PHARMACY & THERAPEUTICS COMMITTEE

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

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

Location: Microsoft Teams
Meeting ID: 252 789 222 02
Password: Xi4j6z

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,,510814501# 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	DESCRIPTION	TIME	VOTE
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
	• DSNP go-live 2026
	  ○ partnering w/clinics
	  ○ 365-day operations & TATs
	  ○ STAR measures
	• Formulary [CMS selected drug list change d/t generic availability (Part D program) - Stelara, Xarelto, Entresto]
		15 min	-

III)	**Pharmacy Utilization Reports (Quarter 3, 2025)** *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: 12/16/2025*** *(formulary changes only; no trade secrets will be disclosed)*		

IV) E-Voting Material/Consent Agenda

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

Luke Lim, R.Ph., Senior Pharmacy Director – Alameda Alliance
Benita Ochoa, CPhT, Lead Pharmacy Technician – Alameda Alliance
(All matters listed on the Consent Calendar are to be approved with one motion unless a member of the P&T Committee removes an item for separate action. Any consent calendar item for which separate action is requested shall be heard as the next Agenda item in closedsession.)

Monographs/Class Reviews	Changes
Blood Glucose Test Strips Class Review	• No changes
Multivitamins Drug List Review	• No changes
Topical Antivirals Class Review	• No changes
Urinary Tract Antispasmodics Class Review	• No changes
Medication Request Guidelines	**Changes**
Oral and Injectable Oncology Medications	• No changes
Non-Formulary/Prior Authorization Required Medications	• No changes
Step Therapy Exception	• No changes
Prior Authorization Exception	• No changes
Butorphanol (Stadol NS)	• No changes
Endari	• Change naming convention to reflect generic availability of Endari
Diclofenac sodium (Solaraze) 3% gel	• No changes
Growth Hormone	• Remove Saizen as it has been discontinued
Rapid-Acting Insulin	• No changes
Long-Acting Basal Insulin	• Remove Levemir as it has been discontinued
Gonadotropin Releasing Hormone (GNRH) Agonists	• No changes
Ophthalmic Anti-Inflammatory Agents	• No changes
Fentanyl Citrate	• Remove Lazanda and Subsys as they have been discontinued
Proton Pump Inhibitors (PPIs)	• Change naming convention to reflect generic availability of Nexium oral granules packet
Ranolazine (Ranexa, Aspruzyo)	• No changes
Injectable Methotrexate	• Remove Otrexup as it has been discontinued
Temazepam (Restoril)	• No changes
Testosterone Agents	• Remove Androderm as it has been discontinued
Thalomid (thalidomide)	• No changes
Topical Diclofenac	• No changes
Oral Anti-Fungals	• No changes
Gattex (teduglutide)	• No changes
Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors	• No changes
Otezla (apremilast) for Behcet Disease	• No policy changes, add Otezla XR formulation for completeness

10 min EV

Rayaldee (calcifediol ER)	• No changes
Korlym (mifepristone)	• No changes
Tetracycline Antibiotics	• No changes
Botulinum Toxins A&B	• No changes
Agents for graft versus host disease	• No changes
Janus Kinase Inhibitors for Nonsegmental Vitiligo	• No changes
Budesonide Nebulization Solution (Pulmicort Respules)	• No changes
HIF-PH Inhibitors (Hypoxia-inducible Factor Prolyl Hydroxylase Inhibitors) for CKD Anemia	• No changes
Lodoco	• No changes
Nemluvio	• No changes
Yorvipath	• No changes
Cobenfy	• No changes
Specialty Biologic Agents	• Add new Actemra biosimilar Avtozma to step 2 agents and new Tysabri biosimilar Tyruko to step 3
Thrombocytopenia Agents	• Switch brand to generic Promacta tablet listed preference and add new Wayrilz to NF section
Complement Inhibitors for the Treatment of Myasthenia Gravis	• Add new Maavy to list of drugs not to be used with Zibrysq
Ileal bile acid transporter inhibitors (IBATs)	• Add trial agents based on recent guidelines
Sohonos	• Expand coverage duration to 12 months to mirror primary endpoint in trials
Isotretinoin	• Add Accutane to F-PA coding to match criteria
Physician Administered Drug (PAD) Guidelines	**Changes**
Injectable/Specialty Medications	• No changes
Oral and Injectable Oncology Medications	• No changes
Viltepso	• No changes, minor grammatical correction
Neuromyelitis Optica Spectrum Disorder	• No changes
Botulinum Toxins A&B	• No changes
Veopoz	• No changes
Lantidra	• No changes
Gene Therapy for Sickle Cell Disease	• Change naming convention to reflect generic availability of Endari
Tecelra	• No changes
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Agents	• No changes
Interim Formulary Updates	
• See p. 150 in packet	
Summary of Physician Administered Drug (PAD) Updates	
• See p. 152 in packet	

Policy & Procedure Update
• RX-013 Physician Facility-Administered Drugs (PAD) Prior Authorization Review Process
DSNP Pharmacy Policy & Procedure (NEW)
• RX-D-033 Medicare TrOOP, FIR and Nx Transactions
• RX-D-035 Member Symptom Management Process
ED Oversight
• No changes
90 Day Maintenance List updates
• No changes
P&T Meeting Minutes
• P&T Meeting Minutes Q3 September 16,2025

V) New Business

Iryna Makukh, PharmD, Pharmacist – PerformRx

- QL recommendations continued

New MRG

- Anzupgo
- Brinsupri
- Phenylalanine Hydroxylase Activators
- Nitisinone Products

New PAD

- Skysona
- Spravato

VI) Class Reviews, Monographs, and Recommendations

Iryna Makukh, PharmD, Pharmacist – PerformRx

1. Hereditary Angioedema Agents Class Review
2. PCSK9 Inhibitors Class Review

VII) Medication Request Guidelines

Rahel Negash, PharmD, Pharmacist – Alameda Alliance

45 min V

1. Pulmonary Hypertension (PH) Agents
2. Agents for Primary Biliary Cholangitis
3. Ohtuvayre
4. Complement Inhibitors for the Treatment of PNH
5. Injectable/Infusible Bone-Modifying Agents for Oncology Indications
6. Injectable/Infusible Agents for Osteoporosis and Paget's Disease
7. Wegovy
8. Zepbound for Moderate to Severe Obstructive Sleep Apnea
9. Anti-Obesity Medications
10. Rezdiffra

VIII) Physician Administered Drug (PAD) Policies

Iryna Makukh, PharmD, Pharmacist – PerformRx

1. Healthcare professional (HCP) administered/IV Disease Modifying Therapies (DMTs) for Multiple Sclerosis (MS) — 10 min — V
2. Complement Inhibitors
3. Myasthenia Gravis Agents
4. Injectable/Infusible Agents for Osteoporosis and Paget's Disease

IX) Informational Updates on New Developments in Pharmacy

Iryna Makukh, PharmD, Pharmacist – PerformRx

- New Product Review — 2 min — V

X) Old Business

- MRG criteria update Topical Antibiotics — 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**
March 17, 2026	June 16, 2026 September 15,2026 December 15, 2026

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 3rd Quarter 2025

- The top 50 drugs accounted for **1,341 claims** for **688 members** and cost **$1,685,511**, which is an increase of $61,035 in spend from the previous quarter.
- Biktarvy remains at number one with 39 claims for 15 members. There was an increase of 4 claims since the previous quarter.
- Ozempic is at numbers 2, 3, and 5, with 267 total claims for 123 members. There was a decrease of 11 claims and 8 members from the previous quarter.
- Vemlidy is down to number 4 with 52 claims for 24 members. There was a decrease of 3 claims for 24 members from the previous quarter. This medication is managed via the Hepatitis B MRG, which requires trial and failure of, intolerance to, or reason not to use, entecavir.
- Skyrizi is up at number 6 with 3 claims for 3 members. There was an increase of 1 claim and one additional member from the previous quarter. The medication is managed via the Specialty Biologic Agents MRG.

Rank	DDID	Label Name	Claims	Unique Members	Total Cost
1	201625	Biktarvy Oral Tablet 50-200-25 MG	39	15	$158,335.42
2	218338	Ozempic (2 MG/DOSE) Subcutaneous Solution Pen-injector 8 MG/3ML	93	39	$88,569.11
3	221271	Ozempic (0.25 or 0.5 MG/DOSE) Subcutaneous Solution Pen-injector 2 MG/3ML	93	48	$87,976.61
4	195609	Vemlidy Oral Tablet 25 MG	52	24	$86,844.11
5	209911	Ozempic (1 MG/DOSE) Subcutaneous Solution Pen-injector 4 MG/3ML	81	36	$76,542.06
6	214809	Skyrizi Pen Subcutaneous Solution Auto-injector 150 MG/ML	3	3	$66,001.08
7	199758	Verzenio Oral Tablet 100 MG	4	1	$62,963.00
8	206142	Kisqali (600 MG Dose) Oral Tablet Therapy Pack 200 MG	3	1	$57,542.10
9	177191	Eliquis Oral Tablet 5 MG	87	35	$49,249.76
10	189014	Tolvaptan Oral Tablet Therapy Pack 45 & 15 MG	3	1	$48,825.00
11	182336	Farxiga Oral Tablet 10 MG	79	41	$44,287.86
12	215133	Wegovy Subcutaneous Solution Auto-injector 2.4 MG/0.75ML	34	12	$44,241.75
13	198848	Nerlynx Oral Tablet 40 MG	4	1	$38,549.60
14	223809	Cosentyx UnoReady Subcutaneous Solution Auto-injector 300 MG/2ML	5	2	$38,247.08

Rank	DDID	Label Name	Claims	Unique Members	Total Cost
15	219459	Paxlovid (300/100) Oral Tablet Therapy Pack 20 x 150 MG & 10 x 100MG	24	24	$34,660.08
16	190802	Genvoya Oral Tablet 150-150-200-10 MG	8	4	$32,549.70
17	207961	Rybelsus Oral Tablet 7 MG	33	18	$31,233.95
18	193035	Ocaliva Oral Tablet 10 MG	3	1	$29,150.22
19	184849	Jardiance Oral Tablet 25 MG	50	22	$28,743.60
20	207962	Rybelsus Oral Tablet 14 MG	30	12	$28,327.16
21	186088	Ofev Oral Capsule 150 MG	2	1	$28,192.24
22	212379	Cabenuva Intramuscular Suspension Extended Release 600 & 900 MG/3ML	4	2	$26,748.65
23	120500	Dasatinib Oral Tablet 20 MG	3	1	$25,937.43
24	229071	Mounjaro Subcutaneous Solution Auto-injector 2.5 MG/0.5ML	24	13	$24,588.23
25	218613	Camzyos Oral Capsule 5 MG	3	1	$23,841.51
26	226896	Cimzia (2 Syringe) Subcutaneous Prefilled Syringe Kit 200 MG/ML	4	1	$23,697.76
27	201117	Steglatro Oral Tablet 15 MG	71	28	$23,478.29
28	197146	Cosentyx Sensoready (300 MG) Subcutaneous Solution Auto-injector 150 MG/ML	3	1	$22,482.39
29	192096	Odefsey Oral Tablet 200-25-25 MG	6	2	$22,089.90
30	219135	Skyrizi Subcutaneous Solution Cartridge 360 MG/2.4ML	1	1	$21,995.36
31	229072	Mounjaro Subcutaneous Solution Auto-injector 5 MG/0.5ML	21	12	$21,531.30
32	216252	Invega Hafyera Intramuscular Suspension Prefilled Syringe 1560 MG/5ML	1	1	$19,511.09
33	215136	Wegovy Subcutaneous Solution Auto-injector 1.7 MG/0.75ML	15	7	$19,456.95
34	122702	Januvia Oral Tablet 100 MG	64	29	$19,433.48

Rank	DDID	Label Name	Claims	Unique Members	Total Cost
35	225121	Zepbound Subcutaneous Solution Auto-injector 10 MG/0.5ML	18	9	$18,635.12
36	215132	Wegovy Subcutaneous Solution Auto-injector 1 MG/0.5ML	14	11	$18,114.56
37	182335	Farxiga Oral Tablet 5 MG	32	15	$18,037.92
38	215134	Wegovy Subcutaneous Solution Auto-injector 0.5 MG/0.5ML	13	8	$16,846.22
39	229078	Mounjaro Subcutaneous Solution Auto-injector 7.5 MG/0.5ML	15	9	$15,345.42
40	184045	Erlotinib HCl Oral Tablet 25 MG	2	1	$15,145.12
41	204204	Shingrix Intramuscular Suspension Reconstituted 50 MCG/0.5ML	61	55	$14,529.78
42	205122	Actemra ACTPen Subcutaneous Solution Auto-injector 162 MG/0.9ML	3	1	$14,334.66
43	189098	Entresto Oral Tablet 24-26 MG	23	11	$13,555.31
44	127437	FreeStyle Lite Test In Vitro Strip	173	108	$12,769.96
45	229075	Mounjaro Subcutaneous Solution Auto-injector 12.5 MG/0.5ML	12	5	$12,528.14
46	225120	Zepbound Subcutaneous Solution Auto-injector 7.5 MG/0.5ML	12	9	$12,432.51
47	225062	Xphozah Oral Tablet 30 MG	4	2	$12,164.08
48	229056	Dupixent Subcutaneous Solution Auto-injector 300 MG/2ML	3	2	$11,815.26
49	227898	Adbry Subcutaneous Solution Auto-injector 300 MG/2ML	3	1	$11,734.86
50	217569	Adbry Subcutaneous Solution Prefilled Syringe 150 MG/ML	3	1	$11,698.26
TOTAL			**1,341**	**688**	**$1,685,511.01**

Medi-Cal Top 50 Drugs by Cost for 3rd Quarter 2025

- The top 50 drugs accounted for 31,791 claims for 27,189 members and cost $66,059,008 which is an increase of $3,108,517 spend and 1721 members (25,468) from 2Q2025.
- MCAL membership April 404,947 vs July 405,754
- Compare 31,791 claims vs 29,741 claims in 2Q2025
- Biktarvy roughly stable utilization 907 vs 928 claims 2Q2025.
- Jardiance both strengths also roughly stable.
- Large increase in Skyrizi utilization from 119/110 to 143/131 over 2Q2025
- Wegovy with 17% increase from 1183 to 1383 claims since 2Q2025
- GLP1 for weight loss will be discontinued by Medi-Cal Rx starting 1/1/2026
- Impact will be Wegovy, Zepbound, Saxenda: 5401 members in 100 days ending 11/25/2025
- Dupixent from 221 claims to 286 (29% increase)
-

Rank	GCN	Label Name	Claims	Unique Members	Total Cost
1	44426	BIKTARVY 50-200-25 MG TABLET	907	753	$6,965,030.04
2	49591	SKYRIZI 150 MG/ML PEN	143	131	$3,448,605.96
3	36723	JARDIANCE 25 MG TABLET	2316	2104	$3,160,672.09
4	36716	JARDIANCE 10 MG TABLET	2227	2011	$2,896,711.01
5	49754	WEGOVY 2.4 MG/0.75 ML PEN	1383	998	$2,847,660.28
6	53536	OZEMPIC 0.25-0.5 MG/DOSE PEN	1924	1505	$2,380,466.34
7	52125	OZEMPIC 2 MG/DOSE (8 MG/3 ML)	1278	980	$2,059,380.44
8	48277	DUPIXENT 300 MG/2 ML PEN	286	223	$1,996,532.70
9	49752	WEGOVY 1 MG/0.5 ML PEN	1127	914	$1,875,269.14
10	48208	OZEMPIC 1 MG/DOSE (4 MG/3 ML)	1252	999	$1,865,853.31
11	49749	WEGOVY 0.5 MG/0.5 ML PEN	1172	984	$1,780,534.63
12	43506	HUMIRA(CF) PEN 40 MG/0.4 ML	136	108	$1,717,118.88
13	49748	WEGOVY 0.25 MG/0.5 ML PEN	1133	1020	$1,667,068.50
14	49099	CABENUVA ER 600 MG-900 MG SUSP	206	177	$1,586,758.34

Rank	GCN	Label Name	Claims	Unique Members	Total Cost
15	49753	WEGOVY 1.7 MG/0.75 ML PEN	941	721	$1,546,702.26
16	27418	INVEGA SUSTENNA 234 MG/1.5 ML	244	175	$1,522,595.92
17	42624	VEMLIDY 25 MG TABLET	472	388	$1,516,076.13
18	33935	ELIQUIS 5 MG TABLET	1202	981	$1,327,502.27
19	34394	FARXIGA 10 MG TABLET	823	724	$1,153,955.97
20	54988	ZEPBOUND 2.5 MG/0.5 ML PEN	830	723	$1,039,655.17
21	54989	ZEPBOUND 5 MG/0.5 ML PEN	787	635	$1,038,416.19
22	47136	TRIKAFTA 100-50-75 MG/150 MG	19	15	$1,036,984.27
23	94200	DEXCOM G7 SENSOR	848	732	$969,180.45
24	40953	DESCOVY 200-25 MG TABLET	281	228	$949,684.57
25	49468	COSENTYX UNOREADY 300 MG PEN	47	36	$941,363.38
26	49487	APRETUDE ER 600 MG/3 ML VIAL	174	153	$892,581.96
27	97724	ENBREL 50 MG/ML SURECLICK	69	60	$881,901.49
28	46966	RYBELSUS 14 MG TABLET	399	355	$876,459.90
29	51742	PAXLOVID 300-100 MG DOSE PACK	606	600	$866,437.62
30	54456	FERRIPROX 1,000 MG TAB(2X/DAY)	14	11	$830,590.90
31	40133	TAGRISSO 80 MG TABLET	26	20	$829,340.69
32	46965	RYBELSUS 7 MG TABLET	428	378	$822,687.30
33	54991	ZEPBOUND 7.5 MG/0.5 ML PEN	551	450	$792,862.33
34	28159	STELARA 90 MG/ML SYRINGE	27	22	$777,266.34
35	44014	HUMIRA(CF) PEN 80 MG/0.8 ML	22	18	$763,491.96

Rank	GCN	Label Name	Claims	Unique Members	Total Cost
36	43968	SYMTUZA 800-150-200-10 MG TAB	91	78	$751,613.90
37	25200	FREESTYLE LITE TEST STRIP	4331	4149	$737,373.44
38	38702	INVEGA TRINZA 819 MG/2.63 ML	63	61	$684,827.93
39	98637	BASAGLAR 100 UNIT/ML KWIKPEN	1435	1200	$679,851.74
40	97400	JANUVIA 100 MG TABLET	802	739	$651,494.78
41	37682	ABILIFY MAINTENA ER 400 MG SYR	124	92	$630,983.55
42	54992	ZEPBOUND 10 MG/0.5 ML PEN	368	301	$528,469.95
43	43699	MAVYRET 100-40 MG TABLET	30	30	$518,497.96
44	40092	GENVOYA TABLET	60	53	$510,303.83
45	43148	ILARIS 150 MG/ML VIAL	6	6	$507,423.67
46	46822	RINVOQ ER 15 MG TABLET	36	30	$454,179.35
47	43114	ELOCTATE 6,000 UNIT NOMINAL	4	1	$454,151.51
48	37633	ODEFSEY TABLET	59	50	$444,539.18
49	43222	DUPIXENT 300 MG/2 ML SYRINGE	63	56	$442,535.57
50	43167	KISQALI 600 MG DAILY DOSE	19	11	$439,363.44
TOTAL			**31,791**	**27,189**	**$66,059,008.53**

636 IHSS Top 50 PA Requests by Volume for the 3rd Quarter 2025

- Top 50 PA requests = 278. There were 399 total PA requests for quarter 3.
  - 71 requests (26%) were approved. This approval rate is the same as it was observed last quarter.
  - 207 requests (74%) were denied or partially approved.
- Wegovy is at numbers 1, 6, 8, 10 and 12 with 59 total requests and 13 approvals (22%).
  - 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.
- Zepbound is at numbers 2, 9, 15 & 35 with 40 total requests and 8 approvals (20%).
  - Zepbound to reduce excess body weight requires a diagnosis of class III/severe obesity (BMI ≥40) and trial and failure or inability to use Qsymia and Contrave.
  - Zepbound for moderate to severe obstructive sleep apnea requires trial and failure regarding lifestyle changes and behavioral modifications to reach BMI <30 kg/m^2 and trial and failure or inability to use PAP therapy.
- Lidocaine 5% patch is at number 3 with 25 requests and 4 approvals (16%).
  - Lidocaine requires a diagnosis of neuropathic pain and a trial and failure of gabapentin or pregabalin and one other formulary alternative (e.g., duloxetine, venlafaxine, amitriptyline) used for neuropathic pain or morphine MME ≧ 50/day for 3 months.
- Jardiance is at numbers 4 & 5 with 31 total requests and 8 approvals (26%).
  - 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 number 7 with 8 requests. There were 4 approvals (50%).
  - Mounjaro requires trial and failure of a metformin containing product.

RANK	DRUGS	Total	Approved		Denied		Partially Approved	
1	WEGOVY Soln Auto-inj 0.25MG/0.5ML	30	7	23.33%	23	76.67%	0	0.00%
2	ZEPBOUND Soln Auto-inj 2.5MG/0.5ML	26	4	15.38%	22	84.62%	0	0.00%

RANK	DRUGS	Total	Approved		Denied		Partially Approved	
3	LIDOCAINE Patch 5%	25	4	16.00%	20	80.00%	1	4.00%
4	JARDIANCE Tablet 25MG	17	6	35.29%	6	35.29%	5	29.41%
5	JARDIANCE Tablet 10MG	14	2	14.29%	12	85.71%	0	0.00%
6	WEGOVY Soln Auto-inj 1MG/0.5ML	10	2	20.00%	7	70.00%	1	10.00%
7	MOUNJARO Soln Auto-inj 2.5MG/0.5ML	8	4	50.00%	4	50.00%	0	0.00%
8	WEGOVY Soln Auto-inj 2.4MG/0.75ML	7	2	28.57%	3	42.86%	2	28.57%
9	ZEPBOUND Soln Auto-inj 5MG/0.5ML	7	1	14.29%	6	85.71%	0	0.00%
10	WEGOVY Soln Auto-inj 0.5MG/0.5ML	6	0	0.00%	4	66.67%	2	33.33%
11	VEMLIDY Tablet 25MG	6	3	50.00%	0	0.00%	3	50.00%
12	WEGOVY Soln Auto-inj 1.7MG/0.75ML	6	2	33.33%	4	66.67%	0	0.00%
13	OXYCODONE HCL Tablet 5MG	5	4	80.00%	1	20.00%	0	0.00%
14	TRETINOIN Cream 0.05%	5	3	60.00%	2	40.00%	0	0.00%
15	ZEPBOUND Soln Auto-inj 10MG/0.5ML	4	2	50.00%	1	25.00%	1	25.00%
16	XIFAXAN Tablet 550MG	4	2	50.00%	1	25.00%	1	25.00%
17	PHENTERMINE HCL Capsule 15MG	4	3	75.00%	1	25.00%	0	0.00%
18	PHENTERMINE-TOPIRAMATE ER Capsule ER 24HR 3.75;23MG	4	0	0.00%	3	75.00%	1	25.00%
19	XPHOZAH Tablet 20MG	4	0	0.00%	3	75.00%	1	25.00%
20	TRELEGY ELLIPTA Aero Pow Br Act 100;62.5;25MCG/ACT	4	0	0.00%	4	100.00%	0	0.00%
21	CYCLOSPORINE Emulsion 0.05%	4	1	25.00%	3	75.00%	0	0.00%
22	ICOSAPENT ETHYL Capsule 1GM	4	0	0.00%	4	100.00%	0	0.00%
23	TRETINOIN Cream 0.1%	4	2	50.00%	1	25.00%	1	25.00%
24	OPZELURA Cream 1.5%	4	0	0.00%	4	100.00%	0	0.00%
25	TRANEXAMIC ACID Tablet 650MG	3	0	0.00%	3	100.00%	0	0.00%
26	JANUVIA Tablet 100MG	3	0	0.00%	1	33.33%	2	66.67%
27	DUPIXENT Soln Auto-inj 300MG/2ML	3	0	0.00%	0	0.00%	3	100.00 %
28	ZTLIDO Patch 1.8%	3	0	0.00%	3	100.00%	0	0.00%
29	LINZESS Capsule 72MCG	3	2	66.67%	1	33.33%	0	0.00%
30	BUPRENORPHINE HCL-NALOXONE HCL Film 8;2MG	3	3	100.00%	0	0.00%	0	0.00%
31	DEXLANSOPRAZOLE Capsule DR 60MG	3	0	0.00%	3	100.00%	0	0.00%
32	OFEV Capsule 150MG	3	0	0.00%	2	66.67%	1	33.33%
33	VEOZAH Tablet 45MG	3	0	0.00%	2	66.67%	1	33.33%
34	ZORYVE Cream 0.15%	3	0	0.00%	3	100.00%	0	0.00%
35	ZEPBOUND Soln Auto-inj 15MG/0.5ML	3	1	33.33%	2	66.67%	0	0.00%
36	RAMELTEON Tablet 8MG	3	1	33.33%	1	33.33%	1	33.33%
37	REPATHA SURECLICK Soln Auto-inj 140MG/ML	3	1	33.33%	1	33.33%	1	33.33%

RANK	DRUGS	Total	Approved		Denied		Partially Approved	
38	TRETINOIN Cream 0.025%	3	1	33.33%	2	66.67%	0	0.00%
39	XIIDRA Solution 5%	2	0	0.00%	0	0.00%	2	100.00 %
40	SEMGLEE (YFGN) Soln Pen-inj 100UNIT/ML	2	2	100.00%	0	0.00%	0	0.00%
41	MESALAMINE Tablet DR 1.2GM	2	1	50.00%	1	50.00%	0	0.00%
42	TACROLIMUS Ointment 0.1%	2	1	50.00%	0	0.00%	1	50.00%
43	AZELAIC ACID Gel 15%	2	2	100.00%	0	0.00%	0	0.00%
44	CEQUA Solution 0.09%	2	1	50.00%	1	50.00%	0	0.00%
45	BREZTRI AEROSPHERE Aerosol 160;9;4.8MCG/ACT	2	0	0.00%	2	100.00%	0	0.00%
46	AFREZZA Powder 90 x 4 UNIT &90x8 UNIT	2	0	0.00%	2	100.00%	0	0.00%
47	LUBIPROSTONE Capsule 24MCG	2	1	50.00%	1	50.00%	0	0.00%
48	LUMIGAN Solution 0.01%	2	0	0.00%	2	100.00%	0	0.00%
49	CONTRAVE Tablet ER 12HR 8;90MG	2	0	0.00%	1	50.00%	1	50.00%
50	OZEMPIC (1 MG/DOSE) Soln Pen-inj 4MG/3ML	2	0	0.00%	1	50.00%	1	50.00%
TOTAL		**278**	**71**	**26%**	**174**	**62%**	**33**	**12%**

Medi-Cal Top 50 Prior Authorization Requests by Volume for 3rd Quarter 2025

- The top 50 PA requests = 3,173
- #1 most requested item is Freestyle Libre CGM
- #3 Dexcom G7 Sensor is also CGM item
- #4 Opzelura is a surprise; reformulation of oral Jakafi (ruxolitinib) for atopic dermatitis
- Wegovy, Zepbound, and Ozempic are in top 10 – I predict volume will shift to Ozempic bc it does not have weight-loss indication
- Sildenafil – ED indication, obviously very low 1.4% approval rate
- Tadalafil – PAH indication so approval rate is higher at 10.4%
- Estradiol valerate, Xcopri, Dupixent Pen, Sacubitril/valsartan have top 4 approval rates
- Ozempic has third-lowest approval rate at 24.1%

Rank	Drug Name	Total	Approved		Denied	
1	FREESTYLE LIBRE 3 PLUS SENSOR	305	233	76.4%	72	23.6%
2	WEGOVY	208	134	64.4%	74	35.6%
3	DEXCOM G7 SENSOR	143	115	80.4%	28	19.6%
4	OPZELURA	135	119	88.1%	16	11.9%
5	FREESTYLE LIBRE 2 PLUS SENSOR	113	97	85.8%	16	14.2%
6	ZEPBOUND	111	78	70.3%	33	29.7%
7	ALPRAZOLAM	95	71	74.7%	24	25.3%
8	OMNIPOD 5 DEXG7G6 PODS (GEN 5)	87	80	92.0%	7	8.0%
9	FREESTYLE LIBRE 3 READER	85	58	68.2%	27	31.8%
10	OZEMPIC	83	20	24.1%	63	75.9%
11	AZELAIC ACID	78	51	65.4%	27	34.6%
12	FREESTYLE LIBRE 2 SENSOR	74	40	54.1%	34	45.9%
13	SILDENAFIL CITRATE	70	1	1.4%	69	98.6%
14	OXYCODONE HCL	69	63	91.3%	6	8.7%

Rank	Drug Name	Total	Approved		Denied	
15	TADALAFIL	67	7	10.4%	60	89.6%
16	FREESTYLE LIBRE 3 SENSOR	66	49	74.2%	17	25.8%
17	SACUBITRIL-VALSARTAN	66	62	93.9%	4	6.1%
18	TESTOSTERONE	66	47	71.2%	19	28.8%
19	XIFAXAN	66	56	84.8%	10	15.2%
20	DUPIXENT PEN	62	60	96.8%	2	3.2%
21	DEXCOM G7 RECEIVER	61	45	73.8%	16	26.2%
22	SCOPOLAMINE	49	35	71.4%	14	28.6%
23	SKYRIZI PEN	48	41	85.4%	7	14.6%
24	BELBUCA	45	29	64.4%	16	35.6%
25	NOVASOURCE RENAL 2 CAL	43	37	86.0%	6	14.0%
26	MOUNJARO	41	14	34.1%	27	65.9%
27	PHENTERMINE HCL	41	35	85.4%	6	14.6%
28	ENTRESTO	40	28	70.0%	12	30.0%
29	ENSURE ORIGINAL	39	33	84.6%	6	15.4%
30	PIMECROLIMUS	39	22	56.4%	17	43.6%
31	REZDIFFRA	39	19	48.7%	20	51.3%
32	SANTYL	39	35	89.7%	4	10.3%
33	TERBINAFINE	39	22	56.4%	17	43.6%
34	VTAMA	39	11	28.2%	28	71.8%
35	MOMETASONE FUROATE	37	20	54.1%	17	45.9%

Rank	Drug Name	Total	Approved		Denied	
36	FREESTYLE LIBRE 2 READER	35	26	74.3%	9	25.7%
37	METRONIDAZOLE	35	20	57.1%	15	42.9%
38	LORAZEPAM	34	29	85.3%	5	14.7%
39	NORETHINDRONE ACETATE	34	19	55.9%	15	44.1%
40	TRELEGY ELLIPTA	34	25	73.5%	9	26.5%
41	ESTRADIOL VALERATE	33	33	100.0%	0	0.0%
42	NEMLUVIO	33	28	84.8%	5	15.2%
43	OXYCONTIN	33	31	93.9%	2	6.1%
44	DOXEPIN HCL	32	17	53.1%	15	46.9%
45	HYDROCODONE-ACETAMINOPHEN	31	24	77.4%	7	22.6%
46	VRAYLAR	31	21	67.7%	10	32.3%
47	CARISOPRODOL	30	10	33.3%	20	66.7%
48	FINASTERIDE	30	8	26.7%	22	73.3%
49	OMNIPOD 5 DEXG7G6 INTRO(GEN 5)	30	25	83.3%	5	16.7%
50	XCOPRI	30	30	100.0%	0	0.0%
TOTAL		**3,173**	**2,213**	**68.5%**	**960**	**31.5%**

Diagnostic Agents, Blood Glucose Test Strips

Executive Summary

Class Overview

This review includes diagnostic test strips for blood glucose. Blood glucose test strips are primarily used in patient self-management of diabetes to guide the need for glucose or insulin therapy. Blood glucose trends can also be used by providers to guide changes to treatment regimens. All products contained within this review are classified as devices and available over-the-counter. The American Diabetes Association Standards of Medical Care in Diabetes has been updated for 2025. It is worth noting that while continuous glucose monitoring (CGM) devices are more commonly available and used, there remains a need for testing with test strips, even for patients who use CGM devices, for calibration and to confirm readings discordant with symptoms.

Utilization Findings

There were 178 claims for 110 members, for a total cost of $16,501.26 and an average cost per claim of $92.70. The most highly utilized were Freestyle Lite test strips with 175 claims, followed by Precision Xtra test strips with 3 claims. There were no prior authorization requests.

Recommendations

- No changes

Clinical Summary

This review includes diagnostic test strips for blood glucose. Blood glucose test strips are primarily used in patient self-management of diabetes to guide the need for glucose or insulin therapy. Blood glucose trends can also be used by providers to guide changes to treatment regimens. All products contained within this review are classified as devices and available over-the-counter. The American Diabetes Association Standards of Medical Care in Diabetes has been updated for 2025. It is worth noting that while CGM devices are more commonly available and used, there remains a need for testing with test strips, even for patients who use CGM devices, for calibration and to confirm readings discordant with symptoms.

Practice Guidelines

American Diabetes Association Professional Practice Committee. 6. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes-2025. Diabetes Care. 2025 Jan 1;48(1 Suppl 1):S128-S145.

Statement on Glycemic Assessment by Blood Glucose Monitoring (BGM)

- For many people with diabetes, glucose monitoring, either using BGM by capillary (finger-stick) devices or CGM in addition to regular A1C testing, is key for achieving glycemic goals.
- Major clinical trials of insulin-treated individuals have included BGM as part of multifactorial interventions to demonstrate the benefit of intensive glycemic control on diabetes complications.
- An integral component of effective therapy for individuals taking insulin is BGM; people with diabetes should be provided with BGM devices as indicated by their circumstances, preferences, and treatment.

Recommendations for CGM

- In recent years, CGM has become a standard method for glucose monitoring for most people with type 1 diabetes; both approaches to glucose monitoring allow people with diabetes to evaluate individual responses to therapy and assess whether glycemic goals are being safely achieved.
- The specific needs and goals of individuals with diabetes should dictate BGM frequency and timing and people using CGM devices must also have access to BGM at all times. A
- People who are taking insulin and using BGM should be encouraged to check their blood glucose levels when appropriate based on their insulin therapy which may include checking when fasting, prior to meals and snacks, after meals, at bedtime, in the middle of the night, prior to, during, and after exercise, when hypoglycemia is suspected, after treating low blood glucose levels until they are normoglycemic, when hyperglycemia is suspected, and prior to and while performing critical tasks such as driving. B
- Health care professionals should be aware of the differences in accuracy among blood glucose meters; only meters approved by the U.S. Food and Drug Administration (FDA) (or comparable regulatory agencies for other geographical locations) with proven accuracy should be used, with unexpired test strips purchased from a pharmacy or licensed distributor and properly stored. E
- Although BGM in people on noninsulin therapies has not consistently shown clinically significant reductions in A1C levels, it may be helpful when altering meal plans, physical activity plans, and/or medications (particularly medications that can cause hypoglycemia) in conjunction with a treatment adjustment program. E
- Health care professionals should be aware of medications and other factors that can interfere with glucose meter accuracy and provide clinical management as indicated. E

Recommendation Definitions

Class/Level	Definition
A	Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including • Evidence from a well-conducted multicenter trial • Evidence from a meta-analysis that incorporated quality ratings in the analysis Compelling nonexperimental evidence, i.e., "all or none" rule developed by the Centre for Evidence-Based Medicine at the University of Oxford Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including • Evidence from a well-conducted trial at one or more institutions Evidence from a meta-analysis that incorporated quality ratings in the analysis
B	Supportive evidence from well-conducted cohort studies • Evidence from a well-conducted prospective cohort study or registry • Evidence from a well-conducted meta-analysis of cohort studies Supportive evidence from a well-conducted case-control study
C	Supportive evidence from poorly controlled or uncontrolled studies • Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results • Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls) • Evidence from case series or case reports Conflicting evidence with the weight of evidence supporting the recommendation
E	Expert consensus or clinical experience

Formulary Placement, Utilization and Cost Experience (07-01-2025 to 09-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Accu-Chek Aviva Plus Test Strp	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Accu-Chek Guide Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Accu-Chek Smartview Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Accutrend Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Advance Micro-Draw Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Advance Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Cvs Advanced Glucose Test Str	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Advocate Redi-Code Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Advocate Redi-Code+ Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Advocate Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Agamatrix Amp Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Assure 3 Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Assure 4 Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Assure Ii Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Assure Platinum Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Assure Prism Multi Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Assure Pro Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Bioscanner Glucose Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Gs Blood Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Blulink Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Caresens N Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Caretouch Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Clever Choice Micro Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Clever Choice Pro Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Clever Choice Talk Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Clever Choice Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Clever Choice Voice+ Tst Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change

Contour Next Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Contour Plus Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Contour Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Cool Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Diatrue Plus Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Duo-Care Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easy Plus Ii Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easy Pro Plus Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easy Step Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easy Talk Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easy Talk Plus Ii Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easy Touch Blulink Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easy Touch Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easy Trak Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easy Trak Ii Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easygluco Plus Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easygluco Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easymax Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easymax 15 Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Easypro Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Element Compact Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Element Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Embrace Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Embrace Evo Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Embrace Pro Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Embrace Talk Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Evencare Glucose Tst Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Evencare G2 Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Evencare G3 Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Evencare Mini Glucose Test Str	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Evencare Proview Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Evolution Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Exactech Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Exactech Rsg Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change

Fifty50 Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora 6 Connect Glucose Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora 6conn-Gtel-Tn'g Adv Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora D15g Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora D20 Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora D40-G31 Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora G20 Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora G30-Premium V10 Test Strp	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora Gd50 Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora Gtel Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora Blood Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora Tn'g Advan Pro Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora Tn'g Voice Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora V10 Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora V10-V12-D10-D20 Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora V12 Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fora V20 Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Foracare Gd20 Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Foracare Gd40 Glucose Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fortiscare G1 Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Fortiscare Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Freestyle Insulinx Strip Nfrs	0	0	$0.00	$0.00	0	0 (0%)	F-QL (200/30)	No change
Freestyle Lite Test Strip Nfrs	175	109	$16,090.08	$91.94	0	0 (0%)	F-QL (200/30)	No change
Freestyle Prec Neo Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Freestyle Test Strips	0	0	$0.00	$0.00	0	0 (0%)	F-QL (200/30)	No change
Ge100 Blood Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Ge333 Blood Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Gluco Navii Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Glucocard 01 Sensor Plus Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Glucocard Expression Test Strp	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Glucocard Shine Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Glucocard Vital Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change

Glucocard X-Sensor Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Glucocom Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Blood Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Gojji Blood Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Harmony Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Healthpro Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Iglucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Ihealth Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Infinity Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Infinity Voice Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Keynote Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Liberty Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Relion Micro Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Microdot Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Myglucohealth Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Neutek 2tek Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Nova Max Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
On Call Express Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Onetouch Ultra Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Onetouch Verio Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Optium Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Optium Ez Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Pharmacist Choice Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Pip Blood Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Pocketchem Ez Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Precision Pcx Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Precision Pcx Plus Test Str	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Precision Point Of Care Str	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Precision Q-I-D Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Precision Sof-Tact Test Str	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Precision Xtra Test Strips	3	1	$411.18	$137.06	0	0 (0%)	F-QL (200/30)	No change
Relion Premier Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Premium Blood Glucose Tst Strp	0	0	$0.00	$0.00	0	0 (0%)	NF	No change

Premium V10 Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Pro Voice V8-V9 Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Prodigy No Coding Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Pts Panels Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Quicktek Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Quintet Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Quintet Ac Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Refuah Plus Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Relion Prime Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Rightest Gs100 Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Rightest Gs300 Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Rightest Gs550 Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Rightest Gt333 Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Smart Sense Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Smartest Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Solus V2 Audible Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Supreme Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Sure Edge Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Sure-Test Easyplus Mini Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Surechek Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Telcare Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Test N'go Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Pharmacist Choice Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
True Metrix Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
True Metrix Pro Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Truetest Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Truetrack Glucose Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Relion Ultima Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Ultratrak Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Ultratrak Ultimate Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Unistrip1 Glucose Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Verasens Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Vivaguard Ino Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change

Vocal Point Test Strip	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Wavesense Jazz Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Wavesense Presto Test Strips	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
TOTAL	**178**	**110**	**$16,501.26**	**$92.70**	**0**	**0 (0%)**		

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

Prior Authorization Criteria

No changes

Blood Glucose Testing Supplies	
Therapeutic Classes (AHFS)	Diabetes mellitus
Medications	Formulary with quantity limits: Members over 21 years on a prenatal vitamin or insulin are allowed 200 strips/30 days, other members allowed 100 strips/30days. Members 0-21 years on a prenatal vitamin are allowed 200 strips/30 days. All other members 0-21, bill CCS **(Check AAH active CCS cases for members < 21 years of age)** FreeStyle InsuLinx Test Strips- 100ct FreeStyle InsuLinx Test Strips- 50ct FreeStyle Lite Test Strips- 100ct FreeStyle Lite Test Strips- 50ct FreeStyle Test Strips- 100ct FreeStyle Test Strips- 50ct Precision Xtra Test Strips- 100ct Precision Xtra Test Strips- 50ct Formulary, limited to 1 meter per 365 days FreeStyle Freedom Lite Meter FreeStyle InsuLinx Meter FreeStyle Lite Meter Precision Xtra Meter ALAMEDA ALLIANCE FOR HEALTH PREFERS USE OF PRECISION OR FREESTYLE BLOOD GLUCOSE TESTING PRODUCTS (MANUFACTURED BY ABBOTT).
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 for members who are not pregnant
Prescriber Restrictions	N/A
Coverage Duration	See "PA Review Criteria". If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	For requests for **Precision or Freestyle preferred test strips**, approve up to 200 strips/30 days for up to 12 months if: • Member is > 21 years of age AND insulin dependent (claims evidence for insulin or documentation from physician if new to plan) OR • Member is any age AND pregnant • For requests for a non-preferred product, documentation or inability to use preferred test strips must be provided. Please consider the preferred alternatives, Precision or Freestyle test strips (with quantity limits). For requests for **Precision or Freestyle preferred test strips**, approve up to a quantity of 100 strips/30 days for up to 12 months if: • Member is > 21 years of age AND no documentation of insulin-dependence or pregnancy

Blood Glucose Testing Supplies	
	• For requests for a non-preferred product, documentation or inability to use preferred test strips must be provided. Please consider the preferred alternatives, Precision or Freestyle test strips (with quantity limits). If member is 0-21 years of age AND no documentation of pregnancy, do not approve. Member is covered by CCS. Check AAH active CCS cases for members < 21 years of age For requests for **Freestyle or Precision Blood Glucose meters**: • Member is allowed 1 meter per year • If request is for a non-preferred product, documentation or inability to use preferred test strips must be provided. Please consider the preferred alternative Freestyle or Precision meters (within fill limits).
Criteria Statement	Freestyle and Precision test strips over a quantity of 100 strips for 30 days are reserved for members who are over 21 years old and insulin dependent OR for members of any age who are pregnant.
Last P&T Review Date	~~12/2024~~12/2025

References

1. American Diabetes Association Professional Practice Committee. 6. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes-2025. Diabetes Care. 2025 Jan 1;48(1 Suppl 1):S128-S145.

Multivitamins (abbreviated) Drug List Review

Utilization Findings

There were 11 claims for 6 members, for a total cost of $3.24, and an average cost per claim of $0.29. The most highly utilized medication was multivitamin tablet with 6 claims, followed by one-daily multi-vitamin tablet with 4 claims. There were no prior authorization requests.

Recommendations

- No changes

PERFORMRx℠

Formulary Placement, Utilization and Cost Experience (07-01-2025 to 09-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Multiple Vitamin Cap								
Chlorocaps Capsule	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Ze-Plus Softgel	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Zeldana 159 mg Capsule	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Dekas Essential Capsule	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Mv-One Oral Capsule	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Antioxidant Formula Oral Capsule 250-10000-200	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Nutra-Z+ Oral Capsule	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Viteyes Classic Zinc Free Oral Capsule	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Novite Oral Capsule	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Multiple Vitamin Tab								
Stresstabs Energy Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Folcyteine Caplet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Altrixa Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Amladex Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Adult One Daily Multivit Tab	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Daily Multivitamin With D3 Tab	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Omnicap Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
One Daily Essential Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
One Daily Essentials Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Vitalee Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Daily Multiple Vitamin Tab	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Daily Value Multivitamin Tab	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Daily Vitamin Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Daily Vitamin Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Daily Vite Tablet	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Daily Vite Tablet	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Multiple Vitamins Tablet	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Multiple Vitamin Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change

Multivitamin Tablet	6	3	$1.80	$0.30	0	0 (0%)	F	No change
Multivitamins Tablet	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Once Daily Tablet	0	0	$0.00	$0.00	0	0 (0%)	F	No change
One Daily Essential Tablet	0	0	$0.00	$0.00	0	0 (0%)	F	No change
One Daily Multivitamin Tab	0	0	$0.00	$0.00	0	0 (0%)	F	No change
One-Daily Multi-Vitamin Tab	4	2	$1.14	$0.29	0	0 (0%)	F	No change
Daily-Vite Tablet	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Daily-Vite Tablet	1	1	$0.30	$0.30	0	0 (0%)	F	No change
High Potency Multivitamin Tab	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
One Daily Multivitamin Tablet	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Onevite Daily Multivitamin Tab	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Quintabs Tablet	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Tab-A-Vite Tablet	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Tab-A-Vite Tablet	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Thera Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Therems Multivitamin Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Tm-Daily Vite Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
True Multivitamin Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Stress Formula Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Thera-Tabs Caplet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Hair, Skin and Nails Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Stress Formula/Zinc/Energy Oral Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Multivitamin Iron-Free Oral Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
One Daily Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Multiple Vitamin-Folic Acid Oral Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Estrofactors Oral Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
QC Essentials Oral Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Neomultivite Oral Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
True Daily Vite Oral Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Anti-Oxidant Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
E-400 C-500 & Beta Caro Tab	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Multiple Vitamin Tab ER								
Daily Stress Relief Tab	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Multiple Vitamin Chew Tab								
Davimet-M Chewable Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Dermacinrx Davimet Chew Tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Multiple Vitamin Liquid								

Wellesse Mult Vitamin Plus Liq	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
DEKAs Essential Liquid	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Dialyvite 800 Oral Liquid	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Mommy's Bliss Mv Organic Drops Oral Liquid	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Multiple Vitamin IV Emulsion								
Vitlipid N Adult Ampule	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Multiple Vitamin IV Solution								
Infuvite Adult Vial	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
TOTAL	**11**	**6**	**$3.24**	**$0.29**	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

Topical Antivirals

Executive Summary

Class Overview

Antiviral agents are medication therapies that demonstrate inhibitory activity against host cells infected with viral DNA or RNA. Each antiviral class has unique activity that involves inhibiting viral DNA synthesis through selective inhibition. Mutations may occur in viral DNA or RNA, viral thymidine kinase, or viral DNA polymerase genes, leading to resistance to these agents. Human papillomavirus (HPV) is responsible for anogenital warts as well as some cervical cancers. Although not considered antiviral agents, topical immunomodulators like imiquimod (Aldara®) and sinecatechins (Veregen®) exhibit antiviral activity against HPV. Imiquimod increases the activity of the patient's own immune system to attack genital warts caused by HPV while sinecatechins' mechanism is unknown but may involve anti-oxidative activity.

Herpes simplex virus (HSV) is responsible for both genital herpes and herpes labialis ("cold sores"). Antiviral therapy can shorten the duration of signs and symptoms of herpes infection and reduce the likelihood of viral shedding but cannot cure the infection. In cells infected with HSV, antivirals inhibit viral DNA synthesis, and topical formulations of acyclovir and penciclovir are available. Primary infection with Varicella Zoster Virus (VZV), a herpesvirus, results in varicella, or chickenpox, characterized by vesicular lesions on the face, trunk, and extremities. Herpes zoster, or shingles, is characterized by painful, unilateral vesicular eruptions resulting from the reactivation of latent VZV infection within the sensory ganglia. It occurs primarily in adults over 60 years of age and can lead to severe pain and postherpetic neuralgia. The herpes zoster vaccines (Zostavax®, Shingrix®) may be used as prophylaxis, however antiviral treatment with acyclovir (Zovirax®), penciclovir (Denavir®), and docosanol (Abreva®) may be used as treatment to reduce the duration of an outbreak. This review will primarily focus on topical antiviral therapies indicated for the treatment of HPV and HSV.

Utilization Findings

There were no claims and no prior authorization requests.

Recommendations

- No changes

Clinical Summary

External anogenital warts (condyloma acuminate) are nonmalignant squamous cell tumors caused by sexual transmission of human papillomavirus (HPV) types 6 and 11. This disease affects approximately 1% of sexually active adults in the United States and Europe with 1 million new cases diagnosed every year. Although not life-threatening and usually asymptomatic, anogenital warts can cause substantial discomfort, pain, social discomfort, and problems with sexual intercourse depending on the size and location. Current topical therapies include self-administered podofilox, imiquimod, sinecatechins, and interferon. The majority of genital warts are cleared by a course of medical therapy, and no treatment is significantly superior to another or appropriate for all patients and all types of warts.

Immune-mediated therapies initiate a local immune response on site and may immediately clear lesions. Imiquimod (Aldara®, Zyclara®) is an immunomodulator used to treat external genital and perianal warts, actinic keratosis, and squamous cell carcinoma. It is a toll-like receptor 7 agonist that causes powerful cytokine induction, stimulating the production of interferon-alpha, tumor necrosis factor, and interleukins-1, 6, and 8. The precise mechanism of action is unknown. Imiquimod is also used off-label for acyclovir resistant herpes simplex virus infection and common warts. Its application and dosage is dependent on the disease being treated.

Veregen® (sinecatechins 15% ointment) is an immunomodulator used to treat external genital and perianal warts. It is composed of a standardized extract of green tea leaves from Camellia sinensis containing tea polyphenols, more than 85% of which are catechins. Sinecatechins ointment contains the most biologically active catechin, called (-)-epigallocatechin gallate. Green tea catechins exhibit potent antiviral and antioxidant activity by binding certain enzymes involved in the generation of inflammatory mediators, proteases promoting tumor invasion, and kinases needed in tumor cell signaling. They also promote cell cycle modification and induce apoptosis. These immune-stimulatory, anti-oxidative, antiviral, and antitumor properties are thought to contribute to the therapeutic effect of sinecatechins ointment, but the exact mechanism is unknown. Veregen® is a topical ointment applied three times daily to all external genital and perianal warts until all warts have been cleared and can be used for a maximum of 16 weeks.

Herpes simplex virus (HSV) is a common infection affecting millions of Americans and is characterized by a type 1 (HSV-1) or type two (HSV-2) infection (2015-2016 prevalence was 47.8% for HSV-1 and 11.9% for HSV-2). HSV-1 or herpes labialis may result in vesicular lesions affecting the oral mucosa, commonly referred to as “cold sores,” while HSV-2 is most commonly associated with genital herpes. HSV-1, however, may also lead to clinical disease in the genitalia, liver, lungs, eyes, and central nervous system. An HSV outbreak is considered “primary” if the patient was HSV-seronegative for HSV-1 and HSV-2 before the occurrence of genital lesions. Nonprimary episode infection refers to HSV-2 infection in patients with preexisting HSV-1 immunity and often presents with less severe infection. Along with painful genital lesions, genital HSV infection is associated with fever, malaise, headache, and dysuria lasting two to four weeks if left untreated. Primary infection with Varicella Zoster Virus (VZV), a herpesvirus, results in varicella, or chickenpox, characterized by vesicular lesions on the face, trunk, and extremities. Herpes zoster, or shingles, is characterized by painful, unilateral vesicular eruptions resulting from the reactivation of latent VZV infection within the sensory ganglia. It occurs primarily in adults over 60 years of age and can lead to severe pain and postherpetic neuralgia.

Antiviral therapy can shorten the duration of signs and symptoms of herpes or varicella infection and reduce the likelihood of viral shedding. Current treatment strategies are based on frequency of disease, the severity of symptoms, and the patient's level of concern about transmitting HSV to an uninfected partner. While general approach includes both episodic and suppressive therapy, topical therapy does not have a role in general due to lack of efficacy compared to oral and no effect on reduction of new lesion therapy. It is also not recommended as an add-on therapy. However, agents do remain available and may be chosen based on patient preference despite having minimal clinical benefit.

Acyclovir (Zorivax®) 5% cream/ointment is a synthetic HSV nucleoside analogue DNA polymerase inhibitor used to treat recurrent herpes labilalis (cold sores) in immunocompetent adults and adolescents 12 years and older. The inhibitory activity of acyclovir is highly selective due to its affinity for the enzyme thymidine kinase (TK) encoded by HSV. This viral enzyme converts acyclovir into acyclovir monophosphate, a nucleotide analogue. The monophosphate is further converted into diphosphate by cellular guanylate kinase and into triphosphate by a number of cellular enzymes. In cell culture, acyclovir triphosphate stops replication of herpes viral DNA. This inhibition is accomplished in 3 ways: 1) competitive inhibition of viral DNA polymerase, 2) incorporation into and termination of the growing viral DNA chain, and 3) inactivation of the viral DNA polymerase. Acyclovir is applied five times daily for four days to all lesions including the outer edge.

Penciclovir (Denavir®) 1% cream is a nucleoside analog HSV DNA polymerase inhibitor indicated for the treatment of recurrent herpes labialis (cold sores) in adults and children 12 years of age or older. In cells infected with HSV-1 or HSV-2, the viral thymidine kinase phosphorylates penciclovir to a monophosphate form that, in turn, is converted by cellular kinases to the active form penciclovir triphosphate. Penciclovir triphosphate inhibits HSV polymerase competitively with deoxyguanosine triphosphate. Consequently, herpes viral DNA synthesis and, therefore, replication are selectively inhibited. Denavir® is applied every 2 hours during waking hours for a period of 4 days. Treatment should be started as early as possible (i.e., during the prodrome or when lesions appears).

Docosanol (Abreva®) 10% cream is a non-prescription product indicated for the treatment of acute episodes of recurrent oral-facial herpes simplex (fever blister or cold sores) in adults. It works by inhibiting the fusion between plasma membrane and the HSV envelope which blocks viral entry into the cell and subsequent viral replication. Docosanol is applied topically 5 times daily and continued until the lesion is healed up to a maximum of 10 days. Treatment is most effective if applied at the first symptoms (pain, itching, burning or tingling) or sign (redness), prior to the formation of a papule or a blister.

Xerese® (acyclovir 5% and hydrocortisone 1% cream) is a combination of a nucleoside analog DNA polymerase inhibitor and a corticosteroid, indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time in adults and children (6 years of age and older). Acyclovir mechanism of action is similar to above-mentioned. Hydrocortisone is the main glucocorticoid secreted by the adrenal cortex. It is used topically for its anti-inflammatory effects which suppress the manifestations of the disease in a wide range of disorders where inflammation is prominent.

Indications, Dosing and Administration

Medication	Indications	Dosing/Administration
Human Papilloma Virus		
Imiquimod (Aldara®) 5% cream packet	• External genital and perianal warts/condyloma acuminata in patients 12 years or older	• **External genital and perianal warts:** Apply thin layer 3 times per week until total clearance or for a maximum of 16 weeks
Zyclara® (imiquimod) 2.5% cream pump Imiquimod (Zylcara®) 3.75% cream pump Imiquimod (Zyclara®) 3.75% cream		• **External genital and perianal warts:** Apply thin layer (up to 0.25 grams as one packet or one full actuation) once a day until total clearance or for up to 8 weeks • **HSV infection, acyclovir-resistant (off-label):** Apply once daily for 5 consecutive days
Veregen® (sinecatechins) 15% ointment	• External genital and perianal warts *(Condylomata acuminata)* in immunocompetent patients 18 years and older	• Apply a thin layer (~0.5 cm strand) 3 times daily to all warts until clearance or for a maximum of 16 weeks
Herpes Simplex Virus		
Xerese® (acyclovir-hydrocortisone) 5%-1% cream	• Recurrent herpes labialis (cold sores) in adults and children (6 years of age and older)	• Apply 5 times a day for 5 days
Acyclovir (Zovirax®) 5% ointment	• Initial genital herpes and in limited non-life-threatening mucocutaneous Herpes simplex virus infections in immunocompromised patients	• Apply ½ inch ribbon for a 4 inch square surface area every 3 hours (6 times daily) for 7 days
Acyclovir (Zovirax®) 5% cream	• Recurrent herpes labialis (cold sores) in immunocompetent adults and adolescents 12 years and older	• Apply 5 times a day for 4 days
Penciclovir (Denavir®) 1% cream	• Recurrent herpes labialis (cold sores) in adults and children 12 years of age and older	• Apply at first sign or symptom of cold sore or appearance of lesion every 2 hours during waking hours for 4 days
Docosanol (Abreva®) 10% cream		• Apply to affected area of face or lips 5 times daily at first sign of cold sore and continue until healed (maximum 10 days)

Boxed Warnings and Contraindications

Medication	Boxed Warnings	Contraindications
Human Papilloma Virus		
Imiquimod (Aldara®) cream packet Zyclara® (imiquimod) cream pump Imiquimod (Zyclara®) cream pump Imiquimod (Zyclara®) cream Veregen® (sinecatechins) ointment	None.	None.
Herpes Simplex Virus		
Xerese® (acyclovir-hydrocortisone) cream	None.	None.
Acyclovir (Zovirax®) ointment Acyclovir (Zovirax®) cream	None.	None.
Penciclovir (Denavir®) cream	None.	• Hypersensitivity to penciclovir or any component of the formulation
Docosanol (Abreva®) cream	None.	• Hypersensitivity to docosanol or any component of the formulation

Warnings/Precautions

Medication	Warnings/Precautions
Human Papilloma Virus (HPV)	
Imiquimod (Aldara®) cream packet Zyclara® (imiquimod) cream pump Imiquimod (Zyclara®) cream pump Imiquimod (Zyclara®) cream	**Concerns related to adverse effects:** • Intense local inflammatory reactions including skin weeping or erosion may occur accompanied by systemic symptoms including fever, malaise, and myalgia. May exacerbate inflammatory conditions of the skin including chronic graft-versus-host disease. • May increase the potential for photosensitivity • Flu-like symptoms including arthralgias, chills, fatigue, fever, malaise, myalgias, nausea, and rigors may accompany local inflammatory reactions. • Severe local inflammation of female external genitalia following topical application may lead to severe vulvar swelling and urinary retention. **Disease related concerns:** • Safety and efficacy in immunosuppressed patients have not been established. • Imiquimod has not been evaluated for the treatment of urethral, intravaginal, cervical, rectal, or intra-anal HPV disease **Dosage forms specific issues:** • Some dosage forms contain benzyl alcohol which has been associated with potentially fatal toxicity ("gasping syndrome") in neonates **Other warnings/precautions:** • Not intended for oral, nasal, intravaginal, or ophthalmic use
Veregen® (Sinecatechins) ointment	**Concerns related to adverse effects:** • Local skin reactions are common and include erythema, erosion, edema, itching, and burning; women may be at increased risk **Disease-related concerns:** • Not intended for the treatment of urethral, intravaginal, cervical, rectal, or intra-anal HPV disease **Special populations:** • Safety and efficacy have not been established in immunosuppressed patients **Other warnings/precautions:** • For topical use only • Continue treatment until all warts have been cleared for a maximum of 16 weeks; safety and efficacy > 16 weeks have not been established
Herpes Simplex Virus (HSV)	
Xerese® (acyclovir-hydrocortisone) cream Acyclovir (Zovirax®) ointment Acyclovir (Zovirax®) cream	**Concerns related to adverse effects:** • Cream may be irritating and cause contact sensitization **Disease related concerns:** • Treatment should be with the first signs or symptoms. For genital herpes, physical contact should be avoided when lesions are present but transmission may also occur in the absence of symptoms. There is no data to support use for the prevention of transmission of infection or prevent recurrent infections if no symptoms are present. **Special populations:**

Medication	Warnings/Precautions
	• Use and safety has not been studied in immunocompromised patients **Dosage form specific issues:** • Some products may contain milk protein concentrate
Penciclovir (Denavir®) cream	**Special populations:** • The effect of penciclovir has not been established in immunocompromised patients **Other warnings/precautions:** • Should only be used on herpes labialis on the lips and face due to lack of data
Docosanol (Abreva®) cream	**Concerns related to adverse effects:** • Severe allergic reactions including hives, facial swelling, wheezing/difficulty breathing, rash, and shock may occur with use **Dosage form specific issues:** • Some dosage forms contain benzyl alcohol which has been associated with potentially fatal toxicity ("gasping syndrome") in neonates **Other warnings/precautions:** • For external use only; apply at first sign or symptoms

Practice Guidelines

CDC 2021 Sexually Transmitted Diseases Treatment Guidelines
Centers for Disease Control and Prevention. (2021). Human Papilloma Virus (HPV) Infection. Retrieved from https://www.cdc.gov/std/treatment-guidelines/anogenital-warts.htm
Human Papillomavirus (HPV) Infection – Anogenital warts

- Aim of treatment of anogenital warts is the removal of the warts and amelioration of symptoms
- Treatment results in the resolution of warts in most patients
- If left untreated, warts can resolve spontaneously, remain unchanged, or increase in size or number; however, spontaneous resolution may occur in one year
- Treatment of anogenital warts is guided by wart size, number, site, patient preference, cost of treatment, adverse effects, and provider experience
- Some clinicians employ combination therapy but there is limited evidence regarding the safety and efficacy of this type of treatment regimen
- The recommended regimens for treatment of anogenital warts are:
    - Imiquimod 5% cream should be applied once at bedtime, 3 times/week for up to 16 weeks
    - Imiquimod 3.75% cream should be applied once at bedtime every night for up to 8 weeks
    - Podofilox should be applied to anogenital warts 2 times/day for 3 day, followed by 4 days of no therapy; repeat as needed up to 4 cycles
    - Sinecatechins 15% ointment should be applied 3 times/day with a thin layer until complete clearance of warts is achieved; do not continue for >16 weeks
- Podofilox and sinecatechins should not be used during pregnancy

Centers for Disease Control and Prevention. (2021). Genital HSV Infections. Retrieved from https://www.cdc.gov/std/treatment-guidelines/herpes.htm.
Herpes Simplex Virus (HSV) – Genital herpes

- Goals for use of antiviral medications are to prevent symptomatic genital herpes recurrences and improve quality of life
- All individuals with the first clinical episode of genital herpes should receive antiviral therapy
- Treatment can be extended if healing is incomplete after 10 days of therapy
- Topical therapy with antiviral drugs offers minimal clinical benefit and is not recommended

The American College of Obstetricians and Gynecologists. (2020). Management of Genital Herpes in Pregnancy. Retrieved from https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/05/management-of-genital-herpes-in-pregnancy
Herpes Simplex Virus (HSV) – Genital herpes

- Primary genital herpes infection during pregnancy constitutes a higher risk of perinatal transmission than does recurrent infection
- Antiviral therapy should be administered orally to pregnant women at the time of initial outbreak to reduce the duration and severity of symptoms as well as duration of viral shedding
- Topical antiviral therapy has not been shown to be of benefit and therefore not recommended

Clinical Trials/Systematic Reviews/Meta-Analyses

Citation	Design	Endpoints
Rosen T, Nelson A, Ault K. Imiquimod cream 2.5% and 3.75% applied once daily to treat external genital warts in men. Cutis. 2015; 96(4):277-82.	Inclusion Criteria: Patients age 12 and older with 2 to 30 external genital warts and a total wart area of 150mm^2 or greater. Two multicenter, randomized, double-blind, placebo-controlled studies: 447 male subjects received imiquimod cream 3.75%, 2.5%, or placebo once daily until complete clearance or a maximum of 8 weeks, followed by an 8 week follow-up in patients who did not achieve clearance, and a 12-week observational follow-up period for those achieving clearance to assess recurrence.	• Primary efficacy endpoint was complete clearance rate. • Secondary efficacy endpoints included wart count from baseline to the end of study, percentage change in wart count, and median time to complete clearance. Safety was also assessed.
Results: In both studies, complete clearance rates were significantly higher with imiquimod cream 3.75% compared to placebo at weeks 10-16. In study 2, complete clearance rates were significantly higher with imiquimod cream 2.5% compared to placebo from week 14-16. The proportion of male participants with at least a 75% reduction in wart count was statistically superior in the imiquimod cream 3.75% and 2.5% compared to placebo. The percentage change in wart count was statistically significant in the imiquimod cream 3.75% group in both studies but only statistically significant for imiquimod cream 2.5% in one study. The median time to complete clearance was shorter in the active treatment groups compared to placebo but not statistically significant. Less than one-third of male participants experienced adverse events and those that did had generally mild local skin reactions. **Conclusion**: Imiquimod 2.5% and 3.75% cream is safe and exhibited dose-dependent efficacy for complete clearance, percentage change in wart count, and time to complete clearance of anogenital warts.		
Citation	**Design**	**Endpoints**
Hull CM, Harmenberg J, Arlander E, Aoki F, Bring J, Darpö B, Levin MJ, Tyring S, Spruance SL; ME-609 Study Group. Early treatment of cold sores with topical ME-609 decreases the frequency of ulcerative lesions: a randomized, double-blind, placebo-controlled, patient-initiated clinical trial. J Am	Inclusion criteria: male and female patients 18 years or older in good health who experience HSL symptoms at least 3 times per year. Participants had to have experienced prodromal symptoms 50% of the time, ulcerative lesions progressed through the vesicle and crust stages 75% of the time. Randomized, double-blind, placebo-controlled trial: 1443 participants were randomized to receive ME-609 (Xerese), acyclovir in ME-609, or the placebo and instructed to apply five times daily for five days at the first sight of recurrent herpes labialis	• Primary endpoint was the prevention of ulcerative herpes labialis lesions

Acad Dermatol. 2011 Apr;64(4):696.e1-11. doi: 10.1016/j.jaad.2010.08.012.		
Results: 42% of participants receiving ME-609 did not develop ulcerative lesions compared to 35% of participants treated with acyclovir in ME-609 (P = .014) and 26% of participants receiving the placebo (P<0.0001). The duration of healing time was reduced in participants receiving ME-609 and acyclovir in ME-609 when compared to the participants receiving the placebo (P<0.01 for both). The cumulative lesion area was significantly reduced by 50% in participants receiving ME-609 treatment compared to the placebo (P<0.0001) and the adverse events were similar among all treatments. **Conclusion**: ME-609 significantly decreased the occurrence of ulcerative lesions from cold sores and significantly reduced the cumulative lesion area when compared with the treatment of acyclovir and the placebo.		
Citation	**Design**	**Endpoints**
Tatti S, et al. Obstetrics & Gynecology. 2008; 111 (6):1371-1379.	Inclusion criteria: Male and female patients aged 18 years and older with 2 to 30 anogenital warts ranging from 21-600 mm^2 total wart area. Multicenter, randomized, double-blind, vehicle-controlled trial: 502 subjects applied sinecatechins ointment 15%, 10%, or vehicle three times daily for a maximum of 16 weeks or until complete clearance of all warts, followed by a 12-week treatment-free follow-up to assess recurrence.	• The primary endpoint was the percentage of subjects with complete clearance of all external anogenital warts. • Secondary endpoints included the percentage reduction in size of wart from baseline, local tolerability, and adverse events.
Results: Of the 495 patients treated, 57.2% in the sinecatechins ointment 15% group, 56.3% of patients in the sinecatechins ointment 10% group, and 33.7% of patients in the vehicle group achieved complete clearance of all external anogenital warts (p<0.001). Partial clearance rates of at least 50% were reported for 78.4% and 74% of patients in the sinecatechins ointment 15% and 10% compared to 51.5% in the vehicle group. Superiority of sinecatechins ointment 15% and 10% to vehicle was shown at week 4 and 6, respectively, and then at all subsequent visits. Wart recurrence did not show a statistically significant difference between active and vehicle groups. **Conclusion**: Sinecatechins 10% and 5% ointment is safe and effectively cleared anogenital warts in about 55% of patients, achieved partial clearance in about 75% of patients by week 4-6 of treatment but did not improve recurrence rates.		
Citation	**Design**	**Endpoints**
Stockfleth E, Beti H, Orasan R, et al. Topical Polyphenon E in the treatment of external genital and	Inclusion criteria: Male and female patients aged 18 and older with 2 to 30 anogenital warts with a total wart area of 12-600mm^2.	• Primary endpoint was the percentage of subjects with complete clearance of all external anogenital warts

perianal warts: a randomized controlled trial. British Journal of Dermatology. 2008; 158: 1329-1338.	Multicenter, randomized, double-blind, three-arm parallel-group, vehicle-controlled trial: 503 subjects applied sinecatechins ointment 15%, 10%, or vehicle three times daily until complete clearance of all anogenital warts or for up to 16 weeks, followed by a 12-week treatment-free follow-up period for patients with complete clearance.	• Secondary endpoints included complete clearance of baseline warts, total wart number, total wart area, partial clearance, and recurrent and new warts.
Results: About 53% of patients treated with sinecatechins 15% ointment, 51% of patients treated with sinecatechins 10% ointment, and 37% of patients in the vehicle group showed complete clearance of all baseline and new anogenital warts (p=0.01 and 0.03 respectively). Women (60%) responded better than men (45%) in both active groups achieving complete clearance. Time to complete clearance was comparable for both strengths of ointment. About 78% of all patients treated with either strength of sinecatechins showed wart clearance rates of 50% or better. Less than 6% and 4% of patients in sinecatechins 15% and 10%, respectively, experienced wart recurrence during follow-up. The majority of adverse events were mild to moderate local application site reactions. **Conclusion:** Sinecatechins 10% and 15% ointment is safe and effectively cleared anogenital warts in about half of participants, produced wart clearance rates of 50% or better in 78% of patients, and reduced wart recurrence in about 95% of patients with complete clearance.		
Citation	**Design**	**Endpoints**
Spruance SL, Nett R, Marbury T, Wolff R, Johnson J, Spaulding T. Acyclovir cream for treatment of herpes simplex labialis: results of two randomized, double-blind, vehicle-controlled, multicenter clinical trials. Antimicrob Agents Chemother. 2002 Jul;46(7):2238-43. doi: 10.1128	Inclusion criteria: male and female patients 18 years and over in good general health with recurrent episodes of herpes labialis (≥3 episodes in past year) with a history of prodromal symptoms and lesions from greater than 50% of episodes. Two independent, identical, parallel, randomized, double-blind trials: 324 patients received acyclovir and 346 patients received vehicle cream (placebo) in study 1, and 328 patients received acyclovir and 343 patients received vehicle cream (placebo) in study 2. Patients were advised to apply cream 5times daily for 4 days	• Primary endpoint included the duration of the herpes labialis episode. • Secondary endpoint included the duration of pain associated with the virus and the formation of lesions
Results: In both studies, acyclovir cream demonstrated statistically significant efficacy on the duration of herpes labialis episodes as well as on the duration of pain associated with the virus. Study 1 showed the duration of the episodes were reduced by 0.5 days (10%; *P* = 0.007), and in Study 2 the episode duration had a reduction of 0.6 days (12%; *P* = 0.006)**.** Study 1 demonstrated a 0.3-day reduction in lesion pain (9%; *P* = 0.017), and in Study 2 lesion pain was reduced by 0.4 days (11%; *P* = 0.014). **Conclusion**: Both studies concluded that there was a statistically significant reduction in the duration in duration of herpes labialis episodes and duration of lesion pain. However, there was no significant results to determine that acyclovir cream prevents the formation of herpes labialis lesions.		
Citation	**Design**	**Endpoints**

Raborn GW, Martel AY, Lassonde M, Lewis MA, Boon R, Spruance SL; Worldwide Topical Penciclovir Collaborative Study Group. Effective treatment of herpes simplex labialis with penciclovir cream: combined results of two trials. J Am Dent Assoc. 2002 Mar;133(3):303-9. doi: 10.14219	inclusion criteria: male and female immunocompetent participants with a history of recurrent herpes simplex labialis or HSL (> 3 episodes per year) that resulted in classical lesions. Two randomized, double-blind, parallel group clinical trials: 3,057 participants applied 1% penciclovir cream or the vehicle control cream (placebo) six times per day during the first day and then every two hours while awake during the next four consecutive days.	• Primary endpoint was efficacy of the topical 1% penciclovir cream in the healing of lesions and pain compared to the placebo
Results: the combined data from both trials indicated that participants treated with penciclovir cream lost lesions 31% faster than participants being treated with the placebo cream (hazard ratio, or HR, = 1.31; 95 percent confidence interval, or CI, 1.20 to 1.42; P = .0001) and penciclovir treated participants also experienced a 28% faster resolution of lesion pain (HR = 1.28; 95 percent CI, 1.17 to 1.39; P = .0001). Also, benefits were seen with penciclovir whether treatment was initiated early (P= 0.001) or later (P=0.0055). **Conclusion:** Penciclovir cream has demonstrated significant efficacy in the healing of classical lesions and resolution of pain associated with recurrent herpes simplex labialis compared to the placebo.		

