OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday, January 14, 2026

No live meeting is scheduled for January.
January 2026 will be a packet-only meeting.

Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, OK 73105

The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – January 14, 2026

DATE: January 7, 2026

NOTE: **No live January meeting. January 2026 is a packet-only meeting.**

Enclosed are the following items related to the January packet meeting. Material is arranged in order of the agenda.

DUR Board Meeting Minutes – Appendix A

Update on the Medication Coverage Authorization Unit – Appendix B

Appropriate Use of Riluzole in the SoonerCare Population – Appendix C

Annual Review of Adiposity-Based Chronic Disease (ABCD) Medications and 30-day Notice to Prior Authorize Zepbound® (Tirzepatide) – Appendix D

Annual Review of Antihyperlipidemics and 30-Day Notice to Prior Authorize Redemplo® (Plozasiran) – Appendix E

Annual Review of Antihypertensive Medications and 30-day Notice to Prior Authorize Aceon® (Perindopril), Arbli™ (Losartan Oral Suspension), Bisoprolol Fumarate 2.5mg Tablet, Hemiclor™ (Chlorthalidone 12.5mg Tablet), Inzirqo™ (Hydrochlorothiazide Oral Suspension), Javadin™ (Clonidine Oral Solution), Lopressor® (Metoprolol Tartrate Oral Solution) and Univasc® (Moexipril) – Appendix F

Annual Review of Bowel Preparation Medications and 30-day Notice to Prior Authorize MoviPrep® (Polyethylene Glycol 3350/Sodium Sulfate/ Sodium Chloride/ Potassium Chloride/Sodium Ascorbate/Ascorbic Acid for Oral Solution) – Appendix G

Annual Review of Gastrointestinal (GI) Cancer Medications – Appendix H

Annual Review of Non-Malignant Solid Tumor Medications and 30-day Notice to Prior Authorize Gomekli® (Mirdametinib), Papzimeos™ (Zopapogene Imadenovec-drba), and Romvimza™ (Vimseltinib) – Appendix I

Annual Review of Systemic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and 30-day Notice to Prior Authorize Coxanto® (Oxaprozin 300mg Capsule), Ibuprofen 300mg Tablet, Vyscoxa™ (Celecoxib Oral Suspension), and Xifyrm™ (Meloxicam Injection) – Appendix J

Annual Review of Ophthalmic Antibiotic Medications and 30-day Notice to Prior Authorize Levofloxacin Ophthalmic Solution – Appendix K

Annual Review of Vasomotor Symptom (VMS) Medications and 30-day Notice to Prior Authorize EstroGel® (Estradiol 0.06% Gel) and Lynkuet® (Elinzanetant) – Appendix L

30-Day Notice to Prior Authorize Alyglo™ [Immune Globulin (IG) Intravenous (IV), Human-stwk], Asceniv™ (IGIV, Human-slra), Bivigam® (IGIV, Human), Cuvitru® (IG Subcutaneous (SC), Human), Gammaplex® (IGIV, Human), Hizentra® (IGSC, Human), Octagam® (IGIV, Human), Panzyga® (IGIV, Human-ifas), and Xembify® (IGSC, Human) – Appendix M

U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates – Appendix N

Future Business

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Packet Meeting – January 14, 2026

NOTE: ***No live January meeting. January 2026 is a packet-only meeting.***

AGENDA

Review of the following items:

Items reviewed by Dr. Haymore, Chairman:

1. **DUR Board Meeting Minutes – See Appendix A**
   A. December 10, 2025 DUR Board Meeting Minutes
   B. December 10, 2025 DUR Board Recommendations Memorandum

Items reviewed by Dr. O'Halloran, Dr. Haymore, Chairman:

2. **Update on Medication Coverage Authorization Unit – See Appendix B**
   A. Pharmacy Help Desk Activity for December 2025
   B. Medication Coverage Activity for December 2025

Items reviewed by Dr. Wilson, Dr. Haymore, Chairman:

3. **Appropriate Use of Riluzole in the SoonerCare Population – Update – See Appendix C**
   A. Introduction
   B. Riluzole Utilization Trends in the SoonerCare Population
   C. Mailing Summary
   D. Results: Utilization of Riluzole Tablets
   E. Conclusions
   F. Recommendations

Items reviewed by Dr. O'Halloran, Dr. Haymore, Chairman:

4. **Annual Review of Adiposity-Based Chronic Disease (ABCD) Medications and 30-day Notice to Prior Authorize Zepbound® (Tirzepatide) – See Appendix D**
   A. Current Prior Authorization Criteria
   B. Utilization of ABCD Medications
   C. Prior Authorization of ABCD Medications
   D. Market News and Updates
   E. Zepbound® (Tirzepatide) Product Summary
   F. College of Pharmacy Recommendations
   G. Utilization Details of ABCD Medications

Items reviewed by Dr. Moss, Dr. Haymore, Chairman:

5. **Annual Review of Antihyperlipidemics and 30-Day Notice to Prior Authorize Redemplo® (Plozasiran) – See Appendix E**
   A. Current Prior Authorization Criteria
   B. Utilization of Antihyperlipidemics
   C. Prior Authorization of Antihyperlipidemics
   D. Market News and Updates
   E. Redemplo® (Plozasiran) Product Summary
   F. College of Pharmacy Recommendations
   G. Utilization Details of Antihyperlipidemics

Items reviewed by Dr. DeRemer, Dr. Haymore, Chairman:

6. **Annual Review of Antihypertensive Medications and 30-day Notice to Prior Authorize Aceon® (Perindopril), Arbli™ (Losartan Oral Suspension), Bisoprolol Fumarate 2.5mg Tablet, Hemiclor™ (Chlorthalidone 12.5mg Tablet), Inzirqo™ (Hydrochlorothiazide Oral Suspension), Javadin™ (Clonidine Oral Solution), Lopressor® (Metoprolol Tartrate Oral Solution), and Univasc® (Moexipril) – See Appendix F**
   A. Current Prior Authorization Criteria
   B. Utilization of Antihypertensive Medications
   C. Prior Authorization of Antihypertensive Medications
   D. Market News and Updates
   E. Cost Comparisons
   F. College of Pharmacy Recommendations
   G. Utilization Details of Antihypertensive Medications

Items reviewed by Dr. Wilson, Dr. Haymore, Chairman:

7. **Annual Review of Bowel Preparation Medications and 30-day Notice to Prior Authorize MoviPrep® (Polyethylene Glycol 3350/Sodium Sulfate/ Sodium Chloride/Potassium Chloride/Sodium Ascorbate/Ascorbic Acid for Oral Solution) – See Appendix G**
   A. Current Prior Authorization Criteria
   B. Utilization of Bowel Preparation Medications
   C. Prior Authorization of Bowel Preparation Medications
   D. Market News and Updates
   E. College of Pharmacy Recommendations
   F. Utilization Details of Bowel Preparation Medications

Items reviewed by Dr. Sinko, Dr. Haymore, Chairman:

8. **Annual Review of Gastrointestinal (GI) Cancer Medications – See Appendix H**
   A. Current Prior Authorization Criteria
   B. Utilization of GI Cancer Medications
   C. Prior Authorization of GI Cancer Medications
   D. Market News and Updates

E. College of Pharmacy Recommendations
F. Utilization Details of GI Cancer Medications

Items reviewed by Dr. Sinko, Dr. Haymore, Chairman:

9. **Annual Review of Non-Malignant Solid Tumor Medications and 30-day Notice to Prior Authorize Gomekli® (Mirdametinib), Papzimeos™ (Zopapogene Imadenovec-drba), and Romvimza™ (Vimseltinib) – See Appendix I**

A. Current Prior Authorization Criteria
B. Utilization of Non-Malignant Solid Tumor Medications
C. Prior Authorization of Non-Malignant Solid Tumor Medications
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Non-Malignant Solid Tumor Medications

Items reviewed by Dr. Wilson, Dr. Haymore, Chairman:

10. **Annual Review of Systemic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and 30-day Notice to Prior Authorize Coxanto® (Oxaprozin 300mg Capsule), Ibuprofen 300mg Tablet, Vyscoxa™ (Celecoxib Oral Suspension), and Xifyrm™ (Meloxicam Injection) – See Appendix J**

A. Current Prior Authorization Criteria
B. Utilization of NSAIDs
C. Prior Authorization of NSAIDs
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of NSAIDs

Items reviewed by Dr. DeRemer, Dr. Haymore, Chairman:

11. **Annual Review of Ophthalmic Antibiotic Medications and 30-day Notice to Prior Authorize Levofloxacin Ophthalmic Solution – See Appendix K**

A. Current Prior Authorization Criteria
B. Utilization of Ophthalmic Antibiotic Medications
C. Prior Authorization of Ophthalmic Antibiotic Medications
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Ophthalmic Antibiotic Medications

Items reviewed by Dr. Moss, Dr. Haymore, Chairman:

12. **Annual Review of Vasomotor Symptom (VMS) Medications and 30-day Notice to Prior Authorize EstroGel® (Estradiol 0.06% Gel) and Lynkuet® (Elinzanetant) – See Appendix L**

A. Current Prior Authorization Criteria
B. Utilization of VMS Medications

C. Prior Authorization of VMS Medications
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of VMS Medications

Items reviewed by Dr. DeRemer, Dr. Haymore, Chairman

13. 30-Day Notice to Prior Authorize Alyglo™ [Immune Globulin (IG) Intravenous (IV), Human-stwk], Asceniv™ (IGIV, Human-slra), Bivigam® (IGIV, Human), Cuvitru® (IG Subcutaneous (SC), Human), Gammaplex® (IGIV, Human), Hizentra® (IGSC, Human), Octagam® (IGIV, Human), Panzyga® (IGIV, Human-ifas) and Xembify® (IGSC, Human) – See Appendix M

A. Introduction
B. Cost Comparison: IGIV Products
C. Cost Comparison: IGSC Products
D. College of Pharmacy Recommendations

Items reviewed by Dr. O'Halloran, Dr. Haymore, Chairman:

14. U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates – See Appendix N

Items reviewed by Dr. Adams, Dr. Haymore, Chairman:

15. Future Business* (Upcoming Product and Class Reviews)

A. Anticonvulsants
B. Anti-Migraine Medications
C. Cardamyst™ (Etripamil Nasal Spray)
D. Cholestatic Liver Disease and Bile Acid Disorder Medications
E. Crenessity™ (Crinecerfont)
F. Insomnia Medications
G. Kebilidi™ (Eladocagene Exuparvovec-tneq)
H. Pulmonary Hypertension Medications

*Future product and class reviews subject to change.

NOTE: An analysis of the atypical [Aged, Blind, and Disabled (ABD)] patient subgroup of the Oklahoma Medicaid population has been performed pertaining to all recommendations included in this DUR Board meeting packet to ensure fair and knowledgeable deliberation of the potential impact of the recommendations on this patient population.

NOTE: Oklahoma Medicaid transitioned from a fee-for-service (FFS) pharmacy benefit to a managed care pharmacy benefit for most members on April 1, 2024. At that time, the majority of SoonerCare members were transitioned to one of the three managed care SoonerSelect plans: Aetna, Humana, or Oklahoma Complete Health. SoonerSelect data has been provided to the College of Pharmacy and has been used in analyses throughout this DUR Board meeting packet. The data

included in this DUR Board meeting packet combines FFS and managed care utilization data. The managed care utilization and prior authorization (PA) data reported in this packet is based solely on the data provided by the SoonerSelect plans.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING DECEMBER 10, 2025

DUR BOARD MEMBERS:	PRESENT	ABSENT
Cassidy Blaiss, Pharm.D., BCOP		X
Christen Ground, D.O.	X	
Bret Haymore, M.D.; Chairman	X	
Bethany Holderread, Pharm.D.	X	
Matt John, Pharm. D., MBA	X	
T. Craig Kupiec II, M.D., MSPH	X	
Lee Muñoz, D.Ph.	X	
Edna Patatanian, Pharm.D., FASHP; Vice Chairwoman		X
Jennifer Weakley, M.D., DipABLM		X

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Alanah Canfield Miller, Pharm.D.; Clinical Pharmacist		X
Michaela DeRemer, Pharm.D., MBA, BCIDP, BCPS; Clinical Pharmacist	X	
Darius Dorsey, Pharm.D.; Pharmacy Resident		X
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor	X	
Peggy Snyder, Pharm.D.; Clinical Pharmacist	X	
Ashley Teel, Pharm.D.; Clinical Pharmacist		X
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	X	
Devin Wilcox, D.Ph.; Pharmacy Director	X	
Justin Wilson, Pharm.D.; Clinical Pharmacist	X	
PA Oncology Pharmacists: Whitney Bueno, Pharm.D., BCOP		X
Christine Hughes, Pharm.D., MBA, BCOP		X
Lauren Sinko, Pharm.D., BCOP	X	
Graduate Students: Matthew Dickson, Pharm.D.		X
Mark Wendelboe	X	
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Josh Anderson, Chief of Staff		X
Mark Brandenburg, M.D., MSC; Medical Director	X	
Clay Bullard; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	
Darla Koone	X	
Melissa Miller, State Medicaid Director		X

Christine Picart	X	
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Chief Medical Officer		X
Laura Short	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Sharon Smith, Pharm.D.; Clinical Pharmacist	X	
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
***Legal representative**		
Travis Dennis, J.D.; Deputy General Counsel		X
Gentry Kincade, J.D.; Deputy General Counsel	X	
Gwendolyn Maxey, J.D.; Deputy General Counsel		X
Conner Mulvaney, J.D.; Deputy General Counsel		X

OTHERS PRESENT:	
Andrew Delgado, Bristol Myers Squibb	Jamie Tobitt, Apellis
Priya Rangan, Novartis	Brent Milovac, Leo Pharma
Bryan Steffan, Boehringer	Julie Vandaveer, Johnson & Johnson
Scott Burns, Johnson & Johnson	Kristen Winters, Centene
Kellie Vazzana, Alkermes	David Prather, Novo Nordisk
Brent Parker, Merck	Kenneth Berry, Alkermes
Lee Stout, Chiesi	Irene Chung, Aetna
Deidra Williams, Humana	Jenna Doerr, Artia Solutions
Melissa Abbott, Galderma	Porscha Showers, Gilead
Mike Thiem, Incyte	Valerie Willard, Glaukos
Pam Storey, PTC Bio	Shawn Akey, Concis Labs
Melanie Kitto, BioCryst	Michael Pericozzi, Sanofi
John Suelzer, Leo Pharma	Dave Miley, Teva
Jennifer Tamburo, AstraZeneca	Lindsey Walter, Novartis
Gary Parenteau, Dexcom	Payal Tejani, Biogen
Sherry Andes, Insmed	Mathhew Grew, Leo Pharma
Steve Kahn, Sobi	Michael Zarob, Argenx
Jeff Forshey, Rhythm	Nick Trombold, Alexion

PRESENT FOR PUBLIC COMMENT:	
Priya Rangan, Novartis	Brent Milovac, Leo Pharma
Andrew Delgado, Bristol Myers Squibb	Jamie Tobitt, Apellis
Julie Vandaveer, Johnson & Johnson	

AGENDA ITEM NO. 1: **CALL TO ORDER**

1A: ROLL CALL

Dr. Haymore called the meeting to order at 4:00pm. Roll call by Dr. Wilcox established the presence of a quorum.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: **PUBLIC COMMENT FORUM**

2A: AGENDA ITEM NO. 10 PRIYA RANGAN
2B: AGENDA ITEM NO. 12 BRENT MILOVAC
2C: AGENDA ITEM NO. 16 ANDREW DELGADO
2D: AGENDA ITEM NO. 17 JAMIE TOBITT

2E: AGENDA ITEM NO. 22 JULIE VANDAVEER
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 3:</u> APPROVAL OF DUR BOARD MEETING MINUTES
3A: NOVEMBER 12, 2025 DUR MINUTES
Materials included in agenda packet; presented by Dr. Haymore
Dr. Muñoz moved to approve; seconded by Dr. Kupiec
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 4:</u> UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT
4A: PHARMACY HELPDESK ACTIVITY FOR NOVEMBER 2025
4B: MEDICATION COVERAGE ACTIVITY FOR NOVEMBER 2025
Non-presentation item; materials included in agenda packet by Dr. Moss
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 5:</u> ACADEMIC DETAILING PROGRAM UPDATE
5A: BACKGROUND
5B: CURRENT TOPICS: CO-PRESCRIBING OPIOID MEDICATIONS WITH BENZODIAZEPINES (BZD) AND NALOXONE
5C: PRESCRIBER MAILINGS AND RESULTS: CO-PRESCRIBING OPIOID MEDICATIONS WITH BZD AND NALOXONE
5D: SUMMARY
Materials included in agenda packet; presented by Dr. Snyder
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 6:</u> SOONERCARE MAINTENANCE DRUG LIST
6A: INTRODUCTION
6B: SOONERCARE MAINTENANCE DRUG LIST
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 7:</u> VOTE TO PRIOR AUTHORIZE BRINSUPRI™ (BRENSOCATIB)
7A: MARKET NEWS AND UPDATES
7B: BRINSUPRI™ (BRENSOCATIB) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 8:</u> VOTE TO PRIOR AUTHORIZE BILDYOS® (DENOSUMAB-NXXP), BILPREVDA® (DENOSUMAB-NXXP), BOMYNTRA® (DENOSUMAB-BNHT), CONEXXENCE® (DENOSUMAB-BNHT), OSENVELT® (DENOSUMAB-BMWO), AND STOBOCLO® (DENOSUMAB-BMWO) AND UPDATE THE APPROVAL CRITERIA FOR THE BONE DENSITIY REGULATORS
8A: MARKET NEWS AND UPDATES
8B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Muñoz moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE FORZINITY™ (ELAMIPRETIDE)**

9A: MARKET NEWS AND UPDATES
9B: FORZINITY™ (ELAMIPRETIDE) PRODUCT SUMMARY
9C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Ground
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: **VOTE TO PRIOR AUTHORIZE RHAPSIDO® (REMIBRUTINIB)**

10A: MARKET NEWS AND UPDATES
10B: RHAPSIDO® (REMIBRUTINIB) PRODUCT SUMMARY
10C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: **VOTE TO PRIOR AUTHORIZE HARLIKU™ (NITISINONE), ORFADIN® (NITISINONE), NITYR® (NITISINONE), AND SEPHIENCE™ (SEPIPTERIN) AND UPDATE THE APPROVAL CRITERIA FOR THE AMINO ACID DISORDER MEDICATIONS**

11A: MARKET NEWS AND UPDATES
11B: PRODUCT SUMMARIES
11C: COST COMPARISONS
11D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss
Dr. Ground moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: **VOTE TO PRIORI AUTHORIZE ANZUPGO® (DELGOCITINIB 2% CREAM) AND UPDATE THE APPROVAL CRITERIA FOR ATOPIC DERMATITIS (AD) MEDICATIONS**

12A: MARKET NEWS AND UPDATES
12B: ANZUPGO® (DELGOCITINIB 2% CREAM) PRODUCT SUMMARY
12C: COST COMPARISONS
12D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Kupiec
ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: **VOTE TO PRIOR AUTHORIZE OMLYCLO® (OMALIZUMAB-IGEC) AND UPDATE THE APPROVAL CRITERIA FOR THE ASHTMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS**

13A: MARKET NEWS AND UPDATES
13B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: **VOTE TO PRIOR AUTHORIZE BORUZU® (BORTEZOMIB) AND LYNOZYFIC™ (LINVOSELTAMAB-GCPT) AND UPDATE THE APPROVAL CRITERIA FOR THE MULTIPLE MYELOMA MEDICATIONS**

14A: MARKET NEWS AND UPDATES
14B: LYNOZYFIC™ (LINVOSELTAMAB-GCPT) PRODUCT SUMMARY
14C: COST COMPARISON: BORTEZOMIB PRODUCTS
14D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Sinko
Dr. Muñoz moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

AGENDA ITEM NO. 15: **ANNUAL REVIEW OF SKYSONA® (ELIVALDOGENE AUTOTEMCEL)**

15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF SKYSONA® (ELIVALDOGENE AUTOTEMCEL)
15C: PRIOR AUTHORIZATION OF SKYSONA® (ELIVALDOGENE AUTOTEMCEL)
15D: MARKET NEWS AND UPDATES
15E: COLLEGE OF PHARMACY RECOMMENDATIOSN

Materials included in agenda packet; presented by Dr. Moss
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 16: **ANNUAL REVIEW OF SKIN CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE KEYTRUDA QLEX™ (PEMBROLIZUMAB/BERAHYALURONIDASE ALFA-PMPH) AND OPDIVO QVANTIG™ (NIVOLUMAB/HYALURONIDASE-NVHY)**

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF SKIN CANCER MEDICATIONS
16C: PRIOR AUTHORIZATION OF SKIN CANCER MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: PRODUCT SUMMARIES
16F: COLLEGE OF PHARMACY RECOMMENDATIONS
16G: UTILIZATION DETAILS OF SKIN CANCER MEDICATIONS

Materials included in agenda packet; presented by Dr. Sinko
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 17: **ANNUAL REVIEW OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE IMAAVY™ (NIPOCALIMAB-AAHU)**

17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS
17C: PRIOR AUTHORIZATION OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS
17D: MARKET NEWS AND UPDATES
17E: IMAAVY™ (NIPOCALIMAB-AAHU) PRODUCT SUMMARY
17F: COST COMPARISONS
17G: COLLEGE OF PHARMACY RECOMMENDATIONS
17H: UTILIZATION DETAILS OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS

Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 18: **30-DAY NOTICE TO PRIOR AUTHORIZE ALYGLO™ [IMMUNE GLOBULIN (IG) INTRAVENOUS (IV), HUMAN-STWK], ASCENIV™ (IGIV, HUMAN-SLRA), CUVITRU® (IG SUBCUTANEOUS (SC), HUMAN), GAMMAGARD LIQUID® (IG INFUSION, HUMAN), GAMMAGARD S/D® (IGIV, HUMAN), GAMMAPLEX® (IGIV, HUMAN), HIZENTRA® (IGSC, HUMAN), PANZYGA® (IGIV, HUMAN-IFAS), PRIVIGEN® (IGIV, HUMAN), AND XEMBIFY® (IGSC, HUMAN-KLHW)**

18A: INTRODUCTIONS
18B: COST COMPARISONS
18C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. DeRemer

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 19: **ANNUAL REVIEW OF THROMBOCYTOPENIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE DOPTELET® SPRINKLE (AVATROMBOPAG) AND WAYRILZ™ (RILZABRUTINIB)**

19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF THROMBOCYTOPENIA MEDICATIONS
19C: PRIOR AUTHORIZATION OF THROMBOCYTOPENIA MEDICATIONS
19D: MARKET NEWS AND UPDATES
19E: WALYRILZ™ (RILZABRUTINIB) PRODUCT SUMMARY
19F: COLLEGE OF PHARMACY RECOMMENDATIONS
19G: UTILIZATION DETAILS OF THROMBOCYTOPENIA MEDICATIONS

Materials included in agenda packet; presented by Dr. O'Halloran

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 20: **ANNUAL REVIEW OF MUSCLE RELAXANT MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ATMEKSI® (METHOCARBAMOL ORAL SUSPENSION), METAXALONE 640MG TABLET, AND TANLOR® (METHOCARBAMOL 1,000MG TABLET)**

20A: CURRENT PRIOR AUTHORIZATION CRITERIA
20B: UTILIZATION OF MUSCLE RELAXANT MEDICATIONS
20C: PRIOR AUTHORIZATION OF MUSCLE RELAXANT MEDICATIONS
20D: MARKET NEWS AND UPDATES
20E: PRODUCT SUMMARIES
20F: CARISOPRODOL PRODUCTS COST COMPARISON
20G: COLLEGE OF PHARMACY RECOMMENDATIONS
20H: UTILIZATION DETAILS OF MUSCLE RELAXANT MEDICATIONS

Materials included in agenda packet; presented by Dr. Wilson

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 21: **30-DAY NOTICE TO PRIOR AUTHORIZE ANDEMBRY® (GARADACIMAB-GXII), DAWNZERA™ (DONIDALORSEN), AND EKTERLY® (SEBETRALSTAT) AND CREATE A PRODUCT BASED PRIOR AUTHORIZATION (PBPA) CATEGORY FOR THE HEREDITARY ANGIOEDEMA (HAE) MEDICATIONS**

21A: CURRENT PRIOR AUTHORIZATION CRITERIA
21B: MARKET NEWS AND UPDATES
21C: PRODUCT SUMMARIES
21D: ESTIMATION OF SAVINGS
21E: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. DeRemer

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 22: **ANNUAL REVIEW OF ANTIDEPRESSANTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ESCITALOPRAM 15MG CAPSULE AND RALDESY™ (TRAZODONE ORAL SOLUTION)**

22A: CURRENT PRIOR AUTHORIZATION CRITERIA
22B: UTILIZATION OF ANTIDEPRESSANTS
22C: PRIOR AUTHORIZATION OF ANTIDEPRESSANTS
22D: MARKET NEWS AND UPDATES
22E: COST COMPARISONS
22F: COLLEGE OF PHARMACY RECOMMENDATIONS
22G: UTILIZATION DETAILS OF ANTIDEPRESSANTS

Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 23: **U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES**
Non-presentation item; materials included in agenda packet by Dr. Moss
ACTION: NONE REQUIRED

AGENDA ITEM NO. 24: **FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)**
NO LIVE DUR MEETING IS SCHEDULED FOR JANUARY 2026. JANUARY 2026 WILL BE A PACKET ONLY MEETING.

24A: ADIPOSITY-BASED CHRONIC DISEASE (ABCD) MEDICATIONS
24B: ANTIHYPERLIPIDEMICS
24C: ANTIHYPERTENSIVE MEDICATIONS
24D: GASTROINTESTINAL (GI) CANCER MEDICATIONS
24E: NON-MALIGNANT SOLID TUMOR MEDICATIONS
24F: NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)
24G: OPHTHALMIC ANTIBIOTIC MEDICATIONS

*Future product and class reviews subject to change.
Non-presentation item; materials included in agenda packet by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 25: **ADJOURNMENT**
The meeting was adjourned at 5:57pm.

The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: December 12, 2025

To: Terry Cothran, D.Ph.
Pharmacy Director
Oklahoma Health Care Authority

From: Michyla Adams, Pharm.D.
Drug Utilization Review (DUR) Manager
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting on December 10, 2025

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Academic Detailing (AD) Program Update

NO ACTION REQUIRED.

Recommendation 3: SoonerCare Maintenance Drug List

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following additions to the maintenance drug list based on net costs (changes shown in red):

- Alzheimer's Medications
- Anticonvulsants
- Antidepressants/Anxiolytics
- Antihistamines
- Antihypertensive Medications
- Antipsychotic Medications
- Anti-Ulcer Medications
- Bladder Control Medications

- Benign Prostatic Hyperplasia (BPH) Medications
- Cardiovascular Medications
- Chronic Obstructive Pulmonary Disease (COPD) Medications
- Diabetes Medications
- Fluoride Preparations
- Glaucoma Medications
- Hyperlipidemia Medications
- Non-Controlled Attention-Deficit/Hyperactivity Disorder (ADHD) Medications
- Osteoporosis Medications
- Parkinson's Medications
- Preeclampsia Prevention
- Smoking Cessation
- Thyroid Medications

Recommendation 4: Vote to Prior Authorize Brinsupri™ (Brensocatib)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Brinsupri™ (brensocatib) with the following criteria (shown in red):

Brinsupri™ (Brensocatib) Approval Criteria:

1. An FDA approved diagnosis of non-cystic fibrosis bronchiectasis (NCFB). Diagnosis must be confirmed by both of the following:
   a. Chest computed tomography (CT) scan; and
   b. Clinical history consistent with NCFB (e.g., cough, chronic sputum production, and/or recurrent respiratory infections); and
2. Member must be 12 years of age or older; and
3. Member must not have cystic fibrosis; and
4. Member must have a history of pulmonary exacerbation(s) (e.g., required treatment with antibiotics and/or required hospitalization or emergency room visit) in the last 12 months according to member's age:
   a. Members 18 years of age or older: ≥2 exacerbations; or
   b. Members 12-17 years of age: ≥1 exacerbation; and
5. Prescriber must verify that any underlying cause of NCFB is adequately treated, if applicable; and
6. Brinsupri™ must be prescribed by, or in consultation with, a pulmonary or infectious disease specialist (or an advanced care practitioner with a supervising physician who is a pulmonary or infectious disease specialist); and
7. Initial approvals will be for the duration of 6 months. For continued authorization, prescriber must verify member demonstrated a positive clinical response to Brinsupri™ as demonstrated by a decrease in NCFB

symptoms and/or exacerbations. Subsequent approvals will be for 1 year.

Recommendation 5: Vote to Prior Authorize Bildyos® (Denosumab-nxxp), Bilprevda® (Denosumab-nxxp), Bomyntra® (Denosumab-bnht), Conexxence® (Denosumab-bnht), Osenvelt® (Denosumab-bmwo), and Stoboclo® (Denosumab-bmwo) and Update the Approval Criteria for the Bone Density Regulators

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Osteoporosis Medications Product Based Prior Authorization (PBPA) category (changes shown in red in the following PBPA Tier chart and additional criteria):

1. The prior authorization of Bildyos® (denosumab-nxxp), Conexxence® (denosumab-bnht), and Stoboclo® (denosumab-bmwo) with placement into the Special PA Tier with additional criteria similar to Prolia®; and
2. Designating Jubbonti® (denosumab-bbdz) at parity with Prolia® (denosumab) as the preferred osteoporosis-indicated denosumab products based on net costs.

Osteoporosis Medications*		
Tier-1	**Tier-2**	**Special PA¥**
alendronate tabs (Fosamax®)	alendronate + vitamin D tabs (Fosamax® + D)	abaloparatide inj (Tymlos®)
calcium + vitamin D†	risedronate tabs (Actonel®)	alendronate effervescent tabs (Binosto®)
ibandronate tabs (Boniva®)		alendronate soln (Fosamax®)
zoledronic acid inj (Reclast®)		denosumab inj (Prolia®)
		denosumab-bbdz inj (Jubbonti®)
		denosumab-bmwo inj (Stoboclo®)
		denosumab-bnht inj (Conexxence®)
		denosumab-nxxp inj (Bildyos®)
		ibandronate inj (Boniva® IV)
		risedronate 30mg tabs (Actonel®)
		risedronate DR tabs (Atelvia®)
		romosozumab-aqqg (Evenity®)
		teriparatide inj (Forteo®) – **Brand Preferred**

Osteoporosis Medications*		
Tier-1	**Tier-2**	**Special PA¥**
		teriparatide inj (Bonsity®)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
†OTC calcium + vitamin D must be used at recommended doses in conjunction with Tier-1 bisphosphonates for trial to be accepted unless member has a recent laboratory result showing adequate vitamin D or member is unable to tolerate calcium. OTC calcium + vitamin D are only covered for members with osteoporosis who are being treated with a bisphosphonate.
¥Unique criteria applies to medications in the Special PA Tier.
DR = delayed-release; inj = injection; PA = prior authorization; soln = solution; tabs = tablets

Bildyos® (Denosumab-nxxp), Boniva® [Ibandronate Intravenous (IV) Solution], Conexxence® (Denosumab-bnht), Jubbonti® (Denosumab-bbdz), ~~and~~ Prolia® (Denosumab), and Stoboclo® (Denosumab-bmwo) Approval Criteria:

1. A minimum of a 12-month trial with a Tier-1 or Tier-2 bisphosphonate medication plus adequate calcium and vitamin D; or
2. Contraindication to or intolerable adverse effects with Tier-1 and Tier-2 bisphosphonate medications (including oral and intravenous routes of administration); and
3. For Bildyos®, Conexxence®, ~~Jubbonti®,~~ and Stoboclo® a patient-specific, clinically significant reason why the member cannot use Jubbonti® or Prolia® must be provided.
    a. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

The College of Pharmacy also recommends the prior authorization of Bilprevda® (denosumab-nxxp), Bomyntra® (denosumab-bnht), and Osenvelt® (denosumab-bmwo) with criteria similar to Xgeva® (denosumab) and to designate Wyost® (denosumab-bbdz) as a preferred oncology-indicated denosumab product along with Xgeva® based on net costs (changes shown in red):

Bilprevda® (Denosumab-nxxp), Bomyntra® (Denosumab-bnht), Osenvelt® (Denosumab-bmwo), Wyost® (Denosumab-bbdz), and Xgeva® (Denosumab) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Prevention of skeletal-related events in members with multiple myeloma and in members with bone metastases from solid tumors; or
    b. Treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity; and
        i. Prescriber must document that tumor is unresectable or that surgical resection is likely to result in severe morbidity; or

c. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy; and
    i. Member must have albumin-corrected calcium of >12.5mg/dL (3.1mmol/L) despite treatment with intravenous bisphosphonate therapy in the last 30 days prior to initiation of ~~Xgeva®~~ therapy; and

2. For Bilprevda®, Bomyntra®, and Osenvelt® ~~Wyost® (denosumab-bbdz),~~ a patient-specific, clinically significant reason why the member cannot use Wyost® or Xgeva® must be provided.
    a. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.
3. These products will be covered as a medical benefit only.

Recommendation 6: Vote to Prior Authorize Forzinity™ (Elamipretide)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Forzinity™ (elamipretide) with the following criteria (shown in red):

Forzinity™ (Elamipretide) Approval Criteria:

1. An FDA approved diagnosis of Barth syndrome; and
    a. Diagnosis must be confirmed by genetic testing identifying a hemizygous pathogenic variant in the *TAFAZZIN* gene (results of genetic testing must be submitted); and
2. Member's current weight must be provided and must be ≥30kg; and
3. Member's current estimated glomerular filtration rate (eGFR) must be provided and:
    a. Requested dose must be appropriate for the member's eGFR, per package labeling; and
    b. Member must not be on dialysis; and
4. Must be prescribed by, or in consultation with, a specialist with expertise in the treatment of Barth syndrome (or an advanced care practitioner with a supervising physician who is a specialist with expertise in the treatment of Barth syndrome); and
5. Prescriber must confirm the member and/or caregiver will be trained on the proper administration and storage of Forzinity™ prior to starting treatment; and
6. Initial approvals will be for a duration of 6 months. After 6 months of treatment, subsequent approvals (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by an improvement in muscle strength, fatigue, or other clinical symptoms of the disease; and
7. A quantity limit of 14mL per 28 days will apply.

Recommendation 7: Vote to Prior Authorize Rhapsido® (Remibrutinib)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Rhapsido® (remibrutinib) with the following criteria (shown in red):

Rhapsido® (Remibrutinib) Approval Criteria:

1. An FDA approved diagnosis of chronic spontaneous urticaria (CSU); and
2. Member must be 18 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. Member must have an Urticaria Activity Score (UAS) ≥16; and
5. Rhapsido® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Member must have a documented trial of (or have a contraindication or documented intolerance to) all of the following therapies:
    a. Second-generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and
    b. Xolair® (omalizumab) for at least 12 weeks at recommended dosing; and
7. Initial approvals will be for the duration of 3 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment (e.g., improvement in baseline UAS score, improvement in symptoms, reduction in exacerbations). Additionally, compliance will be evaluated for continued approval.

Recommendation 8: Vote to Prior Authorize Harliku™ (Nitisinone), Orfadin® (Nitisinone), Nityr® (Nitisinone), and Sephience™ (Sepiapterin) and Update the Approval Criteria for the Amino Acid Disorder Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Harliku™ (nitisinone), Nityr® (nitisinone), and Orfadin® (nitisinone) with the following criteria (shown in red):

Harliku™ (Nitisinone), Nityr® (Nitisinone), and Orfadin® (Nitisinone) Approval Criteria [Alkaptonuria (AKU) Diagnosis]:

1. An indication to reduce urine homogentisic acid (HGA) in patients with alkaptonuria (AKU); and
    a. The diagnosis of AKU must be confirmed by 1 of the following (results of the selected test must be submitted with the request):

i. Genetic testing identifying biallelic pathogenic or likely pathogenic variants in the homogentisate 1,2-dioxygenase (HGD) gene; or
ii. Urine test for HGA showing >0.4 grams of HGA excreted in 24 hours; and

2. Nitisinone must be prescribed by, or in consultation with, a geneticist, rheumatologist, or specialist with expertise in the treatment of AKU; and
3. The prescriber must confirm the member will receive a baseline ophthalmologic examination prior to initiating nitisinone treatment; and
4. The prescriber must confirm the member has been counseled to report any unexplained ocular, neurologic, or other symptoms to their health care provider; and
5. Use of Harliku™ will require a documented failed trial of both generic nitisinone 2mg capsules and Nityr® (nitisinone) 2mg tablets and clinical justification as to why Harliku™ would be expected to confer a different response since it contains the same active ingredient (nitisinone); and
6. A quantity limit of 30 tablets for 30 days will apply; and
7. Initial approvals will be for the duration of 6 months; and
8. Subsequent approvals will be for the duration of 1 year; and
9. Reauthorization requires the following:
   a. Verification from the prescriber of continued response to therapy (i.e., decrease in urine HGA levels, improvement in joint pain, decrease in visible ochronosis).

Nityr® (Nitisinone) and Orfadin® (Nitisinone) Approval Criteria [Hereditary Tyrosinemia (HT-1) Diagnosis]:

1. An FDA approved diagnosis of HT-1; and
   a. The diagnosis of HT-1 must be confirmed by 1 of the following (results of the selected test must be submitted with the request):
      i. Genetic testing identifying biallelic pathogenic or likely pathogenic variants in the fumarylacetoacetase hydrolase (FAH) gene; or
      ii. Elevated succinylacetone concentrations in the blood or urine; and
2. Documentation of active management with a tyrosine and phenylalanine restricted diet; and
3. Nitisinone must be prescribed by, or in consultation with, a geneticist or specialist with expertise in the treatment of HT-1; and
4. The prescriber must verify the member will receive appropriate ophthalmologic examinations; and
5. The prescriber must confirm the member has been counseled to report any unexplained ocular, neurologic, or other symptoms to their health care provider; and

6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the package labeling; and
7. Initial approvals will be for the duration of 6 months; and
8. Subsequent approvals will be for the duration of 1 year; and
9. Reauthorization requires the following:
    a. Documentation of active management with a tyrosine and phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy (i.e., decrease in plasma and/or urine succinylacetone concentration).

The College of Pharmacy recommends the prior authorization of Sephience™ (sepiapterin) with the following criteria (shown in red):

Sephience™ (Sepiapterin) Approval Criteria:

1. An FDA approved diagnosis of phenylketonuria (PKU); and
2. Documentation of active management with a phenylalanine restricted diet; and
3. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
4. Sephience must be prescribed by, or in consultation with, a geneticist, neurologist, or specialist with expertise in the treatment of PKU; and
5. Concomitant use with Palynziq® (pegvaliase-pqpz) will not be approved except to allow for temporary coverage during the titration of Palynziq®; and
6. Member must meet 1 of the following (documentation must be provided):
    a. A 3-month trial with sapropterin with inadequate response, defined as blood phenylalanine ≥360micromol/L, despite consistent use in combination with dietary phenylalanine restriction; or
    b. Member is a non-responder to sapropterin defined as ≤30% decrease in phenylalanine after 30 days of sapropterin therapy in combination with dietary phenylalanine restriction; or
    c. A diagnosis of classic PKU (blood phenylalanine ≥1,200micromol/L at diagnosis or 2 null mutations in *trans*); or
    d. A patient specific, clinically significant reason why the member cannot use generic Kuvan® (sapropterin) must be provided; and
7. Initial approvals will be for 2 weeks. After which time, the prescriber must verify that the member responded to treatment as defined by laboratory documentation of ≥30% reduction in blood phenylalanine levels from baseline; and
    a. Members younger than 2 years of age will be approved for a longer dosage titration per the package labeling up to the maximum daily dosage of 60mg/kg/day. After which time, the prescriber must

verify that the member responded to treatment as defined by laboratory documentation of ≥30% reduction in blood phenylalanine levels from baseline; or
   b. If the member was initiated at 60mg/kg/day, then no additional approvals will be granted after a trial period of 2 weeks if the member did not respond to treatment as defined by laboratory documentation of ≥30% reduction in blood phenylalanine levels from baseline; and
8. Subsequent approvals will be for the duration of 1 year; and
9. Reauthorization requires the following:
   a. Documentation of active management with a phenylalanine restricted diet; and
   b. Verification from the prescriber of continued response to therapy (i.e., blood phenylalanine level, increase in dietary phenylalanine tolerance, improvement in clinical symptoms).

The College of Pharmacy also recommends updating the current approval criteria for the sapropterin products and Palynziq® (pegvaliase-pqpz) based on the new FDA approvals, guideline updates, and clinical practice (changes shown in red):

Javygtor™ (Sapropterin), ~~and~~ Kuvan® (Sapropterin), and Zelvysia™ (Sapropterin) Approval Criteria:

1. An FDA approved diagnosis of phenylketonuria (PKU); and
2. Documentation of active management with a phenylalanine restricted diet; and
3. Member must not have 2 null mutations in *trans*; and
4. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
5. Sapropterin must be prescribed by, or in consultation with, a geneticist, neurologist, or specialist with expertise in the treatment of PKU; and
6. Concomitant use with Palynziq® (pegvaliase-pqpz) will not be approved except to allow for temporary coverage during the titration of Palynziq®; and
7. Use of Javygtor™ (sapropterin) or Zelvysia™ (sapropterin) will require a patient specific, clinically significant reason why other generic formulations of sapropterin cannot be used; and
8. Initial approvals will be for the duration of 30 days. After which time, the prescriber must verify that the member responded to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; and
   a. If the member was initiated at 10mg/kg/day dose, then a subsequent trial of 20mg/kg/day for a duration of 30 days can be approved, after which time the prescriber must verify the member

responded to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; or

b. If the member was initiated at 20mg/kg/day dose, then no additional approvals will be granted after a trial period of 30 days if the member did not respond to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; and

9. Subsequent approvals will be for the duration of 1 year; and
10. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy (i.e., blood phenylalanine level, increase in dietary phenylalanine tolerance, improvement in clinical symptoms).

Palynziq® (Pegvaliase-pqpz) Approval Criteria:

1. An FDA approved indication to reduce blood phenylalanine concentrations in members with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations >600micromol/L on existing management; and
2. Documentation of active management with a phenylalanine restricted diet; and
3. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
4. Palynziq® must be prescribed by, or in consultation with, a geneticist, neurologist, or specialist with expertise in the treatment of PKU; and
5. Concomitant use with Kuvan® (sapropterin) or Sephience™ (sepiapterin) will not be approved except to allow for temporary coverage during the titration of Palynziq®; and
6. Prescriber, pharmacy, and member must be enrolled in the Palynziq® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
7. Initial dose must be administered under the supervision of a health care provider equipped to manage anaphylaxis and observe the member for at least 60 minutes following injection; and
8. Member must be prescribed auto-injectable epinephrine and be counseled on its appropriate use; and
9. ~~Initial approvals will be for the duration of 33 weeks to allow for initial titration and for 24 weeks of maintenance treatment with 20mg once daily dosing. Members should then be assessed for a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L. Slower dose titrations may be approved based on member's response and tolerability; and~~

a. ~~If member has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, approvals may be granted for the 40mg once daily dosing for a duration of 16 weeks; and~~
b. ~~If after at least 16 weeks with the 40mg dose, member has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, approvals may be granted for the 60mg once daily dosing for an additional 16 weeks of treatment; or~~
c. ~~If member has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, subsequent approvals will be for the duration of 1 year; and~~

10. Initial approvals will be for 1 year to allow for initial titration and maintenance treatment. Reauthorization may be granted if the following information is provided (documentation must be submitted):
    a. Member has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline; or
    b. Member has achieved a blood phenylalanine concentration ≤600micromol/L; or
    c. Member is currently in the titration/maintenance phase of treatment, and the dose is being titrated up to the maximum daily dose of 60mg once daily. Slower dose titrations may be approved based on member's response and tolerability; and
11. Members who do not achieve at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L after at least 16 weeks of continuous treatment with the maximum dosage of 60mg once daily will not be approved for subsequent approvals; and
12. Dose titrations up to the maximum daily dose of 60mg once daily will be permitted to allow members to achieve a blood phenylalanine level ≤360micromol/L based on the current treatment guideline goal for blood phenylalanine level; and
13. Subsequent approvals will be for the duration of 1 year; and
14. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy (i.e., blood phenylalanine level, increase in dietary phenylalanine tolerance, improvement in clinical symptoms).

Recommendation 9: Vote to Prior Authorize Anzupgo® (Delgocitinib 2% Cream) and Update the Approval Criteria for the Atopic Dermatitis (AD) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Anzupgo® (delgocitinib 2% cream) with the following criteria (shown in red):

Anzupgo® (Delgocitinib 2% Cream) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe chronic hand eczema (CHE) meeting 1 of the following:
   a. Hand eczema has persisted for >3 months; or
   b. Hand eczema has returned twice or more within the last 12 months; and
2. Member must be 18 years of age or older; and
3. Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
4. Prescriber must attest that the member has been counseled regarding standard non-medicated skin care, including but not limited to:
   a. Frequent use of emollients/moisturizers; and
   b. Washing hands in lukewarm (not hot) water; and
   c. Avoidance of known and relevant irritants and allergens where possible; and
5. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); and
   b. 1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
6. Concurrent use with other Janus kinase (JAK) inhibitors or potent immunosuppressants will not generally be approved; and
7. Member must be counseled to apply Anzupgo® only to the hands and wrists. Anzupgo® will not be approved for application to any other area; and
8. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
9. A quantity limit of 60 grams per 30 days will apply.

The College of Pharmacy also recommends updating the Nemluvio® (nemolizumab-ilto) and Opzelura® (ruxolitinib 1.5% cream) approval criteria based on recent FDA approvals and DUR Board recommendations from the November 2025 DUR Board meeting (changes shown in red):

Nemluvio® (Nemolizumab-ilto) Approval Criteria [Atopic Dermatitis Diagnosis]:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies; and
2. Member must be 12 years of age or older; and
3. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
    b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
4. Member must agree to continue using a topical corticosteroid and/or a topical calcineurin inhibitor in combination with Nemluvio® until the disease has sufficiently improved; and
5. Member's body surface area (BSA) of atopic dermatitis involvement must be provided and the member must have a documented BSA involvement of ≥10% (can apply to member's current BSA or a historical value prior to treatment); and
6. A patient-specific, clinically significant reason the member cannot use Adbry® (tralokinumab-ldrm) must be provided; and
7. Must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
8. Requests for concurrent use of Nemluvio® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Nemluvio® has not been studied in combination with other biologic therapies); and
9. Initial approvals will be for the initial dosing for the duration of 16 weeks; and
10. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
    a. A dosage of 30mg every 8 weeks will be approved for reauthorization; or
    b. If a dosage of 30mg every 4 weeks is requested for reauthorization, additional patient-specific information will be required to support the need for continuing the every 4 week dosing regimen.

Opzelura® (Ruxolitinib 1.5% Cream) Approval Criteria [Atopic Dermatitis Diagnosis]:

1. An FDA approved indication for short-term and non-continuous treatment of mild-to-moderate atopic dermatitis; and

2. Member must be ~~12~~ 2 years of age or older; and
3. Member must not be immunocompromised; and
4. Member must have a body surface area (BSA) involvement ≤20%; and
5. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with ~~all~~ 2 of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); ~~and~~ or
   b. 1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; ~~and~~ or
   c. Eucrisa® (crisaborole); and
6. Concurrent use with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants (e.g., azathioprine, cyclosporine) will not generally be approved; and
7. Prescriber must verify female members are not breastfeeding; and
8. If the member is pregnant or becomes pregnant, prescriber must verify member has been counseled on potential risks of this medication and will report the exposure to the Opzelura® pregnancy registry; and
9. Approvals will be for a maximum duration of 8 weeks of treatment; and
10. Reauthorization may be considered if member has a recent TCS, TCI, or Eucrisa® trial (or a contraindication or documented intolerance); and
    a. Additionally, the prescriber must document the member had a positive response to and tolerated previous treatment with Opzelura®; and
11. Subsequent approvals will only be considered once each 90-day period to ensure appropriate short-term and non-continuous utilization.

Next, the College of Pharmacy recommends updating the Zoryve® (roflumilast) approval criteria based on recent FDA approvals and DUR Board recommendations from the November 2025 DUR Board meeting (changes shown in red):

Zoryve® (Roflumilast 0.15% or 0.05% Cream) Approval Criteria [Atopic Dermatitis Diagnosis]:

1. An FDA approved diagnosis of mild-to-moderate atopic dermatitis; and
2. ~~Member must be 6 years of age or older; and~~
3. Requested product must be FDA approved for the member's age; and
   a. 0.15% Cream: Member must be 6 years of age or older; or
   b. 0.05% Cream: Member must be 2 to 5 years of age; and
4. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); and
   b. 1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and

c. Eucrisa® (crisaborole); and
5. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
6. A quantity limit of 60 grams per 30 days will apply.

Zoryve® (Roflumilast 0.3% Cream or 0.3% Foam) Approval Criteria [Plaque Psoriasis Diagnosis]:

1. An FDA approved diagnosis of plaque psoriasis; and
2. ~~Member must be 6 years of age or older; and~~
3. Requested product must be FDA approved for the member's age; and
   a. 0.3% Cream: Member must be 6 years of age or older; or
   b. 0.3% Foam: Member must be 12 years of age or older; and
4. Member must have a body surface (BSA) involvement of ≤20% (or ≤25% if both the scalp and body are being treated); and
5. Member must not have moderate or severe hepatic impairment (Child-Pugh B or C); and
6. ~~Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and~~
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance):
   a. An ultra-high to high potency topical corticosteroid (TCS); or
   b. A generic topical calcipotriene product; or
   c. A topical tazarotene product; and
8. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
9. A quantity limit of 60 grams per 30 days will apply.

Zoryve® (Roflumilast 0.3% Foam) Approval Criteria [Seborrheic Dermatitis Diagnosis]:

1. An FDA approved diagnosis of seborrheic dermatitis; and
2. Prescriber must confirm member's condition is moderate or severe; and
3. Member must be 9 years of age or older; and
4. Member must have a body surface area (BSA) involvement of ≤20%; and
5. Member must not have moderate or severe hepatic impairment (Child-Pugh B or C); and
6. ~~Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and~~
7. If the affected area is limited to the scalp, member must have documented trials within the last 6 months for a minimum of 2 weeks

that resulted in failure with at least 1 product from all of the following categories (or have a contraindication or documented intolerance):
   a. Over-the-counter (OTC) antifungal shampoo (e.g., selenium sulfide, zinc pyrithione); and
   b. OTC coal tar shampoo; and
   c. Tier-1 prescription antifungal shampoo (e.g., ketoconazole 2% shampoo); and
   d. Tier-1 topical corticosteroid; and
8. If the affected area includes the face or body, member must have documented trials within the last 6 months for a minimum of at least 2 weeks that resulted in failure with at least 1 product from all of the following categories (or have a contraindication or documented intolerance):
   a. Tier-1 topical antifungal (e.g., ketoconazole, ciclopirox); and
   b. Tier-1 topical corticosteroid; and
   c. Topical calcineurin inhibitor (e.g., pimecrolimus 1% cream, tacrolimus 0.1% ointment); and
9. Initial approvals will be for a duration of 8 weeks. After 8 weeks, the prescriber will need to provide clinical documentation that the member is improving on the medication and provide justification for continuation of therapy; and
10. A quantity limit of 60 grams per 30 days will apply.

Lastly, the College of Pharmacy recommends updating the Elidel® (pimecrolimus cream) and Protopic® (tacrolimus ointment) approval criteria based on DUR Board recommendations from the November 2025 DUR Board meeting (changes shown in red):

Elidel® (Pimecrolimus Cream) and Protopic® (Tacrolimus Ointment) Approval Criteria:

1. The first 90 days of a 12-month period will be covered without prior authorization; and
2. After the initial period, authorization may be granted with documentation of 1 trial with a Tier-1 topical corticosteroid at least 6 weeks in duration within the past 90 days; and
3. Therapy will be approved only once each 90-day period to ensure appropriate short-term and intermittent utilization as advised by the FDA; and
4. Quantities will be limited to 30 grams for use on the face, neck, and groin, and 100 grams for all other areas; and
5. Authorizations will be restricted to those members who are not immunocompromised; and
~~6. Members must meet all of the following criteria:~~
   ~~a. An FDA approved indication:~~
      ~~i. Elidel®: Short-term and intermittent treatment for mild-to-moderate atopic dermatitis (eczema); or~~

~~ii. Protopic®: Short-term and intermittent treatment for moderate-to-severe atopic dermatitis (eczema); and~~

~~b. Age restrictions:~~

~~i. Elidel® 1% is restricted to 2 years of age and older; and~~

~~ii. Protopic® 0.03% is restricted to 2 years of age and older; and~~

~~iii. Protopic® 0.1% is restricted to 15 years of age and older; or~~

7. Clinical exceptions for the trial requirement may be considered for the following:
   a. Documented adverse effect, drug interaction, or contraindication to Tier-1 topical corticosteroids; or
   b. Atopic dermatitis of the face or groin where prescriber does not want to use topical corticosteroids.~~; or~~

~~8. Clinical exceptions for the age restrictions (for members younger than the FDA approved age) may be considered for the following:~~

~~a. Prescribed by a dermatologist.~~

Recommendation 10: Vote to Prior Authorize Omlyclo® (Omalizumab-igec) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Omlyclo® (omalizumab-igec) with criteria similar to Xolair® (omalizumab) and recommends updating the approval criteria for the asthma diagnosis to reflect the Global Initiative for Asthma (GINA) guidelines, for the chronic idiopathic urticaria diagnosis to be consistent with the FDA approved label, and all other diagnoses based on clinical practice (changes shown in red):

Omlyclo® (Omalizumab-igec Injection) and Xolair® (Omalizumab Injection) Approval Criteria [Asthma Diagnosis]:

1. Diagnosis of severe persistent asthma [as per Global Initiative for Asthma (GINA) ~~National Asthma Education and Prevention Program (NAEPP)~~ guidelines]; and
2. Member must be between 6 and 75 years of age; and
3. Member must have a positive skin test to at least 1 perennial aeroallergen (positive perennial aeroallergens must be listed on the prior authorization request); and
4. Member must have a pretreatment serum IgE level between 30 and 1,300 IU/mL (depending on member age); and
5. Member's weight must be between 20kg and 150kg; and
6. Member must have failed a medium-to-high-dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
7. Prescribed ~~Xolair®~~ dose must be an FDA approved regimen per package labeling; and

8. For authorization ~~Xolair®~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
9. For authorization of the ~~Xolair®~~ prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses ~~of Xolair®~~ under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage ~~of Xolair®~~; and
10. ~~Xolair®~~ Must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
11. Member must have been in the emergency room (ER) or hospitalized, due to an asthma exacerbation, twice in the past 12 months (date of visits must be listed on the prior authorization request), or member must have been determined to be dependent on systemic corticosteroids to prevent serious exacerbations; and
12. For Omlyclo® (omalizumab-igec), a patient-specific, clinically significant reason why the member cannot use Xolair® (omalizumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
13. Initial approvals will be for the duration of 6 months ~~after which time compliance will be evaluated for continued approval.~~ Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Omlyclo® (Omalizumab-igec Injection) and Xolair® (Omalizumab Injection) Approval Criteria [Chronic ~~Idiopathic~~ Spontaneous Urticaria (~~CIU~~ CSU) Diagnosis]:

1. An FDA approved diagnosis of ~~CIU~~ CSU; and
2. Member must be 12 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. ~~Other potential causes of urticaria must be ruled out; and~~
5. Member must have an Urticaria Activity Score (UAS) ≥16; and
6. For authorization ~~of Xolair®~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and

7. For authorization of the ~~Xolair®~~ prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses ~~of Xolair®~~ under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage ~~of Xolair®~~; and
8. Prescriber must be an allergist, immunologist, or dermatologist (or an advanced care practitioner with a supervising physician that is an allergist, immunologist, or dermatologist); and
9. A trial of a second-generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and
10. For Omlyclo® (omalizumab-igec), a patient-specific, clinically significant reason why the member cannot use Xolair® (omalizumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
11. Initial dosing will only be approved for 150mg every 4 weeks. If the member has inadequate results at this dose, then the dose may be increased to 300mg every 4 weeks; and
12. ~~Initial approvals will be for the duration of 3 months at which time compliance will be evaluated for continued approval.~~
13. Initial approvals will be for the duration of 3 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment (e.g., improvement in baseline UAS score, improvement in symptoms, reduction in exacerbations). Additionally, compliance will be evaluated for continued approval.

Omlyclo® (Omalizumab-igec Injection) and Xolair® (Omalizumab Injection) Approval Criteria [Immunoglobulin E (IgE)-Mediated Food Allergy Diagnosis]:

1. An FDA approved diagnosis of IgE-mediated food allergy for the reduction of allergic reactions; and
2. Member must be 1 year of age or older; and
3. Member must have a diagnosis of peanut, milk, egg, wheat, cashew, hazelnut, or walnut allergy confirmed by a positive skin test, positive in vitro test for food-specific IgE, or positive clinician-supervised oral food challenge; and
4. Prescriber must confirm member will use the requested product ~~Xolair®~~ with an allergen-avoidant diet; and

5. Member must have a pretreatment serum IgE level between 30 and 1,850 IU/mL; and
6. Member's weight must be between 10kg and 150kg; and
7. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for immediate use at all times; and
8. Prescribed ~~Xolair®~~ dose must be an FDA approved regimen per package labeling; and
9. For authorization ~~of Xolair®~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
10. For authorization of the ~~Xolair®~~ prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses ~~of Xolair®~~ under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of ~~Xolair®~~; and
11. ~~Xolair®~~ Must be prescribed by an allergist or immunologist or the member must have been evaluated by an allergist or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and
12. For Omlyclo® (omalizumab-igec), a patient-specific, clinically significant reason why the member cannot use Xolair® (omalizumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
13. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to therapy. Additionally, compliance will be evaluated for continued approval.

