OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
March 11, 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:
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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 – March 11, 2026

DATE: March 4, 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 March 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

Spring Pipeline Update – Appendix C

Action Item – Vote to Prior Authorize Yutrepia™ (Treprostinil Powder for Inhalation) and Update the Approval Criteria for the Pulmonary Hypertension Medications – Appendix D

Action Item – Vote to Prior Authorize Brekiya® [Dihydroergotamine (DHE) Autoinjector] and Update the Approval Criteria for the Anti-Migraine Medications – Appendix E

Action Item – Vote to Prior Authorize Cardamyst™ (Etripamil Nasal Spray) – Appendix F

Action Item – Annual Review of Hemophilia Medications – Appendix G

Action Item – Annual Review of Muscular Dystrophy Medications – Appendix H

Annual Review of Leukemia and Lymphoma Medications and 30-Day Notice to Prior Authorize Komzifti™ (Ziftomenib), Lymphir™ (Denileukin Diftitox-cxdl), Lunsumio VELO™ (Mosunetuzumab-axgb), Nilotinib D-Tartrate, and Phyrago™ (Dasatinib) – Appendix I

30-Day Notice to Prior Authorize Fesilty™ (Fibrinogen, Human-chmt) – Appendix J

30-Day Notice to Prior Authorize Waskyra™ (Etuvetidigene Autotemcel) – Appendix K

Annual Review of Growth-Related Disorder Medications and 30-Day Notice to Prior Authorize Palsonify™ (Paltusotine), Vykat™ XR [Diazoxide Choline Extended-Release (ER)], and Yuviwel® (Navepegritide) – Appendix L

Annual Review of Glaucoma Medications and 30-Day Notice to Prior Authorize Zolymbus™ (Bimatoprost Ophthalmic Gel) – Appendix M

Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers and 30-Day Notice to Prior Authorize Nypozi™ (Filgrastim-txid) – Appendix N

Annual Review of Dry Eye Disease (DED) Medications and 30-Day Notice to Prior Authorize Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) – Appendix O

Annual Review of Topical Antibiotic Products and 30-Day Notice to Prior Authorize Clindesse® (Clindamycin Phosphate 2% Vaginal Cream) – Appendix P

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – March 11, 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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https://oklahoma.zoom.us/webinar/register/WN_B7-m8jKcQWaA9HEiV7QRQA
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: 928 6649 0447
Passcode: 80744869

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. February 11, 2026 DUR Board Meeting Minutes
   B. February 11, 2026 DUR Board Recommendations Memorandum

Non-presentation items reviewed by Dr. O'Halloran, 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. **Spring Pipeline Update – See Appendix C**
   A. Introduction
   B. Product Summaries
   C. Pipeline Table

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

6. **Action Item – Vote to Prior Authorize Yutrepia™ (Treprostinil Powder for Inhalation) and Update the Approval Criteria for the Pulmonary Hypertension Medications – See Appendix D**
   A. Market News and Updates
   B. Yutrepia™ (Treprostinil Powder for Inhalation) Product Summary
   C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Brekiya® [Dihydroergotamine (DHE) Autoinjector] and Update the Approval Criteria for the Anti-Migraine Medications – See Appendix E**
   A. Market News and Updates
   B. Cost Comparison: DHE Products
   C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Cardamyst™ (Etripamil Nasal Spray) – See Appendix F**
   A. Market News and Updates
   B. Cardamyst™ (Etripamil Nasal Spray) Product Summary
   C. College of Pharmacy Recommendations

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

9. **Action Item – Annual Review of Hemophilia Medications – See Appendix G**
   A. Current Prior Authorization Criteria
   B. Utilization of Hemophilia Medications
   C. Prior Authorization of Hemophilia Medications
   D. Market News and Updates
   E. Oklahoma Health Care Authority Recommendations
   F. Utilization Details of Hemophilia Medications

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

10. **Action Item – Annual Review of Muscular Dystrophy Medications – See Appendix H**
    A. Current Prior Authorization Criteria
    B. Utilization of Muscular Dystrophy Medications
    C. Prior Authorization of Muscular Dystrophy Medications
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Muscular Dystrophy Medications

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

11. **Annual Review of Leukemia and Lymphoma Medications and 30-Day Notice to Prior Authorize Komzifti™ (Ziftomenib), Lymphir™ (Denileukin Diftitox-cxdl), Lunsumio VELO™ (Mosunetuzumab-axgb), Nilotinib D-Tartrate, and Phyrago™ (Dasatinib) – See Appendix I**
    A. Current Prior Authorization Criteria
    B. Utilization of Leukemia and Lymphoma Medications
    C. Prior Authorization of Leukemia and Lymphoma Medications
    D. Market News and Updates
    E. Product Summaries
    F. College of Pharmacy Recommendations
    G. Utilization Details of Leukemia and Lymphoma Medications

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

12. **30-Day Notice to Prior Authorize Fesilty™ (Fibrinogen, Human-chmt) – See Appendix J**
    A. Introduction
    B. Fesilty™ (Fibrinogen, Human-chmt) Product Summary
    C. College of Pharmacy Recommendations

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

13. **30-Day Notice to Prior Authorize Waskyra™ (Etuvetidigene Autotemcel) – See Appendix K**
    A. Introduction
    B. Waskyra™ (Etuvetidigene Autotemcel) Product Summary
    C. College of Pharmacy Recommendations

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

14. **Annual Review of Growth-Related Disorder Medications and 30-Day Notice to Prior Authorize Daybue® Stix (Trofinetide Packet), Palsonify™ (Paltusotine), Vykat™ XR [Diazoxide Choline Extended-Release (ER)], and Yuviwel® (Navepegritide) – See Appendix L**
    A. Current Prior Authorization Criteria
    B. Utilization of Growth-Related Disorder Medications
    C. Prior Authorization of Growth-Related Disorder Medications
    D. Market News and Updates
    E. Product Summaries
    F. College of Pharmacy Recommendations
    G. Utilization Details of Growth-Related Disorder Medications

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

15. **Annual Review of Glaucoma Medications and 30-Day Notice to Prior Authorize Zolymbus™ (Bimatoprost Ophthalmic Gel) – See Appendix M**
    A. Current Prior Authorization Criteria
    B. Utilization of Glaucoma Medications

C. Prior Authorization of Glaucoma Medications
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Glaucoma Medications

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

16. **Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers and 30-Day Notice to Prior Authorize Nypozi™ (Filgrastim-txid) – See Appendix N**

A. Current Prior Authorization Criteria
B. Utilization of G-CSFs and Stem Cell Mobilizers
C. Prior Authorization of G-CSFs and Stem Cell Mobilizers
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of G-CSFs and Stem Cell Mobilizers

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

17. **Annual Review of Dry Eye Disease (DED) Medications and 30-Day Notice to Prior Authorize Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) – See Appendix O**

A. Current Prior Authorization Criteria
B. Utilization of DED Medications
C. Prior Authorization of DED Medications
D. Market News and Updates
E. Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of DED Medications

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

18. **Annual Review of Topical Antibiotic Products and 30-Day Notice to Prior Authorize Clindesse® (Clindamycin Phosphate 2% Vaginal Cream) – See Appendix P**

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

Non-presentation items reviewed by Dr. O'Halloran, Dr. Haymore, Chairman:

19. **U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates – See Appendix Q**

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

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

A. Age-Related Macular Degeneration (AMD) Medications
B. Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications
C. Interstitial Lung Disease (ILD) Medications
D. Lung Cancer Medications
E. Multiple Sclerosis (MS) Medications
F. Primary Immunoglobulin A Nephropathy (IgAN) Medications
G. Rethymic® (Allogeneic Processed Thymus Tissue-agdc)
H. Sofdra™ (Sofpironium)
I. Spinal Muscular Atrophy (SMA) Medications

*Future product and class reviews subject to change.

21. 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. SoonerSelect PA data only includes medications billed as pharmacy claims (NDC) and does not include those billed as medical claims (HCPCS), where applicable.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING FEBRUARY 11, 2026

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

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

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

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

OTHERS PRESENT:	
Bob Atkins, Biogen	Brad Burris, Liquidia
Chrissie Cleghorn, Liquidia	Jamie Tobitt, Apellis
Bryan Steffan, Boehringer	Dr. Syed Hussain
Deidra Williams, Humana	Jay Milton, Bayer
Mark Kaiser, Otsuka	Lee Stout, Chiesi
Brent Parker, Merck	David Mendoza, Otsuka
David Prather, Novo Nordisk	Irene Chung, Aetna
Saurabh Patel, AbbVie	Porscha Showers, Gilead
Pam Story, PTC Bio	Laura Cordell, Sanofi
Bren Fushimi, UCB	Scott Burns, Johnson & Johnson
Andy Berg, Concis Labs	David Miley, Teva
Jenna Doerr, Petauri	Ginger Papesh, Novo Nordisk
Gary Parenteau, Dexcom	Jason Dickerson, Jazz Pharmaceuticals
Payal Tejani, Biogen	John Omick, Travere
Christine Shaffer, SpringWorks Therapeutics	Jeff Forshey, Rhythm
Shelley Bagwell, Centene	Ray Kong, Neurocrine
Peter Barrio, United Therapeutics	Jennifer Davis, Gilead
Susan Raspa, Liquidia	Kent Douglas
Todd Thomas, United Therapeutics	Lisa Henzel, Kura Oncology
Audrey Rattan, Alexion	Derek Bush, Sarepta
Judi Ross, PANTHERx	Michael Faithe, Jazz Pharmaceuticals

PRESENT FOR PUBLIC COMMENT:	
Jamie Tobitt, Apellis	Dr. Syed Hussain

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

1A: ROLL CALL

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

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO. 10 JAMIE TOBITT

2B: AGENDA ITEM NO. 28 DR. SYED HUSSAIN

ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MEETING MINUTES
3A: DECEMBER 10, 2025 DUR MINUTES
Materials included in agenda packet; presented by Dr. Haymore
Dr. Muñoz moved to approve; seconded by Dr. Ground
ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT
4A: PHARMACY HELPDESK ACTIVITY FOR JANUARY 2026
4B: MEDICATION COVERAGE ACTIVITY FOR JANUARY 2026
Non-presentation item; materials included in agenda packet by Dr. Moss
ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: ACADEMIC DETAILING PROGRAM UPDATE
5A: BACKGROUND
5B: CURRENT TOPIC: PEDIATRIC OBESITY
5C: RESULTS: PEDIATRIC OBESITY-RELATED CARE
5D: PROVIDER SATISFACTION
5E: ACADEMIC MEETING PRESENTATION(S)
5F: SUMMARY
Materials included in agenda packet; presented by Dr. Travers
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: NARROW THERAPEUTIC INDEX (NTI) DRUG LIST
6A: INTRODUCTION
6B: SOONERCARE NTI DRUG LIST
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Non-presentation item; materials included in agenda packet by Dr. Moss
ACTION: NONE REQUIRED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE DOPTELET® SPRINKLE (AVATROMBOPAG) AND WAYRILZ™ (RILZABRUTINIB) AND UPDATE THE APPROVAL CRITERIA FOR THE THROMBOCYTOPENIA MEDICATIONS
7A: MARKET NEWS AND UPDATES
7B: WAYRILZ™ (RILZABRUTINIB) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Holderread moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE ANDEMBRY® (GARADACIMAB-GXII), DAWNZERA™ (DONIDALORSEN), AND EKTERLY® (SEBETRALSTAT) AND CREATE A PRODUCT BASED PRIOR AUTHORIZATION (PBPA) CATEGORY FOR THE HEREDITARY ANGIOEDEMA (HAE) MEDICATIONS
8A: MARKET NEWS AND UPDATES
8B: PRODUCT SUMMARIES
8C: ESTIMATION OF SAVINGS
8D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Holderread moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE ATMEKSI® (METHOCARBAMOL ORAL SUSPENSION), METAXALONE 640MG TABLET, AND TANLOR® (METHOCARBAMOL 1,000MG TABLET) AND UPDATE THE APPROVAL CRITERIA FOR THE MUSCLE RELAXANT MEDICATIONS**