Formulary Placement, Utilization and Cost Experience (07-01-2025 to 09-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	**Rx**	**Mbrs**	**Total**	**Avg/Rx**	**Total**	**Approved (%)**	**Current**	**Recommend**
Human Papilloma Virus								
Imiquimod (Aldara®) 5% cream packet	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Zyclara® (imiquimod) 2.5% cream pump	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Imiquimod (Zyclara®) 3.75% cream pump	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Imiquimod (Zyclara®) 3.75% cream	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Veregen® (sinecatechins) 15% ointment	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Herpes Simplex Virus								
Xerese® (acyclovir-hydrocortisone) 5%-1% cream	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Acyclovir (Zovirax®) 5% ointment	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Acyclovir (Zovirax®) 5% cream	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Penciclovir (Denavir®) 1% cream	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Docosanol (Abreva®) 10% cream	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
TOTAL	**0**	**0**	**$0.00**	**$0.00**	**0**	**0 (0%)**		

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

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3. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed on July 23, 2025.
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5. Centers for Disease Control and Prevention. (2021). Human Papilloma Virus (HPV) Infection. Available at https://www.cdc.gov/std/treatment-guidelines/anogenital-warts.htm.
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Urinary Tract Antispasmodics

Executive Summary

Class Overview

Overactive bladder (OAB), which may occur with or without incontinence, and urinary incontinence (UI), are underdiagnosed and undertreated and can significantly impact quality of life. Urinary incontinence, in particular, is associated with increased rates of depression and altered activities of daily living as a coping mechanism. Urinary tract antispasmodics are used in the treatment of OAB and urge urinary incontinence (UUI) in both men and women, adults and children. Antispasmodic agents can be categorized by mechanism of action into two types: antimuscarinics and β-3 agonists. Antimuscarinics act by antagonizing the effects of acetylcholine on muscarinic receptors reducing smooth muscle tone, increasing bladder capacity and decreasing detrusor overactivity. Antimuscarinics include oxybutynin (Oxytrol®, Gelnique®), darifenacin, fesoterodine (Toviaz®), solifenacin (Vesicare®), tolterodine (Detrol®/Detrol® LA), trospium and flavoxate. The marketed β-3 agonists Gemtesa® (vibegron) and mirabegron (Myrbetriq®) act by activating β-3 adrenergic receptors in the bladder thereby relaxing the detrusor smooth muscle and increasing bladder capacity. Due to anticholinergic properties, antimuscarinics tend to have more side effects compared to β-3 agonists; this is a factor to be considered when selecting an appropriate therapeutic agent.

Various United States guidelines are available for the treatment of OAB/urge incontinence, most directed toward the treatment in women. Notably, the American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) published updated guidelines pertaining to treatment of idiopathic OAB in 2024. This guideline eliminated the concept of "step therapy," and instead emphasized the importance of shared decision-making to select the best therapy or therapies, regardless of invasiveness, based on the patient's needs, desires, and side effect tolerance. The American College of Physicians (ACP) published Nonsurgical Management of Urinary Incontinence in Women: A Clinical Practice Guideline from the American College of Physicians in 2014. Annals of Internal Medicine International guidelines pertaining to the treatment of UI, pelvic organ prolapse (POP), and fecal incontinence were published by the Sixth International Consultation on Incontinence Recommendations of the International Scientific Committee in 2018 and put forth recommendations for both non-neurogenic and neurogenic UI. Specific guideline recommendations are presented later in this review.

Utilization Findings

There were 54 claims for 37 members, for a total cost of $4,134.64 and an average cost per claim of $76.57. The most highly utilized medication was oxybutynin tablet with 21 claims, followed by mirabegron tablet with 10 claims. There were 4 prior authorization requests with 2 approvals (50%).

Recommendations

- No changes

Clinical Summary

OAB, which may occur with or without incontinence, and UI, are underdiagnosed and undertreated and can significantly impact quality of life. A clinical diagnosis of OAB, as defined by the International Continence Society, includes “urinary urgency, usually accompanied by frequency and nocturia, with or without urinary incontinence, in the absence of urinary tract infection or other obvious pathology. Because diagnosis of OAB is based on symptom assessment, the quality of life impact of OAB is a critical component in seeking treatment. Urinary incontinence, in particular, is associated with increased rates of depression and altered activities of daily living as a coping mechanism. In population-based studies, the prevalence of OAB ranges from 7% to 27% in men and 9% to 43% in women, with symptoms of OAB worsening with age. UUI is consistently more common in women than men. Risk factors for OAB include age over 40 years, current smoking, obesity, diabetes, and prior vaginal delivery.

Urinary tract antispasmodics are used in the treatment of OAB and urinary urge incontinence in both men and women, adults and children. Antispasmodic agents can be categorized by mechanism of action into two types: antimuscarinics and β-3 agonists. Antimuscarinics act by antagonizing the effects of acetylcholine on muscarinic receptors reducing smooth muscle tone, increasing bladder capacity and decreasing detrusor overactivity. Antimuscarinics include oxybutynin (Oxytrol®, Gelnique®), darifenacin, fesoterodine (Toviaz®), solifenacin (Vesicare®), tolterodine (Detrol®/Detrol® LA), trospium and flavoxate. The marketed β-3 agonists Gemtesa® (vibegron) and mirabegron (Myrbetriq®) act by activating β-3 adrenergic receptors in the bladder thereby relaxing the detrusor smooth muscle and increasing bladder capacity. Due to anticholinergic properties, antimuscarinics tend to have more side effects compared to β-3 agonists; this is a factor to be considered when selecting an appropriate therapeutic agent. There are no drugs to treat OAB or UI in the pipeline and slated for approval in the coming year.

Indications, Dosing and Administration

Medication	Indications	Dosing/Administration
Oxybutynin (Gelnique®, Oxytrol®)	OAB with symptoms of urinary urge incontinence, urgency, frequency, urinary leakage, dysuria	Oral: – Immediate release (IR): 5 mg 2 to 3 times daily, adjust dose as needed in 5 mg increments every 2 weeks; max dose: 5 mg 4 times daily – Extended release (ER): 5 to 10 mg once daily, adjust dose as needed in 5 mg increments at weekly intervals; max dose: 30 mg once daily Topical gel: 1 sachet (100 mg/g) once daily Transdermal (TDS): One patch (3.9 mg) twice weekly (every 3 to 4 days); change on the same 2 days each week OTC labeling (*Oxytrol®* only): One patch (3.9 mg) every 4 days
	OAB symptoms due to a neurological condition (e.g., spina bifida) in patients ≥ 6 years (*ER tablets* only)	
Fesoterodine (Toviaz®)	OAB with symptoms of urinary urge incontinence, urgency, or frequency	4 mg orally once daily; may increase to max dose of 8 mg once daily based on response/tolerability
	Neurogenic detrusor overactivity (NDO) in pediatric patients ≥ 6 years of age and weighing > 25 kg	– Patients > 25 kg to ≤ 35 kg: 4 mg orally once daily; may increase to 8 mg once daily based on response/tolerability – Patients > 35 kg: 4 mg orally once daily; after 1 week increase to 8 mg once daily; max dose: 8 mg/day
Tolterodine (Detrol®, Detrol® LA)	OAB with symptoms of urinary urge incontinence, urgency, or frequency	IR: 1 mg orally twice daily; may increase to 2 mg twice daily after 2 to 6 weeks based on response and tolerability ER: 2 mg orally once daily; may increase to 4 mg once daily after 2 to 6 weeks based on response and tolerability
Darifenacin		7.5 mg orally once daily, may be increased to 15 mg once daily after a minimum of 2 weeks
Trospium		IR: 20 mg orally twice daily ER: 60 mg orally once daily in the morning
Flavoxate	Symptomatic relief of dysuria, nocturia, suprapubic pain, urgency, frequency, and incontinence in patients with cystitis, urethritis, urethrocystitis, urethrotrigonitis, and prostatitis	100 to 200 mg orally 3 to 4 times daily; reduce the dose when symptoms improve

Medication	Indications	Dosing/Administration
Solifenacin (Vesicare®, Vesicare LS™)	OAB with symptoms of urinary urge incontinence, urgency, or frequency (*Vesicare*® only)	5 mg orally once daily, may increase to 10 mg once daily
	NDO in pediatric patients ≥ 2 years of age (*Vesicare LS*™ only)	– 9 to 15 kg: 2 mg orally once daily, may titrate every 3 weeks to lowest effective dose; max dose: 4 mg/day – 15 kg to 30 kg: 3 mg orally once daily, may titrate every 3 weeks to lowest effective dose; max dose: 5 mg/day – 30 kg to 45 kg: 3 mg orally once daily, may titrate every 3 weeks to lowest effective dose; max dose: 6 mg/day – 45 kg to 60 kg: 4 mg orally once daily, may titrate every 3 weeks to lowest effective dose; max dose: 8 mg/day – > 60 kg: 5 mg orally once daily, may titrate every 3 weeks to lowest effective dose; max dose: 10 mg/day
Myrbetriq® (mirabegron)	OAB in adults with symptoms of UI, urgency, or frequency, as monotherapy or in combination with an antimuscarinic agent *(tablets* only)	25 mg orally once daily, may increase to 50 mg once daily after 4 to 8 weeks based on response/tolerability
	NDO in pediatric patients ≥ 3 years of age	Tablets (≥35 kg only): 25 mg orally once daily; after 4 to 8 weeks, the dose may be increased to 50 mg orally once daily Granules: 3 ml (24 mg) to 6 ml (48 mg) orally once daily depending on patient weight; after 4 to 8 weeks, the dose may be increased if needed up to a max dose of 10 ml (80 mg) once daily
Gemtesa® (vibegron)	OAB in adults with symptoms of urge UI, urgency, and frequency	75 mg orally once daily
	OAB in adult males on pharmacological therapy for benign prostatic hyperplasia (BPH) with symptoms of urge UI, urgency, and frequency	

Boxed Warnings and Contraindications

Medication	Boxed Warnings	Contraindications
Oxybutynin (Gelnique®, Oxytrol®)	None	Hypersensitivity to oxybutynin or any component of the formulation; patients with or at risk for uncontrolled narrow-angle glaucoma, urinary retention, gastric retention, or conditions with severely decreased GI motility OTC labeling (*Oxytrol®* only): Do not use in the following settings – if experiencing symptoms of urinary tract infection (UTI) such as dysuria, fever or chills, hematuria, unexplained lower back or side pain, pyuria, or foul-smelling urine – in male patients – < 18 years of age – stress incontinence – urinary, gastric retention – glaucoma – hypersensitivity to oxybutynin
Fesoterodine (Toviaz®) Tolterodine (Detrol®, Detrol® LA) Darifenacin Trospium Solifenacin (Vesicare®, Vesicare LS™)		Hypersensitivity to the active ingredient or any component of the formulation; patients with or at risk for uncontrolled narrow-angle glaucoma, urinary retention, or gastric retention *Tolterodine and fesoterodine* only*:* Hypersensitivity to either drug (both are metabolized to 5-hydroxymethyl tolterodine [HMT]) *Trospium ER* only: severe renal impairment (CrCl < 30 mL/min)
Flavoxate		Pyloric or duodenal obstruction; gastrointestinal hemorrhage; obstructive intestinal lesions; ileus; achalasia; obstructive uropathies of lower urinary tract (e.g., benign prostatic hypertrophy [BPH])
Myrbetriq® (mirabegron)		Hypersensitivity to the active ingredient or any component of the formulation
Gemtesa® (vibegron)		

Warnings/Precautions

Medication	Warnings/Precautions
Oxybutynin (Gelnique®, Oxytrol®) Fesoterodine (Toviaz®) Tolterodine (Detrol®, Detrol® LA) Darifenacin Trospium Solifenacin (Vesicare®, Vesicare LS™)	Concerns related to adverse effects: – Angioedema: Of the face, lips, tongue, and/or larynx has been reported – CNS effects: Anticholinergic effects may impair physical or mental abilities – Cognitive impairment: Anticholinergic agents may increase risk of cognitive adverse effects – Heat prostration: May occur in the presence of increased environmental temperature – Hypersensitivity reactions: Anaphylactic reactions have been reported rarely; may be life-threatening (*solifenacin* only) – QT prolongation: Caution in patients with a history of QT prolongation or those receiving QT interval prolonging medications (*tolterodine* and *solifenacin* only); prolongation may be more likely in CYP2D6 poor metabolizers or in the presence of inhibitors of CYP2D6 and CYP3A4 (*tolterodine* only) Disease-related concerns: – Alzheimer disease (AD): Anticholinergics may adversely affect the clinical course of AD in patients receiving cholinesterase inhibitors – Bladder outlet obstruction (BOO): Increased risk of urinary retention in patients with BOO – GI obstructive disorders: Increased risk of gastric retention in patients with decreased GI motility or gastrointestinal obstructive disorders – Glaucoma: May exacerbate angle-closure glaucoma – Myasthenia gravis: May exacerbate condition – *Oxybutynin* only ○ Hiatal hernia: Use with caution ○ Hyperthyroidism: May exacerbate hyperthyroidism ○ Parkinson disease: May aggravate symptoms ○ Caution due to limited experience in hepatic/renal impairment – *Tolterodine* only: Dose adjustment required in hepatic/renal impairment – *Fesoterodine* only: Not recommended in severe hepatic impairment; dose adjust in severe renal impairment (CrCl <30 mL/min) – *Darifenacin* only: Dose adjust in moderate hepatic impairment, not recommended in severe hepatic impairment – *Trospium* only: Caution in moderate or severe hepatic impairment; dose adjust IR formulation in renal impairment; use caution in patients with ulcerative colitis due to decreased GI motility – *Solifenacin* only: Dose adjust in moderate hepatic impairment, not recommended in severe hepatic impairment; dose adjust in severe (CrCl <30 mL/minute) renal impairment Concurrent drug therapy issues: – Drug-drug interactions: ○ *Tolterodine* only: Lower dose when used concomitantly with CYP3A4 inhibitors ○ *Trospium* only: Use caution with other medications that are eliminated by active tubular secretion; effects with other sedative drugs or ethanol may be potentiated

Medication	Warnings/Precautions
	Dosage form specific issues: – *Oxybutynin* only ○ ER formulation: Drug is contained within a nondeformable matrix, the use of which has been rarely associated with obstruction in patients with stricture/narrowing of the GI tract ○ Topical gel: Cover the treated area with clothing after gel has dried to prevent unintended exposure; skin irritation may occur; contains ethanol, do not expose to open flame or smoking until dry ○ TD patch: May contain conducting metal (e.g., aluminum), remove prior to MRI – *Trospium* only ○ ER formulation: Ethanol should not be ingested within 2 hours of the administration of the ER formulation; may increase incidence of drowsiness – *Solifenacin* only ○ Propylene glycol: Some dosage forms may contain propylene glycol; use caution as large amounts are potentially toxic
Flavoxate	Concerns related to adverse effects: – CNS effects: Anticholinergic effects may impair physical or mental abilities Disease-related concerns: – Glaucoma: Use with caution Concurrent drug therapy issues: – Sedatives: Use with other sedative drugs or ethanol may potentiate CNS effects
Myrbetriq® (mirabegron)	Concerns related to adverse effects: – Angioedema: Of the face, lips, tongue, and/or larynx has been reported Disease-related concerns: – Hepatic impairment: Use with caution in mild to moderate hepatic impairment; dose adjust in moderate hepatic impairment; use is not recommended in severe hepatic impairment – Hypertension (HTN): Use with caution in patients with controlled and less severe HTN; use is not recommended in patients with uncontrolled HTN – Renal impairment: Use with caution; dose adjust in patients with severe renal impairment; use is not recommended in end-stage renal disease (ESRD) (eGFR < 15 mL/min/1.73 m^2 with or without hemodialysis) Dosage form specific issues: – Product interchangeability: ER granules and ER tablets are not interchangeable; products should not be combined to achieve a total dose; select appropriate product based on patient's indication and weight; granules are not approved for adult use
Gemtesa® (vibegron)	Concerns related to adverse effects: – Angioedema: Of the face and/or larynx has been reported Disease-related concerns: – BOO: Increased risk of urinary retention in patients with BOO and in patients using concomitant muscarinic antagonists – Hepatic impairment: Not recommended in severe hepatic impairment – Renal impairment: Not recommended for use in patients with ESRD (eGFR < 15 mL/min/1.73 m^2 with or without hemodialysis)

Practice Guidelines

Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU Guideline on the Diagnosis and Treatment of Idiopathic Overactive Bladder. J Urol. 2024;212(1):11-20.

Non-Invasive Therapies

- Clinicians should discuss incontinence management strategies (e.g., pads, diapering, barrier creams) with all patients who have urgency urinary incontinence. (Expert Opinion)
- Clinicians should offer bladder training to all patients with OAB (Strong Recommendation; Evidence Level: Grade A)
- Clinicians should offer behavioral therapies to all patients with OAB. (Clinical Principle)
- Clinicians may offer select non-invasive therapies to all patients with OAB. (Clinical Principle)
- In patients with OAB whose symptoms do not adequately respond to monotherapy, clinicians may combine one or more of the following: behavioral therapy, non-invasive therapy, pharmacotherapy, and/or minimally invasive therapies. (Expert Opinion)

Pharmacotherapy

- Clinicians should offer antimuscarinic medications or beta-3 agonists to patients with OAB to improve urinary urgency, frequency, and/or urgency urinary incontinence. (Strong Recommendation; Evidence Level: Grade A).
- Clinicians should counsel patients with OAB on the side effects of all oral medication options; treatment should be chosen based on side effect profiles and in the context of shared decision-making. (Clinical Principle)
- Clinicians should discuss the potential risk for developing dementia and cognitive impairment with patients with OAB who are taking, or who are prescribed, antimuscarinic medications. (Clinical Principle)
- Clinicians should use antimuscarinic medications with extreme caution in patients with OAB who have narrow-angle glaucoma, impaired gastric emptying, or a history of urinary retention. (Clinical Principle).
- Clinicians should assess patients with OAB who have initiated pharmacotherapy for efficacy and for onset of treatment side effects. (Expert Opinion)
- In patients with OAB who experience intolerable side effects or who do not achieve adequate improvement with an OAB medication, clinicians may offer a different medication in the same class or a different class of medication to obtain greater tolerability and/or efficacy. (Clinical Principle).
- In patients with OAB who do not achieve adequate improvement with a single OAB medication, clinicians may offer combination therapy with a medication from a different class. (Conditional Recommendation; Evidence Level: Grade B)

Minimally Invasive Therapies

- Clinicians may offer minimally invasive procedures to patients with OAB who are unable or unwilling to undergo behavioral, non-invasive, or pharmacologic therapies. (Clinical Principle)
- Clinicians may offer patients with OAB, in the context of shared decision-making, minimally invasive therapies without requiring trials of behavioral, non-invasive, or pharmacologic management. (Expert Opinion)
- In patients with OAB who have an inadequate response to, or have experienced intolerable side effects from, pharmacotherapy or behavioral therapy, clinicians should offer sacral neuromodulation, tibial nerve stimulation, and/or intradetrusor botulinum toxin injection. (Moderate Recommendation; Evidence Level: Grade A)

Recommendation Definitions

Recommendation Type	Definition
Strong	Benefits are greater than risks/burdens (or vice versa). Net benefit (or net harm) is substantial.
Moderate	Benefits are greater than risks/burdens (or vice versa). Net benefit (or net harm) is moderate.
Conditional	Balance between benefits and risks/burdens are unclear. Best action depends on individual patient circumstances.
Clinical Principle	A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature.
Expert Opinion	A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence.

Evidence Grade	Definition
Grade A	Well-conducted randomized controlled trials (RCT) or exceptionally strong observational studies.
Grade B	RCTs with some weaknesses of procedure or generalizability or generally strong observational studies.
Grade C	Observational studies that are inconsistent, have small sample sizes or have other problems that potentially confound interpretation of data.

Abrams P, Andersson KE, Apostolidis A, et al. Sixth International Consultation on Incontinence Recommendations of the International Scientific Committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. Neurourol Urodyn. 2018 Sep;37(7):2271-2272.

<u>Children</u>

Initial management

- Initial treatment for mono-symptomatic nocturnal enuresis should include:
  - Parental and child counseling and motivation
  - Review of bladder diary with attention to night-time polyuria
  - Age-appropriate education and demystification or explanation
- A choice between either bed wetting alarm (Grade A) or anti-diuretic hormone analogues of desmopressin (Grade A). It may be a parental and child choice if advantages and disadvantages are well explained.
- Daytime incontinence should be managed holistically including:
  - Counselling, timed voiding, behavior modification and bowel management when necessary (Grade B)
  - Antimuscarinics may be used if the child has OAB symptoms (Grade A)

Specialized management

- The treatment of incontinence associated with urinary tract anomalies is complex and cannot easily be dealt with in an algorithm. In many children more than one pathology demands treatment. If there are complex congenital abnormalities present, the treatment is mostly surgical and it should be individualized according to the type and severity of the problem.
- Initial treatment should be non-surgical:
  - For stress urinary incontinence (SUI): Pelvic floor muscle training (Grade C)

- For OAB symptoms: Fluid/voiding regimens and antimuscarinics (Grade A)
- For voiding dysfunction: Timed voiding, voiding re-education, pelvic floor muscle relaxation (+/- biofeedback), α-blocker therapy, and intermittent catheterization (when post-void residual [PVR] >30% of bladder capacity) (Grade A/B)
- For bowel dysfunction: High fiber diet and laxatives as appropriate, and transanal irrigation in severe cases (Grade A)

Men

Initial management

- For men with stress, urgency or mixed urgency/stress incontinence, initial treatment should include appropriate lifestyle advice, pelvic floor muscle training, scheduled voiding regimes, behavioral therapies and medication. In particular:
  - Antimuscarinic/β3-adrenoceptor agonists drugs for OAB symptoms with or without urgency incontinence (Grade B) if the patient has no evidence of significant post-void residual urine
  - α-blockers can be added if itis thought that there may also be BOO (Grade C)

Specialized management

- When basic management has been unsuccessful and if the patient's incontinence markedly disrupts his quality of life, then invasive therapies should be considered:
  - For sphincter incompetence the recommended option is the artificial urinary sphincter (Grade B). Other options, such as a male sling, may be considered (Grade C)
  - For refractory idiopathic detrusor overactivity, (with intractable OAB symptoms) the recommended therapies are: Botulinum toxin A (Grade B), and SNS (Grade C)
  - If incontinence is associated with BOO, then consideration should be given to surgical treatment to relieve obstruction (Grade B). α-blockers and/or 5α-reductase inhibitors would be an optional treatment (Grade C)
  - There is increased evidence for the safety of antimuscarinics for OAB symptoms in men, chiefly in combination with an α-blocker (Grade B)

Women

Initial management

- For women with stress, urgency or mixed urinary incontinence, initial treatment should include appropriate lifestyle advice, pelvic floor muscle training (PFMT), scheduled voiding regimes, behavioral therapies and medication. In particular:
  - If estrogen deficiency and/or UTI is found, the patient should be treated at initial assessment and then reassessed after using vaginal estrogens for a suitable period (Grade B)
  - Antimuscarinics/β3-adrenoceptor agonists for OAB symptoms with or without urgency incontinence (Grade A); duloxetine* may be considered for SUI (Grade B)

Specialized management

- Antimuscarinics/β3-adrenoceptor agonists for OAB symptoms with or without urgency incontinence (Grade A); duloxetine* may be considered for SUI (Grade B)
- Refractory urgency incontinence (OAB) secondary to idiopathic detrusor overactivity may be treated by botulinum toxin A (Grade A), sacral nerve stimulation (Grade B) or bladder augmentation/intestinal cystoplasty (Grade D)

Neurogenic Urinary Incontinence

Initial management

- Initial treatment for patients with incontinence due to suprapontine pathology, like stroke, need to be assessed for degree of mobility and ability to cooperate. Initial recommended treatments are behavioral therapy (Grade C) and anti-muscarinic drugs for presumed detrusor overactivity (Grade A). If incontinence persists and if operative procedures are not indicated, then continence products (Grade B) or catheters (Grade C) may be necessary on a long-term basis. These can also be necessary in non-cooperative or less mobile patients.
- Pharmacological detrusor relaxation and/or antibiotics may be useful in cases of persistent bypass leakage and/or recurrent UTI (patients with continuous drainage)

Specialized management

- Antimuscarinics (Grade A)
- α-1 blockers (Grade C)
- Oral cannabinoid agonists (multiple sclerosis) (Grade C)
- β3-adrenoceptor agonist alone or as an add-on to antimuscarinic (Grade D)

Frail Older Men and Women

Initial management

- For the select cognitively intact older person with UI or fecal incontinence, pelvic floor muscle therapy can be considered, but there are few studies (Grade C). Antimuscarinics may be added to conservative therapy of UUI (Grade A-C, depending on agent)
- α-blockers may be cautiously considered in frail men with suspected prostatic obstruction (Grade C). All drugs should be started at the lowest dose and titrated with regular review until either care goals are met or adverse effects are intolerable

**Duloxetine is not approved for use in United States. In Europe it is approved for use in severe stress incontinence (see committee report on pharmacological management for information regarding efficacy, adverse events (AEs), and 'black box' warning by the Food and Drug Administration of the United States).*

Recommendation Definitions

Evidence Grade	Definition
Grade A	High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect
Grade B	Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
Grade C	Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate.
Grade D	Any estimate of effect is very uncertain.

Qaseem A, Dallas P, Forciea MA, et al. Nonsurgical Management of Urinary Incontinence in Women: A Clinical Practice Guideline From the American College of Physicians. Ann Intern Med. 2014 Sep 16;161(6):429-40.

- ACP recommends first-line treatment with pelvic floor muscle training in women with SUI (Grade: Strong recommendation, high-quality evidence)
- ACP recommends bladder training in women with UUI (Grade: Strong recommendation, moderate-quality evidence)

- ACP recommends pelvic floor muscle training with bladder training in women with mixed UI (Grade: Strong recommendation, moderate-quality evidence)
- ACP recommends against treatment with systemic pharmacologic therapy for stress UI (Grade: Strong recommendation, low-quality evidence)
- ACP recommends pharmacologic treatment in women with UUI if bladder training was unsuccessful. Clinicians should base the choice of pharmacologic agents on tolerability, adverse effect profile, ease of use, and cost of medication (Grade: Strong recommendation, high-quality evidence)
- ACP recommends weight loss and exercise for obese women with UI (Grade: Strong recommendation, moderate-quality evidence)

Recommendation Definitions

Strength of Recommendation	Definition
Strong	Benefits clearly outweigh risks and burden OR risks and burden clearly outweigh benefits.
Weak	Benefits finely balanced with risks and burden.

Evidence Grade	Definition
High	High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
Low	Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate.
Insufficient	Evidence either is unavailable or does not permit a conclusion.

Clinical Trials/Systematic Reviews/Meta-Analyses

Citation	Design	Endpoints
Maman K, Aballea S, Nazir J, et al. Comparative efficacy and safety of medical treatments for the management of overactive bladder: a systematic literature review and mixed treatment comparison. Eur Urol. 2014 Apr;65(4):755-65. doi: 10.1016/j.eururo.2013.11.010.	Systematic review (as per Centre for Reviews and Dissemination [CRD] and Preferred Reporting Items for Systematic Reviews and Meta-analysis guidelines) and Bayesian mixed treatment comparison to evaluate the relative safety and efficacy of OAB medications N=44 RCTs; 27,309 participants	Efficacy: micturition frequency, incontinence episodes, UUI (all per 24 hours) Safety: incidence of dry mouth, constipation, blurred vision

Results:

Efficacy:

- Micturition frequency: Mirabegron was found to be as effective as antimuscarinics except solifenacin 10 mg which was found to be more effective (mean difference vs mirabegron 50 mg of −0.584 [95% CrI*, −0.837 to −0.332]).
- Incontinence: Mirabegron was found to be as effective as antimuscarinics; solifenacin (5 mg and 10 mg) were 97% more probable to be effective compared to mirabegron.
- UUI: Mirabegron was found to be as effective as antimuscarinics; solifenacin 10 mg was significantly more efficacious compared to mirabegron (mean difference vs mirabegron 50 mg of −0.422 urgency incontinence episodes per day [95% CrI, −0.786 to −0.060]).

Safety: Antimuscarinics were associated with higher rates of dry mouth and constipation compared to mirabegron and solifenacin had a significantly higher risk of constipation compared to mirabegron with OR ranging from 1.914 (95% CrI, 1.135–3.032) to 7.603 (95% CrI, 2.076–22.660).

Conclusion: The authors concluded that mirabegron had similar efficacy compared to most antimuscarinics and lower rates of dry mouth. A significant strength of this study is that it met the CRD Database of Abstracts of Reviews of Effects (DARE) scientific quality criteria for systematic reviews. This adds to the credibility and reliability of the results and conclusions.

**CrI – Credibility interval*

Citation	Design	Endpoints
Nalliah S, Wg P, Masten Singh PK, Naidu P, Lim V, Ahamed AA. Comparison of efficacy and tolerability of pharmacological treatment for the overactive bladder in women: A network	Systematic review and network meta-analysis (NMA) of RCTs and prospective cohort studies of "commonly prescribed pharmacological agents" for the treatment of OAB sourced from PubMed and Cochrane between July 31, 2000 and July 31, 2015. N=5 studies; 5356 participants	Efficacy: Relative efficacy as measured by OR Safety: Number of AEs (e.g., dry mouth, dry eyes, blurred vision and constipation)

meta-analysis. Aust Fam Physician. 2017 Mar;46(3):139-144.		

Results:

Efficacy: Solifenacin 10 mg was the most effective followed by oxybutynin 3 mg TDS > solifenacin 5 mg QD > darifenacin 15 mg QD > fesoterodine 8 mg QD > darifenacin 7.5 mg QD > tolterodine 4 mg QD.

Safety: Darifenacin 7.5 mg QD had the fewest AEs, whereas solifenacin 10 mg QD caused the most AEs when compared with every other intervention except oxybutynin 3 mg TDS.

Conclusion: The authors concluded that, considering effectiveness, adverse effects, and cost, solifenacin 5 mg is the drug of choice. This study included relatively few RCTs, and it did not include an assessment of the relative effectiveness or safety of the β3 agonist mirabegron. It was conducted in Australia; it is possible mirabegron was not available in Australia during the search timeframe.

Citation	Design	Endpoints
Kelleher C, Hakimi Z, Zur R, et al. Efficacy and Tolerability of Mirabegron Compared with Antimuscarinic Monotherapy or Combination Therapies for Overactive Bladder: A Systematic Review and Network Meta-analysis. Eur Urol. 2018 Sep;74(3):324-333. doi: 10.1016/j.eururo.2018.03.020. Epub 2018 Apr 23.	A systematic review and NMA of RCTs from 2000 to 2017 assessing mirabegron and antimuscarinics monotherapies and combination therapies for OAB N=64 studies; 46,666 participants	Efficacy: Mean change from baseline for micturition frequency, UUI episodes, and incontinence episodes (all per 24 hours) Safety: Dry mouth, constipation, blurred vision, HTN, urinary retention, UTI, tachycardia, withdrawal for any reason, and withdrawal due to lack of efficacy

Results:

Efficacy:

- Micturition frequency: Efficacy of mirabegron 50 mg did not differ significantly from the other active treatments, except for solifenacin 10 mg monotherapy and solifenacin 5 mg + mirabegron 50 mg (combination), both of which were more efficacious than mirabegron 50 mg (mean change: –0.37 [95% CrI: –0.62, –0.13] and –0.59 [95% CrI: –0.87, –0.30], respectively)
- UUI episodes: Efficacy of mirabegron 50 mg did not differ significantly from the other active treatments, except for solifenacin 5 mg + mirabegron 25 or 50 mg (combinations) and fesoterodine 8 mg, all of which were more efficacious than mirabegron 50 mg monotherapy
- Incontinence episodes: Mirabegron was significantly more efficacious than placebo; no significant differences were observed versus other comparators except for solifenacin 5 and 10 mg monotherapy and solifenacin/mirabegron combinations (all of which were more efficacious than mirabegron)

Safety:

- Dry mouth: The risk with mirabegron 50 mg was similar to that with placebo (OR: 0.82 [95% CrI: 0.65, 1.03]) and significantly lower compared with all other active treatments except for oxybutynin IR 5 mg (OR: 2.99 [95% CrI: 0.68, 13.75])

- Constipation: The risk was significantly lower for mirabegron 50 mg compared with nine active treatments (darifenacin 7.5 and 15 mg, fesoterodine 8 mg, propiverine 20 mg, solifenacin 5 mg + mirabegron 25 or 50 mg, solifenacin 5 and 10 mg, and trospium 60 mg)
- HTN: The risk for mirabegron 50 mg was similar to that for placebo (OR: 0.97 [95% CrI: 0.76, 1.25]) and all other treatments
- Urinary retention: Mirabegron 50 mg had a significantly lower frequency of urinary retention compared with seven active treatments (fesoterodine 4 and 8 mg, oxybutynin IR 9 mg, solifenacin 10 mg, solifenacin 5 mg combined with mirabegron 25 or 50 mg, and trospium 60 mg). No significant differences were seen versus mirabegron 50 mg for the remaining four comparators (placebo, propiverine 20 mg, solifenacin 5 mg, and tolterodine ER 4 mg)
- Blurred vision, UTI, Tachycardia: There were no significant differences
- Withdrawal for any reason: Mirabegron was significantly better tolerated compared with oxybutynin IR (OR: 2.14 [95% CrI: 1.36, 3.37])
- Withdrawal due to lack of efficacy: Mirabegron was significantly better tolerated compared with placebo (OR: 1.95 [95% CrI: 1.21, 3.24])

Conclusion: The authors concluded that "relief of key OAB symptoms produced by mirabegron 50 mg is significantly better than placebo, and similar to a range of common antimuscarinics, with the benefit of significantly fewer bothersome anticholinergic side effects such as dry mouth." Additionally, combination treatment of solifenacin + mirabegron was found to improve efficacy although with additional anticholinergic side effects.

Citation	Design	Endpoints
Lozano-Ortega G, Walker DR, Johnston K, et al. Comparative safety and efficacy of treatments for overactive bladder among older adults: a network meta-analysis. Drugs Aging. 2020;37(11):801-816.	Systematic review and NMA of RCTs among older adults with OAB that reported the safety and efficacy outcomes associated with the use of mirabegron and/or antimuscarinics sourced from PubMed and Cochrane between January 1, 2000 and August 21, 2018. N=21 studies	Efficacy: Incontinence episodes per 24 hours, UUI episodes per 24 hours, micturitions per 24 hours, volume voided per micturition, and urgency episodes per 24 hours Safety: Urinary retention, dry mouth, constipation, overall treatment-emergent AEs, and AE-related treatment discontinuations

Results:

Efficacy:

- A similar treatment effect was observed across all efficacy endpoints between mirabegron and antimuscarinics.

Safety:

- Mirabegron was not associated with an increased odds of dry mouth (OR: 0.76 [95% CrI: 0.26, 2.37]) or constipation (OR: 1.08 [95% CrI: 0.39, 3.02]) relative to placebo, whereas antimuscarinics were strongly associated with these events (OR range: 3.78 to 7.85 and 2.12 to 4.66, respectively)
- Mirabegron was associated with similar odds of experiencing AE-related treatment discontinuations relative to placebo (OR: 0.99 [95% CrI: 0.57, 1.70]), while the odds of experiencing an AE-related treatment discontinuation for antimuscarinics had a range of 1.14–3.03 (in most cases, the association was mild)
- No increased odds of experiencing overall treatment-emergent AEs was observed for mirabegron or antimuscarinics (OR range: 1.25 to 1.55), apart from fesoterodine (OR: 2.23 [95% CrI: 1.37, 3.37])

Conclusion: The authors concluded that the safety and efficacy profile of mirabegron remains favorable compared with antimuscarinics among older adults. This includes safety outcomes typically associated with anticholinergic burden, which were less frequently observed in patients treated with mirabegron.

Citation	Design	Endpoints
Su S, Liang L, Lin J, Liu L, Chen Z, Gao Y. Systematic review and meta-analysis of the efficacy and safety of vibegron vs antimuscarinic monotherapy for overactive bladder. Medicine (Baltimore). 2021;100(5):e23171.	Systematic review and NMA of RCTs of vibegron vs. antimuscarinic monotherapy for OAB sourced from PubMed and Cochrane to March 2020. N=3 studies; 1751 participants	Efficacy: Mean number of micturitions episodes per day, mean number of urgency episodes per day, mean number of UUI episodes per day, mean number of incontinence episodes per day, and mean volume voided/micturition Safety: Dry mouth, drug related treatment-emergent AEs, serious AEs, and discontinuations due to AEs

Results:

Efficacy:

- The mean number of micturitions episodes per day (p= 0.16), the mean number of urgency episodes per day (p=0.05), mean number of UUI episodes per day (p=0.11), and mean number of incontinence episodes per day (p=0.14) indicated that vibegron and antimuscarinic therapy had no significant differences in terms of OAB treatment efficacy

Safety:

- With regard to dry mouth and drug related treatment-emergent AEs, vibegron showed better tolerance than antimuscarinics. Serious AEs and discontinuations due to AE did not show a significant difference between the two groups

Conclusion: The authors concluded that the therapeutic effect of vibegron is similar to that of antimuscarinics, but vibegron does not increase the risk of AEs.

Citation	Design	Endpoints
Kennelly M, Wielage R, Shortino D, Thomas E, Mudd PN. Long-term efficacy and safety of vibegron versus mirabegron and anticholinergics for overactive bladder: a systematic review and network meta-analysis. Drugs Context. 2022;11:2022-4-2.	Systematic review and NMA of RCTs of vibegron, mirabegron, and anticholinergics for the treatment of OAB sourced from MEDLINE, Embase and Cochrane and performed on September 16, 2020 N=6 studies; 2492 participants	Efficacy: Change from baseline to week 48-52 in mean daily total UI episodes, mean daily micturitions, and volume voided per micturition Safety: AEs

Results:

Efficacy:

- Mean (95% credible interval) change from baseline in total UI episodes for vibegron 75 mg (–2.2; –2.9 to –1.5) showed a significantly greater reduction than mirabegron 50 mg (–1.3; –1.9 to –0.8) and tolterodine 4 mg extended release (–1.6; –2.1 to –1.1)
- No significant differences were observed between vibegron and comparators for daily micturitions or volume voided/micturition

Safety:

- The 4 most common AEs (range) for anticholinergics included dry mouth (5.2–90.0%), constipation (7.7–65.0%), blurred vision (3.8–35.0%) and hypertension (8.6–9.6%)
- The 4 most commonly reported AEs for β3-adrenergic agonists included hypertension (8.8–9.2%), urinary tract infection (5.9–6.6%), headache (5.5%) and nasopharyngitis (4.8–5.2%)

Conclusion: Vibegron was associated with significantly greater improvement in daily total UI episodes at 52 weeks than mirabegron and tolterodine. The most common AE for anticholinergics was dry mouth and for β3-adrenergic agonists was hypertension.

Citation	Design	Endpoints
He W, Zhang Y, Huang G, Tian Y, Sun Q, Liu X. Efficacy and safety of vibegron compared with mirabegron for overactive bladder: A systematic review and network meta-analysis. Low Urin Tract Symptoms. 2023;15(3):80-88.	A systematic search was performed on Pubmed, Web of Science, Embase, and the Cochrane Central Register of Controlled Trials databases to identify studies from the date of database inception to January 1, 2022. All randomized controlled trials comparing mirabegron or vibegron with tolterodine, imidafenacin, or placebo were eligible. N=11 studies; 10806 patients	Efficacy: Outcomes assessed at week 12 - Mean voided volume per micturition - Mean daily micturitions - Mean daily incontinence episodes - Urgency episodes per day - UUI episodes [er day - Nocturia Safety: AEs

Results:

Efficacy:

- All treatments resulted in a significant improvement in mean voided volume per micturition compared with placebo. Only vibegron had significantly higher values compared with mirabegron and any other group at week 12.
- All active treatments showed a statistically significant reduction versus placebo at week 12. No significant difference was found between vibegron and mirabegron in the mean number of micturitions at week 12. However, vibegron resulted in a significantly greater improvement than tolterodine, and mirabegron was similar to tolterodine.
- All five active interventions showed a significantly greater reduction compared with placebo in incontinence episodes. There was no significant difference between vibegron and mirabegron in the mean number of incontinence episodes at week 12, whereas mirabegron showed a significantly greater improvement than tolterodine, and vibegron was similar to tolterodine.
- Compared with placebo, all active treatment groups showed a significantly greater reduction in urgency episodes per day and UUI episodes per day, whereas all treatment groups except tolterodine had a significantly greater reduction than placebo in nocturia. No significant differences were observed between vibegron and mirabegron in urgency episodes per day, UUI episodes per day, and nocturia at week 12.

Safety:

- Compared with placebo, vibegron and mirabegron were not associated with an increased risk of dry mouth, constipation, hypertension, and urinary tract infection.
- Mirabegron had higher rates of nasopharyngitis and cardiovascular AEs than placebo.

Conclusion: Both vibegron and mirabegron seem to be comparable and well tolerated, particularly as direct comparisons are not available. However, vibegron may be more effective than mirabegron in reducing mean voided volume.

Citation	Design	Endpoints
Liang P, Yu L, Xia B, Zhang D. Comparative Efficacy and Safety of Mirabegron and Vibegron in Female Patients with Overactive Bladder: A Systematic Review and Meta-analysis of Randomized Controlled Trials. *Urology*. 2025;199:182-190.	A systematic search was performed on PubMed, EMBASE, Cochrane Library, and Web of Science databases to identify RCTs referred to the use of mirabegron and vibegron in female patients with OAB. N=3 studies; 371 patients	Efficacy: - Changes in urgency urinary incontinence per 24 hours - OAB symptom score differences - Differences in urgency outcomes - Postintervention quality of life (QOL) - Mean volume voided per micturition Safety: AEs

Results:

Efficacy:

- Vibegron was associated with decreased frequency of urgency urinary incontinence (mean difference -0.25 events/24 hours, 95% CI [-0.47 to -0.04 events/24 hours]) in analysis of all trials.
- No statistically significant decrease in OAB symptom score between the groups after treatment (mean difference -0.22 points, 95% CI [-0.76 to 0.32]) in analysis of all trials.
- No significant differences were demonstrated in urgency or quality of life. Results demonstrated that the mean volume voided per micturition were similar among mirabegron and vibegron groups.

Safety:

- Results demonstrated no significant difference between groups in the risk of total adverse events, dry mouth, constipation, elevated post void residual, or dizziness

Conclusion: Mirabegron and vibegron have similar efficacy and safety in improving the symptoms of female overactive bladder patients. Vibegron may be more effective than mirabegron in relieving urgency urinary incontinence.

Formulary Placement, Utilization and Cost Experience (07-01-2025 to 09-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	Rx	Mbrs	Total	Avg/Rx	Total	Approved (%)	Current	Recommend
Antimuscarinics - Rx								
Tolterodine (Detrol®) 1 mg, 2 mg oral tablets	2	2	$121.03	$60.52	0	0 (0%)	F-ST (oxybutynin IR or ER or solifenacin required; pay for members 65yrs/older)	No change
Tolterodine (Detrol® LA) 2 mg, 4 mg ER oral capsules	4	3	$145.54	$36.39	0	0 (0%)	F-ST (oxybutynin IR or ER or solifenacin required; pay for members 65yrs/older)	No change
Oxybutynin 2.5 mg, 5 mg oral tablets	9	8	$110.39	$12.27	0	0 (0%)	F-5mg NF-2.5mg	No change
Oxybutynin 5 mg/5 mL oral syrup	0	0	$0.00	$0.00	0	0 (0%)	F	No change
Oxybutynin 5 mg, 10 mg, 15 mg ER oral tablets	21	17	$392.91	$18.71	0	0 (0%)	F	No change
Gelnique® (oxybutynin) 10 % (100 mg/gram) transdermal gel packet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Oxytrol® (oxybutynin) 3.9 mg/24 hr transdermal patch	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Flavoxate 100 mg oral tablet	0	0	$0.00	$0.00	0	0 (0%)	F-PA	No change
Trospium 20 mg oral tablet	3	2	$103.42	$34.47	1	1 (100%)	F-ST (oxybutynin IR or ER or solifenacin required; pay for members 65yrs/older)	No change
Trospium 60 mg ER oral capsule	0	0	$0.00	$0.00	0	0 (0%)	F-ST (oxybutynin IR or ER or solifenacin required; pay for members 65yrs/older)	No change
Fesoterodine (Toviaz®) 4 mg, 8 mg ER oral tablets	0	0	$0.00	$0.00	0	0 (0%)	F-PA	No change
Solifenacin (Vesicare®) 5 mg, 10 mg oral tablets	5	2	$51.22	$10.24	0	0 (0%)	F	No change
Vesicare LS® (solifenacin) 1 mg/mL oral suspension	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Darifenacin 7.5 mg, 15 mg ER oral tablets	0	0	$0.00	$0.00	0	0 (0%)	F-PA	No change

Antimuscarinics - OTC								
Oxytrol® For Women (oxybutynin) 3.9 mg/24 hour transdermal patch	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Beta-3 Agonists								
Mirabegron (Myrbetriq®) 25 mg, 50 mg ER oral tablets	10	3	$3,210.13	$321.01	3	1 (33%)	F-PA	No change
Myrbetriq® (mirabegron) 8 mg/mL ER oral suspension	0	0	$0.00	$0.00	0	0 (0%)	F-PA	No change
Gemtesa® (vibegron) 75 mg oral tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
TOTAL	**54**	**37**	**$4,134.64**	**$76.57**	**4**	**2 (50%)**		

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

Prior Authorization Criteria

No changes

Urinary Incontinence Agents	
Therapeutic Classes (AHFS)	Antimuscarinics and Beta-3-Adrenergic Agonists
Medications	**Formulary, preferred:** Oxybutynin (Ditropan), Oxybutynin ER (Ditropan XL), solifenacin (Vesicare) **Formulary, step therapy required:** Tolterodine (Detrol), Tolterodine ER (Detrol LA), Trospium (Sanctura), Trospium ER (Sanctura XR) **Formulary, prior authorization required:** Darifenacin (Enablex), fesoterodine (Toviaz), flavoxate (Urispas), mirabegron (Myrbetriq) **Non-formulary:** Gemtesa (vibegron), Vesicare LS (solifenacin) oral suspension, Oxytrol (oxybutynin) patch, Gelnique (oxybutynin), Oxytrol for women OTC **Any other non-formulary agent for urinary incontinence**
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 of **tolterodine, tolterodine ER, trospium, or trospium ER:** • Documented trial and failure, intolerance, contraindication, or inability to use oxybutynin or oxybutynin ER or solifenacin for at least 4 weeks (28 days) of therapy within the past 6 months OR • Member aged 65 years or older. Criteria for approval of: **darifenacin, Oxytrol, fesoterodine, Gelnique, flavoxate, Gemtesa, Vesicare LS, or mirabegron (Myrbetriq):** • Documented trial and failure, intolerance, contraindication, or inability to use oxybutynin or oxybutynin ER or solifenacin • AND tolterodine, tolterodine ER, trospium, or trospium ER for at least 4 weeks (28 days) of therapy within the past 6 months.
Criteria Statement	Tolterodine, tolterodine ER, trospium, or trospium ER are reserved for members who have used (or cannot/should not use) oxybutynin or oxybutynin ER or solifenacin or are over age 65 years. Darifenacin, Oxytrol, fesoterodine, Gelnique, flavoxate, Gemtesa, Vesicare LS or mirabegron (Myrbetriq) are reserved for members who have used (or cannot/should not use) oxybutynin or oxybutynin ER or solifenacin AND tolterodine, tolterodine ER, trospium, or trospium ER.
Last P&T Review Date	~~12/2024~~12/2025

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Alameda MRGs for review Q4 2025 P&T Consent Agenda

Recommendation: No changes

Oral and Injectable Oncology Medications	
Therapeutic Classes (AHFS)	Antineoplastics
Medications	Oral and Injectable Oncology Medications without medication specific 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 Healthcare Professional (USP DI), and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
Exclusion Criteria	N/A
Required Clinical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	**Initial requests:** Prescriber must be an oncologist. **Reauthorization requests**: Prescriber must be an oncologist. An exception can be made if the prescriber is in consultation with an oncologist (see Coverage Duration section for approval duration for reauthorizations exceptions).
Coverage Duration	**Initial Approval (for new treatment or dose changes to existing treatment)**: 6 months duration with a day supply limit of up to a 15 day supply for the first fill (for medications that must be stored in the original container, a supply of up to 30 days is allowed). Subsequent fills have a day supply limit of up to 30 days **Later Approvals (with no dose change, given that at least 15 days of therapy are completed)**: Prescribed by an oncologist: 6 months with a day supply limit of up to 30 days Reauthorization exceptions: 1 month with a day supply limit of up to 30 days If criteria is not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review.
PA Review Criteria	All of the following criteria must be met: • Requested indication must be supported by NCCN category 1 or 2A level of evidence. If the request is for a category 2B recommendation then the medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication). • Documentation provided of results of genetic testing where required per drug package insert. • Documentation provided of results of all required laboratory values and member specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert. • The medication is being prescribed at a dose that is within FDA approved/NCCN guidelines. • For any medication where a biosimilar is available (Kanjinti, Zirabev etc), the member must have documented 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.

	• Requests for abiraterone (Zytiga) 500mg tablets should be modified into two abiraterone acetate 250mg tablets. • Requests for Lenvima must be for the most appropriate package size based on the dose requested. Requests for Lenvima should be approved for only the correct daily dosage package size (i.e. for Lenvima 20mg daily, the Lenvima 20mg Daily Dose packaging must be used, and not two packages of Lenvima 10mg Daily Dose)
Criteria Statement	Oral and injectable oncology medications without specific criteria are reserved for indications supported by NCCN category 1 or 2A level of evidence.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Non-Formulary/Prior Authorization Required Medications	
Therapeutic Classes (AHFS)	N/A
Medications	• Non-formulary/ PA Required Medications and/or specialty drugs without drug or class specific prior authorization criteria • Brand drugs and reference biologics when a therapeutic equivalent generic drug or biosimilar/interchangeable biologic is available *** The Oral and Injectable Oncology Medications prior authorization criteria will be applied to oncology drugs without drug or class specific 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), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "**PA Review Criteria**" below
Age Restrictions	According to package insert Check AAH active CCS cases for members < 21 years of age **unless** the medication is being requested for one of the following conditions: • Asthma • Acne • Atopic Dermatitis/Eczema • Psoriasis (except disfiguring condition) • Turner's syndrome • Migraine (not as a result of a CCS coverable condition) • Autism • ADHD • Depression • Failure to thrive • Exogenous obesity • Contraception (Birth control) • Smoking cessation
Prescriber Restrictions	N/A
Coverage Duration	If all of the conditions are met, requests will be approved for up to 12 months (depending on the diagnosis and usual treatment duration).
PA Review Criteria	**If the request is for a brand name medication with a generic or biosimilar available, all requests must be reviewed by a clinical pharmacist first and then forwarded to AAH for review** ****The use of medications for cosmetic purposes is NOT a covered benefit, unless used to treat gender dysphoria, mental health, or substance use disorder. Medications for cosmetic purposes ARE a covered benefit when used to treat gender dysphoria, mental health, or substance use disorder, when other formulary alternatives are not available**** **Authorization:** • The drug is requested for an appropriate use (per the references outlined in "Covered Uses" • The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses")

	• Patient meets one of the four following criteria:
	  ○ Documented trial and failure or intolerance with up to two formulary/preferred medications appropriate for the requested use (per the references outlined in "Covered Uses" or has a medical reason why these drug(s) cannot be used (e.g. intolerance, contraindication). For medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated.
	  ○ No other preferred medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia.
	  ○ All other preferred medications are contraindicated based on the patient's diagnosis, other medical conditions, or other medication therapy.
	  ○ The member has tried and failed the 2 separate formulary components of the combination medication OR 2 separate therapeutic equivalents to the components of the combination medication, if available on formulary OR the provider has submitted a medical reason why the requested combination medication would be superior to the required prerequisite trial(s) with formulary drug(s) [e.g. Yosprala (aspirin/omeprazole), the 2 separate components would need to be tried and failed]
	  AND, if applicable:
	  ○ The dose should be consolidated if clinically appropriate (ex: if a request is for Trintellix 10mg tablet, take 2 tablets (=20mg) once daily, a 20mg tablet should be approved, dosed once daily.)
	• If the request is for a brand drug with a therapeutically equivalent (A-rated) generic drug currently available, documentation of the following:
	  ○ The provider either verbally or in writing has submitted a medical or member specific reason why the brand name drug is required based on the member's condition or treatment history; **AND** if the member had side effects or a reaction to the generic drug, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. The MedWatch form must be included with the prior authorization request
	• If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following:
	  ○ The prescriber has verbally or in writing submitted a medical or member specific reason why the reference biologic is required based on the member's condition or treatment history; **AND** if the member had side effects or a reaction to all biosimilar or interchangeable biologics, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. The MedWatch form must be included with the prior authorization
	  ○ The currently available biosimilar product(s) does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested

Criteria Statement	N/A
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Step Therapy Exception	
Therapeutic Classes (AHFS)	N/A
Medications	Drugs on the Alameda Alliance's formulary with a step therapy restriction which do not meet step therapy requirements
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	**Initial Approval** 12 months **Later Approvals** 12 months If criteria is not met, request will be sent to a clinical reviewer for medical necessity review.
PA Review Criteria	• The provider has demonstrated knowledge of step therapy requirements. AND • The provider verbally or in writing has submitted a medical reason why required step therapy drug(s) would be ineffective or have the potential to cause harm or deterioration of the member's condition. OR • The provider has submitted a medical reason why the requested drug would be superior to the required prerequisite trial(s) with formulary drug(s).
Criteria Statement	N/A
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Prior Authorization Exception	
Therapeutic Classes (AHFS)	N/A
Medications	Requests for exception to the drug's prior authorization criteria requirements
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 either verbally or in writing has submitted a medical or member specific reason why prior authorization criteria all or in part is not applicable to the member. ○ Medical reasons may include but are not limited to: ▪ Criteria requirements are not applicable to the member based on the uniqueness of the member's condition or other physical characteristics of the member's condition. OR ○ Member specific reasons may include but are not limited to: ▪ Psychiatric, intellectual, physical, cultural, and/or linguistic characteristics of the member which may inhibit the provider from obtaining all necessary prior authorization criteria requirements.
Criteria Statement	N/A
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Butorphanol (Stadol NS)	
Therapeutic Classes (AHFS)	Opiate, partial agonists
Medications	Butorphanol (Stadol NS) 10 mg/ml nasal spray
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	Pain specialist: pain management, neurologist, headache/migraine specialist
Coverage Duration	**Initial Approval** 3 months (quantity limit of 1 bottle/30 days) **Later Approvals** 6 months (quantity limit of 1 bottle/30 days) If criteria is not met, request will be sent to a clinical reviewer for medical necessity review.
PA Review Criteria	****All requests for narcotics must be reviewed by a clinical pharmacist.**** **INITIAL AUTHORIZATION FOR DIAGNOSIS OF PAIN:** 1. Diagnosis of pain. 2. Documented trial and failure with therapeutic doses or intolerance to at least three oral narcotic medications including: oxycodone, oxycodone/acetaminophen, hydromorphone, hydrocodone/acetaminophen, acetaminophen/codeine, and morphine sulfate (first line therapies) **INITIAL AUTHORIZATION FOR DIAGNOSIS OF PAIN DUE TO MIGRAINE HEADACHE** 1. Diagnosis of pain from migraine headache 2. Documented trial with therapeutic doses of at least one recommended migraine preventative therapy (i.e., topiramate, propranolol, timolol, divalproex sodium, amitriptyline, nortriptyline, Emgality, or verapamil) 3. Documented trial and failure with therapeutic doses or intolerance to at least one triptan (unless contraindicated). **REAUTHORIZATION FOR DIAGNOSIS OF PAIN AND PAIN DUE TO MIGRAINE HEADACHE** 1. Documentation submitted supporting re-evaluation of member OR medical necessity of continued use of medication
Criteria Statement	Butorphanol is reserved for members with a diagnosis of pain who have used (or cannot/should not use) at least three oral narcotic medications including: oxycodone, oxycodone/acetaminophen, hydromorphone, hydrocodone/acetaminophen, acetaminophen/codeine, and morphine sulfate. Butorphanol is reserved for members with diagnosis of migraine headache pain and who have used (or cannot/should not use) at least one recommended migraine preventative therapy (topiramate, propranolol, timolol, divalproex sodium, amitriptyline, nortriptyline, Emgality, or verapamil) and at least one triptan.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: Change naming convention to reflect generic availability

Endari	
Therapeutic Classes (AHFS)	Other Miscellaneous Therapeutic Agents
Medications	Non-formulary ~~Endari (~~L-Glutamine~~)~~ (Endari)
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	Prescriber must be a hematologist
Coverage Duration	**Initial/Later Approval** — **If all of the conditions are met, requests will be approved for a 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: • Member has diagnosis of sickle cell disease • Documentation was provided that the member had 2 or more crises in the last 12 months • Documentation was provided the member has been on hydroxyurea at the maximum tolerated dose and was compliant within the last 6 months (or a medical reason was provided why member is unable to use hydroxyurea) • Request is for an FDA approved dose Reauthorization: • Prescriber attests member had reduction in number of sickle cell crises • Request is for an FDA approved dose
Criteria Statement	L-Glutamine (Endari): ~~Endari~~ is reserved for members who have unstable sickle cell disease and are taking the highest tolerated dose of hydroxyurea or cannot/should not take hydroxyurea.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Diclofenac sodium (Solaraze) 3% gel	
Therapeutic Classes (AHFS)	Antineoplastic Agents
Medications	Formulary, PA required Diclofenac sodium (Solaraze) 3% gel
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 dermatologist
Coverage Duration	**Initial/Re-Approval** If all conditions are met, the request will be approved for up to 3 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 actinic keratosis (AK) • Documented trial and failure of one formulary alternative [i.e. fluorouracil (Efudex) cream or imiquimod (Aldara) cream]
Criteria Statement	Diclofenac sodium 3% gel is reserved for members who have actinic keratosis and have used (or cannot/should not use) one formulary alternative such as fluorouracil (Efudex) or Imiquimod (Aldara) creams.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: Remove Saizen as it has been discontinued

Growth Hormone	
Therapeutic Classes (AHFS)	Pituitary
Medications	Formulary, Prior Authorization Required **Omnitrope – preferred agent** Non-formulary: Genotropin, GenotropinMiniQuick Humatrope Norditropin FlexPro Nutropin AQ NuSpin ~~Saizen~~ Serostim Zomacton Skytrofa Ngenla Sogroya Any other newly marketed growth hormone 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 the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), the American College of Obstetricians and Gynecologists (ACOG), or the American Academy of Pediatrics (AAP) standard of care guidelines.
Exclusion Criteria	Treatment of idiopathic short stature (ISS)-not a covered benefit and will not be approved
Required Clinical Information	See "**PA Review Criteria**" below
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is an endocrinologist or specialist in diagnosis being treated
Coverage Duration	**Initial Approval** CO-GHD, CKD, AO-GHD, Genetic causes: 12 months HIV/AIDS-wasting syndrome: 3 months **Later Approvals** CO-GHD, CKD, AO-GHD, Genetic causes: 12 months HIV/AIDS-wasting syndrome: 3 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** **If request is not for Omnitrope, documentation of medical reason, intolerance, inability, or contraindication to use Omnitrope must be provided.** **Initial Authorization** **Childhood-onset growth hormone deficiency (CO-GHD)** • If diagnosis is childhood-onset GH deficiency (CO-GHD) ○ And member is currently **pediatric**, **all** of the following ▪ IGF-1 and insulin-like growth factor binding protein-3 (IGFBP-3) deficiency (< 0 SD below reference range for age and gender)* with prescriber attestation of growth failure ▪ Provider attests that MRI or CT has been completed to exclude possibility of a pituitary tumor ▪ Provider attests that member's epiphyses are open

Growth Hormone	
	○ And member is currently **adult, <u>one</u>** of the following ▪ If diagnosis is idiopathic isolated GHD, documentation was provided that indicates GH therapy is still medically necessary (IGF-1 retesting during the transition period after a minimum 1 month of therapy discontinuation reveals continued GH deficiency) ▪ Diagnosis is GHD associated with multiple (≥3) pituitary hormone deficiencies (MPHD), genetic defect affecting the HPA axes, or member with hypothalamic pituitary structural brain defect **<u>Growth failure due to chronic renal insufficiency (CRI)/ Chronic kidney disease (CKD):</u>** ▪ Documentation of either pretreatment height is < -1.88 standard deviations (SD) below the mean for age or a height velocity–for-age < 3rd percentile that persists beyond 3 months • Provider attests that the member's epiphysis are open **<u>Short stature associated with Prader-Willi Syndrome, Noonan Syndrome, Turner Syndrome, short stature homeobox-containing gene (SHOX) mutation, or other underlying genetic cause</u>** ▪ Documentation of confirmatory genetic test **<u>Adult-onset growth hormone deficiency (AO-GHD)</u>** • If the diagnosis is adult-onset GH deficiency (AO-GHD), documentation of **<u>one</u>** of the following: ○ Insulin Growth Factor (IGF-1) deficiency (< -2 SD below reference range for age and gender)* and multiple (≥3) pituitary hormone deficiencies (MPHD) ○ Evidence of genetic defects affecting the hypothalamic pituitary axes (HPA) (e.g. pituitary disease) ○ Evidence of hypothalamic pituitary structural brain defects (e.g. hypothalamic disease) ○ Positive results of GH stimulatory test (e.g. insulin tolerance test [ITT], glucagon, or macimorelin) **<u>HIV/AIDS-wasting syndrome (Serostim)</u>** • Member is on antiviral therapy • 10% unintentional weight loss over 12 months • Documentation of inadequate response to previous therapy including exercise training, nutritional supplements, appetite stimulants or steroid hormones such as megestrol acetate. **<u>Reauthorization</u>** • Documentation of diagnosis [Note: Idiopathic Short Stature (ISS) is not a covered benefit] • Documented IGF-1 levels do not exceed upper limit of normal (ULN) (> 2 SD above reference range for age and gender)*, or if the IGF-1 levels do not exceed ULN, the dose has been reduced • In CO-GHD, growth response (as demonstrated by length/height and calculated height velocity within previous 6 months). • For HIV/AIDs wasting syndrome: documented clinical response including increase in muscle mass and weight

Growth Hormone	
	*IGF-1 levels are highly age and gender specific. In the event the form provides a value and not the corresponding reference range, refer to published reference ranges for interpretation.
Criteria Statement	• Growth hormone other than Omnitrope is reserved for members who have used (or cannot/should not use) Omnitrope. • For childhood-onset growth deficiency where the member is currently pediatric, growth hormone is reserved for members with growth failure and the epiphysis are open. • For childhood-onset growth deficiency where the member is currently an adult, growth hormone is reserved for members where growth hormone is still medically necessary. • For growth failure due to chronic renal insufficiency, growth hormone is reserved for members with height at least -1.88 standard deviations (SD) below the normal for age and or a height velocity–for-age less than the 3rd percentile that persists beyond 3 months and epiphysis are open. • For short stature in Turner Syndrome, Prader-Willi Syndrome, Noonan Syndrome, short stature homeobox-containing gene (SHOX) mutation, or other underlying genetic cause growth hormone is reserved for members with a confirmatory genetic test. • For adult-onset growth hormone deficiency, growth hormone is reserved for members with pituitary disease and positive results of a growth hormone stimulation test. • For HIV/AIDS wasting syndrome, growth hormone is reserved for members using antiretroviral therapy and have lost at least 10% of initial weight over 12 months and have used (or cannot/should not use) exercise training, nutritional supplements, appetite stimulants or steroid hormones such as megestrol acetate.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Rapid-Acting Insulin	
Therapeutic Classes (AHFS)	Insulins
Medications	Formulary with quantity limits: Admelog U-100 vial and Admelog Solostar Insulin Lispro 100 units/ml vial, pen Non-formulary Apidra 100 units/ml vial Apidra Solostar 100 units/ml Humalog KwikPen 100 units/ml, 200 units/ml Humalog 100 units/ml vial, cartridge Novolog 100 units/ml vial Novolog FlexPen100 units/ml Fiasp vial, FlexTouch, penfill Lyumjev KwikPen (insulin lispro-aabc) 100units/ml, 200units/ml Insulin aspart 100 units/ml 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	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 conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	For requests for non-formulary rapid acting insulin, approve if: • Diagnosis of Type I or Type II Diabetes • Documentation of trial and failure, inability to use, intolerance, or contraindication to one of the formulary rapid acting insulins. If request is for pen formulation, documentation of trial and failure, inability to use, intolerance, or contraindication to using Admelog Solostar or Insulin Lispro 100 units/ml vial or pen must be provided.
Criteria Statement	Non-formulary rapid acting insulins are reserved for members with diabetes who have used (or cannot/should not use) Admelog vial, Admelog Solostar, Insulin Lispro 100 units/ml vial or pen.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: Remove Levemir as it has been discontinued

Long-Acting Basal Insulin	
Therapeutic Classes (AHFS)	Insulins
Medications	Formulary with quantity limit (30/30): Insulin glargine-yfgn solution 100 unit/ml vial and pen injector **PREFERRED** Rezvoglar (insulin glargine-aglr) 100unit/ml KwikPen **PREFERRED** Lantus Solostar (insulin glargine) 100 unit/ml, Lantus (insulin glargine) 100 unit/ml vial **PREFERRED** Non-formulary Semglee (YFGN) (insulin glargine) 100 unit/ml vial and pen Insulin glargine (Winthrop) 100 unit/ml vial, Solostar ~~Levemir FlexTouch (insulin detemir), Levemir (insulin detemir) vial~~ Toujeo Solostar (insulin glargine) 300 unit/ml pen Tresiba (insulin degludec) 100 unit/ml vial and pen, 200 unit/ml pen Basaglar (insulin glargine) KwikPen 100 unit/ml 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	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 conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	For requests for non-formulary basal insulin, approve if: • Diagnosis of Type I or Type II Diabetes • Documentation of trial and failure, inability to use, intolerance, or contraindication to one formulary preferred long-acting insulin 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	Non-formulary basal insulins are reserved for members with diabetes who have used (or cannot/should not use) one preferred formulary basal insulin: insulin glargine-yfgn solution 100 unit/ml vial / pen injector, Lantus Solostar/ vial, or Rezvoglar KwikPen.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Gonadotropin Releasing Hormone (GNRH) Agonists	
Therapeutic Classes (AHFS)	Gonadotropins
Medications	**Preferred GnRH Agonist(s) for their respective indications:** Lupron Depot (leuprolide acetate) Lupron Depot-Ped (leuprolide acetate) Zoladex (goserelin acetate) **Non-Preferred GnRH Agonist(s):** Fensolvi (leuprolide acetate) Supprelin LA (histrelin acetate) Synarel (nafarelin acetate) Triptodur (triptorelin pamoate) Any newly marketed GnRH agonist
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	Prescriber must be a specialist in the field to treat the member's condition.
Coverage Duration	**Initial Approval** For central precocious puberty: the request will be approved for up to 12 months. If all of the conditions are met, the request will be approved for up to 3-6 months as indicated below for other indications as recommended per FDA approved indications and/or as defined by the medical compendium or standard of care guidelines. **Later Approvals** See Initial Approvals If criteria is not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review
PA Review Criteria	****IF DIAGNOSIS IS CANCER, USE Oral and Injectable Oncology Medications CRITERIA**** **PEDIATRIC POPULATION** *For GID/gender dysphoria coverage, please refer to the Gender Dysphoria medication guidelines for age less than 21.* **ADULT POPULATION** *For GID/gender dysphoria coverage, please refer to the Gender Dysphoria medication guidelines for age 21 years of age or older.* **INITIAL AUTHORIZATION for ALL REQUESTS:** • The medication is being prescribed for an FDA approved/standard of care guideline indication and within FDA approved/standard of care dosing guidelines. AND the member meets the following for the respective diagnosis: Criteria for central precocious puberty:

	• Onset of secondary sexual characteristics occurred when member was aged less than 8 years for females or aged less than 9 years for males
	• Diagnosis of central precocious puberty as defined by one of the following
	  ○ Pubertal response to a GnRH stimulation test and/or measurement of gonadotropins (FSH/LH)
	  ○ Bone age advanced one year beyond the chronological age
	  ▪ Members with low or intermediate basal levels of LH should have a GnRH stimulation test to clarify the diagnosis.
	  • If basal levels of ultrasensitive LH are markedly elevated [e.g. more than 0.3ml IU/L (where IU-International units)] in a child with precocious puberty, then a diagnosis of CPP can be made without proceeding to a GnRH stimulation test.
	• Brain magnetic resonance imaging (MRI) has been performed for all boys with CPP and for girls with onset of secondary sexual characteristics before the age of six years of age to rule out a tumor.
	• If the request is for any agent other than Lupron Depot-Ped the member has had a documented trial and failure with Lupron Depot-Ped or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use Lupron Depot-Ped
	
	<u>Endometriosis:</u>
	• Member has a confirmed diagnosis (e.g. laparoscopy, etc.) of endometriosis
	• Documented contraindication to or trial and failure of the use of a combined oral estrogen-progestin contraceptive OR a progestin only AND non-steroidal anti-inflammatory agents.
	  ○ If one of the following drugs has been tried previously, a trial of OCPs is not required: Orilissa (elagolix), Myfembree, danazol, or aromatase inhibitors (e.g. anastrozole, letrozole)
	• Member is receiving “add back” hormonal therapy (e.g. norethindrone acetate, conjugated estrogen or progestin therapy, etc.)
	• If the request is for a non-preferred agent, the member has had a documented trial and failure with one of the preferred agents or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use these medications
	• Approval is 6 months
	
	<u>Leiomyomata/fibroids:</u>
	• Member has a confirmed diagnosis (e.g. pelvic examination, etc.)
	• If the request is for any agent other than Lupron Depot the member has had a documented trial and failure with Lupron Depot or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use Lupron Depot
	• Approval is 3 months
	
	<u>Endometrial thinning</u>
	• Documentation indicates member is scheduled for endometrial ablation for dysfunctional uterine bleeding.
	• If the request is for any agent other than Zoladex the member has had a documented trial and failure with Zoladex or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use Zoladex
	• Approval is 3 months
	
	<u>REAUTHORIZATION for all requests:</u>

	• The medication is being prescribed for an FDA approved indication and within FDA approved dosing guidelines. • Documentation was provided supporting continued treatment (e.g. member still has symptoms), and medication is being continued as recommended in package insert or standard of care guidelines. <u>AND meets the following per diagnosis:</u> <u>Central precocious puberty (CPP)</u> • If the medication reauthorization is for central precocious puberty, the child is male and < 12 years or female and < 11 years of age OR a documented medical reason to continue treatment was provided with request, and includes current height and bone age <u>Endometriosis</u> • Prescriber has evaluated member for osteoporosis (e.g. Dexascan), and member is receiving "add back" hormonal therapy (e.g. norethindrone acetate, conjugated estrogen or progestin therapy, etc., AND calcium and vitamin D supplementation. • The member has not received cumulative doses of the GnRH agonist greater than 12 months of therapy. <u>Fibroids</u> • The member has not received cumulative doses of the GnRH agonist greater than 6 months of therapy
Criteria Statement	**Central Precocious Puberty:** Lupron Depot-Ped is reserved for members who have met the criteria for the diagnosis and treatment of central precocious puberty. **Endometriosis**: Zoladex and Lupron Depot/Ped are reserved for members who have met the criteria for the diagnosis and treatment of endometriosis. **Uterine leiomyomas (Fibroids):** Lupron Depot is reserved for members who have met the criteria for the diagnosis and treatment of uterine leiomyomas (fibroids). **Endometrial thinning:** Zoladex is reserved for members who have met the criteria for the diagnosis and treatment of endometrial thinning. **Non-preferred agents:** <Insert agent> is reserved for members who have met the criteria for the diagnosis and treatment of <insert indication> and have used (or cannot/ should not use) the preferred agent for the diagnosis <Insert agent(s)>.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Ophthalmic Anti-Inflammatory Agents	
Therapeutic Classes (AHFS)	EENT Nonsteroidal and Corticosteroid anti-inflammatory agents
Medications	Prolensa (bromfenac) 0.07% Bromsite (bromfenac) 0.075% Ketorolac (Acular LS) 0.4% Acuvail (ketorolac) 0.45% Ilevro (nepafenac) 0.3% Nevanac (nepafenac) 0.1% Bromfenac 0.09% Difluprednate (Durezol) 0.05% (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/Re-auth** If all criteria are met, approve for up to a 12 month duration with a quantity limit of 1 bottle; 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 USE: • Documentation of trial and failure, intolerance, contraindication, or inability to use TWO preferred formulary alternatives: diclofenac 0.1%, flurbiprofen 0.03%, ketorolac 0.5% drops, prednisolone 1%, or dexamethasone 0.1% eye drops for at least 30 days each within the last 12 months. • If diagnosis is uveitis: Documentation of trial and failure, intolerance, contraindication, or inability to use both preferred formulary alternatives: prednisolone 1% AND dexamethasone 0.1% eye drops
Criteria Statement	Difluprednate (Durezol), Prolensa, Bromsite, ketorolac (Acular LS), Acuvail, Ilevro, Nevanac, and Bromfenac are reserved for members who have used (or cannot/should not use) TWO preferred formulary alternatives diclofenac 0.1%, flurbiprofen 0.03%, ketorolac 0.5% drops, prednisolone 1%, or dexamethasone 0.1% eye drops for at least 30 days within the last 12 months. For uveitis patients, difluprednate (Durezol) is reserved for members who have used (or cannot/should not use) preferred formulary alternatives prednisolone 1% AND dexamethasone 0.1% eye drops
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: Remove Lazanda and Subsys as they have been discontinued.