Omlyclo® (Omalizumab-igec Injection) and Xolair® (Omalizumab Injection) Approval Criteria [Nasal Polyps Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of nasal polyps in adult members with inadequate response to nasal corticosteroids; and
2. Member must be 18 years of age or older; and
3. Member must have a trial of intranasal corticosteroids for at minimum the past 4 weeks; and
4. Prescriber must verify member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and

5. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/ pressure, reduction or loss of smell, nasal blockade/obstruction/ congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
6. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
7. Member must have a pretreatment serum IgE level between 30 and 1,500 IU/mL; and
8. Member's weight must be between 31kg and 150kg; and
9. Prescribed ~~Xolair®~~ dose must be an FDA approved regimen per package labeling; and
10. For authorization ~~of Xolair®~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
11. For authorization of the ~~Xolair®~~ prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses ~~of Xolair®~~ under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage ~~of Xolair®~~; and
12. ~~Xolair®~~ Must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
13. For Omlyclo® (omalizumab-igec), a patient-specific, clinically significant reason why the member cannot use Xolair® (omalizumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
14. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Next, the College of Pharmacy recommends the following changes to the Dupixent® (dupilumab), Nucala (mepolizumab), and Tezspire® (tezepelumab-ekko) approval criteria based on the new FDA approvals and to be consistent with the current guidelines (changes shown in red):

Dupixent® (Dupilumab Injection) Approval Criteria [Bullous Pemphigoid (BP) Diagnosis]:

1. An FDA approved diagnosis of BP; and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that all other potential causes and/or diagnoses with a similar presentation to BP have been ruled out; and
4. Member must have both of the following:
    a. Bullous Pemphigoid Disease Area Index (BPDAI) activity score ≥24; and
    b. Worst-Itch Numeric Rating Scale (WI-NRS) score of ≥4; and
5. Dupixent® must be prescribed by a dermatologist, or the member must have been evaluated by a dermatologist for BP within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist); and
6. Member must be using Dupixent® in combination with a tapering course of oral corticosteroids as outlined in the package labeling (or have a contraindication or documented intolerance); and
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; or
    b. Oral corticosteroids; or
    c. Immunosuppressive agents (e.g., methotrexate, azathioprine, mycophenolate, cyclophosphamide); or
    d. Oral antibiotic agents (e.g., doxycycline, dapsone); and
8. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Dupixent® (Dupilumab Injection) Approval Criteria [Chronic Spontaneous Urticaria (CSU) Diagnosis]:

1. An FDA approved diagnosis of CSU; and
2. Member must be 12 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. Member must have an Urticaria Activity Score (UAS) ≥16; and
5. Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or

an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Member must have a documented trial of a second-generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and
7. A patient-specific, clinically significant reason why the member cannot use Xolair® (omalizumab) must be provided; and
8. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use. (Dupixent® has not been studied in combination with other biologic therapies); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment (e.g., improvement in baseline UAS score, improvement in symptoms, reduction in exacerbations). Additionally, compliance will be evaluated for continued approval.

Dupixent® (Dupilumab injection) Approval Criteria [Chronic Obstructive Pulmonary Disease (COPD) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with inadequately controlled COPD; and
2. Member must be 18 years of age or older; and
3. Member ~~has moderate to severe disease [i.e., GOLD 2 or GOLD 3 airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV_1) ≥30% and <80% predicted] and~~ is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2, COPD Assessment Test (CAT) ≥10]; and
4. Member must have a blood eosinophil count of ≥300 cells/mcL (can apply to either a recent level or a historical level prior to treatment); and
5. Member must have experienced ≥2 moderate exacerbations (e.g., required treatment with systemic corticosteroids and/or antibiotics) or ≥1 severe exacerbation (e.g., required hospitalization or 24-hour observation in emergency department) in the last 12 months; and
6. Member is inadequately controlled on triple therapy combination (LABA/LAMA/ICS) used compliantly within the last 3-6 consecutive months, unless contraindicated; and
7. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
8. Dupixent® must be prescribed by a pulmonologist or pulmonary specialist or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months. ~~after which time compliance will be evaluated for continued approval~~ Reauthorization

may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and

10. Quantities approved must not exceed FDA recommended dosing requirements.

Dupixent® (Dupilumab injection) Approval Criteria [Eosinophilic Esophagitis (EoE) Diagnosis]:

1. An FDA approved diagnosis of eosinophilic esophagitis (EoE) defined as:
   a. The presence of clinical symptoms of EoE ≥2 times per week (i.e., dysphagia, emesis, epigastric pain); and
   b. Intraepithelial eosinophilia [≥15 eosinophils per high-power field (eos/hpf) in the esophagus]; and
2. Member must be 1 years of age or older and weigh ≥15kg; and
3. Dupixent® must be prescribed by a gastroenterologist, allergist, or immunologist, or the member must have been evaluated by a gastroenterologist, allergist, or immunologist within the last 12 months (or be an advanced care practitioner with a supervising physician who is a gastroenterologist, allergist, or immunologist); and
4. Member must have documented trials for a minimum of 8 weeks that resulted in failure with 1 ~~both~~ of the following therapies (or have a contraindication or documented intolerance):
   a. One high-dose proton pump inhibitor; or ~~and~~
   b. One swallowed respiratory corticosteroid (e.g., budesonide); and
5. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use; and
6. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
7. A quantity limit of 8mL (4 syringes) every 28 days will apply.

Nucala (Mepolizumab) Approval Criteria [Chronic Obstructive Pulmonary Disease (COPD) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with inadequately controlled COPD; and
2. Member must be 18 years of age or older; and
3. Member is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2, COPD Assessment Test (CAT) ≥10]; and
4. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or a historical level prior to treatment); and
5. Member must have experienced ≥2 moderate exacerbations (e.g., required treatment with systemic corticosteroids and/or antibiotics) or

≥1 severe exacerbation (e.g., required hospitalization or 24-hour observation in emergency department) in the last 12 months; and
6. Member is inadequately controlled on triple therapy combination (LABA/LAMA/ICS) used compliantly within the last 3-6 consecutive months, unless contraindicated; and
7. For authorization of Nucala in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
9. Nucala must be prescribed by a pulmonologist or pulmonary specialist or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
10. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.
11. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.

Tezspire® (Tezepelumab-ekko) Approval Criteria [Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment in members with inadequately controlled CRSwNP; and
2. Member must be 12 years of age or older; and
3. Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and
4. Member must meet 1 of the following:
    a. Member has required prior sino-nasal surgery; or
    b. Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and
5. Tezspire® must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
6. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/

congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
7. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
8. Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
9. For authorization of Tezspire® in a health care facility, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis; or
10. For authorization of Tezspire® pre-filled pen for self-administration, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis or the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Tezspire®; and
11. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
12. A quantity limit of 1.91mL (1 single-dose glass vial or single-dose pre-filled syringe) per 28 days will apply.

Next the College of Pharmacy recommends updating the Cinqair® (resilizumab), Dupixent® (dupilumab), Fasenra® (benralizumab), Nucala (mepolizumab), and Tezspire® (tezepelumab-ekko) criteria to be consistent with the other asthma-indicated monoclonal antibodies (changes shown in red):

Cinqair® (Reslizumab) Approval Criteria:

1. An FDA approved indication of add-on maintenance treatment of members with severe asthma with an eosinophilic phenotype; and
2. Member must be 18 years of age or older; and
3. Member must have a blood eosinophil count ≥400cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and

7. Cinqair® must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
8. Cinqair® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months. ~~after which time compliance will be evaluated for continued approval~~ Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
10. Member's weight should be provided on prior authorization requests. Weights should have been taken within the last 4 weeks to provide accurate weight-based dosing.

Dupixent® (Dupilumab Injection) Approval Criteria [Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment in members with inadequately controlled CRSwNP; and
2. Member must be 12 years of age or older; and
3. Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and
4. Member must meet 1 of the following:
    a. Member has required prior sino-nasal surgery; or
    b. Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and
5. Dupixent® must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
6. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
7. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
8. Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
9. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and

10. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use; and
11. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
12. A quantity limit of 2 syringes every 28 days will apply.

Dupixent® (Dupilumab Injection) Approval Criteria [Eosinophilic Phenotype Asthma or Oral Corticosteroid-Dependent Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with moderate-to-severe eosinophilic phenotype asthma or oral corticosteroid-dependent asthma; and
2. Member must be 6 years of age or older; and
3. Member must meet 1 of the following:
    a. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); or
    b. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
4. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
5. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
6. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
7. Dupixent® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
8. Initial approvals will be for the duration of 6 months. ~~after which time compliance will be evaluated for continued approval~~ Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
9. Quantities approved must not exceed FDA recommended dosing requirements.

Dupixent® (Dupilumab) Approval Criteria [Prurigo Nodularis (PN) Diagnosis]:

1. An FDA approved diagnosis of PN for at least 3 months; and
2. Member must have a Worst-Itch Numeric Rating Scale (WI-NRS) score of ≥7; and
3. Member must have ≥20 PN lesions; and
4. Member must be 18 years of age or older; and
5. Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist for PN within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Prescriber must verify that all other causes of pruritus have been ruled out; and
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
8. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Fasenra® (Benralizumab injection) Approval Criteria [Eosinophilic Granulomatosis with Polyangiitis (EGPA) diagnosis]:

1. An FDA approved indication for the treatment of EGPA; and
2. Member must be 18 years of age or older; and
3. Member meets 1 of the following:
   a. Member must have a past history of at least 1 confirmed EGPA relapse [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of immunosuppressive therapy, or hospitalization] within the past 12 months; or
   b. Member must have refractory disease within the last 6 months following induction of standard treatment regimen administered compliantly for at least 3 months; and
4. Diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) will not be approved; and

5. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent equal to or greater than 7.5mg/day) for a minimum of 4 weeks duration; and
6. Fasenra® must be prescribed by an allergist, pulmonologist, pulmonary specialist, or rheumatologist or the member must have been evaluated by an allergist, pulmonologist, pulmonary specialist, or rheumatologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, pulmonary specialist, or rheumatologist); and
7. For authorization of Fasenra® in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Fasenra® prefilled autoinjector pen for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Fasenra; and
9. A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 28 days will apply; and
10. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant, and prescriber must verify the member is responding to Fasenra® as demonstrated by a Birmingham Vasculitis Activity Score (BVAS) of 0 (zero), fewer EGPA relapses from baseline, or a decrease in daily OCS dose regimen from baseline. Subsequent approvals will be for 1 year.

Fasenra® (Benralizumab injection) Approval Criteria [Eosinophilic Phenotype Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and
2. Member must be 6 years of age or older; and
3. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and

6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
7. For authorization of Fasenra® in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Fasenra® prefilled autoinjector pen for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Fasenra; and
9. Fasenra must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
10. For members who require weight-based dosing, the member's recent weight, taken within the last 3 weeks, must be provided on the prior authorization request in order to authorize the appropriate dose according to package labeling; and
11. Initial approvals will be for the duration of 6 months. ~~after which time compliance will be evaluated for continued approval~~ Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
12. A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 56 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment in adult members with inadequately controlled CRSwNP; and
2. Member must be 18 years of age or older; and
3. Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and
4. Member must meet 1 of the following:
    a. Member has required prior sino-nasal surgery; or
    b. Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and
5. Nucala must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care

practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
6. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/ pressure, reduction or loss of smell, nasal blockade/obstruction/ congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
7. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
8. Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
9. For authorization of Nucala in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
10. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
11. Requests for concurrent use of Nucala with other biologic medications will be reviewed on a case-by-case basis and will require patient specific information to support the concurrent use; and
12. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
13. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Eosinophilic Granulomatosis with Polyangiitis (EGPA) Diagnosis]:

1. An FDA approved diagnosis of EGPA; and
2. Member must be 18 years of age or older; and
3. Member meets 1 of the following:
    a. Member must have a past history of at least 1 confirmed EGPA relapse [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of immunosuppressive therapy, or hospitalization] within the past 12 months; or
    b. Member must have refractory disease within the last 6 months following induction of a standard treatment regimen administered compliantly for at least 3 months; and
4. Diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) will not be approved; and
5. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent ≥7.5mg/day) for a minimum of 4 weeks duration; and

6. Nucala must be prescribed by an allergist, pulmonologist, pulmonary specialist, or rheumatologist or the member must have been evaluated by an allergist, pulmonologist, pulmonary specialist, or rheumatologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, pulmonary specialist, or rheumatologist); and
7. For authorization of Nucala in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
9. A quantity limit of 3 vials, prefilled autoinjectors, or prefilled syringes per 28 days will apply; and
10. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant and prescriber must verify the member is responding to Nucala as demonstrated by a Birmingham Vasculitis Activity Score (BVAS) of 0 (zero), fewer EGPA relapses from baseline, or a decrease in daily OCS dosing from baseline. Subsequent approvals will be for 1 year.

Nucala (Mepolizumab Injection) Approval Criteria [Eosinophilic Phenotype Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and
2. Member must be 6 years of age or older; and
3. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and

7. For authorization of Nucala in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
9. Nucala must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
10. Initial approvals will be for the duration of 6 months. ~~after which time compliance will be evaluated for continued approval~~ Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
11. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Hypereosinophilic Syndrome (HES) Diagnosis]:

1. An FDA approved diagnosis of HES for ≥6 months without an identifiable non-hematologic secondary cause; and
2. Member must be 12 years of age or older; and
3. Member must have a past history of at least 2 confirmed HES flares [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of cytotoxic or immunosuppressive therapy, or hospitalization] within the past 12 months; and
4. Member must have a baseline blood eosinophil count of ≥1,000 cells/mcL in the last 4 weeks prior to initiating Nucala; and
5. Diagnosis of FIP1L1-PDGFRα kinase-positive HES will not be approved; and
6. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent ≥10mg/day) for a minimum of 4 weeks duration or member is unable to tolerate corticosteroid therapy due to significant side effects from corticosteroid therapy; and
7. Nucala must be prescribed by a hematologist or a specialist with expertise in treatment of HES (or an advanced care practitioner with a supervising physician who is a hematologist or a specialist with expertise in treatment of HES); and
8. For authorization of Nucala in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or

9. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
10. A quantity limit of 3 vials, prefilled autoinjectors, or prefilled syringes per 28 days will apply; and
11. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant and prescriber must verify the member is responding to Nucala as demonstrated by fewer HES flares from baseline or a decrease in daily OCS dosing from baseline. Subsequent approvals will be for 1 year.

Tezspire® (Tezepelumab-ekko) Approval Criteria [Severe Asthma Diagnosis]:

1. An FDA approved diagnosis of add-on maintenance treatment for severe asthma; and
2. Member must be 12 years of age or older; and
3. Member must have experienced ≥2 asthma exacerbations requiring oral or injectable corticosteroids or that resulted in hospitalization in the last 12 months; and
4. Member must have failed a medium-to-high dose inhaled corticosteroid (ICS) used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
5. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
6. For authorization of Tezspire® in a health care facility, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis; or
7. For authorization of Tezspire® pre-filled pen for self-administration, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis or the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Tezspire®; and
8. Tezspire® must be prescribed by a pulmonologist or pulmonary specialist, or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months. ~~after which time compliance will be evaluated for continued approval~~ Reauthorization may be granted for the duration of 1 year, if the prescriber documents

the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and

10. A quantity limit of 1.91mL (1 single-dose glass vial or single-dose pre-filled syringe) per 28 days will apply.

Additionally, the College of Pharmacy recommends the prior authorization of umeclidinium/vilanterol (unbranded Anoro® Ellipta®) and removing the prior authorization from brand name Anoro® Ellipta® (umeclidinium/vilanterol) and designating it as brand preferred based on net costs, the following changes to the Ohtuvayre® (ensifentrine) approval criteria to be consistent with the current guidelines, and removing the prior authorization from Daliresp® (roflumilast) based on net costs (changes shown in red):

Umeclidinium/Vilanterol (Unbranded Anoro® Ellipta®) ~~Anoro® Ellipta® (Umeclidinium/Vilanterol)~~, Bevespi Aerosphere® (Glycopyrrolate/ Formoterol Fumarate), Duaklir® Pressair® (Aclidinium Bromide/Formoterol Fumarate), and Stiolto® Respimat® (Tiotropium/Olodaterol) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use Tier-1 long-acting beta$_2$ agonist (LABA) and long-acting muscarinic antagonist (LAMA) individual components or brand name Anoro® Ellipta® must be provided; and
4. Anoro® Ellipta® is brand preferred. Requests for unbranded umeclidinium/vilanterol will require a patient-specific, clinically significant reason why the member cannot use brand name Anoro® Ellipta®, which is available without prior authorization.

Ohtuvayre® (Ensifentrine) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
2. Member must be 18 years of age or older; and
3. Member ~~has moderate to severe disease [i.e., GOLD 2 or GOLD 3 airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV_1) ≥30% and <80% predicted] and~~ is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2, COPD Assessment Test (CAT) ≥10]; and
4. Member is inadequately controlled on dual or triple combination long-acting bronchodilator therapy (must have ≥3 claims for long-acting bronchodilators in the previous 6 months); and
5. Member must not be taking Daliresp® (roflumilast) concurrently with Ohtuvayre™; and
6. A quantity limit of 60 ampules (150mL) per 30 days will apply.

~~**Daliresp® (Roflumilast) Approval Criteria:**~~

~~1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD) with history of chronic bronchitis; and~~
~~2. Forced expiratory volume (FEV) ≤50% of predicted; and~~
~~3. Member is inadequately controlled on long-acting bronchodilator therapy (must have 3 or more claims for long-acting bronchodilators in the previous 6 months).~~

Finally, the College of Pharmacy recommends the following changes to the Asthma and COPD Maintenance Medications Product Based Prior Authorization (PBPA) categories based on net costs (changes noted in red in the following PBPA Tier charts):

1. Moving Striverdi® Respimat® (olodaterol inhalation spray) from Tier-2 to Tier-1; and
2. Moving Tudorza® PressAir® (aclidinium inhalation powder) from Tier-1 to Tier-2; and
3. Making Arnuity® Ellipta® (fluticasone furoate) brand preferred.

Long-Acting Beta$_2$ Agonists (LABA) and Long-Acting Muscarinic Antagonists (LAMA)	
Tier-1	**Tier-2**
Long-Acting Beta$_2$ Agonists* (LABA)	
olodaterol inhalation spray (Striverdi® Respimat®)	arformoterol nebulizer solution (Brovana®)
salmeterol inhalation powder (Serevent®)	formoterol nebulizer solution (Perforomist®)
	formoterol nebulizer solution kit
	~~**olodaterol inhalation spray (Striverdi® Respimat®)**~~
Long-Acting Muscarinic Antagonists (LAMA)	
~~**aclidinium inhalation powder (Tudorza® PressAir®)**~~	**aclidinium inhalation powder (Tudorza® PressAir®)**
tiotropium inhalation powder (Spiriva® HandiHaler®) – **Brand Preferred**	revefenacin inhalation solution (Yupelri®)
tiotropium soft mist inhaler (Spiriva® Respimat®)	
umeclidinium inhalation powder (Incruse® Ellipta®)	

*Tier-1 combination products that contain a long-acting beta$_2$ agonist (LABA) qualify for the LABA trial requirement.
Tier-1 medications do not require prior authorization.
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Inhaled Corticosteroids (ICS) and Combination Products	
Tier-1	**Tier-2***
beclomethasone dipropionate (QVAR® RediHaler®)	budesonide/formoterol (Symbicort Aerosphere®)
budesonide (Pulmicort Flexhaler®)	ciclesonide (Alvesco®)

budesonide/formoterol (Symbicort®)β – **Brand Preferred**	fluticasone propionate (Flovent®)
fluticasone furoate (Arnuity® Ellipta®) – **Brand Preferred**	fluticasone furoate/vilanterol (Breo® Ellipta®) – **Brand Preferred**
fluticasone propionate/salmeterol (Advair®)	fluticasone propionate/salmeterol (AirDuo RespiClick®)
mometasone furoate (Asmanex®)	mometasone furoate/formoterol 50mcg/5mcg (Dulera®)
mometasone furoate/formoterol (Dulera®)◊	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria apply to each Tier-2 product.
βDoes not include Breyna®; authorization of Breyna® requires a reason why the member cannot use the brand formulation (Symbicort®).
◊Includes all strengths other than Dulera® 50mcg/5mcg.

Recommendation 11: Vote to Prior Authorize Boruzu® (Bortezomib) and Lynozyfic™ (Linvoseltamab-gcpt) and Update the Approval Criteria for the Multiple Myeloma Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Boruzu® (bortezomib) and Lynozyfic™ (linvoseltamab-gcpt) with the following criteria (shown in red):

Boruzu® (Bortezomib) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use generic Velcade® (bortezomib), which is available without a prior authorization, must be provided.

Lynozyfic™ (Linvoseltamab-gcpt) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Member has received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody; and
3. Member must be 18 years of age or older; and
4. Health care facilities must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements.

Next, the College of Pharmacy recommends adding new approval criteria for Blenrep (belantamab mafodotin-blmf) based on the recent FDA approval (new criteria shown in red):

Blenrep (Belantamab Mafodotin-blmf) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Member must be 18 years of age or older; and
3. Used in combination with bortezomib and dexamethasone; and
4. Member has received at least 2 prior lines of therapy, including a proteasome inhibitor and immunomodulatory agent; and
5. Prescriber must verify the member will receive eye exams, including visual acuity and slit lamp ophthalmic examinations, at baseline, prior to each dose and promptly for any new or worsening symptoms; and
6. Prescriber must comply with the risk evaluation and mitigation strategy (REMS) requirements.

Additionally, the College of Pharmacy recommends updating the approval criteria for Abecma® (idecabtagene vicleucel) and Carvykti® (ciltacabtagene autoleucel) to be consistent with recent FDA label updates (changes shown in red):

Abecma® (Idecabtagene Vicleucel) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM):
    a. Member has received ≥2 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor (PI), and an anti-CD38 monoclonal antibody; and
        i. Induction with or without autologous hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen; and
        ii. Must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and
    b. Member must have measurable disease, including at least 1 of the following:
        i. Serum M-protein ≥0.5g/dL; or
        ii. Urine M-protein ≥200mg/24hr; or
        iii. Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or
        iv. Bone marrow plasma cells >30% of total bone marrow cells; and
    c. Member must not have any central nervous system involvement with multiple myeloma.
2. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
3. Approvals will be for 1 dose per member per lifetime.

Carvykti® (Ciltacabtagene Autoleucel) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM):
    a. Member has received ≥1 prior line of therapy, including an immunomodulatory agent and a proteasome inhibitor; and
        i. Member must be refractory to lenalidomide; and
        ii. Member must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and
    b. Member must have measurable disease, including at least 1 of the following:
        i. Serum M-protein ≥0.5g/dL; or
        ii. Urine M-protein ≥200mg/24hr; or
        iii. Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or
        iv. Bone marrow plasma cells >30% of total bone marrow cells; and
    c. Member must not have any central nervous system involvement with multiple myeloma; and
2. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
3. Approvals will be for 1 dose per member per lifetime.

Lastly, the College of Pharmacy recommends updating the approval criteria for Darzalex® (daratumumab), Darzalex Faspro® (daratumumab/ hyaluronidase-fihj), Ninlaro® (ixazomib), Sarclisa® (isatuximab-irfc), Talvey® (talquetamab-tgvs), Tecvayli® (teclistamab-cqyv), and Xpovio® (selinexor) based on National Comprehensive Cancer Network (NCCN) recommendations (changes shown in red):

Darzalex® (Daratumumab) and Darzalex Faspro® (Daratumumab/ Hyaluronidase-fihj) Approval Criteria [Light Chain Amyloidosis Diagnosis]:

1. Relapsed/refractory light chain amyloidosis ~~as a single agent~~; ~~or~~ and
    a. Used as a single agent; or
    b. Used in combination with venetoclax for t(11;14) translocation; or
2. Newly diagnosed light chain amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone.

~~**Darzalex® (Daratumumab) and Darzalex Faspro® (Daratumumab/ Hyaluronidase-fihj) Approval Criteria [Multiple Myeloma Diagnosis]:**~~

~~1. Diagnosis of multiple myeloma; and~~
~~2. Used in 1 of the following settings:~~
    ~~a. In combination with lenalidomide and dexamethasone as primary therapy in members who are ineligible for autologous stem cell~~

~~transplant (ASCT) or in members who have received at least 1 prior therapy; or~~

~~b. In combination with bortezomib, melphalan, and prednisone as primary therapy in members who are ineligible for ASCT; or~~

~~c. In combination with bortezomib, thalidomide, and dexamethasone or bortezomib, lenalidomide, and dexamethasone as primary therapy in members who are eligible for ASCT; or~~

~~d. After at least 1 prior therapy, in combination with 1 of the following:~~

~~i. Dexamethasone and bortezomib; or~~

~~ii. Carfilzomib and dexamethasone; or~~

~~iii. Dexamethasone and lenalidomide; or~~

~~iv. Cyclophosphamide, bortezomib, and dexamethasone; or~~

~~v. Pomalidomide and dexamethasone* [*previous therapy for this combination must include lenalidomide and a proteasome inhibitor (PI)]; or~~

~~vi. Selinexor and dexamethasone; or~~

~~e. In combination with lenalidomide and dexamethasone for members who are ineligible for ASCT or with cyclophosphamide, bortezomib, and dexamethasone as primary therapy or for disease relapse after 6 months following primary induction therapy with the same regimen; or~~

~~f. As a single agent in members who have received ≥3 prior therapies, including a PI and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.~~

Darzalex® (Daratumumab) and Darzalex Faspro® (Daratumumab/ Hyaluronidase-fihj) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of multiple myeloma; and
2. Used in 1 of the following settings:
   a. As primary therapy in members who are ineligible for autologous stem cell transplant (ASCT) and used in combination with:
      i. Lenalidomide and dexamethasone; or
      ii. Bortezomib, melphalan, and prednisone; or
   b. As primary therapy in members who are eligible for ASCT and used in combination with:
      i. Bortezomib and thalidomide or lenalidomide and dexamethasone; or
      ii. Carfilzomib, lenalidomide, and dexamethasone; or
   c. As maintenance therapy for response or stable disease following hematopoietic stem cell transplant (HCT) or primary myeloma therapy; and
      i. Used as a single agent; or
      ii. Used in combination with lenalidomide; or
   d. For disease relapse after 6 months following primary induction therapy with the same regimen and used in combination with:
      i. Lenalidomide and dexamethasone; or

ii. Cyclophosphamide, bortezomib, and dexamethasone; or

e. After at least 1 prior therapy, in combination with 1 of the following:
   i. Bortezomib and dexamethasone; or
   ii. Carfilzomib and dexamethasone; or
   iii. Lenalidomide and dexamethasone; or
   iv. Pomalidomide and dexamethasone (if previous therapy for this combination included lenalidomide and a proteasome inhibitor); or
   v. Cyclophosphamide, bortezomib, and dexamethasone; or
   vi. Selinexor and dexamethasone; or
   vii. Venetoclax and dexamethasone for patients with t(11:14) translocation; or

f. Used as a single-agent in members who have received ≥3 prior therapies, including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.

Darzalex® (Daratumumab) and Darzalex Faspro® (Daratumumab/ Hyaluronidase-fihj) Approval Criteria [Smoldering Myeloma Diagnosis]:

1. Diagnosis of high-risk smoldering myeloma (asymptomatic); and
2. Used a single agent.

Ninlaro® (Ixazomib) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of symptomatic multiple myeloma; and
2. Used in 1 of the following settings:
   a. As primary therapy; or
   b. Following disease relapse after 6 months following primary induction therapy with the same regimen, used in combination with 1 of the following regimens:
      i. Lenalidomide and dexamethasone; or
      ii. Cyclophosphamide and dexamethasone for transplant candidates only; or
      iii. Pomalidomide and dexamethasone if member has failed ≥2 prior therapies and demonstrated disease progression within 60 days; or
   c. As a single agent for maintenance therapy following response to primary myeloma therapy in transplant candidates or following hematopoietic stem cell transplant.

~~3. As a single-agent for the maintenance treatment of disease.~~

Sarclisa® (Isatuximab-irfc) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of multiple myeloma; and
   a. ~~Used in the first line setting~~ As primary therapy; and
      i. Used in combination with bortezomib, lenalidomide, and dexamethasone; ~~and~~ or
      ii. Used in combination with carfilzomib, lenalidomide, and dexamethasone for transplant eligible members; or

iii. Used in combination with lenalidomide and dexamethasone for transplant-deferred or when transplant is not indicated; or

~~b. Member is considered ineligible for autologous stem cell transplantation; or~~

2. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and
   a. Used in 1 of the following settings:
      i. Used in combination with pomalidomide and dexamethasone after ≥2 prior therapies [previous treatment must have included lenalidomide and a proteasome inhibitor (PI)]; or
      ii. Used in combination with carfilzomib and dexamethasone after 1 to 3 prior therapies.

Talvey® (Talquetamab-tgvs) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Must meet 1 of the following:
   a. Used as a single agent in those who have ~~Member has~~ received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody; ~~and~~ or
   b. Used in combination with teclistamab-cgyv in those who have received at least 3 prior lines of therapy; and
3. Health care facilities must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements.

Tecvayli® (Teclistamab-cqyv) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Must meet 1 of the following:
   a. Used as a single agent in those who have ~~Member has~~ received ≥4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody; ~~and~~ or
   b. Used in combination with talquetamab-tgvs in those who have received at least 3 prior lines of therapy; and
3. Health care facilities must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements.

Xpovio® (Selinexor) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and
2. Used in 1 of the following settings:
   a. In combination with dexamethasone in members who have received ≥4 prior therapies including refractory disease to ≥2 proteasome inhibitors (PIs), ≥2 immunomodulatory agents, and an anti-CD38 monoclonal antibody; or

b. Used in combination with bortezomib and dexamethasone in members who have failed at least 1 prior therapy; or
c. Used in combination with daratumumab or daratumumab/hyaluronidase and dexamethasone in members who have failed at least 1 prior therapy.

Recommendation 12: Fiscal Year 2025 Annual Review of Skysona® (Elivaldogene Autotemcel)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Skysona® (elivaldogene autotemcel) prior authorization criteria based on the FDA label updates (changes shown in red):

Skysona® (Elivaldogene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of early, active cerebral adrenoleukodystrophy (CALD) in male members 4 to 17 years of age; and
2. Diagnosis must be confirmed by all of the following:
   a. Molecular genetic testing confirming a mutation in the *ABCD1* gene (results of genetic testing must be submitted); and
      i. Members must not have a full deletion of the *ABCD1* gene; and
   b. Lab results indicating elevated very long-chain fatty acids (VLCFAs); and
   c. Active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating the following:
      i. Loes score between 0.5 and 9 on the 34-point scale; and
      ii. Gadolinium enhancement (GdE+) on MRI of demyelinating lesions; and
   d. Neurological Function Score (NFS) of ≤1; and
3. Skysona® must be prescribed by a neurologist, endocrinologist, or hematologist/oncologist with expertise in the treatment of CALD and the administration of Skysona®; and
4. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
5. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
6. Member must not be taking statins, Lorenzo's oil, or dietary regimens used to lower VLCFA levels; and
7. Member must not have an immediate family member with known or suspected familial cancer syndrome (FCS); and
8. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to the package labeling; and

9. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Skysona®); and
10. Members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Skysona®; and
11. Prescriber must verify members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member or member's caregiver; and
12. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Skysona®; and
13. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at least every 3 months ~~month 6 and month 12~~ and through assessments for evidence for clonal expansion or predominance at least twice in the first year after treatment with Skysona®, then ~~at least~~ annually thereafter for at least 15 years, ~~and with integration site analysis at months 6, 12,~~ and as warranted; and
14. Skysona® must be administered at a Skysona® qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Skysona® dose from receipt to storage to administration; and
15. Approvals will be for 1 dose per member per lifetime.

Recommendation 13: Fiscal Year 2025 Annual Review of Skin Cancer Medications and 30-Day Notice to Prior Authorize Keytruda Qlex™ (Pembrolizumab/Berahyaluronidase alfa-pmph) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 14: Fiscal Year 2025 Annual Review of Complement Inhibitors and Miscellaneous Immunomodulatory Agents and 30-Day Notice to Prior Authorize Imaavy™ (Nipocalimab-aahu)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 15: 30-Day Notice to Prior Authorize Alyglo™ [Immune Globulin (IG) Intravenous (IV), Human-stwk], Asceniv™ (IGIV, Human-slra), Cuvitru® (IG Subcutaneous (SC), Human), Gammagard Liquid® (IG Infusion, Human), Gammagard S/D® (IGIV, Human), Gammaplex® (IGIV, Human), Hizentra® (IGSC, Human), Panzyga® (IGIV, Human-ifas), Privigen® (IGIV, Human), and Xembify® (IGSC, Human – klhw)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 16: Fiscal Year 2025 Annual Review of Thrombocytopenia Medications and 30-Day Notice to Prior Authorize Doptelet® Sprinkle (Avatrombopag) and Wayrilz™ (Rilzabrutinib)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 17: Fiscal Year 2025 Annual Review of Muscle Relaxant Medications and 30-Day Notice to Prior Authorize Atmeksi® (Methocarbamol Oral Suspension), Metaxalone 640mg Tablet, and Tanlor® (Methocarbamol 1,000mg Tablet)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 18: 30-Day Notice to Prior Authorize Andembry® (Garadacimab-gxii), Dawnzera™ (Donidalorsen), and Ekterly® (Sebetralstat) and Create a Product Based Prior Authorization (PBPA) Category for the Hereditary Angioedema (HAE) Medications

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 19: Fiscal Year 2025 Annual Review of Antidepressants and 30-Day Notice to Prior Authorize Escitalopram 15mg Capsule and Raldesy™ (Trazodone Oral Solution)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 20: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

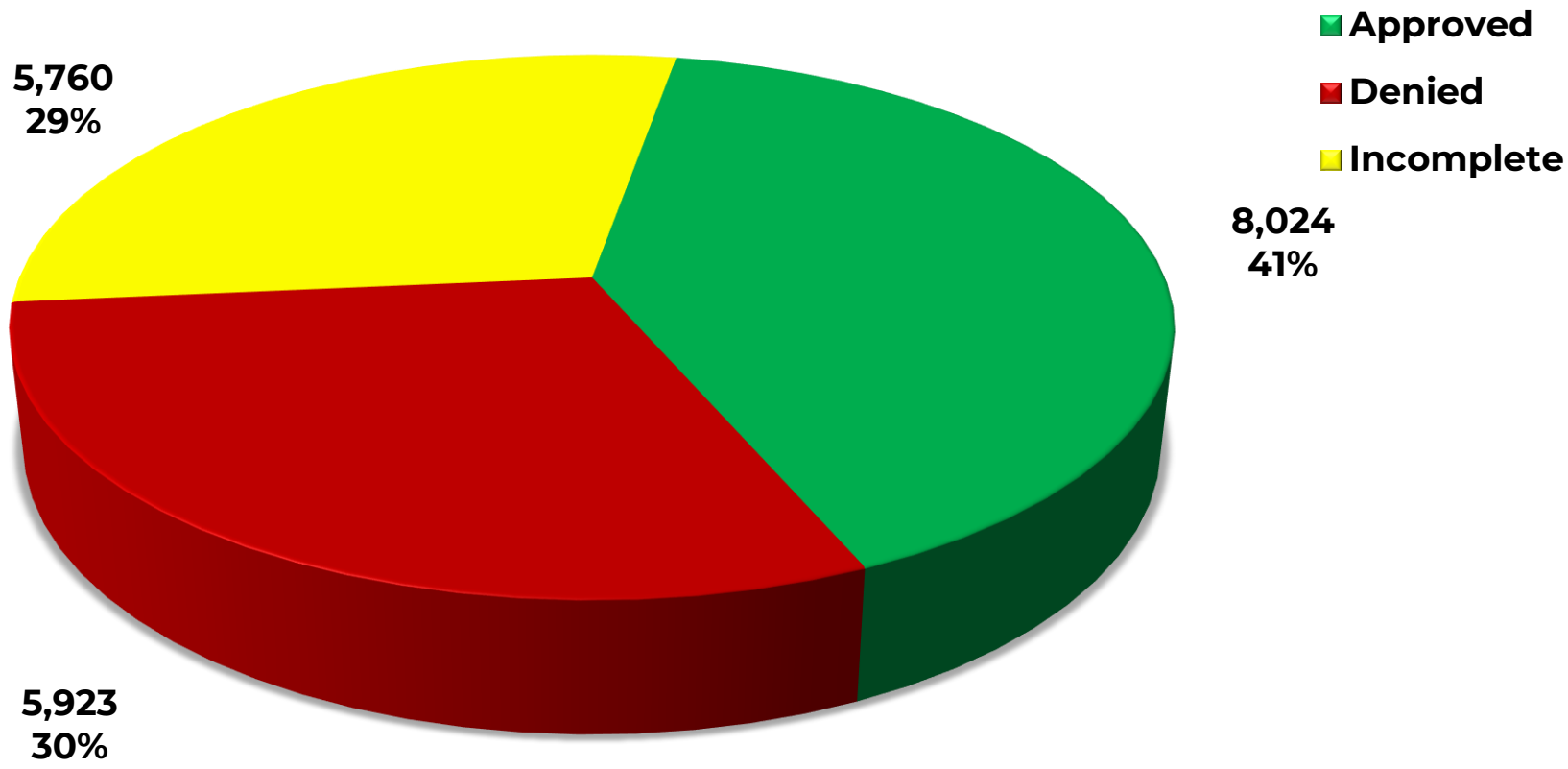
Recommendation 21: Future Business

NO ACTION REQUIRED.

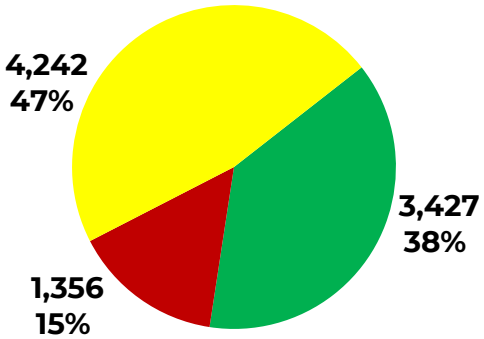
- No live DUR Board meeting is scheduled for January 2026. January 2026 will be a packet-only meeting.

Appendix B

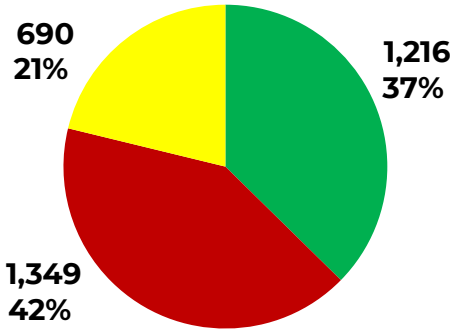
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: DECEMBER 2025



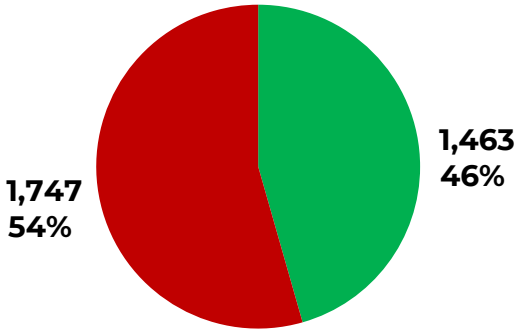
SoonerCare FFS



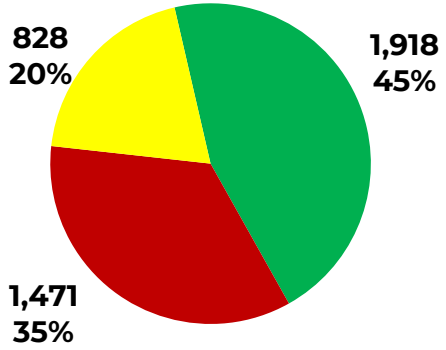
SoonerSelect Aetna



SoonerSelect Humana

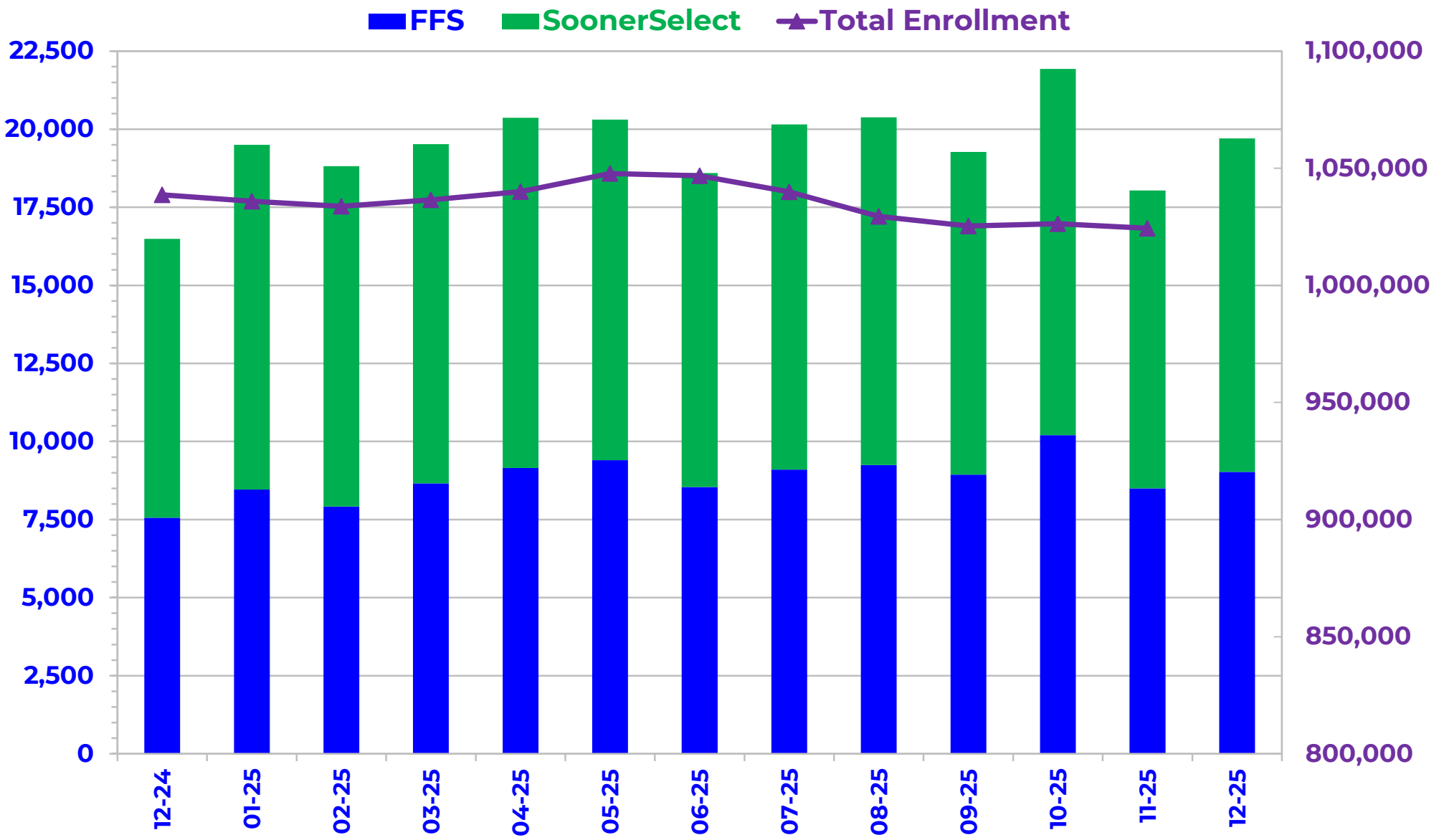


SoonerSelect OK Complete Health



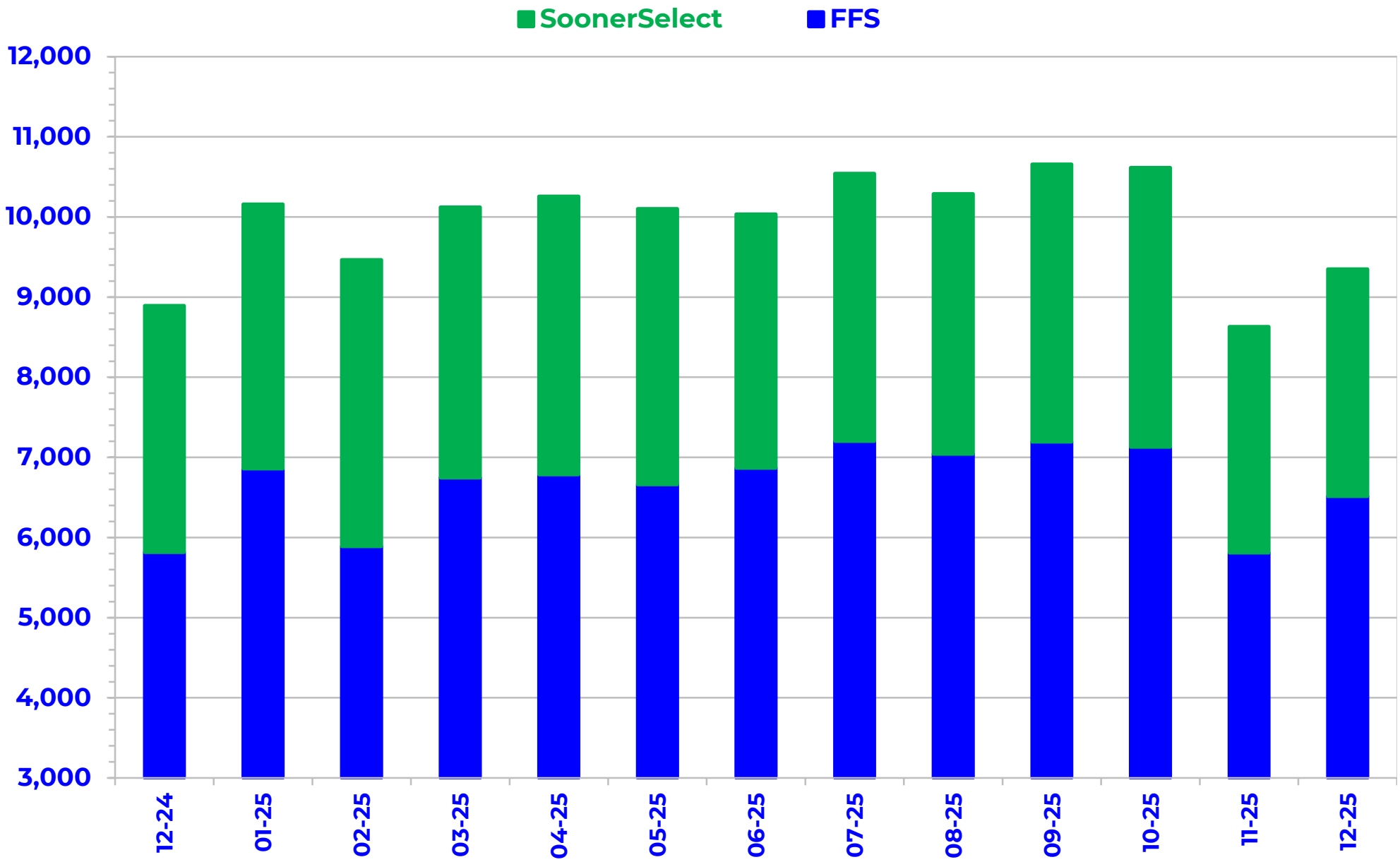
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

PRIOR AUTHORIZATION (PA) REPORT: DECEMBER 2024 – DECEMBER 2025



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: DECEMBER 2024 – DECEMBER 2025



SoonerCare FFS Prior Authorization Activity

12/1/2025 Through 12/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	7	1	4	2	360
Amphetamines	854	424	71	359	352
Analgesics - Anti-Inflammatory	202	83	23	96	320
Analgesics - Nonnarcotic	13	2	4	7	357
Analgesics - Opioid	300	119	24	157	129
Androgens - Anabolic	77	24	19	34	340
Anorectal and Related Products	5	0	3	2	0
Anorexiants Non-Amphetamine	1	0	1	0	0
Anthelmintics	19	3	4	12	26
Anti-Infective Agents - Misc.	28	8	5	15	101
Anti-Obesity Agents	121	13	76	32	101
Antianginal Agents	1	0	0	1	0
Antianxiety Agents	31	5	2	24	292
Antiarrhythmics	1	0	0	1	0
Antiasthmatic and Bronchodilator Agents	541	111	105	325	435
Antibiotics	25	10	1	14	85
Anticoagulants	18	0	3	15	0
Anticonvulsants	241	110	12	119	382
Antidepressants	202	65	29	108	454
Antidiabetics	1,273	392	257	624	383
Antidiarrheal/Probiotic Agents	1	0	0	1	0
Antidotes and Specific Antagonists	9	2	0	7	222
Antiemetics	17	3	4	10	18
Antifungals	2	0	0	2	0
Antihistamines	9	4	1	4	358
Antihyperlipidemics	47	8	15	24	229
Antihypertensives	22	10	1	11	470
Antimalarials	1	0	0	1	0
Antineoplastics and Adjunctive Therapies	203	129	7	67	181
Antiparkinson and Related Therapy Agents	13	3	2	8	847
Antipsychotics/Antimanic Agents	297	121	22	154	365
Antivirals	32	11	7	14	0
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	230	156	6	68	1,016
Beta Blockers	10	6	0	4	968
Calcium Channel Blockers	14	6	1	7	602
Cardiovascular Agents - Misc.	117	54	9	54	387
Contraceptives	20	18	1	1	363
Corticosteroids	10	1	1	8	360
Cough/Cold/Allergy	1	0	1	0	0
Dermatologicals	490	159	104	227	243
Diagnostic Products	46	15	0	31	132
Dietary Products/Dietary Management Products	4	0	3	1	0
Digestive Aids	9	7	0	2	360
Diuretics	12	6	0	6	669
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	0	1	0
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	159	65	24	70	248

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Estrogens	7	3	1	3	360
Gastrointestinal Agents - Misc.	332	97	73	162	254
Genitourinary Agents - Misc.	5	1	1	3	359
Gout Agents	11	2	1	8	270
Hematological Agents - Misc.	26	12	1	13	343
Hematopoietic Agents	57	14	13	30	137
Hemostatics	1	0	0	1	0
Hypnotics/Sedatives/Sleep Disorder Agents	63	8	7	48	143
Laxatives	12	4	3	5	360
Medical Devices and Supplies	269	47	60	162	268
Migraine Products	416	95	98	223	267
Minerals and Electrolytes	5	1	0	4	360
Miscellaneous Therapeutic Classes	67	31	7	29	302
Multivitamins	7	6	0	1	303
Musculoskeletal Therapy Agents	51	2	16	33	359
Nasal Agents - Systemic and Topical	27	1	9	17	85
Neuromuscular Agents	67	32	13	22	343
Ophthalmic Agents	59	17	8	34	156
Other*	61	21	7	33	216
Otic Agents	29	6	2	21	77
Passive Immunizing and Treatment Agents	3	0	0	3	0
Progestins	12	5	3	4	304
Psychotherapeutic and Neurological Agents - Misc.	289	82	57	150	241
Respiratory Agents - Misc.	26	17	0	9	315
Stimulants - Misc.	251	117	17	117	342
Thyroid Agents	9	4	2	3	542
Ulcer Drugs/Antispasmodics/Anticholinergics	75	17	9	49	754
Urinary Antispasmodics	42	7	8	27	569
Vaccines	2	0	0	2	0
Vaginal and Related Products	1	0	0	1	0
Vitamins	36	2	24	10	84
Total	**8,054**	**2,805**	**1,292**	**3,957**	

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	31	16	1	14	274
Compound	28	22	0	6	12
Cumulative Early Refill	1	1	0	0	1
Dosage Change	168	147	2	19	20
High Dose	1	1	0	0	1091
Ingredient Duplication	5	3	0	2	71
Lost/Broken Rx	38	34	3	1	17
MAT Override	3	2	0	1	100
NDC vs Age	135	72	18	45	557
NDC vs Sex	12	9	2	1	360
Nursing Home Issue	37	33	0	4	13
Opioid MME Limit	55	15	2	38	153
Opioid Quantity	21	11	3	7	176
Other	43	30	6	7	41
Quantity vs Days Supply	322	190	18	114	327
STBS/STBSM	13	7	4	2	105

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Step Therapy Exception	6	0	5	1	0
Stolen	14	13	0	1	24
Third Brand Request	38	16	0	22	21
Overrides Total	**971**	**622**	**64**	**285**	
Total Regular PAs + Overrides	**9,025**	**3,427**	**1,356**	**4,242**	

Denial Reasons	
Unable to verify required trials.	3,749
Does not meet established criteria.	1,399
Lack required information to process request.	570
Other PA Activity	
Duplicate Requests	1,081
Letters	43,250
No Process	1
Helpdesk Initiated Prior Authorizations	348
PAs Missing Information	280
Pharmacotherapy	83
Changes to Existing PAs	605

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

SoonerSelect Aetna Prior Authorization Activity

12/1/2025 Through 12/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	253	150	78	25	351
Analgesics - Anti-Inflammatory	121	73	31	17	314
Analgesics - Nonnarcotic	4	0	3	1	0
Analgesics - Opioid	114	51	32	31	118
Androgens - Anabolic	52	7	44	1	365
Anthelmintics	5	3	1	1	22
Antianxiety Agents	44	10	10	24	316
Antiasthmatic and Bronchodilator Agents	149	32	79	38	359
Antibiotics	15	3	2	10	253
Anticoagulants	8	2	0	6	182
Anticonvulsants	71	25	22	24	305
Antidepressants	211	52	88	71	554
Antidiabetics	473	145	254	74	303
Antidiarrheal/Probiotic Agents	4	1	1	2	103
Antiemetics	13	2	0	11	57
Antifungals	2	1	1	0	365
Antihistamines	9	3	5	1	182
Antihyperlipidemics	53	7	21	25	301
Antihypertensives	23	2	5	16	365
Anti-Infective Agents - Misc.	2	0	0	2	0
Antineoplastics and Adjunctive Therapies	24	11	0	13	293
Anti-Obesity Agents	85	3	76	6	140
Antiparkinson and Related Therapy Agents	4	0	1	3	0
Antipsychotics/Antimanic Agents	135	47	52	36	338
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	82	59	16	7	781
Beta Blockers	17	0	2	15	0
Calcium Channel Blockers	10	1	1	8	1,096
Cardiovascular Agents - Misc.	30	15	11	4	301
Contraceptives	17	1	14	2	365
Corticosteroids	24	23	1	0	132
Dermatologicals	260	113	116	31	237
Diagnostic Products	41	29	9	3	381
Digestive Aids	3	2	0	1	365
Diuretics	11	1	0	10	365
Endocrine and Metabolic Agents - Misc.	65	36	25	4	273
Estrogens	7	2	4	1	365
Gastrointestinal Agents - Misc.	91	45	40	6	211
Genitourinary Agents - Misc.	1	0	0	1	0
Gout Agents	2	1	1	0	30
Hematological Agents - Misc.	4	3	0	1	161
Hematopoietic Agents	4	1	3	0	365
Hypnotics/Sedatives/Sleep Disorder Agents	27	1	17	9	365
Laxatives	18	1	10	7	365
Local Anesthetics - Parenteral	28	28	0	0	29
Medical Devices and Supplies	55	13	28	14	365
Migraine Products	178	60	105	13	233

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Minerals and Electrolytes	7	1	1	5	0
Miscellaneous Therapeutic Classes	33	31	2	0	365
Multivitamins	4	3	1	0	365
Musculoskeletal Therapy Agents	43	0	8	35	0
Nasal Agents - Systemic and Topical	11	1	9	1	365
Neuromuscular Agents	22	19	0	3	364
Ophthalmic Agents	22	5	10	7	105
Other	14	0	1	13	0
Otic Agents	14	0	14	0	0
Progestins	2	2	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	26	10	11	5	172
Respiratory Agents - Misc.	5	3	1	1	365
Stimulants - Misc.	91	59	27	5	352
Thyroid Agents	1	0	0	1	0
Ulcer Drugs/Antispasmodics/Anticholinergics	57	6	15	36	309
Urinary Antispasmodics	11	2	7	2	365
Vaccines	5	5	0	0	258
Vitamins	38	4	33	1	196
****Total**	**3,255**	**1,216**	**1,349**	**690**	

**PA overrides are also reported within the drug categories included in the PA Activity report.

Overrides					
Other	695	5	0	690	0
Quantity Level Limit	35	35	0	0	329
Step Therapy Met	5	5	0	0	30
Overrides Total	**735**	**45**	**0**	**690**	

Denial Reason	
Benefit	69
Experimental/Investigational	115
Medical Necessity	1,078
Lack Required Information to Determine Medical Necessity	87
Other PA Activity	
Duplicate Requests	22
Letters	3,846
No Process	258
Changes to existing PAs	0
Helpdesk initiated PA	4
PAs missing info	20

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

SoonerSelect Humana Prior Authorization Activity

12/1/2025 Through 12/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	11	5	6	0	547
Analgesics - Anti-Inflammatory	74	63	11	0	326
Analgesics - Opioid	73	38	35	0	236
Androgens - Anabolic	56	13	43	0	180
Anorectal and Related Products	4	1	3	0	91
Anthelmintics	4	3	1	0	304
Antianxiety Agents	1	1	0	0	365
Antiasthmatic and Bronchodilator Agents	126	50	76	0	229
Antibiotics	5	2	3	0	274
Anticonvulsants	18	10	8	0	353
Antidepressants	46	28	18	0	412
Antidiabetics	284	103	181	0	324
Antiemetics	7	3	4	0	284
Antifungals	1	0	1	0	0
Antihyperlipidemics	15	5	10	0	296
Antihypertensives	2	1	1	0	183
Antineoplastics and Adjunctive Therapies	38	34	4	0	229
Anti-Obesity Agents	49	3	46	0	16
Antiparkinson and Related Therapy Agents	2	1	1	0	365
Antipsychotics/Antimanic Agents	2	1	1	0	365
Antivirals	5	3	2	0	434
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	11	9	2	0	517
Beta Blockers	1	1	0	0	365
Cardiovascular Agents - Misc.	23	9	14	0	380
Contraceptives	46	33	13	0	213
Corticosteroids	4	2	2	0	547
Dermatologicals	152	106	46	0	282
Diagnostic Products	13	10	3	0	346
Digestive Aids	3	1	2	0	183
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	37	28	9	0	268
Estrogens	2	1	1	0	730
Gastrointestinal Agents - Misc.	76	39	37	0	280
Gout Agents	4	1	3	0	365
Hematological Agents - Misc.	3	2	1	0	90
Hematopoietic Agents	8	4	4	0	238
Hypnotics/Sedatives/Sleep Disorder Agents	6	1	5	0	365
Laxatives	6	1	5	0	365
Medical Devices and Supplies	16	6	10	0	1,095
Migraine Products	135	93	42	0	228
Miscellaneous Therapeutic Classes	11	8	3	0	304
Multivitamins	1	1	0	0	365
Musculoskeletal Therapy Agents	20	12	8	0	344
Neuromuscular Agents	30	23	7	0	249
Ophthalmic Agents	25	9	16	0	196
Other	1	1	0	0	182
Progestins	1	1	0	0	365

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Psychotherapeutic and Neurological Agents - Misc.	30	19	11	0	213
Respiratory Agents - Misc.	10	7	3	0	319
Stimulants - Misc.	16	10	6	0	319
Ulcer Drugs/Antispasmodics/Anticholinergics	16	5	11	0	228
Urinary Antispasmodics	17	3	14	0	396
Vitamins	29	2	27	0	100
Total	**1,577**	**816**	**761**	**0**	
Overrides					
Ingredient Duplication	131	75	56	0	190
NDC vs Age	407	253	154	0	241
Opioid MME Limit	5	3	2	0	222
Opioid Quantity	5	5	0	0	451
Other	200	48	152	0	90
Quantity vs Days Supply	200	134	66	0	263
STBS/STBSM	416	8	408	0	11
Step Therapy Exception	269	121	148	0	178
Overrides Total	**1,633**	**647**	**986**	**0**	
Total Regular PAs + Overrides	**3,210**	**1,463**	**1,747**	**0**	
Denial Reasons					
Benefit					743
Medical Necessity					1,004

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

SoonerSelect Oklahoma Complete Health Prior Authorization Activity

12/1/2025 Through 12/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	4	3	1	0	1,095
Alternative Medicines	1	0	0	1	0
Amphetamines	482	238	132	112	1,067
Analgesics - Anti-Inflammatory	90	44	29	17	924
Analgesics - Nonnarcotic	13	1	10	2	14
Analgesics - Opioid	308	130	116	62	222
Androgens - Anabolic	69	4	56	9	1,095
Anorexiants Non-Amphetamine	4	0	1	3	0
Anthelmintics	7	1	5	1	180
Antianxiety Agents	17	5	10	2	657
Antiasthmatic and Bronchodilator Agents	238	78	118	42	681
Antibiotics	16	10	1	5	474
Anticoagulants	7	3	2	2	16
Anticonvulsants	66	32	23	11	873
Antidepressants	139	58	65	16	879
Antidiabetics	666	334	227	105	913
Antiemetics	18	3	6	9	365
Antifungals	2	1	1	0	19
Antihistamines	14	4	8	2	1,095
Antihyperlipidemics	16	4	11	1	1,095
Antihypertensives	1	1	0	0	23
Anti-Infective Agents - Misc.	10	1	0	9	21
Antineoplastics and Adjunctive Therapies	68	36	6	26	595
Anti-Obesity Agents	86	3	36	47	608
Antiparkinson and Related Therapy Agents	4	1	0	3	1,095
Antipsychotics/Antimanic Agents	149	73	48	28	813
Antivirals	10	5	4	1	467
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	242	185	38	19	1,044
Beta Blockers	6	3	2	1	1,095
Calcium Channel Blockers	8	7	0	1	199
Cardiovascular Agents - Misc.	36	13	8	15	1,003
Chemicals	1	0	0	1	0
Contraceptives	26	6	16	4	377
Corticosteroids	12	1	5	6	90
Cough/Cold/Allergy	1	1	0	0	8
Dermatologicals	291	112	125	54	539
Diagnostic Products	50	28	16	6	809
Endocrine and Metabolic Agents - Misc.	50	19	23	8	823
Estrogens	9	4	5	0	825
Gastrointestinal Agents - Misc.	86	34	44	8	718
Genitourinary Agents - Misc.	1	1	0	0	365
Gout Agents	3	0	2	1	0
Hematological Agents - Misc.	15	7	4	4	786
Hematopoietic Agents	23	6	8	9	524
Hypnotics/Sedatives/Sleep Disorder Agents	24	13	8	3	216

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Laxatives	14	4	6	4	462
Medical Devices and Supplies	125	79	23	23	1,051
Migraine Products	159	64	84	11	729
Minerals and Electrolytes	1	0	0	1	0
Miscellaneous Therapeutic Classes	21	11	5	5	680
Mouth/Throat/Dental Agents	2	1	0	1	23
Multivitamins	7	4	3	0	1,095
Musculoskeletal Therapy Agents	23	7	13	3	228
Nasal Agents - Systemic and Topical	7	1	2	4	1,095
Neuromuscular Agents	24	16	0	8	322
Ophthalmic Agents	30	5	16	9	164
Other	15	3	0	12	209
Otic Agents	12	1	9	2	365
Passive Immunizing and Treatment Agents	1	1	0	0	1,095
Psychotherapeutic and Neurological Agents - Misc.	50	17	18	15	863
Respiratory Agents - Misc.	5	2	1	2	1,095
Stimulants - Misc.	255	161	37	57	802
Thyroid Agents	14	9	2	3	856
Ulcer Drugs/Antispasmodics/Anticholinergics	35	7	23	5	824
Urinary Antispasmodics	21	8	7	6	287
Vaccines	1	1	0	0	180
Vaginal and Related Products	4	1	2	1	22
Vasopressors	1	1	0	0	365
Vitamins	1	1	0	0	365
****Total**	**4,217**	**1,918**	**1,471**	**828**	

**PA overrides are also reported within the drug categories included in the PA Activity report.

Denial Reasons	
Medical Necessity	1,470
Benefit	1

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

Appendix C

Appropriate Use of Riluzole in the SoonerCare Population – Update

Oklahoma Health Care Authority
January 2026

Introduction[1,2,3,4]

Rilutek® (riluzole 50mg oral tablet) was approved by the U.S. Food and Drug Administration (FDA) in 1995 as the first medication for the treatment of amyotrophic lateral sclerosis (ALS). The use of riluzole is also recommended in guidelines for the treatment of ALS from the American Academy of Neurology (AAN), last updated in 2009, to help slow the progression of the disease to a modest extent. More recent guidelines from the European Academy of Neurology (EAN) from 2024 recommend that lifelong riluzole should be offered to all patients with ALS unless its use is limited by adverse events. Since 2003, generic riluzole tablets have been approved by the FDA. Riluzole is not currently FDA approved for any indications other than ALS.

