 Trial MYR301: Efficacy Outcomes of HEPCLUDEX versus Delayed Treatment at Week 48**

	HEPCLUDEX (Immediate Treatment) (N=50)	Delayed Treatment (N=51)	Rate Difference 96% CI (%)
Combined Response[a]	48%	2%	46%[d] (96% CI: 31% to 61%)
Virologic Response[b]	76%	4%	NA
ALT Normalization[c]	56%	12%	NA

CI=Confidence Interval, NA=Not applicable

a. Defined as virologic response (HDV RNA undetectable or ≥ 2 $\log_{10}$ IU/mL decline) and ALT normalization.
b. Defined as HDV RNA below lower limit of quantification (LLOQ) (50 IU/mL) with target not detected or ≥ 2 $\log_{10}$ IU/mL decline from baseline.
c. Defined as an ALT value within the normal range: Russian sites, ≤ 31 U/L for females and ≤ 41 U/L for males; all other sites, ≤ 34 U/L for females and ≤ 49 U/L for males.
d. $p < 0.0001$ (by Fisher's exact test) for HEPCLUDEX vs. Delayed Treatment. The 96% confidence interval was calculated using score statistics with unconditional confidence limits method. A two-sided significance level of 0.04 was used to control the overall Type I error rate of 0.05 following a prespecified interim analysis conducted at the 0.01 level.

Primary:

- At week 48, the bulevirtide 8.5 mg group met the primary efficacy endpoint, achieving a combined response of HDV RNA reduction and ALT normalization in 48% of patients compared to 2% of those who underwent a 48-week treatment delay (P<0.0001)

Secondary:

- The HDV RNA level at week 48 was undetectable in 20% in the bulevirtide 8.5 mg group compared with 0% in the delayed treatment group (P=0.41); at weeks 96 and 144, these rates increased to 36% and 50%, respectively, in the bulevirtide 8.5 mg group
- At week 96, the bulevirtide 8.5 mg group demonstrated a 56% combined response rate, 82% virologic response rate (defined as undetectable HDV RNA or ≥2 $\log_{10}$ IU/mL decline from baseline), and 64% ALT normalization rate; at week 144, these rates were 54%, 76%, and 60%, respectively
- Participants in the delayed treatment group switched to bulevirtide 8.5 mg once daily at week 48; at week 144 (after 96 weeks of treatment), the combined response rate in the delayed treatment group was 56%, the rate of undetectable HDV RNA was 52%, virologic response rate was 92%, and ALT normalization rate was 58%

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	• At posttreatment week 24, 32% and 20% of participants in the bulevirtide 8.5 mg group and the delayed treatment group, respectively, had combined response, and 26% and 18% of participants, respectively, had undetectable HDV RNA • Bulevirtide was generally well tolerated through up to 144 weeks of on-treatment exposure, with the most frequent adverse reactions being injection site reactions (30%), headache (20%), abdominal pain (18%), fatigue (14%), and pruritus (14%); bile salt elevations occurred in 100% of patients treated with bulevirtide due to its mechanism of action.
Conclusion	After 48 weeks of bulevirtide treatment, HDV RNA and ALT levels were reduced in patients with chronic hepatitis D.
Interpretation	In this trial involving patients with chronic HDV, a significantly greater percentage of patients treated with bulevirtide compared to the delayed treatment group had a virologic and biochemical response, as assessed by analysis of the HDV RNA and ALT levels, respectively, at week 48. Limitations of this trial include the lack of a blinded control group, as daily injection of placebo is considered to be unethical, and the fact that not all HDV and HBV genotypes were represented. However, in vitro data suggest that bulevirtide has activity against every HDV and HBV genotype. Finally, the efficacy results for bulevirtide are based on surrogate biomarkers. While these endpoints are considered to be a reasonably likely predictor of improved clinical outcomes in patients with hepatitis D, longer-term data are still needed to confirm the clinical benefit of bulevirtide.

Ongoing

Title	A Study to Evaluate Tobevibart + Elebsiran in Participants with Chronic HDV Infection Not Virologically Suppressed with Bulevirtide NCT: 07128550
Design	Phase 3, multicenter, open label, randomized clinical study to evaluate tobevibart + elebsiran in participants with chronic HDV infection not virologically suppressed with bulevirtide
Completion Date	December 2026

Title	A Trial Evaluating Brelovitug (BJT-778) vs Bulevirtide for the Treatment of Chronic Hepatitis Delta Infection (AZURE-2) NCT: 07200908

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Design	Phase 3, global, randomized, open-label, multicenter, trial evaluating brelovitug vs. bulevirtide for the treatment of chronic HDV
Completion Date	June 30, 2027

Title	Study to Evaluate Switching to Brelovitug for the Treatment of Chronic HDV in Participants Receiving Bulevirtide NCT: 07454837
Design	Phase 2b/3, randomized, open-label, multicenter trial evaluating the efficacy and safety of switching from bulevirtide to brelovitug for the treatment of chronic HDV
Completion Date	August 31, 2027

Guidelines

Ghany MG, Pan CQ, Lok AS, et al. AASLD IDSA practice guideline on treatment of chronic hepatitis B. Hepatology. 2026;83(4):974-997.

Terrault NA, Lok ASF, McMahon BJ, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. Hepatology. 2018;67:1560–1599.

The American Association for the Study of Liver Diseases (AASLD) guidelines were recently updated in 2026; however, recommendations related to HDV testing and treatment have remain unchanged. Guidelines recommend screening for patients with chronic HBV who are at high risk for HDV, including those with HIV infection, injection drug users, men who have sex with men (MSM), those at risk for sexually transmitted diseases, and immigrants from areas of high HDV endemicity. In addition, patients who are hepatitis B surface antigen (HBsAg)–positive with low or undetectable HBV DNA levels but high ALT levels should be considered for HDV testing. With regards to treatment, AASLD guidelines recommend off-label use of pegylated interferon (peg-IFN) alfa-2a or 2b for 12 months in patients with elevated HDV RNA and ALT levels. If HBV DNA levels are also elevated, concurrent therapy with entecavir or tenofovir is recommended.

Clinical Opinions

Hepatitis D is a liver disease caused by the hepatitis delta virus (HDV) and is known as a “satellite virus,” because it can only infect people who are also infected by the hepatitis B virus (HBV). HDV infection can be acquired either

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simultaneously with HBV as a co-infection or as a superinfection in those who already have chronic HBV. The prevalence of HDV is estimated to impact about 1%–4% of patients with chronic HBV, or approximately 40,000–80,000 people in the US. Chronic HDV is associated with accelerated progression to cirrhosis, increased risk of hepatic decompensation, and higher incidence of hepatocellular carcinoma (HCC) compared to HBV alone. Prior to Hepcludex® (bulevirtide), the only available treatment option for chronic HDV was off-label use of pegylated interferon (peg-IFN) alfa-2a or 2b. However, interferon treatment has not been viewed favorably due to its low efficacy and significant side effect profile.

Hepcludex® is a subcutaneous injection, dosed once daily, that is indicated for chronic HDV infection in adults without cirrhosis or with compensated cirrhosis. It is the first FDA-approved treatment for HDV. The accelerated approval of Hepcludex® was based on results from the Phase 3 MYR301 study, where Hepcludex® met the primary efficacy endpoint, achieving a combined response of HDV RNA reduction and alanine aminotransferase (ALT) normalization in 48% of patients compared to 2% of those who underwent a 48-week treatment delay. While Hepcludex® offers a novel therapy for a disease state with limited treatment options, it only offers marginal efficacy at a very high price. The one significant advantage Hepcludex® does offer is improved tolerability over interferon treatment.

Additionally, the optimal duration of treatment with Hepcludex® is unclear. Patients in clinical trials were treated safely for up to 144 weeks, however, its efficacy after 144 weeks of treatment appears to offer little long-term advantage over interferon treatment for most patients once treatment is stopped. Long-term follow-up indicates that some patients who achieve early and durable HDV undetectability may be able to discontinue Hepcludex® and maintain viral suppression. While these characteristics may be helpful clinically to determine which patients may safely discontinue Hepcludex®, they are not sufficiently defined to guide utilization management policies and protocols. Payers will most likely cover Hepcludex® for multiple years of therapy until the patient or physician opts to discontinue treatment. While Hepcludex® will not face any competition in the short-term, two additional products may be FDA-approved for HDV within the next 1–2 years, that may offer more convenient dosing schedules and potentially stronger efficacy data.

Alternatives

Drug Name^	Formulary Status	Dosage Form	Price*
Pegasys® (peginterferon alfa-2a)	F-PA	180 mcg/0.5 ml subcutaneous syringe, vial	$4,454

^The manner in which the Drug Name is listed implies its availability. The generic name is listed first, with brand in parenthesis, if the product is available as a generic. The brand name is listed first, with the generic name in parenthesis, if the product is available as a brand only.