Fentanyl Citrate	
Therapeutic Classes (AHFS)	Opiate agonists
Medications	**Non-formulary and require prior authorization:** **Fentanyl citrate (Actiq)** lozenge -PREFERRED Fentanyl citrate (**Fentora**) buccal tablet ~~**Lazanda (fentanyl citrate)** nasal spray pump~~ ~~**Subsys (fentanyl citrate)** sublingual spray~~ **Any other short-acting oral/buccal/sublingual/nasal fentanyl formulation**
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	Oncologist, hospice/palliative care physician, hematologist, or attestation that the requesting prescriber is working in consultation with one of the aforementioned specialty types.
Coverage Duration	**Initial Approval** 6 months not to exceed #120 per 30 days; ~~Lazanda is limited to 15 bottles per 30 days~~ ~~Subsys is limited to 4 boxes per 30 days~~ **Later Approvals** 6 months not to exceed #120 per 30 days; ~~Lazanda is limited to 15 bottles per 30 days~~ ~~Subsys is limited to 4 boxes per 30 days~~ If criteria is not met, request will be sent to a clinical reviewer for medical necessity review.
PA Review Criteria	****All requests for narcotics must be reviewed by a clinical pharmacist.**** **<u>Authorization for Fentanyl Citrate:</u>** • A diagnosis of cancer pain AND • Member is on a maintenance dose of an around-the-clock controlled release pain medication consisting of daily doses of at least morphine 60 mg orally or daily use of an equianalgesic dose of another opioid for a week or longer [e.g. sustained relief morphine, oxycodone ER, fentanyl transdermal patches, morphine ER capsule (Kadian or Avinza)]. AND • Member is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrolled nausea/vomiting OR documentation of trial and failure of at least 2 of the following immediate-release oral pain medications: morphine sulfate, oxycodone/acetaminophen, oxycodone immediate release, hydrocodone/acetaminophen, and hydromorphone. • For requests for (fentanyl citrate) Fentora, ~~Fentora, Subsys, and Lazanda,~~ all criteria listed above must be met AND documentation required of trial and failure, intolerance, contraindication to fentanyl citrate (Actiq) lozenges
Criteria Statement	Fentanyl citrate (Actiq) lozenges are reserved for members with cancer pain who are on maintenance doses of controlled release opioids and who are unable to swallow or has used (or cannot/should not use) at least 2 of the following immediate-release oral pain medications: morphine sulfate, oxycodone/acetaminophen, oxycodone immediate release, hydrocodone/acetaminophen, and hydromorphone. (Fentanyl citrate) Fentora~~, Subsys, or Lazanda are~~ <u>is</u> reserved for members with cancer pain who are on maintenance doses of controlled release opioids and member is unable to swallow or has used (or cannot/should not use) at least 2 of the following

	immediate-release oral pain medications: morphine sulfate, oxycodone/acetaminophen, oxycodone immediate release, hydrocodone/acetaminophen, and hydromorphone AND fentanyl citrate (Actiq) lozenges.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: Change naming convention to reflect generic availability of Nexium oral granules packet

Proton Pump Inhibitors (PPIs)	
Therapeutic Classes (AHFS)	Proton Pump Inhibitors
Medications	Formulary Omeprazole (Prilosec) capsule Pantoprazole (Protonix) tablet Lansoprazole (Prevacid) DR capsule Formulary, step therapy required Rabeprazole (Aciphex) tablet Esomeprazole (Nexium) capsule Formulary, PA required Dexlansoprazole (Dexilant) capsule Non-Formulary Omeprazole tablet and capsule (Prilosec OTC) Omeprazole/sodium bicarbonate (Zegerid) capsules and packets Lansoprazole (Prevacid) orally disintegrating tablets Esomeprazole (Nexium 24 HR) tablet ~~Nexium DR (e~~Esomeprazole~~)~~ (Nexium) oral granules packet Rabeprazole (Aciphex) sprinkle capsules Pantoprazole (Protonix) packet for oral suspension Prilosec packet for oral suspension Any other non-formulary proton pump inhibitor medication or dosage formulation
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "**PA Review Criteria**" below
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	**Initial Approval** 12 months **Reauthorization** 12 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	Criteria for approval: Rabeprazole tablets or esomeprazole capsules are approved when the following criteria is met: • Documentation of a trial and failure, or intolerance to omeprazole 40mg capsules AND pantoprazole 40 mg or lansoprazole DR capsule Dexlansoprazole (Dexilant) and non-formulary medications are approved when the following criteria are met: • Documentation of a trial and failure, or intolerance to at least 4 of the following formulary alternatives: omeprazole capsule, pantoprazole tablet, lansoprazole DR capsule, as first line; esomeprazole capsule or rabeprazole tablet as second line
Criteria Statement	Rabeprazole tablets or esomeprazole capsules are reserved for members who have used (or cannot/should not use) omeprazole 40 mg capsules AND pantoprazole 40 mg or lansoprazole DR capsules.

Proton Pump Inhibitors (PPIs)	
	Dexlansoprazole (Dexilant) and non-formulary proton pump inhibitors are reserved for members who have used (or cannot/should not use) at least 4 of the following formulary alternatives: omeprazole capsule, pantoprazole tablet, lansoprazole DR capsule, as first line; esomeprazole tablet DR or rabeprazole tablet as second line.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Ranolazine (Ranexa, Aspruzyo)	
Therapeutic Classes (AHFS)	CARDIAC DRUGS, MISCELLANEOUS
Medications	Ranolazine ER (Ranexa) Aspruzyo Sprinkle (ranolazine granules)
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 **Later Approvals** 12 months If criteria is not met, request will be sent to a clinical reviewer for medical necessity review.
PA Review Criteria	CRITERIA FOR AUTHORIZATION Ranolazine ER (Ranexa): • Diagnosis of chronic angina pectoris AND • Documented trial and failure, contraindication, or intolerance to use a beta-blocker, calcium channel blocker AND long-acting nitrate. OR • Documentation member's blood pressure is too low to tolerate additional medications Aspruzyo Sprinkle (ranolazine) • All of the above criteria are met • Documented trial and failure, contraindication, or intolerance to ranolazine ER (Ranexa)
Criteria Statement	Ranolazine ER (Ranexa) is reserved for members who have used (or cannot/should not use) a beta-blocker, calcium channel blocker, and long-acting nitrate. Aspruzyo Sprinkle (ranolazine) is reserved for members who have used (or cannot/should not use) a beta-blocker, calcium channel blocker, and long-acting nitrate AND ranolazine ER (Ranexa).
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: Remove Otrexup and all references to the drug from the criteria as it has been discontinued

Injectable Methotrexate	
Therapeutic Classes (AHFS)	Antineoplastic agents
Medications	Rasuvo (methotrexate) ~~Otrexup (methotrexate)~~ Any other newly approved injectable methotrexate medication
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 is a dermatologist or rheumatologist.
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 of Rasuvo:~~
	• For diagnosis of severe, active polyarticular juvenile idiopathic arthritis, approve if:
	  ○ Documented trial and failure, intolerance, contraindication, or inability to use methotrexate tablet AND generic methotrexate injection solution
	• For diagnosis of severe, recalcitrant psoriasis, approve if:
	  ○ Documented trial and failure, intolerance, contraindication, or inability to use one of the following alternatives: topical corticosteroids AND topical vitamin D analogue (e.g., calcipotriene)
	  ○ Documented trial and failure, intolerance, contraindication, or inability to use methotrexate tablet AND generic methotrexate injection solution
	• For diagnosis of severe, active rheumatoid arthritis, approve if:
	  ○ Documented trial and failure, intolerance, contraindication, or inability to use methotrexate tablet AND generic methotrexate injection solution
	
	~~Criteria for approval of Otrexup:~~
	~~• Criteria above for Rasuvo must be met, per diagnosis AND~~
	~~• Documented trial and failure, intolerance, contraindication, or inability to use Rasuvo~~

Criteria Statement	For members with juvenile idiopathic arthritis or severe rheumatoid arthritis, Rasuvo is reserved for members who have used (or cannot/should not use) generic methotrexate tablet and injection. ~~Otrexup is reserved for members who have used (or cannot/should not use) Rasuvo.~~ For members with severe psoriasis, Rasuvo is reserved for members who have used (or cannot/should not use) topical corticosteroids AND topical vitamin D analogue (e.g., calcipotriene) AND methotrexate tablet AND methotrexate injection. ~~Otrexup is reserved for members who have used (or cannot/should not use) Rasuvo.~~
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Temazepam (Restoril)	
Therapeutic Classes (AHFS)	BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)
Medications	Temazepam (Restoril) 7.5, 22.5 mg
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** 6 months **Later Approvals** 12 months If criteria is not met, request will be sent to a clinical reviewer for medical necessity review.
PA Review Criteria	**CRITERIA FOR AUTHORIZATION** • Request is for 7.5 mg or 22.5 mg: ○ Diagnosis of insomnia. ○ Documented trial and failure, intolerance, or inability to use 3 of the following: 1) temazepam 15mg or 30mg capsules, 2) zolpidem, 3) eszopiclone, 4) zaleplon for at least 2 weeks (14 days) of therapy each.
Criteria Statement	Temazepam 7.5 mg or 22.5 mg are reserved for members who have used (or cannot/should not use) three of the following medications: temazepam 15mg or 30mg, zolpidem, eszopiclone, or zaleplon for at least 2 weeks (14 days) of therapy each
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: Remove Androderm as it has been discontinued

Testosterone Agents	
Therapeutic Classes (AHFS)	Androgens
Medications	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 (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 • Xyosted (testosterone enanthate) subcutaneous auto-injector • Jatenzo (testosterone undecanoate) oral capsules • Tlando (testosterone undecanoate) oral capsules • Kyzatrex (testosterone undecanoate) oral capsules Any other newly marketed agents in this class *Requests for greater than indicated Quantity Limits will be reviewed on a case by case basis
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 "**PA Review Criteria**" below
Required Clinical Information	See "**PA Review Criteria**" below
Age Restrictions	See "**PA Review Criteria**" below
Prescriber Restrictions	N/A
Coverage Duration	**Initial Approval** If all conditions are met, the request will be approved for up to 3 months. If all criteria are not met, the request is referred to Clinical Reviewer for medical necessity review. **Later Approvals** 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.

Testosterone Agents	

PA Review Criteria	*For GID/gender dysphoria coverage, please refer to the Gender Dysphoria medication guidelines for age less than 21 or greater than or equal to 21 years old.*
	
	INITIAL AUTHORIZATION CRITERIA:
	• Formulary, PA required (second-line) agents are approved if:
	  ○ Diagnosis of primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired)
	  ○ Male member
	  ○ Documented testosterone level(s) below 300ng/dL(9.8-10.4 nmol/l) on two separate occasions with levels drawn before 10:00 am
	  ○ Documented trial and failure, contraindication, or intolerance to one formulary first line injectable testosterone AND one formulary first line topical testosterone
	• Non-formulary testosterone products are approved if:
	  ○ Diagnosis of primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired)
	  ○ Male member
	  ○ Documented testosterone level(s) below 300ng/dL(9.8-10.4 nmol/l) on two separate occasions with levels drawn before 10:00 am
	  ○ Documented trial and failure, contraindication, or intolerance to one formulary first line injectable testosterone AND one formulary first line topical testosterone AND at least one formulary, PA required (second-line) agent
	REAUTHORIZATION CRITERIA
	• Diagnosis of primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired).
	
	<u>For requests over the quantity limit:</u>
	• The member must have a documented treatment failure with the drug prescribed at the health plan's quantity limit **OR** the member requires a dose within prescribing guidelines that exceeds the plan's quantity limit. **AND**
	• The provider has submitted a medical reason why the plan's quantity limit will be inadequate based on the member's condition and treatment history. **AND**
	• The dose requested is supported by the Medical Compendia or current treatment guidelines.

Criteria Statement	(Formulary, PA required (second-line) medications) <INSERT: testosterone packets/tube/solution pump or testosterone enanthate> are reserved for members who have previously used (or cannot/should not take) testosterone cypionate injection AND testosterone (Vogelxo) 1% gel pump or testosterone (Androgel) 1.62% gel pump. 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. 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	~~12/2024~~<u>12/2025</u>

Recommendation: No changes

Thalomid (thalidomide)	
Therapeutic Classes (AHFS)	IMMUNOMODULATORY AGENTS
Medications	Thalomid (thalidomide)
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	Prescribing physician is infectious disease specialist, oncologist, nephrologist, dermatologist, or hematologist
Coverage Duration	**Initial Approval** 12 months **Later Approvals** 12 months If criteria is not met, request will be sent to a clinical reviewer for medical necessity review.
PA Review Criteria	Thalomid is approved if: • Diagnosis of one of the following: ○ erythema nodosum leprosum ○ multiple myeloma ○ chronic graft-versus-host disease (GVHD) in hematopoietic stem cell transplant ○ AIDS-related aphthous stomatitis ○ Waldenstrom's macroglobunemia ○ Systemic light chain amyloidosis
Criteria Statement	Thalomid is reserved for members with erythema nodosum leprosum, multiple myeloma, chronic graft-versus-host disease (GVHD) in hematopoietic stem cell transplant, AIDS-related aphthous stomatitis, Waldenstrom's macroglobunemia, systemic light chain amyloidosis
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Topical Diclofenac	
Therapeutic Classes (AHFS)	Non-steroidal Anti-Inflammatory Agents
Medications	Formulary, Prior Authorization Required Diclofenac epolamine (Flector) 1.3% patch Diclofenac (Pennsaid) 2% pump Diclofenac (Pennsaid) 1.5% solution Non-Formulary Licart (diclofenac) 1.3% patch
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-auth** If all criteria are met, approve diclofenac (Pennsaid) 2% pump or diclofenac (Pennsaid) 1.5% solution for up to a 12 month duration or diclofenac (Flector) patch or Licart (diclofenac) patch for up to a 3 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 approval: • Diagnosis of osteoarthritis [diclofenac (Pennsaid) 1.5% topical solution] or acute pain [diclofenac (Flector) 1.3% patch] AND one of the following conditions are met: ○ Member is over 65 years ○ Member is currently taking oral anticoagulant ○ Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to one oral NSAID medication. AND ○ For diclofenac (Pennsaid) 1.5% topical solution, trial and failure or contraindication to use diclofenac (Voltaren) gel. OR ○ For diclofenac (Pennsaid) 2% pump, trial and failure or contraindication to use diclofenac (Voltaren) gel AND diclofenac (Pennsaid) 1.5% topical solution OR ○ For Licart (diclofenac) 1.3% patch, trial and failure or contraindication to use diclofenac epolamine (Flector) 1.3% patch
Criteria Statement	Diclofenac (Pennsaid) 1.5% solution is reserved for members with osteoarthritis who are either 65 years of age or currently using an oral anticoagulant and who have used (or cannot/should not use) one oral NSAID AND diclofenac (Voltaren) gel. Diclofenac (Flector) patch is reserved for members with acute pain who are either 65 years of age, currently using an oral anticoagulant, or who have used (or cannot/should not use) one oral NSAID. Diclofenac (Pennsaid) 2% pump is reserved for members with osteoarthritis who are either 65 years of age or currently using an oral anticoagulant and who have used (or cannot/should not use) one oral NSAID AND who have used (or cannot/should not use) diclofenac (Voltaren) gel and diclofenac (Pennsaid) 1.5% topical solution. Licart (diclofenac) 1.3% patch is reserved for members with acute pain who are either 65 years of age or currently using an oral anticoagulant and who have used (or cannot/should not use) one oral NSAID AND who have used (or cannot/should not use) diclofenac epolamine (Flector) 1.3% patch.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Oral Anti-Fungals	
Therapeutic Classes (AHFS)	Azoles; antifungals miscellaneous
Medications	Formulary fluconazole 50, 100, 150, 200 mg tablet and 10, 40 mg/ml suspension terbinafine 250 mg tablet Formulary, with age restriction: limited to members ≤ 12 years griseofulvin microsize 125 mg/5 ml suspension Formulary, step therapy griseofulvin microsized 500 mg and ultramicrosized 125, 250 mg tablet Formulary, prior authorization required /Non-formulary voriconazole (Vfend) 50, 200 mg tablet and 200 mg/5 ml suspension itraconazole 100 mg capsules and 10 mg/ml suspension posaconazole delayed release-tablet posaconazole (Noxafil) oral suspension Cresemba (isavuconazonium) capsule Flucytosine 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	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	N/A
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	For **voriconazole**, approve if one of the following:
	• Diagnosis of one of the following:
	  • Invasive pulmonary aspergillus infections
	  • A serious fungal infection caused by Scedosporium apiospermum or Fusarium species
	  • Treatment of invasive candidiasis in critically ill patients
	  • Primary prophylaxis for aspergillus infections for special populations such as lung transplant, acute myeloid leukemia (AML), allo-stem cell transplant with prolonged neutropenia from chemotherapy AND high risk for infection
	• For esophageal candidiasis or candidemia in nonneutropenic patients: documentation of trial and failure, intolerance, or contraindication to fluconazole or nystatin
	• For blastomycosis or histoplasmosis: documentation of trial and failure, intolerance, or contraindication to itraconazole
	
	For **itraconazole** capsules, approve if one of the following:
	• Diagnosis of aspergillosis and documentation of intolerance or disease refractory to voriconazole capsules
	• Diagnosis of blastomycosis, histoplasmosis
	• Diagnosis of coccidioidal infections and documentation of trial and failure, intolerance, contraindication, or inability to use fluconazole
	• Diagnosis of oropharyngeal or esophageal candidiasis and the member is immunocompromised. If the member is not immunocompromised,

Oral Anti-Fungals	
	documentation of trial and failure, intolerance, contraindication, or inability to use oral fluconazole • Diagnosis of onchomycosis and documentation of trial and failure, intolerance, contraindication, or inability to use terbinafine or fluconazole For **griseofulvin** tablets, approve if: • Diagnosis of dermatophyte infections of the skin, hair, and nails: tinea barbae, capitis, corporis, cruris, pedis, unguium (onchomycosis) and documentation of trial and failure, intolerance, inability to use, or contraindication to use terbinafine 250 mg or topical therapy (e.g. ciclopirox 8% solution, terbinafine cream, gel, or solution) • If request is for oral solution, the above criteria must be met and documentation of inability or difficulty swallowing must be provided For **posaconazole tablets**, approve if one of the following: • For prophylaxis of invasive aspergillus or candida in patients at high risk of developing invasive aspergillus or candida due to being severely immunocompromised: trial and failure or inability to use voriconazole • For the treatment of invasive aspergillosis: trial and failure or inability to use voriconazole For **posaconazole suspension,** approve if: • For oropharyngeal candidiasis, there is documentation of trial and failure, intolerance, or contraindication to fluconazole For **Cresemba**, approve if one of the following: • Diagnosis of invasive mucormycosis in adults • For invasive aspergillosis in adults, there is documentation of trial and failure, intolerance, or contraindication to voriconazole For **flucytosine**, approve if one of the following: • Diagnosis of cryptococcal meningitis or cryptococcosis • Diagnosis of candidiasis with CNS involvement, symptomatic urinary tract infections (e.g. cystitis, pyelonephritis, or fungal masses), endocarditis or infected cardiac devices, endophthalmitis, septicemia, or pulmonary infections **Reauthorization** • Documentation is provided that the member has responded to therapy • Additional therapy is medically necessary and clinically appropriate **NOTE**: ○ Requests for itraconazole solution require a documented trial and failure, or intolerance to itraconazole oral capsules unless the oral solution is being requested for diagnosis of oropharyngeal or esophageal candidiasis. ○ Requests for voriconazole suspension require a documented trial and failure, or intolerance to voriconazole tablets ○ Requests for flucytosine require combination therapy with amphotericin B for systemic candidiasis, cryptococcal meningitis, or cryptococcosis
Criteria Statement	**Voriconazole** tablets are reserved for members who have used (or cannot/should not use) a formulary medication (i.e. fluconazole or nystatin). For blastomycosis or histoplasmosis, voriconazole tablets are reserved for members who have used (or cannot/should not use) itraconazole.

Oral Anti-Fungals	
	Voriconazole oral suspension is reserved for members who have used (or cannot/should not use) voriconazole tablets. **Itraconazole** capsules are reserved for members who have used (or cannot/should not use) fluconazole or terbinafinetablets, **Itraconazole** oral solution is reserved for members who have used (or cannot/should not use) itraconazole capsules unless the oral solution is being requested for diagnosis of oropharyngeal or esophageal candidiasis. **Griseofulvin** tablets are reserved for members who have used (or cannot/should not use) terbinafine 250 mg tablet or topical medications. **Griseofulvin** oral solution is reserved for members who have used (or cannot/should not use) griseofulvin tablets. **Posaconazole** tablets are reserved for members who have used (or cannot/should not use) voriconazole. **Posaconazole** suspension is reserved for members who have used (or cannot/should not use) fluconazole. **Cresemba** is reserved for members who have used (or cannot/should not use) voriconazole. **Flucytosine** is reserved for members who have a diagnosis of cryptococcal meningitis or cryptococcosis, candidiasis with CNS involvement, symptomatic urinary tract infections (e.g. cystitis, pyelonephritis, or fungal masses), endocarditis or infected cardiac devices, endophthalmitis, septicemia, or pulmonary infection.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Gattex (teduglutide)	
Therapeutic Classes (AHFS)	GI DRUGS, MISCELLANEOUS
Medications	Gattex (teduglutide)
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	**Initial Approval** 12 month duration with a quantity limit of 1 kit per 30 days **Later Approvals** 12 month duration with a quantity limit of 1 kit 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 • Diagnosis of Short Bowel Syndrome (SBS) AND • Dependent on intravenous parenteral nutrition, defined as requiring parenteral nutrition at least three times per week.
Criteria Statement	Gattex is reserved for members with short bowel syndrome and who are dependent on intravenous parenteral nutrition at least 3 times a week.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors	
Therapeutic Classes (AHFS)	Vesicular Monoamine Transport 2 Inhibitor
Medications	Non-formulary, PA required: Ingrezza (valbenazine) capsules Austedo (deutetrabenazine) tablets Tetrabenazine (Xenazine) tablets 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	Concurrent use of monoamine oxidase inhibitors (MAOIs)
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	**Initial Authorization:** • Dose is within FDA-approved limits • Prescriber attests patient will not be receiving treatment with any other VMAT2 inhibitor **For approval for use in tardive dyskinesia (TD):** • Member must have clinical diagnosis of tardive dyskinesia that has persisted for the last 90 days, with documented baseline evaluation (e.g., Abnormal Involuntary Movement Scale (AIMS), the Tardive Dyskinesia Rating Scale (TDRS), etc.) • For members on antipsychotics, the antipsychotic dose(s) must have been stable for a continuous 90 day period at some point prior to the request • Prescriber has attempted at least ONE of the following strategies to manage the patient's condition, or has provided a clinical reason why NONE of the following are possible: o Reducing the dose of the drug responsible for causing dyskinesia o Discontinuing the drug responsible for causing dyskinesia o For members on first generation antipsychotics, switching to a second generation antipsychotic o Trial of benzodiazepines • For VMAT2 inhibitors other than tetrabenazine, member has a documented medical reason (e.g., treatment failure, intolerance, hypersensitivity, contraindication) for not using tetrabenazine AND o For Austedo requests: ▪ Prescriber attests patient has no signs of hepatic impairment ▪ For patients at risk for QT prolongation, prescriber attests a baseline ECG has been obtained o For Ingrezza requests: ▪ Must be dosed at one capsule per day **For approval for use in chorea associated with Huntington's Disease (HD):** • Patient must have diagnosis of moderate to severe Huntington's with chorea, with documented baseline Total Maximal Chorea (TMC) score provided

	• For VMAT2 inhibitors other than tetrabenazine, member has a documented medical reason (e.g., treatment failure, intolerance, hypersensitivity, contraindication) for not using tetrabenazine AND
	  ○ For Austedo requests:
	  ▪ Prescriber attests patient has no signs of hepatic impairment
	  ▪ For patients at risk for QT prolongation, prescriber attests a baseline ECG has been obtained
	  ○ For Ingrezza requests:
	  ▪ Must be dosed at one capsule per day
	
	Reauthorization:
	• Documentation or provider attestation of positive clinical response (e.g., improvement from baseline in average scores on the previously submitted symptom rating scale, decrease in symptoms, etc.)
	• Dose is within FDA approved limits

Criteria Statement	For a diagnosis of chorea with Huntington's disease, Austedo and Ingrezza are reserved for members who have used (or cannot/should not use) tetrabenazine. For a diagnosis of tardive dyskinesia, Austedo and Ingrezza are reserved for members who have used (or cannot/should not use) tetrabenazine.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No policy changes, add Otezla XR formulation for completeness

Otezla (apremilast) for Behcet Disease	
Therapeutic Classes (AHFS)	Disease-Modifying Antirheumatic Agents
Medications	Otezla/Otezla XR (apremilast)
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	Concurrent use with a biologic DMARD or targeted synthetic DMARD
Required Clinical Information	See "**PA Review Criteria**" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescriber is a rheumatologist or a dermatologist or is working in consultation with a rheumatologist or dermatologist
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 initial authorization: • Drug is being requested at an FDA approved dose. • Documentation of clinical diagnosis of Behcet disease • Documentation of at least one active oral ulcer • Member is not concurrently taking a biologic DMARD (i.e. Orencia, Humira, Stelara, etc.) or a targeted synthetic DMARD (i.e. Olumiant, Xeljanz, etc.) • Documentation that the member has had (consistent with pharmacy claims data OR for new members to the health plan consistent with medical chart history) adequate trial and failure or intolerance to at least one formulary topical steroid and colchicine. Criteria for re-authorization: • Drug is being requested at an FDA approved dose. • Documentation that condition has improved or stabilized with therapy
FCriteria Statement	Otezla (apremilast) is reserved for members who have at least one active oral ulcer associated with Behcet disease and have used (or cannot/should not use) at least one formulary topical steroid and colchicine.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Rayaldee (calcifediol ER)	
Therapeutic Classes (AHFS)	Vitamin D Analog
Medications	Non-formulary, PA required Rayaldee (calcifediol ER)
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 nephrologist or endocrinologist (or working in consultation with a nephrologist or endocrinologist)
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	The following criteria must be met for initial requests: • Drug is being requested at an FDA approved dose. • Treatment of secondary hyperparathyroidism associated with a diagnosis of stage 3 or 4 chronic kidney disease (CKD) and is not on dialysis • A serum total 25-hydroxyvitamin D level less than 30 ng/mL and a serum corrected total calcium below 9.8 mg/dL • Documented trial and failure, contraindication, or documented inability to use a preferred vitamin D analog (ex. calcitriol) The following criteria must be met for renewal requests: • Drug is being requested at an FDA approved dose. • Serum total 25-hydroxyvitamin D levels between 30 and 100 ng/mL • Intact parathyroid hormone (PTH) levels within the desired therapeutic range of 10-65 ng/L • Serum calcium (corrected for low albumin) within the normal range for member • Serum phosphorus below 5.5 mg/dL
Criteria Statement	For the treatment of secondary hyperparathyroidism associated with stage 3 or 4 chronic kidney disease (CKD), Rayaldee is reserved for members who have used (or cannot/should not use) a preferred vitamin D analog (ex. calcitriol). Members must also have a serum total 25-hydroxyvitamin D level less than 30 ng/mL and a serum corrected total calcium below 9.8 mg/dl. The request will not be approved for patients with a diagnosis of stage 5 chronic kidney disease or end-stage renal disease on dialysis.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Korlym (mifepristone)	
Therapeutic Classes (AHFS)	Cortisol receptor blocker
Medications	Non-formulary, PA required Korlym (mifepristone)
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	Pregnancy
Required Clinical Information	See "**PA Review Criteria**" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
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	The following criteria must be met for initial requests: • Diagnosis of hyperglycemia secondary to endogenous Cushing's syndrome with type 2 diabetes mellitus (T2DM) or impaired glucose tolerance (IGT) • Drug is being requested at an FDA approved dose. • Member has failed pituitary surgery or is not a candidate for pituitary surgery • Documented trial and failure of insulin and at least 2 other conventional anti-hyperglycemic medications (ex. metformin, sulfonylurea, DPP-4 inhibitor, etc.) or a documented medical reason for not utilizing these medications. • For females of reproductive age: Must have documentation of a baseline negative pregnancy test within the previous 14 days The following criteria must be met for renewal requests: • Drug is being requested at an FDA approved dose. • Documentation of an improvement in or stabilization of glucose control (ex. reduction in fasting blood glucose, oral glucose tolerance test, or Hemoglobin A1c). • For females of reproductive age: Must have documentation of a recent negative pregnancy test within the previous 14 days
Criteria Statement	Korlym is reserved for members with hyperglycemia from Cushing's syndrome with type 2 diabetes or impaired glucose tolerance who have failed surgery or are not candidates for surgery. The member should have used (or cannot/should not use) other conventional anti-diabetic medications and female members must have a negative pregnancy test.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Tetracycline Antibiotics	
Therapeutic Classes (AHFS)	Tetracycline antibiotics
Medications	Formulary Doxycycline monohydrate 50mg, 100mg capsule Doxycycline monohydrate 100mg tablet Tetracycline 250mg, 500mg capsule Formulary, step therapy required Minocycline 100mg 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	N/A
Coverage Duration	**Minocycline ST and NF Tetracyclines Approval:** 6 months **Approval to Exceed QL:** 3 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	**ALL medications in the tetracycline class are limited to a combined total of 180 days supply per 365 days** Minocycline capsule step therapy criteria: • Dose is appropriate per label or supported by compendia/standard of care guidelines, and is within posted quantity limits • Documentation of a trial and failure or intolerance to doxycycline required. **OR** • Documentation of culture and sensitivity data, showing minocycline is the only treatment option. Non-formulary and formulary, prior authorization required tetracyclines • Appropriate diagnosis/Indication for requested non-formulary or formulary, prior authorization required medication or meets off-label criteria below AND o Off-label criteria: ▪ No other formulary preferred medication has a medically accepted use for the patient's specific diagnosis as referenced in the medical compendia AND ▪ 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 • Appropriate dose of medication based on age (i.e. pediatric and elderly populations) and indication AND • Documentation of a trial and failure or intolerance with 3 formulary preferred tetracyclines required **OR**

	• Documentation of culture and sensitivity data, showing the non-formulary/prior authorization required tetracycline is the only treatment option <u>Request for exceeding quantity limit of 180 days per 365 days</u> • The member must have a documented treatment failure with the drug prescribed at the health plan's quantity limit OR the member requires a dose within prescribing guidelines that exceeds the plan's quantity limit. AND • The provider has submitted a medical reason why the plan's quantity limit will be inadequate based on the member's condition and treatment history. AND • The dose requested is supported by the Medical Compendia or current treatment guidelines.
	Minocycline capsule is reserved for members who have used (or cannot/should not use) doxycycline. Medications in the tetracycline class that are non-formulary or formulary, prior authorization required are reserved for members who have used (or cannot/should not use) at least 3 formulary preferred tetracyclines. Medications in the tetracycline class prescribed in quantities over 180 days supply per 365 days are reserved for members who have used (or cannot/should not use) tetracyclines under the quantity limit, whose prescriber has submitted a reason why this is necessary.
Last P&T Review Date	~~12/2024~~<u>12/2025</u>

Recommendation: No changes

Botulinum Toxins A&B	
Therapeutic Classes (AHFS)	OTHER MISCELLANEOUS THERAPEUTIC AGENTS
Medications	PA required Xeomin (incobotulinumtoxinA) - Preferred Non-Formulary Botox (onabotulinumtoxinA) Myobloc (RimabotulinumtoxinB) Dysport (ibobotulinumtoxinA) Daxxify (daxibotulinumtoxinA) 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	Cosmetic use
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 conditions are met, the request will be approved for 12 month duration. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.

PA Review Criteria	***The use of these medications for cosmetic purposes is NOT a covered benefit***
	Xeomin is the preferred product for all FDA approved indications
	
	The following criteria must be met for initial requests:
	• Dose is appropriate per label or supported by compendia/standard of care guidelines
	• Documentation was submitted, that the member had an adequate trial (consistent with pharmacy claims) standard first line therapy for their condition and/or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc) for not taking first line therapy to treat their medical condition.
	• If the diagnosis is **chronic migraine** (≥15 days per month with headache lasting 4 hours a day or longer), the member has a documented adequate trial, for at least 4 weeks EACH, at minimum effective doses (consistent with pharmacy claims data) of two of the following classes of drugs:
	  ○ Beta blockers (e.g. propranolol, timolol, etc.) or candesartan
	  ○ Amitriptyline or venlafaxine
	  ○ Divalproex ER or DR, valproic acid or topiramate
	  ○ Or a medical reason was submitted (intolerance, hypersensitivity, contraindication, etc) why the member is not able to utilize these therapies.
	• If the diagnosis is **overactive bladder**, the member has a documented adequate trial (consistent with pharmacy claims data) of at least 2 formulary medications (e.g. oxybutynin)
	• If the diagnosis is **Hyperhidrosis,** the member has tried and failed a prescription strength antiperspirant (e.g. 20% aluminum chloride hexahydrate)
	• If the diagnosis is **Chronic Sialorrhea**,

	○ Documentation is provided that the member has had sialorrhea lasting at least 3 months ○ The member has tried and failed at least two anticholinergic medications (e.g. glycopyrrolate, hyoscyamine, benztropine) • For all FDA-approved indications, if the medication request is for a botulinum toxin other than Xeomin, the member has a documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure etc) for not using to treat their medical condition. The following criteria must be met for re-authorization requests: • Dose and indication continue to be appropriate per label or supported by compendia/standard of care guidelines • Documentation submitted indicates a clinical benefit was observed and rationale for continuation of treatment
Criteria Statement	Xeomin is reserved for members with medical conditions which these medications are approved for use in. The member should have used (or cannot/should not use) other preferred treatments for the condition prior to the approval of Xeomin. Non-formulary botulinum toxin medications are reserved for members with medical conditions which these medications are approved for use in and who have used (or cannot/should not use) other preferred treatments for the condition and who have used (or cannot/should not use) Xeomin.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Agents for graft versus host disease	
Therapeutic Classes (AHFS)	OTHER MISCELLANEOUS THERAPEUTIC AGENTS, ANTINEOPLASTIC AGENTS
Medications	Rezurock (belumosudil) Imbruvica (ibrutinib) Jakafi (ruxolitinib phosphate) Orencia (abatacept)
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	N/A
Required Clinical Information	See "other criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescriber must be a hematologist, oncologist, or other specialist in the treatment of hematopoietic cell transplants
Coverage Duration	Jakafi, Rezurock, and Imbruvica: If all of the conditions are met, the request will be approved for up to a 3 month duration for initial requests and up to a 6 month duration for renewal requests. Orencia: If all of the conditions are met, the request will be approved for 1 month duration (4 total treatments) If criteria is not met, request will be sent to a Medical Director/clinical reviewer for medical necessity review.
PA Review Criteria	****For oncological indications, please refer to the "Oral and Injectable Oncology Medications" policy**** **Initial Authorization:** • Imbruvica o Member has a diagnosis of chronic graft versus host disease o Member has tried and failed or cannot use a systemic corticosteroid or documentation is provided as to why a systemic corticosteroid cannot be used o The drug is prescribed at an FDA-approved dose • Jakafi o Member has a diagnosis of acute graft versus host disease or a diagnosis of chronic graft versus host disease o Member has tried and failed or cannot use a systemic corticosteroid or documentation is provided as to why a systemic corticosteroid cannot be used o The drug is prescribed at an FDA-approved dose • Rezurock o Member has a diagnosis of chronic graft versus-host disease o Member has tried and failed at least two lines of systemic immunosuppressive therapy (e.g. corticosteroids, calcineurin inhibitors, mycophenolate mofetil, ibrutinib, ruxolitinib), one of which must be a systemic corticosteroid, or documentation is provided as to why a systemic corticosteroid cannot be used o The drug is prescribed at an FDA-approved dose • Orencia o Orencia is being requested for prophylaxis against acute graft versus host disease

	○ Member will be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor ○ Member will be receiving Orencia in combination with a calcineurin inhibitor (e.g., tacrolimus, cyclosporine) and methotrexate ○ Member will be receiving antiviral prophylactic treatment for Epstein-Barr virus reactivation and will continue for 6 months following HSCT ○ Attestation provider has considered prophylactic antivirals for cytomegalovirus (CMV) infection/reactivation during treatment and for 6 months following HSCT ○ The drug is prescribed at an FDA-approved dose **Re-Authorization:** • Documentation is provided that the member has achieved a clinical benefit from medication (e.g. symptom improvement, reduction in corticosteroid dose) • The drug is prescribed at an FDA-approved dose
Criteria Statement	Imbruvica is reserved for members with a diagnosis of chronic graft versus host disease who have used (or cannot /should not use) a systemic corticosteroid. Jakafi is reserved for members with a diagnosis of acute graft versus host disease or a diagnosis of chronic graft versus host disease who have used (or cannot/should not use) a systemic corticosteroid. Rezurock is reserved for members with a diagnosis of chronic graft versus-host disease who have used (or cannot /should not use) at least two lines of systemic immunosuppressive therapy (e.g. corticosteroids, calcineurin inhibitors, mycophenolate mofetil, ibrutinib, ruxolitinib), one of which must be a systemic corticosteroid. Orencia is reserved for members with a need for prophylaxis against acute graft versus host disease who will be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor, using Orencia in combination with a calcineurin inhibitor (e.g., tacrolimus, cyclosporine) and methotrexate.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Janus Kinase Inhibitors for Nonsegmental Vitiligo	
Therapeutic Classes (AHFS)	SKIN AND MUCOUS MEMBRANE AGENTS, MISC.
Medications	Opzelura (ruxolitinib)
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	> 12 years of age
Prescriber Restrictions	Dermatologist, immunologist, or specialist experienced in the treatment of vitiligo
Coverage Duration	**Initial Approval** 6 months **Later Approvals** 12 months If criteria is not met, request will be sent to a clinical reviewer for medical necessity review.
PA Review Criteria	**Initial Authorization** ○ Diagnosis of nonsegmental vitiligo ○ Documentation of depigmented lesions including measurements and locations is provided ○ Prescriber attests that the total body vitiligo area (facial and nonfacial) being treated does not exceed 10% BSA ○ Trial and failure of, or intolerance to, ALL of the following: ○ Topical corticosteroids ○ Topical calcineurin inhibitors ○ Targeted phototherapy ○ Prescriber attests that the member will not concomitantly use therapeutic biologics, other Janus kinase inhibitors, potent immunosuppressants, or phototherapy for repigmentation purposes ○ Request is for an FDA-approved dose ****A MAXIMUM OF ONE 60 GRAM TUBE OF OPZELURA PER WEEK OR ONE 100 GRAM TUBE EVERY TWO WEEKS MAY BE APPROVED**** **Reauthorization** ○ Prescriber attests that the member has experienced a clinical benefit (e.g. reduction in size or quantity of or stabilization of existing depigmented lesions; absence of new depigmented lesions) ○ Request is for an FDA-approved dose
Criteria Statement	Opzelura is reserved for members with a diagnosis of nonsegmental vitiligo, with the total body vitiligo area (facial and nonfacial) being treated not exceeding 10% body surface area (BSA), who have used (or cannot/should not use) all of the following: topical corticosteroids, topical calcineurin inhibitors, and targeted phototherapy
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Budesonide Nebulization Solution (Pulmicort Respules)	
Therapeutic Classes (AHFS)	ORALLY INHALED PREPARATIONS (STEROIDS)
Medications	Budesonide nebulization solution (Pulmicort Respules)
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 **Later Approvals** 12 months If criteria is not met, request will be sent to a clinical reviewer for medical necessity review.
PA Review Criteria	○ Documentation as to why the member cannot use a preferred formulary corticosteroid via inhaler ○ Total daily dose should not exceed 2 mg. Doses beyond 2 mg/day should be reviewed for medical necessity.
Criteria Statement	Budesonide nebulization solution (Pulmicort Respules) are reserved for members who have used (or cannot/should not use) a preferred formulary corticosteroid via inhaler at doses that do not exceed 2mg per day.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

HIF-PH Inhibitors (Hypoxia-inducible Factor Prolyl Hydroxylase Inhibitors) for CKD Anemia	
Therapeutic Classes (AHFS)	Hematopoietic Agents
Medications	Vafseo (vadadustat)
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 uncontrolled hypertension
Required Clinical Information	See "**PA Review Criteria**" below
Age Restrictions	Member must be at least 18 years of age
Prescriber Restrictions	Prescriber must be a hematologist or nephrologist
Coverage Duration	If all conditions are met, the request will be approved with a 6 month duration. If conditions are not met, the request will be sent to a clinical reviewer.

PA Review Criteria	**Initial Authorization:**
	• Member has a diagnosis of chronic kidney disease (CKD) and has been undergoing dialysis for minimum time required by FDA-approved labeling
	• Member has a documented hemoglobin between 8.0 and 11.0 g/dL
	• Member has documentation of trial and failure, intolerance, contraindication, or inability to use erythropoietin stimulating agents (ESA)
	• The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:
	  ○ Serum ferritin level (> 100ng/mL)
	  ○ Transferrin saturation (TSAT) (> 20%)
	• Provider attests that member has no history of myocardial infarction, cerebrovascular event, or acute coronary syndrome in the past 3 months
	• Member will not be receiving concurrent treatment with an ESA
	• Request is for an FDA-approved dose
	• All submitted lab results have been drawn within 30 days of the request
	
	Reauthorization:
	• All submitted lab results have been drawn within 30 days of the reauthorization request.
	• Member has a documented increase in hemoglobin from baseline
	• The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:
	  ○ Serum ferritin level (> 100ng/mL)
	  ○ Transferrin saturation (TSAT) (> 20%)
	• Member will not be receiving concurrent treatment with an ESA
	• Request is for an FDA-approved dose

Criteria Statement	Vafseo is reserved for members with a diagnosis of chronic kidney disease (CKD) who have been undergoing dialysis for minimum time required by FDA-approved labeling , with a documented hemoglobin between 8.0 and 11.0 g/dL, with normal serum ferritin and transferrin saturation lab values (or the member MUST be receiving, or is beginning therapy, to correct the deficiency), with no history of myocardial infarction,

	cerebrovascular event, or acute coronary syndrome in the past 3 months who have used (or cannot should not use) erythropoietin stimulating agents (ESA).
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Lodoco	
Therapeutic Classes (AHFS)	OTHER MISCELLANEOUS THERAPEUTIC AGENTS
Medications	Lodoco (colchicine) tablets
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 cardiologist
Coverage Duration	If all the criteria are met, the initial request will be approved for 12 months.

PA Review Criteria	**Initial Authorization**:
	• Patient has established atherosclerotic disease or multiple risk factors for cardiovascular disease
	• Patient is currently receiving statin therapy, or documentation has been provided that the member has a medical reason statin therapy is not appropriate
	• Documentation is provided that guideline directed medical therapies targeted to patient's specific risk factors are being maximized, such as medications targeted at reduction in cholesterol, blood pressure, antiplatelet therapies, and diabetes
	• Patient does not have pre-existing blood dyscrasias (ex. leukopenia, thrombocytopenia)
	• Patient does not have renal failure (CrCl less than 15 ml/min) or severe hepatic impairment
	• Patient is not currently taking medications contraindicated for concurrent use with Lodoco
	  ○ Strong CYP3A4 inhibitors (ex. atazanavir, clarithromycin, darunavir/ritonavir, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, tipranavir/ritonavir)
	  ○ P-glycoprotein inhibitors (ex. cyclosporine, ranolazine)

Criteria Statement	Lodoco is reserved for members with a diagnosis of established atherosclerotic disease or multiple risk factors for cardiovascular disease who are currently taking a statin (or cannot/should not take a statin) and does not have pre-existing blood dyscrasias or renal failure (CrCl less than 15 ml/min) or severe hepatic impairment.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Nemluvio	
Therapeutic Classes (AHFS)	Immunomodulatory Agent
Medications	Nemluvio (nemolizumab-ilto)
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	18 years of age and older Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescriber must be allergist, immunologist, or a dermatologist
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 severe prurigo nodularis (PN) with ≥ 6 weeks of pruritus
	• Member has ≥ 20 PN lesions
	• Documentation of member weight
	• Member has a ≥ 2-week trial of one of the following:
	  ○ Moderate potency or higher topical corticosteroid (TCS)
	  ○ Topical calcineurin inhibitor (TCI)
	• Medication is prescribed at an FDA approved dose
	
	Re-Authorization:
	• Documentation or provider attestation of positive clinical response (reduced nodular lesion count, decreased pruritis, etc.)
	• Documentation of member weight
	• Medication is prescribed at an FDA approved dose

Criteria Statement	Nemluvio is reserved for members who have a diagnosis of severe PN with pruritus for at least 6 weeks, ≥ 20 PN lesions, and trial of moderate potency or higher topical corticosteroid or topical calcineurin inhibitor for at least 2 weeks.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Yorvipath	
Therapeutic Classes (AHFS)	Parathyroid Agents
Medications	Yorvipath (palopegteriparatide)
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	Members with acute postsurgical hypoparathyroidism (HP) or those who are at increased risk for osteosarcoma
Required Clinical Information	See "**PA Review Criteria**" below
Age Restrictions	18 years of age and older Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescriber must be an endocrinologist or in consultation with an endocrinologist
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:**
	• Confirmed diagnosis of chronic hypoparathyroidism (HP) of postsurgical, autoimmune, genetic, or idiopathic origins, for at least 6 months
	• Provider attestation that patient is currently receiving conventional therapy, including active vitamin D (calcitriol) and elemental calcium, and that patient's disease cannot be adequately controlled on conventional therapy alone
	• Current labs (within 60 days of request) have been submitted for the following:
	  ○ Albumin-corrected serum calcium (must be ≥ 7.8mg/dL to start therapy)
	  ○ Serum vitamin D level (must be ≥ 20 ng/mL to start therapy)
	• Medication is prescribed at an FDA approved dose
	
	Re-Authorization:
	• Documentation of a recent albumin-corrected serum calcium in the lower-half of the normal reference range or just below the normal reference range (~8–9 mg/dL)
	• ONE of the following:
	  ○ Patient no longer requires active vitamin D or therapeutic doses of calcium, OR
	  ○ Patient has had a significant reduction in required dosages of active vitamin D or therapeutic doses of calcium and is still actively titrating doses of Yorvipath
	• Medication is prescribed at an FDA approved dose

Criteria Statement	Yorvipath is reserved for members who have a confirmed diagnosis of HP of postsurgical, autoimmune, genetic, or idiopathic origins for at least 6 months, and are not adequately controlled on conventional therapy, and have albumin-corrected serum calcium ≥ 7.8mg/dL and serum vitamin D ≥ 20 ng/mL to start therapy.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No changes

Cobenfy	
Therapeutic Classes (AHFS)	Antipsychotics, Miscellaneous
Medications	Cobenfy (xanomeline and trospium chloride)
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	18 years of age and older Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescribed by a psychiatrist or in consultation with a psychiatrist
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. 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 schizophrenia, consistent with the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria
	• Documented trial and failure with two alternative formulary/preferred antipsychotic agents, or a medical reason is provided for not using any typical or atypical antipsychotic agents
	• Medication is prescribed at an FDA approved dose
	• Provider attestation is provided patient does not have any of the following:
	  ○ Moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment
	  ○ Untreated Narrow-Angle Glaucoma
	  ○ Urinary Retention
	  ○ Gastric Retention
	
	Re-Authorization:
	• Documentation or provider attestation of positive clinical response (i.e. improvement in positive and/or negative symptoms of schizophrenia)
	• Medication is prescribed at an FDA approved dose

Criteria Statement	Cobenfy is reserved for members who have a diagnosis of schizophrenia, who tried and failed or were unable to use two alternative formulary/preferred antipsychotic agents, and who do not have hepatic impairment, untreated narrow-angle glaucoma, urinary and gastric retention.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation:

- Add newly approved Actemra biosimilar Avtozma (tocilizumab-anoh) to step 2 agents list as it is priced similarly to Tyenne and Tofidence biosimilars
- Add newly approved Tysabri biosimilar Tyruko to step 3 agents based on pricing

Specialty Biologic Agents	
Therapeutic Classes (AHFS)	Disease-Modifying Antirheumatic Agents
Medications	Step 1: Preferred (pays at point-of-sale) Hadlima (adalimumab-bwwd) Adalimumab-fkjp (Hulio) Adalimumab-aaty (Yuflyma)-- 80mg/0.8mL dose formulation available Simlandi (adalimumab-ryvk) Step 2: Preferred (PA required) Enbrel (etanercept) Simponi, Simponi Aria (golimumab) Infliximab Inflectra (infliximab-dyyb) Avsola (infliximab-axxq) Renflexis (infliximab-abda) Orencia (abatacept) Xeljanz, Xeljanz XR (tofacitinib) Kineret (anakinra) Otezla (Apremilast) Siliq (brodalumab) Kevzara (sarilumab) Avtozma (tocilizumab-anoh) Tyenne (tocilizumab-aazg) Tofidence (tocilizumab-bavi) Olumiant (baricitinib) Entyvio (vedolizumab) Otulfi (ustekinumab-aauz) Yesintek (ustekinumab-kfce) Imuldosa (ustekinumab-srlf) Step 3: Non-Preferred (PA required) Humira (adalimumab) Stelara (ustekinumab) Skyrizi (risankizumab) Actemra (tocilizumab) Arcalyst (rilonacept) Ilaris (canakinumab) Tremfya (guselkumab) Remicade (infliximab) Cosentyx (secukinumab) Zeposia (ozanimod) Taltz (ixekizumab) Tysabri (natalizumab) Tyruko (natalizumab-sztn) Cimzia (certolizumab) Rinvoq (upadacitinib) Ilumya (tildrakizumab-asmn) Sotyktu (deucravacitinib) Bimzelx (bimekizumab) Omvoh (mirikizumab)

	Zymfentra (infliximab) All adalimumab biosimilar agents not listed in step 1(ex. Amjevita, Cyltezo, Hyrimoz, Yuflyma, etc.) Litfulo (ritlecitinib) All Stelara biosimilars not listed in step 2 (ex. Steqeyma, Selarsdi, etc.) Or any newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines. **** Non-FDA approved (i.e. off-label) uses; refer to the "Off-Label Use" policy****
Exclusion Criteria	N/A
Required Clinical Information	See "**PA Review Criteria**" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescribed by a specialist in the field to treat the member's respective medical condition
Coverage Duration	If all of the conditions are met, requests will be approved for 12 months.

PA Review Criteria	**Initial Authorization:**
	• The drug is being requested for an appropriate use (per the references outlined in "Covered Uses")
	• The dose requested is appropriate for the requested use (per the references outlined in "Covered Uses")
	• If the request is for a preferred Step 2 agent, documentation has been provided that the member has tried and failed or has a medical reason why (e.g. intolerance, contraindication) they cannot use a preferred Step 1 agent appropriate for the requested use (per the references outlined in "Covered Uses")
	• If the request is for a non-preferred Step 3 agent, documentation has been provided that the member has tried and failed or has a medical reason why (e.g. intolerance, contraindication) they cannot use one preferred step 1 agent and one preferred step 2 agent appropriate for the requested use (per the references outlined in covered uses)
	AND:
	• If the request is for a reference biologic drug with a biosimilar or interchangeable biologic drug (ex. Humira, Remicade, Stelara), documentation of one of the following:
	  • The provider has verbally, or in writing, submitted a member-specific reason why the reference biologic is required based on the member's condition or treatment history; AND if the member had side effects or a reaction to the biosimilar or interchangeable biologic, the provider has completed and submitted an FDA MedWatch form to justify the member's need to avoid these drugs. MedWatch form must also be included with the prior authorization request.
	Form FDA 3500 – Voluntary Reporting
	  • The currently available biosimilar product does not have the same appropriate use (per the references outlined in "Covered Uses") as the reference biologic drug being requested
	*NOTE:
	• Requests for 80mg/0.8mL dose presentations of Humira or non-preferred biosimilar adalimumab agents, preferred biosimilar adalimumab-aaty 80mg/0.8mL should be used
	• Requests for Humira 10 mg/0.1 mL in pediatric patients may be approved without a trial of a step 1 or step 2 agent, when requested for an appropriate use (per the references outlined in "Covered Uses")

	Reauthorization: • Documentation submitted indicates that the member has obtained clinical benefit from the medication. • The drug is being requested for an appropriate use and dose (per the references outlined in “Covered Uses”)
Criteria Statement	Step 2 preferred prior authorization required medications are reserved for members with an appropriate indication and dose, who have used (or cannot/should not use) a preferred step 1 medication. Step 3 non-preferred prior authorization required medications are reserved for members with an appropriate indication and dose, who have used (or cannot/should not use) a preferred step 1 medication and a step 2 preferred prior authorization required medication.
Last P&T Review Date	~~9/2025~~12/2025

Recommendation:

- Change naming convention to reflect generic availability of Promacta as eltrombopag
- Add new agent Wayrilz to policy. It's a kinase inhibitor approved for the treatment of adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

Thrombocytopenia Agents	
Therapeutic Classes (AHFS)	Hematopoietic agents
Medications	Formulary, PA required ~~Promacta (e~~Eltrombopag (Promacta) tablets Mulpleta (lusutrombopag) Nplate (romiplostim) Doptelet (avatrombopag) Alvaiz (eltrombopag) Non-Formulary Promacta (eltrombopag) powder packets Tavalisse (fostamatinib) Wayrilz (rilzabrutinib)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.
Exclusion Criteria	N/A
Required Clinical Information	See "**PA Review Criteria**" below
Age Restrictions	N/A
Prescriber Restrictions	Prescriber is a hematology specialist or working in consultation with a hematologist
Coverage Duration	**Initial Approval** If the criteria are met, the request will be approved for 12 months for Eltrombopag (Promacta), Nplate, Doptelet (for the indication of chronic immune thrombocytopenia), Alvaiz, Wayrilz and Tavalisse. Doptelet will be approved for a maximum of 5 days (for the indication of chronic liver disease-associated thrombocytopenia) Mulpleta will be approved for a maximum of 7 days. If all of the criteria are not met, the request is referred to a clinical reviewer for medical necessity review.
PA Review Criteria	For all indications below, the medication is prescribed at an FDA-approved dose for indication and age **Chronic immune (idiopathic) thrombocytopenia (ITP):** • Platelet count < 30,000 cells/microL • Documented trial and failure, intolerance, or contraindication to use ONE of the following: glucocorticoids, intravenous immune globulin (IVIG), rituximab or splenectomy • For Doptelet, Nplate, Alvaiz, Wayrilz or Tavalisse, the member must also have a documented trial and failure, intolerance, or contraindication to eltrombopag (Promacta) tablets **Severe aplastic anemia:** Eltrombopag (Promacta) & Alvaiz only: • Documented trial and failure, intolerance or contraindication to at least one immunosuppressive agent **OR** is being prescribed in conjunction with at least one immunosuppressive agent

	AND • Platelet count < 20,000 cells/microL OR < 30,000 cells/microL with bleeding OR reticulocyte count < 20,000 cells/microL OR absolute neutrophil count < 500 cells/microL • For Alvaiz, member must also have a documented trial and failure, intolerance, or contraindication to eltrombopag (Promacta) tablets **Thrombocytopenia in patients with Hepatitis C infection:** Eltrombopag (Promacta) & Alvaiz only: • Diagnosis of chronic hepatitis C **AND** • Documented treatment with interferon-based therapy **AND** • Patient's degree of thrombocytopenia prevents the initiation or limits the ability to maintain interferon-based therapy **AND** • Medical reason for why patient needs to be treated with interferon over new DAA medication **AND** • Platelet count < 50,000 cells/microL • For Alvaiz, member must also have a documented trial and failure, intolerance, or contraindication to eltrombopag (Promacta) tablets **Thrombocytopenia associated with chronic liver disease in adult patients requiring elective surgery** Doptelet and Mulpleta only: • Patient has a diagnosis of chronic liver disease and is scheduled to undergo a procedure **AND** • Platelet count < 50,000 cells/microL **AND** • For Mulpleta, approve if there is documentation of trial and failure, intolerance, or contraindication to use Doptelet For Promacta powder, approve if there is a documentation of trial and failure, intolerance or contraindication to use eltrombopag (Promacta) tablets, and all other Promacta criteria above are met.
Criteria Statement	Eltrombopag (Promacta) is reserved for members with chronic immune (idiopathic) thrombocytopenia (ITP), who have used (or cannot/ should not use) one of the following: glucocorticoids, intravenous immune globulin (IVIG), rituximab, or splenectomy. Doptelet, Nplate, Alvaiz, Wayrilz and Tavalisse are reserved for members with chronic immune (idiopathic) thrombocytopenia (ITP), who have used (or cannot/ should not use) eltrombopag (Promacta) tablets. Eltrombopag (Promacta) is reserved for members with severe aplastic anemia who have used (or cannot/ should not use) an immunosuppressive agent or is being used in conjunction with an immunosuppressive agent. Alvaiz is reserved for members with severe aplastic anemia who have used (or cannot/should not use) eltrombopag (Promacta) tablets. Eltrombopag (Promacta) is reserved for members with hepatitis C infection in patients who must be treated with interferon-based therapy. Alvaiz is reserved for members with hepatitis C infection in patients who must be treated with interferon-based therapy who have used (or cannot/should not use) eltrombopag (Promacta) tablets.

	Doptelet is reserved for members who have thrombocytopenia associated with chronic liver disease in adult patients requiring elective surgery. Mulpleta is reserved for members who have thrombocytopenia associated with chronic liver disease in adult patients requiring elective surgery and who have used (or cannot/ should not use) Doptelet.
Last P&T Review Date	~~3/2025~~12/2025

Recommendation: Add new agent Imaavy to the list of drugs that should not be used concurrently with Zilbrysq

Complement Inhibitors for the Treatment of Myasthenia Gravis	
Therapeutic Classes (AHFS)	Complement Inhibitors
Medications	Zilbrysq (zilucoplan) subcutaneous 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), 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 ≥ 18 years
Prescriber Restrictions	Prescribed by a neurologist or rheumatologist
Coverage Duration	Initial request: 6 months Continuation of therapy: 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 generalized myasthenia gravis (gMG)
	  ○ Patient has a positive serological test for Anti-AChR antibodies
	• Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV
	• Patient has tried and failed, or has contraindication, to one of the following:
	  ○ Two (2) or more conventional therapies (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)
	  ○ Failed at least 1 conventional therapy and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin
	• Medication is prescribed at an FDA approved dose
	• No concurrent use of Vyvgart, Vyvgart Hytrulo, Rystiggo, Soliris, BKEMV, Epysqli, Imaavy, or Ultomiris
	• Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal infections in patients receiving a complement inhibitor
	
	Re-Authorization:
	• Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality-of-life scores, MG-ADL scores, etc).
	• Medication is prescribed at an FDA approved dose.

Criteria Statement	Zilbrysq is reserved for members who have a diagnosis of generalized myasthenia gravis clinical classification of class II, III or IV and have tried and failed 2 or more conventional therapies or at least 1 conventional therapy and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin, and who have complied with the ACIP current vaccination recommendations against meningococcal infections in patients receiving a complement inhibitor.
Last P&T Review Date	~~6/2025~~12/2025

Recommendation: Add additional trial agents based on most recent guidelines

Ileal bile acid transporter inhibitors (IBATs)	
Therapeutic Classes (AHFS)	Cholelitholytic Agents
Medications	Bylvay (odevixibat), Livmarli (maralixibat)
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 a gastroenterologist or hepatologist
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:**
	Progressive Familial Intrahepatic Cholestasis
	• Diagnosis of progressive familial intrahepatic cholestasis (PFIC).
	  ○ For Bylvay: PFIC type 1 or 2 with confirmed biallelic mutations via genetic testing.
	  ○ For Livmarli: PFIC type 1, 2, 3, 4 or 6, with confirmed biallelic mutations via genetic testing
	• Documentation that patient does not have an *ABCB11* variant that results in non-functional or complete absence of bile salt export pump protein
	• Documented history of moderate to very severe pruritus
	• Documentation of patient's weight
	• Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment
	• Baseline serum bile acid level is provided
	• Documentation of trial and failure OR contraindication to two of the following:
	  ○ Ursodiol
	  ○ Cholestyramine or colesevelam
	  ○ Rifampin
	  ○ Fibrates (ex. fenofibrate)
	• The prescribed dose is within FDA approved dosing guidelines
	
	Alagille Syndrome
	• Diagnosis of Alagille syndrome (ALGS)
	• Documented history of moderate to very severe pruritus
	• Documentation of trial and failure OR medical reason why the member is unable to use two of the following:
	  ○ Ursodiol
	  ○ Rifampin~~,~~
	  ○ Cholestyramine or colesevelam
	  ○ Fibrates (ex. fenofibrate)
	• Prescriber attests that the member has cholestasis
	• Baseline serum bile acid level is provided
	• Documentation of patient's weight
	• Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment
	• The prescribed dose is within FDA approved dosing guidelines

	Re-Authorization:
	• Documentation of clinical benefit indicating each of the following:
	  ○ An improvement in pruritus (e.g. improved observed scratching, decreased sleep disturbances/nighttime awakenings due to scratching, etc.)
	  ○ Reduction in serum bile acid level from baseline
	• Documentation of patient's weight
	• Prescriber attests to monitor liver function tests and FSV levels during treatment
	• Prescriber attests that patient has had no evidence of hepatic decompensation (e.g. variceal hemorrhage, ascites, hepatic encephalopathy, portal hypertension, etc.)
	• The prescribed dose is within FDA approved dosing guidelines

Criteria Statement	Bylvay and Livmarli are reserved for members who have a diagnosis of PFIC with confirmed biallelic mutations and history of moderate to very severe pruritis, do not have ABCB11 variant, and had trial and failure or contraindication to two of the following: ursodiol, rifampin, fibrates, and cholestyramine or colesevelam. Additionally, Bylvay and Livmarli are reserved for members who have a diagnosis of ALGS with history of moderate to very severe pruritus~~,~~ and had trial and failure or contraindication to two of the following: ~~ursodiol~~ursodiol, fibrates, ~~and~~ rifampin or cholestyramine or colesevelam.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: Update coverage duration to 12 months based on primary endpoint measurement in trials

Sohonos	
Therapeutic Classes (AHFS)	Other Miscellaneous Therapeutic Agents
Medications	Sohonos (palovarotene)
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	• Pregnancy • Use in patients younger than 8 years of age for females and 10 years of age for males
Required Clinical Information	See "**PA Review Criteria**" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age Per package insert
Prescriber Restrictions	Prescribed by an orthopedic specialist or provider who specializes in rare connective tissue diseases
Coverage Duration	If all of the criteria are met, the initial or reauthorization request will be approved for up to ~~6~~ 12 months ~~taking into account patient specific scenarios~~
PA Review Criteria	**Initial Authorization:** • Documented diagnosis of fibrodysplasia ossificans progressiva (FOP) • Documented genetic testing of ACVR1 R206H mutation • Attestation that patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose (if applicable) • Documentation of weight for patients younger than 14 years old • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of clinical benefit (i.e. volume reduction of heterotopic ossification) or worsening (i.e. flare-up presence and/or worsening of flare-ups) • Attestation that patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose (if applicable) • Documentation of weight for patients younger than 14 years old • Medication is prescribed at an FDA approved dose
Criteria Statement	Sohonos is reserved for members with a diagnosis of fibrodysplasia ossificans progressiva (FOP) with documented genetic testing of ACVR1 R206H mutation, who is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose (if applicable), with a weight documentation for those members younger than 14 years old.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: No criteria changes, add Accutane to F-PA to match the criteria status

Isotretinoin capsules	
Therapeutic Classes (AHFS)	Skin and mucous membrane agents, miscellaneous
Medications	Formulary, PA required PREFERRED • Claravis (isotretinoin) • Zenatane (isotretinoin) • Amnesteem (isotretinoin) • Accutane (isotretinoin) • Isotretinoin Formulary, PA required NON-PREFERRED • Isotretinoin (Absorica) • Absorica LD (isotretinoin) Or any newly marketed oral retinoid 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/Re-Approval** 6 months **Later Approvals** If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	All of the following conditions must be met for approval: • Diagnosis of moderate to severe recalcitrant nodular acne. • Documented treatment with a therapeutic trial and failure or intolerance to one or more first line topical therapies (e.g. topical antibiotics or topical retinoids) IN COMBINATION WITH one or more first line oral therapies (e.g. doxycycline, tetracycline, or minocycline) for at least 4 weeks (28 days) of therapy of each drug in the previous 365days • If the request is for a non-preferred drug, documentation has been provided that the member has tried and failed two preferred drugs or has a medical reason why these drugs cannot be used
Criteria Statement	Preferred generic isotretinoin medications (e.g., Claravis, Zenatane, Amnesteem, Accutane) are reserved for members with moderate to severe recalcitrant nodular acne who have used (or cannot/should not use) oral antibiotics. Isotretinoin (Absorica) or Absorica LD (isotretinoin) are reserved for members who have severe acne, who have used (or cannot/should not use) topical therapies (e.g. topical antibiotics or topical retinoids) AND oral antibiotics. Non-preferred agents are reserved for members with moderate to severe recalcitrant nodular acne who have used (or cannot/should not use) oral antibiotics. Isotretinoin (Absorica) 25mg or 35mg capsules or Absorica LD (isotretinoin) are reserved for members who have severe acne, who have used (or cannot/should not use) topical therapies (e.g. topical antibiotics or topical retinoids) AND oral antibiotics AND at least two preferred agents.
Last P&T Review Date	~~12/2024~~12/2025

Alameda PADs for review Q4 2025 P&T Consent Agenda

Recommendation: No changes

Injectable/Specialty Medications	
Medications	INJECTABLE/SPECIALTY MEDICATIONS WITH NO OTHER DRUG-SPECIFIC OR DIAGNOSIS-SPECIFIC CRITERIA *** The Oral and Injectable Oncology Medications Physician Administered Drug (PAD) medication request guideline will be applied to oncology drugs without drug or class specific 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), 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	Up to a 12 month duration depending upon the diagnosis and usual treatment therapies
Maximum Billable Units	Variable
Other Criteria	**Initial Approval** 1. The request for the medication is for an FDA approved indication, and/or is used for a medical condition that is supported by the medical compendium (Micromedex, American Hospital Formulary Service, Drug Points, and Drug Package Insert) as defined in the Social Security Act 1927 and/or per recognized standard of care guidelines. 2. Prescribed dosing of medication is within FDA approved indications and/or is supported by the medical compendium as defined above and/or per recognized standard of care guidelines. 3. For any medication where a biosimilar is available, when indicated, the member must have documented 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. 4. If all of the above conditions are met, the request will be approved for up to 12 months or as recommended per FDA approved indications and/or as defined by the medical compendium as defined above and/or per recognized 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. **Reauthorization of Medication** 1. The prescribing physician has provided documentation as to the clinical benefits of the medication supporting continued treatment, **OR** the medication is being continued in accordance with the recommended time as defined by FDA drug package insert, and/or per recommendations of the medical compendium as described above, and/or per recognized standard of care guidelines. 2. Prescribed dosing of medication is within FDA approved indications or per supported by the medical compendium as defined above and/or per recognized standard of care guidelines.