Riluzole Utilization Trends in the SoonerCare Population

ALS is considered a rare condition, and utilization of ALS medications is expected to be low in the SoonerCare population. Additionally, many members with ALS also qualify for Medicare coverage, and their medications would therefore be reimbursed through Medicare rather than Medicaid, further limiting the expected utilization even for existing members with a documented ALS diagnosis. Due to the limited utilization expected for its FDA approved indication and the relatively low costs of the generic formulation, riluzole tablets were covered by SoonerCare without a prior authorization (PA) until 09/16/2024. Despite no PA requirements, utilization of riluzole in the SoonerCare population historically has been minimal, with only a few utilizing members each year. However, toward the end of 2021, utilization of riluzole began to increase dramatically and unexpectedly. The increased utilization was investigated and determined to be due to off-label prescribing of riluzole for a large variety of psychiatric disorders, including, but not limited to, depression, anxiety, bipolar disorder, schizophrenia, and autism. An evaluation of the existing medical literature, including published studies and clinical practice guidelines, did not provide significant support for the safe or effective use of riluzole for any of these off-label indications. As a result, the College of Pharmacy (COP) and the Oklahoma Health Care Authority (OHCA), through discussion with 2 OHCA-contracted psychiatrists, decided to implement a PA requirement for riluzole tablets to ensure safe and appropriate use of the medication for its FDA approved indication and to

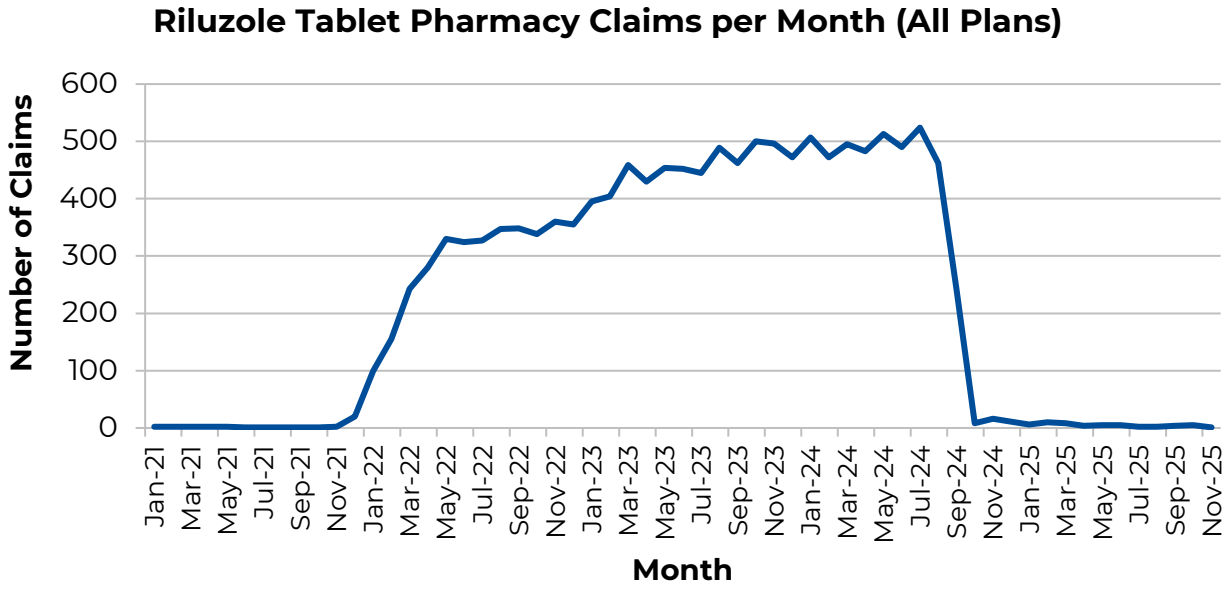
bring the utilizing members' care into closer alignment with accepted best practice recommendations. The Drug Utilization Review (DUR) Board voted unanimously in favor of the PA recommendations in July 2024 to require an ALS diagnosis and prescription by a neurologist or other specialist with expertise in the treatment of ALS.

Mailing Summary

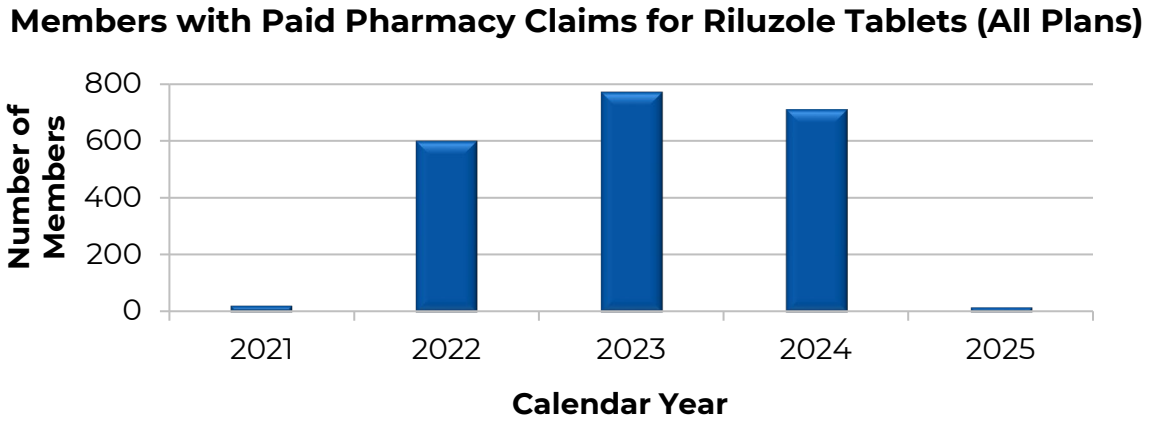
In August 2024, the COP and OHCA mailed letters to 62 providers and 496 fee-for-service (FFS) members who did not have a documented ALS diagnosis, but who had paid pharmacy claims for riluzole tablets. The letters informed the members and providers of the intent to add a PA requirement for riluzole tablets in an effort to discontinue inappropriate and potentially unsafe use of riluzole for diagnoses other than ALS. Each provider also received a list of their riluzole-utilizing FFS members to assist in identifying the impacted members. Additionally, a fax blast was sent to pharmacies and posted on OHCA's website notifying of the pending PA implementation. Following this notification process, the PA requirement for riluzole tablets went into effect on 09/16/2024.

Results: Utilization of Riluzole Tablets

Data was collected for calendar years 2021 through 2025. However, throughout this report, all 2025 data includes the calendar year data only through 11/30/2025. Data for the month of December 2025 was not yet available at the time of reporting. The following graph shows the monthly paid claim totals for riluzole tablets from 2021 through 2025.



The following graph shows the number of unique members with paid pharmacy claims for riluzole since 2021.



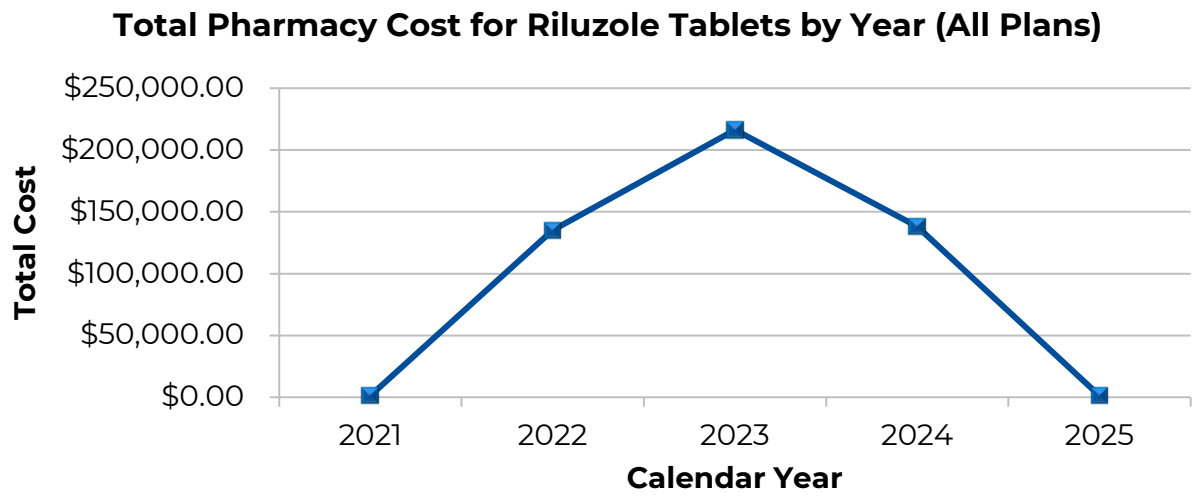
The following table (Table 1) shows additional utilization details for riluzole tablets, including the average number of units used per day. The FDA approved dosing of riluzole tablets is (1) 50mg tablet twice daily. This corresponds with the use of 2 tablets (or units) per day. Notably, the off-label prescribing of riluzole for psychiatric diagnoses coincided with a concerning increase in the dosages being used, with many members being prescribed higher-than-normal doses despite a lack of safety data for those doses for the indications being treated. The number of claims per member also increased considerably.

Table 1: Pharmacy Utilization of Riluzole Tablets by Calendar Year

Calendar Year	*Total Members	Total Claims	Total Cost	Units/ Day	Cost/ Member	Claims/ Member
2021	23	37	$1,292.58	1.96	$56.20	1.61
2022	599	3,506	$135,178.82	2.36	$225.67	5.85
2023	771	5,458	$216,251.92	2.3	$280.48	7.08
2024	710	4,223	$138,246.12	2.23	$194.71	5.95
2025	17	52	$1,311.14	2.35	$77.13	3.06

*Total number of unduplicated utilizing members.

Although the implementation of a PA requirement for riluzole tablets was not motivated by any cost containment considerations, the off-label prescribing of riluzole was nevertheless associated with significant pharmacy costs without any corresponding evidence of safety and/or efficacy. The following graph shows the total cost of the paid riluzole pharmacy claims annually since 2021. The last full year of riluzole utilization prior to implementation of the PA requirement was 2023. When comparing 2023 utilization to 2025 utilization (after the PA implementation), the PA requirement was associated with an annual cost savings of $214,940.78. This may be a conservative estimate of cost savings, as the utilization of riluzole was still trending upwards at the time the PA was implemented.



An analysis of prescriber specialty was also conducted for paid riluzole claims. Table 2 and Table 3 below show that the majority of the off-label prescribing of riluzole was initiated by psychiatrists. Although the initial prescribing was often from a psychiatrist, riluzole was frequently continued by other providers, as demonstrated by the increasing number of provider specialties represented and the decreasing percentage of claims specifically prescribed by psychiatrists during subsequent years. More specifically, as shown in Table 2, the initial paid riluzole claim was attributable to a single psychiatrist (Psychiatrist A) or mid-level practitioners supervised by Psychiatrist A in more than 83% of the utilizing members. In contrast, all other psychiatrists combined (and their mid-level practitioners) accounted for only about 6% of initial riluzole prescriptions, highlighting the atypical nature of the prescribing, even among other psychiatrists.

Table 2: Prescriber Specialties by Number (#) of Claims per Calendar Year

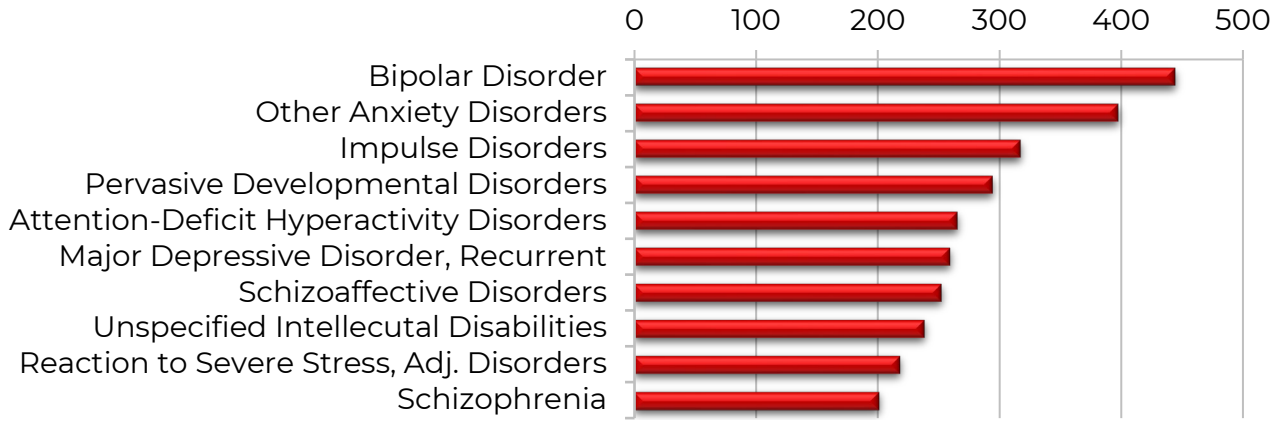
Specialty	2021		2022		2023		2024		2025	
	#	%	#	%	#	%	#	%	#	%
Psychiatrist	19	51.35%	2,838	80.95%	3,837	70.30%	2,778	65.78%	17	32.69%
Family Pract	12	32.43%	318	9.07%	533	9.77%	421	9.97%	7	13.46%
Neurologist	5	13.51%	9	0.26%	16	0.29%	4	0.09%	3	5.77%
Physician Asst	1	2.70%	17	0.48%	57	1.04%	27	0.64%		
Nurse Pract			210	5.99%	770	14.11%	818	19.37%	25	48.08%
Internist			114	3.25%	210	3.85%	139	3.29%		
Emergency Med					24	0.44%	16	0.38%		
General Ped					6	0.11%	8	0.19%		
Cardiologist					5	0.09%	8	0.19%		
Endocrinologist							4	0.09%		
Yearly Totals	**37**	**100%**	**3,506**	**100%**	**5,458**	**100%**	**4,223**	**100%**	**52**	**100%**

Asst = assistant; Med = medicine; Ped = pediatrician; Pract = practitioner

Table 3: Initial Riluzole Prescriber for Each Utilizing Member, 2021-2025		
Prescriber Groups	**Total # of Members**	**% of Total Members**
Psychiatrist A (and associated mid-level providers)	914	83.78%
All other psychiatrists (and associated mid-level providers)	67	6.14%
All neurologists (and associated mid-level providers)	7	0.64%
All other prescribers	103	9.44%
Total	**1,091**	**100%**

Because riluzole tablets did not require any PA or clinical review prior to 09/16/2024, it is not possible to know the specific intended indication in most cases. However, an analysis of reported International Classification of Diseases, 10th Revision (ICD-10) diagnosis codes, limited to mental, behavioral, and neurodevelopmental disorders (i.e., the F01 to F99 range of ICD-10 codes) was conducted. The following graph shows the top 10 ICD-10 diagnosis categories reported within 30 days before or after the initial riluzole claim.

Top Diagnosis Categories Reported by Number of Members (All Plans)



Additionally, the following table (Table 4) shows the number of riluzole-utilizing members with an appropriate diagnosis of ALS reported.

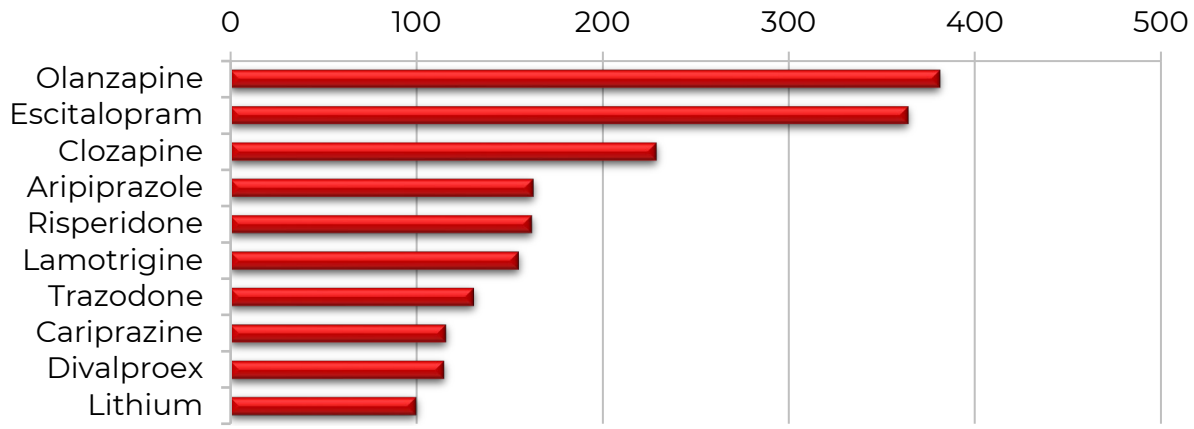
Table 4: Riluzole-Utilizing Members with a Reported ALS Diagnosis			
Time Period	**Total # of Members**	**# of Members with ALS**	**Percentage of Total**
Before 09/16/2024 (Prior to PA)	1,091	14	1.28%
Since 09/16/2024 (After PA)	35	1	2.86%

ALS = amyotrophic lateral sclerosis; PA = prior authorization

At the time of the initial riluzole prescription, members prescribed riluzole were also frequently using other psychiatric medications, such as antidepressants, antipsychotics, and select anticonvulsive therapies. Not including the riluzole, members using riluzole were also using an average of 4.4 psychiatric medications within 30 days before or after the initial riluzole claim, raising significant polypharmacy concerns. The number of concurrent

psychiatric medications ranged from 1 to 14 depending on the specific member. The following chart shows the top 10 medications that were used near the time of the initial riluzole claim. The data includes all formulations of the listed medications, including oral or injectable formulations. Additionally, this data includes the listed medications used for any diagnosis. In the case of lamotrigine and divalproex, members may have been receiving appropriate treatment for an existing seizure diagnosis.

Top Concurrent Psychiatric Medications by Number of Members (All Plans)



For the subset of riluzole-utilizing members with continuous enrollment from 6 months prior to the initial riluzole claim to 6 months after the PA was implemented (i.e., 03/15/2025), an analysis of emergency department (ED) visits was conducted to see if the discontinuation of riluzole was associated with adverse consequences which could be reflected by increased ED visits. The resulting data did not show an increase in ED utilization during the 6 months after the PA was implemented when compared to the 6-month period prior to initiating riluzole. During the time of riluzole utilization between the initial riluzole claim and 09/16/2024, the average number of ED visits per member increased to 6.94; however, this number may be falsely elevated. Although the “pre-riluzole” and “post-riluzole” time periods were 6 months each, the “during riluzole” time period was variable and depended on when a particular member initiated riluzole relative to 09/16/2024. Therefore, the “during riluzole” period may have included a longer duration of time to incur more ED visits. However, the fact that there was not an increase in ED utilization in the post-riluzole period compared to the pre-riluzole period is reassuring evidence. The following table (Table 5) summarizes ED visit data for riluzole-utilizing members during the 3 different time periods.

Table 5: ED Visits for Members Before, During, and After Riluzole Utilization			
Time Period	**# of Members***	**Total ED Visits**	**Average # of ED Visits per Member**
Pre-Riluzole: 6 months prior to initial riluzole claim	214	1,030	4.81
During Riluzole: From initial riluzole claim to 09/15/2024	477	3,309	6.94
Post-Riluzole: From 09/16/2024 (PA implementation and presumed riluzole discontinuation) to 03/15/2025	267	1,086	4.07

*Number of members with continuous enrollment during each time period
ED = emergency department; PA = prior authorization

Conclusions

After the implementation of the PA requirement for riluzole tablets, the utilization of riluzole decreased significantly. In August 2024 (the month before the PA requirement) there were 462 paid pharmacy claims for riluzole and in October 2024 (the month after the PA requirement) there were 8 paid claims for riluzole, a 98.3% decrease in claims. Similar decreases in the number of utilizing members and total cost have also been observed. Implementation of the PA requirement, and presumed discontinuation of the medication by SoonerCare members, was not associated with an increase in ED utilization. It is important to note that these analyses are based on SoonerCare claims data and ICD-10 diagnosis codes submitted to SoonerCare; thus, any member receiving riluzole through a non-SoonerCare source (i.e., private insurance, free clinics, Indian Health Services) would not be reflected in the data.

Recommendations

Implementation of the PA for riluzole tablets has been effective in reducing the amount of inappropriate off-label prescribing for riluzole. However, the majority of members still utilizing riluzole appear to be doing so without an FDA approved diagnosis of ALS. Continued monitoring and enforcement of the PA requirement is needed. The College of Pharmacy recommends continuing the PA requirement for riluzole tablets to ensure appropriate and safe use of the medication in the SoonerCare population.

[1] Rilutek® (Riluzole) Prescribing Information. Covis Pharma. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/020599s021lbl.pdf. Last revised 09/2025. Last accessed 12/18/2025.

[2] Miller, RG, Jackson CE, Kasarskis EJ, et al. Practice Parameter Update: The Care of the Patient with Amyotrophic Lateral Sclerosis: Drug, Nutritional, and Respiratory Therapies (an Evidence-Based Review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* 2009; 73(15):1218-26. doi: 10.1212/WNL.0b013e3181bc0141.

[3] Van Damme P, Al-Chalabi A, Andersen PM, et al. European Academy of Neurology (EAN) guideline on the management of amyotrophic lateral sclerosis in collaboration with European Reference Network for Neuromuscular Diseases (ERN EURO-NMD). *Eur J Neurol* 2024; 31(6):e16264. doi: 10.1111/ene.16264.

[4] IMPAX Laboratories, Inc. IMPAX Receives FDA Approval for Generic Rilutek®. Available online at: https://investors.amneal.com/news/press-releases/press-release-details/2003/IMPAX-Receives-FDA-Approval-for-Generic-Rilutek/default.aspx. Issued 01/30/2003. Last accessed 12/18/2025.

Appendix D

Fiscal Year 2025 Annual Review of Adiposity-Based Chronic Disease (ABCD) Medications and 30-day Notice to Prior Authorize Zepbound® (Tirzepatide)

Oklahoma Health Care Authority
January 2026

Current Prior Authorization Criteria

Current prior authorization criteria and utilization is only applicable to ABCD medications with an FDA approved diagnosis that is not a coverage exclusion and a current federal drug rebate agreement.

Imcivree® (Setmelanotide) Approval Criteria:

1. An FDA approved indication of chronic weight management in adult and pediatric members 6 years of age and older with obesity due to 1 of following:
    a. Proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency; or
    b. Bardet-Biedl syndrome (BBS); and
2. For POMC-, PCSK1-, or LEPR-deficiency, diagnosis must be confirmed by molecular genetic testing to confirm homozygous variants in the POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (results of genetic testing must be submitted); and
3. For BBS, diagnosis must be confirmed by the following:
    a. Molecular genetic testing to confirm homozygous or compound heterozygous variants in a BBS gene that are interpreted as pathogenic or likely pathogenic (results of genetic testing must be submitted); and
    b. Clinical features of BBS supported by detailed clinical documentation of each feature (medical records/clinical documentation of each feature must be submitted), as follows:
        i. Four primary features (i.e., rod-cone dystrophy, polydactyly, obesity, learning disabilities, hypogonadotropic hypogonadism and/or genitourinary anomalies, renal anomalies); or
        ii. Three of the primary features previously listed in 3.b.i. plus 2 secondary features [i.e., speech disorder/delay, strabismus/cataracts/astigmatism, brachydactyly/syndactyly, developmental delay, poor coordination/imbalance, mild spasticity (especially lower limbs), diabetes mellitus, dental

crowding/hypodontia/small roots/high arched palate, left ventricular hypertrophy/congenital heart disease, hepatic fibrosis]; and

4. Requests for Imcivree® for obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign, or other types of obesity not related to POMC, PCSK1 or LEPR deficiency, or BBS including obesity associated with other genetic syndromes, or general obesity will not be approved; and
5. Member is currently on a dietician-guided diet and exercise program and has previously failed a dietician-guided diet and exercise program alone; and
6. Member's baseline weight and body mass index (BMI) must be provided; and
7. Baseline BMI must be ≥30kg/m^2 for adults or ≥95th percentile on BMI-for-age growth chart assessment for children; and
8. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Imcivree® therapy and throughout treatment; and
9. Prescriber must verify member has been counseled on potential sexual adverse reactions and when to seek emergency medical care; and
10. Prescriber must verify member does not have end stage renal disease [estimated glomerular filtration rate (eGFR) <15mL/min/1.73m^2] and must confirm the dose will be adjusted per package labeling for members with severe renal impairment (eGFR 15 to 29mL/min/1.73m^2); and
11. Prescriber must verify female member is not pregnant or breastfeeding; and
12. Prescriber must confirm member or caregiver has been trained on the proper storage and administration of Imcivree® prior to the first dose; and
13. For POMC-, PCSK1-, or LEPR-deficiency, initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; or
14. For BBS, approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; and
15. A quantity limit of 9mL per 30 days will apply.

Myalept® (Metreleptin) Approval Criteria:

1. An FDA approved diagnosis of leptin deficiency in members with congenital or acquired generalized lipodystrophy; and
2. Approvals will not be granted for the following diagnoses:

   a. Metabolic disease without current evidence of generalized lipodystrophy; or
   b. HIV-related lipodystrophy; or
   c. General obesity not associated with congenital leptin deficiency; and
3. Myalept® must be prescribed by an endocrinologist; and
4. Prescriber must agree to test for neutralizing antibodies in members who experience severe infections or if they suspect Myalept® is no longer effective; and
   a. Baseline HbA1c, fasting glucose, and fasting triglycerides must be stated on prior authorization request; and
   b. Re-approvals will require recent lab values (HbA1c, fasting glucose, and fasting triglycerides) to ensure neutralizing antibodies have not developed; and
5. Prescriber and pharmacy must be enrolled in the Myalept® Risk Evaluation and Mitigation Strategies (REMS) program; and
6. Approvals will be for the duration of 3 months to evaluate compliance and ensure the prescriber is assessing continued efficacy; and
7. A quantity limit of one vial per day will apply.

Rezdiffra® (Resmetirom) Approval Criteria:

1. An FDA approved indication of noncirrhotic nonalcoholic steatohepatitis (NASH); and
2. Member must be 18 years of age or older; and
3. Member must have moderate-to-advanced liver fibrosis (e.g., stage F2 or F3) confirmed by at least 1 of the following (results of the selected test must be submitted with the request):
   a. FibroScan with vibration controlled transient elastography (VCTE) ≥8.5kPa and controlled attenuation parameter (CAP) ≥280dB/min; or
   b. Enhanced Liver Fibrosis (ELF) biochemical test score ≥9; or
   c. Liver biopsy showing stage F2 or F3 fibrosis with NASH; and
4. Member must not have known liver cirrhosis (e.g., stage F4); and
5. Must be used in conjunction with diet and exercise [clinical documentation (e.g., office notes) of member's diet and exercise program must be included with the request]; and
6. Prescriber must attest that metabolic comorbidities are being appropriately managed, including treatment for all of the following, if applicable:
   a. Type 2 diabetes; and
   b. Dyslipidemia; and
   c. Hypertension; and

7. Member must not be taking strong CYP2C8 inhibitors (e.g., gemfibrozil) or OATP1B1/OATP1B3 inhibitors (e.g., cyclosporine) concurrently with Rezdiffra®; and
8. If member is taking a moderate CYP2C8 inhibitor (e.g., clopidogrel) concurrently with Rezdiffra®, prescriber must agree to reduce the dose as required in the package labeling; and
9. If the member is taking a statin, prescriber must agree to adjust the statin dosage (when necessary) and monitor for statin-related adverse reactions; and
10. Must be prescribed by a gastroenterologist or hepatologist (or an advanced care practitioner with a supervising physician who is a gastroenterologist or hepatologist); and
11. Initial approvals will be for the duration of 6 months. Subsequent approvals (for the duration of 1 year) will be approved if the prescriber documents the member is tolerating and responding well to the medication; and
12. A quantity limit of 30 tablets per 30 days will apply.

Wegovy® (Semaglutide) Approval Criteria [Cardiovascular (CV) Risk Reduction Indication Only]:

1. An FDA approved indication to reduce the risk of major adverse cardiovascular (CV) events in members with established CV disease (CVD) and either obesity or overweight; and
    a. Wegovy® will not be approved for obese or overweight members in the absence of established CVD; and
2. Member must be 45 years of age or older; and
3. Member must have established CVD with a history of 1 of the following (documentation must be submitted with the request):
    a. Previous myocardial infarction; or
    b. Previous stroke; or
    c. Symptomatic peripheral arterial disease confirmed by 1 of the following:
        i. Intermittent claudication with ankle-brachial index <0.85 at rest; or
        ii. Peripheral arterial revascularization procedure; or
        iii. Amputation due to atherosclerotic disease; and
4. Member has a body mass index (BMI) ≥27kg/m^2; and
5. Member does not have type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM); and
6. Member has a hemoglobin A1C (HbA1c) <6.5%; and
7. Member will not be using Wegovy® in combination with other semaglutide-containing products or any other glucagon-like peptide-1 (GLP-1) receptor agonist; and

8. Member is currently receiving guideline-directed management and therapy (GDMT) for CVD (e.g., antihypertensives, lipid-lowering agents, antiplatelets), as documented in the member's pharmacy claims history, unless contraindicated; and
9. Wegovy® must be used in conjunction with diet and exercise (clinical documentation of member's diet and exercise program must be included with the request); and
10. Initial approvals will be for the titration period to allow initial and escalation dosing. A separate prior authorization request must be submitted for each dose; and
    a. Approvals will be for 4 weeks at a time to allow for proper dose escalation; and
    b. An additional 4 weeks for each dose may be approved for those who experience intolerable adverse effects during dose escalation with proper documentation; and
    c. Members who cannot tolerate dose escalation after an additional 4 week approval will not be approved for continuation; and
11. Subsequent approvals for the maintenance dose (1.7mg or 2.4mg) will be approved for 1 year if the prescriber documents the following:
    a. Member is tolerating maintenance dosing; and
    b. Member has not developed T1DM or T2DM; and
    c. Member is continuing all of the following in conjunction with Wegovy®:
        i. Reduced calorie diet; and
        ii. Increased physical activity; and
        iii. GDMT for CVD where applicable; and
12. A quantity limit of 4 pens per 28 days will apply; and
13. Wegovy® should be discontinued in members who cannot tolerate at least the 1.7mg once weekly maintenance dosing.

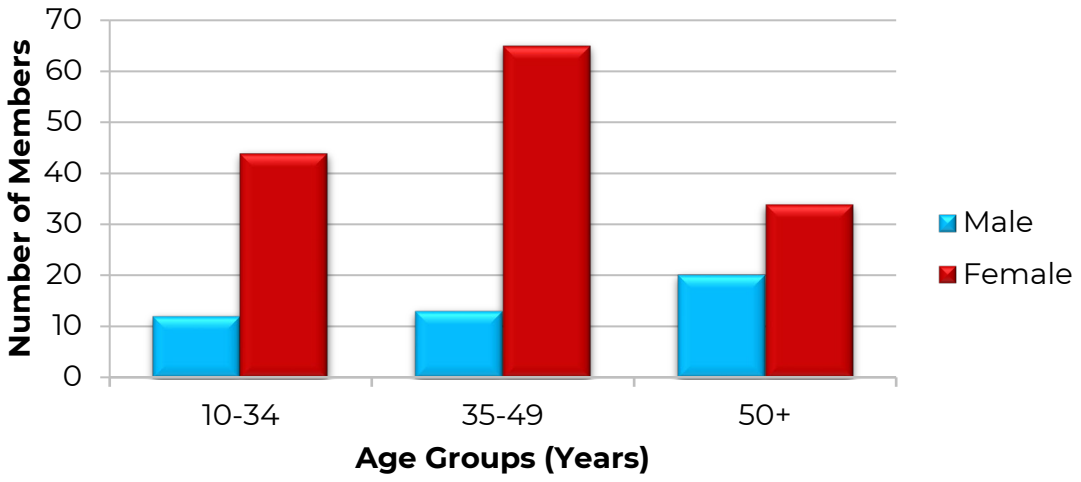
Utilization of ABCD Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

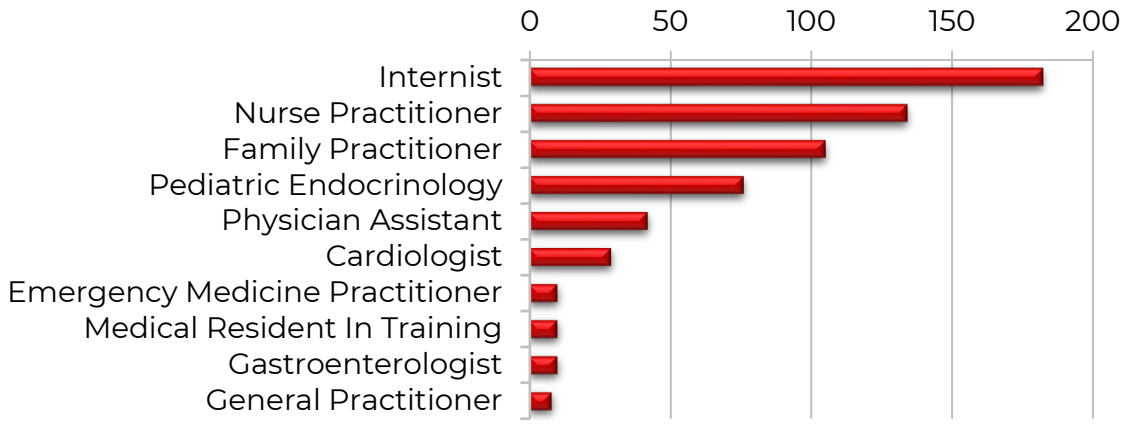
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	47	180	$5,317,164.40	$29,539.80	$997.78	1,521	5,329
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	3	7	$270,706.87	$38,672.41	$1,314.11	55	206
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**48**	**187**	**$5,587,871.27**	**$29,881.66**	**$1,009.55**	**1,576**	**5,535**
Fiscal Year 2025							
FFS	25	138	$2,128,003.64	$15,420.32	$531.87	1,086	4,001
Aetna	96	216	$909,675.49	$4,211.46	$149.08	691	6,102
Humana	43	172	$2,364,529.32	$13,747.26	$480.40	1,280	4,922
OCH	29	93	$1,114,176.37	$11,980.39	$413.88	673	2,692
2025 Total	**188**	**619**	**$6,516,384.82**	**$10,527.28**	**$367.80**	**3,730**	**17,717**
% Change	**291.70%**	**231.00%**	**16.60%**	**-64.80%**	**-63.60%**	**136.70%**	**220.10%**
Change	**140**	**432**	**$928,513.55**	**-$19,354.38**	**-$641.75**	**2,154**	**12,182**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing ABCD Medications: Pharmacy Claims (All Plans)



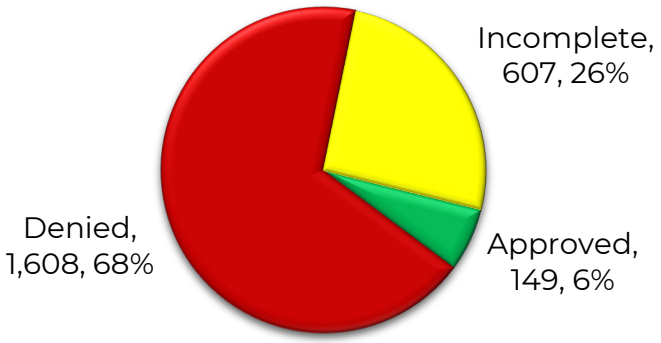
Top Prescriber Specialties of ABCD Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of ABCD Medications

There were 2,364 prior authorization requests submitted for ABCD medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	86	9%	208	22%	637	68%	**931**
Aetna	13	2%	309	58%	211	40%	**533**
Humana	32	7%	0	0%	406	93%	**438**
OCH	18	4%	90	19%	354	77%	**462**
Total	**149**	**6%**	**607**	**26%**	**1,608**	**68%**	**2,364**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16]

Anticipated Patent Expiration(s):

- Imcivree® (setmelanotide): July 2034
- Zepbound® (tirzepatide): July 2039
- Wegovy® (semaglutide): February 2041
- Rezdiffra® (resmetirom): February 2045

New U.S. Food and Drug Administration (FDA) Approval(s):

- **December 2024:** The FDA approved Zepbound® (tirzepatide) for the treatment of moderate to severe obstructive sleep apnea (OSA) in adults with obesity, to be used in combination with a reduced-calorie diet and increased physical activity.
- **December 2024:** The FDA approved an age expansion for Imcivree® (setmelanotide) for the indication to reduce excess body weight and maintain weight reduction long-term in patients 2 years of age and older with syndromic or monogenic obesity due to Bardet-Biedl syndrome (BBS) or genetically confirmed pro-opiomelanocortin (POMC), including proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency or leptin receptor (LEPR) deficiency. Previously, Imcivree® was only approved in patients 6 years of age and older.
- **August 2025:** The FDA granted accelerated approval for a new indication for Wegovy® (semaglutide) for the treatment of metabolic-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), in adults with moderate-to-advanced fibrosis. This approval was based on efficacy from part 1 of the Phase 3 ESSENCE trial comparing Wegovy® to placebo in 800 patients with biopsy-proven MASH and fibrosis stage 2 or 3. The primary endpoint was the resolution of steatohepatitis without worsening of liver fibrosis and ≥1 stage improvement in liver fibrosis without worsening of steatohepatitis, on post-baseline liver biopsies collected at 72 weeks. Interim results showed 63% of participants receiving Wegovy® had MASH resolution and no worsening of liver scarring compared to 34% of participants receiving placebo, and 37% of participants on Wegovy® had improvement in liver scarring and no worsening of MASH, compared to 22% of participants receiving placebo. The trial will continue for a total of 240 weeks to determine whether inflammation and scarring improvements seen after 72 weeks translate into decreases in death, liver transplant, and other liver-related events. Part 2 of the ESSENCE trial will serve as the confirmatory trial, with expected readout in 2029, and its primary objective is to demonstrate that treatment with Wegovy® 2.4mg lowers the risk of liver-related clinical events compared to placebo in adults with MASH and moderate-to-advanced liver fibrosis at 240 weeks.

- **December 2025:** The FDA approved a once-daily oral tablet formulation of Wegovy® (semaglutide) for use in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular (CV) events (CV death, nonfatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight. The approval for this indication is based on data from the SELECT and STEP trials for the injection formulation and data from PIONEER PLUS for Rybelsus® (semaglutide tablets). Wegovy® tablets are available in a 1.5mg, 4mg, 9mg, and 25mg strength. The recommended starting dose is 1.5mg once daily followed by a dose escalation period up to the recommended maintenance dose of 25mg once daily. More information on additional FDA approved indications, dose escalation, and switching between formulations can be found in the *Prescribing Information*.

Guideline Update(s):

- **American Association of Clinical Endocrinology (AACE) Consensus Statement Update:** AACE released the *Algorithm for the Evaluation and Treatment of Adults with Obesity/Adiposity-Based Chronic Disease – 2025 Update* to provide evidence-based algorithms and summaries to assist in the treatment of obesity and ABCD. In 2017, AACE published a position statement that proposed a diagnostic term to explicitly identify obesity as a chronic disease: adiposity-based chronic disease (ABCD). Emphasis is placed on optimizing the patient's overall health and achieving clinical goals rather than a singular focus on body mass index (BMI) (i.e., complication-centric care). The diagnosis of ABCD involves both an anthropometric component to assess adiposity and a clinical component to determine disease severity and the impact of adiposity on health and quality of life. Staging the clinical severity of ABCD is based on the presence of obesity-related complications and diseases (ORCD). This includes stages 1-3, with stage 1 being no known ORCD, stage 2 being ≥1 mild-to-moderate ORCD, and stage 3 being ≥1 severe ORCD or multiple ORCDs. The updates allow providers and patients to develop individualized treatment plans based on the severity and stage of ABCD and ORCD.

Pipeline:

- **Imcivree® (Setmelanotide):** Imcivree® is a melanocortin-4 receptor (MC4R) agonist being studied for the treatment of acquired hypothalamic obesity, a rare form of obesity that occurs following physical injury or structural abnormality of the hypothalamus with MC4R pathway disruption and other functional impairments. Data from the Phase 3 TRANSCEND trial met the primary endpoint of mean BMI change from baseline demonstrating a statistically significant

reduction in BMI of -16.5% for patients on Imcivree® vs. an increase of 3.3% with placebo at 52 weeks (P<0.0001). A supplemental New Drug Application (sNDA) was submitted to the FDA and a Prescription Drug User Fee Act (PDUFA) date was set for December 20, 2025. Rhythm Pharmaceuticals announced in November 2025 that the FDA extended the PDUFA date to March 20, 2026 due to a request for additional sensitivity analyses of clinical efficacy data from the Phase 3 trial in acquired hypothalamic obesity. The additional information has been deemed a 'major amendment,' which allows for additional time for the FDA to review. The major amendment did not include any information relating to the safety or manufacturing of Imcivree®.

- **Orforglipron:** Orforglipron is an investigational once-daily, small molecule, oral glucagon-like peptide-1 (GLP-1) agonist being studied in patients with obesity or overweight for the treatment of multiple indications such as OSA, hypertension, osteoarthritis, and stress urinary incontinence. It is also being studied in patients with type 2 diabetes mellitus (T2DM). In a Phase 3 trial, orforglipron showed superior A1c reduction compared to placebo at 40 weeks lowering A1c by an average of 1.3-1.6% from a baseline of 8%. The overall safety and tolerability of orforglipron were shown to be consistent with the established GLP-1 agonist class with the most commonly reported adverse event being gastrointestinal related. Phase 3 trials for these multiple indications are still ongoing and Eli Lilly expects to submit to regulatory agencies for a weight management indication at the end of 2025 and for the treatment of T2DM in 2026.
- **Retatrutide:** Retatrutide is an investigational, once-weekly, triple hormone receptor agonist that works by activating the body's receptors for glucose-dependent insulinotropic polypeptide (GIP), GLP-1, and glucagon. Retatrutide is being studied in several Phase 3 clinical trials to evaluate its potential efficacy and safety in obesity and overweight with at least 1 weight-related medical problem, T2DM, knee osteoarthritis, moderate-to-severe OSA, chronic low back pain, CV and renal outcomes, and metabolic dysfunction-associated steatotic liver disease (MASLD). The TRIUMPH-4 Phase 3 trial evaluating retatrutide in patients with obesity or overweight and knee osteoarthritis met its co-primary endpoints demonstrating a weight reduction of up to an average of 28.7% (71.2lbs) and reduced pain by up to an average of 4.5 points (75.8%) using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain score. Seven additional Phase 3 trials evaluating retatrutide in obesity and T2DM are expected to be completed in 2026.
- **Tirzepatide:** Tirzepatide is a once-weekly GIP/GLP-1 receptor agonist that is being studied for multiple indications in patients with obesity and/or overweight including, heart failure with preserved ejection

fraction (HFpEF), MASH, chronic kidney disease (CKD), and morbidity and mortality in obesity. The Phase 2 SYNERGY-NASH trial showed 51.8%, 62.8%, and 73.3% of participants taking 5mg, 10mg, and 15mg, respectively, achieved an absence of MASH with no worsening of fibrosis on liver histology compared to 13.2% of participants on placebo at 52 weeks of treatment, meeting the study's primary endpoint. The Phase 3 SUMMIT trial showed tirzepatide significantly reduced the risk of worsening heart failure events in adults with HFpEF and obesity by 38% (P=0.026) compared to placebo meeting its primary composite endpoint. Results from the SUMMIT trial have been submitted to the FDA but no official PDUFA date has been announced at this time.

Zepbound® (Tirzepatide) Product Summary[17,18]

Therapeutic Class: GIP/GLP-1 receptor agonist

Indication(s): Treatment of moderate to severe OSA in adults with obesity in combination with a reduced calorie diet and increased physical activity[Δ]

- **Limitation(s) of Use:** Coadministration with other tirzepatide-containing products or with any other GLP-1 receptor agonist is not recommended.

How Supplied:

- 2.5mg/0.5mL, 5mg/0.5mL, 7.5mg/0.5mL, 10mg/0.5mL, 12.5mg/0.5mL, and 15mg/0.5mL single-dose pens or single-dose vials

Dosing and Administration:

- The recommended starting dose is 2.5mg subcutaneously (sub-Q) once weekly for 4 weeks. After 4 weeks, the dosage should be increased to 5mg sub-Q once weekly. The dose may be increased in 2.5mg increments, after at least 4 weeks on the current dose.
- The recommended maintenance dose for OSA is 10mg or 15mg sub-Q once weekly with a maximum dose of 15mg once weekly for all indications.

Efficacy: The efficacy of Zepbound® for OSA was evaluated in 2 Phase 3, double-blind, placebo-controlled trials comparing Zepbound® to placebo for 52 weeks. Trial 1 included patients who were unable to use or refused positive airway pressure (PAP) therapy. Trial 2 included patients who had used PAP therapy for at least 3 months and planned to continue PAP through the trial.

- Key Inclusion Criteria:
  - 18 years of age or older
  - Diagnosis of moderate-to-severe OSA defined as an apnea-hypopnea index (AHI) ≥15 events per hour

[Δ] For full FDA approved indications, see the package labeling

- Presence of obesity defined as a BMI of ≥30kg/m^2
- History of at least 1 self-reported unsuccessful dietary effort to lose body weight

- Key Exclusion Criteria:
  - Type 1 or 2 diabetes
  - Planned surgery for sleep apnea or obesity
  - Diagnosis of central or mixed sleep apnea
  - Major craniofacial abnormalities
- Intervention(s): Patients were randomized 1:1 to receive Zepbound® or placebo for 52 weeks.
  - Zepbound® doses were escalated over a period of up to 20 weeks to a maximum tolerated dosage of 10mg or 15mg sub-Q once weekly.
- Endpoint(s):
  - Primary Endpoint: Change from baseline in AHI at week 52
  - Key Secondary Endpoints:
    - Percent change in AHI
    - Percentage of patients with ≥50% reduction in AHI from baseline
    - Percentage of patients in remission or with mild non-symptomatic OSA [AHI <5 or AHI 5-14 and Epworth Sleepiness Scale (ESS) ≤10]
- Results:
  - Primary Endpoint:
    - Trial 1:
      - Mean change in AHI was -25.3 events per hour for the Zepbound® group vs. -5.3 events per hour for the placebo group [treatment difference: -20; 95% confidence interval (CI): -25.8, -14.2; P<0.001]
    - Trial 2:
      - Mean change in AHI was -29.3 events per hour for the Zepbound® group vs. -5.5 events per hour for the placebo group (treatment difference: -23.8; 95% CI: -29.6, -17.9; P<0.001)
  - Key Secondary Endpoint(s):
    - Trial 1:
      - Percent change in AHI was -50.7% in the Zepbound® group vs. -3% in the placebo group (treatment difference: -47.7%; 95% CI: -65.8, -29.6; P<0.001)
      - 61.2% of patients on Zepbound® had a ≥50% reduction in AHI events vs. 19% of patients on placebo (treatment difference: 42.8%; 95% CI: 30.8, 54.8; P<0.001)
      - 42.2% of patients on Zepbound® were in remission or had mild non-symptomatic OSA vs. 15.9% of patients on

placebo (treatment difference: 28.7%; 95% CI: 18.3, 39.2; P<0.001)

- Trial 2:
  - Percent change in AHI was -58.7% in the Zepbound® group vs. -2.5% in the placebo group (treatment difference -56.2%; 95% CI: -73.7, -38.7; P<0.001)
  - 72.4% of patients on Zepbound® had a ≥50% reduction in AHI events vs. 23.3% of patients on placebo (treatment difference: 48.6%; 95% CI: 36.6, 60.7; P<0.001)
  - 50.2% of patients on Zepbound® were in remission or had mild non-symptomatic OSA vs. 14.3% of patients on placebo (treatment difference: 33.2%; 95% CI: 22.1, 44.3; P<0.001)

Cost: The National Average Drug Acquisition Cost (NADAC) of Zepbound® 15mg/0.5mL is $525.92 per mL. This results in an estimated cost of $1,051.84 per 28 days or $13,673.92 per year based on recommended maintenance dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Zepbound® (tirzepatide) with the following criteria (shown in red):

Zepbound® (Tirzepatide) Approval Criteria [Obstructive Sleep Apnea (OSA) Indication Only]:

1. An FDA approved indication of moderate to severe OSA in members with obesity; and
   a. Zepbound® will not be approved for obese members in the absence of OSA; and
2. Member must be 18 years of age or older; and
3. Member must have moderate-to-severe OSA defined as an apnea-hypopnea index (AHI) >15 determined by a polysomnography (PSG) or home sleep apnea testing (HSAT) with a technically adequate device; and
4. Member has a body mass index (BMI) ≥30kg/m^2; and
5. Member must not have central or mixed sleep apnea; and
6. Member does not have type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM); and
7. Member has a hemoglobin A1C (HbA1c) <6.5%; and
8. Member will not be using Zepbound® in combination with other tirzepatide-containing products or any other glucagon-like peptide-1 (GLP-1) receptor agonist; and
9. Zepbound® must be used in conjunction with behavioral changes and/or a reduced calorie diet [clinical documentation (e.g., office notes)

of member's diet and exercise program must be included with the request]; and
10. For Zepbound® vials, a patient-specific, clinically significant reason why the member cannot use the pen formulation must be provided (Zepbound® pens are preferred over the vials); and
11. Initial approvals will be for the titration period to allow initial and escalation dosing. A separate prior authorization request must be submitted for each dose; and
    a. Approvals will be for 4 weeks at a time to allow for proper dose escalation; and
    b. An additional 4 weeks for each dose may be approved for those who experience intolerable adverse effects during dose escalation with proper documentation; and
    c. Members who cannot tolerate dose escalation to at least 5mg after an additional 4-week approval will not be approved for continuation; and
12. Subsequent approvals for the maintenance dose (5mg to 15mg) will be approved for 1 year if the prescriber documents the following:
    a. Member is tolerating maintenance dosing and adherent to therapy; and
    b. Clinical improvement of OSA (e.g., patient-reported improvement in daytime sleepiness, partner-reported reduction of snoring episodes or pauses in breathing, reduction of AHI events); and
    c. Member has not developed T1DM or T2DM; and
    d. Member is continuing with behavioral changes and/or a reduced calorie diet in conjunction with Zepbound®; and
13. A quantity limit of 4 pens or vials (2mL) per 28 days will apply.
14. Zepbound® should be discontinued in members who cannot tolerate at least the 5mg once weekly maintenance dosing.

Additionally, the College of Pharmacy recommends the following changes to the Wegovy® (semaglutide) approval criteria based on the new FDA approved indication and formulation and recommends updating the Rezdiffra® (resmetirom) approval criteria based on net costs (changes shown in red):

Wegovy® (Semaglutide Injection) Approval Criteria [Metabolic Dysfunction-Associated Steatohepatitis (MASH) Diagnosis Only]:

1. An FDA approved indication of noncirrhotic MASH; and
    a. Wegovy® will not be approved for obese members in the absence of MASH; and
2. Member must be 18 years of age or older; and
3. Member must have moderate-to-advanced liver fibrosis (e.g., stage F2 or F3) confirmed by at least 1 of the following (results of the selected test must be submitted with the request):

    a. FibroScan with vibration controlled transient elastography (VCTE) ≥8kPa and controlled attenuation parameter (CAP) ≥280dB/min; or
    b. Enhanced Liver Fibrosis (ELF) biochemical test score ≥9; or
    c. Liver biopsy showing stage F2 or F3 fibrosis with MASH; and
4. Member must not have chronic liver disease other than metabolic dysfunction-associated steatotic liver disease (MASLD); and
5. Member does not have type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM); and
6. Wegovy® must be used in conjunction with diet and exercise [clinical documentation (e.g., office notes) of member's diet and exercise program must be included with the request]; and
7. Prescriber must attest that metabolic comorbidities are being appropriately managed, including treatment for all of the following, if applicable:
    a. T2DM; and
    b. Dyslipidemia; and
    c. Hypertension; and
8. Member will not be using Wegovy® in combination with other semaglutide-containing products or any other glucagon-like peptide-1 (GLP-1) receptor agonist; and
9. Must be prescribed by a gastroenterologist or hepatologist (or an advanced care practitioner with a supervising physician who is a gastroenterologist or hepatologist); and
10. Initial approvals will be for the titration period to allow initial and escalation dosing. A separate prior authorization request must be submitted for each dose; and
    a. Approvals will be for 4 weeks at a time to allow for proper dose escalation; and
    b. An additional 4 weeks for each dose may be approved for those who experience intolerable adverse effects during dose escalation with proper documentation; and
    c. Members who cannot tolerate dose escalation after an additional 4 week approval will not be approved for continuation; and
11. Subsequent approvals for the maintenance dose (1.7mg or 2.4mg) will be approved for 1 year if the prescriber documents the following:
    a. Member is tolerating maintenance dosing; and
    b. Member has not developed T1DM or T2DM; and
    c. Member is continuing a reduced calorie diet and increased physical activity in conjunction with Wegovy®; and
12. A quantity limit of 4 pens per 28 days will apply; and
13. Wegovy should be discontinued in members who cannot tolerate at least the 1.7mg once weekly maintenance dosing.

Wegovy® (Semaglutide Injection and Tablets) Approval Criteria [Cardiovascular (CV) Risk Reduction Indication Only]:

1. An FDA approved indication to reduce the risk of major adverse cardiovascular (CV) events in members with established CV disease (CVD) and either obesity or overweight; and
    a. Wegovy® will not be approved for obese or overweight members in the absence of established CVD; and
2. Member must be 45 years of age or older; and
3. Member must have established CVD with a history of 1 of the following (documentation must be submitted with the request):
    a. Previous myocardial infarction; or
    b. Previous stroke; or
    c. Symptomatic peripheral arterial disease confirmed by 1 of the following:
        i. Intermittent claudication with ankle-brachial index <0.85 at rest; or
        ii. Peripheral arterial revascularization procedure; or
        iii. Amputation due to atherosclerotic disease; and
4. Member has a body mass index (BMI) ≥27kg/m^2; and
5. Member does not have type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM); and
6. Member has a hemoglobin A1C (HbA1c) <6.5%; and
7. Member will not be using Wegovy® in combination with other semaglutide-containing products or any other glucagon-like peptide-1 (GLP-1) receptor agonist; and
8. Member is currently receiving guideline-directed management and therapy (GDMT) for CVD (e.g., antihypertensives, lipid-lowering agents, antiplatelets), as documented in the member's pharmacy claims history, unless contraindicated; and
9. Wegovy® must be used in conjunction with diet and exercise (clinical documentation of member's diet and exercise program must be included with the request); and
10. Initial approvals will be for the titration period to allow initial and escalation dosing. A separate prior authorization request must be submitted for each dose; and
    a. Approvals will be for 4 weeks at a time to allow for proper dose escalation; and
    b. An additional 4 weeks for each dose may be approved for those who experience intolerable adverse effects during dose escalation with proper documentation; and
    c. Members who cannot tolerate dose escalation after an additional 4 week approval will not be approved for continuation; and

11. Subsequent approvals for the maintenance dose (1.7mg or 2.4mg for the injection and 25mg for the tablets) will be approved for 1 year if the prescriber documents the following:
    a. Member is tolerating maintenance dosing; and
    b. Member has not developed T1DM or T2DM; and
    c. Member is continuing all of the following in conjunction with Wegovy®:
        i. Reduced calorie diet; and
        ii. Increased physical activity; and
        iii. GDMT for CVD where applicable; and
12. A quantity limit of 4 pens per 28 days or 30 tablets per 30 days will apply; and
13. Wegovy® should be discontinued in members who cannot tolerate at least the 1.7mg once weekly maintenance dosing.

