

Drug Utilization Review Board



OKLAHOMA

Health Care Authority

**Wednesday,
October 14, 2026
4:00pm**

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

Viewing Access Only:

Please register for the webinar at:

https://oklahoma.zoom.us/webinar/register/WN_eBUt3qLzSkycOdDyUyZx5g

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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 – October 14, 2026

DATE: October 7, 2026

NOTE: The DUR Board will meet at 4:00pm at the Oklahoma Health Care Authority (OHCA) at 4345 N. Lincoln Blvd. in Oklahoma City, Oklahoma.

There will be Zoom access to this meeting; however, Zoom access will be set up in view-only mode with no voting, speaking, video, or chat box privileges. Zoom access will allow for viewing of the presentation slides as well as audio of the presentations and discussion during the meeting; however, the DUR Board meeting will not be delayed or rescheduled due to any technical issues that may arise.

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

Call to Order

Public Comment Forum

Action Item – Approval of DUR Board Meeting Minutes – Appendix A

Update on the Medication Coverage Authorization Unit – Appendix B

Fall Pipeline Update – Appendix C

Action Item – Vote to Prior Authorize Cetirizine Oral Solution Unit Dose Cups (UDCs) and Update the Approval Criteria for the Antihistamine Medications (Systemic) – Appendix D

Action Item – Vote to Prior Authorize Epioxa HD/Epioxa (Riboflavin 5'-Phosphate Ophthalmic Solution) and Lumvoa (Veligrotug-vvze) and Update the Approval Criteria for the Various Ophthalmic Medications – Appendix E

Action Item – Vote to Prior Authorize Beizray (Docetaxel), Beizray Kit (Docetaxel/Albumin), Docivvyx (Docetaxel), Inluriyo (Imlunestrant), and Veppanu (Vepdegestrant) and Update the Approval Criteria for the Breast Cancer Medications – Appendix F

Action Item – Annual Review of Constipation and Diarrhea Medications – Appendix G

Action Item – Annual Review of Anticoagulants and Platelet Aggregation Inhibitors – Appendix H

Annual Review of Myeloproliferative Neoplasm (MPN) Medications and 30-Day Notice to Prior Authorize Decnupaz (Pivekimab Sunirine-pvzy), Jakafi XR [Ruxolitinib Extended-Release (ER)], and Mimrylo (Rusfertide) – Appendix I

Annual Review of Targeted Immunomodulator Agents and 30-Day Notice to Prior Authorize Icotyde (Icotrokinra), Immgolol (Golimumab-sldi), Immgolol Intri (Golimumab-sldi), Lisraya (Brepocitinib), and Zimrixby (Rituximab-cdxx) – Appendix J

Annual Review of Fibromyalgia Medications and 30-Day Notice to Prior Authorize Tonmya [Cyclobenzaprine Sublingual (SL) Tablet] – Appendix K

Annual Review of Anemia Medications and 30-Day Notice to Prior Authorize Aqvesme (Mitapivat) – Appendix L

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board (DUR Board)

Meeting – October 14, 2026 @ 4:00pm

at the

Oklahoma Health Care Authority (OHCA)

4345 N. Lincoln Blvd.

Oklahoma City, Oklahoma 73105

NOTE: ***The DUR Board will meet at 4:00pm at OHCA (see address above). There will be Zoom access to this meeting; however, Zoom access will be set up in view-only mode with no voting, speaking, video, or chat box privileges. Zoom access will allow for viewing of the presentation slides as well as audio of the presentations and discussion during the meeting; however, the DUR Board meeting will not be delayed or rescheduled due to any technical issues that may arise.***

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Haymore, Chairman:

1. Call to Order

A. Roll Call – Dr. Wilcox

DUR Board Members:

Dr. Cassidy Blaiss –	participating in person
Ms. Jennifer Boyett –	participating in person
Dr. Christen Ground –	participating in person
Dr. Bret Haymore –	participating in person
Dr. Bethany Holderread –	participating in person
Dr. Matt John –	participating in person
Dr. Craig Kupiec –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. Edna Patatanian –	participating in person
Dr. Jennifer Weakley –	participating in person

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After registering, you will receive a confirmation email containing information about joining the webinar.

Or join by phone:

Dial: +1-602-753-0140 or +1-669-219-2599

Webinar ID: 910 6408 1365

Passcode: 44589980

Public Comment for Meeting:

- Speakers who wish to sign up for public comment at the OHCA DUR Board meeting may do so in writing by visiting the DUR Board page on the OHCA website at www.oklahoma.gov/ohca/about/boards-and-committees/drug-utilization-review/dur-board and completing the [Speaker Registration Form](#). Completed Speaker Registration forms should be submitted to DURPublicComment@okhca.org. Forms must be received after the DUR Board agenda has been posted and no later than 24 hours before the meeting.
- The DUR Board meeting will allow public comment and time will be limited to 40 minutes total for all speakers during the meeting. Each speaker will be given 5 minutes to speak at the public hearing. If more than 8 speakers properly request to speak, time will be divided evenly.
- Only 1 speaker per manufacturer will be allowed.
- Any speakers who sign up for public comment must attend the DUR Board meeting in person at OHCA (see above address). Public comment through Zoom will not be allowed for the DUR Board meeting.
- In lieu of speaking at the DUR Board meeting, written correspondence by members or providers may be submitted to DURPublicComment@okhca.org. Other written correspondence is not permitted.

Items to be presented by Dr. Haymore, Chairman:

2. Public Comment Forum

- A. Acknowledgement of Speakers for Public Comment

Items to be presented by Dr. Haymore, Chairman:

3. Action Item – Approval of DUR Board Meeting Minutes – See Appendix A

- A. September 9, 2026 DUR Board Meeting Minutes
- B. September 9, 2026 DUR Board Recommendations Memorandum
- C. Correspondence

Non-presentation items reviewed by Dr. Grimes, Dr. Haymore, Chairman:

4. Update on Medication Coverage Authorization Unit – See Appendix B

- A. Pharmacy Help Desk Activity for September 2025
- B. Medication Coverage Activity for September 2025

Items to be presented by Dr. Moss, Dr. Haymore, Chairman:

5. Fall Pipeline Update – See Appendix C

- A. Introduction
- B. Product Summaries
- C. Pipeline Table

Items to be presented by Dr. Wilson, Dr. Haymore, Chairman:

6. Action Item – Vote to Prior Authorize Cetirizine Oral Solution Unit Dose Cups (UDCs) and Update the Approval Criteria for the Antihistamine Medications (Systemic) – See Appendix D

- A. Cost Comparison: Cetirizine Products
- B. College of Pharmacy Recommendations

Items to be presented by Dr. Moss, Dr. Haymore, Chairman:

7. Action Item – Vote to Prior Authorize Epioxa HD/Epioxa (Riboflavin 5'-Phosphate Ophthalmic Solution) and Lumvoa (Veligrotug-vvze) and Update the Approval Criteria for the Various Ophthalmic Medications – See Appendix E

- A. Market News and Updates
- B. Lumvoa (Veligrotug-vvze) Product Summary
- C. College of Pharmacy Recommendations

Items to be presented by Dr. Sinko, Dr. Haymore, Chairman:

8. Action Item – Vote to Prior Authorize Beizray (Docetaxel), Beizray Kit (Docetaxel/Albumin), Docivyx (Docetaxel), Inluriyo (Imlunestrant), and Veppanu (Vepdegestrant) and Update the Approval Criteria for the Breast Cancer Medications – See Appendix F

- A. Market News and Updates
- B. Product Summaries
- C. Cost Comparisons
- D. College of Pharmacy Recommendations

Items to be presented by Dr. DeRemer, Dr. Haymore, Chairman:

9. Action Item – Annual Review of Constipation and Diarrhea Medications – See Appendix G

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

Items to be presented by Dr. Grimes, Dr. Haymore, Chairman:

10. Action Item – Annual Review of Anticoagulants and Platelet Aggregation Inhibitors – See Appendix H

- A. Current Prior Authorization Criteria
- B. Utilization of Anticoagulants and Platelet Aggregation Inhibitors
- C. Prior Authorization of Anticoagulants and Platelet Aggregation Inhibitors
- D. Market News and Updates
- E. College of Pharmacy Recommendations
- F. Utilization Details of Anticoagulants and Platelet Aggregation Inhibitors

Items to be presented by Dr. Sinko, Dr. Haymore, Chairman:

11. Annual Review of Myeloproliferative Neoplasm (MPN) Medications and 30-Day Notice to Prior Authorize Decnupaz (Pivekimab Sunirine-pvzy), Jakafi XR [Ruxolitinib Extended-Release (ER)], and Mimrylo (Rusfertide) – See Appendix I

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

Items to be presented by Dr. Wilson, Dr. Haymore, Chairman:

12. Annual Review of Targeted Immunomodulator Agents and 30-Day Notice to Prior Authorize Icotyde (Icotrokinra), Immgolis (Golimumab-sldi), Immgolis Intri (Golimumab-sldi), Lisraya (Brepocitinib), and Zimrixby (Rituximab-cdxx) – See Appendix J

- A. Current Prior Authorization Criteria
- B. Utilization of Targeted Immunomodulator Agents
- C. Prior Authorization of Targeted Immunomodulator Agents
- D. Market News and Updates
- E. Product Summaries
- F. Cost Comparison: Rituximab Products
- G. College of Pharmacy Recommendations
- H. Utilization Details of Targeted Immunomodulator Agents

Items to be presented by Dr. Moss, Dr. Haymore, Chairman:

13. Annual Review of Fibromyalgia Medications and 30-Day Notice to Prior Authorize Tonmya [Cyclobenzaprine Sublingual (SL) Tablet] – See Appendix K

- A. Current Prior Authorization Criteria
- B. Utilization of Fibromyalgia Medications
- C. Prior Authorization of Fibromyalgia Medications
- D. Market News and Updates
- E. Tonmya (Cyclobenzaprine SL Tablet) Product Summary
- F. Cost Comparison
- G. College of Pharmacy Recommendations
- H. Utilization Details of Fibromyalgia Medications

Items to be presented by Dr. O'Halloran, Dr. Haymore, Chairman:

14. Annual Review of Anemia Medications and 30-Day Notice to Prior Authorize Aqvesme (Mitapivat) – See Appendix L

- A. Current Prior Authorization Criteria

- B. Utilization of Anemia Medications
- C. Prior Authorization of Anemia Medications
- D. Market News and Updates
- E. Aqvesme (Mitapivat) Product Summary
- F. College of Pharmacy Recommendations
- G. Utilization Details of Anemia Medications

Non-presentation items reviewed by Dr. Grimes, Dr. Haymore, Chairman:

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

Items to be presented by Dr. Adams, Dr. Haymore, Chairman:

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

- A. Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications
- B. Atopic Dermatitis Medications
- C. Bone Density Regulators
- D. Brinsupri (Brensocatic)
- E. Gonadotropin-Releasing Hormone (GnRH) Medications (Non-Oncology)
- F. Multiple Myeloma Medications
- G. Ophthalmic Anti-Inflammatory Products
- H. Rhapsido (Remibrutinib)

*Future product and class reviews subject to change.

17. Adjournment

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.



**OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING SEPTEMBER 9, 2026**

DUR BOARD MEMBERS:	PRESENT	ABSENT
Cassidy Blaiss, Pharm.D., BCOP		X
Jennifer Boyett, MHS, PA-C	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	
Lezlie Grimes, Pharm.D.; Clinical Pharmacist	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	
Terry Cothran, D.Ph.; Pharmacy Director	X	
Bradford Eckhart, J.D.; Deput General Counsel		X

Elan Gada, M.D.; Chief Medical Officer		X
Sidney Jones; J.D.; Deputy General Counsel	X	
Melissa Miller, State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	

OTHERS PRESENT:	
Jai Persico, Neurocrine	JJ Roth, Mirum
Eardie Curry, Genentech	Scott Burns, Johnson & Johnson
Taha Khan, Vertex	Kristen Winters, Centene
Kellie Vazzana, Alkermes	Bob Atkins, Biogen
Katie Lambert, Exeltis	Roberto Pedraza, Vertex
Brandon Ross, Merck	Ashlee Waring, Organon
Deidra Williams, Humana	Julie Rhodes, AbbVie
Andy Gorzynski, Cytokinetix	Miranda Ryzenman, Artia Solutions
Irene Chung, Aetna	Gary Parenteau, Dexcom
Alice Chan, Mannkind	Sergio Mayorga, Concis Labs
Phillip Lohec, Viatris	Jami Toole, Takeda
Mike Sullivan, Amgen	David Mendoza, Otsuka
Molly Carson, Creative Capitol Strategies	Laura Cordell, Sanofi
Leia Roeges, Neurocrine Biosciences	Melissa Abbott, Compass Pathways
Payal Tejani, Biogen	

PRESENT FOR PUBLIC COMMENT:	
Taha Khan, Vertex	

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.17 TAHA KHAN

ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MEETING MINUTES

3A: JULY 8, 2026 DUR MINUTES

Materials included in agenda packet; presented by Dr. Haymore
Dr. Ground moved to approve; seconded by Dr. Holderread

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: UPDATE ON MEDICATION COVERAGE

AUTHORIZATION UNIT

4A: PHARMACY HELPDESK ACTIVITY FOR AUGUST 2025

4B: MEDICATION COVERAGE ACTIVITY FOR AUGUST 2025

Non-presentation item; materials included in agenda packet by Dr. Grimes

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITOR

UTILIZATION UPDATE

5A: INTRODUCTION

5B: MAILING SUMMARY

5C: MAILING RESULTS

5D: DPP-4 INHIBITOR UTILIZATION IN THE SOONERCARE POPULATION

5E: CONCLUSIONS

5F: RECOMMENDATIONS

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE ENBUMYST™ (BUMETANIDE NASAL SPRAY), LASIX ONYU (FUROSEMIDE ON-BODY INFUSOR), AND MYQORZO (AFICAMTEN) AND UPDATE THE APPROVAL CRITERIA FOR THE HEART FAILURE (HF) MEDICATIONS

6A: MARKET NEWS AND UPDATES

6B: PRODUCT SUMMARIES

6C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Grimes

Dr. Muñoz moved to approve; seconded by Dr. Holderread

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE LEQEMBI IQLIK® (LECANEMAB-IRMB)

7A: MARKET NEWS AND UPDATES

7B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Dorsey

Dr. Muñoz moved to approve; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE AWIQLI (INSULIN ICODEC-ABAE), GLIPIZIDE 15MG TABLET, KIRSTY (INSULIN ASPART-XJHZ), AND LANGLARA (INSULIN GLARGINE-ALDY) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTI-DIABETIC MEDICATIONS AND KERENDIA (FINERENONE)

8A: MARKET NEWS AND UPDATES

8B: AWIQLI (INSULIN ICODEC-ABAE)

8C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

Dr. Muñoz moved to approve; seconded by Dr. Holderread

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE JOVENE (BEVACIZUMAB-NWGD)

9A: MARKET NEWS AND UPDATES

9B: COST COMPARISON: BEVACIZUMAB PRODUCTS

9C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Sinko

Dr. Holderread moved to approve; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE MODEYSO (DORDAVIPRONE) AND VISTOGARD (URIDINE TRIACETATE) AND UPDATE THE APPROVAL CRITERIA FOR THE MISCELLANEOUS CANCER MEDICATIONS

10A: MARKET NEWS AND UPDATES

10B: PRODUCT SUMMARIES

10C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Sinko

Dr. Ground moved to approve; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE IRON PRODUCTS

11A: MARKET NEWS AND UPDATES

11B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson

Dr. Holderread moved to approve; seconded by Dr. Ground

ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE IRON CHELATING AGENTS

12A: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Grimes

Dr. Muñoz moved to approve; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: VOTE TO PRIOR AUTHORIZE AMCINONIDE 0.1% OINTMENT AND UPDATE THE APPROVAL CRITERIA FOR THE TOPICAL CORTICOSTEROIDS

13A: MARKET NEWS AND UPDATES

13B: COLLEGE OF PHARMACY RECOMMENDATIONS

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

Dr. Muñoz moved to approve; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: VOTE TO PRIOR AUTHORIZE CONTEMPO (FOSFOMYCIN FOR INJECTION), DOXYCYCLINE HYCLATE 75MG CAPSULE, AND ORLYNVAH (SULOPENEM ETZADROXIL/PROBENECID) AND UPDATE THE APPROVAL CRITERIA FOR THE VARIOUS SYSTEMIC ANTIBIOTICS

14A: MARKET NEWS AND UPDATES

14B: ORLYNVAH (SULOPENEM ETZADROXIL/PROBENECID) PRODUCT SUMMARY

14C: COST COMPARISONS

14D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. DeRemer

Dr. Muñoz moved to approve; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

AGENDA ITEM NO. 15: VOTE TO PRIOR AUTHORIZE ZYCUBO (COPPER HISTIDINATE)

15A: MARKET NEWS AND UPDATES

15B: ZYCUBO (COPPER HISTIDINATE) PRODUCT SUMMARY

15C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Dorsey

Dr. Muñoz moved to approve; seconded by Dr. Ground

ACTION: MOTION CARRIED

AGENDA ITEM NO. 16: VOTE TO PRIOR AUTHORIZE MORPHINE ORAL SOLUTION SYRINGES AND TAPENTADOL TABLET, EXTENDED-RELEASE (ER) TABLET, AND ORAL SOLUTION AND UPDATE THE APPROVAL CRITERIA FOR THE

**OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT)
MEDICATIONS**

16A: MARKET NEWS AND UPDATES

16B: COST COMPARISONS

16C: 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

**AGENDA ITEM NO. 17: ANNUAL REVIEW OF CYSTIC FIBROSIS (CF)
MEDICATIONS**

17A: CURRENT PRIOR AUTHORIZATION CRITERIA

17B: UTILIZATION OF CF MEDICATIONS

17C: PRIOR AUTHORIZATION OF CF MEDICATIONS

17D: MARKET NEWS AND UPDATES

17E: COLLEGE OF PHARMACY RECOMMENDATIONS

17F: UTILIZATION DETAILS OF CF MEDICATIONS

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

Dr. Patatanian moved to approve; seconded by Dr. Muñoz

ACTION: MOTION CARRIED

**AGENDA ITEM NO. 18: ANNUAL REVIEW OF AMYLOIDOSIS
MEDICATIONS**

18A: CURRENT PRIOR AUTHORIZATION CRITERIA

18B: UTILIZATION OF AMYLOIDOSIS MEDICATIONS

18C: PRIOR AUTHORIZATION OF AMYLOIDOSIS MEDICATIONS

18D: MARKET NEWS AND UPDATES

18E: COLLEGE OF PHARMACY RECOMMENDATIONS

18F: UTILIZATION DETAILS OF AMYLOIDOSIS MEDICATIONS

Materials included in agenda packet; presented by Dr. DeRemer

Dr. Ground moved to approve; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

**AGENDA ITEM NO. 19: ANNUAL REVIEW OF BLADDER CONTROL
MEDICATIONS**

19A: CURRENT PRIOR AUTHORIZATION CRITERIA

19B: UTILIZATION OF BLADDER CONTROL MEDICATIONS

19C: PRIOR AUTHORIZATION OF BLADDER CONTROL MEDICATIONS

19D: MARKET NEWS AND UPDATES

19E: COLLEGE OF PHARMACY RECOMMENDATIONS

19F: UTILIZATION DETAILS OF BLADDER CONTROL MEDICATIONS

Materials included in agenda packet; presented by Dr. Grimes

Dr. Patatanian moved to approve; seconded by Dr. Muñoz

ACTION: MOTION CARRIED

**AGENDA ITEM NO. 20: ANNUAL REVIEW OF BREAST CANCER
MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BEIZRAY
(DOCETAXEL), BEIZRAY KIT (DOCETAXEL/ALBUMIN), DOCIVYX (DOCETAXEL),
INLURIYO (IMLUNESTRANT), AND VEPANU (VEPDEGESTRANT)**

20A: CURRENT PRIOR AUTHORIZATION CRITERIA

20B: UTILIZATION OF BREAST CANCER MEDICATIONS

20C: PRIOR AUTHORIZATION OF BREAST CANCER MEDICATIONS

20D: MARKET NEWS AND UPDATES

20E: PRODUCT SUMMARIES

- 20F: COST COMPARISON: TRASTUZUMAB PRODUCTS**
- 20G: COLLEGE OF PHARMACY RECOMMENDATIONS**
- 20H: UTILIZATION DETAILS OF BREAST CANCER MEDICATIONS**

Materials included in agenda packet; presented by Dr. Sinko

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

AGENDA ITEM NO. 21: ANNUAL REVIEW OF VARIOUS OPHTHALMIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE EPIOXA HD/EPIOXA (RIBOFLAVIN 5'-PHOSPHATE OPHTHALMIC SOLUTION) AND LUMVOA (VELIGROTUG-VVZE)

- 21A: CURRENT PRIOR AUTHORIZATION CRITERIA**
- 21B: UTILIZATION OF VARIOUS OPHTHALMIC MEDICATIONS**
- 21C: PRIOR AUTHORIZATION OF VARIOUS OPHTHALMIC MEDICATIONS**
- 21D: MARKET NEWS AND UPDATES**
- 21E: LUMVOA® (VELIGROTUG-VVZE) PRODUCT SUMMARY**
- 21F: COLLEGE OF PHARMACY RECOMMENDATIONS**
- 21G: UTILIZATION DETAILS OF VARIOUS OPHTHALMIC MEDICATIONS**

Materials included in agenda packet; presented by Dr. Moss

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

AGENDA ITEM NO. 22: ANNUAL REVIEW OF ANTIHISTAMINE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE CETIRIZINE ORAL SOLUTION UNIT DOSE CUPS (UDC)

- 22A: CURRENT PRIOR AUTHORIZATION CRITERIA**
- 22B: UTILIZATION OF SYSTEMIC ANTIHISTAMINE MEDICATIONS**
- 22C: PRIOR AUTHORIZATION OF SYSTEMIC ANTIHISTAMINE MEDICATIONS**
- 22D: MARKET NEWS AND UPDATES**
- 22E: COST COMPARISON: CETIRIZINE PRODUCTS**
- 22F: COLLEGE OF PHARMACY RECOMMENDATIONS**
- 22G: UTILIZATION DETAILS OF SYSTEMIC ANTIHISTAMINE MEDICATIONS**

Materials included in agenda packet; presented by Dr. Wilson

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

AGENDA ITEM NO. 23: ANNUAL REVIEW OF BENIGN PROSTATIC HYPERPLASIA (BPH) MEDICATIONS

- 23A: CURRENT PRIOR AUTHORIZATION CRITERIA**
- 23B: UTILIZATION OF BPH MEDICATIONS**
- 23C: PRIOR AUTHORIZATION OF BPH MEDICATIONS**
- 23D: COLLEGE OF PHARMACY RECOMMENDATIONS**
- 23E: UTILIZATION DETAILS OF BPH MEDICATIONS**

Non-presentation item; materials included in agenda packet by Dr. Dorsey

ACTION: NONE REQUIRED

AGENDA ITEM NO. 24: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTRATION (DEA) UPDATES

Non-presentation item; materials included in agenda packet by Dr. Grimes

ACTION: NONE REQUIRED

AGENDA ITEM NO. 25: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)

- 25A: ANEMIA MEDICATIONS**
- 25B: ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS**
- 25C: CONSTIPATION AND DIARRHEA MEDICATIONS**
- 25D: FIBROMYALGIA MEDICATIONS**

25E: MYELOPROLIFERATIVE NEOPLASM (MPN) MEDICATIONS

25F: TARGETED IMMUNOMODULATOR AGENTS

*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. 26: ADJOURNMENT

The meeting was adjourned at 5:18pm.



The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: September 11, 2026

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 Packet Meeting on
September 9, 2026

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Utilization Update

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Enbumyst™ (Bumetanide Nasal Spray), Lasix® ONYU (Furosemide On-Body Infusor), and Myqorzo™ (Aficamten) and Update the Approval Criteria for the Heart Failure (HF) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Enbumyst™ (bumetanide nasal spray), Lasix® ONYU (furosemide on-body infusor), and Myqorzo™ (aficamten) with the following criteria (shown in red):

Enbumyst™ (Bumetanide Nasal Spray) Approval Criteria:

1. An FDA approved indication of the treatment of edema associated with congestive heart failure, hepatic disease, or renal disease, including nephrotic syndrome; and
2. Member must be 18 years of age or older; and
3. Member is currently showing signs of edema; and
4. Member must not currently have significant nasal mucosal or structural abnormalities, such as acute episodes of rhinitis or congestion due to any cause; and
5. Enbumyst™ must be prescribed by, or in consultation with, a specialist in the area of the patient's diagnosis (e.g., cardiologist, nephrologist, hepatologist, gastroenterologist); and
6. Member has been established on maintenance therapy with and is refractory to a dose escalation with at least 1 of the following loop diuretics, at maximally tolerated doses:
 - a. Bumetanide oral tablets; or
 - b. Furosemide oral tablets; or
 - c. Torsemide oral tablets; and
7. Prescriber must verify the member will discontinue oral diuretics during the treatment with Enbumyst™ and will transition back to oral diuretic maintenance therapy when practical; and
8. Prescriber must verify the member or caregiver will be counseled on the proper administration of Enbumyst™; and
9. Approvals will be issued per incident of edema; and
 - a. A quantity limit of 36 nasal spray devices per 36 days will apply; or
 - b. For requests exceeding the quantity limit, clinical documentation supporting the need for additional supply must be provided for a quantity limit override; and
10. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of edema.

Lasix® ONYU (Furosemide On-Body Infusor) Approval Criteria:

1. An FDA approved indication for the treatment of edema in members with chronic heart failure; and
2. Member must be 18 years of age or older; and
3. Must be prescribed by, or in consultation with, a cardiologist or a provider trained in managing acute decompensated heart failure (ADHF); and
4. Member is currently showing signs of edema; and
5. Member has been established on maintenance therapy with and is refractory to a dose escalation with at least 1 of the following loop diuretics, at maximally tolerated doses:
 - a. Bumetanide oral tablets; or
 - b. Furosemide oral tablets; or
 - c. Torsemide oral tablets; and

6. Prescriber must verify the member will discontinue oral diuretics during the treatment with Lasix® ONYU and will transition back to oral diuretic maintenance therapy when practical; and
7. Prescriber must verify the member or caregiver will be trained on the proper use of Lasix® ONYU and is able to detect and respond to the device alarms; and
8. Member must not have any contraindications for use of Lasix® ONYU; and
9. Member must not have conditions that require immediate hospitalization; and
10. The following quantity limits will apply:
 - a. Approval quantities for the kit (i.e., co-packaged prefilled-cartridge and disposable unit) will be issued per incident of edema; and
 - b. 1 Reusable Unit (drug delivery device) per year; or
 - i. For requests exceeding this limit, approval of an additional Reusable Unit will be granted upon verification that the previously dispensed Reusable Unit has reached its lifespan of 48 uses, as indicated in package labeling; and
 - ii. Only 1 Reusable Unit will be approved at a time; and
11. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of edema.

Myqorzo™ (Aficamten) Approval Criteria:

1. An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
2. Member must be 18 years of age or older; and
3. Member must have New York Heart Association (NYHA) class II to III heart failure; and
4. Must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and
5. Member must have left ventricular ejection fraction (LVEF) $\geq 55\%$ to initiate therapy; and
 - a. Prescriber must agree to assess the member's clinical status and LVEF during treatment and adjust or interrupt the Myqorzo™ dose accordingly; and
6. Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or non-dihydropyridine calcium channel blockers; and
7. Prescriber must evaluate the potential for drug interactions, including the need for dose adjustments or increased monitoring according to package labeling, prior to and during treatment with Myqorzo™; and
8. Prescriber, pharmacy, and member must be enrolled in the Myqorzo™ Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and

9. A quantity limit of 30 tablets per 30 days will apply; and
10. Initial approvals will be for the duration of 6 months. Subsequent approvals, for the duration of 1 year, may be granted if the prescriber attests that the member is tolerating and responding well to treatment.

The College of Pharmacy also recommends updating the approval criteria for Camzyos® (mavacamten), Furoscix® (furosemide on-body infusor), and Verquvo® (vericiguat) based on recent FDA approvals (changes shown in red):

Camzyos® (Mavacamten) Approval Criteria:

1. An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
2. Member must be 18 years of age or older; and
3. Member must have New York Heart Association (NYHA) class II to III heart failure; and
4. Camzyos® must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and
5. Member must have left ventricular ejection fraction (LVEF) $\geq 55\%$; and
 - a. Prescriber must agree to assess the member's clinical status and LVEF during treatment and adjust or interrupt the Camzyos® dose accordingly; and
6. Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or non-dihydropyridine calcium channel blockers; and
- ~~7. Member must not be taking concurrent strong CYP2C19 inhibitors (e.g., fluvoxamine, fluconazole), moderate to strong CYP2C19 inducers (e.g., rifampin), or moderate to strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin); and~~
- ~~8. If the member is taking moderate to strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin) or weak to moderate CYP2C19 inhibitors (e.g., proton pump inhibitors, clopidogrel, voriconazole), the prescriber must verify that the Camzyos® dose will be adjusted according to the package labeling; and~~
9. Prescriber must evaluate the potential for drug interactions, including the need for dose adjustments, according to package labeling, prior to and during treatment with Camzyos®; and
10. Member must not be taking or planning to take disopyramide, ranolazine, or a combination of a beta blocker and a calcium channel blocker concomitantly with Camzyos®; and
11. Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 4 months after the final dose of Camzyos®; and

12. Prescriber, pharmacy, and member must be enrolled in the Camzyos® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
13. A quantity limit of 30 capsules per 30 days will apply; and
14. Initial approvals will be for the duration of 6 months. Subsequent Further approvals, for the duration of 1 year, may be granted if the prescriber attests documents that the member is tolerating and responding well to treatment.; and
- ~~15. Subsequent approvals will be for the duration of 1 year.~~

Furoscix® (Furosemide On-Body Injection) Approval Criteria:

1. An FDA approved indication for the treatment of edema in members with chronic heart failure or chronic kidney disease (CKD), including nephrotic syndrome; and
- ~~2. Member must be 18 years of age or older; and~~
3. Member must weigh $\geq 43\text{kg}$; and
4. Furoscix® must be prescribed by, or in consultation with, a cardiologist, nephrologist, or a provider trained in managing acute decompensated heart failure (ADHF) or CKD; and
5. Member is currently showing signs of edema; and
6. Member has been established on maintenance therapy with and is refractory to a dose escalation with at least 1 of the following loop diuretics, at maximally tolerated doses:
 - a. Bumetanide oral tablets; or
 - b. Furosemide oral tablets; or
 - c. Torsemide oral tablets; and
7. Prescriber must verify the member will discontinue oral diuretics during the treatment with Furoscix® and will transition back to oral diuretic maintenance therapy when practical; and
- ~~8. Prescriber must verify the member is stable and suitable for at-home treatment with Furoscix®, as determined by:
 - a. Oxygen saturation $\geq 90\%$ on exertion; and
 - b. Respiratory rate < 24 breaths per minute; and
 - c. Resting heart rate < 100 beats per minute; and
 - d. Systolic blood pressure $> 100\text{mmHg}$; and~~
- ~~9. Member must have an adequate environment for at-home administration, have been trained on the proper use of Furoscix®, and be able to detect and respond to the device alarms; and~~
10. Prescriber must verify the member or caregiver will be trained on the proper use of Furoscix® and is able to detect and respond to the device alarms; and
11. Member must not have any contraindications for use of Furoscix® including anuria or hepatic cirrhosis; and
12. Member must not have conditions that require immediate hospitalization; and
13. Approvals will be issued per incident of edema fluid overload; and

14. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident ~~of edema fluid overload~~.

Verquvo® (Vericiguat) Approval Criteria:

1. An FDA approved indication to reduce the risk of cardiovascular death and hospitalization for heart failure (HF) in adults with all of the following:
 - a. Chronic symptomatic HF [New York Heart Association (NYHA) Class II, III, or IV]; and
 - b. Reduced left ventricular ejection fraction (LVEF) <45%; and
 - c. Already receiving guideline-directed medical therapy for HF, as documented in member's pharmacy claims history; and
2. Member has evidence of worsening HF (decompensation) demonstrated by at least 1 of the following:
 - a. Hospitalization for HF within the past 6 months; or
 - b. Received outpatient intravenous (IV) diuretics within the past 3 months; and
3. Member must be 18 years of age or older; and
4. Member must not be taking concomitant soluble guanylate cyclase (sGC) stimulators (e.g., riociguat); and
5. Female members of reproductive potential must not be breastfeeding, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during treatment and for 1 month after the final dose of Verquvo®; and
6. Prescriber must attest that the member will be assessed for symptomatic hypotension before initiation and during treatment per package labeling; and
7. Prescriber must verify that the dose will be adjusted per package labeling for members at increased risk for symptomatic hypotension; and
8. Prescriber must agree to titrate to the target maintenance dose according to package labeling, as tolerated by the member; and
9. Initial approvals will be for the duration of 6 months. Compliance will be checked for continued approval every 6 months; and
10. A quantity limit of 30 tablets per 30 days will apply.

Recommendation 4: Vote to Prior Authorize Leqembi Iqlik® (Lecanemab-irmb)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Leqembi Iqlik® (lecanemab-irmb) with criteria similar to Leqembi® (lecanemab-irmb), including updates to the magnetic resonance imaging (MRI) monitoring criteria based on the Drug Safety Communication and corresponding label updates (changes shown in red):

Leqembi® and Lecanemab-irmb® (Lecanemab-irmb) Approval Criteria:

1. An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:
 - a. Mini-Mental State Exam (MMSE) score between 22 and 30; or
 - b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5 or 1; or
 - c. Montreal Cognitive Assessment (MoCA) score ≥ 19 ; or
 - d. Quick Dementia Rating System (QDRS) score ≤ 5 ; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Lecanemab-irmb Leqembi® must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and
5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE $\epsilon 4$ status has been completed if appropriate; and
7. Member must not be taking anticoagulant or antiplatelet agents except for aspirin or clopidogrel, and the prescriber must attest that the increased safety risks for developing intracerebral hemorrhage with the concomitant use have been discussed and are acceptable to the member prior to initiating Lecanemab-irmb Leqembi®; and
8. Member must not have had a stroke, transient ischemic attack (TIA), or unexplained loss of consciousness in the past year; and
9. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
10. Member must not have risk factors for intracerebral hemorrhage, including the following:
 - a. Prior cerebral hemorrhage $>1\text{cm}$ in greatest diameter; or
 - b. >4 microhemorrhages; or
 - c. An area of superficial siderosis; or
 - d. Evidence of vasogenic edema; or
 - e. Evidence of cerebral contusion, aneurysms, vascular malformations, or infective lesions; or
 - f. Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Lecanemab-irmb, Leqembi® and after 1 month, 2

months, 3 months, and 6 months of treatment, and as clinically indicated ~~the 5th, 7th, and 14th infusions~~; and

12. Prescriber must confirm that the member will be monitored for ARIA during the first 14 weeks and throughout treatment with ~~lecanemab-irmb~~ ~~Leqembi®~~; and
13. If ≥ 10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation confirming resolution of symptoms, if present, and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H) have been completed; and
14. ~~Verification that lecanemab-irmb will be shipped via cold chain supply to the administering location (i.e., member's home, clinic) and storage and handling requirements will be followed as per the package labeling; and~~
15. ~~Requests for Leqembi® IV will require the following:~~
 - a. ~~Leqembi® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration; and~~
 - i. ~~Leqembi® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and~~
 - b. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
16. ~~Requests for Leqembi Iqlik® subcutaneous (sub-Q) formulation will require the following:~~
 - a. ~~Member has received treatment with the IV formulation at a dose of 10mg/kg every 2 weeks for 18 months; and~~
 - b. ~~Leqembi Iqlik® must be initiated under the guidance and supervision of a health care professional; and~~
 - c. ~~For self or caregiver administration, the prescriber must attest to the following:~~
 - i. ~~Direct guidance for at least 2 consecutive sub-Q doses has been provided by a health care professional; and~~
 - ii. ~~Member or caregiver will be trained by a health care professional on the sub-Q administration, ability to recognize and manage symptoms of hypersensitivity, and proper storage of Leqembi Iqlik®; and~~
17. ~~For maintenance dosing, the prescriber must verify the member has completed 18 months of an FDA-approved starting dosage regimen; and~~
18. Initial approvals will be for 6 months. Confirmation that MRIs have been completed ~~per package labeling~~ and were acceptable to the provider ~~prior to the 5th and 7th infusions~~ is required for continuation; and

19. Subsequent approvals will be for 6 months, and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy for each subsequent approval; and
20. Approval quantities will be dependent on the member's weight and/or dosing based on package labeling; and
21. The maximum dose approvable is 10mg/kg per 14 days for the IV formulation and 10mL per 28 days for the sub-Q formulation; and
22. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

Recommendation 5: Vote to Prior Authorize Awiqli® (Insulin Icodec-abae), Glipizide 15mg Tablet, Kirsty™ (Insulin Aspart-xjhz), and Langlara™ (Insulin Glargine-aldy) and Update the Approval Criteria for the Anti-Diabetic Medications and Kerendia® (Finerenone)

MOTION CARRIED by unanimous approval.

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

1. Prior authorization of glipizide 15mg tablet and placement into the Special Prior Authorization (PA) Tier with the following additional criteria; and
2. Designating Januvia® (sitagliptin) and Janumet® (sitagliptin/metformin) as brand preferred and moving generic sitagliptin, generic sitagliptin/metformin, and Janumet XR® (sitagliptin/metformin ER) to the Special PA Tier with the following additional criteria based on net costs; and
3. Moving Onglyza® (saxagliptin) from the Special PA Tier to Tier-3 based on net costs; and
4. Moving Nesina® (alogliptin) and Oseni® (alogliptin/pioglitazone) from Tier-3 to the Special PA Tier based on net costs; and
5. Moving Zituvio® (sitagliptin), Zituvimet® (sitagliptin/metformin), and Zituvimet® XR (sitagliptin/metformin ER) from Special PA to Tier-2 based on net costs and generic availability; and
6. Removing the brand preferred status from Farxiga® (dapagliflozin) and moving generic dapagliflozin from the Special PA Tier to Tier-1 based on net costs; and
7. Updating the GLP-1 Agonists and Glucose-Dependent Insulinotropic Polypeptide (GIP)/GLP-1 Agonists Special PA Approval Criteria based on clinical practice and for clarity.

Anti-Diabetic Medications			
Tier-1	Tier-2	Tier-3	Special PA
Alpha-Glucosidase Inhibitors			
acarbose (Precose®)		miglitol (Glyset®)	
Amylinomimetics			
			pramlintide (Symlin®)*
Biguanides			
metformin (Glucophage®)			metformin ER (Fortamet®, Glumetza®)
metformin SR (Glucophage XR®)			metformin soln (Riomet®)
metformin/glipizide (Metaglip®)			metformin 625mg & 750mg tab
metformin/glyburide (Glucovance®)			
DPP-4 Inhibitors			
	linagliptin (Tradjenta®)	alogliptin (Nesina®)	alogliptin (Nesina®)
	linagliptin/metformin (Jentadueto®) – Brand Preferred	alogliptin/metformin (Kazano®)	alogliptin/pioglitazone (Oseni®)
	linagliptin/metformin ER (Jentadueto® XR)	alogliptin/pioglitazone (Oseni®)	linagliptin/metformin (generic)*
	sitagliptin (Januvia®) – Brand Preferred	saxagliptin (Onglyza®)	saxagliptin (Onglyza®)
	sitagliptin (Zituvio®)		saxagliptin/metformin (Kombiglyze®, Kombiglyze XR®)
	sitagliptin/metformin (Janumet®) – Brand Preferred		sitagliptin (generic Januvia®)*
	sitagliptin/metformin ER (Janumet XR®)		sitagliptin (Zituvio®)*
	sitagliptin/metformin (Zituvimet®)		sitagliptin/metformin (generic Janumet®)*
	sitagliptin/metformin ER (Zituvimet® XR)		sitagliptin/metformin ER (Janumet XR®)*
			sitagliptin/metformin (Zituvimet®)*
			sitagliptin/metformin ER (Zituvimet® XR)*
			sitagliptin oral solution (Brynovin®)*

Anti-Diabetic Medications			
Tier-1	Tier-2	Tier-3	Special PA
DPP-4 Inhibitors/SGLT-2 Inhibitors			
empagliflozin/ linagliptin (Glyxambi®)			dapagliflozin/ saxagliptin (Qtern®)
			ertugliflozin/sitagliptin (Steglujan®)
Dopamine Agonists			
		bromocriptine (Cycloset®)	
Glinides			
repaglinide (Prandin®)	nateglinide (Starlix®)		
	repaglinide/ metformin (Prandimet®)		
GIP/GLP-1 Agonists			
	dulaglutide (Trulicity®)	semaglutide (Ozempic®)	exenatide (Byetta®)*
	liraglutide (Victoza®) – Brand Preferred	semaglutide (Rybelsus®)	liraglutide (generic)*
			tirzepatide (Mounjaro®)*
GLP-1 Agonists/Insulin			
		insulin degludec/ liraglutide (Xultophy® 100/3.6)*	
		insulin glargine/ lixisenatide (Soliqua® 100/33)*	
SGLT-2 Inhibitors			
dapagliflozin (Farxiga®) – Brand Preferred	dapagliflozin/ metformin ER (Xigduo® XR) – Brand Preferred	canagliflozin (Invokana®)	dapagliflozin (generic)*
empagliflozin (Jardiance®)		canagliflozin/ metformin (Invokamet®)	dapagliflozin/ metformin ER (generic)*
empagliflozin/ metformin (Synjardy®)		canagliflozin/ metformin ER (Invokamet® XR)	ertugliflozin (Steglatro®)
empagliflozin/ metformin ER (Synjardy® XR)			ertugliflozin/metformin (Segluromet®)
			sotagliflozin (Inpefa®)*
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)			

Anti-Diabetic Medications			
Tier-1	Tier-2	Tier-3	Special PA
Sulfonylureas			
glimepiride (Amaryl®)			glimepiride 3mg tablet*
glipizide (Glucotrol®)			glipizide 2.5mg immediate-release tablet*
glipizide SR (Glucotrol XL®)			glipizide 15mg immediate-release tablet*
glyburide (Diabeta®)			
glyburide micronized (Micronase®)			
Thiazolidinediones			
pioglitazone (Actos®)		pioglitazone/ glimepiride (Duetact®)	
		pioglitazone/ metformin (Actoplus Met®, Actoplus Met XR®)	
		rosiglitazone (Avandia®)	

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 applies.

DPP-4 = dipeptidyl peptidase-4; ER = extended-release; GIP = gastric inhibitory polypeptide; GLP-1 = glucagon-like peptide-1; PA = prior authorization; SGLT-2 = sodium-glucose cotransporter-2; soln = solution; SR = sustained-release; susp = suspension

Anti-Diabetic Medications Special PA Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. Member must be currently stabilized on the requested product or have attempted at least 3 other categories of Tier-2 or Tier-3 medications, or have a documented clinical reason why the requested product is necessary for the member; and
3. Use of Brynovin® (sitagliptin oral solution) will require a patient-specific, clinically significant reason why a special formulation is needed and why the member cannot use all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors); and
4. Use of generic ~~dapagliflozin~~ or dapagliflozin/metformin ER will require a patient-specific, clinically significant reason why the member cannot use brand name ~~Farxiga® (dapagliflozin)~~ or Xigduo® XR (dapagliflozin/metformin ER) and all available lower-tiered sodium-glucose cotransporter-2 (SGLT-2) inhibitors; and
5. Use of glimepiride 3mg tablet will require a patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including using the lower strengths of glimepiride to achieve the 3mg dose; and

6. Use of glipizide 2.5mg immediate-release tablet will require a patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products including splitting a glipizide 5mg tablet to achieve a 2.5mg dose; and
7. Use of glipizide 15mg tablet will require a patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including using the lower strengths of glipizide to achieve the 15mg dose; and
8. Use of generic linagliptin/metformin will require a patient-specific, clinically significant reason why the member cannot use brand name Jentadueto® (linagliptin/metformin); and
9. Use of generic sitagliptin (generic Januvia®) or sitagliptin/metformin (generic Janumet®) will require a patient-specific, clinically significant reason why the member cannot use brand name Januvia® (sitagliptin) or Janumet® (sitagliptin/metformin) and all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors); and
10. Use of Janumet XR® (sitagliptin/metformin ER) ~~Zituvio® (sitagliptin), and Zituvimet® (sitagliptin/metformin), and Zituvimet®-XR (sitagliptin/metformin)~~ will require a patient-specific, clinically significant reason why the member cannot use all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors).

Glucagon-Like Peptide-1 (GLP-1) Agonists and Glucose-Dependent Insulinotropic Polypeptide (GIP)/GLP-1 Agonists Special PA Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. ~~Member must be currently stabilized on the requested product (documentation must be provided) or a patient-specific, clinically significant reason (other than convenience) why the member cannot use all available lower-tiered GLP-1 or GIP/GLP-1 agonists must be provided; and~~
3. Documentation of member's current A1c and goal A1c must be submitted with all requests; and
4. Member must meet 1 of the following:
 - a. Member must be currently stabilized on the requested product [documentation must be provided (e.g., pharmacy records and clinical documentation of glycemic control and/or reduction in A1c while on therapy)]; or
 - b. Member must have failed to achieve glycemic control and/or goal A1c reduction despite a trial at least 3 months in duration and at recommended dosing (and member must be adherent to therapy) with all available lower-tiered GLP-1 or GIP/GLP-1 agonists and have a documented clinical reason why the member cannot continue treatment with the lower tier medications; and

- i. Clinical documentation of follow-up glycemic status after trials (e.g., A1c levels, blood glucose levels) must be provided; and
 - ii. For members who did not complete a 3-month trial with a lower-tiered GLP-1 or GIP/GLP-1 agonist (i.e., due to intolerable adverse effects), detailed information regarding adverse effects occurring with the lower-tiered medication(s) that are not expected to occur with the requested medication must be provided; and
- 5. Use of generic liraglutide will require a patient-specific, clinically significant reason why the member cannot use brand name Victoza® (liraglutide); and
- 6. A clinical exception will apply for medications with a unique FDA approved indication or guideline supported efficacy not covered by all Tier-2 and Tier-3 GLP-1 or GIP/GLP-1 agonists. Tier structure rules for unique FDA approved indications and guideline supported efficacy will apply.

Additionally, the College of Pharmacy recommends the prior authorization of Awiqli® (insulin icodec-abae) with the following criteria, Kirsty™ (insulin aspart-xjhz) with criteria similar to Merilog™ (insulin aspart-szjj), and Langlara™ (insulin glargine-aldy) with criteria similar to Rezvoglar™ (insulin glargine-aglr) (changes shown in red):

Awiqli® (Insulin Icodec-abae) Approval Criteria:

- 1. An FDA approved diagnosis of type 2 diabetes mellitus; and
- 2. Member must be 18 years of age or older; and
- 3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use a daily basal insulin must be provided.

Kirsty™ (Insulin Aspart-xjhz) and Merilog™ (Insulin Aspart-szjj) Approval Criteria:

- 1. An FDA approved diagnosis of diabetes mellitus; and
- 2. A patient-specific, clinically significant reason why the member cannot use Novolog® (insulin aspart) or Fiasp® (insulin aspart) 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.

Langlara™ (Insulin Glargine-aldy) and Rezvoglar™ (Insulin Glargine-aglr) Approval Criteria:

- 1. An FDA approved diagnosis of diabetes mellitus; and
- 2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Semglee® (insulin glargine-yfgn) 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.

Next, the College of Pharmacy recommends removing the prior authorization from Humalog® KwikPen® U-200 (insulin lispro 200 units/mL), Lyumjev® U-100 (insulin lispro-aabc 100 units/mL), and brand name Tresiba® (insulin degludec) based on net costs and updating the Xultophy® 100/3.6 (insulin degludec/liraglutide) approval criteria based on the removal of the prior authorization from Tresiba® (changes shown in red):

Admelog® (Insulin Lispro) and Lyumjev® U-100 (Insulin Lispro-aabc 100 Units/mL) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use insulin lispro U-100 (unbranded Humalog® U-100) or Lyumjev® U-100 (insulin lispro-aabc 100 units/mL).

Humalog® KwikPen® U-200 (Insulin Lispro 200 Units/mL) and Lyumjev® KwikPen® U-200 (Insulin Lispro-aabc 200 Units/mL) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. Authorization of the 200 units/mL strength requires a patient-specific, clinically significant reason why the member cannot use the 100 units/mL strength; and
3. A patient-specific, clinically significant reason why the member cannot use Humalog® KwikPen® U-200 (insulin lispro 200 units/mL).

~~Tresiba® (Insulin Degludec) Approval Criteria:~~

- ~~1. An FDA approved diagnosis of diabetes mellitus; and~~
- ~~2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Semglee® (insulin glargine-yfgn) must be provided.~~

Xultophy® 100/3.6 (Insulin Degludec/Liraglutide) Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine), ~~or~~ Semglee® (insulin glargine-yfgn), or brand name Tresiba® (insulin degludec) with Victoza® (liraglutide) must be provided; and
3. Current Tier-3 criteria will apply.

Next, the College of Pharmacy recommends updating the Afrezza® (insulin human inhalation powder) approval criteria based on the FDA approved age expansion (changes shown in red):

Afrezza® (Insulin Human Inhalation Powder) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus (DM); and
2. Member must be **6 ~~18~~** years of age or older; and

3. A patient-specific, clinically significant reason why other rapid-acting injectable insulins are not appropriate must be provided; and
4. For the diagnosis of type 1 DM, the member must use Afrezza® with a long-acting insulin; and
5. Member must not smoke or have chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD).

Additionally, the College of Pharmacy recommends updating the Kerendia® (finerenone) approval criteria based on the new FDA approved indication and clinical practice (changes shown in red):

Kerendia® (Finerenone) Approval Criteria:

1. An FDA approved indication **of 1 of the following:**
 - a. To reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure (HF) in adult members with chronic kidney disease (CKD) associated with type 2 diabetes mellitus (T2DM); and
 - i. Member must be receiving a maximum tolerated dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or have a contraindication to use; and
 - ii. **Member has albuminuria (urine albumin-to-creatinine ratio $\geq 30\text{mg/g}$) despite maximum tolerated dosing of an ACE or ARB; or**
 - b. **To reduce the risk of cardiovascular death, hospitalization for HF, and urgent HF visits in adult members with HF with left ventricular ejection fraction (LVEF) $\geq 40\%$; and**
 - i. **Member is currently receiving guideline-directed management and therapy (GDMT) appropriate to their stage of HF or has a contraindication or documented intolerance to GDMT; and**
2. **Member is currently stabilized on a sodium-glucose cotransporter-2 (SGLT-2) inhibitor or** a patient specific, clinically significant reason why the member cannot use an SGLT-2 inhibitor must be provided; and
3. Member must not be receiving concomitant treatment with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir); and
4. Member must not have adrenal insufficiency; and
5. Member must not have severe hepatic impairment (Child Pugh C); and
6. Prescriber must measure serum potassium and eGFR **and verify the member meets the following** prior to initiation of Kerendia®; and
 - a. Serum potassium $\leq 5\text{mEq/L}$; and
 - b. eGFR $\geq 25\text{mL/min/1.73m}^2$; and
- ~~7. Prescriber must verify serum potassium is not $> 5.0\text{mEq/L}$ prior to treatment initiation with Kerendia®; and~~

8. Prescriber must agree to monitor serum potassium levels 4 weeks after a dose adjustment and throughout treatment and adjust the dose accordingly per package labeling; and
- ~~9. Initial authorization will be for 4 weeks, after which time serum potassium levels will be required for continued approval; and~~
10. A quantity limit of 30 tablets per 30 days will apply. The member's eGFR should be provided for initiation of treatment to ensure the correct recommended dose per package labeling. The following initial dose will be approved based on eGFR:
 - a. Kerendia® 10mg once daily in members with eGFR 25 to <60mL/min/1.73m²; or
 - b. Kerendia® 20mg once daily in members with eGFR ≥60mL/min/1.73m²; and
- ~~11. A maximum approvable dose will apply based on indication per the package labeling:
 - a. CKD associated with T2DM: 20mg once daily; or
 - b. HF with LVEF ≥40%: 40mg once daily; and~~
- ~~12. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and that serum potassium levels and eGFR are monitored periodically and the dose is adjusted accordingly per the package labeling. Subsequent approvals will be for 1 year.~~

Finally, the College of Pharmacy recommends updating the Tzield® (teplizumab-mzwv) approval criteria based on the new FDA approvals and label updates (changes shown in red):

Tzield® (Teplizumab-mzwv) Approval Criteria:

1. An FDA approved diagnosis of **1 of the following**:
 - a. Stage 2 Type 1 diabetes mellitus (DM). Diagnosis must be confirmed by the following:
 - i. Laboratory testing confirming the presence of ≥2 pancreatic islet autoantibodies (documentation must be submitted with results of autoantibody testing); and
 - ii. Documented evidence of dysglycemia without overt hyperglycemia as demonstrated by 1 of the following (results of lab testing must be submitted):
 1. Fasting plasma glucose ≥100mg/dL and <126mg/dl; or
 2. 2-hour plasma glucose ≥140 mg/dL and <200mg/dl; or
 3. Hemoglobin A1c ≥5.7% and <6.5% or ≥10% increase in A1c; or
 4. 30-, 60-, or 90-minute value ≥200mg/dl on 2 separate occasions; **and or**
 - b. **Recently diagnosed Stage 3 Type 1 DM. Diagnosis must be confirmed by the following:**
 - i. **Member was diagnosed within the last 8 weeks; and**

- ii. Laboratory testing confirming the presence of ≥ 1 pancreatic islet autoantibody (documentation must be submitted with results of autoantibody testing); and
 - iii. Peak C-peptide ≥ 0.2 pmol/mL on a mixed-meal tolerance test (MMTT) or alternative if MMTT is not available (results of lab testing must be submitted); and
- 2. Member must be:
 - a. ~~8 years~~ 1 year of age or older for Stage 2 Type 1 DM; or
 - b. 8 to 17 years of age for Stage 3 Type 1 DM; and
- 3. ~~Prescriber must confirm that member's clinical history does not suggest a diagnosis of Type 2 DM; and~~
- 4. Prescriber must confirm that the member's diagnosis is of autoimmune origin and does not suggest insulin resistance due to obesity, type 2 diabetes mellitus (T2DM), or dysglycemia due to other forms of diabetes including but not limited to genetic forms of diabetes, maturity-onset diabetes of the young (MODY), latent autoimmune diabetes in adults (LADA), or diabetes secondary to medications or surgery; and
- 5. Tzield® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
- 6. ~~All of the following will be required for initiation of treatment:~~
 - a. ~~Verification that female members of reproductive potential are not pregnant and are currently using reliable contraception; and~~
 - b. ~~Verification that the member has no active infection(s); and~~
 - c. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
 - d. ~~Liver function tests and verification that levels are acceptable to the prescriber; and~~
 - e. ~~Verification that all age appropriate vaccinations have been administered prior to treatment; and~~
 - f. ~~Prescriber must agree to premedicate the member for the first 5 days of dosing and as needed with a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, an antihistamine, and/or an antiemetic; and~~
- 7. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Tzield®; and
- 8. Prescriber must confirm that the member does not have any contraindications for use of Tzield®; and
- 9. Prescriber must verify that Tzield® treatment will be interrupted and/or discontinued when appropriate, as per the package labeling [e.g., prolonged severe lymphopenia, viral reactivation, liver enzymes > 5 times the upper limit of normal (ULN), or bilirubin > 3 times ULN, severe cytokine release syndrome, serious infections]; and

10. Tziel® must be administered by a health care professional. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Tziel® will be administered; and
 - a. Tziel® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
 - b. Tziel® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of Tziel®; and
11. The member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
12. ~~A quantity limit of 28mL per 14 days will apply; and~~
13. ~~Approval quantities will be based on the recommended dosing per package labeling based on the member's diagnosis and recent BSA; and~~
14. Approvals will be for ~~the following:~~
 - a. Stage 2 TDM: (1) 14-day cycle per member per lifetime; or
 - b. Stage 3 TDM: (2) 12-day cycles per member per lifetime.

Recommendation 6: Vote to Prior Authorize Jobevne™ (Bevacizumab-nwgd) and Update the Approval Criteria for the Colorectal Cancer (CRC) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Jobevne™ (bevacizumab-nwgd) with criteria similar to the other non-preferred bevacizumab products based on net costs and recommends making Vegzelma® (bevacizumab-adcd) a preferred product based on net cost (changes shown in red):

Alymsys® (Bevacizumab-maly), Avzivi® (Bevacizumab-tnjn), and Jobevne™ (Bevacizumab-nwgd), and Vegzelma® (Bevacizumab-adcd) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Avastin® (bevacizumab), Mvasi® (bevacizumab-awwb), ~~Vegzelma® (bevacizumab-adcd)~~, or Zirabev® (bevacizumab-bvzr), which are available without prior authorization, 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.