9A: MARKET NEWS AND UPDATES
9B: PRODUCT SUMMARIES
9C: COST COMPARISON: CARISOPRODOL PRODUCTS
9D: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 10: **VOTE TO PRIOR AUTHORIZE IMAAVY™ (NIPOCALIMAB-AAHU) AND UPDATE THE APPROVAL CRITERIA FOR THE COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS**

10A: MARKET NEWS AND UPDATES
10B: IMAAVY™ (NIPOCALIMAB-AAHU) PRODUCT SUMMARY
10C: COST COMPARISONS
10D: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 11: **VOTE TO PRIOR AUTHORIZE ESCITALOPRAM 15MG CAPSULE AND RALDESY™ (TRAZODONE ORAL SOLUTION) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTIDEPRESSANTS**

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

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

AGENDA ITEM NO. 12: **VOTE TO PRIOR AUTHORIZE KEYTRUDA QLEX™ (PEMBROLIZUMAB/BERAHYALURONIDASE ALFA-PMPH) AND OPDIVO QVANTIG™ (NIVOLUMAB/HYALURONIDASE-NVHY) AND UPDATE THE APPROVAL CRITERIA FOR THE SKIN CANCER MEDICATIONS**

12A: MARKET NEWS AND UPDATES
12B: PRODUCT SUMMARIES
12C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 13: **VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE GASTROINTESTINAL (GI) CANCER MEDICATIONS**

13A: MARKET NEWS AND UPDATES
13B: 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. 14: **VOTE TO PRIOR AUTHORIZE GOMEKLI® (MIRDAMETINIB), PAPZIMEOS™ (ZOPAPOGENE IMADENOVEC-DRBA), AND ROMVIMZA™ (VIMSELTINIB) AND UPDATE THE APPROVAL CRITERIA FOR THE NON-MALIGNANT SOLID TUMOR MEDICATIONS**

14A: MARKET NEWS AND UPDATES
14B: PRODUCT SUMMARIES
14C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 15: **VOTE TO PRIOR AUTHORIZE ALYGLO™ [IMMUNE GLOBULIN (IG) INTRAVENOUS (IV), HUMAN-STWK], ASCENIV™ (IGIV, HUMAN-SLRA), BIVIGAM® (IGIV, HUMAN), CUVITRU® [IG SUBCUTANEOUS (SC), HUMAN], GAMMAPLEX® (IGIV, HUMAN), HIZENTRA® (IGSC, HUMAN), OCTAGAM® (IGIV, HUMAN), PANZYGA® (IGIV, HUMAN-IFAS) AND XEMBIFY® (IGSC, HUMAN)**

15A: COST COMPARISON: IGIV PRODUCTS
15B: COST COMPARISON: IGSC PRODUCTS
15C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 16: **VOTE TO PRIOR AUTHORIZE REDEMPLO® (PLOZASIRAN) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTIHYPERLIPIDEMICS**

16A: MARKET NEWS AND UPDATES
16B: REDEMPLO® (PLOZASIRAN) PRODUCT SUMMARY
16C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 17: **VOTE TO PRIOR AUTHORIZE COXANTO® (OXAPROZIN 300MG CAPSULE), IBUPROFEN 300MG TABLET, VYSCOXA™ (CELECOXIB ORAL SUSPENSION), AND XIFYRM™ (MELOXICAM INJECTION) AND UPDATE THE APPROVAL CRITERIA FOR THE SYSTEMIC NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)**

17A: MARKET NEWS AND UPDATES
17B: PRODUCT SUMMARIES
17C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 18: **VOTE TO PRIOR AUTHORIZE ZEPBOUND® (TIRZEPATIDE) AND UPDATE THE APPROVAL CRITERIA FOR THE ADIPOSITY-BASED CHRONIC DISEASE (ABCD) MEDICATIONS**

18A: MARKET NEWS AND UPDATES
18B: ZEPBOUND® (TIRZEPATIDE) PRODUCT SUMMARY
18C: COST COMPARISON: MASH/NASH MEDICATIONS
18D: COLLEGE OF PHARMACY RECOMMENDATION

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

Dr. Kupiec made a motion to amend the Zepbound® and Wegovy® criteria from 4 weeks to 8 weeks durations of initial/titration approvals; seconded by Dr. Weakley
Dr. Blaiss moved to approve criteria as amended; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 19:</u> VOTE TO PRIOR AUTHORIZE LEVOFLOXACIN OPHTHALMIC SOLUTION AND UPDATE THE APPROVAL CRITERIA FOR THE OPHTHALMIC ANTIBIOTIC MEDICATIONS
19A: MARKET NEWS AND UPDATES
19B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 20:</u> VOTE TO PRIOR AUTHORIZE ESTRADIOL 0.06% GEL (GENERIC ESTROGEL®) AND LYNKUET™ (ELINZANETANT) AND UPDATE THE APPROVAL CRITERIA FOR THE VASOMOTOR SYMPTOM (VMS) MEDICATIONS
20A: MARKET NEWS AND UPDATES
20B: PRODUCT SUMMARIES
20C: COST COMPARISONS
20D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Ground moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 21:</u> VOTE TO PRIOR AUTHORIZE MOVIPREP® [POLYETHYLENE GLYCOL 3350 (PEG 3350)/SODIUM SULFATE/SODIUM CHLORIDE/POTASSIUM CHLORIDE/SODIUM ASCORBATE/ASCORBIC ACID FOR ORAL SOLUTION] AND UPDATE THE APPROVAL CRITERIA FOR THE BOWEL PREPARATION MEDICATIONS
21A: MARKET NEWS AND UPDATES
21B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Ground
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 22:</u> VOTE TO PRIOR AUTHORIZE ACEON® (PERINDOPRIL), ARBLI™ (LOSARTAN ORAL SUSPENSION), BISOPROLOL FUMARATE 2.5MG TABLET, HEMICLOR™ (CHLORTHALIDONE 12.5MG TABLET), INZIRQO™ [HYDROCHLOROTHIAZIDE (HCTZ) ORAL SUSPENSION], JAVADIN™ (CLONIDINE ORAL SOLUTION), LOPRESSOR® (METOPROLOL TARTRATE ORAL SOLUTION), AND UNIVASC® (MOEXIPRIL) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTIHYPERTENSIVE MEDICATIONS
22A: MARKET NEWS AND UPDATES
22B: COST COMPARISONS
22C: 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

<u>AGENDA ITEM NO. 23:</u> ANNUAL REVIEW OF CHOLESTATIC LIVER DISEASE AND BILE ACID DISORDER MEDICATIONS
23A: CURRENT PRIOR AUTHORIZATION CRITERIA

23B: UTILIZATION OF CHOLESTATIC LIVER DISEASE AND BILE ACID DISORDER MEDICATIONS
23C: PRIOR AUTHORIZATION OF CHOLESTATIC LIVER DISEASE AND BILE ACID DISORDER MEDICATIONS
23D: MARKET NEWS AND UPDATES
23E: COLLEGE OF PHARMACY RECOMMENDATIONS
23F: UTILIZATION DETAILS OF CHOLESTATIC LIVER DISEASE AND BILE ACID DISORDER MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Blaiss
ACTION: MOTION CARRIED

AGENDA ITEM NO. 24: ANNUAL REVIEW OF ANTICONVULSANTS
24A: CURRENT PRIOR AUTHORIZATION CRITERIA
24B: UTILIZATION OF ANTICONVULSANTS
24C: PRIOR AUTHORIZATION OF ANTICONVULSANTS
24D: MARKET NEWS AND UPDATES
24E: COLLEGE OF PHARMACY RECOMMENDATIONS
24F: UTILIZATION DETAILS OF ANTICONVULSANTS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Blaiss moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 25: ANNUAL REVIEW OF INSOMNIA MEDICATIONS
25A: CURRENT PRIOR AUTHORIZATION CRITERIA
25B: UTILIZATION OF INSOMNIA MEDICATIONS
25C: PRIOR AUTHORIZATION OF INSOMNIA MEDICATIONS
25D: MARKET NEWS AND UPDATES
25E: COLLEGE OF PHARMACY RECOMMENDATIONS
25F: UTILIZATION DETAILS OF INSOMNIA MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Blaiss
ACTION: MOTION CARRIED

AGENDA ITEM NO. 26: 30-DAY NOTICE TO PRIOR AUTHORIZE CARDAMYST™ (ETRIPAMIL NASAL SPRAY)
26A: INTRODUCTION
26B: CARDAMYST™ (ETRIPAMIL NASAL SPRAY) PRODUCT SUMMARY
26C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN MARCH

AGENDA ITEM NO. 27: ANNUAL REVIEW OF ANTI-MIGRAINE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BREKIYA® [DIHYDROERGOTAMINE (DHE) AUTOINJECTOR]
27A: CURRENT PRIOR AUTHORIZATION CRITERIA
27B: UTILIZATION OF ANTI-MIGRAINE MEDICATIONS
27C: PRIOR AUTHORIZATION OF ANTI-MIGRAINE MEDICATIONS
27D: MARKET NEWS AND UPDATES
27E: COST COMPARISON: DHE PRODUCTS
27F: COLLEGE OF PHARMACY RECOMMENDATIONS
27G: UTILIZATION DETAILS OF ANTI-MIGRAINE MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN MARCH

AGENDA ITEM NO. 28: **ANNUAL REVIEW OF PULMONARY HYPERTENSION MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE YUTREPIA™ (TREPROSTINIL POWDER FOR INHALATION)**

28A: CURRENT PRIOR AUTHORIZATION CRITERIA
28B: UTILIZATION OF PULMONARY HYPERTENSION MEDICATIONS
28C: PRIOR AUTHORIZATION OF PULMONARY HYPERTENSION MEDICATIONS
28D: MARKET NEWS AND UPDATES
28E: YUTREPIA™ (TREPROSTINIL POWDER FOR INHALATION) PRODUCT SUMMARY
28F: COLLEGE OF PHARMACY RECOMMENDATIONS
28G: UTILIZATION DETAILS OF PULMONARY HYPERTENSION MEDICATIONS

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

AGENDA ITEM NO. 29: **ANNUAL REVIEW OF CRENESSITY® (CRINECERFONT)**

29A: CURRENT PRIOR AUTHORIZATION CRITERIA
29B: UTILIZATION OF CRENESSITY® (CRINECERFONT)
28C: PRIOR AUTHORIZATION OF CRENESSITY® (CRINECERFONT)
29D: MARKET NEWS AND UPDATES
29E: COLLEGE OF PHARMACY RECOMMENDATIONS
29F: UTILIZATION DETAILS OF CRENESSITY® (CRINECERFONT)

Non-presentation item; materials included in agenda packet by Dr. O'Halloran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 30: **ANNUAL REVIEW OF KEBILIDI™ (ELADOCAGENE EXUPARVOVEC-TNEQ)**

30A: CURRENT PRIOR AUTHORIZATION CRITERIA
30B: UTILIZATION OF KEBILIDI™ (ELADOCAGENE EXUPARVOVEC-TNEQ)
30C: PRIOR AUTHORIZATION OF KEBILIDI™ (ELADOCAGENE EXUPARVOVEC-TNEQ)
30D: COLLEGE OF PHARMACY RECOMMENDATIONS

Non-presentation item; materials included in agenda packet by Dr. DeRemer
ACTION: NONE REQUIRED

AGENDA ITEM NO. 31: **U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES**

Non-presentation item; materials included in agenda packet by Dr. Moss
ACTION: NONE REQUIRED

AGENDA ITEM NO. 32: **FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)**

32A: DRY EYE DISEASE (DED) MEDICATIONS
32B: FESILTY (FIBRINOGEN, HUMAN-CHMT)
32C: GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS) AND STEM CELL MOBILIZERS
32D: GROWTH-RELATED DISORDER MEDICATIONS
32E: HEMOPHILIA MEDICATIONS
32F: LEUKEMIA AND LYMPHOMA MEDICATIONS
32G: MUSCULAR DYSTROPHY MEDICATIONS
32H: TOPICAL ANTIBIOTIC PRODUCTS
32I: WASKYRA (ETUVETIDIGENE AUTOTEMCEL)

*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. 33: ADJOURNMENT

The meeting was adjourned at 5:29pm.