	3. For any medication where a biosimilar is available, when indicated, the member must have documented 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. 4. If all of the above conditions are met, the request will be approved for up to 12 months or as recommended per FDA approved indications and/or as defined by medical compendium as defined above and/or per recognized 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	~~12/2024~~12/2025

Recommendation: No changes

Oral and Injectable Oncology Medications	
Medications	Oral and Injectable Oncology Medications without medication-specific 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 Healthcare Professional (USP DI), and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)
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	Prescriber must be an oncologist
Coverage Duration	Up to a 6 month duration depending upon the diagnosis and usual treatment therapies
Maximum Billable Units	Variable
Other Criteria	All of the following criteria must be met: • Requested indication must be supported by NCCN category 1 or 2A level of evidence. If the request is for a category 2B recommendation then the medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication). • Documentation provided of results of genetic testing where required per drug package insert. • Documentation provided of results of all required laboratory values and member specific information (e.g., weight, ALT/AST, creatinine kinase, etc.) when recommended/required per drug package insert. • The medication is being prescribed at a dose that is within FDA approved/NCCN guidelines. • For any medication where a biosimilar is available, when indicated, the member must have documented 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. • For requests for IV medications: attestation medication is administered by a healthcare professional (Medi-Cal only). If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review
Last Review Date	~~12/2024~~12/2025

Recommendation: No changes, minor grammatical correction

Viltepso	
Medications	Viltepso (viltolarsen)
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	Concomitant use with another antisense oligonucleotide (e.g. Vyondys 53)
Required Clinical Information	See "other criteria"
Age Restrictions	Age ≤ 20 years Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescriber must be a neurologist, or a provider who specializes in the treatment of DMD
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:** • Member has a confirmed diagnosis of Duchenne's Muscular Dystrophy (DMD) and lab test was submitted confirming the mutation of dystrophin gene amenable to exon 53 skipping • Member is ambulatory • Member has stable pulmonary and cardiac function • Attestation of renal function monitoring is provided with request • Baseline dystrophin levels AND 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)] • Member must be on a stable corticosteroid regimen for at least 3 months • The request is for an FDA approved dose **Reauthorization:** • Documentation is provided that the member had an increase in dystrophin levels from baseline • Documentation is provided that the member had a positive clinical response (e.g. improvement, stabilization, or reduction of deterioration in 6MWT, TTSTAND, TTRW, NSAA, or TTCLIMB) • Member is ambulatory • Attestation of renal function monitoring is provided with request • The 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	~~12/2024~~12/2025

Recommendation: No changes

Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents	
Medications	Rituximab (Rituxan, Truxima - biosimilar , Ruxience - biosimilar, Riabni - biosimilar) Enspryng (satralizumab-mwge) Uplizna (inebilizumab-cdon) Soliris (eculizumab) Ultomiris (ravulizumab-cwvz)
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	For Enspryng, Uplizna, Soliris, Ultomiris: Anti-aquaporin-4 (AQP4) antibody **negative** neuromyelitis optica spectrum disorder (NMOSD)
Required Clinical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by an immunologist, neurologist or hematologist
Coverage Duration	If all of the conditions are met, requests will be approved for 12 months.
Maximum Billable Units	Variable

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.**
	
	Initial Authorization:
	For rituximab:
	• Member has a diagnosis of NMOSD
	• Documentation indicating that the member has been screened for HBV (hepatitis B virus) prior to initiation of treatment
	• Dosing is supported by compendia or standard of care guidelines
	
	For Enspryng:
	• Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody **positive** NMOSD
	• Provider attests to completion of the following assessments prior to the first dose of Enspryng as outlined in the prescribing information:
	  ○ Hepatitis B virus screening
	  ○ Tuberculosis screening
	  ○ Liver transaminase screening
	  ○ Member has not received live or attenuated-live virus vaccines within 4 weeks before the start of Enspryng therapy
	• Documented medical contraindication to rituximab, azathioprine, or mycophenolate mofetil
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
	
	For Uplizna:
	• Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody **positive** NMOSD

	• Provider attests to completion of appropriate assessments prior to the first dose of Uplizna as outlined in the prescribing information:
	  ○ Hepatitis B virus screening
	  ○ Quantitative serum immunoglobulins
	  ○ Tuberculosis screening
	  ○ Member has not received live or attenuated-live virus vaccines within 4 weeks before the start of Uplizna therapy
	• Documented medical contraindication to rituximab, azathioprine, or mycophenolate mofetil
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
	
	<u>For Soliris/Ultomiris:</u>
	• Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody **positive** NMOSD
	• Documented medical contraindication to rituximab, azathioprine, or mycophenolate mofetil
	• Documented medical contraindication to rituximab, azathioprine, or mycophenolate mofetil
	• Documentation of vaccination against meningococcal disease or a documented medical reason why the member cannot receive vaccination or vaccination needs to be delayed
	• Antimicrobial prophylaxis with oral antibiotics (penicillin, or macrolides if penicillin-allergic) for two weeks if the meningococcal vaccine is administered < 2 weeks before starting therapy or a documented medical reason why the member cannot receive oral antibiotic prophylaxis.
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
	
	<u>Reauthorization:</u>
	• Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit)
	• Request is for an FDA approved/medically accepted 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	~~12/2024~~12/2025

Recommendation: No changes

Botulinum Toxins A&B	
Medications	Xeomin (incobotulinumtoxinA) Botox (onabotulinumtoxinA) Myobloc (rimabotulinumtoxinB) Dysport (ibobotulinumtoxinA) Daxxify (daxibotulinumtoxinA) 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	Cosmetic use
Required Clinical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	If all of the criteria are met, the initial request will be approved for up to a 12 month duration; reauthorization requests will be approved for up to 12 months.
Maximum Billable Units	Variable

Other Criteria	***The use of these medications for cosmetic purposes is NOT a covered benefit***
	
	The following criteria must be met for initial requests:
	• Dose is appropriate per label or supported by compendia/standard of care guidelines
	• Documentation was submitted, that the member had an adequate trial (consistent with pharmacy claims) standard first line therapy for their disease state and/or has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) for not taking first line therapy to treat their medical condition.
	• If the diagnosis is **chronic migraine** (≥15 days per month with headache lasting 4 hours a day or longer), the member has a documented adequate trial, for at least 4 weeks EACH, at minimum effective doses (consistent with pharmacy claims data) of two of the following classes of drugs:
	  ○ Beta blockers (e.g. propranolol, timolol, etc.) or candesartan
	  ○ Amitriptyline or venlafaxine
	  ○ Divalproex ER or DR, valproic acid or topiramate
	  ○ Or a medical reason was submitted (intolerance, hypersensitivity, contraindication, etc.) why member is not able to utilize these therapies.
	• If the diagnosis is **overactive bladder**, the member has a documented adequate trial (consistent with pharmacy claims data) of at least 2 formulary medications (e.g. oxybutynin)
	• If the diagnosis is **Hyperhidrosis,** the member has tried and failed a prescription strength antiperspirant (e.g. 20% aluminum chloride hexahydrate)
	• If the diagnosis is **Chronic Sialorrhea**,
	  ○ Documentation is provided that the member has had sialorrhea lasting at least 3 months
	  ○ The member has tried and failed at least two anticholinergic medications (e.g. glycopyrrolate, hyoscyamine, benztropine)
	The following criteria must be met for re-authorization requests:
	• Dose and indication continue to be appropriate per label or supported by compendia/standard of care guidelines

	• Documentation submitted indicates a clinical benefit was observed and rationale for continuation of 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	~~12/2024~~12/2025

Recommendation: No changes

Veopoz	
Medications	Veopoz (pozelimab-bbfg)
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 with unresolved Neisseria meningitidis infection • Concurrent use of another complement inhibitor (i.e. Soliris)
Required Clinical Information	See "**Other Criteria**" below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescriber must have experience in treating complement related disorders (i.e., gastroenterologist, immunologist, cardiologist, 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.
Other Criteria	**Initial Authorization:** • Medication is prescribed at an FDA approved dose • Diagnosis of CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease • Documentation of hypoalbuminemia (serum albumin <3.5 g/dL) • Documentation of patient weight **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. symptom improvement, normalization of labs such as serum albumin (3.5-5.5 g/dL) and IgG concentrations, reduced hospitalizations and severe adverse events, increased quality of life, etc.) • Documentation of patient weight • 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	~~12/2024~~12/2025

Recommendation: No changes

Lantidra	
Medications	Lantidra (donislecel)
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 18 years of age and older
Prescriber Restrictions	Prescriber must be an endocrinologist
Coverage Duration	If all criteria are met, the request will be approved for one infusion. A member may only receive a maximum of 3 infusions per lifetime as there is no data regarding the efficacy or safety for treatment with more than 3 infusions.

Other Criteria	**Initial Authorization**
	• Documentation of Type 1 Diabetes diagnosis for more than 5 years
	• Documentation of blood glycated hemoglobin (HbA1c) above target goal
	• Documentation of intensive insulin management efforts (i.e., adjusting insulin regimen to multiple daily injections, frequently monitoring blood glucose levels daily, the use of devices such as a continuous glucose monitor, etc.)
	• Member has at least one of the following, despite intensive insulin management efforts:
	  ○ Inability to sense hypoglycemia until the blood glucose falls to less than 54 mg/dL
	  ○ At least 1 or more episodes of severe hypoglycemia (blood glucose below 50 mg/dL) in the past 3 years
	• Provider must confirm the following:
	  ○ Blood glycosylated hemoglobin (HbA1c) is not higher than 12%
	  ○ Member has an insulin requirement of no more than 0.7 International Units (IU)/kilogram/day
	  ○ Member has a Body Mass Index (BMI) less than 27 kg/m^2
	  ○ Member is not diagnosed with a psychiatric disorder (i.e., schizophrenia, bipolar disorder, or major depression)
	  ○ Member does not have severe cardiac disease as defined by: Recent myocardial infarction within the past 6 months, angiographic evidence of non-correctable coronary artery disease, or evidence of ischemia on a functional cardiac exam
	• Provider attests that member will be receiving concomitant immunosuppression therapy
	• Drug is being requested at an FDA-approved dose
	• Member's weight
	
	Reauthorization
	• Member has not achieved independence from exogenous insulin within one year of infusion OR member has lost independence from exogenous insulin within one year after a previous infusion
	• Provider attests that member will be receiving concomitant immunosuppression therapy

	• Drug is being requested at an FDA-approved dose • Member's weight 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	~~12/2024~~12/2025

Recommendation: Change naming convention to reflect generic availability of Endari

Gene Therapy for Sickle Cell Disease	
Medications	Casgevy (exagamglogene autotemcel), Lyfgenia (lovotibeglogene autotemcel)
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	Repeat use of same gene therapy agent Trial of a different gene therapy agent after another has been used
Required Clinical Information	See "other criteria"
Age Restrictions	Per FDA approved prescribing information
Prescriber Restrictions	Prescriber must be a hematologist or specialist in the treatment of sickle cell disease
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment for one gene therapy agent
Maximum Billable Units	Variable

Other Criteria	**Initial Authorization:**
	• Medication is prescribed at an FDA approved dose
	• Member has a diagnosis of sickle cell disease
	• Member has experienced at least 2 severe vaso-occlusive crises/events (VOE) per year in the past 2 years defined as either:
	  ○ VOE requiring a hospitalization or multiple visits to an emergency department/urgent care over 72 hours and receiving intravenous medications at each visit
	  ○ priapism lasting > 2 hours and requiring a visit to a medical facility
	  ○ acute chest syndrome
	  ○ splenic sequestration
	  ○ hepatic sequestration
	• Documentation was provided that the member has been taking hydroxyurea at the maximum tolerated dose and has been compliant within the last 6 months (or a medical reason was provided why the patient is unable to use hydroxyurea)
	• Documentation was provided that the member had a trial and failure of, or a medical reason was provided why the patient is unable to trial one of the following agents:
	  ○ L-Glutamine (Endari)
	  ○ Adakveo
	• Prescriber attests pregnancy has been ruled out prior to initiation of treatment (if applicable)
	• Patient has not had a prior HSCT or gene therapy treatment
	
	The safety and effectiveness of repeat administration of Casgevy or Lyfgenia 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	~~12/2024~~12/2025

Recommendation: No changes

Tecelra (afamitresgene autoleucel)	
Medications	Tecelra (afamitresgene 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	Homozygous or heterozygous for HLA-A*02:05P
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 an oncologist
Coverage Duration	If all of the criteria are met, the initial request will be approved for a one-time treatment
Maximum Billable Units	Variable
Other Criteria	**Initial Authorization:** • Diagnosis of unresectable or metastatic synovial sarcoma • Documentation that patient is HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive • Documentation that the tumor expresses the MAGE-A4 antigen • Documentation of treatment with prior chemotherapy • Member must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 • Medication is being prescribed at an FDA approved dose **The safety and effectiveness of repeat administration of Tecelra has not been evaluated and will not be approved.** 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	~~12/2024~~12/2025

Recommendation: No changes

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Agents	
Medications	Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)
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	Per FDA-approved labeling Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescriber must be a neurologist or neuromuscular specialist
Coverage Duration	Initial requests will be approved for 3 months. Reauthorization requests will be approved for 12 months.
Maximum Billable Units	Variable
Other Criteria	**Initial Authorization:** • Diagnosis of CIDP confirmed by electrodiagnostic test results (e.g. electromyography or nerve conduction studies) • Patient has progressive or relapsing/remitting disease course for ≥2 months • Patient has an inadequate response, significant intolerance, or contraindication to intravenous immunoglobulin (IVIG) or subcutaneous immunoglobulin (SCIG) • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of significant clinical improvement in neurologic symptoms or stabilization of disease • 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	~~12/2024~~12/2025

Alameda Alliance for Health (IHSS)

Q4 2025 INTERIM FORMULARY UPDATES

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

Medication	Formulary Change
Prezcobix Oral Tablet 675-150 MG	NF to F
Fluticasone Furoate Ellipta Inhalation Aerosol Powder Breath Activated 100 MCG/ACT	NF to F
Fluticasone Furoate Ellipta Inhalation Aerosol Powder Breath Activated 50 MCG/ACT	NF to F
Fluticasone Furoate Ellipta Inhalation Aerosol Powder Breath Activated 200 MCG/ACT	NF to F
Arnuity Ellipta Inhalation Aerosol Powder Breath Activated 100 MCG/ACT	F to NF
Arnuity Ellipta Inhalation Aerosol Powder Breath Activated 50 MCG/ACT	F to NF
Arnuity Ellipta Inhalation Aerosol Powder Breath Activated 200 MCG/ACT	F to NF
Anusol-HC Rectal Suppository 25 MG	F to NF
Hemmorex-HC Rectal Suppository 25 MG	F to NF
Hemmorex-HC Rectal Suppository 30 MG	F to NF
Anucort-HC Rectal Suppository 25 MG	F to NF
Comirnaty 5-11 Years Intramuscular Suspension 10 MCG/0.3ML	NF to F
Comirnaty 5-11 Years Intramuscular Suspension 10 MCG/0.3ML	NF to F
Nuvaxovid COVID-19 Vaccine Intramuscular Suspension Prefilled Syringe 5 MCG/0.5ML	NF to F
Nuvaxovid COVID-19 Vaccine Intramuscular Suspension Prefilled Syringe 5 MCG/0.5ML	NF to F
Sacubitril-Valsartan Oral Tablet 24-26 MG	NF to F-QL (60/30)
Sacubitril-Valsartan Oral Tablet 49-51 MG	NF to F-QL (60/30)
Sacubitril-Valsartan Oral Tablet 97-103 MG	NF to F-QL (60/30)
Entresto Oral Tablet 24-26 MG	F-QL to NF
Entresto Oral Tablet 49-51 MG	F-QL to NF
Entresto Oral Tablet 97-103 MG	F-QL to NF
Eliquis Oral Capsule Sprinkle 0.15 MG	NF to F-QL (74/30)
Eliquis (2 MG Pack) Oral Tablet Soluble 4 x 0.5 MG	NF to F
Eliquis Oral Tablet Soluble 0.5 MG	NF to F
Eliquis (1.5 MG Pack) Oral Tablet Soluble 3 x 0.5 MG	NF to F
Otulfi Subcutaneous Solution 45 MG/0.5ML	NF to F-PA
Otezla/Otezla XR Initiation Pk Oral Tablet Therapy Pack 10&20&30&(ER)75 MG	NF to F-PA-QL (41/30)

Medication	Formulary Change
Otezla XR Oral Tablet Extended Release 24 Hour 75 MG	NF to F-PA-QL (30/30)
Doptelet Oral Capsule Sprinkle 10 MG	NF to F-PA

Alameda Alliance for Health Q4 2025 PAD Updates

This list only includes summary of changes to prior authorization (PA) for physician administered drugs for quarter 4 2025 and is not comprehensive.

HCPCS Code	HCPCS Description	Action
J3389	PRADEMAGENE ZAMIKERACEL (ZEVASKYN)	Add
J9256	NIPOCALIMAB-AAHU (IMAAVY)	Add
J9326	ELISOTUZUMAB VEDOTIN-TLLV (EMRELIS)	Add
J3387	ELIVALDOGENE AUTOTEMCEL (SKYSONA)	Add
J0013	ESKETAMINE (SPRAVATO)	Add
Q5160	BEVACIZUMAB-NWGD (JOBEVNE), BIOSIMILAR	Add
Q5139	ECULIZUMAB-AEEB (BKEMV)	Remove
J9037	BELANTAMAB MAFODOTIN-BLMF (BLENREP)	Remove
J9371	VINCRISTINE SULFATE LIPOSOME (MARQIB)	Remove
J9259	PACLITAXEL PROTEIN-BOUND PARTICLES (AMERICAN REGENT)	Remove
J2503	PEGAPTANIB SODIUM (MACUGEN)	Remove
J2796	ROMIPLOSTIM (NPLATE)	Remove
J9037	BELANTAMAB MAFODONTIN-BLMF (BLENREP)	Remove
J9258	PACLITAXEL PROTEIN-BOUND PARTICLES (TEVA)	Remove
S0013	ESKETAMINE (SPRAVATO)	Remove

ALAMEDA Alliance FOR HEALTH
Health care you can count on.
Service you can trust.

POLICY AND PROCEDURE

Policy Number	RX-013
Policy Name	Medical Benefit Physician/Facility-Administered Drugs (PAD) Prior Authorization Review Process
Department Name	Pharmacy Services
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy Services
Line(s) of Business	MCAL, IHSS, DSNP
Effective Date	7/17/2023
Administrative Oversight Committee Approval Date	~~5/21/2025~~ TBD

POLICY STATEMENT

The Alameda Alliance for Health (the "Alliance") has an established process for reviewing and processing physician-administered drugs (PAD) authorization requests when requested under medical benefit for medical necessity. The Alliance is committed to ensuring that all eligible Alliance members have timely and efficient access to covered pharmaceutical services that require authorization. The Alliance's pharmaceutical authorization process complies with the standards set by the California Health & Safety Code, Sections 1367.01, 1373.96; the California Code of Regulations (CCR) Title 28, Sections 1363.5.~~,~~ ~~.~~ The Alliance ensures parity in coverage of pharmaceuticals used to treat medical/surgical, mental health, gender dysphoria and substance abuse disorders.

PROCEDURE

I. The Alliance is responsible for reviewing physician-administered drugs (PAD) or medical drugs ~~(PAD) drugs~~ when billed as medical claims. Drug classes ~~except for drug classes~~ "carved out" to Medi-Cal Fee-~~-~~For-~~-~~Service (FFS) in the Medi-Cal manual will not be reviewed. "Carved out" drugs shall be referred to Medi-Cal FFS for review.~~as specified in the Medi-Cal manual.~~

~~I.~~II. The Alliance is responsible for reviewing Medicare Part B drugs, in accordance with Medicare coverage criteria. See Appendix II for definitions of Part B drugs.

~~II.~~ **Prior Authorization Process Guidelines**

III.

~~III.~~ Prior ~~a~~Authorization review and approval ~~hierarchal~~ criteria or PAD Medication Review Guidelines are utilized and required ~~as outlined in UM-001 (or with PAD Medication Review Guidelines) fo~~for ~~the appropriate~~ medical drug ~~pharmacy~~ authorizations.

~~A.~~ The Alliance utilizes evidence-based prior authorization criteria approved by the P&T Committee. Prior authorization criteria are developed and reviewed annually. ~~and are based~~Sources used to create criteria may include (in no particular order): ~~established by organizations such as~~

A. Medi-Cal guidelines ~~(if~~ for Medi-Cal line of business)~~,~~

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B. Medicare National Coverage Determinations (NCD) or Local Coverage Determinations (LCD)
C. Food and Drug Administration (FDA) Package Insert labeling
D. Peer-reviewed scientific literature
E. Professional medical society treatment Standards of Care including but not limited to:
   a) Infectious Disease Society of America (IDSA)
   b) American Medical Association (AMA)
   c) American Academy of Orthopedic Surgeons (AAOS)
   d) American Academy of Pediatrics (AAP)
   e) American Psychiatric Association (APA)
   f) American College of Rheumatology (ACR)
   g) American Diabetes Association (ADA)
   h) American Academy of Dermatology (AAD)
   i) American Academy of Ophthalmology (AAO)
   j) American Association of Clinical Endocrinologists (AACE)
   k) American College of Cardiology (ACC)
F. Pharmaceutical care compendia including but not limited to:
   a) American Hospital Formulary Services (AHFS)
   b) Truven Health Analytics
   c) Micromedex DrugDeX (DrugDex)
   d) Elsevier/Gold Standard Clinical Pharmacology
   e) Wolters Kluwer Lexi-Drugs (Lexicomp®, Facts & Comparisons®, and UpToDate®)
G. Milliman Care Guidelines~~,~~
H. ~~Food and Drug Administration (FDA),~~ National Comprehensive Cancer Network (NCCN)~~,~~
I. ~~UpToDate, and~~ National Institutes of Health (NIH)

~~,~~The Alliance

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IV. covers pharmaceuticals in accordance with 42 CFR section 438.900 et seq, to ensure parity in medical/surgical, mental health, and substance abuse benefits and treatment.

~~IV.~~V. Prior Authorization Procedures

~~A.~~ All providers are required to submit prior authorization for PAD drugs billed on medical claim. ~~Healthcare Common Procedure Coding System (HCPCS) / National Drug Code (NDC) codes that are listed and in alignment with P&T committee approved PA criteria as appropriate.~~

~~B.~~A. Required information provided on all requests should include:

a) Member demographic information
b) Practitioner demographic information
c) Requested service/procedure to include specific Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) code(s)
d) Member diagnosis (Specific International Classification of Disease (ICD) Code/Description)
e) Clinical indications necessitating service
f) Pertinent medical history, treatment, or clinical data
g) Location of service to be provided
h) Requested/anticipated duration of therapy
~~i)~~ Proposed date(s) of services
i)

~~C.~~B. Prior authorization requests ~~must~~ may be submitted electronically, phone or by fax to the Alliance UM Department.

~~a) Pharmacy department will manage the end-to-end process when providers send a PAD PA for the Alliance members. This entails some of the following duties below:~~
~~i. Verify eligibility, coverage, and network~~
~~ii. Check if there are benefit restrictions~~
~~iii. Generate letter of notifications for approval, partial approval, and denial~~

~~A. Retro Requests: The Alliance does not accept post-service or retrospective authorization requests for nonemergent or non-urgent services that would require prior authorization more than 90 days past the date of service.~~

~~The exception criteria under which a post service / retrospective request greater than 90 days after the date of service may be considered are:~~
~~1. Member eligibility issues, i.e., unable to validate eligibility at time of service, incorrect eligibility information at time of service.~~
~~2. In patient services where the facility is unable to confirm enrollment with the Alliance.~~

~~B. Pre-Service/Post-Service Review for Pharmacy Technician (PT)~~
~~A. Upon receipt of the authorization request, the PT will review the request for:~~
~~(1) Member eligibility~~
~~(2) Completeness of the request~~
~~(a) Presence of medical codes,~~
~~(b) Presence of medical records~~
~~B. Once the authorization request review is complete, the PT enters the authorization request into the clinical information system and routes it to the appropriate UM PT processing queue.~~
~~C. Upon selecting authorization request from the queue, the assigned PT reviews the pre-service/post-service authorization request that includes:~~

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(1) The UM PT reviewer performs a review of the pre-service/post-service/ associated with PAD authorization request and clinical information presented using the appropriate UM criteria, according to UM-001 Utilization Management Policy or UM Program.

(a) The PT Reviewer documents the decision-making process in the clinical information system.

(b) The PT Reviewer workflow includes:

(i) For authorization requests meeting criteria under the scope of the PT, the PT Reviewer approves the request and generates the Member and Provider approval notification.

(ii) For authorization requests not consistent with the request (i.e., conflicting CPT Codes to diagnosis, conflicting HCPCs to documentation, etc.), or otherwise are outside of PT scope, where there is a potential for delay, denial, modification, or termination, and for cases involving benefit exhaustion or benefit termination, the PT Reviewer forwards the request to the Pharmacist Reviewer.

C. Pre-Service/Post-Service Review Pharmacist Reviewer (PR)

A. Pharmacist ~~Reviewer performs a medical necessity~~ reviews ~~of~~ the authorization request ~~and clinical information presented~~ using ~~the appropriate UM~~ criteria established by Pharmacy & Therapeutics (P&T) Committee. If authorization criteria does not exist, reviewer will perform a medical necessity review using clinical evidence from sources referenced in III. Prior Authorization Process Guidelines.

~~A. , according to UM- 001 Utilization Management Policy or UM Program.~~

~~(1) The PR utilizes evidence-based criteria approved through P&T Committee and hierarchical criteria process for approving, modifying, and deferring , requested services (as applicable).~~

~~(a) The hierarchal criteria process:~~

~~(i) Regulatory and contractual requirements~~

~~(ii) Evidence based guidelines~~

~~(iii) Alliance specific guidelines~~

~~(iv) National medical association consensus~~

~~(v) Medical necessity/medical judgement~~

~~(2) The PR Reviewer documents the clinical decision-making process in the clinical information. The documentation must include a review of the clinical information and application of the appropriate criteria used in the determination.~~

B. The Pharmacist Reviewer determination decision will be entered into the care decision platform database and will be communicated to the member and prescriber.

C. Requests which cannot be approved by the reviewing Pharmacist will be sent for Medical Director review.

Retro Requests: The Alliance does not accept post-service or retrospective authorization requests for nonemergent or non-urgent services that would require prior authorization more than 90 days past the date of service. Retro requests will be reviewed for medical necessity as per UM-57.

The exception criteria under which a post service / retrospective request greater than 90 days after the date of service may be considered are:

1. Member eligibility issues, i.e., unable to validate eligibility at time of service, incorrect eligibility information at time of service.
2. In-patient services where the facility is unable to confirm enrollment with the Alliance.

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~~G. Retro requests will be reviewed for medical necessity as per UM-57.~~

~~V.~~VI. The Alliance's Pharmacy Department processes pharmacy authorization requests in accordance with the procedures described in UM Policy # 001 – Utilization Management and UM Policy #057 (as it may relate to pharmacy services).

a. Outreach calls (up to 3 attempts) may be made to the requesting provider to request reasonably necessary clinical information when needed to make a PA decision or enter missing required clinical information for medication requests. For each outreach attempt, the reviewer is to document the following:

i. Name and title of person spoken to

ii. Phone number called (if different from one already noted in the PA system)

iii. What specific information was requested

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~~**VI. Continuity of Care for Covered Services for Newly Enrolled Medi-Cal and GroupCare Beneficiaries**~~

~~A. PAD CoC requests are managed using the same mechanisms and processes as UM Policy #036 Continuity of Care for Terminated and Non-Participating Providers, UM Policy #058, Continuity of Care for New Enrollees Transitioned to Managed Care After Receiving A Medical Exemption, and UM Policy#059 Continuity of Care for Medi-Cal Beneficiaries Who Transition into MediCal Managed Care.~~

VII. Continuation of Therapy

A. The Alliance shall allow continuation of therapy for members using medically necessary drugs when it can be shown through clinic notes or medication fill history that the member has been taking the medication prior to enrollment.

B. For transitioning members until the Beneficiary can be seen by a Plan provider to establish a care plan, as required by Welfare & Institutions (W&I) Code, Section 14185(b), the Alliance will allow for continuation of medically necessary medications if provided clinic notes showing all of the following:

1. Patient name
2. Medication name, dose, and route of administration
3. Quantity distributed
4. Date medication was started and date last given/filled

VIII. Annual Review of PAD Prior Authorization and UM Criteria

a. All PAD utilization management criteria undergo annual evaluation for appropriateness and effectiveness. Criteria are updated when necessary. The P&T committee reviews the pharmacy UM program, including delegated elements. The review encompasses scope, policies and procedures, and criteria as appropriate.

IX. Monitoring of the PA process

a. Inter-rater Reliability- the Alliance evaluates the consistency of decision making for those health care professionals involved in applying PAD Criteria.

X. Pharmacy Department will communicate with Utilization Management (UM), Communications & Outreach, Medical Directors, Provider Services (PR), Member Services (MSR), Claims and Benefit Configuration Departments to implement prior authorization restriction requirements in Heath Suite and outreach to providers and members.

~~**XI.**~~ Pharmacy Services will comply with appropriate UM policies as they relate to pharmacy supported authorizations, NOA letters and regulatory requirements (see RX-011 Decision and Notification Requirements~~related policies section for reference~~).

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DEFINITIONS / ACRONYMS

- PAD: Physician/Facility-Administered Drugs
- NCQA: National Committee on Quality Assurance
- UM: Utilization Management

AFFECTED DEPARTMENTS/PARTIES

Pharmacy Services
Utilization Management
Claims

Benefit Configuration
Member Services
Provider Relations
Communications and Outreach

RELATED POLICIES AND PROCEDURES

RX-011 Decision and Notification Requirements
UM-001 Utilization Management
UM-057
~~UM-036 Continuity of Care for Terminated and Non-Participating Providers~~
~~UM-051 Timeliness of UM Decision Making and Notification~~
~~UM-051 Attachment A UM Timeliness Standards for Medi-Cal and Group Care~~
~~UM-054 Notice of Action~~
~~UM-057 Authorization Service Request~~
~~UM-058 Continuity of Care for New Enrollees Transitioned to Managed Care After Receiving A Medical Exemption~~
~~UM-059 Continuity of Care for Medi-Cal Beneficiaries Who Transition into MediCal Managed Care~~

REVISION APPROVAL HISTORY

6/20/2023, 12/19/2023,**8/21/2024**,
5/21/2025~~,~~ 9/2025

Blue = Material updates

REFERENCES

- NCQA UM 12, Element A**,** B, D
- Alliance Provider Manual
- Health & Safety Code, Sections 1363.5, 1367.01, 1367.21, 1367.215, 1373.96, 1374.72
- Senate Bill 855 – Mental Health as a Medical Necessity
- DHCS All Plan Letter 22-012 Governor's Executive Order N-01-19, regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal Rx
- DMHC APL 20-035 (OPL): Medi-Cal Pharmacy Benefit Carve Out – Medi-Cal Rx
- DHCS All Plan Letter 22-032 Continuity of Care for Medi-Cal Beneficiaries Who Newly Enroll in Medi-Cal Managed Care from Medi-Cal FFS, and for Medi-Cal Members who Transition into a New Medi-Cal Managed Care Health Plan on or after January 1, 2023
- DHCS APL 23-004 Skilled Nursing Facilities -- Long Term Care Benefit Standardization And Transition Of Members To Managed Care
- DHCS APL 23-027, Subacute Care Facilities -- Long Term Care Benefit Standardization and Transition of Members to Managed Care
- DHCS APL 23-023 – Intermediate Care Facilities for Individuals with Developments Disabilities – Long Term Care Benefit Standardization and Transition of Members to Managed Care
- DHCS Contract #23-30212, Exhibit A – Scope of Work
- 2024 Medi-Cal Managed Care Plan Transition Policy Guide
- 42 CFR section 438.900 et seq
- CMS Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements

~~MONITORING~~

~~This policy will be reviewed annually to ensure effectiveness.~~

~~APPENDIX~~

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~~**Table 1: Medical Benefit Determination Turnaround Timetable of Different Regulatory Bodies**~~

~~Type of Request~~	~~NCQA~~	~~DHCS~~	~~DMHC~~		~~**Alliance**~~
~~Prospective, Urgent~~	~~72 hours~~	~~72 hours~~	~~72 hours~~		~~**72 hours**~~

~~Prospective, Non-Urgent~~	~~Medi-Cal: 14 calendar days Group Care: 15 calendar days~~	~~5 business days~~	~~5 business days~~	~~**5 business days**~~
~~Post-service~~	~~30 calendar days~~	~~30 calendar days~~	~~30 calendar days~~	~~**30 calendar days**~~

~~**Table 1: Medical Benefit Determination Turnaround Timetable of Different Regulatory Bodies**~~

~~Type of Request~~	~~Medi-Cal~~	~~IHSS~~	~~DSNP~~
~~Prospective, Urgent~~	~~24 hours~~	~~72 hours~~	~~24 hours~~
~~Prospective, Non-Urgent~~	~~24 hours~~	~~5 business days~~	~~72 hours~~
~~Post-service~~	~~30 calendar days~~	~~30 calendar days~~	~~30 calendar days~~

APPENDIX II Medicare Part B Drugs

- For determination of Medicare Part B drugs, please refer to CMS Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements, Appendices B & C.

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POLICY AND PROCEDURE TEMPLATE

Policy Number	RX-D-033
Policy Name	Medicare Part True-Out-of-Pocket (TrOOP), Financial Information Reporting (FIR),and Nx Transactions
Department Name	Pharmacy Services
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy Services
Line(s) of Business	D-SNP
Effective Date	TBD
Subcommittee Name	Pharmacy and Therapeutics Committee
Subcommittee Approval Date	TBD
Administrative Oversight Committee Approval Date	TBD

POLICY STATEMENT

Alameda Alliance for Health (Alliance), in collaboration with their PBM will maintain systems and procedures to accurately track, report and monitor True-Out-of-Pocket (TrOOP) costs, including beneficiary payments and qualifying payments for coordination of benefits (COB), in compliance with 42 CFR 423.464.

The Alliance Pharmacy Department will be responsible for review, monitoring, investigation and/or correction of FIR (Financial Information Reporting) and Nx transaction performance.

PROCEDURE

1.0 **TrOOP**

Data sharing to ensure accurate TrOOP tracking includes Coordination of Benefits (COB), enrollment records, Other Health Insurance (OHI) details, TrOOP, gross drug spending, and supplemental payer data. Standard transaction sets allow electronic COB data transfers to record supplemental payments between pharmacies and Part D plans, as well as among Part D plans when beneficiaries switch during the contract year. The CMS-

contracted Part D Transaction Facilitator (PDTF) processes these transactions, categorizing them by involved entities and processing purpose. Accurate transaction documentation by the PDTF is key to avoid benefit coordination delays. The following table summarizes transaction types and descriptions processed through the PDTF.

PDTF Transaction Types and Description

Transaction Type	Transaction Name	Description	Purpose	Involved Parties
FIR	Financial Information Reporting Transaction TrOOP and gross drug spend data	To transfer beneficiary information, TrOOP and Total Drug Spend accumulated when beneficiaries change plans within plan year	Allows a plan that is receiving a beneficiary mid-year to place the enrollee in the correct phase of the benefit; for example, if the deductible is paid in the initial plan the FIR data would reflect that the beneficiary would not need to pay deductible again when joining the new plan	Financial values transmitted from original plan to PDTF. PDTF conveys values to new plan (i.e. Automated TrOOP balance transfer (ATBT))
Nx	Information Reporting Transaction-supplemental payer	Informs the Part D plan of payments made by supplemental payers so payments can be adjusted	Allows a plan to adjust TrOOP based on payments made by supplemental payers.	PDTF sends to Part D sponsors so TrOOP can be adjusted. Pharmacy processes claim and processor sends transaction which contains pharmacy claim request and payer response information to PDTF. PDTF sends to Part D sponsors so TrOOP can be adjusted.

1.1 PBM is responsible to calculate the amount required to be applied to a beneficiary's TrOOP.
1.1.2 TrOOP eligible claims will adhere to CMS eligible third parties as defined in 42 CFR § 423.100 and 42 CFR 423.464.
1.2. The PBM is responsible for all claim adjustments and retroactive TrOOP changes.
1.3 Alliance will execute a Business Associate Agreement with the Part D Transaction Facilitation Contractor (PDTF (Relay Health)) and provide annual FIR and Nx Report

distribution emails. Current year templates available at Annual Report Distribution Email Setup and Changes after Annual Submission | Medicare Part D Transaction Facilitator.

2.0 **Financial Information Reporting (FIR) Transaction Process**

There are three types of FIR transactions:

- F1 Financial Information Reporting Inquiry
  - This transaction is sent to the very first plan for the beneficiary in a calendar year.
- F2 Financial Information Reporting Update
  - This transaction is sent to the last plan on record during the calendar year as of the date of the FIR transaction. This is also called the current plan of record for the beneficiary.
- F3 Financial Information Reporting Exchange
  - This transaction is sent to any additional plans between the first plan of record for the calendar year and the last or current plan of record for the calendar year. This transaction contains accumulators from any prior plans and allows for the plan(s) receiving the F3 to report their accumulators in addition to those reported by others in their response to this transaction.
- Every time a beneficiary changes plans in a calendar year, there will be at minimum two FIR transaction types (F1 and F2) generated. However if the beneficiary has more than two plans in a calendar year, there will be three transaction types (F1, F2, and F3).
- The entire process of sending FIR transactions to each of the beneficiary's plans in called a Sequence. Each FIR transaction is sent sequentially from the oldest (first plan in a calendar year) to the most recent plan. Each Sequence will contain at a minimum an F1 and an F2, but may also include an F3 if more than two plans exist for a beneficiary in a calendar year.
  2.1 PBM is responsible for FIR transaction processing for transactions received from the PDTF.
  2.2 Alliance Pharmacy is responsible for monitoring the Daily Cumulative FIR Aging Reporting provided by the PDTF. Alliance will resolve eligibility errors within 15 days from the time of initial error. Adjudication based errors will be escalated to the PBM for research and resolution within 15 days.

3.0 Nx Transaction (Information Reporting)

PBM will process Nx transactions related to secondary claims by other payers generated by the PDTF and adjust TrOOP accumulation in accordance with CMS requirements for TrOOP accounting and COB. Nx transactions are defined as:

- N1 Information Reporting
- N2 Information Reporting Reversal
- N3 Information Reporting Rebill

3.1 PDTF triggers real-time OHI reporting initiated with the B (billing) transaction, which delivers the Nx transaction. All supplemental billing claims are routed through a switch that directs transactions to PDTF for TrOOP reporting.

3.2 Alliance Medicare Ops is responsible for notification to enrollees of other prescription coverage reported on COB from CMS and OHI information updates with the Benefits Coordination & Recovery Center (BCRC)
3.3 Alliance Enrollment/IT will provide OHI on the eligibility file in accordance with current accepted codes and descriptions.
3.4 Alliance Pharmacy will review, monitor and track the bi-monthly CMS Nx Performance Reports (summary and detailed) to identify potential issues. Alliance Pharmacy will work with the PBM to mitigate any Nx transaction rejections. Alliance Pharmacy will utilize the Relay Health Report Guide available at Nx Reject Reports for Part D Plan | Medicare Part D Transaction Facilitator to guide resolution.

DEFINITIONS / ACRONYMS

ATBT – Automated TrOOP Balance Transfer
BCRC – Benefits Coordination & Recovery Center
CMS – Centers for Medicare & Medicaid Services
COB – Coordination of Benefits
FIR – Financial Information Reporting
HPMS – Health Plan Management System
MSP – Medicare Secondary Payor
NCPDP – National Council for Prescription Drug Programs
Nx – Set of reporting transactions developed by NCPDP to provide transaction reporting information
N1 transactions – Transmission of a record of a beneficiary's supplemental coverage information. Information Reporting (N1) is a transaction request and a response.
N2 transaction – Transmission reversal a previously submitted N1 transaction. Information Reporting Reversal (N2) is a transaction request and a response.
N3 transaction – An implied reversal. It is used to cancel an N1 Information Reporting submitted that had been processed previously and to submit a new Information Reporting in the same transaction. (Two step process: 1) reverse a previous N1 supplemental coverage information transaction and 2) submit new supplemental coverage information, but both steps are done in the same transaction.) Information Reporting Rebill (N3) is a transaction request and a response.
Other Health Insurance (OHI) – Other insurance that can be primary or supplemental to Part D.
PDTF (Part D Transaction Facilitator) – The Part D Transaction Facilitator is a federal contractor which is responsible, in conjunction with CMS, for establishing procedures for facilitating eligibility queries (E1 transactions) at point of sale (POS), identifying costs reimbursed by other payers (Information Reporting (N) transactions) and alerting Part D sponsors about such transactions, and facilitating the transfer of TrOOP-related data (financial information reporting (FIR) transactions) when a beneficiary changes plan enrollment during the coverage year.
Supplemental Payors (Other Payor) – A payer that is supplemental to Part D offers benefits or coverage after Part D benefits have been determined. These benefits are usually in the form of copay/coinsurance reduction.
PBM – Pharmacy Benefit Manager

TrOOP – True Out of Pocket

AFFECTED DEPARTMENTS/PARTIES

Pharmacy Services
Pharmacy Benefit Manager (Currently – PerformRx)
Enrollment
Operations

RELATED POLICIES AND PROCEDURES

RX-D 20- Part D Delegation Oversight Auditing (PBM)
RX-D 13-Explanation of Benefits (EOB) Oversight and Monitoring
RX-D 28 - Medicare Part D Coordination of Benefits (COB)

RELATED WORKFLOW DOCUMENTS OR OTHER ATTACHMENTS

See attachments I -V below

REVISION HISTORY

New Policy

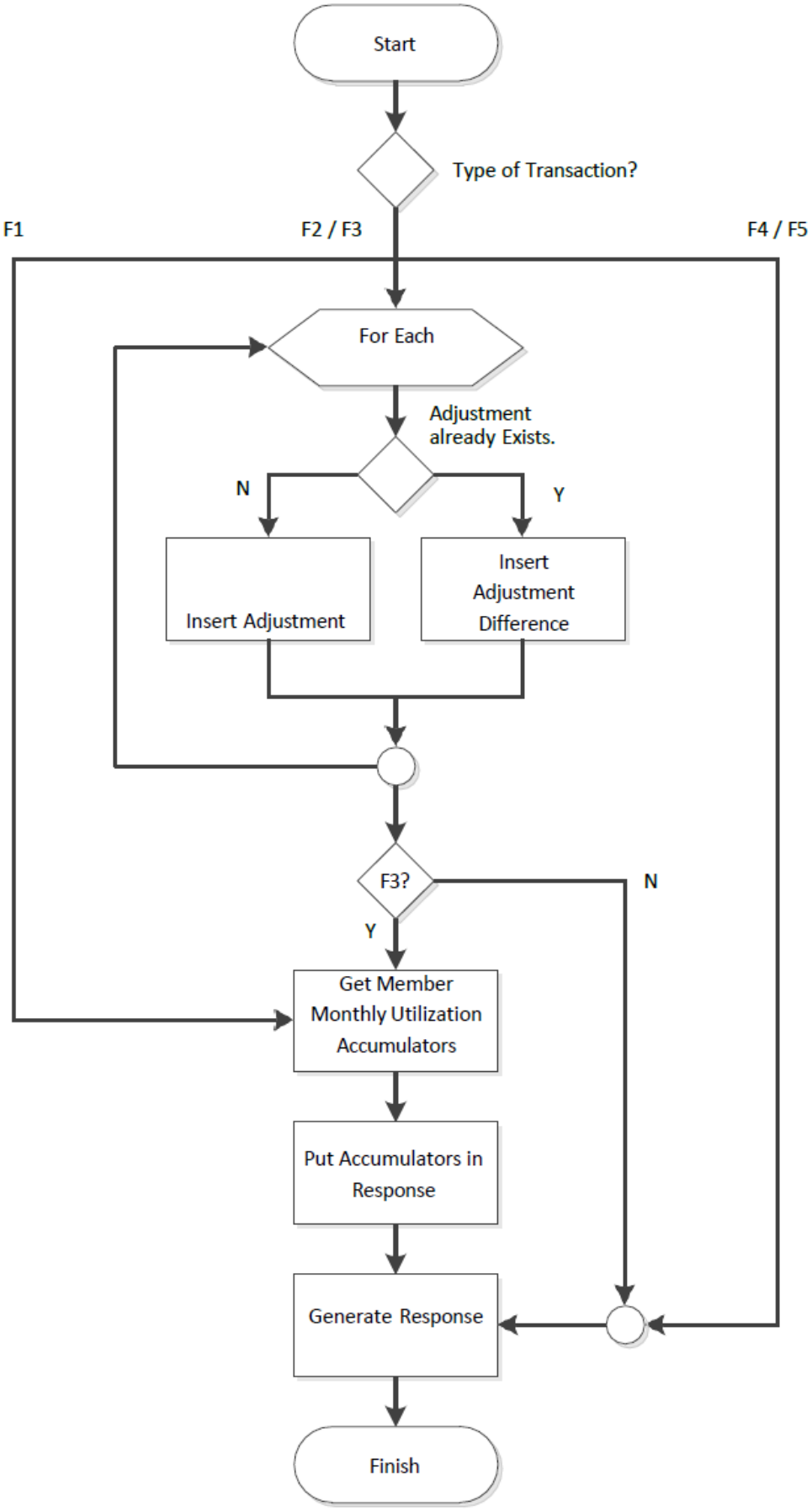
REFERENCES

43 CFR 423.308
HPMS Memo Update: Clarification of True Out-of-Pocket (TrOOP) Costs for Calendar year 2025, April 23, 2025
Final CY 2026 Part D Redesign Program Instructions
Medicare Prescription Drug Benefit Manual (PDBM) Chapter 14- Coordination of Benefits- September 17, 2018
https://medifacd.mckesson.com

MONITORING

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

Figure 1: FIR Transaction Adjudication



Attachment I

Annual Distribution List of Plan Associates/Employees receiving Part D FIR (ATBT) and TrOOP Nx performance reports

NOTE: Plans participating in the Hospice Pilot must include email addresses and check the Hospice Report column to continue receiving Hospice Performance Reports in 2025.

This is a full file replace - this file must be completed with all emails that should receive reports by report type and plan year.

-Email addresses may not be for Plan Business Associates. Only Plan employees should be entered. Plans wishing to supply report data to their Business Associates, such as PBM/Processors, must make arrangments withint their internal systems to forward or supply the reports.

-If emails need to be changed for multiple plan years please complete one row for each plan year

-To indicate that an email applies to a particular year or report, please place a single x value in the field.

-***This list must be submitted by 12/19/2024 to be effective for 2025. All emails previously submitted will be terminated as of January 1st and those on this form will be active as of January 1, 2025. If this form is not received, prior years and current year reports will no longer be sent.***

-NO PBMs on this form. For distribution emails for the PBM report please complete the Annual PBM Reject Aging Report distribution form

Please email completed form to TBTSupport@relayhealth.com with the subject title "Annual email list"

Contract # (1 per row)	Email Address (1 per row)	2022	2023	2024	2025	FIR Report	NX Report	Hospice Report

Attachment II

PBM Email address for PBM FIR Reject Aging Reports

Use this form for indicating PBM/Processor recipients of FIR Reject Aging Reports

This is a full file replace- this file is reflective of all emails that should receive reports by type and year

-Submitter of the request must be a plan representative

-Only one PBM email address per plan year is allowed. No Plan emails should be sent.

-If emails need to be changed for multiple plan years please complete one row for each plan year

-To indicate that an email applies to a particular year or report, please place a singe x value in the field.

-***This list must be submitted by 12/19/2024 to be effective for 2025. All emails previously submitted will be terminated as of January 1 and those on this form will be active as of January 1, 2025. If this form is not received, prior years and current year reports will no longer be sent.***

Please email completed form to TBTSupport@relayhealth.com with the subject title "PBM Report email list"

Contract # (1 per row)	Email Address (1 per row)	2022	2023	2024	2025

Part D Contract Processor Change

Use this form to:
1) change in processor
2) Please email completed form to TBTSupport@relayhealth.com

General Contract Information	
Plan Name:	
Contract ID:	
Request Submitter Name:	
Request Submitter Email:	
NEW PBM/Processor Name:	
OLD PBM/Processor Name:	
Today's Date:	
Effective Date:	

NOTE: Please keep in mind that the Nx Reject Reports have transactions that span multiple years. For example an N transaction may be received in 2015 that is for a date of service for 2014. As such, if your plan has changed processors, you will need to be sure to remove emails from the old processor and may need to selectively send them Nx report information related to the years they are responsible for processing.

To add or remove emails as a result of the processor change, please use the Part D Contract Aannual ATBT and Nx Report Distribution Email List which can be found at:
http://medifacd.relayhealth.com/fir/setting-up-points-of-contact-for-a-contract-id

7 Examples for the Daily Cumulative FIR Aging Report

Note that in all examples, during the CMS Social Security Removal Initiative transition period, both the MBI and the MBI fields will be populated.

After the transition period has ended the MBI will no longer be reported in the MBI field, and it will remain blank. Only the MBI(s) and associated effective and termination dates will be reported. The MBI field will not be removed to eliminate the need to recode a new layout.

7.1 Scenario One

The beneficiary left Plan H1234 and is effective with Plan S5678 03/1/2013. A FIR series is started 03/1/2013. (Series = F1 to H1234; F2 to S5678)

Plan H1234 is effective for the same beneficiary 01/01/2013. The plan has a termination date of 02/28/2013. The FIR (F1) processed the first time 03/01/2013 successfully. The FIR (F1) rejected the second time it was run on 03/08/2012.

Plan S5678 is effective for the same beneficiary 03/01/2013. The plan has no termination date (open-ended). The FIR (F2) rejected the first time 03/01/2013. The FIR cannot process the second time it was run, (03/08/2013) because Plan H1234 rejected (F1) on 03/08/2013.

The results are as follows:

1. There is no report to Plan H1234 on 03/02/2013 because the FIR processed.
2. Daily Cumulative FIR Aging Report to Plan S5678 on 03/02/2013 (report date)

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Fail Age	Reject Code	Failed Pre-F Indicator	Transaction Type	Contract ID
2013	1EG4TE5MK73	20130301		1	04	N	F2	S5678

3. Daily Cumulative FIR Aging Report to Plan H1234 on 03/09/2013

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Fail Age	Reject Code	Failed Pre-F Indicator	Transaction Type	Contract ID
2013	1EG4TE5MK73	20130308	20130301	1	02	N	F1	H1234

4. Daily Cumulative FIR Aging Report to Plan S5678 on 03/09/2013

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Fail Age	Reject Code	Failed Pre-F Indicator	Transaction Type	Contract ID
2013	1EG4TE5MK73	20130301		8	04	Y	F2	S5678

5. The Failed Pre-F Indicator (value Y) indicates that a FIR (F2) was previously rejected by Plan S5678, however since that time a prior plan (H1234) has rejected the FIR (F1) and therefore Plan

S5678 cannot determine whether or not the fix was successful. This beneficiary still does not have a successful FIR.

7.2 Scenario Two

Assume scenario one identified problems are resolved. This is specific to a FIR generated on 07/01/2013.

The beneficiary left Plan H1234, went to Plan S5678 and then returned to Plan H1234 in the same year. A new FIR series is started on 07/01/2013 because a new plan (H1234) is effective 07/01/2013. The original FIR series started 03/01/2013 is terminated.

Plan H1234 is effective for the same beneficiary 01/01/2013. The plan has a termination date of 02/28/2013. The FIR (F1) processed the first time 07/01/2013 successfully.

Plan S5678 is effective for the same beneficiary 03/01/2013. The plan has a termination date of 06/30/2013. The FIR (F3) rejected with the first run 07/01/2013.

Plan H1234 is effective for the same beneficiary 07/01/2013. The plan has no termination date (open-ended).

The results are as follows:

1. There is no report to Plan H1234 on 07/02/2013 because the FIR processed.
2. Daily Cumulative FIR Aging Report to Plan S5678 on 07/02/2013 (report date)

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Fail Age	Reject Code	Failed Pre-F Indicator	Transaction Type	Contract ID
2013	1EG4TE5MK73	20130701		1	04	N	F3	S5678

7.3 Scenario Three

This example is built on Scenario Two and is specific to a FIR generated on 07/08/2013.

The beneficiary left Plan H1234, went to Plan S5678 and then returned to Plan H1234 in the same year. A FIR series is started 07/01/2013, the following sequence in the series is run 07/08/2013.

Plan H1234 is effective for the same beneficiary 01/01/2013. The plan has a termination date of 02/28/2013. The FIR (F1) processed the first time 07/01/2013 successfully. The FIR (F1) rejected the second time it was run on 07/08/2013.

Plan S5678 is effective for the same beneficiary 03/01/2013. The plan has a termination date of 06/30/2013. The FIR (F3) rejected with the first run 07/01/2013.

Plan H1234 is effective for the same beneficiary 07/01/2013. The plan has no termination date (open-ended).

The results are as follows:

1. Daily Cumulative FIR Aging Report to Plan H1234 on 07/09/2013 (report date)

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Fail Age	Reject Code	Failed Pre-F Indicator	Transaction Type	Contract ID
2013	1EG4TE5MK73	20130708	20130701	1	04	N	F1	H1234

2. Daily Cumulative FIR Aging Report to Plan S5678 on 07/09/2013 (report date)

Last Failed Transmission Date is 07/01/2013 for Plan S5678 since prior Plan H1234 has rejected. Plan S5678 has not been able to successfully respond to a FIR since that time period, because a prior plan (H1234) is stopping the transaction. The aging continues even if the prior plan continues to stop the transaction.

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Fail Age	Reject Code	Failed Pre-F Indicator	Transaction Type	Contract ID	First Contract ID in a Plan Year
2013	1EG4TE5MK73	20130701		8	02	Y	F3	S5678	H1234

7.4 Scenario Four

All FIRs in this scenario have been sent and received successfully as of 07/10/2013.

The beneficiary left Plan H1234, went to Plan S5678 and then returned to Plan H1234 in the same year. The FIR series started 07/01/2013, the following sequence in the series is run 07/08/2013. On 07/10/2013, the third sequence in the series is run.

Plan H1234 is effective for the same beneficiary 01/01/2013. The plan has a termination date of 02/28/2013. The FIR (F1) processed the first time 07/01/2013 successfully. The FIR (F1) rejected the second time it was run on 07/08/2013, when the FIR (F1) processed third time on 07/10/2013, it was processed successfully.

Plan S5678 is effective for the same beneficiary 03/01/2013. The plan has a termination date of 06/30/2013. The FIR (F3) processed successfully 07/10/2013.

Plan H1234 is effective for the same beneficiary 07/01/2013. The plan has no termination date (open-ended).

The results are as follows:

1. Nothing will be reported on the Daily Cumulative FIR Aging Report on 07/11/2013 for these FIRs as they were all successful.

7.5 Scenario Five

This is specific to a FIR generated on 07/08/2013. The beneficiary left Plan H1234, went to Plan S5678 and then returned to Plan H1234 in the same year. This is a scenario where the same plan is a plan of record twice in the same benefit plan year. A FIR series is started 07/01/2013, the following sequence in the series is run 07/08/2013.

Plan H1234 is effective for the same beneficiary 01/01/2013. The plan has a termination date of 02/28/2013. The FIR (F1) processed the first time 07/01/2013 successfully. The FIR (F1) rejected the second time it was run on 07/08/2013.

Plan S5678 is effective for the same beneficiary 03/01/2013. The plan has a termination date of 06/30/2013. The FIR (F3) processed the first time 07/01/2013 successfully. However, the plan never received a FIR transaction (F3) on 07/08/2013 due to the H1234 rejection.

Plan H1234 is effective for the same beneficiary 07/01/2013. The plan has no termination date (open-ended).

The results are as follows:

1. Daily Cumulative FIR Aging Report to Plan H1234 effective 01/01/2013 on 07/09/2013 (report date)

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Fail Age	Reject Code	Failed Pre-F Indicator	Transaction Type	Contract ID
2013	1EG4TE5MK73	20130708	20130701	1	04	N	F1	H1234

2. There is no report to Plan S5678 on 07/09/2013 because the FIR for the prior plan rejected.

Plan H1234 will receive the report that reflects the rejection of the F1 for the plan period effective 01/01/2013 through 02/28/2013. Plan H1234 will not receive the F2 expected for the plan period beginning 07/01/2013, due to Plan S5678 not receiving the F3 due to the prior plan rejection.

7.6 Scenario Six

This scenario is specific to a FIR transaction scheduled for 03/08/2013 run, however the FIR is actually sent after midnight. The beneficiary left Plan H1234 and is effective with Plan S5678 03/01/2013. A FIR series started 03/01/2013.

Plan H1234 is effective for the same beneficiary 01/01/2013. The plan has a termination date of 02/28/2013. The FIR (F1) rejected the first time sent on 03/01/2013. The FIR (F1) rejected the second time it was run on 03/08/2012.

The results are as follows:

1. Daily Cumulative FIR Aging Report to Plan H1234 on 03/02/2013 (report date)

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Next Scheduled Automated Transmission Date	Contract Send Count	Fail Age	Reject Code	Transaction Type	Contract ID
2013	1EG4TE5MK73	20130301		20130308	1	1	04	F1	H1234

2. Daily Cumulative FIR Aging Report to Plan H1234 on 03/09/2013 (report date)

Note: Plan S5678 will not receive a report due to the FIR (F2) not received due to the upstream plan rejecting.

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Next Scheduled Automated Transmission Date	Contract Send Count	Fail Age	Reject Code	Transaction Type	Contract ID
2013	1EG4TE5MK73	20130301		20130308	1	8	04	F1	H1234

Note: Since the FIR transaction actually processed on 03/09/2013 due to volumes (missed cut-off), the "Next Scheduled Automated Transmission Date" will reflect the next date based on the FIR schedule (0308/2013) and "Contract Send Count" on the 03/09/2013 report will not reflect that FIR transaction because the FIR was actually sent on 03/09/2013.

3. Daily Cumulative FIR Aging Report to Plan H1234 on 03/10/2013 (report date)

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Next Scheduled Automated Transmission Date	Contract Send Count	Fail Age	Reject Code	Transaction Type	Contract ID
2013	1EG4TE5MK73	20130301		20130310	2	9	04	F1	H1234

On the 03/10/2013 report the Contract Send Count will reflect the fact that the FIR was actually sent on 03/09/2013. The Next Scheduled Automated Transmission Date will still reflect the date based on the FIR schedule (03/10/2013)

7.7 Scenario Seven

This scenario is specific to a rejected FIR transaction for a previous benefit plan year corrected after the automated period of 03/31/2013. Any FIR exceptions (rejections) for a prior benefit plan year corrected after the automated period through March 31 of the subsequent benefit plan year, will require a manual retrigger request. The period available to request a manual retrigger for the prior plan year is April 1 through May 31.

Until this manual retrigger is requested, the report will continue to report the rejection and the rejection will continue to age. Additionally, the next Scheduled Automated Transmission Date will be blank as the automated timeframe expired as of 03/31/2013.

Plan H1234 is effective the beneficiary 07/01/2012, and an automated trigger (F2) was done on 03/31/2013, resulting in a rejection. The plan corrects the rejection on 04/01/2013. The plan requests a manual retrigger 04/03/2013 and the FIR (F2) was successful.

The results are as follows:

1. Daily Cumulative FIR Aging Report to Plan H1234 on 04/01/2013

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Next Scheduled Automated Transmission Date	Contract Send Count	Fail Age	Reject Code	Transaction Type	Contract ID
2012	1EG4TE5MK73	20130331			1	1	04	F2	H1234

2. Daily Cumulative FIR Aging Report to Plan H1234 on 04/02/2013

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Next Scheduled Automated Transmission Date	Contract Send Count	Fail Age	Reject Code	Transaction Type	Contract ID
2012	1EG4TE5MK73	20130331			1	2	04	F2	H1234

3. Daily Cumulative FIR Aging Report to Plan H1234 on 04/03/2013

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Next Scheduled Automated Transmission Date	Contract Send Count	Fail Age	Reject Code	Transaction Type	Contract ID
2012	1EG4TE5MK73	20130331			1	3	04	F2	H1234

The 04/03/2013 report reflects transactions as of 04/02/2013.

4. There is no Daily Cumulative FIR Aging report to Plan H1234 on 04/04/2013 due to the FIR (F2) was successful.

1. The Daily Cumulative FIR Aging Report to Plan A1111 on the report date 1 day after the 1st FIR transaction could not be generated.

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Next Scheduled Automated Transmission Date	Contract Send Count	Fail Age	Reject Code	Transaction Type	Contract ID
2024	98754321	20241001		20240831		1	T*A1	F3	A1111

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Next Scheduled Automated Transmission Date	Contract Send Count	Fail Age	Reject Code	Transaction Type	Contract ID
2023	IEXXX	20231001		20231003		2	T*C2	F1	H1234

3. Plan H1234 updated the beneficiary's 4Rx information in the Medicare Advantage Prescription Drug System (MARx) with a valid RxID and the FIR (F1) was generated and accepted on a subsequent sequence.

   Once the F1 is generated and accepted by the plan, the transaction is removed from the report.

7.9 Scenario Nine

Plan in sequence with Missing or Invalid RxBIN – PDTransFac Exception code T*A1 M/I RxBIN

Note: Effective 08/01/2023 – When only the following exceptions occur, subsequent plan(s) in the sequence will receive a FIR sequence transaction with a $0.0 TrOOP accumulation reported for the failed FIR.

- T*A1 (M/I RxBIN)
- T*C2 (M/I Cardholder ID)

A beneficiary has added a new plan that is reported in the CMS eligibility file with an effective date of 09/01/2024. A FIR TrOOP sequence series is initiated.

PDTransfac identifies the beneficiary had 2 preceding plans:

Contract ID B2222 effective 01/01/2024 – 04/30/2024

Contract ID A1111 effective 05/01/2024 – 08/31/2024 with an invalid Rx BIN value 1AB23.

The F1 is accepted and a response received for plan B2222.

The F3 FIR transaction could not be generated to plan A1111.

The Daily Cumulative FIR Aging Report for plan A1111 reports the transaction as follows:

- **Note**: The transaction will appear on each daily report with "Fail Age" incrementing, until a valid RxBIN is received, and a resulting FIR transaction for the beneficiary has been accepted by plan A1111.

1. The Daily Cumulative FIR Aging Report to Plan A1111 on the report date 1 day after the 1st FIR transaction could not be generated.

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Next Scheduled Automated Transmission Date	Contract Send Count	Fail Age	Reject Code	Transaction Type	Contract ID
2024	98754321	20241001		20240831		1	T*A1	F3	A1111

2. The transaction on the next daily report

Plan Year	MBI	Last Failed Transmission Date	Last Successful Transmission Date	Next Scheduled Automated Transmission Date	Contract Send Count	Fail Age	Reject Code	Transaction Type	Contract ID
2024	98754321	20241001		20240901		2	T*A1	F3	A1111

3. Plan A1111 updated the beneficiary's 4Rx information in the Medicare Advantage Prescription Drug System (MARx) with a valid RxBIN. During the next sequence the FIR (F3) was generated and accepted by pan A1111. The failed FIR transaction for this beneficiary is removed from the report.

Attachment V

Field Name	Definition	Example	Max Size	Format
Report Date	Date of report (CCYYMMDD)	20130709	8	Numeric
Plan Year	Current Benefit Plan Year (CCYY)	2013	4	Numeric
Beneficiary ID	Medicare beneficiary identifier.	AB123456789	1	Alpha/Numeric
Transaction ID	A unique identifier sent by the Facilitator on all FIR transactions.		21	Alpha/Numeric
Date of the First FIR in the Series	First time the series was sent, even if this F could not be sent. (CCYYMMDD)	20130601	8	Numeric
First Failed Transmission Date	First time this FIR was sent and rejected. (CCYYMMDD)	20130601	8	Numeric
Last Failed Transmission Date	Last time this FIR was sent and rejected. (CCYYMMDD) If this is the first time the FIR has failed, this date will equal the First Failed Transmission Date.	20130608	8	Numeric
Last Successful Transmission Date	Last time this FIR succeeded. (CCYYMMDD) This field is reported when there was a successful FIR previous to this report.	20130615	8	Numeric
Date of Last Transmission	This is the most recent date the series being reported was run. (CCYYMMDD)	20130622	8	Numeric
Next Scheduled Automated Transmission Date	Next time the series being reported on will run. (CCYYMMDD). This field will be blank when there is no “next scheduled automated transmission date”.	20130629	8	Numeric
Failed Pre-F Indicator	This indicator is Y when a FIR previously rejected for the reported Plan ID has since rejected by a preceding plan - because of a prior plan. Value: Y = Yes N = No	Y	1	Alpha/Numeric
Fail Age	Report generation date minus First Failed Transmission Date. (DD) (Calculated Field)	22	3	Numeric
Number of Pre-F's for this Series	Number of FIRs sent to prior plan for this series where Failed Pre-F Indicator = Y (reject by prior plan) Date is based upon the First FIR in the series. No leading zeros will be provided. There are zero “Pre-F’s” a zero value will be reported.	2	3	Numeric
Date of last Pre-F	Date of last FIR sent to prior plan where prior plan rejected. (CCYYMMDD)	20130629	8	Numeric
Contract Send Count	The number of times this FIR has been sent.	3	3	Numeric
Sequence Send Count	The number of times the sequence has been sent. 99 = This is the final FIR reported in the series. No more automated series.	1	3	Numeric
Number of Automated Tries Left	The number of remaining FIR transmissions for the series.	2	3	Numeric

Processor Name	The name that RelayHealth has associated with the Bank Identification Number (BIN)	ABC Health	50	Alpha/Numeric
Contract ID	The ID assigned by CMS to the health plan when contracted for Part D	A1234	5	Alpha/Numeric
PBP ID	Medicare Part D Plan Benefit Package ID assigned by CMS for the Plan Benefit Package	992	3	Alpha/Numeric
BIN	The Bank Identification Number (BIN) is the identifier number for the payer.	121212	6	Numeric
PCN	Processor Control Number is the identifier number for the processor.	23232323bb	10	Alpha/Numeric
Group ID	Plan group identifier assigned by plan	1234	15	Alpha/Numeric
Cardholder ID	Beneficiary identifier assigned by plan	123456711	20	Alpha/Numeric
Date of Birth	Beneficiary date of birth (CCYYMMDD)	19250711	8	Numeric
Reject Code	Plan Processor, or Facilitator (PDTransFac) Reject Reason Code. See: FIR Reject Codes Generated by the Plan-Processor or Transaction Facilitator in "Related Documents" on the FIR Reports page of the MediFacD site at: https://medifacd.mckesson.com/FIR/Reports/	004	3	Alpha/Numeric
Reject Description	Definition of the Reject Code	M/I Processor Control Number	100	Alpha/Numeric
Transaction Type	The type of FIR transaction (F1, F2, or F3)	F1	2	Alpha/Numeric
LIS Indicator	This indicator is Y when a beneficiary has Low Income Subsidy effective coverage. This information is valid as of the date and delivery of the report. Value: Y = Yes N = No	Y	1	Alpha/Numeric
Non-Plan of Record	A=Audit-off (Indicates Contract ID is a current non plan of record for the beneficiary) (Automated from CMS Eligibility File) P=Proxy Add (Indicates Contract ID is a current non plan of record for the beneficiary) (Manual Request or POS-FE Add)	P	1	Alpha/Numeric
Non-Plan of Record Effective Date	The effective date of the Non-Plan of Record. (CCYYMMDD) This field is reported when the Non-Plan of Record field is equal to "A".	20130601	8	Numeric
Non-Plan of Record Termination Date	The termination date of the Non-Plan of Record. (CCYYMMDD) This date reflects the received date for the automated eligibility change received by the Transaction Facilitator. However, plans may pay for additional days past this period and need to ensure that the plan report these days. This field is reported when the Non-Plan of Record field is equal to "A".	20130630	8	Numeric

Plan Of Record	Plan of Record (POR), which means the plan was listed in the most recent update from CMS (not necessarily the current active plan). Identifies whether the entity receiving the report is a Plan of Record or not. Values: Y = Yes N = No	Y	1	Alpha/Numeric
Contract ID 1	The first Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	A2345	5	Alpha/Numeric
Contract ID 2	The second Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	B2345	5	Alpha/Numeric
Contract ID 3	The third Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric
Contract ID 4	The fourth Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric
Contract ID 5	The fifth Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric
Contract ID 6	The sixth Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric
Contract ID 7	The seventh Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric
Contract ID 8	The eighth Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric
Contract ID 9	The ninth Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric
Contract ID 10	The tenth Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric
Contract ID 11	The eleventh Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric
Contract ID 12	The twelfth Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric
Contract ID 13	The thirteenth Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric
Contract ID 14	The fourteenth Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric
Contract ID 15	The fifteenth Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric
Contract ID 16	The sixteenth Contract ID in the send order of the Plans listed at RelayHealth effective for the benefit plan year.	C2345	5	Alpha/Numeric

Gender	Gender of the Patient	1	1	Numeric
Current MBI	Current Medicare beneficiary identifier.	AB123456789	11	Alpha/Numeric
Effective Date	Current MBI effective date. (CCYYMMDD	20130630	8	Numeric
MBI	Medicare beneficiary identifier.	AB123456789	11	Alpha/Numeric
Effective Date	MBI effective date. (CCYYMMDD)	20130630	8	Numeric
Termination Date	MBI termination date. (CCYYMMDD)	20130630	8	Numeric

Field Name	Definition	Example	Max Size	Format
MBI	Medicare beneficiary identifier.	AB123456789	11	Alpha/Numeric
Effective Date	MBI effective date. (CCYYMMDD)	20130630	8	Numeric
Termination Date	MBI termination date. (CCYYMMDD)	20130630	8	Numeric
MBI	Medicare beneficiary identifier.	AB123456789	11	Alpha/Numeric
Effective Date	MBI effective date. (CCYYMMDD)	20130630	8	Numeric
Termination Date	MBI termination date. (CCYYMMDD)	20130630	8	Numeric
MBI	Medicare beneficiary identifier.	AB123456789	11	Alpha/Numeric
Effective Date	MBI effective date. (CCYYMMDD)	20130630	8	Numeric
Termination Date	MBI termination date. (CCYYMMDD)	20130630	8	Numeric
MBI	Medicare beneficiary identifier.	AB123456789	11	Alpha/Numeric
Effective Date	MBI effective date. (CCYYMMDD)	20130630	8	Numeric
Termination Date	MBI termination date. (CCYYMMDD)	20130630	8	Numeric

ALAMEDA Alliance FOR HEALTH
Health care you can count on.
Service you can trust.