**Price per month unless otherwise noted. Pricing for multi-source generic medications based on National Average Drug Acquisition Cost (NADAC). Pricing for single-source branded medications and generic drugs without NADAC data based on Wholesale Acquisition Cost (WAC).*

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PA Criteria

Hepcludex	
Therapeutic Classes (AHFS)	Entry Inhibitors
Medications	Hepcludex (bulevirtide-gmod)
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	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for up to 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:** • Documentation of positive hepatitis D virus (HDV) antibody test or HDV ribonucleic acid (RNA) polymerase chain reaction (PCR) at least 6 months prior to start of treatment • Documentation of current positive HDV PCR result • Member's alanine transaminase level (ALT) is >1 but <10 x upper limit of normal (ULN) • Prescriber attests member has no history of decompensated liver disease • Prescriber attests member does not have uncontrolled HIV or active hepatitis C virus • Dosing is consistent with FDA-approved labeling **Re-Authorization:** • Documentation of positive clinical benefit (i.e., undetectable HDV RNA or decrease from baseline, ALT normalization, etc.) • Dosing is consistent with FDA-approved labeling
Criteria Statement	Hepcludex is reserved for members who have positive HDV antibody test or HDV RNA PCR at least 6 months prior to start of treatment and current positive HCV PCR result, have ALT >1 but <10 x upper limit of normal, and have no history of decompensated liver disease, uncontrolled HIV or active Hepatitis C virus.
Last P&T Review Date	9/2026

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New

Hepcludex	
Therapeutic Classes (AHFS)	Entry Inhibitors
Medications	Hepcludex (bulevirtide-gmod)
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	N/A
Coverage Duration	If all of the criteria are met, the request will be approved for up to 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:** • Documentation of positive hepatitis D virus (HDV) antibody test or HDV ribonucleic acid (RNA) polymerase chain reaction (PCR) at least 6 months prior to start of treatment • Documentation of current positive HDV PCR result • Member's alanine transaminase level (ALT) is >1 but <10 x upper limit of normal (ULN) • Prescriber attests member has no history of decompensated liver disease • Prescriber attests member does not have uncontrolled HIV or active hepatitis C virus • Dosing is consistent with FDA-approved labeling **Re-Authorization:** • Documentation of positive clinical benefit (i.e., undetectable HDV RNA or decrease from baseline, ALT normalization, etc.) • Dosing is consistent with FDA-approved labeling
Criteria Statement	Hepcludex is reserved for members who have positive HDV antibody test or HDV RNA PCR at least 6 months prior to start of treatment and current positive HCV PCR result, have ALT >1 but <10 x upper limit of normal, and have no history of decompensated liver disease, uncontrolled HIV or active Hepatitis C virus.
Last P&T Review Date	9/2026

New

Mucopolysaccharidosis II (Hunter Syndrome) Agents	
Medications	Elaprase (idursulfase), Avlayah (tividenofusp alfa-eknm)
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	Concomitant use of Elaprase and Avlayah
Required Clinical Information	See "Other Criteria" below
Age Restrictions	According to package insert Check AAH active CCS cases for members < 21 years of age for MCAL
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the management of Mucopolysaccharidosis II (geneticist, endocrinologist, neurologist, rheumatologist, etc.)
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	**Initial Authorization**
	• Diagnosis of Mucopolysaccharidosis II as confirmed by one of the following:
	  ○ Enzyme assay demonstrating a deficiency of iduronate 2-sulfatase activity
	  ○ Genetic testing
	• Requests for Avlayah also require all of the following:
	  ○ Documentation of neurologic manifestations associated with Mucopolysaccharidosis II OR patient is presymptomatic and at risk for neurologic manifestations
	  ○ Documentation that patient does not have advanced neurologic impairment
	• Patient's weight provided
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
	
	Reauthorization
	• Patient has demonstrated a beneficial response (i.e., stabilization or improvement in cerebrospinal fluid (CSF) or urine heparan sulfate (HS), neurologic or functional status, 6-minute walk test [6-MWT], forced vital capacity [FVC]), urinary glycosaminoglycan (GAG) levels, liver volume, spleen volume, etc.)
	• Patient's weight provided
	• 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	9/2026

New

Cartilaginous Repair Agents	
Medications	Euflexxa (hyaluronate sodium) Hyalgan (hyaluronate sodium) Durolane (hyaluronate sodium) Genvisc 850 (hyaluronate sodium) Trivisc (hyaluronate sodium) Synvisc (hylan G-F 20) Synvisc-One (hylan G-F 20) Orthovisc (sodium hyaluronate) Monovisc (sodium hyaluronate) Gel-One (sodium hyaluronate) Visco-3 (sodium hyaluronate) Hymovis (sodium hyaluronate) Triluron (sodium hyaluronate) Gelsyn-3 (sodium hyaluronate) Supartz FX (sodium hyaluronate) 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 “Other 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)
Maximum Billable Units	Variable
Other Criteria	**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) **Reauthorization** • 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 hyaluronic acid derivative (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 all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review
Last Review Date	9/2026

Alameda MRGs for review Q3 2026 P&T Changes

Recommendation: Update naming convention to show generic availability of Syndros oral solution and add trial and failure of brand Syndros before generic for cost containment

Dronabinol	
Therapeutic Classes (AHFS)	Antiemetics, Miscellaneous
Medications	Formulary, PA required Dronabinol (Marinol): pays at point of sale for members with diagnosis of HIV ICD 10 B20, for all other diagnoses, prior authorization is required Non-formulary Dronabinol (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)
	  ○ NK1 receptor antagonist (Aprepitant, fosaprepitant)
	  ○ 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
	  ○ In addition, if the request is for Syndros generic product, trial and failure of brand Syndros is required

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	~~9/2025~~9/2026

Recommendation:

- Add new pegfilgrastim biosimilar Armlupeg to the list of NF drugs
- Add new filgrastim biosimilar Filkri to policy and to formulary with PA
- Add Nypozi and Filkri to the list of drugs that have acute hematopoietic radiation injury syndrome indication

White Blood Cell Stimulators	
Therapeutic Classes (AHFS)	Hematopoietic agents
Medications	Formulary, PA required Fulphila (pegfilgrastim-jmdb) –PREFERRED AGENT Udenyca (pegfilgrastim-cbqv) Udenyca Onbody (pegfilgrastim-cbqv) Stimufend (pegfilgrastim-fpgk) Fylnetra (pegfilgrastim-pbbk) Ziextenzo (pegfilgrastim-bmez) Nivestym (filgrastim-aafi) – PREFERRED AGENT Zarxio (filgrastim-sndz) Releuko (filgrastim-ayow) Nypozi (filgrastim-txid) Filkri (filgrastim-laha) Non-formulary Nyvepria (pegfilgrastim-apgf) Neulasta (pegfilgrastim) Neulasta (pegfilgrastim) Onpro Armlupeg (pegfilgrastim-unne) Neupogen (filgrastim) Granix (filgrastim-aafi) Rolvedon (eflapegrastim-xnst) Ryzneuta (efbemalengrastim 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, 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 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, Fylnetra 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, 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, Nypozi, Filkri, or Releuko 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 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, Filkri and Granix are reserved for members who have used (or cannot/should not use) Nivestym. Neulasta, Ziextenzo, Nyvepria, Stimufend, Fylnetra, Armlupeg, 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	~~9/2025~~9/2026

Recommendation: Update age restrictions for Linzess as a result of new age approvals

Constipation agents	
Therapeutic Classes (AHFS)	N/A
Medications	Formulary, Prior Authorization Required Linzess (linaclotide) capsule lubiprostone (Amitiza) Movantik (naloxegol) Relistor (methylnaltrexone) Symproic (naldemedine) prucalopride (Motegrity) 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~~2 to 17 years old; IBS-C: 7 years of age and older
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-inducted 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-inducted 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	~~9/2025~~9/2026

Recommendation:

- Remove Ixchiq (chikungunya), TDVax, PreHevbrio, and Prevnar 13 as they have been discontinued
- Add Vimkunya—new chikungunya virus vaccine recommended for travelers visiting areas experiencing active outbreaks or elevated risk

Immunizations	
Therapeutic Classes (AHFS)	Toxoids;vaccines
Medications	Formulary, 1st line (fill limits indicated if applicable) 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 Heplisav-B (Hepatitis B) – 2 fills per lifetime; age minimum 18 years ~~PreHevbrio (Hepatitis B trivalent) - 3 fills per lifetime; age minimum 18 years~~ Gardasil-9 (HPV) – 3 fills per lifetime; age maxiumum 45 years IPOL (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 Penmenvy (Meningococcal)—2 fills per lifetime; age limit: 10-25 years Bexsero (Meningococcal) – 2 fills per lifetime; age maximum 25 years Trumenba (Meningococcal) – 3 fills per lifetime; age maximum 25 years ~~Prevnar 13 (Pneumococcal) – 1 fill per lifetime~~ Prevnar 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 18 years and older Non-Formulary, with PA required Biothrax (Anthrax) Ixiaro (Japanese encephalitis) Typhim Vi (Typhoid) YF-Vax (Yellow Fever)