Recommendation 7: Vote to Prior Authorize Modeyso™ (Dordaviprone) and Vistogard® (Uridine Triacetate) and Update the Approval Criteria for the Miscellaneous Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Modeyso™ (dordaviprone) and Vistogard® (uridine triacetate) with the following criteria (shown in red):

Modeyso™ (Dordaviprone) Approval Criteria [Glioma Diagnosis]:

1. Diagnosis of diffuse midline glioma; and
2. Member must be 1 year of age or older; and
3. Presence of H3 K27M mutation; and
4. Member has progressed on at least 1 prior therapy.

Vistogard® (Uridine Triacetate) Approval Criteria:

1. Member received fluorouracil or capecitabine within the previous 96 hours; and
2. Member meets 1 of the following:
 - a. Following fluorouracil or capecitabine overdose regardless of the presence of symptoms; or
 - b. Exhibits early-onset, severe or life-threatening toxicity affecting cardiac or central nervous system; or
 - c. Exhibits early-onset, unusually severe adverse reactions; and
3. A quantity limit of 20 packets for 5 days will apply; and
 - a. Doses administered in an emergency room (ER) or inpatient (IP) setting do not require prior authorization. The number of remaining doses (following any ER or IP doses) must be specified on the request. Only the number of remaining doses for outpatient use will be approved.

Next, the College of Pharmacy recommends updating the Omisirge® (omidubicel-only) and Tecelra® (afamitresgene autoleucel) approval criteria based on recent FDA approvals with the following updates (shown in red):

Omisirge® (Omidubicel-only) Approval Criteria [Severe Aplastic Anemia Diagnosis]:

1. Diagnosis of severe aplastic anemia; and
2. Member is 6 years of age or older; and
3. Allogeneic stem cell transplant using umbilical cord blood donor source is planned; and
 - a. No compatible donor is available; and
 - b. Documentation of the donor source must be provided; and
4. Reduced intensity conditioning regimen will be used; and
 - a. Documentation of the member's conditioning regimen must be provided; and

5. Will be used to reduce time to neutrophil recovery and incidence of infection.

Tecelra® (Afamitresgene Autoleucel) Approval Criteria [Synovial Sarcoma Diagnosis]:

1. Diagnosis of unresectable or metastatic synovial sarcoma; and
2. Member must be ~~18~~ 12 years of age or older; and
3. Has received previous anthracycline or ifosfamide-containing chemotherapy; and
4. HLA-A*02:01P, -A*02:02P, A*02:03P, or -A*02:06P positive; and
5. Tumor expresses melanoma-associated antigen A4 (MAGE-A4) as detected by an FDA-approved test; and
6. Health care facilities must be able to administer cellular therapies and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities; and
7. Approvals will be for 1 dose per member per lifetime.

Lastly, the College of Pharmacy recommends updating Voranigo® (vorasidenib) approval criteria to be consistent with the FDA approved age range with the following updates (shown in red):

Voranigo® (Vorasidenib) Approval Criteria [Astrocytoma or Oligodendroglioma Diagnosis]:

1. Diagnosis of grade 2 astrocytoma or oligodendroglioma; and
2. Member must be 12 years of age or older; and
3. Presence of susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation following surgery including biopsy, sub-total resection, or gross total resection.

Recommendation 8: Vote to Update the Approval Criteria for the Iron Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Accrufer® (ferric maltol) approval criteria based on the recent FDA approved age expansion with the following changes (shown in red):

Accrufer® (Ferric Maltol) Approval Criteria:

1. Diagnosis of iron deficiency anemia (IDA); and
2. Lab results verifying IDA must be submitted; and
3. Member must be ~~18~~ 10 years of age or older; and
4. For members 18 years of age or older, all of the following must be met:
 - a. Member must have a documented diagnosis of chronic kidney disease (CKD) or inflammatory bowel disease (IBD) (e.g., Crohn's disease, ulcerative colitis); and

- b. Documentation of intolerance or inadequate response to over-the-counter (OTC) oral iron therapy after at least 3 months at recommended dosing; and
 - c. A recent, failed trial of Feraheme® (ferumoxytol), Infed® (iron dextran), or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, Infed®, and Venofer® must be provided; and
 - d. A patient-specific clinically significant reason why the member cannot utilize all other forms of intravenous (IV) iron must be provided; and
5. For members younger than 18 years of age, all of the following must be met:
- a. Documentation of intolerance or inadequate response to over-the-counter (OTC) oral iron therapy after at least 3 months at recommended dosing; and
 - b. A patient-specific clinically significant reason why the member cannot utilize IV iron must be provided; and
6. Initial approvals will be for the duration of 3 months of treatment. Subsequent approvals (for 3 months of treatment) will require updated recent laboratory results documenting continued IDA.

Recommendation 9: Vote to Update the Approval Criteria for the Iron Chelating Agents

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Jadenu® (deferasirox), Jadenu® Sprinkle (deferasirox), and Ferriprox® (deferiprone) approval criteria with regard to Exjade® (deferasirox) for clarity and to include additional criteria for Ferriprox® tablet (deferiprone twice daily formulation) based on net cost (changes shown in red):

Jadenu® (Deferasirox), Jadenu® Sprinkle (Deferasirox), and Ferriprox® (Deferiprone) Approval Criteria:

- 1. An FDA approved diagnosis; and
- 2. A patient-specific, clinically significant reason other than convenience why the member cannot use Exjade® (deferasirox), **which is available without prior authorization**, must be provided; and
- 3. For Jadenu® Sprinkle (deferasirox oral granules), an age restriction of 6 years of age and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why Jadenu® oral tablets cannot be used even when the tablets are crushed; and
- 4. **For Ferriprox® 1,000mg tablet (deferiprone twice daily formulation), a patient-specific, clinically significant reason other than convenience why the member cannot use and Ferriprox® 1,000mg tablet (deferiprone 3 times daily formulation); and**

5. 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 package labeling.

Recommendation 10: Vote to Prior Authorize Amcinonide 0.1% Ointment and Update the Approval Criteria for the Topical Corticosteroids

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Topical Corticosteroids Product Based Prior Authorization (PBPA) Tier chart based on net costs (changes are shown in red in the following Tier chart):

1. Ultra-High to High Potency:
 - a. Prior authorization of amcinonide 0.1% ointment and placement into Tier-3; and
 - b. Move augmented betamethasone dipropionate 0.05% (Diprolene®) gel, clobetasol propionate/skin cleanser 0.05% (Clodan®) kit, desoximetasone 0.05% (Topicort®) gel, and halobetasol propionate 0.05% (Ultravate®) lotion from Tier-2 to Tier-3; and
 - c. Move desoximetasone 0.25% (Topicort®) spray from Tier-3 to Tier-2; and
 - d. Move clobetasol propionate 0.05% (Temovate® Emollient) emollient cream from Tier-1 to Tier-2; and
2. Medium-High to Medium Potency:
 - a. Move hydrocortisone butyrate 0.1% solution from Tier-2 to Tier-3; and
 - b. Move triamcinolone acetonide 0.1% lotion from Tier-1 to Tier-2; and
3. Low Potency:
 - a. Move fluocinolone acetonide/skin cleanser 0.01% (Synalar® TS) kit from Tier-2 to Tier-3.

Topical Corticosteroids					
Tier-1		Tier-2		Tier-3	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (Diprolene®) Diprolene AF®)	C,L,O	augmented betamethasone dipropionate 0.05% (Diprolene®)	G	amcinonide 0.1%	C,O
betamethasone dipropionate 0.05% (Diprosone®)	C,O	clobetasol propionate 0.05% (Clobex®, Clodan®)	L,Sh,Spr	augmented betamethasone dipropionate 0.05% (Diprolene®)	G
clobetasol propionate 0.05% (Olux®)	F	clobetasol propionate/skin cleanser 0.05% kit (Clodan®)	Sh	clobetasol propionate 0.025% (Impoyz®)	C

Topical Corticosteroids					
Tier-1		Tier-2		Tier-3	
clobetasol propionate 0.05% (Temovate®)	C,O,So	clobetasol propionate 0.05% (Temovate®)	G	clobetasol propionate emollient 0.05% (Olux-E®, Tovet®)	F
clobetasol propionate emollient 0.05% (Temovate® Emollient)	C	clobetasol propionate emollient 0.05% (Temovate® Emollient)	C	clobetasol propionate/skin cleanser 0.05% kit (Clodan®)	Sh
desoximetasone 0.25% (Topicort®)	C,O	desoximetasone 0.05% (Topicort®)	G	desoximetasone 0.25% (Topicort®)	Spr
fluocinonide 0.05%	C,O,So	desoximetasone 0.25% (Topicort®)	Spr	desoximetasone 0.05% (Topicort®)	G
fluocinonide 0.1% (Vanos®)	C	fluocinonide 0.05%	G	diflorasone diacetate 0.05% (Apexicon®)	C,O
halobetasol propionate 0.05% (Ultravate®)	C,O	halobetasol propionate 0.05% (Ultravate®)	L	halcinonide 0.1% (Halog®)	C,So
				halobetasol propionate 0.05%	F
				halobetasol propionate 0.05% (Ultravate®)	L
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	L	betamethasone valerate 0.12% (Luxiq®)	F	betamethasone dipropionate/ calcipotriene 0.064%/0.005% (Taclonex®)	O,Sus
betamethasone valerate 0.1% (Beta-Val®)	C,O	betamethasone valerate 0.1% (Beta-Val®)	L	clocortolone pivalate 0.1% (Cloderm®)	C
fluticasone propionate 0.005% (Cutivate®)	O	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (Enstilar®)	F	desoximetasone 0.05% (Topicort LP®)	C,O
fluticasone propionate 0.05% (Cutivate®)	C	fluocinolone acetonide 0.025% (Synalar®)	C,O	flurandrenolide 0.05%	L

Topical Corticosteroids					
Tier-1		Tier-2		Tier-3	
hydrocortisone valerate 0.2% (Westcort®)	C	fluocinolone acetonide/emollient 0.025% kit (Synalar®)	C,O	fluticasone propionate 0.05% (Cutivate®)	L
mometasone furoate 0.1% (Elocon®)	C,L,O, So	fluocinonide emollient 0.05% (Lidex E®)	C	hydrocortisone butyrate 0.1%	C,L, So
triamcinolone acetonide 0.025%	O	hydrocortisone butyrate 0.1%	O, Se	triamcinolone acetonide 0.147mg/g (Kenalog®)	Spr
triamcinolone acetonide 0.1%	C, L ,O	hydrocortisone probutate 0.1% (Pandel®)	C		
triamcinolone acetonide 0.5%	C,O	hydrocortisone valerate 0.2% (Westcort®)	O		
		triamcinolone acetonide 0.05% (Trianex®)	O		
		triamcinolone acetonide 0.1%	L		
Low Potency					
desonide emollient 0.05%	C,O	alclometasone dipropionate 0.05% (Aclovate®)	C,O	desonide 0.05%	L
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®) – Brand Preferred	Oil	fluocinolone acetonide/skin cleanser 0.01% kit (Synalar® TS)	C
hydrocortisone acetate 1%	C,O	fluocinolone acetonide 0.01% (Synalar®)	C	hydrocortisone 2.5% (Texacort®)	So
hydrocortisone acetate 2.5%	C,L,O	fluocinolone acetonide/skin-cleanser 0.01% kit (Synalar® TS)	C		
triamcinolone acetonide 0.025%	C,L				

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).

C = cream; F = foam; G = gel; L = lotion; O = ointment; Sh = shampoo; So = solution; Spr = spray; Sus = suspension

Recommendation 11: Vote to Prior Authorize Contepo™ (Fosfomycin for Injection), Doxycycline Hyclate 75mg Capsule, and Orlynvah™ (Sulopenem Etzadroxil/Probenecid) and Update the Approval Criteria for the Various Systemic Antibiotics

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Contepo™ (fosfomycin for injection) and Orlynvah™ (sulopenem etzadroxil/probenecid) with the following criteria (shown in red):

Contepo™ (Fosfomycin for Injection) Approval Criteria:

1. An FDA approved diagnosis of complicated urinary tract infection (cUTI), including acute pyelonephritis, caused by *Escherichia coli* or *Klebsiella pneumoniae* (culture/sensitivity results must be submitted with the request); and
2. A patient-specific, clinically significant reason why the member cannot use an appropriate cephalosporin (e.g., cefuroxime, ceftriaxone, cefepime), penicillin/beta lactamase inhibitor combination (e.g., piperacillin/ tazobactam), a fluoroquinolone (e.g., ciprofloxacin or levofloxacin), or other cost-effective therapeutic equivalent alternative(s); and
3. A quantity limit of 42 vials per 14 days will apply.

Orlynvah™ (Sulopenem Etzadroxil/Probenecid) Approval Criteria:

1. An FDA approved diagnosis of uncomplicated urinary tract infection (uUTI) caused by designated susceptible microorganisms in members who have limited or no alternative oral treatment options (culture/sensitivity results must be submitted); and
 - a. Must not be used for the treatment of complicated urinary tract infections (cUTI) or complicated intraabdominal infections (cIAI) or as step-down treatment after intravenous antibacterial treatment of cUTI or cIAI; and
2. Member must be a female 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and
4. A quantity limit of 10 tablets per 5 days will apply.

The College of Pharmacy recommends updating the approval criteria for Blujepa (gepotidacin) based on the new FDA approved indication and for clarity (changes shown in red):

Blujepa (Gepotidacin) Approval Criteria:

1. An FDA approved diagnosis of **1 of the following:**
 - a. Uncomplicated urinary tract infection (uUTI) caused by ~~the designated microorganisms~~ *Escherichia coli*, *Klebsiella*

pneumoniae, *Citrobacter freundii* complex, *Staphylococcus saprophyticus*, ~~and or~~ *Enterococcus faecalis* (culture/sensitivity results must be submitted); and

- i. Member must be a female 12 years of age or older and weigh $\geq 40\text{kg}$; ~~and or~~
 - b. Uncomplicated urogenital gonorrhea in members who have limited or no alternative treatment options; and
 - i. Member must be 12 years of age or older and weigh $\geq 45\text{kg}$; and
2. Member must have an estimated glomerular filtration rate (eGFR) $>30\text{mL/min/1.73m}^2$ and must not be on dialysis; and
3. Member must not have severe hepatic impairment (Child Pugh C); and
- ~~4. Prior to and during treatment, the potential for drug interactions should be evaluated, including:~~
 - ~~a. Avoid concomitant administration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole) or inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and~~
 - ~~b. Avoid concomitant administration with CYP3A4 substrates with a narrow therapeutic index (e.g., quinidine, cyclosporine); and~~
 - ~~c. Monitor digoxin serum concentrations as clinically indicated; and~~
 - ~~d. Monitor for adverse effects with concomitant administration with acetylcholinesterase inhibitors, anticholinergic medications, or non-depolarizing neuromuscular blocking agents; and~~
5. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Blujepa and agree to address interactions with concomitant medications according to package labeling; and
6. Prescriber must verify that members with medical conditions that may be exacerbated by acetylcholinesterase inhibition will be monitored for adverse effects; and
7. If administration of Blujepa cannot be avoided in members with a history of QTc interval prolongation, taking antiarrhythmic medications, or taking other medications that may prolong the QTc interval, prescriber must verify that serum electrolyte abnormalities will be corrected and monitored and an ECG should be collected prior to administration and during treatment, as clinically indicated; and
- ~~8. A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and~~
9. A patient-specific, clinically significant reason why the member cannot use a cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis (e.g., ceftriaxone, nitrofurantoin, fosfomycin, sulfamethoxazole/trimethoprim) must be provided; and
- ~~10. A quantity limit of 20 tablets per 5 days will apply.~~
11. Approval quantity will be based on package labeling and FDA-approved dosing regimens.

The College of Pharmacy also recommends replacing the Oral Antibiotic Special Formulation approval criteria with individual criteria describing the preferred cost-effective therapeutic equivalent products for clarity and recommends the prior authorization of doxycycline hyclate 75mg capsule within the new approval criteria for the doxycycline special formulations (changes shown in red):

Oral Antibiotic Special Formulation Approval Criteria:

- ~~1.—Member must have a patient-specific, clinically significant reason why the immediate-release formulation and/or other cost-effective therapeutic equivalent medication(s) cannot be used.~~
- ~~2.—The following oral antibiotics currently require prior authorization and the special formulation approval criteria will apply:~~
 - ~~*—Amoxicillin/clavulanate potassium extended-release (ER) tablets (Augmentin XR[®])~~
 - ~~*—Cephalexin 250mg and 500mg tablets~~
 - ~~*—Cephalexin 750mg capsules~~
 - ~~*—Doxycycline hyclate 75mg and 150mg tablets (Acticlate[®])~~
 - ~~*—Doxycycline hyclate 50mg tablet (Targadox[®])~~
 - ~~*—Doxycycline hyclate delayed-release (DR) tablets (Doryx[®]; Doryx[®] MPC)~~
 - ~~*—Doxycycline monohydrate 75mg capsules~~
 - ~~*—Doxycycline monohydrate 150mg capsules and tablets~~
 - ~~*—Doxycycline monohydrate DR 40mg capsules (Oracea[®])~~
 - ~~*—Metronidazole 125mg tablets~~
 - ~~*—Metronidazole 375mg capsules~~
 - ~~*—Minocycline ER tablets (Minolira[™])~~
 - ~~*—Minocycline ER tablets (Solodyn[®])~~
 - ~~*—Nitrofurantoin 50mg/5mL suspension~~

Amoxicillin/Clavulanate Potassium Extended Release (ER) Tablets (Augmentin XR[®]) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the generic immediate release (IR) tablet formulations, which are available without prior authorization, must be provided.

Cephalexin 750mg Capsule and Cephalexin 250mg and 500mg Tablets Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use the 250mg or 500mg capsule formulations, which are available without prior authorization, must be provided.

Doxycycline Hyclate 75mg and 150mg Tablets (Acticlate®), Doxycycline Hyclate 75mg Capsule, Doxycycline Hyclate 50mg Tablet (Targadox®), Doxycycline Hyclate Delayed Release (DR) Tablets (Doryx®, Doryx® MPC), Doxycycline Monohydrate 75mg Capsule, Doxycycline Monohydrate 150mg Capsules and Tablets, and Doxycycline Monohydrate DR 40mg Capsules (Oracea®) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use generic immediate release (IR) doxycycline hyclate 20mg tablet, 50mg capsule, or 100mg capsule or tablet or doxycycline monohydrate 50mg capsule or tablet, 75mg tablet, or 100mg capsule or tablet, which are available without prior authorization, must be provided; and
2. For doxycycline hyclate 75mg capsule, a patient specific, clinically significant reason why the member cannot use the doxycycline hyclate 75mg tablet formulation must be provided.

Metronidazole 125mg Tablet and 375 mg Capsule Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use a dosing regimen with the 250mg or 500mg generic metronidazole tablets, which are available without prior authorization, must be provided.

Minocycline (50mg, 75mg, and 100mg) Immediate-Release (IR) Tablet, Minocycline ER Tablet (Minolira™), and Minocycline ER Tablet (Solodyn®) Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member ~~requires the IR tablet formulation and~~ cannot use the IR capsule formulation and/or other cost effective therapeutic equivalent medication(s).

Nitrofurantoin 50mg/5mL Suspension Approval Criteria:

1. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral capsule formulations cannot be used; and
2. A patient-specific, clinically significant reason why the member cannot use the generic nitrofurantoin 25mg/5mL suspension, which is available without prior authorization for members 10 years of age or younger, must be provided.

The College of Pharmacy also recommends updating the approval criteria for Avycaz® (ceftazidime/avibactam), Baxdela® (delafloxacin), ciprofloxacin 250mg/mL and 500mg/mL oral suspension and levofloxacin 25mg/mL oral solution, Likmez® (metronidazole 500mg/5mL suspension), and Zerbaxa® (ceftolozane/avibactam) based on clinical practice and for clarity (changes shown in red):

Avycaz® (Ceftazidime/Avibactam) Approval Criteria:

1. ~~An FDA approved~~ A diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
 - a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or
 - b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
 - c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); ~~and or~~
 - d. ~~Other diagnosis in which treatment with Avycaz® is supported by compendia or clinical literature (documentation must be submitted with the request); and~~
2. Member must be at least 31 weeks gestational age or older; and
3. For the diagnosis of cIAI, Avycaz® must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use ~~a an-appropriate~~ penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole when indicated, or other cost-effective therapeutic equivalent alternative(s) ~~appropriate for the diagnosis~~ must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Baxdela® (Delafloxacin) Tablet and Vial Approval Criteria ~~[Acute Bacterial Skin and Skin Structure Infection (ABSSSI) Diagnosis]:~~

1. ~~An FDA approved diagnosis of 1 of the following caused by designated susceptible bacteria (culture/sensitivities must be provided):~~
 - a. ~~Acute Bacterial Skin and Skin Structure Infection (ABSSSI) caused by designated susceptible bacteria; and or~~
 - b. ~~Community Acquired Bacteria Pneumonia (CABP); and~~
2. ~~A patient-specific, clinically significant reason why the member cannot use a cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis (e.g., other fluoroquinolone, beta-lactam, doxycycline, linezolid, trimethoprim/sulfamethoxazole, vancomycin) must be provided; and~~
3. ~~A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid, doxycycline, trimethoprim/sulfamethoxazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and~~
4. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and
 - a. For Baxdela® vials, an initial quantity limit of 6 vials for a 3-day supply will apply. Continued authorization will require a patient-

specific, clinically significant reason why the member cannot switch to the oral tablets for the remainder of therapy.

~~Baxdela® (Delafloxacin) Tablet and Vial Approval Criteria [Community-Acquired Bacterial Pneumonia (CABP) Diagnosis]:~~

- ~~1. An FDA approved diagnosis of CABP caused by designated susceptible bacteria; and~~
- ~~2. A patient specific, clinically significant reason why the member cannot use an appropriate beta lactam (e.g., ceftriaxone, cefotaxime, ceftaroline, ertapenem, ampicillin/sulbactam) in combination with a macrolide (e.g., azithromycin, clarithromycin) or doxycycline, monotherapy with a respiratory fluoroquinolone (e.g., levofloxacin, moxifloxacin, gemifloxacin), or other cost-effective therapeutic equivalent alternative(s) must be provided; and~~
- ~~3. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and~~

Ciprofloxacin 250mg/mL and 500mg/mL Oral Suspension and Levofloxacin 25mg/mL Oral Solution Approval Criteria:

- ~~1. Members older than 6 years of age require a patient specific, clinically significant reason why the oral tablet formulations cannot be used.~~
- ~~2. Products will be available without prior authorization for members 6 years of age and younger. Members older than 6 years of age require a patient-specific, clinically significant reason why the oral tablet formulations, which are available without prior authorization, cannot be used, including but not limited to:~~
 - ~~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. Treatment course was initiated inpatient; and~~
- ~~3. For members who require weight-based dosing, the member's recent weight (within the last 3 months) must be provided on the prior authorization request.~~

Likmez® (Metronidazole 500mg/5mL Suspension) Approval Criteria:

- ~~1. Products will be available without prior authorization for members 6 years of age and younger. Members older than 6 years of age require a~~
A ~~patient-specific clinically significant reason (beyond convenience) must be provided regarding why the member cannot use the 250mg and 500mg tablets, which are available without prior authorization, including but not limited to:~~
 - ~~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. Treatment course was initiated inpatient; and~~

2. For members who require weight-based dosing, the member's recent weight (within the last 3 months) must be provided on the prior authorization request; and
3. A quantity limit of 200mL per 10 days will apply

Zerbaxa® (Ceftolozane/Tazobactam) Approval Criteria:

1. ~~An FDA approved~~ A diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
 - a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or
 - b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
 - c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); ~~and or~~
 - d. Other diagnosis in which treatment with Zerbaxa® is supported by compendia or clinical literature (documentation must be submitted with the request); and
2. For the diagnosis of HABP/VABP, member must be 18 years of age or older; and
3. For the diagnosis of cIAI, Zerbaxa® must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use ~~a an-appropriate~~ penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole when indicated, or other cost-effective therapeutic equivalent alternative(s) ~~appropriate for the diagnosis~~ must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Lastly, the College of Pharmacy recommends adding age restriction criteria for the nitrofurantoin 25mg/5mL suspension, which is available without prior authorization, for clarity (shown in red):

Nitrofurantoin 25mg/5mL Suspension Approval Criteria:

1. Nitrofurantoin 25mg/5mL suspension will not require prior authorization for members 10 years of age or younger. For members 11 years of age or older, a patient-specific, clinically significant reason why the member cannot use nitrofurantoin oral capsules must be provided.

Recommendation 12: Vote to Prior Authorize Zycubo® (Copper Histidinate)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization Zycubo® (copper histidinate) with the following criteria (shown in red):

Zycubo® (Copper Histidinate) Approval Criteria:

1. An FDA approved diagnosis of Menkes disease; and
2. Diagnosis must be confirmed by 1 of the following (results of the selected test must be submitted):
 - a. Plasma catecholamine analysis indicating elevated ratios of dihydroxyphenylacetic acid to dihydroxyphenylglycol and dopamine to norepinephrine; or
 - b. Genetic testing identifying pathogenic or likely pathogenic variants in the *ATP7A* gene; or
 - c. If plasma catecholamine analysis or genetic testing is pending:
 - i. Documentation of clinical signs and symptoms consistent with Menkes disease; and
3. Member must be younger than 18 years of age; and
4. Member must not have occipital horn syndrome; and
5. Zycubo® must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of Menkes disease (or an advanced care practitioner with a supervising physician who is a geneticist, neurologist, or other specialist with expertise in the treatment of Menkes disease); and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Zycubo®; and
7. For member or caregiver administration, the prescriber must verify the member or caregiver will be trained by a health care provider on proper preparation, administration, and storage of Zycubo®; and
8. Initial approval and subsequent approvals will be for the duration of 1 year. Subsequent approvals will be granted if the prescriber documents the member is responding well to therapy; or
 - a. If the diagnosis of Menkes disease was based on clinical signs and symptoms, initial approvals will be for 3 months. Subsequent approvals for the duration of 1 year will require submitted documentation of a plasma catecholamine analysis or genetic testing confirming the diagnosis; and
9. A quantity limit of 1 vial (2.9mg) per day will apply; or
 - a. For members younger than 1 year of age, a quantity limit override will be granted based on FDA approved dosing.

Recommendation 13: Vote to Prior Authorize Morphine Oral Solution Syringes and Tapentadol Tablet, Extended-Release (ER) Tablet, and Oral Solution and Update the Approval Criteria for the Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Opioid Analgesics Product Based Prior Authorization (PBPA) category based on net costs (changes noted in red in the following Tier chart and approval criteria):

1. Prior authorization of tapentadol tablet, tapentadol oral solution, and tapentadol ER tablet with placement into the Special PA Tier with the following additional criteria; and
2. Prior authorization of morphine oral solution syringes with placement into the Special PA Tier with the following additional criteria; and
3. Making buprenorphine ER buccal film (Belbuca®) brand preferred; and
4. Moving hydrocodone/ibuprofen (IBU) 5/200mg and 7.5/200mg tablets (Vicoprofen®, Ibudone®, Reprexain™) from Tier-1 to Tier-2.

Opioid Analgesics*			
Tier-1	Tier-2	Tier-3	Special PA
Long-Acting			
buprenorphine patch (Butrans®) – Brand Preferred	fentanyl patch (Duragesic®)	buprenorphine ER buccal film (Belbuca®) – Brand Preferred	methadone soln (Dolophine®)
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – Brand Preferred	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab
tramadol ER tab (Ultram® ER)	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – Brand Preferred	hydrocodone ER tab (Hysingla® ER) – Brand Preferred	tapentadol ER tab
	tramadol ER tab (Ryzolt®)	hydromorphone ER tab (Exalgo®)	tramadol ER cap (ConZip®)
		methadone tab (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
Short-Acting			
APAP/butalbital/caff/codeine cap 50/325/40/30mg (Fioricet® with Codeine)	hydrocodone/IBU tab 10/200mg (Ibudone®, Reprexain™, Vicoprofen®)		APAP/butalbital/caff/codeine cap 50/300/40/30mg (Fioricet® with Codeine)
ASA/butalbital/caff/codeine cap (Fiorinal® with Codeine)	oxymorphone IR tab (Opana®)		APAP/codeine elixir & soln

Opioid Analgesics*			
Tier-1	Tier-2	Tier-3	Special PA
codeine tab			hydrocodone/ APAP soln
codeine/APAP tab (Tylenol® with Codeine)			hydrocodone/ APAP tab (Xodol®)
hydrocodone/ APAP tab (Norco®)			levorphanol tab
hydrocodone/IBU tab 5/200mg, 7.5/200mg only (Vicoprofen®; Ibudone®; Reprexain™)			morphine oral soln syringes
hydromorphone tab & soln (Dilaudid®)			oxycodone tab (RoxyBond™)
meperidine tab & soln (Demerol®)			oxycodone/APAP tab (Nalocet®)
morphine IR tab & soln (MSIR®)			oxycodone/APAP tab & soln (Prolate®)
oxycodone/APAP tab & soln (Percocet®)			tapentadol tab & soln
oxycodone IR cap (Oxy IR®)			tramadol 25mg, 75mg, & 100mg tab
oxycodone IR tab & soln (Roxicodone®)			tramadol soln (Qdolo™)
tramadol 50mg tab (Ultram®)			Oncology Only:
tramadol/APAP (Ultracet®)			fentanyl transmucosal lozenge (Actiq®)

*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).
APAP = acetaminophen; ASA = aspirin; caff = caffeine; cap = capsule; ER = extended-release; IBU = ibuprofen; IR = immediate-release; PA = prior authorization; SL = sublingual; soln = solution; tab = tablet

Opioid Analgesics Special Prior Authorization (PA) Approval Criteria:

1. Actiq® is approved for oncology-related diagnoses only.
2. ConZip® [Tramadol Extended-Release (ER) Capsule] Approval Criteria:
 - a. A patient-specific, clinically significant reason why the member cannot use the ER tablet formulation must be provided. Tier structure rules apply.
3. Acetaminophen (APAP)/Codeine Elixir and Solution Approval Criteria:
 - a. Authorization consideration for members younger than 12 years of age requires a patient-specific, clinically significant reason for use

- of these products despite the medication being contraindicated for the member's age; or
- b. For members 12 years of age or older, a patient-specific, clinically significant reason why the member cannot use the tablet formulation, which is available without a prior authorization, must be provided.
4. Fioricet® with Codeine (Butalbital/APAP/Caffeine/Codeine 50mg/300mg/40mg/30mg) Approval Criteria:
 - a. A patient-specific, clinically significant reason why the member cannot take the 325mg APAP formulation butalbital/APAP/caffeine/codeine 50mg/325mg/40mg/30mg), which is available generically, must be provided.
 5. Hydrocodone/APAP Unique Formulations and Strengths Approval Criteria:
 - a. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®) or Xodol® (hydrocodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg), a patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) tablets must be provided; or
 - b. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®), a prior authorization is not required for members 14 years of age or younger. For members older than 14 years of age, a prior authorization is required, unless the prescription is written by an otolaryngologist or a dentist; and
 - c. For hydrocodone/APAP oral solution unit dose cups, a prior authorization is required for all members and a patient-specific, clinically significant reason why the member cannot use hydrocodone/APAP in bulk solution must be provided.
 6. Levorphanol Tablet Approval Criteria:
 - a. A patient-specific, clinically significant reason why the member cannot use alternative treatment options for pain (e.g., non-opioid analgesics, lower-tiered opioid analgesics) must be provided.
 7. Methadone Oral Solution Approval Criteria:
 - a. For the lower strengths of methadone (5mg/5mL or 10mg/5mL), a prior authorization is not required for members 1 year of age and younger; or
 - b. For members older than 1 year of age, a patient specific clinically significant reason why the member cannot use methadone tablets and other lower-tiered opioid analgesics must be provided.
 8. Morphine Oral Solution Syringes (5mg/0.25mL Syringe, 10mg/0.5mL Syringe, and 20mg/mL Syringe) Approval Criteria:
 - a. For morphine oral solution syringes, a patient-specific, clinically significant reason why the member cannot use morphine oral solution in bulk solution must be provided.
 9. Oxycodone (RoxyBond™) Approval Criteria:

- a. A patient specific, clinically significant reason why the member cannot use any other available short-acting opioid analgesic must be provided.
10. Oxycodone/APAP Unique Formulations and Strengths Approval Criteria:
- a. For Nalocet® (oxycodone/APAP 2.5mg/300mg) tablet and Prolate® (oxycodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg) tablets, a patient specific, clinically significant reason why the member cannot use generic Percocet® (oxycodone/APAP 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg, or 10mg/325mg) tablets must be provided; and
 - b. For Prolate® (10mg-300mg/5mL) oral solution, a patient specific, clinically significant reason why the member cannot use generic oxycodone/APAP tablets and generic oxycodone/APAP (5mg-325mg/5mL) oral solution must be provided.
11. Oxymorphone ER Tablet Approval Criteria:
- a. A patient specific, clinically significant reason why the member cannot use any other available ER opioid analgesic must be provided.
12. Qdolo™ (Tramadol 5mg/mL Oral Solution) Approval Criteria:
- a. A patient-specific, clinically significant reason why the member cannot use tramadol 50mg tablets, even when tablets are crushed, must be provided; and
 - b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the prescriber must provide patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
 - c. A quantity limit of 2,400mL per 30 days will apply.
13. Tapentadol ER Tablet Approval Criteria:
- a. A patient specific, clinically significant reason why the member cannot use any other lower-tiered ER opioid analgesic must be provided.
14. Tapentadol Tablet Approval Criteria:
- a. A patient specific, clinically significant reason why the member cannot use any other lower-tiered short-acting opioid analgesic must be provided.
15. Tapentadol Oral Solution Approval Criteria:
- a. A patient specific, clinically significant reason why the member cannot use lower-tiered opioid analgesic oral solutions must be provided; and
 - b. For members 12 years of age or older, a patient-specific, clinically significant reason why the member cannot use the tablet formulation must be provided.
16. Tramadol 25mg, 75mg, and 100mg Tablet Approval Criteria:

- a. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose or split a tramadol 50mg tablet to achieve a 25mg or 75mg dose must be provided; and
- b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age.

The College of Pharmacy also recommends the following changes to the MAT medications based on clinical practice (changes shown in red):

Suboxone® [Buprenorphine/Naloxone Sublingual (SL) Film] and Zubsolv® (Buprenorphine/ Naloxone SL Tablet) Approval Criteria:

1. Generic buprenorphine/naloxone SL tablet and buprenorphine SL tablet are the preferred products. Authorization consideration of Zubsolv® and Suboxone® films (brand and generic) requires a patient-specific, clinically significant reason why the preferred SL tablets are not appropriate; and
2. Member must have an FDA approved diagnosis of opioid abuse/dependence [i.e., opioid use disorder (OUD)]; and
3. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
4. Approvals will be for the duration of ~~90 days~~ 6 months to allow for concurrent medication monitoring; and
5. The following limitations will apply:
 - a. Suboxone® 2mg/0.5mg and 4mg/1mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
 - b. Suboxone® 8mg/2mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
 - c. Suboxone® 12mg/3mg SL films: A quantity limit of 60 SL films per 30 days will apply.
 - d. Subutex® 2mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
 - e. Subutex® 8mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
 - f. Zubsolv® 0.7mg/0.18mg, 1.4mg/0.36mg, and 2.9mg/0.71mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
 - g. Zubsolv® 5.7mg/1.4mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
 - h. Zubsolv® 8.6mg/2.1mg: A quantity limit of 60 SL tablets per 30 days will apply.

Sublocade® [Buprenorphine Extended-Release (ER) Injection] Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe opioid use disorder (OUD); and
2. Member must have initiated treatment with a single dose of a transmucosal buprenorphine product or is currently treated with buprenorphine; and
3. Concomitant treatment with opioids (including tramadol) will be denied; and
4. Medication should only be prepared and administered by a health care provider; and
5. A patient-specific, clinically significant reason why the member cannot use the preferred buprenorphine product(s) (buprenorphine/naloxone sublingual (SL) tablets or buprenorphine SL tablets) must be provided; and
6. For new starts, a patient-specific, clinically reason why the member cannot use Brixadi® (buprenorphine ER injection), which is available without a prior authorization, must be provided. Members currently stable on Sublocade® may be approved for continuation of therapy; and
7. In general, concomitant treatment with transmucosal buprenorphine will not be approved long term; and
8. Approvals will be for the duration of ~~90 days~~ 6 months to allow for concurrent medication monitoring; and
9. The following quantity limits will apply:
 - a. Sublocade® 100mg/0.5mL and 300mg/1.5mL: 1 monthly dose per 28 days
 - i. A quantity limit override will be approved for initial dosing for members who need the second injection 1 week after the first injection when requested.

Recommendation 14: Fiscal Year 2026 Annual Review of Cystic Fibrosis (CF) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Alyftrek® (vanzacaftor/tezacaftor/deutivacaftor) and Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) approval criteria based on the new FDA approved label expansions and to be consistent with clinical practice (changes shown in red):

Alyftrek® (Vanzacaftor/Tezacaftor/Deutivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 ~~variant F508del mutation~~ in the CF transmembrane conductance regulator (CFTR) gene ~~or a mutation in the CFTR gene~~ that is responsive based on clinical and/or *in vitro* data ~~or results in production of CFTR protein~~; and

- a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of **at least 1 variant in the *CFTR* gene that is responsive based on clinical and/or *in vitro* data or results in production of CFTR protein** ~~a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use;~~ and
 - b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Member must be 6 years of age or older; and
3. Members using Alyftrek® must be supervised by a pulmonary specialist; and
- ~~4. If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor), Symdeko® (tezacaftor/ivacaftor and ivacaftor), or Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi®, Symdeko®, or Trikafta® use, the prescriber must indicate that information on the prior authorization request; and~~
5. Prescriber must verify that member has been counseled on proper administration of Alyftrek® including taking with a fat-containing food; and
- ~~6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Alyftrek®; and~~
- ~~7. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Alyftrek®; and~~
- ~~8. Prescriber must verify that liver functions tests (ALT, AST, alkaline phosphate, and bilirubin) will be assessed prior to initiating Alyftrek®, every month for the first 6 months, every 3 months for the next 12 months, and annually thereafter; and~~
- ~~9. Prescriber must verify that the member does not have severe hepatic impairment; and~~
- ~~10. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
- ~~11. Member must not be taking strong or moderate CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone) concomitantly with Alyftrek®; and~~
12. The following quantity limits will apply:
 - a. Alyftrek® 4/20/50mg tablets: A quantity limit of 3 tablets per day or 84 tablets per 28 days; or
 - b. Alyftrek® 10/50/125mg tablets: A quantity limit of 2 tablets per day or 56 tablets per 28 days; and
13. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

14. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV₁), will be required for continued approval. ~~Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi[®] (lumacaftor/ivacaftor), Symdeko[®] (tezacaftor/ivacaftor and ivacaftor), or Trikafta[®] (elexacaftor/tezacaftor/ivacaftor and ivacaftor); and~~
15. Subsequent approvals will be for the duration of 1 year.

Trikafta[®] (Elexacaftor/Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 ~~variant F508del mutation~~ in the CF transmembrane conductance regulator (CFTR) gene ~~or a mutation in the CFTR gene~~ that is responsive based on clinical and/or *in vitro* data ~~or results in production of CFTR protein~~; and
 - a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of ~~at least 1 variant in the CFTR gene that is responsive based on clinical and/or in vitro data or results in production of CFTR protein~~ ~~a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use~~; and
 - b. Documentation must be submitted with results of CFTR genetic testing; and
2. Member must be 2 years of age or older; and
3. Members using Trikafta[®] must be supervised by a pulmonary specialist; and
- ~~4. If member is currently stabilized on Orkambi[®] (lumacaftor/ivacaftor) or Symdeko[®] (tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi[®] or Symdeko[®] use, the prescriber must indicate that information on the prior authorization request; and~~
5. Prescriber must verify that member has been counseled on proper administration of Trikafta[®] including taking with a fat-containing food; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Trikafta[®]; and
7. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Trikafta[®]; and
- ~~8. Prescriber must verify that liver functions tests (ALT, AST, alkaline phosphate, and bilirubin) will be assessed prior to initiating Trikafta[®], every month for the first 6 months, every 3 months for the next 12 months, and annually thereafter; and~~

- ~~9. Prescriber must verify that the member does not have severe hepatic impairment; and~~
- ~~10. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
- ~~11. Member must not be taking any of the following medications concomitantly with Trikafta[®]: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort; and~~
12. The following quantity limits will apply:
 - a. Oral tablets: A quantity limit of 3 tablets per day or 84 tablets per 28 days; or
 - b. Oral granules: A quantity limit of 2 packets per day or 56 packets per 28 days; and
13. For Trikafta[®] oral granules, an age restriction of 2 years to 5 years of age will apply. Members 6 years of age or older will require a patient-specific, clinically significant reason why the Trikafta[®] tablets cannot be used; and
14. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
15. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV₁), will be required for continued approval. ~~Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi[®] (lumacaftor/ivacaftor) or Symdeko[®] (tezacaftor/ivacaftor and ivacaftor);~~ and
16. Subsequent approvals will be for the duration of 1 year.

Additionally, the College of Pharmacy recommends updating the Kalydeco[®] (ivacaftor), Orkambi[®] (lumacaftor/ivacaftor), and Symdeko[®] (tezacaftor/ivacaftor) approval criteria to be consistent with the other CF transmembrane conductance regulator (CFTR) modulators (changes shown in red):

Kalydeco[®] (Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) with a mutation in the CF transmembrane conductance regulator (*CFTR*) gene detected by genetic testing that is responsive to ivacaftor based on clinical and/or *in vitro* assay data; and
 - a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing

- when recommended by the mutation test's instructions for use; and
- b. Documentation must be submitted with results of *CFTR* genetic testing; and
- 2. Member must be 1 month of age or older; and
- 3. Members using Kalydeco® must be supervised by a pulmonary disease specialist; and
- 4. Prescriber must verify the member has been counseled on proper administration of Kalydeco® including taking with a fat-containing food; and
- 5. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Kalydeco®; and
- 6. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Kalydeco®; and
- ~~7. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Kalydeco®, every 3 months during the first year of treatment, and annually thereafter; and~~
- ~~8. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
- ~~9. Member must not be taking any of the following medications concomitantly with Kalydeco®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and~~
- 10. For members 1 month to younger than 6 months of age:
 - a. Member must not have any level of hepatic impairment; and
 - b. Member must not be taking concomitant moderate or strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); and
- 11. The following quantity limits will apply:
 - a. Oral tablets: A quantity limit of 2 tablets per day or 56 tablets per 28 days; or
 - b. Oral granules: A quantity limit of 2 packets per day or 56 packets per 28 days; and
- 12. An age restriction of 1 month to 5 years of age will apply to Kalydeco® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
- 13. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
- 14. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV₁), will be required for continued approval; and

15. Subsequent approvals will be for 1 year.

Orkambi® (Lumacaftor/Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation in the CF transmembrane conductance regulator (*CFTR*) gene detected by genetic testing; and
 - a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene; and
 - b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Orkambi® will not be approved for members with CF other than those homozygous for the *F508del* mutation; and
3. Member must be 12 months of age or older; and
4. Members using Orkambi® must be supervised by a pulmonary specialist; and
5. Prescriber must verify the member has been counseled on proper administration of Orkambi® including taking with a fat-containing food; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Orkambi®; and
7. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Orkambi®; and
- ~~8. The prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Orkambi®, every 3 months during the first year of treatment, and annually thereafter; and~~
- ~~9. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
- ~~10. Members must not be taking any of the following medications concomitantly with Orkambi®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and~~
11. The following quantity limits will apply:
 - a. Oral tablets: A quantity limit of 4 tablets per day or 112 tablets per 28 days will apply; or
 - b. Oral granules: A quantity limit of 2 granule packets per day or 56 packets per 28 days will apply; and
12. An age restriction of 12 months to 5 years of age will apply to Orkambi® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
13. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

14. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV₁), will be required for continued approval; and
15. Subsequent approvals will be for the duration of 1 year.

Symdeko® (Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation or who have at least 1 mutation in the CF transmembrane conductance regulator (*CFTR*) gene detected by genetic testing that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence; and
 - a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use; and
 - b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Member must be 6 years of age or older; and
3. Members using Symdeko® must be supervised by a pulmonary specialist; and
- ~~4. If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) and experiencing adverse effects associated with Orkambi® use, the prescriber must indicate that information on the prior authorization request; and~~
5. Prescriber must verify that member has been counseled on proper administration of Symdeko® including taking with a fat-containing food; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Symdeko®; and
7. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Symdeko®; and
- ~~8. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Symdeko®, every 3 months during the first year of treatment, and annually thereafter; and~~
- ~~9. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
- ~~10. Member must not be taking any of the following medications concomitantly with Symdeko®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and~~
11. A quantity limit of 2 tablets per day or 56 tablets per 28 days will apply; and
12. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable.

- For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
13. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV₁), will be required for continued approval. ~~Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events must be provided for members who switched from Orkambi® to Symdeko®;~~ and
 14. Subsequent approvals will be for the duration of 1 year.

Recommendation 15: Fiscal Year 2026 Annual Review of Amyloidosis Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Amvuttra® (vutrisiran) approval criteria based on net costs and for consistency with the approval criteria for the other amyloidosis medications (changes shown in red):

Amvuttra® (Vutrisiran) Approval Criteria:

1. An FDA approved indication of 1 of the following:
 - a. The treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR-PN) amyloidosis; or
 - b. The treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) to reduce cardiovascular (CV) mortality, CV hospitalizations, and urgent heart failure visits; and
2. For the diagnosis of hATTR-PN:
 - a. Diagnosis confirmed by genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
 - b. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; or
3. For the diagnosis of ATTR-CM:
 - a. Diagnosis confirmed by:
 - i. Genetic confirmation of transthyretin (*TTR*) gene mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
 - ii. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
 - b. Presence of amyloid deposits confirmed by:
 - i. Nuclear scintigraphy; or
 - ii. Endomyocardial biopsy; and
 - c. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and

- d. Member must have medical history of heart failure (NYHA Class I to III); and
4. Member must be 18 years of age or older; and
5. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
6. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
7. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
8. Prescriber must confirm the member has not undergone a liver transplant; and
9. Amvuttra® will not be approved for concomitant use with Attruby® (acoramidis), Onpattro® (patisiran), Vyndamax® (tafamidis), or Wainua® (eplontersen); and
- ~~10. Authorization for Amvuttra® for the diagnosis of hATTR-PN will also require a patient-specific, clinically significant reason why the member cannot use Onpattro®; and~~
11. A quantity limit of 0.5mL per 90 days will apply; and
12. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

The College of Pharmacy also recommends updating the Attruby® (acoramidis), Onpattro® (patisiran), and Vyndamax® (tafamidis) approval criteria for consistency with the approval criteria for the other amyloidosis medications (changes shown in red):

Attruby® (Acoramidis) Approval Criteria:

1. An FDA approved indication for the treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) ~~in adults~~ to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
 - a. Genetic confirmation of transthyretin (*TTR*) mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
 - b. Cardiac imaging (including ultrasound or MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
 - a. Nuclear scintigraphy; or
 - b. Endomyocardial biopsy; and
4. Member must be 18 years of age or older; and
5. Member must have medical history of heart failure (NYHA Class I to III); and

6. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
7. Attruby™ must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
8. Attruby™ will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Vyndamax® (tafamidis), or Wainua® (eplontersen); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approval will be for 1 year; and
10. A quantity limit of 112 tablets per 28 days will apply.

Onpattro® (Patisiran) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Member must be 18 years of age or older; and
5. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
6. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
7. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
8. Prescriber must confirm the member has not undergone a liver transplant; and
9. Prescriber must confirm the member will be pre-medicated with intravenous (IV) corticosteroid, oral acetaminophen, IV histamine-1 (H1) antagonist, and IV histamine-2 (H2) antagonist 60 minutes prior to administration to reduce the risk of infusion-related reaction(s); and
10. Onpattro® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby® (acoramidis), Vyndamax® (tafamidis), or Wainua® (eplontersen); and
11. Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
12. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

Vyndamax® (Tafamidis) Approval Criteria:

1. An FDA approved indication for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) ~~in adults~~ to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
 - a. Genetic confirmation of transthyretin (*TTR*) mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
 - b. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
 - a. Nuclear scintigraphy; or
 - b. Endomyocardial biopsy; and
4. Member must be 18 years of age or older; and
5. Member must have medical history of heart failure (NYHA Class I to III); and
6. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. Vyndamax® must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
9. Vyndamax® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby® (acoramidis), Onpattro® (patisiran), or Wainua® (eplontersen); and
10. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if prescriber documents member is responding well to treatment and member has not undergone a liver transplant; and
11. A quantity limit of 1 Vyndamax® capsule per day will apply.

Lastly, the College of Pharmacy recommends updating the Wainua® (eplontersen) criteria based on the approval of the single-dose prefilled syringe and for consistency with the approval criteria for the other amyloidosis medications (changes shown in red).

Wainua® (Eplontersen) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy associated with hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
3. Member must be 18 years of age or older; and
4. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and

5. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
6. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
7. **For authorization of the single-dose autoinjector, the** prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Wainua®; and
8. **For authorization of the single-dose prefilled syringe, the prescriber must verify the injection will be administered by a health care professional; and**
9. Prescriber must confirm the member has not undergone a liver transplant; and
10. Wainua® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby® (acoramidis), Onpattro® (patisiran), or Vyndamax® (tafamidis); and
11. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant; and
12. A quantity limit of 0.8mL per 28 days will apply.

Recommendation 16: Fiscal Year 2026 Annual Review of Bladder Control Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Bladder Control Medications Product Based Prior Authorization (PBPA) category based on net costs (changes shown in red):

1. Moving oxybutynin patch (Oxytrol®) from the Special PA Tier to Tier-1 and removing the unique criteria; and
2. Moving tolterodine ER (Detrol LA®) from Tier-2 to Tier-1; and
3. Moving fesoterodine (Toviaz®) from Tier-1 to Tier-2; and
4. Moving darifenacin (Enablex®) from Tier-3 to Tier-2; and
5. Updating the approval criteria for Gemtesa® (vibegron) based on net costs and clinical practice.

Bladder Control Medications			
Tier-1	Tier-2	Tier-3	Special PA
fesoterodine (Toviaz®)	tolterodine (Detrol®)	darifenacin (Enablex®)	oxybutynin 2.5mg tablets ⁺
mirabegron (Myrbetriq®) tablets – Brand Preferred	tolterodine-ER (Detrol-LA®)	mirabegron (Myrbetriq®) granules ^β	oxybutynin patch (Oxytrol®)⁺
oxybutynin (Ditropan®) tablets and syrup	fesoterodine (Toviaz®)	trospium ER (Sanctura XR®)	vibegron (Gemtesa®) ⁺

Bladder Control Medications			
Tier-1	Tier-2	Tier-3	Special PA
oxybutynin ER (Ditropan XL®)	darifenacin (Enablex®)		
oxybutynin patch (Oxytrol®)			
solifenacin (VESIcare®)			
tolterodine ER (Detrol LA®)			
trospium (Sanctura®)			

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 specific to Gemtesa® (vibegron); ~~and oxybutynin 2.5mg tablets, and Oxytrol® (oxybutynin patch)~~ applies.

†The Myrbetriq® granule formulation is covered for members 3 years of age or older weighing <35kg. Members weighing ≥35kg will require a patient-specific, clinically significant reason why the granule formulation is needed in place of the regular tablet formulation.

ER = extended-release; PA = prior authorization; susp = suspension

Gemtesa® (Vibegron) Approval Criteria:

1. An FDA approved indication of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
 - a. For members with a contraindication to anticholinergics, documentation of the contraindication and a patient-specific, clinically significant reason why the member cannot use Myrbetriq® (mirabegron) must be provided; and
 - b. For members unable to take Myrbetriq® (mirabegron) due to hypertension, the prescriber must attest that the member has severe, uncontrolled hypertension as defined in the Myrbetriq® package labeling (i.e., systolic blood pressure ≥180mmHg and/or diastolic blood pressure ≥110mmHg) and documentation of member's blood pressure readings must be provided; and
4. A quantity limit of 30 tablets per 30 days will apply.

Oxytrol® (Oxybutynin 3.9mg/Day Patch) Approval Criteria:

- ~~1. An FDA approved diagnosis of overactive bladder; and~~
- ~~2. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and~~
- ~~3. A quantity limit of 8 patches per 30 days will apply.~~

Recommendation 17: Fiscal Year 2026 Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Beizray™ (Docetaxel), Beizray™ Kit (Docetaxel/Albumin), Docivyx™ (Docetaxel), Inluriyo™ (Imlunestrant), and Veppanu™ (Vepdegestrant)

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

Recommendation 18: Fiscal Year 2026 Annual Review of Various Ophthalmic Medications and the 30-Day Notice to Prior Authorize Epioxa® HD/Epioxa® (Riboflavin 5'-Phosphate Ophthalmic Solution) and Lumvoa® (Veligrotug-vvze)

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

Recommendation 19: Fiscal Year 2026 Annual Review of Antihistamine Medications (Systemic) and 30-Day Notice to Prior Authorize Cetirizine Oral Solution Unit-Dose Cups (UDCs)

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

Recommendation 20: Fiscal Year 2026 Annual Review of Benign Prostatic Hyperplasia (BPH) Medications

NO ACTION REQUIRED.

Recommendation 21: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 22: Future Business

NO ACTION REQUIRED.



HS Connect

September 21, 2026

Drug Utilization Review Commission
c/o Oklahoma Health Care Authority
4345 N Lincoln Blvd
Oklahoma City, OK 73105

Cc: Devin Wilcox, Pharmacy Director, Oklahoma College of Pharmacy; Melissa Miller, Oklahoma Medicaid Director

Dear Members of the Oklahoma Medicaid Drug Utilization Review Commission,

On behalf of HS Connect, a national patient-centered organization dedicated to improving access to care and outcomes for people living with Hidradenitis Suppurativa (HS), we write to share concerns regarding Oklahoma Medicaid's current utilization management requirements for biologic treatment of HS.

HS is a chronic, inflammatory disease characterized by recurrent painful nodules, abscesses, sinus tracts, and permanent scarring, often affecting sensitive areas of the body. It is widely recognized as one of the most painful dermatologic conditions and is associated with significant physical disability, mental health burden, and reduced quality of life. HS disproportionately affects individuals with lower incomes and those who rely on Medicaid coverage. For these patients, delays in accessing effective treatment can allow the disease to progress and cause irreversible damage.

From the patient perspective, the current utilization management requirements can create substantial barriers to timely care. Many individuals with moderate-to-severe HS spend years cycling through therapies that fail to adequately control their disease. During this time, patients often experience repeated flares, emergency department visits, missed work, and worsening mental health. These delays not only prolong suffering but may also contribute to disease progression, increased disability, and avoidable healthcare utilization.

We are particularly concerned that some aspects of the current policy, such as the requirement for multiple prior treatment failures and numeric lesion thresholds, do not reflect how HS presents or progresses in real-world clinical practice. HS severity

hsconnect.org // brindley@hsconnect.org // 12911 120th Avenue East Puyallup, WA 98374



HS Connect

cannot be reliably captured by simple lesion counts alone, and prolonged use of systemic antibiotics frequently provides only temporary relief while exposing patients to additional risks. For many individuals, these requirements result in extended cycles of ineffective treatment before they can access therapies that may meaningfully control their disease.

Patients consistently report that delayed access to biologic therapy is associated with increased emergency care, repeated surgical procedures, opioid exposure, and significant psychological distress. These outcomes are devastating for patients and their families and may also drive higher long-term costs for the Medicaid program. To improve patient outcomes, we respectfully urge the Oklahoma Medicaid Drug Utilization Review Commission to consider updating its HS coverage policy by:

- Maintaining the requirement for confirmed moderate-to-severe HS (Hurley Stage II or III);
- Removing the requirement for ≥ 3 abscesses or inflammatory nodules; and
- Allowing access to biologic therapy after failure of one appropriate systemic therapy.

These changes would better align Oklahoma's policy with clinical practice, reduce unnecessary treatment delays, and improve access to effective, evidence-based care for Medicaid beneficiaries living with HS.

HS Connect stands ready to collaborate with the Commission, share patient perspectives, and support policy solutions that promote earlier intervention and better long-term outcomes for Oklahomans living with HS.

Thank you for your time and consideration.

Sincerely,

Brindley Brooks
Founder & CEO

Drug Utilization Review Commission
c/o Oklahoma Health Care Authority
4345 N Lincoln Blvd
Oklahoma City, OK 73105

Cc: Devin Wilcox, Pharmacy Director, Oklahoma College of Pharmacy
Melissa Miller, Oklahoma Medicaid Director

Subject: Request to Update Oklahoma Medicaid Step Therapy Policy for Hidradenitis
Suppurativa

Dear Members of the Oklahoma Medicaid Drug Utilization Review Commission,

My name is Dr George Monks and I am a physician practicing in Tulsa, Oklahoma. I care for patients living with hidradenitis suppurativa (HS), a chronic, painful, and often debilitating inflammatory skin disease. I am writing to respectfully urge the Commission to review and update Oklahoma Medicaid's utilization management (UM) criteria and step therapy requirements for biologic treatment of HS.