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

Memorandum

Date: February 13, 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 February 11, 2026

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Academic Detailing Program Update

NO ACTION REQUIRED.

Recommendation 3: Narrow Therapeutic Index (NTI) Drug List

NO ACTION REQUIRED.

Recommendation 4: Vote to Prior Authorize Doptelet® Sprinkle (Avatrombopag) and Wayrilz™ (Rilzabrutinib) and Update the Approval Criteria for the Thrombocytopenia Medications

MOTION CARRIED by unanimous approval.

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

Wayrilz™ (Rilzabrutinib) Approval Criteria:

1. An FDA approved diagnosis of persistent or chronic immune thrombocytopenia (ITP); and

2. Member must be 18 years of age or older; and
3. Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of ITP; and
4. Previous insufficient response to at least 2 of the following treatments:
    a. Corticosteroids; or
    b. Immunoglobulins; or
    c. Splenectomy; or
    d. Thrombopoietin receptor agonists; or
    e. Fostamatinib; or
    f. Rituximab; and
5. Prescriber must attest that all other causes of thrombocytopenia, including malignancy and liver disease, have been ruled out; and
6. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Wayrilz™ and during treatment as clinically indicated; and
7. Prescriber must verify that the member will be monitored for signs and symptoms of infection while on Wayrilz™; and
8. Member must not be taking any of the following medications concomitantly with Wayrilz™:
    a. Moderate to strong CYP3A inhibitors (e.g., itraconazole, clarithromycin); and
    b. Moderate to strong CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin); and
    c. Proton pump inhibitors; and
9. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during therapy and for at least 1 week after the last dose; and
10. Female members must not be breastfeeding during treatment and for at least 1 week after discontinuation of treatment; and
11. A quantity limit of 60 tablets per 30 days will apply.

Additionally, the College of Pharmacy recommends the prior authorization of Doptelet® Sprinkle (avatrombopag) and updating the Doptelet® approval criteria based on the recent FDA approval and clinical practice (changes shown in red):

Doptelet® (Avatrombopag) and Doptelet® Sprinkle (Avatrombopag) Approval Criteria [Persistent or Chronic Immune Thrombocytopenia (ITP) Diagnosis]:

1. An FDA approved indication for the treatment of 1 of the following:
    a. Thrombocytopenia in adult members with chronic ITP who have had an insufficient response to a previous treatment; ~~and~~ or
    b. Thrombocytopenia in pediatric members 1 year of age or older with persistent or chronic ITP who have had an insufficient response to a previous treatment; and

2. Member must be 1 ~~18~~ years of age or older; and
3. Previous insufficient response with at least 1 of the following treatments:
   a. Corticosteroids; or
   b. Immunoglobulins; or
   c. Splenectomy; and
4. A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and
5. Prescriber must verify the degree of thrombocytopenia and clinical condition increase the risk for bleeding; and
6. Prescriber must verify platelet counts will be assessed as per package labeling:
   a. Initiation of treatment: Weekly until a stable platelet count ~~>~~ ≥50 x 10^9/L has been achieved, and then obtained monthly thereafter; and
   b. Change in formulation: Weekly until a stable platelet count and dose will be adjusted as needed before resuming monthly monitoring; and
   c. Discontinuation: Weekly for 4 weeks following discontinuation; and
7. Must be prescribed by, or in consultation with, a hematologist or oncologist; and
~~8. Doptelet® must not be used in an attempt to normalize platelet counts; and~~
9. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
10. Prescriber must verify female member is not breastfeeding; and
11. An age restriction will apply for Doptelet® Sprinkle. The sprinkle capsule formulation may be approvable for members 1 to 5 years of age. Members 6 years of age and older must use the tablet formulation; and
12. For Doptelet® Sprinkle, prescriber must verify that the member and/or caregiver has been counseled on the proper preparation and administration of Doptelet® Sprinkle; and
13. A quantity limit of 60 tablets or sprinkle capsules per 30 days will apply.

Doptelet® (Avatrombopag) Approval Criteria [Thrombocytopenia in Chronic Liver Disease (CLD) Diagnosis]:

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with CLD who are scheduled to undergo a procedure; and
2. Date of procedure must be listed on the prior authorization request; and
3. Prescriber must verify the member will have the procedure within 5 to 8 days after the member receives the last dose of Doptelet®; and
4. Member must have a baseline platelet count <50 x 10^9/L (recent baseline platelet count must be provided); and

5. Must be prescribed by, or in consultation with, a hematologist, gastroenterologist, or hepatologist; and
~~6. Doptelet® must not be used in an attempt to normalize platelet counts; and~~
7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
8. Prescriber must verify female member is not breastfeeding; and
9. A quantity limit of 15 tablets per scheduled procedure will apply.

Finally, the College of Pharmacy recommends making Promacta® (eltrombopag) brand preferred based on net costs and recommends updating the Alvaiz® (eltrombopag) and Mulpleta® (lusutrombopag) approval criteria based on clinical practice (changes show in red):

Eltrombopag (Generic Promacta®) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 1 year of age or older; and
3. Promacta® is brand preferred. Requests for generic eltrombopag will require a patient-specific, clinically significant reason why the member cannot use the brand formulation, which is available without prior authorization.

Alvaiz® (Eltrombopag) Approval Criteria [Persistent or Chronic Immune Thrombocytopenia (ITP) Diagnosis]:

1. An FDA approved diagnosis of persistent or chronic ITP; and
2. Member must have a platelet count of <30 x 10^9/L; and
~~3. Alvaiz® must not be used in an attempt to normalize platelet counts; and~~
4. Member must be 6 years of age or older; and
5. Member must not have a recent diagnosis of myelodysplastic syndromes; and
6. Previous insufficient response to at least 1 of the following treatments:
   a. Corticosteroids; or
   b. Immunoglobulins; or
   c. Splenectomy; and
7. A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and
8. Prescriber must attest that all other causes of thrombocytopenia, including malignancy and liver disease, have been ruled out; and
9. Prescriber must verify that members will receive baseline and follow-up ocular examinations as recommended in the package labeling; and
10. Prescriber must agree to monitor hepatic function prior to and during treatment with Alvaiz®; and
11. Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of ITP; and

12. Quantity limits will apply based on FDA-approved dosing, up to a maximum of 54mg per day, as follows:
    a. 9mg strength: 30 tablets per 30 days; or
    b. 18mg strength: 90 tablets per 30 days; or
    c. 36mg strength: 30 tablets per 30 days; or
    d. 54mg strength: 30 tablets per 30 days.

Mulpleta® (Lusutrombopag) Approval Criteria:

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with chronic liver disease (CLD) who are scheduled to undergo a procedure; and
2. Date of procedure must be listed on the prior authorization request; and
3. Prescriber must verify the member will have the procedure 2 to 8 days after the member receives the last dose of Mulpleta®; and
4. Member must have a baseline platelet count <50 x 10^9/L (recent baseline platelet count must be provided); and
5. Must be prescribed by, or in consultation with, a hematologist, gastroenterologist, or hepatologist; and
6. ~~Mulpleta® must not be used in an attempt to normalize platelet counts; and~~
7. A quantity limit of 7 tablets per scheduled procedure will apply.

Recommendation 5: Vote to Prior Authorize Andembry® (Garadacimab-gxii), Dawnzera™ (Donidalorsen), and Ekterly® (Sebetralstat) and Create a Product Based Prior Authorization (PBPA) Category for the Hereditary Angioedema (HAE) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends establishing a PBPA category for the HAE prophylaxis products with additional criteria shown below in place of the current HAE medications prior authorization criteria and recommends the prior authorization of Andembry® (garadacimab-gxii) and Dawnzera™ (donidalorsen) with placement into the Special PA Tier of the HAE Prophylaxis Products PBPA category (changes shown in red):

Hereditary Angioedema (HAE) Prophylaxis Products			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Orladeyo® (berotralstat)	**Cinryze® (C1 esterase inhibitor)**	**Takhzyro® (lanadelumab-flyo)**	**Andembry® (garadacimab-gxii)**
	Haegarda® (C1 esterase inhibitor)		**Dawnzera™ (donidalorsen)**

PA = prior authorization

Initial Approval Criteria for All HAE Prophylaxis Products:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for prophylaxis of HAE; and
3. Member must not currently be taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
4. Based on HAE attack frequency, attack severity, comorbid conditions, and member's access to emergent treatment, the prescriber has determined long-term prophylaxis is appropriate for the member; or
5. Approval consideration will be given if the member has a recent hospitalization for a severe episode of angioedema; and
6. Prescriber must verify the member or caregiver has been trained by a health care professional on proper storage and administration of the prescribed product; and
7. For products requiring weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
8. Quantity limits will apply based on FDA-approved dosing.

HAE Prophylaxis Products Tier-2 Approval Criteria:

1. Initial Approval Criteria for All HAE Prophylaxis Products must be met; and
2. A patient specific, clinically significant reason why the member cannot use all Tier-1 products must be provided.

HAE Prophylaxis Products Tier-3 Approval Criteria:

1. Initial Approval Criteria for All HAE Prophylaxis Products must be met; and
2. A patient specific, clinically significant reason why the member cannot use all Tier-1 and Tier-2 products must be provided.

HAE Prophylaxis Products Special Prior Authorization (PA) Approval Criteria:

1. Initial Approval Criteria for All HAE Prophylaxis Products must be met; and
2. A patient specific, clinically significant reason why the member cannot use all other available lower-tiered HAE prophylaxis products must be provided.

Additionally, the College of Pharmacy recommends establishing a PBPA category for the HAE treatment products with the additional criteria shown below in place of the current HAE medications prior authorization criteria and recommends the prior authorization of Ekterly® (sebetralstat) with placement into the Special PA Tier of the HAE Treatment Products PBPA category (changes shown in red):

Hereditary Angioedema (HAE) Treatment Products		
Tier-1	**Tier-2**	**Special PA**
Firazyr® (icatibant)	**Berinert® (C1 esterase inhibitor)**	**Ekterly® (sebetralstat)**
	Sajazir™ (icatibant)	**Kalbitor® (ecallantide)**
		Ruconest® (C1 esterase inhibitor)

PA = prior authorization

Initial Approval Criteria for All HAE Treatment Products:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for the treatment of acute attacks of HAE; and
3. Prior authorization requests for products administered via injection must indicate if the product is to be self-administered or to be administered by a health care provider; and
    a. For products approved for self-administration per FDA package labeling, the prescriber must verify the member or caregiver has been trained by a health care professional on proper storage and administration of the prescribed product; or
    b. For products not recommended for self-administration by FDA package labeling, the prescriber must verify the product will be administered by a health care provider; and
4. For products requiring weight-based dosing, the member's recent weight must be provided on the prior authorization request.

HAE Treatment Products Tier-2 Approval Criteria:

1. Initial Approval Criteria for All HAE Treatment Products must be met; and
2. A patient specific, clinically significant reason why the member cannot use all Tier-1 products must be provided.