Immunizations	
	Dengvaxia (dengue) Ticovac (tick-borne encephalitis) Vimkunya ~~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~~Vimkunya, 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~~Vimkunya, 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	~~9/2025~~9/2026

Recommendation:

- Remove the requirement for Sirturo to be used with Pretomanid to align with guidelines
- Remove medical reason why other guideline-recommended regimens cannot be used before Pretomanid as both recommended regimens contain Pretomanid per newer guidelines

Medications for the treatment of Multi-Drug Resistant Tuberculosis	
Therapeutic Classes (AHFS)	Antitubercular agents
Medications	Formulary, Step Therapy required 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 Formulary PA required 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: 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) ▪ 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) • Is being prescribed in combination with other TB medications ~~• Is being used in combination with Pretomanid as below~~ Pretomanid • Diagnosis is laboratory confirmed pulmonary extensively drug resistant (XDR)-TB or treatment-intolerant or non-responsive MDR-TB or RR-TB with an isolate showing genotypic or phenotypic resistance to RIF • 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 when used as part of a 3-drug 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	~~9/2025~~9/2026

Recommendation: Retire criteria as Palforzia was discontinued

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 the initial dose escalation per the prescribing information • 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	~~9/2025~~9/2026

Recommendation:

- Add platelet count requirement as per PI Duvyzat should not be initiated in patients with a platelet count less than 150 x 10^9/L
- Minor grammatical correction

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~~who 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	**Initial Authorization:** • 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 • ~~-~~Patient's platelet count is ≥ 150 x 10^9/L **Re-Authorization:** • 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	~~9/2025~~9/2026

Recommendation: Add new GLP-1 receptor agonist Foundayo to criteria and to formulary (F-PA-QL: 30/30)

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) Contrave (naltrexone/bupropion) Saxenda (liraglutide) Wegovy (semaglutide) injection, tablets Zepbound (tirzepatide) auto-injector, Kwikpen Foundayo (orfoglipron) tablets Any other newly marketed agent ****Please Note: If the request is for Wegovy to reduce the risk of major adverse cardiovascular events, MASH, or for Zepbound for OSA, please refer to the "GLP1 Receptor Agonists (Wegovy/Zepbound) for Non-Weight Loss Indications" 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	**INITIAL CRITERIA FOR APPROVAL** Phentermine HCL (Adipex-P) • Diagnosis of obesity (including documentation of BMI ≥ 30) OR BMI ≥27 and at least one weight-related-comorbidity (such as diabetes, controlled hypertension, hyperlipidemia etc) or history of heart attack, despite diet and exercise • For phentermine (Lomaira): trial and failure or medical reason for not using generic phentermine (Adipex-P) Alli • Diagnosis of obesity (including documentation of BMI ≥ 30) OR BMI ≥27 and at least one weight-related-comorbidity (such as diabetes, controlled hypertension, hyperlipidemia etc) or history of heart attack, despite diet and exercise Phentermine/topiramate (Qsymia) • **For adults:** Diagnosis of obesity (including documentation of BMI ≥ 30) OR BMI ≥27 and at least one weight-related-comorbidity (such as diabetes, controlled hypertension, hyperlipidemia etc) or history of heart attack, despite diet and exercise **OR** ○ **For pediatrics**: BMI in the ≥95th percentile standardized for age and sex

	▪ https://www.cdc.gov/healthyweight/bmi/calculator.html • Clinic notes and paid claims to confirm trial and failure, contraindication, or intolerance to use phentermine HCL (Adipex-P) and topiramate as separate ingredients Contrave • Diagnosis of obesity (including documentation of BMI ≥ 30) OR BMI ≥27 and at least one weight-related-comorbidity (such as diabetes, controlled hypertension, hyperlipidemia etc) or history of heart attack, despite diet and exercise • Clinic notes and paid claims to confirm trial and failure, contraindication, or intolerance to use phentermine/topiramate (Qsymia) Saxenda, Wegovy, Foundayo, and Zepbound • Diagnosis of class III/severe obesity (including documentation of BMI ≥ 40) • Clinic notes and paid claims to confirm trial and failure, contraindication, or intolerance to use phentermine/topiramate (Qsymia) AND Contrave • Members who have been established on a GLP-1 agonist are permitted to switch to a different GLP-1 agonist with appropriate indication without meeting requirements above • For Wegovy tablets, please provide a medical reason for not using Wegovy injection • For Zepbound auto-injectors, please provide medical reason for not using Zepbound Kwikpens Xenical: • Diagnosis of obesity (including documentation of BMI ≥ 30) OR BMI ≥27 and at least one weight-related-comorbidity (such as diabetes, controlled hypertension, hyperlipidemia etc) or history of heart attack, despite diet and exercise • Documented trial and failure, contraindication, or intolerance to Alli dosed at 120 mg (2 capsules) three times daily. **REAUTHORIZATION CRITERIA FOR APPROVAL** • Documented weight loss of 5% of body weight or more, compared with baseline
Criteria Statement	Phentermine is reserved for members who are obese with body mass index of ≥ 30 or ≥ 27 with a comorbidity such as diabetes or hypertension. Generic Lomaira is reserved for members who have used (or cannot/should not use) generic Adipex-P. Alli is reserved for members who are obese with a body mass index of ≥ 30 or ≥ 27 with a comorbidity such as diabetes, hypertension, or heart attack. Phentermine/topiramate (Qsymia) is reserved for adult members who are obese with a body mass index of ≥ 30 or ≥ 27 with a comorbidity such as diabetes, hypertension, or heart attack or pediatric members who are obese with a BMI in the 95th percentile standardized for age and sex and who have used (or cannot/should not use) phentermine and topiramate as separate ingredients. Contrave is reserved for members who are obese with a body mass index of ≥ 30 or ≥ 27 with a comorbidity such as diabetes, hypertension, or heart attack and who have used (or cannot/should not use) phentermine/topiramate (Qsymia). Saxenda, Wegovy, Foundayo, 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. Additionally, for Wegovy tablets, a medical reason should be provided for not using Wegovy injection. For Zepbound auto-injectors, a medical reason should be provided for not using Zepbound Kwikpens. Xenical is reserved for obese members with a body mass index of ≥ 30 or ≥ 27 with a comorbidity such as diabetes, hypertension, or heart attack and who have used (or cannot/should not use) Alli.
Last P&T Review Date	~~6/2026~~9/2026

Recommendation: Add new biosimilars for Xgeva (Jubereq) and Prolia (Osvyrti) to policy

Injectable/Infusible Bone-Modifying Agents for Oncology Indications	
Therapeutic Classes (AHFS)	Bone resorption inhibitors
Medications	**Preferred Agent, prior authorization required** Pamidronate disodium: 3mg/ml, 6 mg/ml, 9 mg/ml liquid in10 ml vials, 30 mg, 90 mg vials Zoledronic Acid 4 mg/5 ml vial **Non-preferred Agents, prior authorization required** Xgeva (denosumab) Xgeva biosimilars: Bilprevda, Xtrenbo, Wyost, Bomyntra, Osenvelt, Xbryk, Aukelso, Jubereq Prolia (denosumab) Prolia biosimilars: Bildyos, Enoby, Jubbonti, Conexxence, Stoboclo, Ospomyv, Bosaya, Osvyrti
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) or an Xgeva biosimilar, the patient has a documented trial and failure of Bilprevda (denosumab-nxxp) or Xtrenbo (denosumab-qbde), or has a medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc.) for not utilizing this agent to manage their medical condition • If the request is for Prolia (denosumab) or a Prolia biosimilar, the patient has a documented trial and failure of Bildyos (denosumab-nxxp) or Enoby (denosumab-qbde), or has a medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc.) for not utilizing this agent to manage their medical condition • If the request is for Xgeva (denosumab) or an Xgeva biosimilar 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 if for Xgeva (denosumab) or an Xgeva biosimilar 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) or a Prolia biosimilar 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) or a Prolia biosimilar for prostate cancer, approve.
Criteria Statement	Xgeva or Xgeva biosimilars are 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. In addition, if the request is for Xgeva or Xgeva biosimilar, the patient has a documented trial and failure or inability to use Bilprevda or Xtrenbo biosimilar. Prolia is reserved for members with cancer indications who have used (or cannot/should not use) pamidronate or zoledronic acid. In addition, if the request is for Prolia or Prolia biosimilar, the patient has a documented trial and failure or inability to use Bildyos or Enoby biosimilar.
Last P&T Review Date	~~6/2026~~9/2026