Rezdiffra® (Resmetirom) Approval Criteria:

1. An FDA approved indication of noncirrhotic nonalcoholic steatohepatitis (NASH); and
2. Member must be 18 years of age or older; and
3. Member must have moderate-to-advanced liver fibrosis (e.g., stage F2 or F3) confirmed by at least 1 of the following (results of the selected test must be submitted with the request):
    a. FibroScan with vibration controlled transient elastography (VCTE) ≥8.5kPa and controlled attenuation parameter (CAP) ≥280dB/min; or
    b. Enhanced Liver Fibrosis (ELF) biochemical test score ≥9; or
    c. Liver biopsy showing stage F2 or F3 fibrosis with NASH; and
4. Member must not have known liver cirrhosis (e.g., stage F4); and
5. Must be used in conjunction with diet and exercise [clinical documentation (e.g., office notes) of member's diet and exercise program must be included with the request]; and
6. Prescriber must attest that metabolic comorbidities are being appropriately managed, including treatment for all of the following, if applicable:
    a. Type 2 diabetes; and
    b. Dyslipidemia; and
    c. Hypertension; and
7. Member must not be taking strong CYP2C8 inhibitors (e.g., gemfibrozil) or OATP1B1/OATP1B3 inhibitors (e.g., cyclosporine) concurrently with Rezdiffra; and
8. If member is taking a moderate CYP2C8 inhibitor (e.g., clopidogrel) concurrently with Rezdiffra®, prescriber must agree to reduce the dose as required in the package labeling; and

9. If the member is taking a statin, prescriber must agree to adjust the statin dosage (when necessary) and monitor for statin-related adverse reactions; and
10. A trial of Wegovy® (semaglutide injection) at maintenance dosing for at least 3 months (unless contraindicated) that did not provide an adequate response; and
    a. If combination therapy of Rezdiffra® with Wegovy® is being requested, a patient-specific, clinically significant reason why the member requires combination therapy must be provided; and
11. Must be prescribed by a gastroenterologist or hepatologist (or an advanced care practitioner with a supervising physician who is a gastroenterologist or hepatologist); and
12. Initial approvals will be for the duration of 6 months. Subsequent approvals (for the duration of 1 year) will be approved if the prescriber documents the member is tolerating and responding well to the medication; and
13. A quantity limit of 30 tablets per 30 days will apply.

Finally, the College of Pharmacy recommends the following changes to the Imcivree® (setmelanotide) approval criteria based on the new FDA approved age expansion and clinical practice (changes shown in red):

Imcivree® (Setmelanotide) Approval Criteria:

1. An FDA approved indication of chronic weight management in adult and pediatric members ~~6~~ 2 years of age and older with obesity due to 1 of following:
    a. Proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency; or
    b. Bardet-Biedl syndrome (BBS); and
2. For POMC-, PCSK1-, or LEPR-deficiency, diagnosis must be confirmed by molecular genetic testing to confirm homozygous or compound heterozygous variants in the POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (results of genetic testing must be submitted); and
3. For BBS, diagnosis must be confirmed by the following:
    a. Molecular genetic testing to confirm homozygous or compound heterozygous variants in a BBS gene that are interpreted as pathogenic or likely pathogenic (results of genetic testing must be submitted); and
    b. Clinical features of BBS supported by detailed clinical documentation of each feature (medical records/clinical documentation of each feature must be submitted), as follows:

    i. Four primary features (i.e., rod-cone dystrophy, polydactyly, obesity, learning disabilities, hypogonadotropic hypogonadism and/or genitourinary anomalies, renal anomalies); or
    ii. Three of the primary features previously listed in 3.b.i. plus 2 secondary features [i.e., speech disorder/delay, strabismus/cataracts/astigmatism, brachydactyly/syndactyly, developmental delay, poor coordination/imbalance, mild spasticity (especially lower limbs), diabetes mellitus, dental crowding/hypodontia/small roots/high arched palate, left ventricular hypertrophy/congenital heart disease, hepatic fibrosis]; and
4. Requests for Imcivree® for obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign, or other types of obesity not related to POMC, PCSK1 or LEPR deficiency, or BBS including obesity associated with other genetic syndromes, or general obesity will not be approved; and
5. Member is currently on a dietician-guided diet and exercise program and has previously failed a dietician-guided diet and exercise program alone; and
6. Member's baseline weight and body mass index (BMI) must be provided; and
7. Baseline BMI must be ≥30kg/m^2 for adults or ≥95th percentile on BMI-for-age growth chart assessment for children; and
8. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Imcivree® therapy and throughout treatment; and
9. Prescriber must verify member has been counseled on potential sexual adverse reactions and when to seek emergency medical care; and
10. Prescriber must verify member does not have end stage renal disease [estimated glomerular filtration rate (eGFR) <15mL/min/1.73m^2] and must confirm the dose will be adjusted per package labeling for members with severe renal impairment (eGFR 15 to 29mL/min/1.73m^2); and
11. Prescriber must verify female member is not pregnant or breastfeeding; and
12. Prescriber must confirm member or caregiver has been trained on the proper storage and administration of Imcivree® prior to the first dose; and
13. For POMC-, PCSK1-, or LEPR-deficiency, initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; or

14. For BBS, approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; and
15. A quantity limit of 9mL per 30 days will apply.

Utilization Details of ABCD Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SEMAGLUTIDE PRODUCTS						
WEGOVY INJ 0.25MG/0.5ML	135	100	$177,272.27	$1,313.13	1.35	2.72%
WEGOVY INJ 0.5MG/0.5ML	100	64	$131,140.01	$1,311.40	1.56	2.01%
WEGOVY INJ 1.7MG/0.75ML	53	25	$69,536.74	$1,312.01	2.12	1.07%
WEGOVY INJ 1MG/0.5ML	48	38	$62,982.66	$1,312.14	1.26	0.97%
WEGOVY INJ 2.4MG/0.75ML	31	14	$40,716.57	$1,313.44	2.21	0.62%
SUBTOTAL	**367**	**241**	**$481,648.25**	**$1,312.39**	**1.52**	**7.39%**
SETMELANOTIDE PRODUCTS						
IMCIVREE INJ 10MG/ML	175	24	$5,016,292.49	$28,664.53	7.29	76.98%
SUBTOTAL	**175**	**24**	**$5,016,292.49**	**$28,664.53**	**7.29**	**76.98%**
RESMETIROM PRODUCTS						
REZDIFFRA TAB 80MG	23	7	$94,503.87	$4,108.86	3.29	1.45%
REZDIFFRA TAB 100MG	20	7	$81,713.52	$4,085.68	2.86	1.25%
SUBTOTAL	**43**	**14**	**$176,217.39**	**$4,098.08**	**3.07**	**2.70%**
TIRZEPATIDE PRODUCTS						
ZEPBOUND INJ 2.5/0.5ML	10	6	$10,566.47	$1,056.65	1.67	0.16%
ZEPBOUND INJ 5MG/0.5ML	9	5	$9,543.85	$1,060.43	1.8	0.15%
ZEPBOUND INJ 7.5MG/0.5ML	3	3	$3,190.32	$1,063.44	1	0.05%
SUBTOTAL	**22**	**14**	**$23,300.64**	**$1,059.12**	**1.57**	**0.36%**
METRELEPTIN PRODUCTS						
MYALEPT INJ 11.3MG	12	1	$818,926.05	$68,243.84	12	12.57%
SUBTOTAL	**12**	**1**	**$818,926.05**	**$68,243.84**	**12**	**12.57%**
TOTAL	**619**	**188***	**$6,516,384.82**	**$10,527.28**	**3.29**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix E

Fiscal Year 2025 Annual Review of Antihyperlipidemics and 30-Day Notice to Prior Authorize Redemplo® (Plozasiran)

Oklahoma Health Care Authority
January 2026

Current Prior Authorization Criteria

Evkeeza® (Evinacumab-dgnb) Approval Criteria:

1. An FDA approved diagnosis of homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:
    a. Documented functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
    b. An untreated LDL >500mg/dL and at least 1 of the following:
        i. Documented evidence of definite HeFH in both parents; or
        ii. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; and
2. Member must be 5 years of age or older; and
3. Documented trial of high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy at least 12 weeks in duration; and
4. Members with statin intolerance must meet 1 of the following:
    a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Documented trial of a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®) at least 12 weeks in duration; and
6. Member requires additional lowering of LDL-cholesterol (LDL-C) (baseline, current, and goal LDL-C levels must be provided); and
7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation. Female members of

reproductive potential must be willing to use effective contraception while on therapy and for 5 months after discontinuation of therapy; and

8. Initial approvals will be for the duration of 6-months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Fibric Acid Derivative Medications	
Tier-1	**Tier-2**
choline fenofibrate DR cap 45mg (Trilipix®)	choline fenofibrate DR cap 135mg (Trilipix®)
fenofibrate micronized cap 67mg, 134mg (Lofibra®)	fenofibrate cap 50mg, 150mg (Lipofen®)
fenofibrate tab 48mg, 145mg (Tricor®)	fenofibrate micronized cap 43mg, 130mg (Antara®)
fenofibrate tab 54mg, 160mg (Lofibra®)	fenofibrate tab 40mg, 120mg (Fenoglide®)
fenofibrate micronized cap 200mg (Lofibra®)	fenofibric acid tab (Fibricor®) 105mg
gemfibrozil tab 600mg (Lopid®)	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
cap = capsule; DR = delayed release; tab = tablet

Fibric Acid Derivative Medications Tier-2 Approval Criteria:

1. Laboratory documented failure with a Tier-1 medication after a 6-month trial; or
2. Documented adverse drug effect, drug interaction, or contraindication to all Tier-1 medication(s); or
3. Prior stabilization on the Tier-2 medication documented within the last 100 days.

Juxtapid® (Lomitapide) Approval Criteria:

1. An FDA approved diagnosis of homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following criteria:
   a. A documented functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
   b. An untreated LDL >500mg/dL and triglycerides <300mg/dL and at least 1 of the following:
      i. Documented evidence of definite HeFH in both parents; or
      ii. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; and

2. Documented trial of high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy at least 12 weeks in duration; and
3. Members with statin intolerance must meet 1 of the following:
    a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
4. Documented trial of a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®) at least 12 weeks in duration; and
5. Member requires additional lowering of LDL-cholesterol (LDL-C) (baseline, current, and goal LDL-C levels must be provided); and
6. Prescriber must be certified with Juxtapid® Risk Evaluation and Mitigation Strategy (REMS) program.

Leqvio® (Inclisiran) Approval Criteria:

1. An FDA approved indication as an adjunct to diet and statin therapy for the treatment of 1 of the following:
    a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
        i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. Both of the following:
            1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
            2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
        iii. Dutch Lipid Clinic Network Criteria score of >8; or
    b. Established atherosclerotic cardiovascular disease (ASCVD); and
        i. Supporting diagnoses/conditions and dates of occurrence signifying established ASCVD; or
    c. Primary hyperlipidemia; and
        i. Member's untreated LDL-C level must be ≥190mg/dL; and
        ii. Current LDL-C level is ≥100mg/dL; and
2. Member must be 18 years of age or older; and
3. Documented trial of all of the following for at least 12 weeks in duration each:

    a. High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy; and
    b. Ezetimibe; and
    c. Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®); and
4. Members with statin intolerance must meet 1 of the following:
    a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C must be provided); and
6. Leqvio® must be administered by a health care professional. Approvals will not be granted for self-administration; and
    a. Prior authorization requests must indicate how Leqvio® will be administered (e.g., prescriber, pharmacist, home health care provider); and
        i. Leqvio® must be shipped to the facility where the member is scheduled to receive treatment; or
        ii. Prescriber must verify the member has been counseled on the proper storage of Leqvio®; and
7. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Nexletol® (Bempedoic Acid) and Nexlizet® (Bempedoic Acid/Ezetimibe) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. As an adjunct to diet and other low-density lipoprotein cholesterol (LDL-C) lowering therapies or alone when concomitant LDL-C lowering therapies are not possible to reduce LDL-C in those with heterozygous familial hypercholesterolemia (HeFH). HeFH must be confirmed by 1 of the following:
        i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. Both of the following:

1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or

iii. Dutch Lipid Clinic Network Criteria score of >8; or

b. As an adjunct to diet and other LDL-C lowering therapies or alone when concomitant LDL-C lowering therapies are not possible to reduce LDL-C in those with primary hyperlipidemia; and
   i. Member's untreated LDL-C level must be ≥190mg/dL; and
   ii. Current LDL-C level is ≥100mg/dL; and
c. To reduce the risk of myocardial infarction and coronary revascularization in those unable to take recommended statin therapy with 1 of the following:
   i. High risk for a cardiovascular disease (CVD) event without established atherosclerotic CVD (ASCVD); or
   ii. Established ASCVD; and
   iii. Supporting diagnoses/conditions/risk factors and dates of occurrences must be submitted; and

2. Member must be 18 years of age or older; and
3. Member must be on a stable dose of maximally tolerated statin therapy for at least 4 weeks (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
   a. LDL-C levels should be included following at least 4 weeks of treatment; and
   b. Member must not be taking simvastatin at doses >20mg or pravastatin at doses >40mg due to drug interactions with Nexletol® and Nexlizet®; and
4. Members with statin intolerance must meet 1 of the following:
   a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
   b. An FDA labeled contraindication to all statins; or
   c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
   d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
6. A quantity limit of 30 tablets per 30 days will apply; and
7. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Praluent® (Alirocumab) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
        i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles know to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. Both of the following:
            1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
            2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
        iii. Dutch Lipid Clinic Network Criteria score of >8; or
    b. Homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:
        i. Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. An untreated LDL >500mg/dL and at least 1 of the following:
            1. Documented evidence of definite HeFH in both parents; or
            2. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; or
    c. As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease (CVD); and
        i. Documentation of established CVD; and
        ii. Supporting diagnoses/conditions and date of occurrence signifying established CVD; or
    d. Primary hyperlipidemia; and
        i. Member's untreated LDL-C level must be ≥190mg/dL; and
        ii. Current LDL-C level is ≥100mg/dL; and
2. For HeFH, member must be 8 years of age or older; and
3. For FDA approved indications other than HeFH, the member must be 18 years of age or older; and
4. Member must be on high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or on maximally tolerated statin therapy; and
    a. Statin trials must be at least 12 weeks in duration (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and

b. LDL-C levels should be included following at least 12 weeks of treatment; and

5. Members with statin intolerance must meet 1 of the following:
   a. Creatinine kinase (CK) labs verifying rhabdomyolysis; or
   b. An FDA labeled contraindication to all statins; or
   c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
   d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
6. Member must have a recent trial with a statin with ezetimibe, or a recent trial of ezetimibe without a statin for members with a documented statin intolerance, or a patient-specific, clinically significant reason why ezetimibe is not appropriate must be provided; and
7. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
8. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
9. A quantity limit of 2 syringes or pens per 28 days will apply; and
10. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Repatha® (Evolocumab) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
      i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles know to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
      ii. Both of the following:
         1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
         2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
      iii. Dutch Lipid Clinic Network Criteria score of >8; or
   b. Homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:

        i. Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. An untreated LDL >500mg/dL and at least 1 of the following:
            1. Documented evidence of definite HeFH in both parents; or
            2. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; or
    c. As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease (CVD); and
        i. Documentation of established CVD; and
        ii. Supporting diagnoses/conditions and date of occurrence signifying established CVD; or
    d. Primary hyperlipidemia; and
        i. Member's untreated LDL-C level must be ≥190mg/dL; and
        ii. Current LDL-C level is ≥100mg/dL; and
2. For HeFH or HoFH, member must be 10 years of age or older; and
3. For FDA approved indications other than HeFH or HoFH, the member must be 18 years of age or older; and
4. Member must be on high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or on maximally tolerated statin therapy; and
    a. Statin trials must be at least 12 weeks in duration (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
    b. LDL-C levels should be included following at least 12 weeks of treatment; and
5. Members with statin intolerance must meet 1 of the following:
    a. Creatinine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
6. Member must have a recent trial with a statin with ezetimibe, or a recent trial of ezetimibe without a statin for members with a documented statin intolerance, or a patient-specific, clinically significant reason why ezetimibe is not appropriate must be provided; and

7. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
8. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
9. A quantity limit of 2 syringes or auto-injectors per 28 days will apply; and
10. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Statin Medications and Ezetimibe	
Tier-1	**Special PA**
atorvastatin (Lipitor®)	atorvastatin suspension (Atorvaliq®)
ezetimibe (Zetia®)	fluvastatin (Lescol® & Lescol® XL)
lovastatin (Mevacor®)	lovastatin ER (Altoprev®)
pravastatin (Pravachol®)	pitavastatin (Livalo®)
rosuvastatin (Crestor®)	pitavastatin magnesium (Zypitamag®)
simvastatin (Zocor®)	simvastatin/ezetimibe (Vytorin®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ER = extended-release; PA = prior authorization

Statin Medications Special Prior Authorization (PA) Approval Criteria:

1. Use of any Special PA medication will require a patient-specific, clinically significant reason why lower tiered medications with similar or higher low-density lipoprotein-cholesterol (LDL-C) reduction cannot be used; and
2. Use of Atorvaliq® (atorvastatin oral suspension) will require:
   a. An FDA approved indication; and
   b. Member must be 10 years of age or older; and
   c. A patient specific, clinically significant reason why the member cannot use atorvastatin oral tablets, even when the tablets are crushed.

Tryngolza® (Olezarsen) Approval Criteria:

1. An FDA approved indication to reduce triglyceride levels in adults with familial chylomicronemia syndrome (FCS); and
2. Diagnosis of FCS must be confirmed by the following:
   a. Fasting triglyceride levels ≥880mg/dL; and
   b. One of the following:

i. Genetic testing identifying biallelic pathogenic variants in the *LPL, GPIHBP1, APOA5, APOC2*, or *LMF1* genes (results of genetic testing must be submitted); or
ii. Familial chylomicronemia score ≥10; or
iii. North American familial chylomicronemia syndrome score ≥45; or
iv. History of clinical signs and symptoms associated with FCS (i.e., pancreatitis and/or abdominal pain, eruptive xanthomas, lipemia retinalis, lipemic plasma) and a diagnosis of multifactorial chylomicronemia syndrome (MCS) has been ruled out; and

3. Member must be 18 years of age or older; and
4. Must be prescribed by, or in consultation with, a cardiologist, an endocrinologist, or a specialist with expertise in the treatment of disorders related to severe hypertriglyceridemia; and
5. Prescriber must verify the member is on a low-fat diet of ≤20g of fat per day and will continue the low-fat diet while on treatment with Tryngolza®; and
6. Member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tryngolza®; and
7. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment, as indicated by a reduction in fasting triglyceride levels, decreased episodes of acute pancreatitis, and/or other documentation of a positive clinical response to therapy. Subsequent approvals will be for the duration of 1 year.

Vascepa® (Icosapent Ethyl) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Severe hypertriglyceridemia; and
      i. Laboratory documentation of severe hypertriglyceridemia (fasting triglycerides ≥500mg/dL) and controlled diabetes (fasting glucose <150mg/dL at the time of triglycerides measurement and HgA1c <7.5%); and
      ii. Previous failure with fibric acid medications; and
      iii. Previous failure of or a patient-specific, clinically significant reason why the member cannot use omega-3-acid ethyl esters (generic Lovaza®), which is available without prior authorization; or
   b. As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult members with elevated triglyceride levels; and

i. Member must be on a stable dose of maximally tolerated statin therapy for at least 4 weeks (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
ii. Laboratory documentation of fasting triglycerides ≥150mg/dL; and
iii. Member must have 1 of the following:
    1. Established cardiovascular disease; or
    2. Diabetes mellitus and ≥2 additional risk factors for cardiovascular disease; and

2. Use of Vascepa® 0.5 gram requires a patient-specific, clinically significant reason why the member cannot use Vascepa® 1 gram.

Welchol® (Colesevelam) Packets for Oral Suspension Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the oral tablet formulation of colesevelam, which is available without prior authorization, must be provided; and
3. The following quantity limits will apply:
    a. 30 packets for oral suspension per 30 days.

Utilization of Antihyperlipidemics: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	44,489	126,253	$2,105,629.99	$16.68	$0.25	8,673,479	8,382,408
Aetna	4,426	5,692	$114,402.21	$20.10	$0.29	405,192	392,738
Humana	5,992	8,645	$169,801.57	$19.64	$0.33	535,631	514,598
OCH	4,449	5,894	$118,906.77	$20.17	$0.33	370,783	357,279
2024 Total	**47,649**	**146,484**	**$2,508,740.54**	**$17.13**	**$0.26**	**9,985,084**	**9,647,023**
Fiscal Year 2025							
FFS	22,435	68,625	$1,175,956.46	$17.14	$0.28	4,378,358	4,239,245
Aetna	8,638	22,945	$448,164.37	$19.53	$0.27	1,705,796	1,659,850
Humana	11,289	34,921	$881,563.84	$25.24	$0.38	2,392,129	2,315,740
OCH	9,044	25,099	$500,217.61	$19.93	$0.29	1,768,796	1,717,671
2025 Total	**46,165**	**151,590**	**$3,005,902.28**	**$19.83**	**$0.30**	**10,245,079**	**9,932,506**
% Change	**-3.10%**	**3.50%**	**19.80%**	**15.80%**	**15.40%**	**2.60%**	**3.00%**
Change	**-1,484**	**5,106**	**$497,161.74**	**$2.70**	**$0.04**	**259,995**	**285,483**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

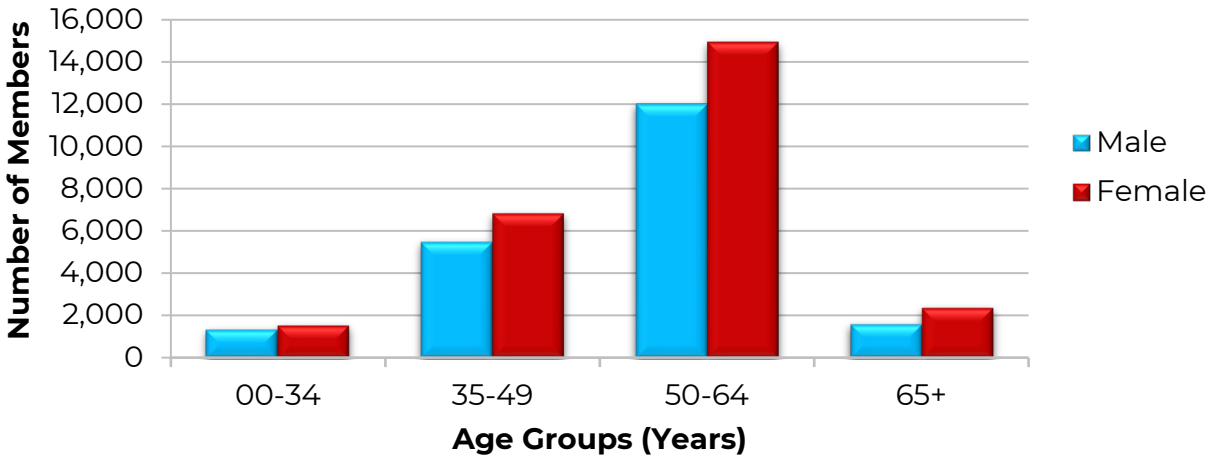
- Aggregate drug rebates collected during fiscal year 2025 for antihyperlipidemics totaled $480,015.35.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	4	6	$20,564.44	$3,427.41	1.5
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**4**	**6**	**$20,564.44**	**$3,427.41**	**1.5**
Fiscal Year 2025					
FFS	2	2	$6,946.64	$3,473.32	1
Aetna	1	1	$3,457.96	$3,457.96	1
Humana	2	2	$6,955.16	$3,477.58	1
OCH	0	0	$0.00	$0.00	0
2025 Total	**5**	**5**	**$17,359.76**	**$3,471.95**	**1**
% Change	**25.00%**	**-16.67%**	**-15.58%**	**1.30%**	**-33.33%**
Change	**1**	**-1**	**-$3,204.68**	**$44.54**	**-0.5**

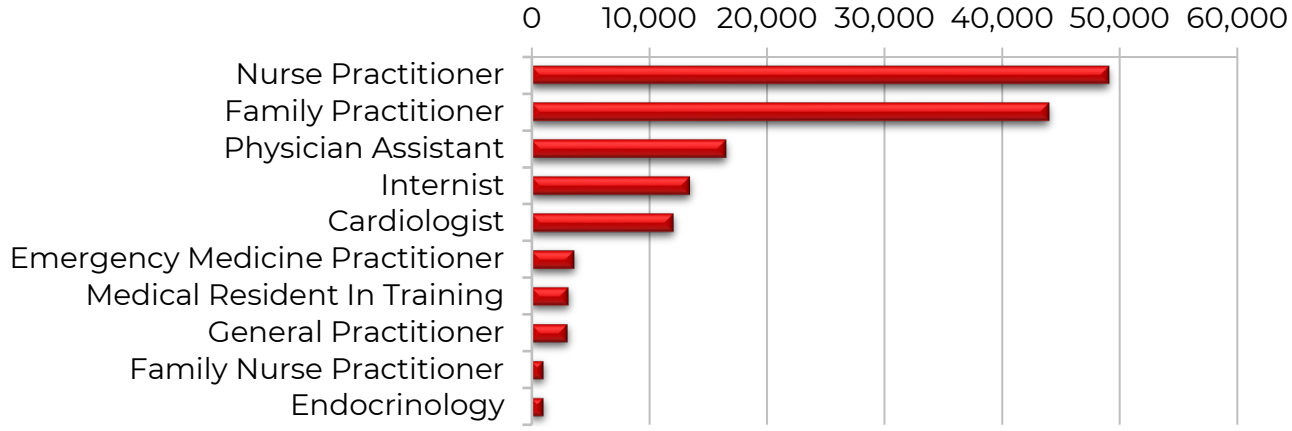
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing Antihyperlipidemics: Pharmacy Claims (All Plans)



[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

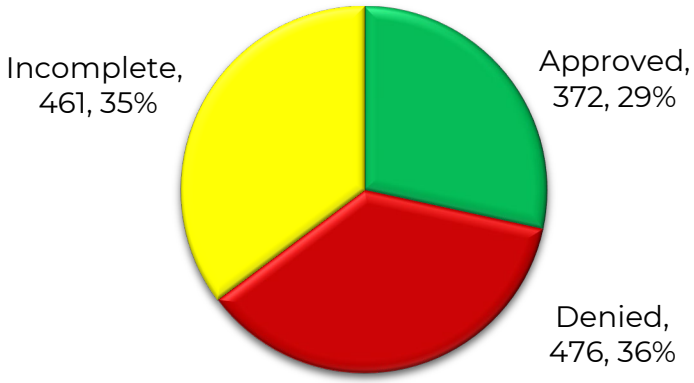
Top Prescriber Specialties of Antihyperlipidemics by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Antihyperlipidemics

There were 1,309 prior authorization requests submitted for antihyperlipidemics during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	225	30%	324	43%	204	27%	**753**
Aetna	24	10%	114	49%	96	41%	**234**
Humana	43	34%	0	0%	82	66%	**125**
OCH	80	41%	23	12%	94	48%	**197**
Total	**372**	**29%**	**461**	**35%**	**476**	**36%**	**1,309**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12]

Anticipated Patent Expiration(s):

- Juxtapid® (lomitapide capsule): August 2027
- Zypitamag® (pitavastatin magnesium tablet): January 2031
- Vascepa® (icosapent ethyl capsule): June 2033
- Tryngolza® (olezarsen injection): May 2034
- Leqvio® (inclisiran solution): August 2036
- Atorvaliq® (atorvastatin oral suspension): June 2037
- Redemplo® (plozasiran solution): September 2038
- Nexletol® (bempedoic acid tablet): June 2040
- Nexlizet® (bempedoic acid/ezetimibe tablet): June 2040

New U.S. Food and Drug Administration (FDA) Approval(s):

- **July 2025:** The FDA approved a label update for Leqvio® (inclisiran) which removed the requirement for Leqvio® to be used in combination with a statin. Leqvio® is now approved as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).
- **August 2025:** The FDA approved a label expansion for Repatha® (evolocumab) to include those at risk of major adverse cardiovascular (CV) events due to uncontrolled LDL-C. This removed the prior requirement that the patient had to have established CV disease.
- **September 2025:** The FDA approved an age expansion for Evkeeza® (evinacumab-dgnb) down to 1 year of age or older to treat homozygous familial hypercholesterolemia (HoFH). Previously, Evkeeza® was approved in patients 5 years of age or older. The efficacy of Evkeeza® was studied in 6 patients 1 year to younger than 5 years of age in an expanded access program, which showed a reduction in LDL-C.
- **October 2025:** The FDA approved a label expansion for Praluent® (alirocumab) to include those at risk of major adverse CV events due to uncontrolled LDL-C. This removed the prior requirement that the patient had to have established CV disease.
- **November 2025:** The FDA approved Redemplo® (plozasiran) as an adjunct to diet to reduce triglycerides (TG) in adults with familial chylomicronemia syndrome (FCS).
- **November 2025:** The FDA approved revisions to the indications in the Nexletol® (bempedoic acid) and Nexlizet® (bempedoic acid/ezetimibe) *Prescribing Information* to clarify that bempedoic acid is indicated to reduce the risk of major adverse CV events, such as CV death, myocardial infarction, stroke, or coronary revascularization, in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking a statin). Additionally, for the

HeFH diagnosis, bempedoic acid should be used in combination with exercise along with diet.

Pipeline:

- **Olezarsen:** Olezarsen is being studied for a new indication to treat people with severe hypertriglyceridemia (sHTG). The results of the CORE and CORE2 Phase 3 clinical trials were announced in November 2025, which showed that patients treated with olezarsen achieved a statistically significant placebo-adjusted mean reduction in fasting TG levels of up to 72% at 6 months. Olezarsen is currently FDA approved under the brand name Tryngolza® (olezarsen) for treatment of adults with FCS. Ionis, the manufacturer of olezarsen, stated they plan to submit a supplemental New Drug Application (sNDA) at the end of 2025.

Redemplo® (Plozasiran) Product Summary[13,14]

Therapeutic Class: Apolipoprotein C-III (apoC-III)-directed small interfering ribonucleic acid (siRNA)

Indication(s): Adjunct to diet to reduce TG in adults with FCS

How Supplied: 25mg/0.5mL solution in a single-dose pre-filled syringe

Dosing and Administration:

- The recommended dosage of Redemplo® is 25mg injected subcutaneously (sub-Q) once every 3 months.
- Redemplo® should be injected sub-Q into the front of the thigh or abdomen. The outer area of the upper arm can be used as an injection site if a health care provider or caregiver administers the injection.

Efficacy: The efficacy of Redemplo® was studied in the PALISADE clinical trial, a randomized, placebo-controlled, double-blind trial in adult patients with genetically confirmed or clinically diagnosed FCS who were maintained on a low-fat diet (≤20 grams of fat per day).

- Key Inclusion Criteria:
  - 18 years of age or older
  - Fasting TGs ≥880mg/dL at screening
  - Diagnosis of severe hypertriglyceridemia that was resistant to standard lipid-lowering therapy
  - A documented history of a fasting TGs of >1,000mg/dL on ≥3 occasions
  - Genetically confirmed FCS or symptomatic persistent chylomicronemia
- Exclusion Criteria:
  - Uncontrolled diabetes

    - Use of corticosteroids or anabolic steroids
    - Chronic kidney disease
- Intervention(s): 75 eligible patients were randomly assigned in a 2:1:2:1 ratio to receive 25mg of Redemplo® or volume-matched placebo or to receive 50mg of Redemplo® or volume-matched placebo sub-Q every 3 months for 12 months.
- Primary Endpoint: The primary endpoint was the median percent change from baseline in the fasting TG level at 10 months.
- Results:
    - The median relative reduction from baseline in the fasting TG level was −80% in the 25mg Redemplo® group, −78% in the 50mg Redemplo® group, and −17% in the placebo group.
    - The median percent change in the fasting TG level in the Redemplo® group compared with placebo was −59% points [95% confidence interval (CI): −90, −28; P<0.001] in the 25mg group and −53% points (95% CI: −83, –22; P<0.001) in the 50mg group.

Cost Comparison:

Medication	Cost Per Syringe	Cost Per Year
Redemplo® (plozasiran) 25mg/0.5mL injection	**$15,000**	**$60,000[α]**
Tryngolza® (olezarsen) 80mg/0.8mL injection	$49,584	$595,008[β]

Costs do not reflect rebated prices or net costs. Cost based on wholesale acquisition cost (WAC).
[α]Cost based on the FDA approved dose of 25mg/0.5mL once every 3 months.
[β]Cost based on the FDA approved dose of 80mg/0.8mL once monthly.

Recommendations

The College of Pharmacy recommends the prior authorization of Redemplo® (plozasiran) with the following criteria and recommends updating the approval criteria for Tryngolza® (olezarsen) based on the FDA approval of Redemplo®, net cost, and clinical practice (shown in red):

Redemplo® (Plozasiran) Approval Criteria:

1. An FDA approved indication to reduce triglyceride levels in adults with familial chylomicronemia syndrome (FCS); and
2. Diagnosis of FCS must be confirmed by the following:
    a. Fasting triglyceride levels ≥880mg/dL; and
    b. One of the following:
        i. Genetic testing identifying biallelic pathogenic variants in the *LPL, GPIHBP1, APOA5, APOC2*, or *LMF1* genes (results of genetic testing must be submitted); or
        ii. Familial chylomicronemia score ≥10; or
        iii. North American familial chylomicronemia syndrome score ≥45; or

iv. History of clinical signs and symptoms associated with FCS (i.e., pancreatitis and/or abdominal pain, eruptive xanthomas, lipemia retinalis, lipemic plasma) and a diagnosis of multifactorial chylomicronemia syndrome (MCS) has been ruled out; and

3. Member must be 18 years of age or older; and
4. Must be prescribed by, or in consultation with, a cardiologist, an endocrinologist, or a specialist with expertise in the treatment of disorders related to severe hypertriglyceridemia; and
5. Prescriber must verify the member is on a low-fat diet of ≤20g of fat per day and will continue the low-fat diet while on treatment with Redemplo®; and
6. Member or caregiver will be trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Redemplo®; and
7. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment, as indicated by a reduction in fasting triglyceride levels, decreased episodes of acute pancreatitis, and/or other documentation of a positive clinical response to therapy. Subsequent approvals will be for the duration of 1 year.

Tryngolza® (Olezarsen) Approval Criteria:

1. An FDA approved indication to reduce triglyceride levels in adults with familial chylomicronemia syndrome (FCS); and
2. Diagnosis of FCS must be confirmed by the following:
   a. Fasting triglyceride levels ≥880mg/dL; and
   b. One of the following:
      i. Genetic testing identifying biallelic pathogenic variants in the *LPL, GPIHBP1, APOA5, APOC2*, or *LMF1* genes (results of genetic testing must be submitted); or
      ii. Familial chylomicronemia score ≥10; or
      iii. North American familial chylomicronemia syndrome score ≥45; or
      iv. History of clinical signs and symptoms associated with FCS (i.e., pancreatitis and/or abdominal pain, eruptive xanthomas, lipemia retinalis, lipemic plasma) and a diagnosis of multifactorial chylomicronemia syndrome (MCS) has been ruled out; and
3. Member must be 18 years of age or older; and
4. Must be prescribed by, or in consultation with, a cardiologist, an endocrinologist, or a specialist with expertise in the treatment of disorders related to severe hypertriglyceridemia; and

5. Prescriber must verify the member is on a low-fat diet of ≤20g of fat per day and will continue the low-fat diet while on treatment with Tryngolza®; and
6. Member or caregiver ~~has been~~ will be trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tryngolza®; and
7. A patient specific, clinically significant reason why the member cannot use Redemplo® (plozasiran) must be provided; and
8. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment, as indicated by a reduction in fasting triglyceride levels, decreased episodes of acute pancreatitis, and/or other documentation of a positive clinical response to therapy. Subsequent approvals will be for the duration of 1 year.

Additionally, the College of Pharmacy recommends updating the approval criteria for Evkeeza® (evinacumab-dgnb), Leqvio® (inclisiran), Nexletol® (bempedoic acid), Nexlizet® (bempedoic acid/ezetimibe), Praluent® (alirocumab), and Repatha® (evolocumab) based on the new FDA approved label expansions and clinical practice (changes shown in red):

Evkeeza® (Evinacumab-dgnb) Approval Criteria:

1. An FDA approved diagnosis of homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:
    a. Documented functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
    b. An untreated LDL >500mg/dL and at least 1 of the following:
        i. Documented evidence of definite HeFH in both parents; or
        ii. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; and
2. Member must be ~~5~~ 1 year~~s~~ of age or older; and
3. Documented trial of high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy at least 12 weeks in duration; and
4. Members with statin intolerance must meet 1 of the following:
    a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or

d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and

5. Documented trial of a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®) at least 12 weeks in duration; and
6. Member requires additional lowering of LDL-cholesterol (LDL-C) (baseline, current, and goal LDL-C levels must be provided); and
7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy and for 5 months after discontinuation of therapy; and
8. Initial approvals will be for the duration of 6-months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Leqvio® (Inclisiran) Approval Criteria:

1. An FDA approved indication as an adjunct to diet and exercise ~~statin therapy~~ for the treatment of 1 of the following:
   a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
      i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
      ii. Both of the following:
         1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
         2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
      iii. Dutch Lipid Clinic Network Criteria score of >8; or
   b. Established atherosclerotic cardiovascular disease (ASCVD); and
      i. Supporting diagnoses/conditions and dates of occurrence signifying established ASCVD; or
   c. Primary hyperlipidemia; and
      i. Member's untreated LDL-C level must be ≥190mg/dL; and
      ii. Current LDL-C level is ≥100mg/dL; and
2. Member must be 18 years of age or older; and
3. Documented trial of all of the following for at least 12 weeks in duration each:
   a. High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy; and

b. Ezetimibe; and
c. Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®); and

4. Members with statin intolerance must meet 1 of the following:
   a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
   b. An FDA labeled contraindication to all statins; or
   c. Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
   d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C must be provided); and
6. Leqvio® must be administered by a health care professional. Approvals will not be granted for self-administration; and
   a. Prior authorization requests must indicate how Leqvio® will be administered (e.g., prescriber, pharmacist, home health care provider); and
      i. Leqvio® must be shipped to the facility where the member is scheduled to receive treatment; or
      ii. Prescriber must verify the member has been counseled on the proper storage of Leqvio®; and
7. Initial approvals will be for the duration of 6 months. Continued authorization at that time will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of this medication, and compliance will be checked at that time and every 6 months thereafter for continued approval.

Nexletol® (Bempedoic Acid) and Nexlizet® (Bempedoic Acid/Ezetimibe) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. As an adjunct to diet and exercise, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies or alone when concomitant LDL-C lowering therapies are not possible to reduce LDL-C in those with heterozygous familial hypercholesterolemia (HeFH). HeFH must be confirmed by 1 of the following:
      i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
      ii. Both of the following:

1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or

iii. Dutch Lipid Clinic Network Criteria score of >8; or

b. As an adjunct to diet and exercise, in combination with other LDL-C lowering therapies or alone when concomitant LDL-C lowering therapies are not possible to reduce LDL-C in those with primary hyperlipidemia; and
   i. Member's untreated LDL-C level must be ≥190mg/dL; and
   ii. Current LDL-C level is ≥100mg/dL; and
c. To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, and coronary revascularization) in ~~those~~ adults at increased risk for these events who are unable to take recommended statin therapy; and ~~with 1 of the following:~~
   ~~i. High risk for a cardiovascular disease (CVD) event without established atherosclerotic CVD (ASCVD); or~~
   ~~ii. Established ASCVD; and~~
   iii. Supporting diagnoses/conditions/risk factors ~~and dates of occurrences must be submitted~~ signifying increased risk of major adverse CV events must be submitted; and

2. Member must be 18 years of age or older; and
3. Member must be on a stable dose of maximally tolerated statin therapy for at least 4 weeks (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
   a. LDL-C levels should be included following at least 4 weeks of treatment; and
   b. Member must not be taking simvastatin at doses >20mg or pravastatin at doses >40mg due to drug interactions with Nexletol® and Nexlizet®; and
4. Members with statin intolerance must meet 1 of the following:
   a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
   b. An FDA labeled contraindication to all statins; or
   c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
   d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
6. A quantity limit of 30 tablets per 30 days will apply; and
7. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber

to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Praluent® (Alirocumab) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
        i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles know to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. Both of the following:
            1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
            2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
        iii. Dutch Lipid Clinic Network Criteria score of >8; or
    b. Homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:
        i. Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. An untreated LDL >500mg/dL and at least 1 of the following:
            1. Documented evidence of definite HeFH in both parents; or
            2. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; or
    c. ~~As an adjunct to maximally tolerated statin therapy~~ To reduce the risk of major adverse cardiovascular (CV) events (coronary heart disease death, myocardial infarction, stroke, and unstable angina requiring hospitalization) ~~coronary revascularization~~ in adults at increased risk for these events ~~with established cardiovascular disease (CVD)~~; and
        ~~i. Documentation of established CVD; and~~
        ii. Supporting diagnoses/conditions/risk factors ~~and date of occurrence~~ signifying ~~established CVD~~ increased risk of major adverse CV events must be submitted; or
    d. Primary hyperlipidemia; and
        i. Member's untreated LDL-C level must be ≥190mg/dL; and
        ii. Current LDL-C level is ≥100mg/dL; and
2. For HeFH, member must be 8 years of age or older; and

3. For FDA approved indications other than HeFH, the member must be 18 years of age or older; and
4. Member must be on high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or on maximally tolerated statin therapy; and
    a. Statin trials must be at least 12 weeks in duration (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
    b. LDL-C levels should be included following at least 12 weeks of treatment; and
5. Members with statin intolerance must meet 1 of the following:
    a. Creatinine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
6. Member must have a recent trial with a statin with ezetimibe, or a recent trial of ezetimibe without a statin for members with a documented statin intolerance, or a patient-specific, clinically significant reason why ezetimibe is not appropriate must be provided; and
7. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
8. Prescriber must verify that member ~~has been~~ will be counseled on appropriate use, storage of the medication, and administration technique; and
9. A quantity limit of 2 syringes or pens per 28 days will apply; and
10. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Repatha® (Evolocumab)] Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
        i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles know to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or

ii. Both of the following:
1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or

iii. Dutch Lipid Clinic Network Criteria score of >8; or

b. Homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:
i. Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
ii. An untreated LDL >500mg/dL and at least 1 of the following:
1. Documented evidence of definite HeFH in both parents; or
2. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; or

c. ~~As an adjunct to maximally tolerated statin therapy~~ To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or ~~and~~ coronary revascularization) in adults at increased risk for these events ~~with established cardiovascular disease (CVD)~~; and
i. ~~Documentation of established CVD; and~~
ii. Supporting diagnoses/conditions/risk factors ~~and date of occurrence~~ signifying ~~established CVD~~ increased risk of major adverse CV events must be submitted; or

d. Primary hyperlipidemia; and
i. Member's untreated LDL-C level must be ≥190mg/dL; and
ii. Current LDL-C level is ≥100mg/dL; and

2. For HeFH or HoFH, member must be 10 years of age or older; and
3. For FDA approved indications other than HeFH or HoFH, the member must be 18 years of age or older; and
4. Member must be on high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or on maximally tolerated statin therapy; and
a. Statin trials must be at least 12 weeks in duration (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
b. LDL-C levels should be included following at least 12 weeks of treatment; and
5. Members with statin intolerance must meet 1 of the following:
a. Creatinine kinase (CK) labs verifying rhabdomyolysis; or
b. An FDA labeled contraindication to all statins; or

c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and

6. Member must have a recent trial with a statin with ezetimibe, or a recent trial of ezetimibe without a statin for members with a documented statin intolerance, or a patient-specific, clinically significant reason why ezetimibe is not appropriate must be provided; and
7. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
8. Prescriber must verify that member ~~has been~~ will be counseled on appropriate use, storage of the medication, and administration technique; and
9. A quantity limit of 2 syringes or auto-injectors per 28 days will apply; and
10. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Utilization Details of Antihyperlipidemics: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
STATIN PRODUCTS AND EZETIMIBE						
TIER-1 UTILIZATION						
ATORVASTATIN TAB 40MG	34,013	12,392	$480,626.02	$14.13	2.74	15.99%
ATORVASTATIN TAB 20MG	25,741	9,784	$349,199.09	$13.57	2.63	11.62%
ATORVASTATIN TAB 10MG	15,633	5,523	$201,156.36	$12.87	2.83	6.69%
ATORVASTATIN TAB 80MG	11,707	4,121	$180,024.12	$15.38	2.84	5.99%
ROSUVASTATIN TAB 20MG	8,832	3,423	$136,894.88	$15.50	2.58	4.55%
ROSUVASTATIN TAB 10MG	8,214	3,265	$115,129.09	$14.02	2.52	3.83%
EZETIMIBE TAB 10MG	7,719	2,357	$115,653.76	$14.98	3.27	3.85%
ROSUVASTATIN TAB 40MG	5,147	1,950	$86,681.88	$16.84	2.64	2.88%
ROSUVASTATIN TAB 5MG	4,032	1,629	$62,482.34	$15.50	2.48	2.08%
SIMVASTATIN TAB 20MG	3,151	1,073	$38,252.17	$12.14	2.94	1.27%
PRAVASTATIN TAB 40MG	2,510	844	$40,709.36	$16.22	2.97	1.35%
SIMVASTATIN TAB 40MG	2,402	774	$32,540.54	$13.55	3.1	1.08%
PRAVASTATIN TAB 20MG	1,948	689	$29,607.10	$15.20	2.83	0.98%
SIMVASTATIN TAB 10MG	1,738	550	$21,782.23	$12.53	3.16	0.72%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PRAVASTATIN TAB 10MG	957	334	$13,587.31	$14.20	2.87	0.45%
LOVASTATIN TAB 20MG	924	337	$12,548.63	$13.58	2.74	0.42%
PRAVASTATIN TAB 80MG	571	207	$11,548.41	$20.22	2.76	0.38%
LOVASTATIN TAB 40MG	564	182	$7,682.82	$13.62	3.1	0.26%
SIMVASTATIN TAB 80MG	272	78	$3,969.50	$14.59	3.49	0.13%
LOVASTATIN TAB 10MG	196	97	$2,752.89	$14.05	2.02	0.09%
SIMVASTATIN TAB 5MG	153	48	$1,867.37	$12.21	3.19	0.06%
LIPITOR TAB 20MG	2	2	$3,271.60	$1,635.80	1	0.11%
LIPITOR TAB 10MG	2	1	$1,140.69	$570.35	2	0.04%
LIPITOR TAB 40MG	1	1	$1,613.95	$1,613.95	1	0.05%
SUBTOTAL	**136,429**	**49,661**	**$1,950,722.11**	**$14.30**	**2.75**	**64.90%**
SPECIAL PA UTILIZATION						
PITAVASTATIN TAB 2MG	27	6	$1,903.94	$70.52	4.5	0.06%
EZETIM/SIMVA TAB 10-40MG	12	5	$456.96	$38.08	2.4	0.02%
PITAVASTATIN TAB 4MG	12	4	$831.84	$69.32	3	0.03%
PITAVASTATIN TAB 1MG	11	1	$482.80	$43.89	11	0.02%
EZETIM/SIMVA TAB 10-20MG	7	2	$265.21	$37.89	3.5	0.01%
LESCOL XL TAB 80MG	5	1	$2,039.28	$407.86	5	0.07%
VYTORIN TAB 10-80MG	5	1	$4,718.05	$943.61	5	0.16%
LIVALO TAB 2MG	2	1	$635.98	$317.99	2	0.02%
LIVALO TAB 4MG	2	2	$635.87	$317.94	1	0.02%
FLUVASTATIN CAP 20MG	1	1	$121.92	$121.92	1	0.00%
EZETIM/SIMVA TAB 10-80MG	1	1	$46.52	$46.52	1	0.00%
SUBTOTAL	**85**	**25**	**$12,138.37**	**$142.80**	**3.4**	**0.40%**
STATINS AND EZETIMIBE TOTAL	**136,514**	**49,686**	**$1,962,860.48**	**$14.38**	**2.75**	**65.30%**
FIBRIC ACID DERIVATIVE PRODUCTS						
TIER-1 UTILIZATION						
FENOFIBRATE TAB 145MG	4,438	1,115	$68,789.63	$15.50	3.98	2.29%
FENOFIBRATE TAB 160MG	2,337	614	$38,725.75	$16.57	3.81	1.29%
GEMFIBROZIL TAB 600MG	1,370	385	$24,231.31	$17.69	3.56	0.81%
FENOFIBRATE TAB 48MG	1,219	337	$18,436.19	$15.12	3.62	0.61%
FENOFIBRATE TAB 54MG	889	247	$12,366.64	$13.91	3.6	0.41%
FENOFIBRATE CAP 134MG	685	205	$11,734.76	$17.13	3.34	0.39%
FENOFIBRATE CAP 67MG	176	44	$2,518.74	$14.31	4	0.08%
FENOFIBRIC CAP 45MG DR	162	25	$2,317.88	$14.31	6.48	0.08%
FENOFIBRATE CAP 200MG	93	24	$1,601.72	$17.22	3.88	0.05%
TRICOR TAB 48MG	6	1	$170.40	$28.40	6	0.01%
SUBTOTAL	**11,375**	**2,997**	**$180,893.02**	**$15.90**	**3.8**	**6.02%**
TIER-2 UTILIZATION						
FENOFIBRATE TAB 120MG	53	12	$38,693.58	$730.07	4.42	1.29%
FENOFIBRIC CAP 135MG DR	48	14	$1,415.76	$29.50	3.43	0.05%
FENOFIBRATE TAB 40MG	37	12	$9,495.70	$256.64	3.08	0.32%
FENOFIBRATE CAP 50MG	25	11	$2,478.17	$99.13	2.27	0.08%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FENOFIBRATE CAP 130MG	21	4	$662.16	$31.53	5.25	0.02%
FENOFIBRATE CAP 43MG	21	3	$608.22	$28.96	7	0.02%
FENOFIBRATE CAP 150MG	21	6	$5,301.04	$252.43	3.5	0.18%
SUBTOTAL	**226**	**62**	**$58,654.63**	**$259.53**	**3.65**	**1.95%**
FIBRIC ACID DERIVATIVE TOTAL	**11,601**	**3,059**	**$239,547.65**	**$20.65**	**3.79**	**7.97%**
OMEGA-3 FATTY ACID PRODUCTS						
OMEGA-3-ACID CAP 1GM	1,743	623	$69,846.99	$40.07	2.8	2.32%
ICOSAPENT CAP 1GM	290	85	$26,473.07	$91.29	3.41	0.88%
VASCEPA CAP 1GM	16	8	$4,417.71	$276.11	2	0.15%
LOVAZA CAP 1GM	2	2	$1,020.28	$510.14	1	0.03%
OMEGA-3 FATTY ACIDS TOTAL	**2,051**	**718**	**$101,758.05**	**$49.61**	**2.86**	**3.39%**
PCSK9 INHIBITORS						
REPATHA SURE INJ 140MG/ML	667	156	$376,034.96	$563.77	4.28	12.51%
REPATHA INJ 140MG/ML	141	29	$76,202.02	$540.44	4.86	2.54%
PRALUENT INJ 150MG/ML	62	10	$31,236.88	$503.82	6.2	1.04%
PRALUENT INJ 75MG/ML	55	11	$27,720.08	$504.00	5	0.92%
REPATHA PUSH INJ 420MG/3.5ML	1	1	$595.96	$595.96	1	0.02%
PCSK9 INHIBITORS TOTAL	**926**	**207**	**$511,789.90**	**$552.69**	**4.47**	**17.03%**
COLESEVELAM PRODUCTS						
COLESEVELAM TAB 625MG	432	122	$15,648.99	$36.22	3.54	0.52%
COLESEVELAM PAK 3.75GM	1	1	$105.65	$105.65	1	0.00%
COLESEVELAM PRODUCTS TOTAL	**433**	**123**	**$15,754.64**	**$36.38**	**3.52**	**0.52%**
BEMPEDOIC ACID AND EZETIMIBE PRODUCTS						
NEXLIZET TAB 180/10MG	32	8	$13,124.92	$410.15	4	0.44%
BEMPEDOIC ACID/EZETIMIBE TOTAL	**32**	**8**	**$13,124.92**	**$410.15**	**4**	**0.44%**
BEMPEDOIC ACID PRODUCTS						
NEXLETOL TAB 180MG	30	11	$12,280.41	$409.35	2.73	0.41%
BEMPEDOIC ACID TOTAL	**30**	**11**	**$12,280.41**	**$409.35**	**2.73**	**0.41%**
OLEZARSEN PRODUCTS						
TRYNGOLZA INJ 80MG/0.8ML	3	1	$148,786.23	$49,595.41	3	4.95%
OLEZARSEN TOTAL	**3**	**1**	**$148,786.23**	**$49,595.41**	**3**	**4.95%**
TOTAL	**151,590**	**46,165***	**$3,005,902.28**	**$19.83**	**3.28**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DR = delayed-release; EZETIM/SIMVA = ezetimibe/simvastatin; INJ = injection; PA = prior authorization; PAK = packet; PUSH = Pushtronex®; SURE = SureClick®; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
INCLISIRAN INJ (J1306)	5	5	$17,359.76	$3,471.95	1
TOTAL	**5**	**5**	**$17,359.76**	**$3,471.95**	**1**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
INJ = injection
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix F

Fiscal Year 2025 Annual Review of Antihypertensive Medications and 30-Day Notice to Prior Authorize Aceon® (Perindopril), Arbli™ (Losartan Oral Suspension), Bisoprolol Fumarate 2.5mg Tablet, Hemiclor™ (Chlorthalidone 12.5mg Tablet), Inzirqo™ (Hydrochlorothiazide Oral Suspension), Javadin™ (Clonidine Oral Solution), Lopressor® (Metoprolol Tartrate Oral Solution), and Univasc® (Moexipril)

Oklahoma Health Care Authority
January 2026

Current Prior Authorization Criteria

There are 6 major subcategories of antihypertensive medications divided by drug class currently included in the Antihypertensive Medications Product Based Prior Authorization (PBPA) category:

1. Angiotensin I Converting Enzyme Inhibitors (ACEIs)
2. ACEI/Hydrochlorothiazide (HCTZ) Combination Products
3. Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products
4. Calcium Channel Blockers (CCBs)
5. ACEI/CCB Combination Products
6. Direct Renin Inhibitors (DRIs) and DRI Combination Products

Angiotensin I Converting Enzyme Inhibitors (ACEIs)		
Tier-1	**Tier-2**	**Special PA**
benazepril (Lotensin®)	captopril (Capoten®)	enalapril oral solution (Epaned®)
enalapril (Vasotec®)		lisinopril oral solution (Qbrelis®)
enalaprilat (Vasotec® IV)		
fosinopril (Monopril®)		
lisinopril (Prinivil®, Zestril®)		
moexipril (Univasc®)		
perindopril (Aceon®)		
quinapril (Accupril®)		
ramipril (Altace®)		
trandolapril (Mavik®)		

ACEI/Hydrochlorothiazide (HCTZ) Combination Products		
Tier-1	**Tier-2**	**Special PA**
benazepril/HCTZ (Lotensin® HCT)	captopril/HCTZ (Capozide®)	fosinopril/HCTZ (Monopril® HCT)
enalapril/HCTZ (Vaseretic®)		
lisinopril/HCTZ (Prinzide®, Zestoretic®)		
moexipril/HCTZ (Uniretic®)		
quinapril/HCTZ (Accuretic®)		
Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products		
Tier-1	**Tier-2**	**Tier-3**
candesartan (Atacand®)	olmesartan/amlodipine/HCTZ (Tribenzor®)	azilsartan (Edarbi®)
irbesartan (Avapro®)	telmisartan/HCTZ (Micardis® HCT)	azilsartan/chlorthalidone (Edarbyclor®)
irbesartan/HCTZ (Avalide®)		candesartan/HCTZ (Atacand® HCT)
losartan (Cozaar®)		telmisartan/amlodipine (Twynsta®)
losartan/HCTZ (Hyzaar®)		valsartan 4mg/mL oral solution+
olmesartan (Benicar®)		
olmesartan/amlodipine (Azor®)		
olmesartan/HCTZ (Benicar HCT®)		
telmisartan (Micardis®)		
valsartan (Diovan®)		
valsartan/amlodipine (Exforge®)		
valsartan/amlodipine/HCTZ (Exforge® HCT)		
valsartan/HCTZ (Diovan HCT®)		
Calcium Channel Blockers (CCBs)		
Tier-1	**Tier-2**	**Special PA**
amlodipine (Norvasc®)	amlodipine/atorvastatin (Caduet®)	amlodipine oral solution (Norliqva®)
diltiazem (Cardizem®)	diltiazem LA (Cardizem® LA, Matzim® LA)	amlodipine oral suspension (Katerzia®)
diltiazem (Tiazac®, Taztia XT®)	diltiazem SR (Cardizem® SR)	diltiazem CD 360mg (Cardizem® CD)
diltiazem CD (Cardizem® CD)*	isradipine (Dynacirc®, Dynacirc CR®)	levamlodipine (Conjupri®)

diltiazem ER (Cartia XT®, Diltia XT®)	nicardipine (Cardene®)	
diltiazem XR (Dilacor® XR)	nicardipine (Cardene® SR)	
felodipine (Plendil®)	nisoldipine (Sular®)	
nifedipine (Adalat®, Procardia®)	verapamil (Covera-HS®)	
nifedipine ER (Adalat® CC)	verapamil ER (Verelan®, Verelan® PM)	
nifedipine XL (Nifedical XL®, Procardia XL®)		
nimodipine (Nimotop®)		
verapamil (Calan®, Isoptin®)		
verapamil SR (Calan® SR, Isoptin® SR)		
ACEI/CCB Combination Products		
Tier-1	**Tier-2**	**Special PA**
Tier-1 ACEI + Tier-1 CCB	trandolapril/verapamil (Tarka®)	
benazepril/amlodipine (Lotrel®)		

+Unique criteria apply.
*All strengths other than 360mg.
CD = controlled-delivery; ER, XR, XL = extended-release; LA = long-acting; SR = sustained-release

Antihypertensive Medications Tier-2 Approval Criteria:
(or Tier-3 approval criteria when no Tier-2 medications exist)

1. A documented inadequate response to 2 Tier-1 medications (trials must include medication(s) from all available classes where applicable); or
2. An adverse drug reaction to all Tier-1 classes of medications; or
3. Previous stabilization on the Tier-2 medication; or
4. A unique indication for which the Tier-1 antihypertensive medications lack.

Antihypertensive Medications Tier-3 Approval Criteria:

1. A documented inadequate response to 2 Tier-1 medications and documented inadequate response to all available Tier-2 medication(s); or
2. An adverse drug reaction to all Tier-1 and Tier-2 classes of medications; or
3. Previous stabilization on the Tier-3 medication; or
4. A unique indication which the lower tiered antihypertensive medications lack.