POLICY AND PROCEDURE

Policy Number	RX-D-035 Member Symptom Management Process
Policy Name	Member Symptom Management Process
Department Name	Pharmacy
Department Officer	Chief Medical Officer
Policy Owner	Senior Director, Pharmacy
Lines of Business	MCAL, D-SNP
Effective Date	1/1/2026
Subcommittee Name	
Subcommittee Approval Date	
Administrative Oversight Committee Approval Date	

POLICY STATEMENT

The purpose of this policy is to ensure that Alameda Alliance for Health (AAH) members receive timely assistance when they report symptoms that may require urgent or emergent medical or behavioral health intervention. This policy establishes the procedures for both non-clinical and licensed pharmacy staff when encountering members reporting symptoms during outreach calls.

It is the policy of Alameda Alliance for Health (AAH) to prioritize member safety and facilitate rapid connection to appropriate medical or behavioral health resources.

- Non-clinical pharmacy staff must not provide medical advice, symptom assessment, or clinical guidance.
- Licensed pharmacists may provide limited clinical triage within the scope of practice, consistent with AAH protocols.
- All pharmacy staff must follow the escalation procedures below to ensure members receive appropriate and timely care.

This policy applies to all non-clinical pharmacy outreach staff who conduct outbound calls to members for the purpose of medication review, medication adherence, or other quality-related Stars measures.

PROCEDURE

1. Physical Symptoms Reported During Outreach Calls
   1.1. Non-Clinical Pharmacy Staff: if a member reports any current or new physical symptoms:
      1.1.1. Remain calm and empathetic
      1.1.2. Document member's statements verbatim
      1.1.3. Avoid providing clinical advice or interpretation of symptoms

1.1.4. Use the following scripted response: “I am not a licensed medical professional, so I can’t advise you about your symptoms. I will transfer you to our 24-hour nurse advice line so they can advise you how to proceed.”

1.1.5. Warm transfer the call to the 24-hour nurse advice line **(888-433-1876)**. Stay on the call with the member until connection with a nurse is confirmed.

1.1.6. Notify the Pharmacy supervisor of the member interaction and submit a Care Management referral in TruCare.

1.2. Licensed Pharmacist Escalation

1.2.1. If a licensed pharmacist determines the member needs urgent or emergent medical care, the following procedure applies:

- Pharmacists may assess within their scope to determine if the situations appear emergent or life-threatening.
- Advise the member to go to the nearest urgent care or emergency department.

1.2.2. Notify the Pharmacy supervisor of the member interaction and submit a Care Management referral in TruCare.

1.3. Emergent or Life-Threatening Physical Symptoms **(All pharmacy staff)**

1.3.1. If a member mentions any of the following emergent or life-threatening symptoms, the staff must immediately dial 911 for EMS to assist the member. Stay on the line until the member is successfully connected with the 911 operator.

- Chest pain or pressure
- Severe shortness of breath
- Sudden weakness, numbness or paralysis
- Sudden confusion or slurred speech
- Severe headache, dizziness or fainting
- Uncontrolled bleeding
- Swelling of face or throat
- Severe allergic reaction

1.3.2. Notify the Pharmacy supervisor of the member interaction and submit a Care Management referral in TruCare.

2. Behavioral Health Symptoms: If a member makes statements of wanting to harm/hurt themselves, harm/hurt others, or is experiencing hallucinations or delusions:

2.1. Keep the member on the phone; do not place the member on hold

2.2. Document member’s statements verbatim

2.3. Obtains the member’s current location (In the event the call is accidentally terminated, and onsite crisis intervention is needed)

2.4. Attempt to determine if caller is alone or with another person

2.5. Engages the caller in conversation

2.6. Immediately contact the BH clinical team via the Teams BH Emergent Chat, and warm transfer to the AAH BH Care Management Team (Clinician). The BH Care Management Team can be reached by dialing BH – **MH Emergent Phone Queue extension 2539 in Finesse OR through communication with the BH Emergent queue chat in Teams.**

2.6.1. Contact the Behavioral Health Manager or Senior Director Behavioral Health for instructions to add members to the “BH Emergent” Teams chat.

2.7. If the AAH BH Clinician is unavailable, warm transfer the call to 988 or **Alameda County Mental Health Crisis Line 1-800-309-2131**. Remain on the line until a Crisis Line staff member is reached to assist the member.

2.8. Immediately dial 911 (EMS/Police) when failure to intervene will put the member's life or others in immediate jeopardy. Instances where such a call may be required include the following:

2.8.1. A member with specific intent to harm self or others, along with a stated plan and means

2.8.2. A member with a behavioral health emergency

2.8.3. A member who is severely intoxicated and/or who acknowledges having overdosed.

2.8.4. Notify the Pharmacy supervisor of the member interaction and submit a Care Management referral in TruCare.

3. Documentation Requirements:

3.1. For every member interaction involving symptom escalation (physical, behavioral, or emergent), the staff member must document the following in TruCare:

3.1.1. Date and time of the call

3.1.2. Member's statements or reported symptoms verbatim

3.1.3. Actions taken (warm transfer, Teams chat, or 911)

3.1.4. Outcome (successful transfer, emergency services contacted, etc.)

3.1.5. Notification to Pharmacy Supervisor and Care Management

3.1.6. Name and title of staff member completing the documentation

DEFINITIONS

AFFECTED DEPARTMENTS/PARTIES

Pharmacy staff

RELATED POLICIES AND PROCEDURES

MBR-062 MS Referrals and Triage

REVISION HISTORY

REFERENCES

MONITORING

This policy will be monitored at a minimum annually.

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

PHARMACY & THERAPEUTICS COMMITTEE

Record of Committee Meeting Minutes

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

Status	Voting Committee Members	Organization	Initials	Officer / Notes
P	Donna Carey, MD	Chief Medical Officer-Alliance	DC	Chairman
P	Luke Lim, R.Ph.	Senior Director of Pharmacy Services – Alliance	LL	Co-Chair
A	Rahel Negash, Pharm D	Pharmacy Services Supervisor – Alliance	RN	
P	Aaron Basrai, PharmD	Haller's Pharmacy	AB	BOG
P	Paul Bayard, MD	La Clinica de la Raza (CHCN)	PB	
P	Ivan Lee, MD	Private Practice	IL	
P	Bao Dao, MD	Epic Care	BD	
P	Charles Raynor, PharmD	Alameda County Behavioral Health Dept.	CR	

P=Present; PH=Call-in; A=Absent; CMO = Chief Medical Officer; DOPS=Director of Pharmacy Services; BOG = Board of Governors Representative

Status	Regular Guests	Organization	Initials	Role / Department
P	Iryna Makukh	PerformRx	IM	Pharmacy Formulary Management.
A	Liza Rosendale	PerformRx	LR	Clinical Program Manager
P	Pat DeHoratius	PerformRx	PD	Manager Formulary/DUR
P	Barrie Cheung	PerformRx	BC	Regional Pharmacy Director
P	Ramon Tran Tang, PharmD	Alameda Alliance	RT	Clinical Pharmacist
P	Jefferey Bencini, Pharm D	Alameda Alliance	JB	Clinical Pharmacist
P	Timothy Tong, Pharm D	Alameda Alliance	TT	Clinical Pharmacist
A	Beverly Juan, MD	Alameda Alliance	BJ	Medical Director
A	Darryl Crowder	Alameda Alliance	DC	Provider Relations
P	Bibek Sandhu, PharmD, MBA	PillarRX	SB	Consulting Pharmacist

Other Guests	

Follow-up Items:

Clerk of the Committee: Benita Ochoa

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
I) Call to Order	D. Carey	• Agenda Overview	Call to order at: 5:00PM	
II) Informational Updates	D. Carey L. Lim	Informational Update • Stipend update CR: Have we looked at the time spent on each meeting? Dollar amount per meeting doesn't tell the entire story. Thank you! DC: The goal was not to attempt to pay a certain amount per hour, but rather a general amount for all committee participation. PB: How do you compare the actual amount of work done by each committee? The work of this committee has increased quite a lot. Are other committees also reviewing Medicare D P&Ps, for example? DC: Good question. When our legal team reviewed the committee stipends, they considered the community standard and reviewed the committee stipends of several of our sister plans. As I stated, our committee stipends are above the stipends of local sister plans, for the same committees. This is not to negate the amount of time required from members of this committee. PB: Question still stands; did you compare the number of hours and the expectations for the relevant committees? I am quite surprised you would get committee members willing to put in 6 hours of work for a total of $100. DC: Not directly. Yes, I was quite surprised as well. • NCQA audit • DSNP policies wrapping up **<u>Questions:</u>**		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes

III) **Pharmacy Utilization Reports (Quarter 2,2025)**	L. Lim	(All matters listed on the Consent Calendar are to be approved with one motion unless a member of the P&T Committee removes an item for separate action. Any consent calendar item for which separate action is requested shall be heard as the next Agenda item in closed session.)
		
		Top 50 Drugs by Cost (IHSS)
		- The top 50 drugs accounted for 1,374 claims for 683 members and cost $1,624,476, which is an increase of $160,509 in spend from the previous quarter.
		- Biktarvy remains at number one, claims having gone up by 1, and there is one additional member since the previous quarter.
		- Ozempic is at numbers 2, 4, and 5, with 278 total claims for 131 members. There was an increase of 4 claims and 4 members from the previous quarter.
		- Vemlidy is up to number 3 with 55 claims for 22 members. There was an increase of 1 claim for 22 members from the previous quarter. This medication is managed via the Hepatitis B MRG, which requires trial and failure of, intolerance to, or reason not to use, entecavir.
		- Nerlynx is up at number 6 with 7 claims for 1 member. There was an increase of 2 claims for one member from the previous quarter. This medication is managed via Oncology MRG.
		
		Top 50 Drugs by Cost (Medi-Cal)
		- The top 50 drugs accounted for 29,741 claims for 25,468 members and cost $62,950,490 which is an increase of $2,543,207 in spend from 1Q2025.
		- Claims increased 5.7% compared with 1Q2025.
		- Unique utilizers increased 6.1% compared with 1Q2025.
		- Spend increased 4.2% compared with 1Q2025.
		- Biktarvy down 41 claims.
		- Jardiance each up about 100 claims.
		- Ozempic 0.25mg 2085->2039 claims
		- Wegovy 2.4mg 1004->1183 claims
		- Wegovy 0.5mg 996->1149 claims
		- Ozempic 2mg 1137->1242 claims
		- Ozempic 1mg 1281->1305 claims
		- Pursuant to 2025-2026 State Budget, effective January 1, 2026: Drugs used for weight loss and weight loss-related-indications will be excluded from Medi-Cal Rx coverage for all Medi-Cal members.
		
		Top 50 PA Reviewed Drugs by Volume (IHSS)
		- Top 50 PA requests = 247. There were 378 total PA requests for quarter 2.
		  o 64 requests (26%) were approved. This approval rate is lower by 2% than it was observed last quarter.
		  o 183 requests (74%) were denied or partially approved.
		- Wegovy is at numbers 1, 4, 12, 16 and 22 with 53 total requests and 11 approvals (21%).
		  o 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.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		○ Wegovy to reduce the risk of major adverse cardiovascular events requires a documentation that the patient is obese or has BMI ≥27, has an established cardiovascular disease (prior myocardial infarction, stroke or symptomatic peripheral arterial disease), patient is on standard of care treatment for CVD and does not have diabetes. - Jardiance is at numbers 2 & 6 with 29 total requests and 3 approvals (10%). ○ Jardiance requires trial and failure of one of the following: metformin, branded/generic drug containing metformin, branded angiotensin receptor/neprilysin inhibitor (ARNi), generic angiotensin-converting enzyme inhibitor (ACEi), generic angiotensin receptor blocker (ARB), generic mineralocorticoid receptor antagonist (MRA), or generic beta blocker AND documentation of trial and failure, intolerance, contraindication or inability to use one preferred formulary step therapy medication. - Zepbound is at numbers 3, 20, & 26 with 24 total requests and 7 approvals (29%). ○ Zepbound to reduce excess body weight requires a diagnosis of class III/severe obesity (BMI ≥40) and trial and failure or inability to use Qsymia and Contrave. ○ Zepbound for moderate to severe obstructive sleep apnea requires trial and failure regarding lifestyle changes and behavioral modifications to reach BMI <30 kg/m^2 and trial and failure or inability to use PAP therapy. - Lidocaine 5% patch is at number 5 with 12 requests and 0 approvals (0%). ○ Lidocaine requires a diagnosis of neuropathic pain and a trial and failure of gabapentin or pregabalin and one other formulary alternative (e.g., duloxetine, venlafaxine, amitriptyline) used for neuropathic pain or morphine MME ≥ 50/day for 3 months. - Vemlidy is at number 7 with 11 requests. There were 6 approvals (55%). ○ Vemlidy requires a diagnosis of Hepatitis B and trial and failure of, intolerance to, or inability to use entecavir tablets. **Top 50 PA Reviewed Drugs by Volume (Medi-Cal)** - The top 50 drugs accounted for 224,703 claims for 201,794 members at a cost of $4,993,486. This is a 1256 claim increase (+0.5%) from 2Q2025 and cost increase of $143,867 (+3%). - Chronic condition drugs appear as #4, and not again until #9. - Analgesics occupy #1 (diclofenac), #3 (ibuprofen), #5 (APAP) of the top 10 - Allergies occupy #2 (fluticasone), #6 (cetirizine), #8 (loratadine)		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
IV) E-Voting Material/Consent Agenda	L. Lim B. Ochoa	**E-Voting Material/Consent Agenda** **The following items have been sent to the voting committee for review via E-voting** *Luke Lim, R.Ph., Senior Pharmacy Director – Alameda Alliance* *Benita Ochoa, CPhT, Lead Pharmacy Technician – Alameda Alliance* *(All matters listed on the Consent Calendar are to be approved with one motion unless a member of the P&T Committee removes an item for separate action. Any consent calendar item for which separate action is requested shall be heard as the next Agenda item in closed session.)*	Approved via e-voting: Yes: 6 No: 0 Abstained: 1	

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

Agenda Item	Discussion Leader	Discussion Summary		Action	Notes
		Atovaquone-proguanil (Malarone)	• No changes		
		Intranasal Steroids	• No changes		
		Topical Acne Agents	• No changes		
		Injectable/Infusible Bone-Modifying Agents for Oncology Indications	• No changes		
		Alosetron (Lotronex)	• No changes		
		Viberzi (eluxadoline)	• No changes		
		Rifabutin (Mycobutin)	• No changes		
		Tranexamic acid (Lysteda)	• No changes		
		Santyl Ointment	• No changes		
		Topical Antibiotics	• No changes		
		Injectable/Infusible Agents for Osteoporosis and Paget's Disease	• No changes		
		Vowst	• No changes		
		Duvyzat	• No changes		
		Rho Kinase Inhibitors	• No changes		
		Xolremdi	• No changes		
		Anti-obesity medications	• Update naming conventions to show the availability of generic Qsymia		
		Physician Administered Drug (PAD) Guidelines	**Changes**		
		Adakveo	• No changes		
		Injectable/Infusible Agents for Osteoporosis and Paget's Disease	• No changes		
		Exondys 51	• No changes		
		Erythropoiesis-Stimulating Agents	• No changes		
		Iron-containing Products	• No changes		
		Tepezza	• No changes		

Agenda Item	Discussion Leader	Discussion Summary		Action	Notes
		B-Cell Maturation Antigen (BCMA) Directed Chimeric Antigen Receptor (CAR) T-Cell Therapy	• No changes		
		Gene Therapy for Hemophilia B	• No changes		
		Fecal microbiota	• No changes		
		Omisirge	• No changes		
		Qalsody (tofersen)	• No changes		
		Lamzede	• No changes		
		Enzyme Replacement Therapies for Fabry Disease	• No changes		
		Roctavian	• No changes		
		Enzyme replacement therapy for acid sphingomyelinase deficiency (ASMD)	• No changes		
		Rytelo (imetelstat)	• No changes		
		Interim Formulary Updates			
		• See p. 210 in packet			
		Summary of Physician Administered Drug (PAD) Updates			
		• See P. 213 in packet			
		Pharmacy Policy & Procedure Updates			
		• RX-007 Pharmaceutical Patient Safety, Drug Recalls, Quality Assurance			
		DSNP Policy & Procedure Updates			
		• RX-D 008 Part D Coverage	• RX-D 11 Medicare Part D End Stage Renal Disease		
		• RX-D 026 Medicare Part D Annual Reporting	• RX-D-028 Medicare Part D Coordination of Benefits (COB)		
		• RX-D 027 Pharmacy Network Access Contracting	• RX-D 031 Medicare Part D Emergency Preparedness		
		• RX-D 029 Medicare Part D Low Income Subsidy	• RX-D-034 Medicare Part D Negative Formulary Change Notification		
		• RX-D 032 Medicare Part D Early Prescription Refill			
		ED Oversight			
		• None			
		90 Day Maintenance List updates			

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		• Minor updates & Add HIV PreP **P&T Meeting Minutes** • P&T Meeting Minutes Q2 June 17, 2025		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes

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
Embecta Pen Needle U/F Miscellaneous 31G X 5 MM	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 31G X 5/16" 0.5 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 31G X 5/16" 1 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 31G X 15/64" 0.5 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 31G X 15/64" 1 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U-100 Miscellaneous 27G X 5/8" 1 ML	NF to F-QL (200 EA per 30 days)
Embecta Pen Needle U/F Miscellaneous 31G X 8 MM	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U/F Miscellaneous 31G X 5/16" 0.3 ML	NF to F-QL (200 EA per 30 days)
Embecta Ins Syr U/F 1/2 Unit Miscellaneous 31G X 5/16" 0.3 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe U-100 Miscellaneous 28G X 1/2" 1 ML	NF to F-QL (200 EA per 30 days)
Embecta Insulin Syringe Miscellaneous 28G X 1/2" 1 ML	NF to F-QL (200 EA per 30 days)
Embecta Pen Needle U/F Miscellaneous 32G X 6 MM	NF to F-QL (200 EA per 30 days)

Agenda Item	Discussion Leader	Discussion Summary		Action	Notes
		Embecta Insulin Syringe U/F Miscellaneous 31G X 15/64" 0.3 ML	NF to F-QL (200 EA per 30 days)		
		Embecta Insulin Syringe U/F Miscellaneous 30G X 1/2" 0.5 ML	NF to F-QL (200 EA per 30 days)		
		Embecta Pen Needle U/F Miscellaneous 29G X 12.7MM	NF to F-QL (200 EA per 30 days)		
		Embecta Ins Syr U/F 1/2 Unit Miscellaneous 31G X 15/64" 0.3 ML	NF to F-QL (200 EA per 30 days)		
		Embecta Insulin Syringe Miscellaneous 28G X 1/2" 0.5 ML	NF to F-QL (200 EA per 30 days)		
		Embecta Pen Needle Nano 2 Gen Miscellaneous 32G X 4 MM	NF to F-QL (200 EA per 30 days)		
		Embecta Pen Needle Nano Miscellaneous 32G X 4 MM	NF to F-QL (200 EA per 30 days)		
		Embecta AutoShield Duo Miscellaneous 30G X 5 MM	NF to F-QL (200 EA per 30 days)		
		Embecta Insulin Syringe U/F Miscellaneous 30G X 1/2" 1 ML	NF to F-QL (200 EA per 30 days)		
		Embecta Insulin Syringe U/F Miscellaneous 30G X 1/2" 0.3 ML	NF to F-QL (200 EA per 30 days)		
		Eltrombopag Olamine Oral Tablet 12.5 MG	NF to F-PA		
		Eltrombopag Olamine Oral Tablet 50 MG	NF to F-PA		
		Eltrombopag Olamine Oral Tablet 75 MG	NF to F-PA		
		Eltrombopag Olamine Oral Tablet 25 MG	NF to F-PA		
		Promacta Oral Tablet 12.5 MG	F-PA to NF		
		Promacta Oral Tablet 50 MG	F-PA to NF		
		Promacta Oral Tablet 75 MG	F-PA to NF		
		Promacta Oral Tablet 25 MG	F-PA to NF		

Agenda Item	Discussion Leader	Discussion Summary		Action	Notes
		Phentermine-Topiramate Oral Capsule Extended Release 24 Hour 3.75-23 MG	NF to F-PA		
		Phentermine-Topiramate Oral Capsule Extended Release 24 Hour 7.5-46 MG	NF to F-PA		
		Phentermine-Topiramate Oral Capsule Extended Release 24 Hour 11.25-69 MG	NF to F-PA		
		Phentermine-Topiramate Oral Capsule Extended Release 24 Hour 15-92 MG	NF to F-PA		
		Qsymia Oral Capsule Extended Release 24 Hour 3.75-23 MG	F-PA to NF		
		Qsymia Oral Capsule Extended Release 24 Hour 7.5-46 MG	F-PA to NF		
		Qsymia Oral Capsule Extended Release 24 Hour 11.25-69 MG	F-PA to NF		
		Qsymia Oral Capsule Extended Release 24 Hour 15-92 MG	F-PA to NF		
		Edurant PED Oral Tablet Soluble 2.5 MG	NF to F		
		Emtricitab-Rilpivir-Tenofov DF Oral Tablet 200-25-300 MG	NF to F		
		Complera Oral Tablet 200-25-300 MG	F to NF		
		Yeztugo Subcutaneous Solution 463.5 MG/1.5ML	NF to F		
		Yeztugo Oral Tablet 300 MG	NF to F		
		Afluria Intramuscular Suspension	NF to F-QL-AL (1 fill per 270 days, 12 years and above)		
		Afluria Preservative Free Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 12 years and above)		
		Fluad Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 65 years and above)		

Agenda Item	Discussion Leader	Discussion Summary		Action	Notes
		Fluarix Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 12 years and above)		
		Flublok Intramuscular Solution Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 12 years and above)		
		Flucelvax Intramuscular Suspension	NF to F-QL-AL (1 fill per 270 days, 12 years and above)		
		Flucelvax Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 12 years and above)		
		Flulaval Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 12 years and above)		
		FluMist Nasal Liquid	NF to F-QL-AL (1 fill per 270 days, 12 -49 years)		
		Fluzone High-Dose Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 65 years and above)		
		Fluzone Intramuscular Suspension	NF to F-QL-AL (1 fill per 270 days, 12 years and above)		
		Fluzone Intramuscular Suspension Prefilled Syringe 0.5 ML	NF to F-QL-AL (1 fill per 270 days, 12 years and above)		
		Penmenvy Intramuscular Suspension Reconstituted	NF to F-QL-AL (1 vial per 1 fill, 2 fills per lifetime, 10-25 years)		
		mNexspike Intramuscular Suspension Prefilled Syringe 10 MCG/0.2ML	NF to F		

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

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
V) New Business	Iryna Makukh	- QL recommendations **New MRG** **Vykat XR** - 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 - Vykat XR is reserved for members who have a confirmed diagnosis of PWS and experience symptoms of hyperphagia related to PWS. - **Immunoglobulin A (IgA) Nephropathy Agents** - Medications: Fabhalta (iptacopan), Filspari (sparsentan), Tarpeyo (budesonide), Vanrafia (atrasentan) - Exclusions: For Filspari and Vanrafia only: pregnancy - Coverage duration: If all of the criteria are met, it will be approved as follows: - Initial requests: Fabhalta: 6 months; Filspari, Tarpeyo, Vanrafia: 9 months - Reauthorization: Fabhalta, Filspari, Vanrafia: 12 months; Reauthorization requests for Tarpeyo will not be allowed as the safety and efficacy of subsequent courses have not been established - If the conditions are not met, the request will be sent to a clinical reviewer for medical necessity review - Initial Authorization: - • Diagnosis of primary IgA nephropathy verified by biopsy - • Member is on an ACE inhibitor or ARB at a maximally tolerated dose OR there is a medical reason that they cannot be on one - • Member has proteinuria (defined as total urine protein ≥1 g/day) - • Member has an estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73 m2 - • Medication is prescribed at an FDA approved dose - • For Fabhalta: - Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria - o Member is at risk for disease progression as defined by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g - For Filspari:	Move to approve: 1st: BD 2nd: AB	

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Documentation of baseline liver function - Attestation that member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists, and/or aliskiren upon initiation of Filspari - For Vanrafia: - Member is at risk for disease progression as defined by a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g - Re-Authorization: - Documentation of positive clinical response (e.g. decrease in UPCR, stabilization of eGFR) - Medication is prescribed at an FDA approved dose - For Filspari: - Documentation of liver function - Reauthorization requests for Tarpeyo will not be allowed as the safety and efficacy of subsequent courses have not been established*** **New PAD** **Encelto** - 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 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 mm2 measured by spectral domain-optical coherence tomography (SD-OCT) - Best corrected visual acuity (BCVA) score of 54 letters or better (20/80 or better Snellen equivalent) measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart - Prescriber attests that member has no evidence of neovascular MacTel type 2 - Member has not previously received an Encelto implant for treated eye - Reauthorizations are not permitted, as members are limited to a single implant per eye per lifetime **Nulibry** - 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 - Initial Authorization: - Member has a diagnosis of molybdenum cofactor deficiency (MoCD) type A confirmed by genetic testing OR		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes

		- 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
		
		Zevaskyn
		- Exclusion Criteria
		- Receipt of any prior chemical or biologic product for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), including Vyjuvek and Filsuvez
		- 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
		- 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 cm2
		- Documentation is provided that there is no evidence of or history of squamous cell carcinoma in the wound(s) to be treated
		- Medication is prescribed at an FDA approved dose
		- The safety and effectiveness of repeat administration of Zevaskyn to the same treatment site have not been evaluated and will not be approved.
		- If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review
		
		Amvuttra
		- New PAD policy based on approved MRG policy
		- Prescriber Restrictions:
		- Prescriber must be neurologist, cardiologist, or specialist in the treatment of amyloidosis
		- Coverage Duration:		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes

		- If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 6 months.
		- Initial Authorization:
		  o Regimen does not exceed FDA-approved dose/frequency
		  o Patient has not undergone a liver or heart transplant
		- If the request is for Polyneuropathy Type:
		  o Patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by documented transthyretin variant by genotyping
		  o One of the following:
		- Patient has baseline polyneuropathy disability (PND) score ≤ IIIb
		- Patient has a baseline Familial Amyloid Polyneuropathy (FAP) Stage 1 or 2
		- Patient has baseline neuropathy impairment (NIS) score ≥ 5 and ≤ 130
		- Patient has clinical signs/symptoms of neuropathy
		If the request is for Cardiomyopathy Type:
		- Patient has confirmed diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis
		- Documented amyloid deposit by biopsy or positive technetium 99m pyrophosphate (Tc 99m PYP) cardiac imaging
		- Patient has New York Heart Association (NYHA) functional class I, II, or III heart failure symptoms
		- Patient has contraindication to/or previous trial and failure or continued clinical progression with use of Vyndaqel, Vyndamax or Attruby
		Re-authorization:
		- Patient's regimen does not exceed FDA-approved dose/frequency for the agent
		- Patient has not undergone a liver or heart transplant
		- Documented positive clinical response to therapy from baseline (stabilization/slowing of disease progression, improved neurological impairment, motor functions, improved NIS score, stabilization/reduced rate of decline in 6-minute walk test, etc.)
		- Patient has continued NYHA functional class I, II, or III heart failure symptoms
		- If all the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
		Questions/Comments:		

VI) Class Reviews, Monographs, and Recommendations-	Iryna Makukh	**1. Ophthalmic Antibiotics and Antibiotic-Corticosteroid Combinations Class Review** - This review covers antibiotic products for ophthalmic use, with and without a corticosteroid. These preparations are only available as a prescription and are used for various infectious and inflammatory indications involving the eye. - Judicious use of products containing ocular corticosteroids is generally recommended due to risks related to excessive exposure, such as cataracts and glaucoma. - There were 59 claims for 52 members, for a total cost of $801.75 and an average cost per claim of $13.59. The most highly utilized medication was Ofloxacin eye drops, with 15 claims, followed by Erythromycin eye ointment with 11 claims. There were no prior authorization requests.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Recommendation: Change Tobradex 0.3-0.1% eye ointment to F-PA to align with MRG PA Criteria and for cost containment.		
		2. <u>Ctexli Monograph and new MRG criteria New PAD: Tecelra</u> - Change Tobradex 0.3-0.1% eye ointment to F-PA to align with MRG PA Criteria and for cost containment. - Exclusion Criteria: Concurrent use with Cholbam (cholic acid) - 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 - 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 - Ctexli is reserved for members who have a diagnosis of CTX confirmed by genetic testing. **<u>Questions/Comments:</u>**		
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. Quantity Limit Exception** - Recommendation: - Add language on requiring members to use an optimized dose and strength of a medication - Policy will now include formulary and non-formulary medications that exceed published quantity limits **<u>Comments:</u>** Guideline (Changes): **2. Antiemetics**	Move to approve: 1st: AB 2nd: BD	

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Recommendation: Add new product Focinvez—new IV formulation of fosaprepitant Guideline (Changes): **3. Ophthalmic Anti-inflammatory Immunomodulators** - Recommendation: Add new product Tryptyr indicated for the treatment of signs and symptoms of dry eye disease in adults. **Comments:** Guideline (Changes): **4. Dronabinol** - Recommendation: Expand language on aprepitant to allow other NK1 receptor antagonists such as fosaprepitant **Comments:** Guideline (Changes): **5. White Blood Cell Stimulators** - Recommendation: - Add new filgrastim biosimilar Nypozi (filbrastim-txid) to criteria and to F-PA as it is cost-effective - Add Udenyca Onbody as it is missing from the policy - Reorganize drug list for more clarity - Add new long-acting CSF Ryzneuta (efbemalenograstim alfa-vuxw) to policy for completeness - Add Fylnetra to the acute hematopoietic radiation injury syndrome for pegfilgrastim products section, since it also has this indication - Add treatment failure requirement with biosimilars Zarxio and Releuko to acute hematopoietic radiation injury syndrome section for filgrastim products, since both of these filgrastim biosimilars have this indication **Comments:** Guideline (Changes): **6. Constipation agents** - Recommendation: Update criteria with newly available generic for Motegrity as it is more cost-effective and update on formulary to F-PA **Comments:**		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		Guideline (Changes): **7. Mesalamine** - Recommendation: Add mesalamine DR (Asacol HD) as it is missing from the policy. **Comments:** Guideline (Changes): **8. Scabicides and Pediculicides** - Recommendation: Add new product Pruradik (crotamiton) lotion indicated for eradication of scabies for completeness. Guideline (Changes): **9. Rifamycin Antibiotics** - Recommendation: Remove Aemcolo (rifamycin) as it has been discontinued. Guideline (Changes): **10. Medications for the treatment of Multi-Drug-Resistant Tuberculosis** - Recommendation: - Change coverage duration for Sirturo to 12 months to match current guideline recommendations - Remove "short course" and "long course" language from Sirturo section to align with clinical practice guideline updates that now recommend the use of a 6-month treatment rather than the 15-month or longer for regimens containing bedaquiline - Remove resistance to fluoroquinolones (FQ) requirement from Sirturo and Pretomanid sections, since per guideline updates BPaLM or BPaL regimens are now recommended regardless of FQ resistance. Guideline (Changes): **11. Palforzia** - Recommendation: Revise language on the initial dose escalation tolerance requirement in re-authorization section. Guideline (Changes): **12. Specialty Biologic Agents** - Recommendation: Add new product Imuldosa—new cost-effective Stelara biosimilar Guideline (Changes): **13. Immunizations** - Recommendation: Update the age limit for MResvia from 60 years and older to 18 years and older to account for the updated indication for individuals 18 through 59 years of age who are at increased risk for lower respiratory tract disease (LRTD) caused by RSV.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		- Add new meningococcal vaccination Penmenvy to criteria to align with other meningococcal vaccinations on formulary Guideline (Changes): **14. Vyalev** - Add new medication Onapgo and change the name of the policy to encompass all drugs. Onapgo is a subcutaneous apomorphine infusion device for the treatment of motor fluctuations in adults with advanced Parkinson's disease. - Add exclusion criteria for Onapgo per contraindication in the PI - Change coverage duration to 6 months for initial requests to better match safety and efficacy evaluations in clinical trials Guideline (Changes): **15. Antifibrotic Respiratory Tract Agents** - Recommendation: Remove attestation on drug interactions requirement Guideline (Changes): **16. Filspari** - Recommendation: Retire criteria as Filspari is included in the new Immunoglobulin A (IgA) Nephropathy Agents policy **Comments:** No changes recommended at this time. No further discussion.		

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
VIII) Physician Administered Drug (PAD) Policies	Iryna Makukh	Guideline (Changes): **1. White Blood Cell Stimulators** - Recommendation: - Add new filgrastim biosimilar Nypozi (filbrastim-txid) - Add Udenyca Onbody as it is missing from the policy - Add new long-acting CSF Ryzneuta (efbemalenograstim alfa-vuxw) - Remove acute hematopoietic radiation injury section for filgrastim products, since there are two Neupogen biosimilars that have an indication for acute hematopoietic radiation injury syndrome (Zarxio and Releuko) **Comments:** Guideline (Changes): **2. Elevidys** - Recommendation: No changes Sarepta Therapeutics had to suspend shipments of Elevidys on 7/22/2025 as there have been two deaths in the last few months. As of July 28, 2025 the FDA recommended removal of the voluntary hold for ambulatory patients who may now receive Elevidys. The investigation has concluded that the death was unrelated to the gene therapy product itself. The FDA continues to work with the manufacturer regarding non ambulatory patients, which remains subject to a voluntary hold. **Comments:** Guideline (Changes): **3. Vyalev** - Recommendation: - Add new medication Onapgo and change the name of the policy to encompass all drugs. Onapgo is a subcutaneous apomorphine infusion device for the treatment of motor fluctuations in adults with advanced Parkinson's disease. - Add exclusion criteria for Onapgo per contraindication in the PI - Change coverage duration to 6 months for initial requests to better match safety and efficacy evaluations in clinical trials **Comments:**	Approved 1st: AB 2nd: PB	
IX) Informational Updates on New Developments in Pharmacy	Iryna Makukh	New Product Review • New Products were discussed.	Approved 1st: BD 2nd: IL	

BRAND NAME	GENERIC NAME/DOSAGE FORM	RECOMMENDATION
Vykat XR	diazoxide choline oral tablet extended release 24 hour 25mg, 75mg, 150mg	Non-formulary (see new MRG criteria)
Vanrafia	Atrasentan oral tablet 0.75 mg	Non-formulary (see new MRG criteria)
dilTIAZem HCl-Sodium Chloride	dilTIAZem HCl-sodium chloride intravenous solution 100-0.72 mg/100ml-%	Non-formulary
Bisoprolol Fumarate	Bisoprolol fumarate oral tablet 2.5 mg	Non-formulary
Dolobid	Diflunisal oral tablet 375 mg	Non-formulary
Symbravo	Meloxicam-rizatriptan oral tablet 20-10 mg	Non-formulary
Lurbipr	Flurbiprofen oral tablet 100 mg	Non-formulary
Clemasz	Clemastine fumarate oral tablet 2.68 mg	Non-formulary
Ustekinumab	Ustekinumab intravenous solution 130mg/26ml, subcutaneous solution 45mg/0.5ml, subcutaneous solution prefilled syringe 45mg/0.5ml, 90mg/ml	Non-formulary

			Hemiclor	Chlorthalidone oral tablet 12.5 mg	Non-formulary			
			Imaavy	Nipocalimab-aahu intravenous solution 1200 mg/6.5ml	Non-formulary			
			Tepylute	Thiotepa intravenous solution 15 mg/1.5ml, 100 mg/10ml	Non-formulary			
			Ustekinumab-aekn	Ustekinumab-aekn subcutaneous solution prefilled syringe 45 mg/0.5ml, 90 mg/ml	Non-formulary			
			Escitalopram	Escitalopram oxalate oral solution 10 mg/10ml	Non-formulary			
			Wyost	Denosumab-bbdz subcutaneous solution 120 mg/1.7ml	Non-formulary			
			Jubbonti	Denosumab-bbdz subcutaneous solution prefilled syringe 60 mg/ml	Non-formulary			
			Livmarli	Maralixibat oral tablet 10mg, 15mg, 20mg, 30mg	Non-formulary			
			Miudella	Intrauterine Copper Device	Add to F			
			Midazolam-Sodium Chloride	Midazolam-Sodium Chloride (PF) intravenous solution 50-0.9 mg/50ml-% and 100-0.9 mg/100ml-% intravenous solution	Non-formulary			

			Edurant PED	Rilpivirine Oral Tablet Soluble 2.5 MG	F (already added via CRF)			
			Avmapki Fakzynja Co-Pack	Avutometinib & Defactinib co-pack oral therapy pack 0.8 & 200 mg	Non-formulary			
			Ryzneuta	Efbemalenograstim alfa-vuxw subcutaneous solution prefilled syringe 20 mg/ml	Non-formulary (see updated MRG & PAD criteria)			
			Emrelis	Telisotuzumab vedotin-tllv 20mg, 100mg intravenous solution reconstituted	Non-formulary			
			EPINEPHrine Bitartrate-NaCl	EPINEPHrine Bitartrate-NaCl intravenous solution 16-0.9 mg/250ml-%	Non-formulary			
			Bucapsol	Buspirone 7.5mg, 10mg, 15mg oral capsules	Non-formulary			
			Emblaveo	Aztreonam-Avibactam Sodium Intravenous Solution Reconstituted 1.5-0.5 GM	Non-formulary			
			Khindivi	Hydrocortisone oral solution 1 mg/ml	Non-formulary			
			Yutrepia	Treprostinil inhalation capsule 26.5mcg, 53mcg, 79.5mcg, 106mcg	Non-formulary			
			Rosyrah	levonorgestrel and ethinyl estradiol and ethinyl estradiol oral tablet 42-21-21-7 days	Non-formulary			

			Merilog Merilog SoloStar	Insulin Aspart-szjj subcutaneous solution 100 unit/ml Insulin Aspart-szjj subcutaneous solution pen-injector 100 unit/ml	Non-formulary			
			Glassia	Alpha1-proteinase inhibitor 4gm/200ml, 5gm/250ml intravenous solution	Non-formulary			
			Leqselvi	Deuruxolitinib 8mg oral tablet	Non-formulary			
			Stoboclo	Denosumab-bmwo Subcutaneous Solution Prefilled Syringe 60 MG/ML	Non-formulary			
			Osenvelt	Denosumab-bmwo subcutaneous solution 120 mg/1.7ml	Non-formulary			
			Ensacove	ensartinib 25mg, 100mg oral capsules	Non-formulary			
			Arbli	Losartan oral suspension 10 mg/ml	Non-formulary			
			Zelsuvmi	Berdazimer external gel 10.3 %	Non-formulary			
			Zevaskyn	Prademagene zamikeracel external sheet	Non-formulary (see new PAD criteria)			
			Bonsity	Teriparatide subcutaneous solution pen-injector 560 mcg/2.24ml	Non-formulary			

			Meleya	Norethindrone Oral Tablet 0.35 MG	Non-formulary			
			Galbriela	Ethinyl estradiol and norethindrone oral tablet chewable 0.8-25 mg-mcg	Add to F			
			Pruradik	Crotamiton external lotion 10 %	Non-formulary (see updated MRG criteria)			
			hydrocodone-acetaminophen	HYDROcodone-Acetaminophen Oral Solution 10-300 MG/15ML	Non-formulary			
			Enflonsia	clesrovimab-cfor 105 mg/0.7 mL prefilled syringe	Non-formulary			
			Nilotinib D-Tartrate	Nilotinib D-Tartrate 50mg, 150mg, 200mg oral capsule	Non-formulary			
			Promethazine	Promethazine HCl oral syrup 6.25 mg/5ml	Add to F			
			Zepbound	tirzepatide subcutaneous solution 12.5 mg/0.5mL, 15 mg/0.5 mL	Non-formulary, remove Zepbound 2.5mg/0.5ml and 5mg/0.5ml single dose vials from formulary			
			Xifyrm	meloxicam intravenous solution 30 mg/mL	Non-formulary			
			Gonal-f RFF	follitropin alfa rediject subcutaneous solution pen-injector 900 unit/1.44 mL	Non-formulary			

			Imuldosa	ustekinumab-srlf subcutaneous solution prefilled syringe 45 mg/0.5 mL, 90 mg/mL, intravenous solution 130 mg/26 mL	Add to F-PA (see updated MRG criteria)			
			Crenessity	crinecerfont oral capsule 25 mg	Non-formulary			
			Zusduri	mitomycin intravesical solution reconstituted 40 mg, 80 mg	Non-formulary			
			Averi	desogestrel-ethinyl estradiol oral tablet 0.15-0.03 mg	Add to F			
			Ibtrozi	taletrectinib adipate oral capsule 200 mg	Non-formulary			
			Yeztugo	lenacapavir subcutaneous solution 463.5 mg/1.5 mL, oral tablet 300 mg	F (already added via CRF)			
			Abigale Lo	estradiol-norethindrone	Non-formulary			
			GNP Naloxone (OTC)	naloxone nasal liquid 4 mg/0.1 mL	Add to F			
			COVID-19 Flu A+B Antigen Test In Vitro Kit	COVID-19 Flu A+B Antigen Test In Vitro Kit	Non-formulary			
			Insupen32G Extr3me	Insulin pen needles 32G X 6 mm	Non-formulary			

			Tryptyr	acoltremon ophthalmic solution 0.003 %	Add to F-PA (see updated PA criteria)			
			Lopressor	metoprolol oral solution 10 mg/mL	Non-formulary			
			Fanapt	iloperidone titration pack C oral miscellaneous 1 & 2 & 6 mg, titration pack B oral miscellaneous 1 & 2 & 6 & 8 mg	Non-formulary			
			Pyzchiva	ustekinumab-ttwe subcutaneous solution 45 mg/0.5 mL	Non-formulary			
			Conexxence	denosumab-bnht subcutaneous solution prefilled syringe 60 mg/ mL	Non-formulary			
			Bomyntra	denosumab-bnht subcutaneous solution Prefilled Syringe 120 mg/1.7 mL, vial 120 mg/1.7 mL	Non-formulary			
			Abigale	estradiol-norethindrone oral tablet 1-0.5 mg	Non-formulary			
			Aerochamber2GO	aerochamber 2go anti-static device	Non-formulary			
			Fanapt	iloperidone titration pack C oral miscellaneous 1 & 2 & 4 & 6 mg, titration pack A	Non-formulary			
			Lynozyfic	linvoseltamab-gcpt 5 mg/2.5ml, 200 mg/10ml intravenous solution	Non-formulary			

Agenda Item	Discussion Leader	Discussion Summary	Action	Notes
		Carbzah | Carbinoxamine 4 mg/5ml oral solution | Non-formulary		
X) Old Business		- MRG criteria review for Lidocaine patch, Alprazolam (Xanax), and Diuretics - New Product Review of Q2 2025 - Pharmacy strategy update (Dr. Carey) **Comments:**		
XI) Public Comment	D. Carey	• No comment		
Adjournment	D. Carey	• P&T Committee Member Forms **Meeting adjourned at 6:48PM**	None	

Signed by:
Luke W. Lim, R.Ph.
Pharmacy Director
D19D620D20E5400...

Luke Lim, R.Ph.
Senior Pharmacy Director,
Alameda Alliance for Health

11/03/2025 | 2:54 PM PST
Date

DocuSigned by:
Donna Carey
93FF13824FC54CD...

Donna Carey, MD
Chief Medical Officer
Alameda Alliance for Health

11/04/2025 | 10:29 AM PST
Date

Drug Description	DDID	GPI	QL Recommendation
Abacavir Sulfate Oral Tablet 300 MG	58632	12105005100320	60 tabs/30 days
Abilify Asimtufii Intramuscular Prefilled Syringe 720 MG/2.4ML	222664	5925001500E455	2.4 mL/56 days
Abilify Asimtufii Intramuscular Prefilled Syringe 960 MG/3.2ML	222665	5925001500E465	3.2 mL/56 days
Abilify Maintena Intramuscular Prefilled Syringe 300 MG	199661	5925001500E430	1 syringe/28 days
Abilify Maintena Intramuscular Prefilled Syringe 400 MG	199663	5925001500E440	1 syringe/28 days
Abilify Maintena Intramuscular Suspension Reconstituted ER 300 MG	199660	5925001500G230	1 vial/28 days
Abilify Maintena Intramuscular Suspension Reconstituted ER 400 MG	199662	5925001500G240	1 vial/28 days
Adempas Oral Tablet 0.5 MG	181413	40134050000310	90 tabs/30 days
Adempas Oral Tablet 1 MG	181415	40134050000320	90 tabs/30 days
Adempas Oral Tablet 1.5 MG	181416	40134050000330	90 tabs/30 days
Adempas Oral Tablet 2 MG	181417	40134050000340	90 tabs/30 days
Adempas Oral Tablet 2.5 MG	181418	40134050000350	90 tabs/30 days
Ajovy Subcutaneous Solution Auto-injector 225 MG/1.5ML	210050	6770203020D520	1.5 mL/30 days
Ajovy Subcutaneous Solution Prefilled Syringe 225 MG/1.5ML	204143	6770203020E520	1.5 mL/30 days
Alyftrek Oral Tablet 10-50-125 MG	230199	45309903850325	60 tabs/30 days
Alyftrek Oral Tablet 4-20-50 MG	230198	45309903850310	90 tabs/30 days
Apretude Intramuscular Suspension Extended Release 600 MG/3ML	217440	1210301000G120	Loading dose: 6 mL/56 days Maintenance: 3 mL/56 days
Aptiom Oral Tablet 200 MG	182757	72600024100320	30 tabs/30 days
Aptiom Oral Tablet 400 MG	182758	72600024100330	30 tabs/30 days
Aptiom Oral Tablet 600 MG	182759	72600024100340	60 tabs/30 days
Aptiom Oral Tablet 800 MG	182760	72600024100360	60 tabs/30 days
Aptivus Oral Capsule 250 MG	95356	12104585000120	120 caps/30 days
Breztri Aerosphere Inhalation Aerosol 160-9-4.8 MCG/ACT	211699	44209903303220	10.7g/30 days
Cabenuva Intramuscular Suspension Extended Release 400 & 600 MG/2ML	212378	1210990225G120	4 mL/30 days
Cabenuva Intramuscular Suspension Extended Release 600 & 900 MG/3ML	212379	1210990225G130	6 mL/30 days
Cimduo Oral Tablet 300-300 MG	202269	12109902470330	30 tabs/30 days
Combivent Respimat Inhalation Aerosol Solution 20-100 MCG/ACT	174202	44209902013420	8g/30 days
Darunavir Oral Tablet 600 MG	216659	12104520000325	60 tabs/30 days
Darunavir Oral Tablet 800 MG	216660	12104520000350	30 tabs/30 days
Delstrigo Oral Tablet 100-300-300 MG	204131	12109903270320	30 tabs/30 days
Descovy Oral Tablet 120-15 MG	217906	12109902290310	30 tabs/30 days
Descovy Oral Tablet 200-25 MG	192525	12109902290320	30 tabs/30 days
Dovato Oral Tablet 50-300 MG	206357	12109902260320	30 tabs/30 days
Edurant Oral Tablet 25 MG	166297	12109080100320	30 tabs/30 days
Edurant PED Oral Tablet Soluble 2.5 MG	231786	12109080107320	180 tabs/30 days
Efavirenz-Emtricitab-Tenofo DF Oral Tablet 600-200-300 MG	220739	12109903300320	30 tabs/30 days
Efavirenz-lamiVUDine-Tenofovir Oral Tablet 400-300-300 MG	201621	12109903330330	30 tabs/30 days
Efavirenz-lamiVUDine-Tenofovir Oral Tablet 600-300-300 MG	177359	12109903330340	30 tabs/30 days
Emtricitabine Oral Capsule 200 MG	82691	12106030000120	30 caps/30 days
Emtricitabine-Tenofovir DF Oral Tablet 100-150 MG	192430	12109902300308	30 tabs/30 days
Emtricitabine-Tenofovir DF Oral Tablet 133-200 MG	192431	12109902300312	30 tabs/30 days
Emtricitabine-Tenofovir DF Oral Tablet 167-250 MG	192432	12109902300316	30 tabs/30 days
Emtricitabine-Tenofovir DF Oral Tablet 200-300 MG	88876	12109902300320	30 tabs/30 days
Emtricitab-Rilpivir-Tenofov DF Oral Tablet 200-25-300 MG	168355	12109903400320	30 tabs/30 days
Enbrel Mini Subcutaneous Solution Cartridge 50 MG/ML	199970	6629003000E230	8 mL/28 days
Enbrel Subcutaneous Solution 25 MG/0.5ML	211618	66290030002015	4 mL/28 days
Enbrel Subcutaneous Solution Prefilled Syringe 25 MG/0.5ML	185602	6629003000E525	4 mL/28 days
Enbrel Subcutaneous Solution Prefilled Syringe 50 MG/ML	185603	6629003000E530	8 mL/28 days
Enbrel SureClick Subcutaneous Solution Auto-injector 50 MG/ML	185612	6629003000D530	8 mL/28 days
Entyvio Pen Subcutaneous Solution Auto-injector 108 MG/0.68ML	229093	5250308000D520	1.36mL/28 days
Etravirine Oral Tablet 100 MG	132845	12109035000320	120 tabs/30 days
Etravirine Oral Tablet 200 MG	163383	12109035000340	60 tabs/30 days
Evotaz Oral Tablet 300-150 MG	187265	12109902220330	30 tabs/30 days
fentaNYL Transdermal Patch 72 Hour 100 MCG/HR	65039	65100025008650	10 patches/30 days
fentaNYL Transdermal Patch 72 Hour 12 MCG/HR	94418	65100025008610	10 patches/30 days
fentaNYL Transdermal Patch 72 Hour 25 MCG/HR	65036	65100025008620	10 patches/30 days
fentaNYL Transdermal Patch 72 Hour 50 MCG/HR	65037	65100025008630	10 patches/30 days
fentaNYL Transdermal Patch 72 Hour 75 MCG/HR	65038	65100025008640	10 patches/30 days
Fluticasone Furoate-Vilanterol Inhalation Aerosol Powder Breath Activated 100-25 M	220094	44209902758020	60 EA/30 days
Fluticasone Furoate-Vilanterol Inhalation Aerosol Powder Breath Activated 200-25 M	220097	44209902758030	60 EA/30 days
Fluticasone Propionate Diskus Inhalation Aerosol Powder Breath Activated 100 MCG	225049	44400033208020	60 EA/30 days
Fluticasone Propionate Diskus Inhalation Aerosol Powder Breath Activated 250 MCG	225023	44400033208030	60 EA/30 days
Fluticasone Propionate Diskus Inhalation Aerosol Powder Breath Activated 50 MCG/	225047	44400033208010	60 EA/30 days
Fosamprenavir Calcium Oral Tablet 700 MG	84444	12104525100330	120 tabs/30 days
Fuzeon Subcutaneous Solution Reconstituted 90 MG	172579	12102530002120	60 vials/30 days
Glyxambi Oral Tablet 10-5 MG	187346	27996502300320	30 tabs/30 days
Glyxambi Oral Tablet 25-5 MG	187348	27996502300330	30 tabs/30 days
Intelence Oral Tablet 25 MG	173455	12109035000310	120 tabs/30 days
Invega Sustenna Intramuscular Suspension Prefilled Syringe 117 MG/0.75ML	206121	5907005010E632	0.75 mL/28 days
Invega Sustenna Intramuscular Suspension Prefilled Syringe 156 MG/ML	206114	5907005010E635	1 mL/28 days
Invega Sustenna Intramuscular Suspension Prefilled Syringe 234 MG/1.5ML	206120	5907005010E638	1.5 mL/28 days

Invega Sustenna Intramuscular Suspension Prefilled Syringe 39 MG/0.25ML	206117	5907005010E626	0.25 mL/28 days
Invega Sustenna Intramuscular Suspension Prefilled Syringe 78 MG/0.5ML	206124	5907005010E629	0.5 mL/28 days
Jentadueto Oral Tablet 2.5-1000 MG	171539	27992502400340	60 tabs/30 days
Jentadueto Oral Tablet 2.5-500 MG	171537	27992502400320	60 tabs/30 days
Jentadueto Oral Tablet 2.5-850 MG	171538	27992502400330	60 tabs/30 days
Jentadueto XR Oral Tablet Extended Release 24 Hour 2.5-1000 MG	193329	27992502407520	60 tabs/30 days
Jentadueto XR Oral Tablet Extended Release 24 Hour 5-1000 MG	193330	27992502407530	30 tabs/30 days
Juluca Oral Tablet 50-25 MG	200562	12109902280320	30 tabs/30 days
Kalydeco Oral Packet 13.4 MG	222778	45302030003005	56 EA/28 days
Kalydeco Oral Packet 25 MG	206531	45302030003010	56 EA/28 days
Kalydeco Oral Packet 5.8 MG	224717	45302030003002	56 EA/28 days
Kalydeco Oral Packet 50 MG	187761	45302030003020	56 EA/28 days
Kalydeco Oral Packet 75 MG	187762	45302030003030	56 EA/28 days
Kalydeco Oral Tablet 150 MG	171534	45302030000320	56 tabs/28 days
Kevzara Subcutaneous Solution Auto-injector 150 MG/1.14ML	202882	6650006000D520	2.28 mL/28 days
Kevzara Subcutaneous Solution Auto-injector 200 MG/1.14ML	202883	6650006000D530	2.28 mL/28 days
Kevzara Subcutaneous Solution Prefilled Syringe 150 MG/1.14ML	197599	6650006000E520	2.28 mL/28 days
Kevzara Subcutaneous Solution Prefilled Syringe 200 MG/1.14ML	197084	6650006000E530	2.28 mL/28 days
Lidocaine External Patch 5 %	65482	90850060005930	90 EA/30 days
Linzess Oral Capsule 145 MCG	176224	52557050000120	30 caps/30 days
Linzess Oral Capsule 290 MCG	176225	52557050000140	30 caps/30 days
Linzess Oral Capsule 72 MCG	196626	52557050000110	30 caps/30 days
Liraglutide Subcutaneous Solution Pen-injector 18 MG/3ML	181847	2717005000D220	9 mL/30 days
Lopinavir-Ritonavir Oral Tablet 100-25 MG	131622	12109902550310	240 tabs/30 days
Lopinavir-Ritonavir Oral Tablet 200-50 MG	98666	12109902550320	120 tabs/30 days
Lubiprostone Oral Capsule 24 MCG	100254	52450045000120	60 caps/30 days
Lubiprostone Oral Capsule 8 MCG	134687	52450045000110	60 caps/30 days
Maraviroc Oral Tablet 150 MG	129739	12102060000320	60 tabs/30 days
Maraviroc Oral Tablet 300 MG	129740	12102060000330	120 tabs/30 days
Nevirapine ER Oral Tablet Extended Release 24 Hour 400 MG	165017	12109050007520	30 tabs/30 days
Nevirapine Oral Suspension 50 MG/5ML	57986	12109050001820	1,200 mL/30 days
Nevirapine Oral Tablet 200 MG	44638	12109050000320	60 tabs/30 days
Nexletol Oral Tablet 180 MG	209626	39380020000320	30 tabs/30 days
Nexlizet Oral Tablet 180-10 MG	211032	39991002200320	30 tabs/30 days
Norvir Oral Packet 100 MG	202783	12104560003020	360 EA/30 days
Nuedexta Oral Capsule 20-10 MG	162671	62609902300120	60 caps/30 days
Ofev Oral Capsule 100 MG	186087	45554050200120	60 caps/30 days
Ofev Oral Capsule 150 MG	186088	45554050200130	60 caps/30 days
Opsumit Oral Tablet 10 MG	181539	40160050000320	30 tabs/30 days
Orencia ClickJect Subcutaneous Solution Auto-injector 125 MG/ML	193353	6640001000D520	4 mL/28 days
Orencia Subcutaneous Solution Prefilled Syringe 125 MG/ML	185623	6640001000E520	4 mL/28 days
Orencia Subcutaneous Solution Prefilled Syringe 50 MG/0.4ML	198086	6640001000E510	1.6 mL/28 days
Orencia Subcutaneous Solution Prefilled Syringe 87.5 MG/0.7ML	198087	6640001000E515	2.8 mL/28 days
Orkambi Oral Packet 100-125 MG	203758	45309902303010	60 EA/30 days
Orkambi Oral Packet 150-188 MG	203756	45309902303020	60 EA/30 days
Orkambi Oral Packet 75-94 MG	219858	45309902303005	60 EA/30 days
Orkambi Oral Tablet 100-125 MG	195013	45309902300310	120 tabs/30 days
Orkambi Oral Tablet 200-125 MG	189040	45309902300320	120 tabs/30 days
Otulfi Subcutaneous Solution Prefilled Syringe 45 MG/0.5ML	230741	9025058579E520	Initial: 1 mL/28 days Maintenance: 0.5mL/84 days Initial: 2mL/28 days
Otulfi Subcutaneous Solution Prefilled Syringe 90 MG/ML	230742	9025058579E540	Maintenance: 1 mL/56 days Initial: 1 mL/28 days
Otulfi Subcutaneous Solution 45 MG/0.5ML	233186	90250585792020	Maintenance: 0.5mL/84 days
Pifeltro Oral Tablet 100 MG	204132	12109025000320	30 tabs/30 days
Prezcobix Oral Tablet 800-150 MG	186161	12109902270320	30 tabs/30 days
Prezcobix Oral Tablet 675-150 MG	232827	12109902270315	30 tabs/30 days
Prezista Oral Suspension 100 MG/ML	178261	12104520001820	400 mL/30 days
Prezista Oral Tablet 150 MG	143275	12104520000310	240 tabs/30 days
Prezista Oral Tablet 75 MG	140984	12104520000305	300 tabs/30 days
Relistor Oral Tablet 150 MG	194459	52580050100320	90 tabs/30 days
Relistor Subcutaneous Solution 12 MG/0.6ML	134911	52580050102020	18 mL/30 days
Relistor Subcutaneous Solution 8 MG/0.4ML	171466	52580050102015	12 mL/30 days
risperiDONE Microspheres ER Intramuscular Suspension Reconstituted ER 12.5 MG	206442	5907007010G210	2 EA/28 days
risperiDONE Microspheres ER Intramuscular Suspension Reconstituted ER 25 MG	206444	5907007010G220	2 EA/28 days
risperiDONE Microspheres ER Intramuscular Suspension Reconstituted ER 37.5 MG	206445	5907007010G230	2 EA/28 days
risperiDONE Microspheres ER Intramuscular Suspension Reconstituted ER 50 MG	206446	5907007010G240	2 EA/28 days
Rukobia Oral Tablet Extended Release 12 Hour 600 MG	211459	12102330407420	60 tabs/30 days
Savella Oral Tablet 100 MG	142472	62504050100350	60 tabs/30 days
Savella Oral Tablet 12.5 MG	142473	62504050100320	60 tabs/30 days
Savella Oral Tablet 25 MG	142474	62504050100330	60 tabs/30 days
Savella Oral Tablet 50 MG	142476	62504050100340	60 tabs/30 days
Savella Titration Pack Oral Miscellaneous 12.5 & 25 & 50 MG	142480	62504050106320	55 tabs/28 days

Saxenda Subcutaneous Solution Pen-injector 18 MG/3ML	188019	6125205000D220	15 mL/30 days
Segluromet Oral Tablet 2.5-1000 MG	201572	27996002450320	60 tabs/30 days
Segluromet Oral Tablet 2.5-500 MG	201570	27996002450310	120 tabs/30 days
Segluromet Oral Tablet 7.5-1000 MG	201574	27996002450340	60 tabs/30 days
Segluromet Oral Tablet 7.5-500 MG	201573	27996002450330	60 tabs/30 days
Serevent Diskus Inhalation Aerosol Powder Breath Activated 50 MCG/ACT	220062	44201058108020	60 EA/30 days
Siliq Subcutaneous Solution Prefilled Syringe 210 MG/1.5ML	197428	9025052000E520	Initial: 4.5 mL/14 days Maintenance: 3 mL/28 days
Simponi Subcutaneous Solution Auto-injector 100 MG/ML	185618	6627004000D540	Initial: 2 mL/7 days Maintenance: 1 ML/28 days
Simponi Subcutaneous Solution Auto-injector 50 MG/0.5ML	185619	6627004000D520	0.5 mL/28 days Initial: 2 mL/7 days
Simponi Subcutaneous Solution Prefilled Syringe 100 MG/ML	185617	6627004000E540	Maintenance: 1 ML/28 days
Simponi Subcutaneous Solution Prefilled Syringe 50 MG/0.5ML	185620	6627004000E520	0.5 mL/28 days
Steglujan Oral Tablet 15-100 MG	201175	27996502350330	30 tabs/30 days
Steglujan Oral Tablet 5-100 MG	201173	27996502350320	30 tabs/30 days
Stribild Oral Tablet 150-150-200-300 MG	175277	12109904300320	30 tabs/30 days
SUMAtriptan Succinate Subcutaneous Solution 6 MG/0.5ML	141848	67406070102010	6 mL/30 days
SUMAtriptan Succinate Subcutaneous Solution Auto-injector 4 MG/0.5ML	182041	6740607010D510	6 mL/30 days
Sunlenca Oral Tablet 300 MG	220929	12101555200350	10 tabs/365 days
Sunlenca Oral Tablet Therapy Pack 4 x 300 MG	221413	1210155520B720	8 tabs/365 days
Sunlenca Oral Tablet Therapy Pack 5 x 300 MG	221414	1210155520B725	10 tabs/365 days
Sunlenca Subcutaneous Solution 463.5 MG/1.5ML	220930	12101555202030	6 mL/365 days
Symdeko Oral Tablet Therapy Pack 100-150 & 150 MG	201699	4530990280B720	56 tabs/28 days
Symdeko Oral Tablet Therapy Pack 50-75 & 75 MG	207127	4530990280B710	56 tabs/28 days
Symproic Oral Tablet 0.2 MG	199755	52580057200320	30 tabs/30 days
Tivicay Oral Tablet 50 MG	180568	12103015100320	60 tabs/30 days
Tivicay PD Oral Tablet Soluble 5 MG	211296	12103015107320	180 tabs/30 days
Tradjenta Oral Tablet 5 MG	165800	27550050000320	30 tabs/30 days
Trijardy XR Oral Tablet Extended Release 24 Hour 10-5-1000 MG	209743	27996703407520	30 tabs/30 days
Trijardy XR Oral Tablet Extended Release 24 Hour 12.5-2.5-1000 MG	209742	27996703407530	60 tabs/30 days
Trijardy XR Oral Tablet Extended Release 24 Hour 25-5-1000 MG	209744	27996703407540	30 tabs/30 days
Trijardy XR Oral Tablet Extended Release 24 Hour 5-2.5-1000 MG	209741	27996703407510	60 tabs/30 days
Trikafta Oral Tablet Therapy Pack 100-50-75 & 150 MG	208417	4530990340B740	84 tabs/28 days
Trikafta Oral Tablet Therapy Pack 50-25-37.5 & 75 MG	215185	4530990340B720	84 tabs/28 days
Trikafta Oral Therapy Pack 100-50-75 & 75 MG	222630	4530990340B140	56 tabs/28 days
Trikafta Oral Therapy Pack 80-40-60 & 59.5 MG	222629	4530990340B120	56 tabs/28 days
Trintellix Oral Tablet 10 MG	186525	58120093100320	30 tabs/30 days
Trintellix Oral Tablet 20 MG	186526	58120093100340	30 tabs/30 days
Trintellix Oral Tablet 5 MG	186524	58120093100310	30 tabs/30 days
Triumeq Oral Tablet 600-50-300 MG	185186	12109903150320	30 tabs/30 days
Triumeq PD Oral Tablet Soluble 60-5-30 MG	218391	12109903157320	180 tabs/30 days
Trulance Oral Tablet 3 MG	196768	52543060000320	30 tabs/30 days
Tyenne Subcutaneous Solution Auto-injector 162 MG/0.9ML	227798	6650007017D520	3.6 mL/28 days
Tyenne Subcutaneous Solution Prefilled Syringe 162 MG/0.9ML	227882	6650007017E520	3.6 mL/28 days
Ubrelvy Oral Tablet 100 MG	209141	67701080000340	16 tabs/30 days
Ubrelvy Oral Tablet 50 MG	209140	67701080000320	16 tabs/30 days
Uptravi Oral Tablet 1000 MCG	191436	40120070000330	60 tabs/30 days
Uptravi Oral Tablet 1200 MCG	191441	40120070000335	60 tabs/30 days
Uptravi Oral Tablet 1400 MCG	191437	40120070000340	60 tabs/30 days
Uptravi Oral Tablet 1600 MCG	191438	40120070000345	60 tabs/30 days
Uptravi Oral Tablet 200 MCG	191431	40120070000310	60 tabs/30 days
Uptravi Oral Tablet 400 MCG	191432	40120070000315	60 tabs/30 days
Uptravi Oral Tablet 600 MCG	191434	40120070000320	60 tabs/30 days
Uptravi Oral Tablet 800 MCG	191435	40120070000325	60 tabs/30 days
Uptravi Titration Oral Tablet Therapy Pack 200 & 800 MCG	191440	4012007000B720	200 tabs/365 days
Verquvo Oral Tablet 10 MG	213502	40900085000340	30 tabs/30 days
Verquvo Oral Tablet 2.5 MG	213500	40900085000321	30 tabs/30 days
Verquvo Oral Tablet 5 MG	213501	40900085000330	30 tabs/30 days
Viracept Oral Tablet 250 MG	49657	12104545200320	270 tabs/30 days
Viracept Oral Tablet 625 MG	86969	12104545200340	120 tabs/30 days
Vumerity Oral Capsule Delayed Release 231 MG	208474	62405530006540	120 caps/30 days
Xeljanz Oral Solution 1 MG/ML	213730	66603065102020	600 mL/30 days
Xeljanz Oral Tablet 10 MG	203197	66603065100330	60 tabs/30 days
Xeljanz Oral Tablet 5 MG	176358	66603065100320	60 tabs/30 days
Xeljanz XR Oral Tablet Extended Release 24 Hour 11 MG	192103	66603065107530	30 tabs/30 days
Xeljanz XR Oral Tablet Extended Release 24 Hour 22 MG	209103	66603065107550	30 tabs/30 days
Xigduo XR Oral Tablet Extended Release 24 Hour 10-1000 MG	186281	27996002307525	30 tabs/30 days
Xigduo XR Oral Tablet Extended Release 24 Hour 10-500 MG	186280	27996002307520	30 tabs/30 days
Xigduo XR Oral Tablet Extended Release 24 Hour 2.5-1000 MG	201261	27996002307507	60 tabs/30 days
Xigduo XR Oral Tablet Extended Release 24 Hour 5-1000 MG	186279	27996002307515	60 tabs/30 days
Xigduo XR Oral Tablet Extended Release 24 Hour 5-500 MG	186277	27996002307510	30 tabs/30 days
Yesintek Subcutaneous Solution 45 MG/0.5ML	230450	90250585782020	0.5 mL/28 days

Yesintek Subcutaneous Solution Prefilled Syringe 45 MG/0.5ML	230449	9025058578E520	0.5 mL/28 days
Yesintek Subcutaneous Solution Prefilled Syringe 90 MG/ML	230451	9025058578E540	1 mL/28 days
Zavzpret Nasal Solution 10 MG/ACT	223008	67701090202020	8 EA/30 days
Olumiant Oral Tablet 1 MG	208457	66603010000310	30 tabs/30 days
Olumiant Oral Tablet 2 MG	203031	66603010000320	30 tabs/30 days
Olumiant Oral Tablet 4 MG	219083	66603010000340	30 tabs/30 days
Nurtec Oral Tablet Disintegrating 75 MG	209654	67701060707220	18 tabs/30 days
ZTlido Patch 1.8 % External	204136	90850060005910	90 EA/30 days
Camzyos Oral Capsule 2.5 MG	218612	40190050000110	30 tabs/30 days
Camzyos Oral Capsule 5 MG	218613	40190050000120	30 tabs/30 days
Camzyos Oral Capsule 10 MG	218614	40190050000130	30 tabs/30 days
Camzyos Oral Capsule 15 MG	218615	40190050000140	30 tabs/30 days

New

Anzupgo	
Therapeutic Classes (AHFS)	Janus Kinase Inhibitors
Medications	Anzupgo (delgocitinib)
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	Current use of Opzelura (ruxolitinib), systemic JAK inhibitors, or potent immunosuppressants
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 initial request will be approved for 6 months, 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 moderate to severe chronic hand eczema (CHE) • Documentation of hand eczema persisting for >3 months or recurring ≥2 times within 12-month time frame • Trial and failure, intolerance or contraindication to ≥2 formulary moderate/high-potency topical corticosteroids **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. significant clearing of the skin, reduction in itching) • Medication is prescribed at an FDA approved dose
Criteria Statement	Anzupgo is reserved for members with a diagnosis of moderate to severe chronic hand eczema (CHE), who tried and failed or were unable to use at least 2 formulary moderate/high potency topical corticosteroids.
Last P&T Review Date	12/2025

New

Brinsupri	
Therapeutic Classes (AHFS)	Neutrophil Serine Protease (NSP) Inhibitors
Medications	Brinsupri (brensocatib)
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 a pulmonologist
Coverage Duration	If all the criteria are met, the initial 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 bronchiectasis confirmed by chest CT scan • Documentation patient does not have Cystic Fibrosis • At least 2 exacerbations in the past 12 months requiring an antibiotic prescription, urgent care or emergency room visit, or hospitalization • Medication is prescribed at an FDA approved dose **Re-Authorization:** • Documentation or provider attestation of positive clinical response (i.e. decrease in cough, sputum production, exacerbations, etc.) • Medication is prescribed at an FDA approved dose
Criteria Statement	Brinsupri is reserved for members with a confirmed diagnosis of bronchiectasis, who do not have cystic fibrosis and had at least 2 exacerbations in the past 12 months.
Last P&T Review Date	12/2025

New

Phenylalanine Hydroxylase Activators	
Therapeutic Classes (AHFS)	Enzyme Cofactors/Chaperones
Medications	Sapropterin dihydrochloride (Kuvan), Sephience (sepiapterin)
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	Prescribed by a specialist experienced in treating PKU
Coverage Duration	**Initial:** If all the criteria are met, the request will be approved for a duration of 1 month **Reauthorization:** If the criteria are met, sapropterin requests will be approved for a duration of 1 month for patients who require a dose increase to 20 mg/kg/day due to non-responsiveness. Sephience requests will be approved for a duration of 1 month for patients who require a dose increase from their previous dose (up to the max dose of 60 mg/kg/day) due to non-responsiveness. For all other patients the request will be approved for a duration of 3 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 a confirmed diagnosis of Phenylketonuria (PKU) • Documentation of the patient's baseline blood Phe level (within 30 days of the request) • Documentation consistent with order forms, receipts, or chart notes (within 30 days of request) that the patient is currently utilizing a Phe-restricted diet • Requests for Sephience also require a documented trial and failure, intolerance, or contraindication to sapropterin in combination with Phe-restricted diet • Documentation of the patient's current weight. • The medication is being prescribed at an FDA approved dosage **Re-Authorization:** • Documentation of the patient's current weight. • Documentation of at least two separate blood Phe level results after initiation of therapy (within 30 days of request). • The medication is being prescribed at an FDA approved dosage. *For **sapropterin**: Patients that were dosed at 20mg/kg/day and did not have a decrease in Phe from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized.* *For **Sephience**: Patients that were dosed at 60 mg/kg/day and did not have a decrease in Phe from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized.*
Criteria Statement	Sapropterin dihydrochloride and Sephience are reserved for members with a confirmed diagnosis of PKU and who are utilizing a Phe-restricted diet. Sephience is reserved for members who tried and failed or were unable to use sapropterin.
Last P&T Review Date	12/2025

New

Nitisinone Products	
Therapeutic Classes (AHFS)	Enzyme Inhibitors
Medications	Nitisinone (Orfadin) capsules Orfadin (nitisinone) suspension Nityr (nitisinone) tablets Harliku (nitisinone) tablets
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 specialist in the diagnosis submitted
Coverage Duration	If all criteria are met, initial requests will be approved for 6 months and reauthorization requests 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 for alkaptonuria (AKU) (Harliku and generic nitisinone only):**
	• Diagnosis of AKU confirmed by one of the following
	  ○ Urinary homogentisic acid (HGA) excretion of >0.4 g/24 hours
	  ○ Genetic testing reveals variations in the homogentisate 1,2 dioxygenase (HGD) gene
	• Documented clinical manifestation of AKU (e.g. urine that darkens when exposed to air, ochronosis, chronic joint pain)
	• For Harliku, documented trial and failure, or intolerance to treatment with generic nitisinone prescribed at a dose for the treatment of AKU
	• Drug is prescribed at an FDA approved dose
	
	Initial Authorization for Hereditary Tyrosinemia Type 1 (all nitisinone products EXCEPT Harliku):
	• Diagnosis of Hereditary Tyrosinemia Type 1 confirmed by one of the following:
	  ○ DNA testing
	  ○ Detection of succinylacetone (SA) in urine or blood test
	• Documentation provided attesting to diet restricting tyrosine and phenylalanine
	• If request is for Nityr tablet or Orfadin suspension, documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to use generic nitisinone (Orfadin) capsule
	• Drug is prescribed at an FDA approved dose
	
	Re-Authorization:
	• Attestation that member is achieving a clinical benefit from treatment
	  ○ For Harliku, clinical benefit evidenced by decrease in urinary homogentisic acid [HGA] levels, decrease in visible ochronosis, and/or improvement/stabilization in joint-related symptoms
	• Medication is prescribed at an FDA approved dose

Criteria Statement	Nitisinone capsules are reserved for members with a confirmed diagnosis of AKU who have clinical manifestations of AKU. Harliku is reserved for members with a confirmed diagnosis of AKU who have clinical manifestations of AKU and tried and failed or were unable to use generic nitisinone. All nitisinone products, except Harliku, are reserved for members with a diagnosis of hereditary tyrosinemia type 1 and who are on a diet restricting tyrosine and

	phenylalanine. Nityr tablet and Orfadin suspension are reserved for members who tried and failed or were unable to use generic nitisinone capsules.
Last P&T Review Date	12/2025

New

Skysona	
Medications	Skysona (elivaldogene autotemcel)
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	• Cerebral adrenoleukodystrophy secondary to head trauma • Positive for human immunodeficiency virus type 1 or 2 • Female patients
Required Clinical Information	See “Other Criteria” below
Age Restrictions	Check AAH active CCS cases for members < 21 years of age Member must be 4-17 years of age
Prescriber Restrictions	Prescriber must be a specialist in the disease being treated
Coverage Duration	If all criteria are met, the request will be approved for a one-time treatment
Maximum Billable Units	Variable

Other Criteria	**Initial Authorization**
	• Member has a diagnosis of early, active cerebral adrenoleukodystrophy (CALD) defined as all of the following:
	  ○ elevated very long chain fatty acid (VLCFA) levels
	  ○ confirmed mutations in the ABCD1 gene
	  ○ asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1)
	  ○ Gadolinium enhancement on brain magnetic resonance imaging (MRI) of demyelinating lesions and Loes scores of 0.5-9
	• Medication is prescribed at an FDA approved dose
	• Member has not had a prior allogeneic hematopoietic stem-cell transplant (HSCT)
	• Member has no HLA-matched sibling donor for HSCT, or a reason why HSCT with matched sibling donor is not appropriate.
	