Recommendation: Add new Prolia biosimilar Osvyrti to policy

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) Prolia biosimilars: Bildyos, Enoby, Jubbonti, Conexxence, Stoboclo, Ospomyv, Bosaya, Osvyrti 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
	• If the request is for Prolia (denosumab) or a Prolia biosimilar, the member has a documented trial and failure with the biosimilar Bildyos (denosumab-nxxp) or Enoby (denosumab-qbde), or a medical reason (e.g. intolerance, contraindication, etc.) as to why the member is unable to use this medication is provided
	
	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: o A bone mineral density (BMD) value consistent with osteoporosis (i.e., T-scores equal to or less than –2.5) o Has had an osteoporotic fracture o 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: o Documented trial and failure of ibandronate (Boniva) or zoledronic acid (Reclast) AND a denosumab product or has a medical reason (e.g. intolerance, contraindication, etc.) why these therapies are not suitable to be used o 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. o 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: o Documentation that the member is currently utilizing glucocorticoid therapy for a minimum of 3 months o Dosage of the glucocorticoid therapy is greater than 2.5 mg of prednisone daily or its equivalent o 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: o 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 a denosumab product 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/Prolia biosimilars, 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 a denosumab product. 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/Prolia biosimilars 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 a denosumab product. Additionally, Forteo is reserved for members who have used (or cannot/should not use) Teriparatide, In addition, if the request is for Prolia or Prolia biosimilar, the patient has a documented trial and failure or inability to use Bildyos or Enoby biosimilar. 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	~~6/2026~~9/2026

Recommendation: Update requirements for airflow limitation to FEV1 <90% or FEV1/FVC <0.80 for all patients based on provider feedback

Pulmonary Biologics for Respiratory and Eosinophilic Conditions	
Therapeutic Classes (AHFS)	Interleukin antagonists
Medications	Nucala (mepolizumab) Fasenra (benralizumab) Cinqair (reslizumab) Dupixent (dupilumab) Tezspire (tezepelumab) Exdensur (depemokimab) Any other newly marketed 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), and the Drug Package Insert.
Exclusion Criteria	• When being used for relief of acute bronchospasm or status asthmaticus • In combination with another monoclonal antibody for the treatment of respiratory or eosinophilic conditions
Required Clinical Information	See "PA Review Criteria" below
Age Restrictions	Per Package Insert; Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescriber must be an allergist, pulmonologist, immunologist, rheumatologist, gastroenterologist, dermatologist, or other provider who specializes in the treatment of asthma or eosinophilic conditions, or in consultation with one of these specialists
Coverage Duration	Initial Approval 4 months Later Approvals 6 months If conditions are not met, the request will be sent to a clinical reviewer
PA Review Criteria	**Initial Authorization:** Asthma: • Confirmed diagnosis of one of the following: o Nucala, Fasenra, Cinqair, and Exdensur: Severe Eosinophilic Asthma o Dupixent: Moderate-to-Severe eosinophilic asthma o Tezspire: Severe Asthma • Documentation has been provided of blood eosinophil count within ONE of the following ranges: o Nucala, Dupixent, and Exdensur: ≥ 150 cells/mcL (within 6 weeks of request) OR ≥ 300 cells/mcL (within the past 12 months) o Fasenra: ≥ 150 cells/mcL (within the past 12 months) o Cinqair: ≥ 400 cells/mcL (within the past 12 months) o Tezspire: No baseline blood eosinophil counts are required • The member has a documented baseline FEV_1 < ~~80%~~90% of predicted with evidence of reversibility by bronchodilator response or FEV1/FVC <0.8. ~~o If age is < 18 years, the member has a documented baseline FEV_1 < 90% of predicted with evidence of reversibility by bronchodilator response~~ • Documentation has been provided indicating that that the member continues to experience significant symptoms while compliant on a maximally tolerated inhaled corticosteroid with long-acting beta2 agonist (ICS/LABA) AND long-acting muscarinic antagonist (LAMA) (or a documented medical reason must be provided why the member is unable to use these therapies) and ONE of the following: o Nucala: ≥ 2 exacerbations in the past 12 months o Fasenra: ≥ 1 exacerbation in the past 12 months o Cinqair: ≥ 1 exacerbation in the past 12 months requiring systemic

	corticosteroids o Dupixent: ≥ 1 exacerbation in the past 12 months requiring systemic corticosteroids or hospitalization o Exdensur: ≥ 2 exacerbations in the past 12 months requiring systemic corticosteroids o Tezspire: ≥ 2 exacerbations requiring systemic corticosteroids OR ≥ 1 exacerbation in the past 12 months requiring hospitalization • The prescribed dose is within FDA approved dosing guidelines <u>Chronic Obstructive Pulmonary Disease (COPD) (*Dupixent and Nucala only*)</u>: • Confirmed diagnosis of COPD • Documentation has been provided of blood eosinophil count within one of the following ranges: o Dupixent: ≥ 300 cells/mcL (within the past 12 months) o Nucala: ≥ 150 cells/mcL (within 6 weeks of request) OR ≥ 300 cells/mcL (within the past 12 months) • The member has a documented post-bronchodilator FEV_1/FVC ratio < 0.7 and post-bronchodilator FEV_1 of 20% to 80% predicted • Documentation has been provided indicating that the member continues to experience significant symptoms (i.e., chronic productive cough) while compliant on maintenance triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta2 agonist (LABA), and inhaled corticosteroid (ICS) (or a documented medical reason must be provided why the member is unable to use these therapies) and ONE of the following: o ≥ 2 exacerbations in the past 12 months, where systemic corticosteroids were required for at least one of them o ≥ 1 exacerbation in the past 12 months requiring hospitalization • The prescribed dose is within FDA approved dosing guidelines <u>Oral Corticosteroid Dependent Asthma: (*Dupixent only*)</u> • Confirmed diagnosis of oral corticosteroid (OCS) dependent asthma with at least 5 mg oral prednisone or equivalent per day for at least 4 weeks within the last 3 months • The patient has a documented baseline FEV1 < 80% of predicted with evidence of reversibility by bronchodilator response. • Documentation has been provided indicating patient still is having significant symptoms with ≥ 1 exacerbations in the previous 12 months requiring additional medical treatment, (emergency room visits, hospital admissions) while compliant on a high-dose inhaled corticosteroid with a long-acting B2 agonist AND a long-acting muscarinic antagonist (LAMA). If the patient has not utilized these therapies, a documented medical reason must be provided why patient is unable to do so. • The prescribed dose is within FDA approved dosing guidelines <u>Eosinophilic Esophagitis (EoE) (*Dupixent only):*</u> • Confirmed diagnosis of EoE by endoscopic biopsy indicating ≥15 intraepithelial eosinophils per high-power field (eos/hpf) • Documentation of baseline esophageal intraepithelial eosinophil count and Dysphagia Symptom Questionnaire (DSQ) scores • Member has a history of at least 2 episodes of dysphagia (with intakes of solids) per week in the last 4 weeks • Documented trial and failure, intolerance, or contraindication to one proton pump inhibitor at a maximally tolerated dose for a minimum of 8 weeks • Member has a documented weight greater than or equal to 15 kg • The prescribed dose is within FDA approved dosing guidelines

	Prurigo Nodularis (PN) (*Dupixent only*):
	• Confirmed diagnosis of PN lasting for at least three months prior to request
	• Member has a Worst-itch Numeric Rating Scale (WI-NRS) score of 7 or higher indicating severe or very severe itching
	• Member has at least 20 PN lesions in total
	• Documented trial and failure, intolerance, or contraindication to at least two of the following for a minimum of two weeks:
	  o One medium to super-high potency topical corticosteroid
	  o One topical calcineurin inhibitor
	  o UVB phototherapy or psoralen plus UVA phototherapy
	• The prescribed dose is within FDA approved dosing guidelines
	
	Chronic Spontaneous Urticaria (CSU) *(Dupixent only)*:
	• Confirmed diagnosis of CSU
	• Documented history of urticaria for at least 6 weeks
	• Member remains symptomatic despite a minimum two-week trial of a second generation H1 antihistamine at the maximum tolerated dose; or has a medical reason for not utilizing a second-generation antihistamine
	• The prescribed dose is within FDA approved dosing guidelines
	
	Bullous Pemphigoid *(Dupixent only)*:
	• Confirmed diagnosis of bullous pemphigoid
	• Member has a Bullous Pemphigoid Disease Area Index (BPDAI) activity score ≥24
	• Member has a Peak Pruritus Numeric Rating Scale (NRS) score ≥4
	• Documented trial and failure, intolerance, or contraindication to at least three of the following:
	  o High potency topical corticosteroids
	  o Oral corticosteroids
	  o Doxycycline
	  o Immunosuppressive therapies (ex. azathioprine, mycophenolate, methotrexate, etc.)
	• The prescribed dose is within FDA approved dosing guidelines
	