Antihypertensive Medications Special Prior Authorization (PA) Approval Criteria:

1. **Angiotensin I Converting Enzyme Inhibitors (ACEIs):**
    a. **Epaned® (Enalapril Solution) Approval Criteria:**
        i. An age restriction of 7 years or older will apply with the following criteria:
            1. A patient-specific, clinically significant reason why the member cannot use the oral tablet formulation in place of the oral solution formulation, even when the tablets are crushed or used to prepare an oral suspension, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and
            2. Clinical exceptions for the age restriction (younger than the FDA-approved age) may be considered; and
        ii. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.
    b. **Qbrelis® (Lisinopril Oral Solution) Approval Criteria:**
        i. A patient-specific, clinically significant reason why the member cannot use lisinopril oral tablets in place of the oral solution formulation, even when the tablets are crushed, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and
        ii. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.
2. **ACEI/Hydrochlorothiazide (HCTZ) Combination Products:**
    a. **Monopril-HCT® (Fosinopril/HCTZ) Approval Criteria:**
        i. A patient-specific, clinically significant reason why the member cannot use the individual components separately must be provided.
3. **Calcium Channel Blockers (CCBs):**
    a. **Cardizem® CD (Diltiazem CD 360mg Capsules) Approval Criteria:**
        i. A patient-specific, clinically significant reason why the member cannot use (2) 180mg Cardizem® CD (diltiazem CD) capsules must be provided.
    b. **Conjupri® (Levamlodipine Tablets) Approval Criteria:**
        i. A patient-specific, clinically significant reason why the member cannot use amlodipine oral tablets, which are available without prior authorization, must be provided.
    c. **Katerzia® (Amlodipine Oral Suspension) and Norliqva® (Amlodipine Oral Solution) Approval Criteria:**

i. An FDA approved diagnosis of 1 of the following:
    1. Hypertension in adults and pediatric members 6 years of age and older; or
    2. Coronary artery disease; or
    3. Chronic stable angina; or
    4. Vasospastic angina; and
ii. A patient specific, clinically significant reason why the member cannot use amlodipine oral tablets, even when the tablets are crushed, must be provided; and
iii. Clinical exceptions for age restrictions may be considered for doses stabilized inpatient or for clinically indicated doses that cannot be achieved by splitting available tablet formulations; and
iv. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
v. A quantity limit of 300mL per 30 days will apply.

CaroSpir® (Spironolactone Oral Suspension) Approval Criteria:

1. An FDA approved indication; and
2. A patient-specific, clinically significant reason why the member cannot use spironolactone oral tablets must be provided, including, but not limited to the following:
    a. Member is unable to swallow the oral tablet (i.e., has diagnosis characterized by difficulty or inability to swallow); or
    b. Clinically indicated dose cannot be achieved with available tablet formulations; or
    c. Dose was stabilized inpatient; and
3. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.

Hemangeol® (Propranolol Hydrochloride Oral Solution) Approval Criteria:

1. An FDA approved indication for the treatment of proliferating infantile hemangioma requiring systemic therapy; and
2. For the 50mL bottle of Hemangeol®, a patient-specific, clinically significant reason why the member cannot use the 120mL bottle, which is the preferred package size, must be provided.

Kapspargo Sprinkle® [Metoprolol Succinate Extended-Release (ER) Capsules] Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use metoprolol succinate ER tablets, which are available without prior authorization, must be provided.

Labetalol Hydrochloride 400mg Tablet Approval Criteria:

1. An FDA-approved indication of the management of hypertension; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use labetalol hydrochloride 200mg tablets, which are available without prior authorization, to achieve a 400mg dose must be provided.

Nexiclon™ XR [Clonidine Extended-Release (ER) Tablet] Approval Criteria:

1. An FDA approved diagnosis of hypertension; and
2. A patient-specific, clinically significant reason why the member cannot utilize clonidine immediate-release tablet and clonidine transdermal patch, which are available without a prior authorization, must be provided; and
3. Request must be for an FDA-approved once-daily dosing regimen, according to package labeling.

Nymalize® (Nimodipine Oral Solution) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use nimodipine liquid-filled capsules, which are available without prior authorization and can be opened for administration of the liquid contents via oral syringe for members unable to swallow the capsules whole, must be provided.

Sotylize® (Sotalol Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of life-threatening ventricular arrhythmias or for the maintenance of normal sinus rhythm in members with highly symptomatic atrial fibrillation/flutter; and
2. A patient-specific, clinically significant reason why the member cannot use sotalol oral tablets in place of the oral solution formulation must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and
3. For pediatric members, a recent weight or body surface area (BSA) must be provided on the prior authorization request; and
4. A quantity limit of 64mL per day or 1,920mL per 30 days will apply.

Tekturna® (Aliskiren Oral Pellets and Tablets) and Tekturna HCT® (Aliskiren/Hydrochlorothiazide) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 6 years of age or older; and
3. A recent trial, within the previous 6 months and at least 4 weeks in duration, of an angiotensin I converting enzyme inhibitor (ACEI) [or an angiotensin II receptor blocker (ARB) if previous trial of an ACEI] and a diuretic, used concomitantly at recommended doses, that did not yield adequate blood pressure control; and
4. May be used in either monotherapy or combination therapy; and

5. For Tekturna® oral pellets, a patient-specific, clinically significant reason why the member cannot use Tekturna® oral tablets must be provided.

Tryvio™ (Aprocitentan) Approval Criteria:

1. An FDA approved diagnosis of hypertension; and
2. Member has a reported systolic blood pressure of ≥140mmHg confirmed on at least 2 separate blood pressure readings on 2 separate occasions within the last month (documentation of blood pressure readings with dates must be submitted); and
3. Prescriber must rule out other causes of elevated blood pressure including:
    a. Inaccurate readings due to faulty or inappropriate equipment (i.e., cuff size) or improper technique; and
    b. White coat hypertension; and
    c. Prescription non-adherence. Compliance with antihypertensive medications will be evaluated prior to initiation of Tryvio™; and
4. Member must be currently on at least 3 antihypertensive medications at optimal (or maximally tolerated) doses for at least 4 weeks prior to systolic blood pressure reading of ≥140mmHg; and
5. Member must have tried at least 6 different classes of medications, including a diuretic, in the past 12 months that did not yield adequate blood pressure control. Medications can include, but are not limited to, angiotensin I converting enzyme inhibitors (ACEIs), angiotensin II receptor blockers (ARBs), calcium channel blockers (CCBs), direct renin inhibitors (DRIs), beta blockers, alpha blockers, alpha agonists, or diuretics; and
6. Female members of reproductive potential must not be pregnant or breastfeeding during treatment with aprocitentan and must be willing to use an effective method of contraception during treatment and for 1 month after discontinuing aprocitentan; and
7. Female members of reproductive potential must have a negative pregnancy test prior to initiation of aprocitentan and must agree to take pregnancy tests monthly during treatment and for 1 month after discontinuing aprocitentan; and
8. Member, pharmacy, and provider must be registered under the Tryvio™ Risk Evaluation and Mitigation Strategy (REMS) program; and
9. Member must not have elevated aminotransferases >3 times the upper limit of normal (ULN) or moderate to severe hepatic impairment (Child Pugh class B or C); and
10. Prescriber must attest that they will monitor liver transaminase levels during treatment and discontinue Tryvio™ if a sustained, unexplained, clinically relevant elevation occurs or if elevations occur with an increase in bilirubin that is >2 times the ULN; and

11. Member must not have severe anemia prior to initiation of aprocitentan; and
12. A quantity limit of 30 tablets per 30 days will apply; and
13. Initial approvals will be for the duration of 3 months. After 3 months, compliance with all antihypertensive medications, including aprocitentan, will be evaluated and the provider must provide documentation that the member has had a positive response to treatment, including a decrease in blood pressure. Inadequate compliance or a lack of positive response will result in denial of continuation. Subsequent approvals will be for 1 year.

Valsartan 4mg/mL Oral Solution Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Hypertension in adults and pediatric members 6 years of age and older; or
    b. Heart failure; or
    c. Post-myocardial infarction; and
2. A patient specific, clinically significant, reason why the member cannot use valsartan tablets or the oral suspension prepared from the tablets must be provided (i.e., dose was stabilized inpatient); and
3. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
4. A quantity limit of 360mL per 36 days will apply.

Vecamyl® (Mecamylamine) Approval Criteria:

1. An FDA approved diagnosis of moderately-severe-to-severe essential hypertension or uncomplicated malignant hypertension; and
2. Use of at least 6 classes of medications, in the past 12 months, that did not yield adequate blood pressure control. Treatment must have included combination therapy with a diuretic and therapy with at least a 4-drug regimen. Medications can be from, but not limited to, the following classes: angiotensin I converting enzyme inhibitors (ACEIs), angiotensin II receptor blockers (ARBs), calcium channel blockers (CCBs), direct renin inhibitors (DRIs), beta blockers, alpha blockers, alpha agonists, or diuretics; and
3. Prescriber must verify member does not have any of the following contraindications:
    a. Coronary insufficiency; or
    b. Recent myocardial infarction; or
    c. Rising or elevated blood urea nitrogen (BUN), or known renal insufficiency; or
    d. Uremia; or
    e. Glaucoma; or
    f. Organic pyloric stenosis; or

g. Currently receiving sulfonamides or antibiotics; or
h. Known sensitivity to Vecamyl® (mecamylamine).

Utilization of Antihypertensive Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

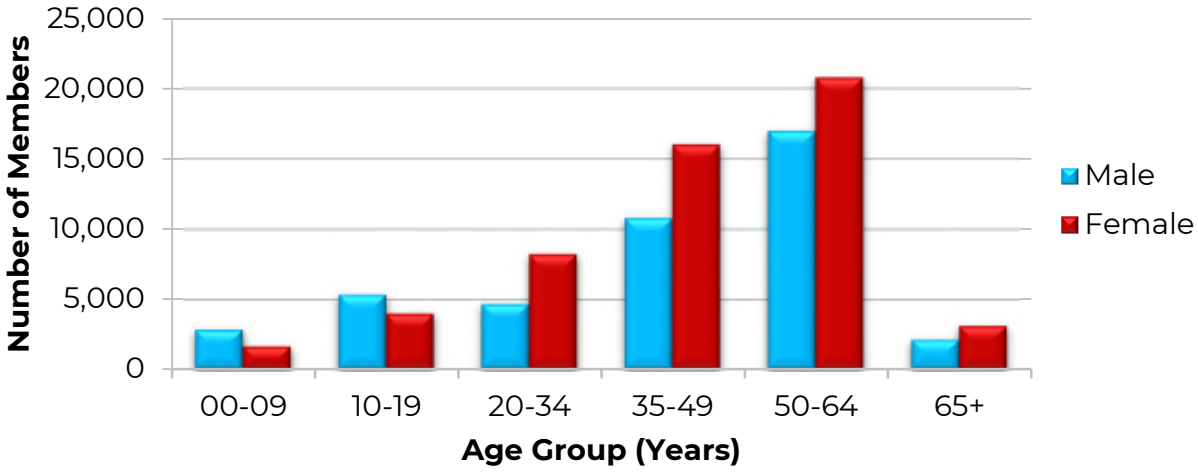
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	96,763	389,936	$5,469,655.92	$14.03	$0.25	26,521,124	22,215,107
Aetna	10,406	18,439	$267,473.59	$14.51	$0.25	1,213,821	1,052,584
Humana	12,586	23,129	$340,105.16	$14.70	$0.25	1,579,728	1,374,026
OCH	11,273	19,448	$290,158.34	$14.92	$0.26	1,291,300	1,103,493
2024 Total	**102,660**	**450,952**	**$6,367,393.01**	**$14.12**	**$0.25**	**30,605,973**	**25,745,210**
Fiscal Year 2025							
FFS	46,483	187,593	$2,851,399.26	$15.20	$0.28	12,170,476	10,105,934
Aetna	19,211	74,182	$1,144,492.86	$15.43	$0.25	5,152,447	4,492,436
Humana	22,730	97,712	$1,464,412.64	$14.99	$0.25	6,652,055	5,800,302
OCH	21,227	81,953	$1,270,057.65	$15.50	$0.25	5,810,591	5,030,956
2025 Total	**96,163**	**441,440**	**$6,730,362.41**	**$15.25**	**$0.26**	**29,785,570**	**25,429,628**
% Change	**-6.30%**	**-2.10%**	**5.70%**	**8.00%**	**4.00%**	**-2.70%**	**-1.20%**
Change	**-6,497**	**-9,512**	**$362,969.40**	**$1.13**	**$0.01**	**-820,403**	**-315,582**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

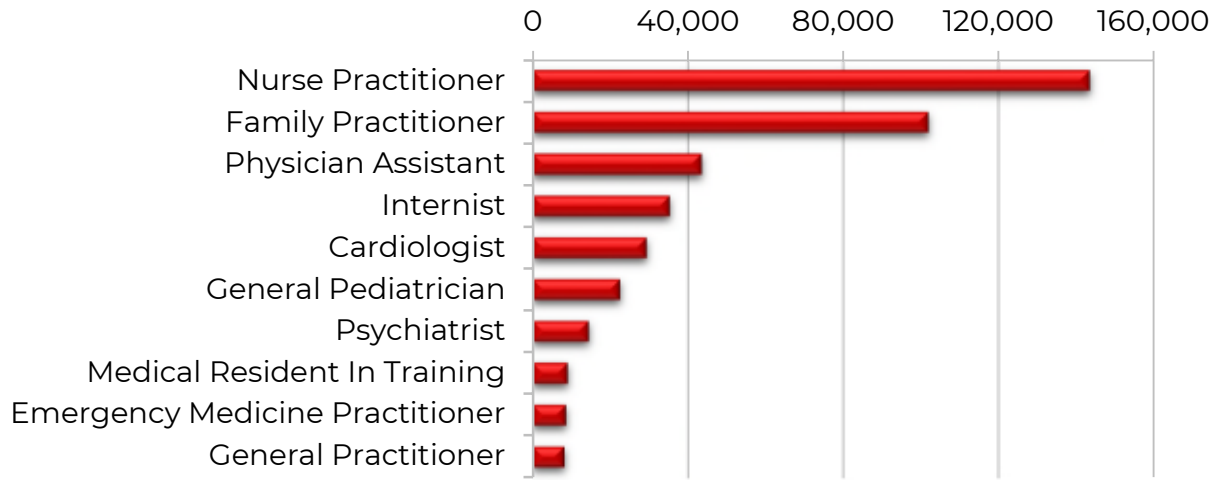
- Aggregate drug rebates collected during fiscal year 2025 for antihypertensive medications totaled $396,889.20.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Demographics of Members Utilizing Antihypertensive Medications (All Plans)



Top Prescriber Specialties of Antihypertensive Medications by Number of Claims (All Plans)



Prior Authorization of Antihypertensive Medications

There were 1,608 prior authorization requests submitted for antihypertensive medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	515	62%	267	32%	54	6%	**836**
Aetna	37	10%	149	39%	198	52%	**384**
Humana	8	62%	0	0%	5	38%	**13**
OCH	270	72%	84	22%	21	6%	**375**
Total	**830**	**52%**	**500**	**31%**	**278**	**17%**	**1,608**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11]

Anticipated Patent Expiration(s):

- Tekturna® (aliskiren tablet): August 2026
- Edarbi® (azilsartan tablet): March 2028
- Hemangeol® (propranolol hydrochloride oral solution): October 2028
- Edarbyclor® (azilsartan/chlorthalidone tablet): July 2031
- Kapspargo Sprinkle® [metoprolol succinate extended-release (ER) capsule]: July 2035
- Nexiclon™ XR [clonidine ER tablet]: September 2031
- Sotylize® (sotalol oral solution): August 2035
- Qbrelis® (lisinopril oral solution): November 2035
- Epaned® (enalapril oral solution): March 2036
- CaroSpir® (spironolactone oral suspension): October 2036
- Nymalize® (nimodipine oral solution): April 2038
- Tryvio™ (aprocitentan tablet): July 2038
- Katerzia® (amlodipine oral suspension): April 2039
- Norliqva® (amlodipine oral solution): February 2041
- Arbli™ (losartan oral suspension): October 2041
- Javadin™ (clonidine oral solution): July 2042
- Inzirqo™ (hydrochlorothiazide oral suspension): January 2044

New U.S. Food and Drug Administration (FDA) Approval(s):

- **January 2025:** The FDA approved Inzirqo™ (HCTZ oral suspension) for the treatment of hypertension (HTN) in adult and pediatric patients as monotherapy or in combination with other antihypertensive agents, to lower blood pressure and for the treatment of edema associated with congestive heart failure, hepatic cirrhosis, and renal disease including nephrotic syndrome. Inzirqo™ is supplied as a powder for oral suspension that is reconstituted to a concentration of 10mg/mL prior to dispensing.
- **March 2025:** The FDA approved Arbli™ (losartan oral suspension), a 10mg/mL oral suspension formulation of the angiotensin II receptor blocker (ARB) losartan. Arbli™ was approved for the treatment of HTN, to lower blood pressure in adult and pediatric patients 6 years of age and older; for the reduction of the risk of stroke in patients with HTN and left ventricular hypertrophy; and for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes mellitus and a history of HTN.
- **March 2025:** The FDA approved bisoprolol in a new 2.5mg tablet formulation through an Abbreviated New Drug Application (ANDA). Bisoprolol 2.5mg tablet joins the 5mg and 10mg tablets on the market.
- **March 2025:** The FDA approved Hemiclor™ (chlorthalidone 12.5mg tablet) for the treatment of HTN in adults, to lower blood pressure. Chlorthalidone was previously only available as generic chlorthalidone 25mg and 50mg tablets or branded Thalitone® 15mg or 25mg tablets.
- **March 2025:** The FDA determined that the Tryvio™ Risk Evaluation and Mitigation Strategy (REMS) is not necessary to ensure the benefits of use outweighs the risk of embryo-fetal toxicity. The Tryvio™ package labeling was updated to remove text regarding the REMS and requirements for monthly pregnancy test monitoring during therapy.
- **April 2025:** The FDA approved Lopressor® (metoprolol tartrate oral solution), a 10mg/mL solution, for the treatment of HTN, to lower blood pressure; for the long-term treatment of angina pectoris; and for the treatment of hemodynamically stable patients with definite or suspected myocardial infarction, to reduce the risk of cardiovascular mortality when used in conjunction with intravenous metoprolol therapy.
- **October 2025:** The FDA approved Javadin™ (clonidine oral solution) for the treatment of HTN in adults to lower blood pressure. Javadin™ is supplied as a ready-to-use solution with a concentration of 0.02mg/mL.

Guideline Update(s):

- **American Heart Association (AHA)/American College of Cardiology (ACC):** The 2025 AHA/ACC Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults replaces

the 2017 version of the guidelines; selected key updates for the 2025 version include:

- Reaffirming the 2017 overarching blood pressure treatment goal of <130/80mmHg for the general adult population based on the continued collection of supporting evidence; and
- Reemphasizing the importance of lifestyle interventions in the management of HTN and including a recommendation for the use of potassium-based salt substitutes to prevent or treat elevated blood pressure; and
- Lowering the pharmacological treatment threshold to include adults with HTN without clinical cardiovascular disease (CVD) but with diabetes or chronic kidney diseases (CKD) or those at an increased 10-year CVD risk of ≥7.5% based on PREVENT and an average of ≥130mmHg systolic blood pressure (SBP) or ≥80mmHg diastolic blood pressure (DBP); and
- Strengthening the recommendation regarding the utilization of angiotensin converting enzyme inhibitors (ACEIs) or ARBs in adults with diabetes, HTN, and CKD or albuminuria and including that these therapies may be considered for mild albuminuria to delay progression of diabetic kidney disease; and
- Simplifying the recommendation to treat adults with HTN and CKD with albuminuria with either an ACEI or ARB to decrease CVD and delay the progression of kidney disease.

Pipeline:

- **Baxdrostat:** AstraZeneca submitted a New Drug Application (NDA) for baxdrostat that has been accepted by the FDA for Priority Review for the treatment of adult patients with hard-to-control (e.g., uncontrolled or treatment resistant) HTN as an add-on to other antihypertensive medications. Baxdrostat was studied in the Phase 3 BaxHTN trial where, when combined with standard of care regimens, it met the primary and secondary endpoints, including a statistically significant reduction in mean seated SBP from baseline. The Prescription Drug User Fee Act (PDUFA) date is anticipated to be in the second quarter of 2026.

Cost Comparison: Losartan Products

Product	Cost Per Unit	Cost Per 30 Days*
Arbli™ (losartan) 10mg/mL solution	**$3.61**	**$541.50**
losartan 50mg tablet (generic)	$0.03	$0.90

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per 30 days based on a dose of 50mg once daily, the usual adult dose and maximum pediatric dose for the treatment of HTN per FDA package labeling

Cost Comparison: Bisoprolol Products

Product	Cost Per Tablet	Cost Per 30 Days*
bisoprolol fumarate 2.5mg tablet (generic)	**$2.58**	**$77.40**
bisoprolol fumarate 5mg tablet (generic)	$0.18	$2.70

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per day based on 2.5mg once daily for the treatment of HTN per FDA package labeling

Cost Comparison: Chlorthalidone Products

Product	Cost Per Tablet	Cost Per 30 Days*
Hemiclor™ (chlorthalidone) 12.5mg tablet	**$0.95**	**$28.50**
chlorthalidone 25mg tablet (generic)	$0.08	$1.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per day based on a starting dose of 12.5mg once daily for the treatment of HTN per FDA package labeling

Cost Comparison: Hydrochlorothiazide Products

Product	Cost Per Unit	Cost Per 30 Days*
Inzirqo™ (hydrochlorothiazide) 10mg/mL suspension	**$4.69**	**$351.75**
hydrochlorothiazide 25mg tablet (generic)	$0.01	$0.30

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per day based on a starting dose of 25mg once daily for the treatment of HTN per FDA package labeling

Cost Comparison: Clonidine Products

Product	Cost Per Unit	Cost Per 30 Days*
Javadin™ (clonidine) 0.02mg/mL solution	**$1.60**	**$480.00**
clonidine 0.1mg tablet (generic)	$0.03	$1.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per day based on a recommended starting dose of 0.1mg twice daily for the treatment of HTN per FDA package labeling

Cost Comparison: Metoprolol Products

Product	Cost Per Unit	Cost Per 30 Days*
Lopressor® (metoprolol tartrate) 10mg/mL solution	**$1.25**	**$375.00**
metoprolol tartrate 50mg tablet (generic)	$0.02	$1.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per day based on the recommended starting dose of 50mg twice daily for the treatment of HTN per FDA package labeling

Recommendations

The College of Pharmacy recommends the following changes within the Antihypertensive Medication Product Based Prior Authorization (PBPA) category (changes noted in red in the following tier chart and in the following additional criteria):

1. Renaming Tier-3 of the ARBs and ARB Combination Products as a Special PA Tier and removing the associated antihypertensive medications Tier-3 Approval Criteria; and
2. Moving Aceon® (perindopril) and Univasc® (moexipril) from Tier-1 to Tier-2 based on net costs; and
3. Moving Monopril® HCT (fosinopril/HCTZ) from the Specia PA Tier to Tier-2 and removing the additional approval criteria based on net costs; and
4. Moving Edarbi® (azilsartan) and Edarbyclor® (azilsartan/chlorthalidone) from Tier-3 (now the Special PA Tier) to Tier-1 based on net costs; and
5. Moving Exforge® HCT (valsartan/amlodipine/HCTZ) from Tier-1 to Tier-2 based on net costs; and
6. Moving Atacand® HCT (candesartan/HCTZ) and Twynsta® (telmisartan/amlodipine) from Tier-3 (now the Special PA Tier) to Tier-2 based on clinical practice and net costs; and
7. Moving Micardis® HCT (telmisartan/HCTZ) from Tier-2 to Tier-1 based on net costs; and
8. The prior authorization of Arbli™ (losartan oral suspension) with placement into the Special PA Tier and with additional criteria; and
9. Moving Cardizem® CD (diltiazem CD 360mg) from the Special PA Tier to Tier-1 with the other strengths and removing the additional approval criteria based on net costs; and
10. Updating the Norliqva® (amlodipine oral solution), Katerzia® (amlodipine oral suspension), Epaned® (enalapril oral solution), Qbrelis® (lisinopril oral solution), and valsartan 4mg/mL oral solution approval criteria based on clinical practice, for clarity, and for consistency with other criteria within the Antihypertensive Medications PBPA category.

Angiotensin I Converting Enzyme Inhibitors (ACEIs)		
Tier-1	**Tier-2**	**Special PA**
benazepril (Lotensin®)	captopril (Capoten®)	enalapril oral solution (Epaned®)
enalapril (Vasotec®)	**moexipril (Univasc®)**	lisinopril oral solution (Qbrelis®)
enalaprilat (Vasotec® IV)	**perindopril (Aceon®)**	
fosinopril (Monopril®)		
lisinopril (Prinivil®, Zestril®)		
~~**moexipril (Univasc®)**~~		
~~**perindopril (Aceon®)**~~		
quinapril (Accupril®)		
ramipril (Altace®)		
trandolapril (Mavik®)		
ACEI/Hydrochlorothiazide (HCTZ) Combination Products		
Tier-1	**Tier-2**	**Special PA**
benazepril/HCTZ (Lotensin® HCT)	captopril/HCTZ (Capozide®)	~~**fosinopril/HCTZ (Monopril® HCT)**~~
enalapril/HCTZ (Vaseretic®)	**fosinopril/HCTZ (Monopril® HCT)**	
lisinopril/HCTZ (Prinzide®, Zestoretic®)		
moexipril/HCTZ (Uniretic®)		
quinapril/HCTZ (Accuretic®)		
Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products		
Tier-1	**Tier-2**	~~**Tier-3**~~ **Special PA**
azilsartan (Edarbi®)	**candesartan/HCTZ (Atacand® HCT)**	~~**azilsartan (Edarbi®)**~~
azilsartan/chlorthalidone (Edarbyclor®)	olmesartan/amlodipine/HCTZ (Tribenzor®)	~~**azilsartan/chlorthalidone (Edarbyclor®)**~~
candesartan (Atacand®)	~~**telmisartan/HCTZ (Micardis® HCT)**~~	~~**candesartan/HCTZ (Atacand® HCT)**~~
irbesartan (Avapro®)	**telmisartan/amlodipine (Twynsta®)**	**losartan oral suspension (Arbli™)**
irbesartan/HCTZ (Avalide®)	**valsartan/amlodipine/HCTZ (Exforge® HCT)**	~~**telmisartan/amlodipine (Twynsta®)**~~
losartan (Cozaar®)		valsartan 4mg/mL oral solution+
losartan/HCTZ (Hyzaar®)		
olmesartan (Benicar®)		
olmesartan/amlodipine (Azor®)		
olmesartan/HCTZ (Benicar HCT®)		

telmisartan (Micardis®)		
telmisartan/HCTZ (Micardis® HCT)		
valsartan (Diovan®)		
valsartan/amlodipine (Exforge®)		
~~**valsartan/amlodipine/HCTZ (Exforge® HCT)**~~		
valsartan/HCTZ (Diovan HCT®)		
Calcium Channel Blockers (CCBs)		
Tier-1	**Tier-2**	**Special PA**
amlodipine (Norvasc®)	amlodipine/atorvastatin (Caduet®)	amlodipine oral solution (Norliqva®)
diltiazem (Cardizem®)	diltiazem LA (Cardizem® LA, Matzim® LA)	amlodipine oral suspension (Katerzia®)
diltiazem (Tiazac®, Taztia XT®)	diltiazem SR (Cardizem® SR)	~~**diltiazem CD 360mg (Cardizem® CD)**~~
diltiazem CD (Cardizem® CD)~~*~~	isradipine (Dynacirc®, Dynacirc CR®)	levamlodipine (Conjupri®)
diltiazem ER (Cartia XT®, Diltia XT®)	nicardipine (Cardene®)	
diltiazem XR (Dilacor® XR)	nicardipine (Cardene® SR)	
felodipine (Plendil®)	nisoldipine (Sular®)	
nifedipine (Adalat®, Procardia®)	verapamil (Covera-HS®)	
nifedipine ER (Adalat® CC)	verapamil ER (Verelan®, Verelan® PM)	
nifedipine XL (Nifedical XL®, Procardia XL®)		
nimodipine (Nimotop®)		
verapamil (Calan®, Isoptin®)		
verapamil SR (Calan® SR, Isoptin® SR)		
ACEI/CCB Combination Products		
Tier-1	**Tier-2**	**Special PA**
Tier-1 ACEI + Tier-1 CCB	trandolapril/verapamil (Tarka®)	
benazepril/amlodipine (Lotrel®)		

~~*Unique criteria apply.~~
~~*All strengths other than 360mg.~~
CD = controlled-delivery; ER, XR, XL = extended-release; LA = long-acting; SR = sustained-release

~~**Antihypertensive Medications Tier-3 Approval Criteria:**~~

~~1. A documented inadequate response to 2 Tier-1 medications and documented inadequate response to all available Tier-2 medication(s); or~~
~~2. An adverse drug reaction to all Tier-1 and Tier-2 classes of medications; or~~
~~3. Previous stabilization on the Tier-3 medication; or~~
~~4. A unique indication which the lower tiered antihypertensive medications lack.~~

Antihypertensive Medications Special Prior Authorization (PA) Approval Criteria:

1. **Angiotensin I Converting Enzyme Inhibitors (ACEIs):**
   - ~~**a. Epaned® (Enalapril Solution) Approval Criteria:**~~
     - ~~i. An age restriction of 7 years or older will apply with the following criteria:~~
       - ~~1. A patient-specific, clinically significant reason why the member cannot use the oral tablet formulation in place of the oral solution formulation, even when the tablets are crushed or used to prepare an oral suspension, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and~~
       - ~~2. Clinical exceptions for the age restriction (younger than the FDA-approved age) may be considered; and~~
     - ~~ii. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.~~
   - **b. Epaned® (Enalapril Solution) and Qbrelis® (Lisinopril Oral Solution) Approval Criteria:**
     - i. A patient-specific, clinically significant reason why the member cannot use the ~~lisinopril~~ oral tablets in place of the oral solution formulation, even when the tablets are crushed, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and
     - ii. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
     - iii. A quantity limit of 300mL per 60 days will apply. For members who require doses exceeding this quantity limit, a quantity limit override may be approved with the submission of supporting clinical documentation.

2. **Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products:**
    a. **Arbli™ (Losartan Oral Suspension) Approval Criteria:**
        i. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the oral tablet formulation in place of the oral suspension, even when the tablets are split or crushed, must be provided (e.g., dose stabilized inpatient, clinically indicated dose cannot be achieved with available tablet formulations); and
        ii. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.
        iii. A quantity limit of 330mL per 33 days will apply.
    b. **Valsartan ~~4mg/mL~~ Oral Solution Approval Criteria:**
        ~~i. An FDA approved diagnosis of 1 of the following:~~
            ~~1. Hypertension in adults and pediatric members 6 years of age and older; or~~
            ~~2. Heart failure; or~~
            ~~3. Post-myocardial infarction; and~~
        ii. A patient specific, clinically significant, reason why the member cannot use valsartan tablets or the oral suspension prepared from the tablets must be provided (i.e., dose was stabilized inpatient); and
        iii. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
        iv. A quantity limit of 360mL per 36 days will apply.

~~**3. ACEI/Hydrochlorothiazide (HCTZ) Combination Products:**~~
    ~~**a. Monopril-HCT® (Fosinopril/HCTZ) Approval Criteria:**~~
        ~~i. A patient-specific, clinically significant reason why the member cannot use the individual components separately must be provided.~~

4. **Calcium Channel Blockers (CCBs):**
    ~~**a. Cardizem® CD (Diltiazem CD 360mg Capsules) Approval Criteria:**~~
        ~~i. A patient-specific, clinically significant reason why the member cannot use (2) 180mg Cardizem® CD (diltiazem CD) capsules must be provided.~~
    b. **Conjupri® (Levamlodipine Tablets) Approval Criteria:**
        i. A patient-specific, clinically significant reason why the member cannot use amlodipine oral tablets, which are available without prior authorization, must be provided.
    c. **Katerzia® (Amlodipine Oral Suspension) and Norliqva® (Amlodipine Oral Solution) Approval Criteria:**
        ~~i. An FDA approved diagnosis of 1 of the following:~~

~~1. Hypertension in adults and pediatric members 6 years of age and older; or~~
~~2. Coronary artery disease; or~~
~~3. Chronic stable angina; or~~
~~4. Vasospastic angina; and~~

ii. A patient specific, clinically significant reason why the member cannot use amlodipine oral tablets, even when the tablets are split or crushed, must be provided (i.e., dose was stabilized inpatient or dose cannot be achieved with available tablet formulations); and

~~iii. Clinical exceptions for age restrictions may be considered for doses stabilized inpatient or for clinically indicated doses that cannot be achieved by splitting available tablet formulations; and~~

iv. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

v. A quantity limit of 300mL per 30 days will apply.

Next, the College of Pharmacy recommends the prior authorization of bisoprolol fumarate 2.5mg tablet, Hemiclor™ (chlorthalidone 12.5mg tablet), Inzirqo™ (hydrochlorothiazide oral suspension), and Lopressor® (metoprolol tartrate oral solution) with the following criteria (shown in red):

Bisoprolol Fumarate 2.5mg Tablet Approval Criteria:

1. A patient-specific, clinically specific reason (beyond convenience) why the member cannot split the 5mg tablet, which is available without prior authorization, to achieve the 2.5mg dose must be provided; and
2. A quantity limit of 30 tablets per 30 days will apply.

Hemiclor™ (Chlorthalidone 12.5mg Tablet) Approval Criteria:

1. A patient-specific, clinically specific reason (beyond convenience) why the member cannot split a generic chlorthalidone 25mg tablet, which is available without prior authorization, to achieve a 12.5mg dose must be provided; and
2. A quantity limit of 240 tablets per 30 days will apply.

Inzirqo™ (Hydrochlorothiazide Oral Suspension) Approval Criteria:

1. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the oral tablet formulation available without prior authorization, even when the tablets are crushed or split, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved with available tablet formulations); and
2. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

3. A quantity limit of 240mL per 30 days will apply. For members who require doses that exceed this quantity limit, a quantity limit override may be approved with the submission of supporting clinical documentation.

Lopressor® (Metoprolol Tartrate Oral Solution) Approval Criteria:

1. A patient-specific, clinically specific reason (beyond convenience) why the member cannot use oral tablet formulation available without prior authorization, even when the tablets are crushed or split, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved with available tablet formulations); and
2. A quantity limit of 1,200mL per 30 days will apply. For members who require doses that exceed this quantity limit, a quantity limit override may be approved with the submission of supporting clinical documentation.

The College of Pharmacy also recommends the prior authorization of Javadin™ (clonidine oral solution) with criteria similar to Nexiclon™ XR (clonidine ER tablet) (changes shown in red):

Nexiclon™ XR [Clonidine Extended-release (ER) Tablet] and Javadin™ (Clonidine Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of hypertension; and
2. A patient-specific, clinically significant reason why the member cannot utilize clonidine immediate-release tablet and clonidine transdermal patch, which are available without a prior authorization, must be provided; and
3. For Nexiclon™ XR, the ~~R~~request must be for an FDA-approved once-daily dosing regimen, according to package labeling~~.~~; and
4. For Javadin™, the following will apply:
    a. Member must be 18 years of age or older; and
    b. A quantity limit of 1,000mL per 30 days will apply. For members who require doses greater than this quantity limit, a quantity limit override may be approved with the submission of supporting clinical documentation.

Lastly, the College of Pharmacy recommends updating the Tryvio™ (aprocitentan) approval criteria based on changes to the FDA package labeling and the discontinuation of the REMS program (changes shown in red):

Tryvio™ (Aprocitentan) Approval Criteria:

1. An FDA approved diagnosis of hypertension; and
2. Member has a reported systolic blood pressure of ≥140mmHg confirmed on at least 2 separate blood pressure readings on 2 separate

occasions within the last month (documentation of blood pressure readings with dates must be submitted); and

3. Prescriber must rule out other causes of elevated blood pressure including:
   a. Inaccurate readings due to faulty or inappropriate equipment (i.e., cuff size) or improper technique; and
   b. White coat hypertension; and
   c. Prescription non-adherence. Compliance with antihypertensive medications will be evaluated prior to initiation of Tryvio™; and
4. Member must be currently on at least 3 antihypertensive medications at optimal (or maximally tolerated) doses for at least 4 weeks prior to systolic blood pressure reading of ≥140mmHg; and
5. Member must have tried at least 6 different classes of medications, including a diuretic, in the past 12 months that did not yield adequate blood pressure control. Medications can include, but are not limited to, angiotensin I converting enzyme inhibitors (ACEIs), angiotensin II receptor blockers (ARBs), calcium channel blockers (CCBs), direct renin inhibitors (DRIs), beta blockers, alpha blockers, alpha agonists, or diuretics; and
6. Female members of reproductive potential must not be pregnant or breastfeeding during treatment with Tryvio™ and must be willing to use an effective method of contraception during treatment and for 1 month after discontinuing Tryvio™; and
7. Female members of reproductive potential must have a negative pregnancy test prior to initiation of Tryvio™ and ~~must agree to take pregnancy tests monthly during treatment and for 1 month after discontinuing Tryvio™~~ if pregnancy occurs during therapy, Tryvio™ must be discontinued immediately; and
8. ~~Member, pharmacy, and provider must be registered under the Tryvio™ Risk Evaluation and Mitigation Strategy (REMS) program; and~~
9. Member must not have elevated aminotransferases >3 times the upper limit of normal (ULN) or moderate to severe hepatic impairment (Child Pugh class B or C); and
10. Prescriber must attest that they will monitor liver transaminase levels during treatment and discontinue Tryvio™ if a sustained, unexplained, clinically relevant elevation occurs or if elevations occur with an increase in bilirubin that is >2 times the ULN; and
11. Member must not have severe anemia prior to initiation of aprocitentan; and
12. A quantity limit of 30 tablets per 30 days will apply; and
13. Initial approvals will be for the duration of 3 months. After 3 months, compliance with all antihypertensive medications, including aprocitentan, will be evaluated and the provider must provide documentation that the member has had a positive response to

treatment, including a decrease in blood pressure. Inadequate compliance or a lack of positive response will result in denial of continuation. Subsequent approvals will be for 1 year.

Utilization Details of Antihypertensive Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CLONIDINE PRODUCTS						
NO PA REQUIRED						
CLONIDINE TAB 0.1MG	53,898	13,991	$584,873.78	$10.85	3.85	8.69%
CLONIDINE TAB 0.2MG	23,225	4,529	$263,746.33	$11.36	5.13	3.92%
CLONIDINE TAB 0.3MG	7,305	1,285	$84,216.71	$11.53	5.68	1.25%
CLONIDINE PATCH 0.1MG/24HR	523	172	$19,544.87	$37.37	3.04	0.29%
CLONIDINE PATCH 0.2MG/24HR	492	155	$27,709.18	$56.32	3.17	0.41%
CLONIDINE PATCH 0.3MG/24HR	456	110	$32,734.61	$71.79	4.15	0.49%
CLONIDINE POW	4	4	$56.48	$14.12	1	0.00%
NO PA SUBTOTAL	**85,903**	**20,246**	**$1,012,881.96**	**$11.79**	**4.24**	**15.05%**
SPECIAL PA UTILIZATION						
CLONIDINE ER TAB 0.17MG	3	2	$1,196.73	$398.91	1.5	0.02%
SPECIAL PA SUBTOTAL	**3**	**2**	**$1,196.73**	**$398.91**	**1.5**	**0.02%**
CLONIDINE TOTAL	**85,906**	**20,248**	**$1,014,078.69**	**$11.80**	**4.24**	**15.07%**
ANGIOTENSIN I CONVERTING ENZYME INHIBITORS (ACEIs)						
TIER-1 UTILIZATION						
LISINOPRIL TAB 20MG	22,853	8,851	$275,916.69	$12.07	2.58	4.10%
LISINOPRIL TAB 10MG	22,851	9,118	$257,450.79	$11.27	2.51	3.83%
LISINOPRIL TAB 40MG	13,487	4,824	$193,699.34	$14.36	2.8	2.88%
LISINOPRIL TAB 5MG	9,728	3,783	$106,479.19	$10.95	2.57	1.58%
LISINOPRIL TAB 2.5MG	4,350	1,661	$46,777.15	$10.75	2.62	0.70%
LISINOPRIL TAB 30MG	2,035	736	$25,674.74	$12.62	2.76	0.38%
ENALAPRIL TAB 20MG	650	213	$13,225.26	$20.35	3.05	0.20%
ENALAPRIL TAB 5MG	569	143	$8,648.03	$15.20	3.98	0.13%
ENALAPRIL TAB 10MG	548	159	$8,834.91	$16.12	3.45	0.13%
ENALAPRIL TAB 2.5MG	507	120	$7,897.64	$15.58	4.23	0.12%
BENAZEPRIL TAB 40MG	284	88	$3,836.93	$13.51	3.23	0.06%
BENAZEPRIL TAB 20MG	262	99	$3,926.73	$14.99	2.65	0.06%
RAMIPRIL CAP 10MG	245	91	$3,566.60	$14.56	2.69	0.05%
BENAZEPRIL TAB 10MG	169	58	$2,513.43	$14.87	2.91	0.04%
RAMIPRIL CAP 5MG	85	40	$1,033.09	$12.15	2.13	0.02%
RAMIPRIL CAP 2.5MG	61	23	$777.47	$12.75	2.65	0.01%
BENAZEPRIL TAB 5MG	30	14	$433.59	$14.45	2.14	0.01%
RAMIPRIL CAP 1.25MG	27	12	$467.37	$17.31	2.25	0.01%
FOSINOPRIL TAB 10MG	27	9	$613.94	$22.74	3	0.01%
FOSINOPRIL TAB 20MG	17	3	$348.60	$20.51	5.67	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FOSINOPRIL TAB 40MG	15	5	$350.41	$23.36	3	0.01%
PERINDOPRIL TAB 4MG	5	2	$251.75	$50.35	2.5	0.00%
PERINDOPRIL TAB 8MG	3	2	$142.33	$47.44	1.5	0.00%
TRANDOLAPRIL TAB 4MG	2	1	$55.01	$27.51	2	0.00%
MOEXIPRIL TAB 15MG	1	1	$25.89	$25.89	1	0.00%
TIER-1 SUBTOTAL	**78,811**	**30,056**	**$962,946.88**	**$12.22**	**2.62**	**14.31%**
TIER-2 UTILIZATION						
CAPTOPRIL TAB 25MG	45	11	$1,295.76	$28.79	4.09	0.02%
CAPTOPRIL TAB 50MG	36	6	$1,214.06	$33.72	6	0.02%
CAPTOPRIL TAB 100MG	8	2	$445.30	$55.66	4	0.01%
CAPTOPRIL TAB 12.5MG	3	2	$175.82	$58.61	1.5	0.00%
TIER-2 SUBTOTAL	**92**	**21**	**$3,130.94**	**$34.03**	**4.38**	**0.05%**
SPECIAL PA UTILIZATION						
ENALAPRIL SOL 1MG/ML	1,236	232	$154,368.75	$124.89	5.33	2.29%
QBRELIS SOL 1MG/ML	142	24	$74,223.71	$522.70	5.92	1.10%
EPANED SOL 1MG/ML	98	17	$44,326.73	$452.31	5.76	0.66%
SPECIAL PA SUBTOTAL	**1,476**	**273**	**$272,919.19**	**$184.90**	**5.41**	**4.06%**
ACEI TOTAL	**80,379**	**30,350**	**$1,238,997.01**	**$15.41**	**2.65**	**18.41%**
CALCIUM CHANNEL BLOCKERS (CCBs)						
TIER-1 UTILIZATION						
AMLODIPINE TAB 10MG	29,974	10,994	$342,385.16	$11.42	2.73	5.09%
AMLODIPINE TAB 5MG	25,376	10,008	$292,983.53	$11.55	2.54	4.35%
AMLODIPINE TAB 2.5MG	4,289	1,698	$49,890.33	$11.63	2.53	0.74%
NIFEDIPINE TAB 30MG ER	2,564	1,321	$44,924.89	$17.52	1.94	0.67%
NIFEDIPINE TAB 30MG ER	1,445	724	$23,463.82	$16.24	2	0.35%
NIFEDIPINE TAB 60MG ER	1,337	579	$24,623.97	$18.42	2.31	0.37%
DILTIAZEM CAP 120MG ER	1,012	422	$19,785.55	$19.55	2.4	0.29%
NIFEDIPINE TAB 60MG ER	900	401	$16,638.62	$18.49	2.24	0.25%
DILTIAZEM CAP 180MG ER	667	257	$15,170.55	$22.74	2.6	0.23%
DILTIAZEM CAP 240MG ER	592	205	$13,479.63	$22.77	2.89	0.20%
NIFEDIPINE TAB 90MG ER	501	207	$12,273.87	$24.50	2.42	0.18%
VERAPAMIL TAB 240MG ER	397	92	$6,972.72	$17.56	4.32	0.10%
VERAPAMIL TAB 120MG ER	375	142	$8,472.96	$22.59	2.64	0.13%
NIFEDIPINE TAB 90MG ER	373	138	$8,250.02	$22.12	2.7	0.12%
NIFEDIPINE CAP 10MG	322	215	$10,271.73	$31.90	1.5	0.15%
DILTIAZEM TAB 30MG	322	116	$5,185.19	$16.10	2.78	0.08%
VERAPAMIL TAB 180MG ER	217	82	$4,786.39	$22.06	2.65	0.07%
DILTIAZEM TAB 120MG	216	75	$3,935.50	$18.22	2.88	0.06%
DILTIAZEM TAB 60MG	160	70	$3,155.02	$19.72	2.29	0.05%
VERAPAMIL TAB 80MG	158	52	$2,390.49	$15.13	3.04	0.04%
VERAPAMIL TAB 120MG	141	52	$2,550.28	$18.09	2.71	0.04%
DILTIAZEM CAP 120MG/24HR	140	53	$3,185.81	$22.76	2.64	0.05%
CARTIA XT CAP 240MG/24HR	119	56	$2,820.78	$23.70	2.13	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VERAPAMIL TAB 40MG	111	51	$2,375.27	$21.40	2.18	0.04%
CARTIA XT CAP 180MG/24HR	91	49	$2,065.66	$22.70	1.86	0.03%
DILT-XR CAP 240MG	91	35	$4,780.10	$52.53	2.6	0.07%
DILTIAZEM CAP 300MG ER	86	33	$2,383.85	$27.72	2.61	0.04%
DILT-XR CAP 120MG	84	35	$2,126.90	$25.32	2.4	0.03%
DILTIAZEM CAP 360MG ER	82	27	$3,715.07	$45.31	3.04	0.06%
DILTIAZEM CAP 240MG/24HR	81	32	$2,259.49	$27.89	2.53	0.03%
DILTIAZEM CAP 120MG ER	79	21	$2,151.29	$27.23	3.76	0.03%
DILTIAZEM TAB 90MG	77	22	$1,776.21	$23.07	3.5	0.03%
DILT-XR CAP 180MG	76	29	$3,132.38	$41.22	2.62	0.05%
DILTIAZEM CAP 120MG ER	72	20	$11,031.17	$153.21	3.6	0.16%
CARTIA XT CAP 120MG/24HR	70	47	$1,397.63	$19.97	1.49	0.02%
DILTIAZEM CAP 60MG ER	62	20	$6,556.10	$105.74	3.1	0.10%
NIFEDIPINE CAP 20MG	51	27	$3,386.92	$66.41	1.89	0.05%
DILTIAZEM CAP 180MG/24HR	48	28	$1,269.85	$26.46	1.71	0.02%
DILTIAZEM CAP 180MG ER	43	21	$1,891.64	$43.99	2.05	0.03%
DILTIAZEM CAP 300MG ER	41	9	$1,344.96	$32.80	4.56	0.02%
FELODIPINE TAB 5MG ER	38	13	$733.85	$19.31	2.92	0.01%
FELODIPINE TAB 10MG ER	30	9	$677.40	$22.58	3.33	0.01%
DILTIAZEM CAP 90MG ER	29	10	$3,301.93	$113.86	2.9	0.05%
CARTIA XT CAP 300MG/24HR	29	10	$739.10	$25.49	2.9	0.01%
TIADYLT CAP 120MG/24HR	22	7	$421.13	$19.14	3.14	0.01%
DILTIAZEM CAP 240MG ER	20	11	$1,031.06	$51.55	1.82	0.02%
TIADYLT CAP 360MG/24HR	15	4	$866.40	$57.76	3.75	0.01%
DILTIAZEM CAP 420MG/24HR	12	3	$852.36	$71.03	4	0.01%
NIMODIPINE CAP 30MG	11	9	$1,368.99	$124.45	1.22	0.02%
FELODIPINE TAB 2.5MG ER	11	4	$229.43	$20.86	2.75	0.00%
TIADYLT CAP 240MG/24HR	6	5	$204.77	$34.13	1.2	0.00%
TIADYLT CAP 180MG/24HR	3	1	$158.43	$52.81	3	0.00%
CARDIZEM CD CAP 240MG/24HR	2	1	$8,594.96	$4,297.48	2	0.13%
NORVASC TAB 10MG	1	1	$1,031.95	$1,031.95	1	0.02%
TAZTIA XT CAP 360MG/24HR	1	1	$26.90	$26.90	1	0.00%
VERAPAMIL POW	1	1	$11.41	$11.41	1	0.00%
TIER-1 SUBTOTAL	**73,073**	**28,555**	**$991,491.37**	**$13.57**	**2.56**	**14.73%**
TIER-2 UTILIZATION						
VERAPAMIL CAP 240MG SR	61	22	$4,722.59	$77.42	2.77	0.07%
AMLOD/ATORVA TAB 10-40MG	44	12	$3,174.65	$72.15	3.67	0.05%
VERAPAMIL CAP 120MG SR	43	13	$2,906.59	$67.60	3.31	0.04%
DILTIAZEM ER TAB 180MG	43	13	$3,045.28	$70.82	3.31	0.05%
DILTIAZEM TAB 360MG ER	41	7	$4,539.10	$110.71	5.86	0.07%
VERAPAMIL CAP 180MG SR	40	11	$2,018.32	$50.46	3.64	0.03%
VERAPAMIL CAP 240MG ER	38	9	$1,759.89	$46.31	4.22	0.03%
VERAPAMIL CAP 360MG SR	37	10	$8,910.49	$240.82	3.7	0.13%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DILTIAZEM TAB 240MG ER	28	10	$2,128.80	$76.03	2.8	0.03%
DILTIAZEM TAB 120MG ER	26	7	$1,971.37	$75.82	3.71	0.03%
AMLOD/ATORVA TAB 5-20MG	25	5	$1,276.05	$51.04	5	0.02%
DILTIAZEM ER TAB 360MG	22	5	$2,976.74	$135.31	4.4	0.04%
AMLOD/ATORVA TAB 10-20MG	21	6	$1,295.62	$61.70	3.5	0.02%
AMLOD/ATORVA TAB 10-10MG	18	7	$1,113.32	$61.85	2.57	0.02%
MATZIM LA TAB 180MG/24HR	15	4	$952.05	$63.47	3.75	0.01%
AMLOD/ATORVA TAB 10-80MG	15	5	$1,651.05	$110.07	3	0.02%
DILTIAZEM ER TAB 420MG	12	4	$1,395.46	$116.29	3	0.02%
ISRADIPINE CAP 2.5MG	12	9	$917.98	$76.50	1.33	0.01%
VERAPAMIL CAP 300MG ER	10	2	$1,835.40	$183.54	5	0.03%
DILTIAZEM ER TAB 240MG	10	5	$780.81	$78.08	2	0.01%
VERAPAMIL CAP 120MG ER	9	5	$638.92	$70.99	1.8	0.01%
MATZIM LA TAB 300MG/24HR	7	2	$819.29	$117.04	3.5	0.01%
AMLOD/ATORVA TAB 5-10MG	6	2	$483.40	$80.57	3	0.01%
DILTIAZEM TAB 300MG ER	6	2	$469.68	$78.28	3	0.01%
ISRADIPINE CAP 5MG	5	3	$205.13	$41.03	1.67	0.00%
MATZIM LA TAB 240MG/24HR	5	3	$327.45	$65.49	1.67	0.00%
VERAPAMIL CAP 180MG ER	5	3	$357.92	$71.58	1.67	0.01%
VERAPAMIL CAP 100MG ER	4	1	$1,454.90	$363.73	4	0.02%
CARDIZEM LA TAB 120MG	3	1	$363.87	$121.29	3	0.01%
MATZIM LA TAB 360MG/24HR	2	2	$314.05	$157.03	1	0.00%
CADUET TAB 10-10MG	1	1	$561.09	$561.09	1	0.01%
NICARDIPINE CAP 20MG	1	1	$231.91	$231.91	1	0.00%
VERAPAMIL CAP 200MG ER	1	1	$138.68	$138.68	1	0.00%
TIER-2 SUBTOTAL	**616**	**193**	**$55,737.85**	**$90.48**	**3.19**	**0.83%**
SPECIAL PA UTILIZATION						
KATERZIA SUS 1MG/ML	228	32	$96,356.37	$422.62	7.13	1.43%
NORLIQVA SOL 1MG/ML	178	30	$70,008.29	$393.31	5.93	1.04%
DILTIAZEM CAP 360MG ER	30	11	$582.30	$19.41	2.73	0.01%
DILTIAZEM CAP 360MG CD	1	1	$18.91	$18.91	1	0.00%
SPECIAL PA SUBTOTAL	**437**	**74**	**$166,965.87**	**$382.07**	**5.91**	**2.48%**
CCB TOTAL	**74,126**	**28,822**	**$1,214,195.09**	**$16.38**	**2.57**	**18.04%**
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs) AND ARB COMBINATION PRODUCTS						
TIER-1 UTILIZATION						
LOSARTAN TAB 50MG	15,963	6,351	$217,273.12	$13.61	2.51	3.23%
LOSARTAN TAB 25MG	13,214	5,461	$167,835.17	$12.70	2.42	2.49%
LOSARTAN TAB 100MG	12,422	4,565	$168,341.09	$13.55	2.72	2.50%
LOSARTAN/HCTZ TAB 100-25MG	3,190	1,215	$54,178.80	$16.98	2.63	0.80%
LOSARTAN/HCTZ TAB 50-12.5MG	2,866	1,209	$39,081.33	$13.64	2.37	0.58%
LOSARTAN/HCTZ TAB 100-12.5MG	1,796	655	$30,606.99	$17.04	2.74	0.45%
OLMESARTAN TAB 20MG	1,789	774	$31,843.68	$17.80	2.31	0.47%
OLMESARTAN TAB 40MG	1,468	508	$31,242.26	$21.28	2.89	0.46%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VALSARTAN TAB 160MG	1,420	553	$32,233.98	$22.70	2.57	0.48%
VALSARTAN TAB 80MG	1,399	547	$26,885.14	$19.22	2.56	0.40%
VALSARTAN TAB 320MG	780	314	$20,045.17	$25.70	2.48	0.30%
VALSARTAN TAB 40MG	739	294	$14,081.94	$19.06	2.51	0.21%
TELMISARTAN TAB 40MG	707	292	$16,961.46	$23.99	2.42	0.25%
TELMISARTAN TAB 80MG	705	244	$17,241.46	$24.46	2.89	0.26%
CANDESARTAN TAB 8MG	576	180	$22,361.86	$38.82	3.2	0.33%
CANDESARTAN TAB 16MG	499	134	$17,328.16	$34.73	3.72	0.26%
TELMISARTAN TAB 20MG	463	210	$10,161.62	$21.95	2.2	0.15%
VALSAR/HCTZ TAB 160-12.5	460	168	$8,937.67	$19.43	2.74	0.13%
VALSAR/HCTZ TAB 320-25MG	442	176	$12,096.55	$27.37	2.51	0.18%
OLM/HCTZ TAB 40-25MG	421	155	$10,614.81	$25.21	2.72	0.16%
IRBESARTAN TAB 300MG	403	124	$8,206.93	$20.36	3.25	0.12%
IRBESARTAN TAB 150MG	393	160	$7,637.87	$19.43	2.46	0.11%
OLMESARTAN TAB 5MG	370	150	$5,834.81	$15.77	2.47	0.09%
AMLOD/VALSAR TAB 10-320MG	336	111	$16,246.41	$48.35	3.03	0.24%
CANDESARTAN TAB 4MG	330	129	$12,323.43	$37.34	2.56	0.18%
OLM/HCTZ TAB 20-12.5MG	327	136	$14,232.95	$43.53	2.4	0.21%
VALSAR/HCTZ TAB 160-25MG	305	108	$6,043.80	$19.82	2.82	0.09%
AMLOD/VALSAR TAB 5-160MG	270	113	$9,776.99	$36.21	2.39	0.15%
AMLOD/OLM TAB 10-40MG	234	76	$6,380.04	$27.27	3.08	0.09%
IRBESARTAN TAB 75MG	225	78	$3,935.24	$17.49	2.88	0.06%
VALSAR/HCTZ TAB 80-12.5MG	213	71	$3,940.72	$18.50	3	0.06%
CANDESARTAN TAB 32MG	201	50	$8,489.42	$42.24	4.02	0.13%
AMLOD/VALSAR TAB 10-160MG	167	66	$7,076.82	$42.38	2.53	0.11%
AMLOD/OLM TAB 5-20MG	159	59	$4,085.34	$25.69	2.69	0.06%
VALSAR/HCTZ TAB 320-12.5MG	158	60	$3,758.37	$23.79	2.63	0.06%
OLM/HCTZ TAB 40-12.5MG	156	72	$5,889.98	$37.76	2.17	0.09%
AMLOD/OLM TAB 10-20MG	151	47	$3,496.28	$23.15	3.21	0.05%
AMLOD/VAL/HCTZ TAB 10-325-25MG	115	37	$45,019.17	$391.47	3.11	0.67%
AMLOD/OLM TAB 5-40MG	106	35	$2,822.36	$26.63	3.03	0.04%
IRBESAR/HCTZ TAB 300-12.5MG	92	33	$2,228.54	$24.22	2.79	0.03%
IRBESAR/HCTZ TAB 150-12.5MG	92	33	$1,923.24	$20.90	2.79	0.03%
AMLOD/VAL/HCTZ TAB 5-160-12.5MG	59	15	$13,783.27	$233.61	3.93	0.20%
AMLOD/VALSAR TAB 5-320MG	58	24	$2,635.13	$45.43	2.42	0.04%
AMLOD/VAL/HCTZ TAB 10-160-25MG	53	17	$15,363.03	$289.87	3.12	0.23%
AMLOD/VAL/HCTZ TAB 10-160-12.5MG	31	13	$9,223.94	$297.55	2.38	0.14%
AMLOD/VAL/HCTZ TAB 5-160-25MG	15	7	$1,153.95	$76.93	2.14	0.02%
COZAAR TAB 50MG	2	1	$752.27	$376.14	2	0.01%
EXFORGE TAB 10-320MG	1	1	$1,321.34	$1,321.34	1	0.02%
BENICAR TAB 20MG	1	1	$847.07	$847.07	1	0.01%
FOSINOPRIL/HCTZ TAB 10/12.5MG	1	1	$21.14	$21.14	1	0.00%
TIER-1 SUBTOTAL	**66,343**	**25,833**	**$1,173,802.11**	**$17.69**	**2.57**	**17.44%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-2 UTILIZATION						
TELMISAR/HCTZ TAB 80-25MG	61	20	$2,130.77	$34.93	3.05	0.03%
TELMISAR/HCTZ TAB 40-12.5MG	59	20	$1,499.37	$25.41	2.95	0.02%
TELMISAR/HCTZ TAB 80-12.5MG	56	18	$1,727.14	$30.84	3.11	0.03%
OLM/AMLOD/HCTZ TAB 40-10-25MG	52	19	$3,925.67	$75.49	2.74	0.06%
OLM/AMLOD/HCTZ TAB 20-5-12.5MG	23	8	$1,412.94	$61.43	2.88	0.02%
OLM/AMLOD/HCTZ TAB 40-5-12.5MG	20	4	$933.14	$46.66	5	0.01%
OLM/AMLOD/HCTZ TAB 40-5-25MG	17	5	$1,229.34	$72.31	3.4	0.02%
OLM/AMLOD/HCTZ TAB 40-10-12.5MG	6	3	$535.11	$89.19	2	0.01%
TIER-2 SUBTOTAL	**294**	**97**	**$13,393.48**	**$45.56**	**3.03**	**0.20%**
TIER-3 UTILIZATION						
EDARBYCLOR TAB 40-25MG	31	6	$8,005.61	$258.25	5.17	0.12%
CANDESAR/HCTZ TAB 32-12.5MG	17	2	$909.05	$53.47	8.5	0.01%
EDARBYCLOR TAB 40-12.5MG	16	5	$7,389.80	$461.86	3.2	0.11%
CANDESAR/HCTZ TAB 16-12.5MG	12	1	$405.82	$33.82	12	0.01%
TELMISAR/AMLOD TAB 80-5MG	9	1	$1,323.29	$147.03	9	0.02%
EDARBI TAB 40MG	5	1	$1,300.99	$260.20	5	0.02%
CANDESAR/HCTZ TAB 32-25MG	5	2	$418.46	$83.69	2.5	0.01%
TELMISAR/AMLOD TAB 40-10MG	4	3	$267.13	$66.78	1.33	0.00%
TELMISAR/AMLOD TAB 40-5MG	3	1	$254.16	$84.72	3	0.00%
SPECIAL PA SUBTOTAL	**102**	**22**	**$20,274.31**	**$198.77**	**4.64**	**0.30%**
ARB TOTAL	**66,739**	**25,952**	**$1,207,469.90**	**$18.09**	**2.57**	**17.94%**
METOPROLOL PRODUCTS						
NO PA REQUIRED						
METOPROLOL SUC TAB 25MG ER	16,749	6,454	$234,747.07	$14.02	2.6	3.49%
METOPROLOL TAR TAB 25MG	12,309	4,569	$136,512.07	$11.09	2.69	2.03%
METOPROLOL SUC TAB 50MG ER	11,960	4,395	$177,682.79	$14.86	2.72	2.64%
METOPROLOL TAR TAB 50MG	6,979	2,493	$85,500.96	$12.25	2.8	1.27%
METOPROLOL SUC TAB 100MG ER	5,588	2,049	$100,839.58	$18.05	2.73	1.50%
METOPROLOL TAR TAB 100MG	2,516	848	$29,963.19	$11.91	2.97	0.45%
METOPROLOL SUC TAB 200MG ER	949	314	$24,538.83	$25.86	3.02	0.36%
METOPROLOL TAR TAB 75MG	198	76	$4,652.18	$23.50	2.61	0.07%
METOPROLOL TAR TAB 37.5MG	58	28	$1,061.06	$18.29	2.07	0.02%
TOPROL XL TAB 50MG	3	1	$153.35	$51.12	3	0.00%
TOPROL XL TAB 25MG	2	1	$139.14	$69.57	2	0.00%
NO PA SUBTOTAL	**57,311**	**21,228**	**$795,790.22**	**$13.89**	**2.7**	**11.82%**
PA REQUIRED						
KAPSPARGO CAP 25MG	4	4	$259.62	$64.91	1	0.00%
KAPSPARGO CAP 50MG	2	2	$129.61	$64.81	1	0.00%
PA SUBTOTAL	**6**	**6**	**$389.23**	**$64.87**	**1**	**0.01%**
METOPROLOL TOTAL	**57,317**	**21,234**	**$796,179.45**	**$13.89**	**2.7**	**11.83%**
SPIRONOLACTONE PRODUCTS						
NO PA REQUIRED						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SPIRONOLACTONE TAB 25MG	12,611	4,656	$159,033.54	$12.61	2.71	2.36%
SPIRONOLACTONE TAB 50MG	7,646	2,903	$128,882.42	$16.86	2.63	1.91%
SPIRONOLACTONE TAB 100MG	4,854	1,773	$105,131.25	$21.66	2.74	1.56%
SPIRONOLACTONE POW	13	1	$348.92	$26.84	13	0.01%
ALDACTONE TAB 50MG	3	1	$899.01	$299.67	3	0.01%
NO PA SUBTOTAL	**25,127**	**9334**	**$394,295.14**	**$15.69**	**2.69**	**5.86%**
PA REQUIRED						
SPIRONOLACTONE SUS 25MG/5ML	175	54	$42,200.67	$241.15	3.24	0.63%
CAROSPIR SUS 25MG/5ML	40	7	$20,990.01	$524.75	5.71	0.31%
PA SUBTOTAL	**215**	**61**	**$63,190.68**	**$293.91**	**3.52**	**0.94%**
SPIRONOLACTONE TOTAL	**25,342**	**9,395**	**$457,485.82**	**$18.05**	**2.7**	**6.80%**
ACEI/HCTZ COMBINATION PRODUCTS						
TIER-1 UTILIZATION						
LISINOP/HCTZ TAB 20-12.5MG	5,460	2,075	$76,903.31	$14.08	2.63	1.14%
LISINOP/HCTZ TAB 20-25MG	4,755	1,772	$57,486.39	$12.09	2.68	0.85%
LISINOP/HCTZ TAB 10-12.5MG	3,415	1,339	$42,224.39	$12.36	2.55	0.63%
BENAZEP/HCTZ TAB 20-12.5	75	26	$2,113.07	$28.17	2.88	0.03%
ENALAP/HCTZ TAB 10-25MG	50	19	$1,070.71	$21.41	2.63	0.02%
BENAZEP/HCTZ TAB 10-12.5	48	15	$1,071.76	$22.33	3.2	0.02%
BENAZEP/HCTZ TAB 20-25MG	22	8	$558.77	$25.40	2.75	0.01%
ENALAP/HCTZ TAB 5-12.5MG	15	10	$375.52	$25.03	1.5	0.01%
BENAZEP/HCTZ TAB 5-6.25MG	4	1	$188.16	$47.04	4	0.00%
ACEI/HCTZ TOTAL	**13,844**	**5,265**	**$181,992.08**	**$13.15**	**2.63**	**2.70%**
PROPRANOLOL SOL PRODUCTS						
NO PA REQUIRED						
PROPRANOLOL SOL 20MG/5ML	986	242	$24,057.84	$24.40	4.07	0.36%
PROPRANOLOL SOL 40MG/5ML	51	11	$852.01	$16.71	4.64	0.01%
NO PA SUBTOTAL	**1,037**	**253**	**$24,909.85**	**$24.02**	**4.1**	**0.37%**
PA REQUIRED						
HEMANGEOL SOL 4.28/ML	108	32	$83,157.06	$769.97	3.38	1.24%
PA SUBTOTAL	**108**	**32**	**$83,157.06**	**$769.97**	**3.38**	**1.24%**
PROPRANOLOL SOL TOTAL	**1,145**	**285**	**$108,066.91**	**$94.38**	**4.02**	**1.61%**
ACEI/CCB COMBINATION PRODUCTS						
TIER-1 UTILIZATION						
AMLOD/BENAZEP CAP 10-40MG	358	107	$6,838.81	$19.10	3.35	0.10%
AMLOD/BENAZEP CAP 10-20MG	240	95	$4,686.39	$19.53	2.53	0.07%
AMLOD/BENAZEP CAP 5-10MG	193	73	$3,225.61	$16.71	2.64	0.05%
AMLOD/BENAZEP CAP 5-20MG	157	65	$2,996.59	$19.09	2.42	0.04%
AMLOD/BENAZEP CAP 5-40MG	37	20	$823.22	$22.25	1.85	0.01%
AMLOD/BENAZEP CAP 2.5-10MG	12	8	$247.31	$20.61	1.5	0.00%
ACEI/CCB TOTAL	**997**	**368**	**$18,817.93**	**$18.87**	**2.71**	**0.28%**
MISCELLANEOUS (MISC) COMBINATION PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NO PA REQUIRED						
BISOPROLOL/HCTZ TAB 5-6.25MG	233	68	$5,423.34	$23.28	3.43	0.08%
ATENOLOL/CHLOR TAB 50-25MG	153	51	$4,157.32	$27.17	3	0.06%
BISOPROLOL/HCTZ TAB 10/6.25MG	140	53	$3,765.96	$26.90	2.64	0.06%
METOPROLOL/HCTZ TAB 50-25MG	78	23	$4,192.34	$53.75	3.39	0.06%
BISOPROLOL/HCTZ TAB 2.5/6.25MG	72	25	$1,637.82	$22.75	2.88	0.02%
ATENOLOL/CHLOR TAB 100-25MG	62	22	$2,276.79	$36.72	2.82	0.03%
METOPROLOL/HCTZ TAB 100-25MG	32	12	$3,087.64	$96.49	2.67	0.05%
METOPROLOL/HCTZ TAB 100-50MG	1	1	$59.32	$59.32	1	0.00%
MISC TOTAL	**771**	**255**	**$24,600.53**	**$31.91**	**3.02**	**0.37%**
SOTALOL PRODUCTS						
NO PA REQUIRED						
SOTALOL HCL TAB 80MG	255	74	$4,388.09	$17.21	3.45	0.07%
SOTALOL HCL TAB 120MG	112	29	$1,882.28	$16.81	3.86	0.03%
SOTALOL HCL TAB 160MG	25	6	$626.56	$25.06	4.17	0.01%
SOTALOL AF TAB 80MG	24	6	$522.11	$21.75	4	0.01%
SOTALOL AF TAB 120MG	2	1	$50.91	$25.46	2	0.00%
NO PA SUBTOTAL	**418**	**116**	**$7,469.95**	**$17.87**	**3.6**	**0.11%**
PA REQUIRED						
SOTYLIZE SOL 5MG/ML	104	18	$61,710.06	$593.37	5.78	0.92%
PA SUBTOTAL	**104**	**18**	**$61,710.06**	**$593.37**	**5.78**	**0.92%**
SOTALOL TOTAL	**522**	**134**	**$69,180.01**	**$132.53**	**3.9**	**1.03%**
HCTZ PRODUCTS						
NO PA REQUIRED						
HCTZ TAB 25MG	15,568	6,155	$160,078.80	$10.28	2.53	2.38%
HCTZ TAB 12.5MG	7,643	2,635	$78,486.69	$10.27	2.9	1.17%
HCTZ CAP 12.5MG	3,736	1,560	$43,650.19	$11.68	2.39	0.65%
HCTZ TAB 50MG	1,234	476	$13,526.35	$10.96	2.59	0.20%
HCTZ TOTAL	**28,181**	**10,826**	**$295,742.03**	**$10.49**	**2.60**	**4.39%**
CHLORTHALIDONE PRODUCTS						
NO PA REQUIRED						
CHLORTHALIDONE TAB 25MG	4,275	1,303	$61,789.65	$14.45	3.28	0.92%
THALITONE TAB 15MG	21	12	$3,365.71	$160.27	1.75	0.05%
CHLORTHALIDONE TAB 50MG	587	178	$8,986.69	$15.31	3.3	0.13%
CHLORTHALIDONE TOTAL	**4,883**	**1,493**	**$74,142.05**	**$15.18**	**3.27**	**1.10%**
BISOPROLOL PRODUCTS						
NO PA REQUIRED						
BISOPROLOL TAB 5MG	884	333	$18,357.65	$20.77	2.65	0.27%
BISOPROLOL TAB 10MG	404	135	$11,057.26	$27.37	2.99	0.16%
BISOPROLOL TOTAL	**1,288**	**468**	**$29,414.91**	**$22.84**	**2.75**	**0.44%**
TOTAL	**441,440**	**96,163***	**$6,730,362.41**	**$15.25**	**2.85**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AF = atrial fibrillation; AMLOD = amlodipine; ATORVA = atorvastatin; BENAZEP = benazepril; CANDESAR = candesartan; CAP = capsule; CD = controlled-delivery; CHLOR = chlorthalidone; ENALEP = enalapril; ER = extended-release; HCL = hydrochloride; HCTZ = hydrochlorothiazide; HR = hour; IRBESAR = irbesartan; LA = long-acting; LISINOP = lisinopril; OLM = olmesartan; PA = prior authorization; POW = powder; SOL = solution; SR = sustained-release; SUC = succinate; SUS = suspension; TAB = tablet; TAR = tartrate; TELMISAR = telmisartan; VAL = valsartan; VALSAR = valsartan; XR = extra-release; XT = extra-time
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix G