In my clinical experience, Oklahoma's current policy creates significant and unnecessary barriers to effective care. The requirement that patients document three or more abscesses or inflammatory nodules and fail multiple prior therapies before qualifying for biologic treatment can delay appropriate therapy and allow the disease to worsen. Many patients endure years of severe pain, recurrent infections, and progressive tissue damage before gaining access to treatments that could significantly improve their condition.

HS is one of the most painful conditions in dermatology. Nearly 70% of patients report severe pain, and many describe their pain as extreme and debilitating. The disease frequently affects sensitive areas of the body and can cause abscesses, sinus tracts, and permanent scarring that significantly impair mobility, daily functioning, and quality of life. In addition to its physical burden, HS is strongly associated with depression, anxiety, and social isolation.

Systemic antibiotics and other conventional treatments may provide temporary relief but are often insufficient for long-term control of moderate-to-severe disease. Prolonged reliance on these therapies can allow HS to progress, leading to irreversible structural damage such as scarring and tunnel formation beneath the skin. Once this damage occurs, it becomes far more difficult, and costly, to manage.

Earlier access to biologic therapy can help interrupt disease progression, reduce pain, and decrease the need for emergency care, surgical interventions, and long-term opioid use.

From both a clinical and health system perspective, timely access to effective therapy is essential for improving outcomes for patients living with HS.

Oklahoma's current criteria also appear more restrictive than those in most other states. Many Medicaid programs allow biologic treatment for HS after failure of a single prior systemic therapy. Additionally, Oklahoma Medicaid requires fewer step restrictions for psoriasis, another chronic inflammatory skin disease, despite HS often producing equal or greater levels of pain, functional impairment, and healthcare utilization.

For these reasons, I respectfully request that the DUR Commission consider the following updates to Oklahoma Medicaid's HS biologic coverage criteria:

1. Maintain the requirement of a confirmed diagnosis of moderate-to-severe HS (e.g., Hurley Stage II or III);
2. Remove the requirement for documentation of three or more abscesses or inflammatory nodules, which is not supported by HS clinical guidelines; and
3. Allow access to biologic therapy after failure of a single prior systemic therapy.

These changes would better align Oklahoma Medicaid policy with current clinical evidence and national treatment standards while helping ensure that patients receive timely and appropriate care before their disease progresses to irreversible stages.

Thank you for your consideration and for your ongoing work to ensure Oklahoma Medicaid policies support effective, evidence-based care for patients. I would welcome the opportunity to provide additional clinical perspective if helpful to the Commission.

Sincerely,

George W. Monks, M.D.

Tulsa Dermatology Clinic

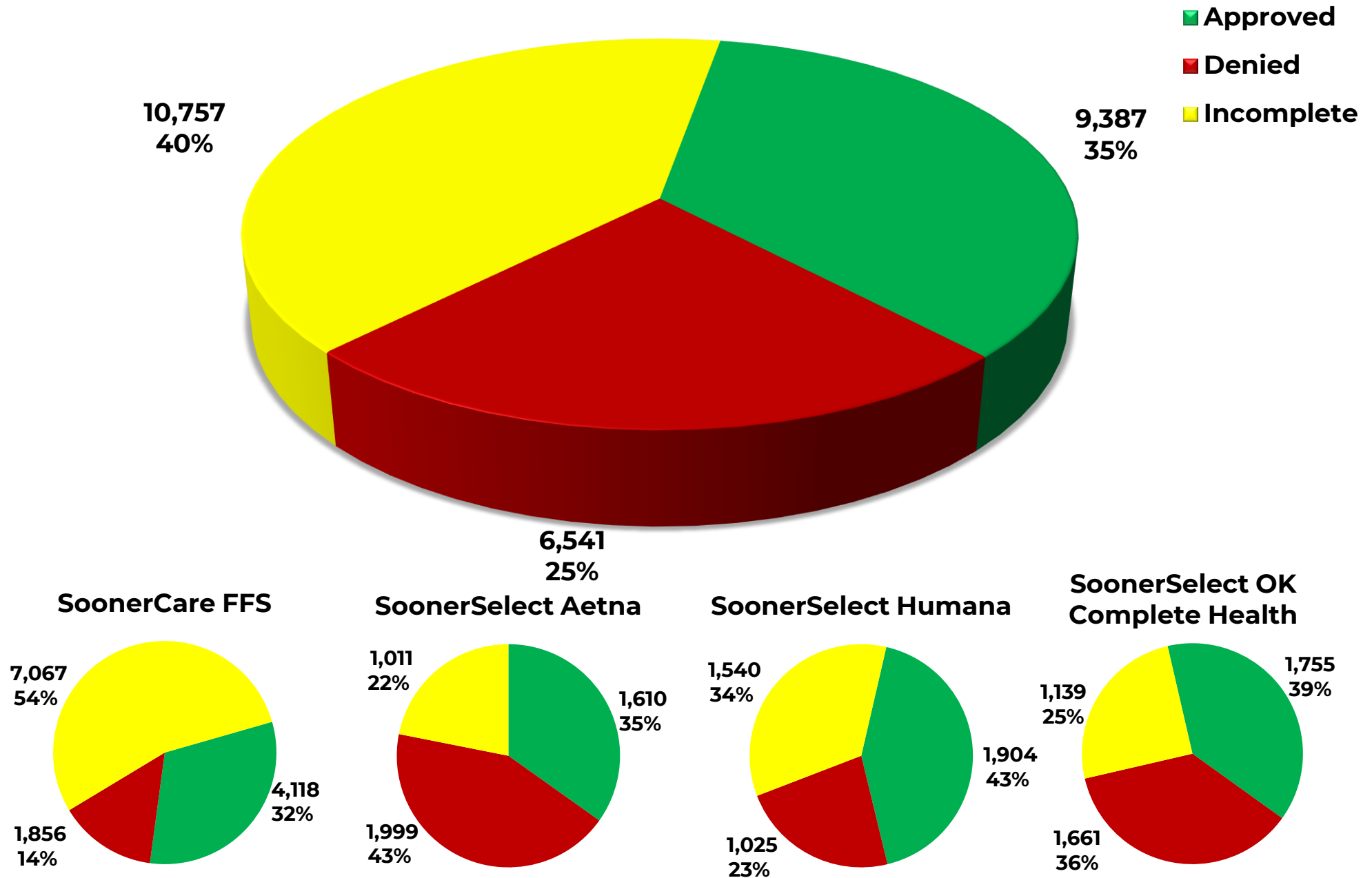
Volunteer Assistant Clinical Professor, University of Oklahoma

Past President Oklahoma State Medical Association

Past President Oklahoma State Dermatological Society

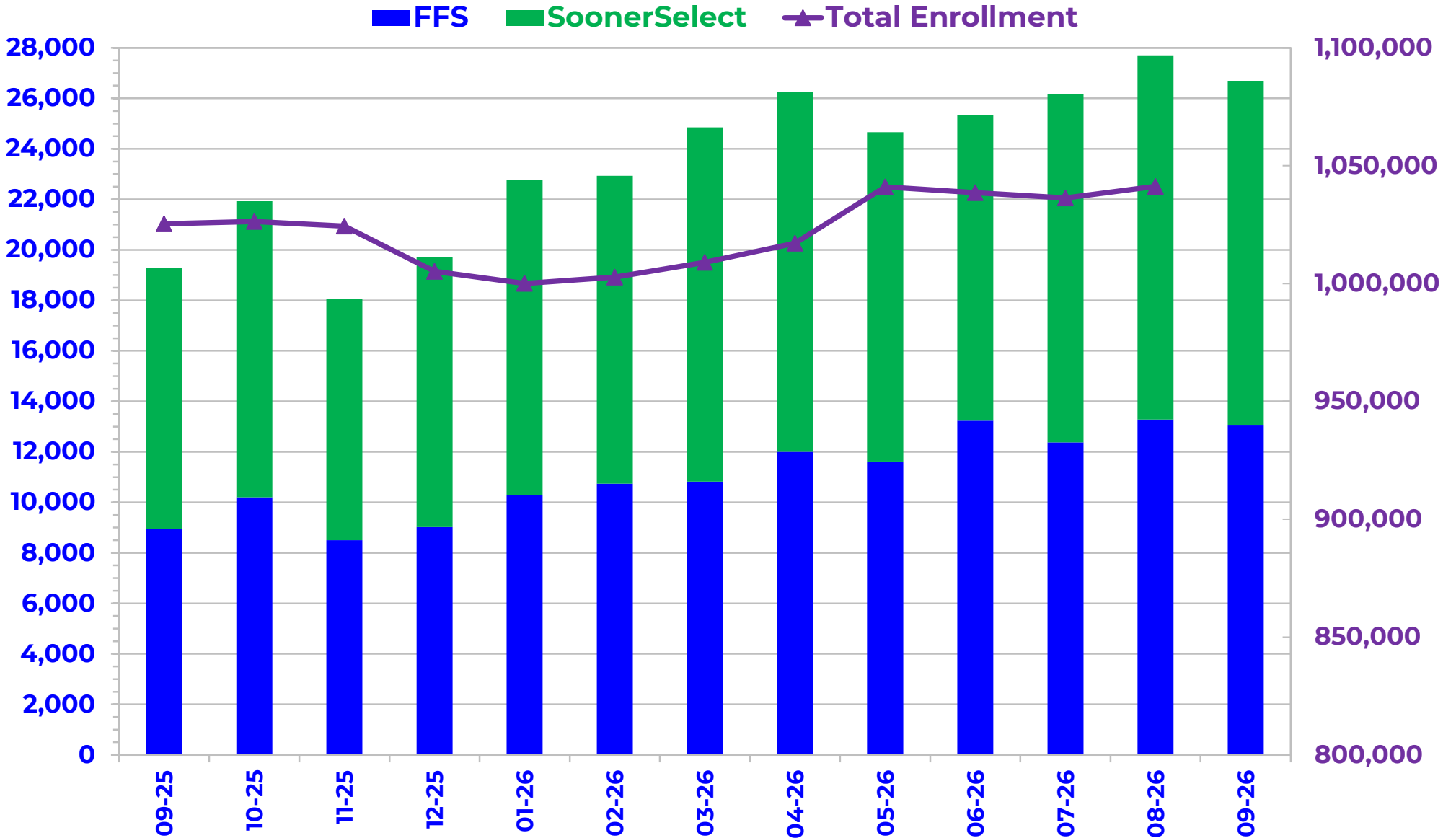


PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: SEPTEMBER 2026



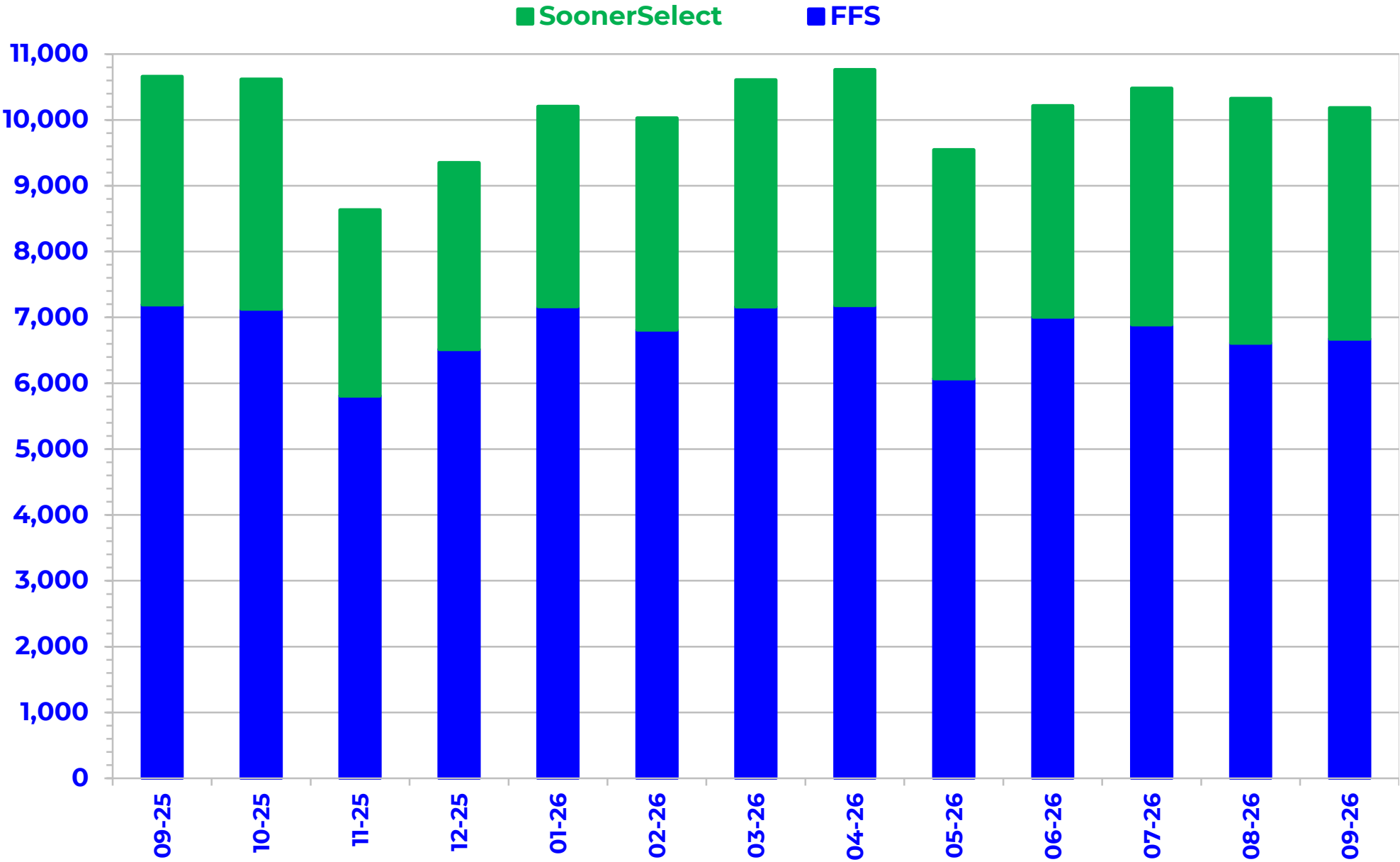
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

PRIOR AUTHORIZATION (PA) REPORT: SEPTEMBER 2025 – SEPTEMBER 2026



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: SEPTEMBER 2025 – SEPTEMBER 2026



SoonerCare FFS Prior Authorization Activity

9/1/2026 Through 9/30/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	2	2	0	0	150
Amphetamines	1,067	490	96	481	356
Analgesics - Anti-Inflammatory	310	99	48	163	337
Analgesics - Nonnarcotic	21	2	4	15	360
Analgesics - Opioid	327	122	29	176	164
Androgens - Anabolic	76	6	22	48	339
Anorectal and Related Products	2	0	0	2	0
Anorexiant Non-Amphetamine	2	0	0	2	0
Antacids	3	1	1	1	360
Anthelmintics	21	4	7	10	13
Anti-Infective Agents - Misc.	35	9	6	20	18
Anti-Obesity Agents	586	127	216	243	107
Antianginal Agents	2	0	0	2	0
Antianxiety Agents	42	6	5	31	359
Antiarrhythmics	3	0	0	3	0
Antiasthmatic and Bronchodilator Agents	1,062	162	116	784	397
Antibiotics	53	16	3	34	220
Anticoagulants	32	6	2	24	238
Anticonvulsants	318	112	18	188	388
Antidepressants	391	90	49	252	529
Antidiabetics	2,008	555	315	1,138	359
Antidiarrheal/Probiotic Agents	2	1	0	1	4
Antidotes and Specific Antagonists	6	2	0	4	356
Antiemetics	35	1	4	30	360
Antifungals	18	5	1	12	126
Antihistamines	38	6	9	23	315
Antihyperlipidemics	120	23	16	81	296
Antihypertensives	47	13	5	29	696
Antimalarials	7	1	0	6	54
Antineoplastics and Adjunctive Therapies	207	145	6	56	178
Antiparkinson and Related Therapy Agents	8	1	1	6	1,088
Antipsychotics/Antimanic Agents	452	131	48	273	406
Antivirals	19	5	2	12	118
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	383	210	26	147	952
Beta Blockers	16	5	3	8	701
Calcium Channel Blockers	9	2	0	7	360
Cardiovascular Agents - Misc.	129	43	12	74	569
Chemicals	3	1	2	0	360
Contraceptives	52	21	5	26	271
Corticosteroids	18	6	1	11	268
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	636	145	150	341	243
Diagnostic Products	51	18	2	31	212
Dietary Products/Dietary Management Products	2	1	1	0	360
Digestive Aids	3	2	0	1	268
Diuretics	12	4	3	5	481
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIIs)	5	1	0	4	360

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Emergency PA	1	1	0	0	0
Endocrine and Metabolic Agents - Misc.	246	97	17	132	238
Estrogens	42	4	7	31	358
Gastrointestinal Agents - Misc.	459	105	84	270	307
Genitourinary Agents - Misc.	15	7	0	8	541
Gout Agents	9	1	0	8	176
Hematological Agents - Misc.	19	6	1	12	197
Hematopoietic Agents	73	17	3	53	153
Hypnotics/Sedatives/Sleep Disorder Agents	52	6	8	38	298
Laxatives	19	9	0	10	175
Medical Devices and Supplies	467	79	85	303	296
Migraine Products	559	136	120	303	254
Minerals and Electrolytes	9	1	3	5	360
Miscellaneous Therapeutic Classes	75	28	11	36	365
Mouth/Throat/Dental Agents	3	0	0	3	0
Multivitamins	9	2	4	3	360
Musculoskeletal Therapy Agents	74	6	11	57	314
Nasal Agents - Systemic and Topical	37	3	10	24	247
Neuromuscular Agents	102	30	29	43	348
Nutrients	1	1	0	0	7
Ophthalmic Agents	127	23	23	81	268
Other*	80	36	4	40	219
Otic Agents	54	19	3	32	16
Passive Immunizing and Treatment Agents	22	6	3	13	172
Progestins	3	1	0	2	360
Psychotherapeutic and Neurological Agents - Misc.	336	95	57	184	271
Respiratory Agents - Misc.	36	21	0	15	297
Stimulants - Misc.	243	125	13	105	358
Thyroid Agents	10	1	4	5	7
Ulcer Drugs/Antispasmodics/Anticholinergics	141	21	23	97	707
Urinary Antispasmodics	66	14	13	39	391
Vaginal and Related Products	18	2	2	14	52
Vitamins	57	4	39	14	277
Total	12,106	3,509	1,811	6,786	
Overrides					
Brand	17	10	2	5	397
Compound	21	18	0	3	12
Diabetic Supplies	2	2	0	0	191
Dosage Change	153	111	0	42	17
Ingredient Duplication	2	2	0	0	24
Lost/Broken Rx	57	39	1	17	14
MAT Override	3	2	0	1	175
NDC vs Age	122	81	14	27	498
NDC vs Sex	6	3	1	2	361
Nursing Home Issue	64	54	0	10	18
Opioid MME Limit	42	16	1	25	138
Opioid Quantity	35	18	4	13	148
Other	48	33	1	14	18
Prescriber Temp Unlock	1	1	0	0	1,091

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Quantity vs Days Supply	275	178	13	84	316
STBS/STBSM	17	4	6	7	91
Step Therapy Exception	12	3	2	7	248
Stolen	14	10	0	4	12
Third Brand Request	44	24	0	20	13
Overrides Total	935	609	45	281	
Total Regular PAs + Overrides	13,041	4,118	1,856	7,067	

Denial Reasons

Unable to verify required trials.	6,835
Does not meet established criteria.	1,915
Lack required information to process request.	398

Other PA Activity

Duplicate Requests	1,748
Letters	59,350
No Process	1
Helpdesk Initiated Prior Authorizations	313
PAs Missing Information	331
Pharmacotherapy	97
Changes to Existing PAs	714

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

SoonerSelect Aetna Prior Authorization Activity

9/1/2026 Through 9/30/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	2	0	1	1	0
Amphetamines	526	376	116	34	359
Analgesics - Anti-Inflammatory	106	49	30	27	320
Analgesics - Nonnarcotic	23	3	16	4	183
Analgesics - Opioid	120	58	37	25	141
Androgens - Anabolic	62	9	51	2	365
Anorectal and Related Products	8	0	6	2	0
Antacids	1	1	0	0	365
Anthelmintics	4	2	2	0	22
Antianginal Agents	2	0	0	2	0
Antianxiety Agents	40	7	10	23	298
Antiasthmatic and Bronchodilator Agents	251	53	83	115	312
Antibiotics	22	2	6	14	106
Anticoagulants	14	6	3	5	273
Anticonvulsants	72	22	22	28	334
Antidepressants	295	79	113	103	521
Antidiabetics	568	144	333	91	336
Antiemetics	23	3	2	18	183
Antifungals	4	1	3	0	84
Antihistamines	29	11	18	0	469
Antihyperlipidemics	34	7	18	9	267
Antihypertensives	42	5	2	35	365
Anti-Infective Agents - Misc.	3	0	1	2	0
Antineoplastics and Adjunctive Therapies	42	14	3	25	235
Anti-Obesity Agents	352	66	269	17	98
Antiparkinson and Related Therapy Agents	9	1	3	5	365
Antipsychotics/Antimanic Agents	218	73	93	52	343
Antivirals	4	2	2	0	98
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	103	78	20	5	675
Beta Blockers	18	2	5	11	365
Calcium Channel Blockers	21	2	4	15	365
Cardiovascular Agents - Misc.	29	10	16	3	365
Contraceptives	21	4	14	3	365
Corticosteroids	27	9	16	2	243
Dermatologicals	298	119	144	35	261
Diagnostic Products	34	20	7	7	547
Digestive Aids	10	2	1	7	273
Diuretics	30	0	0	30	0
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	1	0	0	181
Endocrine and Metabolic Agents - Misc.	43	18	19	6	287
Estrogens	28	4	12	12	273
Gastrointestinal Agents - Misc.	100	41	51	8	214
General Anesthetics	6	4	2	0	0
Genitourinary Agents - Misc.	2	2	0	0	0
Gout Agents	10	2	3	5	365
Hematological Agents - Misc.	7	0	0	7	0

*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
Hematopoietic Agents	16	10	5	1	238
Histamine H3-Receptor Antagonist/Inverse Agonists	1	0	1	0	0
Hypnotics/Sedatives/Sleep Disorder Agents	37	8	15	14	151
Laxatives	22	4	4	14	253
Local Anesthetics-Parenteral	10	4	6	0	0
Medical Devices and Supplies	94	24	47	23	537
Migraine Products	211	57	135	19	254
Minerals and Electrolytes	19	6	4	9	81
Miscellaneous Therapeutic Classes	52	44	6	2	332
Mouth/Throat/Dental Agents	1	0	1	0	0
Multivitamins	4	3	1	0	365
Musculoskeletal Therapy Agents	77	6	23	48	81
Nasal Agents - Systemic and Topical	15	0	11	4	0
Neuromuscular Agents	20	13	4	3	263
Ophthalmic Agents	36	16	16	4	256
Other	11	0	5	6	0
Otic Agents	25	0	22	3	0
Passive Immunizing and Treatment Agents	2	1	0	1	181
Psychotherapeutic and Neurological Agents - Misc.	31	10	15	6	296
Respiratory Agents - Misc.	5	4	1	0	273
Stimulants - Misc.	101	69	29	3	357
Thyroid Agents	2	1	0	1	181
Ulcer Drugs/Antispasmodics/Anticholinergics	86	9	33	44	247
Urinary Antispasmodics	13	4	5	4	319
Vaccines	1	1	0	0	181
Vaginal and Related Products	4	0	0	4	0
Vitamins	60	4	53	3	242
**Total	4,620	1,610	1,999	1,011	

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

Overrides					
Brand	1	1	0	0	91
Other	117	117	0	0	300
Quantity Level Limit	37	37	0	0	338
Step Therapy Met	1	1	0	0	30
Vacation Override	1	1	0	0	30
Overrides Total	157	157	0	0	

Denial Reason	
Benefit	165
Experimental/Investigational	165
Lack Required Information to Process Request	132
Medical Necessity	1520
Other	17
Other PA Activity	
Duplicate Requests	21
Letters	5619
No Process	264
Changes to existing PAs	0
PAs missing info	14

*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

9/1/2026 Through 9/30/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	2	1	0	1	91
Amphetamines	4	2	1	1	107
Analgesics - Anti-Inflammatory	89	68	6	15	319
Analgesics - Nonnarcotic	1	0	0	1	0
Analgesics - Opioid	49	26	18	5	257
Androgens - Anabolic	63	10	33	20	269
Anorectal and Related Products	4	0	1	3	0
Antacids	1	1	0	0	365
Anthelmintics	6	1	3	2	91
Antianxiety Agents	3	0	0	3	0
Antiasthmatic and Bronchodilator Agents	116	62	44	10	330
Antibiotics	4	1	0	3	365
Anticonvulsants	28	13	7	8	318
Antidepressants	58	26	19	13	415
Antidiabetics	337	121	156	60	256
Antiemetics	16	1	1	14	365
Antihistamines	1	0	0	1	0
Antihyperlipidemics	27	11	8	8	217
Antihypertensives	3	1	0	2	182
Anti-Infective Agents - Misc.	5	1	0	4	122
Antineoplastics and Adjunctive Therapies	84	44	4	36	201
Anti-Obesity Agents	292	69	95	128	72
Antipsychotics/Antimanic Agents	20	14	3	3	294
Antivirals	2	1	1	0	168
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	14	7	3	4	514
Beta Blockers	1	1	0	0	365
Calcium Channel Blockers	1	1	0	0	365
Cardiovascular Agents - Misc.	38	24	4	10	373
Contraceptives	27	5	9	13	148
Corticosteroids	11	3	1	7	172
Dermatologicals	213	136	40	37	250
Diagnostic Products	19	17	2	0	356
Digestive Aids	4	3	0	1	274
Diuretics	1	0	0	1	0
Endocrine and Metabolic Agents - Misc.	50	24	7	19	312
Estrogens	7	2	3	2	365
Gastrointestinal Agents - Misc.	108	57	34	17	205
Gout Agents	6	3	0	3	304
Hematological Agents - Misc.	2	1	0	1	365
Hematopoietic Agents	21	3	3	15	154
Hypnotics/Sedatives/Sleep Disorder Agents	11	2	8	1	110
Laxatives	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
Medical Devices and Supplies	21	19	1	1	961
Migraine Products	159	102	35	22	201
Minerals and Electrolytes	2	0	0	2	0
Miscellaneous Therapeutic Classes	15	10	2	3	295
Musculoskeletal Therapy Agents	36	10	5	21	290
Nasal Agents - Systemic and Topical	2	0	2	0	0
Neuromuscular Agents	39	27	0	12	286
Ophthalmic Agents	28	15	5	8	247
Other	10	4	0	6	364
Otic Agents	2	0	1	1	0
Passive Immunizing and Treatment Agents	10	3	0	7	365
Psychotherapeutic and Neurological Agents - Misc.	48	26	12	10	263
Respiratory Agents - Misc.	4	2	0	2	730
Stimulants - Misc.	18	11	4	3	312
Ulcer Drugs/Antispasmodics/Anticholinergics	22	6	8	8	199
Urinary Antispasmodics	19	2	13	4	563
Vaginal and Related Products	2	0	0	2	0
Vasopressors	1	0	0	1	0
Vitamins	96	5	0	91	22
Total	2,284	1,006	602	676	

Overrides					
Dosage Change	164	69	84	11	130
Ingredient Duplication	179	102	51	26	175
NDC vs Age	519	367	15	137	258
NDC vs Sex	2	2	0	0	365
Opioid MME Limit	3	3	0	0	446
Opioid Quantity	5	5	0	0	416
Other	356	71	92	193	91
Quantity vs Days Supply	225	141	40	44	241
STBS/STBSM	563	53	84	426	33
Step Therapy Exception	163	85	53	25	184
Third Brand Request	6	0	4	2	0
Overrides Total	2,185	898	423	864	
Total Regular PAs + Overrides	4,469	1,904	1,025	1,540	

Denial Reasons	
Alternatives Not Met	281
Medical Necessity	744

*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

9/1/2026 Through 9/30/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Alternative Medicines	1	0	0	1	0
Amphetamines	334	158	140	36	1,061
Analgesics - Anti-Inflammatory	114	50	30	34	884
Analgesics - Nonnarcotic	4	0	4	0	0
Analgesics - Opioid	269	91	115	63	247
Androgens - Anabolic	58	6	42	10	1,095
Anorectal and Related Products	9	0	4	5	0
Anorexiant Non-Amphetamine	2	0	0	2	0
Antacids	1	1	0	0	365
Anthelmintics	9	1	7	1	365
Antianxiety Agents	18	5	11	2	399
Antiasthmatic and Bronchodilator Agents	381	198	102	81	546
Antibiotics	40	15	12	13	281
Anticoagulants	2	1	1	0	100
Anticonvulsants	78	28	32	18	859
Antidepressants	183	53	91	39	991
Antidiabetics	650	287	212	151	957
Antiemetics	22	5	8	9	299
Antifungals	9	4	4	1	189
Antihistamines	18	3	11	4	851
Antihyperlipidemics	27	3	19	5	1,095
Antihypertensives	15	6	5	4	767
Anti-Infective Agents - Misc.	6	0	0	6	0
Antineoplastics and Adjunctive Therapies	88	51	8	29	445
Anti-Obesity Agents	326	83	95	148	365
Antiparkinson and Related Therapy Agents	2	1	0	1	1,095
Antipsychotics/Antimanic Agents	161	72	48	41	919
Antivirals	5	1	2	2	1,095
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	119	68	36	15	1,095
Beta Blockers	6	1	4	1	1,095
Calcium Channel Blockers	3	2	0	1	599
Cardiovascular Agents - Misc.	34	10	7	17	986
Chemicals	1	1	0	0	30
Contraceptives	41	10	23	8	474
Corticosteroids	13	2	3	8	80
Cough/Cold/Allergy	3	1	0	2	365
Dermatologicals	301	97	130	74	575
Diagnostic Products	26	10	11	5	727
Dietary Products/Dietary Management Products	1	1	0	0	365
Digestive Aids	1	0	1	0	0
Diuretics	3	2	1	0	607
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	1	1	0	1,095
Endocrine and Metabolic Agents - Misc.	42	19	18	5	1,007
Estrogens	22	13	4	5	376
Gastrointestinal Agents - Misc.	109	35	50	24	604
Genitourinary Agents - Misc.	2	0	1	1	0
Gout Agents	4	1	3	0	112
Hematological Agents - Misc.	19	4	6	9	251

*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
Hematopoietic Agents	28	6	11	11	169
Hypnotics/Sedatives/Sleep Disorder Agents	28	3	16	9	217
Laxatives	14	6	3	5	350
Medical Devices and Supplies	138	80	30	28	943
Migraine Products	242	85	114	43	694
Minerals and Electrolytes	9	0	6	3	0
Miscellaneous Therapeutic Classes	33	17	6	10	628
Multivitamins	4	2	0	2	594
Musculoskeletal Therapy Agents	33	9	19	5	505
Nasal Agents - Systemic and Topical	12	5	6	1	358
Neuromuscular Agents	47	18	11	18	297
Ophthalmic Agents	63	27	26	10	256
Other	64	3	8	53	852
Otic Agents	24	0	17	7	0
Passive Immunizing and Treatment Agents	3	0	2	1	0
Progestins	3	1	0	2	111
Psychotherapeutic and Neurological Agents - Misc.	38	12	18	8	812
Respiratory Agents - Misc.	2	1	1	0	1,095
Stimulants - Misc.	108	55	33	20	1,009
Thyroid Agents	5	3	0	2	107
Ulcer Drugs/Antispasmodics/Anticholinergics	42	13	17	12	447
Urinary Antispasmodics	21	5	11	5	353
Vaccines	4	1	3	0	90
Vaginal and Related Products	3	0	0	3	0
Vasopressors	2	1	1	0	1,095
Vitamins	1	1	0	0	180
**Total	4,555	1,755	1,661	1,139	

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

Denial Reasons	
Medical Necessity	1,661
Benefit	200

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



Fall 2026 Pipeline Update

Oklahoma Health Care Authority
October 2026

Introduction

The following report is a pipeline review compiled by the University of Oklahoma College of Pharmacy: Pharmacy Management Consultants. Information in this report is focused on medications not yet approved by the U.S. Food and Drug Administration (FDA). The pipeline report is not an all-inclusive list, and medications expected to be highly utilized or have a particular impact in the SoonerCare population have been included for review. Pipeline data is collected from a variety of sources and is subject to change; dates listed are projections and all data presented are for informational purposes only. Costs listed in the following report do not reflect rebated prices or net costs.

Asundexian^{1,2,3}

Anticipated Indication(s): Secondary Stroke Prevention

Clinical Trial(s): In May 2026, the FDA accepted the New Drug Application (NDA) for asundexian, a Factor XIa (FXIa) inhibitor, for the prevention of ischemic stroke in patients after a non-cardioembolic ischemic stroke or transient ischemic attack (TIA). The application was supported by data from a Phase 3, double-blind, event-driven, randomized, placebo-controlled trial called OCEANIC-STROKE. The trial included 12,327 patients who were 18 years of age or older with a non-cardioembolic ischemic stroke or high-risk TIA who were within 72 hours after the onset of symptoms and there was a plan for treatment with dual or single antiplatelet therapy. Eligible patients were randomized 1:1 to receive asundexian 50mg once daily or placebo in addition to planned dual or single antiplatelet therapy (e.g., aspirin, clopidogrel). The primary efficacy outcome was the first occurrence of ischemic stroke, and the primary safety outcome was major bleeding defined by the International Society on Thrombosis and Haemostasis (ISTH). The results showed that ischemic stroke occurred less frequently in the asundexian treated group with 384 patients (6.2%) having an ischemic stroke versus 518 (8.4%) in the placebo group [cause-specific hazard ratio (HR): 0.74; 95% confidence interval (CI): 0.65, 0.84; P<0.001]. Additionally, ISTH major bleeding was similar between groups and occurred in 117 (1.9%) in the asundexian treated group versus 107 (1.7%) patients who received placebo (cause-specific HR: 1.10; 95% CI: 0.85, 1.44; P=0.46).

Place in Therapy: FXI is a coagulation factor involved in the intrinsic pathway of coagulation. Previous studies have shown those with an FXI deficiency or inhibition have protection against thrombosis with minimal bleeding and those with increased levels of FXI have a higher risk of ischemic stroke. Asundexian is a FXIa inhibitor and at the 50mg daily dose, it has been shown to inhibit activated FXI by more than 90% making it a potential therapeutic target for stroke prevention. Current treatment options for secondary stroke prevention include antiplatelet therapy with aspirin or clopidogrel, either as monotherapy or dual therapy. If approved, asundexian would be the first anticoagulant approved as add-on therapy to antiplatelets for secondary stroke prevention. Previously approved anticoagulants have not shown enough benefit to outweigh the increased risk of bleeding in this patient population. The results of OCEANIC-STROKE showed asundexian reduced the incidence of ischemic stroke without increasing the risk of major bleeding.

Projected FDA Decision: 11/09/2026

SoonerCare Impact: During fiscal year 2026, there were 21,470 paid claims for antiplatelet medications for 6,338 unique members, which accounted for a total cost of \$713,327.76 and an average cost per claim of \$33.22.

Delpacibart Zotadirsen (Del-Zota)^{4,5,6,7,8,9}

Anticipated Indication(s): Duchenne Muscular Dystrophy (DMD)

Clinical Trial(s): In June 2026, the FDA accepted the Biologics License Application (BLA) for del-zota for the treatment of patients with DMD who have a genetic variant that may be treated through exon 44 skipping. The application was supported by safety and efficacy data from the Phase 1/2 EXPLORE44 and EXPLORE44-OLE trials. EXPLORE44 was a randomized, placebo-controlled, double-blind Phase 1/2 trial that studied del-zota in 26 ambulatory and non-ambulatory patients 7 to 27 years of age with a confirmed DMD gene mutation amenable to exon 44 skipping. Patients were randomized 3:1 to del-zota or placebo and received 3 intravenous (IV) infusions of del-zota at either 5mg/kg every 6 weeks, 10mg/kg every 8 weeks, or placebo. Muscle biopsies were performed at baseline and 1 month after the last dose. The results showed the del-zota treated patients had consistent and high phosphorodiamidate morpholino oligonucleotide (PMO) muscle concentrations, an increase in exon 44 skipping, and an increase in dystrophin production. Additionally, in the patients treated with del-zota, their creatine kinase (CK) levels, a marker of muscle damage, returned to near normal levels, and this was sustained through 1 year. In a subgroup analysis, the results were the same regardless of ambulatory status. EXPLORE44-OLE was an open-label extension of EXPLORE44 and allowed patients to transition over to the selected study dose of 5mg/kg every 6 weeks. It

included 39 total patients aged 7 to 27 years of age with 26 ambulatory patients and 13 non-ambulatory patients. The results showed improvements in the del-zota treated group compared to a natural history cohort of patients in functional assessments such as the 4-stair climb (4SC), 10-meter walk/run test (10MWRT), time to rise (TTR), and performance of upper limb (PUL).

Place in Therapy: Del-zota is an antibody oligonucleotide conjugate (AOC) designed to deliver PMO to skeletal muscle and heart tissue to skip exon 44 of the dystrophin gene and restore dystrophin production. Current exon skipping therapies have limited clinical efficacy due to poor muscle delivery. The AOC technology in del-zota is designed to improve the delivery of the oligonucleotide to muscle tissue by combining the PMO with a monoclonal antibody. There is currently no cure for DMD, but there are 2 primary treatment strategies for DMD which include improving muscle function by treating patients with anti-inflammatory agents (i.e., prednisone, Agamree, Emflaza, Duvyzat) and by restoring dystrophin function through gene therapy (i.e., Elevidys) or exon-skipping therapies (i.e., Amondys 45, Exondys 51, Viltepso, Vyondys 53). Del-zota will be the first exon skipping therapy to target exon 44. Approximately 6-7% of patients with DMD have a mutation amenable to exon 44 skipping.

Projected FDA Decision: 02/25/2027

SoonerCare Impact: During fiscal year 2026, there were 118 paid claims for muscular dystrophy medications, for 9 unique members, which accounted for a total cost of \$6,888,160.71 and an average cost per claim of \$58,374.24. These costs do not reflect rebated prices or net costs.

Aroxybutynin/Atomoxetine (AD109)^{10,11,12,13}

Anticipated Indication(s): Obstructive Sleep Apnea (OSA)

Clinical Trial(s): In July 2026, the FDA accepted the NDA for AD109 for the treatment of adults with OSA. The efficacy of AD109 was studied in 2 clinical trials, SynAIRgy and LunAIRo, which were Phase 3, randomized, double-blind, placebo-controlled trials. Both trials included patients 18 years of age or older with a diagnosis of mild to severe OSA who had failed or refused positive airway pressure (PAP) therapy. Additionally, patients had an apnea-hypopnea index (AHI) ≥ 5 and a body mass index (BMI) between 18.5 to 42kg/m². In both trials, patients were randomized 1:1 to receive AD109 or placebo. The primary endpoint was the change in AHI from baseline to week 26. Both studies completed an intent to treat (ITT) analysis, which included all patients who received ≥ 1 dose of AD109 or placebo, and a modified intent to treat (mITT) analysis, which included those in the ITT who had ≥ 1 post-baseline polysomnogram on treatment. In SynAIRgy, the mean change in AHI from baseline to week 26 in the ITT was -3.3 events/hour (95% CI: -5.1, -1.5) in the

AD109 group versus 0.7 events/hour (95% CI: -1.0 to 2.4) in the placebo group for an estimated mean treatment difference of -4.0 events/hour (95% CI: -6.4, -1.6; P=0.001). In LunAIRo, in the ITT, AD109 significantly reduced AHI by -3.9 events/hour (95% CI: -5.4, -2.4) versus 0.2 events/hour (95% CI: -1.2, -1.7) in the placebo group (P<0.001). The mITT analysis showed an even better improvement with an estimated mean treatment difference of -6.5 events/hour (95% CI: -8.8, -4.3; P<0.0001) between treatment groups in the SynAIRgy trial, and in the LunAIRo trial, AD109 significantly reduced AHI by -5.8 (95% CI: -7.5, -4.2) versus -0.0 (95% CI: -1.6, 1.5) with placebo (P<0.0001). Both trials showed other improvements in secondary endpoints such as oxygen desaturation index and hypoxic burden.

Place in Therapy: AD109 is a once daily fixed oral dose of aroxybutynin 2.5mg, an antimuscarinic agent, and atomoxetine 75mg, a selective norepinephrine reuptake inhibitor (SNRI). Research has shown that in OSA, a decrease in noradrenergic activity and an increase in muscarinic inhibition contribute to upper airway obstruction. AD109 was designed to target both of these mechanisms and to stabilize the upper airway muscle activation during sleep. Current treatment options for OSA include Zepbound, which treats OSA by reducing airway crowding through weight loss, and then Nuvigil, Provigil, and Sunosi, which improve daytime sleepiness with OSA but do not treat the underlying cause. If approved, AD109 would be the first treatment to target the underlying neuromuscular cause of upper airway obstruction in patients with OSA regardless of their BMI.

Projected FDA Decision: 02/28/2027

SoonerCare Impact: During fiscal year 2026, there were 1,796 paid claims for OSA medications for 547 unique members, which accounted for a total cost of \$587,209.09 and an average cost per claim of \$326.95. This data includes medications indicated for OSA; however, the data does not differentiate between OSA and other diagnoses, for which use may be appropriate.

Pipeline Table^{14,15}

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
pritelivir (AIC-316)	Aicuris	HSV	PO	NDA	10/13/2026
olanzapine long-acting injection (TV-44749)	Teva	Schizophrenia	sub-Q	505(b)(2) NDA	10/20/2026
atropine (low dose)	Sydnexis	Progression of pediatric myopia	OPH	NDA	10/23/2026
bepirovirsen	GSK	HBV treatment	sub-Q	NDA; Brk Thru; Fst Trk	10/26/2026
doruxapapogene ralaplasmid (INO-3107)	Inovio	Respiratory papillomatosis	IM	BLA; Brk Thru; OD	10/30/2026
cemdisiran	Regeneron	Myasthenia gravis	sub-Q	NDA; OD	11/2026
asundexian	Bayer	Secondary stroke prevention	PO	NDA; Fst Trk	11/09/2026
adrabetadex	Mandos	Niemann-Pick disease (type C)	Intra-theal	NDA; Brk Thru; OD	11/17/2026
deramiocecl	Capricor Therapeutics	DMD-related cardiomyopathy	IV	BLA; OD	11/22/2026
molgramostim	Savara	Acute pulmonary alveolar proteinosis	Inhaled	BLA; Brk Thru; Fst Trk; OD	11/22/2026
venglustat	Sanofi	Gaucher's disease (type 3)	PO	NDA; Brk Thru; OD	11/25/2026
ribitol (BBP-418)	BridgeBio	Limb-girdle muscular dystrophy (type 2I/R9)	PO	NDA; Fst Trk; Brk Thru	11/27/2026
saroglitazar	Zydus	Primary biliary cholangitis (in combination with UDCA)	PO	NDA; Fst Trk; OD	11/27/2026
doxycycline polymer-lipid encapsulation matrix (D-PLEX)	PolyPid	Surgical Site Infections	Surgical Implant	505(b)(2) NDA; Brk Thru; Fst Trk	11/28/2026
bezuclastinib	Cogent	Mastocytosis (nonadvanced, systemic)	PO	NDA; Brk Thru; OD	11/30/2026
povetacicept	Vertex	IgA nephropathy	sub-Q	BLA; Brk Thru	11/30/2026
gefurulimab	AstraZeneca	Myasthenia gravis	sub-Q	BLA; OD	12/10/2026
imsidolimab	Vanda	GPP	IV	BLA; OD	12/12/2026

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
meloxicam (fast acting)	Viartis	Acute pain (moderate to severe)	PO	505(b)(2) NDA	12/17/2026
relacorilant	Corcept Therapeutics	Cushing's Syndrome	PO	NDA	12/17/2026
octreotide (CAM-2029)	Camurus	Acromegaly	sub-Q	NDA	12/18/2026
imlifidase	Sarepta	Kidney transplant rejection	IV	BLA; Fst Trk; OD	12/19/2026
lorundrostat (MT-4129)	Mineralys	HTN (uncontrolled or resistant)	PO	NDA	12/22/2026
relutrigine (PRAX-562)	Praxis	Developmental and epileptic encephalopathy (SCN2A and SCN8 variants)	PO	NDA; Brk Thru; OD	12/27/2026
sodium dichloroacetate (SL-1009)	Saol	Pyruvate dehydrogenase complex deficiency	PO	NDA; Fst Trk; OD	12/30/2026
apixaban oral dissolving film (TAH3311)	Taho	Thrombotic disorders	PO	505(b)(2) NDA	2H 2026
lorezivint	Biosplice	Osteoarthritis (knee)	Intra-articular	NDA	01/06/2027
tegoprazan	Sebela	Erosive esophagitis (healing and maintenance); nonerosive reflux disease	PO	NDA	01/09/2027
zeleciment rostudirsen	Dyne	DMD (amendable to exon 51 skipping)	IV	BLA; Brk Thru; Fst Trk; OD	01/21/2027
ulixacaltamide	Praxis Precision	Essential tremor	PO	NDA; Brk Thru	01/29/2027
cenobamate oral suspension	SK Biopharmaceuticals	Focal seizures	PO	BDA	01/31/2027
tinlarebant	Belite Bio	Stargardt disease (type 1)	PO	NDA; Brk Thru; Fst Trk; OD	02/12/2027
ecopipam	Teva	Tourette's syndrome (pediatric)	PO	NDA; Fst Trk; OD	02/18/2027
zalunfiban	CeleCor	STEMI	sub-Q	NDA; Fst Trk	02/24/2027

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
delpacibart zotadirsen (del- zota)	Avidity Biosciences/Nov artis	DMD (amendable to exon 44 skipping)	IV	BLA; OD	02/25/2027
atomoxetine/ aroxybutynin (AD109)	Apnimed	OSA	PO	NDA; Fst Trk	02/28/2027
povorcitinib	Incyte	Hidradenitis suppurativa	PO	NDA	1Q 2027
midomafetamine	Lykos Therapeutics	PTSD	PO	NDA	1Q 2027
deucricitibant	Pharvaris	HAE	PO	NDA; OD	04/23/2027
azimplacel	Organogenesis	Osteoarthritis	Intra- articular	BLA; RMAT	04/24/2027
dersimelagon	Tanabe Pharma	Protoporphyrin	PO	NDA	04/30/2027
nitric oxide- donating bimatoprost (NCX-470)	Nicox	Open-angle glaucoma	OPH	NDA	04/30/2027
reboxetine	Axsome, Pfizer	Narcolepsy- related cataplexy	PO	NDA; Brk Thru; OD	05/01/2027
encaleret	BridgeBio	Autosomal dominant hypocalcemia type 1	PO	NDA	05/08/2027
obixelimab	Zenas, Amgen	IgG4-related disease	sub-Q	BLA; OD	05/27/2027
ralinepag	United Therapeutics	PAH	PO	NDA	06/24/2027
cytisinicline	Achieve Life Sciences	Smoking cessation	PO	NDA; Brk Thru	1H 2027

*Most biosimilars and oncology medications are excluded from the table. Medications known to have received a Complete Response Letter (CRL) from the FDA that have not resubmitted were also excluded. Admin = administration; BLA = biologic license application; Brk Thru = breakthrough; CNPV = Commissioner's National Priority Voucher; DMD = Duchenne Muscular Dystrophy; Fst Trk = fast track; GPP = generalized pustular psoriasis; GSK = GlaxoSmithKline; H = half; HAE = hereditary angioedema; HBV = hepatitis B virus; HSV = herpes simplex virus; HTN = hypertension; IgA = immunoglobulin A; IgG = immunoglobulin G; IV = intravenous; MCT8 = monocarboxylate transporter 8; MPS = mucopolysaccharidosis; NDA = new drug application; OD = orphan drug; OPH = ophthalmic; OSA = obstructive sleep apnea; PAH = pulmonary arterial hypertension; PO = by mouth; PTSD = post-traumatic stress disorder; Q = quarter; sub-Q = subcutaneous; T2DM = type 2 diabetes mellitus; STEMI = ST-elevation myocardial infarction; UDCA = ursodeoxycholic acid

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Vote to Prior Authorize Cetirizine Oral Solution Unit-Dose Cups (UDCs) and Update the Approval Criteria for the Antihistamine Medications (Systemic)

Oklahoma Health Care Authority
October 2026

Cost Comparison: Cetirizine Products

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
cetirizine 5mg/5mL oral sol unit-dose cup	\$0.40	\$120.00	\$1,440.00
cetirizine 1mg/mL oral solution	\$0.03	\$9.00	\$108.00
cetirizine 10mg tablet	\$0.05	\$1.50	\$18.00

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 the use of 10mg per day for each product.

Sol = solution; Unit = each tablet or milliliter

Recommendations

The College of Pharmacy recommends the following changes to the Systemic Antihistamine Medications Product Based Prior Authorization (PBPA) category (changes noted in red in the following PBPA Tier chart and approval criteria):

1. Prior authorization of cetirizine oral solution UDCs and placement into Tier-3 with additional criteria shown below; and
2. Moving levocetirizine tablets from Tier-2 to Tier-1 based on net cost; and
3. Moving desloratadine tablets from Tier-3 to Tier-2 based on net cost; and
4. Updating the Tier-2 and Tier-3 approval criteria based on Drug Utilization Review (DUR) Board recommendations and to clarify the trial requirements for age-appropriate dosage formulations.

Oral Antihistamine Medications		
Tier-1*	Tier-2	Tier-3
OTC cetirizine (Zyrtec) sol, tab	desloratadine (Clarinet) tab	cetirizine sol UDC
OTC levocetirizine (Xyzal) tab	OTC levocetirizine (Xyzal)* sol	clemastine syr, tab
OTC loratadine (Claritin) ODT, sol, tab		desloratadine (Clarinet)* ODT, sol

*Tier-1 products are covered for pediatric members with no authorization necessary. OTC products are only covered for pediatric members.

*~~Xyzal is only covered for members 0 to 20 years of age.~~ Xyzal solution is available for children 6 months to 6 years of age.

†An age restriction of 6 years to 11 years of age applies for Clarinet ~~ODT Reditabs~~.

ODT = orally disintegrating tablet; OTC = over-the-counter; sol = solution; syr = syrup; tab = tablet; UDC = unit-dose cup

Oral Antihistamine Medications Tier-2 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. Member must have a 14-day trial of **2 age-appropriate** Tier-1 products within the last 30 days; and
3. Approvals will be for the duration of 1 year.

Oral Antihistamine Medications Tier-3 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. Member must have a 14-day trial of **2 age-appropriate** Tier-1 products and **1 age-appropriate** Tier-2 products within the last 60 days (unless no age-appropriate Tier-2 product exists); and
 - a. Requests for cetirizine unit-dose cups (UDCs) will require a patient-specific, clinically significant reason why the member cannot use cetirizine bulk solution, which is available without a prior authorization; and
3. Approvals will be for the duration of 1 year.



Vote to Prior Authorize Epioxa HD/Epioxa (Riboflavin 5'-Phosphate Ophthalmic Solution) and Lumvoa (Veligrotug-vvze) and Update the Approval Criteria for the Various Ophthalmic Medications

Oklahoma Health Care Authority
October 2026

Market News and Updates^{1,2,3,4}

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

- **October 2025:** The FDA approved Epioxa HD/Epioxa (riboflavin 5'-phosphate) to treat keratoconus in adults and pediatric patients 13 years of age and older, in conjunction with the O₂n System and the Boost Goggles. Epioxa HD/Epioxa does not require the removal of the epithelium like the previously approved Photrexa/Photrexa Viscous (riboflavin 5'-phosphate). The efficacy of Epioxa HD/Epioxa with epithelium-on corneal collagen cross-linking (CXL) with UV-A irradiation and supplemental oxygen in patients with keratoconus was evaluated in 2 prospective, randomized, parallel-group, sham procedure/vehicle-controlled trials. The primary endpoint was a change from baseline in the maximum corneal curvature (K_{max}) in the CXL treatment group and in the sham procedure/vehicle control group. In both studies, the CXL treatment group showed an improvement in K_{max} (decrease in corneal curvature) whereas the sham procedure/vehicle control group showed deterioration (increase in corneal curvature). The treatment difference between groups was about -1.0 diopter in both trials, which was determined to be statistically significant. The Wholesale Acquisition Cost (WAC) of Epioxa HD/Epioxa is \$78,500 per kit; therefore, to treat both eyes, the cost would be \$157,000.
- **June 2026:** The FDA approved Lumvoa (veligrotug-vvze) for the treatment of thyroid eye disease (TED).

News:

- **January 2026:** Glaukos announced the discontinuation of Photrexa/Photrexa Viscous (riboflavin 5'-phosphate) cross-linking kit.

Lumvoa (Veligrotug-vvze) Product Summary^{5,6,7,8,9}

Therapeutic Class: Insulin-like growth factor-1 receptor (IGF-1R) inhibitor

Indication(s): For the treatment of TED regardless of thyroid eye disease activity or duration

How Supplied: 500mg/10mL(50mg/1mL) solution in a single-dose vial

Dosing and Administration:

- The recommended dose of Lumvoa is 10mg/kg every 3 weeks for a total of 5 infusions.
- Lumvoa should be administered by intravenous (IV) infusion over 30 to 45 minutes.

Efficacy: The efficacy of Lumvoa was evaluated in 2 randomized, double masked, placebo-controlled trials, THRIVE (active TED) and THRIVE-2 (chronic TED).

- Key Inclusion Criteria:
 - ≥18 years of age
 - Must agree to use highly effective contraception as specified in the protocol
 - Female TED participants must have a negative serum pregnancy test at screening
 - THRIVE:
 - Moderate to severe active TED with documented evidence of ocular symptoms or signs that began within 15 months prior to screening.
 - Clinical Activity Score (CAS) of ≥3 on the 7-item scale of the study eye
 - THRIVE-2:
 - Moderate to severe chronic TED with documented evidence of ocular symptoms or signs that began greater than 15 months prior to screening
 - A clinical diagnosis of TED, with any CAS (0-7)
- Key Exclusion Criteria:
 - Prior treatment with another anti-IGF-1R therapy
 - Previous orbital irradiation or surgery for TED in the study eye; however, prior orbital decompression surgery was permitted in either study if surgery was limited to the bone
- Intervention:
 - Randomized to receive Lumvoa or placebo in a 2:1 ratio
 - The study eye was the most proptotic eye by exophthalmometry, with the other designated as the non-study eye.
- Primary Outcome: Proptosis responder rate (PRR) in study eye at week 15 which was defined as the percent of patients with ≥2mm reduction in proptosis in the study eye from baseline without ≥2mm increase in the non-study eye measured by exophthalmometer.

- Results:
 - THRIVE:
 - The percent PRR at week 15 was 70% in the Lumvoa treated group and 5% in the placebo treated group with a treatment difference of 65% [95% confidence interval (CI): 52, 78; P<0.01].
 - The proptosis average change from baseline at week 15 was -2.9mm in the Lumvoa treated group versus -0.5mm in the placebo treated group with a treatment difference of -2.4mm (95% CI: -3, -1.8; P<0.01).
 - THRIVE-2:
 - The percent PRR at week 15 was 57% in the Lumvoa treated group and 8% in the placebo treated group with a treatment difference of 49% (95% CI: 38, 60, P<0.01).
 - The proptosis average change from baseline at week 15 was -2.4mm in the Lumvoa treated group versus -0.5mm in the placebo treated group with a treatment difference of -1.9mm (95% CI: -2.4, -1.4; P<0.01).

Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment Course
Lumvoa (veligrotug-vvze) 500mg/10mL sol	\$4,480	\$448,000[¥]
Tepezza (teprotumumab-trbw) 500mg vial	\$19,451.83	\$447,392.09*

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).

sol = solution; Unit = mL or vial

[¥]Cost per treatment course is based on a 75kg patient receiving the FDA approved dose of 10mg/kg every 3 weeks for a total of 5 infusions.

*Cost per treatment course is based on a 75kg patient receiving the FDA approved dose of 10mg/kg for the initial dose followed by 20mg/kg every 3 weeks for 7 additional infusions.