	Eosinophilic granulomatosis with polyangiitis (EGPA) (*Nucala & Fasenra only*):
	• Confirmed diagnosis of EGPA and eosinophilic asthma lasting for ≥6 months
	• Member has a history of relapsing disease defined as at least one EGPA relapse requiring additional corticosteroids or immunosuppressant or hospitalization within the past 2 years OR member has a history of refractory disease defined as failure to attain remission in the prior 6 months following induction treatment with standard therapy
	• Member must be on a stable dose of oral corticosteroids for at least 4 weeks prior to request
	• Member has a blood eosinophil count ≥1,000 cells/mcL OR > 10% of total leukocyte count
	• Documented trial and failure, intolerance, or contraindication to cyclophosphamide, rituximab, azathioprine, methotrexate, OR mycophenolate mofetil
	• If the request is for Nucala, member must also have a documented trial and failure, intolerance, or contraindication to Fasenra
	• The prescribed dose is within FDA approved dosing guidelines
	
	Hypereosinophilic Syndrome (HES) (*Nucala only*):

	• Confirmed diagnosis of FIP1 like 1-platelet derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative HES lasting for ≥6 months without an identifiable non-hematologic secondary cause • Member has a history of two or more HES flares (worsening of HES-related symptoms necessitating therapy escalation or ≥2 courses of rescue oral corticosteroids) within the past 12 months • Member has a blood eosinophil count ≥1,000 cells/mcL • Documented trial and failure, intolerance, or contraindication to oral corticosteroids AND at least one second-line agent (e.g. hydroxyurea, interferon, imatinib, methotrexate, cyclophosphamide, cyclosporine, azathioprine) (member must be on stable dose of at least one agent for at least 4 weeks prior to request) **Criteria for re-authorization**: • Documentation submitted indicates the member has had a positive clinical response (e.g. Asthma & COPD: improved FEV1, reduced exacerbations; HES: symptomatic improvement, reduced oral corticosteroid dose; EGPA: reduction in relapse frequency or severity, disease remission, symptomatic improvement, reduced oral corticosteroid dose; EoE: histological remission, improvement in DSQ scores; PN: improvement in WI-NRS score, symptomatic improvement; CSU: decrease in severe itching or urticaria activity; Bullous Pemphigoid: sustained remission, improvement in Peak Pruritus NRS score). • The prescribed dose is within FDA approved dosing guidelines
Criteria Statement	For asthma, Nucala, Dupixent, Fasenra, Cinqair, Tezspire, and Exdensur are reserved for members who have used (or cannot/should not use) a maximally tolerated inhaled corticosteroid with a long acting B2 agonist (ICS/LABA) AND a long-acting muscarinic antagonist (LAMA), who have eosinophils in the treatment range per package insert, and who have had asthma exacerbations during the previous 12 months. For COPD, Dupixent and Nucala are reserved for members with a diagnosis of COPD, eosinophil count in the treatment range per package insert, who continue to experience significant symptoms while compliant on maintenance triple therapy consisting of LAMA, LABA, and ICS, and who have had COPD exacerbations in the previous 12 months. For oral corticosteroid dependent asthma, Dupixent is reserved for members with a diagnosis of oral corticosteroid dependent asthma, who have used (or cannot/should not use) a high-dose inhaled corticosteroid with a long acting B2 agonist (ICS/LABA) AND a long-acting muscarinic antagonist (LAMA), and who have been using oral corticosteroids for at least 4 weeks within the past 3 months and who have had asthma exacerbations during the previous 12 months. For eosinophilic esophagitis (EoE), Dupixent is reserved for members with a diagnosis of eosinophilic esophagitis with a history of at least 2 episodes of dysphagia (with intakes of solids) per week in the last 4 weeks, who have used (or cannot/should not use) one proton pump inhibitor at a maximum dose for 8 weeks, with a weight greater than or equal to 15kg. For prurigo nodularis (PN), Dupixent is reserved for members with a diagnosis of prurigo nodularis with a Worst-itch Numeric Rating Scale (WI-NRS) score of 7 or higher indicating severe or very severe itching AND at least 20 PN lesions in total AND who have used (or cannot/should not use) at least two of the following: one medium to super-high potency topical corticosteroid or one topical calcineurin inhibitor or UVB phototherapy or psoralen plus UVA phototherapy.

	For Chronic Spontaneous Urticaria (CSU), Dupixent is reserved for members with a diagnosis of CSU with history of urticaria for at least 6 weeks, who remain symptomatic despite trial of second generation H1 antihistamine. For Bullous Pemphigoid, Dupixent is reserved for members with a diagnosis of bullous pemphigoid with BPDAI activity score of at least 24 and NRS score of at least 4, who had trial and failure or were unable to use at least three of the following: high potency topical corticosteroids, oral corticosteroids, doxycycline, immunosuppressive therapies. For eosinophilic granulomatosis with polyangiitis (EGPA), Nucala and Fasenra are reserved for members with a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), with a history of relapsing disease, who have used (or cannot/should not use) cyclophosphamide, rituximab, azathioprine, methotrexate, OR mycophenolate mofetil. Additionally, Nucala is reserved for members who have used (or cannot/should not use) Fasenra. For hypereosinophilic syndrome (HES), Nucala is reserved for members with a diagnosis of hypereosinophilic syndrome, who have a history of 2 or more flares within the past 12 months, who have used (or cannot/should not use) oral corticosteroids AND at least one second-line agent (e.g. hydroxyurea, interferon, imatinib, methotrexate, cyclophosphamide, cyclosporine, or azathioprine).
Last P&T Review Date	~~3/2026~~9/2026

Recommendation:

- Add new drug Lynavoy—ileal bile acid transporter (IBAT) inhibitor FDA-approved specifically for the treatment of cholestatic pruritus in patients with primary biliary cholangitis (PBC).
- Update coverage duration to 12 and 6 months for initial requests for Iqirvo/Livdelzi and Lynavoy, respectively, to align with primary endpoints evaluations in clinical trials.
- Add trial and failure requirements for Lynavoy per AASLD guidelines.
- Specify that complete biliary obstruction is a contraindication only for Iqirvo and Livdelzi.
- Add reauthorization requirements for Lynavoy.

Agents for Primary Biliary Cholangitis	
Therapeutic Classes (AHFS)	GI Drugs, Miscellaneous
Medications	Iqirvo (elafibranor), Livdelzi (seladelpar), Lynavoy (linerixibat)
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 Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a hepatologist or gastroenterologist
Coverage Duration	Lynavoy: If the criteria are met, the request will be approved for a ~~3~~ 6 month duration for initial authorization and up to a 12 month duration for reauthorization. Iqirvo & Livdelzi: If the criteria are met, the request will be approved for up to a 12 month duration. If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	**Initial Authorization**: • Diagnosis of primary biliary cholangitis (PBC) confirmed by at least two of the following criteria: a) Positive antimitochondrial antibody (AMA) test, or presence of other PBC-specific autoantibodies, including sp100 or gp210, if AMA test is negative b) Elevated serum alkaline phosphatase (ALP) level c) Histologic evidence of primary biliary cholangitis from a liver biopsy • If the request is for Iqirvo or Livdelzi, ~~D~~drug is being requested in addition to ursodeoxycholic acid (UDCA) due to patient having an inadequate response to UDCA monotherapy for at least 1 year, OR member has a documented medical reason (e.g. contraindication, intolerance, hypersensitivity) why UDCA cannot be used and is taking the requested drug as monotherapy • If the request is for Lynavoy, drug is being requested for the treatment of cholestatic pruritus associated with PBC AND patient has a documented trial and failure, intolerance, or contraindication to at least 3 of the following: a) Anion-exchange resins (e.g., cholestyramine, colestipol, or colesevelam) b) Naltrexone c) Sertraline d) Rifampicin • Prescriber attests the patient does not have complete biliary obstruction (for Iqirvo or Livdelzi requests only), or decompensated cirrhosis (e.g., Child-Pugh Class B or C) • Submission of the following test results within 30 days of request: a) Serum ALP b) Total bilirubin

	Re-authorization: • Provider attests that the patient has not developed complete biliary obstruction (for Iqirvo or Livdelzi requests only), or decompensated cirrhosis (e.g., Child-Pugh Class B or C) • If the request is for Iqirvo or Livdelzi, ~~S~~submission of lab tests confirming each of the following: o A decrease in ALP of ≥ 15% from baseline o ALP is less than 1.67 times the upper limit normal (ULN); defined as 118 U/L for females and 124 U/L for males o Total bilirubin ≤ ULN defined as 1.1 mg/dL for females and 1.5 mg/dL for males • If the request is for Lynavoy, documentation confirming improvement in pruritus
Criteria Statement	Iqirvo, and Livdelzi are reserved for members with a confirmed diagnosis of primary biliary cholangitis (PBC), who have used (or cannot/should not use) ursodeoxycholic acid (UDCA). Lynavoy is reserved for members with cholestatic pruritus associated with PBC, who had trial and failure to at least 3 of the following: anion-exchange resins, naltrexone, sertraline, or rifampicin. Additionally, members should not have complete biliary obstruction (for Iqirvo or Livdelzi requests) or decompensated cirrhosis (e.g., Child-Pugh Class B or C). Recent (within 30 days of the request) serum ALP and total bilirubin lab test results must be submitted.
Last P&T Review Date	~~12/2025~~9/2026