Fiscal Year 2025 Annual Review of Bowel Preparation Medications and 30-day Notice to Prior Authorize MoviPrep® [Polyethylene Glycol 3350 (PEG 3350)/ Sodium Sulfate/Sodium Chloride/Potassium Chloride/ Sodium Ascorbate/Ascorbic Acid for Oral Solution]

Oklahoma Health Care Authority
January 2026

Current Prior Authorization Criteria

Clenpiq®, Suflave™, Suprep®, and Sutab® Approval Criteria:

1. An FDA approved indication for use in cleansing of the colon as a preparation for colonoscopy; and
2. A patient-specific, clinically significant reason, other than convenience, why the member cannot use other bowel preparation medications available without prior authorization must be provided; and
3. If the member requires a low volume polyethylene glycol electrolyte lavage solution, MoviPrep® is available without prior authorization. Other medications currently available without a prior authorization include: Gavilyte® and Golytely®.

Utilization of Bowel Preparation Medications: Fiscal Year 2025

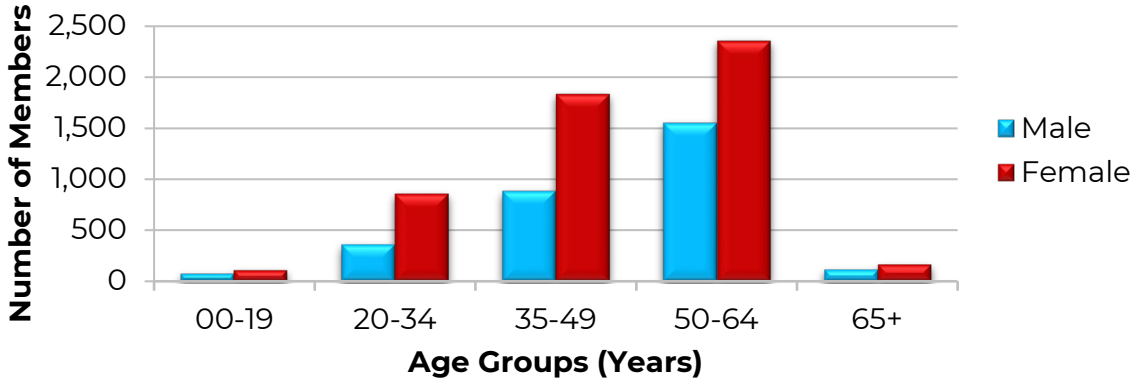
Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	6,780	7,302	$216,014.07	$29.58	$16.75	26,858,882	12,893
Aetna	428	438	$21,387.74	$48.83	$46.70	1,316,794	458
Humana	649	675	$35,316.60	$52.32	$23.33	1,992,567	1,514
OCH	421	431	$22,693.07	$52.65	$38.08	1,200,683	596
2024 Total	**8,205**	**8,846**	**$295,411.48**	**$33.39**	**$19.11**	**31,368,926**	**15,461**
Fiscal Year 2025							
FFS	2,725	2,954	$81,972.59	$27.75	$16.51	10,976,214	4,966
Aetna	1,664	1,792	$58,518.95	$32.66	$27.73	6,272,760	2,110
Humana	2,258	2,413	$85,422.70	$35.40	$18.05	8,303,726	4,732
OCH	1,692	1,797	$64,233.92	$35.75	$26.41	6,141,664	2,432
2025 Total	**8,298**	**8,956**	**$290,148.16**	**$32.40**	**$20.38**	**31,694,364**	**14,240**
% Change	**1.10%**	**1.20%**	**-1.80%**	**-3.00%**	**6.60%**	**1.00%**	**-7.90%**
Change	**93**	**110**	**-$5,263.32**	**-$0.99**	**$1.27**	**325,438**	**-1,221**

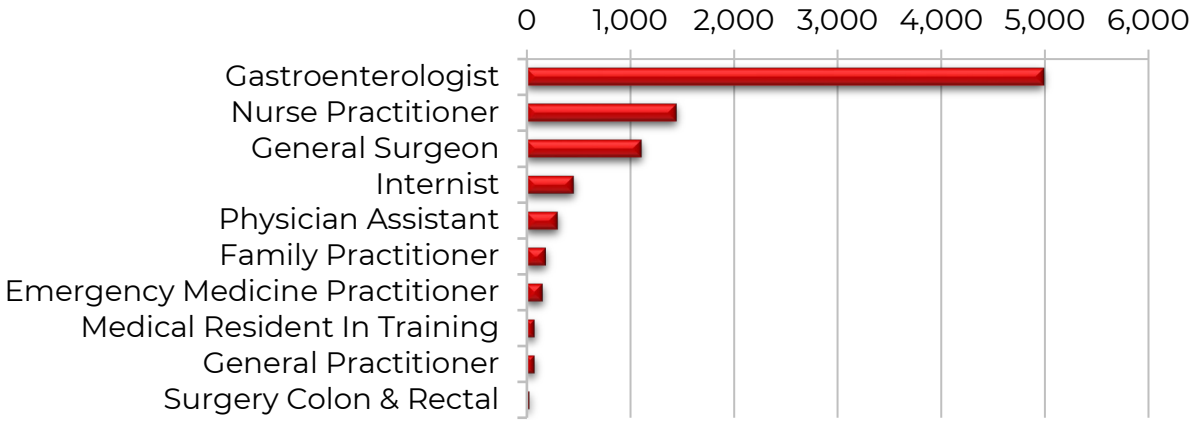
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

- Aggregate drug rebates collected during fiscal year 2025 for bowel preparation medications totaled $65,843.50.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Bowel Preparation Medications (All Plans)



Top Prescriber Specialties of Bowel Preparation Medications by Number of Claims (All Plans)

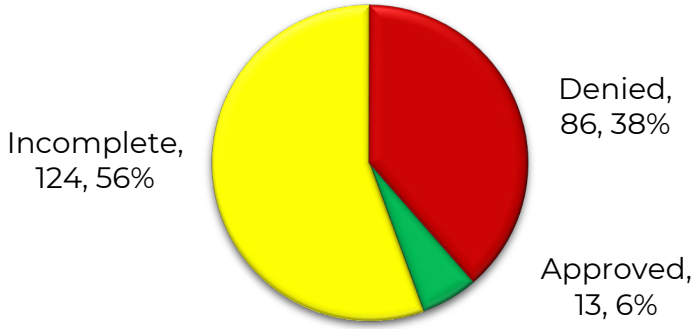


Prior Authorization of Bowel Preparation Medications

There were 223 prior authorization requests submitted for bowel preparation medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	2	2%	84	79%	20	19%	**106**
Aetna	4	7%	31	53%	24	41%	**59**
Humana	3	14%	0	0%	19	86%	**22**
OCH	4	11%	9	25%	23	64%	**36**
Total	**13**	**6%**	**124**	**56%**	**86**	**38%**	**223**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1]

Anticipated Patent Expiration(s):

- Sutab® (sodium sulfate/magnesium sulfate/potassium chloride): August 2037
- Clenpiq® (sodium picosulfate/magnesium oxide/anhydrous citric acid): January 2038
- Suflave™ (PEG 3350/sodium sulfate/potassium chloride/magnesium sulfate/sodium chloride): August 2044

News:

- **October 2025:** Salix Pharmaceuticals, the manufacturer of MoviPrep® (PEG 3350/sodium sulfate/sodium chloride/potassium chloride/sodium ascorbate/ascorbic acid), voluntarily ended their Federal Drug Rebate Agreement with the Centers for Medicare and Medicaid Services (CMS). As a result, SoonerCare no longer covers brand name MoviPrep®. A generic formulation is available and is covered by SoonerCare; however, the net cost is significantly higher.

Recommendations

The College of Pharmacy recommends the prior authorization of generic MoviPrep® (PEG 3350/sodium sulfate/sodium chloride/potassium chloride/ sodium ascorbate/ascorbic acid) and recommends removing the prior authorization requirement for brand name Suprep® (sodium sulfate/ potassium sulfate/magnesium sulfate) based on net cost with the following criteria changes (shown in red):

Clenpiq®, Generic MoviPrep®, Suflave™, Generic Suprep®, and Sutab® Approval Criteria:

1. An FDA approved indication for use in cleansing of the colon as a preparation for colonoscopy; and
2. A patient-specific, clinically significant reason, other than convenience, why the member cannot use other bowel preparation medications available without prior authorization must be provided; and
3. If the member requires a low volume ~~polyethylene glycol electrolyte lavage solution~~ product, ~~MoviPrep®~~ brand name Suprep® is available without prior authorization. Other medications currently available without a prior authorization include: Gavilyte® and Golytely®; and
    a. Suprep® is brand preferred. Requests for the generic will require a patient-specific, clinically significant reason why the member cannot use the brand name product.

Utilization Details of Bowel Preparation Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GAVILYTE-G SOL	3,375	3,167	$86,059.52	$25.50	1.07	29.66%
PEG-3350 SOL ELECT 236GM	3,063	2,884	$67,024.62	$21.88	1.06	23.10%
GAVILYTE-C SOL	832	797	$16,512.02	$19.85	1.04	5.69%
PEG/KCL/NACL/NASUL/NAAS SOL	574	545	$45,174.59	$78.70	1.05	15.57%
PEG-3350/KCL/NABI/NACL SOL	391	374	$12,605.00	$32.24	1.05	4.34%
NASUL/KSUL/MGSUL SOL	255	251	$17,908.15	$70.23	1.02	6.17%
GAVILYTE-N SOL FLAV PK	176	170	$5,178.59	$29.42	1.04	1.78%
SUTAB TAB	114	114	$19,483.42	$170.91	1	6.71%
GOLYTELY SOL	53	52	$1,626.42	$30.69	1.02	0.56%
CLENPIQ SOL	45	42	$8,075.31	$179.45	1.07	2.78%
PLENVU SOL	40	40	$5,726.00	$143.15	1	1.97%
MOVIPREP SOL	16	16	$2,091.78	$130.74	1	0.72%
SUFLAVE SOL	12	12	$1,601.11	$133.43	1	0.55%
SUPREP BOWEL SOL PREP KIT	9	9	$1,061.06	$117.90	1	0.37%
PEG-3350 SOL ELECT 240GM	1	1	$20.57	$20.57	1	0.01%
TOTAL	**8,956**	**8,298***	**$290,148.16**	**$32.40**	**1.08**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ELECT = electrolytes; FLAV PK = flavor pack; KCL = potassium chloride; KSUL= potassium sulfate; MGSUL = magnesium sulfate; NAAS = sodium ascorbate; NABI = sodium bicarbonate; NACL = sodium chloride; NASUL = sodium sulfate; PEG = polyethylene glycol; SOL = solution; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 12/2025. Last accessed 12/30/2025.

Appendix H

Fiscal Year 2025 Annual Review of Gastrointestinal (GI) Cancer Medications

Oklahoma Health Care Authority
January 2026

Current Prior Authorization Criteria

Utilization data for Enhertu® (fam-trastuzumab deruxtecan-nxki), Herceptin® (trastuzumab), Hercessi™ (trastuzumab-strf), Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), Ogivri® (trastuzumab-dkst), Ontruzant® (trastuzumab-dttb), and Trazimera® (trastuzumab-qyyp) and approval criteria for indications other than GI cancer can be found in the September 2025 Drug Utilization Review (DUR) Board packet. These medications and criteria are reviewed annually with the breast cancer medications. Utilization data for Imfinzi® (durvalumab) and approval criteria for indications other than GI cancer can be found in the May 2025 DUR Board packet. This medication and criteria are reviewed annually with the lung cancer medications. Utilization data for Keytruda® (pembrolizumab), Opdivo® (nivolumab), and Yervoy® (ipilimumab) and approval criteria for indications other than GI cancer can be found in the December 2025 DUR Board packet. These medications and criteria are reviewed annually with the skin cancer medications. Utilization data for Lonsurf® (trifluridine/tipiracil) and Stivarga® (regorafenib) and approval criteria for indications other than GI cancer can be found in the July 2025 DUR Board packet. These medications and criteria are reviewed annually with the colorectal cancer medications. Utilization data for Sprycel® (dasatinib) and Tasigna® (nilotinib) and approval criteria for indications other than GI cancer can be found in the March 2025 DUR Board packet. These medications and criteria are reviewed annually with the leukemia and lymphoma medications.

Ayvakit® (Avapritinib) Approval Criteria [Advanced Systemic Mastocytosis (AdvSM) Diagnosis]:

1. Diagnosis of AdvSM, including members with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematologic neoplasm, or mast cell leukemia; and
2. Member must be 18 years of age or older; and
3. Platelet count ≥50 x 10^9/L.

Ayvakit® (Avapritinib) Approval Criteria [Gastrointestinal Stromal Tumor (GIST) Diagnosis]:

1. Diagnosis of unresectable or metastatic GIST; and
2. Member must be 18 years of age or older; and

3. Member has a PDGFRA exon 18 mutation (including PDGFRA D842V mutations).

Ayvakit® (Avapritinib) Approval Criteria [Indolent Systemic Mastocytosis (ISM) Diagnosis]:

1. Diagnosis of ISM; and
2. Member must be 18 years of age or older; and
3. Platelet count ≥50 x 10^9/L.

Cyramza® (Ramucirumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of CRC; and
2. Subsequent therapy for metastatic disease after progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine; and
3. In combination with an irinotecan-based regimen.

Cyramza® (Ramucirumab) Approval Criteria [Esophageal Cancer Diagnosis]:

1. Diagnosis of esophageal or esophagogastric junction adenocarcinoma; and
2. Member is not a surgical candidate or has unresectable, locally advanced, recurrent, or metastatic disease; and
3. Karnofsky performance score ≥60% or ECOG performance score ≤2; and
4. Used as second-line or subsequent therapy; and
5. As a single agent or in combination with paclitaxel.

Cyramza® (Ramucirumab) Approval Criteria [Gastric Cancer Diagnosis]:

1. Diagnosis of gastric cancer; and
2. Member is not a surgical candidate or has unresectable, locally advanced, recurrent, or metastatic disease; and
3. Karnofsky performance score ≥60% or ECOG performance score ≤2; and
4. Used as second-line or subsequent therapy; and
5. As a single agent or in combination with paclitaxel.

Cyramza® (Ramucirumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of HCC; and
2. Second-line or greater therapy; and
3. Previously failed sorafenib; and
4. Alpha-fetoprotein concentration ≥400ng/mL; and
5. As a single agent.

Cyramza® (Ramucirumab) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and

2. First-line in combination with erlotinib; and
    a. Epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation; or
3. Subsequent therapy for metastatic disease; and
    a. In combination with docetaxel.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic gastric or GEJ adenocarcinoma; and
2. Human epidermal growth factor receptor 2 (HER2)-positive disease; and
3. Member has received at least 1 prior trastuzumab-based regimen.

Herceptin® (Trastuzumab), Hercessi™ (Trastuzumab-strf), Herzuma® (Trastuzumab-pkrb), Kanjinti® (Trastuzumab-anns), Ogivri® (Trastuzumab-dkst), Ontruzant® (Trastuzumab-dttb), and Trazimera® (Trastuzumab-qyyp) Approval Criteria [Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma Diagnosis]:

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic gastric or gastroesophageal junction adenocarcinoma; and
2. Preferred trastuzumab products include Kanjinti®, Ontruzant®, and Trazimera®. Authorization of non-preferred trastuzumab products (Herceptin®, Hercessi™, Herzuma®, or Ogivri®) will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products (Kanjinti®, Ontruzant®, or Trazimera®). Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Imfinzi® (Durvalumab) Approval Criteria [Biliary Tract Cancer (BTC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic BTC; and
2. Used in combination with gemcitabine and cisplatin.

Keytruda® (Pembrolizumab) Approval Criteria [Biliary Tract Cancer (BTC) Diagnosis]:

1. Diagnosis of locally advanced unresectable or metastatic BTC; and
2. Used in combination with gemcitabine and cisplatin.

Keytruda® (Pembrolizumab) Approval Criteria [Esophageal or Gastroesophageal Junction (GEJ) Carcinoma Diagnosis]:

1. Diagnosis of locally advanced, recurrent, or metastatic esophageal or GEJ carcinoma; and

2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. For first-line therapy:
    a. In combination with platinum- and fluoropyrimidine-based chemotherapy; or
4. For second-line or greater therapy:
    a. Following disease progression after 1 or more prior lines of systemic therapy; and
    b. Tumor must be squamous cell histology; and
    c. Used as a single agent; and
    d. Tumor expresses programmed death ligand 1 (PD-L1) [combined positive score (CPS ≥10).

Keytruda® (Pembrolizumab) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of locally advanced, unresectable, or metastatic gastric or GEJ adenocarcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. For first-line therapy:
    a. Human epidermal receptor 2 (HER2)-positive disease; and
        i. Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; and
        ii. Tumor is positive for expression of programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1; or
    b. HER2-negative disease; and
        i. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy.

Lonsurf® (Trifluridine/Tipiracil) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of metastatic gastric or GEJ adenocarcinoma; and
2. Previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, paclitaxel, docetaxel, or irinotecan; and
3. If human epidermal receptor type 2 (HER2)-positive disease, prior treatment should have included HER2 targeted therapy.

Lytgobi® (Futibatinib) Approval Criteria [Intrahepatic Cholangiocarcinoma Diagnosis]:

1. Diagnosis of unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma; and
2. Member was previously treated with at least 1 prior therapy; and
3. Tumor is positive for fibroblast growth factor receptor 2 (FGFR2) gene fusion or rearrangement.

Opdivo® (Nivolumab) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) or Esophageal or Gastroesophageal Junction (GEJ) Cancer Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic ESCC; and
    a. Used in the first-line setting; and
    b. Used in combination with 1 of the following:
        i. Fluoropyrimidine- and platinum-based chemotherapy; or
        ii. Ipilimumab; or
2. Diagnosis of esophageal or GEJ cancer; and
    a. Member has received preoperative chemoradiation; and
    b. Member underwent R0 (complete) resection and has residual disease; and
    c. As a single agent; or
3. Palliative therapy for members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease; and
    a. Human epidermal receptor 2 (HER2)-negative disease; and
        i. Used in first-line setting; and
            1. Used in combination with oxaliplatin and fluorouracil or capecitabine; and
            2. Adenocarcinoma pathology; or
        ii. Used in the second-line or greater setting; and
            1. As a single agent; and
            2. Squamous cell pathology.

Opdivo® (Nivolumab) Approval Criteria [Gastric Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic disease; and
2. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy.

Pemazyre® (Pemigatinib) Approval Criteria [Cholangiocarcinoma Diagnosis]:

1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma; and
2. Must have failed 1 or more prior therapies; and
3. Disease is positive for a fibroblast growth factor receptor 2 (FGFR2) gene fusion or other FGFR rearrangement.

Pemazyre® (Pemigatinib) Approval Criteria [Myeloid/Lymphoid Neoplasms (MLNs) Diagnosis]:

1. Diagnosis of relapsed or refractory MLNs; and
2. Disease is positive for a fibroblast growth factor receptor 1 (FGFR1) rearrangement.

Qinlock® (Ripretinib) Approval Criteria [Gastrointestinal Stromal Tumor (GIST) Diagnosis]:

1. Diagnosis of advanced GIST; and
2. Previously received ≥3 kinase inhibitors, including imatinib; and
3. As a single agent.

Sprycel® (Dasatinib) Approval Criteria [Soft Tissue Sarcoma – Gastrointestinal Stromal Tumors (GIST) Diagnosis]:

1. Diagnosis of soft tissue sarcoma – GIST; and
2. Used for gross residual disease (R2 resection), unresectable primary disease, tumor rupture, or recurrent/metastatic disease; and
3. Used as second-line therapy as single agent; and
4. Member has progressive disease after treatment with avapritinib; and
5. PDGFRA exon 18 mutations that are insensitive to imatinib (including D842V).

Stivarga® (Regorafenib) Approval Criteria [Gastrointestinal Stromal Tumor (GIST) Diagnosis]:

1. Diagnosis of locally advanced unresectable or metastatic GIST; and
2. Previously treated with imatinib and sunitinib.

Tasigna® (Nilotinib) Approval Criteria [Soft Tissue Sarcoma – Gastrointestinal Stromal Tumors (GIST) Diagnosis]:

1. Diagnosis of soft tissue sarcoma – GIST; and
2. Used as single agent for gross residual disease (R2 resection), unresectable primary disease, tumor rupture, or recurrent/metastatic disease; and
3. Member must have progressive disease and failed imatinib, sunitinib, regorafenib, and standard dose ripretinib.

Tevimbra® (Tislelizumab-jsgr) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) Diagnosis]:

1. Diagnosis of unresectable or metastatic ESCC; and
2. Used in 1 of the following settings:
    a. Used after disease progression on prior systemic chemotherapy; and
        i. Member has not previously failed other programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitors; and
        ii. Used as a single agent; or
    b. Used as first-line treatment; and
        i. Tumor expresses PD-L1 ≥1%; and
        ii. Used in combination with platinum-containing chemotherapy.

Tevimbra® (Tislelizumab-jsgr) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of unresectable or metastatic gastric or GEJ adenocarcinoma; and
2. Used in the first-line setting in combination with platinum and fluoropyrimidine-based chemotherapy; and
3. Human epidermal receptor 2 (HER2)-negative disease; and
4. Tumor expresses programmed death ligand 1 (PD-L1) ≥1%.

Vyloy® (Zolbetuximab-clzb) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. Claudin (CLDN) 18.2 positive (defined as ≥75% of tumor cells demonstrating moderate to strong membranous CLDN18 immunohistochemical staining); and
4. Used for first-line treatment; and
5. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; and
6. Member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug required according to package labeling.

Yervoy® (Ipilimumab) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic ESCC; and
    a. Used in the first-line setting; and
    b. Used in combination with nivolumab.

Ziihera® (Zanidatamab-hrii) Approval Criteria [Biliary Tract Cancer (BTC) Diagnosis]:

1. Diagnosis of unresectable or metastatic BTC; and
2. Human epidermal growth factor receptor 2 (HER2)-positive immunohistochemistry (IHC) 3+; and
3. Used for subsequent-line therapy; and
4. As a single agent.

Oncology Medications Additional Criteria:

1. Approvals for oncology medications will be for the duration of 6 months unless otherwise specified in a particular medication's approval criteria; and
    a. Unless otherwise specified in a medication's approval criteria, continuation requests will be approved for the duration of 6

months if there is no evidence of disease progression or adverse drug reactions; and

2. The following situations require the request to be reviewed by a board-certified oncology pharmacist (BCOP) or plan-contracted oncologist or other oncology physician:
   a. Any request for an oncology medication which does not meet approval criteria; or
   b. Any continuation request if the member has evidence of disease progression or adverse drug reactions while on the requested medication; or
   c. Any level-1 appeal request for an oncology medication; or
   d. Any peer-to-peer request for an oncology medication.

Utilization of GI Cancer Medications: Fiscal Year 2025

The following utilization data includes medications indicated for GI cancer; however, the data does not differentiate between GI cancer diagnoses and other diagnoses, for which use may be appropriate.

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	0	0	$0.00	$0.00	$0.00	0	0
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	1	2	$48,686.74	$24,343.37	$869.41	280	56
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**1**	**2**	**$48,686.74**	**$24,343.37**	**$869.41**	**280**	**56**
Fiscal Year 2025							
FFS	2	7	$223,291.87	$31,898.84	$1,220.17	162	183
Aetna	1	1	$38,940.41	$38,940.41	$1,298.01	30	30
Humana	1	10	$246,353.54	$24,635.35	$879.83	1,400	280
OCH	0	0	$0.00	$0.00	$0.00	0	0
2025 Total	**4**	**18**	**$508,585.82**	**$28,254.77**	**$1,031.61**	**1,592**	**493**
% Change	**300.00%**	**800.00%**	**944.60%**	**16.10%**	**18.70%**	**468.60%**	**780.40%**
Change	**3**	**16**	**$459,899.08**	**$3,911.40**	**$162.20**	**1,312**	**437**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Comparison of Fiscal Years: Medical Claims (All Plans)

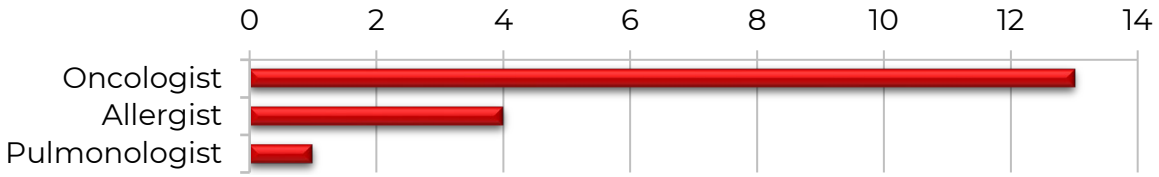
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	23	177	$864,286.95	$4,882.98	7.7
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	1	3	$20,954.00	$6,984.67	3
2024 Total	**23**	**180**	**$885,240.95**	**$4,918.01**	**7.83**
Fiscal Year 2025					
FFS	4	54	$188,780.20	$3,495.93	13.5
Aetna	3	18	$86,082.08	$4,782.34	6
Humana	2	3	$14,229.20	$4,743.07	1.5
OCH	2	4	$33,406.80	$8,351.70	2
2025 Total	**11**	**79**	**$322,498.28**	**$4,082.26**	**7.18**
% Change	**-52.17%**	**-56.11%**	**-63.57%**	**-16.99%**	**-8.30%**
Change	**-12**	**-101**	**-$562,742.67**	**-$835.75**	**-0.65**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing GI Cancer Medications: Pharmacy Claims (All Plans)

- Due to the limited number of members utilizing GI cancer medications during fiscal year 2025, detailed demographic information could not be provided.

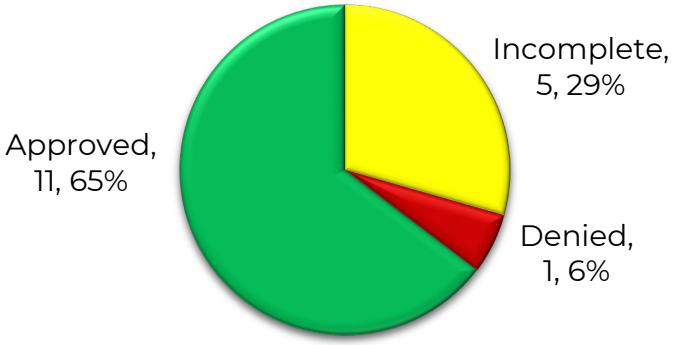
Top Prescriber Specialties of GI Cancer Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of GI Cancer Medications

There were 17 prior authorization requests submitted for GI cancer medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	9	64%	5	36%	0	0%	**14**
Aetna	0	N/A	0	N/A	0	N/A	**0**
Humana	2	100%	0	0%	0	0%	**2**
OCH	0	0%	0	0%	1	100%	**1**
Total	**11**	**65%**	**5**	**29%**	**1**	**6%**	**17**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health

Market News and Updates[1,2]

Anticipated Patent or Exclusivity Expiration(s):

- Lytgobi® (futibatinib): November 2039
- Pemazyre® (pemigatinib): August 2040
- Ayvakit® (avapritinib): March 2042
- Qinlock® (ripretinib): October 2042

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for hepatocellular carcinoma (HCC) allow for the use of tislelizumab-jsgr as first-line systemic therapy.

Recommendations

The College of Pharmacy recommends updating the Tevimbra® (tislelizumab-jsgr) approval criteria based on NCCN recommendations with the following criteria (shown in red):

Tevimbra® (Tislelizumab-jsgr) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of HCC; and
2. Used in 1 of the following settings:
   a. Disease is liver-confined, unresectable, and member is ineligible for transplant; or
   b. Disease is extrahepatic/metastatic and member is ineligible for resection, transplant, or locoregional therapy; and
3. Used as first-line systemic therapy; and
4. As a single agent.

Utilization Details of GI Cancer Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FUTIBATINIB PRODUCTS						
LYTGOBI TAB 4MG	10	1	$246,353.54	$24,635.35	10	48.44%
AVAPRITINIB PRODUCTS						
AYVAKIT TAB 25MG	5	2	$202,318.05	$40,463.61	2.5	39.78%
PEMIGATINIB PRODUCTS						
PEMAZYRE TAB 13.5MG	3	1	$59,914.23	$19,971.41	3	11.78%
TOTAL	**18**	**4***	**$508,585.82**	**$28,254.77**	**4.5**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9308 RAMUCIRUMAB INJ	79	11	$322,498.28	$4,082.26	7.18
TOTAL	**79**	**11**	**$322,498.28**	**$4,082.26**	**7.18**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 12/2025. Last accessed 12/11/2025.
[2] National Comprehensive Cancer Network (NCCN). Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Last revised 10/22/2025. Last accessed 12/30/2025.

Appendix I

Fiscal Year 2025 Annual Review of Non-Malignant Solid Tumor Medications and 30-Day Notice to Prior Authorize Gomekli® (Mirdametinib), Papzimeos™ (Zopapogene Imadenovec-drba), and Romvimza™ (Vimseltinib)

Oklahoma Health Care Authority
January 2026

Current Prior Authorization Criteria

Hyftor® (Sirolimus Topical Gel) Approval Criteria [Facial Angiofibromas Associated with Tuberous Sclerosis Complex (TSC) Diagnosis]:

1. Documented diagnosis of TSC; and
2. Member has facial angiofibromas that are at least 2mm in diameter with redness in each; and
3. Member must be 6 to 20 years of age; or
    a. For members older than 20 years of age, a clinical exception may apply for medical issues caused by facial angiofibromas (specific documentation of clinically significant medical issues must be provided; Hyftor® is not covered for cosmetic use); and
4. Initial approvals will be for a duration of 12 weeks, as the need for continuing Hyftor® should be reevaluated if symptoms do not improve within 12 weeks of treatment. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and documents the anticipated duration of treatment.

Koselugo® (Selumetinib) Approval Criteria [Neurofibromatosis Type 1 (NF1) Diagnosis]:

1. Diagnosis of NF1 with symptomatic, inoperable plexiform neurofibromas; and
2. Member must be 2 years of age or older.

Ogsiveo® (Nirogacestat) Approval Criteria [Desmoid Tumor Diagnosis]:

1. Diagnosis of desmoid tumor; and
2. Tumor is progressing, requiring systemic treatment; and
3. As a single agent.

Turalio® (Pexidartinib) Approval Criteria [Soft Tissue Sarcoma – Pigmented Villonodular Synovitis (PVNS)/Tenosynovial Giant Cell Tumor (TGCT) Diagnosis]:

1. Member must not be a candidate for surgery; and
2. As a single agent.

Oncology Medications Additional Criteria:

1. Approvals for oncology medications will be for the duration of 6 months unless otherwise specified in a particular medication's approval criteria; and
    a. Unless otherwise specified in a medication's approval criteria, continuation requests will be approved for the duration of 6 months if there is no evidence of disease progression or adverse drug reactions; and
2. The following situations require the request to be reviewed by a board-certified oncology pharmacist (BCOP) or plan-contracted oncologist or other oncology physician:
    a. Any request for an oncology medication which does not meet approval criteria; or
    b. Any continuation request if the member has evidence of disease progression or adverse drug reactions while on the requested medication; or
    c. Any level-1 appeal request for an oncology medication; or
    d. Any peer-to-peer request for an oncology medication.

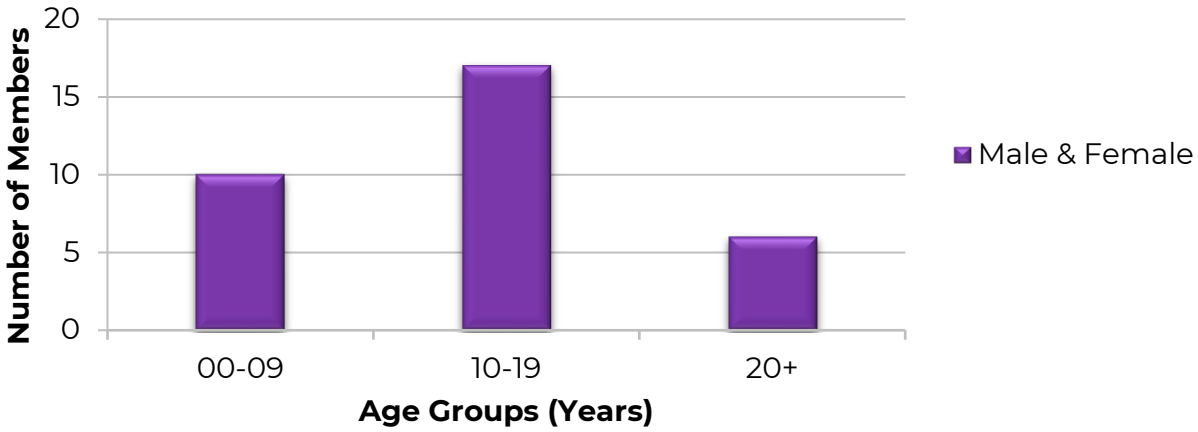
Utilization of Non-Malignant Solid Tumor Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

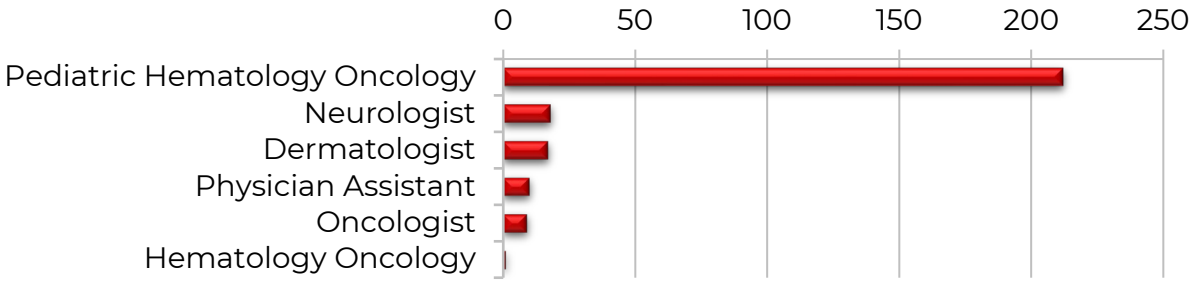
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	32	222	$2,445,873.88	$11,017.45	$383.37	20,012	6,380
Aetna	4	9	$119,945.84	$13,327.32	$487.58	1,138	246
Humana	1	2	$19,728.66	$9,864.33	$328.81	120	60
OCH	9	26	$322,199.98	$12,392.31	$453.80	2,570	710
2024 Total	**34**	**259**	**$2,907,748.36**	**$11,226.83**	**$393.15**	**23,840**	**7,396**
Fiscal Year 2025							
FFS	18	113	$1,488,242.24	$13,170.29	$459.19	8,562	3,241
Aetna	6	39	$551,525.07	$14,141.67	$479.17	3,680	1,151
Humana	4	27	$268,147.94	$9,931.41	$331.87	1,842	808
OCH	11	88	$1,456,339.59	$16,549.31	$563.16	8,352	2,586
2025 Total	**33**	**267**	**$3,764,254.84**	**$14,098.33**	**$483.46**	**22,436**	**7,786**
% Change	**-2.90%**	**3.10%**	**29.50%**	**25.60%**	**23.00%**	**-5.90%**	**5.30%**
Change	**-1**	**8**	**$856,506.48**	**$2,871.50**	**$90.31**	**-1,404**	**390**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing Non-Malignant Solid Tumor Medications: Pharmacy Claims (All Plans)



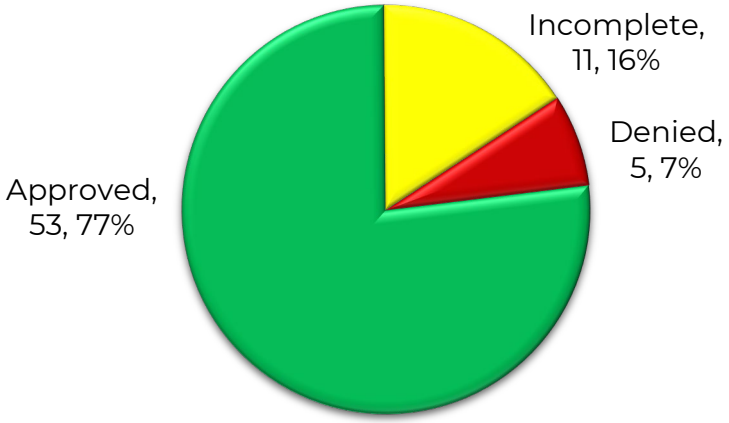
Top Prescriber Specialties of Non-Malignant Solid Tumor Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Non-Malignant Solid Tumor Medications

There were 69 prior authorization requests submitted for non-malignant solid tumor medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	37	74%	10	20%	3	6%	**50**
Aetna	2	50%	1	25%	1	25%	**4**
Humana	4	100%	0	0%	0	0%	**4**
OCH	10	91%	0	0%	1	9%	**11**
Total	**53**	**77%**	**11**	**16%**	**5**	**7%**	**69**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5,6]

Anticipated Patent or Exclusivity Expiration(s):

- Hyftor® (sirolimus gel): March 2029
- Koselugo® (selumetinib): March 2029
- Turalio® (pexidartinib): July 2038
- Ogsiveo® (nirogacestat): May 2043
- Gomekli® (mirdametinib): October 2044
- Romvimza™ (vimseltinib): December 2044

New U.S. Food and Drug Administration (FDA) Approval(s):

- **February 2025:** The FDA approved Gomekli® (mirdametinib) for the treatment of adult and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas not amenable to complete resection.
- **February 2025:** The FDA approved Romvimza™ (vimseltinib) for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.
- **August 2025:** The FDA approved Papzimeos™ (zopapogene imadenovec-drba) for the treatment of adults with recurrent respiratory papillomatosis.
- **September 2025:** The FDA approved Koselugo® (selumetinib) for an age expansion for the treatment of pediatric patients 1 year of age and older with NF1 who have symptomatic, inoperable plexiform neurofibromas. Previously, Koselugo® was FDA approved for this indication in patients 2 years of age or older. Additionally, the FDA approved a new oral granule formulation of Koselugo® for use in patients who have difficulty swallowing whole capsules. The oral granules are available in 5mg and 7.5mg strengths and are contained within capsules that can be opened and mixed with a small amount of smooth yogurt or fruit puree containing apple, banana, pear, or strawberry prior to consuming.
- **November 2025:** The FDA approved Koselugo® (selumetinib) for a new indication for the treatment of adults with NF1 who have symptomatic,

inoperable plexiform neurofibromas. Previously, Koselugo® was only FDA approved for pediatric patients with this indication.

Gomekli® (Mirdametinib) Product Summary[7]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult and pediatric patients 2 years of age and older with NF1 who have symptomatic plexiform neurofibromas not amenable to complete resection

How Supplied:
- Capsules: 1mg and 2mg
- Tablets for oral suspension: 1mg

Dosing and Administration:
- The recommended dose is 2mg/m^2 orally twice daily (approximately every 12 hours) with or without food for the first 21 days of each 28-day cycle.
- The maximum dose is 4mg twice daily.
- Treatment should be continued until disease progression or unacceptable toxicity.
- The capsules should be swallowed whole and should not be opened, broken, or chewed. The tablets can be swallowed whole or can be dispersed in drinking water and administered orally as a liquid.

Cost: The Wholesale Acquisition Cost (WAC) is $206.25 for each 1mg capsule/tablet or $412.50 for each 2mg capsule. For a member using the maximum recommended dose of 4mg twice daily for the first 21 days of each 28-day cycle, this would result in an estimated cost of $34,650 per 28-day cycle or $450,450 per year.

Papzimeos™ (Zopapogene Imadenovec-drba) Product Summary[8]

Therapeutic Class: Non-replicating adenoviral vector-based immunotherapy

Indication(s): Treatment of adults with recurrent respiratory papillomatosis

How Supplied: Single-dose vial (SDV) containing 5×10^{11} particle units (PU) in an extractable volume of 1mL of suspension

Dosing and Administration:
- The recommended dose is 5×10^{11} PU per injection administered by subcutaneous (sub-Q) injection 4 times over a 12-week interval.
- The second dose should be administered 2 weeks after dose 1, the 3rd dose should be administered 6 weeks after dose 1, and the 4th dose should be administered 12 weeks after dose 1.

- Prior to initial administration, a surgical debulking of visible papilloma should be performed to establish minimal residual disease.
- To maintain minimal residual disease during treatment with Papzimeos™, visible papilloma should be removed, if present, prior to the 3rd and 4th administration of Papzimeos™.

Cost: The WAC is $115,000 per SDV, resulting in an estimated cost of $460,000 for the recommended 4-dose treatment series.

Romvimza™ (Vimseltinib) Product Summary[9]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult patients with symptomatic TGCT for which surgical resection will potentially cause worsening functional limitation or severe morbidity

How Supplied: 14mg, 20mg, and 30mg oral capsules

Dosing and Administration:
- The recommended dose is 30mg orally taken twice weekly, with or without food, with a minimum of 72 hours between doses; doses should be taken on the same days each week.
- Dose reductions to 20mg twice weekly or 14mg twice weekly may be needed due to adverse reactions.

Cost: The WAC is $3,266 for each 30mg capsule. For a member using the recommended dose of 30mg twice weekly, this would result in an estimated cost of $26,128 per 28 days or $339,664 per year.

Recommendations

The College of Pharmacy recommends the prior authorization of Gomekli® (mirdametinib), Papzimeos™ (zopapogene imadenovec-drba), and Romvimza™ (vimseltinib) with the following criteria (shown in red):

Gomekli® (Mirdametinib) Approval Criteria [Neurofibromatosis Type 1 (NF1) Diagnosis]:
1. Diagnosis of NF1; and
2. Member must be 2 years of age or older; and
3. Member has symptomatic plexiform neurofibromas not amenable to complete resection; and
4. Member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug required according to package labeling.

Papzimeos™ (Zopapogene Imadenovec-drba) Approval Criteria [Recurrent Respiratory Papillomatosis Diagnosis]:

1. Diagnosis of recurrent respiratory papillomatosis; and
2. Member must be 18 years of age or older; and
3. Initial administration will follow surgical debulking of visible papilloma to maintain minimal residual disease; and
4. Visible papilloma will be removed, if present, prior to the third and fourth administration; and
5. Approvals will be for no more than 4 doses per member per lifetime.

Romvimza™ (Vimseltinib) Approval Criteria [Tenosynovial Giant Cell Tumor (TGCT) Diagnosis]:

1. Diagnosis of TGCT; and
2. Member is 18 years of age or older; and
3. Member is not a candidate for surgical resection.

Additionally, the College of Pharmacy recommends updating the Koselugo® (selumetinib) approval criteria based on recent FDA approvals with the following changes (shown in red):

Koselugo® (Selumetinib) Approval Criteria [Neurofibromatosis Type 1 (NF1) Diagnosis]:

1. Diagnosis of NF1 with symptomatic, inoperable plexiform neurofibromas; and
2. Member must be ~~2 years~~ 1 year of age or older; and
3. Member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug required according to package labeling; and
4. For the 5mg and 7.5mg oral granule formulation, the request must indicate that the member is unable to swallow whole capsules.

Utilization Details of Non-Malignant Solid Tumor Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SELUMETINIB PRODUCTS						
KOSELUGO CAP 10MG	110	16	$1,226,939.42	$11,153.99	6.88	32.59%
KOSELUGO CAP 25MG	91	10	$1,360,150.35	$14,946.71	9.1	36.13%
SUBTOTAL	**201**	**26**	**$2,587,089.77**	**$12,871.09**	**7.73**	**68.73%**
MIRDAMETINIB PRODUCTS						
GOMEKLI CAP 2MG	14	5	$346,659.74	$24,761.41	2.8	9.21%
GOMEKLI CAP 1MG	7	2	$60,717.37	$8,673.91	3.5	1.61%
GOMEKLI TAB 1MG	4	1	$138,645.64	$34,661.41	4	3.68%
SUBTOTAL	**25**	**8**	**$546,022.75**	**$21,840.91**	**3.13**	**14.51%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SIROLIMUS PRODUCTS						
HYFTOR GEL 0.2%	22	7	$76,440.13	$3,474.55	3.14	2.03%
SUBTOTAL	**22**	**7**	**$76,440.13**	**$3,474.55**	**3.14**	**2.03%**
NIROGACESTAT PRODUCTS						
OGSIVEO TAB 150MG	15	4	$438,656.55	$29,243.77	3.75	11.65%
OGSIVEO TAB 50MG	4	1	$116,045.64	$29,011.41	4	3.08%
SUBTOTAL	**19**	**5**	**$554,702.19**	**$29,194.85**	**3.8**	**14.74%**
TOTAL	**267**	**33***	**$3,764,254.84**	**$14,098.33**	**8.09**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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[2] U.S. FDA. FDA Approves Mirdametinib for Adult and Pediatric Patients with Neurofibromatosis Type 1 Who Have Symptomatic Plexiform Neurofibromas Not Amenable to Complete Resection. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-mirdametinib-adult-and-pediatric-patients-neurofibromatosis-type-1-who-have-symptomatic. Issued 02/11/2025. Last accessed 12/16/2025.
[3] U.S. FDA. FDA Approves Vimseltinib for Symptomatic Tenosynovial Giant Cell Tumor. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-vimseltinib-symptomatic-tenosynovial-giant-cell-tumor. Issued 02/14/2025. Last accessed 12/16/2025.
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[6] U.S. FDA. FDA Approves Selumetinib for Adults with Neurofibromatosis Type 1 with Symptomatic, Inoperable Plexiform Neurofibromas. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-selumetinib-adults-neurofibromatosis-type-1-symptomatic-inoperable-plexiform. Issued 11/19/2025. Last accessed 12/16/2025.
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[8] Papzimeos™ (Zopapogene Imadenovec-drba) Prescribing Information. Precigen, Inc. Available online at: https://www.fda.gov/media/188264/download?attachment. Last revised 08/2025. Last accessed 12/16/2025.
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Appendix J

Fiscal Year 2025 Annual Review of Systemic Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) and 30-Day Notice to Prior Authorize Coxanto® (Oxaprozin 300mg Capsule), Ibuprofen 300mg Tablet, Vyscoxa™ (Celecoxib Oral Suspension), and Xifyrm™ (Meloxicam Injection)

Oklahoma Health Care Authority
January 2026

Current Prior Authorization Criteria

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
celecoxib (Celebrex®) caps	diclofenac ER (Voltaren® XR)	celecoxib (Elyxyb®) oral solution
diclofenac potassium (Cataflam®)	diclofenac sodium/ misoprostol (Arthrotec®)	diclofenac epolamine (generic Flector® Patch)
diclofenac sodium (Voltaren®) 50mg & 75mg tabs	diclofenac sodium (Voltaren®) 25mg tabs	diclofenac potassium (Cambia®) powder pack
diclofenac sodium 1% (Voltaren® Gel)	diflunisal 500mg tabs	diclofenac potassium (Lofena™) tabs
etodolac (Lodine®) tabs	etodolac ER (Lodine® XL)	diclofenac potassium (Zipsor®) caps
ibuprofen (Motrin®)	flurbiprofen (Ansaid®)	diclofenac sodium (Pennsaid®) topical drops
indomethacin (Indocin®) caps	indomethacin (Indocin® SR) ER caps	diflunisal (Dolobid™) 250mg and 375mg tabs
meloxicam (Mobic®)	mefenamic acid (Ponstel®)	fenoprofen (Nalfon®)
nabumetone (Relafen®)	naproxen DR (EC-Naprosyn®) 500mg tab	ibuprofen (Caldolor®) inj
naproxen* (Naprosyn®)	naproxen sodium (Anaprox®) 275mg & 550mg tabs	ibuprofen/acetaminophen (Combogesic® IV) inj+
naproxen DR (EC-Naprosyn®) 375mg tab	oxaprozin (Daypro®)	ibuprofen/famotidine (Duexis®)
sulindac (Clinoril®)	piroxicam (Feldene®)	indomethacin (Indocin®) supp & susp
		ketoprofen (Orudis®) caps
		ketoprofen ER (Oruvail®)
		ketorolac tromethamine (Sprix®) nasal spray

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
		meclofenamate (Meclomen®)
		meloxicam (Vivlodex®) caps
		nabumetone 1,000mg (Relafen DS®)
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)
		tolmetin (Tolectin®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Naproxen oral suspension is available without prior authorization for members 12 years of age and younger. Members older than 12 years of age require a reason why a special formulation product is needed in place of the regular tablet formulation.
†Unique criteria applies.
caps = capsules; DR = delayed-release; ER = extended-release; EC = enteric-coated; inj = injection; ODT = orally disintegrating tablet; PA = prior authorization; supp = suppository; susp = suspension; tabs = tablets

NSAIDs Tier-2 Approval Criteria:

1. Previous use of at least 2 Tier-1 NSAID products (from different product lines) plus a proton pump inhibitor (PPI) within the last 120 days.