Recommendations

The College of Pharmacy recommends the prior authorization of Epioxa HD/ Epioxa (riboflavin 5'-phosphate) with the following criteria (shown in red):

Epioxa HD/Epioxa (Riboflavin 5'-Phosphate) Approval Criteria:

1. A diagnosis of 1 of the following:
 - a. Keratoconus; or
 - b. Corneal ectasia following refractive surgery; and
2. Member must be 13 years of age or older; and
3. Must be administered by an optometrist or ophthalmologist trained in the corneal cross-linking procedure; and
4. Must be used in combination with the O₂n System and Boost Goggles in the corneal cross-linking (CXL) procedure; and

5. Must be administered using the epithelial-on procedure as specified in the package labeling; and
6. Member must not have any contraindications to Epioxa HD/Epioxa or to the CXL procedure or have any current or previous ocular conditions in the eye to be treated that may predispose the eye for future complications after the procedure; or
 - a. The prescriber has assessed the member and determined the risks outweigh the benefits of the procedure and has counseled the member on the potential risks; and
7. Member must not have previous use of Photrex/Photrex Viscous (riboflavin 5'-phosphate) with the CXL procedure in the eye to be treated; and
8. A quantity limit of 1 kit (4mL) per eye per lifetime will apply.

The College of Pharmacy recommends the prior authorization of Lumvoo (veligrotug-vvze) with the following criteria (shown in red):

Lumvoo (Veligrotug-vvze) Approval Criteria:

1. An FDA approved indication for the treatment of thyroid eye disease (TED) in adult members 18 years of age and older; and
 - a. Member must have thyroid blood levels in the normal range or must be undergoing active treatment working toward normal range; and
2. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
3. Female members of reproductive potential must be willing to use effective contraception prior to initiation, during treatment with Lumvoo, and for at least 6 months after the last dose of Lumvoo; and
4. Member must not have had prior surgical treatment for TED unless eye surgery was limited to the bone; or
 - a. A prior authorization request with patient-specific information may be submitted for consideration of Lumvoo for members who have had prior surgical treatment for TED, including but not limited to patient-specific, clinically significant information regarding the member's prior surgery and the need for Lumvoo; and
5. Member must have medical supervision by an ophthalmologist in conjunction with an endocrinologist for the treatment of TED; and
 - a. ~~The name of the ophthalmologist and endocrinologist recommending treatment with Lumvoo must be provided on the prior authorization request; and~~
6. Lumvoo must be administered as an intravenous (IV) infusion at the recommended infusion rate per package labeling, with appropriate pre-medication(s) based on the member's risk of infusion reactions; and

7. Lumvoa must be administered by a health care professional. Prior authorization requests must indicate how Lumvoa will be administered; and
 - a. Lumvoa must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
 - b. Lumvoa must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member (or the member's caregiver) must be trained on the proper storage of Lumvoa; and
8. The member's current weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
9. Member must not have received previous treatment with Tepezza (teprotumumab-trbw); and
10. Approvals will be for a maximum of 5 total infusions.

The College of Pharmacy also recommends updating the approval criteria for Tepezza (teprotumumab-trbw) based on the FDA approval of Lumvoa (veligrotug-vvze) (changes shown in red):

Tepezza (Teprotumumab-trbw) Approval Criteria:

1. An FDA approved indication for the treatment of thyroid eye disease (TED) in adult members 18 years of age and older; and
 - a. Member must have thyroid blood levels in the normal range or must be undergoing active treatment working toward normal range; and
2. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
3. Female members of reproductive potential must be willing to use effective contraception prior to initiation, during treatment with Tepezza, and for at least 6 months after the last dose of Tepezza; and
4. Member must not have had prior surgical treatment for TED; or
 - a. A prior authorization request with patient-specific information may be submitted for consideration of Tepezza for members who have had prior surgical treatment for TED, including but not limited to patient-specific, clinically significant information regarding the member's prior surgery and the need for Tepezza; and
5. **Member must have** medical supervision by an ophthalmologist in conjunction with an endocrinologist for the treatment of TED; and
 - ~~a. The name of the ophthalmologist and endocrinologist recommending treatment with Tepezza must be provided on the prior authorization request; and~~

6. Tepezza must be administered as an intravenous (IV) infusion at the recommended infusion rate per package labeling, with appropriate pre-medication(s) based on the member's risk of infusion reactions; and
7. Tepezza must be administered by a health care professional. Prior authorization requests must indicate how Tepezza will be administered; and
 - a. Tepezza must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
 - b. Tepezza must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member (or the member's caregiver) must be trained on the proper storage of Tepezza; and
8. The member's current weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
9. Member must not have received previous treatment with Lumvoa (veligrotug-vvze); and
10. Approvals will be for a maximum of 8 total infusions.

¹ Glaukos. Glaukos Announces FDA Approval of Epioxa. Available online at: <https://investors.glaukos.com/news/news-details/2025/Glaukos-Announces-FDA-Approval-of-Epioxa/default.aspx>. Issued 10/20/25. Last accessed 09/21/2026.

² Epioxa HD and Epioxa Prescribing Information. Glaukos. Available online at: <https://www.epioxa.com/wp-content/uploads/2025/10/epioxa-prescribing-information-final.pdf>. Last revised 10/2025. Last accessed 09/21/2026.

³ Viridian Therapeutics, Inc. Viridian Therapeutics Announces U.S. FDA Approval and Launch of Lumvoa (Veligrotug-vvze) for the Treatment of Thyroid Eye Disease. Available online at: <https://www.businesswire.com/news/home/20260625016249/en/Viridian-Therapeutics-Announces-U.S.-FDA-Approval-and-Launch-of-Lumvoa-veligrotug-vvze-for-the-Treatment-of-Thyroid-Eye-Disease>. Issued 06/26/2026. Last accessed 09/21/2026.

⁴ Glaukos Corporation – Discontinuation of Photrexa (Riboflavin 5-Phosphate) Cross-Linking Kit. OptumRx. Available online: <https://business.optum.com/content/dam/noindex-resources/business/support-documents/drug-recalls-availability/drugwithdrawal-photrexa-012726.pdf>. Issued 01/20/2026. Last accessed 09/21/2026.

⁵ Lumvoa (Veligrotug-vvze) Prescribing Information. Viridian Therapeutics, Inc. Available online at: <https://www.lumvoahcp.com/content/lumvoa-prescribing-information.pdf>. Last revised 06/2026. Last accessed 09/21/2026.

⁶ A Safety, Tolerability and Efficacy Study of Veligrotug (VRDN 001) in Health Volunteers and Participants With Thyroid Eye Disease (TED) (THRIVE). *ClinicalTrials.gov*. Available online at: <https://clinicaltrials.gov/study/NCT05176639>. Last revised 07/18/2025. Last accessed 09/21/2026.

⁷ An Efficacy, Safety, and Tolerability Study of Veligrotug (VRDN-001), in Participants with Chronic Thyroid Eye Disease (TED) (THRIVE-2). *ClinicalTrials.gov*. Available online at: <https://clinicaltrials.gov/study/NCT06021054>. Last revised 10/23/2025. Last accessed 09/21/2026.

⁸ Yen M, Cockerham K, Saeed P, et al. THRIVE: A Phase 3, Randomized, Double-Masked, Placebo-Controlled Study of Veligrotug for Active Thyroid Eye Disease. *Ophthalmology* 2026; 133(9): 1085-1096. doi: 10.1016/j.ophtha.2026.04.022.

⁹ Tepezza (Teprotumumab-trbw) Prescribing Information. Horizon Therapeutics. Available online at: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/tepezza/tepezza_fpi_english.pdf. Last revised 11/2025. Last accessed 09/21/2026.



Vote to Prior Authorize Beizray (Docetaxel), Beizray Kit (Docetaxel/Albumin), Docivyx (Docetaxel), Inluriyo (Imlunestrant), and Veppanu (Vepdegestrant) and Update the Approval Criteria for the Breast Cancer Medications

Oklahoma Health Care Authority
October 2026

Market News and Updates^{1,2,3,4,5,6,7,8,9,10,11,12,13}

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

- **November 2022:** The FDA approved Docivyx (docetaxel) as a new formulation of docetaxel. It is indicated for all of the same indications as Taxotere (docetaxel), including for use in the treatment of breast cancer, non-small cell lung cancer (NSCLC), castration-resistant prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck.
- **October 2024:** The FDA approved Beizray (docetaxel) as a new formulation of docetaxel. It is indicated for all of the same indications as Taxotere (docetaxel), including for use in the treatment of breast cancer, NSCLC, castration-resistant prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck. Beizray was not covered by SoonerCare until October 2025, when the current manufacturer began marketing the product.
- **September 2025:** The FDA approved Inluriyo (imlunestrant) for the treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor-1 (ESR1)-mutated advanced or metastatic breast cancer with disease progression following at least 1 line of endocrine therapy.
- **December 2025:** The FDA approved Enhertu (fam-trastuzumab deruxtecan-nxki) for a new indication, in combination with pertuzumab, as first-line treatment of adult patients with unresectable or metastatic HER2-positive immunohistochemistry (IHC) 3+ or in situ hybridization (ISH)-positive breast cancer, as determined by an FDA-authorized test.
- **May 2026:** The FDA approved Veppanu (vepdegestrant) for the treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least 1 line of endocrine therapy.

- **May 2026:** The FDA approved Enhertu (fam-trastuzumab deruxtecan-nxki) for 2 new indications for early breast cancer. The first new indication is as neoadjuvant treatment of adult patients with HER2-positive IHC 3+ or ISH-positive Stage II or III breast cancer, as determined by an FDA-authorized test, followed by a taxane, trastuzumab, and pertuzumab (THP). The second new indication is as adjuvant treatment of adult patients with HER2-positive IHC 3+ or ISH-positive breast cancer who have residual invasive disease following neoadjuvant trastuzumab (with or without pertuzumab) and taxane-based treatment.
- **May 2026:** The FDA approved Datroway (datopotamab deruxtecan-dlnk) for a new indication for the treatment of adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who are not candidates for programmed death 1 (PD-1)/programmed death ligand 1 (PD-L1) inhibitor therapy.
- **June 2026:** The FDA approved Truqap (capivasertib) for a new indication, in combination with abiraterone and prednisone, for the treatment of adult patients with metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer that is PTEN-deficient as detected by an FDA-authorized test.
- **June 2026:** The FDA approved Ibrance (palbociclib) for a new indication, in combination with trastuzumab, with or without pertuzumab, and endocrine therapy for the maintenance treatment of adult patients with hormone receptor (HR)-positive, HER2-positive locally advanced or metastatic breast cancer following induction treatment.
- **June 2026:** The FDA approved Trodelvy (sacituzumab govitecan-hziy) for 2 new indications for the first-line treatment of TNBC. The first new indication is as a single agent for the first-line treatment of adult patients with unresectable locally advanced or metastatic TNBC who are not candidates for PD-1 or PD-L1 inhibitor-based therapy. The second new indication is for use in combination with pembrolizumab or pembrolizumab/berahyaluronidase alfa-pmph for the first-line treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 combined positive score (CPS) ≥ 10 as determined by an FDA-authorized test.
- **September 2026:** The FDA approved Inluriyo (imlunestrant) for a new indication, in combination with Verzenio (abemaciclib), for the treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least 1 line of endocrine therapy.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for colon and rectal cancer no longer recommend the use of lapatinib in combination with trastuzumab for a diagnosis of unresectable, advanced, or metastatic HER2-amplified colorectal cancer.

Beizray (Docetaxel) and Beizray Kit (Docetaxel/Albumin) Product Summary¹⁴

Therapeutic Class: Microtubule inhibitor

Indication(s): Indicated for all of the same indications as Taxotere (docetaxel), including for use in the treatment of breast cancer, NSCLC, castration-resistant prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck

How Supplied:

- Single-dose vials (SDVs):
 - 20mg/mL SDV
 - 80mg/4mL SDV
- Kits containing the following:
 - 80mg Kit: 1 SDV of Beizray 80mg/4mL plus 1 SDV of intravenous (IV) solution stabilizer (50mL, 25% albumin human USP solution)
 - 160mg Kit: 2 SDVs of Beizray 80mg/4mL plus 1 SDV of IV solution stabilizer (50mL, 25% albumin human USP solution)

Dosing and Administration: The recommended dosage depends on the specific indication. Please refer to the full *Prescribing Information* for dosage and administration details.

Docivyx (Docetaxel) Product Summary¹⁵

Therapeutic Class: Microtubule inhibitor

Indication(s): Indicated for all of the same indications as Taxotere (docetaxel), including for use in the treatment of breast cancer, NSCLC, castration-resistant prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck

How Supplied:

- 20mg/2mL SDV
- 80mg/8mL SDV
- 160mg/16mL SDV

Dosing and Administration: The recommended dosage depends on the specific indication. Please refer to the full *Prescribing Information* for dosage and administration details.

Cost Comparison: Docetaxel Products

Product	Cost Per mg	Cost Per 21 Days*	Cost Per 6 Doses
Beizray (docetaxel) vial or kit J9174	\$46.81	\$7,489.60	\$44,937.60
Docivyx (docetaxel) vial J9172	\$46.29	\$7,406.40	\$44,438.40
docetaxel vial (generic) J9171	\$0.46	\$73.60	\$441.60

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS), National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

*Cost based on use of up to 160mg per dose every 3 weeks and continued for 6 doses.

Inluriyo (Imlunestrant) Product Summary¹⁶

Therapeutic Class: Estrogen receptor antagonist

Indication(s):

- Treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least 1 line of endocrine therapy
- Treatment, in combination with abemaciclib, of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer, with disease progression following at least 1 line of endocrine therapy

How Supplied: 200mg oral tablet

Dosing and Administration: The recommended dosage is 400mg orally once daily, on an empty stomach, until disease progression or unacceptable toxicity.

Cost: The Wholesale Acquisition Cost (WAC) is \$401.79 per 200mg tablet. This would result in an estimated cost of \$22,500.24 per 28 days or \$292,503.12 per year based on recommended dosing.

Veppanu (Vepdegestrant) Product Summary¹⁷

Therapeutic Class: Heterobifunctional protein degrader

Indication(s): Treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least 1 line of endocrine therapy

How Supplied: 100mg and 200mg oral tablets

Dosing and Administration: The recommended dose is 200mg orally once daily with food continued until disease progression or unacceptable toxicity.

Cost: The WAC is \$980.00 per 200mg tablet. This would result in an estimated cost of \$29,400.00 per 30 days or \$352,800.00 per year based on recommended dosing.

Cost Comparison: Trastuzumab Products

Product	Cost Per 10mg	Cost Per 21 Days*	Cost Per Year
Herceptin (trastuzumab) J9355	\$68.87	\$3,099.15	\$52,685.55
Kanjinti (trastuzumab-anns) Q5117	\$63.87	\$2,874.15	\$48,860.55
Herzuma (trastuzumab-pkrb) Q5113	\$55.30	\$2,488.50	\$42,304.50
Ontruzant (trastuzumab-dttb) Q5112	\$32.79	\$1,475.55	\$25,084.35
Hercessi (trastuzumab-strf) Q5146	\$30.26	\$1,361.70	\$23,148.90
Ogivri (trastuzumab-dkst) Q5114	\$29.51	\$1,327.95	\$22,575.15
Trazimera (trastuzumab-qyyp) Q5116	\$11.27	\$507.15	\$8,621.55

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS), National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

*Cost per 21 days based on use of (3) 150mg vials per dose (6mg/kg every 3 weeks for a 75kg member)

Recommendations

The College of Pharmacy recommends the prior authorization of Beizray (docetaxel), Beizray Kit (docetaxel/albumin), Docivyx (docetaxel), Inluriyo (imlunestrant), and Veppanu (vepdegestrant) with the following criteria (shown in red):

Beizray (Docetaxel), Beizray Kit (Docetaxel/Albumin), and Docivyx (Docetaxel) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use generic docetaxel formulations, which are available without a prior authorization, must be provided.

Inluriyo (Imlunestrant) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer; and
2. Estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease; and
3. Tumor is positive for estrogen receptor-1 (ESR-1) mutation; and
4. Disease has progressed following at least 1 line of endocrine therapy; and
5. Meets 1 of the following:
 - a. Used as a single agent; or
 - b. Used in combination with abemaciclib; and
6. Member must be 18 years of age or older.

Veppanu (Vepdegestrant) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer; and
2. Disease is recurrent unresectable (local or regional), or metastatic; and
3. Estrogen receptor (ER)-positive, human epidermal growth factor 2 (HER2)-negative disease; and
4. Tumor is positive for estrogen receptor-1 (ESR1) mutation; and
5. Has progressed after at least 1 line of endocrine therapy; and
6. Member is 18 years of age or older.

The College of Pharmacy also recommends updating the approval criteria for Datroway (datopotamab deruxtecan-dlnk), Enhertu (fam-trastuzumab deruxtecan-nxki), Ibrance (palbociclib), Trodelvy (sacituzumab govitecan-hziy), Truqap (capivasertib), and Verzenio (abemaciclib) based on recent FDA approvals with the following changes (shown in red):

Datroway (Datopotamab Deruxtecan-dlnk) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of unresectable or metastatic breast cancer; and
2. **Used in 1 of the following settings:**
 - a. Disease is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative; and
 - i. Member has received prior endocrine-based therapy and chemotherapy; **and or**
 - b. **Disease is triple-negative breast cancer (TNBC); and**
 - i. **Member has received no prior systemic therapy; and**
 - ii. **Member is not a candidate for programmed death 1 (PD-1)/programmed death ligand 1 (PD-L1) inhibitor therapy; and**
 - iii. **No germline BRCA 1/2 pathogenic variant; and**
3. Used as a single agent.

Enhertu (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Breast Cancer Diagnosis]:

1. Adult members with unresectable or metastatic disease; and
 - a. For human epidermal growth factor receptor 2 (HER2)-positive **[immunohistochemistry (IHC) 3+ or in situ hybridization (ISH)-positive]** disease, must meet the following:
 - i. **Used as first-line treatment, in combination with pertuzumab; or**
 - ii. **Used as monotherapy; and**
 1. Member received prior therapy in the metastatic, neoadjuvant, or adjuvant setting and developed disease recurrence during or within 6 months of completing therapy; and
 2. Member has received ≥ 1 prior anti-HER2-based regimens; or

- iii. Stage II or III disease, used as neoadjuvant treatment, and followed by a taxane, trastuzumab, and pertuzumab (THP); or
 - iv. Residual invasive disease following neoadjuvant treatment with trastuzumab (with or without pertuzumab) and taxane-based treatment; or
- b. For HER-2 low [immunohistochemistry (IHC) 1+ or IHC 2+/in situ hybridization (ISH)-] disease, must meet 1 of the following:
 - i. Member received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy; or
 - ii. Disease is hormone receptor (HR)-positive, and member has received 1 or more prior endocrine therapies in the metastatic setting and has progressed on that endocrine therapy; or
- c. For HER-2 ultralow (IHC 0 with membrane staining) disease, must meet the following:
 - i. Disease is HR-positive, and member has received 1 or more prior endocrine therapies in the metastatic setting and has progressed on that endocrine therapy.

Ibrance (Palbociclib) Approval Criteria [Breast Cancer Diagnosis]:

- 1. Diagnosis of **locally** advanced **or** metastatic, hormone receptor positive; ~~human epidermal growth factor receptor 2 (HER2)-negative~~ breast cancer; and
- 2. For human epidermal growth factor receptor 2 (HER2)-negative disease:
 - a. Used in combination with:
 - i. An aromatase inhibitor in female members; or
 - ii. Fulvestrant in women with disease progression following endocrine therapy; or
 - iii. An aromatase inhibitor or fulvestrant in male patients; or
 - iv. Inavolisib and fulvestrant in patients with disease progression following endocrine therapy; **or**
- 3. For HER2-positive disease:
 - a. Used in combination with trastuzumab, with or without pertuzumab, and endocrine therapy; and
 - b. Used as maintenance treatment following induction treatment.

Trodelvy (Sacituzumab Govitecan-hziy) Approval Criteria [Breast Cancer Diagnosis]:

- 1. Diagnosis of triple-negative breast cancer; and
 - a. Used as first line therapy:
 - i. Used as monotherapy if member is not a candidate for PD-1 or PD-L1 inhibitor therapy; or

- ii. Used in combination with pembrolizumab for tumors expressing PD-L1 (CPS ≥ 10) as determined by an FDA-authorized test; or
- b. Used as second line or later therapy:
 - i. Unresectable locally advanced or metastatic disease; and
 - ii. Member must have received ≥ 2 prior therapies, at least 1 of which was for metastatic disease; or
- 2. Diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
 - a. Unresectable locally advanced or metastatic disease; and
 - b. Member has previously received endocrine-based therapy and ≥ 2 additional systemic therapies in the metastatic setting.

Truqap (Capivasertib) Approval Criteria [Prostate Cancer Diagnosis]:

- 1. Diagnosis of metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer; and
- 2. Used in combination with abiraterone and prednisone; and
- 3. Disease is PTEN-deficient as detected by FDA-authorized test; and
- 4. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
- 5. Member is 18 years of age or older.

Verzenio® (Abemaciclib) Approval Criteria [Breast Cancer Diagnosis]:

- 1. Diagnosis of advanced or metastatic breast cancer; and
 - a. Hormone receptor positive disease; and
 - b. Human epidermal receptor 2 (HER2)-negative disease; and
 - i. Used in 1 of the following settings:
 - 1. In combination with an aromatase inhibitor as initial endocrine-based therapy; or
 - 2. In combination with fulvestrant with disease progression following endocrine therapy; or
 - 3. In combination with imlunestrant in estrogen receptor 1 (ESR1)-mutated disease that has progressed following at least 1 line of endocrine therapy; or
 - 4. As monotherapy for disease progression following endocrine therapy and prior chemotherapy; or
- 2. Diagnosis of early-stage breast cancer; and
 - a. Hormone receptor positive disease; and
 - b. HER2-negative disease; and
 - c. Node-positive disease high risk for recurrence; and
 - d. Used as adjuvant treatment in combination with endocrine therapy.

Additionally, the College of Pharmacy recommends updating the Tykerb (lapatinib) approval criteria based on NCCN recommendations (changes shown in red):

~~Tykerb (Lapatinib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:~~

- ~~1.—Diagnosis of unresectable, advanced, or metastatic disease; and~~
- ~~2.—Member has human epidermal receptor 2 (HER2) amplified disease; and~~
- ~~3.—Member has wild-type RAS and BRAF disease; and~~
- ~~4.—Member meets 1 of the following:~~
 - ~~a.—Has tried at least 1 chemotherapy regimen; or~~
 - ~~b.—Is not a candidate for intensive therapy, according to the prescriber; and~~
- ~~5.—Used in combination with trastuzumab; and~~
- ~~6.—Member has not been previously treated with a HER2 inhibitor.~~

Lastly, the College of Pharmacy recommends updating the approval criteria for the trastuzumab products based on net costs to remove the prior authorization requirement for the preferred trastuzumab products Hercessi (trastuzumab-strf), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), and Trazimera (trastuzumab-qyyp) and to replace the existing criteria for clarity (changes and additions shown in red):

~~Herceptin (Trastuzumab), Herceptin Hylecta (Trastuzumab/Hyaluronidase-oysk), Hercessi (Trastuzumab-strf), Herzuma (Trastuzumab-pkrb), Kanjinti (Trastuzumab-anns), Ogivri (Trastuzumab-dkst), Ontruzant (Trastuzumab-dttb), and Trazimera (Trastuzumab-qyyp) Approval Criteria [Breast Cancer Diagnosis]:~~

- ~~1.—Diagnosis of human epidermal growth factor receptor 2 (HER2) positive breast cancer; and~~
- ~~2.—Preferred trastuzumab products include Hercessi, Kanjinti, Ontruzant, and Trazimera. Authorization of non-preferred trastuzumab products (Herceptin, Herceptin Hylecta, Hercessi, Herzuma, Kanjinti, or Ogivri) will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products (Hercessi, 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.~~

~~Herceptin (Trastuzumab), Hercessi (Trastuzumab-strf), Herzuma (Trastuzumab-pkrb), Kanjinti (Trastuzumab-anns), Ogivri (Trastuzumab-dkst), Ontruzant (Trastuzumab-dttb), and Trazimera (Trastuzumab-qyyp)~~
~~Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:~~

- ~~1.—Diagnosis of human epidermal receptor type 2 (HER2)-positive CRC; and~~
- ~~2.—RAS and BRAF mutation negative; and~~
- ~~3.—Used in combination with pertuzumab, lapatinib, or tucatinib; and~~
- ~~4.—Used in 1 of the following settings:
 - ~~a.—If first-line therapy, patient should not be a candidate for intensive therapy; or~~
 - ~~b.—For the treatment of advanced or metastatic disease following disease progression; and~~~~
- ~~5.—Preferred trastuzumab products include Hercessi, Kanjinti, Ontruzant, and Trazimera. Authorization of non-preferred trastuzumab products (Herceptin, Herceptin Hylecta, Hercessi, Herzuma, Kanjinti, or Ogivri) will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products (Hercessi, 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.~~

~~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 Hercessi, Kanjinti, Ontruzant, and Trazimera. Authorization of non-preferred trastuzumab products (Herceptin, Herceptin Hylecta, Hercessi, Herzuma, Kanjinti, or Ogivri) will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products (Hercessi, 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.~~

Herceptin (Trastuzumab), Herceptin Hylecta (Trastuzumab/Hyaluronidase-oysk), Herzuma (Trastuzumab-pkrb), and Kanjinti (Trastuzumab-anns) Approval Criteria [Breast Cancer Diagnosis]:

1. A patient-specific, clinically significant reason why the member cannot use Hercessi (trastuzumab-strf), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), and Trazimera (trastuzumab-qyyp), which are available without prior authorization, 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.

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² U.S. FDA. Beizray™ NDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/218711Orig1s000ltr.pdf. Issued 10/23/2024. Last accessed 09/29/2026.

³ U.S. FDA. FDA Approves Imlunestrant for ER-Positive, HER2-Negative, ESR1-Mutated Advanced or Metastatic Breast Cancer. Available online at: <https://www.fda.gov/drugs/resources-information->

[approved-drugs/fda-approves-implunestrant-er-positive-her2-negative-esr1-mutated-advanced-or-metastatic-breast](#). Issued 09/25/2025. Last accessed 09/29/2026.

⁴ U.S. FDA. FDA Approves Fam-Trastuzumab Deruxtecan-nxki with Pertuzumab for Unresectable or Metastatic HER2-Positive Breast Cancer. Available online at: <https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-fam-trastuzumab-deruxtecan-nxki-pertuzumab-unresectable-or-metastatic-her2-positive>. Issued 12/15/2025. Last accessed 09/29/2026.

⁵ U.S. FDA. FDA Approves Vepdegestrant for ER-Positive, HER2-Negative, ESR1-Mutated Advanced or Metastatic Breast Cancer. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-vepdegestrant-er-positive-her2-negative-esr1-mutated-advanced-or-metastatic-breast>. Issued 05/01/2026. Last accessed 09/29/2026.

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⁷ U.S. FDA. FDA Approves Datopotamab Deruxtecan-dlnk for Unresectable or Metastatic Triple-Negative Breast Cancer. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-datopotamab-deruxtecan-dlnk-unresectable-or-metastatic-triple-negative-breast-cancer>. Issued 05/22/2026. Last accessed 09/29/2026.

⁸ U.S. FDA. FDA Approves Capivasertib with Abiraterone and Prednisone for PTEN-Deficient Androgen Pathway Modulation-Naïve or -Sensitive Prostate Cancer. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-capivasertib-abiraterone-and-prednisone-pten-deficient-androgen-pathway-modulation>. Issued 06/12/2026. Last accessed 09/29/2026.

⁹ U.S. FDA. FDA Approves Palbociclib with Trastuzumab, with or without Pertuzumab, and Endocrine Therapy for the Maintenance Treatment of HR-Positive, HER2-Positive Metastatic Breast Cancer. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-palbociclib-trastuzumab-or-without-pertuzumab-and-endocrine-therapy-maintenance>. Issued 06/24/2026. Last accessed 09/29/2026.

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¹¹ U.S. FDA. FDA Approves Imlunestrant in Combination with Abemaciclib for ER-Positive, HER2-Negative, ESR1-Mutated Advanced or Metastatic Breast Cancer. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-implunestrant-combination-abemaciclib-er-positive-her2-negative-esr1-mutated-advanced-or>. Issued 09/18/2026. Last accessed 09/29/2026.

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¹³ NCCN. Rectal Cancer Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Last revised 04/07/2026. Last accessed 09/29/2026.

¹⁴ Beizray (Docetaxel) and Beizray Kit (Docetaxel/Albumin) Prescribing Information. Zydus Pharmaceuticals (USA), Inc. Available online at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8fb7d980-d6c7-468b-a9f0-adff16101a4b>. Last revised 12/2025. Last accessed 09/29/2026.

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Fiscal Year 2026 Annual Review of Constipation and Diarrhea Medications

Oklahoma Health Care Authority
October 2026

Current Prior Authorization Criteria: Constipation Medications

Amitiza (Lubiprostone) Approval Criteria [Chronic Idiopathic Constipation (CIC) or Irritable Bowel Syndrome with Constipation (IBS-C) Diagnosis]:

1. An FDA approved diagnosis of CIC in members 18 years of age or older, or IBS-C in female members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Linzess (linaclotide) must be provided; and
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
8. A quantity limit of 60 capsules per 30 days will apply.

Amitiza (Lubiprostone) Approval Criteria [Opioid-Induced Constipation (OIC) Diagnosis]:

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, except methadone, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and

3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
7. Amitiza must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A quantity limit of 60 capsules per 30 days will apply.

Ibsrela (Tenapanor) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Amitiza (lubiprostone) or Linzess (linaclotide), or must be provided; and
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
8. A quantity limit of 60 tablets per 30 days will apply.

Linzess (Linaclotide) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
 - a. Chronic idiopathic constipation (CIC) in members 18 years of age or older; or
 - b. Irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; or
 - c. Functional constipation in members 6 to 17 years of age; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 30 capsules per 30 days will apply.

Motegrity (Prucalopride) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and

- b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
- 6. A patient-specific, clinically significant reason why the member cannot use Amitiza (lubiprostone) or Linzess (linaclotide) must be provided; and
- 7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
- 8. A quantity limit of 30 tablets per 30 days will apply.

Movantik (Naloxegol) Approval Criteria:

- 1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
- 2. Member must not have known or suspected gastrointestinal obstruction; and
- 3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
- 4. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy(results must be submitted); and
- 5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
- 6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
- 7. Movantik must be discontinued if treatment with the opioid pain medication is also discontinued; and
- 8. A quantity limit of 30 tablets per 30 days will apply.

Relistor (Methylnaltrexone) Injection Approval Criteria [Opioid-Induced Constipation (OIC) in Chronic Non-Cancer Pain Diagnosis]:

- 1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and

2. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and
3. Member must have current use of opioid medications; and
4. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and
5. Documentation of hydration attempts and trials of at least 3 different products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. Member must not have known or suspected gastrointestinal obstruction; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza (lubiprostone), Movantik (naloxegol), or Symproic (naldemedine) must be provided; and
8. A patient-specific, clinically significant reason why the member cannot use the tablet formulation of Relistor must be provided; and
9. The 12mg single-use vials, syringes, or kits will be the preferred products. Criteria for consideration of 8mg single-use syringes:
 - a. Weight range of 38kg to 62kg; and/or
 - b. Caregiver unable to draw up dose from vial; and
10. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
11. Relistor must be discontinued if treatment with the opioid pain medication is also discontinued; and
12. A quantity limit of 30 units per month will apply.

Relistor (Methylnaltrexone) Tablets Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and
4. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and

5. Documentation of hydration attempts and trials of at least 3 different types of products that have failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Amitiza (lubiprostone), Movantik (naloxegol), or Symproic (naldemedine) must be provided; and
7. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
8. Relistor must be discontinued if treatment with the opioid pain medication is also discontinued; and
9. A quantity limit of 90 tablets per 30 days will apply.

Symproic (Naldemedine) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. Symproic must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A quantity limit of 30 tablets per 30 days will apply.

Trulance (Plecanatide) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners; and
 - a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. A quantity limit of 30 tablets per 30 days will apply.

Current Prior Authorization Criteria: Diarrhea Medications

Dicyclomine 40mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient specific, clinically significant reason why the member cannot use the 20mg tablet, which is available without a prior authorization, to achieve the dose must be provided.

Motofen (Difenoxin/Atropine) Approval Criteria:

1. An FDA approved diagnosis of acute nonspecific diarrhea or acute exacerbations of chronic functional diarrhea; and
2. Member must be 2 years of age or older. Use is contraindicated in pediatric patients younger than 2 years of age; and
3. Member must not have diarrhea associated with organisms that penetrate the intestinal mucosa (e.g., toxigenic *Escherichia coli*, *Salmonella* species, *Shigella*) or pseudomembranous colitis associated with broad spectrum antibiotics; and
4. A patient-specific, clinically significant reason why the member cannot use Lomotil (diphenoxylate/atropine) and loperamide must be provided; and
5. A quantity limit of 16 tablets per 2 days will apply.

Mytesi (Crofelemer) Approval Criteria:

1. An FDA approved diagnosis of non-infectious diarrhea in adult members with human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) currently on anti-retroviral therapy; and
2. Duration of diarrhea has been ≥ 4 weeks; and
3. Dietary modifications have failed; and
4. Prescribers must verify that infectious diarrhea has been ruled out via confirmation of all of the following:
 - a. CD4 count has been measured and possible opportunistic infections have been ruled out; and
 - b. Member does not have fever; and
 - c. Stool studies for pathogens are negative including:
 - i. Bacterial cultures; and
 - ii. Ova, parasite, cryptosporidium, and/or giardia; and
 - iii. *Clostridium difficile* (*Clostridium difficile* testing should include a glutamate dehydrogenase screen and if positive, should be followed by a confirmatory test or nucleic acid amplification test in members with documented diarrhea; a toxin enzyme immunoassay should not be used as a stand-alone test); and
5. If stool study results are negative and the member has severe symptoms, particularly in the case of advanced immunodeficiency, an endoscopy with biopsy is recommended, at the prescriber's discretion, to rule out inflammatory bowel disease, cancer, cytomegalovirus (CMV) infection, microsporidium, or mycobacterium avium complex (MAC); and
6. A quantity limit of 60 tablets per 30 days will apply. Initial approvals will be for 4 weeks of therapy. Subsequent approvals may be granted for 6 months if the prescriber documents the member is responding well to treatment.

Viberzi (Eluxadoline) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with diarrhea (IBS-D); and
2. Member must be 18 years of age or older; and
3. Member must not have any of the contraindications for use of Viberzi (i.e., removed gallbladder; biliary duct obstruction or sphincter of Oddi disease or dysfunction; alcoholism, alcohol abuse, or alcohol addiction; history of pancreatitis or structural diseases of the pancreas; severe hepatic impairment; history of chronic or severe constipation; mechanical gastrointestinal obstruction); and
4. Documentation of trials of 2 of the following 3 medications that failed to relieve diarrhea: loperamide, dicyclomine, or diphenoxylate/atropine

(each trial should be for at least 10 to 14 consecutive days at the recommended dosing). Trials must be within the past 90 days. Documentation should be provided including dates, dosing, and reason for trial failure; and

5. Approval will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
6. A quantity limit of 60 tablets per 30 days will apply.

Xifaxan (Rifaximin) 200mg Approval Criteria:

1. An FDA approved diagnosis of traveler's diarrhea; and
2. Member must be 12 years of age or older; and
3. Traveler's diarrhea must be due to noninvasive strains of *Escherichia coli*; and
4. A quantity limit of 9 tablets per 3 days will apply.

Xifaxan (Rifaximin) 550mg Approval Criteria:

1. An FDA approved indication for the reduction in risk of overt hepatic encephalopathy (HE) recurrence; or
2. An FDA approved diagnosis of irritable bowel syndrome with diarrhea (IBS-D); and
 - a. For the diagnosis of IBS-D: Documentation of trials of 2 of the following 3 medications that failed to relieve diarrhea: loperamide, dicyclomine, or diphenoxylate/atropine (each trial should be for at least 10 to 14 consecutive days at the recommended dosing). Trials must be within the past 90 days. Documentation should be provided including dates, dosing, and reason for trial failure; and
 - b. For the diagnosis of IBS-D: Member must be 18 years of age or older; and
3. A quantity limit of 60 tablets per 30 days will apply. Patients with the diagnosis of IBS-D needing 42 tablets for a 14-day treatment regimen (550mg 3 times daily for 14 days) will be approved for a quantity limit override upon meeting Xifaxan approval criteria. Patients with IBS-D who experience a recurrence of symptoms can be retreated up to 2 times with the same 14-day treatment regimen (550mg 3 times daily for 14 days).

Utilization of Constipation and Diarrhea Medications: Fiscal Year 2026

Comparison of Fiscal Years: Constipation Medications: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
Fiscal Year 2025							
FFS	392	1,740	\$888,125.49	\$510.42	\$17.04	55,057	52,133
Aetna	273	817	\$474,117.46	\$580.32	\$18.21	27,389	26,030
Humana	428	1,535	\$841,464.40	\$548.19	\$18.28	48,963	46,031
OCH	320	983	\$522,491.08	\$531.53	\$17.88	30,467	29,222
2025 Total	1,350	5,075	\$2,726,198.43	\$537.18	\$17.77	161,876	153,416
Fiscal Year 2026							
FFS	453	1,940	\$761,266.35	\$392.41	\$13.07	60,726	58,252
Aetna	334	1,094	\$460,457.15	\$420.89	\$14.09	34,789	32,681
Humana	585	2,099	\$890,807.75	\$424.40	\$14.08	68,459	63,262
OCH	420	1,327	\$558,479.91	\$420.86	\$14.08	41,921	39,667
2026 Total	1,725	6,460	\$2,671,011.16	\$413.47	\$13.78	205,895	193,862
% Change	27.80%	27.30%	-2.00%	-23.00%	-2.50%	27.20%	26.40%
Change	375	1,385	-\$55,187.27	-\$123.71	-\$3.99	44,019	40,446

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Comparison of Fiscal Years: Diarrhea Medications: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
Fiscal Year 2025							
FFS	275	1,088	\$3,260,219.48	\$2,996.53	\$106.44	65,613	30,631
Aetna	64	259	\$784,697.05	\$3,029.72	\$106.76	14,794	7,350
Humana	119	396	\$1,207,753.35	\$3,049.88	\$108.42	22,591	11,140
OCH	75	287	\$888,958.47	\$3,097.42	\$107.50	16,663	8,269
2025 Total	491	2030	\$6,141,628.35	\$3,025.43	\$107.02	119,661	57,390
Fiscal Year 2026							
FFS	128	261	\$790,599.38	\$3,029.12	\$107.29	14,662	7,369
Aetna	36	74	\$218,457.84	\$2,952.13	\$103.78	4,044	2,105
Humana	62	120	\$341,605.29	\$2,846.71	\$100.74	6,665	3,391
OCH	46	82	\$259,659.86	\$3,166.58	\$111.06	5,026	2,338
2026 Total	254	537	\$1,610,322.37	\$2,998.74	\$105.92	30,397	15,203
% Change	-48.30%	-73.50%	-73.80%	-0.90%	-1.00%	-74.60%	-73.50%
Change	-237	-1,493	-\$4,531,305.98	-\$26.69	-\$1.10	-89,264	-42,187

Costs do not reflect rebated prices or net costs.

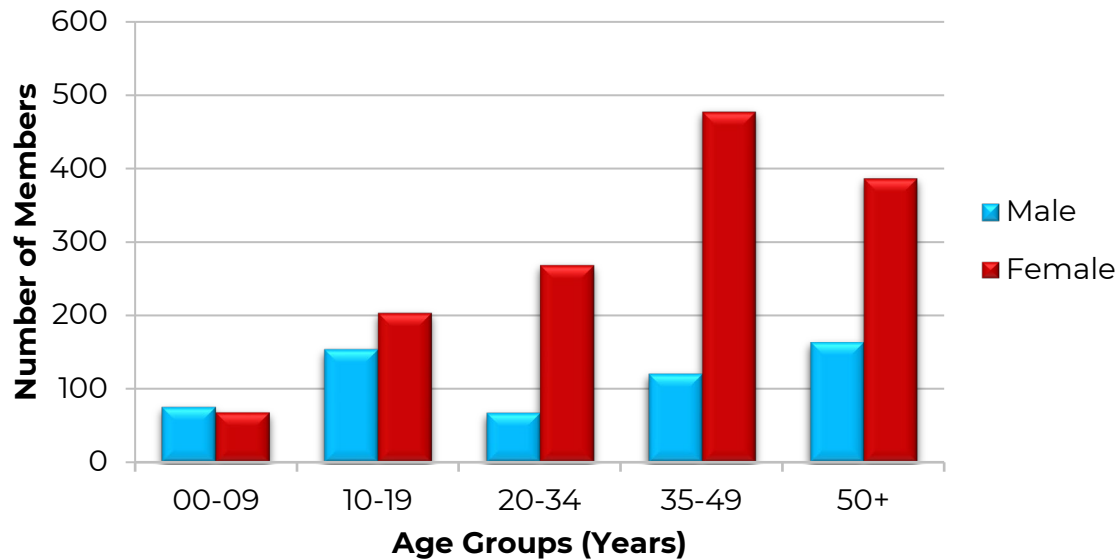
*Total number of unduplicated utilizing members.

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

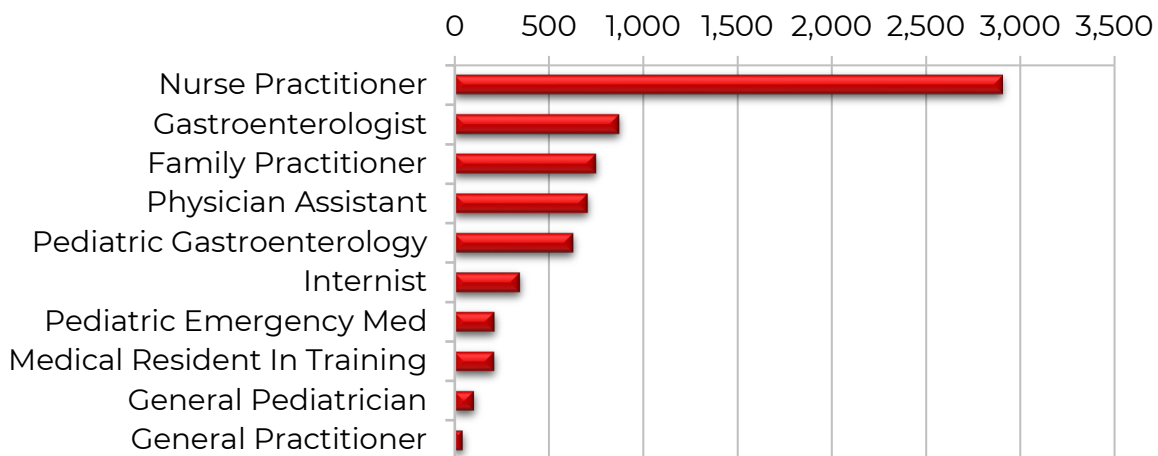
Fiscal Year 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Please note: The above table includes Xifaxan (rifaximin), which has historically had a significant federal rebate; however, the Federal Drug Rebate Agreement ended as of 10/01/2025; therefore, Xifaxan is no longer covered by SoonerCare. The majority of utilization of rifaximin was for the 550mg strength for the reduction in risk of overt hepatic encephalopathy (HE) recurrence.

Demographics of Members Utilizing Constipation and Diarrhea Medications: Pharmacy Claims (All Plans)



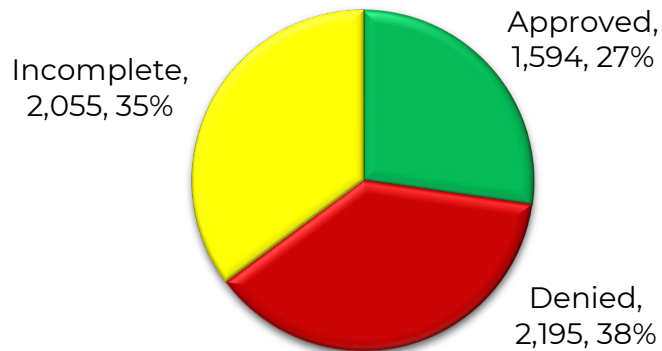
Top Prescriber Specialties of Constipation and Diarrhea Medications by Number of Claims (All Plans)



Prior Authorization of Constipation and Diarrhea Medications

There were 5,844 prior authorization requests submitted for constipation and diarrhea medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	674	21%	1,643	52%	831	26%	3,148
Aetna	281	31%	136	15%	488	54%	905
Humana	388	44%	102	11%	397	45%	887
OCH	251	28%	174	19%	479	53%	904
Total	1,594	27%	2,055	35%	2,195	38%	5,844

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

Market News and Updates^{1,2}

Anticipated Patent Expiration(s):

- Amitiza (lubiprostone): October 2027
- Mytesi (crofelemer): October 2031
- Movantik (naloxegol): April 2032
- Viberzi (eluxadoline): March 2033
- Symproic (naldemedine): May 2033
- Linzess (linaclotide): August 2033
- Ibsrela (tenapanor): November 2042

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

- **November 2025:** Linzess (linaclotide) received an age expansion for the treatment of irritable bowel syndrome with constipation (IBS-C) to include pediatric patients 7 years of age and older.
- **May 2026:** Linzess was approved for an age expansion for the treatment of functional constipation in pediatric patients down to 2 years of age.

Recommendations

The College of Pharmacy recommends the following changes to the Amitiza (lubiprostone) and Movantik (naloxegol) approval criteria based on net costs (changes shown in red):

Amitiza (Lubiprostone) Approval Criteria [Chronic Idiopathic Constipation (CIC) or Irritable Bowel Syndrome with Constipation (IBS-C) Diagnosis]:

1. An FDA approved diagnosis of CIC in members 18 years of age or older, or IBS-C in female members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
- ~~6. A patient-specific, clinically significant reason why the member cannot use Linzess (linaclotide) must be provided; and~~
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
8. A quantity limit of 60 capsules per 30 days will apply.

Movantik (Naloxegol) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and

5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. Movantik must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A patient-specific, clinically significant reason why the member cannot use Symproic (naldemedine) must be provided; and
9. A quantity limit of 30 tablets per 30 days will apply.

The College of Pharmacy also recommends updating the Linzess (linaclotide) approval criteria based on the FDA-approved age expansions (changes shown in red):

Linzess (Linaclotide) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
 - a. Chronic idiopathic constipation (CIC) in members 18 years of age or older; or
 - b. Irritable bowel syndrome with constipation (IBS-C) in members ~~18~~ 7 years of age or older; or
 - c. Functional constipation in members ~~6~~ 2 to 17 years of age; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
 - a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
 - b. Members with an oncology-related diagnosis are exempt from the trial requirements; and

6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 30 capsules per 30 days will apply.

Utilization Details of Constipation Medications: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
LINACLOTIDE PRODUCTS						
LINZESS CAP 72MCG	2,375	659	\$974,830.46	\$410.45	3.6	36.50%
LINZESS CAP 145MCG	1,650	531	\$678,562.36	\$411.25	3.11	25.40%
LINZESS CAP 290MCG	1,369	358	\$560,443.03	\$409.38	3.82	20.98%
SUBTOTAL	5,394	1,548	\$2,213,835.85	\$410.43	3.48	82.88%
LUBIPROSTONE PRODUCTS						
LUBIPROSTONE CAP 24MCG	260	101	\$14,171.90	\$54.51	2.57	0.53%
LUBIPROSTONE CAP 8MCG	62	33	\$3,643.60	\$58.77	1.88	0.14%
AMITIZA CAP 24MCG	9	4	\$2,499.54	\$277.73	2.25	0.09%
SUBTOTAL	331	138	\$20,315.04	\$61.37	2.4	0.76%
NALOXEGOL PRODUCTS						
MOVANTIK TAB 25MG	266	113	\$113,906.81	\$428.22	2.35	4.26%
MOVANTIK TAB 12.5MG	36	16	\$15,647.70	\$434.66	2.25	0.59%
SUBTOTAL	302	129	\$129,554.51	\$428.99	2.34	4.85%
PLECANATIDE PRODUCTS						
TRULANCE TAB 3MG	192	101	\$105,756.75	\$550.82	1.9	3.96%
SUBTOTAL	192	101	\$105,756.75	\$550.82	1.9	3.96%
PRUCALOPRIDE PRODUCTS						
PRUCALOPRIDE TAB 2MG	85	32	\$7,282.50	\$85.68	2.66	0.27%
MOTEGRITY TAB 2MG	30	6	\$16,323.89	\$544.13	5	0.61%
MOTEGRITY TAB 1MG	7	1	\$3,806.51	\$543.79	7	0.14%
PRUCALOPRIDE TAB 1MG	5	2	\$158.96	\$31.79	2.5	0.01%
SUBTOTAL	127	41	\$27,571.86	\$217.10	3.1	1.03%
TENAPANOR PRODUCTS						
IBSRELA TAB 50MG	61	19	\$114,667.08	\$1,879.79	3.21	4.29%
SUBTOTAL	61	19	\$114,667.08	\$1,879.79	3.21	4.29%
NALDEMEDINE PRODUCTS						
SYMPROIC TAB 0.2MG	37	13	\$17,689.16	\$478.09	2.85	0.69%
SUBTOTAL	37	13	\$17,689.16	\$478.09	2.85	0.69%
METHYLNALTREXONE PRODUCTS						
RELISTOR TAB 150MG	13	8	\$31,394.80	\$2,414.98	1.63	1.18%
RELISTOR INJ 8/0.4ML	2	1	\$4,612.20	\$2,306.10	2	0.17%
RELISTOR INJ 12/0.6ML	1	1	\$5,613.91	\$5,613.91	1	0.21%
SUBTOTAL	16	10	\$41,620.91	\$2,601.31	1.6	1.56%
TOTAL	6,460	1,725*	\$2,671,011.16	\$413.47	3.74	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CAP = capsule; INJ = injection; TAB = tablet

Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Utilization Details of Diarrhea Medications: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RIFAXAMIN PRODUCTS						
XIFAXAN TAB 550MG	493	244	\$1,548,033.45	\$3,140.03	2.02	96.13%
XIFAXAN TAB 200MG	1	1	\$107.86	\$107.86	1	0.01%
SUBTOTAL	494	245	\$1,548,141.31	\$3,133.89	2.02	96.14%
ELUXADOLINE PRODUCTS						
VIBERZI TAB 100MG	30	4	\$43,893.25	\$1,463.11	7.5	70.59%
VIBERZI TAB 75MG	8	1	\$10,755.27	\$1,344.41	8	17.30%
SUBTOTAL	38	5	\$54,648.52	\$1,438.12	7.6	87.89%
CROFELEMER PRODUCTS						
MYTESI TAB 125MG	5	5	\$7,532.54	\$1,506.51	1	12.11%
SUBTOTAL	5	5	\$7,532.54	\$1,506.51	1	12.11%
TOTAL	537	254*	\$1,610,322.37	\$2,988.74	2.11	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

TAB = tablet

Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Please note: The above table includes Xifaxan (rifaximin), which has historically had a significant federal rebate; however, the Federal Drug Rebate Agreement ended as of 10/01/2025; therefore, Xifaxan is no longer covered by SoonerCare. The majority of utilization of rifaximin was for the 550mg strength for the reduction in risk of overt hepatic encephalopathy (HE) recurrence.

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 09/2025. Last accessed 09/29/2026.

² Linzess (Linaclotide) Prescribing Information. AbbVie and Ironwood Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/202811s0231bl.pdf. Last revised 05/21/2026. Last accessed 09/29/2026.



Fiscal Year 2026 Annual Review of Anticoagulants and Platelet Aggregation Inhibitors

Oklahoma Health Care Authority
October 2026

Current Prior Authorization Criteria

Brilinta (Ticagrelor) Approval Criteria:

1. The first 365 days of therapy with generic Brilinta® 90mg twice daily does not require prior authorization; and
2. After the first 365 days, a patient-specific, clinically significant reason for continuing the 90mg twice daily dosage will need to be provided or the member should be switched to the 60mg twice daily dosage; and
3. Brilinta 60mg tablet is brand preferred. Requests for generic ticagrelor 60mg tablets will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
4. Approvals will be for the duration of 1 year.

Eliquis (Apixaban) Tablet for Oral Suspension and Eliquis Sprinkle (Apixaban) Capsule for Oral Suspension Approval Criteria:

1. Eliquis tablet for oral suspension and Eliquis Sprinkle capsule for oral suspension will not require prior authorization for members 10 years of age or younger. For members 11 years of age or older, a patient-specific, clinically significant reason why the member cannot use Eliquis tablets must be provided; and
2. Clinical exceptions for the age restriction may be considered for approval (e.g., documented dysphagia, weight-based dose cannot be achieved with the tablet formulation).

Pradaxa (Dabigatran) Approval Criteria:

1. Pradaxa capsules require the following:
 - a. An FDA approved indication of 1 of the following:
 - i. Non-valvular atrial fibrillation; or
 - ii. Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) after treatment with a parenteral anticoagulant for 5 to 10 days; or
 - iii. To reduce the risk of recurrent DVT or PE in members who have been previously treated; or
 - iv. For the prophylaxis of DVT and PE in members who have undergone hip replacement surgery; or

- v. Treatment of venous thromboembolic events (VTE) in pediatric members 8 to 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days; or
 - vi. To reduce the risk of recurrent VTE in pediatric members 8 to 18 years of age who have been previously treated.
 - b. A patient-specific, clinically significant reason why the member cannot use Eliquis (apixaban) and Xarelto (rivaroxaban) must be provided.
2. Pradaxa oral pellets require the following:
- a. An FDA approved indication of 1 of the following:
 - i. Treatment of VTE in members who have been treated with a parenteral anticoagulant for at least 5 days; or
 - ii. To reduce the risk of recurrent VTE in members who have been previously treated; and
 - b. Member must be 3 months of age or older; and
 - c. Members older than 7 years of age require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
 - d. A patient-specific, clinically significant reason why the member cannot use Xarelto (rivaroxaban) oral suspension must be provided.

Rivaroxaban 10mg, 15mg, and 20mg tablet (generic Xarelto) Approval Criteria:

- 1. Authorization of generic rivaroxaban 10mg, 15mg, or 20mg tablets (in place of brand Xarelto) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred for the 10mg, 15mg and 20mg tablets).

Savaysa (Edoxaban) Approval Criteria:

- 1. An FDA approved indication of 1 of the following:
 - a. To reduce the risk of stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation (NVAF); or
 - b. Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) following 5 to 10 days of initial therapy with a parenteral anticoagulant; and
- 2. Requests for therapy for the treatment of DVT and PE must verify that the member has undergone 5 to 10 days of initial therapy with a parenteral anticoagulant; and
- 3. Members with NVAF must not have a creatinine clearance (CrCl) >95mL/min due to increased risk of ischemic stroke compared to warfarin at the highest dose studied (60mg); and
- 4. A patient-specific, clinically significant reason why the member cannot use Eliquis (apixaban), Pradaxa (dabigatran), and Xarelto (rivaroxaban) must be provided; and

5. A quantity limit of 30 tablets per 30 days will apply.

Xarelto (Rivaroxaban) Oral Suspension Approval Criteria:

1. Xarelto oral suspension will not require prior authorization for members 10 years of age or younger. For members 11 years of age or older, a patient-specific, clinically significant reason why the member cannot use rivaroxaban tablets must be provided; and
2. Clinical exceptions for the age restriction may be considered for members with documented dysphagia.