Alameda PADs for review Q3 2026 P&T Changes

Recommendation: Add newer biosimilar agents to policy and several additional indications for bevacizumab per compendia

Ophthalmic indications for bevacizumab	
Medications	Avastin (bevacizumab) Mvasi (bevacizumab-awwb) - biosimilar Zirabev (bevacizumab-bvzr) ~~–~~ biosimilar Jobevne (bevacizumab-nwgd) - biosimilar Alymsys (bevacizumab-maly) - biosimilar Vegzelma (bevacizumab-adcd) - 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
	  ○ Neovascular angle closure glaucoma
	  ○ Angioid streaks of choroid - Choroidal retinal neovascularization
	• 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	~~9/2025~~9/2026

Recommendation: Add new pegfilgrastim biosimilar Armlupeg and new filgrastim biosimilar Filkri to policy for completeness

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 Fylnetra (pegfilgrastim-pbbk) – biosimilar Stimufend (pegfilgrastim-fpgk) – biosimilar Armlupeg (pegfilgrastim-unne) – biosimilar Rolvedon (eflapegrastim-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 Filkri (filgrastim-laha) - 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 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, 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 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~~9/2026

Recommendation: Add coverage duration for iron deficiency with heart failure indication for Injectafer and minor language update to initial authorization requirements for clarity

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: Iron deficiency anemia: two (2) doses of up to 750mg maximum at least seven (7) days apart, or 1 dose of up to 1000mg maximum once. Iron deficiency with heart failure: two (doses) of up to 1000 mg on day 1 and week 6. For both indications: 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 and one of the following:
	  ○ 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
	  ○ Member~~s~~ 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	~~9/2025~~9/2026

Recommendation:

- Add new drug Lumvoa to policy and change the name of the criteria to encompass all drugs.
- Update coverage duration section to include the new drug.
- Modify diagnosis requirements to better tailor the targeted study populations for both active and inactive/chronic thyroid eye disease (TED).
- Remove trial and failure of rehabilitative surgery for chronic/inactive disease as patients with prior surgical rehabilitative surgery were excluded from Tepezza trial. Use of steroids is not supported in inactive disease and is only appropriate for active disease. Step through surgery as an option for inactive/chronic disease makes criteria overly strict and likely clinically inappropriate since Tepezza has the best evidence when diplopia or proptosis is the most prominent feature.
- Add requirement that patient has not had prior treatment with either Tepezza or Lumvoa as there is no clinical evidence to support use of multiple IGF-1R therapies.

~~Tepezza~~ Insulin-Like Growth Factor-1 Receptor (Igf-1r) Antagonists For Thyroid Eye Disease	
Medications	Tepezza (teprotumumab-trbw) Lumvoa (veligrotug)
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	Tepezza: 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. Lumvoa: If all of the criteria are met, the request will be approved for up to 12 weeks of treatment (5 total infusions). Retreatment requests will not be allowed beyond the 5 dose limit.
Maximum Billable Units	Variable
Other Criteria	**Initial Authorization:** ~~Tepezza~~ A request for Igf-1r antagonist 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 one of the following: ~~•~~○ ~~Documentation of m~~Moderate to~~-~~ severe active thyroid eye disease (TED) with CAS ≥4 ~~as evidenced by~~ and 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 ○ Chronic/inactive TED with one of the following: ▪ ≥3-mm increase in proptosis from before diagnosis of TED ~~○~~▪ ~~▪~~ Proptosis ≥3 mm above normal values for race and sex • 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~~ ~~○~~ Member has not had prior treatment with either Tepezza or Lumvoa **Re-authorization:** • Retreatment or renewal requests beyond a single course of therapy ~~total of (~~24 weeks of treatment/ ~~(~~8 total infusions~~)~~ for Tepezza or 12 weeks of treatment/5 total infusions for Lumvoa) 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	~~9/2025~~9/2026

Recommendation: Remove Beqvez from policy as it has been discontinued

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	**Initial Authorization:**
	• 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 ≤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~~ has~~ve~~ 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~~9/2026

Recommendation:

- Add hematologist and transplant specialist to prescriber restrictions as these specialists may also prescribe Omisirge
- Add new indication for Omisirge for the treatment of adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning
- Add trial and failure or intolerance to immunosuppressive therapy for patients with severe aplastic anemia since this was the population included in clinical trials and it also aligns with clinical guidelines.

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, hematologist, or transplant specialist
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 one of the following: ○ ~~Patient has a~~ A hematologic malignancy planned for umbilical cord blood transplantation (UCBT) following myeloablative conditioning ○ Diagnosis of severe aplastic anemia (SAA) as evidenced by bone marrow cellularity < 30% (excluding lymphocytes) AND at least two of the following: ▪ Absolute neutrophil count (ANC) < 500 cells/µL ▪ Platelet count < 20,000/µL ~~○~~▪ Reticulocyte count < 60,000/µL • 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 allogenic HSCT • Patient does not have known allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material • Requests for severe aplastic anemia also require a trial and failure, intolerance, or contraindication to immunosuppressive therapy (i.e., anti-thymocyte globulin [ATG] + cyclosporine, eltrombopag + cyclosporine, etc.) **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	~~9/2025~~9/2026

Recommendation: Add attestation requirement that patient is ambulatory per updated indication

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	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Documentation of weight • Genetically confirmed diagnosis of DMD and copies of testing were submitted with request • Attestation patient is ambulatory • 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	~~9/2025~~9/2026

Recommendation: Add new biosimilars for Xgeva (Jubereq) and Prolia (Osvyrti) to policy

Injectable/Infusible Bone-Modifying Agents for Oncology Indications	
Medications	Pamidronate disodium: 3mg/ml, 6 mg/ml, 9 mg/ml liquid in10 ml vials, 30 mg, 90 mg vials Zoledronic Acid 4 mg/5 ml vial Xgeva (denosumab) Xgeva biosimilars: Bilprevda, Xtrenbo, Wyost, Bomyntra, Osenvelt, Xbryk, Aukelso, Jubereq Prolia (denosumab) Prolia biosimilars: Bildyos, Enoby, Jubbonti, Conexxence, Stoboclo, Ospomyv, Bosaya, Osvyrti 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 "Other Criteria" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age for MCAL
Prescriber Restrictions	Prescriber must be an oncologist or endocrinologist
Coverage Duration	If all conditions are met, the request will be approved for up to 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.
Maximum Billable Units	Variable

Other 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), the patient has a documented trial and failure with the biosimilar product, or has a medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc.) for not utilizing this agent to manage their medical condition
	• If the request is for Prolia (denosumab), the patient has a documented trial and failure with the biosimilar product, or has a medical reason (intolerance, hypersensitivity, contraindication, renal insufficiency, etc.) for not utilizing this agent to manage their medical condition
	• If the request is for Xgeva (denosumab) or an Xgeva biosimilar 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 if for Xgeva (denosumab) or an Xgeva biosimilar 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) or a Prolia biosimilar 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) or a Prolia biosimilar for prostate cancer, approve. If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review
Last Review Date	~~6/2026~~9/2026

Recommendation: Add new Prolia biosimilar Osvyrti to policy

Injectable/Infusible Agents for Osteoporosis and Paget's Disease	
Medications	ibandronate (Boniva) injection zoledronic acid (Reclast) Prolia (denosumab) Prolia biosimilars: Bildyos, Enoby, Jubbonti, Conexxence, Stoboclo, Ospomyv, Bosaya, Osvyrti 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 • If the request is for Prolia (denosumab), the member has a documented trial and failure with the biosimilar product, or a medical reason (e.g. intolerance, contraindication, etc.) as to why the member is unable to use biosimilar is provided **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: o A bone mineral density (BMD) value consistent with osteoporosis (i.e., T-scores equal to or less than –2.5) o Has had an osteoporotic fracture o 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: o Documented trial and failure of ibandronate (Boniva) or zoledronic acid (Reclast) AND a denosumab product or has a medical reason (e.g. intolerance, contraindication, etc.) why these therapies are not suitable to be used o 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. o 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: o Documentation that the member is currently utilizing glucocorticoid therapy for a minimum of 3 months o Dosage of the glucocorticoid therapy is greater than 2.5 mg of prednisone daily or its equivalent o 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: o 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 a denosumab product 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	~~6/2026~~9/2026