NSAIDs Special Prior Authorization (PA) Approval Criteria:

1. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or
2. Previous use of at least 2 Tier-1 NSAID products (from different product lines); and
3. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product; and
4. Additionally, use of Dolobid™ (diflunisal) 250mg or 375mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic diflunisal 500mg tablets; and
5. Additionally, use of Elyxyb® (celecoxib oral solution) will require a diagnosis of acute migraine treatment in adults 18 years of age and older and a patient-specific, clinically significant reason why the member cannot use Cambia® (diclofenac potassium powder); and
6. Additionally, use of Lofena™ (diclofenac potassium) will require a patient-specific, clinically significant reason why the member cannot use all other available generic diclofenac products.

Combogesic® IV (Ibuprofen/Acetaminophen Injection) Approval Criteria:

1. An FDA approved indication in members where an intravenous (IV) route of administration is considered clinically necessary for 1 of the following:
    a. Relief of mild-to-moderate pain; or

b. Management of moderate-to-severe pain as an adjunct to opioid analgesics; and

2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member requires IV administration and cannot use Tier-1 oral and/or topical alternatives must be provided; and
4. A quantity limit of 2,000mL (20 vials) per 5 days will apply; and
5. A maximum approval duration of 5 days will apply, as Combogesic® IV is only indicated for short-term use of 5 days or less.

Utilization of NSAIDs: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	107,603	200,037	$2,673,478.00	$13.36	$0.54	9,908,676	4,935,605
Aetna	8,358	11,163	$161,847.13	$14.50	$0.68	485,574	236,283
Humana	9,860	14,045	$206,156.22	$14.68	$0.67	625,415	306,464
OCH	8,573	11,149	$159,526.85	$14.31	$0.69	486,560	232,499
2024 Total	**121,388**	**236,394**	**$3,201,008.20**	**$13.54**	**$0.56**	**11,506,225**	**5,710,851**
Fiscal Year 2025							
FFS	40,241	76,758	$1,040,054.63	$13.55	$0.53	3,791,994	1,974,931
Aetna	24,948	44,980	$640,962.52	$14.25	$0.55	2,262,089	1,169,039
Humana	28,403	59,009	$852,499.96	$14.45	$0.58	2,863,400	1,481,304
OCH	27,161	52,061	$716,075.92	$13.75	$0.65	2,224,350	1,104,266
2025 Total	**114,368**	**232,808**	**$3,249,593.03**	**$13.96**	**$0.57**	**11,141,833**	**5,729,540**
% Change	**-5.80%**	**-1.50%**	**1.50%**	**3.10%**	**1.80%**	**-3.20%**	**0.30%**
Change	**-7,020**	**-3,586**	**$48,584.83**	**$0.42**	**$0.01**	**-364,392**	**18,689**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

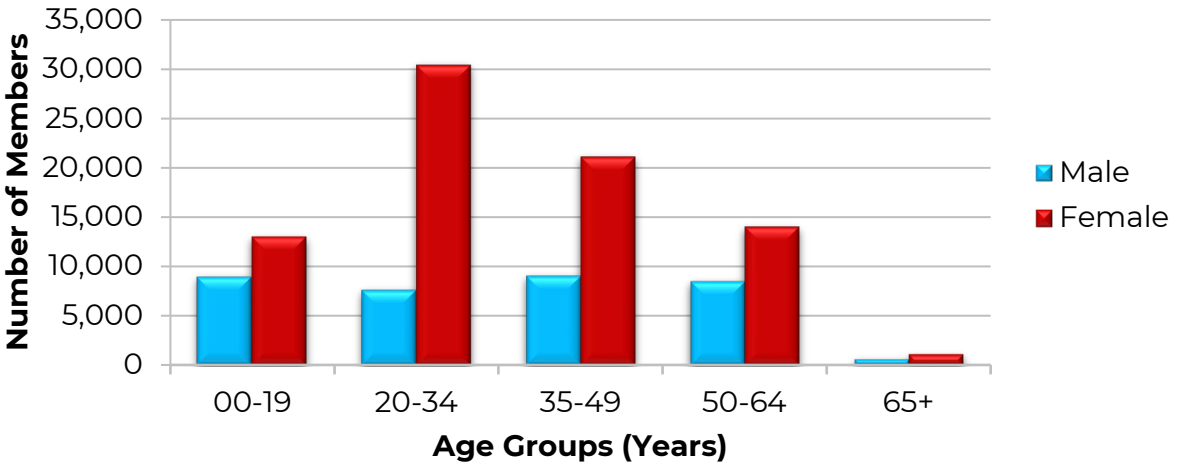
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2025					
FFS	0	0	$0.00	$0.00	0
Aetna	2	2	$17.76	$8.88	1
Humana	1	1	$23.68	$23.68	1
OCH	3	5	$71.04	$14.21	1.67
2025 Total	**6**	**8**	**$112.48**	**$14.06**	**1.33**

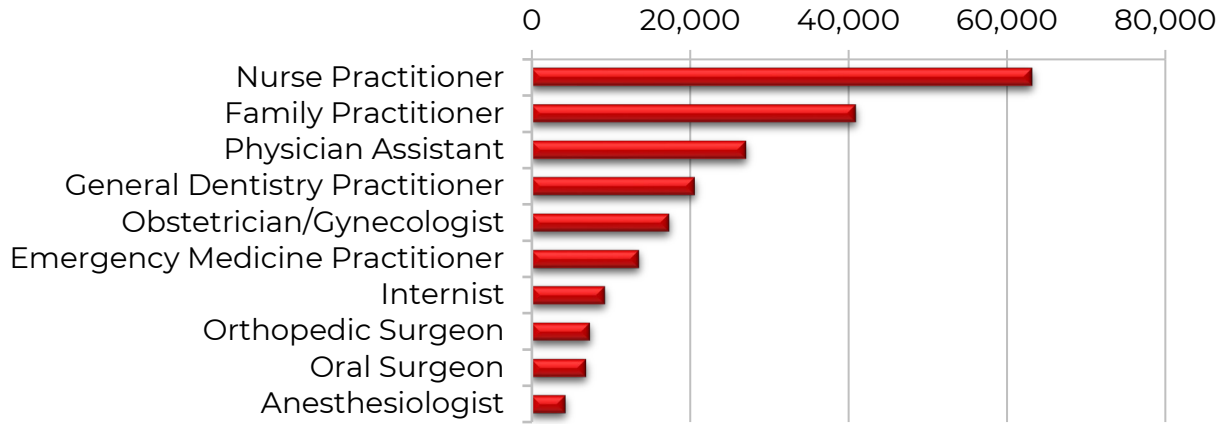
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: There were no paid medical claims during fiscal year 2024 to allow for a fiscal year comparison.

- Aggregate drug rebates collected during fiscal year 2025 for NSAIDs totaled $74,612.82.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing NSAIDs (All Plans)



Top Prescriber Specialties of NSAIDs by Number of Claims (All Plans)

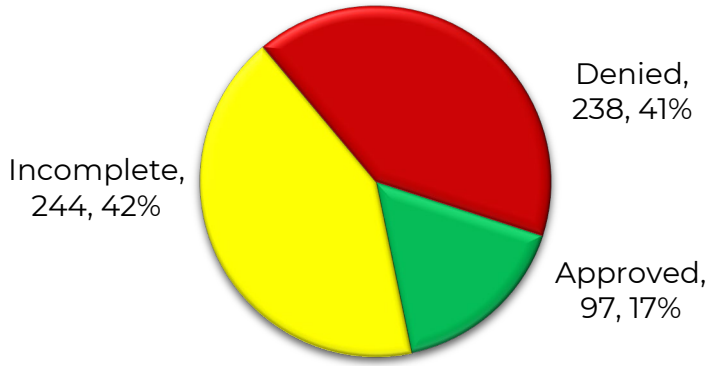


Prior Authorization of NSAIDs

There were 579 prior authorization requests submitted for NSAIDs during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	58	18%	176	55%	88	27%	**322**
Aetna	11	9%	55	44%	59	47%	**125**
Humana	3	9%	0	0%	32	91%	**35**
OCH	25	26%	13	13%	59	61%	**97**
Total	**97**	**17%**	**244**	**42%**	**238**	**41%**	**579**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5]

Anticipated Patent Expiration(s):

- Caldolor® (ibuprofen injection): March 2032
- Combogesic® IV (ibuprofen/acetaminophen injection): January 2036
- Elyxyb® (celecoxib oral solution): May 2036
- Xifyrm™ (meloxicam injection): July 2041

New U.S. Food and Drug Administration (FDA) Approval(s):

- **October 2023:** The FDA approved Coxanto® (oxaprozin 300mg capsule) for the relief of signs and symptoms of osteoarthritis (OA), rheumatoid arthritis (RA), or juvenile rheumatoid arthritis (JRA). Coxanto® has not previously been a covered product through SoonerCare because the manufacturer was not participating with the Medicaid Drug Rebate Program (MDRP) with the Centers for Medicare and Medicaid Services (CMS); however, a new manufacturer began marketing Coxanto® in November 2025, and this manufacturer is participating with the MDRP.
- **June 2025:** The FDA approved Xifyrm™ (meloxicam injection) for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics.
- **July 2025:** The FDA approved Vyscoxa™ (celecoxib oral suspension) for adults with OA, RA, or ankylosing spondylitis (AS) or for pediatric patients 2 years of age and older with JRA.

News:

- **February 2025:** According to the FDA's National Drug Code (NDC) Directory, a new formulation of ibuprofen, available as a 300mg oral tablet, began being marketed in February 2025.

Coxanto® (Oxaprozin 300mg Capsule) Product Summary[6]

Therapeutic Class: NSAID

Indication(s): Relief of signs and symptoms of OA, RA, or JRA

How Supplied: 300mg oral capsule

Dosing and Administration:

- OA: 1,200mg [(4) 300mg capsules] orally once daily
- RA: 1,200mg [(4) 300mg capsules] orally once daily
- JRA: Recommended dose is based on body weight as follows:
  - 22-31kg: 600mg [(2) 300mg capsules] orally once daily
  - 32-54kg: 900mg [(3) 300mg capsules] orally once daily
  - ≥55kg: 1,200mg [(4) 300mg capsules] orally once daily
- The lowest effective dosage should be used for the shortest duration consistent with individual patient treatment goals.

Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Coxanto® (oxaprozin) 300mg capsule	**$42.88**	**$5,145.60**	**$61,747.20**
oxaprozin 600mg tablet (generic)	$0.40	$24.00	$288.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on use of 1,200mg daily
Unit = Each capsule or tablet

Ibuprofen 300mg Tablet Product Summary[7]

Therapeutic Class: NSAID

Indication(s): Relief of the signs and symptoms of RA and OA, for relief of mild to moderate pain, and for the treatment of primary dysmenorrhea

How Supplied: 300mg oral tablets

Dosing and Administration:

- RA and OA: Suggested dosage is 1,200-3,200mg per day (in divided doses, 3-4 times daily)
- Mild to moderate pain or dysmenorrhea: 400mg every 4-6 hours as necessary

Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*	Cost Per Year
ibuprofen 300mg tablet (generic)	**$13.19**	**$3,957.00**	**$47,484.00**
ibuprofen 400mg tablet (generic)	$0.04	$9.60	$115.20
ibuprofen 600mg tablet (generic)	$0.05	$7.50	$90.00
ibuprofen 800mg tablet (generic)	$0.06	$7.20	$86.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on use of up to 3,200mg daily

Vyscoxa™ (Celecoxib Oral Suspension) Product Summary[8]

Therapeutic Class: NSAID

Indication(s): Treatment of adults with OA, RA, or AS or for the treatment of JRA in pediatric patients 2 years of age and older

- **Limitation(s) of Use:** Vyscoxa™ must be administered on an empty stomach at least 2 hours before or 1 hour after food. Taking Vyscoxa™ with food results in plasma exposures of celecoxib up to 50% higher than intended. If patients cannot tolerate Vyscoxa™ in the fasted state, discontinue use of Vyscoxa™.

How Supplied: 10mg/mL unflavored oral suspension in a 473mL bottle

Dosing and Administration:

- OA: 200mg (20mL) once daily or 100mg (10mL) twice daily
- RA: 100mg (10mL) to 200mg (20mL) twice daily
- AS: 200mg (20mL) once daily single dose or 100mg (10mL) twice daily; if no effect is observed after 6 weeks, a trial of 200mg (20mL) twice daily may be of benefit
- JRA: 50mg (5mL) twice daily in patients 10kg to 25kg; 100mg (10mL) twice daily in patients >25kg
- Vyscoxa™ is not recommended at a single dose greater than 200mg (20mL). Single doses of the suspension greater than 200mg may result in celecoxib concentrations higher than intended. For patients who require a single dose over 200mg, a different celecoxib formulation should be used.

Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Vyscoxa™ (celecoxib) 10mg/mL suspension	**$6.12**	**$7,344.00**	**$88,128.00**
celecoxib 200mg capsule (generic)	$0.07	$4.20	$50.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on use of 200mg twice daily
Unit = Each capsule or mL

Xifyrm™ (Meloxicam Injection) Product Summary[9]

Therapeutic Class: NSAID

Indication(s): For use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics

- **Limitation(s) of Use:** Because of delayed onset of analgesia, Xifyrm™ alone is not recommended for use when rapid onset of analgesia is required.

How Supplied: 30mg/mL single-dose vial (SDV)

Dosing and Administration:

- The recommended dose is 30mg once daily, administered by intravenous (IV) bolus injection over 15 seconds.
- Xifyrm™ should be used for the shortest duration consistent with individual patient treatment goals (clinical studies were for a maximum of 3 doses).
- The patient's analgesic response should be monitored and a short-acting, non-NSAID, immediate-release analgesic should be administered if analgesic response is inadequate.
- Patients must be well hydrated before Xifyrm™ administration to reduce the risk of renal toxicity.

Cost Comparison:

Product	Cost Per Unit	Cost Per Day*
Xifyrm™ (meloxicam) 30mg/mL vial	**$30.00**	**$30.00**
meloxicam 15mg tablet (generic)	$0.01	$0.01
meloxicam 7.5mg tablet (generic)	$0.01	$0.01

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per day based on 30mg daily for Xifyrm™ and 1 tablet daily for meloxicam tablets.

Recommendations

The College of Pharmacy recommends the following changes to the NSAIDs Product Based Prior Authorization (PBPA) category based on net costs (changes noted in red in the following PBPA Tier chart and approval criteria):

1. Prior authorization and placement of Coxanto® (oxaprozin 300mg capsule), ibuprofen 300mg tablet, Vyscoxa™ (celecoxib oral suspension), and Xifyrm™ (meloxicam injection) into the Special PA Tier with the additional criteria listed below; and
2. Moving EC-Naprosyn® (naproxen) 375mg tablet from Tier-1 to Tier-2; and
3. Moving Feldene® (piroxicam) from Tier-2 to Tier-1 based on net cost.

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
celecoxib (Celebrex®) caps	diclofenac ER (Voltaren® XR)	celecoxib (Elyxyb®) oral solution
diclofenac potassium (Cataflam®)	diclofenac sodium/ misoprostol (Arthrotec®)	**celecoxib (Vyscoxa™) susp**
diclofenac sodium (Voltaren®) 50mg & 75mg tabs	diclofenac sodium (Voltaren®) 25mg tabs	diclofenac epolamine (generic Flector® Patch)
diclofenac sodium 1% (Voltaren® Gel)	diflunisal 500mg tabs	diclofenac potassium (Cambia®) powder pack
etodolac (Lodine®) tabs	etodolac ER (Lodine® XL)	diclofenac potassium (Lofena™) tabs
ibuprofen (Motrin®) **400mg, 600mg, & 800mg tabs**	flurbiprofen (Ansaid®)	diclofenac potassium (Zipsor®) caps
indomethacin (Indocin®) caps	indomethacin (Indocin® SR) ER caps	diclofenac sodium (Pennsaid®) topical drops
meloxicam (Mobic®)	mefenamic acid (Ponstel®)	diflunisal (Dolobid™) 250mg and 375mg tabs
nabumetone (Relafen®)	naproxen DR (EC-Naprosyn®) ~~**500mg tab**~~	fenoprofen (Nalfon®)
naproxen* (Naprosyn®)	naproxen sodium (Anaprox®) 275mg & 550mg tabs	ibuprofen (Caldolor®) inj
~~**naproxen DR (EC-Naprosyn®) 375mg tab**~~	oxaprozin (Daypro®) **600mg tabs**	**ibuprofen (Motrin®) 300mg tabs**
piroxicam (Feldene®)	~~**piroxicam (Feldene®)**~~	ibuprofen/acetaminophen (Combogesic® IV) inj+
sulindac (Clinoril®)		ibuprofen/famotidine (Duexis®)
		indomethacin (Indocin®) supp & susp
		ketoprofen (Orudis®) caps
		ketoprofen ER (Oruvail®)
		ketorolac tromethamine (Sprix®) nasal spray
		meclofenamate (Meclomen®)
		meloxicam (Vivlodex®) caps
		meloxicam (Xifyrm™) inj+
		nabumetone 1,000mg (Relafen DS®)
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
		oxaprozin (Coxanto®) 300mg caps
		tolmetin (Tolectin®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Naproxen oral suspension is available without prior authorization for members 12 years of age and younger. Members older than 12 years of age require a reason why a special formulation product is needed in place of the regular tablet formulation.
⁺Unique criteria applies.
caps = capsules; DR = delayed-release; ER = extended-release; EC = enteric-coated; inj = injection; ODT = orally disintegrating tablet; PA = prior authorization; supp = suppository; susp = suspension; tabs = tablets

NSAIDs Special Prior Authorization (PA) Approval Criteria:

1. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or
2. Previous use of at least 2 Tier-1 NSAID products (from different product lines); and
3. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product; and
4. Additionally, use of Coxanto® (oxaprozin) 300mg capsule will require a patient-specific, clinically significant reason why the member cannot use generic oxaprozin 600mg tablets, which can be split to achieve the requested dose, must be provided; and
5. Additionally, use of Dolobid™ (diflunisal) 250mg or 375mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic diflunisal 500mg tablets; and
6. Additionally, use of Elyxyb® (celecoxib oral solution) will require a diagnosis of acute migraine treatment in adults 18 years of age and older and a patient-specific, clinically significant reason why the member cannot use Cambia® (diclofenac potassium powder); and
7. Additionally, use of ibuprofen 300mg tablets will require a patient-specific, clinically significant reason why the member cannot use all Tier-1 strengths of ibuprofen tablets and all other lower-tiered NSAIDs; and
8. Additionally, use of Lofena™ (diclofenac potassium) will require a patient-specific, clinically significant reason why the member cannot use all other available generic diclofenac products; and
9. Additionally, use of Vyscoxa™ (celecoxib oral suspension) will require a patient-specific, clinically significant reason why the member cannot use Tier-1 celecoxib capsules, which can be opened and sprinkled on applesauce for members with difficulties swallowing, must be provided.

Xifyrm™ (Meloxicam Injection) Approval Criteria:

1. An FDA approved diagnosis of management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics; and
2. Member must be 18 years of age or older; and
3. Member must be well hydrated before administration to reduce the risk of renal toxicity; and
4. Should be used for the shortest duration consistent with individual patient treatment goals; and
5. A patient-specific, clinically significant reason the member cannot use oral meloxicam tablets or other Tier-1 NSAID products must be provided; and
6. A quantity limit of 3 vials per 3 days will apply; and
7. For consideration of a longer duration of use, a patient-specific, clinically significant reason why the member cannot transition to an oral Tier-1 NSAID product must be provided, along with the anticipated duration of treatment.

Utilization Details of NSAIDs: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
IBUPROFEN PRODUCTS						
IBUPROFEN TAB 800MG	79,455	52,741	$1,065,393.69	$13.41	1.51	32.79%
IBUPROFEN TAB 600MG	17,030	14,747	$204,398.73	$12.00	1.15	6.29%
IBUPROFEN TAB 400MG	2,212	1,704	$31,379.62	$14.19	1.3	0.97%
IBU TAB 800MG	355	255	$5,284.49	$14.89	1.39	0.16%
IBU TAB 600MG	187	160	$2,398.18	$12.82	1.17	0.07%
IBU TAB 400MG	11	11	$130.95	$11.90	1	0.00%
SUBTOTAL	**99,250**	**69,618**	**$1,308,985.66**	**$13.19**	**1.43**	**40.28%**
MELOXICAM PRODUCTS						
MELOXICAM TAB 15MG	40,477	17,460	$463,483.36	$11.45	2.32	14.26%
MELOXICAM TAB 7.5MG	15,292	7,606	$173,167.65	$11.32	2.01	5.33%
SUBTOTAL	**55,769**	**25,066**	**$636,651.01**	**$11.42**	**2.22**	**19.59%**
NAPROXEN PRODUCTS						
NAPROXEN TAB 500MG	24,803	16,432	$309,389.94	$12.47	1.51	9.52%
NAPROXEN TAB 375MG	1,810	1,280	$23,434.06	$12.95	1.41	0.72%
NAPROXEN TAB 250MG	1,566	1,046	$20,231.78	$12.92	1.5	0.62%
NAPROXEN SUS 125MG/5ML	431	247	$34,164.33	$79.27	1.74	1.05%
NAPROXEN DR TAB 375MG	71	51	$1,318.69	$18.57	1.39	0.04%
SUBTOTAL	**28,681**	**19,056**	**$388,538.80**	**$13.55**	**1.51**	**11.96%**
CELECOXIB PRODUCTS						
CELECOXIB CAP 200MG	16,280	5,738	$263,032.41	$16.16	2.84	8.09%
CELECOXIB CAP 100MG	7,241	2,881	$111,487.43	$15.40	2.51	3.43%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CELECOXIB CAP 50MG	292	119	$4,527.96	$15.51	2.45	0.14%
CELECOXIB CAP 400MG	35	25	$866.12	$24.75	1.4	0.03%
CELEBREX CAP 100MG	2	2	$1,170.74	$585.37	1	0.04%
CELEBREX CAP 200MG	2	2	$965.65	$482.83	1	0.03%
SUBTOTAL	**23,852**	**8,767**	**$382,050.31**	**$16.02**	**2.72**	**11.76%**
DICLOFENAC PRODUCTS						
DICLOFENAC TAB 75MG DR	10,704	4,490	$168,495.89	$15.74	2.38	5.19%
DICLOFENAC TAB 50MG DR	3,388	1,676	$52,771.68	$15.58	2.02	1.62%
DICLOFENAC GEL 1%	2,067	1,337	$43,764.86	$21.17	1.55	1.35%
DICLOFENAC POT TAB 50MG	517	279	$9,879.26	$19.11	1.85	0.30%
GNP DICLOFENAC GEL 1%	26	12	$636.65	$24.49	2.17	0.02%
GOODSENSE GEL ART PAIN 1%	3	2	$59.53	$19.84	1.5	0.00%
ART PAIN GEL 1%	2	2	$38.86	$19.43	1	0.00%
SUBTOTAL	**16,707**	**7,798**	**$275,646.73**	**$16.50**	**2.14**	**8.48%**
ETODOLAC PRODUCTS						
ETODOLAC TAB 400MG	1,589	860	$36,646.98	$23.06	1.85	1.13%
ETODOLAC TAB 500MG	762	418	$18,385.26	$24.13	1.82	0.57%
ETODOLAC CAP 300MG	342	310	$5,827.70	$17.04	1.1	0.18%
ETODOLAC CAP 200MG	153	112	$3,663.23	$23.94	1.37	0.11%
SUBTOTAL	**2,846**	**1,700**	**$64,523.17**	**$22.67**	**1.67**	**1.99%**
NABUMETONE PRODUCTS						
NABUMETONE TAB 750MG	1,595	521	$29,085.37	$18.24	3.06	0.90%
NABUMETONE TAB 500MG	1,164	418	$20,559.09	$17.66	2.78	0.63%
SUBTOTAL	**2,759**	**939**	**$49,644.46**	**$17.99**	**2.94**	**1.53%**
INDOMETHACIN PRODUCTS						
INDOMETHACIN CAP 50MG	869	474	$13,327.27	$15.34	1.83	0.41%
INDOMETHACIN CAP 25MG	450	282	$6,784.66	$15.08	1.6	0.21%
SUBTOTAL	**1,319**	**756**	**$20,111.93**	**$15.25**	**1.74**	**0.62%**
SULINDAC PRODUCTS						
SULINDAC TAB 200MG	204	76	$4,700.43	$23.04	2.68	0.14%
SULINDAC TAB 150MG	94	27	$1,835.55	$19.53	3.48	0.06%
SUBTOTAL	**298**	**103**	**$6,535.98**	**$21.93**	**2.89**	**0.20%**
TIER-1 SUBTOTAL	**231,481**	**113,933***	**$3,132,688.05**	**$13.53**	**2.03**	**96.40%**
TIER-2 UTILIZATION						
NAPROXEN PRODUCTS						
NAPROXEN DR TAB 500MG	671	464	$62,700.78	$93.44	1.45	1.93%
NAPROXEN SOD TAB 550MG	118	69	$2,351.08	$19.92	1.71	0.07%
EC-NAPROXEN TAB 500MG	75	60	$5,725.51	$76.34	1.25	0.18%
NAPROXEN SOD TAB 275MG	2	2	$66.22	$33.11	1	0.00%
SUBTOTAL	**866**	**595**	**$70,843.59**	**$81.81**	**1.46**	**2.18%**
DICLOFENAC PRODUCTS						
DICLOFENAC TAB 100MG ER	128	48	$5,249.75	$41.01	2.67	0.16%
DICLOFENAC TAB 25MG DR	49	20	$3,096.68	$63.20	2.45	0.10%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**177**	**68**	**$8,346.43**	**$47.15**	**2.6**	**0.26%**
DICLOFENAC/MISOPROSTOL PRODUCTS						
DICLO/MISOPR TAB 75/0.2MG	55	17	$4,207.01	$76.49	3.24	0.13%
DICLO/MISOPR TAB 50/0.2MG	13	7	$949.18	$73.01	1.86	0.03%
SUBTOTAL	**68**	**24**	**$5,156.19**	**$75.83**	**2.83**	**0.16%**
FLURBIPROFEN PRODUCTS						
FLURBIPROFEN TAB 100MG	34	9	$1,041.04	$30.62	3.78	0.03%
SUBTOTAL	**34**	**9**	**$1,041.04**	**$30.62**	**3.78**	**0.03%**
INDOMETHACIN PRODUCTS						
INDOMETHACIN CAP 75MG ER	27	13	$536.71	$19.88	2.08	0.02%
SUBTOTAL	**27**	**13**	**$536.71**	**$19.88**	**2.08**	**0.02%**
PIROXICAM PRODUCTS						
PIROXICAM CAP 20MG	16	7	$301.38	$18.84	2.29	0.01%
PIROXICAM CAP 10MG	1	1	$21.29	$21.29	1	0.00%
SUBTOTAL	**17**	**8**	**$322.67**	**$18.98**	**2.13**	**0.01%**
ETODOLAC PRODUCTS						
ETODOLAC ER TAB 400MG	11	7	$431.70	$39.25	1.57	0.01%
ETODOLAC ER TAB 600MG	4	3	$173.72	$43.43	1.33	0.01%
ETODOLAC ER TAB 500MG	1	1	$28.60	$28.60	1	0.00%
SUBTOTAL	**16**	**11**	**$634.02**	**$39.63**	**1.45**	**0.02%**
DIFLUNISAL PRODUCTS						
DIFLUNISAL TAB 500MG	15	8	$883.71	$58.91	1.88	0.03%
SUBTOTAL	**15**	**8**	**$883.71**	**$58.91**	**1.88**	**0.03%**
OXAPROZIN PRODUCTS						
OXAPROZIN TAB 600MG	15	6	$682.28	$45.49	2.5	0.02%
SUBTOTAL	**15**	**6**	**$682.28**	**$45.49**	**2.5**	**0.02%**
MEFENAMIC ACID PRODUCTS						
MEFENAMIC ACID CAP 250MG	6	5	$259.42	$43.24	1.2	0.01%
SUBTOTAL	**6**	**5**	**$259.42**	**$43.24**	**1.2**	**0.01%**
TIER-2 SUBTOTAL	**1,241**	**734***	**$88,706.06**	**$71.48**	**1.69**	**2.73%**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION						
DICLOFENAC PRODUCTS						
FLECTOR DIS 1.3%	30	17	$10,359.40	$345.31	1.76	0.32%
DICLOFENAC DIS 1.3%	9	7	$2,146.99	$238.55	1.29	0.07%
DICLOFENAC POW 50MG	6	2	$1,544.35	$257.39	3	0.05%
DICLOFENAC TAB 25MG	4	3	$2,064.88	$516.22	1.33	0.06%
DICLOFENAC SOL 2%	4	3	$696.86	$174.22	1.33	0.02%
DICLOFENAC SOL 1.5%	2	1	$54.04	$27.02	2	0.00%
DICLOFENAC CAP 25MG	1	1	$124.34	$124.34	1	0.00%
SUBTOTAL	**56**	**34**	**$16,990.86**	**$303.41**	**1.65**	**0.52%**
NAPROXEN PRODUCTS						
NAPROXEN SOD TAB 500MG ER	5	4	$2,363.50	$472.70	1.25	0.07%
NAPROXEN SOD TAB 750MG ER	2	1	$1,053.82	$526.91	2	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NAPROXEN SOD TAB 375MG CR	1	1	$341.41	$341.41	1	0.01%
NAPROXEN SOD TAB 375MG ER	1	1	$77.41	$77.41	1	0.00%
SUBTOTAL	**9**	**7**	**$3,836.14**	**$426.24**	**1.29**	**0.12%**
MELOXICAM PRODUCTS						
MELOXICAM CAP 10MG	8	8	$2,476.76	$309.60	1	0.08%
MELOXICAM CAP 5MG	1	1	$273.67	$273.67	1	0.01%
SUBTOTAL	**9**	**9**	**$2,750.43**	**$305.60**	**1**	**0.08%**
IBUPROFEN/FAMOTIDINE PRODUCTS						
IBU/FAMOT TAB 800/26.6MG	7	2	$761.40	$108.77	3.5	0.02%
SUBTOTAL	**7**	**2**	**$761.40**	**$108.77**	**3.5**	**0.02%**
CELECOXIB PRODUCTS						
ELYXYB SOL 120MG/4.8ML	4	2	$3,398.68	$849.67	2	0.10%
SUBTOTAL	**4**	**2**	**$3,398.68**	**$849.67**	**2**	**0.10%**
FENOPROFEN PRODUCTS						
FENOPROFEN CAP 400MG	1	1	$461.41	$461.41	1	0.01%
SUBTOTAL	**1**	**1**	**$461.41**	**$461.41**	**1**	**0.01%**
SPECIAL PA SUBTOTAL	**86**	**51***	**$28,198.92**	**$327.89**	**1.69**	**0.87%**
TOTAL	**232,808**	**114,368***	**$3,249,593.03**	**$13.96**	**2.04**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ART = arthritis; CAP = capsule; CR = controlled-release; DICLO/MISOPR = diclofenac/misoprostol; DIS = patch; DR = delayed-release; EC = enteric-coated; ER = extended-release; IBU/FAMOT = ibuprofen/famotidine; POT = potassium; POW = powder; SOD = sodium; SOL = solution; SUS = suspension; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J1741 IBUPROFEN INJ (CALDOLOR)	8	6	$112.48	$14.06	1.33
TOTAL	**8**	**6**	**$112.48**	**$14.06**	**1.33**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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[9] Xifyrm™ (Meloxicam Injection) Prescribing Information. Azurity Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218395s000lbl.pdf. Last revised 06/2025. Last accessed 12/19/2025.

Appendix K

Fiscal Year 2025 Annual Review of Ophthalmic Antibiotic Medications and 30-day Notice to Prior Authorize Levofloxacin Ophthalmic Solution

Oklahoma Health Care Authority
January 2026

Current Prior Authorization Criteria

Ophthalmic Antibiotic Medications: Liquids		
Tier-1	**Tier-2**	**Tier-3**
azithromycin (Azasite®)	gatifloxacin (Zymaxid®)	
besifloxacin (Besivance®)	neomycin/polymyxin B/ gramicidin (Neosporin®)	
ciprofloxacin (Ciloxan®)	sulfacetamide sodium (Bleph-10®)	
gentamicin (Gentak®)		
moxifloxacin (Vigamox®)		
ofloxacin (Ocuflox®)		
polymyxin B/ trimethoprim (Polytrim®)		
tobramycin (Tobrex®)		

Ophthalmic Antibiotic Medications: Ointments	
Tier-1	**Tier-2**
bacitracin/polymyxin B (AK-Poly-Bac®, Polycin®)	bacitracin (AK-Tracin®)
ciprofloxacin (Ciloxan®)	sodium sulfacetamide (Bleph-10®)
erythromycin (Ilotycin™, Romycin®)	
neomycin/polymyxin B/bacitracin (Neosporin®)	
tobramycin (Tobrex®)	

Ophthalmic Antibiotic/Steroid Combination Products	
Tier-1	**Tier-2**
bacitracin/polymyxin B/neomycin/ hydrocortisone (Neo-Polycin® HC) oint	neomycin/polymyxin B/hydrocortisone (Cortisporin®) susp
neomycin/polymyxin B/ dexamethasone (Maxitrol®) oint & susp	
sulfacetamide/prednisolone 10%/0.23% solution	
tobramycin/dexamethasone 0.3%/0.1% (Tobradex®) oint & susp	

tobramycin/dexamethasone 0.3%/0.05% (Tobradex® ST) susp	
tobramycin/loteprednol (Zylet®) susp	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
HC= hydrocortisone; oint= ointment; susp= suspension

Ophthalmic Antibiotic Medications Tier-2 Approval Criteria:

1. An FDA approved indication/suspected infection by an organism not known to be covered by Tier-1 products, or failure of a Tier-1 product; or
2. Known contraindication to all indicated Tier-1 medications; or
3. Prescription written by an optometrist or ophthalmologist; or
4. When requested medication is being used for pre/post-operative prophylaxis.

Ophthalmic Antibiotic Medications Tier-3 Approval Criteria:

1. An FDA approved indication/suspected infection by an organism not known to be covered by Tier-2 products, or failure of a Tier-2 product; or
2. Known contraindication to all indicated Tier-2 medications; or
3. Prescription written by an optometrist or ophthalmologist; or
4. When requested medication is being used for pre/post-operative prophylaxis.

Ophthalmic Antibiotic/Steroid Combination Products Tier-2 Approval Criteria:

1. Prescription written by an optometrist or ophthalmologist; or
2. When requested medication is being used for pre/post-operative prophylaxis.

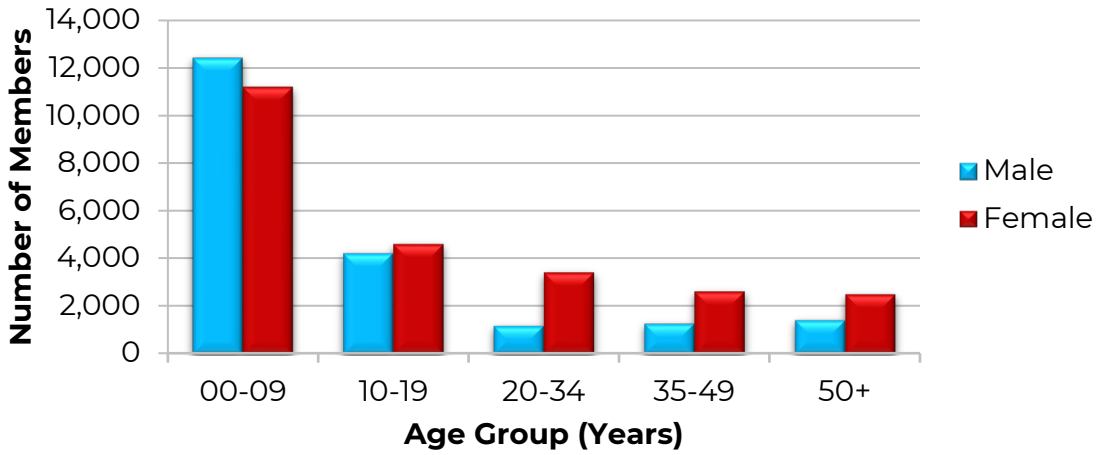
Utilization of Ophthalmic Antibiotic Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

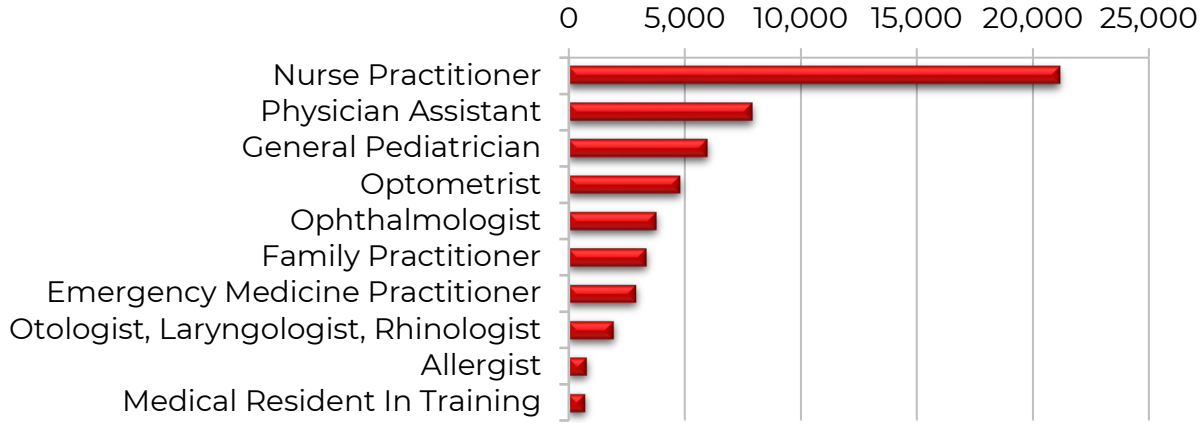
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	41,654	48,680	$936,148.26	$19.23	$1.41	302,903	662,181
Aetna	2,700	2,924	$58,119.10	$19.88	$2.20	18,331	26,449
Humana	2,805	3,105	$64,395.25	$20.74	$1.55	19,409	41,633
OCH	2,731	2,949	$58,689.47	$19.90	$1.52	18,376	38,692
2024 Total	**48,734**	**57,658**	**$1,117,352.08**	**$19.38**	**$1.45**	**359,019**	**768,955**
Fiscal Year 2025							
FFS	13,684	17,162	$328,501.54	$19.14	$1.45	100,823	226,432
Aetna	9,786	11,712	$227,216.77	$19.40	$1.65	71,525	137,656
Humana	9,872	12,001	$231,173.27	$19.26	$1.47	74,180	157,455
OCH	12,027	14,743	$284,041.76	$19.27	$1.53	90,604	185,218
2025 Total	**44,903**	**55,618**	**$1,070,933.34**	**$19.26**	**$1.52**	**337,131**	**706,761**
% Change	**-7.90%**	**-3.50%**	**-4.20%**	**-0.60%**	**4.80%**	**-6.10%**	**-8.10%**
Change	**-3,831**	**-2,040**	**-$46,418.74**	**-$0.12**	**$0.07**	**-21,888**	**-62,194**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing Ophthalmic Antibiotic Medications (All Plans)



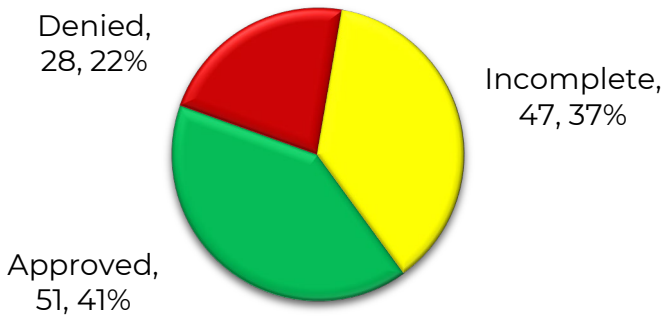
Top Prescriber Specialties of Ophthalmic Antibiotic Medications by Number of Claims (All Plans)



Prior Authorization of Ophthalmic Antibiotic Medications

There were 126 prior authorization requests submitted for ophthalmic antibiotic medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	23	43%	28	52%	3	6%	**54**
Aetna	1	5%	8	38%	12	57%	**21**
Humana	21	70%	0	0%	9	30%	**30**
OCH	6	29%	11	52%	4	19%	**21**
Total	**51**	**41%**	**47**	**37%**	**28**	**22%**	**126**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Tobradex® ST (tobramycin/dexamethasone ophthalmic suspension): August 2028
- Besivance® (besifloxacin ophthalmic suspension): January 2031

News:

- **February 2022:** Levofloxacin ophthalmic solution is an approved generic of the brand name product, Quixin® (levofloxacin ophthalmic solution), which is now a discontinued product per the U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. The most recent marketing start date for the generic product was February 2022.

Recommendations

The College of Pharmacy recommends the prior authorization of levofloxacin ophthalmic solution with placement into Tier-2 of the Ophthalmic Antibiotic Medications Product Based Prior Authorization (PBPA) category based on net cost (changes shown in red):

Ophthalmic Antibiotic Medications: Liquids		
Tier-1	**Tier-2**	**Tier-3**
azithromycin (Azasite®)	gatifloxacin (Zymaxid®)	
besifloxacin (Besivance®)	levofloxacin (Quixin®)	
ciprofloxacin (Ciloxan®)	neomycin/polymyxin B/ gramicidin (Neosporin®)	
gentamicin (Gentak®)	sulfacetamide sodium (Bleph-10®)	
moxifloxacin (Vigamox®)		
ofloxacin (Ocuflox®)		
polymyxin B/ trimethoprim (Polytrim®)		
tobramycin (Tobrex®)		

Ophthalmic Antibiotic Medications: Ointments	
Tier-1	**Tier-2**
bacitracin/polymyxin B (AK-Poly-Bac®, Polycin®)	bacitracin (AK-Tracin®)
ciprofloxacin (Ciloxan®)	sodium sulfacetamide (Bleph-10®)
erythromycin (Ilotycin™, Romycin®)	
neomycin/polymyxin B/bacitracin (Neosporin®)	
tobramycin (Tobrex®)	

Ophthalmic Antibiotic/Steroid Combination Products	
Tier-1	**Tier-2**
bacitracin/polymyxin B/neomycin/ hydrocortisone (Neo-Polycin® HC) oint	neomycin/polymyxin B/hydrocortisone (Cortisporin®) susp
neomycin/polymyxin B/ dexamethasone (Maxitrol®) oint & susp	
sulfacetamide/prednisolone 10%/0.23% solution	
tobramycin/dexamethasone 0.3%/0.1% (Tobradex®) oint & susp	
tobramycin/dexamethasone 0.3%/0.05% (Tobradex® ST) susp	
tobramycin/loteprednol (Zylet®) susp	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
HC= hydrocortisone; oint= ointment; susp= suspension

Utilization Details of Ophthalmic Antibiotic Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OPHTHALMIC ANTIBIOTIC LIQUIDS						
TIER-1 PRODUCTS						
OFLOXACIN DRO 0.3% OP	17,623	15,057	$356,571.06	$20.23	1.17	33.30%
POLY B/TRIMETH SOL	9,593	9,221	$126,992.05	$13.24	1.04	11.86%
CIPROFLOXACIN SOL 0.3% OP	4,602	4,046	$84,448.20	$18.35	1.14	7.89%
TOBRAMYCIN SOL 0.3% OP	2,477	2,330	$32,324.13	$13.05	1.06	3.02%
GENTAMICIN SOL 0.3% OP	1,503	1,411	$22,880.29	$15.22	1.07	2.14%
MOXIFLOXACIN SOL HCL 0.5%	1,254	918	$21,333.04	$17.01	1.37	1.99%
MOXIFLOXACIN SOL 0.5%	69	49	$1,188.11	$17.22	1.41	0.11%
BESIVANCE SUS 0.6%	64	54	$15,376.49	$240.26	1.19	1.44%
AZASITE SOL 1%	9	9	$2,319.46	$257.72	1	0.22%
OCUFLOX DRO 0.3% OP	2	2	$270.94	$135.47	1	0.03%
TIER-1 SUBTOTAL	**37,196**	**33,097**	**$663,703.77**	**$17.84**	**1.12**	**61.97%**
TIER-2 PRODUCTS						
SULFACET SOD SOL 10% OP	280	268	$10,826.09	$38.66	1.04	1.01%
GATIFLOXACIN SOL 0.5%	31	23	$1,211.12	$39.07	1.35	0.11%
NEO/POLY/GRAM SOL OP	21	21	$963.15	$45.86	1	0.09%
TIER-2 SUBTOTAL	**332**	**312**	**$13,000.36**	**$39.16**	**1.06**	**1.21%**
LIQUID SUBTOTAL	**37,528**	**33,409**	**$676,704.13**	**$18.03**	**1.12**	**63.19%**
OPHTHALMIC ANTIBIOTIC OINTMENTS						
TIER-1 PRODUCTS						
ERYTHROMYCIN OIN 5MG/GM	11,152	10,086	$201,644.63	$18.08	1.11	18.83%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BAC/POLY OIN OP	105	90	$2,128.81	$20.27	1.17	0.20%
TOBREX OIN 0.3% OP	40	31	$10,495.41	$262.39	1.29	0.98%
NEO/BAC/POLY OIN OP	28	27	$855.22	$30.54	1.04	0.08%
CILOXAN OIN 0.3% OP	6	6	$1,658.31	$276.39	1	0.15%
TIER-1 SUBTOTAL	**11,331**	**10,240**	**$216,782.38**	**$19.13**	**1.11**	**20.24%**
TIER-2 PRODUCTS						
BACITRACIN OIN 500U/GM OP	3	3	$331.90	$110.63	1	0.03%
TIER-2 SUBTOTAL	**3**	**3**	**$331.90**	**$110.63**	**1**	**0.03%**
OINTMENT SUBTOTAL	**11,334**	**10,243**	**$217,114.28**	**$19.16**	**1.11**	**20.27%**
OPHTHALMIC ANTIBIOTIC/STEROID COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
NEO/POLY/DEX SUS 0.1% OP	4,480	4,084	$89,845.34	$20.05	1.1	8.39%
TOBRA/DEX SUS 0.3-0.1% OP	1,115	1,014	$32,019.00	$28.72	1.1	2.99%
NEO/POLY/DEX OIN 0.1% OP	1,006	861	$20,268.73	$20.15	1.17	1.89%
TOBRADEX ST SUS 0.3-0.05%	61	55	$15,115.73	$247.80	1.11	1.41%
TOBRADEX OIN 0.3-0.1% OP	30	26	$8,260.30	$275.34	1.15	0.77%
SULFACET/PRED NA SOL 0.25% OP	19	16	$450.73	$23.72	1.19	0.04%
ZYLET SUS 0.5-0.3%	17	14	$6,605.87	$388.58	1.21	0.62%
TOBRADEX SUS 0.3-0.1%	8	8	$1,921.66	$240.21	1	0.18%
MAXITROL OIN 0.1% OP	3	3	$708.90	$236.30	1	0.07%
NEO/POLY/BAC OIN/HC 1% OP	3	3	$97.78	$32.59	1	0.01%
MAXITROL SUS 0.1% OP	1	1	$127.27	$127.27	1	0.01%
TIER-1 SUBTOTAL	**6,743**	**6,085**	**$175,421.31**	**$26.02**	**1.11**	**16.38%**
TIER-2 PRODUCTS						
NEO/POLY/HC SUS OP	13	13	$1,693.62	$130.28	1	0.16%
SUBTOTAL	**13**	**13**	**$1,693.62**	**$130.28**	**1**	**0.16%**
COMBINATION SUBTOTAL	**6,756**	**6,098**	**$177,114.93**	**$26.22**	**1.11**	**16.54%**
TOTAL	**55,618**	**44,903***	**$1,070,933.34**	**$19.26**	**1.24**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
BAC = bacitracin; DEX = dexamethasone; DRO = drops; GRAM = gramicidin; HC = hydrocortisone; HCL = hydrochloride; NA = sodium; NEO = neomycin; OIN = ointment; OP = ophthalmic; POLY = polymyxin; PRED = prednisolone; SOD = sodium; SOL = solution; ST = suspension technology; SULFACET = sulfacetamide; SUS = suspension; TOBRA = tobramycin; TRIMETH = trimethoprim; U = unit
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2025. Last Accessed 12/29/2025.
[2] U.S. FDA. National Drug Code Directory. Available online at: https://dps.fda.gov/ndc. Last revised 12/17/2025. Last accessed 12/29/2025.

Appendix L

Fiscal Year 2025 Annual Review of Vasomotor Symptom (VMS) Medications and 30-Day Notice to Prior Authorize EstroGel® (Estradiol 0.06% Gel) and Lynkuet™ (Elinzanetant)

Oklahoma Health Care Authority
January 2026

Current Prior Authorization Criteria

Bijuva® (Estradiol/Progesterone Capsule) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms due to menopause in women with an intact uterus; and
2. A patient-specific, clinically significant reason why the member cannot use all other available estrogen/progestin products indicated for vasomotor symptoms of menopause must be provided; and
3. A quantity limit of 30 capsules (1 pack) per 30 days will apply.

Brisdelle® (Paroxetine Mesylate 7.5mg) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms associated with menopause; and
2. Approvals for Brisdelle® will not be granted for psychiatric indications; and
3. Members must not have any of the contraindications for use of Brisdelle®; and
4. Two previous trials with either a selective serotonin reuptake inhibitor (SSRI) or a selective serotonin norepinephrine reuptake inhibitor (SNRI) or both, or a patient-specific, clinically significant reason why a SSRI or SNRI is not appropriate for the member must be provided; and
5. Authorization requires a patient-specific, clinically significant reason why paroxetine 10mg is not appropriate for the member; and
6. A quantity limit of 30 capsules per 30 days will apply.

Duavee® (Conjugated Estrogens/Bazedoxifene) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms associated with menopause or for prevention of postmenopausal osteoporosis; and
2. Member must be a female with an intact uterus; and
3. For the treatment of moderate-to-severe vasomotor symptoms associated with menopause:
    a. Member must have at least 7 moderate-to-severe hot flushes per day or at least 50 per week prior to treatment; and

4. For the prevention of postmenopausal osteoporosis:
    a. A trial of Fosamax® (alendronate), Actonel® (risedronate), Boniva® (ibandronate), or Reclast® (zoledronic acid) used compliantly for at least 6 months concomitantly with calcium and vitamin D, that failed to prevent fracture or improve bone mineral density (BMD) scores; or
    b. Contraindication to, hypersensitivity to, or intolerable adverse effects with all bisphosphonates indicated for prevention of postmenopausal osteoporosis; and
5. Member must not have any of the contraindications for use of Duavee®; and
6. Members older than 65 years of age will generally not be approved without supporting information; and
7. Approvals will be for the duration of 6 months to ensure the need for continued therapy is reassessed periodically and the medication is being used for the shortest duration possible; and
8. A quantity limit of 30 tablets per 30 days will apply.

Veozah® (Fezolinetant) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe vasomotor symptoms (VMS) due to menopause; and
2. Member must not use CYP1A2 inhibitors (e.g., cimetidine, ciprofloxacin, ethinyl estradiol, fluvoxamine, mexiletine) concomitantly with Veozah®; and
3. Member must not have a history of severe renal impairment, end-stage renal disease, or cirrhosis; and
4. Prescriber must verify baseline renal function and member must have an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2; and
5. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to the initiation of Veozah®, every 3 months for the first 9 months of treatment, and as clinically indicated thereafter; and
6. A patient-specific, clinically significant reason why the member cannot use menopausal hormone therapy must be provided; and
7. A patient-specific, clinically significant reason why the member cannot use other guideline supported non-hormonal therapy for VMS (e.g., gabapentin, paroxetine, venlafaxine) must be provided; and
8. A quantity limit of 30 tablets per 30 days will apply.

Utilization of VMS Medications: Fiscal Year 2025

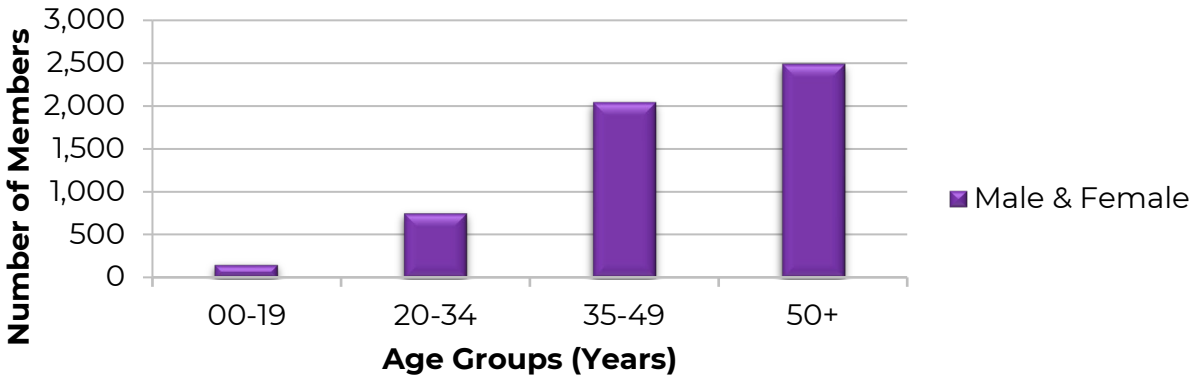
Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	4,749	15,952	$1,223,238.66	$76.68	$1.69	705,964	723,405
Aetna	601	1,139	$74,054.45	$65.02	$2.23	32,785	33,193
Humana	782	1,595	$99,999.90	$62.70	$2.03	44,806	49,198
OCH	615	1,089	$69,960.00	$64.24	$2.20	30,563	31,804
2024 Total	**5,226**	**19,775**	**$1,467,253.01**	**$74.20**	**$1.75**	**814,118**	**837,600**
Fiscal Year 2025							
FFS	2,095	5,781	$524,786.19	$90.78	$1.97	244,623	266,189
Aetna	1,300	4,835	$357,711.82	$73.98	$1.78	183,378	200,407
Humana	1,598	7,330	$502,185.29	$68.51	$1.84	264,807	273,261
OCH	1,249	5,581	$317,362.55	$56.86	$1.94	156,309	163,997
2025 Total	**5,423**	**23,527**	**$1,702,045.85**	**$72.34**	**$1.88**	**849,117**	**903,854**
% Change	**3.80%**	**19.00%**	**16.00%**	**-2.50%**	**7.40%**	**4.30%**	**7.90%**
Change	**197**	**3,752**	**$234,792.84**	**-$1.86**	**$0.13**	**34,999**	**66,254**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

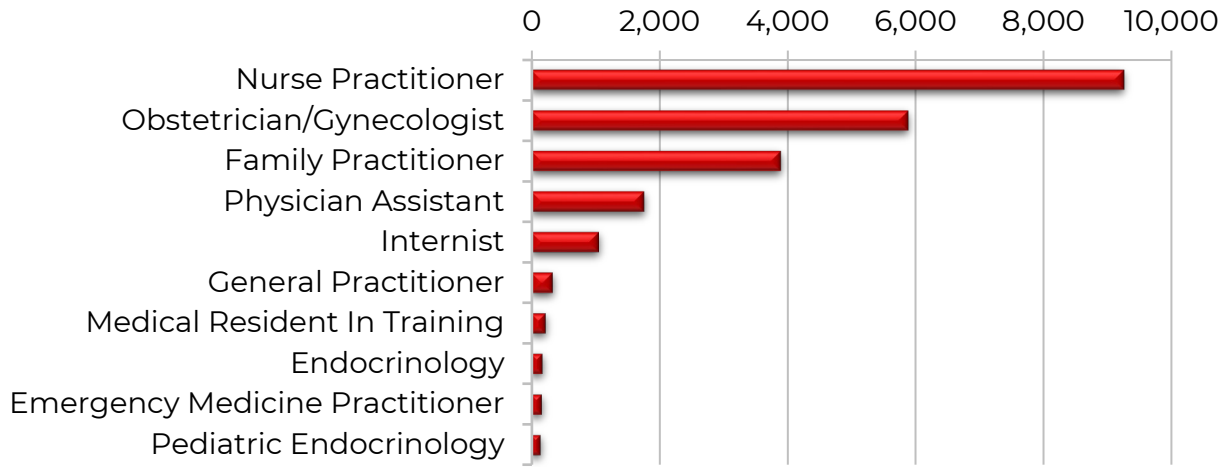
- Aggregate drug rebates collected during fiscal year 2025 for VMS medications totaled $1,195,335.72.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing VMS Medications (All Plans)



[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

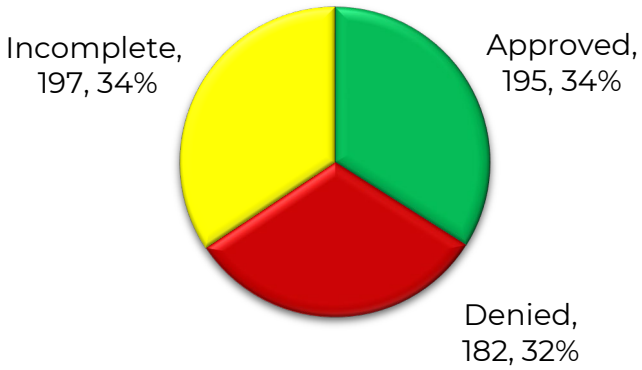
Top Prescriber Specialties of VMS Medications by Number of Claims (All Plans)



Prior Authorization of VMS Medications

There were 574 prior authorization requests submitted for VMS medications during fiscal year 2025. The following chart shows the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	120	35%	156	46%	63	19%	**339**
Aetna	40	41%	35	36%	23	23%	**98**
Humana	19	31%	0	0%	43	69%	**62**
OCH	16	21%	6	8%	53	71%	**75**
Total	**195**	**34%**	**197**	**34%**	**182**	**32%**	**574**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,34,5,6,7]

Anticipated Patent Expiration(s):

- Duavee® (conjugated estrogens/bazedoxifene tablet): March 2027
- Brisdelle® (paroxetine capsule): April 2029
- Minivelle® (estradiol transdermal system): July 2030
- Angeliq® (drospirenone/estradiol tablet): October 2031
- Bijuva® (estradiol/progesterone capsule): November 2032
- Veozah® (fezolinetant): March 2034
- Lynkuet® (elinzanetant): March 2039

New U.S. Food and Drug Administration (FDA) Approval(s):

- **April 2024:** Solaris Pharma Corporation received FDA approval for an Abbreviated New Drug Application (ANDA) for estradiol 0.06% gel, a generic version of EstroGel® which was first approved in 2004. Currently, the manufacturer of the brand name product does not have a federal drug rebate agreement; therefore, it is not covered by SoonerCare.
- **October 2024:** Novitium Pharma received FDA approval for an Abbreviated New Drug Application (ANDA) for estradiol 0.06% gel, a generic version of EstroGel® which was first approved in 2004. Currently, the brand name does not have a federal drug rebate; therefore, it is not covered by SoonerCare.
- **December 2024:** The FDA added a *Boxed Warning* to Veozah® (elinzanetant) to highlight the risk of a rare, but serious liver injury associated with Veozah®. The warning included updates to the timing of hepatic monitoring, counseling for signs/symptoms of hepatic injury, and when to discontinue therapy.
- **October 2025:** The FDA approved Lynkuet® (elinzanetant) for the treatment of moderate to severe VMS due to menopause.
- **November 2025:** The FDA initiated the removal of the *Boxed Warning* from menopausal hormone replacement therapy products following a comprehensive review of scientific literature, an expert panel that met in July, and a public comment period. The FDA specifically recommended updating the labeling to remove references to risks of cardiovascular disease, breast cancer, and probable dementia. However, the FDA is not seeking to remove the *Boxed Warning* for endometrial cancer for systemic estrogen-alone products.