Utilization of Anticoagulants and Platelet Aggregation Inhibitors: Fiscal Year 2026

Comparison of Fiscal Years: Anticoagulants (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
Fiscal Year 2025							
FFS	5,240	22,361	\$10,846,009.66	\$485.04	\$16.13	1,192,915	672,406
Aetna	1,446	6,323	\$3,274,104.07	\$517.81	\$16.36	351,565	200,120
Humana	1,715	8,182	\$4,251,544.53	\$519.62	\$16.96	445,219	250,684
OCH	1,486	6,987	\$3,453,553.97	\$494.28	\$16.70	367,948	206,762
2025 Total	8,548	43,853	\$21,825,212.23	\$497.69	\$16.41	2,357,64	1,329,972
Fiscal Year 2026							
FFS	5,986	25,951	\$10,237,310.53	\$394.49	\$13.79	1,343,928	742,103
Aetna	1,503	6,559	\$2,807,750.34	\$428.08	\$13.85	357,036	202,707
Humana	1,918	8,839	\$3,932,383.65	\$444.89	\$14.13	493,984	278,287
OCH	1,598	7,355	\$3,078,759.75	\$418.59	\$13.76	399,204	223,817
2026 Total	9,545	48,704	\$20,056,204.27	\$411.80	\$13.86	2,594,152	1,446,914
% Change	11.70%	11.10%	-8.10%	-17.30%	-15.50%	10.00%	8.80%
Change	997	4,851	-\$1,769,007.96	-\$85.89	-\$2.55	236,505	116,942

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Comparison of Fiscal Years: Platelet Aggregation Inhibitors (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
Fiscal Year 2025							
FFS	3,435	10,747	\$695,226.86	\$64.69	\$1.27	588,607	548,813
Aetna	966	3,041	\$313,585.15	\$103.12	\$1.91	183,231	164,600
Humana	1,323	4,372	\$422,939.70	\$96.74	\$1.85	254,639	229,223
OCH	1,003	2,830	\$266,875.06	\$94.30	\$1.59	183,748	168,277
2025 Total	5,976	20,990	\$1,698,626.77	\$80.93	\$1.53	1,210,225	1,110,913
Fiscal Year 2026							
FFS	3,665	10,954	\$324,400.36	\$29.61	\$0.59	582,289	546,962

Aetna	1,049	3,023	\$118,627.46	\$39.24	\$0.70	184,565	169,040
Humana	1,321	4,290	\$155,602.60	\$36.27	\$0.68	251,891	230,445
OCH	1,105	3,203	\$114,697.34	\$35.81	\$0.61	201,870	187,993
2026 Total	6,338	21,470	\$713,327.76	\$33.22	\$0.63	1,220,61	1,134,44
% Change	6.10%	2.30%	-58.00%	-59.00%	-58.80%	0.90%	2.10%
Change	362	480	-\$985,299.01	-\$47.71	-\$0.90	10,390	23,527

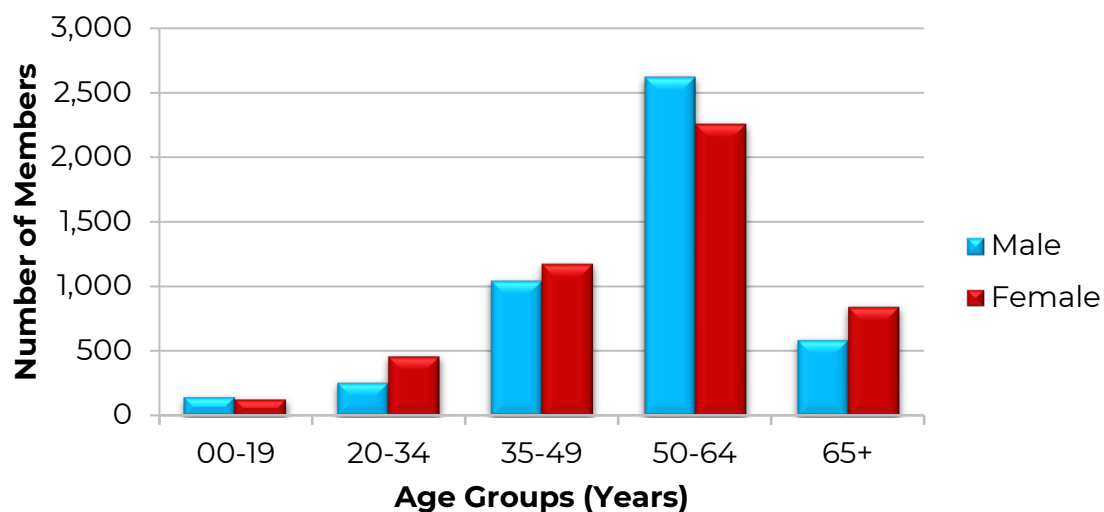
Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

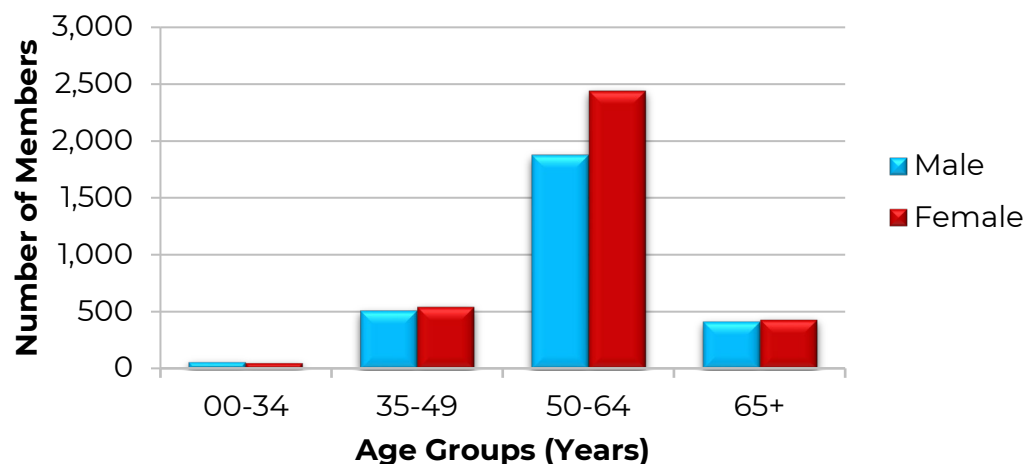
FFS = fee-for-service; OCH = Oklahoma Complete Health

Fiscal Year 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

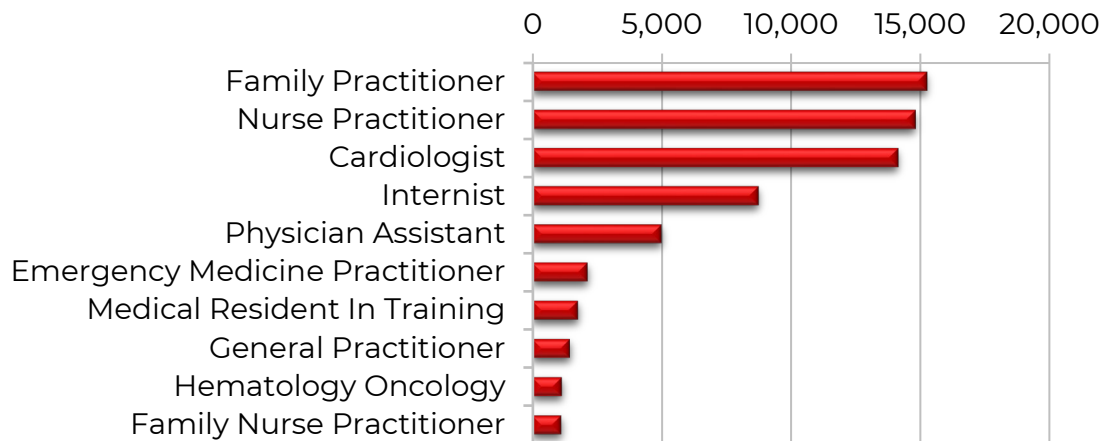
Demographics of Members Utilizing Anticoagulants: Pharmacy Claims (All Plans)



Demographics of Members Utilizing Platelet Aggregation Inhibitors: Pharmacy Claims (All Plans)



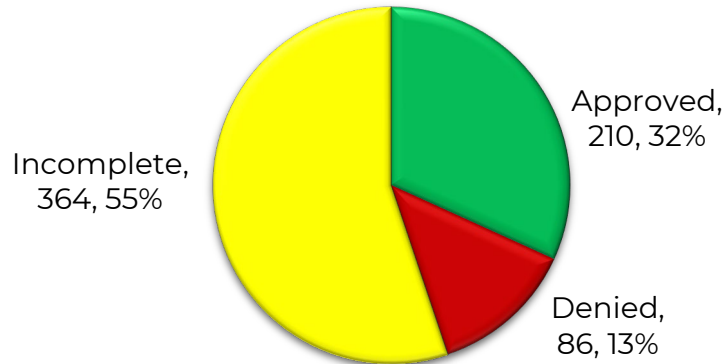
Top Prescriber Specialties of Anticoagulants and Platelet Aggregation Inhibitors by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Anticoagulants and Platelet Aggregation Inhibitors

There were 660 prior authorization requests submitted for the anticoagulants and platelet aggregation inhibitors during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	133	33%	242	60%	27	7%	402
Aetna	25	18%	93	68%	18	13%	136
Humana	5	17%	17	59%	7	24%	29
OCH	47	51%	12	13%	34	37%	93
Total	210	32%	364	55%	86	13%	660

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

Market News and Updates^{1,2,3,4,5,6}

Anticipated Patent Expiration(s):

- Savaysa (edoxaban tablets): March 2028
- Pradaxa (dabigatran capsules): July 2031
- Eliquis (apixaban tablets and tablets for oral suspension): August 2031
- Brilinta (ticagrelor tablets): July 2036
- Eliquis Sprinkle (apixaban capsule for oral suspension): May 2041

News:

- **June 2026:** The American College of Cardiology published a scientific statement focusing on the established indications for direct oral anticoagulants (DOACs), special considerations for DOACs, and recommendations for monitoring and follow-up. This is a helpful resource for prescribers who navigate best practice recommendations for DOAC utilization.
- **September 2026:** The American College of Cardiology published a scientific statement focusing on antiplatelet therapy in the management of atherosclerotic cardiovascular disease. This article provides a summary of current clinical practice guideline recommendations, considerations for weighing ischemic benefit and bleed risk, and antiplatelet therapy in the primary prevention of major adverse cardiac events.

Guideline Update(s):

- **2026 AHA/ACC/ACCP/ACEP/CHEST/SCAI/SHM/SIR/SVM/SVN Guideline for the Evaluation and Management of Acute Pulmonary Embolism (PE) in Adults: A Report of the American College of Cardiology (ACC)/American Heart Association (AHA) Joint Committee on Clinical Practice Guidelines:** In February 2026, the first comprehensive clinical practice guideline for acute PE in adults was published in the United States by ACC/AHA. Prior to this publication, the 2019 European Society of Cardiology (ESC)/European Respiratory Society (ERS) acute PE guideline and the 2021 CHEST antithrombotic therapy for venous thromboembolism (VTE) disease guideline were widely utilized. The new 2026 ACC/AHA Guideline provides guidance based on created disease classifications called Acute PE Clinical Categories which aim to define disease severity that ultimately guides the prognosis and evaluation, treatment recommendations, and monitoring parameters.

Pipeline:

- **Asundexian:** Asundexian is an investigational activated factor XI inhibitor being studied for the prevention of recurrent stroke. In the Phase 3, randomized, double-blind, placebo-controlled OCEANIC-

STROKE trial, asundexian reduced recurrent ischemic stroke in patients with non-cardioembolic ischemic stroke or high-risk transient ischemic attack (TIA) who were concurrently receiving antiplatelet therapy versus placebo [6.2% vs. 8.4%; cause-specific hazard ratio: 0.74; 95% confidence interval (CI): 0.65, 0.84; P<0.001]. Treatment with asundexian was not associated with a statistically significant increase in hemorrhagic stroke or major bleeding events. Asundexian is currently under Priority Review with the FDA for secondary stroke prevention with a Prescription Drug User Fee Act (PDUFA) date of November 9, 2026.

Recommendations

The College of Pharmacy recommends the following changes to the Brilinta (ticagrelor) approval criteria based on net costs (changes shown in red):

Brilinta (Ticagrelor) Approval Criteria:

1. The first 365 days of therapy with generic Brilinta® 90mg twice daily does not require prior authorization; and
2. After the first 365 days, a patient-specific, clinically significant reason for continuing the 90mg twice daily dosage will need to be provided or the member should be switched to the 60mg twice daily dosage; and
- ~~3. Brilinta 60mg tablet is brand preferred. Requests for generic ticagrelor 60mg tablets will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and~~
4. Approvals will be for the duration of 1 year.

Utilization Details of Anticoagulants: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
APIXABAN PRODUCTS						
ELIQUIS TAB 5MG	30,511	6,299	\$13,412,931.28	\$439.61	4.84	66.88%
ELIQUIS TAB 2.5MG	4,205	1,059	\$1,636,509.00	\$389.18	3.97	8.16%
ELIQUIS ST P TAB 5MG	375	360	\$215,241.00	\$573.98	1.04	1.07%
ELIQUIS TAB 1.5MG	8	1	\$3,882.16	\$485.27	8	0.02%
ELIQUIS TAB 2MG	4	1	\$2,624.76	\$656.19	4	0.01%
SUBTOTAL	35,103	7,720	\$15,271,188.20	\$435.04	4.55	76.14%
RIVAROXABAN PRODUCTS						
XARELTO TAB 20MG	5,307	949	\$3,031,429.42	\$571.21	5.59	15.11%
XARELTO TAB 10MG	1,296	287	\$694,371.28	\$535.78	4.52	3.46%
XARELTO TAB 2.5MG	612	180	\$341,429.59	\$557.89	3.4	1.70%
XARELTO TAB 15MG	572	173	\$326,403.36	\$570.64	3.31	1.63%
RIVAROXABAN TAB 2.5MG	571	174	\$42,548.11	\$74.52	3.28	0.21%
RIVAROXABAN SUS 1MG/ML	323	68	\$134,098.86	\$415.17	4.75	0.67%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
XARELTO SUS 1MG/ML	139	45	\$100,484.71	\$722.91	3.09	0.50%
XARELTO ST P TAB 15/20MG	33	33	\$32,716.43	\$999.41	1	0.002%
SUBTOTAL	8,853	1,909	\$4,703,481.76	\$531.29	4.64	23.45%
WARFARIN PRODUCTS						
WARFARIN TAB 5MG	1,532	392	\$26,069.84	\$17.02	3.91	0.13%
WARFARIN TAB 1MG	615	172	\$7,819.23	\$12.71	3.58	0.04%
WARFARIN TAB 4MG	520	133	\$7,470.13	\$14.37	3.91	0.04%
WARFARIN TAB 3MG	427	118	\$5,057.11	\$11.84	3.62	0.03%
WARFARIN TAB 7.5MG	317	94	\$3,882.77	\$12.25	3.37	0.02%
WARFARIN TAB 2.5MG	316	105	\$3,860.01	\$12.22	3.01	0.02%
WARFARIN TAB 2MG	310	105	\$3,733.27	\$12.04	2.95	0.02%
WARFARIN TAB 6MG	295	74	\$3,651.15	\$12.38	3.99	0.02%
WARFARIN TAB 10MG	290	88	\$3,754.13	\$12.95	3.3	0.02%
JANTOVEN TAB 5MG	20	10	\$299.46	\$14.97	2	0.00%
JANTOVEN TAB 3MG	10	3	\$152.79	\$15.28	3.33	0.00%
JANTOVEN TAB 6MG	4	2	\$71.87	\$17.97	2	0.00%
JANTOVEN TAB 2.5MG	2	1	\$35.80	\$17.90	2	0.00%
JANTOVEN TAB 4MG	1	1	\$11.27	\$11.27	1	0.00%
SUBTOTAL	4,659	1,298	\$65,868.83	\$14.14	3.59	0.33%
DABIGATRAN PRODUCTS						
PRADAXA CAP 150MG	38	10	\$7,611.14	\$200.29	3.8	0.04%
DABIGATRAN CAP 150MG	35	14	\$2,215.13	\$63.29	2.5	0.01%
DABIGATRAN CAP 75MG	4	3	\$476.55	\$119.14	1.33	0.00%
SUBTOTAL	77	27	\$10,302.82	\$133.80	2.85	0.05%
EDOXABAN PRODUCTS						
SAVAYSA TAB 60MG	12	1	\$5,362.66	\$446.89	12	0.03%
SUBTOTAL	12	1	\$5,362.66	\$446.89	12	0.03%
TOTAL	48,704	9,545*	\$20,056,204.27	\$411.80	5.1	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CAP = capsule; ST P = starter pack; SUS = suspension; TAB = tablet

Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Utilization Details of Platelet Aggregation Inhibitors: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CLOPIDOGREL PRODUCTS						
CLOPIDOGREL TAB 75MG	16,387	5,464	\$231,646.81	\$14.14	3	32.47%
CLOPIDOGREL TAB 300MG	1	1	\$18.79	\$18.79	1	0.00%
SUBTOTAL	16,388	5,465	\$231,665.60	\$14.14	3	32.48%
TICAGRELOR PRODUCTS						
TICAGRELOR TAB 90MG	2,127	557	\$74,894.06	\$35.21	3.82	10.50%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BRILINTA TAB 90MG	447	161	\$197,923.89	\$442.78	2.78	27.75%
BRILINTA TAB 60MG	312	61	\$131,200.48	\$420.51	5.11	18.39%
TICAGRELOR TAB 60MG	134	43	\$38,800.96	\$289.56	3.12	5.44%
SUBTOTAL	3,020	822	\$442,819.39	\$146.63	3.67	62.08%
PRASUGREL PRODUCTS						
PRASUGREL TAB 10MG	1,933	371	\$35,986.13	\$18.62	5.21	5.04%
PRASUGREL TAB 5MG	112	23	\$2,203.53	\$19.67	4.87	0.31%
SUBTOTAL	2,045	394	\$38,189.66	\$18.67	5.19	5.35%
ASPIRIN/DIPYRIDAMOLE PRODUCTS						
ASA/DIPYRIDA CAP 25-200MG	17	3	\$653.11	\$38.42	5.67	0.09%
SUBTOTAL	17	3	\$653.11	\$38.42	5.67	0.09%
TOTAL	21,470	6,338*	\$713,327.76	\$33.22	3.39	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

ASA = aspirin; CAP = capsule; DIPYRIDA = dipyridamole; TAB = tablet

Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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 09/2026. Last accessed 09/15/2026.

² Kumbhani D, Armbruster A, Cheng R, et al. Direct Oral Anticoagulants in Primary and Secondary Prevention of Thrombotic Events: 2026 ACC Scientific Statement: A Report of the American College of Cardiology. *JACC* 2026; 88(11):1255–1283. doi: 10.1016/j.jacc.2026.05.033.

³ Kumbhani, D, Gibson, C, Kinlay, S. et al. Antiplatelet Therapy in the Management of Atherosclerotic Cardiovascular Disease: 2026 ACC Scientific Statement: A Report of the American College of Cardiology. *JACC* 2026; 88(11):1284–1313. doi.org/10.1016/j.jacc.2026.05.037.

⁴ Creager M, Barnes G, Giri J, et al. 2026 AHA/ACC/ACCP/ACEP/CHEST/SCAI/ SHM/SIR/SVM/SVN Guideline for the Evaluation and Management of Acute Pulmonary Embolism in Adults: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation* 2026; 153(12):e977–e1051. doi:10.1161/CIR.0000000000001415.

⁵ Sharma M, Dong Q, Hirano T, et. al. Asundexian for Secondary Stroke Prevention. *N Engl J Med* 2026; 394(15):1467-1479. doi: 10.1056/NEJMoa2513880.

⁶ OptumRx. RxOutlook 3rd Quarter 2026. Available online at: <https://business.optum.com/content/dam/noindex-resources/business/support-documents/rxoutlook/rxoutlook-3q2026.pdf>. Issued 09/14/2026. Last accessed 09/28/2026.



Fiscal Year 2026 Annual Review of Myeloproliferative Neoplasm (MPN) Medications and 30-Day Notice to Prior Authorize Decnupaz (Pivekimab Sunirine-pvzy), Jakafi XR [Ruxolitinib Extended-Release (ER)], and Mimrylo (Rusfertide)

**Oklahoma Health Care Authority
October 2026**

Current Prior Authorization Criteria

Utilization data for Reblozyl (luspatercept-aamt) and approval criteria for indications other than MPN can be found in the October 2026 Drug Utilization Review (DUR) Board packet. This medication and criteria are reviewed annually with the anemia medications.

Besremi (Ropeginterferon Alfa-2b-njft) Approval Criteria [Polycythemia Vera (PV) Diagnosis]:

1. Diagnosis of PV; and
2. Used as a single agent.

Elzonris (Tagraxofusp-erzs) Approval Criteria [Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) Diagnosis]:

1. Diagnosis of BPDCN; and
2. Member must be 2 years of age or older; and
3. Used as a single agent.

Inrebic (Fedratinib) Approval Criteria [Myelofibrosis (MF) Diagnosis]:

1. Diagnosis of MF in adult members; and
2. Intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia); and
3. In combination with prophylactic thiamine 100mg daily.

Jakafi (Ruxolitinib) Approval Criteria [Graft-Versus-Host Disease (GVHD) Diagnosis]:

1. Diagnosis of acute or chronic GVHD; and
2. Failure of at least 1 prior line of systemic therapy; and
3. Member must be 12 years of age or older.

Jakafi (Ruxolitinib) Approval Criteria [Myelofibrosis (MF) Diagnosis]:

1. Diagnosis of MF; and
2. Used in 1 of the following settings:

- a. Symptomatic lower-risk MF with no response or loss of response to peginterferon alfa-2a or hydroxyurea; or
 - b. Intermediate to high-risk MF; and
3. Member must be 18 years of age or older.

Jakafi (Ruxolitinib) Approval Criteria [Polycythemia Vera (PV) Diagnosis]:

1. Diagnosis of PV; and
2. Inadequate response or loss of response to hydroxyurea or peginterferon alfa-2a therapy; and
3. Member must be 18 years of age or older.

Ojjaara (Mometinib) Approval Criteria [Myelofibrosis (MF) Diagnosis]:

1. Diagnosis of intermediate or high-risk disease (including MF, polycythemia vera, or post-essential thrombocythemia); and
2. Presence of anemia.

Reblozyl (Luspatercept-aamt) Approval Criteria [Myelodysplastic Syndromes (MDS) Diagnosis]:

1. An FDA approved indication of 1 of the following:
 - a. Treatment of adult members with very low-to-intermediate risk MDS with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with anemia failing an erythropoiesis stimulating agent (ESA) and requiring ≥ 2 red blood cell (RBC) units over 8 weeks; or
 - b. Treatment of adult members with very low-to-intermediate risk MDS with anemia who are ESA-naive and who required ≥ 2 RBC units within the last 8 weeks; and
2. For MDS-RS or MDS/MPN-RS-T:
 - a. Member must have had an inadequate response to prior treatment with an ESA, be intolerant of ESAs, or have a serum erythropoietin level $>200\text{U/L}$; and
 - b. Member must not have been previously treated with a disease modifying agent for the treatment of MDS; and
 - c. Prescriber must verify the member does not have deletion 5q (del 5q); and
3. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber and in accordance with package labeling; and
4. Reblozyl must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in treatment of MDS (or an advanced care practitioner with a supervising physician who is a hematologist, oncologist, or specialist with expertise in treating MDS); and
5. Prescriber must verify the member's hemoglobin will be monitored prior to each Reblozyl administration; and

6. Prescriber must verify Reblozyl will be administered by a trained health care provider; and
7. A recent (within the last 3 months) weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Approval quantities will be dependent on member weight and every 3 week dosing in accordance with package labeling; and
9. Initial approvals will be for the duration of 6 months. Further approvals will not be granted if the member does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose of 1.75mg/kg or if unacceptable toxicity occurs at any time. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Vonjo (Pacritinib) Approval Criteria [Myelofibrosis (MF) Diagnosis]:

1. Diagnosis of intermediate or high-risk primary or secondary MF; and
2. Platelet count $<50 \times 10^9/L$.

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 MPN Medications: Fiscal Year 2026

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 2025							
FFS	16	90	\$1,542,605.08	\$17,140.06	\$575.81	5,583	2,679
Aetna	5	39	\$561,357.49	\$14,393.78	\$501.66	1,929	1,119
Humana	5	32	\$510,837.90	\$15,963.68	\$532.12	1,620	960
OCH	5	23	\$394,087.09	\$17,134.22	\$597.10	1,380	660
2025 Total	29	184	\$3,008,887.56	\$16,352.65	\$555.35	10,512	5,418
Fiscal Year 2026							
FFS	18	104	\$1,875,803.25	\$18,036.57	\$612.41	6,039	3,063
Aetna	5	29	\$509,010.89	\$17,552.10	\$585.07	1,710	870
Humana	9	37	\$557,586.61	\$15,069.91	\$511.55	1,495	1,090
OCH	7	39	\$435,899.87	\$11,176.92	\$593.06	1,455	735
2026 Total	34	209	\$3,378,300.62	\$16,164.12	\$586.71	10,699	5,758
% Change	17.20%	13.60%	12.30%	-1.20%	5.60%	1.80%	6.30%
Change	5	25	\$369,413.06	-\$188.53	\$31.36	187	340

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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	0	0	\$0.00	\$0.00	0
Humana	0	0	\$0.00	\$0.00	0
OCH	0	0	\$0.00	\$0.00	0
2025 Total	0	0	\$0.00	\$0.00	0
Fiscal Year 2026					
FFS	1	7	\$133,525.48	\$19,075.07	7
Aetna	0	0	\$0.00	\$0.00	0
Humana	0	0	\$0.00	\$0.00	0
OCH	0	0	\$0.00	\$0.00	0
2026 Total	1	7	\$133,525.48	\$19,075.07	7
% Change	N/A	N/A	N/A	N/A	N/A
Change	1	7	\$133,525.48	\$19,075.07	7

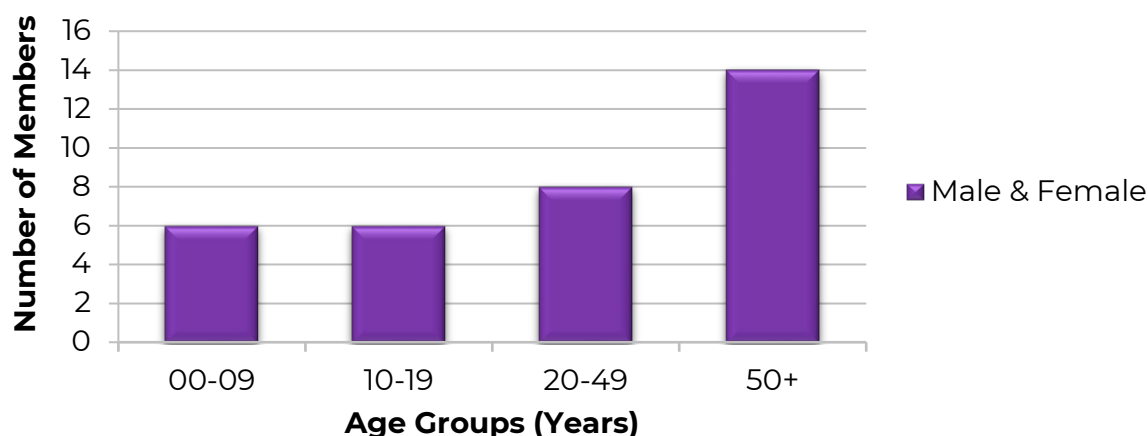
Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

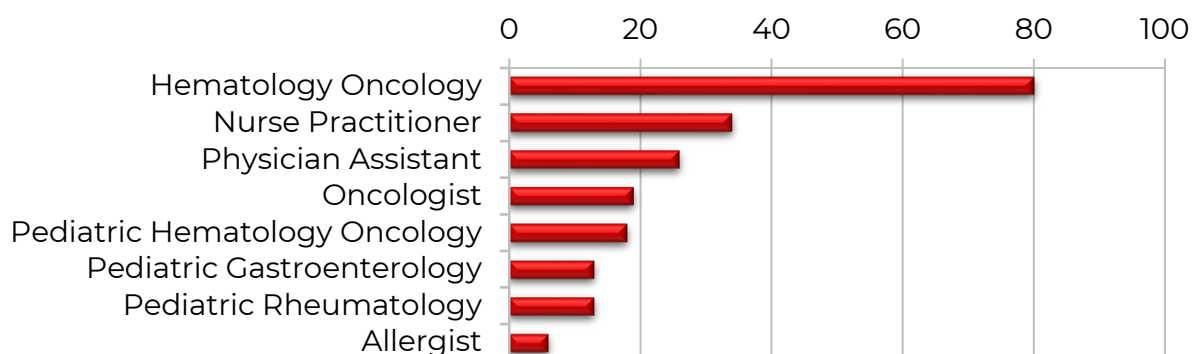
FFS = fee-for-service; N/A = not applicable; OCH = Oklahoma Complete Health

Fiscal Year 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Demographics of Members Utilizing MPN Medications (All Plans)



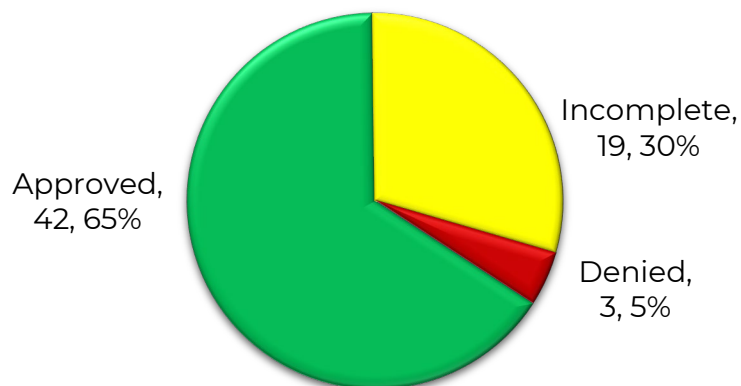
Top Prescriber Specialties of MPN Medications by Number of Claims (All Plans)



Prior Authorization of MPN Medications

There were 64 prior authorization requests submitted for MPN medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	31	66%	15	32%	1	2%	47
Aetna	4	57%	3	43%	0	0%	7
Humana	1	100%	0	0%	0	0%	1
OCH	6	67%	1	11%	2	22%	9
Total	42	65%	19	30%	3	5%	64

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

Market News and Updates^{1,2,3,4,5}

Anticipated Patent Expiration(s):

- Jakafi (ruxolitinib): December 2028
- Vonjo (pacritinib): March 2030
- Jakafi XR (ruxolitinib ER): July 2034
- Inrebic (fedratinib): September 2039
- Ojjaara (mometotinib): December 2040

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

- **May 2026:** The FDA approved Jakafi XR (ruxolitinib ER) as a new once-daily formulation of oral ruxolitinib for the treatment of all the same indications as the existing twice-daily formulation of Jakafi (ruxolitinib), including indications for the treatment of myelofibrosis, polycythemia vera, and graft-versus-host disease. Jakafi XR is available as oral tablets in 11mg, 22mg, 33mg, 44mg, and 55mg strengths.
- **May 2026:** The FDA approved Decnupaz (pivekimab sunirine-pvzy) for the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).
- **August 2026:** The FDA approved Besremi (ropeginterferon alfa-2b-njft) for a new indication for the treatment of adults with essential thrombocythemia.
- **August 2026:** The FDA approved Mimrylo (rusfertide) for the treatment of erythrocytosis in adults with polycythemia vera.

Decnupaz (Pivekimab Sunirine-pvzy) Product Summary⁶

Therapeutic Class: CD123-directed antibody and alkylating agent conjugate

Indication(s): Treatment of adult patients with BPDCN

How Supplied: 2mg lyophilized cake in a single-dose vial (SDV)

Dosing and Administration: The recommended dose is 0.045mg/kg administered as an intravenous (IV) infusion over approximately 15-30

minutes once every 3 weeks until disease progression or unacceptable toxicity.

Cost: The Wholesale Acquisition Cost (WAC) is \$92,325.40 per SDV. For a member weighing 75kg, this would result in an estimated cost of \$184,650.80 per dose or \$3,139,063.60 per year based on recommended dosing.

Mimrylo (Rusfertide) Product Summary⁷

Therapeutic Class: Hepcidin mimetic

Indication(s): Treatment of erythrocytosis in adults with polycythemia vera

How Supplied: Lyophilized powder in SDVs in 9.5mg, 19mg, 28mg, 41mg, and 54mg strengths

Dosing and Administration:

- Mimrylo should be administered subcutaneously (sub-Q) on a weekly dosing schedule.
- The recommended weekly dosage range of Mimrylo is 9.5mg to 108mg.
- The recommended starting dose is 19mg once a week.
- The dose should be adjusted based on efficacy or safety.
- Doses higher than 54mg are administered as 2 injections. If the weekly dosage is greater than 82mg, the first injection should be administered on day 1 and the second injection should be administered on day 4 or 5.

Cost: The WAC is \$4,231 per SDV, regardless of strength. For a member using 1 SDV per week, this would result in an estimated cost of \$16,924 per 28 days or \$220,012 per year. For a member needing 2 SDVs per week, this would result in an estimated cost of \$33,848 per 28 days or \$440,024 per year.

Recommendations

The College of Pharmacy recommends the prior authorization of Decnupaz (pivekimab sunirine-pvzy), Jakafi XR (ruxolitinib ER), and Mimrylo (rusfertide) with the following criteria based on recent FDA approvals and net costs (shown in red):

Decnupaz (Pivekimab Sunirine-pvzy) Approval Criteria [Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) Diagnosis]:

1. Diagnosis of BPDCN; and
2. Member must be 18 years of age or older; and
3. Must be used as a single-agent.

Jakafi (Ruxolitinib) and Jakafi XR [Ruxolitinib Extended-Release (ER)] Approval Criteria [Graft-Versus-Host Disease (GVHD) Diagnosis]:

1. Diagnosis of acute or chronic Graft-Versus-Host Disease (GVHD); and

2. Failure of at least 1 prior line of systemic therapy; and
3. Member must be 12 years of age or older; and
4. Requests for Jakafi XR will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation of Jakafi.

Jakafi (Ruxolitinib) and Jakafi XR [Ruxolitinib Extended-Release (ER)]

Approval Criteria [Myelofibrosis (MF) Diagnosis]:

1. Diagnosis of myelofibrosis; and
2. Used in 1 of the following settings:
 - a. Symptomatic lower-risk myelofibrosis with no response or loss of response to peginterferon alfa-2a or hydroxyurea; or
 - b. Intermediate to high-risk myelofibrosis; and
3. Member must be 18 years of age or older; and
4. Requests for Jakafi XR will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation of Jakafi.

Jakafi (Ruxolitinib) and Jakafi XR [Ruxolitinib Extended-Release (ER)]

Approval Criteria [Polycythemia Vera Diagnosis]:

1. Diagnosis of polycythemia vera; and
2. Inadequate response or loss of response to hydroxyurea or peginterferon alfa-2a therapy; and
3. Member must be 18 years of age or older; and
4. Requests for Jakafi XR will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation of Jakafi.

Mimrylo (Rusfertide) Approval Criteria [Polycythemia Vera (PV) Diagnosis]:

1. Diagnosis of PV; and
2. Member has not achieved adequate control with at least 1 prior therapy.

The College of Pharmacy also recommends updating the approval criteria for Besremi (ropeginterferon alfa-2b-njft) based on recent FDA approvals with the following changes (shown in red):

Besremi (Ropeginterferon Alfa-2b-njft) Approval Criteria [Polycythemia Vera (PV) Diagnosis]:

1. Diagnosis of 1 of the following:
 - a. Essential thrombocythemia; or
 - b. Polycythemia vera; and
2. Used as a single agent.

Utilization Details of MPN Medications: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RUXOLITINIB PRODUCTS						
JAKAFI TAB 5MG	86	14	\$1,452,267.60	\$16,886.83	6.14	42.99%
JAKAFI TAB 10MG	40	10	\$574,846.40	\$14,371.16	4	17.02%
JAKAFI TAB 25MG	35	4	\$510,833.35	\$14,595.24	8.75	15.12%
JAKAFI TAB 20MG	17	4	\$196,723.97	\$11,572.00	4.25	5.82%
JAKAFI TAB 15MG	10	4	\$134,753.10	\$13,475.31	2.5	3.99%
SUBTOTAL	188	36	\$2,869,424.42	\$15,262.90	5.22	84.94%
MOMELOTINIB PRODUCTS						
OJJAARA TAB 200MG	9	4	\$263,068.02	\$29,229.78	2.25	7.79%
OJJAARA TAB 150MG	2	1	\$59,335.26	\$29,667.63	2	1.76%
SUBTOTAL	11	5	\$322,403.28	\$29,309.39	2.2	9.54%
FEDRATINIB PRODUCTS						
INREBIC CAP 100MG	9	2	\$177,271.51	\$19,696.83	4.5	5.25%
SUBTOTAL	9	2	\$177,271.51	\$19,696.83	4.5	5.25%
ROPEGINTERFERON ALFA-2B PRODUCTS						
BESREMI SOL 500MCG	1	1	\$9,201.41	\$9,201.41	1	0.27%
SUBTOTAL	1	1	\$9,201.41	\$9,201.41	1	0.27%
TOTAL	209	34*	\$3,378,300.62	\$16,164.12	6.15	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CAP = capsule; SOL = solution; TAB = tablet

Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS*	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TAGRAXOFUSP-ERZS J9269 (ELZONRIS)	7	1	\$133,525.48	\$19,075.07	7
TOTAL	7	1	\$133,525.48	\$19,075.07	7

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated claims.

*Total number of unduplicated utilizing members.

Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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 09/2026. Last accessed 09/11/2026.

² Incyte. Incyte Announces FDA Approval of Jakafi XR (Ruxolitinib) Extended-Release Tablets for the Treatment of Myelofibrosis, Polycythemia Vera and Graft-Versus-Host Disease. Available online at: <https://investor.incyte.com/news-releases/news-release-details/incyte-announces-fda-approval-jakafi-xrtm-ruxolitinib-extended>. Issued 05/01/2026. Last accessed 09/11/2026.

³ U.S. FDA. FDA Approves Pivekimab Sunirine-pvzy for Blastic Plasmacytoid Dendritic Cell Neoplasm, an Ultra-Rare Hematologic Malignancy. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pivekimab-sunirine-pvzy-blastic-plasmacytoid-dendritic-cell-neoplasm-ultra-rare>. Issued 03/27/2026. Last accessed 09/14/2026.

⁴ U.S. FDA. FDA Approves Treatment for Essential Thrombocythemia. Available online at: <https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-treatment-essential-thrombocythemia>. Issued 08/31/2026. Last accessed 09/14/2026.

⁵ U.S. FDA. FDA Approves First Drug of Its Kind for Polycythemia Vera, a Rare Blood Disorder. Available online at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-its-kind-polycythemia-vera-rare-blood-disorder>. Issued 08/28/2026. Last accessed 09/14/2026.

⁶ Decnupaz (Pivekimab Sunirine-pvzy) Prescribing Information. AbbVie, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761460Orig1s000lbl.pdf. Last revised 05/2026. Last accessed 09/11/2026.

⁷ Mimrylo (Rusfertide) Prescribing Information. Takeda Pharmaceuticals America, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/220605Orig1s000lbl.pdf. Last revised 08/2026. Last accessed 09/11/2026.



Fiscal Year 2026 Annual Review of Targeted Immunomodulator Agents and 30-Day Notice to Prior Authorize Icotyde (Icotrokinra), Immgolis (Golimumab-sldi), Immgolis Intri (Golimumab-sldi), Lisraya (Brepocitinib), and Zimrixby (Rituximab-cdxx)

Oklahoma Health Care Authority
October 2026

Current Prior Authorization Criteria

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	Tier-2*	Tier-3	Special Prior Authorization (PA)
6-mercaptopurine	adalimumab (Humira) ⁺⁺ - Branded Only	abatacept (Orencia, Orencia ClickJect) [±]	adalimumab (Humira) ⁺⁺ - Unbranded Only
azathioprine	adalimumab-adaz (Hyrimoz) ⁺⁺ - Unbranded Only	certolizumab pegol (Cimzia)	adalimumab-aacf (Idacio) ⁺⁺
hydroxychloroquine	adalimumab-aqvh (Yusimry) ⁺⁺	deucravacitinib (Sotyktu)	adalimumab-aaty (Yuflyma) ⁺⁺
leflunomide	adalimumab-bwwd (Hadlima) ⁺⁺ - Branded Only	golimumab (Simponi, Simponi Aria)	adalimumab-adaz (Hyrimoz) ⁺⁺ - Branded Only
mesalamine	adalimumab-fkjp (Hulio) ⁺⁺ - Unbranded Only	infliximab (Remicade) [±] - Branded Only	adalimumab-adbm (Cyltezo) ⁺⁺
methotrexate	adalimumab-ryvk (Simlandi) ⁺⁺ - Branded Only	infliximab-abda (Renflexis) [±]	adalimumab-afzb (Abrilada) ⁺⁺
minocycline	anakinra (Kineret)	infliximab-axxq (Avsola) [±]	adalimumab-atto (Amjevita) ⁺⁺
NSAIDs	apremilast (Otezla) ^β	sarilumab (Kevzara) [§]	adalimumab-bwwd (Hadlima) ⁺⁺ - Unbranded Only
oral corticosteroids	etanercept (Enbrel) [±]	tocilizumab-aazg (Tyenne) [±] - Branded Only	adalimumab-fkjp (Hulio) ⁺⁺ - Branded Only
sulfasalazine	infliximab (Remicade) [±] - Unbranded Only	tofacitinib (Xeljanz, Xeljanz XR, Xeljanz oral solution) ^{**}	adalimumab-ryvk (Simlandi) ⁺⁺ - Unbranded Only
topical corticosteroids	infliximab-dyyb (Inflectra) [±]	vedolizumab intravenous (IV) (Entyvio)	anifrolumab-fnia (Saphnelo) ^{**}

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	Tier-2*	Tier-3	Special Prior Authorization (PA)
	rituximab (Rituxan)~ [‡]		apremilast ER (Otezla XR) ^β
	rituximab-abbs (Truxima) [‡]		avacopan (Tavneos)**
	rituximab-arxx (Riabni) [‡]		baricitinib (Olumiant) [€]
	rituximab-pvvr (Ruxience) [‡]		belimumab (Benlysta)**
	ustekinumab-aekn (Selarsdi) [‡] - Branded Only		bimekizumab-bkzx (Bimzelx) ^Δ
	ustekinumab-hmny (Starjemza) [‡]		brodalumab (Siliq)**
	ustekinumab-kfce (Yesintek) [‡]		canakinumab (Ilaris) [¥]
	ustekinumab-srlf (Imuldosa) [‡]		deuruxolitinib (Leqselvi) [€]
	ustekinumab-stba (Steqeyma) [‡] - Branded Only		etanercept-szzs (Erelzi) [‡]
	ustekinumab-ttwe (Pyzchiva) [‡] - Branded Only		etanercept-ykro (Eticovo) [‡]
			etrasimod (Velsipity)
			guselkumab (Tremfya)
			infliximab-dyyb (Zymfentra) [‡]
			ixekizumab (Taltz)
			mirikizumab-mrkz (Omvoh)
			rilonacept (Arcalyst)**
			risankizumab-rzaa (Skyrizi)
			ritlecitinib (Litfulo) [€]
			secukinumab (Cosentyx) ^Δ
			spesolimab-sbzo (Spevigo)**
			tildrakizumab-asmn (Ilumya)
			tocilizumab (Actemra) ^{π‡}
			tocilizumab-aazg (Tyenne) [‡] - Unbranded Only
			tocilizumab-anoh (Avtozma) [‡]
			tocilizumab-bavi (Tofidence) [‡]

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	Tier-2*	Tier-3	Special Prior Authorization (PA)
			upadacitinib (Rinvoq, Rinvoq LQ) [#]
			ustekinumab (Stelara) [‡]
			ustekinumab-aaaz (Otulfi) [‡]
			ustekinumab-aekn (Selarsdi) [‡] - Unbranded Only
			ustekinumab-auub (Wezlana) [‡]
			ustekinumab-stba (Steqeyma) [‡] - Unbranded Only
			ustekinumab-ttwe (Pyzchiva) [‡] - Unbranded Only
			vedolizumab subcutaneous (sub-Q) (Entyvio) ^{**}
			voclosporin (Lupkynis) ^{**}

DMARDs = disease modifying anti-rheumatic drugs; ER = extended-release; NSAIDs = nonsteroidal anti-inflammatory drugs

*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). Products may be moved to a higher tier based on net cost if the manufacturer chooses not to participate in supplemental rebates.

[‡]Biosimilars or reference products preferred based on lowest net cost product. Authorization of higher net cost biosimilars or reference products requires a patient-specific, clinically significant reason why the member could not use the preferred formulation.

*Unique criteria applies for a diagnosis of hidradenitis suppurativa (HS) and noninfectious intermediate and posterior uveitis and panuveitis.

[‡]Unique criteria applies for a diagnosis of Behçet's disease (BD).

[‡]Unique criteria applies for a diagnosis of cryopyrin-associated periodic syndromes (CAPS), tumor necrosis factor receptor-associated periodic syndrome (TRAPS), hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD), familial Mediterranean fever (FMF), systemic juvenile idiopathic arthritis (SJIA), adult-onset Still's disease (AOSD), or gout flare.

~Unique criteria applies for a diagnosis of pemphigus vulgaris (PV). Unique criteria applies for a diagnosis of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA).

[™]Unique criteria applies for a diagnosis of giant cell arteritis (GCA), chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome (CRS), and systemic sclerosis-associated interstitial lung disease (SSc-ILD).

[‡]Unique criteria applies for acute graft versus host disease (aGVHD) prophylaxis in hematopoietic stem cell transplant (HSCT) recipients.

[#]Unique criteria applies for Rinvoq LQ or for a diagnosis of atopic dermatitis (AD) or giant cell arteritis (GCA).

[€]Unique criteria applies for a diagnosis of alopecia areata.

[§]Unique criteria applies for a diagnosis of polymyalgia rheumatica (PMR).

^ΔUnique criteria applies for a diagnosis of hidradenitis suppurativa (HS).

^{**}Unique criteria applies to this medication for approval.

Targeted Immunomodulator Agents Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and
3. A trial of at least 1 Tier-1 medication (appropriate to the member's disease state) in the last 90 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
4. Prior stabilization on the Tier-2 medication documented within the last 100 days.

Targeted Immunomodulator Agents Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and
3. Recent trials (within the last 360 days) of 1 Tier-1 medication (appropriate to the member's disease state) and at least 2 Tier-2 medications (appropriate to the member's disease state) that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
4. Prior stabilization on the Tier-3 medication documented within the last 100 days; or
5. A unique FDA-approved indication not covered by Tier-2 medications (unique approval criteria may apply).

Targeted Immunomodulator Agents Special Prior Authorization (PA) Approval Criteria:

1. An FDA approved diagnosis; and
2. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and
3. Recent trials (within the last 360 days) of 1 Tier-1 medication (appropriate to the member's disease state), at least 2 Tier-2 medications (appropriate to the member's disease state), and 1 Tier-3 medication (appropriate to the member's disease state) that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
4. Prior stabilization on the Special PA medication documented within the last 100 days; or

5. A unique FDA-approved indication not covered by lower-tiered medications (unique approval criteria may apply).

Abrilada (Adalimumab-afzb), Amjevita (Adalimumab-atto), Cyltezo (Adalimumab-adbm), Unbranded Hadlima (Adalimumab-bwwd), Branded Hulio (Adalimumab-fkjp), Unbranded Humira (Adalimumab), Branded Hyrimoz (Adalimumab-adaz), Idacio (Adalimumab-aacf), Unbranded Simlandi (Adalimumab-ryvk), and Yuflyma (Adalimumab-aaty) Approval Criteria:

1. For a diagnosis of hidradenitis suppurativa (HS) or uveitis, the member must meet the unique adalimumab approval criteria for those indications; or
2. Member must meet Special Prior Authorization (PA) approval criteria; and
3. A patient-specific, clinically significant reason why the member cannot use a preferred Tier-2 adalimumab product 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.

Abrilada (Adalimumab-afzb), Amjevita (Adalimumab-atto), Cyltezo (Adalimumab-adbm), Hadlima (Adalimumab-bwwd), Hulio (Adalimumab-fkjp), Humira (Adalimumab), Hyrimoz (Adalimumab-adaz), Idacio (Adalimumab-aacf), Simlandi (Adalimumab-ryvk), Yuflyma (Adalimumab-aaty), and Yusimry (Adalimumab-aqvh) Approval Criteria [Hidradenitis Suppurativa (HS) Diagnosis]:

1. Diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and
3. Member must have at least 3 abscesses or inflammatory nodules (can refer to current number or a historical number prior to biologic treatment); and
4. Previous failure of at least 2 of the following categories:
 - a. Topical or systemic antibiotics; or
 - b. Oral or intralesional corticosteroids; or
 - c. Dapsone; or
 - d. Cyclosporine; or
 - e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
 - f. Finasteride; or
 - g. Surgery; and
5. For Special Prior Authorization (PA) adalimumab products, a patient-specific, clinically significant reason why the member cannot use a preferred Tier-2 adalimumab product 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.

Abrilada (Adalimumab-afzb), Amjevita (Adalimumab-atto), Cyltezo (Adalimumab-adbm), Hadlima (Adalimumab-bwwd), Hulio (Adalimumab-fkjp), Humira (Adalimumab), Hyrimoz (Adalimumab-adaz), Idacio (Adalimumab-aacf), Simlandi (Adalimumab-ryvk), Yuflyma (Adalimumab-aaty), and Yusimry (Adalimumab-aqvh) Approval Criteria [Noninfectious Intermediate and Posterior Uveitis or Panuveitis Diagnosis]:

1. Diagnosis of noninfectious intermediate uveitis, posterior uveitis, or panuveitis in members 2 years of age and older; and
2. A failed trial with a corticosteroid injection or systemic corticosteroid in which member has had an inadequate response; or
3. A patient-specific, clinically significant reason why a trial of corticosteroid treatment is inappropriate for the member must be provided; and
4. For Special Prior Authorization (PA) adalimumab products, a patient-specific, clinically significant reason why the member cannot use a preferred Tier-2 adalimumab product 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.

Actemra (Tocilizumab), Avtozma (Tocilizumab-anoh), Tofidence (Tocilizumab-bavi), and Unbranded Tyenne (Tocilizumab-aazg) Approval Criteria:

1. For a diagnosis of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS), giant cell arteritis (GCA), or systemic sclerosis-associated interstitial lung disease (SSc-ILD), the member must meet the unique tocilizumab approval criteria for those indications; or
2. Member must meet Special Prior Authorization (PA) approval criteria; and
3. A patient-specific, clinically significant reason why the member cannot use branded Tyenne (tocilizumab-aazg) 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.

Actemra (Tocilizumab), Avtozma (Tocilizumab-anoh), and Tyenne (Tocilizumab-aazg) Approval Criteria [Chimeric Antigen Receptor (CAR) T Cell-Induced Cytokine Release Syndrome (CRS) Diagnosis]:

1. An FDA approved diagnosis of CAR T cell-induced CRS; and
2. Requests for Actemra, Avtozma, or unbranded Tyenne will require a patient-specific, clinically significant reason why the member cannot use branded Tyenne. 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.

Actemra (Tocilizumab), Avtozma (Tocilizumab-anoh), Tofidence (Tocilizumab-bavi), and Tyenne (Tocilizumab-aazg) Approval Criteria [Giant Cell Arteritis (GCA) Diagnosis]:

1. An FDA approved diagnosis of GCA; and
2. Member must be 50 years of age or older; and
3. History of erythrocyte sedimentation rate (ESR) of ≥ 30 mm/hr or a history of C-reactive protein (CRP) ≥ 1 mg/dL; and
4. Member should have a trial of corticosteroids for a minimum of 4 weeks or a reason why this is not appropriate must be provided; and
5. Must be taken in combination with a tapering course of corticosteroids upon initiation; and
6. Member must have baseline liver enzymes, absolute neutrophil count (ANC), lipid panel, and platelet count and verification that they are acceptable to prescriber; and
7. Member must not have severe hepatic impairment; and
8. Should not be initiated in members with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
9. Requests for Actemra, Avtozma, Tofidence, or unbranded Tyenne will require a patient-specific, clinically significant reason why the member cannot use branded Tyenne. 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
10. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Actemra (Tocilizumab) Approval Criteria [Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) Diagnosis]:

1. An FDA approved diagnosis SSc-ILD; and
2. Member must be 18 years of age or older; and

3. Medication must be prescribed by, or in consultation with, a pulmonologist or pulmonary specialist (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
4. Approvals will be for subcutaneous administration using the FDA approved dosing of 162mg once weekly.

Arcalyst (Rilonacept) Approval Criteria [Cryopyrin-Associated Periodic Syndromes (CAPS) Diagnosis]:

1. An FDA approved indication of CAPS verified by genetic testing. This includes familial cold auto-inflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS) in adults and children 12 years of age and older; and
2. A patient-specific, clinically significant reason the member cannot utilize Kineret (anakinra) or Ilaris (canakinumab) must be provided. Tier structure rules apply; and
3. Member must not be using a tumor necrosis factor blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra concomitantly with Arcalyst; and
4. Documentation that the member does not have active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus (HIV), or tuberculosis must be provided; and
5. The following dosing restrictions will apply:
 - a. Dosing should not be more often than once weekly; and
 - b. Approved dosing schedule for members 18 years of age and older:
 - i. Initial treatment: Loading dose of 320mg delivered as (2) 2mL subcutaneous (sub-Q) injections of 160mg each given on the same day at 2 different injection sites; and
 - ii. Continued treatment: (1) 160mg injection given once weekly; or
 - c. Approved dosing schedule for pediatric members 12 to 17 years of age (must have member's recent weight in kilograms):
 - i. Initial treatment: Loading dose of 4.4mg/kg, up to a maximum of 320mg, delivered as 1 or 2 sub-Q injections, with a maximum single-injection volume of 2mL (given at 2 different injection sites if administered as 2 injections); and
 - ii. Continued treatment: 2.2mg/kg, up to a maximum of 160mg, given once weekly; and
6. Approvals will be for the duration of 1 year.

Arcalyst (Rilonacept) Approval Criteria [Deficiency of Interleukin-1 Receptor Antagonist (DIRA) Diagnosis]:

1. An FDA approved indication of maintenance of remission of DIRA verified by genetic testing; and

2. Member must weigh ≥ 10 kg; and
3. Member must not be using a tumor necrosis factor blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra concomitantly with Arcalyst; and
4. Documentation that the member does not have active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus (HIV), or tuberculosis must be provided; and
5. Arcalyst will be used for maintenance of remission following treatment with Kineret (anakinra); and
6. A patient-specific, clinically significant reason the member cannot continue to utilize Kineret (anakinra) instead of switching to Arcalyst must be provided; and
7. 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 package labeling; and
8. The following dosing restrictions will apply:
 - a. Dosing should not be more often than once weekly; and
 - b. Approved dosing schedule for adults and pediatric members weighing ≥ 10 kg is 4.4mg/kg up to a maximum of 320mg, delivered as 1 or 2 injections (2mL/injection) once weekly; and
9. Approvals will be for the duration of 1 year.

Arcalyst (Rilonacept) Approval Criteria [Recurrent Pericarditis Diagnosis]:

1. An FDA approved indication of recurrent pericarditis and reduction in risk of recurrence in members 12 years of age and older; and
2. Member has had at least 2 episodes of pericarditis; and
3. Member has had failure with colchicine, non-steroidal anti-inflammatory drugs (NSAIDs), and corticosteroids defined as symptomatic pericarditis recurrence; and
4. A patient-specific, clinically significant reason the member cannot utilize Kineret (anakinra) must be provided; and
5. Member must not be using a tumor necrosis factor blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra concomitantly with Arcalyst; and
6. Documentation that the member does not have active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus (HIV), or tuberculosis must be provided; and
7. 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 package labeling for members 12 to 17 years of age; and
8. The following dosing restrictions will apply:
 - a. Dosing should not be more often than once weekly; and
 - b. Approved dosing schedule for members 18 years of age and older:

- i. Initial treatment: Loading dose of 320mg delivered as (2) 2mL subcutaneous (sub-Q) injections of 160mg each given on the same day at 2 different injection sites; and
 - ii. Continued treatment: (1) 160mg injection given once weekly; or
- c. Approved dosing schedule for pediatric members 12 to 17 years of age (must have member's recent weight in kilograms):
 - i. Initial treatment: Loading dose of 4.4mg/kg, up to a maximum of 320mg, delivered as 1 or 2 sub-Q injections, with a maximum single-injection volume of 2mL (given at 2 different injection sites if administered as 2 injections); and
 - ii. Continued treatment: 2.2mg/kg, up to a maximum of 160mg, given once weekly; and
- 9. 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 decreased recurrence of pericarditis or improvement in signs and symptoms of recurrent pericarditis (e.g., C-reactive protein, pericarditic chest pain, pericardial effusion). Subsequent approvals will be granted for the duration of 1 year.

Avsola (Infliximab-axxq), Branded Remicade (Infliximab), and Renflexis (Infliximab-abda) Approval Criteria:

- 1. Member must meet Tier-3 trial requirements; and
- 2. A patient-specific, clinically significant reason why the member cannot use Inflectra (infliximab-dyyb) and unbranded Remicade (infliximab) 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.

Benlysta (Belimumab) Approval Criteria:

- 1. The intravenous (IV) formulation will be covered as a medical only benefit while the subcutaneous (sub-Q) formulation will be covered as a pharmacy only benefit; and
- 2. An FDA approved indication of 1 of the following:
 - a. The treatment of members 5 years of age and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) already receiving standard therapy; or
 - b. The treatment of members 5 years of age and older with active lupus nephritis (LN) who are receiving standard therapy; and
- 3. Documented inadequate response to at least 2 of the following medications appropriate to member's specific disease state:
 - a. High-dose oral corticosteroids; or
 - b. Methotrexate; or

- c. Azathioprine; or
- d. Mycophenolate; or
- e. Cyclophosphamide; or
- f. Hydroxychloroquine/chloroquine; and
- 4. Member must not have severe active central nervous system lupus; and
- 5. Benlysta will not be approved for concomitant use with biologic therapies; and
- 6. Benlysta will not be approved for concomitant use with IV cyclophosphamide (exception for induction treatment with IV cyclophosphamide for members with a diagnosis of LN).