	*****Reauthorizations are not permitted, as members are limited to a one-time 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	12/2025

Spravato (esketamine) Intranasal	
Medications	Spravato (esketamine) intranasal
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** 4 weeks **Later Approvals** 6 months
Maximum Billable Units	Variable

Other Criteria	**Initial Authorization:**
	• The member has a diagnosis of at least one of the following:
	  ○ Major depressive disorder with treatment-resistant depression
	  ○ Major depressive disorder with acute suicidal ideation or behavior
	• Medication is being prescribed at an FDA approved dosage.
	• Requests for a diagnosis of major depressive disorder with acute suicidal ideation or behavior (not required for treatment resistant depression):
	  ○ Prescriber attests Spravato will be used in conjunction with an oral antidepressant
	
	Additionally, if member has diagnosis for major depressive disorder with treatment-resistant depression only (i.e. without suicidal ideation or behavior):
	• Documented trial and failure of three preferred oral antidepressants (eg. SSRIs, SNRIs, TCAs) of at least a minimum effective dose for four (4) weeks or longer OR a medical justification as to why the patient cannot use preferred alternative(s).
	
	Re-authorization:
	• Medication is prescribed at an FDA-approved dosage.
	• Medication is being used in conjunction with an oral antidepressant (not required for diagnosis of treatment resistant depression).
	• Documentation was submitted indicating the member has clinically benefited from therapy.
	
	If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review

Last Review Date	12/2025

Hereditary Angioedema

Executive Summary

Class Overview

Hereditary angioedema (HAE) can be classified as a disease resulting from deficiency (type I) or dysfunction (type II) of the inhibitor of C1INH (HAE-C1INH) or with normal C1INH (HAE-nl-C1INH), of known cause (i.e. mutations in gene for factor XII, angiopoietin-1, plasminogen, kininogen-1) or of unknown cause (U-HAE). Acquired C1INH deficiency (C1INH-AAE) is a similar but non-hereditary disorder. HAE is primarily inherited, although approximately 25% of cases result from de novo mutations. The prevalence of HAE-C1INH is 1 in 50,000 persons (~6000 persons in the United States) affecting both genders equally; it is commonly diagnosed in childhood. The prevalence of HAE-nl-C1INH is unknown but rare, affecting females more than males; it is commonly diagnosed in young adulthood. C1INH-AAE is typically acquired, diagnosed in adulthood, and associated with underlying disease, particularly malignancy and autoimmune disorders.

Classification of HAE

HAE-C1INH	HAE-nl-C1INH	
• Type I – deficiency • Type II – dysfunction	Known causes – mutations in gene for… • Factor XII • angiopoietin-1 • plasminogen • kininogen-1	Unknown

The understanding of the pathophysiology of HAE as well as the treatment landscape have evolved rapidly over recent years. Symptoms of HAE-C1INH, HAE-nl-C1INH, and C1INH-AAE are similar and characterized by bradykinin-mediated, recurring angioedema of the skin and mucosa of the upper respiratory and gastrointestinal tracts; notably the episodes are non-pruritic and non-urticarial. Acute attacks typically last two to five days. Before the availability of effective therapy, mortality related to HAE attacks occurred at a rate of approximately 30% in C1INH-HAE, attributable to asphyxiation from laryngeal swelling. Laryngeal attacks occur in more than half of HAE patients at some point in time. The treatment of the various subtypes of HAE is similar although in the setting of HAE-nl-C1INH, replacement with C1INH is generally not employed, except in very limited circumstances. Additionally, the long-term prophylaxis of C1INH-AAE is not well defined.

Agents are available to both treat and prevent HAE attacks. Prophylaxis may be used for the long-term or short-term in anticipation of procedures (pre-procedural prophylaxis) or stressful life events. Ruconest and Berinert are both C1 esterase inhibitors indicated for treatment of acute attacks, although Ruconest is not indicated in the setting of laryngeal attacks which limits its utility. Cinryze and Haegarda are C1 esterase inhibitors indicated for routine prevention. Although not explicitly specified within the prescribing information, C1INH products were not studied for use in HAE-nl-C1INH. Icatibant (Firazyr), a bradykinin B2 receptor antagonist, and Kalbitor (ecallantide), kallikrein inhibitor, are indicated for acute treatment and can theoretically be used in all subtypes of HAE. Ekterly (sebetralstat), a kallikrein inhibitor approved in 2025, is the first approved oral on-demand treatment for acute attacks of HAE. Takhzyro (lanadelumab), a kallikrein inhibitor, is indicated for prophylaxis. Orladeyo (berotralstat) is a kallikrein inhibitor and the first oral agent to be approved for HAE prophylaxis, though it is not the only self-administered therapy marketed for HAE. Andembry (garadacimab-gxii),

an activated Factor XII inhibitor (monoclonal antibody) approved in 2025, is indicated for HAE prophylaxis. The most recently approved HAE agent, with approval in August 2025, is Dawnzera (donidalorsen). Dawnzera targets the kinin-kallikrein system and is indicated for prophylactic treatment of HAE. Danazol carries a labeled indication and tranexamic acid has an off-label indication for the prophylaxis of HAE and can be used in HAE-nl-C1INH. No agents carry a labeled indication for short-term prophylaxis, however, there is some evidence that C1INH is likely more effective than androgen therapy. Agents other than C1INH and androgens are not used for short-term prophylaxis.

Management of HAE always includes access to at least two doses of as needed medication for treatment of acute attacks, short-term prophylaxis for procedures and stressful life events, and may include long-term prophylaxis. The decision to initiate long-term prophylaxis must take into consideration a variety of factors including frequency and severity of attacks, access to medical care, and patient preferences.

Various organizations have published guidelines on the treatment of HAE. Most recently, the US Hereditary Angioedema Association (HAEA) published HAE management guidelines in 2020. This review also includes two older guidelines. Internationally, the World Allergy Organization (WAO) and the European Academy of Allergy and Clinical Immunology (EAACI) collaborated to produce updated guidelines published in 2021.

Utilization Findings

There were no claims and no prior authorization requests.

Recommendations

- No formulary changes, update PA criteria with newly approved agents Ekterly, Andembry, and Dawnzera

Clinical Summary

The understanding of the pathophysiology of HAE as well as the treatment landscape have evolved rapidly over recent years. Symptoms of HAE-C1INH, HAE-nl-C1INH, and C1INH-AAE are similar and characterized by bradykinin-mediated, recurring angioedema of the skin and mucosa of the upper respiratory and gastrointestinal tracts; notably the episodes are non-pruritic and non-urticarial. The treatment is similar although in the setting of HAE-nl-C1INH, replacement with C1INH is generally not employed, except in very limited circumstances. Additionally, the long-term prophylaxis of C1INH-AAE is not well defined.

Symptoms of HAE vary widely from patient to patient and even within individual patients across time. HAE can heavily burden a patient's quality of life causing anxiety and depression and impairing work, social, and educational activities. The often-unpredictable nature of attacks and occurrence in response to emotional stressors make management even more difficult. Consideration must also be given to patient access to emergency treatments as some medications require administration by a healthcare provider. Patient proximity to hospital or other adequate emergency care settings must be factored in. As a result, therapy and management plans must be highly customized.

In 2018, ICER released a report on the comparative clinical effectiveness and value of prophylactic therapies for HAE covering Takhzyro (lanadelumab), and C1 esterase inhibitors Haegarda (C1 esterase inhibitor, human) and Cinryze (C1 esterase inhibitor, human). In 2021, ICER used observational real-world evidence (RWE) to update the value assessment of HAE treatments published in the 2018 assessment. The report found that long-term prophylaxis, when compared to on-demand treatment alone, resulted in lower number of acute attacks, higher costs, and higher QALYs, but with fewer QALYs gained compared to prior analyses. RWE for population parameters and pre-treatment attack severity increased the incremental cost per QALY, while healthcare utilization by attack severity, costs of attacks, and the market share distribution of on-demand drugs reduced the incremental cost. With the addition of observational RWE, the conclusions from the 2018 review were confirmed that at current drug pricing, none of the prophylactic agents meet the traditionally accepted cost-effectiveness thresholds ($50,000 to $150,000 per quality adjusted life year), with incremental cost-effectiveness ratios of Cinryze, Haegarda, and Takhzyro all above $10 million per QALY gained.

There are no agents anticipated to be approved for HAE within the coming 6 months.

Indications, Dosing and Administration

Medication	Indications	Dosing/Administration
Ruconest® (C1 esterase inhibitor, recombinant)	Treatment of acute attacks of HAE in adult and adolescent patients (effectiveness NOT established in HAE with laryngeal attacks)	Treatment: – <84 kg: 50 U/kg IV (maximum dose: 4,200 units) as a single dose – ≥84 kg: 4,200 U IV as a single dose – Note: If symptoms persist, one additional dose may be administered; no more than 2 doses per 24 hours. Prophylaxis (off-label): – <84 kg: 50 U/kg IV (maximum dose: 4,200 units) twice weekly – ≥84 kg: 4,200 U IV twice weekly Note: May reduce frequency of administration to once weekly, ensuring maintenance of symptom control; once-weekly dosing was shown to be more effective than placebo but with the potential for more frequent attacks compared with twice-weekly dosing.
Berinert® (C1 esterase inhibitor, human)	Treatment of acute abdominal, facial, or laryngeal attacks of HAE in adults and pediatric patients	≥5 years: 20 U/kg IV
Cinryze® (C1 esterase inhibitor, human)	Routine prophylaxis against HAE attacks in adults, adolescents, and pediatric patients ≥6 years of age	6 – 11 years: 500 U IV every 3 to 4 days; adjust dose based on individual patient response, up to 1,000 U every 3 to 4 days ≥12 years: 1,000 U IV every 3 to 4 days; if response is not adequate, doses up to 2,500 U (≤100 U/kg) every 3 or 4 days may be considered
Haegarda® (C1 esterase inhibitor, human)	Routine prophylaxis against angioedema attacks in adults and adolescents with HAE	Adolescents and adults: 60 U/kg subcutaneously (SQ) every 3 or 4 days
Icatibant (Firazyr®)	Treatment of acute attacks of HAE	Adults: 30 mg SQ; may repeat every 6 hours if response is inadequate or symptoms recur (maximum dose: 90 mg/day) 2 to <18 years of age (*off-label*): 0.4 mg/kg SQ once; maximum 30 mg/dose
Kalbitor® (ecallantide)	Treatment of acute attacks of HAE	8 to < 12 years (off label); ≥12 years (labeled): 30 mg SQ (as three 10 mg [1 mL]

Medication	Indications	Dosing/Administration
		injections); if attack persists, may repeat an additional 30 mg within 24 hours
Takhzyro™ (lanadelumab)	Prophylaxis to prevent attacks of HAE	300 mg SQ every 2 weeks; dosing every 4 weeks may be considered in some patients
Orladeyo™ (berotralstat)	Prophylaxis to prevent attacks of HAE in adults and pediatric patients ≥12 years	150 mg by mouth (PO) once daily (QD)
Danazol	Labeled: Prevention of attacks of HAE of all types (cutaneous, abdominal, laryngeal) in males and females Off-label: may be considered for short-term/preprocedural and long-term HAE prophylaxis as an alternative to C1 inhibitor (human)	Long-term prophylaxis – Initial: 100 mg every other day up to 200 mg 2 or 3 times daily – Adjustment: after a favorable initial response, decrease the dosage by ≤50% at intervals of ≥ 1 to 3 months if frequency of attacks dictates. If an attack occurs, increase dosage by up to 200 mg/day; dosages >200 mg/day for an extended period of time are not recommended due to side effects Short-term/preprocedural prophylaxis 2.5 to 10 mg/kg/day initially; adjust dose according to patient response (maximum: 600 mg/day); administer 5 days before and 2 to 3 days after procedure
Tranexamic acid (Lysteda®)	Off-label: HAE, long-term prophylaxis	HAE, long-term prophylaxis: 1,000 to 1,500 mg 2 to 3 times daily; reduce to 500 mg/dose once or twice daily when frequency of attacks reduces or 25 mg/kg/dose administered 2 to 3 times daily
Andembry® (garadacimab-gxii)	Prophylaxis to prevent attacks of HAE in adult and pediatric patients ≥12 years	400 mg SQ (two injections of 200 mg) as single loading dose on the first day of treatment, followed by 200 mg SQ monthly
Ekterly® (sebetralstat)	Treatment of acute attacks of HAE in adult and pediatric patients ≥12 years	600 mg (2 tablets) PO at the earliest recognition of acute attack; may repeat 600 mg dose ≥ 3 hours after the first dose if response is inadequate, or if symptoms worsen or recur (maximum dose: 1,200 mg (4 tablets) per 24 hours)
Dawnzera® (donidalorsen)	Prophylaxis to prevent attacks of HAE in adult and pediatric patients ≥12 years	80 mg SQ every 4 weeks; dosing every 8 weeks may be considered in some patients

Boxed Warnings and Contraindications

Medication	Boxed Warnings	Contraindications
Ruconest® (C1 esterase inhibitor, recombinant)	None	Life-threatening immediate hypersensitivity reactions, including anaphylaxis, to C1 esterase inhibitor preparations or any component of the formulation; allergy to rabbits or rabbit-derived products
Berinert®, Cinryze®, Haegarda® (C1 esterase inhibitor, human)	None	History of anaphylactic or life-threatening hypersensitivity reactions to C1 inhibitor (human) or any component of the formulation
Icatibant (Firazyr®)	None	None
Kalbitor® (ecallantide)	Serious hypersensitivity reactions, including anaphylaxis have been reported; administer only by healthcare provider in presence of appropriate medical support to manage anaphylaxis and HAE	Hypersensitivity to ecallantide or any component of the formulation
Takhzyro™ (lanadelumab)	None	None
Orladeyo™ (berotralstat)	None	None
Danazol	Thromboembolic events, life-threatening and fatal, have been reported Hepatic effects: Experience with long-term therapy with danazol is limited; peliosis hepatis and benign hepatic adenoma have been observed Intracranial hypertension: Has been associated with use	Hypersensitivity to danazol or any component of the formulation; undiagnosed abnormal genital bleeding; pregnancy; breastfeeding; porphyria; markedly impaired hepatic, renal, or cardiac function; androgen-dependent tumor; active or history of thrombosis or thromboembolic disease
Tranexamic acid (Lysteda®)	None	Hypersensitivity to tranexamic acid or any component of the formulation; active thromboembolic disease (e.g., cerebral thrombosis, deep vein thrombosis, pulmonary embolism); history of thrombosis or thromboembolism, including retinal vein or artery occlusion; intrinsic risk of thrombosis or thromboembolism (e.g., hypercoagulopathy, thrombogenic cardiac rhythm disease, thrombogenic valvular disease); concurrent use of combination hormonal contraception

Medication	Boxed Warnings	Contraindications
Andembry® (garadacimab-gxii)	None	None
Ekterly® (sebetralstat)	None	None
Dawnzera® (donidalorsen)	None	History of serious hypersensitivity reactions, including anaphylaxis, to donidalorsen or any of the excipients in Dawnzera

Warnings/Precautions

Medication	Warnings/Precautions
Ruconest® (C1 esterase inhibitor, recombinant)	Concerns related to adverse effects: Thrombotic events: Serious arterial and venous thromboembolic events have been reported at recommended doses in patients with risk factors
Berinert®, Cinryze®, Haegarda® (C1 esterase inhibitor, human)	Concerns related to adverse effects: – Thrombotic events: Serious arterial and venous thromboembolic events have been reported at recommended IV doses and when used off-label at doses higher than recommended Dosage form specific issues: – Human plasma: May potentially contain infectious agents Other warnings/precautions: Self-administration: Patients suffering from an acute laryngeal HAE attack and self-administering should immediately seek medical attention following treatment
Icatibant (Firazyr®)	Concerns related to adverse effects: – Airway obstruction: May occur during acute laryngeal attacks of HAE – CNS effects: May cause CNS depression, which may impair physical or mental abilities Special populations: Geriatric considerations: Clearance is reduced resulting in an increased AUC, despite which, no difference in safety and efficacy has been noted
Kalbitor® (ecallantide)	Concerns related to adverse effects: Immunogenicity: Some patients may develop antibodies to ecallantide during therapy; seroconversion may increase the risk of hypersensitivity reaction.
Takhzyro™ (lanadelumab)	Concerns related to adverse effects: – Hypersensitivity reactions: Have occurred. In case of a severe hypersensitivity reaction, discontinue therapy and institute appropriate treatment. Dosage form specific issues: Some dosage forms may contain polysorbate 80 (e.g., Tweens). Hypersensitivity reactions, usually a delayed reaction, have been reported. Thrombocytopenia, ascites, pulmonary deterioration, and renal and hepatic failure have been reported in premature neonates after receiving parenteral products containing polysorbate 80
Orladeyo™ (berotralstat)	Concerns related to adverse effects: QT prolongation: Doses >150 mg have been associated with QT prolongation; avoid additional doses, doses >150 mg, or use for acute attacks.
Danazol	Concerns related to adverse effects: – Androgenic effects: May be irreversible – Blood lipid changes: Anabolic steroids may cause blood lipid changes (decreased HDL and increased LDL) with increased risk of arteriosclerosis and coronary artery disease (CAD) Disease-related concerns:

Medication	Warnings/Precautions
	– Cyclic breast pain (mastalgia) associated with benign breast disorders: Reserve use for severe, refractory cases that have not responded to conservative measures/analgesics – Diabetes: Use with caution; insulin requirements may be increased – Edematous conditions: Use with caution; may cause fluid retention Concurrent drug therapy issues: – Potentially significant drug-drug interactions may exist, requiring dose or frequency adjustment, additional monitoring, and/or selection of alternative therapy Other warnings/precautions: Appropriate use: Reserve for the treatment of pain associated with endometriosis when other agents are not available, due to high incidence of adverse events
Tranexamic acid (Lysteda®)	Concerns related to adverse effects: – CNS depression: May cause CNS depression, which may impair physical or mental abilities – Hypersensitivity reactions: Severe hypersensitivity reactions have been reported – Ocular effects: Visual defects and retinal venous and arterial occlusions have been reported. Use of the injection is contraindicated in patients with acquired defective color vision; ligneous conjunctivitis has been reported with the oral formulation, but resolved upon discontinuation of therapy – Seizure: Has been reported with (most often intraoperative) use and in older patients – Thrombotic events: Venous and arterial thrombosis or thromboembolism, including central retinal artery/vein obstruction, has been reported – Ureteral obstruction: Use the injection with caution in patients with upper urinary tract bleeding; ureteral obstruction due to clot formation has been reported Disease-related concerns: – Disseminated intravascular coagulation (DIC): Use with extreme caution in patients with DIC requiring antifibrinolytic therapy – Renal impairment: Use with caution and dose adjust – Subarachnoid hemorrhage (SAH): Use with caution; cerebral edema and infarction may occur. Per manufacturer's labeling, the injection is contraindicated in patients with SAH; however, use has been described in the literature for aneurysmal SAH and is considered a reasonable treatment option in select patients – Vascular disease: Use with caution in patients with uncorrected cardiovascular or cerebrovascular disease due to the complications of thrombosis Concurrent drug therapy issues: Potentially significant drug-drug interactions may exist, requiring dose or frequency adjustment, additional monitoring, and/or selection of alternative therapy
Andembry® (garadacimab-gxii)	Concerns related to adverse effects: -Nasopharyngitis -Abdominal pain

Medication	Warnings/Precautions
Ekterly® (sebetralstat)	Concerns related to adverse effects: -Nervous System: Headache Concurrent drug therapy issues: -Avoid use of Ekterly with strong CYP3A4 inhibitors. -Reduce dose of Ekterly to one dose of 300 mg (one tablet) orally at the earliest recognition of an HAE attack when used concomitantly with moderate CYP3A4 inhibitors. A second dose of 300 mg (one tablet) may be taken at least 3 hours after the first dose if response is inadequate, or if symptoms worsen or recur. -Use of Ekterly with strong or moderate CYP3A4 inducers is not recommended.
Dawnzera® (donidalorsen)	Concerns related to adverse effects: -Hypersensitivity reactions, including anaphylaxis

Practice Guidelines

Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2021 revision and update. *Allergy*. 2022;77(7):1961-1990. doi:10.1111/all.15214

Recommendation	Percent agreement	Evidence level
We recommend that all attacks are considered for on-demand treatment.	98%	D
We recommend that any attack affecting or potentially affecting the upper airway is treated.	100%	C
We recommend that attacks are treated with either intravenous C1 inhibitor, ecallantide or icatibant.	96%	A
We recommend that intubation or surgical airway intervention is considered early in progressive upper airway edema.	100%	D
We recommend that all patients have sufficient medication for on-demand treatment of at least two attacks and carry on-demand medication at all times.	100%	D
We recommend considering short-term prophylaxis before medical, surgical or dental procedures as well as exposure to other angioedema attack-inducing events.	94%	C
We recommend the use of intravenous plasma-derived C1 inhibitor as first-line short-term prophylaxis.	91%	C
We suggest considering prophylaxis prior to exposure to patient-specific angioedema-inducing situations.	90%	D
We recommend that the goals of treatment are to achieve total control of the disease and to normalize patients' lives.	100%	D
We recommend that patients are evaluated for long-term prophylaxis at every visit, taking disease activity, burden, and control as well as patient preference into consideration.	96%	D

We recommend the use of plasma-derived C1 inhibitor as first-line long-term prophylaxis.	87%	A
We recommend the use of lanadelumab as first-line long-term prophylaxis.	89%	A
We recommend the use of berotralstat as first-line long-term prophylaxis.	81%	A
We recommend the use of androgens only as second-line long-term prophylaxis.	89%	C
We suggest all patients who are using long-term prophylaxis be routinely monitored for disease activity, impact, and control to inform optimization of treatment dosages and outcomes.	98%	A
We recommend testing children from HAE-affected families be carried out as soon as possible and all offspring of an affected parent be tested.	98%	D
We recommend C1 inhibitor or icatibant be used for the treatment of attacks in children under the age of 12.	94%	A
We recommend plasma-derived C1 inhibitor as the preferred therapy during pregnancy and lactation.	100%	D

Recommendation Definitions

Strength of Recommendation	Definition
Strong	We recommend
Weak	We suggest

Evidence Grade	Definition
A	Randomized, double-blind clinical trial of high quality (eg, sample size calculation, flow chart of patient inclusion, intention-to-treat (ITT) analysis and sufficient sample size)
B	Randomized clinical trial of lesser quality (eg, only single-blind, limited sample size: at least 15 patients per study arm)
C	Comparative trial with severe methodological limitations (eg, not blinded, very small sample size and no randomization) or large retrospective observational study, large open-label-study, registry data
D	Adapted from existing consensus document or statement based on expert opinion voting during consensus conference, evidence non A–C

Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021 Jan;9(1):132-150.e3. doi: 10.1016/j.jaip.2020.08.046. Epub 2020 Sep 6.

Recommendation	Strength of Recommendation	Quality of Evidence
On-demand treatment of HAE attacks		

Patients must have ready access to effective on-demand medication to administer at the onset of an HAE attack. An FDA-approved on-demand HAE medication (ecallantide, icatibant, pdC1INH, or rhC1INH) should be used as first-line treatment for attacks whenever possible.	Strong	High for HAE-C1INH Low for HAE-nl-C1INH
On-demand treatment of HAE attacks should be self-administered (or administered by a caregiver) whenever feasible except when treating with ecallantide that needs to be administered by a health care provider.	Strong	High for HAE-C1INH Low for HAE-nl-C1INH
All HAE attacks are eligible for treatment irrespective of the location of the swelling or the severity of the attack.	Strong	High for HAE-C1INH Low for HAE-nl-C1INH
Prophylactic treatment		
Short-term prophylaxis is indicated when patients are at increased risk of having an attack associated with known triggers such as invasive dental or medical procedures or stressful life events.	Strong for HAE-C1INH Weak for HAE-nl-C1INH	Moderate for HAE-C1INH Low for HAE-nl-C1INH
The decision on when to use long-term prophylactic treatment cannot be made on rigid criteria but should reflect the needs of the individual patient.	Strong	High for HAE-C1INH Low for HAE-nl-C1INH
Long-term prophylactic treatment of HAE-C1INH should include first-line medications (IV C1INH, SC C1INH, or lanadelumab).	Strong	High
Progestin-only medication or an antifibrinolytic drug should be considered for initial long-term prophylactic treatment of HAE-nl-C1INH.	Weak	Low
Additional considerations for children		
HAE-C1INH often presents in childhood and an early diagnosis is essential for minimizing the risks of morbidity and mortality.	Strong	High
Indications for the use of first-line HAE medications are the same in children as in adults, although regulatory differences affect the use of some medications depending on the child's age.	Strong	Moderate
Specific issues in the management of HAE in women		
Exogenous estrogens such as birth control pills or hormonal replacement therapy can precipitate HAE attacks and should therefore be used only with caution in individuals with HAE.	Strong	Moderate
During pregnancy and breast-feeding, C1INH is the recommended HAE medication for use as either on-demand or prophylactic therapy.	Strong	Moderate

Recommendation Definitions

Strength of Recommendation	Definition
Strong	Given if the authors were confident in the recommendation based on existing evidence or if the risk/benefit ratio was compelling
Weak	Given in the absence of “Strong” recommendation

Quality of Evidence	Definition
High	Evidence resulting from either well-designed randomized controlled trials or observational studies with very large and clinically important effect sizes
Moderate	Evidence from randomized trials with important limitations or observational studies with clear and consistent effect sizes
Low	Evidence that failed to achieve either high or moderate quality

Clinical Trials/Systematic Reviews/Meta-Analyses

Citation	Design	Endpoints
Walsh S, Bartlett M, Salvo-Halloran EM, et al. Network Meta-Analysis of Pharmacological Therapies for Long-Term Prophylactic Treatment of Patients with Hereditary Angioedema. *Drugs R D*. 2025;25(2):161-178. doi:10.1007/s40268-025-00511-y	Background: There are several long-term prophylaxis (LTP) treatments of HAE (garadacimab, lanadelumab, subcutaneous C1 esterase inhibitor (C1INH), berotralstat), but in the absence of head-to-head comparative evidence, indirect comparison methods are needed to compare LTP treatments Methods: Systematic literature review of RCTs investigating LTP treatments for HAE conducted on 8/11/22 and updated on 9/16/24 in accordance with the PRISMA statement, NMA conducted using Bayesian framework	• Primary: time-normalized number of HAE attacks • Secondary: proportion of attack-free patients, time-normalized number of HAE attacks treated with on-demand therapy, time-normalized number of moderate and/or severe HAE attacks • Treatment-emergent adverse events (TEAE)
Results: The results show improved efficacy, QoL, and reduced rate of adverse events with garadacimab (200 mg once monthly), lanadelumab (300 mg every two or four weeks), subcutaneous C1INH (60 IU/kg twice weekly), and berotralstat (150 mg once daily) compared to placebo in the treatment of patients with HAE. For the primary outcome of time-normalized number of HAE attacks, garadacimab statistically significantly reduced the rate of attacks compared to lanadelumab Q4W and berotralstat. A similar statistically significant reduction was shown for HAE attacks treated with on-demand treatment. Garadacimab showed statistically significant reduction in the rate of moderate and/or severe HAE attacks compared to lanadelumab Q2W. Garadacimab also showed statistical improvements in change from baseline in AE-QoL total score as compared to berotralstat. Not surprisingly, most had higher rates of TEAEs compared with placebo, however, lanadelumab Q2W was the only drug with a statistically significant higher rate of TEAEs. **Conclusion**: Overall, garadacimab ranked as the most probable effective treatment among all comparators assessed, with lanadelumab Q2W or subcutaneous C1INH ranking second, across most outcomes.		

Citation	Design	Endpoints
Watt M, Goldgrub R, Malmenäs M, Haeussler K. Indirect treatment comparison of lanadelumab and a C1-esterase inhibitor in pediatric patients with hereditary angioedema. J Comp Eff Res. 2025;14(2):e240110. doi:10.57264/cer-2024-0110	Methods: systemic literature review to identify studies of LTP in patients with HAE aged <12 years, 2 studies met the inclusion criteria in an indirect treatment comparison of efficacy and safety data in pediatric HAE patients (for lanadelumab (SPRING, NCT04070326) and IV C1-esterase inhibitor (C1-INH[IV], NCT02052141)) A propensity score analysis was performed using a base propensity score model. To avoid convergence issues and underpowered analysis due to the small sample size (n=29), the base case was defined as Poisson regression analyses on monthly attack rate adjusting for exclusively one covariate (baseline attack rate)	• Safety and efficacy outcomes reported in the SPRING lanadelumab study
Results: Lanadelumab 150 mg every 2 weeks (Q2W) reduced the monthly HAE attack rate by 82.1% versus C1-INH(IV) 1000 IU twice weekly (every 3-4 days [BIW]; rate ratio [RR], 0.1792 [95% CI: 0.0296-1.0853]) and by 88.9% versus C1-INH(IV) 500 IU BIW (RR: 0.1107 [95% CI: 0.0234-0.5239]). Treatment with lanadelumab Q2W reduced the risk of		

total adverse events by 56.2% versus C1-INH(IV) 1000 IU BIW (RR:0.4377 [95% CI: 0.1536-1.2469]) and by 66.0% versus C1-INH(IV) 500 IU BIW (RR: 0.3401 [95% CI: 0.1234-0.9371]).
Conclusion: This exploratory analysis suggested a trend toward greater efficacy and fewer adverse events with lanadelumab 150 mg Q2W compared with C1-INH(IV) BIW 1000 IU and 500 IU in pediatric patients with HAE. Future studies could potentially assess larger samples over longer periods of time for the long-term preventative efficacy, safety and tolerability of lanadelumab and C1-INH(IV).

Citation	Design	Endpoints
Riedl MA, Tachdjian R, Lumry WR, et al. Efficacy and Safety of Donidalorsen for Hereditary Angioedema. *N Engl J Med*. 2024;391(1):21-31. doi:10.1056/NEJMoa2402478	Methods: Phase 3, multicenter, double blind, randomized, placebo-controlled study (N=90) Arms: donidalorsen 80 mg SQ once every 4 weeks (n=45), donidalorsen 80 mg once every 8 weeks (n=23), or placebo (n=22) Inclusion criteria: aged ≥ 12 years with documented diagnosis of HAE-1/HAE-2, minimum of 2 HAE attacks during the screening period Exclusion criteria:	Primary: time-normalized number of investigator-confirmed HAE attacks per 4 weeks (attack rate) from week 1 to week 25

Results: A total of 90 patients received donidalorsen every 4 weeks (45 patients), donidalorsen every 8 weeks (23 patients), or placebo (22 patients). The least-squares mean time-normalized attack rate was 0.44 (95% CI, 0.27 to 0.73) in the 4-week group, 1.02 (95% CI, 0.65 to 1.59) in the 8-week group, and 2.26 (95% CI, 1.66 to 3.09) in the placebo group. The mean attack rate from week 1 to week 25 was 81% lower (95% CI, 65 to 89) in the 4-week group than in the placebo group (P<0.001) and 55% lower (95% CI, 22 to 74) in the 8-week group than in the placebo group (P=0.004); the median reduction in the attack rate from baseline was 90% in the 4-week group, 83% in the 8-week group, and 16% in the placebo group. The mean attack rate during weeks 5 to 25 was 87% lower (95% CI, 72 to 94) in the 4-week group than in the placebo group (P<0.001) and 60% lower (95% CI, 25 to 79) in the 8-week group than in the placebo group. Donidalorsen administered every 4 weeks resulted in an improvement in the least-squares mean total score for the change at week 25 on the Angioedema Quality-of-Life Questionnaire (scores range from 0 to 100, with a score of 100 indicating the worst possible quality of life) that was 18.6 points (95% CI, 9.5 to 27.7) better than that with placebo (P<0.001). The most common adverse events were erythema at the injection site, headache, and nasopharyngitis; 98% of adverse events were mild or moderate in severity.
Conclusion: Donidalorsen treatment reduced the hereditary angioedema attack rate, a finding that supports potential prophylactic use for hereditary angioedema.

Citation	Design	Endpoints
Riedl MA, Farkas H, Aygören-Pürsün E, et al. Oral Sebetralstat for On-Demand Treatment of Hereditary Angioedema Attacks. *N Engl J Med*. 2024;391(1):32-43. doi:10.1056/NEJMoa2314192	Design: Phase 3, randomized, double-blind, placebo controlled, three-way crossover trial (N=136) Arms: two oral doses of sebetralstat (300 mg or 600 mg) or placebo for an angioedema attack Inclusion criteria: male/ female patients ≥ 12 years of age with HAE type I/II, ≥ 2 documented HAE attacks within 3 months prior to screening/ randomization or completer of the KVD824-201 trial within 3 months prior to randomization	• Primary: time to beginning of symptom relief, at 2+ consecutive time points within 12 hours after the first administration of the trial agent • Secondary: reduction in attack severity at 2+ consecutive time points within 12

	Exclusion criteria: any concomitant diagnosis of another form of chronic angioedema, such as acquired C1-inhibitor deficiency, HAE with normal C1-INH (previously known as HAE type III), idiopathic angioedema, or angioedema associated with urticaria	hours, complete attack resolution within 24 hours
Result: The time to the beginning of symptom relief with the 300-mg dose and the 600-mg dose was faster than with placebo (P<0.001 and P = 0.001 for the two comparisons, respectively), with median times of 1.61 hours (interquartile range, 0.78 to 7.04), 1.79 hours (1.02 to 3.79), and 6.72 hours (1.34 to >12), respectively. The time to reduction in the attack severity with the 300-mg dose and the 600-mg dose was faster than with placebo (P = 0.004 and P = 0.003), with median times of 9.27 hours (interquartile range, 1.53 to >12), 7.75 hours (2.19 to >12), and more than 12 hours (6.23 to >12). The time to complete resolution was faster with the 300-mg and 600-mg doses than with placebo (P = 0.002 and P<0.001). The percentage of attacks with complete resolution within 24 hours was 42.5% with the 300-mg dose, 49.5% with the 600-mg dose, and 27.4% with placebo. Sebetralstat and placebo had similar safety profiles; no serious adverse events related to the trial agents were reported. **Conclusion:** Oral sebetralstat provided faster times to the beginning of symptom relief, reduction in attack severity, and complete attack resolution than placebo.		

Citation	Design	Endpoints
Craig TJ, Reshef A, Li HH, et al. Efficacy and safety of garadacimab, a factor XIIa inhibitor for hereditary angioedema prevention (VANGUARD): a global, multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2023;401(10382):1079-1090. doi:10.1016/S0140-6736(23)00350-1	Design: Phase 3, multicenter, randomized (3:2), double blind, placebo-controlled, parallel group study (N=64) Arms: 400-mg loading dose of SQ garadacimab as two 200-mg injections or volume-matched placebo on day 1 of the treatment period, followed by five additional self-administered (or caregiver-administered) monthly doses of 200-mg SQ garadacimab or volume-matched placebo Inclusion criteria: male/female ≥ 12 years of age, diagnosed with clinically confirmed C1-INH HAE, experience ≥ 3 attacks during the 3 months before screening Exclusion criteria: concomitant diagnosis of another form of angioedema such as idiopathic/ acquired angioedema, recurrent angioedema associated with urticarial or hereditary angioedema type 3	• Primary: time-normalized number of hereditary angioedema attacks (number of HAE attacks per month) during the 6-month treatment period (day 1 to day 182) • Secondary: monthly rate of HAE attacks requiring on-demand therapy, monthly rate of moderate or severe HAE attacks • Adverse effects
Result: During the 6-month treatment period (day 1 to day 182), the mean number of investigator-confirmed hereditary angioedema attacks per month was significantly lower in the garadacimab group (0·27, 95% CI 0·05 to 0·49) than in the placebo group (2·01, 1·44 to 2·57; p<0·0001), corresponding to a percentage difference in means of –87% (95% CI –96 to –58; p<0·0001). The median number of hereditary angioedema attacks per month was 0 (IQR 0·00–0·31) for garadacimab and 1·35 (1·00–3·20) for placebo. The most common treatment-emergent adverse events were upper-respiratory tract infections, nasopharyngitis, and headaches. FXIIa inhibition was not associated with an increased risk of bleeding or thromboembolic events. **Conclusion:** Monthly garadacimab administration significantly reduced hereditary angioedema attacks in patients aged 12 years and older compared with placebo and had a favourable safety profile. Our results support the use of garadacimab as a potential prophylactic therapy for the treatment of hereditary angioedema in adolescents and adults.		

Citation	Design	Endpoints

Watt M, Malmenäs M, Romanus D, Haeussler K. Network meta-analysis for indirect comparison of lanadelumab and berotralstat for the treatment of hereditary angioedema. J Comp Eff Res. 2023;12(6):e220188. doi:10.57264/cer-2022-0188	Methods: systematic literature review; MEDLINE, Embase, MEDLINE In-Process and The Cochrane Library searched on 6/29/17 and updated on 7/25/18 for publications since database inception to July 2018 Inclusion: RCTs, non-RCTs, observational studies, single-arm studies, cohort studies (prospective and retrospective), long-term follow-up studies or systematic reviews and meta-analyses of RCTs/non-RCTs investigating short-term or long-term prophylactic therapies (C1-INH, lanadelumab, attenuated androgens [danazol, stanozolol], oxandrolone, methyltestosterone and testosterone) for HAE prophylaxis in patients with HAE type I/II aged ≥12 years Exclusion: Case reports, case series, pharmacokinetic studies, economic studies, preclinical studies, reviews, letters/ comment articles	• HAE attack rate per 28 days • ≥90% reduction in the number of monthly HAE attacks
Results: Lanadelumab 300 mg Q2W was associated with the first rank (best outcome) for the outcomes of HAE attack rate per 28 days and ≥90% reduction in the number of monthly HAE attacks when ranked versus the other treatments using a p-score. In a sensitivity analysis, HAE attack rates observed during steady state of days 70 to 180 in the HELP study were considered; the results were consistent with the main analysis, with even more favorable outcomes for lanadelumab when only steady state efficacy was considered. **Conclusion:** Lanadelumab 300 mg administered every 2 weeks or every 4 weeks was associated with statistically significantly higher effectiveness versus berotralstat 150 mg once daily (q.d.) or 110 mg q.d. for both efficacy outcomes assessed.		

Citation	Design	Endpoints
Zuraw B, Lumry WR, Johnson DT, et al. Oral once-daily berotralstat for the prevention of hereditary angioedema attacks: A randomized, double-blind, placebo-controlled phase 3 trial. J Allergy Clin Immunol. 2020 Oct 21;S0091-6749(20)31484-6. doi: 10.1016/j.jaci.2020.10.015.	Design: phase 3, randomized (1:1:1), double blind, placebo controlled N=96 Arms: berotralstat (Orladeyo) 110 mg once daily, 150 mg once daily, placebo Inclusion criteria: ≥ 12 years (U.S./Canada), ≥ 18 years (Europe); HAE types I or II, defined as having a C1INH functional level and a C4 level below the lower limit of the normal (LLN) for reference range; weight ≥ 40 kg; access to and ability to use ≥ 1 acute medication(s) for the treatment of acute attacks of HAE; medically appropriate for on-demand treatment as the sole medicinal management for HAE; ≥ 2 investigator-confirmed attacks during the run-in period; acceptable effective contraception Exclusion criteria: pregnant/breastfeeding; any clinically significant and relevant laboratory parameter abnormality; severe hypersensitivity to medicinal products or severe hypersensitivity/anaphylaxis with unclear etiology; recent/concurrent use of C1INH, androgens, tranexamic acid for prophylaxis of HAE attacks	• Primary: rate of HAE attacks during dosing in the entire 24-week treatment period • Secondary: change from baseline in Angioedema Quality of Life Questionnaire (AE-QoL) total scores at week 24 • Adverse events

Results: Berotralstat demonstrated a significant reduction in attacks at both dose levels relative to placebo: 1.65 attacks/month at 110 mg (P = 0.024); 1.31 attacks/month at 150 mg (P < 0.001); and 2.35 attacks/month with placebo. The change from baseline in AE-QoL total scores at week 24 was not significant versus placebo (LSM difference from placebo: –2.77 [95% CI = –10.08 to 4.53] points in the 110-mg dose of berotralstat group [P = 0.453] and –4.90 [95% CI = –12.23 to 2.43] points in the 150-mg dose of berotralstat group [P = 0.188]). TEAEs occurred at similar rates in all three arms and ranged from 77% in the placebo group to 85% in the berotralstat 150 mg group. The one serious TEAE that occurred in the 100 mg berotralstat group (plasma cell myeloma) was considered unrelated to the study drug.
Conclusion: The authors concluded that "berotralstat is an effective oral prophylactic treatment for patients with HAE–C1-INH." The FDA review came to the same conclusion with no serious concerns in clinical development noted in the summary clinical evaluation.

Citation	Design	Endpoints
Banerji A, Riedl MA, Bernstein JA, et al. Effect of Lanadelumab Compared With Placebo on Prevention of Hereditary Angioedema Attacks: A Randomized Clinical Trial. JAMA. 2018 Nov 27;320(20):2108-2121. doi: 10.1001/jama.2018.16773.	Design: phase 3, randomized (2 lanadelumab:1 placebo; lanadelumab group further randomized 1:1:1 to different dosing regimens), double blind, placebo controlled N=125 Arms: 3 doses of lanadelumab (Takhzyro) (300 mg q2 wks, 300 mg q4 wks, 150 mg q4 wks) in the prophylaxis of types I and II HAE Inclusion criteria: ≥ 12 years of age; HAE type I or II; baseline rate of at least 1 HAE attack/4 weeks; fertile and sexually active males and females must adhere to contraception requirements Exclusion criteria: diagnosis of another form of chronic, recurrent angioedema, such as C1INH-AAE, idiopathic angioedema, or recurrent angioedema associated with urticarial; participation in a prior DX-2930 study; exposure to ACE-is or any estrogen-containing medications within 4 weeks prior to screening or androgens within 2 weeks prior to run-in period; use of long-term prophylactic therapy for HAE within 2 weeks prior to run-in period or short-term prophylaxis for HAE within 7 days prior to run-in period; any of the following liver function test abnormalities: ALT or AST > 3x upper limit of normal (ULN), or total bilirubin > 2x ULN (unless the bilirubin elevation is a result of Gilbert's syndrome); pregnant/breastfeeding	• Primary: Rate of Investigator confirmed HAE attacks during treatment period (day 0 to day 182) • Adverse events

Results: Least square mean (LSM) rate of investigator confirmed HAE in attacks/4 weeks (95% CI): placebo 1.97 (1.64 – 2.36); 150 mg q4wks 0.48 (0.31 – 0.73); 300 mg q2 wks 0.26 (0.14 – 0.46); 300 mg q4wks 0.53 (0.36 – 0.77); p<0.001 for all comparisons. The mean differences in attack rates compared to placebo were statistically significant (P<0.001) for all doses. The 300 mg doses had adverse event rates >7% and greater than placebo; the rate of adverse events in the 150 mg group was 0% and less than placebo. The most common adverse events were injection site reactions and dizziness.
Conclusion: The authors concluded the results supported the use of lanadelumab for the prophylaxis of HAE types I and II as evidenced by a significant reduction in the rate of HAE attacks with lanadelumab treatment compared to placebo. The posted FDA review firmly supported approval based on robust clinical development program and resulting efficacy data.

Citation	Design	Endpoints
Longhurst H, Cicardi M, Craig T, et al. Prevention of Hereditary Angioedema Attacks with a Subcutaneous C1 Inhibitor. N Engl J Med. 2017 Mar 23;376(12):1131-1140. doi: 10.1056/NEJMoa1613627	Design: phase 3, randomized (1:1:1:1), double blind, placebo controlled, crossover assignment N=90 Arms: SQ C1INH (Haegarda) 40 U/kg or 60 U/kg twice weekly then placebo or placebo then SQ C1INH 40 U/kg or 60 U/kg twice weekly Inclusion criteria: ≥ 12 years of age; clinical and central laboratory diagnosis of type I or II HAE (functional C1 inhibitor activity of <50% and C4 antigen level below the normal level); HAE attacks over a consecutive 2-month period that required acute treatment, medical attention, or caused significant functional impairment Exclusion criteria: history of clinical significant arterial or venous thrombosis, or current history of a clinically significant prothrombotic risk; incurable malignancies; clinically significant history of poor response to C1INH therapy for the management of HAE; patients who had received an intravenous C1INH for routine prophylaxis within 3 months before screening; female subjects who started taking or changed dose of any hormonal contraceptive regimen or hormone replacement therapy (i.e., estrogen/progesterone-containing products) within 3 months prior to the screening visit	• Primary: The time-normalized number of HAE attacks (32 week timeframe) • Adverse events
Results: There was a statistically significant improvement in mean difference of HAE attacks compared with placebo for both doses of Haegarda (40 IU: -2.42 attacks per month; 95% CI, -3.38 to -1.46; and 60 IU: -3.51 attacks per month; 95% CI, -4.21 to -2.81; p<0.001 for both comparisons). Adverse events occurred at a similar rates in both treatment and placebo groups. **Conclusion**: Haegarda is effective at reducing the frequency of HAE attacks with a reasonable safety profile. The FDA approval package was posted, and there were no notable reviewer concerns related to this study.		

Formulary Placement, Utilization and Cost Experience (07-01-2025 to 09-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	**Rx**	**Mbrs**	**Total**	**Avg/Rx**	**Total**	**Approved (%)**	**Current**	**Recommend**
Bradykinin B2 Receptor Antagonist								
icatibant (Firazyr®) 30 mg/3 mL subcutaneous syringe	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Sajazir (icatibant) 30 mg/3 ml subcutaneous syringe	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Kallikrein Inhibitor								
Kalbitor® (ecallantide) 10 mg/mL (1 mL) subcutaneous solution	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Takhzyro® (lanadelumab-flyo) 300 mg/2 mL (150 mg/mL) subcutaneous solution	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Takhzyro® (lanadelumab-flyo) 150mg/mL (1mL), 300mg/2mL (2mL) subcutaneous prefilled syringe	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Orladeyo™ (berotralstat) 110 mg, 150 mg capsule	0	0	$0.00	$0.00	0	0 (0%)	F-PA	No change
Ekterly™ (sebetralstat) 300 mg oral tablet	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
C1 Esterase Inhibitor - Human								
Cinryze® (c1 esterase inhibitor, human) 500 unit (5 mL) intravenous solution	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Berinert® (c1 esterase inhibitor, human) 500 unit (10 mL) intravenous kit	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Haegarda® (c1 esterase inhibitor, human) 2,000 unit, 3,000 unit subcutaneous solution	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
C1 Esterase Inhibitor - Recombinant								
Ruconest® (c1 esterase inhibitor, recombinant) 2,100 unit intravenous solution	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Plasma Factor XIIa Inhibitor								
Andembry® (garadacimab-gxii) 200 mg/1.2ml auto-injector pen	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
Prekallikrein-Directed Antisense Oligonucleotide								
Dawnzera™ (donidalorsen) subcutaneous solution auto-injector 80 mg/0.8ml	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
TOTAL	**0**	**0**	**$0.00**	**$0.00**	**0**	**0 (0%)**		

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

Prior Authorization Criteria

Recommendation: add newly approved agents Ekterly, Andembry, and Dawnzera to non-preferred agents since they are more costly and there is no preference of one agent over another per treatment guidelines.

<table>
<tr><th colspan="2">Hereditary Angioedema (HAE)</th></tr>
<tr><td>Therapeutic Classes (AHFS)</td><td>COMPLEMENT INHIBITORS</td></tr>
<tr><td>Medications</td><td><u>Preferred:</u>
Orladeyo (berotralstat) oral capsule
Takhzyro (lanadelumab-flyo) SC injection
icatibant (Firazyr) SC injection
Haegarda (C1 esterase inhibitor, human) SC syringe
Cinryze (C1 esterase inhibitor, human) IV vial
Berinert (C1 esterase inhibitor, human) IV vial
Ruconest (C1 esterase inhibitor, recombinant) IV vial

<u>Non-Preferred:</u>
Kalbitor (ecallantide) SC syringe
Ekterly (sebetralstat) oral tablet
Andembry (garadacimab-gxii) SC injection
Dawnzera (donidalorsen) SC injection</td></tr>
<tr><td>Covered Uses</td><td>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.</td></tr>
<tr><td>Exclusion Criteria</td><td>N/A</td></tr>
<tr><td>Required Clinical Information</td><td>See “PA Review Criteria” below</td></tr>
<tr><td>Age Restrictions</td><td>Check AAH active CCS cases for members < 21 years of age</td></tr>
<tr><td>Prescriber Restrictions</td><td>Prescriber must be an immunologist, allergist, rheumatologist, or hematologist</td></tr>
<tr><td>Coverage Duration</td><td>Initial Approval
If criteria are met, the request will be approved as follows:
• Acute treatment: initial fill + 5 refills
• Pre-procedural prophylaxis: 1 treatment
• Long-term prophylaxis: Initial approval: 6 months

Reauthorization
Long-term prophylaxis: Reauthorization:12 months

If all of the criteria are not met, the request is referred to a clinical reviewer for medical necessity review.</td></tr>
<tr><td>PA Review Criteria</td><td>All requests must meet the following criteria:
• Documentation submitted indicates the medication is being prescribed at FDA approved dose.
• The patient is not taking ACE inhibitors or estrogen containing oral contraceptives or hormone replacement therapy
• Documented diagnosis of one of the following:
▪ HAE with deficient or dysfunctional C1INH (e.g. type I, type II or acquired C1INH deficiency):
<table><tr><td>Deficiency Type</td><td>C4</td><td>C1INH antigenic level</td><td>C1INH functional level</td></tr></table></td></tr>
</table>

Type I (deficiency of C1INH)	Low	Low	Low
Type II (dysfunction of C1INH)	Low	Normal or elevated	Low
Acquired C1INH deficiency	Low	Low or normal	Low

- HAE with normal C1INH:
  - If known origin, documentation of results of confirmatory genetic test (e.g. mutations in gene for factor XII, angiopoietin-1, plasminogen, kininogen-1, myoferlin, heparan sulfate-glucosamine 3-O-sulfotransferase 6)
  - If unknown origin (U-HAE), documentation of a prolonged trial of high-dose non-sedating antihistamines

For acute treatment (Ruconest, Berinert, Kalbitor, icatibant, Ekterly):
- The patient is receiving only one agent for the treatment of acute attacks
- If the request is for a non-preferred agent, the member has documented trial and failure of or intolerance to a preferred agent or medical reason why the member cannot use a preferred agent.

For prophylaxis (Haegarda, Takhzyro, Cinryze, Orladeyo, Andembry, Dawnzera):
- Pre-procedural
  - Documentation that patient will be undergoing a medical, surgical, or dental procedure associated with mechanical impact to the upper aerodigestive tract and anticipated date of the procedure
- Long-term
  - Documentation of at least one HAE attack per month
  - The patient is receiving one prophylactic HAE medication only
  - If the request is for Cinryze, the patient has a documented trial and failure of, or intolerance to, Haegarda
  - If the request is for Takhzyro and the patient has been well controlled (e.g. attack free) for 6 months or more while receiving Takhzyro the patient will be receiving 300 mg every four weeks, or a medical reason has been provided why continued therapy with 300 mg every two weeks is necessary
- If the request is for a non-preferred agent, the member has documented trial and failure of or intolerance to a preferred agent or medical reason why the member cannot use a preferred agent.

Renewal Criteria:
For acute treatment:
- Documentation was submitted that the patient has clinically benefited from medication
- The medication is being prescribed at FDA approved dose.
- The patient is receiving no other medications for acute treatment

For prophylaxis:
- Documentation was submitted that the patient has clinically benefited from prophylactic therapy as demonstrated by a reduced number of attacks
- The medication is being prescribed at an FDA approved dose
- The patient is receiving no other medications for prophylaxis

	• If the request is for Takhzyro and the patient has been well controlled (e.g. attack free) for 6 months or more while receiving Takhzyro the patient will be receiving 300 mg every four weeks, or a medical reason has been provided why continued therapy with 300 mg every two weeks is necessary
	Treatments for hereditary angioedema are reserved for members with a diagnosis of hereditary angioedema (HAE) who are not using ACE inhibitors or estrogen containing oral contraceptives or hormone replacement therapy. If a non-preferred agent is requested for acute treatment, the patient is receiving only one medication for the treatment of acute attacks, and has used (or cannot/should not use) a preferred agent. If a non-preferred agent is requested for long-term prophylaxis, the patient is receiving only one medication for prophylaxis treatment, the member has a history of at least one attack and has used (or cannot/should not use) a preferred agent.
Last P&T Review Date	~~6/2025~~12/2025

HAE On-Demand Treatments					
Medications	icatibant (Firazyr)	Berinert	Kalbitor	Ruconest	Ekterly
Mechanism of Action	Bradykinin B2 receptor antagonist	C1 esterase inhibitor (plasma-derived)	Plasma kallikrein inhibitor	C1 esterase inhibitor (recombinant human)	Plasma kallikrein inhibitor
Route of Administration	SC	IV	SC	IV	PO
Dosing	30 mg	20 U/kg	30 mg	50 U/kg (up to 4200 U)	600 mg
Repeat dosing	Every 6 hours (max 3 doses/day)	1-2 hours (max 2 doses/day)	≥1 hour (max 2 doses/day)	2-4 hours (max 2 doses/day)	≥3 hours (max 2 doses/day)
Self-administration?	Yes	Yes	No	Yes	Yes
Monthly cost	$9,150	$12,815	$34,239	$16,150	$33,440

HAE Prophylaxis Treatments						
Medications	Cinryze	Haegarda	Takhzyro	Orladeyo	Andembry	Dawnzera
Mechanism of Action	C1 esterase inhibitor	C1 esterase inhibitor	Plasma kallikrein inhibitor	Plasma kallikrein inhibitor	Activated factor XII (FXIIa) inhibitor	Prekallikrein-directed antisense oligonucleotide
Route of Administration	IV	SC	SC	PO	SC	SC
Dosing	1,000 U	60 U/kg	300 mg	150 mg	400 mg (LD), then 200 mg	80 mg
Frequency	Every 3-4 days	Every 3-4 days	Every 2 weeks	Once daily	Once monthly	Once monthly/ every 2 months
Self-administration?	Yes	Yes	Yes	Yes	Yes	Yes
Monthly cost	$51,171	$48,410	$52,705	$47,662	$57,100	$57,462

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PCSK9 Inhibitors

Executive Summary

Class Overview

This review covers proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors Praluent (alirocumab) and Repatha (evolocumab), and the siRNA therapy targeting PCSK9 Leqvio (inclisiran), used to treat dyslipidemia. Dyslipidemia is the elevation of cholesterol, triglycerides (TGs), or both that contributes to the development of atherosclerosis. Primary or genetic causes of dyslipidemia are linked to gene mutations that result in overproduction or ineffective clearance of TGs or low-density lipoprotein-cholesterol (LDL-C), or the underproduction or excessive clearance of high-density lipoprotein-cholesterol (HDL-C). Secondary causes of dyslipidemia include sedentary lifestyle and high dietary intake of fats, diabetes, alcohol overuse, chronic kidney disease, hypothyroidism, primary biliary cirrhosis, and some drugs. Secondary causes of low HDL-C include HIV infection, cigarette smoking, anabolic steroids, and nephrotic syndrome.

Revised guidelines for the management of blood cholesterol were released by the American College of Cardiology (ACC) and American Heart Association (AHA) in late 2018. The American Academy of Clinical Endocrinology (AACE) published revised guidelines for adult dyslipidemia management in 2025. Guidelines generally recommend PCSK9 inhibitors as a later line agent after adequate LDL lowering has not been achieved with statins and ezetimibe in patients with familial hypercholesterolemia, with existing cardiovascular disease or those with risk factors.

PCSK9 inhibitors have a storied history. They are very effective at reducing LDL, even when added to very potent high-intensity statin regimens, the gold-standard of care to treat hyperlipidemia. They were initially launched at very high price points (>$14k/year). Uptake was slow and manufacturers eventually responded by reducing prices by ~60% to approximately $5k per year. However, PCSK9 inhibitors still struggle to penetrate the hyperlipidemia market due to high price, payer restrictions, and limited evidence of effect on mortality.

Recent label expansions within the PCSK9 inhibitor category highlight these agents' potent LDL lowering capabilities. In July 2025, Leqvio and Repatha labeling now supports their use as monotherapy instead of as an add-on therapy with traditional statins or other agents to lower LDL cholesterol. Repatha was also given approval for primary prevention of major adverse cardiovascular events (MACE), while Praluent is currently approved for secondary prevention. Leqvio does not have a cardiovascular risk reduction indication, but a dedicated cardiovascular outcomes trial is currently underway, with an expected primary completion date of July 2026.

Lerodalcibep is a novel PCSK9 inhibitor therapy in the drug development pipeline with a potential approval date in December 2025. Lerodalcibep is a recombinant fusion protein with reported increased half-life and solubility. Indications under review by the FDA include LDL-C reduction in patients with primary hyperlipidemia and atherosclerotic

cardiovascular disease (ASCVD) or at high risk, heterozygous familial hyperlipidemia, and homozygous familial hyperlipidemia. Orally administered PCSK9 inhibitors are also in development, but none are currently near-term.

Utilization Findings

There were 20 claims for 7 members, for a total cost of $10,562.27 and an average cost per claim of $528.11. The most highly utilized medication was Repatha SureClick subcutaneous pen injector with 14 claims, followed by Praluent subcutaneous pen injector with 4 claims. There were 3 prior authorization requests with 1 approval (33%).

Recommendations

- Streamline criteria requirements to accommodate expanded indications for Repatha and Praluent
- Remove preferred NDCs from the criteria and add all NDCs to formulary since all are priced the same

Clinical Summary

Dyslipidemia is the elevation of cholesterol, TGs, or both that contributes to the development of atherosclerosis. Primary or genetic causes of dyslipidemia are linked to gene mutations that result in overproduction or ineffective clearance of TGs or LDL-C, or the underproduction or excessive clearance of HDL-C. Secondary causes of dyslipidemia include sedentary lifestyle and high dietary intake of fats, diabetes, alcohol overuse, chronic kidney disease, hypothyroidism, primary biliary cirrhosis, and some drugs. Secondary causes of low HDL-C include HIV infection, cigarette smoking, anabolic steroids, and nephrotic syndrome.

A new PCSK9 inhibitor, inclisiran, was approved in December 2021. While it acts generally by inhibiting PCSK9, it does so by a different mechanism than Praluent (alirocumab) and Repatha (evolocumab) – monoclonal antibodies (mAbs) that bind to PCSK9. Inclisiran is a small interfering ribonucleic acid (siRNA) targeting messenger RNA (mRNA) production of the PCSK9 enzyme; by cleaving the mRNA, cellular instructions to produce PCSK9, the enzyme is not synthesized with downstream effects on the increased clearance of LDL. The commercial attractiveness of inclisiran is every 6-month dosing.

PCSK9 inhibitors are FDA approved for treatment of primary hyperlipidemias including heterozygous and homozygous familial hypercholesterolemias to reduce LDL-C levels, and to reduce cardiovascular disease risk in patients with established CVD or those who do not have established CVD but with risk factors. Both Praluent and Repatha are approved for use in children with familial hypercholesterolemia. PCSK9 inhibitors may be used alone or in conjunction with other lipid lowering agents to address reduction of LDL-C.