HAE Treatment Products Special Prior Authorization (PA) Approval Criteria:

1. Initial Approval Criteria for All HAE Treatment Products must be met; and
2. A patient specific, clinically significant reason why the member cannot use all other available lower-tiered HAE treatment products must be provided.

Recommendation 6: Vote to Prior Authorize Atmeksi® (Methocarbamol Oral Suspension), Metaxalone 640mg Tablet, and Tanlor® (Methocarbamol 1,000mg Tablet) and Update the Approval Criteria for the Muscle Relaxant Medications

MOTION CARRIED by unanimous approval.

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

1. Prior authorization and placement of Atmeksi® (methocarbamol oral suspension), metaxalone 640mg tablet, and Tanlor® (methocarbamol 1,000mg tablet) into the Special PA Tier based on net costs; and
2. Updating the approval criteria for Zanaflex® (tizanidine) capsules based on the approval of the new 8mg capsule and based on net costs; and
3. Updating the approval criteria for Fleqsuvy® (baclofen 25mg/mL oral suspension), Ozobax® (baclofen 5mg/5mL oral solution), and Ozobax® DS [baclofen double strength (DS) 10mg/5mL oral solution] based on the discontinuation of Lyvispah® (baclofen oral granules); and
4. Moving metaxalone 400mg tablet from Tier-2 to the Special PA Tier based on net cost; and
5. Updating the carisoprodol approval criteria based on net costs and for clarity.

Muscle Relaxant Medications		
Tier-1	**Tier-2**	**Special PA***
baclofen 10mg, 20mg (Lioresal®)	metaxalone **800mg tabs** (Skelaxin®)	baclofen 5mg, 15mg (Lioresal®)
chlorzoxazone 500mg (Parafon Forte®)		baclofen oral granules (Lyvispah®)
cyclobenzaprine (Flexeril®)		baclofen 5mg/5mL oral soln (Ozobax®)
methocarbamol (Robaxin®)		baclofen 10mg/5mL oral soln (Ozobax DS®)
orphenadrine (Norflex®)		baclofen 25mg/5mL oral susp (Fleqsuvy®)
tizanidine tabs (Zanaflex®)		carisoprodol 250mg (Soma®)
		carisoprodol 350mg (Soma®)
		chlorzoxazone 250mg tabs
		chlorzoxazone 375mg, 750mg (Lorzone®)
		cyclobenzaprine 7.5mg tabs (Fexmid®)
		cyclobenzaprine ER caps (Amrix®)
		metaxalone 400mg tabs (Skelaxin®)
		metaxalone 640mg tabs
		methocarbamol 1,000mg tabs (Tanlor®)
		methocarbamol oral susp (Atmeksi®)
		orphenadrine/ASA/caffeine tabs (Norgesic®, Norgesic® Forte, Orphengesic® Forte)

Muscle Relaxant Medications		
Tier-1	**Tier-2**	**Special PA***
		tizanidine caps (Zanaflex®)

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.
ASA = aspirin; caps = capsules; ER = extended-release; PA = prior authorization; soln = solution; susp = suspension; tabs = tablets.

Atmeksi® (Methocarbamol Oral Suspension) Approval Criteria:

1. An FDA approved indication as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions; and
2. Member must be 16 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use Tier-1 methocarbamol 500mg or 750mg oral tablets, even when tablets are crushed, must be provided.

Fleqsuvy® (Baclofen 25mg/mL Oral Suspension), Lyvispah® (Baclofen Oral Granules), Ozobax® (Baclofen 5mg/5mL Oral Solution), and Ozobax® DS [Baclofen Double Strength (DS) 10mg/5mL Oral Solution] Approval Criteria:

1. An FDA approved diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and
2. ~~Requests for Fleqsuvy®, Ozobax®, or Ozobax® DS will require a patient-specific, clinically significant reason why the member cannot use Lyvispah®; and~~
3. Members older than 10 years of age require a patient-specific, clinically significant reason why the member cannot use baclofen oral tablets, even when tablets are crushed.

Metaxalone 640mg Tablet and Skelaxin® (Metaxalone 400mg Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all other appropriate lower-tiered products, including metaxalone 800mg tablets, must be provided; and
2. For metaxalone 400mg tablets, a patient-specific, clinically significant reason why the member cannot split an 800mg metaxalone tablet to achieve the requested dose must be provided.

~~**Soma® (Carisoprodol 250mg) Approval Criteria:**~~

~~1. Authorization requires detailed documentation regarding member's inability to use other skeletal muscle relaxants including carisoprodol 350mg, and patient-specific reason(s) why member cannot be drowsy for even a short time period must be provided. Member must not have other sedating medications in current claims history; and~~

~~2. For a diagnosis of acute musculoskeletal pain, the approval will be for the duration of 14 days per 365-day period. Conditions requiring chronic use will not be approved.~~

Soma® (Carisoprodol 250mg or 350mg) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all other appropriate lower-tiered products must be provided; and
~~2. Members may receive 3 months of carisoprodol 350mg per rolling 365 days without prior authorization; and~~
3. Requests for carisoprodol 250mg will require a patient-specific, clinically significant reason why the member cannot use carisoprodol 350mg; and
~~4. After the member has received the 3 months, an additional approval for 1 month may be granted to allow titration or change to a Tier-1 muscle relaxant. This additional 1-month approval will be granted 1 time only. Further authorizations will not be granted; or~~
5. Requests will be approved for a maximum duration of 3 months; or
    a. Clinical exceptions may be made for members with the following diagnoses and approvals will be granted for the duration of 1 year: multiple sclerosis, cerebral palsy, muscular dystrophy, paralysis, or cancer pain; and
6. A quantity limit of 120 tablets per 30 days will apply.

Tanlor® (Methocarbamol 1,000mg Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including using methocarbamol 500mg or 750mg tablets to achieve the requested dose, must be provided.

Zanaflex® (Tizanidine) Capsules Approval Criteria:

1. Tizanidine tablets must be tried prior to consideration of the capsules.
2. The capsules may be considered for approval only if there is supporting information as to why the member cannot take the tablets; and
3. For Zanaflex® 8mg capsule, a patient-specific, clinically significant reason (beyond convenience) why the member cannot use generic tizanidine 2mg, 4mg, or 6mg capsules to achieve the requested dose must be provided.

Recommendation 7: Vote to Prior Authorize Imaavy™ (Nipocalimab-aahu) and Update the Approval Criteria for the Complement Inhibitors and Miscellaneous Immunomodulatory Agents

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the prior authorization criteria for the eculizumab products based on the FDA approved age

expansion for generalized myasthenia gravis (gMG) and based on net costs (changes shown in red):

Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:

1. An FDA approved diagnosis of aHUS; and
2. Prescriber must confirm the member does not have Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HS); and
3. Bkemv™, Epysqli®, or Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS;
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For use of Bkemv™ or ~~Epysqli®~~ Soliris®, a patient-specific, clinically significant reason why the member cannot use ~~Soliris®~~ Epysqli® 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
7. Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with another complement inhibitor used to treat aHUS; and
8. 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 approvals will be for 1 year.

Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 6 years of age and older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must meet 1 of the following:
    a. Failed treatment over 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; or

b. Failed at least 1 IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); and

7. Bkemv™, Epysqli®, Soliris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. For use of Bkemv™ or ~~Epysqli®~~ Soliris®, in patients 18 years of age or older, a patient-specific, clinically significant reason why the member cannot use ~~Soliris®~~ Epysqli® must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
~~11. Use of Bkemv™, Epysqli®, or Soliris® will require a patient specific, clinically significant reason why the member cannot use Ultomiris® (ravulizumab-cwvz); and~~
12. Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with a neonatal Fc receptor blocker or another complement inhibitor used to treat gMG; and
13. Initial approvals will be for the duration of 6 months at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Bkemv™, Epysqli®, or Soliris® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For use of Bkemv™ or ~~Epysqli®~~ Soliris®, a patient-specific, clinically significant reason why the member cannot use ~~Soliris®~~ Epysqli® 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
7. Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with another complement protein C5 inhibitor, complement protein C3 inhibitor, or complement factor B inhibitor used to treat PNH; and
8. 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 approvals will be for 1 year.

The College of Pharmacy recommends the addition of prior authorization criteria for Fabhalta® (iptacopan) for a diagnosis of complement 3 glomerulopathy (C3G) and for Uplizna® (inebilizumab-cdon) for a diagnosis of immunoglobulin G4-related disease (IgG4-RD) and gMG based on the new FDA approved indications with the following criteria (shown in red):

Fabhalta® (Iptacopan) Approval Criteria [Complement 3 Glomerulopathy (C3G) Diagnosis]:

1. An FDA approved indication to reduce proteinuria in adults with C3G; and
2. The diagnosis of C3G must be confirmed by a kidney biopsy (can refer to a recent or historical biopsy); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must have a urine protein-to-creatinine (UPCR) ratio ≥1.0g/g; and
6. Member must have an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2; and
7. Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. Member must not be receiving Fabhalta® in combination with another complement protein C3 inhibitor used to treat C3G; 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 approvals will be for 1 year.

Uplizna® (Inebilizumab-cdon) Approval Criteria [Immunoglobulin G4-Related Disease (IgG4-RD) Diagnosis]:

1. An FDA approved diagnosis of IgG4-RD which meets the classification criteria for IgG4-RD by the 2019 American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR); and
2. Member must be 18 years of age or older; and
3. Member must have a confirmed history of organ involvement; and

4. Uplizna® must be prescribed by, or in consultation with, a gastroenterologist, rheumatologist, or a specialist with expertise in the treatment of IgG4-RD; and
5. Member must have previously been treated with glucocorticoid therapy or have a patient specific, clinically significant reason why glucocorticoid therapy is not appropriate; and
6. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
7. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
8. Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
9. Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and
10. Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and
11. The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and
13. Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and
14. Prescriber must verify the member has not received any live-attenuated or live vaccines within 4 weeks prior to the initiation of therapy and that member will not receive any live-attenuated or live vaccines during treatment with Uplizna® or after discontinuation until B-cell repletion; and
15. A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and
16. 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 approvals will be for 1 year.

Uplizna® (Inebilizumab-cdon) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

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

3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies or anti-muscle-specific tyrosine kinase (MuSK) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Uplizna® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Member must not be receiving Uplizna® in combination with a complement inhibitor or with a neonatal Fc receptor blocker used to treat gMG; and
9. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
10. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
11. Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
12. Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and
13. Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and
14. The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and
15. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and
16. Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and
17. Prescriber must verify the member has not received any live-attenuated or live vaccines within 4 weeks prior to the initiation of therapy and that member will not receive any live-attenuated or live vaccines during treatment with Uplizna® or after discontinuation until B-cell repletion; and
18. A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and

19. 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 approvals will be for 1 year.