Bimzelx (Bimekizumab-bkzx) Approval Criteria [Hidradenitis Suppurativa (HS) Diagnosis]:

- 1. Diagnosis of moderate-to-severe HS; and
- 2. Hurley Stage II or III disease; and
- 3. Member must have at least 3 abscesses or inflammatory nodules (can refer to current number or a historical number prior to biologic treatment); and
- 4. Previous failure of at least 2 of the following categories:
 - a. Topical or systemic antibiotics; or
 - b. Oral or intralesional corticosteroids; or
 - c. Dapsone; or
 - d. Cyclosporine; or
 - e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
 - f. Finasteride; or
 - g. Surgery; and
- 5. Previous failure of a preferred Tier-2 adalimumab product for at least 12 weeks at recommended dosing (or documented intolerance); and
- 6. A patient-specific, clinically significant reason why the member cannot use Cosentyx (secukinumab) must be provided.

Cibinqo (Abrocitinib) and Rinvoq (Upadacitinib) Approval Criteria [Atopic Dermatitis (AD) Diagnosis]:

- 1. An FDA approved diagnosis of moderate-to-severe AD not adequately controlled with other systemic drug products, including biologics, or when those therapies are not advisable; and
- 2. For Cibinqo, member must be 12 years of age or older; and
- 3. For Rinvoq, member must be 12 years of age or older; and
- 4. Member must have a documented trial 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
- 5. Member must have a documented 16-week trial with an FDA approved biologic medication for atopic dermatitis that resulted in inadequate response (or have a contraindication or documented intolerance); and
- 6. Member's body surface area (BSA) of atopic dermatitis involvement must be provided and the member must have a documented BSA involvement of $\geq 10\%$ (can apply to member's current BSA or a historical value prior to treatment); and
- 7. Requested medication 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. For Cibinqo, prescriber must verify the member will not use antiplatelet therapies (e.g., clopidogrel, prasugrel, ticagrelor) concurrently with Cibinqo, except for low-dose aspirin, during the first 3 months of treatment; and
- 9. Cibinqo and Rinvoq will not be approved for use in combination with other Janus kinases (JAK) inhibitors, biologic immunomodulators, or with other immunosuppressant medications; and
- 10. For Rinvoq, a patient-specific, clinically significant reason why the member cannot use Cibinqo must be provided; and
- 11. 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. Additionally, compliance will be evaluated for continued approval; and
- 12. For Rinvoq, the maximum approvable dose for AD is 30mg once daily.

Cosentyx (Secukinumab) Approval Criteria [Hidradenitis Suppurativa (HS) Diagnosis]:

- 1. Diagnosis of moderate-to-severe HS; and
- 2. Hurley Stage II or III disease; and
- 3. Member must have at least 3 abscesses or inflammatory nodules (can refer to current number or a historical number prior to biologic treatment); and
- 4. Previous failure of at least 2 of the following categories:
 - a. Topical or systemic antibiotics; or
 - b. Oral or intralesional corticosteroids; or
 - c. Dapsone; or
 - d. Cyclosporine; or
 - e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
 - f. Finasteride; or
 - g. Surgery; and

5. Previous failure of a preferred Tier-2 adalimumab product for at least 12 weeks at recommended dosing (or documented intolerance).

Entyvio (Vedolizumab) Subcutaneous (Sub-Q) Formulation Approval Criteria:

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. For Entyvio sub-Q administration, member must have received at least 2 initial intravenous (IV) doses of Entyvio; and
 - a. A patient-specific, clinically significant reason (beyond convenience) why the member cannot continue to use the IV formulation must be provided; and
3. A quantity limit of 108mg every 2 weeks will apply for the sub-Q formulation; and
4. Initial approvals will be for the duration of 14 weeks as Entyvio should be discontinued in patients who do not show evidence of therapeutic benefit by week 14.

Erelzi (Etanercept-szza) and Eticovo (Etanercept-ykro) Approval Criteria:

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. A patient-specific, clinically significant reason why the member cannot use Enbrel (etanercept) 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.

Ilaris (Canakinumab) Approval Criteria [Active Systemic Juvenile Idiopathic Arthritis (SJIA) or Adult-Onset Still's Disease (AOSD) Diagnosis]:

1. An FDA approved indication of SJIA or AOSD; and
2. The member should not be using a tumor necrosis factor (TNF) blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra; and
3. Ilaris should not be initiated in members with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
4. Dosing should not be more often than once every 4 weeks; and
 - a. Weight-based dosing in members 2 years of age and older (the member's recent weight must be provided):
 - i. Body weight $\geq 7.5\text{kg}$: 4mg/kg subcutaneous injection every 4 weeks (maximum 300mg/dose); and
5. Recent trials of 1 Tier-1 medication and all appropriate Tier-2 medications that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or

6. Prior stabilization on the Tier-3 medication documented within the last 100 days; and
7. Approvals will be for the duration of 1 year.

Ilaris (Canakinumab) Approval Criteria [Cryopyrin-Associated Periodic Syndromes (CAPS) Diagnosis]:

1. An FDA approved indication of CAPS verified by genetic testing [which includes Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)] in adult and pediatric members 4 years of age and older; and
2. Member must not be using a tumor necrosis factor (TNF) blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra; and
3. Ilaris should not be initiated in members with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
4. The following dosing requirements must be met:
 - a. Dosing should not be more often than once every 8 weeks; and
 - b. Weight-based dosing (the member's recent weight must be provided):
 - i. Body weight >40kg: 150mg; or
 - ii. Body weight 15kg to 40kg: 2mg/kg (if inadequate response, dose may be increased to 3mg/kg); and
5. Approvals will be for the duration of 1 year.

Ilaris (Canakinumab) Approval Criteria [Gout Flare Diagnosis]:

1. An FDA approved indication for the treatment of gout flare; and
2. Member must have had ≥ 3 gout flares in the previous year; and
3. Member must meet 1 of the following:
 - a. Inadequate response or intolerance to recent trials of oral colchicine, nonsteroidal anti-inflammatory drugs (NSAIDs), and corticosteroids (oral, intraarticular, and/or intramuscular) used for the treatment of previous gout flare(s); or
 - b. Colchicine, NSAIDs, and corticosteroids are contraindicated for the member (specific information regarding contraindication must be submitted); and
4. A patient-specific, clinically significant reason why the member cannot use Kineret (anakinra) must be provided; and
5. Approvals will be for (1) 150mg dose at a time. Subsequent approvals will require documentation that the member responded well to previous treatment with Ilaris; and
6. Approvals will not be granted more often than once every 12 weeks.

Ilaris (Canakinumab) Approval Criteria [Tumor Necrosis Factor Receptor-Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), or Familial Mediterranean Fever (FMF) Diagnosis]:

1. Diagnosis of TRAPS with chronic or recurrent disease activity defined as 6 flares per year; or
2. Diagnosis of HIDS/MKD; or
3. Diagnosis of FMF with documented active disease despite colchicine therapy or documented intolerance to effective doses of colchicine; and
4. 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 package labeling.

Kevzara (Sarilumab) Approval Criteria [Polymyalgia Rheumatica (PMR) Diagnosis]:

1. An FDA approved diagnosis of PMR; and
2. Member must be 18 years of age or older; and
3. Prescriber must verify member has had an inadequate response to corticosteroids or cannot tolerate corticosteroid taper; and
4. Prescriber must verify Kevzara will be used in combination with a tapering course of corticosteroids, unless contraindicated.

Leqselvi (Deuruxolitinib), Litfulo (Ritlecitinib), and Olumiant (Baricitinib) Approval Criteria [Alopecia Areata Diagnosis]:

1. An FDA approved diagnosis of severe alopecia areata; and
2. For Litfulo, member must be 12 to 20 years of age; or
3. For Leqselvi or Olumiant, member must be 18 to 20 years of age; and
4. Prescriber must confirm the member or caregiver has been counseled regarding the covered age range for the requested product and that the medication will no longer be covered once the member turns 21 years of age; and
5. Member's baseline Severity of Alopecia Tool (SALT) score must be provided and must be ≥ 50 ; and
6. Must be prescribed by a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
7. Prescriber must agree to screen for tuberculosis and viral hepatitis prior to initiating treatment; and
8. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and
9. Prescriber must provide documentation of patient-specific, clinically significant information (e.g., impacting member's mental health or ability to function in day-to-day living, reason why no treatment or

- cosmetic solutions are not appropriate) to demonstrate the medical necessity of this medication for this member; and
10. Member must have documented trials within the last 6 months that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance to all alternatives):
 - a. Medium potency to very-high potency Tier-1 topical corticosteroid used for at least 12 weeks; or
 - b. Oral corticosteroid used for at least 6 weeks; or
 - c. Cyclosporine; or
 - d. Methotrexate; or
 - e. Contact immunotherapy (e.g., diphenylcyclopropenone, squaric acid dibutyl ester); and
 11. Concurrent use with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants will not be approved; and
 12. Prescriber must verify female members are not breastfeeding; and
 13. 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 pregnancy registry; and
 14. Initial approvals will be for a duration of 24 weeks of treatment; and
 15. Reauthorization may be considered if the prescriber documents the member is responding well to treatment as indicated by a reduction in the member's SALT score (current SALT score must be provided).

Lupkynis (Voclosporin) Approval Criteria:

1. An FDA approved indication for the treatment of adults with active lupus nephritis (LN) in combination with a background immunosuppressive therapy regimen; and
 - a. Lupkynis must be used in combination with mycophenolate mofetil and low dose oral corticosteroids; and
2. Member must be 18 years of age or older; and
3. Lupkynis must be prescribed by a nephrologist, rheumatologist, or other specialist with expertise in the treatment of LN; and
4. Member's current urine protein-to-creatinine ratio (UPCR) must be provided and must be $\geq 1.5\text{mg/mg}$; and
5. Member's current estimated glomerular filtration rate (eGFR) must be provided and must be $>45\text{mL/min/1.73m}^2$ prior to initiating treatment with Lupkynis; and
 - a. Prescriber must agree to monitor renal function regularly during treatment with Lupkynis and modify the dose as needed in accordance with the package labeling; and
6. Member's current blood pressure (BP) must be $\leq 165/105\text{mmHg}$ prior to initiating treatment with Lupkynis; and

- a. Prescriber must agree to monitor BP regularly during treatment with Lupkynis and agree to discontinue treatment if BP is >165/105mmHg or member experiences a hypertensive emergency; and
7. Member must not be taking strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin) concomitantly with Lupkynis; and
8. Prescriber must verify member has been counseled on proper administration of Lupkynis including taking it on an empty stomach every 12 hours; and
9. Lupkynis will not be approved in combination with biologic therapies or cyclophosphamide; and
10. A quantity limit of 180 capsules per 30 days will apply; and
11. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a reduction in the member's UPCR. If the member does not experience therapeutic benefit by 6 months, discontinuation of Lupkynis should be considered.

Orencia (Abatacept) Approval Criteria [Acute Graft Versus Host Disease (aGVHD) Prophylaxis in Hematopoietic Stem Cell Transplant (HSCT) Diagnosis]:

1. An FDA approved indication for the prophylaxis of aGVHD in members undergoing HSCT; and
2. Member must be 2 years of age or older; and
3. Member is undergoing HSCT with a matched or 1 allele-mismatched unrelated donor; and
4. Must be used in combination with a calcineurin inhibitor and methotrexate.

Otezla XR [Apremilast Extended-Release (ER)] Approval Criteria:

1. For a diagnosis of Behçet's disease (BD), the member must meet the unique apremilast approval criteria for that indication; or
2. Member must meet Special Prior Authorization (PA) approval criteria; and
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot continue using the immediate-release formulation of apremilast must be provided.

Otezla (Apremilast) and Otezla XR [Apremilast Extended-Release (ER)] Approval Criteria [Behçet's Disease (BD) Diagnosis]:

1. An FDA approved indication for the treatment of oral ulcers associated with BD; and
2. Member must have had oral ulcers at least 3 times in the last 12 month period; and

3. Member must have had a 2 week trial of the following that resulted in inadequate efficacy or intolerable adverse effects (or be contraindicated for the member):
 - a. Topical corticosteroids (applied topically to the mouth); and
 - b. Colchicine; and
4. For Otezla XR, a patient-specific, clinically significant reason (beyond convenience) why the member cannot continue using the immediate-release formulation of apremilast must be provided; and
5. Quantity limits according to package labeling will apply.

Otulf (Ustekinumab-aaaz), Unbranded Pyzchiva (Ustekinumab-ttwe), Unbranded Selarsdi (Ustekinumab-aekn), Stelara (Ustekinumab), Unbranded Steqeyma (Ustekinumab-stba), and Wezlana (Ustekinumab-auub) Approval Criteria:

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. A patient-specific, clinically significant reason why the member cannot use Imuldosa (ustekinumab-srlf), branded Pyzchiva (ustekinumab-ttwe), branded Selarsdi (ustekinumab-aekn), Starjemza (ustekinumab-hmny), branded Steqeyma (ustekinumab-stba), and Yesintek (ustekinumab-kfce) 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
3. Additionally, initial and continuation requests for branded Stelara will require a patient-specific, clinically significant reason why unbranded Stelara cannot be used.

Riabni (Rituximab-arrx), Rituxan (Rituximab), Ruxience (Rituximab-pvvr), and Truxima (Rituximab-abbs) Approval Criteria [Granulomatosis with Polyangiitis (GPA, Wegener's Granulomatosis) or Microscopic Polyangiitis (MPA) Diagnosis]:

1. An FDA approved diagnosis of GPA or MPA in adult and pediatric members 2 years of age and older; and
2. Must be used in combination with corticosteroids; and
3. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Riabni (Rituximab-arrx), Rituxan (Rituximab), Ruxience (Rituximab-pvvr), and Truxima (Rituximab-abbs) Approval Criteria [Pemphigus Vulgaris (PV) Diagnosis]:

1. Diagnosis of moderate-to-severe PV; and
2. Must be used in combination with a tapering course of corticosteroids; and

3. Initial approvals will be for (2) 1,000mg intravenous (IV) infusions separated by 2 weeks and a 500mg IV infusion at month 12. Subsequent approvals may be authorized based on 6-month evaluations or upon relapse no sooner than 16 weeks after the previous infusion.

Rinvoq (Upadacitinib) Approval Criteria [Giant Cell Arteritis (GCA) Diagnosis]:

1. An FDA approved diagnosis of GCA; and
2. Member must be 50 years of age or older; and
3. History of erythrocyte sedimentation rate (ESR) of ≥ 30 mm/hr or a history of C-reactive protein (CRP) ≥ 1 mg/dL; and
4. Member should have a trial of corticosteroids for a minimum of 4 weeks or a reason why this is not appropriate must be provided; and
5. Must be taken in combination with a tapering course of corticosteroids upon initiation; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling; and
7. A trial of branded Tyenne (tocilizumab-aazg) used in combination with a tapering course of corticosteroids or a patient-specific, clinically significant reason why the member cannot use branded Tyenne must be provided; and
8. Approvals will be for a dose of 15mg once daily and a quantity limit of 30 tablets per 30 days will apply.

Rinvoq LQ (Upadacitinib Oral Solution) Approval Criteria:

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. An age restriction of 2 years of age to 10 years of age will apply. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

Saphnelo (Anifrolumab-fnia) Approval Criteria:

1. An FDA approved indication for the treatment of adult patients with moderate-to-severe systemic lupus erythematosus (SLE), who are receiving standard therapy; and
2. Member must be 18 years of age or older; and
3. Documented inadequate response to at least 1 of the following medications appropriate to member's specific disease state:
 - a. High-dose oral corticosteroids; or
 - b. Methotrexate; or
 - c. Azathioprine; or
 - d. Mycophenolate; or
 - e. Cyclophosphamide; or

- f. Hydroxychloroquine/chloroquine; and
- 4. Member must not have severe active lupus nephritis (LN) or severe active central nervous system lupus; and
- 5. Saphnelo will not be approved for combination use with biologic therapies or cyclophosphamide; and
- 6. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment.

Siliq (Brodalumab) Approval Criteria:

- 1. Member must meet Special Prior Authorization (PA) approval criteria; and
- 2. Members must also be enrolled in the Siliq Risk Evaluation and Mitigation Strategy (REMS) program for approval; and
- 3. Members with a concomitant diagnosis of Crohn's disease will not be approved; and
- 4. Initial authorizations of Siliq (brodalumab) will be for the duration of 12 weeks at which time the prescriber must verify the member is responding to treatment. If an adequate response has not been achieved after 12 to 16 weeks of treatment with brodalumab, consideration should be given to discontinuing therapy.

Spevigo (Spesolimab-sbzo) Approval Criteria [Intravenous (IV) Flare Dosing]:

- 1. An FDA approved indication for the treatment of generalized pustular psoriasis (GPP) flares; and
- 2. Prescriber must verify the member has presence of macroscopically visible sterile pustules on an erythematous base that is not restricted to the acral region or within psoriatic plaques; and
- 3. Member must be currently experiencing a moderate-to-severe GPP flare meeting all the following criteria:
 - a. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score must be provided and must be ≥ 3 ; and
 - b. Presence of fresh pustules (new appearance or worsening of pustules); and
 - c. GPPPGA pustulation sub-score must be provided and must be ≥ 2 ; and
 - d. $\geq 5\%$ of body surface area (BSA) covered with erythema and the presence of pustules; and
- 4. Member must be 12 years of age or older; and
- 5. Must be prescribed by a dermatologist or other specialist with expertise in the treatment of GPP (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of GPP); and

6. Prescriber must submit documentation of negative tuberculosis (TB) test or initiation of anti-TB therapy for latent TB prior to initiation of therapy with Spevigo; and
7. Prescriber must verify the member does not have any clinically significant active infections and the member will be monitored for active infections prior to each dose of Spevigo; and
8. Approvals will be for 1 dose of Spevigo. A second dose of Spevigo may be approved 1 week after the first dose if the prescriber submits documentation that the member has been evaluated and continues to experience GPP flare symptoms; and
9. A quantity limit of 2 doses per year will apply (the safety and efficacy of additional doses of Spevigo have not been assessed); and
 - a. Requests for additional doses of Spevigo to treat new GPP flares occurring within 1 year (after successful resolution of the previous flare) will be reviewed on a case-by-case basis and will require the prescriber to submit patient-specific, clinically significant information documenting the clinical necessity of additional treatment despite the lack of adequate safety and efficacy data; and
10. Subsequent requests for new GPP flares (after 1 year) will require the member to meet all initial approval criteria, and information regarding the member's response to previous treatment with Spevigo must be submitted. Members who did not experience resolution of pustules after previous treatment will not be approved for additional use of Spevigo.

Spevigo (Spesolimab-sbzo) Approval Criteria [Subcutaneous (Sub-Q) Non-Flare Dosing]:

1. An FDA approved indication for the treatment of generalized pustular psoriasis (GPP); and
2. Prescriber must verify the member has presence of macroscopically visible sterile pustules on an erythematous base that is not restricted to the acral region or within psoriatic plaques; and
3. Member must be 12 years of age or older; and
4. Must be prescribed by a dermatologist or other specialist with expertise in the treatment of GPP (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of GPP); and
5. Prescriber must submit documentation of negative tuberculosis (TB) test or initiation of anti-TB therapy for latent TB prior to initiation of therapy with Spevigo; and
6. Prescriber must verify the member does not have any clinically significant active infections and the member will be monitored for active infections during treatment with Spevigo; and

7. Initial approvals will be for the duration of 6 months. Subsequent approvals (for the duration of 1 year) may be approved if the prescriber documents the member is responding well to the medication.

Tavneos (Avacopan) Approval Criteria:

1. An FDA approved diagnosis as adjunctive treatment of adult members with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis [granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)] in combination with standard therapy including corticosteroids; and
2. Member must be 18 years of age or older; and
3. Tavneos must be used in combination with standard immunosuppressive therapy including corticosteroids; and
4. Prescriber must agree to monitor liver function tests prior to initiating Tavneos, every 4 weeks after the start of therapy for the first 6 months of treatment, and as clinically indicated thereafter; and
5. Prescriber must agree to screen the member for hepatitis B virus (HBV) infection prior to initiating treatment with Tavneos; and
6. Prescriber must verify the member has no active, serious infections, including localized infections and will closely monitor member for the development of signs and symptoms of infection during and after treatment with Tavneos; and
7. A quantity limit of 180 tablets per 30 days will apply.

Xeljanz (Tofacitinib Oral Solution) Approval Criteria:

1. Member must meet Tier-3 approval criteria; and
2. An age restriction of 2 years of age to 10 years of age will apply. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

Utilization of Targeted Immunomodulator Agents: Fiscal Year 2026

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 2025							
FFS	1,651	8,272	\$68,821,038.87	\$8,319.76	\$272.04	79,716	252,978
Aetna	956	5,210	\$42,991,595.29	\$8,251.75	\$280.16	45,565	153,455
Humana	893	5,408	\$47,260,237.89	\$8,738.95	\$287.54	51,234	164,359
OCH	937	5,036	\$41,631,262.11	\$8,266.73	\$278.98	40,939	149,225
2025 Total	3,891	23,926	\$200,704,134.16	\$8,388.54	\$278.75	217,454	720,017
Fiscal Year 2026							
FFS	1,736	8,229	\$70,269,166.61	\$8,539.21	\$280.41	77,842	250,597
Aetna	1,081	5,833	\$48,564,313.37	\$8,325.79	\$283.89	49,773	171,066
Humana	1,041	5,851	\$50,549,694.20	\$8,639.50	\$282.84	56,781	178,719
OCH	1,020	5,784	\$48,637,731.93	\$8,409.01	\$282.64	50,572	172,086
2026 Total	4,279	25,697	\$218,020,906.11	\$8,484.29	\$282.24	234,968	772,468
% Change	10.00%	7.40%	8.60%	1.10%	1.30%	8.10%	7.30%
Change	388	1,771	\$17,316,771.95	\$95.75	\$3.49	17,514	52,451

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/Claim	Claims/Member
Fiscal Year 2025					
FFS	417	1,731	\$6,224,553.49	\$3,595.93	4.15
Aetna	217	935	\$2,740,962.28	\$2,931.51	4.31
Humana	130	527	\$1,455,128.71	\$2,761.16	4.05
OCH	217	1,129	\$2,736,502.73	\$2,423.83	5.2
2025 Total	893	4,322	\$13,157,147.21	\$3,044.23	4.84
Fiscal Year 2026					
FFS	471	2,067	\$7,380,977.76	\$3,570.86	4.39
Aetna	278	1,472	\$3,924,633.15	\$2,666.19	5.29
Humana	168	771	\$2,009,754.57	\$2,606.69	4.59
OCH	267	1,379	\$3,350,154.76	\$2,429.41	5.16
2026 Total	1,095	5,689	\$16,665,520.24	\$2,929.43	5.2
% Change	22.62%	31.63%	26.67%	-3.77%	7.44%
Change	202	1,367	\$3,508,373.03	-\$114.80	0.36

Costs do not reflect rebated prices or net costs.

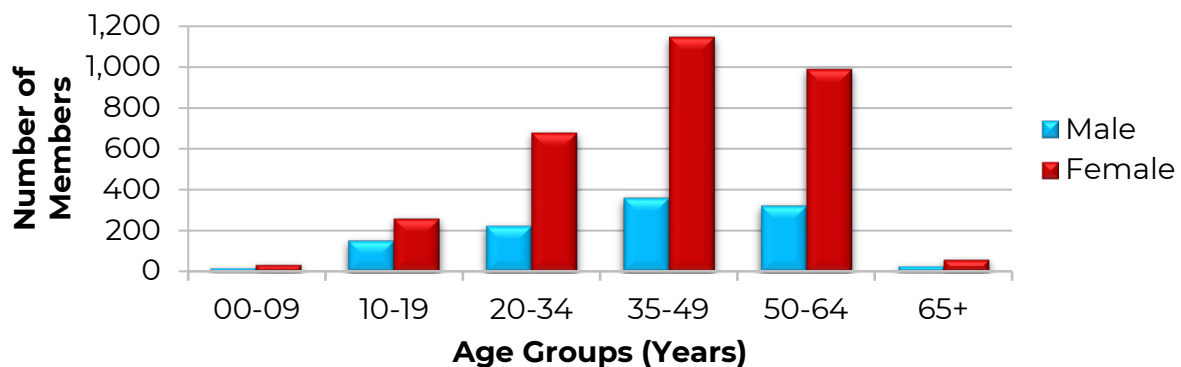
*Total number of unduplicated utilizing members.

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

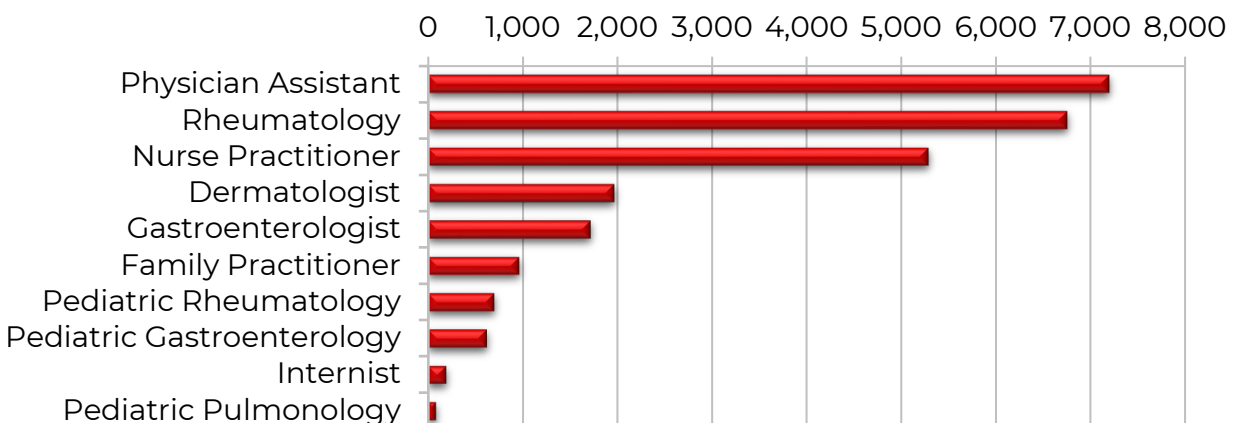
Fiscal Year 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

- Aggregate drug rebates collected during fiscal year 2025 for targeted immunomodulator agents totaled \$148,081,829.16.^Δ Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2025 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2026 (7/1/2025 to 6/30/2026) are still being collected at this time. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Targeted Immunomodulator Agents: Pharmacy Claims (All Plans)



Top Prescriber Specialties of Targeted Immunomodulator Agents by Number of Claims: Pharmacy Claims (All Plans)

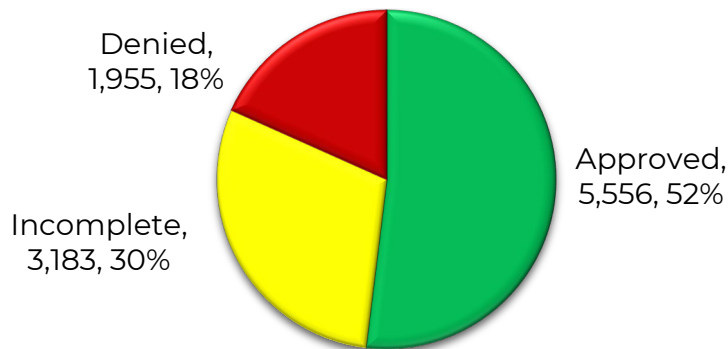


Prior Authorization of Targeted Immunomodulator Agents

There were 10,694 prior authorization requests submitted for targeted immunomodulator agents during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

^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	2,133	41%	2,344	45%	721	14%	5,198
Aetna	1,391	70%	174	9%	412	21%	1,977
Humana	967	70%	173	13%	233	17%	1,373
OCH	1,065	50%	492	23%	589	27%	2,146
Total	5,556	52%	3,183	30%	1,955	18%	10,694

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

Market News and Updates^{1,2,3,4,5,6,7,8}

Anticipated Patent Expiration(s):

- Olumiant (baricitinib tablet): November 2032
- Xeljanz XR [tofacitinib extended-release (ER) tablet]: September 2034
- Otezla (apremilast tablet): November 2034
- Velsipity (etrasimod tablet): June 2036
- Rinvoq LQ (upadacitinib oral solution): October 2036
- Lupkynis (voclosporin capsule): December 2037
- Rinvoq (upadacitinib tablet): March 2038
- Tavneos (avacopan capsule): November 2039
- Litfulo (ritlecitinib capsule): October 2041
- Icotyde (icotrokinra tablet): November 2041
- Otezla XR (apremilast ER): May 2042
- Sotyktu (deucravacitinib tablet): February 2043
- Leqselvi (deuruxolitinib tablet): October 2044

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

- **March 2026:** The FDA approved Icotyde (icotrokinra) for the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40kg who are candidates for systemic therapy or phototherapy.

- **April 2026:** The FDA approved Saphnelo (anifrolumab-fnia) for a new subcutaneous (sub-Q) pen formulation for the treatment of adult patients with moderate-to-severe systemic lupus erythematosus (SLE) who are receiving standard therapy. Previously, Saphnelo was only available in a single-dose vial (SDV) for intravenous (IV) administration.
- **May 2026:** The FDA approved Immgolis (golimumab-sldi) and Immgolis Intrti (golimumab-sldi) as new interchangeable biosimilars to Simponi (golimumab) and Simponi Aria (golimumab), respectively. Immgolis and Immgolis Intrti are FDA approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate. Additionally, Immgolis is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC). The manufacturer plans to announce the commercial launch of these biosimilars later in 2026.
- **May 2026:** The FDA approved Tofidence (tocilizumab-bavi) for a new indication for the treatment of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS) in adults and pediatric patients 2 years of age and older.
- **July 2026:** The FDA approved Zimrixby (rituximab-cdxx), a new biosimilar to Rituxan (rituximab), for the treatment of adults with the following indications: non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), RA, and granulomatosis with polyangiitis (GPA; Wegener's granulomatosis) and microscopic polyangiitis (MPA). Zimrixby contains rituximab, which is a CD20-directed cytolytic antibody.
- **August 2026:** The FDA approved Lisraya (brepocitinib) for the treatment of dermatomyositis in adults.
- **September 2026:** The FDA approved Olumiant (baricitinib) for an age expansion down to 12 years of age for the treatment of severe alopecia areata. Previously, Olumiant was only FDA approved for adults with this indication.

Guideline Update(s):

- **National Alopecia Areata Foundation (NAAF) and American Hair Research Society (AHRS):** The NAAF and AHRS released updated consensus statements on the treatment of severe alopecia areata in adults. Consensus was achieved if there was at least 70% agreement based on systematic literature review and the expert opinion of 31 United States-based alopecia areata experts. Key areas where consensus was achieved include:
 - FDA approved oral Janus kinase (JAK) inhibitors are recommended as the primary (initial) treatment for all adult patients with severe alopecia areata.

- JAK inhibitors should be continued for at least 6 months. For patients who do not experience the treatment goal within that time frame, the dose may be increased, when multiple doses are available, or the patient may be switched to a different oral JAK inhibitor.
- Other therapies, such as oral minoxidil, topical minoxidil, intralesional corticosteroids, high potency topical corticosteroids, or oral corticosteroids are now considered as adjunctive or supplemental therapies to the primary alopecia areata treatment.

Icotyde (Icotrokinra) Product Summary⁹

Therapeutic Class: Interleukin-23 (IL-23) receptor antagonist

Indication(s): Treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh $\geq 40\text{kg}$ who are candidates for systemic therapy or phototherapy

How Supplied: 200mg oral tablets

Dosing and Administration:

- The recommended dose is 200mg orally once daily.
- Icotyde should be administered upon waking on an empty stomach with water, at least 30 minutes before eating food.
- Tablets should be swallowed whole and should not be crushed, split, or chewed.

Efficacy: The efficacy of Icotyde was evaluated in 4 multicenter, randomized, double-blind, placebo and/or active comparator-controlled trials (Trial PSO-1, Trial PSO-2, Trial PSO-3, and Trial PSO-4). These trials included a total of 2,500 patients, of whom 72 were pediatric patients 12 years of age and older and the remainder were adults.

- Key Inclusion Criteria:
 - Trial PSO-1 and PSO-2:
 - 18 years of age or older
 - Moderate-to-severe plaque psoriasis [Investigator's Global Assessment (IGA) score ≥ 3 , Psoriasis Area and Severity Index (PASI) score ≥ 12 , and body surface area (BSA) involvement $\geq 10\%$]
 - Trial PSO-3:
 - 12 years of age or older
 - Moderate-to-severe plaque psoriasis (IGA score ≥ 3 , PASI score ≥ 12 , and BSA involvement $\geq 10\%$)
 - Trial PSO-4:
 - 12 years of age or older

- Moderate-to-severe plaque psoriasis (IGA score ≥ 2 and BSA involvement $\geq 1\%$)
- Presence of at least moderate plaque psoriasis of the scalp, genital area, or hands/feet at baseline
- Previous failure of at least 1 topical therapy for the treatment of plaque psoriasis
- Intervention(s):
 - Trial PSO-1 and PSO-2: Patients were randomized to receive Icotyde 200mg, deucravacitinib 6mg, or placebo once daily for 16 weeks.
 - Trial PSO-3 and PSO-4: Patients were randomized to receive Icotyde 200mg or placebo once daily for 16 weeks.
- Primary Endpoint(s):
 - Trial PSO-1, PSO-2, and PSO-3 Co-Primary Endpoints:
 - Proportion of patients achieving an IGA score of 0 or 1 with a ≥ 2 -grade improvement from baseline at week 16 compared to placebo
 - Proportion of patients achieving at least a 90% improvement in PASI scores from baseline (PASI 90) at week 16 compared to placebo
 - Trial PSO-4:
 - Proportion of patients achieving an IGA score of 0 or 1 with a ≥ 2 -grade improvement from baseline at week 16 compared to placebo
- Results:
 - Trial PSO-1:
 - IGA 0 or 1 with ≥ 2 -grade improvement: Achieved by 68% of patients who received Icotyde compared to 11% of patients who received placebo [treatment difference: 58%; 95% confidence interval (CI): 50, 64]
 - PASI 90: Achieved by 55% of patients who received Icotyde compared to 4% of patients who received placebo (treatment difference: 51%; 95% CI: 44, 57)
 - Trial PSO-2:
 - IGA 0 or 1 with ≥ 2 -grade improvement: Achieved by 71% of patients who received Icotyde compared to 9% of patients who received placebo (treatment difference: 63%; 95% CI: 53, 70)
 - PASI 90: Achieved by 58% of patients who received Icotyde compared to 1% of patients who received placebo (treatment difference: 57%; 95% CI: 49, 62)
 - Trial PSO-3:
 - IGA 0 or 1 with ≥ 2 -grade improvement: Achieved by 65% of patients who received Icotyde compared to 8% of patients

who received placebo (treatment difference: 56%; 95% CI: 50, 62)

- PASI 90: Achieved by 50% of patients who received Icotyde compared to 4% of patients who received placebo (treatment difference: 45%; 95% CI: 40, 50)
- Trial PSO-4:
 - IGA 0 or 1 with ≥ 2 -grade improvement: Achieved by 57% of patients who received Icotyde compared to 6% of patients who received placebo (treatment difference: 51%; 95% CI: 42, 59)

Cost: The Wholesale Acquisition Cost (WAC) is \$276.17 per tablet, resulting in an estimated cost of \$8,285.10 per month or \$99,421.20 per year based on recommended dosing.

Lisraya (Brepocitinib) Product Summary¹⁰

Therapeutic Class: JAK and tyrosine kinase 2 (TYK2) inhibitor

Indication(s): Treatment of dermatomyositis in adult patients

How Supplied: 30mg oral tablets

Dosing and Administration:

- The recommended dose is 30mg orally once daily with or without food.

Efficacy: The efficacy of Lisraya was evaluated in a Phase 3, randomized, double-blind, multicenter, placebo-controlled trial that enrolled 241 adult patients with dermatomyositis.

- Key Inclusion Criteria:
 - Confirmed diagnosis of dermatomyositis
 - 18 years of age to less than 75 years of age
 - Active muscle and skin disease at screening and baseline
 - Prior or current use of at least 1 corticosteroid or non-steroid immunomodulatory/immunosuppressive therapy (hydroxychloroquine alone is not sufficient to meet this)
- Intervention(s):
 - Patients were randomized 1:1:1 to receive brepocitinib 30mg, brepocitinib 15mg, or placebo once daily for 52 weeks.
 - Patients were able to continue receiving standard background therapies (at stable dosages) for dermatomyositis, such as oral corticosteroids, non-steroid immunosuppressive therapy, and anti-malarial therapies. Brepocitinib 15mg is not an FDA approved or recommended dosage.

- Primary Endpoint(s):
 - Mean Total Improvement Score (TIS) at week 52 on a scale ranging from 0 to 100, with higher scores representing greater myositis improvement on a composite index reflecting changes in 6 core set measures
- Results:
 - The least squares mean TIS score was 47.5 in the brepocitinib group compared to 33.3 in the placebo group (treatment difference: 14.2; 95% CI: 5.5, 22.9), demonstrating greater improvement in the brepocitinib group.

Cost: The WAC is \$1,166.67 per tablet, resulting in an estimated cost of \$35,000.10 per month or \$420,001.20 per year based on recommended dosing.

Cost Comparison: Rituximab Products

Product	Cost Per 10mg	Cost Per Dose*	Cost Per Year*
Rituxan (rituximab) (J9312)	\$72.09	\$7,209.00	\$28,836.00
Truxima (rituximab-abbs) (Q5115)	\$35.99	\$3,599.00	\$14,396.00
Riabni (rituximab-arxx) (Q5123)	\$21.08	\$2,108.00	\$8,432.00
Ruxience (rituximab-pvvr) (Q5119)	\$5.79	\$579.00	\$2,316.00

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS), National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

*Cost per dose and cost per year based on the FDA approved dosing for rheumatoid arthritis (RA), using (2) 1,000mg doses separated by 2 weeks and repeated every 24 weeks (4 doses per year)

Please note: Cost information is not yet available for Zimrixby (rituximab-cdxx).

Recommendations^{11,12}

The College of Pharmacy recommends the following additions and changes to the Targeted Immunomodulator Agents Product Based Prior Authorization (PBPA) Tier chart (changes shown in red in the following Tier chart and additional criteria):

1. Removing the current Tier-1 products, shifting the current Tier-2 and Tier-3 products down by 1 Tier, and removing the PA requirement for the new Tier-1 products based on net cost and to allow earlier access, when appropriate, to the preferred targeted immunomodulator agents based on net cost and current guideline recommendations; and
2. Moving selected Special PA products to Tier-3 for clarity; and
3. Prior authorization and placement of Icotyde (icotrokinra) into Tier-3 based on net cost; and

4. Prior authorization and placement of Immgolis (golimumab-sldi), Immgolis Intri (golimumab-sldi), Lisraya (brepocitinib), and Zimrixby (rituximab-cdxx) into the Special PA Tier based on net costs; and
5. Updating the Saphnelo (anifrolumab-fnia) and Tofidence (tocilizumab-bavi) approval criteria based on recent FDA approvals; and
6. Updating the Benlysta (belimumab) criteria to be consistent with the Saphnelo criteria; and
7. Moving Rituxan (rituximab) from Tier-2 to the Special PA Tier and updating the rituximab approval criteria based on net costs; and
8. Moving branded Remicade (infliximab), Renflexis (infliximab-abda), and Avsola (infliximab-axxq) from Tier-3 to the Special PA Tier and updating the infliximab approval criteria based on net costs; and
9. Moving Litfulo (ritlecitinib) from the Special PA Tier to Tier-2 and updating the unique alopecia areata criteria based on net costs and guideline recommendations; and
10. Updating the hidradenitis suppurativa criteria based on clinical practice and current guideline recommendations; and
11. Moving unbranded Selarsdi (ustekinumab-aekn) from the Special PA Tier to Tier-1 and updating the ustekinumab approval criteria based on net costs.

Targeted Immunomodulator Agents*				
Tier-1 (DMARDs appropriate to disease state)	Tier-1 2*	Tier-2 3	Tier-3	Special Prior Authorization (PA)
6-mercaptopurine	adalimumab (Humira) ^{†‡} - Branded Only	abatacept (Orencia, Orencia ClickJect) [‡]	baricitinib (Olumiant)[€]	adalimumab (Humira) ^{†‡} - Unbranded Only
azathioprine	adalimumab-adaz (Hyrimoz) ^{†‡} - Unbranded Only	certolizumab pegol (Cimzia)	bimekizumab-bkzx (Bimzelx)^Δ	adalimumab-aacf (Idacio) ^{†‡}
Hydroxy-chloroquine	adalimumab-aqvh (Yusimry) ^{†‡}	deucravacitinib (Sotyktu)	deuruxolitinib (Leqselvi)[€]	adalimumab-aaty (Yuflyma) ^{†‡}
leflunomide	adalimumab-bwwd (Hadlima) ^{†‡} - Branded Only	golimumab (Simponi, Simponi Aria) [‡]	etrasimod (Velsipity)	adalimumab-adaz (Hyrimoz) ^{†‡} - Branded Only
mesalamine	adalimumab-fkjp (Hulio) ^{†‡} - Unbranded Only	infliximab (Remicade)[‡] - Branded Only	guselkumab (Tremfya)	adalimumab-adbm (Cyltezo) ^{†‡}
methotrexate	adalimumab-ryvk (Simlandi) ^{†‡} - Branded Only	infliximab-abda (Renflexis)[‡]	icotrokinra (Icotyde)	adalimumab-afzb (Abrilada) ^{†‡}
minocycline	anakinra (Kineret)	infliximab-axxq (Avsola)[‡]	ixekizumab (Taltz)	adalimumab-atto (Amjevita) ^{†‡}

Targeted Immunomodulator Agents*				
Tier-1 (DMARDs appropriate to disease state)	Tier-1 2*	Tier-2 3	Tier-3	Special Prior Authorization (PA)
NSAIDs	apremilast (Otezla) ^β	ritlecitinib (Litfulo)[€]	mirikizumab-mrkz (Omvoh)	adalimumab-bwwd (Hadlima) ^{+‡} - Unbranded Only
oral corticosteroids	etanercept (Enbrel) [‡]	sarilumab (Kevzara) [§]	risankizumab-rzaa (Skyrizi)	adalimumab-fkjp (Hulio) ^{+‡} - Branded Only
sulfasalazine	infliximab (Remicade) [‡] - Unbranded Only	tocilizumab-aazg (Tyenne) ^{+‡} - Branded Only	secukinumab (Cosentyx)^Δ	adalimumab-ryvk (Simlandi) ^{+‡} - Unbranded Only
topical corticosteroids	infliximab-dyyb (Inflectra) [‡]	tofacitinib (Xeljanz, Xeljanz XR, Xeljanz oral solution) ^{**}	tildrakizumab-asmn (Ilumya)	anifrolumab-fnia (Saphnelo) ^{**}
	rituximab (Rituxan)^{~‡}	vedolizumab intravenous (IV) (Entyvio)	upadacitinib (Rinvoq, Rinvoq LQ)[#]	apremilast ER (Otezla XR) ^{β**}
	rituximab-abbs (Truxima) [‡]			avacopan (Tavneos) ^{**}
	rituximab-arxx (Riabni) [‡]			baricitinib (Olumiant)[€]
	rituximab-pvvr (Ruxience) [‡]			belimumab (Benlysta) ^{**}
	ustekinumab-aekn (Selarsdi) [‡] - Branded Only			bimekizumab-bkzx (Bimzelx)^Δ
	ustekinumab-hmny (Starjemza) [‡]			brodalumab (Siliq) ^{**}
	ustekinumab-kfce (Yesintek) [‡]			canakinumab (Ilaris) ^{¥**}
	ustekinumab-srlf (Imuldosa) [‡]			deuruxolitinib (Leqselvi)[€]
	ustekinumab-stba (Steqeyma) [‡] - Branded Only			etanercept-szsz (Erelzi) [‡]
	ustekinumab-ttwe (Pyzchiva) [‡] - Branded Only			etanercept-ykro (Eticovo) [‡]
				etrasimod (Velsipity)
				golimumab-sldi (Immgolis, Immgis Intri)[‡]
				guselkumab (Tremfya)

Targeted Immunomodulator Agents*				
Tier-1 (DMARDs appropriate to disease state)	Tier-1 2*	Tier-2 3	Tier-3	Special Prior Authorization (PA)
				infliximab (Remicade)[‡] - Branded Only
				infliximab-abda (Renflexis)[‡]
				infliximab-axxq (Avsola)[‡]
				infliximab-dyyb (Zymfentra) [‡]
				ixekizumab (Taltz)
				mirikizumab-mrkz (Omnih)
				rilonacept (Arcalyst) ^{**}
				risankizumab-rzaa (Skyrizi)
				ritlecitinib (Litfulo)[€]
				rituximab (Rituxan)^{~‡}
				secukinumab (Cosentyx)^Δ
				spesolimab-sbzo (Spevigo) ^{**}
				tildrakizumab- asmn (Ilumya)
				tocilizumab (Actemra) ^{¶±}
				tocilizumab-aazg (Tyenne) ^{¶±} - Unbranded Only
				tocilizumab-anoh (Avtozma) ^{¶±}
				tocilizumab-bavi (Tofidence) ^{¶±}
				upadacitinib (Rinvoq, Rinvoq LQ)[#]
				ustekinumab (Stelara) [‡]
				ustekinumab-aauz (Otuifi) [‡]
				ustekinumab- aekn (Selarsdi)[‡]- Unbranded Only

Targeted Immunomodulator Agents*				
Tier-1 (DMARDs appropriate to disease state)	Tier-1 2*	Tier-2 3	Tier-3	Special Prior Authorization (PA)
				ustekinumab-auub (Wezlana) [‡]
				ustekinumab-stba (Steqeyma) [‡] - Unbranded Only
				ustekinumab-ttwe (Pyzchiva) [‡] - Unbranded Only
				vedolizumab subcutaneous (sub-Q) (Entyvio) ^{**}
				voclosporin (Lupkynis) ^{**}

~~DMARDs = disease modifying anti-rheumatic drugs; ER = extended-release; NSAIDs = nonsteroidal anti-inflammatory drugs~~

*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). Products may be moved to a higher tier based on net cost if the manufacturer chooses not to participate in supplemental rebates.

[‡]Biosimilars or reference products preferred based on lowest net cost product. Authorization of higher net cost biosimilars or reference products requires a patient-specific, clinically significant reason why the member could not use the preferred formulation.

[†]Unique criteria applies for a diagnosis of hidradenitis suppurativa (HS) and noninfectious intermediate and posterior uveitis and panuveitis.

[‡]Unique criteria applies for a diagnosis of Behçet's disease (BD).

~~^{*}Unique criteria applies for a diagnosis of cryopyrin-associated periodic syndromes (CAPS), tumor necrosis factor receptor-associated periodic syndrome (TRAPS), hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD), familial Mediterranean fever (FMF), systemic juvenile idiopathic arthritis (SJIA), adult-onset Still's disease (AOSD), or gout flare.~~

~~[~]Unique criteria applies for a diagnosis of pemphigus vulgaris (PV). Unique criteria applies for a diagnosis of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA).~~

[™]Unique criteria applies for a diagnosis of giant cell arteritis (GCA), chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome (CRS), and systemic sclerosis-associated interstitial lung disease (SSc-ILD).

[‡]Unique criteria applies for acute graft versus host disease (aGVHD) prophylaxis in hematopoietic stem cell transplant (HSCT) recipients.

[#]Unique criteria applies for Rinvoq LQ or for a diagnosis of atopic dermatitis (AD) or giant cell arteritis (GCA).

[€]Unique criteria applies for a diagnosis of alopecia areata.

[§]Unique criteria applies for a diagnosis of polymyalgia rheumatica (PMR).

^ΔUnique criteria applies for a diagnosis of hidradenitis suppurativa (HS).

^{**}Unique criteria applies to this medication for approval.

Targeted Immunomodulator Agents Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening)

will be performed as recommended in the package labeling for the requested product; and

3. Recent trials (within the last 360 days) ~~of 1 Tier-1 medication (appropriate to the member's disease state) and at least 2 Tier-2 medications~~ of at least 3 lower-tiered medications (appropriate to the member's disease state) that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
4. Prior stabilization on the Tier-3 medication documented within the last 100 days; or
5. A unique FDA-approved indication not covered by Tier-2 medications (unique approval criteria may apply).

Targeted Immunomodulator Agents Special Prior Authorization (PA) Approval Criteria:

- ~~1. An FDA-approved diagnosis; and~~
- ~~2. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and~~
- ~~3. Recent trials (within the last 360 days) of 1 Tier-1 medication (appropriate to the member's disease state), at least 2 Tier-2 medications (appropriate to the member's disease state), and 1 Tier-3 medication (appropriate to the member's disease state) that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or~~
- ~~4. Prior stabilization on the Special PA medication documented within the last 100 days; or~~
- ~~5. A unique FDA-approved indication not covered by lower-tiered medications (unique approval criteria may apply).~~

Adalimumab Non-Preferred (Special Prior Authorization Tier) Products ~~Abrilada (Adalimumab-afzb), Amjevita (Adalimumab-atto), Cyltezo (Adalimumab-adbm), Unbranded Hadlima (Adalimumab-bwwd), Branded Hulio (Adalimumab-fkjp), Unbranded Humira (Adalimumab), Branded Hyrimoz (Adalimumab-adaz), Idacio (Adalimumab-aacf), Unbranded Simlandi (Adalimumab-ryvk), and Yuflyma (Adalimumab-aaty)~~ Approval Criteria:

1. For a diagnosis of hidradenitis suppurativa (HS) or uveitis, the member must meet the unique adalimumab approval criteria for those indications; or
- ~~2. Member must meet Special Prior Authorization (PA) approval criteria; and~~
3. A patient-specific, clinically significant reason why the member cannot use a preferred ~~Tier-2~~ Tier-1 adalimumab product 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.

Adalimumab Non-Preferred (Special Prior Authorization Tier) Products
~~Abrilada (Adalimumab-afzb), Amjevita (Adalimumab-atto), Cyltezo (Adalimumab-adbm), Hadlima (Adalimumab-bwwd), Hulio (Adalimumab-fkjp), Humira (Adalimumab), Hyrimoz (Adalimumab-adaz), Idacio (Adalimumab-aacf), Simlandi (Adalimumab-ryvk), Yuflyma (Adalimumab-aaty), and Yusimry (Adalimumab-aqv)~~
Approval Criteria [Hidradenitis Suppurativa (HS) Diagnosis]:

1. Diagnosis of moderate-to-severe HS; and
 2. Hurley Stage II or III disease; and
 3. ~~Member must have at least 3 abscesses or inflammatory nodules (can refer to current number or a historical number prior to biologic treatment); and~~
 4. Previous failure of at least ~~2~~ 1 of the following categories (can refer to a recent trial or historical trial prior to biologic therapy):
 - a. Topical or systemic antibiotics; or
 - b. Oral or intralesional corticosteroids; or
 - c. Dapsone; or
 - d. Cyclosporine; or
 - e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
 - f. Finasteride; or
 - g. Surgery; and
 5. For Special Prior Authorization (PA) adalimumab products, a patient-specific, clinically significant reason why the member cannot use a preferred ~~Tier-2~~ Tier-1 adalimumab product 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.

Adalimumab Non-Preferred (Special Prior Authorization Tier) Products
~~Abrilada (Adalimumab-afzb), Amjevita (Adalimumab-atto), Cyltezo (Adalimumab-adbm), Hadlima (Adalimumab-bwwd), Hulio (Adalimumab-fkjp), Humira (Adalimumab), Hyrimoz (Adalimumab-adaz), Idacio (Adalimumab-aacf), Simlandi (Adalimumab-ryvk), Yuflyma (Adalimumab-aaty), and Yusimry (Adalimumab-aqv)~~
Approval Criteria [Noninfectious Intermediate and Posterior Uveitis or Panuveitis Diagnosis]:

1. Diagnosis of noninfectious intermediate uveitis, posterior uveitis, or panuveitis in members 2 years of age and older; and

2. A failed trial with a corticosteroid injection or systemic corticosteroid in which member has had an inadequate response; or
3. A patient-specific, clinically significant reason why a trial of corticosteroid treatment is inappropriate for the member must be provided; and
4. For Special Prior Authorization (PA) adalimumab products, a patient-specific, clinically significant reason why the member cannot use a preferred ~~Tier-2~~ Tier-1 adalimumab product 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.

Actemra (Tocilizumab), Avtozma (Tocilizumab-anoh), Tofidence (Tocilizumab-bavi), and Unbranded Tyenne (Tocilizumab-aazg) Approval Criteria:

1. For a diagnosis of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS), giant cell arteritis (GCA), or systemic sclerosis-associated interstitial lung disease (SSc-ILD), the member must meet the unique tocilizumab approval criteria for those indications; or
- ~~2. Member must meet Special Prior Authorization (PA) approval criteria; and~~
3. A patient-specific, clinically significant reason why the member cannot use branded Tyenne (tocilizumab-aazg) 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.

Actemra (Tocilizumab), Avtozma (Tocilizumab-anoh), ~~Tofidence~~ (Tocilizumab-bavi), and Tyenne (Tocilizumab-aazg) Approval Criteria [Chimeric Antigen Receptor (CAR) T Cell-Induced Cytokine Release Syndrome (CRS) Diagnosis]:

1. An FDA approved diagnosis of CAR T cell-induced CRS; and
2. Requests for Actemra, Avtozma, ~~Tofidence~~, or unbranded Tyenne will require a patient-specific, clinically significant reason why the member cannot use branded Tyenne. 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.

Avsola (Infliximab-axxq), Branded Remicade (Infliximab), and Renflexis (Infliximab-abda) Approval Criteria:

- ~~1. Member must meet Tier 3 trial requirements; and~~
2. A patient-specific, clinically significant reason why the member cannot use Inflectra (infliximab-dyyb) and unbranded Remicade (infliximab) 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.

Benlysta (Belimumab) Approval Criteria:

- ~~1. The intravenous (IV) formulation will be covered as a medical only benefit while the subcutaneous (sub-Q) formulation will be covered as a pharmacy only benefit; and~~
2. An FDA approved indication of 1 of the following:
 - a. The treatment of members 5 years of age and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) already receiving standard therapy; or
 - b. The treatment of members 5 years of age and older with active lupus nephritis (LN) who are receiving standard therapy; and
3. Documented inadequate response to at least 2 of the following medications appropriate to member's specific disease state:
 - a. High-dose oral corticosteroids; or
 - b. Methotrexate; or
 - c. Azathioprine; or
 - d. Mycophenolate; or
 - e. Cyclophosphamide; or
 - f. Hydroxychloroquine/chloroquine; and
4. Member must not have severe active central nervous system lupus; and
5. Benlysta will not be approved for concomitant use with biologic therapies; and
6. For the intravenous (IV) formulation, Benlysta must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
 - a. Must be shipped to the health care facility where the member is scheduled to receive treatment; and
7. Benlysta will not be approved for concomitant use with IV cyclophosphamide (exception for induction treatment with IV cyclophosphamide for members with a diagnosis of LN).

Bimzelx (Bimekizumab-bkzx) Approval Criteria [Hidradenitis Suppurativa (HS) Diagnosis]:

1. Diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and

- ~~3. Member must have at least 3 abscesses or inflammatory nodules (can refer to current number or a historical number prior to biologic treatment); and~~
4. Previous failure of at least **2** 1 of the following categories (can refer to a recent trial or historical trial prior to biologic therapy):
 - a. Topical or systemic antibiotics; or
 - b. Oral or intralesional corticosteroids; or
 - c. Dapsone; or
 - d. Cyclosporine; or
 - e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
 - f. Finasteride; or
 - g. Surgery; and
5. Previous failure of a preferred ~~Tier-2~~ Tier-1 adalimumab product for at least 12 weeks at recommended dosing (or documented intolerance); and
6. A patient-specific, clinically significant reason why the member cannot use Cosentyx (secukinumab) must be provided.

Cosentyx (Secukinumab) Approval Criteria [Hidradenitis Suppurativa (HS) Diagnosis]:

1. Diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and
- ~~3. Member must have at least 3 abscesses or inflammatory nodules (can refer to current number or a historical number prior to biologic treatment); and~~
4. Previous failure of at least **2** 1 of the following categories (can refer to a recent trial or historical trial prior to biologic therapy):
 - a. Topical or systemic antibiotics; or
 - b. Oral or intralesional corticosteroids; or
 - c. Dapsone; or
 - d. Cyclosporine; or
 - e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
 - f. Finasteride; or
 - g. Surgery; and
5. Previous failure of a preferred ~~Tier-2~~ Tier-1 adalimumab product for at least 12 weeks at recommended dosing (or documented intolerance).

Entyvio (Vedolizumab) Subcutaneous (Sub-Q) Formulation Approval Criteria:

- ~~1. Member must meet Special Prior Authorization (PA) approval criteria; and~~
2. For Entyvio sub-Q administration, member must have received at least 2 initial intravenous (IV) doses of Entyvio; and

- a. A patient-specific, clinically significant reason (beyond convenience) why the member cannot continue to use the IV formulation must be provided; and
3. A quantity limit of 108mg every 2 weeks will apply for the sub-Q formulation; and
4. Initial approvals will be for the duration of 14 weeks as Entyvio should be discontinued in patients who do not show evidence of therapeutic benefit by week 14.