Indications, Dosing and Administration

Medication	Indications	Dosing/Administration
Praluent® (alirocumab)	• Primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH]) – as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia to reduce low-density LDL-C • HeFH - as an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 8 years and older to reduce LDL-C • HoFH - as an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia to reduce LDL-C • Secondary prevention, cardiovascular events - to reduce the risk of myocardial infarction (MI), stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease (CVD)	In adults with established cardiovascular disease or with primary hyperlipidemia, including HeFH: 75 mg SQ once every 2 weeks OR 300 mg SQ once every 4 weeks (monthly); titrate to 150 mg SQ every 2 weeks based on patient response HeFH undergoing LDL apheresis or in adults with HoFH: 150 mg SQ once every 2 weeks In pediatric patients with HeFH: <50 kg: 150 mg SQ once every 4 weeks ≥50 kg: 300 mg SQ once every 4 weeks. If the LDL-C response is inadequate, the dosage may be adjusted for patients with a body weight less than 50 kg to 75 mg subcutaneously once every 2 weeks or for patients with a body weight of 50 kg or more to 150 mg subcutaneously once every 2 weeks.
Repatha® (evolocumab)	• Hypercholesterolemia – as an adjunct to diet and exercise in adults to reduce LDL-C • HeFH - as an adjunct to diet and exercise in pediatric patients aged 10 years and older to reduce LDL-C • HoFH - as an adjunct to diet and exercise in adults and children 10 years and older to reduce LDL-C • Primary and secondary prevention, cardiovascular	In adults with increased risk for CVD events or with hypercholesterolemia: 140 mg SQ every 2 weeks OR 420 mg SQ once monthly In adults and pediatric patients aged 10 years and older with HeFH: 140 mg SQ every 2 weeks OR 420 mg SQ once monthly In adults and pediatric patients aged 10 years and older with HoFH: 420 mg SQ once monthly; can be increased to 420 mg

Medication	Indications	Dosing/Administration
	events - to reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults at increased risk for these events	every 2 weeks if a clinically meaningful response is not achieved in 12 weeks. Patients on lipid apheresis may initiate treatment with 420 mg every 2 weeks to correspond with their apheresis schedule.
Leqvio® (inclisiran)	• Primary hyperlipidemia (including HeFH) – as an adjunct to diet and exercise for the treatment of adults with to reduce LDL-C in adults	284 mg SQ initially, again at 3 months, and then every 6 months

Boxed Warnings and Contraindications

Medication	Boxed Warnings	Contraindications
Praluent® (alirocumab)	N/A	Hypersensitivity to the active ingredient, component of the formulation or other PCSK9s
Repatha® (evolocumab)		
Leqvio® (inclisiran)		

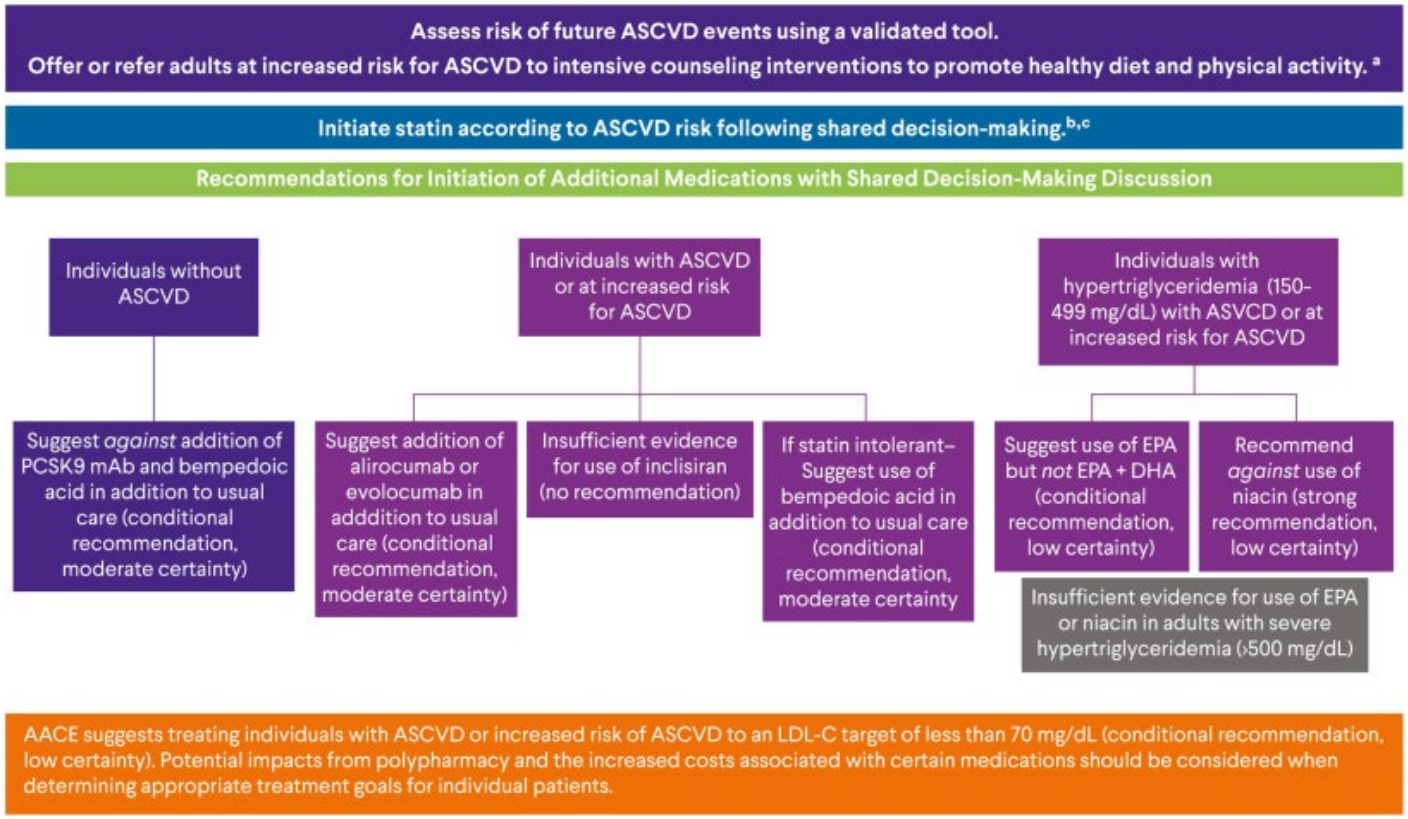
Warnings/Precautions

Medication	Warnings/Precautions
Praluent® (alirocumab)	Concerns related to adverse effects: • Hypersensitivity reactions, including some severe reactions requiring hospitalization (e.g. hypersensitivity vasculitis, angioedema), have been reported. Discontinue treatment and initiate supportive treatment in patients who develop serious allergic reaction. Other hypersensitivity reactions, including pruritus, rash, and urticaria, have been reported.
Repatha® (evolocumab)	Concerns related to adverse effects: • Hypersensitivity reactions (e.g. angioedema, rash, urticaria) have been reported, some requiring discontinuation. Discontinue treatment and initiate supportive treatment in patients who develop signs/symptoms of serious allergic reaction; monitor until symptoms resolve. Dosage form specific issues: • Latex: The packaging (needle cap of prefilled syringe and autoinjector) may contain dry natural rubber, which is a derivative of latex.
Leqvio® (inclisiran)	N/A in the label

Practice Guidelines

Patel SB, Wyne KL, Afreen S, et al. American Association of Clinical Endocrinology Clinical Practice Guideline on Pharmacologic Management of Adults With Dyslipidemia. Endocr Pract. 2025;31(2):236-262. doi:10.1016/j.eprac.2024.09.016

Summary of Recommendations: Pharmacotherapy for Adults with Dyslipidemia to Prevent ASCVD Events



The 2025 updated recommendations for additional medications were developed using the GRADE framework focused on patient-important outcomes including mortality, ASCVD events, and treatment discontinuations. Current evidence does not show meaningful improvement in prediction of ASCVD risk with the addition of non-traditional risk factors (i.e. CAC score, ApoB, or Lp(a)) to the risk model. Shared decision-making should include a discussion of the benefits and harms of individual medications, costs, resource utilization, and access to healthcare. For specific recommendations related to use of statins, refer to the 2022 AACE Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan and the 2022 USPSTF Recommendation Statement on Statin Use for Primary Prevention of Cardiovascular Disease.[b,c]

[a] US Preventive Services Task Force. Behavioral Counseling Interventions to Promote a Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults Without Cardiovascular Disease Risk Factors: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2022;328(4):367–374. doi:10.1001/jama.2022.10951
[b] Blonde L, Umpierrez GE, Reddy SS, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan—2022 Update. *Endocrine Practice*. 2022;doi:10.1016/j.eprac.2022.08.002
[c] US Preventive Services Task Force. Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2022;328(8):746–753: https://doi.org/10.1001/jama.2022.13044

1. For primary prevention in adults with dyslipidemia, AACE recommends for the use of a validated tool or calculator to predict future risk of ASCVD events as part of shared decision-making around treatment. (Good practice statement, ungraded)
    - ASCVD risk assessment is a central component in person-centered management of dyslipidemia. However, there is limited utility in broad application in adding CAC scores, ApoB, and Lp(a) measurements. Additional testing may be considered for individuals at intermediate risk who understand the potential additional costs of testing and still value the risk information ascertained from using CAC score, ApoB, and/or Lp(a) to inform a treatment decision.
2. In adults with dyslipidemia who are on maximally tolerated statins and have ASCVD or are at increased risk for ASCVD but who are not at goal (LDL-C <70 mg/dL), AACE suggests for the use of evolocumab or alirocumab in addition to usual care. (Conditional recommendation, moderate certainty of evidence)
3. In adults with dyslipidemia who do not have ASCVD, AACE suggests against the use of evolocumab or alirocumab in addition to usual care. (Conditional recommendation, moderate certainty of evidence).
    i. There is currently no direct evidence comparing evolocumab to alirocumab; use of either monoclonal antibody may be considered.
    ii. Most trial participants were at increased risk for ASCVD or were being treated for secondary prevention. It is unclear if the benefits outweigh the harms for use of these agents in adults at lower risk for ASCVD.
    iii. The task force considered ASCVD risk to include individuals with known risk factors based on clinical judgment or validated risk assessment tool.
4. There is insufficient evidence to make a recommendation for or against the use of inclisiran in adults with dyslipidemia. (No recommendation, insufficient evidence)
    i. Overall, there were very few trials and cardiovascular events, preventing determination of the balance of potential benefits and harms for use of inclisiran in addition to usual care. Adequately powered longer-term cardiovascular outcomes trials are needed.
5. In adults with dyslipidemia who are statin intolerant and have ASCVD or are at increased risk for ASCVD, AACE suggests for the use of bempedoic acid in addition to usual care. (Conditional recommendation, moderate certainty of evidence)
6. In adults with dyslipidemia who do not have ASCVD and who may tolerate other lipid-lowering medications, AACE suggests against the use of bempedoic acid in addition to usual care. (Conditional recommendation, moderate certainty of evidence)
    i. Patients should be informed that while bempedoic acid may lead to a small reduction in myocardial infarction, there may be a risk of potential harms (gout, cholelithiasis, and tendon rupture); therefore, a shared decision-making approach that includes a discussion about the potential benefits and harms should guide the treatment choice.
    ii. There was substantial heterogeneity in the trial populations related to the use of other lipid-lowering medications, including some participants taking low-dose statins.
    iii. Evidence for primary prevention is limited. A secondary analysis from the largest trial showed a potential for benefit in primary prevention; however, the number of individuals was small, and all participants were at high risk for ASCVD.
7. In adults with hypertriglyceridemia (150-499 mg/dL) who have cardiovascular disease or who are at increased risk for ASCVD, AACE suggests for the use of EPA (IPE) in addition to statins. (Conditional recommendation, low certainty of evidence)
8. There is insufficient evidence to recommend for or against the use of EPA (IPE) in adults with severe hypertriglyceridemia (≥500 mg/dL). (No recommendation, insufficient evidence)

   i. Patients should be informed that while EPA monotherapy may lead to a small reduction in myocardial infarction, there may be a risk of potential harms (small increased risk of developing atrial fibrillation and major bleeding). Therefore, a shared decision-making approach that includes a discussion about the potential benefits and harms, should guide treatment choice.
   ii. Individuals with severe hypertriglyceridemia (≥500 mg/dL) were not included in any of the trials. In addition, the trials did not report effects of EPA or IPE monotherapy on pancreatitis.
9. In adults with hypertriglyceridemia (150-499 mg/dL) who have cardiovascular disease or are at increased risk for cardiovascular disease, AACE suggests against the use of EPA plus DHA in addition to statin therapy. (Conditional recommendation, low certainty of evidence)
10. There is insufficient evidence to recommend for or against the use of EPA plus DHA in adults with severe hypertriglyceridemia (≥500 mg/dL). (No recommendation, insufficient evidence)
   i. Patients should be informed that treatment with doses of ≥1.8 grams per day of EPA plus DHA resulted in no clinically meaningful reduction in cardiovascular events or mortality and that there may be a risk of potential harms (small increased risk of developing atrial fibrillation and major bleeding). Therefore, a shared decision-making approach including a discussion about the potential benefits and harms should guide treatment choice.
   ii. Individuals with severe hypertriglyceridemia (≥500mg/dL) were not included in any of the trials. Additionally, the trials did not report effects of EPA plus DHA on pancreatitis.
11. In adults with hypertriglyceridemia (150-499 mg/dL) who have ASCVD or are at increased risk for ASCVD, AACE recommends against the use of niacin in addition to usual care. (Strong recommendation, low certainty of evidence)
12. There is insufficient evidence to recommend for or against the use of niacin in adults with severe hypertriglyceridemia (≥500 mg/dL). (No recommendation, insufficient evidence)
   i. Niacin, in combination with statins, may lead to a trivial reduction in myocardial infarction, but there is a risk of serious potential harms (small to moderate increased risk of infection, bleeding, and hospitalization due to hyperglycemic events).
   ii. Combination drugs containing niacin and statin are no longer approved by the FDA.
   iii. Individuals with severe hypertriglyceridemia (≥500 mg/dL) were not included in any of the trials. In addition, the trials did not report effects of EPA (IPE) on pancreatitis.
13. In adults undergoing pharmacotherapy for dyslipidemia who have ASCVD or are at increased risk for ASCVD, AACE suggests for treatment to an LDL-C target of <70 mg/dL. (Conditional recommendation, low certainty of evidence)
   i. The 2017 recommendation for lower LDL-C treatment targets (<55 mg/dL) was informed by a single trial on statin plus ezetimibe. Subsequent meta-analyses of numerous trials and multiple types of agents did not show a difference in cardiovascular events or mortality.
   ii. Clinicians should engage patients in shared decision-making including the trivial to small benefits and trivial adverse effects, costs, patient preferences, and impact on equity with lower treatment targets.

Abbreviations: AACE = American Association of Clinical Endocrinology; ApoB = apolipoprotein B; ASCVD = atherosclerotic cardiovascular disease; CAC = coronary artery calcium; DHA = docosahexaenoic acid; EPA = eicosapentaenoic acid; FDA = U.S. Food and Drug Administration; IPE = icosapent ethyl; Lp(a) = lipoprotein a; LDL-C = low-density lipoprotein cholesterol.

Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019 Jun 18; 139(25): e1082–e1143. doi: 10.1161/CIR.0000000000000625

Recommendations for Statin Therapy Use in Patients with ASCVD		
COR	LOE	Recommendations
I	A	In patients who are 75 years of age or younger with clinical ASCVD,* high-intensity statin therapy should be initiated or continued with the aim of achieving a 50% or greater reduction in LDL-C levels
I	A	In patients with clinical ASCVD in whom high-intensity statin therapy is contraindicated or who experience statin-associated side effects, moderate-intensity statin therapy should be initiated or continued with the aim of achieving a 30% to 49% reduction in LDL-C levels.
I	B-NR	In patients with clinical ASCVD who are judged to be very high risk and considered for PCSK9 inhibitor therapy, maximally tolerated LDL-C lowering therapy should include maximally tolerated statin therapy and ezetimibe.
IIa	A	In patients with clinical ASCVD who are judged to be very high risk and who are on maximally tolerated LDL-C lowering therapy with LDL-C 70 mg/dL or higher (≥1.8 mmol/L) or a non–HDL-C level of 100 mg/dL or higher (≥2.6 mmol/L), it is reasonable to add a PCSK9 inhibitor following a clinician– patient discussion about the net benefit, safety, and cost.
IIa	B-R	In patients with clinical ASCVD who are on maximally tolerated statin therapy and are judged to be at very high risk and have an LDL-C level of 70 mg/dL or higher (≥1.8 mmol/L), it is reasonable to add ezetimibe therapy.
Value Statement: Low Value (LOE: B-NR)		At mid-2018 list prices, PCSK9 inhibitors have a low-cost value (>$150 000 per QALY) compared to good cost value (<$50 000 per QALY) (Section 7 provides a full discussion of the dynamic interaction of different prices and clinical benefit).
IIa	B-R	In patients older than 75 years of age with clinical ASCVD, it is reasonable to initiate moderate- or high-intensity statin therapy after evaluation of the potential for ASCVD risk reduction, adverse effects, and drug– drug interactions, as well as patient frailty and patient preferences.
IIa	C-LD	In patients older than 75 years of age who are tolerating high-intensity statin therapy, it is reasonable to continue high-intensity statin therapy after evaluation of the potential for ASCVD risk reduction, adverse effects, and drug-drug interactions, as well as patient frailty and patient preferences.
IIb	B-R	In patients with clinical ASCVD who are receiving maximally tolerated statin therapy and whose LDL-C level remains 70 mg/dL or higher (≥1.8 mmol/L), it may be reasonable to add ezetimibe
IIb	B-R	In patients with heart failure (HF) with reduced ejection fraction attributable to ischemic heart disease who have a reasonable life expectancy (3 to 5 years) and are not already on a statin because of ASCVD, clinicians may consider initiation of moderate-intensity statin therapy to reduce the occurrence of ASCVD events.

**Clinical atherosclerotic cardiovascular disease (ASCVD) includes acute coronary syndrome (ACS), those with history of myocardial infarction (MI), stable or unstable angina or coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), or peripheral artery disease (PAD) including aortic aneurysm, all of atherosclerotic origin.*

Recommendations for Primary Severe Hypercholesterolemia (LDL-C ≥ 190 mg/dL [≥4.9 mmol/L])		
COR	LOE	Recommendations
I	B-R	In patients 20 to 75 years of age with an LDL-C level of 190 mg/dL or higher (≥4.9 mmol/L), maximally tolerated statin therapy is recommended.
IIa	B-R	In patients 20 to 75 years of age with an LDL-C level of 190 mg/dL or higher (≥4.9 mmol/L) who achieve less than a 50% reduction in LDL-C while receiving maximally tolerated statin therapy and/ or have an LDL-C level of 100 mg/dL or higher (≥2.6 mmol/L), ezetimibe therapy is reasonable.
IIb	B-R	In patients 20 to 75 years of age with a baseline LDL-C level of 190 mg/dL or higher (≥4.9 mmol/L), who achieve less than a 50% reduction in LDL-C levels and have fasting TGs 300 mg/dL or lower (≤3.4 mmol/L), while taking maximally tolerated statin and ezetimibe therapy, the addition of a bile acid sequestrant may be considered.
IIb	B-R	In patients 30 to 75 years of age with heterozygous FH and with an LDL-C level of 100 mg/dL or higher (≥2.6 mmol/L) while taking maximally tolerated statin and ezetimibe therapy, the addition of a PCSK9 inhibitor may be considered.
IIb	C-LD	In patients 40 to 75 years of age with a baseline LDL-C level of 220 mg/dL or higher (≥5.7 mmol/L) and who achieve an on-treatment LDL-C level of 130 mg/ dL or higher (≥3.4 mmol/L) while receiving maximally tolerated statin and ezetimibe therapy, the addition of a PCSK9 inhibitor may be considered.
Value Statement: Uncertain Value (B-NR)		Among patients with FH without evidence of clinical ASCVD taking maximally tolerated statin and ezetimibe therapy, PCSK9 inhibitors provide uncertain value at mid2018 US list prices.

Recommendations for Patients with Diabetes Mellitus		
COR	LOE	Recommendations
I	A	In adults 40 to 75 years of age with diabetes mellitus, regardless of estimated 10-year ASCVD risk, moderate-intensity statin therapy is indicated.
IIa	B-NR	In adults 40 to 75 years of age with diabetes mellitus and an LDL-C level of 70 to 189 mg/dL (1.7 to 4.8 mmol/L), it is reasonable to assess the 10-year risk of a first ASCVD event by using the race and sex-specific PCD to help stratify ASCVD risk.
IIa	B-R	In adults with diabetes mellitus who have multiple ASCVD risk factors, it is reasonable to prescribe high-intensity statin therapy with the aim to reduce LDL-C levels by 50% or more.
IIa	B-NR	In adults older than 75 years of age with diabetes mellitus and who are already on statin therapy, it is reasonable to continue statin therapy.
IIb	C-LD	In adults with diabetes mellitus and 10-year ASCVD risk of 20% or higher, it may be reasonable to add ezetimibe to maximally tolerated statin therapy to reduce LDL-C levels by 50% or more.
IIb	C-LD	In adults older than 75 years with diabetes mellitus, it may be reasonable to initiate statin therapy after a clinician–patient discussion of potential benefits and risks.
IIb	C-LD	In adults 20 to 39 years of age with diabetes mellitus that is either of long duration (≥10 years of type 2 diabetes mellitus, ≥20 years of type 1 diabetes mellitus), albuminuria (≥30 mcg of albumin/mg creatinine), estimated glomerular filtration rate (eGFR) less than 60

		mL/min/1.73 m2, retinopathy, neuropathy, or ankle-brachial index (ABI; <0.9), it may be reasonable to initiate statin therapy.

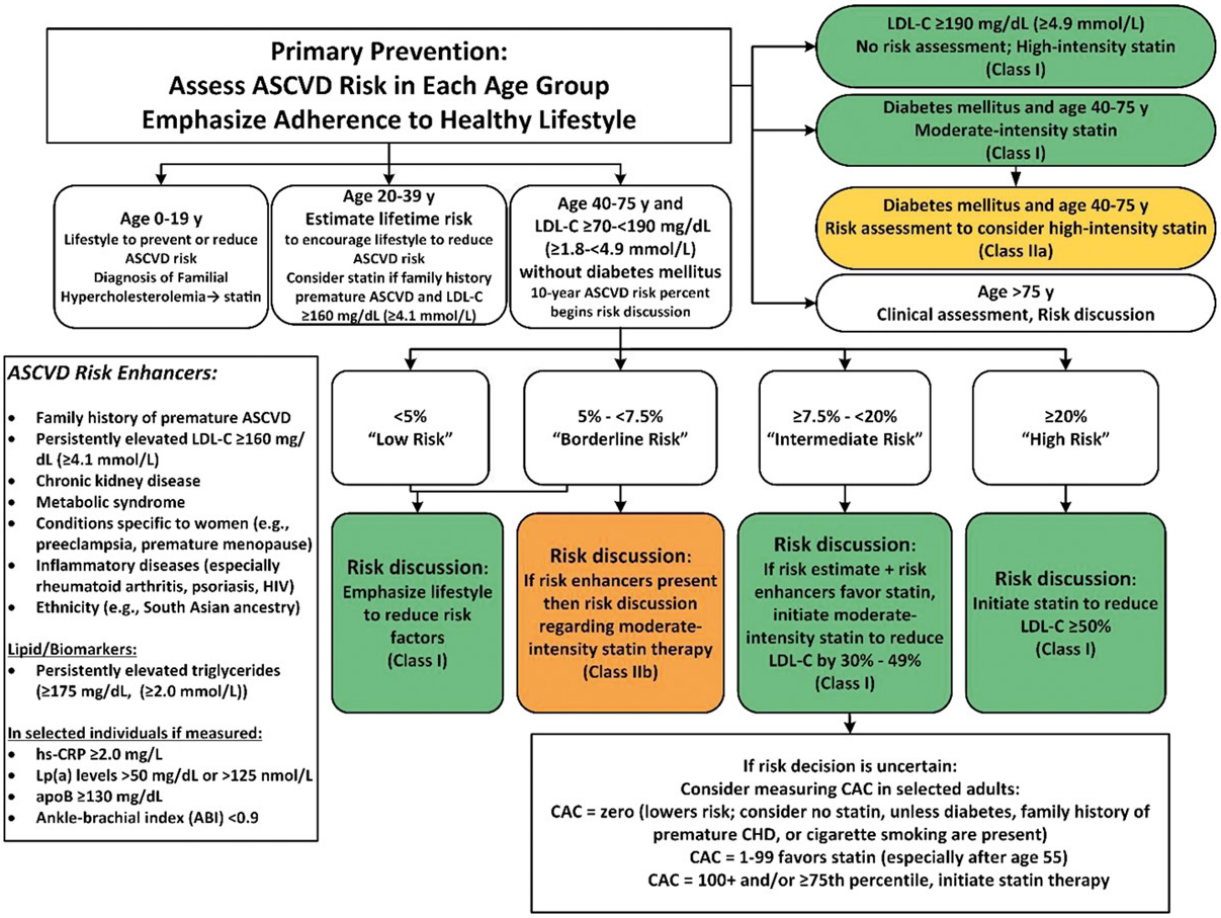
Primary Prevention Recommendations for Adults 40 to 75 years of Age with LDL Levels 70 to 189 mg/dL (1.7 to 4.8 mmol/L)		
COR	LOE	Recommendations
I	A	In adults at intermediate-risk, statin therapy reduces risk of ASCVD, and in the context of a risk discussion, if a decision is made for statin therapy, a moderate-intensity statin should be recommended.
I	A	In intermediate-risk patients, LDL-C levels should be reduced by 30% or more, and for optimal ASCVD risk reduction, especially in high-risk patients, levels should be reduced by 50% or more.
I	B-NR	For the primary prevention of clinical ASCVD* in adults 40 to 75 years of age without diabetes mellitus and with an LDL-C level of 70 to 189 mg/dL (1.7 to 4.8 mmol/L), the 10-year ASCVD risk of a first “hard” ASCVD event (fatal and nonfatal MI or stroke) should be estimated by using the race- and sex-specific PCE, and adults should be categorized as being at low risk (<5%), borderline risk (5% to <7.5%), intermediate risk (≥7.5% to <20%), and high-risk (≥20%).
I	B-NR	Clinicians and patients should engage in a risk discussion that considers risk factors, adherence to healthy lifestyle, the potential for ASCVD risk-reduction benefits, and the potential for adverse effects and drug–drug interactions, as well as patient preferences, for an individualized treatment decision.
IIa	B-R	In intermediate-risk adults, risk-enhancing factors favor initiation or intensification of statin therapy.
IIa	B-NR	In intermediate-risk or selected borderline-risk adults, if the decision about statin use remains uncertain, it is reasonable to use a CAC score in the decision to withhold, postpone or initiate statin therapy.
IIa	B-NR	In intermediate-risk adults or selected borderline-risk adults in whom a CAC score is measured for the purpose of making a treatment decision, AND • If the coronary calcium score is zero, it is reasonable to withhold statin therapy and reassess in 5 to 10 years, as long as higher risk conditions are absent (diabetes mellitus, family history of premature CHD, cigarette smoking); • If CAC score is 1 to 99, it is reasonable to initiate statin therapy for patients ≥55 years of age; • If CAC score is 100 or higher or in the 75th percentile or higher, it is reasonable to initiate statin therapy.
IIb	B-R	In intermediate-risk adults who would benefit from more aggressive LDL-C lowering and in whom high-intensity statins are advisable but not acceptable or tolerated, it may be reasonable to add a non-statin drug (ezetimibe or bile acid sequestrant) to a moderate-intensity statin.
IIb	B-R	In patients at borderline risk, in risk discussion, the presence of risk-enhancing factors may justify initiation of moderate-intensity statin therapy.

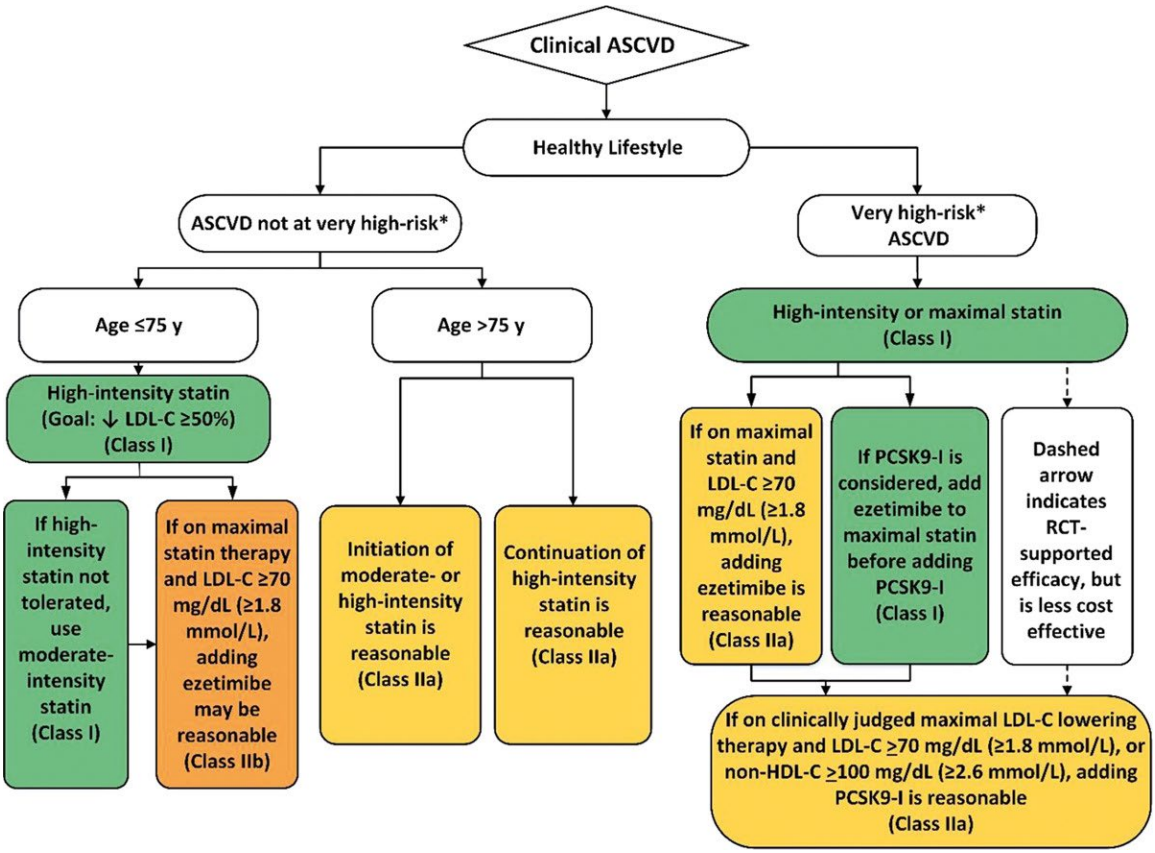
**Definition of clinical ASCVD includes acute coronary syndrome (ACS), those with history of myocardial infarction (MI), stable or unstable angina or coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), or peripheral artery disease (PAD) including aortic aneurysm, all of atherosclerotic origin.*

Recommendations for Older Adults		
COR	LOE	Recommendations
IIb	B-R	In adults 75 years of age or older with an LDL-C level of 70 to 189 mg/dL (1.7 to 4.8 mmol/L), initiating a moderate-intensity statin may be reasonable.
IIb	B-R	In adults 75 years of age or older, it may be reasonable to stop statin therapy when functional decline (physical or cognitive), multimorbidity, frailty, or reduced life expectancy limits the potential benefits of statin therapy.
IIb	B-R	In adults 76 to 80 years of age with an LDL-C level of 70 to 189 mg/dL (1.7 to 4.8 mmol/L), it may be reasonable to measure CAC to reclassify those with a CAC score of zero to avoid statin therapy

Recommendations for Children and Adolescents		
COR	LOE	Recommendations
I	A	In children and adolescents with lipid disorders related to obesity, it is recommeded to inteinsify lifestyle therapy, including moderate caloric restrion and regular aerobic physical exercise.
I	B-NR	In children and adolescents with lipid abnormalities, lifestyle counseling is beneficial for lowering LDL-C.
IIa	B-R	In children and adolescents 10 years of age or older with an LDL-C level persistently 190 mg/dL or higher (≥4.9 mmol/L) or 160 mg/dL or higher (4.1 mmol/L) with a clinical presentation consistent with FH (see Section 4.2.) and who do not respond adequately with 3 to 6 months of lifestyle therapy, it is reasonable to initiate statin therapy.
IIa	B-NR	In children and adolescents with a family history of either early CVD* or significant hypercholesterolemia,† it is reasonable to measure a fasting or nonfasting lipoprotein profile as early as age 2 years to detect FH or rare forms of hypercholesterolemia.
IIa	B-NR	In children and adolescents found to have moderate or severe hypercholesterolemia, it is reasonable to carry out reverse-cascade screening of family members, which includes cholesterol testing for first-, second-, and when possible, third-degree biological relatives, for detection of familial forms of hy percholesterolemia.
IIa	C-LD	In children and adolescents with obesity or other metabolic risk factors, it is reasonable to measure a fasting lipid profile to detect lipid disorders as components of the metabolic syndrome.
IIb	B-NR	In children and adolescents without cardiovascular risk factors or family history of early CVD, it may be reasonable to measure a fasting lipid profile or nonfasting non HDL-C once between the ages of 9 and 11 years, and again between the ages of 17 and 21 years, to detect moderate to severe lipid abnormalities.

**Family history of early CVD is defined here as MI, documented angina, or atherosclerosis by angiography in parents, siblings, grandparents, aunts, or uncles (<55 years of age for men, <65 years of age for women).*
†TC ≥240 mg/dL (≥6.2 mmol/L), LDL-C ≥190 mg/dL (≥4.9 mmol/L), non–HDL-C ≥220 mg/dL (≥5.7 mmol/L), or known primary hypercholesterolemia.





Recommendation Definitions

Level (Quality) of Evidence† (LOE)	Definition
A	High-quality evidence† from more than 1 randomized controlled trial (RCT) Meta-analyses of high quality RCTs One or more RCTs corroborated by high-quality registry studies
B-R (Randomized)	Moderate-quality evidence† from 1 or more RCTs Meta-analyses of moderate quality RCTs
B-NR (Non-randomized)	Moderate-quality evidence† from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies Meta-analyses of such studies
C-LD (Limited Data)	Randomized or nonrandomized observational or registry studies with limitations of design or execution Meta-analyses of such studies Physiological or mechanistic studies in human subjects
C-EO (Expert Opinion)	Consensus of expert opinion based on clinical experience

Class (Strength) of Recommendation (COR)	Definition
I	Strong; Benefit >>> Risk
IIa	Moderate; Benefit >> Risk
IIb	Weak; Benefit > Risk
III: No Benefit	Moderate; Benefit = Risk
III: Harm	Strong; Risk > Benefit

COR and LOE are determined independently (any COR may be paired with any LOE).
A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.
† The method of assessing quality is evolving, including the application of standardized, widely used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

Clinical Trials/Systematic Reviews/Meta-Analyses

Citation	Design	Endpoints
Robinson JG, et al. Efficacy and safety of alirocumab in reducing lipids and cardiovascular events ODYSSEY LONG TERM. N Engl J Med. 2017; 372(16): 1489-1499	Phase III randomized, placebo controlled, double-blind trial enrolled 2,341 participants. Randomized 2:1 to receive either alirocumab 150 mg every 2 weeks for 78 weeks (n = 1553)or placebo every 2 weeks for 78 weeks (n = 788) Inclusion Criteria: Adults ≥ 18 years of age, diagnosis of HeFH or established coronary heart disease or coronary heart disease risk equivalent, LDL-C ≥ 70 mg/dL, receiving high dose statin therapy or maximally tolerated dose with or without other lipid-lowering therapy, lipid-lowering regimen was continued through study Exclusion Criteria: Currently taking a statin that is not simvastatin, atorvastatin, or rosuvastatin, Recent MI, unstable angina leading to hospitalization, uncontrolled cardiac arrhythmia, CABG, PCI, carotid surgery or stenting, cerebrovascular accident, transient ischemic attack, endovascular procedure or surgical intervention for peripheral vascular disease. Plans to undergo PCI, CABG, carotid or peripheral revascularization, History of New York Heart Association (NYHA) Class III or IV heart failure, homozygous FH, hemorrhagic stroke, cancer, HIV, SBP >180 mmHg or DBP >110 mmHg, Use of systemic corticosteroids, HRT	**Primary:** Percentage change in calculated LDL cholesterol level from baseline to week 24, analyzed with the use of an intention-to-treat approach. **Secondary:** Safety outcomes: adverse events, including symptoms, laboratory abnormalities, vital-sign abnormalities, electrocardiographic abnormalities, and adjudicated cardiovascular events, that occurred after the first injection and up to 10 weeks after the last injection

Results:

Primary:

- Percentage change from baseline to week 24: -61.0 ± 0.7 in the alirocumab group compared with 0.8 ± 1.0; 95% CI -64.3 to -59.4 p < 0.001

Safety:

- Serious adverse event: 290 patients (18.7%) in the alirocumab group compared with 154 patients (19.5%) in the placebo group (p=0.66)
- Death from coronary heart disease, including death from unknown cause: 4 patients in the alirocumab group (03%) compared with 7 patients (0.9%) in the placebo group (p = 0.26)
- Nonfatal myocardial infarction: 14 patients (0.9%) in the alirocumab group compared with 18 patients (2.3%) in the placebo group (p=0.01)
- Fatal or nonfatal ischemic stroke: 9 patients (0.6%) in the alirocumab group compared with 2 patients (0.3%) in the placebo group (p=0.35)
- Unstable angina requiring hospitalization: 0 patients in the alirocumab group compared with 1 patient (0.1%) in the placebo group (p=0.34)

- Congestive heart failure requiring hospitalization: 9 patients (0.6%) in the alirocumab group compared with 3 patients (0.4%) in the placebo group (p=0.76)
- Ischemia-driven coronary revascularization procedure: 48 patients (3.1%) in the alirocumab group compared with 24 (3.0%) in the placebo group (p=1)

Conclusion: The addition of alirocumab as compared with placebo reduced LDL-C level by an additional 62 percent in high-risk patients when added to statin therapy at the maximum tolerated dose, with or without other lipid-lowering therapy. The effect was consistent over 78 weeks of therapy.

Citation	Design	Endpoints
Bays H, et al. Alirocumab as add-on to atorvastatin versus other lipid treatment strategies: ODYSSEY OPTIONS I randomized trial. J Clin Endocrinol Metab. 2015;100(8):3140-3148.	Randomized, double-dummy, double-blind, multi-center trial enrolled 355 participants. Subjects on a baseline atorvastatin 20 mg daily regimen (n=169) were randomized to: Alirocumab 75 mg SC every 2 weeks add-on therapy; Ezetimibe 10 mg daily add-on therapy; Doubling of the dose of atorvastatin dose to 40 mg daily Subjects on a baseline atorvastatin 40 mg daily regimen (n=186) were randomized to: Alirocumab 75 mg SC every 2 weeks add-on therapy; Ezetimibe 10 mg daily add-on therapy; Doubling of the dose of atorvastatin to 80 mg daily; Switching to rosuvastatin 40 mg daily; Alirocumab dose was increased to 150 mg every 2 weeks if the week 8 LDL level was above the prespecified goal Inclusion criteria: Adults with very high CVD risk and LDL ≥ 70 mg/dL or at a high risk and LDL ≥ 100 mg/dL and baseline statin regimen of atorvastatin 20 mg/day Exclusion criteria: Concomitant treatment with other statins, ezetimibe, fibrates (other than fenofibrate), and red yeast rice products.	Primary endpoint: ▪ Percentage change in LDL from baseline to week 24 in the ITT analysis Secondary endpoints: ▪ Percent change in other lipid parameters ▪ Percentage of subjects achieving the protocol-defined LDL goal (i.e.., < 100 mg/dL for high-risk subjects and < 70 mg/dL for very high-risk subjects) • Percentage of subjects reaching LDL < 70 mg/dL at week 24 in both ITT and on-treatment analyses

Results:

Primary: Among atorvastatin 20 and 40 mg regimens respectively, add-on alirocumab reduced LDL at week 24 by 44.1% and 54% (p<0.001 vs all comparators); add-on ezetimibe 20.5% and 22.6%; doubling of atorvastatin dose 5% and 4.8%; and switching to rosuvastatin 21.4%

Secondary: For subjects receiving alirocumab added to atorvastatin 20 and 40 mg, the combined proportion of subjects achieving protocol-defined LDL goals of < 70 mg/dL and <100 mg/dL, respectively, at week 24, was > 80%

Achievement of the LDL goal of < 70 mg/dL was achieved by 77% to 79% of subjects in the alirocumab add-on groups Alirocumab reduced apo B and non-HDL from baseline to week 24 vs all comparators regardless of background atorvastatin regimen, and significantly reduced lipoprotein a when compared with all comparators on a background of atorvastatin 40 mg (p<0.001) **Conclusion:** Adding alirocumab to atorvastatin produced significantly greater LDL reduction vs adding ezetimibe, doubling the atorvastatin dose, or switching to rosuvastatin.		
Citation	**Design**	**Endpoints**
Farnier M, et al. Efficacy and safety of adding alirocumab to rosuvastatin versus adding ezetimibe or doubling the rosuvastatin dose in high cardiovascular-risk patients: the ODYSSEY OPTIONS II randomized trial. Atherosclerosis. 2016;244:138-146	Randomized, double-dummy, double-blind, multi-center controlled trial enrolled 305 participants. After a 2 to 6 week screening period, patients were then randomized to: add-on therapy with alirocumab 75 mg SC every 2 weeks; add-on therapy with ezetimibe 10 mg/day; or doubling of the rosuvastatin dose. Subjects also received SC or oral placebo as appropriate; the alirocumab dose could be increased to 150 mg SC every 2 weeks at week 12 under certain conditions Inclusion criteria: Adults with hypercholesterolemia at very high or high CV risk who were receiving rosuvastatin 10 (n=145) or 20 (n=160) mg/day for at least 4 weeks prior to screening Exclusion criteria: Concomitant treatment with other statins, fibrates, and red yeast rice products.	Primary endpoint: ▪ Percent change from baseline in LDL at week 24 in ITT population Secondary endpoints: ▪ Percent change in other lipid parameters • Proportion of very high and high CV risk patients reaching LDL < 70 mg/dL or <100 mg/dL at week 24
Results: Primary: In the ITT rosuvastatin 10 mg group, the addition of alirocumab significantly reduced LDL levels at week 24 as compared to the other treatments: -50.6% add-on alirocumab vs -14.4% add-on ezetimibe vs -16.3% doubling the rosuvastatin dose; p<0.0001 for both comparisons. Reductions in the ITT rosuvastatin 20 mg group were also seen: -36.3% add-on alirocumab vs -11% add-on ezetimibe vs -15.9% doubling the rosuvastatin dose; p=0.0136 for alirocumab vs ezetimibe and p=0.0453 for alirocumab vs doubling the rosuvastatin dose. However, the pre-specified threshold p value for these comparisons was 0.0125; therefore, both comparisons failed to reach statistical significance. Secondary: Proportion of patients at very high and high CV risk who reached a LDL < 70 mg/dL or < 100 mg/dL: rosuvastatin 10 mg group – 84.9% add-on alirocumab; 57.2% add-on ezetimibe (p=0.0007); 45% doubling the rosuvastatin dose (p<0.001) Proportion of patients at very high and high CV risk who reached a LDL < 70 mg/dL or < 100 mg/dL: rosuvastatin 20 mg group – 66.7% add-on alirocumab; 52.2% add-on ezetimibe (p=0.1177); 40.1% doubling the rosuvastatin dose (p=0.0022)		

Proportion of patients at very high and high CV risk who reached a LDL < 70 mg/dL: rosuvastatin 10 mg group – 77.8% add-on alirocumab; 43.1% add-on ezetimibe (p<0.0001); 31.3% doubling the rosuvastatin dose (p<0.0001) Proportion of patients at very high and high CV risk who reached a LDL < 70 mg/dL: rosuvastatin 20 mg group – 60.1% add-on alirocumab; 43.6% add-on ezetimibe (p=0.0657); 29.9% doubling the rosuvastatin dose (p=0.0006) Significant reductions in apo B, non-HDL, lipoprotein a were seen in the alirocumab add-on group as compared to comparators in the baseline rosuvastatin 10 mg regimen In the 20 mg baseline rosuvastatin group, decreases in apo B, non-HDL, and lipoprotein were seen in the alirocumab group as compared to add-on ezetimibe or doubling the rosuvastatin dose. **Conclusion:** The addition of alirocumab to low dose rosuvastatin provided incremental LDL lowering as compared to adding ezetimibe or doubling the rosuvastatin dose in patients at very high or high CV risk.		
Citation	**Design**	**Endpoints**
Cannon CP, et al. Efficacy and safety of alirocumab in high cardiovascular risk patients with inadequately controlled hypercholesterolemia on maximally tolerated doses of statins: the ODYSSEY COMBO II randomized controlled trial. Eur Heart J. 2015;36(19):1186-1194.	Randomized, double-blind, double-dummy, multi-centered trial enrolled 720 participants. Participants were randomized following a 3 week screening period: Alirocumab 75 mg SC every 2 weeks plus oral placebo daily (n=479) Ezetimibe 10 mg daily plus SC placebo every 2 weeks (n=241) Alirocumab dose was increased to 150 mg every 2 weeks if the week 8 LDL ≥ 70 mg/dL Inclusion criteria: Hypercholesterolemia and established CHD or CHD risk equivalents treated with a maximally tolerated dose of statin therapy or on a lower dose provided the reason for doing so was documented Exclusion criteria: Fasting serum TG > 4.5 mmol/L, currently on statin that is not simvastatin atorvastatin, or rosuvastatin taken at a daily registered dose, use of concomitant ezetimibe, omega-3 fatty acid (at doses ≥ 1000 mg daily), nicotinic acid, bile acid sequestrants, or red yeast rice products in past 4 week prior to screening; use of fibrates in prior 6 week before screening.	Primary endpoint: ▪ Percentage change in LDL from baseline to week 24 in the ITT analysis Secondary endpoints: ▪ Percentage change in LDL from baseline to week 24 in the on-treatment analysis and from baseline to week 12 for both the ITT and on-treatment analyses ▪ Percentage change in LDL from baseline to week 52 in the ITT analysis ▪ Changes in other lipoprotein markers • Percentage of subjects with LDL < 70 mg/dL
Results:		

Primary: LS mean percentage change in LDL from baseline to week 24 in the ITT analysis: -50.6% alirocumab vs -20.7% ezetimibe; p<0.0001 Secondary: LS mean percentage change in LDL from baseline to week 24 in on-treatment analysis: -52.4% alirocumab vs -21.8% ezetimibe; p<0.0001 Percentage of subjects with LDL < 70 mg/dL at week 24 (ITT analysis): 77% alirocumab vs 45.6% ezetimibe; p<0.0001 Alirocumab therapy was associated with significant improvements in apo B, lipoprotein A, non-HDL, and HDL (all p<0.0001) at week 24 as compared to ezetimibe No significant difference between groups was noted with regard to TG reduction Mean achieved LDL at week 24: 50 mg/dL alirocumab vs 81 mg/dL ezetimibe; this was maintained through week 52 Overall percentage of subjects who experienced at least 1 TEAE: 71.2% alirocumab vs 67.2% ezetimibe Percentage of subjects experiencing a serious AE: 18.8% alirocumab vs 17.8% ezetimibe Percentage of subjects experiencing TEAEs leading to treatment discontinuation: 7.5% alirocumab vs 5.4% ezetimibe **Conclusion:** Among subjects at high CV risk with inadequately controlled LDL, alirocumab resulted in significantly greater LDL reduction vs ezetimibe with a similar safety profile.		
Citation	**Design**	**Endpoints**
Kereiakes DJ, et al. Efficacy and safety of the proprotein convertase subtilisin/kexin type 9 inhibitor alirocumab among high cardiovascular risk patients on maximally tolerated statin therapy: the ODYSSEY COMBO I study. Am Heart J. 2015;169(6):906-915.	Phase III randomized, double-blind, placebo-controlled, multi-center trial enrolled 316 participants. Participants were randomized to either alirocumab 75 mg SC every 2 weeks (n=209); Placebo (n=107) If LDL ≥ 70 mg/dL at week 8, alirocumab was increased to 150 mg SC every 2 weeks starting at week 12 All subjects received a stable, maximally tolerated statin dose with or without other lipid lowering therapy Inclusion criteria: Adult patients (≥18 years of age) with HeFH or established coronary heart disease or a coronary heart disease risk equivalent LDL cholesterol level of 70 mg/dL or more. Receiving either high-dose statin therapy or statin therapy at the maximum tolerated dose; this lipid-lowering regimen was continued throughout the study.	Primary endpoint: ▪ Percentage change in LDL from baseline to week 24 in ITT analysis Secondary endpoints: ▪ Percentage change in LDL from baseline to week 24 in on-treatment analysis ▪ Percentage changes in other lipid parameters ▪ Percentage of subjects achieving a LDL < 70 mg/dL

	Exclusion criteria: Currently taking a statin that is not simvastatin, atorvastatin, or rosuvastatin. Daily doses above atorvastatin 80 mg, rosuvastatin 40 mg or simvastatin 40 mg (except for patients on simvastatin 80 mg for more than one year, who are eligible). Use of fibrates other than fenofibrate within 6 weeks prior to screening visit	

Results:

Primary: Mean percentage change in LDL from baseline to week 24 in the ITT analysis: -48.2% alirocumab vs -2.3% placebo; p<0.0001

Secondary:

Mean percentage change in LDL from baseline to week 24 in on-treatment analysis: -50.7% alirocumab vs -0.8% placebo; p<0.0001

Percentage of subjects achieving LDL < 70 mg/dL at week 24 in ITT analysis: 75% vs 9%; p<0.0001

With alirocumab therapy significant improvements in non-HDL, apo B, TC, and lipoprotein a were noted as compared to placebo at week 24 (p<0.0001)

No significant change in TG levels was seen

Alirocumab was associated with a significant increase in HDL vs placebo (3.5% vs -3.8%; p<0.0001)

The incidence of TEAEs and serious TEAEs was similar between treatment groups

TEAEs leading to death or study drug discontinuation were uncommon in both groups

A total of 13 alirocumab-treated subjects had a positive response for the anti-alirocumab antibody

Conclusion: Alirocumab therapy was associated with a significantly greater LDL reduction and a greater percentage of subjects achieving LDL goals as compared to placebo. The frequency of AEs was similar between alirocumab and placebo.

Citation	Design	Endpoints
Schwartz GG, Steg PG, Szarek M, et al. Alirocumab and Cardiovascular Outcomes after Acute Coronary Syndrome. N Engl J Med. 2018 Nov 29;379(22):2097-2107. doi: 10.1056/NEJMoa1801174. Epub 2018 Nov 7.	Phase III, randomized (1:1), double-blind, placebo-controlled N=18,924 Arms: alirocumab 75 mg to 150 mg SQ every 2 weeks or placebo, each with concurrent lipid modifying therapy (LMT) (maximally tolerated atorvastatin or rosuvastatin +/- other LMT)	**Primary:** • % of observed participants with major adverse cardiovascular event (MACE), a composite of death from coronary heart disease (CHD), nonfatal MI, fatal or nonfatal ischemic stroke, or unstable angina requiring hospitalization **Secondary:** • Any CHD or CV event • Composite of death from any cause

		• Individual components of the primary endpoint (e.g. non-fatal MI, non-fatal ischemic stroke)

Results:

Primary:

- % of observed participants with MACE composite endpoint – 903 patients (9.5%) in the alirocumab group and in 1052 patients (11.1%) in the placebo group (hazard ratio, 0.85; 95% confidence interval [CI], 0.78 to 0.93; P<0.001)

Secondary:

- Any CHD or CV event, composite of death from any cause, non-fatal MI, non-fatal ischemic stroke – risks were lower among patients treated with alirocumab than among those who received placebo (no p-values reported)
- Composite death from any cause – 334 patients (3.5%) in the alirocumab group and 392 patients (4.1%) in the placebo group died (hazard ratio, 0.85; 95% CI, 0.73 to 0.98) (no p-value reported)

Conclusion: The authors concluded "Among patients who had a previous acute coronary syndrome and who were receiving high intensity statin therapy, the risk of recurrent ischemic cardiovascular events was lower among those who received alirocumab than among those who received placebo."

Citation	Design	Endpoints
Sabatine MS, et al. Evolocumab and clinical outcomes in patients with cardiovascular disease FOURIER. N Engl J Med. 2017; 376(18): 1713-1722.	Phase III randomized, double-blind, placebo-controlled trial enrolled 27,564 participants. Participants were randomized 1:1 to receive either • Evolocumab (140 mg every 2 weeks or 420 mg every month according to patient preference) [n = 13,784] • Matching placebo [n=13,780] Inclusion criteria: Men and women aged 40 – 85 years of age, Clinical evident atherosclerotic cardiovascular disease (history of MI, nonhemorrhagic stroke, or symptomatic peripheral artery disease), LDL-C ≥70 mg/dL, Non-HDL-C ≥100 mg/dL , Taking optimized regimen of lipid-lowering therapy (high intensity statin preferred, must be at least atorvastatin 20 mg or equivalent with or without ezetimibe) Exclusion Criteria: Patients with prevalent diabetes were excluded.	**Primary:** • Major cardiovascular events, defined as the composite of cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization **Secondary:** • Composite of cardiovascular death, myocardial infarction, or stroke

Results:
Primary:
Cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization: occurred in 1344 patients (9.8%) in the evolocumab group compared with 1563 patients (11.9%) in the placebo (p<0.001)
Secondary:
Cardiovascular death, myocardial infarction, or stroke: occurred in 316 patients (5.9%) in the evolocumab group compared with 1013 patients (7.4%) in the placebo group (p<0.001)
Conclusion: Evolocumab lowered LDL-C levels by 59% from baseline compared with placebo. The addition of evolocumab to statin therapy significantly reduced the risk of cardiovascular events, with a 15% reduction in the risk of the primary composite end point of cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization and a 20% reduction in the risk of the more clinically serious key secondary end point of cardiovascular death, myocardial infarction, or stroke.

Citation	Design	Endpoints
Sabatine MS, et al. Efficacy and safety of evolocumab in reducing lipids and cardiovascular events OSLER-1 and OSLER-2. N Engl J Med. 2015;372(16):1500-1509.	OSLER-1 and -2 are longer-term, OL extension trials OSLER-1 included subjects from at least 1 of 5 phase 2 studies of evolocumab OSLER-2 included subjects from 1 of 7 phase 3 studies of evolocumab OSLER-1: Evolocumab 420 mg SC monthly OSLER-2: Evolocumab 140 mg SC every 2 weeks or 420 mg SC monthly (per patient choice) 4,465 subjects were included who had enrolled in and completed on of the 12 parent studies. Subjects randomized to evolocumab in the OSLER trials (n=2976) also received standard therapy. These subjects were compared to standard therapy alone (n=1489). Standard of care therapy in both groups was based on local guidelines for LDL treatment Inclusion Criteria: Participants had not had an AE that led to discontinuation of the study drug, did not have an unstable medical condition, and were not expected to need unblinded lipid measurements or adjustment of background	Primary endpoint: ▪ Incidence of AEs Secondary endpoints: ▪ Percent change in LDL level • Changes in other lipid parameters Incidence of CV events

	lipid-regulating therapy during the first 12 weeks of participation in the OSLER trials Exclusion Criteria: Participants could not have had an adverse event during the first 12 weeks.	

Results:
Primary: Incidence of AEs: 69.2% evolocumab vs 64.8% standard therapy
Serious AEs: 7.5% evolocumab and standard therapy
Neurocognitive AEs occurred rarely (<1%), but were reported more frequently in the evolocumab group
Secondary:
Percentage change in LDL at week 12: reduction in LDL of 61% with evolocumab as compared to standard therapy (p<0.001)
Percentage of subjects with LDL ≤ 100 mg/dL at week 12: 90.2% evolocumab vs 26% standard therapy
Percentage of subjects with LDL ≤ 70 mg/dL at week 12: 73.6% evolocumab vs 3.8% standard therapy
Significant reductions were also seen in non-HDL (52%), apo B (47.3%), TC (36.1%), TGs (12.6%), and lipoprotein a (25.5%) with evolocumab as compared to standard therapy (p<0.001 for all comparisons)
Evolocumab also significantly improved HDL (7%) and apo A1 (4.2%); p<0.001 for both comparisons
Subjects in the evolocumab group had a significantly lower rate of all CV events compared to standard therapy (Kaplan-Meier estimates at 1 year, 0.95% and 2.18%, respectively; HR 0.47; 95% CI: 0.28 to 0.78; p=0.003)
Conclusion: During approximately 1 year of therapy, evolocumab plus standard therapy was associated with a significant reduction in LDL levels and reduced incidence of CV events as compared to standard therapy alone.

Citation	Design	Endpoints
Blom DJ, et al. A 52-week placebo-controlled trial of evolocumab in hyperlipidemia DESCARTES trial. N Engl J Med. 2014;370(19):1809-1819.	Double-blind, placebo controlled, randomized trial enrolled 905 participants. During a 4 to 12 week run-in, OL lipid-lowering therapy was given and patients were counseled on an appropriate diet. Eligible patients were stratified to 1 of 4 lipid-lowering regimens: Diet alone (n=112); Atorvastatin 10 mg daily (n=385); Atorvastatin 80 mg daily (n=219); Atorvastatin 80 mg daily + ezetimibe 10 mg daily (n=189). Patients with an LDL of ≥ 75 mg/dL were then randomized in each group to: Evolocumab 420 mg SC every 4 weeks (n=599); Placebo (n=302) Inclusion Criteria: Adults (18 to 75 years of age) with LDL ≥75 mg/dL and a fasting TG ≤ 400 mg/dL	Primary endpoint: ▪ Percentage change in LDL from baseline at week 52 Secondary endpoints: ▪ Absolute change from baseline in LDL at week 52 ▪ Percentage change from baseline in LDL at week 12 ▪ Percentage of patients with LDL < 70 mg/dL at week 52

	Exclusion Criteria: Heart failure, recent myocardial infarction, recent or planned revascularization procedure, uncontrolled hypertension (HTN), hyperthyroidism or hypothyroidism, moderate-to-severe renal dysfunction, and active liver disease or hepatic dysfunction	▪ Changes in other lipoprotein markers endpoints •
Results: Primary: LS mean percent change in LDL from baseline at week 52: evolocumab -57%; p<0.001 vs placebo Secondary: LS mean percent change in LDL from baseline at week 52: diet alone -55.7%, diet + atorvastatin 10 mg -61.6%, diet + atorvastatin 80 mg -56.8%, diet + atorvastatin 80 mg + ezetimibe -48.5%; p<0.0001 for all vs placebo LS mean percent change in LDL from baseline at week 12: evolocumab -57.5% Percentage of subjects with LDL < 70 mg/dL at week 52: 82.3% evolocumab vs 6.4% placebo Evolocumab therapy resulted in significant LS mean percent reductions from baseline in apo B, non-HDL, lipoprotein(a), and TGs as compared with placebo Significant LS mean increases in HDL and apo A1 with evolocumab as compared to placebo were noted (p<0.001 for both) Overall incidence of AEs was similar between groups: 74.8% evolocumab vs 74.2% placebo. Serious AEs occurred in 5.5% of patients administered evolocumab vs 4.3% placebo. AEs leading to therapy discontinuation were more common with evolocumab (2.2% vs 1%) **Conclusion:** Alirocumab, when added to diet alone, low-dose atorvastatin, or high-dose atorvastatin with or without ezetimibe, significantly reduced LDL in patients with a range of CV risks.		
Citation	**Design**	**Endpoints**
Koren MJ, et al. A 52-week placebo-controlled trial of evolocumab in hyperlipidemia MENDEL-2 trial. N Engl J Med. 2014;370(19):1809-1819.	Double-blind, placebo-controlled, multi-center trial enrolled 615 adults who were randomized to receive evolocumab140 mg SC biweekly or 420 mg SC monthly (n=306); ezetimibe (n=154); placebo (n=155) Inclusion Criteria: Adults (18 to 80 years of age) with LDL levels ≥ 100 mg/dL and < 190 mg/dL, TGs ≤ 400 mg/dL, and 10-year Framingham CHD risk scores ≤ 10% Exclusion Criteria: Heart failure, recent myocardial infarction, recent or planned revascularization, uncontrolled HTN, hyperthyroidism or hypothyroidism, moderate-to-severe renal dysfunction, active liver disease or hepatic dysfunction	Primary endpoint: ▪ Percentage change from baseline in LDL averaged at weeks 10 and 12 and at week 12 Secondary endpoints: ▪ Incidence of TEAEs ▪ Serious AEs ▪ Development of anti-evolocumab antibodies •
Results: Primary: Mean percentage decrease from baseline in LDL at week 12: 57% evolocumab, 0.1% placebo, 17.8% ezetimibe (p<0.001 for all comparisons)		

LDL percent changes from baseline for the mean of weeks 10 and 12 and the absolute mean LDL reductions were significant in all evolocumab groups as compared with placebo and ezetimibe (p<0.001) Secondary: For subjects given monthly evolocumab, the mean 12-week LDL reduction was 56.1% evolocumab, 1.3% placebo, and 18.6% ezetimibe (p<0.001 for all comparisons) Percentage of subjects achieving LDL < 70 mg/dL at weeks 10 and 12, respectively: 72% and 69% evolocumab, 0% and 1% placebo, and 2% and 1% ezetimibe Evolocumab significantly reduced apo B, lipoprotein a, non-HDL, and apoB:apoA1 levels (p<0.001) Significant HDL increases were seen with evolocumab (p<0.05) Serious AEs: 4 in the evolocumab group vs 1 each in the placebo and ezetimibe groups **Conclusion:** Evolocumab therapy resulted in significant LDL reductions compared with placebo or ezetimibe and was well tolerated.		
Citation	**Design**	**Endpoints**
Robinson JG, et al. Effect of evolocumab or ezetimibe added to moderate- or high-intensity statin therapy on LDL-C lowering in patients with hypercholesterolemia. JAMA. 2014;311(18):1870-1882.	Eligible subjects were initially randomized to OL: Moderate intensity statin: Atorvastatin10 mg daily; Rosuvastatin 5 mg daily High-intensity statin: Simvastatin 40 mg daily; Atorvastatin 80 mg daily; Rosuvastatin 40 mg daily After a 4 week lipid stabilization period, subjects taking rosuvastatin or simvastatin were then randomized to: Evolocumab 140 mg SC every 2 weeks; Matching placebo or Evolocumab 420 mg SC once monthly; Matching placebo Patients taking atorvastatin during stabilization were then randomized to: Evolocumab 140 mg SC every 2 weeks and oral placebo daily; Evolocumab 420 mg SC monthly and oral placebo daily; Placebo SC injection every 2 weeks and oral placebo daily or ezetimibe 10 mg daily; Placebo SC injection monthly and oral placebo daily or ezetimibe 10 mg daily Inclusion criteria: Subjects (18 to 80 years of age) with a screening LDL ≥ 150 mg/dL with no statin therapy, ≥ 100 mg/dL with nonintensive statin therapy, or ≥ 80 mg/dL with intensive statin therapy and fasting TGs ≥ 400 mg/dL Exclusion Criteria: NYHA class III or IV, or last known LVEF <30%, Uncontrolled serious cardiac arrhythmia ≤3 months prior to randomization, planned cardiac	Primary endpoint: ▪ Percentage change from baseline in LDL averaged at weeks 10 and 12 and at week 12 Secondary endpoints: ▪ Mean at weeks 10 and 12 and at week 12 for the change from baseline in LDL ▪ Percentage change from baseline in additional lipid parameters ▪ Proportion of subjects achieving LDL < 70 mg/dL

	surgery, type 1 diabetes, poorly controlled type2 diabetes SBP >160 mm Hg or DBP >100 mm Hg, bile acid–sequestering resins, fibrates or derivatives, red yeast rice, >200 mg/day niacin, or >1000 mg/day omega-3 fatty acids	

Results:

Primary: Evolocumab reduced LDL levels by 66% to 75% (every 2 weeks) and by 63% to 75% (monthly) vs placebo at the mean of weeks 10 and 12 in the moderate- and high-intensity statin-treated groups. LDL reductions at week 12 were comparable

Secondary:

In subjects treated with atorvastatin, the addition of ezetimibe resulted in LDL reductions from baseline of 17% to 24% vs addition of evolocumab every 2 weeks, which reduced LDL by 61% to 62% (treatment differences vs placebo and ezetimibe both p<0.001)

Addition of monthly evolocumab reduced LDL values by 62% to 65% from baseline (treatment differences vs placebo and ezetimibe both p<0.001)

For subjects administered a moderate-intensity statin, evolocumab every 2 weeks reduced LDL values from a baseline mean of 115 to 124 mg/dL to an on-treatment mean of 39 to 49 mg/dL; 88% to 94% achieved a LDL < 70 mg/dL

For subjects administered a moderate-intensity statin, evolocumab every month reduced LDL values from a baseline mean of 123 to 126 mg/dL to an on-treatment mean of 43 to 48 mg/dL; 86% to 90% achieved a LDL < 70 mg/dL

For subjects administered a high-intensity statin, evolocumab every 2 weeks reduced LDL values from a baseline mean of 89 to 94 mg/dL to an on-treatment mean of 35 to 38 mg/dL; 94% achieved a LDL < 70 mg/dL

For subjects administered a high-intensity statin, monthly evolocumab reduced LDL values from a baseline mean of 89 to 94 mg/dL to an on-treatment mean of 33 to 35 mg/dL; 93% to 95% achieved a LDL < 70 mg/dL

Evolocumab administered every 2 weeks and monthly resulted in significant reductions in non-HDL, apo B, and lipoprotein a for all statin groups

AEs occurred in 36% of evolocumab-treated subjects, 40% of ezetimibe-treated subjects, and 39% of placebo-treated subjects

Conclusion: Evolocumab therapy, added to moderate- or high-intensity statin therapy resulted in additional LDL lowering.

Citation	Design	Endpoints
Ray KK, Phil M, Wright RS, et al. Two Phase 3 Trials of Inclisiran in Patients with Elevated LDL Cholesterol. N Engl J Med. 2020 Apr 16;382(16):1507-1519. doi: 10.1056/NEJMoa1912387. Epub 2020 Mar 18.	Two phase III randomized (1:1), double-blind, placebo-controlled, parallel-group trials. Orion-10 (N=1561), Orion-11 (N=1617) Arms: Inclisiran 300 mg or placebo SQ days 1 and 90 then every 6 months Inclusion Criteria: adults with ASCVD (Orion-11 only – or an ASCVD risk equivalent [type 2 diabetes, familial hypercholesterolemia, or a 10-year risk of a cardiovascular event of ≥ 20% as assessed by the Framingham Risk Score for Cardiovascular Disease or equivalent]); LDL-C ≥ 70 mg/dL (1.8 mmol/L); TGs <	Primary Endpoints: • Percentage change in LDL-C from baseline to day 510 • The time-adjusted percentage change in LDL-C from baseline after day 90 and up to day 540 Secondary Endpoint:

	4.52 mmol/L (<400 mg/dL); receiving maximally tolerated statin (or documented intolerance to all doses of ≥ 2 statins) Exclusion Criteria: NYHA class IV HF, uncontrolled arrhythmia/HTN; active liver disease; recent treatment with PCSK9-directed mAbs	• Absolute change in LDL-C from baseline to day 510 • Time-adjusted absolute Change in LDL-C from baseline after day 90 and up to day 540 • Safety

Results:

Primary:

Orion-10:

- The percentage change in LDL: between-group difference of −52.3% (95% CI, −55.7 to −48.8; P<0.001).
- The time-adjusted change in LDL: between-group difference of −53.8% (95% CI, −56.2 to −51.3; P<0.001).

Orion-11:

- The percentage change in LDL: between-group difference of −49.9% (95% CI, −53.1 to −46.6; P<0.001).
- The time-adjusted change in LDL cholesterol level: between-group difference of −49.2% (95% CI, −51.6 to −46.8; P<0.001).

Secondary:

Orion-10:

- Absolute change in LDL cholesterol level at day 510: between group difference of −54.1 mg/dL (95% CI, −57.4 to −50.9 mg/dL; P<0.001).
- The time-adjusted absolute change in LDL level: between-group difference of −53.3 mg/dL (95% CI, −55.8 to −50.8 mg/dL; P<0.001).
- Adverse events:
  - Overall incidence: 73.5% of patients in the inclisiran group and 74.8% of patients in the placebo group
  - Serious: 22.4% of inclisiran group and 26.3% of placebo group; 1.5% of patients in the inclisiran group died compared to 1.4% of patients in the placebo group

Orion-11:

- Absolute change in LDL cholesterol level at day 510: between-group difference of −51.9 mg/dL (95% CI, −55.0 to −48.7 mg/dL; P<0.001).
- The time-adjusted absolute change in LDL level: between-group difference of −48.9 mg/dL (95% CI, −51.4 to −46.5 mg/dL; P<0.001).
- Adverse events:
  - Overall: 82.7% of patients in the inclisiran group and 81.5% of patients in the placebo group
  - Serious: 22.3% of inclisiran group and 22.5% of placebo group; 1.7% of patients in the inclisiran group died compared to 1.9% of patients in the placebo group

Conclusion: The authors concluded "Reductions in LDL cholesterol levels of approximately 50% were obtained with inclisiran, administered subcutaneously every 6 months. More injection-site adverse events occurred with inclisiran than with placebo."

Citation	Design	Endpoints
Raal FJ, Kallend D, Ray KK, et al. Inclisiran for the Treatment of Heterozygous Familial Hypercholesterolemia. N Engl J Med. 2020 Apr 16;382(16):1520-1530. doi: 10.1056/NEJMoa1913805. Epub 2020 Mar 18.	Phase III randomized (1:1), double-blind, placebo-controlled, multi-center trial N=482 Arms: inclisiran 300 mg SC or placebo on days 1, 90, 270, and 450. Inclusion criteria: Adult patients (≥18 years of age) with HeFH having LDL-C ≥ 100 mg/dL and fasting TG < 400 mg/dL at screening. Receiving maximally tolerated statin dose or having documented intolerance to all doses of at least 2 different statins; any lipid-lowering therapies (statin and/or ezetimibe) should be stable for ≥ 30 days with no plan for change during study duration. Exclusion criteria: Receiving PCSK9 mAb within 90 days of screening	**Primary:** • Percent change from baseline in LDL-C level at day 510 • Time-adjusted percent change from baseline in LDL-C between day 90 and 540 **Secondary:** • Mean absolute change from baseline in LDL-C at day 510 • Time- averaged observed difference in LDL-C from baseline between day 90 and 540 • Adverse events

Results:

Primary

Percentage change in LDL-C from baseline to day 510 (95% CI)

- Inclisiran: -39.7% (-43.7 to -35.7)
- Placebo: +8.2% (4.3 to 12.2)
- Between group difference: -47.9% (-53.5 to -42.3; P<0.001)

Time-averaged percentage change in LDL-C between day 90 and 540 (95% CI)

- Inclisiran: -38.1% (-41.1 to -35.1)
- Placebo: +6.2% (3.3 to 9.2)
- Between group difference: -44.3% (-48.5 to -40.1; P<0.001)

Secondary

Mean absolute change from baseline in LDL-C at day 510 (95% CI)

- Inclisiran: -59.0 mg/dL (-64.8 to -53.2)
- Placebo: +9.9 mg/dL (4.1 to 15.8)

- Between group difference: -68.9 mg/dL (-77.1 to -60.7; P<0.001)

Time-averaged observed difference in LDL-C between day 90 and 540

- Inclisiran: -56.9 mg/dL
- Placebo: +5.8 mg/dL
- Between group difference: -62.6 mg/dL (P<0.001)
- Adverse event (including serious adverse events) frequency was similar in the two groups.

Conclusion: Infrequent inclisiran dosing showed significantly lower levels of LDL-C than placebo in patients with HeFH with an acceptable safety profile.

Formulary Placement, Utilization and Cost Experience (07-01-2025 to 09-30-2025)

UTILIZATION HISTORY			COST		PRIOR AUTH HISTORY		FORMULARY PLACEMENT	
Medication	**Rx**	**Mbrs**	**Total**	**Avg/Rx**	**Total**	**Approved (%)**	**Current**	**Recommend**
PCSK9 Inhibitors								
Praluent Pen (alirocumab) 75 mg/mL, 150 mg/mL subcutaneous pen injector	4	1	$2,039.12	$509.78	0	0 (0%)	F-PA	No change
Repatha (evolocumab) SureClick 140 mg/mL subcutaneous pen injector	14	5	$7,724.23	$551.73	3	1 (33%)	F-PA	No change
Repatha (evolocumab) Syringe 140 mg/mL subcutaneous syringe	2	1	$798.92	$399.46	0	0 (0%)	F-PA	No change
Repatha (evolocumab) Pushtronex 420 mg/3.5 mL subcutaneous wearable injector	0	0	$0.00	$0.00	0	0 (0%)	F-PA	No change
Small Interfering RNA (siRNA) PCSK9 Inhibitors								
Leqvio (inclisiran) 284 mg/1.5 mL syringe	0	0	$0.00	$0.00	0	0 (0%)	NF	No change
TOTAL	**20**	**7**	**$10,562.27**	**$528.11**	**3**	**1 (33%)**		

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:

- Streamline criteria requirements based on new expanded indications for Repatha and Praluent. Label expansion includes adults at increased risk for major adverse cardiovascular events (MACE) due to uncontrolled LDL cholesterol and not just patients with established cardiovascular disease.
- Remove preferred NDCs from the criteria and add all NDCs to formulary since all are priced the same

PCSK-9 Monoclonal Antibodies (mAbs)	
Therapeutic Classes (AHFS)	PCSK9 Monoclonal Antibodies (mAbs)
Medications	Formulary, prior authorization • Repatha (evolocumab) ~~Preferred NDCs: 72511-0770-01, 72511-0750-01, 72511-0760-02, 72511-0760-01~~ • Praluent (alirocumab) ~~Preferred NDCs: 61755-0021-02, 61755-0020-02~~
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 cardiologist or a specialist in the treatment of lipid disorders.
Coverage Duration	**Initial Approval** 3 months **Later Approvals** 6 months If conditions are not met, the request will be sent to a clinical reviewer.
PA Review Criteria	**INITIAL AUTHORIZATION:** **For all requests** • Request is appropriate for member (e.g. age) as indicated in package labeling or standard of care guidelines • One of the following: ○ Provider indicates member's LDL-C is above goal OR ○ Genetic test submitted with request for diagnosis of familial hypercholesterolemia (FH only) • Patient has tried and failed simvastatin 40mg, atorvastatin 40mg-80mg, or rosuvastatin 20-40mg (consistently for 3 months via claim history or chart notes). If patient is not able to tolerate simvastatin, atorvastatin or rosuvastatin, documentation was provided that patient is taking another statin at the highest tolerated dose, or a medical reason was provided why the member is not able to use these therapies. • If prescriber indicates member is "statin intolerant", documentation was provided including description of the side effects, duration of therapy, "wash out", re-trial, and then change of agents. • Patient has tried and failed ezetimibe in combination with highest-tolerated intensity statin (if clinically appropriate) consistently for 3 months, OR, patient has an LDL-C that is >25% above goal LDL-C while adherent to treatment with highest-tolerated intensity statin (if clinically appropriate) consistently for 3 months

PCSK-9 Monoclonal Antibodies (mAbs)	

- Documentation was provided indicating provider has counseled member on smoking cessation and following a “heart healthy diet”.