Additionally, the College of Pharmacy recommends updating the approval criteria for Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) based on the FDA approval of the prefilled syringe (changes shown in red):

Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc) Approval Criteria [Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Diagnosis]:

1. An FDA approved diagnosis of CIDP; and
2. Member must be 18 years of age or older; and
3. Vyvgart® Hytrulo 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. Member must have previously failed treatment with intravenous immunoglobulin (IVIG) or a patient specific, clinically significant reason why the member cannot use IVIG must be provided; and
5. For member self-administration or caregiver administration of the prefilled syringe, the prescriber must verify the member or caregiver will be trained by a health care provider on proper administration and storage of Vyvgart® Hytrulo prefilled syringe; and
6. Initial approvals will be for 12 weeks. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Vyvgart® (Efgartigimod Alfa-fcab) and Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥5; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Vyvgart® or Vyvgart® Hytrulo must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Member must not be receiving Vyvgart® or Vyvgart® Hytrulo in combination with a complement inhibitor or with another neonatal Fc receptor blocker used to treat gMG; and

9. For member self-administration or caregiver administration of Vyvgart® Hytrulo prefilled syringe, the prescriber must verify the member or caregiver will be trained by a health care provider on proper administration and storage of Vyvgart® Hytrulo prefilled syringe; and
10. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

The College of Pharmacy also recommends the prior authorization of Imaavy® (nipocalimab-aahu) with the following criteria (shown in red):

Imaavy™ (Nipocalimab-aahu) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 12 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies or anti-muscle-specific tyrosine kinase (MuSK) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Imaavy™ must be prescribed by, or in consultation with, a neurologist, or a specialist with expertise in the treatment of gMG; and
8. Member must not be receiving Imaavy in combination with a complement inhibitor or with another neonatal Fc receptor blocker used to treat gMG; and
9. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the package labeling; and
10. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

The College of Pharmacy recommends the addition of prior authorization criteria for Empaveli® (pegcetacoplan) based on the new FDA approved diagnosis with the following criteria (shown in red):

Empaveli® (Pegcetacoplan) Approval Criteria [Complement 3 Glomerulopathy (C3G) or Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN) Diagnosis]:

1. An FDA approved diagnosis to reduce proteinuria in members with C3G or primary IC-MPGN; and
2. The diagnosis of C3G or IC-MPGN must be confirmed by a kidney biopsy (can refer to a recent or historical biopsy); and
3. Member must be 12 years of age or older and weigh at least 30kg; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must have a urine protein-to-creatinine (UPCR) ratio ≥1.0g/g; and
6. Member must have an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2; and
7. Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver will be trained by a health care provider on proper administration and storage of Empaveli®; and
9. Member must not be receiving Empaveli® in combination with another complement inhibitor used to treat C3G; and
10. 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 approvals will be for 1 year.

Finally, the College of Pharmacy recommends updating the immunoglobulin A nephropathy (IgAN) criteria for Fabhalta® and the neuromyelitis optica spectrum disorder (NMOSD) criteria for Uplizna® (inebilizumab-cdon) to be consistent with clinical practice (changes shown in red):

Fabhalta® (Iptacopan) Approval Criteria [Immunoglobulin A Nephropathy (IgAN) Diagnosis]:

1. An FDA approved indication to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy (can refer to a recent or historical biopsy); and
   b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and

5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day; and
6. Member must be on a stable dose of a maximally tolerated angiotensin convert enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and
7. Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. 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 approvals will be for 1 year.

Uplizna® (Inebilizumab-cdon) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months, or at least 2 attacks in the prior 24 months, requiring rescue therapy; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤8; and
5. Uplizna® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
7. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
8. Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
9. Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and
10. Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and
11. The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and

13. Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and
14. Prescriber must verify the member has not received any live-attenuated or live vaccines ~~vaccinations~~ within 4 weeks prior to initiation of therapy and member will not receive any live-attenuated or live vaccines during treatment with Uplizna® or after discontinuation until B-cell repletion; and
15. Member must not be receiving Uplizna® in combination with other immunomodulators to treat NMOSD; and
16. A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and
17. 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 approvals will be for 1 year.

Recommendation 8: Vote to Prior Authorize Escitalopram 15mg Capsule and Raldesy™ (Trazodone Oral Solution) and Update the Approval Criteria for the Antidepressants

MOTION CARRIED by unanimous approval.

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

1. Prior authorization of Raldesy™ (trazodone oral solution) and escitalopram 15mg capsule and placement into the Special PA Tier with the following additional criteria; and
2. Updating the Drizalma Sprinkle™ and Irenka™ approval criteria to encompass all FDA approved diagnoses; and
3. Updating the Spravato® (esketamine) approval criteria for the treatment-resistant depression (TRD) diagnosis based on the new FDA approval; and
4. Updating the Zurzuvae® (zuranolone) approval criteria to be consistent with the current American College of Obstetrics and Gynecology (ACOG) guideline recommendations.

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram tabs & soln (Celexa®)			citalopram 30mg caps
escitalopram tabs & soln (Lexapro®)			citalopram 20mg/10mL soln (UDC)
fluoxetine caps & soln (Prozac®)			**escitalopram 15mg caps**

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
fluvoxamine (Luvox®)			escitalopram 10mg/10mL soln (UDC)
paroxetine (Paxil®)			fluoxetine 20mg/5mL soln (UDC)
sertraline tabs & soln (Zoloft®)			fluoxetine tabs
			fluoxetine DR (Prozac® Weekly™)
			fluvoxamine CR (Luvox CR®)
			paroxetine CR (Paxil CR®)
			sertraline 150mg & 200mg caps
Dual-Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, XL®)	desvenlafaxine succinate ER (Pristiq®)	desvenlafaxine ER	bupropion ER (Forfivo XL®)
duloxetine (Cymbalta®)		levomilnacipran (Fetzima®)	duloxetine (Drizalma Sprinkle™)
mirtazapine (Remeron®, Remeron SolTab®)		nefazodone (Serzone®)	duloxetine 40mg (Irenka™)
trazodone 50mg, 100mg, & 150mg tabs (Desyrel®)		vilazodone (Viibryd®)	trazodone 300mg tabs (Desyrel®)
venlafaxine ER caps (Effexor XR®)			**trazodone oral soln (Raldesy™)**
venlafaxine IR tabs (Effexor®)			venlafaxine besylate ER 112.5mg tablets
venlafaxine 37.5mg. 75mg & 150mg ER tabs (Effexor XR®)			venlafaxine ER 225mg tabs (Effexor XR®)
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	isocarboxazid (Marplan®)
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
		vortioxetine (Trintellix®)	dextromethorphan/ bupropion (Auvelity®)
			esketamine nasal spray (Spravato®)
			gepirone (Exxua™)

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
			zuranolone (Zurzuvae®)

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.
caps = capsules; CR = controlled-release; DR = delayed-release; ER = extended-release; PA = prior authorization; soln = solution; tabs = tablets

Escitalopram Capsule Approval Criteria:

1. An FDA approved indication; and
2. Member must have initiated treatment with escitalopram tablets for dose titration; and
3. A patient-specific, clinically significant reason why the member cannot use escitalopram tablets, including splitting an escitalopram 10mg tablet to achieve a 15mg dose, must be provided; and
4. Escitalopram capsules will not be approved for members 65 years of age or older or for members with hepatic impairment; and
5. A quantity limit of 30 capsules per 30 days will apply.

Drizalma Sprinkle™ (Duloxetine Capsule) Approval Criteria ~~[Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]:~~

1. An FDA approved diagnosis ~~of diabetic peripheral neuropathy or chronic musculoskeletal pain~~; and
2. For non-depression related diagnoses, a patient-specific, clinically significant reason why the member cannot use generic duloxetine 20mg, 30mg, or 60mg capsules, which are available without prior authorization, in place of Drizalma Sprinkle™ must be provided; and
3. For depression-related diagnoses, a patient-specific, clinically significant reason why the member cannot use all other available lower tiered medications, including generic duloxetine 20mg, 30mg, or 60mg capsules, must be provided; and
4. A quantity limit of 30 capsules per 30 days will apply.

Irenka™ (Duloxetine 40mg Capsule) Approval Criteria ~~[Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]~~:

1. An FDA approved diagnosis ~~of diabetic peripheral neuropathy or chronic musculoskeletal pain~~; and
2. A patient-specific, clinically significant reason why the member cannot use 2 duloxetine 20mg capsules in place of Irenka™ 40mg capsules must be provided; and
3. A quantity limit of 30 capsules per 30 days will apply; and

Raldesy™ (Trazodone Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of major depressive disorder (MDD); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use the tablet formulation must be provided; and

4. Requests for the 150mL package size will require a patient-specific, clinically significant reason why the member cannot use the 300mL package size; and
5. The following quantity limits will apply:
    a. 150mL package size: 450mL per 30 days; or
    b. 300mL package size: 1,200mL per 30 days.

Spravato® (Esketamine Nasal Spray) Approval Criteria [Treatment-Resistant Depression Diagnosis]:

1. An FDA approved diagnosis of treatment-resistant depression in adults; and
2. Member must be 18 years of age or older; and
3. ~~Spravato® must be used in conjunction with an oral antidepressant; and~~
4. Member must have had an inadequate response to at least 2 different antidepressants from different classes at least 4 weeks in duration each and titrated to recommended dosing during the current depressive episode, unless contraindicated or clinically significant adverse effects; and
5. Prescriber must agree that member will be monitored by a health care provider for at least 2 hours after each administration; and
6. Prescriber must agree that member's blood pressure will be monitored prior to and after administration of Spravato® in accordance with package labeling; and
7. Member must not have any contraindications to therapy [e.g., aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation; intracerebral hemorrhage; hypersensitivity to esketamine, ketamine, or any of the excipients]; and
8. Member must not have severe hepatic impairment (Child Pugh C); and
9. Prescriber must verify that female member is not currently pregnant and will use effective contraception while receiving treatment with Spravato®; and
10. Prescriber must verify female member is not breastfeeding; and
11. Pharmacy and health care setting must be certified in the Spravato® Risk Evaluation and Mitigation Strategy (REMS) program; and
12. Member must be enrolled in the Spravato® REMS program; and
13. Spravato® must be administered under the direct observation of a health care provider in a REMS certified health care setting; and
14. Initial approvals will be for the duration of the induction phase. For continued authorization, prescriber must verify member demonstrated an adequate response during the induction phase ~~and verify member is using Spravato® in combination with an oral antidepressant~~; and
15. A quantity limit of 4 kits per 28 days will apply for maintenance dosing.

Zurzuvae® (Zuranolone) Approval Criteria:

1. An FDA approved diagnosis of moderate to severe postpartum depression (PPD); and
2. Member must be ≤12 months postpartum and the date of delivery must be provided; and
3. Member must be a female 18 years of age or older; and
4. Prescriber must verify the following:
    a. Member has been counseled on the proper administration of Zurzuvae® including taking with a fat-containing meal; and
    b. Member has been counseled on the central nervous system (CNS) depression effects of Zurzuvae® and the member agrees not to drive or engage in other potentially hazardous activities until at least 12 hours after administration; and
    c. Member is not currently pregnant and will use effective contraception while receiving treatment and for 7 days after the last dose of Zurzuvae®; and
    ~~d. Member is not breastfeeding or has agreed to temporarily hold breastfeeding during Zurzuvae® therapy and for 7 days after the last dose; or~~
    ~~e. If the member does not agree to cease breastfeeding, the following must be provided:~~
        ~~i. Prescriber attests that the benefits of Zurzuvae® therapy while breastfeeding outweigh the risks to the infant due to studies showing that Zurzuvae® is present in breastmilk; and~~
        ~~ii. Member has been counseled on the potential risks of CNS depression effects that may occur in the infant; and~~
5. Dosing and approval duration will be limited to the following:
    a. 50mg once daily for 14 days; or
    b. For members with severe hepatic impairment, moderate to severe renal impairment, or concomitant use with CYP3A4 inhibitors:
        i. 30mg once daily for 14 days; and
    c. If a dose reduction to 40mg once daily is required due to CNS depression effects, the prescriber should contact the specialty pharmacy that filled the member's initial Zurzuvae® prescription to obtain the 20mg capsules from the manufacturer for the remainder of the member's treatment course; and
6. Approvals will be for 1 treatment course.

Recommendation 9: Vote to Prior Authorize Keytruda Qlex™ (Pembrolizumab/Berahyaluronidase Alfa-pmph) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) and Update the Approval Criteria for the Skin Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Keytruda Qlex™ (pembrolizumab/berahyaluronidase alfa-pmph) with criteria similar to Keytruda® (pembrolizumab) and recommends additional updates based on recent FDA approvals, National Comprehensive Cancer Network (NCCN) recommendations for pembrolizumab, and to be consistent with current FDA approved indications for pembrolizumab (changes and new criteria shown in red):

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Biliary Tract Cancer (BTC) Diagnosis]:

1. Diagnosis of locally advanced unresectable or metastatic BTC; and
2. Used in combination with gemcitabine and cisplatin or carboplatin (if ineligible for cisplatin).