Ilaris (Canakinumab) Approval Criteria [Active Systemic Juvenile Idiopathic Arthritis (SJIA) or Adult-Onset Still's Disease (AOSD) Diagnosis]:

1. An FDA approved indication of SJIA or AOSD; and
2. The member should not be using a tumor necrosis factor (TNF) blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra; and
3. Ilaris should not be initiated in members with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
4. Dosing should not be more often than once every 4 weeks; and
 - a. Weight-based dosing in members 2 years of age and older (the member's recent weight must be provided):
 - i. Body weight $\geq 7.5\text{kg}$: 4mg/kg subcutaneous injection every 4 weeks (maximum 300mg/dose); and
- ~~5. Recent trials of 1 Tier 1 medication and all appropriate Tier 2 medications that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or~~
- ~~6. Recent trial of Tyenne (tocilizumab-aazg) that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or~~
- ~~7. Prior stabilization on the Tier 3 Special Prior Authorization medication documented within the last 100 days; and~~
8. Approvals will be for the duration of 1 year.

Immgolis (Golimumab-sldi) and Immgolix Intri (Golimumab-sldi) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Simponi (golimumab) and Simponi Aria (golimumab) 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.

Leqselvi (Deuruxolitinib), Litfulo (Ritlecitinib), and Olumiant (Baricitinib) Approval Criteria [Alopecia Areata Diagnosis]:

1. An FDA approved diagnosis of severe alopecia areata; and
2. For Litfulo **or** Olumiant, member must be 12 to 20 years of age; or

3. For Leqselvi ~~or Olumiant~~, member must be 18 to 20 years of age; and
4. Prescriber must confirm the member or caregiver has been counseled regarding the covered age range for the requested product and that the medication will no longer be covered once the member turns 21 years of age; and
5. Member's baseline Severity of Alopecia Tool (SALT) score must be provided and must be ≥ 50 ; and
6. Must be prescribed by a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
- ~~7. Prescriber must agree to screen for tuberculosis and viral hepatitis prior to initiating treatment; and~~
8. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and
9. Prescriber must provide documentation of patient-specific, clinically significant information (e.g., impacting member's mental health or ability to function in day-to-day living, reason why no treatment or cosmetic solutions are not appropriate) to demonstrate the medical necessity of this medication for this member; and
- ~~10. Member must have documented trials within the last 6 months that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance to all alternatives):
 - ~~a. Medium-potency to very high-potency Tier 1 topical corticosteroid used for at least 12 weeks; or~~
 - ~~b. Oral corticosteroid used for at least 6 weeks; or~~
 - ~~c. Cyclosporine; or~~
 - ~~d. Methotrexate; or~~
 - ~~e. Contact immunotherapy (e.g., diphenylcyclopropenone, squaric acid dibutyl ester); and~~~~
11. Concurrent use with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants will not be approved; and
12. Prescriber must verify female members are not breastfeeding; and
13. 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 pregnancy registry; and
- ~~14. Requests for Leqselvi (deuruxolitinib) or Olumiant (baricitinib) will require a patient-specific, clinically significant reason why the member cannot use Litfulo (ritlecitinib); and~~
15. Initial approvals will be for a duration of 24 weeks of treatment; and
16. Reauthorization may be considered if the prescriber documents the member is responding well to treatment as indicated by a reduction in the member's SALT score (current SALT score must be provided).

Lisraya (Brepocitinib) Approval Criteria:

1. An FDA approved diagnosis of dermatomyositis meeting both of the following based on American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) classification criteria:
 - a. Definite or probable idiopathic inflammatory myopathy (IIM); and
 - b. Dermatomyositis subtype; and
2. Member must be 18 years of age or older; and
3. Must be prescribed by a dermatologist, neurologist, rheumatologist, or other specialist with expertise in the treatment of dermatomyositis; and
4. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling; and
5. Member must be receiving treatment with a corticosteroid and at least 1 of the following other immunomodulatory/immunosuppressive therapies (unless there is documented previous failure or intolerance):
 - a. Methotrexate; or
 - b. Azathioprine; or
 - c. Mycophenolate mofetil or mycophenolic acid; or
 - d. Leflunomide; or
 - e. Sulfasalazine; or
 - f. Hydroxychloroquine; and
6. A patient-specific, clinically significant reason why the member cannot use guideline-recommended, second-line treatments (e.g., abatacept, intravenous immunoglobulin, rituximab); and
7. Concurrent use with other Janus kinase (JAK) inhibitors, other tyrosine kinase 2 (TYK2) inhibitors, or biologic disease modifying anti-rheumatic drugs (DMARDs) will not be approved; and
8. Initial approvals will be for a duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Otezla XR [Apremilast Extended-Release (ER)] Approval Criteria:

1. For a diagnosis of Behçet's disease (BD), the member must meet the unique apremilast approval criteria for that indication; or
- ~~2. Member must meet Special Prior Authorization (PA) approval criteria; and~~
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot continue using the immediate-release formulation of apremilast must be provided.

~~Riabni (Rituximab-arrx), Rituxan (Rituximab), Ruxience (Rituximab-pvvr), and Truxima (Rituximab-abbs) Approval Criteria [Granulomatosis with Polyangiitis (GPA, Wegener's Granulomatosis) or Microscopic Polyangiitis (MPA) Diagnosis]:~~

- ~~1. An FDA approved diagnosis of GPA or MPA in adult and pediatric members 2 years of age and older; and~~
- ~~2. Must be used in combination with corticosteroids; and~~
- ~~3. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).~~

~~Riabni (Rituximab-arrx), Rituxan (Rituximab), Ruxience (Rituximab-pvvr), and Truxima (Rituximab-abbs) Approval Criteria [Pemphigus Vulgaris (PV) Diagnosis]:~~

- ~~1. Diagnosis of moderate to severe PV; and~~
- ~~2. Must be used in combination with a tapering course of corticosteroids; and~~
- ~~3. Initial approvals will be for (2) 1,000mg intravenous (IV) infusions separated by 2 weeks and a 500mg IV infusion at month 12. Subsequent approvals may be authorized based on 6 month evaluations or upon relapse no sooner than 16 weeks after the previous infusion.~~

Rinvoq LQ (Upadacitinib Oral Solution) Approval Criteria:

1. Member must meet ~~Special Prior Authorization (PA) Tier-3~~ approval criteria; and
2. An age restriction of 2 years of age to 10 years of age will apply. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

~~Rituxan (Rituximab) and Zimrixby (Rituximab-cdxx) Approval Criteria:~~

- ~~1. A patient-specific, clinically significant reason why the member cannot use Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), and Truxima (rituximab-abbs) 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.~~

Saphnelo (Anifrolumab-fnia) Approval Criteria:

1. An FDA approved indication for the treatment of adult patients with moderate-to-severe systemic lupus erythematosus (SLE), who are receiving standard therapy; and
2. Member must be 18 years of age or older; and
3. Documented inadequate response to at least 1 of the following medications appropriate to member's specific disease state:

- a. High-dose oral corticosteroids; or
 - b. Methotrexate; or
 - c. Azathioprine; or
 - d. Mycophenolate; or
 - e. Cyclophosphamide; or
 - f. Hydroxychloroquine/chloroquine; and
4. Member must not have severe active lupus nephritis (LN) or severe active central nervous system lupus; and
5. Saphnelo will not be approved for combination use with biologic therapies or cyclophosphamide; and
6. For the intravenous (IV) formulation, Saphnelo must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
 - a. Must be shipped to the health care facility where the member is scheduled to receive treatment; and
7. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment.

Ustekinumab Non-Preferred (Special Prior Authorization Tier) Products ~~Otufi (Ustekinumab-aaaz), Unbranded Pyzchiva (Ustekinumab-ttwe), Unbranded Selarsdi (Ustekinumab-aekn), Stelara (Ustekinumab), Unbranded Steqeyma (Ustekinumab-stba), and Wezlana (Ustekinumab-aaub)~~ Approval Criteria:

- ~~1. Member must meet Special Prior Authorization (PA) approval criteria; and~~
2. A patient-specific, clinically significant reason why the member cannot use ~~a preferred Tier-1 ustekinumab product Imuldosa (ustekinumab-srlf), branded Pyzchiva (ustekinumab-ttwe), branded Selarsdi (ustekinumab-aekn), Starjemza (ustekinumab-hmny), branded Steqeyma (ustekinumab-stba), and Yesintek (ustekinumab-kfee)~~ 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
3. Additionally, initial and continuation requests for branded Stelara will require a patient-specific, clinically significant reason why unbranded Stelara cannot be used.

Xeljanz (Tofacitinib Oral Solution) Approval Criteria:

1. Member must meet ~~Tier-3~~ Tier-2 approval criteria; and
2. An age restriction of 2 years of age to 10 years of age will apply. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

Utilization Details of Targeted Immunomodulator Agents: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-2 PRODUCTS						
ADALIMUMAB PRODUCTS						
HUMIRA PEN INJ 40MG/0.4ML	7,482	1,346	\$59,129,021.83	\$7,902.84	5.56	27.12%
HUMIRA PEN INJ 80MG/0.8ML	936	201	\$13,879,076.09	\$14,828.07	4.66	6.37%
HUMIRA INJ 40MG/0.4ML	580	129	\$4,494,444.85	\$7,749.04	4.5	2.06%
HUMIRA PEN INJ 40MG/0.8ML	392	95	\$3,228,354.65	\$8,235.60	4.13	1.48%
HADLIMA PUSH INJ 40MG/0.4ML	289	66	\$294,147.85	\$1,017.81	4.38	0.13%
ADALIMU-ADAZ INJ 40MG/0.4ML	168	71	\$246,301.44	\$1,466.08	2.37	0.11%
HUMIRA INJ 20MG/0.2ML	152	24	\$1,153,999.63	\$7,592.10	6.33	0.53%
HUMIRA KIT 40MG/0.8ML	144	40	\$1,241,148.42	\$8,619.09	3.6	0.57%
HUMIRA INJ 10MG/0.1ML	70	8	\$658,447.60	\$9,406.39	8.75	0.30%
HUMIRA PEN KIT CD/UC/HS 80MG/0.8ML	63	63	\$1,273,067.49	\$20,207.42	1	0.58%
HUMIRA PEN KIT PS/UV 80MG/0.8ML & 40MG/0.4ML	47	47	\$626,756.04	\$13,335.23	1	0.29%
HADLIMA INJ 40MG/0.4ML	45	11	\$54,867.55	\$1,219.28	4.09	0.03%
ADALIMU-ADAZ INJ 80MG/0.8ML	20	7	\$55,470.80	\$2,773.54	2.86	0.03%
HADLIMA INJ 40MG/0.8ML	18	6	\$23,417.14	\$1,300.95	3	0.01%
ADALIMU-ADAZ INJ 40MG/0.4ML	14	4	\$14,988.58	\$1,070.61	3.5	0.01%
YUSIMRY INJ 40MG/0.8ML	12	2	\$11,533.16	\$961.10	6	0.01%
HADLIMA PUSH INJ 40MG/0.8ML	11	2	\$11,221.03	\$1,020.09	5.5	0.01%
SIMLANDI 2 PEN INJ 40MG/0.4ML	9	5	\$9,810.80	\$1,090.09	1.8	0.00%
ADALIMU-FKJP KIT 40MG/0.8ML	3	1	\$3,019.23	\$1,006.41	3	0.00%
SIMLANDI KIT 40MG/0.4ML	2	1	\$2,098.82	\$1,049.41	2	0.00%
SIMLANDI 1 PEN KIT 40MG/0.4ML	1	1	\$984.65	\$984.65	1	0.00%
SUBTOTAL	10,458	2,130	\$86,412,177.65	\$8,262.78	4.91	39.63%
ETANERCEPT PRODUCTS						
ENBREL SRCLK INJ 50MG/ML	3,731	749	\$30,569,564.84	\$8,193.40	4.98	14.02%
ENBREL INJ 50MG/ML	350	73	\$3,004,631.69	\$8,584.66	4.79	1.38%
ENBREL MINI INJ 50MG/ML	63	12	\$549,377.50	\$8,720.28	5.25	0.25%
ENBREL INJ 25MG	54	8	\$377,293.86	\$6,986.92	6.75	0.17%
ENBREL INJ 25MG/0.5ML	40	10	\$185,024.07	\$4,625.60	4	0.08%
SUBTOTAL	4,238	852	\$34,685,891.96	\$8,184.50	4.97	15.91%
APREMILAST PRODUCTS						
OTEZLA TAB 30MG	1,133	246	\$5,980,317.57	\$5,278.30	4.61	2.74%
OTEZLA TAB 10/20/30MG	90	80	\$479,422.44	\$5,326.92	1.13	0.22%
OTEZLA TAB 20MG	53	16	\$271,428.05	\$5,121.28	3.31	0.12%
OTEZLA TAB 10/20MG	7	7	\$38,144.34	\$5,449.19	1	0.02%
SUBTOTAL	1,283	349	\$6,769,312.40	\$5,276.16	3.68	3.10%
INFLIXIMAB PRODUCTS						
INFLECTRA INJ 100MG	187	37	\$227,886.04	\$1,218.64	5.05	0.10%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INFLIXIMAB INJ 100MG	10	4	\$19,056.56	\$1,905.66	2.5	0.01%
SUBTOTAL	197	41	\$246,942.60	\$1,253.52	4.8	0.11%
USTEKINUMAB PRODUCTS						
YESINTEK INJ 90MG/ML	44	20	\$129,627.02	\$2,946.07	2.2	0.06%
YESINTEK INJ 45MG/0.5ML	28	13	\$42,317.65	\$1,511.34	2.15	0.02%
SELARSDI INJ 45MG/0.5ML	16	8	\$35,658.13	\$2,228.63	2	0.02%
SELARSDI INJ 90MG/ML	14	6	\$62,802.19	\$4,485.87	2.33	0.03%
STEQEYMA INJ 90MG/ML	13	7	\$54,431.42	\$4,187.03	1.86	0.02%
STEQEYMA INJ 45MG/0.5ML	12	4	\$25,195.44	\$2,099.62	3	0.01%
YESINTEK INJ 45MG/0.5ML	6	4	\$10,568.39	\$1,761.40	1.5	0.00%
PYZCHIVA INJ 45MG/0.5ML	6	2	\$12,597.72	\$2,099.62	3	0.01%
PYZCHIVA INJ 90MG/ML	2	1	\$8,367.68	\$4,183.84	2	0.00%
PYZCHIVA INJ 45MG/0.5ML	2	1	\$4,199.24	\$2,099.62	2	0.00%
IMULDOSA INJ 45MG/0.5ML	1	1	\$1,177.47	\$1,177.47	1	0.00%
SELARSDI INJ 130MG/26ML	1	1	\$2,811.41	\$2,811.41	1	0.00%
SELARSDI INJ 45MG/0.5ML	1	1	\$2,099.62	\$2,099.62	1	0.00%
SUBTOTAL	146	69	\$391,853.38	\$2,683.93	2.12	0.18%
ANAKINRA PRODUCTS						
KINERET INJ 100MG/0.67ML	95	20	\$833,311.12	\$8,771.70	4.75	0.38%
SUBTOTAL	95	20	\$833,311.12	\$8,771.70	4.75	0.38%
RITUXIMAB PRODUCTS						
RITUXAN INJ 500MG	2	1	\$11,368.92	\$5,684.46	2	0.01%
SUBTOTAL	2	1	\$11,368.92	\$5,684.46	2	0.01%
TIER-2 SUBTOTAL	16,419	3,462	\$129,350,858.03	\$7,878.12	4.74	59.33%
TIER-3 PRODUCTS						
ABATACEPT PRODUCTS						
ORENCIA CLICKJECT INJ 125MG/ML	513	107	\$2,840,745.41	\$5,537.52	4.79	1.30%
ORENCIA INJ 125MG/ML	82	16	\$326,074.55	\$3,976.52	5.13	0.15%
ORENCIA INJ 250MG	6	2	\$5,766.39	\$961.07	3	0.00%
SUBTOTAL	601	125	\$3,172,586.35	\$5,278.85	4.81	1.46%
TOFACITINIB PRODUCTS						
XELJANZ XR TAB 11MG	293	62	\$1,778,032.16	\$6,068.37	4.73	0.82%
XELJANZ TAB 5MG	217	41	\$1,147,098.85	\$5,286.17	5.29	0.53%
XELJANZ TAB 10MG	15	3	\$91,143.89	\$6,076.26	5	0.04%
XELJANZ SOL 1MG/ML	13	6	\$65,179.50	\$5,013.81	2.17	0.03%
TOFACITINIB TAB 5MG	5	5	\$408.05	\$81.61	1	0.00%
XELJANZ XR TAB 22MG	4	1	\$25,674.28	\$6,418.57	4	0.01%
TOFACITINIB TAB 11MG ER	4	4	\$824.68	\$206.17	1	0.00%
SUBTOTAL	551	122	\$3,108,361.41	\$5,641.31	4.52	1.43%
CERTOLIZUMAB PRODUCTS						
CIMZIA 2-SYR KIT 200MG/ML	395	98	\$2,773,765.77	\$7,022.19	4.03	1.27%
CIMZIA START KIT 200MG/ML	29	29	\$449,543.47	\$15,501.50	1	0.21%
CIMZIA KIT 200MG	4	1	\$6,975.64	\$1,743.91	4	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	428	128	\$3,230,284.88	\$7,547.39	3.34	1.48%
TOCILIZUMAB PRODUCTS						
TYENNE INJ 162MG/0.9ML AUTO	179	41	\$397,382.13	\$2,220.01	4.37	0.18%
TYENNE INJ 162MG/0.9ML SYR	37	9	\$66,857.98	\$1,806.97	4.11	0.03%
SUBTOTAL	216	50	\$464,240.11	\$2,149.26	4.32	0.21%
GOLIMUMAB PRODUCTS						
SIMPONI INJ 50MG/0.5ML AUTO	66	16	\$414,861.29	\$6,285.78	4.13	0.19%
SIMPONI INJ 50MG/0.5ML SYR	20	2	\$126,259.04	\$6,312.95	10	0.06%
SIMPONI ARIA SOL 50MG/4ML	6	1	\$13,479.26	\$2,246.54	6	0.01%
SUBTOTAL	92	19	\$554,599.59	\$6,028.26	4.84	0.25%
DEUCRAVACITINIB PRODUCTS						
SOTYKTU TAB 6MG	76	22	\$528,353.90	\$6,952.03	3.45	0.24%
SUBTOTAL	76	22	\$528,353.90	\$6,952.03	3.45	0.24%
SARILUMAB PRODUCTS						
KEVZARA INJ 200MG/1.14ML AUTO	65	11	\$300,774.93	\$4,627.31	5.91	0.14%
KEVZARA INJ 200MG/1.14ML SYR	4	2	\$18,780.59	\$4,695.15	2	0.01%
KEVZARA INJ 150MG/1.14ML AUTO	4	1	\$18,460.48	\$4,615.12	4	0.01%
SUBTOTAL	73	14	\$338,016.00	\$4,630.36	5.21	0.16%
INFLIXIMAB PRODUCTS						
REMICADE INJ 100MG	73	15	\$150,466.98	\$2,061.19	4.87	0.07%
SUBTOTAL	73	15	\$150,466.98	\$2,061.19	4.87	0.07%
VEDOLIZUMAB PRODUCTS						
ENTYVIO INJ 300MG	18	5	\$116,252.68	\$6,458.48	3.6	0.05%
SUBTOTAL	18	5	\$116,252.68	\$6,458.48	3.6	0.05%
TIER-3 SUBTOTAL	2,128	500	\$11,663,161.90	\$5,480.81	4.26	5.35%
SPECIAL PA PRODUCTS						
UPADACITINIB PRODUCTS						
RINVOQ TAB 15MG ER	1,036	195	\$6,917,515.75	\$6,677.14	5.31	3.17%
RINVOQ TAB 30MG ER	416	66	\$2,784,737.09	\$6,694.08	6.3	1.28%
RINVOQ TAB 45MG ER	96	32	\$1,203,028.62	\$12,531.55	3	0.55%
RINVOQ LQ SOL 1MG/ML	3	2	\$37,309.78	\$12,436.59	1.5	0.02%
SUBTOTAL	1,551	295	\$10,942,591.24	\$7,055.18	5.26	5.02%
SECUKINUMAB PRODUCTS						
COSENTYX UNO INJ 300MG/2ML	700	131	\$7,819,736.35	\$11,171.05	5.34	3.59%
COSENTYX PEN INJ 300MG DOSE	302	60	\$2,579,603.41	\$8,541.73	5.03	1.18%
COSENTYX PEN INJ 150MG/ML	182	44	\$1,716,362.34	\$9,430.56	4.14	0.79%
COSENTYX INJ 300MG DOSE SYR	30	9	\$300,926.64	\$10,030.89	3.33	0.14%
COSENTYX INJ 150MG/ML SYR	27	8	\$307,386.19	\$11,384.67	3.38	0.14%
COSENTYX INJ 75MG/0.5ML	12	1	\$47,259.69	\$3,938.31	12	0.02%
SUBTOTAL	1,253	253	\$12,771,274.62	\$10,192.56	4.95	5.86%
BELIMUMAB PRODUCTS						
BENLYSTA INJ 200MG/ML AUTO	1,152	225	\$5,869,243.80	\$5,094.83	5.12	2.69%
BENLYSTA INJ 200MG/ML SYR	70	9	\$356,357.39	\$5,090.82	7.78	0.16%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	1,222	234	\$6,225,601.19	\$5,094.60	5.22	2.86%
RISANKIZUMAB PRODUCTS						
SKYRIZI PEN INJ 150MG/ML	371	145	\$8,137,222.46	\$21,933.21	2.56	3.73%
SKYRIZI INJ 360MG/2.4ML	308	80	\$6,860,605.62	\$22,274.69	3.85	3.15%
SKYRIZI INJ 180MG/1.2ML	20	4	\$463,902.23	\$23,195.11	5	0.21%
SKYRIZI INJ 150MG/ML	19	7	\$420,395.96	\$22,126.10	2.71	0.19%
SKYRIZI SOL 60MG/ML	2	1	\$17,541.62	\$8,770.81	2	0.01%
SUBTOTAL	720	237	\$15,899,667.89	\$22,082.87	3.04	7.29%
IXEKIZUMAB PRODUCTS						
TALTZ INJ 80MG/ML AUTO	576	87	\$4,929,797.99	\$8,558.68	6.62	2.26%
TALTZ INJ 40MG/0.5ML	63	8	\$477,074.03	\$7,572.60	7.88	0.22%
TALTZ INJ 80MG/ML SYR	31	6	\$279,848.09	\$9,027.36	5.17	0.13%
SUBTOTAL	670	101	\$5,686,720.11	\$8,487.64	6.63	2.61%
GUSELKUMAB PRODUCTS						
TREMFYA INJ 200MG/2ML AUTO	168	31	\$3,175,484.35	\$18,901.69	5.42	1.46%
TREMFYA INJ 100MG/ML PEN	168	47	\$2,408,441.28	\$14,335.96	3.57	1.10%
TREMFYA INJ 100MG/ML AUTO	55	22	\$823,710.81	\$14,976.56	2.5	0.38%
TREMFYA INJ 100MG/ML SYR	23	6	\$332,225.75	\$14,444.60	3.83	0.15%
TREMFYA INJ 200MG/20ML	6	2	\$87,467.10	\$14,577.85	3	0.04%
TREMFYA INJ 200MG/2ML SYR	1	1	\$14,573.85	\$14,573.85	1	0.01%
SUBTOTAL	421	109	\$6,841,903.14	\$16,251.55	3.86	3.14%
BIMEKIZUMAB PRODUCTS						
BIMZELX INJ 320MG/2ML AUTO	209	40	\$4,232,386.44	\$20,250.65	5.23	1.94%
BIMZELX INJ 160MG/ML AUTO	95	19	\$1,045,364.69	\$11,003.84	5	0.48%
BIMZELX INJ 320MG/2ML SYR	14	3	\$274,663.85	\$19,618.85	4.67	0.13%
BIMZELX INJ 160MG/ML SYR	8	3	\$103,068.80	\$12,883.60	2.67	0.05%
SUBTOTAL	326	65	\$5,655,483.78	\$17,348.11	5.02	2.59%
TOCILIZUMAB PRODUCTS						
ACTEMRA INJ ACTPEN 162MG/0.9ML	196	33	\$792,422.43	\$4,042.97	5.94	0.36%
ACTEMRA INJ 162MG/0.9ML	26	9	\$110,728.80	\$4,258.80	2.89	0.05%
ACTEMRA INJ 200MG/10ML	9	2	\$38,604.08	\$4,289.34	4.5	0.02%
SUBTOTAL	231	44	\$941,755.31	\$4,076.86	5.25	0.43%
USTEKINUMAB PRODUCTS						
STELARA INJ 90MG/ML	224	44	\$6,484,229.56	\$28,947.45	5.09	2.97%
STELARA INJ 45MG/0.5ML SYR	40	15	\$578,113.47	\$14,452.84	2.67	0.27%
STELARA INJ 45MG/0.5ML VIAL	10	3	\$147,329.08	\$14,732.91	3.33	0.07%
USTEKINUMAB INJ 90MG/ML	3	1	\$21,898.23	\$7,299.41	3	0.01%
SUBTOTAL	277	63	\$7,231,570.34	\$26,106.75	4.4	3.32%
RITLECITINIB PRODUCTS						
LITFULO CAP 50MG	108	14	\$458,083.64	\$4,241.52	7.71	0.21%
SUBTOTAL	108	14	\$458,083.64	\$4,241.52	7.71	0.21%
CANAKINUMAB PRODUCTS						
ILARIS INJ 150MG/ML	68	11	\$1,674,118.51	\$24,619.39	6.18	0.77%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	68	11	\$1,674,118.51	\$24,619.39	6.18	0.77%
ADALIMUMAB PRODUCTS						
ADALIMU-AATY KIT 40MG/0.4ML	27	11	\$29,332.51	\$1,086.39	2.45	0.01%
AMJEVITA INJ 40MG/0.4ML	11	3	\$56,893.81	\$5,172.16	3.67	0.03%
HYRIMOZ INJ 40MG/0.4ML	7	2	\$46,115.30	\$6,587.90	3.5	0.02%
ADALIMU-AATY KIT 80MG/0.8ML	7	3	\$7,864.87	\$1,123.55	2.33	0.00%
ADALIMU-ADBM KIT 40MG/0.4ML AUTO	6	4	\$9,060.89	\$1,510.15	1.5	0.00%
ADALIMU-ADBM KIT 40MG/0.8ML	1	1	\$1,326.71	\$1,326.71	1	0.00%
ADALIMU-ADBM KIT 40MG/0.4ML SYR	1	1	\$1,326.71	\$1,326.71	1	0.00%
ABRILADA 2 PEN INJ 40MG/0.8ML	1	1	\$1,049.41	\$1,049.41	1	0.00%
ADALIMU-RYVK INJ 40MG/0.4ML	1	1	\$3,761.41	\$3,761.41	1	0.00%
ADALIMU-AATY KIT 40MG/0.4ML	1	1	\$530.41	\$530.41	1	0.00%
AMJEVITA INJ 80MG/0.8ML	1	1	\$2,781.85	\$2,781.85	1	0.00%
SUBTOTAL	64	29	\$160,043.88	\$2,500.69	2.21	0.07%
AVACOPAN PRODUCTS						
TAVNEOS CAP 10MG	55	9	\$1,015,330.35	\$18,460.55	6.11	0.47%
SUBTOTAL	55	9	\$1,015,330.35	\$18,460.55	6.11	0.47%
BARICITINIB PRODUCTS						
OLUMIANT TAB 2MG	30	6	\$95,587.32	\$3,186.24	5	0.04%
OLUMIANT TAB 4MG	8	1	\$43,618.01	\$5,452.25	8	0.02%
SUBTOTAL	38	7	\$139,205.33	\$3,663.30	5.43	0.06%
VEDOLIZUMAB PRODUCTS						
ENTYVIO PEN INJ 108MG/0.68ML	33	7	\$236,978.10	\$7,181.15	4.71	0.11%
SUBTOTAL	33	7	\$236,978.10	\$7,181.15	4.71	0.11%
INFLIXIMAB PRODUCTS						
ZYMFENTRA INJ 120MG/ML AUTO	32	5	\$179,183.00	\$5,599.47	6.4	0.08%
ZYMFENTRA INJ 120MG/ML SYR	1	1	\$4,823.53	\$4,823.53	1	0.00%
SUBTOTAL	33	6	\$184,006.53	\$5,575.96	5.5	0.08%
VOCLOSPORIN PRODUCTS						
LUPKYNIS CAP 7.9MG	25	4	\$415,668.13	\$16,626.73	6.25	0.19%
SUBTOTAL	25	4	\$415,668.13	\$16,626.73	6.25	0.19%
ANIFROLUMAB PRODUCTS						
SAPHNELO SOL 300MG/2ML	16	8	\$88,350.27	\$5,521.89	2	0.04%
SAPHNELO PEN INJ 120MG/0.8ML	2	2	\$12,379.32	\$6,189.66	1	0.01%
SUBTOTAL	18	10	\$100,729.59	\$5,596.09	1.8	0.05%
APREMILAST PRODUCTS						
OTEZLA XR TAB 75MG	16	6	\$88,909.37	\$5,556.84	2.67	0.04%
OTEZLA XR TAB 10/20/30/75MG	1	1	\$5,601.30	\$5,601.30	1	0.00%
SUBTOTAL	17	7	\$94,510.67	\$5,559.45	2.43	0.04%
SPESOLIMAB PRODUCTS						
SPEVIGO INJ 150MG/ML	15	2	\$297,806.35	\$19,853.76	7.5	0.14%
SUBTOTAL	15	2	\$297,806.35	\$19,853.76	7.5	0.14%
BRODALUMAB PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SILIQ INJ 210MG/1.5ML	3	2	\$17,244.66	\$5,748.22	1.5	0.01%
SUBTOTAL	3	2	\$17,244.66	\$5,748.22	1.5	0.01%
ICOTROKINRA PRODUCTS						
ICOTYDE TAB 200MG	2	2	\$16,592.82	\$8,296.41	1	0.01%
SUBTOTAL	2	2	\$16,592.82	\$8,296.41	1	0.01%
SPECIAL PA SUBTOTAL	7,150	1,511	\$77,006,886.18	\$10,770.19	4.73	35.32%
TOTAL	25,697	4,279*	\$218,020,906.11	\$8,484.29	6.01	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

ADALIMU = adalimumab; AUTO = autoinjector; CAP = capsule; CD = Crohn's disease; ER = extended-release; HS = hidradenitis suppurativa; INJ = injection; PED = pediatric; PREFL = prefilled; PS = psoriasis; SOL = solution; SRCLK = SureClick; SYR = syringe; TAB = tablet; UC = ulcerative colitis; UV = uveitis

Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS*	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BENLYSTA IV INJ (J0490)	1,362	167	\$3,959,096.61	\$2,906.83	8.16
INFLECTRA INJ (Q5103)	613	129	\$499,735.19	\$815.23	4.75
SAPHNELO INJ (J0491)	551	130	\$2,937,048.22	\$5,330.40	4.24
SIMPONI ARIA INJ (J1602)	506	109	\$801,250.71	\$1,583.50	4.64
RITUXAN INJ (J9312)	341	113	\$1,631,764.70	\$4,785.23	3.02
INFLIXIMAB INJ (J1745)	330	67	\$316,812.78	\$960.04	4.93
ORENCIA INJ (J0129)	305	66	\$1,099,567.63	\$3,605.14	4.62
ENTYVIO INJ (J3380)	299	70	\$1,890,445.05	\$6,322.56	4.27
REMICADE INJ (J1745)	268	63	\$359,837.54	\$1,342.68	4.25
TRUXIMA INJ (Q5115)	210	55	\$305,470.77	\$1,454.62	3.82
ACTEMRA INJ (J3262)	186	24	\$370,110.71	\$1,989.84	7.75
RENFLEXIS INJ (Q5104)	144	25	\$232,602.30	\$1,615.29	5.76
COSENTYX INJ (J3247)	118	16	\$421,515.45	\$3,572.16	7.38
RUXIENCE INJ (Q5119)	112	34	\$97,533.88	\$870.84	3.29
RIABNI INJ (Q5123)	91	17	\$108,416.48	\$1,191.39	5.35
CIMZIA INJ (J0717)	77	15	\$122,376.50	\$1,589.31	5.13
TYENNE INJ (Q5135)	55	12	\$75,300.80	\$1,369.11	4.58
SKYRIZI IV INJ (J2327)	34	17	\$341,457.28	\$10,042.86	2
ILARIS INJ (J0638)	31	9	\$753,594.03	\$24,309.48	3.44
AVSOLA INJ (Q5121)	27	7	\$36,964.00	\$1,369.04	3.86
TREMFYA INJ (J1628)	15	4	\$201,609.00	\$13,440.60	3.75
ILUMYA INJ (J3245)	5	1	\$63,080.00	\$12,616.00	5
YESINTEK INJ (Q5100)	5	5	\$28,270.90	\$5,654.18	1
STELARA IV INJ (J3358)	3	3	\$11,659.70	\$3,886.57	1
ENBREL INJ (J1438)	1	1	\$0.01	\$0.01	1
TOTAL	5,689	1,095	\$16,665,520.24	\$2,929.43	5.2

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated claims.

*Total number of unduplicated utilizing members.

INJ = injection; IV = intravenous

Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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 09/2026. Last accessed 09/14/2026.

² Johnson & Johnson. FDA Approval of Icotyde (Icotrokinra) Ushers in New Era for First-Line Systemic Treatment of Plaque Psoriasis with a Targeted Oral Peptide. Available online at: <https://www.jnj.com/media-center/press-releases/fda-approval-of-icotyde-icotrokinra-ushers-in-new-era-for-first-line-systemic-treatment-of-plaque-psoriasis-with-a-targeted-oral-peptide>. Issued 03/18/2026. Last accessed 09/15/2026.

³ AstraZeneca. Saphnelo Approved in the US for Subcutaneous Self-Administration as a New Autoinjector for the Treatment of Systemic Lupus Erythematosus. Available online at: <https://www.astrazeneca.com/media-centre/press-releases/2026/saphnelo-self-administration-approved-in-the-US.html>. Issued 04/27/2026. Last accessed 09/15/2026.

⁴ Accord BioPharma, Inc. FDA Approves Immgolis (Golimumab-sldi) and Immgolis Intri (Golimumab-sldi), First Biosimilars to Simponi (Golimumab) and Simponi Aria (Golimumab); Accord BioPharma to Lead U.S. Commercialization. Available online at: <https://www.prnewswire.com/news-releases/fda-approves-immgolis-golimumab-sldi-and-immgolis-intri-golimumab-sldi-first-biosimilars-to-simponi-golimumab-and-simponi-aria-golimumab-accord-biopharma-to-lead-us-commercialization-302774328.html>. Issued 05/18/2026. Last accessed 09/29/2026.

⁵ U.S. FDA. Tofidence (Tocilizumab-bavi) Supplement Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2026/761354Orig1s009ltr.pdf. Issued 05/22/2026. Last accessed 09/15/2026.

⁶ U.S. FDA. Zimrixby (Rituximab-cdxx) BLA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2026/761376Orig1s000ltr.pdf. Issued 07/31/2026. Last accessed 09/21/2026.

⁷ U.S. FDA. FDA Approves First Oral Drug Indicated to Treat Dermatomyositis in Adults. Available online at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-drug-indicated-treat-dermatomyositis-adults>. Issued 08/27/2026. Last accessed 09/21/2026.

⁸ Gregoire S, Dewey E, Biba U, et al. Delphi Consensus Statement on Treatment of Severe Alopecia Areata in US Adults. *JAMA Dermatol* 2026. doi: 10.1001/jamadermatol.2026.2336. Online ahead of print.

⁹ Icotyde (Icotrokinra) Prescribing Information. Janssen Biotech, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/220149Orig1s000lbl.pdf. Last revised 03/2026. Last accessed 09/15/2026.

¹⁰ Lisraya (Brepocitinib) Prescribing Information. Priovent Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/220106Orig1s000lbl.pdf. Last revised 08/2026. Last accessed 09/21/2026.

¹¹ Oldroyd AGS, Lilleker JB, Amin T, et al. British Society for Rheumatology Guideline on Management of Paediatric, Adolescent and Adult Patients with Idiopathic Inflammatory Myopathy. *Rheumatology (Oxford)* 2022 ; 61(5):1760-1768. doi: 10.1093/rheumatology/keac115.

¹² Zouboulis CC, Bechara FG, Benhadou F, et al. European S2k Guidelines for Hidradenitis Suppurativa/Acne Inversa Part 2: Treatment. *J Eur Acad Dermatol Venereol* 2025; 39(5):899-941. doi: 10.1111/jdv.20472.



Fiscal Year 2026 Annual Review of Fibromyalgia Medications and 30-Day Notice to Prior Authorize Tonmya [Cyclobenzaprine Sublingual (SL) Tablet]

Oklahoma Health Care Authority
October 2026

Current Prior Authorization Criteria

Fibromyalgia Medications	
Tier-1	Tier-2
amitriptyline	milnacipran (Savella) – Brand Preferred
cyclobenzaprine	
duloxetine	
fluoxetine	
pregabalin	
tramadol	

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).

Fibromyalgia Medications Tier-2 Approval Criteria:

1. Member must have a documented, recent (within the last 6 months) trial of 2 Tier-1 medications (must include 1 trial with duloxetine) at least 3 weeks in duration that did not provide an adequate response or resulted in intolerable adverse effects; or
2. Contraindication(s) to all available lower tiered medications; or
3. Current stabilization on a Tier-2 medication; and
4. Savella is brand preferred. Requests for generic milnacipran will require a patient-specific, clinically significant reason why the brand name cannot be used.

Utilization of Fibromyalgia Medications: Fiscal Year 2026

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 2025							
FFS	20	99	\$46,165.25	\$466.32	\$14.81	5,690	3,117
Aetna	12	42	\$18,916.67	\$450.40	\$15.84	2,320	1,194
Humana	16	77	\$37,328.39	\$484.78	\$16.28	4,569	2,293
OCH	13	54	\$23,273.20	\$430.99	\$14.60	2,809	1,594
2025 Total	56	272	\$125,683.51	\$462.07	\$15.33	15,388	8,198
Fiscal Year 2026							
FFS	17	83	\$36,530.26	\$440.12	\$14.25	4,917	2,564
Aetna	9	26	\$13,178.38	\$506.86	\$17.50	1,442	753
Humana	29	98	\$47,344.34	\$483.11	\$16.37	5,487	2,893
OCH	18	87	\$44,749.85	\$514.37	\$17.16	5,095	2,608
2026 Total	68	294	\$141,802.83	\$482.32	\$16.08	16,941	8,818
% Change	21.40%	8.10%	12.80%	4.40%	4.90%	10.10%	7.60%
Change	12	22	\$16,119.32	\$20.25	\$0.75	1,553	620

Costs do not reflect rebated prices or net costs.

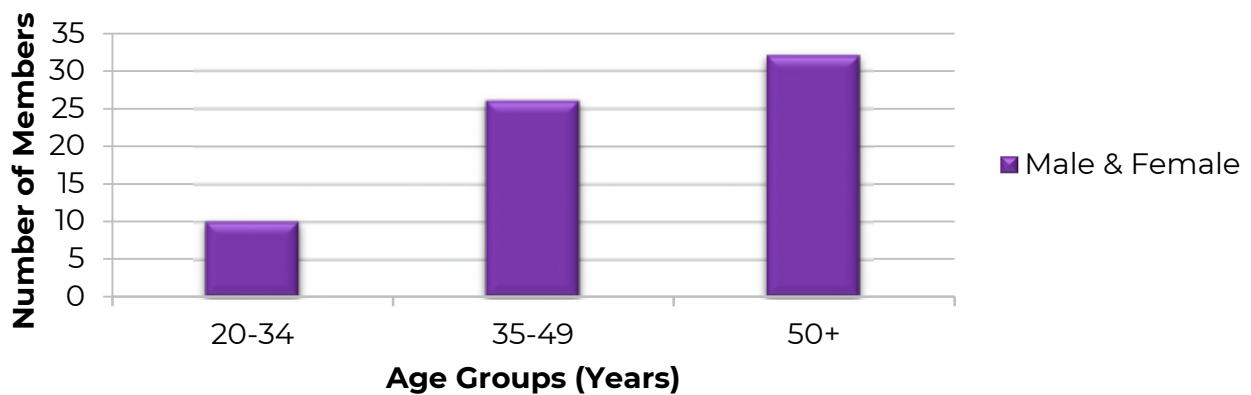
*Total number of unduplicated utilizing members.

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

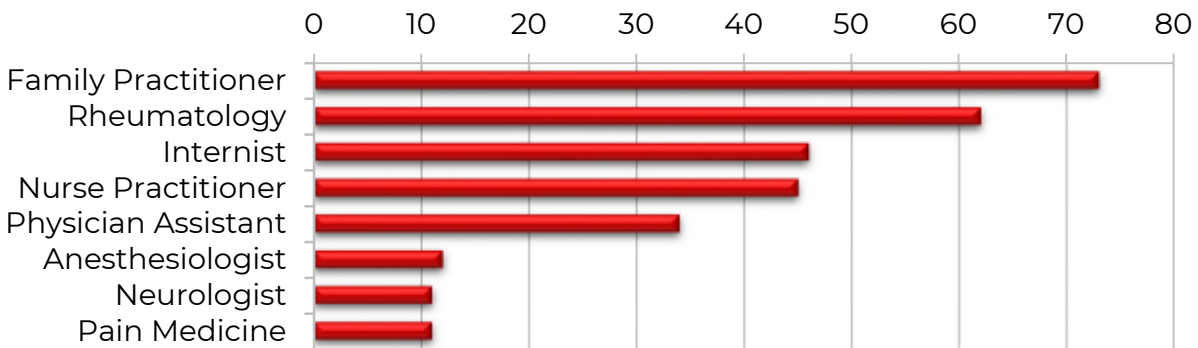
Fiscal Year 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Please note: Tier-1 medications are not included in the utilization data, as they have other FDA approved indications and are reviewed with other categories.

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



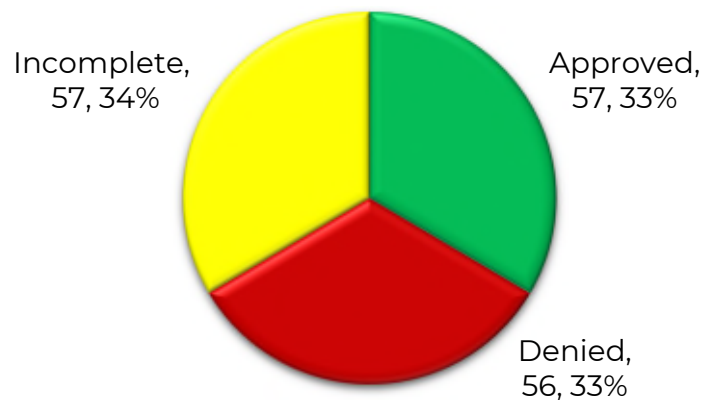
Top Prescriber Specialties of Fibromyalgia Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Fibromyalgia Medications

There were 170 prior authorization requests submitted for fibromyalgia medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	17	25%	38	56%	13	19%	68
Aetna	8	28%	2	7%	19	66%	29
Humana	18	56%	9	28%	5	16%	32
OCH	14	34%	8	20%	19	46%	41
Total	57	33%	57	34%	56	33%	170

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

Market News and Updates^{1,2,3,4}

Anticipated Patent Expiration(s):

- Savella (milnacipran): September 2029
- Tonmya (cyclobenzaprine SL tablet): March 2034

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

- **August 2025:** The FDA approved Tonmya (cyclobenzaprine SL tablet) for the treatment of fibromyalgia through the 505(b)(2) pathway.

Guidelines:

- **European Alliance of Associations for Rheumatology (EULAR):**
 - In 2016, EULAR published the *EULAR Revised Recommendations for the Management of Fibromyalgia*. Within the guidelines, recommended pharmacological therapy includes low-dose amitriptyline, duloxetine, milnacipran, tramadol, pregabalin, or cyclobenzaprine tablets. Selective serotonin reuptake inhibitors (SSRIs), including fluoxetine, received a “weak against” recommendation for the treatment of fibromyalgia. The evaluated trials demonstrated moderate effects on pain and sleep, but no significant effect on fatigue.

Tonmya (Cyclobenzaprine SL Tablet) Product Summary⁵

Therapeutic Class: Skeletal muscle relaxant

Indication(s): Treatment of fibromyalgia in adults

How Supplied: 2.8mg SL tablet

Dosing and Administration:

- The recommended dose is 5.6mg administered SL once daily at bedtime.
 - Tonmya should be initiated at 2.8mg once daily at bedtime for days 1 through 14, then the dose should be increased to 5.6mg once daily at bedtime.
 - The FDA maximum approved dose is 5.6mg once daily.
- The mouth should be moist before SL administration; therefore, the patient should take sips of water before administration.
- Tonmya should not be swallowed whole, cut, crushed, or chewed.
- The maximum recommended dose for geriatric patients 65 years of age and older is 2.8mg.
- In patients with mild hepatic impairment, the maximum recommended daily dose is 2.8mg. Tonmya is not recommended in patients with moderate or severe hepatic impairment.

Efficacy: The efficacy of Tonmya for fibromyalgia was evaluated in 3 randomized, 2-arm, parallel-group, double-blind, placebo-controlled multicenter trials (Trial 1, Trial 2, and Trial 3). All 3 trials had the same study design and enrolled a total of 1,474 patients.

- Key Inclusion Criteria:
 - 18-65 years of age
 - Diagnosis of fibromyalgia based on the 2016 American College of Rheumatology (ACR) criteria
 - Minimum numeric pain rating scale (NPRS) of 4
- Intervention: Randomized to receive bedtime SL treatment of either of the following:
 - Tonmya 2.8mg nightly for the first 2 weeks, then Tonmya 5.6mg through week 14
 - Placebo administered through week 14
- Primary Outcome: The primary endpoint in all 3 trials was the change from baseline to week 14 in the weekly average of daily 24-hour recall pain intensity scores measured by the 11-point (0-10) NPRS.
- Results: Trials 1 and 3 demonstrated a statistically significant reduction in pain intensity scores when compared to placebo; however, Trial 2 showed no statistically significant treatment difference between Tonmya and placebo. The full results of Trial 2 were not listed in the package insert. The results of Trial 1 and Trial 3 were included and are summarized below.
 - Trial 1:
 - The baseline mean NPRS score [standard deviation (SD)] in the Tonmya group was 6.1 (1.06) and the placebo group was 6.0 (1.08).
 - At week 14, the NPRS score (SD) was 4.2 (0.12) in the Tonmya group with a change from baseline of -1.9 (0.12) and 4.6 (0.12) in the placebo group with a change from baseline of -1.5 (0.12).
 - The difference in least squared (LS)-Mean [Standard Error (SE)] in the change from baseline between groups was -0.4 (0.16), [95% confidence interval (CI): -0.7, -0.1, P=0.010].
 - Trial 3:
 - The baseline mean NPRS score (SD) in the Tonmya group was 5.9 (1.05) and the placebo group was 5.9 (1.08).
 - At week 14, the NPRS score (SD) was 4.1 (0.12) in the Tonmya group with a change from baseline of -1.8 (0.12) and 4.7 (0.12) in the placebo group with a change from baseline of -1.2 (0.12).
 - The difference in LS-Mean (SE) in the change from baseline between groups was -0.7 (0.16), (95% CI: -1.0, -0.3, P<0.001).

Cost Comparison

Product	Cost Per Unit	Cost Per 30 Days	Cost Per Year
Tonmya (cyclobenzaprine 2.8mg SL tablet)	\$29.61	\$1,776.60*	\$21,319.20
cyclobenzaprine 10mg tablet (generic)	\$0.02	\$2.40*	\$28.80

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).

SL = sublingual; Unit = tablet

*Cost per 30 days based on the FDA approved maximum dose of 5.6mg per day.

*Cost per 30 days based on the EULAR guideline maximum recommended dose of 40mg per day.

Recommendations

The College of Pharmacy recommends the following changes to the Fibromyalgia Product Based Prior Authorization (PBPA) category based on guidelines and net cost (changes noted in red in the following Tier chart and approval criteria):

1. The removal of fluoxetine from the Tier-1 medications; and
2. The creation of a Special PA Tier; and
3. The prior authorization of Tonmya (cyclobenzaprine SL tablet) with placement into the Special PA Tier with the following additional criteria.

Fibromyalgia Medications		
Tier-1	Tier-2	Special PA
amitriptyline	milnacipran (Savella) – Brand Preferred	cyclobenzaprine SL tablet (Tonmya)
cyclobenzaprine		
duloxetine		
fluoxetine		
pregabalin		
tramadol		

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).

PA = Prior Authorization; SL = sublingual

Fibromyalgia Medications Tier-2 Approval Criteria:

1. Member must have a documented, recent (within the last 6 months) trial of 2 Tier-1 medications (must include 1 trial with duloxetine) at least 3 weeks in duration that did not provide an adequate response or resulted in intolerable adverse effects; or
2. Contraindication(s) to all available lower tiered medications; or
3. Current stabilization on a Tier-2 medication; and
4. Savella is brand preferred. Requests for generic milnacipran will require a patient-specific, clinically significant reason why the brand name cannot be used.

Tonmya (Cyclobenzaprine Sublingual Tablet) Approval Criteria:

1. An FDA approved diagnosis of fibromyalgia; and
2. Member must have a documented, recent (within the last 6 months) trial of 3 lower tiered medications (must include 1 trial with cyclobenzaprine tablets) at least 3 weeks in duration that did not provide an adequate response or resulted in intolerable adverse effects; and
3. Contraindication(s) to all lower tiered products will be taken into consideration; and
4. For the member's cyclobenzaprine tablet trial, the following information must be provided:
 - a. If the member had an improvement in fibromyalgia symptoms, but intolerable adverse effects, please provide detailed information regarding the adverse effects occurring with cyclobenzaprine tablets that are not expected to occur with Tonmya; and
 - b. If the member did not have an improvement in fibromyalgia symptoms, please provide clinical justification as to why Tonmya would be expected to confer a different response since it contains the same active ingredient; and
5. Initial approvals will be for 1 month. Subsequent approvals will be for 1 year if the provider documents the member is responding well to treatment; and
6. A quantity limit of 60 tablets for 30 days will apply.

Utilization Details of Fibromyalgia Medications: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MILNACIPRAN PRODUCTS						
SAVELLA TAB 50MG	110	27	\$54,301.06	\$493.65	4.07	38.29%
SAVELLA TAB 100MG	80	14	\$39,730.93	\$496.64	5.71	28.02%
SAVELLA TAB 12.5MG	21	10	\$9,247.30	\$440.35	2.1	6.52%
MILNACIPRAN TAB 100MG	20	10	\$3,236.96	\$161.85	2	2.28%
SAVELLA TAB 25MG	18	6	\$8,034.97	\$446.39	3	5.67%
SAVELLA MIS TITR PAK	11	9	\$5,051.44	\$459.22	1.22	3.56%
MILNACIPRAN TAB 50MG	11	8	\$2,114.20	\$192.20	1.38	1.49%
MILNACIPRAN TAB 25MG	7	5	\$631.82	\$90.26	1.4	0.45%
MILNACIPRAN TAB 12.5MG	2	1	\$227.56	\$113.78	2	0.16%
SUBTOTAL	280	90	\$122,576.24	\$437.77	3.11	86.44%
CYCLOBENZAPRINE PRODUCTS						
TONMYA SUB 2.8MG	14	8	\$19,226.59	\$1,373.33	1.75	13.56%
SUBTOTAL	14	8	\$19,226.59	\$1,373.33	1.75	13.56%
TOTAL	294	68*	\$141,802.83	\$482.32	4.32	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

SUB = sublingual; TAB = tablet; TITR PAK = titration pack

Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Please note: Tier-1 medications are not included in the utilization data, as they have other FDA approved indications and are reviewed with other categories.

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 09/2026. Last accessed 09/01/2026.

² Tonix Pharmaceuticals. Tonix Pharmaceuticals Announces FDA Approval of Tonmya (Cyclobenzaprine HCL Sublingual Tablets) for the Treatment of Fibromyalgia. Available online at: <https://ir.tonixpharma.com/news-events/press-releases/detail/1585/tonix-pharmaceuticals-announces-fda-approval-of>. Issued 08/15/2025. Last accessed 09/01/2026.

³ U.S. FDA. Tonmya NDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2025/219428Orig1s000ltr.pdf. Issued 08/15/2025. Last accessed 09/18/2026.

⁴ Macfarlane GJ, Kronisch C, Dean LE, et al. EULAR Revised Recommendations for the Management of Fibromyalgia. *Ann Rheum Dis* 2017; 76: 318-328. doi: 10.1136/annrheumdis-2016-209724.

⁵ Tonmya (Cyclobenzaprine Sublingual Tablet) Prescribing Information. Tonix Pharmaceuticals Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219428s000lbl.pdf. Last revised 08/2025. Last accessed 09/18/2026.



Fiscal Year 2026 Annual Review of Anemia Medications and 30-Day Notice to Prior Authorize Aqvesme (Mitapivat)

**Oklahoma Health Care Authority
October 2026**

Current Prior Authorization Criteria

Adakveo (Crizanlizumab-tmca) Approval Criteria:

1. An FDA approved indication to reduce the frequency of vaso-occlusive crises (VOCs) in adult members and in pediatric members 16 years of age and older with sickle cell disease (SCD); and
2. Member must have a history of VOCs; and
3. Adakveo must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of SCD (or an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating SCD); and
4. Prescriber must verify Adakveo will be administered by a trained health care provider. The prior authorization request must indicate how Adakveo will be administered; and
 - a. Adakveo must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
 - b. Adakveo must be shipped via cold chain supply to the member's home and administered by a home health provider, and the member's caregiver must be trained on the proper storage of Adakveo; and
5. A recent (within the last 3 months) weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
6. Approval quantities will be dependent on the member's weight and will include loading doses at week 0 and 2, then subsequent doses every 4 weeks in accordance with package labeling; and
7. Initial approvals will be for the duration of 3 months. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Aranesp (Darbepoetin Alfa) Approval Criteria:

1. An FDA approved indication of 1 of the following:
 - a. Treatment of anemia due to chemotherapy in members with non-myeloid malignancies; or
 - b. Treatment of anemia associated with chronic renal failure; and

- i. For the diagnosis of anemia associated with chronic renal failure: member must not be receiving dialysis [erythropoietin stimulating agents (ESAs) are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately]; and
2. Recent hemoglobin levels must be provided; and
3. Approvals will be for the duration of 16 weeks of therapy. Recent hemoglobin levels must be provided with continuation requests, and further approval may be granted if the member's recent hemoglobin level is <11g/dL.

Casgevy (Exagamglogene Autotemcel) Approval Criteria [Sickle Cell Disease (SCD) Diagnosis]:

1. An FDA approved diagnosis of SCD with recurrent vaso-occlusive crises (VOCs); and
2. Member must be 12 years of age or older; and
3. Member must have evidence of severe disease as demonstrated by 1 of the following (based on prescriber attestation):
 - a. ≥2 severe VOCs per year in the last 2 years; or
 - b. Currently receiving chronic transfusion therapy for recurrent VOCs; and
4. Casgevy must be prescribed by a hematologist with expertise in the treatment of SCD and the administration of Casgevy; and
5. Member has a trial with at least 1 pharmacological treatment option for SCD (i.e., hydroxyurea, L-glutamine, crizanlizumab-tmca); and
6. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
7. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
8. Member must not have previously received treatment with Lyfgenia (lovotibeglogene autotemcel); and
9. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to package labeling; and
10. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Casgevy); and
11. Prescriber must verify the member has discontinued disease modifying therapies 8 weeks prior to mobilization and conditioning; and
12. Prescriber must verify that granulocyte-colony stimulating factor (G-CSF) will not be used for the CD34+ HSC mobilization; and
13. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Casgevy administration; and

14. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Casgevy; and
15. Prescriber must verify male and female 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; and
16. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Casgevy; and
17. Casgevy must be administered at a Casgevy authorized treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Casgevy dose from receipt to storage to administration; and
18. Approvals will be for 1 dose per member per lifetime.

Casgevy (Exagamglogene Autotemcel) Approval Criteria [Transfusion-Dependent Beta Thalassemia (TDT) Diagnosis]:

1. An FDA approved diagnosis of TDT; and
2. Member must be 12 years of age or older; and
3. Member must require regular red blood cell (RBC) transfusions as demonstrated by the following:
 - a. History of $\geq 100\text{mL/kg/year}$ transfusions of packed RBCs in the last 2 years; or
 - b. 10 units of packed RBCs per year in the last 2 years; and
4. Casgevy must be prescribed by a hematologist with expertise in the treatment of TDT and the administration of Casgevy; and
5. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
6. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
7. Member must not have previously received treatment with Zynteglo (betibeglogene autotemcel); and
8. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to 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 Casgevy); and
10. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Casgevy administration; and
11. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Casgevy; and

12. Prescriber must verify male and female 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; and
13. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Casgevy; and
14. Member will not be approved for treatment with Reblozyl (luspatercept-aamt) following Casgevy infusion (current authorizations for luspatercept-aamt will be discontinued upon Casgevy approval); and
15. Casgevy must be administered at a Casgevy authorized treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Casgevy dose from receipt to storage to administration; and
16. Approvals will be for 1 dose per member per lifetime.