~~Diagnosis of Familial Hypercholesterolemia (FH)~~

- ~~Member has a diagnosis of familial hypercholesterolemia, as evidenced by one of the following:~~
  - ~~Documentation provided, including two fasting lipid panel lab reports with abnormal baseline low-density lipoprotein (LDL) levels ≥190 for FH in adults or ≥160 for FH in children.~~
  - ~~Results of positive genetic testing for an LDL-C–raising gene defect (LDL receptor, apoB, or PCSK9)~~

~~Diagnosis of hyperlipidemia (Primary OR Secondary Prevention):~~

- ~~If the diagnosis is primary severe hyperlipidemia (i.e. baseline LDL ≥ 190 mg/dL)~~
  - ~~LDL remains ≥ 100 mg/dL despite maximally tolerated LDL-lowering therapy~~
- ~~If the diagnosis is secondary atherosclerotic cardiovascular disease (ASCVD) prevention~~
  - ~~The patient is “very high risk” (both of the following):~~
    - ~~(i.e. a history of multiple major ASCVD ***events*** or 1 major ASCVD event and multiple high-risk ***conditions***, see table below)~~

~~Major ASCVD Events~~	~~Recent ACS (within past 12 months)~~
	~~History of MI (other than recent ACS event above)~~
	~~History of ischemic stroke~~
	~~Symptomatic PAD~~
~~High-risk Conditions~~	~~Age ≥ 65 years~~
	~~Heterozygous familial hypercholesterolemia~~
	~~History of prior CABG or PCI intervention outside the major ASCVD event(s)~~
	~~DM~~
	~~HTN~~
	~~CKD (eGFR 15-59 mL/min/1.73 m2)~~
	~~Current smoker~~
	~~CHF~~

~~ACS – acute coronary syndrome; CABG – coronary artery bypass graft; CHF – congestive heart failure; CKD – chronic kidney disease; DM – diabetes mellitus; HTN – hypertension; MI – myocardial infarction; PAD – peripheral artery disease; PCI – percutaneous coronary intervention~~

    - ~~LDL remains ≥ 55 mg/dL or non-HDL (i.e. total cholesterol minus HDL) ≥ 85 mg/dL despite maximally tolerated LDL-lowering therapy~~
  - ~~The patient is not at very high risk:~~
    - ~~LDL remains ≥ 70 mg/dL or non-HDL (i.e. total cholesterol minus HDL) ≥ 100 mg/dL despite maximally tolerated LDL-lowering therapy~~

PCSK-9 Monoclonal Antibodies (mAbs)	
	~~If the above criteria are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request will be sent to a clinical reviewer~~. **REAUTHORIZATION CRITERIA FOR ALL INDICATIONS:** • Documentation submitted indicates that the member has obtained clinical benefit from the medication including repeat fasting lipid panel lab report, and the member has had a reduction in LDL from baseline, prior to starting PCSK9 inhibitor therapy • The patient's claim history shows consistent therapy (i.e. monthly fills)
Psck **Criteria Statement**	~~For familial hypercholesterolemia,~~ Repatha and Praluent are reserved for members who have used (or cannot/should not use) simvastatin 40 mg, atorvastatin 40 or 80 mg or rosuvastatin 20 or 40 mg tablets AND ezetimibe, are following a heart healthy diet, a non-smoker or trying to quit smoking, has LDL-C above goal ~~two cholesterol tests with low density lipoprotein (LDL) ≥190 for adults or ≥160 for children~~ or results of positive genetic testing for an LDL-C–raising gene defect. ~~For hyperlipidemia (primary or secondary prevention) Repatha and Praluent are reserved for members who have used (or cannot/should not use) simvastatin 40 mg, atorvastatin 40 or 80 mg or rosuvastatin 20 or 40 mg tablets AND ezetimibe, following a heart healthy diet, a non-smoker or trying to quit smoking. For primary severe hyperlipidemia, LDL that remains ≥ 100 mg/dL despite maximally tolerated LDL-lowering therapy. For secondary atherosclerotic cardiovascular disease (ASCVD), LDL remains ≥ 55 mg/dL or non-HDL (i.e. total cholesterol minus HDL) ≥ 85 mg/dL for those at very high risk, or LDL remains ≥ 70 mg/dL or non-HDL (i.e. total cholesterol minus HDL) ≥ 100 mg/dL for those not at very high risk, despite maximally tolerated LDL-lowering therapy.~~
Last P&T Review Date	~~3/2025~~12/2025

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Alameda MRGs for review Q4 2025 P&T

Recommendation: Add new product Yutrepia, which is a new formulation of treprostinil DPI inhaler

Pulmonary Hypertension (PH) Agents	
Therapeutic Classes (AHFS)	Vasodilating agents (respiratory tract); phosphodiesterase type 5 inhibitors
Medications	**PDE-5 Inhibitors:** Formulary, prior authorization required tadalafil (Adcirca/Tadliq), sildenafil (Revatio) tablet Non-Formulary sildenafil (Revatio/Liqrev) oral suspension **Endothelin Receptor Antagonists (ERA)**: Formulary, prior authorization required ambrisentan (Letairis) tablet, bosentan (Tracleer) tablet, Tracleer (bosentan) tablet for suspension, Opsumit (macitentan) **ERA and Phosphodiesterase-5 (PDE-5) Inhibitor Combinations:** Non-Formulary Opsynvi (macitentan and tadalafil) **Prostaglandin Vasodilators**: Formulary, prior authorization required Orenitram (treprostinil diolamine), treprostinil sodium (Remodulin), Ventavis (iloprost), Tyvaso/Tyvaso DPI/Yutrepia (treprostinil) Non-Formulary Flolan (epoprostenol), epoprostenol (Veletri) **Soluble Guanylate Cyclase (sCG) Stimulators:** Formulary, prior authorization required Adempas (riociguat) **Prostacyclin Receptor Agonists**: Formulary, prior authorization required Uptravi (selexipag) **Transforming Growth Factor-beta (TGF-beta) Signaling Modulator:** Non-Formulary Winrevair (sotatercept-csrk) **and any other newly marketed PAH treatment 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	Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	Prescriber must be pulmonologist or cardiologist.
Coverage Duration	**Approval** Orenitram, Tyvaso, Yutrepia, Adempas, Ventavis: 3 months for initial request Opsynvi: 4 months for initial request Uptravi: Request will be approved for the titration pack for 28 days until the highest tolerated dose (maintenance dose) is

Pulmonary Hypertension (PH) Agents	
	achieved. Once the member has achieved maintenance dosing, further refills can be approved for a 6 month duration. For all others, if all of the conditions are met, the initial request will be approved for a 6 month duration. All reauthorization requests will be approved for a 6 month duration. If conditions are not met, the request will be sent to a clinical reviewer.

PA Review Criteria	**PA CRITERIA FOR INITIAL APPROVAL:**
	• Member has a confirmed diagnosis and request is appropriate for member (e.g. functional class) as indicated in package labeling or standard of care guidelines
	• Documentation of the patient's current weight, dosing, and titration scheduled is provided (if applicable)
	• For Uptravi, Orenitram, Tyvaso/Tyvaso DPI, Yutrepia, Ventavis, Remodulin, Adempas, ONE of the following:
	  ○ Documented trial and failure of one PDE-5 inhibitor (e.g. sildenafil, tadalafil) AND one Endothelin Receptor Antagonist [bosentan (Tracleer), ambrisentan (Letairis), or Opsumit]
	  ○ Diagnosis of WHO Group 1 FC III with evidence of rapid disease progression or FC IV (Uptravi, Orenitram, Tyvaso, Ventavis, Remodulin ONLY)
	  ○ Diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) WHO Group 4 after surgical treatment, or inoperable CTEPH (Adempas ONLY)
	  ○ Diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) WHO Group 3 (Tyvaso ONLY)
	• If the request is for Opsumit the patient must have a documented trial and failure or intolerance to ambrisentan and bosentan, or provide a medical reason why these therapies are not appropriate
	• If the request is for sildenafil oral suspension, Liqrev (sildenafil) oral suspension, Tracleer (bosentan) tablet for suspension, or Tadliq (tadalafil) oral suspension, documentation has been submitted as to why patient is unable to use the same ingredient in a tablet dosage form (e.g. difficulty swallowing)
	• If the request is for Opsynvi, BOTH of the following:
	  ○ Patient has been stable for at least 6 months on combination therapy consisting of a PDE-5 inhibitor AND an ERA
	  ○ Documentation is provided as to why patient is unable to take individual pills for combination therapy (e.g. adherence due to pill burden)
	• If the request is for Winrevair, ALL of the following:
	  ○ Documented trial and failure of, or contraindication to combination therapy including one PDE-5 inhibitor AND one ERA OR Opsynvi
	  ○ Documentation of platelet count of ≥ 50,000/mm^3
	
	PA CRITERIA FOR REAUTHORIZATION:
	• Documentation has been submitted indicating the clinical benefit of therapy (e.g. improvement in functional class, improvement in 6-minute walk test, exercise capacity, or hemodynamics).
	• Documentation of the patient's current weight, dosing, and titration schedule is provided (if applicable).

Pulmonary Hypertension (PH) Agents	
	• Request is appropriate for member (e.g. functional class) as indicated in package labeling or standard of care guidelines
Criteria Statement	Opsumit is reserved for members who have used (or cannot/should not use) bosentan (Tracleer) tablets and ambrisentan (Letairis) tablets. Sildenafil oral suspension, Liqrev (sildenafil) oral suspension, Tracleer (bosentan) tablet for suspension, or Tadliq (tadalafil) oral suspension are reserved for members who have used (or cannot/should not use) the same ingredients in an oral tablet dosage form. Opsynvi is reserved for members that have been stable on combination therapy: a phosphodiesterase 5 enzyme inhibitor (PDE-5) and an endothelin receptor antagonist (ERA) and documentation as to why the member is unable to be treated with individual pills for combination therapy. Winrevair is reserved for members who have documented trial and failure, or contraindication to combination therapy (PDE-5 inhibitor and ERA or Opsynvi) and have platelet count of ≥ 50,000/mm^3.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation:

- Remove Ocaliva from the criteria as Intercept Pharmaceuticals removed the medication from the market following a request from the FDA due to liver-related safety concerns
- Add additional criteria for confirmation of PBC diagnosis. Per guidelines, if AMA test is negative, the presence of PBC specific autoantibodies also would satisfy diagnosis criteria in addition to elevated ALP. Additionally, diagnosis can also be made with histologic evidence of primary biliary cholangitis from a liver biopsy.

Agents for Primary Biliary Cholangitis	
Therapeutic Classes (AHFS)	GI Drugs, Miscellaneous
Medications	~~Ocaliva (obeticholic acid),~~ Iqirvo (elafibranor), Livdelzi (seladelpar)
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	If the criteria are met, the request will be approved for a 3 month duration for initial authorization and up to a 12 month duration for reauthorization
PA Review Criteria	**Initial Authorization**: • Diagnosis of primary biliary cholangitis (PBC) ~~with confirmation of diagnosis~~ confirmed by at least two of the following criteria~~tests~~: 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 ~~b)~~c) Histologic evidence of primary biliary cholangitis from a liver biopsy • 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 • Prescriber attests the patient does not have complete biliary obstruction, decompensated cirrhosis (e.g., Child-Pugh Class B or C) ~~• For Ocaliva, prescriber must also attest the patient does not have compensated cirrhosis (Child-Pugh Class A) with evidence of portal hypertension~~ • 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, decompensated cirrhosis (e.g., Child-Pugh Class B or C) ~~• For Ocaliva, provider must also attest that the patient has not developed compensated cirrhosis (Child-Pugh Class A) with evidence of portal hypertension~~ • 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

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	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 o ~~First reauthorization request for Ocaliva following 3 months at the 5 mg once daily dose can be authorized for the 10 mg once daily dose for 3 months without submission of lab tests confirming clinical benefit~~
Criteria Statement	~~Ocaliva,~~ Iqirvo~~,~~ and Livdelzi are reserved for members with a confirmed diagnosis of primary biliary cholangitis (PBC) ~~with confirmation of the diagnosis by the following tests: positive antimitochondrial antibody test and an elevated serum alkaline phosphatase (ALP) level~~, who have used (or cannot/should not use) ursodeoxycholic acid (UDCA). Additionally, ~~M~~members should not have complete biliary obstruction or decompensated cirrhosis (e.g., Child-Pugh Class B or C). ~~Members should also not have compensated cirrhosis (Child-Pugh Class A) with evidence of portal hypertension for Ocaliva.~~ Recent (within 30 days of the request) serum ALP and total bilirubin lab test results must be submitted.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation: Add prescriber restriction and update trial and failure agents based on updated GOLD guidelines that recommend consideration of Ohtuvayre as add on therapy for patients whose symptoms do not improve despite being established on two long-acting bronchodilators.

Ohtuvayre	
Therapeutic Classes (AHFS)	Dual Phosphodiesterase Inhibitor
Medications	Ohtuvayre (ensifentrine)
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	• Primary diagnosis of asthma • Concomitant use of oral PDE4 inhibitors
Required Clinical Information	See "**PA Review Criteria**" below
Age Restrictions	According to package insert Check AAH active CCS cases for members < 21 years of age
Prescriber Restrictions	~~N/A~~Prescribed by or in consultation with a pulmonologist
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 chronic obstructive pulmonary disease (COPD) • Documentation of a pre- and post-albuterol FEV1/FVC ratio of <0.70 • Documentation of a score of ≥ 2 on the Modified Medical Research Council (mMRC) Dyspnea Scale or a score of ≥ 10 on the COPD Assessment Test (CAT) • Documented trial, intolerance, or contraindication to treatment with a long-acting beta-2 agonist (LABA) plus a long-acting muscarinic antagonist (LAMA) ~~and failure of 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) • The drug is being prescribed at an FDA approved dose **Re-Authorization:** • The member has clinically benefitted from the medication (e.g. improvement in symptoms and exacerbations, improvement in mMRC or CAT, improvement in FEV1/FVC ratio, etc.) • The drug is being prescribed at an FDA approved dose
Criteria Statement	Ohtuvayre is reserved for members who have a diagnosis of COPD, mMRC Dyspnea Scale score ≥ 2 or a score of ≥ 10 on the COPD Assessment Test (CAT) and tried and failed or were unable to use ~~maintenance triple~~LABA plus LAMA therapy.
Last P&T Review Date	~~12/2024~~12/2025

Recommendation:

- Add new indication for complement 3 glomerulopathy (C3G) for Fabhalta and change naming of the policy to include this new indication
- Update the list of prescribers to include nephrologists as a result of the new indication for Fabhalta
- Separate PNH section requirements and update initial authorization criteria to require the presence of a sign or symptom of PNH instead of relying on Hgb value to better align with guidelines
- Add requirements for C3G indication and reference to IgA nephropathy policy, since Fabhalta also received indication for use in IgA nephropathy

Complement Inhibitors for the Treatment of Paroxysmal Nocturnal Hemoglobinuria and C3 Glomerulopathy	
Therapeutic Classes (AHFS)	Complement Inhibitors
Medications	Fabhalta (iptacopan) capsule, Voydeya (danicopan) 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	Check AAH active CCS cases for members < 21 years of age According to the package insert
Prescriber Restrictions	Prescriber must be a hematologist, nephrologist or oncologist
Coverage Duration	For Fabhalta: if the criteria are met, the initial request will be approved for up to 6 month duration; reauthorization requests will be approved for up to 12 months. For Voydeya: if the criteria are met, the initial request will be approved for up to 3 month duration; reauthorization requests will be approved for up to 6 months.
PA Review Criteria	**Initial Authorization:** • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age and concomitant medical conditions • Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria. **Paroxysmal Nocturnal Hemoglobinuria (PNH):** • Documentation of diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by high sensitivity flow cytometry • Presence of 1 or more of the following PNH-related signs or symptoms: o fatigue, hemoglobinuria, abdominal pain, shortness of breath (dyspnea), anemia, history of a major adverse vascular event (including thrombosis), dysphagia, erectile dysfunction, or history of pRBC transfusion due to PNH. • ~~For Fabhalta (iptacopan): Hemoglobin (Hgb) < 10 g/dL~~ • For Voydeya (danicopan) o Member has been receiving eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab) therapy for at least 6 months o Member has clinically evident extravascular hemolysis [defined as anemia (Hgb ≤9.5 gram/deciliter) with absolute reticulocyte count ≥120 x 10^9/liter] despite treatment with eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab)

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	○ Voydeya (danicopan) will be used as add-on therapy to eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris (ravulizumab) **IgA Nephropathy** (Fabhalta only)**:** • Refer to the "IgA Nephropathy Agents" policy **Complement 3 Glomerulopathy (C3G)** (Fabhalta only)**:** • Diagnosis of C3G as confirmed by renal biopsy • Patient's serum C3 level is reduced (defined as less than 0.85 x lower limit of the central laboratory normal range) • Patient's urine protein to creatinine ratio (UPCR) is ≥ 1.0 g/g • Patient has an eGFR ≥ 30 mL/min/1.73 m^2 • Patient has been taking maximally recommended or tolerated dose of an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) for at least 90 days, or a medical reason is provided why this is inappropriate • Patient has a trial and therapy failure of mycophenolate and glucocorticoids, or a medical reason is provided why this is inappropriate. • Patient does not have recurrent C3G post kidney transplant **Re-Authorization:** • Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, increase in Hgb, reduced need for blood transfusions, improvement in UPCR, etc.) • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age, and concomitant medical condition
Criteria Statement	Fabhalta is reserved for members who have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by high sensitivity flow cytometry with PNH related signs or symptoms ~~with a hemoglobin (Hgb) < 10 g/dL~~, who have complied with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria. In addition, Fabhalta is reserved for members with a diagnosis of C3G, who have been taking maximally tolerated dose of ACEI or ARB, tried and failed or were unable to use mycophenolate and glucocorticoids therapies, and do not have recurrent C3G post kidney transplant. Voydeya is reserved for members who have a diagnosis of PNH by high sensitivity flow cytometry with PNH related signs or symptoms,~~a~~ Hgb ≤ 9.5 g/dL and absolute reticulocyte count ≥120 x 10^9/liter despite treatment with eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris for at least 6 months, and will be used as an add-on therapy to eculizumab (Soliris, BKEMV, Epysqli) or Ultomiris.
Last P&T Review Date	~~6/2025~~12/2025

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Recommendation:

- Add newly released Prolia (denosumab) and Xgeva (denosumab) biosimilars to the drug list
- Add trial and failure of the most cost-effective biosimilar Bilprevda before other Xgeva (denosumab) products
- Add trial and failure of the most cost-effective biosimilar Bildyos before other Prolia (denosumab) products

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, Wyost, Bomyntra, Osenvelt, Xbryk Prolia (denosumab) Prolia biosimilars: Bildyos, Jubbonti, Conexxence, Stoboclo, Ospomyv
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 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 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

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	• 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 ~~is~~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 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 biosimilar.
Last P&T Review Date	~~9/2025~~12/2025

Recommendation:

- Add newly released Prolia (denosumab) biosimilars to the drug list
- Add trial and failure of the most cost-effective biosimilar Bildyos before other denosumab (Prolia) products

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, Jubbonti, Conexxence, Stoboclo, Ospomyv 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 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. o 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 ~~Prolia~~ 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 ~~Prolia~~ 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 ~~Prolia~~ 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 ~~Prolia~~ 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 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	~~9/2025~~12/2025

Recommendation:

- Combine criteria for Wegovy and Zepbound to create a new policy for GLP-1 Receptor Agonists for Non-Weight Loss Indications, including indication for Wegovy for risk reduction of major adverse cardiovascular events and indication for Zepbound for OSA
- Add new indication for Wegovy for noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH)

~~Wegovy~~GLP1 Receptor Agonists (Wegovy/Zepbound) for Non-Weight Loss Indications	
Therapeutic Classes (AHFS)	Incretin Mimetics
Medications	Wegovy (semaglutide) injection Zepbound (tirzepatide) injection ****Please Note: If the request is for Wegovy/Zepbound to reduce excess body weight and maintain weight reduction long term, refer to criteria for Anti-Obesity Medications*****
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	• Requests for ~~Wegovy for~~ a diagnosis of weight reduction and maintenance for overweight or obesity • Concurrent use of any glucagon-like-peptide-1 receptor agonist • ~~Personal history of Type 1 or Type 2 diabetes~~ • Personal or family history of medullary thyroid carcinoma • Multiple Endocrine Neoplasia syndrome type 2
Required Clinical Information	See "PA Review Criteria"
Age Restrictions	Wegovy for cardiovascular risk reduction: Member must be ≥ 45 years of age, all others per FDA approved labeling
Prescriber Restrictions	~~N/A~~ Provider is or treatment is in consultation with: •Wegovy for MASH: hepatologist, gastroenterologist, endocrinologist, or a specialist in the treatment of liver disease •Wegovy for CVD risk reduction: N/A •Zepbound for Obstructive Sleep Apnea: specialist in the treatment of sleep disorders; or in consultation with a specialist in the treatment of sleep disorders
Coverage Duration	**Initial Approval** 6 months **Later Approvals** 12 months If the conditions are not met, the request will be sent to a clinical reviewer for medical necessity review

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PA Review Criteria	**Initial Authorization:**
	• All requests: Requested dose is appropriate per labeling
	
	Wegovy Requests:
	For **risk reduction of major adverse cardiovascular events** in adults with established CV disease, the following must be met:
	• Medication is prescribed for reducing the risk of adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with **established cardiovascular** disease. Documentation demonstrates patient has history of one or more of the following:
	  ○ Prior myocardial infarction
	  ○ Prior stroke
	  ○ Symptomatic peripheral arterial disease, as evidenced by ≥1 of the following:
	  ▪ Intermittent claudication with ankle brachial index <0.85 (at rest)
	  ▪ Peripheral arterial revascularization procedure
	  ▪ Amputation due to atherosclerotic disease
	• Documentation is provided that patient is overweight or obese, defined as a body mass index (BMI) ≥ 27 kg/m2
	• Patient is receiving standard of care treatment of CVD, as appropriate/indicated, including an antiplatelet agent (ex. aspirin or P2Y12 inhibitor), lipid-lowering drug (ex. statin, otherwise ezetimibe, fibrate, and/or PCSK-9 inhibitor), antihypertensive (ex. beta blocker, ACE-I, ARB)
	• Patient does not have a personal history of type 1 or type 2 diabetes
	• Documentation is provided patient's Hb A1c ≤ 6.5%
	
	For the treatment of **noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH)**, with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults, all of the following must be met:
	• Diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis
	• Documentation of stage F2 to F3 fibrosis confirmed by biopsy or a noninvasive test (NIT)
	• Prescriber attestation to providing lifestyle counseling on nutrition and exercise
	• Prescriber attestation that member avoids excess alcohol intake
	
	Zepbound Requests:
	For treatment of **moderate to severe obstructive sleep apnea** in adults, the following must be met:
	• Patient's body mass index (BMI) is provided and is 30 kg/m^2 or more
	• Documentation of current diagnosis of moderate to severe obstructive sleep apnea
	• Documentation of trial and failure regarding lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity) to reach a BMI < 30 kg/m^2
	• One of the following:
	  ○ Results of sleep testing showing patient's apnea hypopnea index (AHI) ≥ 15 while currently on PAP therapy
	  ○ Results of sleep testing showing patient's apnea hypopnea index (AHI)

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	≥ 15 and patient had a previous trial and failure of PAP therapy or a medical reason is provided why the patient is not able to use PAP therapy • Patient is not pregnant **Re-Authorization:** **Wegovy Requests:** For **risk reduction of major adverse cardiovascular events** in adults with established CV disease, the following must be met: • Patient is receiving standard of care treatment of CVD, as appropriate/indicated, including an antiplatelet agent (ex. aspirin or P2Y12 inhibitor), lipid-lowering drug (ex. statin, otherwise ezetimibe, fibrate, and/or PCSK-9 inhibitor), antihypertensive (ex. beta blocker, ACE-I, ARB) • Patient continues to not have Type 1 or Type 2 diabetes • Patient is adherent to therapy, as evidenced by claims records demonstrating ≥80% fill rate For the treatment of **noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH)**, with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults, all of the following must be met: • Requested dose is appropriate per labeling • The member continues to have a fibrosis stage of ≤ 3 • Patient is adherent to therapy, as evidenced by claims records demonstrating ≥80% fill rate **Zepbound Requests:** For treatment of **moderate to severe obstructive sleep apnea** in adults, the following must be met: • Requested dose is appropriate per labeling • Documentation of positive clinical response to therapy (i.e., improvement patient's AHI, improvement in daytime sleepiness, sleep arousals, snoring) • Patient is adherent to therapy, as evidenced by claims records demonstrating ≥80% fill rate
Criteria Statement	Wegovy is reserved for risk reduction of major adverse cardiovascular events for members who are overweight or obese, have an established cardiovascular disease, receive standard of care treatment for CVD, have Hb A1c ≤ 6.5% and do not have diabetes. Additionally, Wegovy is reserved for members with a diagnosis of MASH with moderate to advanced liver fibrosis, who avoid excess alcohol intake. Zepbound is reserved for members who have a diagnosis of moderate to severe obstructive sleep apnea, are not pregnant, and have a BMI ≥30 kg/m^2, and who have results of sleep testing showing AHI ≥15 while currently on PAP therapy or AHI ≥15 and had a previous trial and failure of PAP therapy or are unable to use PAP therapy, and who had trial and failure regarding lifestyle changes and behavioral modification.
Last P&T Review Date	~~6/2025~~12/2025

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Recommendation: Retire criteria as it was included in GLP1 Receptor Agonists for Non-Weight Loss Indications policy

Zepbound for Moderate to Severe Obstructive Sleep Apnea	
Therapeutic Classes (AHFS)	Incretin Mimetics
Medications	Zepbound (tirzepatide)
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	• Requests for Zepbound solely for a diagnosis of weight reduction and maintenance for overweight or obesity • Concurrent use of any glucagon-like-peptide-1 receptor agonist • Personal history of Type 1 or Type 2 diabetes • Personal or family history of medullary thyroid carcinoma • Multiple Endocrine Neoplasia syndrome type 2
Required Clinical Information	See "**PA Review Criteria**" below
Age Restrictions	According to package insert
Prescriber Restrictions	Provider must be a specialist in the treatment of sleep disorders, or in consultation with a specialist in the treatment of sleep disorders
Coverage Duration	If all of the criteria are met, the request will be approved for up to 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 (all of the following must be met):**
	• Requested dose is appropriate per labeling
	• Patient's body mass index (BMI) is provided and is ≥30 kg/m^2
	• Documentation of current diagnosis of moderate to severe obstructive sleep apnea
	• Documentation of trial and failure regarding lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity) to reach a BMI < 30 kg/m^2
	• One of the following:
	  ○ Results of sleep testing showing patient's apnea hypopnea index (AHI) ≥ 15 while currently on PAP therapy
	  ○ Results of sleep testing showing patient's apnea hypopnea index (AHI) ≥ 15 and patient had a previous trial and failure of PAP therapy or a medical reason is provided why the patient is not able to use PAP therapy
	• Patient is not pregnant
	Re-Authorization:
	• Requested dose is appropriate per labeling
	• Documentation of positive clinical response to therapy (i.e., improvement patient's AHI, improvement in daytime sleepiness, sleep arousals, snoring)
	• Patient is adherent to therapy, as evidenced by claims records demonstrating ≥80% fill rate

Criteria Statement	Zepbound is reserved for members who have a diagnosis of moderate to severe obstructive sleep apnea, are not pregnant, and have a BMI ≥30 kg/m^2 , and who have results of sleep testing showing AHI ≥15 while currently on PAP therapy or AHI ≥15 and had a previous trial and failure of PAP therapy or are unable to use PAP therapy, and who had trial and failure regarding lifestyle changes and behavioral modification.
Last P&T Review Date	3/2025

Recommendation:

- Update the reference to combined policy for Wegovy and Zepbound for non-weight loss indications
- Add requirement of providing clinic notes and paid claims to confirm trial and failure agents before Qsymia, Contrave and GLP-1 agonists
- Change coverage of weight loss medications back to covering patients with 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 all mediations, except for GLP-1 agonists that will be reserved for patients with severe obesity

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) Zepbound (tirzepatide) 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 ~~class III/severe~~ obesity (including documentation of BMI ≥ 30~~40~~) 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 ~~class III/severe~~ obesity (including documentation of BMI ≥ 30~~40~~) 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 ~~class III/severe~~ obesity (including documentation of BMI ≥ 30~~40~~) 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 ~~of 120% of~~ in the ≥95th percentile standardized for age and sex ~~or ≥35 kg/m²~~ ▪ https://www.cdc.gov/healthyweight/bmi/calculator.html • Clinic notes and paid claims to confirm~~Documented~~ trial and failure, contraindication, or intolerance to use phentermine HCL (Adipex-P) and topiramate as separate ingredients Contrave • Diagnosis of ~~class III/severe~~ obesity (including documentation of BMI ≥ 30~~40~~) 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~~Documented~~ trial and failure, contraindication, or intolerance to use phentermine/topiramate (Qsymia) Saxenda, Wegovy, and Zepbound • Diagnosis of class III/severe obesity (including documentation of BMI ≥ 40) • Clinic notes and paid claims to confirm~~Documented~~ 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 Xenical: • Diagnosis of ~~class III/severe~~ obesity (including documentation of BMI ≥ 30~~40~~) 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 ~~have a diagnosis of class III/severe obesity~~ with body mass index of ≥ 340 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~~have a diagnosis of class III/severe obesity~~ with a body mass index of ≥ 340 or ≥ 27 with a comorbidity such as diabetes, hypertension, or heart attack. Phentermine/topiramate (Qsymia) is reserved for adult members who are obese ~~have a diagnosis of class III/severe obesity~~ with a body mass index of ≥ 340 or ≥ 27 with a comorbidity such as diabetes, hypertension, or heart attack or pediatric members who are obese with a BMI ~~of 120%~~in ~~of~~ the 95th percentile standardized for age and sex

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	~~or ≥35 kg/m²~~and who have used (or cannot/should not use) phentermine and topiramate as separate ingredients. Contrave is reserved for members who are obese~~have a diagnosis of class III/severe obesity~~ with a body mass index of ≥ 340 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, and Zepbound are reserved for members who have a diagnosis of class III/severe obesity with a body mass index of ≥ 40 and who have used (or cannot/should not use) phentermine/topiramate (Qsymia) and Contrave. Xenical is reserved for obese members ~~who have a diagnosis of class III/severe obesity~~ with a body mass index of ≥ 340 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	~~9/2025~~12/2025

Recommendation:

- Add endocrinologist to the list of prescribers, since they also treat patients with NASH
- Add trial and failure of Wegovy for patients without diabetes or patients not taking another GLP1 agonist, since Wegovy received new indication for MASH and is more cost effective than Rezdiffra.
- Remove exclusion criteria for patients with thyroid disease because based on new evidence and FDA review packet that concluded the effect on thyroid laboratory values was minimal and not clinically significant.

Rezdiffra	
Therapeutic Classes (AHFS)	Hepatotropics
Medications	Rezdiffra (resmetirom)
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	• Patients with decompensated cirrhosis
	• ~~Patient with thyroid disease including:~~
	  ○ ~~active hyperthyroidism~~
	  ○ ~~untreated hypothyroidism (TSH >7 IU/L with symptoms of HT or >10 IU/L without symptoms~~

Required Clinical Information	See "PA Review Criteria"
Age Restrictions	Check AAH active CCS cases for members < 21 years of age According to package insert
Prescriber Restrictions	Prescriber must be a hepatologist, gastroenterologist, endocrinologist, or a specialist in the treatment of liver disease
Coverage Duration	**Initial Approval** Up to a 12 month duration **Later Approvals** Up to a 12 month duration 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 noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis • Documentation of stage F2 to F3 fibrosis confirmed by biopsy or a noninvasive test (NIT) • Prescriber attestation to providing lifestyle counseling on nutrition and exercise • Prescriber attestation that member avoids excess alcohol intake • The drug is being prescribed at an FDA approved dose according to the member's weight • In patients without diabetes, or patients not taking another GLP1 receptor agonist: documentation of trial and failure, or documented medical reason for not using Wegovy **Re-Authorization:** • The member has clinically benefited from the medication (e.g. the resolution of steatohepatitis and no worsening of liver fibrosis, or at least one stage improvement in liver fibrosis and no worsening of steatohepatitis) • The member continues to have a fibrosis stage of ≤ 3 • The drug is being prescribed at an FDA approved dose according to the member's weight

Criteria Statement	Rezdiffra is reserved for members who have a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis stage F2 to F3, who were provided lifestyle counseling on nutrition and exercise, and avoid excess alcohol intake. Additionally, documentation of trial and failure or inability to use Wegovy should be provided for members without diabetes or members not taking another GLP1 receptor agonist.
Last P&T Review Date	~~6/2025~~12/2025

Alameda PADs for review Q4 2025 P&T Changes

Recommendation:

- Add Ocrevus Zunovo (hyaluronidase facilitated subcutaneous product for HCP administration) and Tyruko (Tysabri biosimilar) as they are missing from the policy
- Streamline language on immunizations requirement for all products

Healthcare professional (HCP) administered/IV Disease Modifying Therapies (DMTs) for Multiple Sclerosis (MS)	
Medications	**Ocrevus (ocrelizumab)** **Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq)** **Ruxience (rituximab-pvvr) - biosimilar** **Truxima (rituximab-abbs) - biosimilar** **Rituxan (rituximab)** **Riabni (rituximab-arrx) - biosimilar** **Rituxan Hycela (rituximab/hyaluronidase)** **Lemtrada (alemtuzumab)** **Tysabri (natalizumab)** **Tyruko (natalizumab-sztn) - biosimilar** **Briumvi (ublituximab-xiiy)** **Any other newly marketed healthcare professional administrable DMT for MS indicated for the listed diagnoses**
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	Tysabri, Tyruko or Briumvi: • Primary Progressive MS (PPMS) Lemtrada: • Primary Progressive MS (PPMS) • Clinically Isolated Syndrome (CIS)
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 neurologist
Coverage Duration	12 months
Maximum Billable Units	Variable
Other Criteria	For requests for Tysabri for the indication of Crohn's disease, please see the Injectable/Specialty Medications policy **** 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.** **Initial Authorization** Clinically Isolated Syndrome (CIS), Relapsing Remitting MS (RRMS), Secondary Progressive MS (SPMS) ○ Diagnosis of CIS, RRMS, or SPMS ○ The medication is being prescribed at a dose consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

	○ If the request is for Ocrevus (ocrelizumab), Ocrevus Zunovo, Briumvi (ublituximab-xiiy), or rituximab, documentation of the following: ○ Attestation that the member has been screened for and does not have active hepatitis B virus (HBV) ○ Attestation that provider is following administration guidelines for live and ~~the member has received all~~ non-live immunizations in accordance with product's prescribing information and immunization guidelines ~~for rituximab according to immunization guidelines~~ or has a documented medical reason for patient not receiving recommended immunizations ○ If the request is for Rituxan Hycela (rituximab/hyaluronidase) or brand Rituxan, all of the above AND documented medical reason why the member cannot use a rituximab biosimilar product. ○ If the request is for Tysabri (natalizumab) or Tyruko (natalizumab-sztn), documentation of the following ○ Member does not have a history of progressive multifocal leukoencephalopathy (PML) ○ Documentation consistent with pharmacy claims data indicating the member is not currently using any antineoplastic, immunosuppressant, or immunomodulating medications Primary Progressive Multiple Sclerosis (PPMS) ○ Diagnosis of PPMS ○ The medication is being prescribed at a dose consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature ○ If the request is for Ocrevus (ocrelizumab), Ocrevus Zunovo, or rituximab, documentation of the following has been submitted ○ Attestation that the member has been screened for and does not have active HBV ○ Attestation that provider is following administration guidelines for live and ~~Member has received all~~ non-live immunizations in accordance with product's prescribing information and immunization guidelines ~~for rituximab, according to immunization guidelines~~ or has a documented medical reason for patient not receiving recommended immunizations ○ If the request is for Rituxan Hycela (rituximab/hyaluronidase) or brand Rituxan, all of the above AND documented medical reason why the member cannot use a rituximab biosimilar product. **Reauthorization** CIS ○ The medication is being prescribed at a dose consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature ○ Documentation was provided that the prescriber has reviewed the risks and benefits of continuing DMT versus stopping. PPMS, RRMS, or SPMS ○ Documentation was provided that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit) ○ The medication is being prescribed at a dose consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature ○ If the request is for Lemtrada (alemtuzumab), documentation of the following ○ At least 12 months has or will have elapsed since previous treatment

	○ If the request is for Tysabri (natalizumab) or Tyruko (natalizumab-sztn), documentation of the following has been submitted ○ Member does not have a history of PML ○ Documentation consistent with pharmacy claims data was submitted indicating the member is not currently using any antineoplastic, immunosuppressant, or immunomodulating medications 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	~~12/2024~~12/2025

Recommendation:

- Update PNH initial authorization criteria to require the presence of a sign or symptom of PNH instead of relying on anemia/Hgb to align with guideline directed therapy and to encompass all drugs in the policy
- Add trial and failure of the Soliris biosimilar, Epysqli, for cost containment

Complement Inhibitors	
Medications	Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), Syfovre (pegcetacoplan injection), Izervay (avacincaptad pegol injection), PiaSky (crovalimab-akkz), BKEMV (eculizumab-aeeb), Epysqli (eculizumab-aagh)
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	Prescriber must be a hematologist, nephrologist, neurologist, oncologist, ophthalmologist, or other appropriate specialist.
Coverage Duration	If the criteria are met, the initial request will be approved as follows: For eculizumab (Soliris, BKEMV. Epysqli), Ultomiris (ravulizumab), and Empaveli (pegcetacoplan): initial request will be approved for up to a 3 month duration; reauthorization requests will be approved for up to 6 months. For PiaSky (crovalimab-akkz): initial request will be approved for up to 6 months, reauthorization requests will be approved for up to 12 months. For Syfovre (pegcetacoplan injection): initial and reauthorization requests will be approved for up to 12 months. For Izervay (avacincaptad pegol injection): initial request will be approved for up to 12 month duration with no reauthorization.
Maximum Billable Units	Variable
Other Criteria	**Initial Authorization:** • The request is age appropriate according to FDA approved package labeling or nationally recognized compendia; AND • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age, body weight, and concomitant medical conditions; AND • For eculizumab (Soliris, BKEMV, Epysqli), Ultomiris (ravulizumab), Empaveli (pegcetacoplan), and PiaSky (crovalimab-akkz) o Documentation patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria • For Soliris or BKEMV, patient must have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used **For Generalized Myasthenia Gravis (gMG):** • Refer to the "Myasthenia Gravis Agents" policy **For Neuromyelitis Optica Spectrum Disorders (NMOSD):** • Refer to the: **"Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents"**

	policy **For Paroxysmal Nocturnal Hemoglobinuria (PNH):** • Documentation of diagnosis by high sensitivity flow cytometry • Presence of 1 or more of the following PNH-related signs or symptoms: o fatigue, hemoglobinuria, abdominal pain, shortness of breath (dyspnea), anemia, history of a major adverse vascular event (including thrombosis), dysphagia, erectile dysfunction, or history of pRBC transfusion due to PNH. • ~~For Empaveli (pegcetacoplan): Hemoglobin (Hgb) < 10.5 g/dL~~ • For adults: If the request is for Ultomiris (ravulizumab), Empaveli (pegcetacoplan), or PiaSky (crovalimab-akkz), documented trial and failure of, contraindication to, or medical reason for not using ~~eculizumab (Soliris, BKEMV,~~ Epysqli~~) or Ultomiris (ravulizumab)~~ **Atypical Hemolytic Uremic Syndrome (aHUS)/Complement-Mediated HUS)** • Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies; **OR** • Provider attestation treatment is being used empirically and delay in therapy will lead to unacceptable risk to the patient **Geographic Atrophy (GA):** • If the request is for Syfovre (pegcetacoplan injection), member must be ≥ 60 years of age • If the request is for Izervay (avacincaptad pegol injection), member must be ≥ 50 years of age • Diagnosis of GA secondary to age-related macular degeneration (AMD) • Absence of choroidal neovascularization (CNV) in treated eye • Best-corrected visual acuity (BCVA) 24 letters (approximately 20/320) or better using Early Treatment Diabetic Retinopathy Study (ETDRS) • GA lesion size ≥2.5 and ≤17.5 mm2 with at least 1 lesion ≥1.25 mm2 **Re-Authorization:** • Re-authorization may be considered for all agents included in these criteria with the exception of Izervay (avacincaptad pegol injection), which is only indicated for a 12 month duration • Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, increased Hgb, reduced need for blood transfusions, slowing of growth rate of GA lesions, etc.); **AND** • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age, and concomitant medical condition • **If the request is for atypical hemolytic uremic syndrome (aHUS)/ complement-mediated HUS:** o Documentation of confirmed diagnosis as evidenced by: ▪ Complement genotyping ▪ Complement antibodies If all of the above criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review.
Last Review Date	~~6/2025~~12/2025

Recommendation:

- Update the drug list section to include Imaavy—new drug approved for the treatment of gMG in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive
- Update the initial authorization section to also include references to Imaavy
- Add trial and failure of Vyvgart, Vyvgart Hytrulo, or Rystiggo before other more costly agents in adults for cost containment as there is no preference per guidelines

Myasthenia Gravis Agents	
Medications	Vyvgart (efgartigimod) Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase) Rystiggo (rozanolixizumab) Soliris (eculizumab) Ultomiris (ravulizumab) BKEMV (eculizumab-aeeb) Epysqli (eculizumab-aagh) Imaavy (nipocalimab-aahu)
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 Drugs listed in Myasthenia Gravis Agents criteria ≥ 18 years (Except for Soliris ≥ 6 years and Imaavy ≥ 12 years)
Prescriber Restrictions	Prescribed by a neurologist or rheumatologist
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.

Other Criteria	**Initial Authorization:**
	• Diagnosis of generalized myasthenia gravis (gMG)
	• Patient has a positive serological test for one of the following:
	  ○ Anti-AChR antibodies
	  ○ Anti-muscle-specific tyrosine kinase (MuSK) antibodies (Rystiggo and Imaavy only)
	• Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV
	• For adults: patient has tried and failed, or has contraindication, to one of the following:
	  ○ Two (2) or more conventional therapies (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)
	  ○ Failed at least 1 conventional therapy and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin
	• For Soliris in patients 6-17 years and for Imaavy in patients 12-17 years: one of the following:
	  ○ Trial and failure of at least 1 conventional therapy (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)
	  ○ Patient requires maintenance plasma exchange or intravenous immunoglobulin to control symptoms

	• For Soliris or BKEMV, patient must have a documented trial and failure or intolerance to Epysqli or a medical reason why Epysqli cannot be used (does not apply to pediatric patients) • Medication is prescribed at an FDA approved dose • ~~Patient is not using agents covered by this policy concurrently (i.e. n~~No concurrent use of Vyvgart, Vyvgart Hytrulo, Rystiggo, Soliris, BKEMV, Epysqli, Zilbrysq, Imaavy, or Ultomiris) • Requests for Soliris (eculizumab), BKEMV, Epysqli, Imaavy, and Ultomiris (ravulizumab) will also require the following: ○ Documentation that patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal infections in patients receiving a complement inhibitor (does not include Imaavy) ○ For adults: patient has tried and failed, or has contraindication to Vyvgart, Vyvgart Hytrulo, or Rystiggo **Re-Authorization:** • Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality-of-life scores, MG-ADL scores, 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	~~6/2025~~12/2025

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Recommendation:

- Add newly released Prolia (denosumab) biosimilars to the drug list
- Add trial and failure of the biosimilar product before Prolia for cost containment

Injectable/Infusible Agents for Osteoporosis and Paget's Disease	
Medications	ibandronate (Boniva) injection zoledronic acid (Reclast) Prolia (denosumab) Prolia biosimilars: Bildyos, Jubbonti, Conexxence, Stoboclo, Ospomyv 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 ~~Prolia~~ 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 ~~Prolia~~ 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	~~9/2025~~12/2025

New Product Review

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Andembry	garadacimab-gxii subcutaneous solution auto-injector 200 mg/1.2 mL	CSL Behring	An activated Factor XII (FXIIa) inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older.	$57,100 (per month for maintenance dosing)	Haegarda, Takhzyro, Cinryze	Non-formulary (see updated MRG criteria)
Ekterly	Sebetralstat 300mg oral tablet	KalVista Pharmaceuticals, Inc.	For the treatment of acute attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older	$33,440 for a 4 tablet pack	Firazyr, Berinert, and Kalbitor	Non-formulary (see updated MRG criteria)
Kerendia	finerenone oral tablet 40 mg	Bayer	To reduce the risk of: • sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2DM) • cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥ 40%	$687	None	Non-formulary
Penmenvy	meningococcal groups A, B, C, W, and Y vaccine, intramuscular suspension reconstituted	GSK	• for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y in individuals 10 through 25 years of age	$251 per dose	Penbraya	F-QL-AL (Already added via CRF; QL: 2 fills/lifetime, AL: 10-25 years of age)
Orlynvah	sulopenem etzadroxil-probenecid oral tablet 500-500 mg	Iterum	• For the treatment of uncomplicated urinary tract infections (uUTI) caused by the designated microorganisms *Escherichia coli, Klebsiella pneumoniae,* or *Proteus mirabilis* in adult women who have limited or no alternative oral antibacterial treatment options	$2,975 per 5-day course	None	Non-formulary

New Product Review

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Orquidea	norethindrone oral tablet 0.35 mg	Xiromed	• Prevention of pregnancy	$4	Oral contraceptives (ex. Camila, Errin)	Non-formulary
Omnipod 5 Libre2Plus G6 Intro Kit (Gen 5)	omnipod 5 libre2plus g6 intro kit (gen 5)	Insulet	• Intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin	$597	Other insulin delivery devices (vials, pens, pump systems)	Non-formulary
Tyfast Flu A/B Covid-19 Multip In Vitro Kit	tyfast flu A/B covid-19 multip in vitro kit	Cordx	• Intended for in vitro rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen.	$8 per kit	Other COVID-19/influenza testing kits	Non-formulary
Gonal-f RFF	follitripin alfa rediject subcutaneous solution pen-injector 300 unit/0.48 mL, 450 unit/0.72 mL	Serono	• Induction of ovulation and pregnancy in oligoanovulatory women in whom the cause of infertility is functional and not due to primary ovarian failure. • Development of multiple follicles in ovulatory women as part of an Assisted Reproductive Technology (ART) cycle.	$966 per 300 mg device, $1,449 per 450 mg device	Follistim AQ	Non-formulary
Egrifta WR	tesamorelin acetate subcutaneous kit 11.6 mg	Theratechnologies	• For the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy	$7,656	None	Non-formulary
Dicyclomine	dicyclomine hcl oral tablet 40 mg	Trifluent	• For the treatment of patients with functional bowel/irritable bowel syndrome	$2,113	Dicyclomine 20 mg	Non-formulary

New Product Review

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Avgemsi	gemcitabine intravenous Solution 1 gm/26.3 mL, 2 gm/52.6 mL	Avyxa	• In combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy. • In combination with paclitaxel, for first-line treatment of metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated. • In combination with cisplatin, for the treatment of non-small cell lung cancer. • As a single agent for the treatment of pancreatic cancer.	$1,950 per 1 gm vial, $3,900 per 2 gm vial	Generic gemcitabine	Non-formulary
MiCort HC#	hydrocortisone acetate external cream 2.5%	Legacy	• For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses	$298 per tube	Other topical corticosteroids (generic hydrocortisone, betamethasone, triamcinolone)	Non-formulary
Spevigo	spesolimab-sbzo subcutaneous solution prefilled syringe 300 mg/2 mL	Boehringer Ingelheim	• For the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg.	$18,602	None	Non-formulary
Anzupgo	delgocitinib external cream 20 mg/gm	Leo Pharma	• For the topical treatment of moderate to severe chronic hand eczema (CHE) in adults who have had an inadequate response to, or for whom topical corticosteroids are not advisable.	$1,986 per 30 gm tube	Topical corticosteroids (generic hydrocortisone, betamethasone, triamcinolone)	Non-formulary (see new MRG criteria)

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Sephience	sepiapterin oral packet 250 mg, 1000 mg	PTC Therapeutics	• For the treatment of hyperphenylalaninemia (HPA) in adult and pediatric patients 1 month of age and older with sepiapterin-responsive phenylketonuria (PKU). Sephience is to be used in conjunction with a phenylalanine (Phe)restricted diet.	$60,000 for 4000 mg/day (dosing widely variable based on age and weight)	Sapropterin (Kuvan)	Non-formulary (see new MRG criteria)
Tepadina	thiotepa & sodium chloride intravenous solution reconstituted 200 mg/200 mL	Adienne	Tepadina (thiotepa) is an alkylating drug indicated: • To reduce the risk of graft rejection when used in conjunction with high-dose busulfan and cyclophosphamide as a preparative regimen for allogeneic hematopoietic progenitor (stem) cell transplantation (HSCT) for pediatric patients with class 3 beta-thalassemia. • For treatment of adenocarcinoma of the breast or ovary. • For controlling intracavitary effusions secondary to diffuse or localized neoplastic diseases of various serosal cavities. • For treatment of superficial papillary carcinoma of the urinary bladder.	$1,620 per 200 mg bag	Other chemotherapeutic agents	Non-formulary
Fluorouracil#	fluorouracil external cream 0.5 %	Dr. Reddy's	• For the topical treatment of multiple actinic or solar keratoses of the face and anterior scalp	$731 per 30 gm tube	Fluorouracil (Carac, Efudex, Fluoroplex, Tolak), imiquimod (Aldara, Zyclara), turbanibulin (Klisyri), topical diclofenac (Solaraze)	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Triamcinolone Acetonide#	triamcinolone acetonide injection suspension 10 mg/mL	Dr. Reddy's	• The intra-articular or soft tissue administration of triamcinolone acetonide injectable suspension is indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, acute and subacute bursitis, acute nonspecific tenosynovitis, epicondylitis, rheumatoid arthritis, synovitis of osteoarthritis. • The intralesional administration of triamcinolone acetonide injectable suspension is indicated for alopecia areata; discoid lupus erythematosus; keloids; localized hypertrophic, infiltrated, inflammatory lesions of granuloma annulare, lichen planus, lichen simplex chronicus (neurodermatitis), and psoriatic plaques; necrobiosis lipoidica diabeticorum. Triamcinolone acetonide injectable suspension may also be useful in cystic tumors of an aponeurosis or tendon (ganglia).	$11 per 5 mL vial	Triamcinolone acetonide injection, other concentrations	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Pyzchiva	ustekinumab-ttwe subcutaneous solution auto-injector 45 mg/0.5 mL, 90 mg/mL	Cordavis	Treatment of adult patients with: • moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy • active psoriatic arthritis (PsA) • moderately to severely active Crohn's disease (CD) • moderately to severely active ulcerative colitis Treatment of pediatric patients 6 years and older with: • moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy • active psoriatic arthritis (PsA)	$4,150 every 12 weeks (for 90mg dose)	Stelara, Skyrizi, Tremfya, Ilumya, Wezlana & other Stelara biosimilars	Non-formulary
Vizz	aceclidine hcl ophthalmic solution 1.44 %	Lenz	• For the treatment of presbyopia in adults	$75	Vuity	Non-formulary
MODD1	MODD1 patient welcome kit, supply kit	Modular Medical	• Intended for the treatment of diabetes mellitus in persons requiring insulin.	$12 welcome kit, $500 supply kit	Other insulin pump systems (Omnipod)	Non-formulary
Analpram HC#	hydrocortisone-pramoxine external lotion 2.5-1 %	Legacy	• For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses	$337	Procort, Proctocream	Non-formulary

New Product Review

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Hydrocortisone acetate	hydrocortisone acetate external cream 2.5 %	Allegis	• For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.	$1,300	Other generic topical corticosteroids	Non-formulary
Hernexeos	zongertinib oral tablet 60 mg	Boehringer Ingelheim	• For the treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy	$21,667-$32,500 (weight-based dosing)	Enhertu	Non-formulary
Brynovin	sitagliptin oral solution 25 mg/mL	Azurity	• As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	$147	Sitagliptin tablets	Non-formulary
TNKase	tenecteplase intravenous kit 25 mg	Genentech	• For the treatment of acute ischemic stroke (AIS) in adults • To reduce the risk of death associated with acute ST elevation myocardial infarction (STEMI) in adults	$8,297 per vial	Activase	Non-formulary
Prezcobix	cobicistat-darunavir ethanolate oral tablet 675-150 mg	Janssen	• In combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) in treatment-naïve and treatment-experienced adults and pediatric patients weighing at least 25 kg with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V)	$2,467	Evotaz	F-QL (Already added via CRF)

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Remodulin	treprostinil injection solution 8 mg/20 mL	United Therapeutics Corporation	• For the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%) • In patients with PAH requiring transition from epoprostenol, Remodulin is indicated to diminish the rate of clinical deterioration.	$509 per vial	Other prostacyclin agonists (Orenitram, Uptravi, Veletri, Flolan, Yutrepia)	Non-formulary
Modeyso	dordaviprone oral capsule 125 mg	Jazz	• For the treatment of adult and pediatric patients 1 year of age and older with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy.	$64,000	None	Non-formulary
Brinsupri	brensocatib oral tablet 10 mg, 25 mg	Insmed	• For the treatment of non-cystic fibrosis bronchiectasis in adult and pediatric patients 12 years of age and older	$7,333	None	Non-formulary (see new MRG criteria)
Butalbital-APAP-Caffeine#	butalbital-APAP-caffeine oral solution 50-325-40 mg/15 mL	Genus Lifesciences	• For the relief of the symptom complex of tension (or muscle contraction) headache	$1,641 per 473 mL bottle	Butalbital-APAP-caffeine tablet	Non-formulary

New Product Review

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Jaythari	deflazacort oral tablet 6 mg, 18 mg, 30 mg, 36 mg	Zydus	• For the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older. *Additional pediatric use information is approved for PTC Therapeutics, Inc.'s Emflaza™ (deflazacort) tablets. However, due to PTC Therapeutics, Inc.'s marketing exclusivity rights, this drug product is not labeled with that information.*	$12,279 (30 mg dose, variable based on weight)	Other generic deflazacort	Non-formulary
Brukinsa	zanubrutinib oral tablet 160 mg	BeOne Medicines	• Mantle cell lymphoma (MCL) who have received at least one prior therapy • Waldenström's macroglobulinemia • Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti–CD20-based regimen • Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) • Relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy	$15,744	Calquence, Imbruvica	Non-formulary
Kirsty	insulin aspart-xjhz 100 unit/mL vial, pen injector	Biocon	• To improve glycemic control in adults and pediatric patients with diabetes mellitus	$70 per vial, $135 per 5 pens	Novolog, Merilog	Non-formulary

Jobevne	bevacizumab-nwgd intravenous solution 100 mg/4 mL, 400 mg/16 mL	Biocon	• Metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first-or second-line treatment.
			• Metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan-or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen. Limitations of Use: Jobevne is not indicated for adjuvant treatment of colon cancer.
			• Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment.
			• Recurrent glioblastoma in adults.
			• Metastatic renal cell carcinoma in combination with interferon alfa.
			• Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin, or paclitaxel and topotecan.
			• Epithelial ovarian, fallopian tube, or primary peritoneal cancer:
			  ○ in combination with carboplatin and paclitaxel, followed by Jobevne as a single agent, for stage III or IV disease following initial surgical resection
			  ○ in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for
				$796-$3,184 per vial	Mvasi, Vegzelma, Zirabev	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
			platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens ○ in combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by Jobevne as a single agent, for platinum-sensitive recurrent disease			
Kyxata	carboplatin intravenous solution 80 mg/8 mL, 500 mg/50 mL	Avyxa	• As part of a combination regimen, for the initial treatment of advanced ovarian carcinoma • As a single-agent for the treatment of ovarian carcinoma recurrent after prior chemotherapy	$400-$2,500 per vial	Generic carboplatin	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Bosentan	bosentan oral tablet soluble 32 mg	Lupin	• Treatment of pulmonary arterial hypertension (PAH) (WHO Group 1): ○ in adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to-right shunts (18%) ○ in pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability.	$5,251-$42,000	Ambrisentan, Opsumit, bosentan film coated tabs	Non-formulary
Dawnzera	donidalorsen subcutaneous solution auto-injector 80 mg/0.8 mL	Ionis	• For prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years of age and older	$57,462	Oraldeyo, Takhzyro	Non-formulary (see updated MRG criteria)
Unloxcyt	cosibelimab-ipdl intravenous solution 300 mg/5 mL	Checkpoint	• For the treatment of adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.	$18,742	Keytruda, Libtayo	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Papzimeos	zopapogene imadenovec-drba subcutaneous suspension 500000000000 pu/mL	Precigen	• For the treatment of adults with recurrent respiratory papillomatosis	$460,000 per 12-week course	None	Non-formulary
Dexcom G7	dexcom 15-day sensor miscellaneous	Dexcom	• For the management of diabetes in persons 18 years and older	$377	Other CGM systems	Non-formulary
Pen Needle	pen needle/5-bevel tip miscellaneous 31g X 8 mm	Walgreens	• Intended to be used with a pen injection device for the subcutaneous injection of insulin	$10 per 50 count	Other pen needles	Non-formulary
Wayrilz	rilzabrutinib oral tablet 400 mg	Genzyme	• For the treatment of adult patients with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment	$17,500	Immune globulin	Non-formulary (see updated MRG criteria)
Leqembi Iqlik	lecanemab-irmb subcutaneous solution auto-injector 360 mg/1.8 mL	Eisai	• For the treatment of Alzheimer's disease	$1,500	Leqembi IV	Non-formulary
Liomny	liothyronine oral tablet 5 mcg, 25 mcg, 50 mcg	Sigmapharm	• As replacement in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism • As an adjunct to surgery and radioiodine therapy in the management of well-differentiated thyroid cancer • As a diagnostic agent in suppression tests to differentiate suspected mild hyperthyroidism or thyroid gland autonomy	$21-$40	Liothyronine	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Clemsza	clemastine oral tablet 2.68 mg	IPG	• For the relief of symptoms associated with allergic rhinitis such as sneezing, rhinorrhea, pruritus, and lacrimation • For the relief of mild, uncomplicated allergic skin manifestations of urticaria and angioedema	$5,988	Diphenhydramine	Non-formulary
Lurbiro	flurbiprofen oral tablet 100 mg	IPG	• Relief of the signs and symptoms of rheumatoid arthritis • Relief of the signs and symptoms of osteoarthritis	$6,003	Generic flurbiprofen	Non-formulary
Pro Comfort Pen Needles	pen needle miscellaneous 32 g X 8 mm	Home Aide Diagnostics	• Intended to be used with a pen injection device for the subcutaneous injection of insulin	$80 per 100 count	Other pen needles	Non-formulary
Blujepa	gepotidacin oral tablet 750 mg	GSK	• For the treatment of female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms (kg) with uncomplicated urinary tract infections (uUTI) caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, and Enterococcus faecalis.	$1,900 per 5-day course	SMZ-TMP, nitrofurantoin	Non-formulary
Zurnai	nalmefene injection solution auto-injector 1.5 mg/0.5 mL	Purdue	• For the emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression.	$50 per dose	Naloxone	Non-formulary
Brekiya	dihydroergotamine subcutaneous solution auto-injector 1 mg/mL	Amneal	• For the acute treatment of migraine with or without aura and the acute treatment of cluster headaches in adults.	$875 per dose	Dihydroergotamine ampules, nasal spray	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Fibryga	fibrinogen intravenous solution reconstituted 2 gm	Octapharma	• Fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency • Treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia	$2,200 per vial	RiaSTAP	Non-formulary
Adalimumab-ryvk	adalimumab-ryvk (1 pen) subcutaneous auto-injector kit 80 mg/0.8 mL	Teva	• Rheumatoid arthritis • Juvenile idiopathic arthritis • Psoriatic arthritis • Ankylosing spondylitis • Crohn's disease • Ulcerative colitis • Plaque psoriasis • Hidradenitis suppurativa • Uveitis	$1,038 per 80 mg pen	Hadlima, Hyrimoz, Simlandi	Non-formulary
Luizza	norethindrone acetate-ethinyl estradiol 1.5/30 oral tablet 1.5-30 mg-mcg, 1-20 mg-mcg	Xiromed	• For the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception	$7 - $22 per pack	Other generic oral contraceptives	Non-formulary
Zelvysia	sapropterin oral packet 100 mg, 500 mg	Aucta	• To reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). Zelvysia is to be used in conjunction with a Phe-restricted diet.	$43,546 for 4000 mg/day (dosing widely variable based on age and weight)	Generic sapropterin, Kuvan	Non-formulary (see new MRG criteria)

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Pyquvi	deflazacort oral suspension 22.75 mg/mL	Aucta	• For the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older. • *Additional pediatric use information is approved for PTC Therapeutics, Inc.'s Emflaza ® (deflazacort) oral suspension. However, due to PTC Therapeutics, Inc.'s marketing exclusivity rights, this drug product is not labeled with that information.*	$466.66 per mL	Generic deflazacort, Emflaza	Non-formulary
Oxytocin +RFID	oxytocin +RFID injection solution 10 unit/ mL	Fresenius Kabi	Antepartum • Indicated for the initiation or improvement of uterine contractions, where this is desirable and considered suitable, in order to achieve early vaginal delivery for fetal or maternal reasons. Postpartum • To produce uterine contractions during the third stage of labor and to control postpartum bleeding or hemorrhage.	$4 per vial	Oxytocin	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Eliquis	apixaban oral capsule sprinkle 0.15 mg, oral tablet soluble 0.5 mg, (2 mg pack) oral tablet soluble 4 x 0.5 mg, (1.5 mg pack) oral tablet soluble 3 x 0.5 mg	Bristol Myers Squibb	• To reduce the risk of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation. • For the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in adult patients who have undergone hip or knee replacement surgery. • For the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE in adult patients following initial therapy. • Treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in pediatric patients from birth and older after at least 5 days of initial anticoagulant treatment.	$303	Warfarin, rivaroxaban	F (Already added via CRF)
Inlexzo	gemcitabine intravesical device 225 mg	Janssen	• For the treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ*(CIS), with or without papillary tumors.	$69,000 per dose	Adstiladrin, Keytruda	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Otulfi	ustekinumab-aauz subcutaneous solution 45 mg/0.5mL	Fresenius Kabi	Adult patients with: • *moderate to severe plaque psoriasis (PsO)* who are candidates for phototherapy or systemic therapy • *active psoriatic arthritis (PsA)* • *moderately to severely active Crohn's disease (CD)* • *moderately to severely active ulcerative colitis* Pediatric patients 6 years and older with: • *moderate to severe plaque psoriasis*, who are candidates for phototherapy or systemic therapy • *active psoriatic arthritis (PsA)*	$1,810 per dose.	Pyzchiva, Wezlana, Yesintek, Selarsdi	F-PA-QL (Already added via CRF)

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Avtozma	tocilizumab-anoh intravenous solution 80 mg/4mL, 200 mg/10mL, 400 mg/20mL	Celltrion	• Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs) • Adult patients with giant cell arteritis • Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis • Patients 2 years of age and older with active systemic juvenile idiopathic arthritis • Adults and pediatric patients with 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome • Hospitalized adult patients with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)	$345-$1,726 per vial	Tofidence, Tyenne	Add to F-PA (see updated MRG criteria)
Skytrofa	lonapegsomatropin-tcgd subcutaneous cartridge 0.7 mg, 1.4 mg, 1.8 mg, 2.1 mg, 2.5 mg	Ascendis	• Pediatric Patients: Treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH) • Adults: Replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD)	$3,035	Sogroya	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Bildyos	donosumab-nxxp subcutaneous solution prefilled syringe 60 mg/mL	Organon	For treatment: • of postmenopausal women with osteoporosis at high risk for fracture • to increase bone mass in men with osteoporosis at high risk for fracture • of glucocorticoid-induced osteoporosis in men and women at high risk for fracture • to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer • to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer	$844 for a 60 mg dose administered every 6 months	Jubbonti, Conexxence	Add to F-PA (see updated MRG and PAD criteria)
Bilprevda	denosumab-nxxp subcutaneous solution 120 mg/1.7mL	Organon	For treatment: • of postmenopausal women with osteoporosis at high risk for fracture • to increase bone mass in men with osteoporosis at high risk for fracture • of glucocorticoid-induced osteoporosis in men and women at high risk for fracture • to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer • to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer	$1,688	Bomynta, Wyost	Add to F-PA (see updated MRG criteria)

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Phyrago	dasatinib oral tablet 20 mg, 50 mg, 70 mg, 100 mg, 140 mg	Cycle Pharmaceuticals	For the treatment of: • newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase • adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib • adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy • pediatric patients 1 year of age and older with Ph+ CML in chronic phase • pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy	$18,246	Generic dasatinib, imatinib	Non-formulary

Injectafer	ferric carboxymaltose intravenous solution 1000 mg/20 mL	American Regent	• Iron deficiency anemia (IDA) in:
			  ○ adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron
			  ○ adult patients who have non-dialysis dependent chronic kidney disease
			• Iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity
				$1,964 per dose	Iron sucrose, ferumoxytol	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Exxua	gepirone oral tablet extended release 24-hour 18.2 mg, 36.3 mg, 54.5 mg, 72.6 mg, titration pack oral tablet extended release 24-hour 18.2 mg	Fabre Kramer	• Treatment of major depressive disorder (MDD) in adults	$1,822	Fluoxetine, sertraline, escitalopram	Non-formulary
Escitalopram	escitalopram oxalate oral capsule 15 mg	Almatica	• Major depressive disorder (MDD) in adults younger than 65 years of age and pediatric patients 12 years of age and older • Generalized anxiety disorder (GAD) in adults younger than 65 years of age	$170	Escitalopram tablets	Non-formulary

Otezla & Otezla XR	apremilast oral tablet extended release 24-hour 75 mg, initiation pk oral tablet therapy pack 10 mg, 20mg, 30 mg; (ER) 75 mg	Amgen	• Adult patients with:
			  ○ active psoriatic arthritis
			  ○ plaque psoriasis who are candidates for phototherapy or systemic therapy
			  ○ oral ulcers associated with Behçet's Disease
			• Pediatric patients 6 years of age and older with:
			  ○ active psoriatic arthritis
			  ○ moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
			• In the pediatric population, OTEZLA is indicated for patients weighing at least 20 kg, and OTEZLA XR is indicated for patients weighing at least 50 kg
				$5,324	Adalimumab	F-PA-QL (Already added via CRF)

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Tyruko	natalizumab-sztn intravenous concentrate 300 mg/15 mL	Sandoz	• Monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Tyruko increases the risk of PML. When initiating and continuing treatment with Tyruko, physicians should consider whether the expected benefit of Tyruko is sufficient to offset this risk. • For inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-α.	$7,103	Ocrevus, Copaxone, Briumvi Infliximab, ustekinumab, Entyvio	Non-formulary (see updated PAD and MRG criteria)
Doptelet	avatrombopag oral capsule sprinkle 10 mg	AkaRx	• Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure • Thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment • Thrombocytopenia in pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment	$12,657-$25,314	Promacta, Nplate	F-PA (Already added via CRF)
Zanaflex	tizanidine oral capsule 8 mg	Trifluent	• For the treatment of spasticity	$7,000 when dosed 4 capsules per day	Tizanidine tablets	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Krystexxa	pegloticase intravenous solution 8 mg/50 mL	Amgen	• For the treatment of chronic gout in adult patients refractory to conventional therapy	$61,486	Uloric	Non-formulary
Tremfya	guselkumab CD/UC induction subcutaneous solution auto-injector 200 mg/ 2mL	Janssen	• For the treatment of adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with moderate-to-severe plaque psoriasis and who are candidates for systemic therapy or phototherapy • For the treatment of adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with active psoriatic arthritis • For the treatment of adult patients with moderately to severely active ulcerative colitis • For the treatment of adult patients with moderately to severely active Crohn's disease	$30,000 per induction dose (monthly at week 0, 4, and 8)	Ustekinumab, adalimumab	Non-formulary

BRAND NAME	GENERIC NAME/ DOSAGE FORM	MANUFACTURER	INDICATION	PRICING*	FORMULARY ALTERNATIVES	RECOMMENDATION^
Phyrago	dasatanib oral tablet 80 mg	Cycle Pharmaceuticals	For the treatment of: • newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase • adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib • adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy • pediatric patients 1 year of age and older with Ph+ CML in chronic phase • pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy	$10,124	Generic dasatinib, imatinib	Non-formulary
MiloPhene	clomiphene oral tablet 50 mg	Burel Pharmaceuticals	• For the treatment of ovulatory dysfunction in women desiring pregnancy	$109 per 5-day course	Generic clomiphene	Non-formulary
Harliku	nitisinone oral tablet 2 mg	Cycle	• For the reduction of urine homogentisic acid (HGA) in adult patients with alkaptonuria (AKU)	$44,553	None	Non-formulary (see new MRG criteria)

*	Pricing reflects Wholesale Acquisition Cost (WAC) per month unless otherwise noted.
^	The recommendation may be affected by state specific requirements including carve out lists and individual state mandates.
†	Pricing based on standard twice-monthly dosing for most indications.
‡	Pricing is per each kit on items listed as a kit.
#	Re-activation of previously discontinued product (i.e., other available NDCs now inactive)

Recommendation: remove “Formulary step therapy required topical antibiotic criteria for approval” language since all medications are on formulary with quantity limits only.

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	~~Formulary step therapy required topical antibiotic criteria for approval:~~ ~~• Documentation (by either attestation or claims data) of trial and failure, contraindication, or intolerance to topical benzoyl peroxide~~ 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) topical benzoyl peroxide.~~ Formulary topical antibiotic <insert drug> is reserved for members who have used (or cannot/should not use) quantities within the quantity and/or fill limits.
Last P&T Review Date	~~9/2024~~9/2025