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of locally recurrent unresectable or metastatic triple-negative breast cancer; and
    a. Tumors express programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥10; and
    b. Used in combination with chemotherapy; or
2. Diagnosis of early stage triple-negative breast cancer; and
    a. Disease is considered high-risk; and
    b. Used in combination with chemotherapy as neoadjuvant therapy and may be continued as a single agent as adjuvant treatment after surgery.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Cervical Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic cervical cancer; and
    a. Tumor must express programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1)]; and
    b. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
        i. Disease progression on or after chemotherapy; or
        ii. As first-line therapy in combination with chemotherapy, with or without bevacizumab; or
        iii. As second line or subsequent therapy as a single agent; or
2. Diagnosis of FIGO 2014 Stage III-IVA cervical cancer; and
    a. Used in combination with concomitant chemotherapy and radiation.

Keytruda® (Pembrolizumab) Approval Criteria [Classical Hodgkin Lymphoma (cHL) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)]; and
2. For adult members:
    a. Diagnosis of relapsed or refractory cHL and member does not have lymphocyte-predominant Hodgkin lymphoma; and
        i. Used as a single agent; or
        ~~ii. Exception: lymphocyte-predominant Hodgkin lymphoma; or~~
        iii. Used in second-line or subsequent systemic therapy in combination with gemcitabine, vinorelbine, and liposomal doxorubicin (GVD) or ifosfamide, carboplatin, and etoposide (ICE); or
3. For pediatric members:
    a. Used as a single agent; and
    b. Diagnosis of refractory cHL; or
    c. Relapsed disease after ≥2 therapies; or
    d. Decrease in cardiac function is observed.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Cutaneous Squamous Cell Carcinoma (cSCC) Diagnosis]:

1. Diagnosis of locally advanced, recurrent or metastatic disease; and
2. Not curable by radiation or surgery.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Endometrial Cancer Diagnosis]:

1. Member has not previously failed other PD-1 inhibitors [e.g., Opdivo (nivolumab)]; and
2. Disease progression following prior systemic therapy; and
    a. Member is not a candidate for curative surgery or radiation; and
    b. Used in 1 of the following settings:
        i. In combination with lenvatinib for advanced endometrial cancer that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); or
        ii. As a single agent for advanced endometrial cancer that is MSI-H or dMMR; or
3. Primary advanced (newly diagnosed stage III/IVA or stage IVB) or recurrent endometrial cancer; and

a. Used in combination with carboplatin and paclitaxel followed by single-agent maintenance pembrolizumab.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Esophageal or Gastroesophageal Junction (GEJ) Carcinoma Diagnosis]:

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

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

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

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Diagnosis of head and neck cancer; and
2. Squamous cell histology; and
~~3. Used in first-line or recurrent setting; and~~
~~4. If used in the recurrent setting, member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].~~

5. Used in first-line or recurrent setting for resectable locally advanced disease; and
    a. As neoadjuvant and adjuvant addition to standard care (surgery and adjuvant radiotherapy with or without concomitant chemotherapy); and
    b. Tumor expresses PD-L1 [Combined Positive Score (CPS) ≥1]; and
    c. Request must be for Keytruda®. Keytruda Qlex™ may not be used in the neoadjuvant/adjuvant addition setting; or
6. Used in metastatic or unresectable disease, as first-line or subsequent-line therapy, in combination with chemotherapy; and
    a. Pembrolizumab was not previously used; and
    b. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; or
7. As subsequent therapy as a single agent; and
    a. Disease is PD-L1 positive recurrent or metastatic disease; or
    b. Disease is tumor-mutational burden-high (TMB-H) tumors (≥10 mut/Mb); or
    c. Disease has progressed on or after prior platinum therapy.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/Berahyaluronidase Alfa-pmph) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of relapsed or progressive HCC; and
2. Member must have been previously treated with sorafenib; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/Berahyaluronidase Alfa-pmph) Approval Criteria [Melanoma Diagnosis]:

1. Member meets 1 of the following:
    a. Adjuvant treatment of adult and pediatric members 12 years of age or older with stage 2B, 2C, or 3 melanoma following complete resection; or
    b. Diagnosis of unresectable or metastatic melanoma in adults; and
2. Used as a single agent; and
3. Member meets 1 of the following:
    a. Used as first-line therapy; or
    b. Used as second-line therapy or subsequent therapy for disease progression if not previously used; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
5. For adjuvant treatment of melanoma, approvals will be for a maximum duration of 1 year.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. Diagnosis of recurrent, locally advanced, or metastatic MCC; and
2. No history of prior systemic chemotherapy; and
3. Used as a single agent; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
5. Member must be 12 years of age or older; and
6. For use of Keytruda Qlex™, member must weigh ≥40kg.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic malignant pleural mesothelioma; and
2. Used as first-line therapy in adult members; and
3. Used in combination with pemetrexed and platinum chemotherapy.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Metastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. Tumor proportion scores for programmed death ligand 1 (PD-L1) expression as follows:
    a. As a single agent, first-line: ≥1%; or
    b. First-line in combination: No expression required; or
    c. As a single agent, second-line: ≥1%; and
4. Member meets 1 of the following:
    a. Previously untreated, metastatic squamous NSCLC in combination with carboplatin and either paclitaxel or nab-paclitaxel; or
    b. Previously untreated, metastatic non-squamous NSCLC in combination with pemetrexed and carboplatin; or
    c. New diagnosis as first-line therapy (member has not received chemotherapy to treat disease) if:
        i. Tumor does not express sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) translocations; or
    d. Used as a single agent for disease progression on or after platinum-containing chemotherapy (i.e., cisplatin, carboplatin):
        i. Members with EGFR-mutation-positive tumors should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations* (*examples of*

drugs for EGFR-mutation-positive tumors: osimertinib, erlotinib, afatinib, or gefitinib); and

ii. Members with ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations (examples of drugs for ALK-mutation-positive tumors: crizotinib, ceritinib, or alectinib).*

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumor (Tissue/Site-Agnostic) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)]; and
2. MSI-H or dMMR solid tumors that have progressed following prior treatment with no satisfactory alternative treatment options; and
3. For Keytruda®, member must be 6 months of age or older; or
   a. For Keytruda Qlex™, member must be 12 years of age or older and weigh ≥40kg.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Nonmetastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of stage 3 NSCLC; and
   a. Ineligible for surgery or definitive chemoradiation; and
   b. Tumor proportion scores for PD-L1 expression ≥1%; and
   c. Member has not previously failed other PD-1 inhibitors [e.g., Opdivo (nivolumab)]; or
2. Diagnosis of stage 1B (T2a ≥4cm), stage 2, or stage 3A NSCLC; and
   a. Used as adjuvant treatment following resection and platinum-based chemotherapy; or
3. Diagnosis of resectable (tumors ≥4cm or node positive) NSCLC; and
   a. Used as neoadjuvant treatment in combination with platinum-containing chemotherapy; and
   b. Continued as a single agent as adjuvant treatment after surgery.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [~~Non-Muscle Invasive~~ Bladder Cancer ~~(NMIBC)~~ Diagnosis]:

1. For non-muscle invasive bladder cancer (NMIBC):
   a. Diagnosis of high-risk NMIBC; and
   b. Member must have failed therapy with Bacillus Calmette-Guerin (BCG)-therapy; and
   c. Member must be ineligible for or has elected not to undergo cystectomy; or
2. For muscle invasive bladder cancer (MIBC):

a. Used as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment; and
b. Used in combination with enfortumab vedotin; and
c. Member is ineligible for cisplatin-containing chemotherapy.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of new or recurrent stage 4 clear-cell RCC; and
   a. Member has not received previous systemic therapy for advanced disease; and
   b. Must be used in combination with axitinib or lenvatinib; and
   c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; or
2. Diagnosis of RCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of metastatic SCLC; and
2. Progressed on or following a platinum-based regimen and at least 1 other regimen; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Tumor Mutational Burden-High (TMB-H) Solid Tumors Diagnosis]:

1. Diagnosis of unresectable or metastatic TMB-H [≥10 mutations/megabase (mut/Mb)] solid tumors; and
2. Used following disease progression after prior treatment; and
3. No satisfactory alternative treatment options; and
4. For Keytruda®, member must be 6 months of age or older; or
   a. For Keytruda Qlex™, member must be 12 years of age or older and weigh ≥40kg.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Member must have 1 of the following:
   a. As a single agent for locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy; or
   b. As a single agent within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; or

c. As a single agent frontline for members with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy or any platinum-containing chemotherapy; and
    i. Cisplatin ineligibility is defined as:
        1. Baseline creatinine clearance of <60mL/min; or
        2. ECOG performance status of 2; or
        3. Class III heart failure; or
        4. Grade 2 or greater peripheral neuropathy; or
        5. Grade 2 or greater hearing loss; or
d. In combination with enfortumab vedotin-ejfv for locally advanced or metastatic urothelial carcinoma; and

2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)].

Next, the College of Pharmacy recommends the prior authorization of Opdivo Qvantig™ (nivolumab/hyaluronidase-nvhy) with criteria similar to Opdivo® (nivolumab) and recommends additional updates based on recent FDA approvals and NCCN recommendations for nivolumab (changes and new criteria shown in red):

~~**Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Adjuvant Treatment of Melanoma Diagnosis]:**~~

~~1. Member has had complete resection of melanoma; and~~
~~2. Diagnosis of stage 2B, 2C, 3, or 4 melanoma following complete resection; and~~
~~3. Member is 12 years of age or older for Opdivo®; and or~~
    ~~a. Member is 18 years of age or older for Opdivo Qvantig™; and~~
~~4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and~~
~~5. Used as a single agent; and~~
~~6. Opdivo Qvantig™ must not be used in combination with ipilimumab; and~~
~~7. Maximum approval duration of 1 year.~~
~~8. Dose as follows:~~
    ~~a. Adult and pediatric patients ≥40kg: 240mg every 2 weeks or 480mg every 4 weeks; or~~
    ~~b. Pediatric patients <40kg: 3mg/kg every 2 weeks or 6mg/kg every 4 weeks; and~~
    ~~c. Maximum duration of 1 year.~~

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Tumor is microsatellite-instability high (MSI-H), ~~or~~ mismatch repair deficient (dMMR), or has polymerase epsilon/delta (POLE/POLD1)

mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50mut/Mb]; and
3. Used as a single agent or in combination with ipilimumab; and
4. Member must be 12 years of age or older; and
    a. Member must weigh ≥30kg for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Cutaneous ~~Unresectable or Metastatic~~ Melanoma Diagnosis]:

1. Diagnosis of stage 2B, 2C, 3, or 4 melanoma following complete resection; and
    a. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
    b. Used as a single agent; and
    c. Maximum approval duration of 1 year; or
2. Diagnosis of stage 3 disease with clinically positive nodes; and
    a. Used as neoadjuvant therapy; and
    b. Used in combination with ipilimumab or as a single agent; and
    c. Adjuvant nivolumab may be continued after therapeutic lymph node dissection (TLND) for 11 cycles; or
3. Diagnosis of unresectable or metastatic melanoma; and
    a. Used as a single agent or in combination with ipilimumab:
        i. As first-line therapy for untreated melanoma; or
        ii. As second-line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy; and
        iii. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Member ~~is~~ must be 12 years of age or older; and
    a. Member must weigh ≥30kg for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.
~~6. Dose as follows:~~
    ~~a. Single agent:~~
        ~~i. Adult and pediatric patients ≥40kg: 240mg every 2 weeks or 480mg every 4 weeks; or~~
        ~~ii. Pediatric patients <40kg: 3mg/kg every 2 weeks or 6mg/kg every 4 weeks; or~~
    ~~b. In combination with ipilimumab:~~
        ~~i. Adult and pediatric patients ≥40kg: Nivolumab 1mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 240mg every 2 weeks or 480mg every 4 weeks; or~~
        ~~ii. Pediatric patients <40kg: 1mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 3mg/kg every 2 weeks or 6mg/kg every 4 weeks.~~