Endari (L-Glutamine) Approval Criteria:

1. An FDA approved diagnosis of sickle cell disease (SCD); and
2. Member must be 5 years of age or older; and
3. A trial of hydroxyurea or documentation why hydroxyurea is not appropriate for the member must be provided; and
4. Endari must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of SCD (or in consultation with an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating SCD); and
5. Endari (L-glutamine) is brand preferred. Use of generic L-glutamine will require a patient specific, clinically significant reason why the member cannot use the brand formulation; 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 package labeling; and
7. Initial approvals will be for a duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Enjaymo (Sutimlimab-jome) Approval Criteria:

1. An FDA approved diagnosis of primary cold agglutinin disease confirmed by the following:
 - a. Chronic hemolysis; and
 - b. Positive direct antiglobulin (Coombs) test for C3d; and
 - c. Cold agglutinin titer of ≥ 64 at 4° Celsius; and
2. Member must have 1 or more symptoms associated with cold agglutinin disease (i.e., symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, a major adverse vascular event); and

3. Member has a hemoglobin (Hgb) level $\leq 10\text{g/dL}$; and
4. Member has a bilirubin level above the normal reference range; and
5. Enjaymo must be prescribed by a hematologist (or an advanced care practitioner with a supervising physician who is a hematologist); and
6. Member has not received rituximab within 3 months of initiation and will not be using rituximab concomitantly with Enjaymo; and
7. Prescriber must verify the member has been vaccinated against encapsulated bacteria (e.g., *Neisseria meningitides*, *Streptococcus pneumoniae*, *Haemophilus influenzae*) at least 2 weeks prior to initiation of treatment; and
8. Enjaymo must be administered in a health care setting by a health care provider prepared to manage anaphylaxis; and
9. The prescriber must agree to monitor the member for at least 2 hours following the initial infusion for signs or symptoms of an infusion and/or hypersensitivity reaction and for 1 hour following completion of subsequent infusions; and
10. Prescriber must verify the member has no chronic systemic infections [e.g., hepatitis B, hepatitis C, human immunodeficiency virus (HIV)]; and
11. 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 package labeling; and
12. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to therapy, as confirmed by at least 1 of the following:
 - a. Member has an increase in Hgb level of $\geq 2\text{g/dL}$ from baseline; or
 - b. Member has had normalization of Hgb level to $\geq 12\text{g/dL}$; or
 - c. Member has had a decreased number of RBC transfusions since initiation of therapy.

Epogen (Epoetin Alfa), Procrit (Epoetin Alfa), and Retacrit (Epoetin Alfa-epbx) Approval Criteria:

1. An FDA approved indication of 1 of the following:
 - a. Treatment of anemia due to chemotherapy in members with non-myeloid malignancies; or
 - b. Treatment of anemia in zidovudine-treated human immunodeficiency virus (HIV)-infected members; or
 - c. Reduction of allogeneic blood transfusion(s) in members undergoing surgery; or
 - d. Treatment of anemia associated with chronic renal failure; and
 - i. For the diagnosis of anemia associated with chronic renal failure: member must not be receiving dialysis [erythropoietin stimulating agents (ESAs) are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately]; and

2. Recent hemoglobin levels must be provided; and
3. Approvals will be for the duration of 16 weeks of therapy. Recent hemoglobin levels must be provided with continuation requests, and further approval may be granted if the member's recent hemoglobin level is $<11\text{g/dL}$.

Lyfgenia (Lovotibeglogene Autotemcel) Approval Criteria:

1. Confirmatory genetic testing; and
2. Failure or intolerance to hydroxyurea (defined as being unable to take hydroxyurea per health care professional judgement) at any point in the past; and
3. Age $\geq$ twelve (12) years of age or older at the expected time of gene therapy administration; and
4. Clinically stable and fit for transplantation; and
5. Prescribed Manufacturer CGT Product by or in consultation with a board-certified hematologist with SCD expertise; and
6. Eligible Beneficiary's Treatment Center has a Sickle Cell Center; and
7. Either a or b (based on provider's attestation):
 - a. Currently receiving chronic transfusion therapy for recurrent Vaso-Occlusive Events (VOEs); or
 - b. Experienced ≥ 4 VOEs in previous 24 months as determined by the Eligible Beneficiary's treating clinician; and
8. Member must not have previously received treatment with Casgevy.

Pyrukynd (Mitapivat) Approval Criteria:

1. An FDA approved indication of hemolytic anemia in adults with pyruvate kinase (PK) deficiency confirmed by the following:
 - a. Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, with at least 1 missense variant; and
 - i. Hemoglobin (Hgb) $\leq 10\text{g/dL}$; or
 - ii. Member has received ≥ 6 red blood cell (RBC) transfusions in the past year; and
2. Pyrukynd must be prescribed by a hematologist (or an advanced care practitioner with a supervising physician who is a hematologist); and
3. Member must not have moderate or severe hepatic impairment; and
4. If Pyrukynd is to be discontinued, prescriber must verify dose will be tapered gradually according to package labeling and member will be monitored for signs of acute hemolysis and worsening anemia; and
5. Prescriber must verify that all of the following will be completed as per package labeling:
 - a. Hgb levels will be monitored and dose titration and maintenance dosing will be followed; and

- b. Liver function tests (LFTs) will be monitored prior to initiation, every month for the first 6 months, and as clinically indicated thereafter; and
 - c. If clinically significant increases in LFTs are observed or alanine aminotransferase is >5 times the upper limit of normal, Pyrukynd treatment will be interrupted; and
 - d. Treatment will be discontinued if hepatic injury due to Pyrukynd is suspected; and
- 6. Approvals will be for the duration of 6 months, after which time the prescriber must provide Hgb levels to support a dose increase or continuation of current dose; and
 - 7. Pyrukynd should be discontinued in members who do not show evidence of therapeutic benefit (i.e., Hgb increase of ≥ 1 mg/dL from baseline, reduction in number of transfusions, improvement in hemolysis laboratory assessments) by week 24. Members will be granted short term approval to allow for gradual tapering per package labeling.

Reblozyl (Luspatercept-aamt) Approval Criteria [Beta Thalassemia Diagnosis]:

- 1. An FDA approved indication for the treatment of adult members with beta thalassemia who require regular red blood cell (RBC) transfusions; and
- 2. Member must require regular RBC transfusions (no transfusion-free period >35 days during the prior 6-month period); and
- 3. Member must not have previously received treatment with Zynteglo (betibeglogene autotemcel) or Casgevy (exagamglogene autotemcel); and
- 4. Reblozyl must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of beta thalassemia (or an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating beta thalassemia); and
- 5. Prescriber must verify the member's hemoglobin will be monitored prior to each Reblozyl administration; and
- 6. Prescriber must verify Reblozyl will be administered by a trained health care provider; and
- 7. A recent (within the last 3 months) weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
- 8. Approval quantities will be dependent on member weight and every 3 week dosing in accordance with package labeling; and
- 9. Initial approvals will be for the duration of 4 months. Further approvals will not be granted if the member does not experience a decrease in

transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose of 1.25mg/kg (allows for initial dosing of 6 weeks at 1mg/kg). Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Reblozyl (Luspatercept-aamt) Approval Criteria [Myelodysplastic Syndromes (MDS) Diagnosis]:

1. An FDA approved indication of 1 of the following:
 - a. Treatment of adult members with very low-to-intermediate risk MDS with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with anemia failing an erythropoiesis stimulating agent (ESA) and requiring ≥ 2 red blood cell (RBC) units over 8 weeks; or
 - b. Treatment of adult members with very low-to-intermediate risk MDS with anemia who are ESA-naive and who required ≥ 2 RBC units within the last 8 weeks; and
2. For MDS-RS or MDS/MPN-RS-T:
 - a. Member must have had an inadequate response to prior treatment with an ESA, be intolerant of ESAs, or have a serum erythropoietin level $>200\text{U/L}$; and
 - b. Member must not have been previously treated with a disease modifying agent for the treatment of MDS; and
 - c. Prescriber must verify the member does not have deletion 5q (del 5q); and
3. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber and in accordance with package labeling; and
4. Reblozyl must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in treatment of MDS (or an advanced care practitioner with a supervising physician who is a hematologist, oncologist, or specialist with expertise in treating MDS); and
5. Prescriber must verify the member's hemoglobin will be monitored prior to each Reblozyl administration; and
6. Prescriber must verify Reblozyl will be administered by a trained health care provider; and
7. A recent (within the last 3 months) weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Approval quantities will be dependent on member weight and every 3 week dosing in accordance with package labeling; and
9. Initial approvals will be for the duration of 6 months. Further approvals will not be granted if the member does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3

doses) at the maximum dose of 1.75mg/kg or if unacceptable toxicity occurs at any time. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Siklos (Hydroxyurea Tablets) Approval Criteria:

1. An FDA approved diagnosis of sickle cell anemia; and
2. Member must be 2 years of age or older; and
3. Member must have a history of moderate-to-severe, painful crises; and
4. A trial of hydroxyurea capsules or a patient-specific, clinically significant reason why hydroxyurea capsules are not appropriate for the member must be provided; and
5. Prescriber must agree to monitor blood counts every 2 weeks throughout therapy; and
6. Prescriber must agree to monitor the member for the development of secondary malignancies; and
7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
8. Male and female members of reproductive potential must be willing to use effective contraception during and after treatment with Siklos for at least 6 months after therapy; and
9. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Vafseo (Vadadustat) Approval Criteria:

1. An FDA approved indication for the treatment of anemia due to chronic kidney disease (CKD) in adults; and
2. Member must currently be on dialysis and must have been receiving dialysis for ≥ 3 months; and
3. Prescriber must verify that member does not have uncontrolled hypertension; and
4. Prescriber must verify that member does not have an active malignancy; and
5. Prescriber must verify that liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Vafseo treatment, every month for the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
6. Member's pre-treatment hemoglobin (Hgb) must be $< 11\text{g/dL}$. Recent Hgb levels must be provided; and
7. Member must be hyporesponsive to an erythropoiesis-stimulating agent (ESA) (or have a contraindication to use), defined as:
 - a. No increase in Hgb after 1 month of weight-based dosing; or
 - b. 2 increases in ESA dose up to 50% more than previous dose to maintain current Hgb level; and

8. Prescriber must verify that member will not use Vafseo concomitantly with an ESA or another hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor; and
9. Initial and subsequent approvals will be for the duration of 12 weeks of treatment. Subsequent approvals will be granted if the member meets 1 of the following:
 - a. Member has achieved or maintained a clinically meaningful increase in Hgb of $\geq 1\text{g/dL}$ and the member's Hgb level is $< 12\text{g/dL}$; or
 - b. If the member has not achieved or maintained a clinically meaningful increase in Hgb of $\geq 1\text{g/dL}$, then all of the following will be required:
 - i. The dose will be increased as tolerated to a maximum of 600mg per day; and
 - ii. The member has not received 600mg per day for > 12 weeks without achieving a clinically meaningful increase in hemoglobin of $\geq 1\text{g/dL}$; and
 - iii. The member's Hgb is $< 12\text{g/dL}$; and
10. Vafseo should be discontinued in members who do not show evidence of a clinically meaningful increase in Hgb by 24 weeks.

Xromi (Hydroxyurea Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of sickle cell anemia; and
2. Xromi will not require a prior authorization for members 6 years of age and younger. For members 7 years of age and older, a patient-specific, clinically significant reason why the member cannot use hydroxyurea capsules or tablets must be provided; and
3. Member must have a history of moderate-to-severe, painful crises; and
4. Prescriber must agree to monitor blood counts every 2 weeks throughout therapy; and
5. Prescriber must agree to monitor the member for the development of secondary malignancies; and
6. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
7. Male and female members of reproductive potential must be willing to use effective contraception during and after treatment with Xromi for at least 6 months after therapy; and
8. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Zynteglo (Betibeglogene Autotemcel) Approval Criteria:

1. An FDA approved indication for the treatment of adult and pediatric members with beta thalassemia who require regular red blood cell (RBC) transfusions; and

2. Member must be 4 years of age or older; and
3. Member must weigh ≥ 6 kg; and
4. Member must require regular RBC transfusions as demonstrated by the following:
 - a. History of ≥ 100 mL/kg/year transfusions of packed RBCs in the last 2 years; or
 - b. ≥ 8 transfusions of packed RBCs per year in the last 2 years; and
5. Zynteglo must be prescribed by a hematologist or transplant specialist with expertise in the treatment of beta thalassemia and the administration of Zynteglo; and
6. Member must not have a known and available human leukocyte antigen (HLA) fully-matched sibling donor; and
7. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
8. Member must not have previously received treatment with Casgevy (exagamglogene autotemcel) for the transfusion-dependent beta thalassemia (TDT) indication; and
9. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis; and
10. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Zynteglo); and
11. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Zynteglo administration; and
12. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Zynteglo; and
13. Prescriber must verify male and female 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; and
14. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Zynteglo; and
15. Member will not be approved for treatment with Reblozyl (luspatercept-aamt) following Zynteglo infusion (current authorizations for luspatercept-aamt will be discontinued upon Zynteglo approval); and
16. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at month 6 and month 12 after treatment with Zynteglo, then at least annually thereafter for at least 15 years, and with integration site analysis at months 6, 12, and as warranted; and

17. Zynteglo must be administered at a Zynteglo qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Zynteglo dose from receipt to storage to administration; and
18. Approvals will be for 1 dose per member per lifetime.

Utilization of Anemia Medications: Fiscal Year 2026

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 2025							
FFS	147	604	\$375,625.04	\$621.90	\$18.87	34,729	19,906
Aetna	42	161	\$35,432.04	\$220.07	\$7.24	10,602	4,896
Humana	37	178	\$113,170.36	\$635.79	\$18.59	11,357	6,089
OCH	50	216	\$65,289.11	\$302.26	\$10.50	15,238	6,217
2025 Total	250	1,159	\$589,516.55	\$508.64	\$15.89	71,927	37,108
Fiscal Year 2026							
FFS	146	524	\$151,071.87	\$288.31	\$8.91	30,305	16,959
Aetna	42	173	\$32,891.28	\$190.12	\$5.93	14,999	5,545
Humana	50	202	\$28,840.09	\$142.77	\$4.65	10,420	6,197
OCH	54	220	\$42,058.41	\$191.17	\$5.78	16,394	7,277
2026 Total	259	1,119	\$254,861.65	\$227.76	\$7.08	72,117	35,978
% Change	3.60%	-3.50%	-56.80%	-55.20%	-55.40%	0.30%	-3.00%
Change	9	-40	-\$334,654.90	-\$280.88	-\$8.81	190	-1,130

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	*Total Claims	Total Cost	Cost/Claim	Claims/Member
Fiscal Year 2025					
FFS	29	158	\$859,664.84	\$5,440.92	5.45
Aetna	4	5	14002.4	\$2,800.48	1.25
Humana	3	10	2949.48	\$294.95	3.33
OCH	6	18	25853.2	\$1,436.29	3
2025 Total	38	191	\$902,469.92	\$4,724.97	5.03
Fiscal Year 2026					
FFS	25	160	\$859,296.52	\$5,370.60	6.4
Aetna	3	24	\$9,908.00	\$412.83	8
Humana	2	3	\$12,722.00	\$4,240.67	1.5
OCH	8	36	\$158,896.76	\$4,413.80	4.5
2026 Total	37	223	\$1,040,823.28	\$4,667.37	6.03
% Change	-2.63%	16.75%	15.33%	-1.22%	19.91%
Change	-1	32	\$138,353.36	-\$57.60	1

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

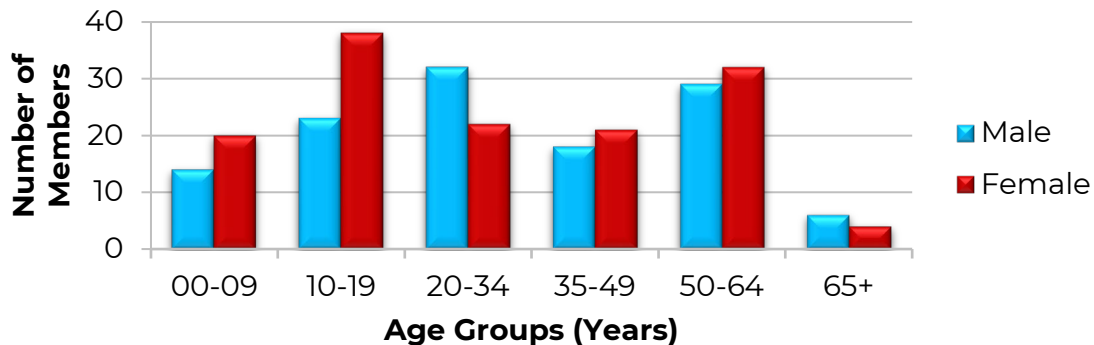
*Total number of unduplicated claims.

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

Fiscal Year 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

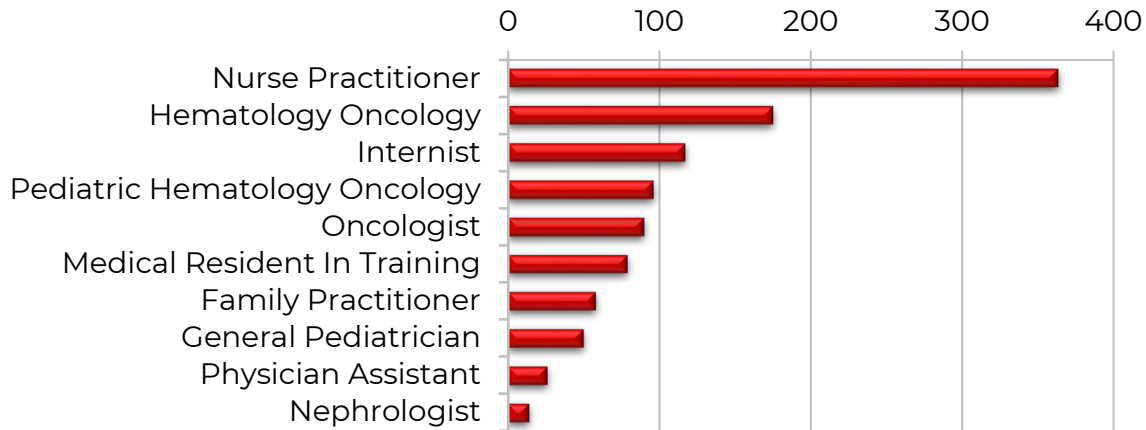
- Aggregate drug rebates collected during fiscal year 2025 for anemia medications totaled \$833,313.65.^Δ Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2025 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2026 are still being collected at this time. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Anemia Medications 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.

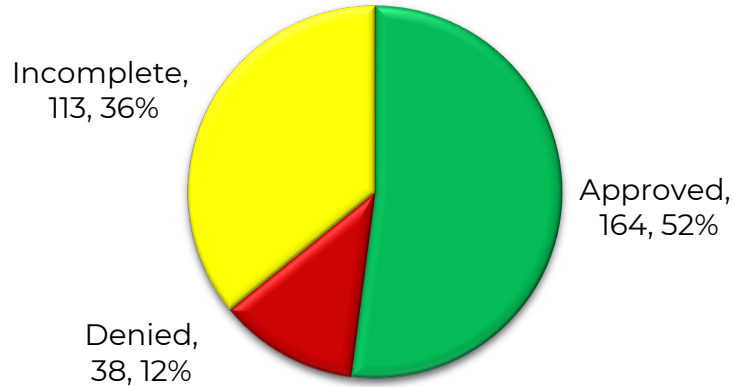
Top Prescriber Specialties of Anemia Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Anemia Medications

There were 315 prior authorization requests submitted for anemia medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	99	48%	98	47%	11	5%	208
Aetna	9	69%	1	8%	3	23%	13
Humana	27	69%	6	15%	6	15%	39
OCH	29	53%	8	15%	18	33%	55
Total	164	52%	113	36%	38	12%	315

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

Market News and Updates^{1,2,3,4,5,6,7}

Anticipated Patent Expiration(s):

- Vafseo (vadadustat tablets): March 2036
- Aqvesme (mitapivat tablets): July 2041
- Pyrukynd (mitapivat tablets): July 2041

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

- **December 2025:** The FDA approved Aqvesme for the treatment of anemia in adults with alpha or beta thalassemia. With this approval, Aqvesme becomes the only FDA-approved medication for anemia in both non-transfusion-dependent and transfusion-dependent alpha or beta thalassemia.
- **July 2026:** The FDA approved Casgevy for an age expansion in patients 2 years of age or older with either sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs) or transfusion-dependent beta thalassemia (TDT). Previously, Casgevy was only FDA approved in patients 12 years of age or older for the same indications.

Pipeline:

- **Etavopivat:** Etavopivat is an investigational pyruvate kinase-R (PKR) activator being studied for the treatment of adults and adolescents with SCD. The safety and efficacy of etavopivat are being studied in the Phase 3 HIBISCUS trial in patients 12 years of age or older with SCD. The trial met both co-primary endpoints demonstrating etavopivat led to superior reduction in the annualized rate of VOCs and superior improvement in hemoglobin (Hgb) response when compared to placebo. Novo Nordisk announced they plan to submit for regulatory approval in the second half of 2026.
- **Mitapivat:** Mitapivat is an oral pyruvate kinase (PK) activator currently FDA approved for PK deficiency and thalassemia and is currently being studied for SCD in patients 16 years of age or older. The Phase 3 RISE UP trial showed that mitapivat demonstrated statistically significant improvements in Hgb response and clinically meaningful reductions in transfusion burden when compared to placebo. A supplemental New Drug Application (sNDA) was submitted to the FDA under the accelerated approval pathway, and a Prescription Drug User Fee Act (PDUFA) date was set for November 1, 2026. If approved, mitapivat would be the first oral PK activator for patients with SCD.
- **Rilzabrutinib:** Rilzabrutinib is a Bruton's tyrosine kinase (BTK) inhibitor currently FDA approved for immune thrombocytopenia (ITP) in adults and is currently being studied for warm autoimmune hemolytic anemia (wAIHA). The FDA granted rilzabrutinib Breakthrough Therapy designation based on data from the ongoing LUMINA 2 Phase 2b trial. The LUMINA 3 Phase 3 trial is currently underway assessing rilzabrutinib

compared to placebo in patients with wAIHA. Additionally, rilzabrutinib has been granted Orphan Drug designation by the FDA for autoimmune hemolytic anemia, IgG4-related disease (IgG4-RD), and SCD. If FDA approved, rilzabrutinib would be the first BTK inhibitor for wAIHA.

Aqvesme (Mitapivat) Product Summary⁸

Therapeutic Class: PK activator

Indication(s): Treatment of anemia in adults with alpha or beta thalassemia

How Supplied: 100mg oral tablet

Dosing and Administration:

- The recommended dose is 100mg twice daily.
- Treatment with Aqvesme is intended to be long-term and should be discontinued if no benefit in hemolytic anemia has been observed, based on the totality of laboratory results and clinical status of the patient, unless there is another explanation for response failure.
- Baseline liver tests including alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, and total bilirubin with fractionation should be assessed before the first Aqvesme dose, every 4 weeks for 24 weeks, and as clinically indicated thereafter.
- See the full *Prescribing Information* for recommendations when drug-induced liver is suspected, interruptions due to non-liver causes, and drug interactions.

Efficacy: Aqvesme was studied in 2 randomized, double-blind, placebo-controlled trials, ENERGIZE-T and ENERGIZE, comparing Aqvesme to placebo.

- Key Inclusion Criteria:
 - 18 years of age or older
 - Documented diagnosis of thalassemia (beta thalassemia with or without alpha-globin gene mutations, Hgb E/beta thalassemia, or alpha thalassemia/Hgb H disease) based on DNA analysis
 - If taking hydroxyurea, must be on a stable dose for ≥ 16 weeks
 - ENERGIZE-T:
 - Transfusion dependent, defined as 6-20 red blood cell (RBC) units transfused and ≤ 6 -week transfusion-free period during the 24-week period before randomization
 - ENERGIZE:
 - Non-transfusion-dependent, defined as ≤ 5 RBC units during the 24-week period before randomization
 - No RBC transfusions ≤ 8 weeks before providing informed consent

- No RBC transfusions during the screening period
- Hgb concentration $\leq 10\text{g/dL}$, based on an average of at least 2 Hgb concentration measurements
- Key Exclusion Criteria:
 - Patients with a documented history of homozygous or heterozygous sickle Hgb or Hgb C
 - Prior exposure to gene therapy or prior bone marrow or stem cell transplantation
 - Currently receiving treatment with Reblozyl or hematopoietic stimulating agents
- Intervention(s): Patients were randomized to receive Aqvesme 100mg twice daily or placebo for 48 weeks in ENERGIZE-T and 24 weeks in ENERGIZE.
- Primary Endpoint(s):
 - ENERGIZE-T: Transfusion reduction response defined as $\geq 50\%$ reduction from baseline in RBC units transfused in any consecutive 12 weeks, with a reduction of at least 2 units
 - ENERGIZE: Hgb response defined as $\geq 1\text{g/dL}$ increase in average Hgb concentration from week 12–week 24 vs. baseline
- Results:
 - ENERGIZE-T:
 - Transfusion reduction response was achieved by 52 patients in the Aqvesme group vs. 11 for placebo [adjusted rate difference: 17.6%; 95% confidence interval (CI): 8, 27.2; $P=0.0003$].
 - ENERGIZE:
 - Hgb response was achieved by 55 patients in the Aqvesme group vs. 1 for placebo (adjusted rate difference: 40.9%; 95% CI: 32, 49.8; $P<0.0001$).

Cost: The Wholesale Acquisition Cost (WAC) of Aqvesme is \$582.32 per tablet. This would result in an estimated cost of \$32,609.92 per 28 days or \$423,928.96 per year based on recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Aqvesme (mitapivat) with the following criteria and recommends updating the Reblozyl (luspatercept-aamt) approval criteria based on the FDA approval of Aqvesme (changes shown in red):

Aqvesme (Mitapivat) Approval Criteria:

1. An FDA approved indication for the treatment of anemia with alpha or beta thalassemia; and
2. Member must be 18 years of age or older; and

3. Member must have 1 of the following:
 - a. A baseline hemoglobin (Hgb) level of $\leq 10\text{g/dL}$; or
 - b. Transfusion-dependent thalassemia requiring regular red blood cell (RBC) transfusions as defined by the following:
 - i. Member has received at least 6 RBC units within the preceding 24 weeks; and
 - ii. Member has not had any transfusion-free period >35 days within the preceding 24 weeks; and
4. Aqvesme must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of alpha or beta thalassemia (or an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating alpha or beta thalassemia); and
5. Member must not have liver cirrhosis; and
6. Prescriber must evaluate the potential for drug interactions, including the need for increased monitoring according to package labeling, prior to and during treatment with Aqvesme; and
7. For transfusion-dependent beta thalassemia, member must not have previously received treatment with Zynteglo (betibeglogene autotemcel) or Casgevy (exagamglogene autotemcel); and
8. Aqvesme will not be approved for concomitant use with Reblozyl (luspatercept-aamt); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the provider documents the member is responding well to therapy (i.e., reduction in number of transfusions or RBC units, Hgb increase, improvements in quality of life or clinical status); and
10. Aqvesme should be discontinued in members who do not show evidence of therapeutic benefit in hemolytic anemia.

Reblozyl (Luspatercept-aamt) Approval Criteria [Beta Thalassemia Diagnosis]:

1. An FDA approved indication for the treatment of adult members with beta thalassemia who require regular red blood cell (RBC) transfusions; and
2. Member must require regular RBC transfusions (no transfusion-free period >35 days during the prior 6-month period); and
3. Member must not have previously received treatment with Zynteglo (betibeglogene autotemcel) or Casgevy (exagamglogene autotemcel); and
4. Reblozyl will not be approved for concomitant use with Aqvesme (mitapivat); and
5. Reblozyl must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of beta thalassemia (or an

advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating beta thalassemia); and

6. Prescriber must verify the member's hemoglobin will be monitored prior to each Reblozyl administration; and
7. Prescriber must verify Reblozyl will be administered by a trained health care provider; and
8. A recent (within the last 3 months) weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
9. Approval quantities will be dependent on member weight and every 3 week dosing in accordance with package labeling; and
10. Initial approvals will be for the duration of 4 months. Further approvals will not be granted if the member does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose of 1.25mg/kg (allows for initial dosing of 6 weeks at 1mg/kg). Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Additionally, the College of Pharmacy recommends updating the Casgevy (exagamglogene autotemcel) and Zynteglo (betibeglogene autotemcel) approval criteria based on the approval of Aqvesme (mitapivat) and the FDA approved age expansion for Casgevy (changes shown in red):

Casgevy (Exagamglogene Autotemcel) Approval Criteria [Sickle Cell Disease (SCD) Diagnosis]:

1. An FDA approved diagnosis of SCD with recurrent vaso-occlusive crises (VOCs); and
2. Member must be ~~2~~ 12 years of age or older; and
3. Member must have evidence of severe disease as demonstrated by 1 of the following (based on prescriber attestation):
 - a. ≥ 2 severe VOCs per year in the last 2 years; or
 - b. Currently receiving chronic transfusion therapy for recurrent VOCs; and
4. Casgevy must be prescribed by a hematologist with expertise in the treatment of SCD and the administration of Casgevy; and
5. Member has a trial with at least 1 pharmacological treatment option for SCD (i.e., hydroxyurea, L-glutamine, crizanlizumab-tmca); and
6. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
7. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
8. Member must not have previously received treatment with Lyfgenia (lovotibeglogene autotemcel); and

9. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to package labeling; and
10. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Casgevy); and
11. Prescriber must verify the member has discontinued disease modifying therapies 8 weeks prior to mobilization and conditioning; and
12. Prescriber must verify that granulocyte-colony stimulating factor (G-CSF) will not be used for the CD34+ HSC mobilization; and
13. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Casgevy administration; and
14. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Casgevy; and
15. Prescriber must verify male and female 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; and
16. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Casgevy; and
17. Casgevy must be administered at a Casgevy authorized treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Casgevy dose from receipt to storage to administration; and
18. Approvals will be for 1 dose per member per lifetime.

Casgevy (Exagamglogene Autotemcel) Approval Criteria [Transfusion-Dependent Beta Thalassemia (TDT) Diagnosis]:

1. An FDA approved diagnosis of TDT; and
2. Member must be 2 ~~12~~ years of age or older; and
3. Member must require regular red blood cell (RBC) transfusions as demonstrated by the following:
 - a. History of ≥ 100 mL/kg/year transfusions of packed RBCs in the last 2 years; or
 - b. 10 units of packed RBCs per year in the last 2 years; and
4. Casgevy must be prescribed by a hematologist with expertise in the treatment of TDT and the administration of Casgevy; and
5. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
6. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and

7. Member must not have previously received treatment with Zynteglo (betibeglogene autotemcel); and
8. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to 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 Casgevy); and
10. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Casgevy administration; and
11. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Casgevy; and
12. Prescriber must verify male and female 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; and
13. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Casgevy; and
14. Member will not be approved for treatment with Reblozyl (luspatercept-aamt) or Aqvesme (mitapivat) following Casgevy infusion (current authorizations for luspatercept-aamt or mitapivat will be discontinued upon Casgevy approval); and
15. Casgevy must be administered at a Casgevy authorized treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Casgevy dose from receipt to storage to administration; and
16. Approvals will be for 1 dose per member per lifetime.

Zynteglo (Betibeglogene Autotemcel) Approval Criteria:

1. An FDA approved indication for the treatment of adult and pediatric members with beta thalassemia who require regular red blood cell (RBC) transfusions; and
2. Member must be 4 years of age or older; and
3. Member must weigh ≥ 6 kg; and
4. Member must require regular RBC transfusions as demonstrated by the following:
 - a. History of ≥ 100 mL/kg/year transfusions of packed RBCs in the last 2 years; or
 - b. ≥ 8 transfusions of packed RBCs per year in the last 2 years; and

5. Zynteglo must be prescribed by a hematologist or transplant specialist with expertise in the treatment of beta thalassemia and the administration of Zynteglo; and
6. Member must not have a known and available human leukocyte antigen (HLA) fully-matched sibling donor; and
7. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
8. Member must not have previously received treatment with Casgevy (exagamglogene autotemcel) for the transfusion-dependent beta thalassemia (TDT) indication; and
9. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis; and
10. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Zynteglo); and
11. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Zynteglo administration; and
12. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Zynteglo; and
13. Prescriber must verify male and female 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; and
14. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Zynteglo; and
15. Member will not be approved for treatment with Reblozyl (luspatercept-aamt) or Aqvesme (mitapivat) following Zynteglo infusion (current authorizations for luspatercept-aamt or mitapivat will be discontinued upon Zynteglo approval); and
16. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at month 6 and month 12 after treatment with Zynteglo, then at least annually thereafter for at least 15 years, and with integration site analysis at months 6, 12, and as warranted; and
17. Zynteglo must be administered at a Zynteglo qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Zynteglo dose from receipt to storage to administration; and
18. Approvals will be for 1 dose per member per lifetime.

Utilization Details of Anemia Medications: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HYDROXYUREA PRODUCTS						
HYDROXYUREA CAP 500MG	866	215	\$17,714.08	\$20.46	4.03	6.95%
XROMI SOL 100MG/ML	83	17	\$59,063.35	\$711.61	4.88	23.17%
DROXIA CAP 400MG	25	10	\$1,456.58	\$58.26	2.5	0.57%
SIKLOS TAB 1000MG	16	3	\$14,918.30	\$932.39	5.33	5.85%
DROXIA CAP 300MG	11	6	\$591.96	\$53.81	1.83	0.23%
DROXIA CAP 200MG	6	3	\$262.02	\$43.67	2	0.10%
SIKLOS TAB 100MG	2	2	\$1,237.16	\$618.58	1	0.49%
SUBTOTAL	1,009	256	\$95,243.45	\$94.39	3.94	37.37%
EPOETIN ALFA PRODUCTS						
EPOGEN INJ 10,000U/ML	20	5	\$5,654.60	\$282.73	4	2.22%
EPOGEN INJ 4,000U/ML	15	4	\$3,529.81	\$235.32	3.75	1.38%
RETACRIT INJ 20,000U/ML	14	2	\$4,171.36	\$297.95	7	1.64%
PROCRIT INJ 10,000U/ML	10	2	\$8,904.40	\$890.44	5	3.49%
PROCRIT INJ 20,000U/ML	5	3	\$5,944.33	\$1,188.87	1.67	2.33%
RETACRIT INJ 40,000U/ML	4	3	\$2,993.32	\$748.33	1.33	1.17%
EPOGEN INJ 20,000U/ML	4	1	\$2,421.02	\$605.26	4	0.95%
PROCRIT INJ 40,000U/ML	3	2	\$12,475.39	\$4,158.46	1.5	4.89%
RETACRIT INJ 10,000U/ML	1	1	\$630.85	\$630.85	1	0.25%
RETACRIT INJ 2,000U/ML	1	1	\$216.47	\$216.47	1	0.08%
SUBTOTAL	77	24	\$46,941.55	\$609.63	3.21	18.42%
DARBEPOETIN ALFA PRODUCTS						
ARANESP INJ 150MCG	9	2	\$41,874.69	\$4,652.74	4.5	16.43%
ARANESP INJ 40MCG	7	3	\$5,447.17	\$778.17	2.33	2.14%
ARANESP INJ 200MCG	6	1	\$9,356.46	\$1,559.41	6	3.67%
ARANESP INJ 100MCG	6	1	\$17,174.82	\$2,862.47	6	6.74%
ARANESP INJ 60MCG	1	1	\$1,869.01	\$1,869.01	1	0.73%
SUBTOTAL	29	8	\$75,722.15	\$2,611.11	3.63	29.71%
L-GLUTAMINE PRODUCTS						
ENDARI POW 5GM	3	2	\$4,337.09	\$1,445.70	1.5	1.70%
SUBTOTAL	3	2	\$4,337.09	\$1,445.70	1.5	1.70%
MITAPIVAT PRODUCTS						
AQVESME TAB 100MG	1	1	\$32,617.41	\$32,617.41	1	12.80%
SUBTOTAL	1	1	\$32,617.41	\$32,617.41	1	12.80%
TOTAL	1,119	259*	\$254,861.65	\$227.76	4.32	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CAP = capsule; INJ = injection; POW = powder; SOL = solution; SUSP = suspension; TAB = tablet; U = unit

Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS*	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ADAKVEO INJ J0791	87	10	\$585,769.00	\$6,732.98	8.7
ARANESP INJ J0881	55	16	\$36,024.76	\$655.00	3.44
REBLOZYL INJ J0896	48	4	\$409,015.00	\$8,521.15	12
PROCRT INJ J0885	33	7	\$10,014.52	\$303.47	4.71
TOTAL	223	37	\$1,040,823.28	\$4,667.37	6.03

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated claims.

*Total number of unduplicated utilizing members.

INJ = injection

Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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 09/2026. Last accessed 09/21/2026.

² Agios Pharmaceuticals. U.S. FDA Approves Agios' Aqvesme (Mitapivat) for the Treatment of Anemia in Adults with Alpha- or Beta-Thalassemia. Available online at: <https://investor.agios.com/news-releases/news-release-details/us-fda-approves-agios-aqvesmetm-mitapivat-treatment-anemia>. Issued 12/23/2025. Last accessed 09/21/2026.

³ U.S. FDA. FDA Approves First Gene Therapy for Young Children with Sickle Cell Disease. Available online at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-young-children-sickle-cell-disease>. Issued 07/01/2026. Last accessed 09/21/2026.

⁴ Novo Nordisk. Etavopivat is the First in A New Class of Drugs to Meet Both Co-Primary Endpoints in the Phase 3 HIBISCUS Trial, Substantially Reducing Vaso-Occlusive Crisis Events and Improving Haemoglobin Response in Sickle Cell Disease. Available online at: <https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=916533>. Issued 04/20/2026. Last accessed 09/21/2026.

⁵ Agios Pharmaceuticals. Agios Showcases RISE UP Phase 3 Results at EHA 2026 Plenary Session Reinforcing Strong Anti-Hemolytic Profile of Mitapivat in Sickle Cell Disease. Available online at: <https://investor.agios.com/news-releases/news-release-details/agios-showcases-rise-phase-3-results-eha-2026-plenary-session>. Issued 06/13/2026. Last accessed 09/21/2026.

⁶ Agios Pharmaceuticals. U.S. FDA Grants Priority Review to Agios' sNDA for Mitapivat in Sickle Cell Disease. Available online at: <https://investor.agios.com/news-releases/news-release-details/us-fda-grants-priority-review-agios-snda-mitapivat-sickle-cell>. Issued 07/07/2026. Last accessed 09/21/2026.

⁷ Sanofi. Sanofi's Rilzabrutinib Designated Breakthrough Therapy in the US and Orphan Drug in Japan for the Treatment of Warm Autoimmune Hemolytic Anemia. Available online at: <https://www.sanofi.com/en/media-room/press-releases/2026/2026-02-09-06-00-00-3234232>. Issued 02/09/2026. Last accessed 09/21/2026.

⁸ Aqvesme (Mitapivat) Prescribing Information. Agios. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/216196Orig1s003lbl.pdf. Last revised 12/2025. Last accessed 09/21/2026.



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: October 5, 2026

FDA Seeks Public Input to Support Ibogaine Research

The FDA announced a request for information (RFI) describing approaches the agency is considering for the design of early-phase clinical trials of ibogaine drug products and seeking public input on those approaches. The RFI seeks comments, data, and information on specific protocol elements relevant to ibogaine drug development, including dose selection and escalation, care setting, safety monitoring, eligibility criteria, stopping rules and safety oversight. This RFI marks the latest FDA action to advance President Trump's April 2026 executive order on Accelerating Medical Treatments for Serious Mental Illness, which directed agencies to accelerate research into psychedelic medicine.

The FDA is seeking comments, data and information in four primary areas, general study design, including appropriate patient populations; dose selection and escalation, including the proposed use of small, sequential dose-ascending groups and a starting dose justified by available data and not exceeding 10 mg/kg; safety considerations, including monitoring for cardiac and neurologic adverse events and other safeguards for clinical trials; and ethical and oversight considerations, including informed consent and appropriate independent safety oversight.

The FDA recognizes the seriousness of the conditions and unmet needs that patients seeking ibogaine treatments face. The information received through this RFI may help the agency better understand the potential uses, benefits and risks of ibogaine drug products and inform approaches to drug development.

The FDA has been working across the federal government to support the responsible development of ibogaine drug products through careful evidence-based processes. In July 2026, the FDA issued its finalized guidance for industry, Psychedelic Drugs: Considerations for Clinical Investigations, which provides general considerations for sponsors developing psychedelic drugs. The FDA has also allowed an early-phase clinical study of noribogaine hydrochloride, a derivative of ibogaine, to proceed under an Investigational New Drug application as a potential treatment for alcohol use disorder.

As part of the approach to advance psychedelic drug development, U.S. Department of Health and Human Services (HHS), through the Advanced Research Projects Agency for Health (ARPA-H), is funding a program to collect safety and efficacy data through early-phase clinical trials, and the

National Institute on Drug Abuse (NIDA) is funding research on ibogaine for the potential treatment of opioid use disorder (OUD). Based on available data and the seriousness of the conditions, HHS is prioritizing two initial populations for federally supported research: adults with OUD and adults with post-traumatic stress disorder (PTSD).

The public will have 45 days following publication in the Federal Register to submit comments, data or information to the docket. Stakeholders are encouraged to submit comments electronically at [regulations.gov](https://www.regulations.gov) by searching for Docket No. FDA-2026-N-10429. Written/paper submissions may also be sent to: Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

The comment period closes Friday, November 20, 2026. Late comments will not be considered.

FDA NEWS RELEASE

For Immediate Release: September 28, 2026

FDA Approves First Treatment for MCT8 Deficiency

The FDA approved Emcitate (tiratricol) tablets for oral suspension to treat peripheral thyrotoxicosis in patients with MCT8 deficiency, also known as Allan-Herndon-Dudley syndrome. Emcitate is the first therapy approved by the FDA to treat symptoms of this very rare, devastating genetic disease. This approval reflects the FDA's dedication to patients with rare genetic diseases, many of whom have serious unmet medical needs.

MCT8 deficiency is a rare genetic disorder that primarily affects males. The condition is caused by a faulty gene that provides instructions for making the MCT8 transporter, a critical protein responsible for carrying thyroid hormone into the brain. Because thyroid hormone cannot cross the blood-brain barrier without the MCT8 transporter, the brain receives too little of this hormone, while excessive levels of the hormone build up in the bloodstream. Many patients with MCT8 deficiency experience a range of debilitating effects, including the inability to walk or sit independently, absent or severely limited speech, intellectual disability, feeding difficulties and chronic stress on the heart and metabolism.

The effectiveness of Emcitate was evaluated in two clinical studies in patients ranging in age from infants to adults, including an international, multi-center, randomized, placebo-controlled trial (NCT05579327) and a longer-term open-label study. Across both studies, patients treated with Emcitate had reductions in excess thyroid hormone levels in the bloodstream and improvements in cardiovascular and metabolic symptoms impacted by thyroid levels, such as systolic blood pressure and heart rate.

Emcitate is taken once daily as a liquid suspension, either by mouth or through a feeding tube for patients who have difficulty swallowing, making it accessible for patients with a wide range of abilities. The most common side effects were diarrhea, vomiting, rash and excessive sweating. Patients taking

another thyroid medication should talk to their healthcare provider before starting Emcitate, as the two should not be used together.

Emcitate was granted Orphan Drug, Rare Pediatric Disease, Fast Track and Breakthrough Therapy designations as well as Priority Review. The approval of Emcitate was granted to Egetis Therapeutics US Inc.

FDA NEWS RELEASE

For Immediate Release: September 17, 2026

FDA Approves First Gene Therapy for Pediatric Patients with Sanfilippo Syndrome Type A

The FDA approved Fayuvi (rebisufligene etisparvovec-hopf), the first treatment for pediatric patients with mucopolysaccharidosis type IIIA (MPS IIIA), also known as Sanfilippo syndrome type A. MPS IIIA is a rare inherited disease that progressively damages the brain and nervous system, causing children to lose cognitive, language, and other developmental abilities over time. Until this approval, treatment was limited to managing symptoms as there was no FDA-approved therapy designed to change the underlying course of the disease.

Fayuvi is a one-time, intravenous (IV) gene therapy that uses a modified, non-infectious virus called an adeno-associated virus serotype 9 (AAV9) to deliver a working copy of the *SGSH* gene into the patient's cells. This enables the body's cells to produce sulfamidase, the enzyme that is missing or deficient in MPS IIIA, allowing heparan sulfate to be properly broken down in lysosomes and reducing its harmful buildup throughout the body and brain.

The safety and effectiveness of Fayuvi were evaluated in an open-label, single-arm, multicenter clinical study in pediatric patients with MPS IIIA. The study measured mean changes in cognitive scores in patients between the ages of 2 and 5 years. Patients treated with Fayuvi maintained or improved cognitive function compared to an untreated historical control cohort. This mean change represented a meaningful divergence from the expected natural disease course of plateau and decline during this critical developmental window.

The safety of Fayuvi was evaluated in pediatric patients who received a single IV infusion across clinical studies. The most common adverse reactions reported in >5% of patients were increases in liver enzymes (AST), nausea and vomiting, fever, decreased appetite, decreased white blood cell and platelet counts, and increased amylase. Important safety warnings include the risk of thrombotic microangiopathy (TMA). As with other AAV-based gene therapies, there is a potential long-term risk that the inserted genetic material could integrate into the genome and potentially lead to tumor development.

Fayuvi is administered in a healthcare setting equipped to manage infusion reactions. All patients receive corticosteroid treatment the day before the infusion and continue for a minimum of 8 weeks.

Fayuvi was granted Orphan Drug and Fast Track, and Breakthrough Therapy designations. The FDA granted Fayuvi approval to Ultragenyx Pharmaceutical, Inc.

FDA NEWS RELEASE

For Immediate Release: September 15, 2026

FDA Launches Expedited IND Pilot, Begins Accepting Applications

The FDA announced the final design of the Expedited Investigational New Drug (IND) Pilot. Accelerating clinical trial timelines and eliminating regulatory hurdles to maintain American leadership in global medical innovation is a core priority for the Trump Administration. Driven by the President's directive, the pilot seeks to accelerate the time it takes from identifying a drug to initiating a first-in-human clinical trial by partnering drug companies with qualified research institutions (QRI) that have scientific expertise to support efficient development of IND applications. The FDA will accept applications to participate in the pilot until October 30, 2026.

Currently, first-in-human clinical trials may take up to 2 years to complete in the United States. The same types of trials are completed much faster in China and Australia, threatening America's leadership in scientific innovation. As a key component of the Trump Administration's healthcare modernization efforts and as part of the U.S. Department of Health and Human Services' Operation TrialBlazer, the FDA has committed to proactively addressing these clinical development challenges through dedicated initiatives such as the Expedited IND Pilot.

First-in-human trials are essential to determine proper dosing, absorption, and other key factors for potential approval of the drug in humans.

The QRIs selected for the pilot will bring specialized and substantial scientific expertise to the IND application preparation process allowing the FDA to review and accept individual components on a rolling review during the pre-IND phase, rather than waiting for all components to begin review. The pilot will help test whether this allows issues with an IND application to be identified and resolved in real time sooner, thereby reducing the risk of the FDA placing the first-in-human clinical trial protocol on hold during the 30-day IND, and making the path from scientific discovery to first-in-human trial faster, more predictable, and more collaborative.

Ultimately, the pilot will generate evidence to inform potential future approaches to modernizing FDA's support for early-stage clinical development. For example, this pilot may inform future policy initiatives which may result in a formal accreditation model that would recognize QRIs demonstrating strong scientific and regulatory judgment, aimed at creating a sustainable, high-quality network of institutions to support drug development and accelerate the time to first-in-human trials for drug sponsors.

The pilot also encourages coordination of activities that may occur alongside IND development and review, such as Institutional Review Board review and clinical trial site activation, where appropriate. By supporting earlier planning and more coordinated development activities, the pilot aims to reduce unnecessary delays between the point at which a drug sponsor begins preparing for an IND submission and the start of first-in-human studies.

The FDA retains full regulatory authority throughout the program, including responsibility for determining whether a clinical investigation may proceed, whether a clinical hold should be imposed, and all other regulatory oversight.

The FDA's Expedited IND Pilot webpage provides detailed information on program eligibility criteria, conflict of interest requirements, and the selection criteria the agency will use to determine participation. Drug sponsors and prospective QRIs will apply as a pair with drug sponsors submitting applications to the FDA.

The application period will be open until October 30, 2026. Applications will undergo review by FDA scientific experts. FDA expects that 8–10 Sponsor-QRI pairs will be selected to participate in the initial pilot cohort.

FDA NEWS RELEASE

For Immediate Release: September 4, 2026

FDA Grants Accelerated Approval to a New Breast Cancer Treatment

The FDA expanded treatment options for adult patients with advanced breast cancer, reflecting the FDA's commitment to advancing medical innovation and getting new treatments to patients who need them. FDA granted accelerated approval to Etcamah (camizestrant) in combination with a CDK4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer upon detection of estrogen receptor-1 (*ESR1*) mutation during aromatase inhibitor and CDK 4/6 inhibitor therapy, based on an FDA-authorized test.

ESR1 mutations are acquired resistance mutations that a tumor may develop during treatment with an aromatase inhibitor, a type of endocrine therapy that is a common front-line treatment for locally advanced or metastatic breast cancer. At the diagnosis of HR-positive metastatic breast cancer, fewer than 5% of patients will have this tumor mutation. After disease progression on an aromatase inhibitor, nearly 40% of patients will have this tumor mutation.

The accelerated approval program allows for earlier approval of drugs that treat serious conditions and fill an unmet medical need based on surrogate or intermediate endpoints. In this case, accelerated approval of Etcamah was granted based on how long patients lived without their disease

worsening, measured from the point when the resistance mutation was first detected in the blood. Since it is not yet confirmed whether intervening at this point, rather than at the time of confirmed disease progression, translates into a clinically meaningful benefit, the FDA has required confirmatory studies to verify and describe clinical benefit.

Circulating tumor DNA is made up of tiny pieces of tumor DNA released into the blood, which can allow for earlier molecular detection of resistance mutations.

To ensure precise patient matching, the FDA also authorized the Guardant360 CDx assay as a companion diagnostic device to identify patients with breast cancer with *ESR1* mutations for treatment with camizestrant. Efficacy was evaluated in a clinical trial to assess switching to Etcamah, an oral tablet, in combination with a CDK4/6 inhibitor versus continuing an aromatase inhibitor in combination with a CDK4/6 inhibitor. Estimated median progression-free survival was 16 months in the Etcamah and CDK4/6 inhibitor arm and 9.2 months in the aromatase inhibitor and CDK4/6 inhibitor arm.

The prescribing information includes a boxed warning for the risk of irregular heart rhythm when Etcamah is taken together with certain other medications, as well as warnings and precautions for an abnormally slow heart rate and potential harm to an unborn baby. Full prescribing information for Etcamah will be posted on Drugs@FDA.

On April 30, 2026, the FDA convened the Oncologic Drugs Advisory Committee for this application. The accelerated approval was granted to AstraZeneca.

FDA NEWS RELEASE

For Immediate Release: September 3, 2026

FDA Approves First Drug to Treat Alexander Disease

The FDA has approved Zanvastro (zilganersen) injection for the treatment of Alexander disease in pediatric and adult patients. Zanvastro is the first FDA-approved treatment for Alexander disease and the first therapy to directly target the protein buildup that drives the disease.

Alexander disease is a rare, progressive neurological disorder caused by mutations in the gene that produces glial fibrillary acidic protein (GFAP). When this protein is abnormal, it accumulates in the brain's supportive cells, causing damage to the nervous system over time. The disease affects less than 1 in a million people and can cause a wide range of serious and potentially life-threatening problems, including seizures, loss of developmental milestones, difficulty walking, muscle weakness, and increased pressure in the brain.

Zanvastro is an antisense oligonucleotide, a type of medicine that works by reducing the production of the abnormal GFAP protein before it

can accumulate and cause further damage. It is administered as an injection into the spinal canal every 3 months by a trained healthcare professional. The efficacy and safety of Zinvastro were evaluated in a multicenter, randomized, controlled clinical study, NCT04849741, enrolling 49 pediatric and adult patients with Alexander disease 2 years of age and older, and in an open-label sub-study of 4 patients less than 2 years of age. Because Alexander disease is so rare and can affect patients across a wide range of ages, the FDA evaluated the available evidence in support of an indication covering patients from infancy through adulthood.

In patients aged 5 years and older who had measurable difficulties with walking at baseline, those treated with Zinvastro showed significantly better walking speed at 61 weeks compared to those who received no treatment. In children aged 2 to 4 years, where walking speed is not a reliable measure of progress, a broader assessment of motor skills including standing, walking, running, and jumping was used instead. Children treated with Zinvastro showed improvement on this measure while those in the control group declined.

For patients under 2 years of age, direct clinical trial data were limited by the rarity of the disease and lack of concurrent control. Pharmacokinetic modeling confirmed that drug levels in this age group are expected to be similar to those seen in older children at the same dose. This observation was also supported by safety data from 4 patients under 2 years of age treated in the study, as well as the safety data observed in the older pediatric patients. This approach supported extending the indication to the youngest patients while maintaining the evidentiary standards required to support approval.

The most common side effects of Zinvastro are vomiting, back pain, cough, headache, and post-lumbar puncture syndrome. Patients and caregivers should inform their healthcare provider if symptoms consistent with meningitis develop, as aseptic meningitis has been reported in patients treated with Zinvastro. Patients and providers should carefully review the full prescribing information when making treatment decisions.

Zinvastro received Orphan Drug, Fast Track, Breakthrough Therapy, and Rare Pediatric Disease and Priority Review Voucher designations, reflecting the serious and rare nature of Alexander disease, and FDA's commitment to rare disease drug development.

The approval of Zinvastro for the treatment of Alexander disease was granted to Ionis Pharmaceuticals, Inc.

Current Drug Shortages Index (as of October 6, 2026):

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>.

Amino Acid Injection	<i>Currently in Shortage</i>
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	<i>Currently in Shortage</i>
Atropine Sulfate Injection	<i>Currently in Shortage</i>
Azacitidine Injection	<i>Currently in Shortage</i>
Bacitracin Ophthalmic Ointment	<i>Currently in Shortage</i>
Bupivacaine Hydrochloride Injection	<i>Currently in Shortage</i>
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	<i>Currently in Shortage</i>
Carboplatin Injection	<i>Currently in Shortage</i>
Cefotaxime Sodium Powder, for Solution	<i>Currently in Shortage</i>
Clindamycin Phosphate Injection	<i>Currently in Shortage</i>
Clonazepam Tablet	<i>Currently in Shortage</i>
Conivaptan Hydrochloride Injection	<i>Currently in Shortage</i>
Cromolyn Sodium Concentrate	<i>Currently in Shortage</i>
Desmopressin Acetate Spray	<i>Currently in Shortage</i>
Dexamethasone Sodium Phosphate Injection	<i>Currently in Shortage</i>
Dexmedetomidine Hydrochloride Injection	<i>Currently in Shortage</i>
Dextrose Monohydrate 10% Injection	<i>Currently in Shortage</i>
Dextrose Monohydrate 5% Injection	<i>Currently in Shortage</i>
Dextrose Monohydrate 50% Injection	<i>Currently in Shortage</i>
Dextrose Monohydrate 70% Injection	<i>Currently in Shortage</i>
Dobutamine Hydrochloride Injection	<i>Currently in Shortage</i>
Dopamine Hydrochloride Injection	<i>Currently in Shortage</i>
Echothiophate Iodide Ophthalmic Solution	<i>Currently in Shortage</i>
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	<i>Currently in Shortage</i>
Etomidate Injection	<i>Currently in Shortage</i>
Fentanyl Citrate Injection	<i>Currently in Shortage</i>
Flurazepam Hydrochloride Capsule	<i>Currently in Shortage</i>
Furosemide Injection	<i>Currently in Shortage</i>
Furosemide Oral Solution	<i>Currently in Shortage</i>
Heparin Sodium Injection	<i>Currently in Shortage</i>
Hydromorphone Hydrochloride Injection	<i>Currently in Shortage</i>
Hydroxocobalamin Injection	<i>Currently in Shortage</i>

Ifosfamide Injection	Currently in Shortage
Isocarboxazid Tablet	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
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
Penicillin G Benzathine Injection	Currently in Shortage
Pentostatin 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
Remifentanyl Hydrochloride Injection	Currently in Shortage
Rifampin Capsule	Currently in Shortage
Rifampin Injection	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 Hexacetonide Injection	Currently in Shortage
Valproate Sodium Injection	Currently in Shortage