New Product Review

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Foundayo	Orforglipron Oral Tablet 0.8 MG, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, 17.2 mg	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.	$649	Wegovy, Zepbound, liraglutide	Add to F-PA-QL (see updated PA criteria; QL: 30/30)
Dapagliflozin	dapagliflozin oral tablet 5 mg, 10 mg	Apotex, Glenmark, Sun, Teva, multiple others	• To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors. • As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	$6 (NADAC)	Jardiance, Invokana, bexagliflozin	F-ST-QL (Already added via CRF; QL: 30/30)
Dapagliflozin-sAXagliptin	dapagliflozin-saxagliptin oral tablet 10-5 mg	Novadoz	Dapagliflozin and saxagliptin tablets is a combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor and saxagliptin a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	$370 (WAC)	Steglujan, Glyxambi	Non-formulary
Nereus	tradipitant oral capsule 85 mg	Vanda	For the prevention of vomiting induced by motion in adults	$255-$510 per dose	Scopolamine, meclizine	Non-formulary
Favlyxa	fluorouracil Intravenous Solution 250 mg/10mL	Avyxa	• Adenocarcinoma of the Colon and Rectum • Adenocarcinoma of the Breast • Gastric Adenocarcinoma • Pancreatic Adenocarcinoma	$350 per vial	Other IV fluorouracil products	Non-formulary
Avopef	etoposide intravenous solution 100 mg/ 5 mL	Avyxa	Avopef is a topoisomerase inhibitor indicated, in combination with other chemotherapy and/or immunotherapy, for the treatment of adult patients with: • Refractory testicular cancer • Small cell lung cancer	$80 per vial	Other IV etoposide products	Non-formulary
Byqlovi	clobetasol ophthalmic suspension 0.05 %	Harrow Eye	For the treatment of post-operative inflammation and pain following ocular surgery.	$380 per 3.5mL bottle	prednisolone	Non-formulary

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New Product Review

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Clonidine	clonidine hcl oral tablet 0.05mg	Trupharma	For the treatment of hypertension	$74	Other clonidine strength tablets, patches	Non-formulary
Ozempic	semaglutide oral tablet 1.5 mg, 4 mg, 9 mg	Novo Nordisk	• As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. • To reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus who are at high risk for these events.	$1,028	Mounjaro	F-QL-ST (Already added via CRF; QL: 30/30; ST: previous trial with a metformin-containing product)
Relgaabi	gabapentin oral capsule 300 mg, 400 mg	Method	• Postherpetic neuralgia in adults • Adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy	$4,131	Other generic gabapentin capsules, tablets	Non-formulary
Widaplik	amlodipine-telmisartan-indapamide oral tablet, 1.25-10-0.625 mg, 2.5-20-1.25 mg, 5-40-2.5 mg	Arbor	Widaplik is indicated for the treatment of hypertension, including as initial treatment, to lower blood pressure	$200	Amlodipine, telmisartan, indapamide taken individually	Non-formulary
Quiofic	folic acid oral solution 0.2 mg/mL	Solubiomix	For the treatment of megaloblastic anemias due to folic acid deficiency in adult and pediatric patients.	$3,117	Folic acid tablets	Non-formulary
Saphnelo	anifrolimab-fnia pen subcutaneous solution auto-injector, prefilled syringe 120 mg/0.8 mL	AstraZeneca	For the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.	$6,180	Benlysta	Non-formulary
Wainua	eplontersen subcutaneous solution prefilled syringe 45 mg/0.8 mL	AstraZeneca	For the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.	$42,831	Amvuttra	Non-formulary

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BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Fesilty	fibrinogen, human-chmt intravenous solution reconstituted 1 gm	Grifols	For the treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency, including hypo- or afibrinogenemia.	$1 per mg	Fibryga	Non-formulary
Idvynso	doravirine and islatravir oral tablet 100-0.25 mg	Merck	As a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of virologic treatment failure and no known substitutions associated with resistance to doravirine.	$4,455	Other HIV antiviral regimens	Add to F-QL (30/30)
Jakafi XR	ruxolitinib oral tablet extended release 24-hour 11 mg, 22 mg, 33 mg, 44 mg, 55 mg	Incyte	• Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis in adults. • Polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea. • Steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older. • Chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.	$18,190	Vonjo, Inrebic (myelofibrosis), Rezurock (chronic GVHD)	Non-formulary
Bysanti	milsaperidone oral tablet 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg; titration packs A, B, C	Vanda	• Treatment of schizophrenia in adults • Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults	$3,775	Risperidone, aripiprazole	Non-formulary
Glipizide	glipizide oral tablet 15 mg	Advagen	An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	$38 (for once daily dosing)	Other strength generic glipizide tablets	Non-formulary
Zolymbus	bimatoprost ophthalmic gel 0.01%	Thea	For the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension	$399	Bimatoprost solution	Non-formulary

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New Product Review

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Xtoro	finafloxacin otic suspension 0.3%	Fonseca	For the treatment of acute otitis externa (AOE) with or without an otowick, caused by susceptible strains of *Pseudomonas aeruginosa* and *Staphylococcus aureus* in patients age 1 year and older	$695	Ciprofloxacin	Non-formulary
Voriconazole	voriconazole intravenous solution 200 mg/20 mL	PAI Pharma	• Invasive aspergillosis • Candidemia in Non-neutropenic Patients and Other Deep Tissue *Candida* Infections • Esophageal Candidiasis • Scedosporiosis and Fusariosis	$35 per vial (weight and indication based dosing)	Vfend	Non-formulary
Baxfendy	baxdrostat oral tablet 1 mg, 2 mg	AstraZeneca	Baxfendy, in combination with other antihypertensive drugs, is indicated for the treatment of hypertension, to lower blood pressure in adults who are not adequately controlled on other agents.	$900	Eplerenone, spironolactone	Non-formulary

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BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Filkri	filgrastim-laha injection solution prefilled syringe 300 mcg/0.5 mL, 480 mcg/0.8 mL	Accord	• Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever • Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML) • Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) • Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia • Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)	$215-$345 per syringe (weight and indication based dosing)	Granix, Nivestym, Releuko	Add to F-PA (see updated PA criteria)
Armlupeg	pegfilgrastim-unne subcutaneous solution prefilled syringe 6 mg/0.6mL	Lupin	• Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. • Increase survival in patients acutely exposed to myelosuppressive doses of radiation.	$6,097 per dose	Fulphila, Ziextenzo, Udenyca	Non-formulary (see updated PA criteria)
Juxtapid	lomitapide oral capsule 2 mg	Chiesi	• As an adjunct to a low-fat diet and exercise and other low-density lipoprotein cholesterol (LDL-C) therapies, to reduce LDL-C in adult and pediatric patients aged 2 years and older with HoFH.	$62,075	None	Non-formulary

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New Product Review

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Hepcludex	bulevirtide subcutaneous solution reconstituted 8.5 mg	Gilead	• For the treatment of chronic hepatitis delta virus (HDV) infection in adults without cirrhosis or with compensated cirrhosis.	$23,286	None	Non-formulary (see new PA criteria)
Dexlyt	dexamethasone oral tablet 0.25 mg	Pangea	• Allergic states • Dermatologic diseases • Endocrine disorders • Gastrointestinal diseases • Hematologic disorders • Neoplastic diseases • Nervous system • Ophthalmic diseases • Renal diseases • Respiratory diseases • Rheumatic disorders • Miscellaneous disorders	$28/tablet (dosing variable based on indication)	Dexamethasone (other available strengths)	Non-formulary
Fenoprofen	fenoprofen calcium oral capsule 200 mg	Atland	• 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	$21/tablet (dosing variable based on indication)	Fenoprofen (other available strengths), ibuprofen, nabumetone	Non-formulary
Benzonatate	benzonatate oral capsule 150 mg	Anvi	• For the symptomatic relief of cough.	$700 (7-day supply)	Benzonatate (other strengths), dextromethorphan	Non-formulary
Pivot	pivot insulin pump starter kit, supply kit	Modular Medical	• Management of diabetes mellitus in adults (18 years and older) who require insulin therapy through subcutaneous delivery of insulin at both set (basal) and variable (bolus) rates.	$575 $275	OmniPod	Non-formulary
Decnupaz	pivekimab sunirine-pvzy for injection, 2 mg	AbbVie	• For the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN)	$266,718	None	Non-formulary

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Atoncy	atomoxetine oral solution 4 mg/mL	Map77	• For the treatment of ADHD in adults and pediatric patients 6 years of age and older.	$680 (40 kg patient)	Atomoxetine capsules, methylphenidate solution	Non-formulary
Evdi	trabectedin injection, 1 mg/20 mL	Apotex	• For the treatment of adult patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen	$19,652 (avg monthly for BSA 1.7m2)	Yondelis	Non-formulary
Tyvaso DPI	treprostinil inhalation powder 112 x 48 mcg & 112 x80 mcg	United Therapeutics	• Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies with Tyvaso 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 with Tyvaso 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%).	$44,296	IV treprostinil	Non-formulary