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) or Esophageal or Gastroesophageal Junction (GEJ) Cancer Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic ESCC; and
    a. Used in the first-line setting; and
    b. Used in combination with 1 of the following:
        i. Fluoropyrimidine- and platinum-based chemotherapy; or
        ii. Ipilimumab; ~~or~~ and
    c. Tumor is positive for expression of programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1; or
2. Diagnosis of esophageal or GEJ cancer; and
    a. Used in 1 of the following settings:
        i. Member has received preoperative chemoradiation; and
            1. Member underwent R0 (complete) resection and has residual disease; and
            2. As a single agent; or
        ii. As induction therapy in members who are medically fit and planned for esophagectomy; and
            1. Squamous cell histology; and
            2. Tumor is positive for expression of PD-L1 with a CPS ≥1 or tumor is microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR); and
            3. Used in combination with fluoropyrimidine- and platinum-based chemotherapy or used in combination with ipilimumab; or
3. Palliative therapy for members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease; and
    a. Human epidermal receptor 2 (HER2)-negative disease; and
        i. Used in first-line setting; and
            1. Used in combination with oxaliplatin and fluorouracil or capecitabine; and
            2. Adenocarcinoma pathology; ~~or~~ and
            3. Tumor is positive for expression of PD-L1 with a CPS ≥1; or
        ii. Used in the second-line or greater setting; and
            1. As a single agent; and
            2. Squamous cell pathology; and
4. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Gastric Cancer Diagnosis]:

1. Diagnosis of locally advanced, recurrent, or metastatic human epidermal receptor 2 (HER2) negative disease; and
2. Tumor is positive for expression of programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1

3. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; and
4. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic head and neck cancer; and
2. Squamous cell histology; and
3. Member has received prior platinum-containing regimen (i.e., cisplatin, carboplatin); and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
5. Member must be 18 years of age or older for Opdivo Qvantig™; and
6. Opdivo Qvantig™ must not be used in combination with ipilimumab.
7. ~~Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.~~

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of HCC; and
2. Member must have unresectable disease and is not a transplant candidate, metastatic disease, or extensive liver tumor burden; and
3. Must meet 1 of the following:
   a. Used as first-line systemic therapy, in combination with ipilimumab, if no previous anti-CTLA-4 combination therapy; or
   b. Used as subsequent therapy, as a single agent, if not previously treated with another checkpoint inhibitor as subsequent therapy; and
   c. ~~If used as first-line therapy, must be used as single agent; and~~
      i. ~~Ineligible for tyrosine kinase inhibitors or anti-angiogenic agents; or~~
   d. ~~If used as second-line or greater therapy, may be used as single agent or in combination with ipilimumab; and~~
      i. ~~Must not have failed other checkpoint inhibitors; and~~
4. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Opdivo® (Nivolumab) Approval Criteria [Hodgkin Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory classical Hodgkin lymphoma and member does not have lymphocyte-predominant Hodgkin lymphoma; and
   a. ~~Exception: lymphocyte-predominant Hodgkin lymphoma~~
2. Nivolumab must be used in 1 of the following settings:
   a. As a single-agent; or
   b. In combination with doxorubicin, vinblastine, and dacarbazine (AVD) for primary systemic therapy in stage III-IV disease or

together with involved-site radiation therapy (ISRT) for state I-II (unfavorable) disease; or
   c. In combination with ISRT plus brentuximab vedotin or as a single agent for primary systemic therapy in members who are not a candidate for anthracyclines; or
   d. In combination with brentuximab vedotin or ifosfamide, carboplatin, and etoposide (ICE) as second line or subsequent therapy after failure of autologous stem cell transplant (SCT), allogeneic SCT, or those who are transplant-ineligible; and
3. Member has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)].

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of NSCLC; and
2. For first-line therapy for recurrent, advanced, or metastatic disease, meeting the following:
   a. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
   b. Used in combination with Yervoy® (ipilimumab) and 2 cycles of platinum-doublet chemotherapy; ~~and~~ or
   ~~c. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and~~
   d. Used in combination with Yervoy® (ipilimumab) and expresses programmed death ligand 1 (PD-L1) ≥1%; or
3. For first-line therapy for resectable disease (>4cm or node positive), meeting the following:
   a. Used in the neoadjuvant setting in combination with platinum-doublet chemotherapy for up to 3 treatment cycles; or
4. For resectable disease (tumors ≥4cm or node positive), meeting the following:
   a. Used in the neoadjuvant setting in combination with platinum-doublet chemotherapy, followed by single-agent nivolumab as adjuvant treatment after surgery; and
   b. No known EGFR mutations or ALK rearrangements; or
5. For second-line therapy for metastatic disease, meeting the following:
   a. Tumor histology is 1 of the following:
      i. Adenocarcinoma; or
      ii. Squamous cell; or
      iii. Large cell; and
   b. Disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin); and
   c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
   d. Used as a single agent; and
   ~~e. Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.~~

6. Member must be 18 years of age or older for Opdivo Qvantig™; and
7. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
2. Used in 1 of the following settings:
    a. For nivolumab monotherapy:
        i. Diagnosis of relapsed or surgically unresectable stage 4 disease; and
        ii. Failed prior therapy with 1 of the following medications:
            1. Sunitinib; or
            2. Sorafenib; or
            3. Pazopanib; or
            4. Axitinib; or
    b. For nivolumab use in combination with ipilimumab:
        i. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; or
    c. For nivolumab use in combination with cabozantinib:
        i. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with advanced RCC; and
        ii. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years; and
3. Member must be 18 years of age or older for Opdivo Qvantig™; and
4. Opdivo Qvantig™ must not be used in combination with ipilimumab.
5. ~~Dose as follows:~~
    ~~a. Single agent: 240mg every 2 weeks or 480mg every 4 weeks; or~~
    ~~b. In combination with ipilimumab: nivolumab 3mg/kg followed by ipilimumab 1mg/kg on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240mg every 2 weeks or 480mg every 4 weeks thereafter; or~~
    ~~c. In combination with cabozantinib: cabozantinib 40mg once daily with nivolumab 240mg every 2 weeks or 480mg every 4 weeks; nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.~~

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Must meet 1 of the following criteria:
    a. Disease relapsed within 6 months of initial chemotherapy; or
    b. Disease is progressive on initial chemotherapy; and
2. Used as a single agent; and

3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Urothelial Bladder Cancer Diagnosis]:

1. Diagnosis of urothelial carcinoma; and
   a. Member has undergone radical resection; and
   b. Disease is at high risk of recurrence; or
2. Diagnosis of metastatic or unresectable locally advanced disease; and
   a. Used as second-line or greater therapy; and
   b. Previous failure of a platinum-containing regimen; and
   c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; or
3. Diagnosis of metastatic or unresectable urothelial carcinoma; and
   a. Used as first-line therapy; and
   b. In combination with cisplatin and gemcitabine; and
   c. Followed by maintenance treatment with nivolumab for a maximum duration of 24 months of therapy; and
4. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Next, the College of Pharmacy also recommends updating the approval criteria for Braftovi® (encorafenib) and Zynyz® (retifanlimab-dlwr) based on recent FDA approvals (new criteria and changes shown in red):

Braftovi® (Encorafenib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of advanced or metastatic colorectal cancer (CRC); and
   a. BRAF V600E mutation positive; and
   b. Used in combination with cetuximab or panitumumab; and
   c. Disease must have progressed following adjuvant therapy within 12 months; or
   d. Used following progression of any line of metastatic therapy; or
2. Diagnosis of metastatic CRC; and
   a. BRAF V600E mutation positive; and
   b. Used in combination with cetuximab and mFOLFOX6 (fluorouracil, leucovorin, and oxaliplatin).

Zynyz® (Retifanlimab-dlwr) Approval Criteria [Squamous Cell Carcinoma of the Anal Canal (SCAC) Diagnosis]:

1. Diagnosis of SCAC; and
2. Used as first-line treatment in combination with carboplatin and paclitaxel; and
   a. Inoperable locally recurrent or metastatic disease; and
   b. A maximum treatment duration of 12 months will apply; or

3. Used as a single agent; and
    a. Locally recurrent or metastatic disease; and
    b. Used as subsequent or second-line therapy if progression or intolerance to platinum-based chemotherapy; and
    c. Member has received no prior immunotherapy; and
    d. A maximum treatment duration of 24 months will apply; and
4. Member must be 18 years of age or older.

Next, the College of Pharmacy recommends updating the Libtayo® (cemiplimab-rwlc), Mekinist® (trametinib), Odomzo® (sonidegib), Tafinlar® (dabrafenib), Yervoy® (ipilimumab), and Zelboraf® (vemurafenib) criteria based on recent FDA approvals and NCCN recommendations (changes and new criteria shown in red):

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Cutaneous Squamous Cell Carcinoma (CSCC) Diagnosis]:

1. Diagnosis of metastatic or locally advanced CSCC; and
2. Member must meet 1 of the following:
    a. Disease is very-high risk; and
        i. Used as neoadjuvant treatment when surgery alone may be insufficient; or
        ii. Used as adjuvant treatment following surgery or radiation in patients at high risk of recurrence; or
    b. Disease is primary or recurrent; and
        i. Used for systemic therapy alone when curative surgery and curative radiation are not feasible; and
~~3. Member is not eligible for curative surgery or radiation; and~~
4. Member has not received prior immunotherapy agent(s) [e.g., Keytruda® (pembrolizumab)~~, Opdivo (nivolumab), Yervoy (ipilimumab)~~].

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of advanced, unresectable, or metastatic NSCLC; and
2. Used in the first-line setting; and
3. No epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS1 mutations; and
4. Used in 1 of the following settings:
    a. Used as a single agent; and
        i. High programmed death ligand 1 (PD-L1) expression [tumor proportion score (TPS) ≥50%]; or
    b. Used in combination with platinum-based chemotherapy; and
        i. No requirement for PD-L1 expression; or
    c. Used as continuation maintenance therapy following first line therapy with cemiplimab; and
        i. Used in combination with pemetrexed; or
        ii. Used as a single agent.

Mekinist® (Trametinib) Approval Criteria [~~Anaplastic~~ Thyroid Cancer ~~(ATC)~~ Diagnosis]:

1. Diagnosis of ~~ATC~~ thyroid cancer; and
2. Locally advanced or metastatic disease; and
2. *BRAF* V600E mutation; and
~~3. No satisfactory locoregional treatment options.~~
4. Used following progression following prior treatment options and no satisfactory alternative treatment options; and
5. Used in combination with dabrafenib.

Mekinist® (Trametinib) Approval Criteria [Serous Ovarian Cancer Diagnosis]:

1. Diagnosis of persistent disease or recurrent low-grade serous carcinoma; and
2. Meets 1 of the following:
    a. Used in combination with dabrafenib; and
        i. Immediate treatment for serially rising CA-125 in members who previously received chemotherapy; or
        ii. Progression on primary, maintenance, or recurrence therapy; or
        iii. Stable or persistent disease (if not on maintenance therapy); or
        iv. Complete remission and relapse after completing chemotherapy; or
    b. Used as a single agent for platinum-sensitive or platinum-resistant recurrence.

Mekinist® (Trametinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member must not have colorectal cancer; and
4. Member must be 1 year of age or older; and
5. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
6. Used in combination with dabrafenib.