EstroGel® (Estradiol 0.06% Gel) Product Summary[8]

Therapeutic Class: Estrogen

Indication(s):

- Treatment of moderate to severe VMS due to menopause

- Treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause
    - Limitation of Use: When prescribing solely for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause, consideration should be given to the use of topical vaginal products first.

How Supplied: Transdermal gel with 1 pump depression of delivering 1.25g of gel containing 0.75mg of estradiol

Dosing and Administration:

- The recommended dose is 1 pump (1.25g) per day for both indications.
- The recommended area of application is the arm, and the gel should be applied in a thin layer over the entire arm on the inside and outside from wrist to shoulder.

Efficacy:

- The efficacy of EstroGel® on VMS in postmenopausal women was studied in a placebo-controlled trial in 145 postmenopausal women who were randomly assigned to receive 1.25g of EstroGel® or placebo for 12 weeks. The results showed a statistically significant reduction in the frequency and severity of moderate to severe hot flushes per day (treatment difference versus placebo of 1.71, P=0.043).

Lynkuet™ (Elinzanetant) Product Summary[9,10]

Therapeutic Class: Neurokinin 1 (NK1) and Neurokinin 3 (NK3) receptor antagonist

Indication(s): Treatment of moderate to severe VMS due to menopause

How Supplied: 60mg capsule

Dosing and Administration:

- The recommended dose is 120mg (two 60mg capsules) orally once daily at bedtime with or without food.
- Capsules should be swallowed whole. The capsules should not be cut, crushed, or chewed.
- See full *Prescribing Information* for dosage modifications due to drug interactions.

Efficacy: The efficacy of Lynkuet® was evaluated in 2 randomized, double-blind, placebo-controlled, multicenter clinical trials (OASIS 1 & OASIS 2).

- Key Inclusion Criteria:
    - Postmenopausal women 40 to 65 years of age
    - Experiencing ≥50 moderate to severe VMS over 7 days during the screening

- Intervention: Randomized 1:1 to receive Lynkuet® or placebo.
  - After 12 weeks, women on placebo were switched over to Lynkuet® for a 14-week extension for up to 26 weeks total exposure.
- Primary Outcome: Mean change in frequency and severity of moderate to severe VMS from baseline to weeks 4 and 12, including day and night hot flashes measured using the Hot Flash Daily Diary (HFDD)
- Results:
  - OASIS 1:
    - Change from baseline to week 4:
      - Least squared (LS)-Means [Standard Error (SE)] in Lynkuet® treated group: -7.60 (0.43) versus -4.31 (0.43) in the placebo group
      - Treatment difference of -3.29 versus placebo [95% confidence interval (CI): -4.47, -2.10, P<0.0001]
    - Change from baseline to week 12:
      - LS-Means (SE) in Lynkuet® treated group: -8.66 (0.58) versus -5.44 (0.59) in the placebo group
      - Treatment difference of -3.22 versus placebo (95% CI: -4.81, -1.63, P<0.0001)
  - OASIS 2:
    - Change from baseline to week 4:
      - LS-Means (SE) in Lynkuet® treated group: -8.58 (0.49) versus -5.54 (0.49) in the placebo group
      - Treatment difference of -3.04 versus placebo (95% CI: -4.40, -1.68, P<0.0001)
    - Change from baseline to week 12:
      - LS-Means (SE) in Lynkuet® treated group: -9.72 (0.50) versus -6.48 (0.49) in the placebo group
      - Treatment difference of -3.24 versus placebo (95% CI: -4.60, -1.88, P<0.0001)

Cost Comparison: Menopausal Hormone Therapy

Product	Cost Per Unit	Cost Per Month	Cost Per Year
estradiol 0.06% gel pump (generic EstroGel®)	**$3.49**	**130.88^{\lambda}$**	**$1,570.50**
estradiol 0.1% gel packet (generic Divigel®)	$1.91	57.30^{\Delta}$	$687.60
estradiol-norethindrone 0.5-0.1mg tablet (generic)	$0.44	$13.20*	$158.40
estradiol 1mg tablet (generic)	$0.06	1.26^{\alpha}$	$16.38

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = gram, packet, or tablet
$^{\lambda}$Cost per month is based on the FDA approved dose of 1 pump (1.25g) per day or 37.5g per month.
$^{\Delta}$Cost per month is based on 1 packet per day.
*Cost per month is based on the FDA approved dose of 1 tablet once daily.
$^{\alpha}$Cost per month is based on the FDA approved dosing of 1mg once daily in a cyclical pattern (3 weeks on, 1 week off)

Cost Comparison: Non-Hormonal Therapy[11]

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Lynkuet™ (elinzanetant) 60mg capsule	**$10.42**	**$625.20**α	**$7,502.40**
Veozah® (fezolinetant) 45mg tablet	$18.08	$542.40*	$6,508.80
venlafaxine 75mg ER capsule (generic)	$0.09	$2.70+	$32.40
gabapentin 300mg capsule (generic)	$0.03	$2.70β	$32.40
paroxetine 10mg tablet (generic)	$0.06	$1.80+	$21.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ER = extended-release; Unit = capsule or tablet
αCost per month is based on the FDA approved 120mg once daily dose.
*Cost per month is based on the FDA approved 45mg daily dose.
+Cost per month is based on the North American Menopause Society (NAMS) Nonhormone Therapy Position Statement 2023 recommended dosing for each product administered once daily.
βCost per month is based on the NAMS guideline recommended dosing of 300mg three times daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Lynkuet® (elinzanetant) with the following criteria (shown in red):

Lynkuet® (Elinzanetant) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms (VMS) due to menopause; and
2. Prescriber must verify the following:
    a. Member will not use strong CYP3A4 inhibitors (e.g., clarithromycin, grapefruit juice, itraconazole, ketoconazole) or moderate/strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort) concomitantly with Lynkuet®; and
    b. Liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be assessed prior to the initiation of Lynkuet®, and member will not start treatment with Lynkuet® if labs are ≥2 times the upper limit of normal; and
    c. Follow-up evaluations of LFTs will be done 3 months after initiation of therapy; and
3. A patient-specific, clinically significant reason why the member cannot use menopausal hormone therapy must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use other guideline supported non-hormonal therapy for VMS (e.g., gabapentin, paroxetine, venlafaxine) must be provided; and
5. A quantity limit of 60 capsules per 30 days will apply.

The College of Pharmacy also recommends updating the approval criteria for Veozah® (fezolinetant) based on the FDA approved label updates (changes shown in red):

Veozah® (Fezolinetant) Approval Criteria:

1. An FDA approved ~~diagnosis~~ indication for the treatment of moderate-to-severe vasomotor symptoms (VMS) due to menopause; and
2. Prescriber must verify the following:
    a. Member ~~must~~ will not use CYP1A2 inhibitors (e.g., cimetidine, ciprofloxacin, ethinyl estradiol, fluvoxamine, mexiletine) concomitantly with Veozah®; and
    b. Member ~~must~~ does not have a history of severe renal impairment, end-stage renal disease, or cirrhosis; and
    c. ~~Prescriber must verify~~ ~~b~~Baseline renal function has been assessed and member ~~must have~~ has an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2; and
    ~~d. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to the initiation of Veozah®, every 3 months for the first 9 months of treatment, and as clinically indicated thereafter; and~~
    e. Liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be assessed prior to the initiation of Veozah®, and member will not start treatment with Veozah® if labs are ≥2 times the upper limit of normal; and
    f. Follow up evaluations of LFTs will be done monthly for the first 3 months of treatment, then at 6 months, and 9 months of treatment, and as clinically indicated thereafter; and
    g. Member will be counseled to discontinue Veozah® immediately and seek medical attention if they experience signs or symptoms that may suggest liver injury (i.e., new onset fatigue, nausea, vomiting, pruritus, jaundice, pale feces, dark urine, or right upper quadrant pain); and
3. A patient-specific, clinically significant reason why the member cannot use menopausal hormone therapy must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use other guideline supported non-hormonal therapy for VMS (e.g., gabapentin, paroxetine, venlafaxine) must be provided; and
5. A quantity limit of 30 tablets per 30 days will apply.

Finally, the College of Pharmacy recommends the prior authorization of EstroGel® (estradiol 0.06% gel) with the following criteria based on net cost (shown in red):

EstroGel® (Estradiol 0.06% Gel) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of moderate to severe vasomotor symptoms due to menopause; or
   b. Treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause; and
2. Member must not have any contraindications for use of EstroGel®; and
3. A patient-specific, clinically significant reason why other topical estradiol formulations (e.g., Divigel®) are not appropriate for the member must be provided; and
4. Members older than 65 years of age will generally not be approved without supporting information; and
5. Approvals will be for the duration of 6 months to ensure the need for continued therapy is reassessed periodically and the medication is being used for the shortest duration possible; and
6. A quantity limit of 37.5 grams per 30 days will apply.

Utilization Details of VMS Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ORAL ESTROGEN PRODUCTS						
ESTRADIOL TAB 1MG	5,894	1,630	$72,186.66	$12.25	3.62	4.24%
ESTRADIOL TAB 2MG	4,591	1,126	$76,223.72	$16.60	4.08	4.48%
ESTRADIOL TAB 0.5MG	2,416	786	$30,676.20	$12.70	3.07	1.80%
PREMARIN TAB 0.625MG	531	127	$167,012.26	$314.52	4.18	9.81%
PREMARIN TAB 1.25MG	328	82	$107,748.34	$328.50	4	6.33%
PREMARIN TAB 0.3MG	292	78	$83,384.66	$285.56	3.74	4.90%
PREMARIN TAB 0.9MG	89	18	$25,980.64	$291.92	4.94	1.53%
PREMARIN TAB 0.45MG	50	18	$12,638.49	$252.77	2.78	0.74%
MENEST TAB 0.625MG	12	3	$1,088.80	$90.73	4	0.06%
MENEST TAB 0.3MG	10	3	$853.08	$85.31	3.33	0.05%
MENEST TAB 1.25MG	1	1	$230.08	$230.08	1	0.01%
SUBTOTAL	**14,214**	**3,872**	**$578,022.93**	**$40.67**	**3.67**	**33.96%**
TOPICAL ESTROGEN PRODUCTS						
DOTTI DIS 0.1MG	777	179	$51,905.39	$66.80	4.34	3.05%
ESTRADIOL DIS 0.1MG BIWEEKLY	641	160	$41,118.09	$64.15	4.01	2.42%
ESTRADIOL DIS 0.1MG WEEKLY	588	148	$32,169.62	$54.71	3.97	1.89%
ESTRADIOL DIS 0.05MG WEEKLY	553	146	$34,823.97	$62.97	3.79	2.05%
DOTTI DIS 0.05MG	514	139	$32,306.14	$62.85	3.7	1.90%
ESTRADIOL DIS 0.05MG BIWEEKLY	480	150	$29,139.24	$60.71	3.2	1.71%
ESTRADIOL DIS 0.025MG WEEKLY	469	135	$24,245.91	$51.70	3.47	1.42%
ESTRADIOL DIS 0.025MG BIWEEKLY	249	82	$14,691.75	$59.00	3.04	0.86%
DOTTI DIS 0.025MG	225	68	$13,274.42	$59.00	3.31	0.78%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DOTTI DIS 0.075MG	225	61	$13,089.41	$58.18	3.69	0.77%
DOTTI DIS 0.0375MG	223	66	$13,941.99	$62.52	3.38	0.82%
ESTRADIOL GEL 1MG/GM	204	56	$16,378.78	$80.29	3.64	0.96%
ESTRADIOL DIS 0.0375MG BIWEEKLY	201	66	$12,304.88	$61.22	3.05	0.72%
ESTRADIOL DIS 0.075MG BIWEEKLY	178	47	$10,682.83	$60.02	3.79	0.63%
ESTRADIOL DIS 0.0375MG WEEKLY	155	46	$8,519.04	$54.96	3.37	0.50%
ESTRADIOL DIS 0.075MG WEEKLY	138	42	$7,828.53	$56.73	3.29	0.46%
ESTRADIOL GEL 0.5MG	116	42	$8,222.00	$70.88	2.76	0.48%
ESTRADIOL GEL 0.75MG	94	25	$6,824.59	$72.60	3.76	0.40%
LYLLANA DIS 0.05MG	92	36	$5,202.00	$56.54	2.56	0.31%
ESTRADIOL GEL 0.06%	72	25	$10,038.98	$139.43	2.88	0.59%
ESTRADIOL DIS 0.06MG WEEKLY	66	16	$3,267.44	$49.51	4.13	0.19%
ESTRADIOL GEL 1.25MG	64	19	$5,064.68	$79.14	3.37	0.30%
ESTRADIOL GEL 0.25MG	48	20	$3,766.57	$78.47	2.4	0.22%
LYLLANA DIS 0.075MG	47	14	$2,822.41	$60.05	3.36	0.17%
EVAMIST SPR 1.53MG	34	9	$5,111.06	$150.33	3.78	0.30%
LYLLANA DIS 0.0375MG	23	11	$1,455.98	$63.30	2.09	0.09%
LYLLANA DIS 0.025MG	20	10	$1,197.14	$59.86	2	0.07%
LYLLANA DIS 0.1MG	17	10	$1,049.71	$61.75	1.7	0.06%
MINIVELLE DIS 0.1MG	15	1	$2,894.17	$192.94	15	0.17%
VIVELLE-DOT DIS 0.025MG	11	1	$1,802.61	$163.87	11	0.11%
MENOSTAR DIS 14MCG	10	2	$1,674.32	$167.43	5	0.10%
CLIMARA DIS 0.06MG	7	1	$561.88	$80.27	7	0.03%
VIVELLE-DOT DIS 0.1MG	7	4	$1,116.59	$159.51	1.75	0.07%
DIVIGEL GEL 0.5MG	6	2	$1,038.91	$173.15	3	0.06%
DIVIGEL GEL 1.25MG	4	2	$609.41	$152.35	2	0.04%
DIVIGEL GEL 1MG/GM	3	3	$518.53	$172.84	1	0.03%
ELESTRIN GEL 0.06%	3	2	$400.30	$133.43	1.5	0.02%
CLIMARA DIS 0.025MG	2	1	$99.28	$49.64	2	0.01%
MINIVELLE DIS 0.05MG	1	1	$233.67	$233.67	1	0.01%
DIVIGEL GEL 0.25MG	1	1	$168.93	$168.93	1	0.01%
VIVELLE-DOT DIS 0.0375MG	1	1	$165.17	$165.17	1	0.01%
SUBTOTAL	**6,584**	**1,850**	**$421,726.32**	**$64.05**	**3.56**	**24.78%**
ORAL ESTROGEN/PROGESTIN PRODUCTS						
PREMPRO TAB 0.3-1.5MG	310	81	$89,520.28	$288.78	3.83	5.26%
PREMPRO TAB 0.625-2.5MG	227	49	$74,456.38	$328.00	4.63	4.37%
ESTRA/NORETH TAB 1-0.5MG	173	41	$5,663.23	$32.74	4.22	0.33%
PREMPRO TAB 0.45-1.5MG	93	26	$30,718.89	$330.31	3.58	1.80%
ESTRA/NORETH TAB 0.5-0.1MG	81	22	$2,544.21	$31.41	3.68	0.15%
PREMPRO TAB 0.625-5MG	50	15	$16,994.91	$339.90	3.33	1.00%
FYAVOLV TAB 0.5-2.5MCG	47	12	$2,370.13	$50.43	3.92	0.14%
MIMVEY TAB 1-0.5MG	39	16	$1,532.56	$39.30	2.44	0.09%
NORETH/ETHIN TAB 1MG-5MCG	37	20	$2,272.76	$61.43	1.85	0.13%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ANGELIQ TAB 0.5-1MG	33	6	$9,638.44	$292.07	5.5	0.57%
ANGELIQ TAB 0.25-0.5MG	31	9	$7,732.33	$249.43	3.44	0.45%
NORETH/ETHIN TAB 0.5-2.5MCG	27	13	$1,447.71	$53.62	2.08	0.09%
PREMPHASE TAB 0.625-5MG	10	1	$2,459.01	$245.90	10	0.14%
BIJUVA CAP 0.5-100MG	7	3	$1,850.93	$264.42	2.33	0.11%
BIJUVA CAP 1-100MG	7	6	$2,273.60	$324.80	1.17	0.13%
FYAVOLV TAB 1MG-5MCG	6	4	$309.75	$51.63	1.5	0.02%
JINTELI TAB 1MG-5MCG	3	3	$118.24	$39.41	1	0.01%
SUBTOTAL	**1,181**	**327**	**$251,903**	**$213.30**	**3.61**	**14.80%**
INJECTABLE ESTROGEN PRODUCTS						
ESTRADIOL VAL INJ 20MG/ML	432	182	$44,471.73	$102.94	2.37	2.61%
DEPO-ESTRADIOL INJ 5MG/ML	114	56	$24,356.08	$213.65	2.04	1.43%
ESTRADIOL VAL INJ 40MG/ML	56	21	$9,147.93	$163.36	2.67	0.54%
ESTRADIOL VAL INJ 10MG/ML	48	16	$4,472.70	$93.18	3	0.26%
DELESTROGEN INJ 10MG/ML	9	3	$1,220.47	$135.61	3	0.07%
SUBTOTAL	**659**	**278**	**$83,668.91**	**$126.96**	**2.37**	**4.92%**
TOPICAL ESTROGEN/PROGESTIN PRODUCTS						
COMBIPATCH DIS 0.05-0.14MG/DAY	200	60	$51,181.08	$255.91	3.33	3.01%
CLIMARA PRO DIS 0.045-0.015MG/DAY	193	60	$48,370.14	$250.62	3.22	2.84%
COMBIPATCH DIS 0.05-0.25MG/DAY	49	16	$12,196.38	$248.91	3.06	0.72%
SUBTOTAL	**442**	**136**	**$111,747.60**	**$252.82**	**3.25**	**6.57%**
FEZOLINETANT PRODUCTS						
VEOZAH TAB 45MG	387	110	$211,781.31	$547.24	3.52	12.44%
SUBTOTAL	**387**	**110**	**$211,781.31**	**$547.24**	**3.52**	**12.44%**
VAGINAL ESTROGEN PRODUCTS						
FEMRING MIS 0.1MG/24H	35	12	$28,668.99	$819.11	2.92	1.68%
FEMRING MIS 0.05MG/24H	18	7	$13,695.33	$760.85	2.57	0.80%
SUBTOTAL	**53**	**19**	**$42,364.32**	**$799.33**	**2.79**	**2.49%**
PAROXETINE PRODUCTS						
PAROXETINE CAP 7.5MG	5	5	$430.75	$86.15	1	0.03%
SUBTOTAL	**5**	**5**	**$430.75**	**$86.15**	**1**	**0.03%**
ORAL ESTROGEN/BAZEDOXIFENE PRODUCTS						
DUAVEE TAB 0.45-20MG	2	1	$400.35	$200.18	2	0.02%
SUBTOTAL	**2**	**1**	**$400.35**	**$200.18**	**2**	**0.02%**
TOTAL	**23,527**	**5,423**	**$1,702,045.85**	**$72.34**	**4.34**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP=capsule; DIS = patch; ESTRA/NORETH = estradiol/norethindrone; INJ = injection; MIS = insert; NORETH/ETHIN = norethindrone/ethinyl estradiol; SPR = spray; TAB = tablet; VAL = valerate
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix M

30-Day Notice to Prior Authorize Alyglo™ [Immune Globulin (IG) Intravenous (IV), Human-stwk], Asceniv™ (IGIV, Human-slra), Bivigam® (IGIV, Human), Cuvitru® (IG Subcutaneous (SC), Human), Gammaplex® (IGIV, Human), Hizentra® (IGSC, Human), Octagam® (IGIV, Human), Panzyga® (IGIV, Human-ifas), and Xembify® (IGSC, human)

Oklahoma Health Care Authority
January 2026

Introduction[1,2,3]

Immune globulin (IG) products intended for intravenous (IV) or subcutaneous (SC) use are immunoglobulins pooled from healthy donors and supplied as concentrated injectable formulations. IGIV and IGSC products provide the recipient with passive immunity against a broad spectrum of antigens, which can be beneficial in the treatment of a plethora of conditions, including immunodeficiencies, auto-immune, and inflammatory disorders.

There are numerous IGIV and IGSC products currently marketed in the United States, that vary regarding inactive ingredients, concentration, osmolality, and other characteristics. While all currently available IGIV and IGSC products in the United States are FDA-approved for primary humoral immunodeficiency (PI), the breadth of FDA-approved indications for each product and concentration differs, and the products are not considered equivalent. However, IGIV and IGSC products are often used off label with the support of clinical literature and clinical practice guidelines recommending product selection based on the preferred route of administration, patient tolerability, excipients, and costs.

Utilization of IGIV and IGSC Products: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	109	1,156	$4,546,241.86	$3,932.74	$158.12	369,018	28,751
Aetna	10	32	$141,617.43	$4,425.54	$157.35	10,630	900
Humana	6	32	$102,339.43	$3,198.11	$117.90	6,260	868
OCH	18	71	$253,049.44	$3,564.08	$170.40	19,444	1,485
2024 Total	**112**	**1,291**	**$5,043,248.16**	**$3,906.47**	**$157.58**	**405,352**	**32,004**
Fiscal Year 2025							
FFS	80	729	$3,540,371.10	$4,856.48	$194.43	269,277	18,209
Aetna	17	151	$765,170.37	$5,067.35	$191.68	57,110	3,992
Humana	14	132	$667,435.41	$5,056.33	$190.10	47,670	3,511
OCH	28	397	$1,211,826.11	$3,052.46	$138.05	91,187	8,778
2025 Total	**128**	**1,409**	**$6,184,802.99**	**$4,389.50**	**$179.32**	**465,244**	**34,490**
% Change	**14.30%**	**9.10%**	**22.60%**	**12.40%**	**13.80%**	**14.80%**	**7.80%**
Change	**16**	**118**	**$1,141,554.83**	**$483.03**	**$21.74**	**59,892**	**2,486**

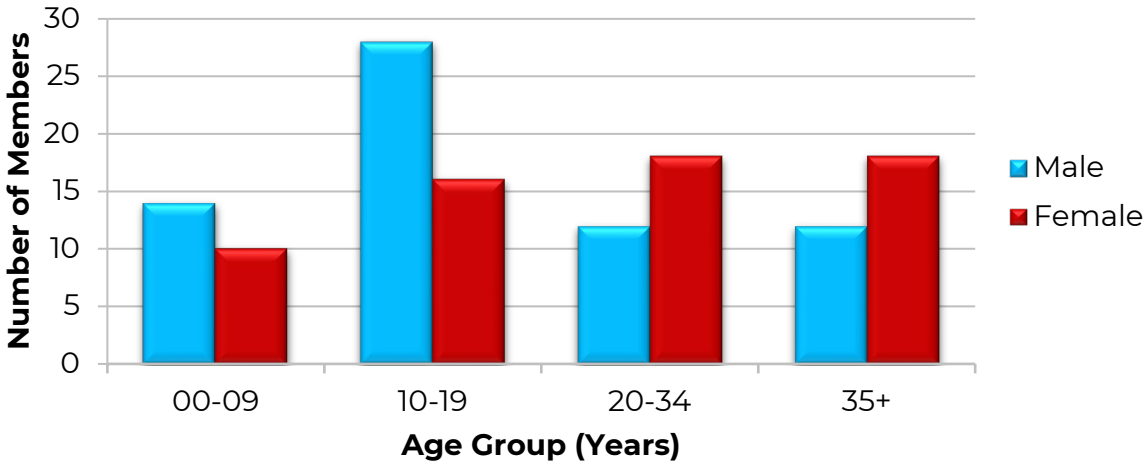
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Comparison of Fiscal Years: Medical Claims (All Plans)

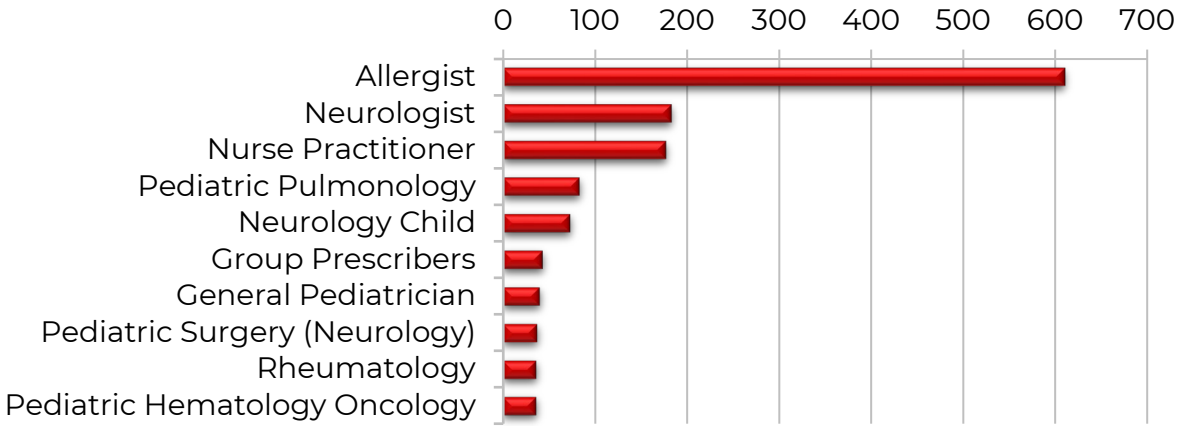
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	140	1520	$3,430,327.86	$2,256.79	10.86
Aetna	0	0	$0.00	$0.00	0
Humana	3	5	$16,011.04	$3,202.21	1.67
OCH	14	38	$110,645.56	$2,911.73	2.71
2024 Total	**143**	**1,563**	**$3,556,984.46**	**$2,275.74**	**10.93**
Fiscal Year 2025					
FFS	102	869	$2,162,254.98	$2,488.21	8.52
Aetna	27	185	$460,157.32	$2,487.34	6.85
Humana	19	175	$439,932.63	$2,513.90	9.21
OCH	39	391	$711,706.88	$1,820.22	10.03
2025 Total	**161**	**1,620**	**$3,774,051.81**	**$2,329.66**	**10.06**
% Change	**18**	**57**	**$217,067.35**	**$53.92**	**-$0.87**
Change	**12.59%**	**3.65%**	**6.10%**	**2.37%**	**-7.94%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing IGIV and IGSC Products: Pharmacy Claims (All Plans)



Top Prescriber Specialties of IGIV and IGSC Products by Number of Claims: Pharmacy Claims (All Plans)



Cost Comparison: IGIV Products

Product	Cost Per Gram	Cost Per Dose*	Cost Per Year⁺
Asceniv™ (IGIV, human-slra) 10%	**$965.40**	**$38,616.00**	**$695,088.00**
Alyglo™ (IGIV, human-stwk) 10%	**$312.90**	**$12,516.00**	**$225,288.00**
Bivigam® (IGIV, human) 10%	**$154.78**	**$6,191.20**	**$111,441.60**
Panzyga® (IGIV, human-ifas) 10%	**$145.99**	**$5,839.60**	**$105,112.80**
Gammaplex® (IGIV, human) 10%	**$127.37**	**$5,094.80**	**$91,706.40**
Octagam® (IGIV, human) 5%	**$95.05**	**$3,802.00**	**$68,436.00**
Gammagard S/D® (IGIV, human) 10g vial	$157.59	$6,303.60	$113,464.80
Privigen® (IGIV, human) 10%	$101.47	$4,058.80	$73,058.40
Gammaked™ (IG inj, human) 10g/100mL	$97.93	$3,917.20	$70,509.60
Gamunex®-C (IG inj, human) 1g/10mL	$97.93	$3,917.20	$70,509.60
Gammagard Liquid® (IG inf, human) 10%	$90.63	$3,625.20	$65,253.60

Costs do not reflect rebated prices or net costs.
Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC), or Specialty Pharmaceutical Allowable Costs (SPAC).
*Cost per dose is based on 500mg/kg, which is the midpoint of the FDA-approved dosing range of 400-600mg/kg for primary immunodeficiency (PI), rounded to the nearest 5 gram for a 75kg patient.
⁺Cost per year is based on IV administration every 3 weeks, which is the shortest interval recommended by the FDA for PI; the cost per year calculation assumes a stable dose (e.g., no titration based on individual patient response or IgG levels).
IGIV = immunoglobulin intravenous; inf =infusion; inj = injection

Cost Comparison: IGSC Products

Product	Cost Per Gram	Cost Per Dose*	Cost Per Year⁺
Xembify® (IGSC, human) 20%	**$197.40**	**$1,974.00**	**$102,648.00**
Cuvitru® (IGSC, human) 20%	**$168.42**	**$1,684.20**	**$87,578.40**
Hizentra® (IGSC, human) 20%	**$143.35**	**$1,433.50**	**$74,542.00**
Cutaquig® (IGSC, human) 16.5%	$127.20	$1,272.00	$66,144.00
Gammaked™ (IG inj, human) 10g/100mL	$97.93	$979.30	$50,923.60
Gamunex®-C (IG inj, human) 1g/10mL	$97.93	$979.30	$50,923.60
Gammagard Liquid® (IG inf, human) 10%	$90.63	$906.30	$47,127.60

Costs do not reflect rebated prices or net costs.
Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC), or Specialty Pharmaceutical Allowable Costs (SPAC).
*Cost per dose is based on the FDA-approved starting dose of 150mg/kg for PI, rounded to the nearest 5 gram, for a 75kg patient.
⁺Cost per year excludes loading doses and is based is SC administration weekly, which is a recommended initiating interval per the FDA; assumes a stable dose (e.g., no titration based on individual patient response or IgG levels).
IGSC= immunoglobulin subcutaneous; inf= infusion; inj = injection

Recommendations

The College of Pharmacy recommends the prior authorization of Alyglo™ (IGIV, human-stwk), Asceniv™ (IGIV, human-slra), Bivigam® (IGIV, human), Cuvitru® (IGSC, human), Gammaplex® (IGIV, human), Hizentra® (IGSC, human), Octagam® (IGIV, human), Panzyga® (IGIV, human-ifas), and Xembify® (IGSC, human) with the following criteria (shown in red):

Alyglo™ [Immune Globulin (IG) Intravenous (IV), Human-stwk], Asceniv™ (IGIV, Human-slra), Bivigam® (IGIV, Human), Cuvitru® [IG Subcutaneous (SC), Human], Gammaplex® (IGIV, Human), Hizentra® (IGSC, Human), Octagam (IGIV, Human), Panzyga® (IGIV, Human-ifas) and Xembify® (IGSC, Human) Approval Criteria:

1. Documentation of prior stabilization on the requested product with documented benefit from therapy (i.e., recent office notes) must be submitted with the request; or
2. For Alyglo™ and Asceniv™, a patient-specific clinically significant reason why the member cannot use all other available immunoglobulin therapy products must be provided; or
3. A patient-specific, clinically significant reason why the member cannot use all of the following, which are available without prior authorization, as appropriate for the requested route of administration:
    a. For intravenous (IV) administration:
        i. Gammagard Liquid® (IG infusion, human); and
        ii. Gammagard S/D® (IGIV, human); and
        iii. Gammaked™ (IG injection, human); and
        iv. Gamunex®-C (IG injection, human); and
        v. Privigen® (IGIV, human); and
    b. For subcutaneous (SC) administration:
        i. Cutaquig® (IGSC, human); and
        ii. Gammagard Liquid® (IG infusion, human); and
        iii. Gammaked™ (IG injection, human); and
        iv. Gamunex®-C (IG injection, human); and
4. Member's recent weight (taken within the last 3 months) utilized for dosing calculations (e.g., actual body weight, ideal body weight, adjusted body weight) and intended dosing frequency must be provided on the prior authorization request in order to authorize the appropriate amount of product; and
5. Initial approvals will be for up to 6 months. Subsequent approval will be for the duration of up to 1 year if there is documentation of clinical effectiveness.

Utilization Details of IGIV and IGSC Products: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GAMUNEX-C INJ 5GM/50ML	112	13	$112,012.36	$1,000.11	8.62	1.81%
GAMUNEX-C INJ 10GM/100ML	100	14	$364,385.76	$3,643.86	7.14	5.89%
GAMMAGARD INJ 30GM/300ML	97	14	$311,397.01	$3,210.28	6.93	5.03%
HIZENTRA SOL 20%	93	13	$227,742.33	$2,448.84	7.15	3.68%
GAMUNEX-C INJ 1GM/10ML	86	8	$31,507.56	$366.37	10.75	0.51%
GAMUNEX-C INJ 20GM/200ML	84	11	$326,220.67	$3,883.58	7.64	5.27%
HIZENTRA INJ 2GM/10ML	69	10	$60,879.21	$882.31	6.9	0.98%
GAMMAGARD INJ 20GM/200ML	65	11	$523,546.13	$8,054.56	5.91	8.47%
GAMMAGARD INJ 10GM/100ML	59	11	$243,910.13	$4,134.07	5.36	3.94%
GAMMAGARD INJ 5GM/50ML	55	12	$77,683.92	$1,412.43	4.58	1.26%
HIZENTRA INJ 10GM/50ML	52	10	$402,984.12	$7,749.69	5.2	6.52%
OCTAGAM INJ 10GM/100ML	40	7	$317,477.86	$7,936.95	5.71	5.13%
XEMBIFY INJ 4GM/20ML	34	8	$140,499.96	$4,132.35	4.25	2.27%
HIZENTRA INJ 4GM/20ML	34	7	$42,467.38	$1,249.04	4.86	0.69%
OCTAGAM INJ 30/300ML	32	5	$261,782.43	$8,180.70	6.4	4.23%
HIZENTRA INJ 1GM/5ML	32	5	$12,188.92	$380.90	6.4	0.20%
XEMBIFY INJ 10GM/50ML	31	8	$321,522.41	$10,371.69	3.88	5.20%
GAMUNEX-C INJ 40GM/400ML	26	5	$897,106.66	$34,504.10	5.2	14.51%
HIZENTRA INJ 2GM/10ML	21	6	$111,036.33	$5,287.44	3.5	1.80%
CUVITRU INJ 2GM/10ML	19	3	$22,367.45	$1,177.23	6.33	0.36%
CUVITRU INJ 8GM/40ML	18	3	$117,206.82	$6,511.49	6	1.90%
OCTAGAM INJ 5GM/50ML	18	3	$60,636.18	$3,368.68	6	0.98%
OCTAGAM INJ 20GM/200ML	16	5	$176,020.92	$11,001.31	3.2	2.85%
CUTAQUIG SOL 1GM	15	2	$164,832.97	$10,988.86	7.5	2.67%
PANZYGA SOL 10GM/100ML	14	2	$63,053.30	$4,503.81	7	1.02%
GAMMAKED INJ 20GM/200ML	13	2	$29,556.93	$2,273.61	6.5	0.48%
GAMMAGARD INJ 2.5GM/25ML	12	1	$11,334.70	$944.56	12	0.18%
HIZENTRA INJ 1GM/5ML	11	3	$3,090.43	$280.95	3.67	0.05%
PANZYGA SOL 5GM/50ML	11	2	$23,805.98	$2,164.18	5.5	0.38%
CUVITRU INJ 4GM/20ML	11	2	$29,573.67	$2,688.52	5.5	0.48%
HIZENTRA INJ 10GM/50ML	10	5	$87,077.90	$8,707.79	2	1.41%
CUTAQUIG SOL 4GM	10	2	$16,736.20	$1,673.62	5	0.27%
XEMBIFY INJ 1GM/5ML	10	4	$11,822.76	$1,182.28	2.5	0.19%
CUVITRU SOL 1GM/5ML	10	2	$3,967.49	$396.75	5	0.06%
GAMMAKED INJ 10GM/100ML	9	2	$19,612.37	$2,179.15	4.5	0.32%
GAMMAPLEX INJ 10%	9	1	$91,676.25	$10,186.25	9	1.48%
GAMMAPLEX INJ 10%	8	3	$91,649.44	$11,456.18	2.67	1.48%
XEMBIFY INJ 2GM/10ML	8	3	$12,368.01	$1,546.00	2.67	0.20%
GAMMAGARD INJ 1GM/10ML	8	3	$8,108.27	$1,013.53	2.67	0.13%
OCTAGAM INJ 2GM/20ML	8	1	$6,337.12	$792.14	8	0.10%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PRIVIGEN INJ 10GM	7	3	$73,853.25	$10,550.46	2.33	1.19%
GAMMAKED INJ 5GM/50ML	7	1	$3,519.47	$502.78	7	0.06%
GAMMAGARD S/D INJ 10GM	7	1	$68,655.07	$9,807.87	7	1.11%
PANZYGA SOL 20GM/200ML	5	2	$21,644.57	$4,328.91	2.5	0.35%
PANZYGA SOL 30GM/300ML	4	3	$16,228.28	$4,057.07	1.33	0.26%
PRIVIGEN INJ 40GM	4	1	$15,555.32	$3,888.83	4	0.25%
GAMMAPLEX INJ 10%	2	1	$20,667.20	$10,333.60	2	0.33%
ASCENIV INJ 10%	1	1	$113,587.81	$113,587.81	1	1.84%
PRIVIGEN INJ 20GM	1	1	$11,497.33	$11,497.33	1	0.19%
GAMMAGARD S/D INJ 5GM	1	1	$2,408.38	$2,408.38	1	0.04%
TOTAL	**1,409**	**128***	**$6,184,802.99**	**$4,389.50**	**11.01**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; SOL = solution
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	+TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
GAMMGARD LIQUID (J1569)	818	63	$2,041,938.84	$2,496.26	12.98
PRIVIGEN (J1459)	458	68	$974,333.05	$2,127.36	6.74
GAMUNEX-C/GAMMAKED (J1561)	302	33	$650,425.49	$2,153.73	9.15
OCTAGAM (J1568)	35	3	$81,631.03	$2,332.32	11.67
XEMBIFY (J1558)	4	1	$1,142.40	$285.60	4
GAMMAGARD S/D (J1566)	3	1	$24,581.00	$8,193.67	3
TOTAL	**1,620**	**161**	**$3,774,051.81**	**$2,329.66**	**10.06**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[1] Arumugham VB, Rayi A. Intravenous Immunoglobulin (IVIG). *StatPearls* [Internet]. Available online at: https://www.ncbi.nlm.nih.gov/books/NBK554446/. Last revised 07/03/2023. Last accessed 12/29/2025.
[2] U.S. Food and Drug Administration (FDA). Immune Globulins. Available online at: https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/immune-globulins. Last revised 03/08/2023. Last accessed 12/29/2025.
[3] American Academy of Allergy, Asthma, & Immunology (AAAAI). Eight Guiding Principles for Effective Use of IVIG for Patients with Primary Immunodeficiency. Available online at: https://www.aaaai.org/Aaaai/media/Media-Library-PDFs/Practice%20Management/Practice%20Tools/IVIG-guiding-principles.pdf. Issued 12/2011. Last accessed 12/29/2025.

Appendix N

U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates*

***Additional information, including the full news release, on the following FDA and DEA updates can be found on the FDA website at: https://www.fda.gov/news-events/fda-newsroom/press-announcements.**

FDA NEWS RELEASE

For Immediate Release: December 19, 2025

FDA Grants Two National Priority Vouchers

The FDA awarded national priority vouchers under the Commissioner's National Priority Voucher (CNPV) pilot program to 2 investigational products for their potential to increase access through affordability for American patients. The products are:

- Enlicitide decanoate: an oral proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor for lowering low-density lipoprotein (LDL) cholesterol; and
- Sacituzumab tirumotecan: a trophoblast cell-surface antigen 2 (TROP2)-directed antibody-drug conjugate

With these awards, 18 products have now received a voucher under the CNPV pilot program since it was established in June 2025. On December 9, the FDA announced its first review decision under the program, achieving significant time savings compared to a typical review timeline.

FDA NEWS RELEASE

For Immediate Release: December 15, 2025

FDA Eliminates Major Barrier to Using Real-World Evidence in Drug and Device Application Reviews

The FDA removed a key limitation on the use of real-world evidence (RWE) used in drug and device applications reviews. In new guidance for certain types of medical device submissions, the FDA states it will accept RWE without requiring that identifiable individual patient data collected from real-world data sources always be submitted in a marketing submission. The FDA similarly intends to consider updating its guidance for drugs and biologics.

While RWE has been promoted as an advance in regulatory policy, past agency expectations have meant that most RWE could not be considered in product applications. Since 2016, 35 drugs, biologics, or vaccines have included RWE in their applications. The integration of RWE into device approvals has been more extensive, with over 250 premarket authorizations including RWE for the same period, although even for devices the rate of RWE-based authorizations has plateaued in recent years.

Historically, the FDA has insisted that any RWE submitted to the agency include private, confidential information at the individual patient

level. This approach makes it impractical to use most large databases with valuable macro-level data.

The FDA is responding to the position of many sponsors and data scientists that meaningful information can be extracted from some big data sources without private, individual information. FDA reviewers will now consider the strength of submitted RWE on an application-by-application basis.

This policy change opens the door to using de-identified databases containing millions of patient records — including national cancer registries like the National Cancer Institute's Surveillance, Epidemiology, and End Results, hospital systems databases, insurance claims databases, and electronic health record networks — resources that have grown exponentially but remained limited for use under previous FDA policy. These comprehensive datasets track patient outcomes across diverse populations and real-world treatment settings, offering insights that traditional clinical trials cannot capture.

FDA NEWS RELEASE

For Immediate Release: December 15, 2025

FDA Proactively Awards National Priority Voucher Based on Strong Phase 3 Study Results

The FDA awarded a national priority voucher to teclistamab in combination with daratumumab (Tec-Dara) for relapsed/refractory multiple myeloma. This brings the total number of products receiving an award under the CNPV pilot program to 16.

In Phase 3 clinical trial data released November 24, Tec-Dara showed significant improvements over the standard of care in both progression-free survival and overall survival among patients previously treated with 1 to 3 prior lines of therapy. At 3 years, more than 80% of Tec-Dara recipients remained free of progression. These results were also published in the *New England Journal of Medicine* on December 9th.

The CNPV pilot program is designed to accelerate the review of products with the potential to address 1 or more of the following key national priorities: addressing a United States public health crisis, delivering more innovative cures for the American people, addressing a large unmet medical need, promoting domestic drug development and manufacturing to advance the health interests of Americans and strengthen United States supply chain resiliency, and increasing affordability. Voucher recipients receive enhanced communications with review staff throughout the development process, and review decisions are targeted for completion within 1-2 months following submission of an application.

FDA NEWS RELEASE

For Immediate Release: December 12, 2025

FDA Approves Two Oral Therapies to Treat Gonorrhea

The FDA recently approved 2 new oral medicines to treat a common sexually transmitted infection called gonorrhea.

The FDA approved Nuzolvence® (zoliflodacin) granules to treat uncomplicated urogenital gonorrhea in adults and children 12 years of age and older who weigh at least 77 pounds. The FDA approved Blujepa (gepotidacin) oral tablets for the same condition in patients 12 years of age and older who weigh at least 99 pounds who have few or no other treatment choices because of limited clinical safety data. Blujepa was first approved in March 2025 to treat urinary tract infections.

Gonorrhea is caused by the bacterium *Neisseria gonorrhoeae* (*N. gonorrhoeae*). Uncomplicated urogenital gonorrhea refers to a localized infection of the urethra or cervix that has not spread to other areas of the body. It can cause painful urination, genital discharge and swelling. If left untreated, it could result in a more widespread infection of the reproductive organs and infertility. In the past, doctors treated this infection with a combination of a ceftriaxone injection and oral azithromycin. More recently, treatment guidelines recommend just a single injection of ceftriaxone.

Researchers tested Nuzolvence® in a study with 930 patients who had uncomplicated urogenital gonorrhea. Two-thirds of patients received a single 3-gram dose of Nuzolvence® dissolved in water. The other third received the standard treatment of a ceftriaxone injection plus oral azithromycin. The study measured how well the medicines cleared the bacteria 4 to 8 days after treatment. The study showed 91% of patients who took Nuzolvence® were cured and 96% of patients who received the standard treatment were cured. This showed that Nuzolvence®'s effectiveness was comparable to the standard treatment.

Researchers tested Blujepa in a study with 628 patients. Half received (2) 3,000mg doses of Blujepa taken 10 to 12 hours apart. The other half received the standard treatment. The study measured bacterial clearance 4 to 10 days after treatment. The study showed 93% of patients who took Blujepa were cured and 91% of patients who received standard treatment were cured. This showed that Blujepa's effectiveness was comparable to the standard treatment.

The most common side effects shown in the Nuzolvence® pivotal study were low white blood cell counts, headache, dizziness, nausea, and diarrhea. Animal studies showed this medicine might cause birth defects, pregnancy loss, or male fertility problems, so there are important safety precautions to follow that are included in labeling. Patients shouldn't take this medicine if they're allergic to it or taking certain other medications that might interact with it.

The most common side effects shown in Blujepa pivotal study were diarrhea, nausea, stomach pain, vomiting, gas, dizziness, soft stools, headache, tiredness, and excessive sweating. This medicine can affect heart rhythm and certain brain chemicals, and it may cause allergic reactions in some people. Blujepa comes with certain warnings and precautions, such as for QTc prolongation, acetylcholinesterase inhibition, and allergic reactions. The FDA granted both Nuzolvence® and Blujepa Fast Track, Qualified Infectious Disease Product, and Priority Review designations for the uncomplicated urogenital gonorrhea indication. FDA approval for Nuzolvence® was granted to Entasis Therapeutics and approval for Blujepa was granted to GSK.

FDA NEWS RELEASE

For Immediate Release: December 9, 2025

FDA Approves First Gene Therapy Treatment for Wiskott-Aldrich Syndrome (WAS)

The FDA approved Waskyra™ (etuvetidigene autotemcel), the first cell-based gene therapy for the treatment of WAS. Waskyra™ is indicated for pediatric patients 6 months of age and older and adults with WAS who have a mutation in the *WAS* gene and for whom hematopoietic stem cell transplantation (HSCT) is appropriate and no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available.

WAS is a rare, life-threatening genetic disease caused by mutations in the *WAS* gene. The condition is characterized by bleeding, eczema, recurrent infections, and increased susceptibility to autoimmunity and lymphoreticular malignancies. Until today, treatment options for patients with WAS have been limited to symptomatic management and allogeneic HSCT, with the latter being most effective when performed early in life and feasible only when matched donors are available.

Waskyra™ consists of the patient's own hematopoietic stem cells (HSCs), which have been genetically modified to include functional copies of the *WAS* gene. Following reduced-intensity conditioning, the gene-corrected cells are infused intravenously to restore blood cell production. Waskyra™ restores functional WAS protein expression in affected cells, addressing the underlying cause of the disease.

The safety and effectiveness of Waskyra™ was assessed based on 2 open-label, single-arm, multinational clinical studies and an expanded access program totaling 27 patients with severe WAS, which demonstrate substantial and sustained clinical benefit for patients with severe WAS, with significant reductions in the primary disease manifestations that drive morbidity and mortality. The rate of severe infections decreased by 93% in the 6 to 18 months post-treatment period compared to the rate 12 months before treatment. Similarly, moderate and severe bleeding events were reduced by 60% in the first 12 months post-treatment compared to the year prior to

treatment. Most patients did not report moderate to severe bleeding after 4 years post treatment.

The most common side effects associated with Waskyra™ include rash, respiratory tract infection, febrile neutropenia, catheter related infection, vomiting, diarrhea, liver injury, and petechiae.

During the review of Waskyra™, the FDA exercised appropriate regulatory flexibility across 4 critical areas: rare disease considerations, clinical trial design, mechanism of action, and chemistry, manufacturing, and controls (CMC). This enabled approval and timely access to the product for this serious, life-threatening disease while carefully balancing pre-approval data requirements with post-market commitments. The FDA permitted the use of relevant manufacturing and quality data submitted to this Biologics License Application (BLA) from a similar, approved product that was justified to be adequately representative of Waskyra™ for these purposes.

The application was granted Orphan Drug, Rare Pediatric Disease, and Regenerative Medicine Advanced Therapy designations. The FDA granted approval of Waskyra™ to Fondazione Telethon ETS. This is the first approved cell and gene therapy product from a non-profit applicant.

FDA NEWS RELEASE

For Immediate Release: December 9, 2025

First Approval in CNPV Pilot Program Strengthens Domestic Antibiotic Manufacturing Capacity

The FDA approved Augmentin XR® (amoxicillin/clavulanate potassium) under the CNPV pilot program, marking the first approval achieved through this review pathway. The approval was completed in just 2 months, representing a major reduction of the review timeline for this type of application.

The Augmentin XR® application demonstrated clear alignment with the CNPV program's national health priorities by strengthening the United States drug supply chain through enhanced domestic manufacturing capacity at a United States facility. This approval will also help address antibiotic shortages in the United States that have plagued the healthcare system over the past 2 decades. This approval was granted to USAntibiotics.

Increasing antibiotic shortages over the past 2 decades have been primarily driven by global supply chain vulnerabilities for active pharmaceutical ingredients and unexpected spikes in clinical demand. These shortages have resulted in significant clinical consequences, including treatment delays and increased reliance on broader-spectrum antibiotics when preferred first-line therapies become unavailable.

Essential medicines like amoxicillin and Augmentin XR® have experienced documented shortages, with 7 shortage reports for amoxicillin and 2 for Augmentin XR®, highlighting the critical need for stable domestic manufacturing capacity to protect public health.

The review of Augmentin XR was conducted by a multidisciplinary team featuring experts in drug substance, drug product, manufacturing, facilities, and biopharmaceutics. The integrated quality assessment and enhanced communications between the FDA and the sponsor throughout the process enabled the accelerated timeline from application receipt to approval within the target 2-month CNPV review window.

The CNPV pilot program seeks to expedite approval of applications that address critical national health priorities, such as bringing innovative therapies to the American people, addressing large unmet medical needs, promoting domestic manufacturing, and increasing affordability.

FDA NEWS RELEASE

For Immediate Release: December 8, 2025

FDA Approves First Cellular Therapy to Treat Patients with Severe Aplastic Anemia (SAA)

The FDA announced it has approved Omisirge® (omidubicel-onlv), the first HSCT therapy to treat patients with SAA. Omisirge® is indicated for adults and pediatric patients 12 years of age and older with hematologic malignancies and now is approved for adults and pediatric patients 6 years of age and older with SAA following reduced intensity conditioning and for whom a compatible donor is not available.

SAA is a rare, life-threatening blood disorder where the bone marrow fails to produce enough red blood cells, white blood cells, and platelets. Treatment for SAA depends on age and usually consists of either immunosuppressive therapy and/or HSCT, preferably from a matched sibling or matched related donor. If a donor is not available, providers may seek the use of umbilical cord transplant to treat SAA. Umbilical cord transplant typically has limitations of use including delayed hematopoietic recovery and increased risks of infections. Omisirge® is a stem cell therapy where donated cord blood stem cells have been chemically enhanced with nicotinamide and then given to a patient to help restore their blood and immune system. Omisirge® addresses the limitations of umbilical cord blood (UCB) as a source including delayed hematopoietic recovery and increased infections and provides additional graft options for patients with SAA who need HSCT.

The safety and effectiveness of Omisirge® were assessed based on an ongoing, open-label, prospective, single arm study evaluating use of Omisirge® in patients 6 years of age and older with SAA. Omisirge® provided early and sustained neutrophil engraftment in 12 of 14 patients in the efficacy population with a median time to neutrophil recovery of 11 days (range 7-20 days).

The most common side effects associated with Omisirge® include febrile neutropenia, viral and bacterial infections, hyperglycemia, immune thrombocytopenia, and pneumonia. Autoimmune cytopenias have occurred in 25% of patients.

The application was granted Orphan Drug and Priority Review designations. The FDA granted approval of Omisirge® to Gamida Cell Ltd.

FDA NEWS RELEASE

For Immediate Release: December 4, 2025

FDA Approves First Chimeric Antigen Receptor (CAR) T-Cell Therapy for Marginal Zone Lymphoma (MZL) In the United States

The FDA approved a new indication for Breyanzi® (lisocabtagene maraleucel) as the first CAR T-cell therapy in the United States for treatment of adults with MZL who have failed treatment with or relapsed after 2 or more prior lines of therapy. Breyanzi® is a CAR T-cell therapy that genetically engineers a patient's own T-cells to target and kill cancer cells.

MZL is a rare slow-growing cancer of the lymphatic system. It presents about 7% of all B-cell non-Hodgkin lymphoma, with approximately 7,460 new cases occurring every year in the United States population. Patients with MZL who failed treatment or relapsed following treatment with upfront therapy have decreased survival.

The safety and effectiveness of Breyanzi® were evaluated in an open-label, multicenter, single-arm trial in adults with relapsed or refractory MZL who had received at least 2 or more lines of systemic therapy or who relapsed after HSCT. Study participants underwent leukapheresis to manufacture Breyanzi®. Patients received a single dose of Breyanzi® 2-7 days following the completion of preparatory chemotherapy to deplete recipient's lymphocytes. Among the 77 patients who underwent leukapheresis, 66 patients received the study specified single infusion of Breyanzi®, of which 95.5% of patients experienced a response to treatment and 62.1% of patients had complete response without signs of MZL on imaging scans. The responses were durable after a median follow-up of 21.6 months.

The most common adverse reactions were cytokine release syndrome (CRS), diarrhea, fatigue, musculoskeletal pain, and headache.

The FDA granted Breyanzi® Priority Review and Orphan Drug designation for this application. The FDA granted traditional approval of Breyanzi® to Juno Therapeutics, Inc.

FDA NEWS RELEASE

For Immediate Release: December 3, 2025

FDA Approves Nerve Scaffold for the Treatment of Sensory Nerve Discontinuity

The FDA granted approval for Avance® (acellular nerve allograft-arwx) in surgical implantation. Avance® is a peripheral nerve scaffold approved for sensory nerve discontinuities (≤25mm) (breaks in the pathway of sensory nerves) in adults and pediatric patients 1 month of age and older. Under the Accelerated Approval pathway, Avance® is also approved for larger sensory nerve discontinuities (>25mm), motor, and mixed nerve discontinuities.

Avance® was studied in patients with sensory nerve discontinuities and additional investigations of mixed and motor nerve discontinuities.

Unlike some current treatments that require surgeons to remove healthy nerve tissue from another part of the patient's body (creating a second surgical site), Avance® is made using nerve tissue from deceased donors that has been specially processed to remove cells while preserving the natural structure that helps nerves regrow.

The study of Avance®'s efficacy compared implantation of Avance® to collagen nerve cuffs. The study met its primary endpoint for the return of sensory function, showing Avance®'s statistical non-inferiority to comparator nerve cuff.

The most common adverse reactions reported in clinical trials were procedural pain and increased sensitivity to sensory stimuli, such as touch, temperature, and pain (hyperesthesia). Patients should be monitored for procedural complications including pain, hyperesthesia, infection, implant site swelling, adhesions, hypertrophic scar formation, impaired motor or sensory function, bleeding, and neuroma formation. Avance® is made from human cadaveric tissue so it may carry a risk of transmitting infectious agents. No cases of transmission of viral diseases have ever been identified for Avance®. All infections thought to be transmitted by Avance® should be reported to the manufacturer. FDA approval for Avance® was granted to Axogen Corporation.

FDA NEWS RELEASE

For Immediate Release: December 2, 2025

FDA Seizes 7-OH Opioids to Protect American Consumers

The FDA, in coordination with the U.S. Department of Justice, announced that the U.S. Marshals Service seized approximately 73,000 units of 7-hydroxymitragynine (7-OH) products, valued at roughly $1 million, from 3 firms in Missouri.

The seizure focused on foods and dietary supplement products, including liquid shots and tablets, containing concentrated 7-OH as an added ingredient. Concentrated 7-OH is increasingly recognized as having potential for abuse because of its ability to bind to opioid receptors. It cannot be lawfully added to dietary supplements or conventional foods. These products are considered adulterated because 7-OH does not meet applicable safety standards. Also, the FDA has not approved 7-OH for medical use.

The FDA worked closely with the Missouri Department of Health and Senior Services in this enforcement action, which builds on the FDA's comprehensive efforts to protect Americans from dangerous, illegal opioid substances. In July of this year, the FDA recommended the scheduling of certain 7-OH products under the Controlled Substances Act and issued warning letters to companies for illegally distributing products containing 7-OH, including tablets, gummies, drink mixes, and shots. The FDA also

notified health care professionals and informed consumers of the risks associated with concentrated 7-OH products.

These recent operations demonstrate coordinated federal enforcement efforts against concentrated 7-OH products. The FDA reminds all manufacturers and distributors that they must ensure their products comply with all applicable federal requirements.

Current Drug Shortages Index (as of December 31, 2025):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma. Additional information regarding drug shortages can be found on the FDA website at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

Albuterol Sulfate Solution	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bacitracin Ophthalmic Ointment	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Powder, for Solution	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate 10% Injection	***Currently in Shortage***
Dextrose Monohydrate 5% Injection	***Currently in Shortage***
Dextrose Monohydrate 50% Injection	***Currently in Shortage***
Dextrose Monohydrate 70% Injection	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***

Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Meperidine Hydrochloride Injection	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methylphenidate Film, Extended Release	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Naltrexone Hydrochloride Tablet	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Peginterferon alfa-2a Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Riluzole Oral Suspension	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***

Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***