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Osvyrti	denosumab-desu subcutaneous solution prefilled syringe 60 mg/mL	Accord	• 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	$1,800 per dose ($300 per month)	Other Prolia biosimilars	Non-formulary (see updated PA criteria)
Jubereq	denosumab-desu subcutaneous solution 120 mg/1.7 mL	Accord	• 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	$3,312	Other Xgeva biosimilars	Non-formulary (see updated PA criteria)
Auvelity	dextromethorphan and bupropion titration pack oral tablet extended-release therapy pack 30-105 mg & 45-105 mg	Axsome	• The treatment of major depressive disorder (MDD) in adults • The treatment of agitation associated with dementia due to Alzheimer's disease	$1,061 per unit	Antidepressants, Rexulti	Non-formulary
Pazopanib	pazopanib hcl oral tablet 400 mg	Torrent	• For the treatment of adults with advanced renal cell carcinoma • for the treatment of adults with advanced soft tissue sarcoma (STS) who have received prior chemotherapy	$8,909	Pazopanib 200 mg	Non-formulary

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Hydroxyzine	hydroxyzine hcl oral syrup 50 mg/25mL unit dose cup	Chartwell	• For symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested. • Useful in the management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses, and in histamine-mediated pruritus. • As a sedative when used as premedication and following general anesthesia, hydroxyzine may potentiate meperidine and barbiturates, so their use in pre-anesthetic adjunctive therapy should be modified on an individual basis. Atropine and other belladonna alkaloids are not affected by the drug. Hydroxyzine is not known to interfere with the action of digitalis in any way and it may be used concurrently with this agent.	$102 per unit dose	Non unit dose hydroxyzine liquid	Non-formulary
Kymbee	deflazacort oral suspension 22.75 mg/ml	Upsher-Smith	• For the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older	$18,200 (35 kg child, 3 bottles per month)	Other generic deflazacort liquid	Non-formulary
Gabapentin	gabapentin oral capsule 200 mg	Pangea	• Management of postherpetic neuralgia in adults • Adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy	$4,131	Relgaabi, other generic gabapentin	Non-formulary
Breztri	budesonide, glycopyrrolate, and formoterol fumarate inhalation aerosol 160-18-4.8 mcg/act	AstraZeneca	• The maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients • The maintenance treatment of asthma in adult and pediatric patients 12 years of age and older	$685	Trelegy	F-PA-QL (Already added via CRF; QL: 10.7gm/30 days)
Xocova	ensitrelvir oral tablet 125 mg	Shionogi	• For post-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents 12 years of age and older following contact with an individual who has COVID-19	$1,400 (5-day course)	None	Non-formulary

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Buspirone	buspirone hcl oral tablet 2.5 mg, 12.5 mg	IPG Pharmaceuticals	• For the management of anxiety disorders or the short-term relief of the symptoms of anxiety	$4,320 (twice daily dosing)	Other available strengths of buspirone tablets	Non-formulary
Mirabegron ER	mirabegron er oral suspension reconstituted 8 mg/mL	Ascend	• Treatment of neurogenic detrusor overactivity in pediatric patients aged 3 years and older	$540	Oxybutynin	F-PA (Already added via CRF)
Romidepsin	romidepsin intravenous solution 27.5 mg/5.5 mL	Amneal	• For the treatment of cutaneous T-cell lymphoma (CTCL) in adult patients who have received at least one prior systemic therapy	$34,800 (per 28 day cycle; BSA dependent dosing, assuming 1 vial per dose)	Istodax, Zolinza	Non-formulary
Omnipod 5	Omnipod 5 Libre intro kit, pods	Insulet	• For people with type 1 diabetes, 2 years of age and older and type 2 diabetes ages 18 years and older	$615 Intro Kit $615 (10 pods monthly)	Other insulin pump (MiniMed 780G, Tandem Mobi)	Non-formulary
Thrombin-JMI Liquid	Thrombin, Topical (Bovine) U.S.P., Solution for topical use 5,000 IU/5 mL, 20,000 IU/20 mL vial	Pfizer	• A topical thrombin indicated to aid hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible and control of bleeding by standard surgical techniques (such as suture, ligature, or cautery) is ineffective or impractical • May be used in conjunction with an absorbable gelatin sponge, USP	$91 - $349 per vial	Other Thrombin-JMI presentations	Non-formulary
Otarmeni	lunsotogene parvec-cwha 3.0 × 10^{13} vg/mL intracochlear infusion	Regeneron	• For the treatment of pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (any frequency >90 dB HL) associated with molecularly confirmed biallelic variants in the *OTOF* gene, preserved outer hair cell function, and no prior cochlear implant in the same ear	$0	none	Non-formulary

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Hympavzi	marstacimab-hncq subcutaneous solution auto-injector 75 mg/0.5 mL	Pfizer	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatric patients 6 years of age and older with: • hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors, or • hemophilia B (congenital factor IX deficiency) with or without factor IX inhibitors	$33,094	Hemlibra, Alhemo, Qfitlia	Non-formulary
Duloxetine	duloxetine hcl oral capsule delayed release particles 80 mg, 90 mg, 120 mg	Almatica	• For treatment of major depressive disorder (MDD) and generalized anxiety disorder (GAD)	$177	Other generic duloxetine	Non-formulary
Lynavoy	linerixibat oral tablet 40 mg	Intercept	• An ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus associated with primary biliary cholangitis (PBC) in adult patients	$12,084	Livdelzi, Iqirvo	Non-formulary (see updated PA criteria)
Nufymco	ranibizumab-leyk intravitreal solution 0.3 mg/0.05 mL, 0.5 mg/0.05 mL	Formycon	For the treatment of patients with: • Neovascular (Wet) Age-Related Macular Degeneration (AMD) • Macular Edema Following Retinal Vein Occlusion (RVO) • Diabetic Macular Edema (DME) • Diabetic Retinopathy (DR) • Myopic Choroidal Neovascularization (mCNV)	$808 - $1,348	Byooviz, Cimerli, Lucentis	Non-formulary
Veppanu	vepdegestrant oral tablet 100 mg, 200 mg	Rigel	• A heterobifunctional protein degrader indicated for the treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor-1 (ESR1)-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy.	$29,400	Inluriyo, Orserdu	Non-formulary
Nystatin	nystatin mouth/throat suspension 500,000 unit/5 mL unit dose cup	Chartwell	• Treatment of infections of the oral cavity caused by *Candida albicans*	$96 per dose cup	Other nystatin suspension (non-unit dose)	Non-formulary

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Tryngolza	olezarsen subcutaneous solution auto-injector 50 mg/0.8 mL	Ionis	As an adjunct to diet • To reduce triglycerides (TG) in adults with familial chylomicronemia syndrome (FCS). • To reduce TG and the risk of acute pancreatitis in adults with severe hypertriglyceridemia (sHTG: TG greater than or equal to 500 mg/dL)	$3,333	Hypertriglyceridemia: Vascepa, fenofibrate	Non-formulary
Lumvoa	veligrotug-vvze intravenous solution 500 mg/10 mL	Viridian	• For the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration.	$448,000 for a 5-dose treatment course	Tepezza	Non-formulary (see updated PA criteria)
Avopef	etoposide intravenous solution 500 mg/25 mL	Avyxa	For the treatment of adult patients with • Refractory testicular cancer • Small cell lung cancer	$2,000 per vial	Generic etoposide	Non-formulary
Evesse	hydrocortisone butyrate topical lotion 0.1 %	Perfero	• For the topical treatment of mild to moderate atopic dermatitis in patients 3 months of age and older	$718 per 118 mL	Generic hydrocortisone butyrate	Non-formulary
Pellix	calcipotriene topical solution 0.005%	Perfero	• For the topical treatment of chronic, moderately severe psoriasis of the scalp. The safety and effectiveness of topical calcipotriene in dermatoses other than psoriasis have not been established	$771 per 60 mL	Generic calcipotriene	Non-formulary
Trilitas	tazarotene topical gel 0.1%	Perfero	• For the topical treatment of patients with plaque psoriasis of up to 20% body surface area involvement • For the topical treatment of patients with facial acne vulgaris of mild to moderate severity. The efficacy of Trilitas™ gel in the treatment of acne previously treated with other retinoids or resistant to oral antibiotics has not been established	$490 per 30 gm	Generic tazarotene	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.

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‡	Pricing is per each kit on items listed as a kit.
#	Re-activation of previously discontinued product (i.e., other available NDCs now inactive)

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