Odomzo® (Sonidegib) Approval Criteria [Basal Cell Carcinoma (BCC) Diagnosis]:

1. Diagnosis of locally advanced BCC that has either:
    a. Recurred following surgery or radiation therapy; or
    b. Surgery or radiation is contraindicated.~~; or~~
~~2. Diagnosis of metastatic BCC.~~

Tafinlar® (Dabrafenib) Approval Criteria [~~Anaplastic~~ Thyroid Cancer ~~(ATC)~~ Diagnosis]:

1. Diagnosis of ~~ATC~~ thyroid cancer; and
2. Locally advanced or metastatic disease; and

3. *BRAF* V600E mutation; and
4. ~~No satisfactory locoregional treatment options.~~
5. Used following progression following prior treatment options and no satisfactory alternative treatment options; and
6. Used in combination with trametinib.

Tafinlar® (Dabrafenib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member must not have colorectal cancer; and
4. Member must be 1 year of age or older; and
5. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
6. Used in combination with trametinib.

~~**Yervoy® (Ipilimumab) Approval Criteria [Adjuvant Treatment of Melanoma Diagnosis]:**~~

~~1. Member has had complete resection of melanoma with lymphadenectomy; and~~
~~2. Member has stage 3 disease with regional nodes of >1mm and no in-transit metastasis; and~~
~~3. Used as a single agent; and~~
~~4. Maximum dose of 10mg/kg will apply.~~

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

1. Diagnosis of unresectable advanced or metastatic ESCC; and
   a. Used in the first-line setting; and
   b. Used in combination with nivolumab; and
   c. Tumor is positive for expression of programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1 or tumor is microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR); or
2. Used as induction therapy in members who are medically fit and planned for esophagectomy; and
   a. Tumor is positive for expression of PD-L1 with a CPS ≥1 or tumor is MSI-H or dMMR; and
   b. Used in combination with nivolumab.

Yervoy® (Ipilimumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Must meet 1 of the following:
   a. Member must have unresectable disease and is not a transplant candidate; or
   b. Metastatic disease or extensive liver tumor burden; and
2. Must meet 1 of the following:
   a. Used in the first-line setting; or

b. Used as second-line or greater therapy in members with progression on or after prior therapy; and
3. Used in combination with nivolumab; and
4. Must not have failed other checkpoint inhibitors.

Yervoy® (Ipilimumab) Approval Criteria [Cutaneous Melanoma Diagnosis]:

1. Stage 3 cutaneous melanoma with regional nodes of >1mm and no in-transit metastasis; and
    a. Used as a single agent; or
2. As neoadjuvant therapy in combination with nivolumab as initial primary treatment for stage III cutaneous melanoma disease with clinically positive nodes; or
3. Unresectable or metastatic melanoma; and
    a. Used in combination with nivolumab as:
        i. First-line therapy; or
        ii. Second-line or subsequent therapy for disease progression if nivolumab was not previously used; or
    b. Used as a single agent for 1 of the following:
        i. First-line therapy as a single course of 4 treatments; or
        ii. Second-line or subsequent lines of therapy as a single course of 4 treatments; or
        iii. Retreatment, consisting of a 4-dose limit, for a member who had:
            1. No significant systemic toxicity during prior ipilimumab therapy; and
            2. Whose disease progressed after being stable >6 months following completion of a prior course of ipilimumab; and
            3. For whom no intervening therapy has been administered.

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

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
    a. Used for first-line therapy ~~and must meet the following:~~; and
    b. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
    c. Used in 1 of the following settings:
        i. Used in combination with nivolumab and member has programmed death ligand 1 (PD-L1) ≥1% expression; or
        ii. Used in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy.~~; and~~
        iii. ~~Expresses programmed death ligand 1 (PD-L1) ≥1%.~~

~~**Yervoy® (Ipilimumab) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:**~~

~~1. Diagnosis of unresectable or metastatic melanoma; and~~

~~2. Used in combination with nivolumab as:~~
~~a. First-line therapy; or~~
~~b. Second-line or subsequent therapy for disease progression if nivolumab was not previously used; or~~
~~3. Used as a single agent for 1 of the following:~~
~~a. First-line therapy as a single course of 4 treatments; or~~
~~b. Second-line or subsequent lines of therapy as a single course of 4 treatments; or~~
~~c. Retreatment, consisting of a 4-dose limit, for a member who had:~~
~~i. No significant systemic toxicity during prior ipilimumab therapy; and~~
~~ii. Whose disease progressed after being stable >6 months following completion of a prior course of ipilimumab; and~~
~~iii. For whom no intervening therapy has been administered; and~~
~~4. Maximum dose of 3mg/kg will apply.~~

Zelboraf® (Vemurafenib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
   a. Vemurafenib is not indicated for wild-type *BRAF* melanoma; and
3. Must meet 1 of the following:
   a. Used as first-line therapy; or
   b. Used as second-line or subsequent therapy; and

   Used as a single agent or in combination with cobimetinib, or in combination with cobimetinib and atezolizumab.

Recommendation 10: Vote to Update the Approval Criteria for the Gastrointestinal (GI) Cancer Medications

MOTION CARRIED by unanimous approval.

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

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

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

Recommendation 11: Vote to Prior Authorize Gomekli® (Mirdametinib), Papzimeos™ (Zopapogene Imadenovec-drba), and Romvimza™ (Vimseltinib) and Update the Approval Criteria for the Non-Malignant Solid Tumor Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Gomekli® (mirdametinib), Papzimeos™ (zopapogene imadenovec-drba), and Romvimza™ (vimseltinib) with the following criteria (shown in red):

Gomekli® (Mirdametinib) Approval Criteria [Neurofibromatosis Type 1 (NF1) Diagnosis]:

1. Diagnosis of NF1; and
2. Member must be 2 years of age or older; and
3. Member has symptomatic plexiform neurofibromas not amenable to complete resection; and
4. Member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug required according to package labeling.

Papzimeos™ (Zopapogene Imadenovec-drba) Approval Criteria [Recurrent Respiratory Papillomatosis Diagnosis]:

1. Diagnosis of recurrent respiratory papillomatosis; and
2. Member must be 18 years of age or older; and
3. Initial administration will follow surgical debulking of visible papilloma to maintain minimal residual disease; and
4. Visible papilloma will be removed, if present, prior to the third and fourth administration; and
5. Approvals will be for no more than 4 doses per member per lifetime.

Romvimza™ (Vimseltinib) Approval Criteria [Tenosynovial Giant Cell Tumor (TGCT) Diagnosis]:

1. Diagnosis of TGCT; and
2. Member is 18 years of age or older; and
3. Member is not a candidate for surgical resection.

Additionally, the College of Pharmacy recommends updating the Koselugo® (selumetinib) approval criteria based on recent FDA approvals with the following changes (shown in red):

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

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

3. Member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug required according to package labeling; and
4. For the 5mg and 7.5mg oral granule formulation, the request must indicate that the member is unable to swallow whole capsules.

Recommendation 12: Vote to Prior Authorize Alyglo™ [Immune Globulin (IG) Intravenous (IV), Human-stwk], Asceniv™ (IGIV, Human-slra), Bivigam® (IGIV, Human), Cuvitru® [IG Subcutaneous (SC), Human], Gammaplex® (IGIV, Human), Hizentra® (IGSC, Human), Octagam® (IGIV, Human), Panzyga® (IGIV, Human-ifas), and Xembify® (IGSC, Human)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Alyglo™ (IGIV, human-stwk), Asceniv™ (IGIV, human-slra), Bivigam® (IGIV, human), Cuvitru® (IGSC, human), Gammaplex® (IGIV, human), Hizentra® (IGSC, human), Octagam® (IGIV, human), Panzyga® (IGIV, human-ifas), and Xembify® (IGSC, human) with the following criteria (shown in red):

Alyglo™ [Immune Globulin (IG) Intravenous (IV), Human-stwk], Asceniv™ (IGIV, Human-slra), Bivigam® (IGIV, Human), Cuvitru® [IG Subcutaneous (SC), Human], Gammaplex® (IGIV, Human), Hizentra® (IGSC, Human), Octagam (IGIV, Human), Panzyga® (IGIV, Human-ifas) and Xembify® (IGSC, Human) Approval Criteria:

1. Documentation of prior stabilization on the requested product with documented benefit from therapy (i.e., recent office notes) must be submitted with the request; or
2. For Alyglo™ and Asceniv™, a patient-specific clinically significant reason why the member cannot use all other available immunoglobulin therapy products must be provided; or
3. A patient-specific, clinically significant reason why the member cannot use all of the following, which are available without prior authorization, as appropriate for the requested route of administration:
    a. For intravenous (IV) administration:
        i. Gammagard Liquid® (IG infusion, human); and
        ii. Gammagard S/D® (IGIV, human); and
        iii. Gammaked™ (IG injection, human); and
        iv. Gamunex®-C (IG injection, human); and
        v. Privigen® (IGIV, human); and
    b. For subcutaneous (SC) administration:
        i. Cutaquig® (IGSC, human); and
        ii. HyQvia® (IG infusion, human and recombinant human hyaluronidase); and
        iii. Gammagard Liquid® (IG infusion, human); and
        iv. Gammaked™ (IG injection, human); and
        v. Gamunex®-C (IG injection, human); and

4. Member's recent weight (taken within the last 3 months) utilized for dosing calculations (e.g., actual body weight, ideal body weight, adjusted body weight) and intended dosing frequency must be provided on the prior authorization request in order to authorize the appropriate amount of product; and
5. Initial approvals will be for up to 6 months. Subsequent approval will be for the duration of up to 1 year if there is documentation of clinical effectiveness.

Recommendation 13: Vote to Prior Authorize Redemplo® (Plozasiran) and Update the Approval Criteria for the Antihyperlipidemics

MOTION CARRIED by unanimous approval.

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

Redemplo® (Plozasiran) Approval Criteria:

1. An FDA approved indication to reduce triglyceride levels in adults with familial chylomicronemia syndrome (FCS); and
2. Diagnosis of FCS must be confirmed by the following:
    a. Fasting triglyceride levels ≥880mg/dL; and
    b. One of the following:
        i. Genetic testing identifying biallelic pathogenic variants in the *LPL, GPIHBP1, APOA5, APOC2*, or *LMF1* genes (results of genetic testing must be submitted); or
        ii. Familial chylomicronemia score ≥10; or
        iii. North American familial chylomicronemia syndrome score ≥45; or
        iv. History of clinical signs and symptoms associated with FCS (i.e., pancreatitis and/or abdominal pain, eruptive xanthomas, lipemia retinalis, lipemic plasma) and a diagnosis of multifactorial chylomicronemia syndrome (MCS) has been ruled out; and
3. Member must be 18 years of age or older; and
4. Must be prescribed by, or in consultation with, a cardiologist, an endocrinologist, or a specialist with expertise in the treatment of disorders related to severe hypertriglyceridemia; and
5. Prescriber must verify the member is on a low-fat diet of ≤20g of fat per day and will continue the low-fat diet while on treatment with Redemplo®; and
6. Member or caregiver will be trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Redemplo®; and

7. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment, as indicated by a reduction in fasting triglyceride levels, decreased episodes of acute pancreatitis, and/or other documentation of a positive clinical response to therapy. Subsequent approvals will be for the duration of 1 year.

Tryngolza® (Olezarsen) Approval Criteria:

1. An FDA approved indication to reduce triglyceride levels in adults with familial chylomicronemia syndrome (FCS); and
2. Diagnosis of FCS must be confirmed by the following:
    a. Fasting triglyceride levels ≥880mg/dL; and
    b. One of the following:
        i. Genetic testing identifying biallelic pathogenic variants in the *LPL, GPIHBP1, APOA5, APOC2*, or *LMF1* genes (results of genetic testing must be submitted); or
        ii. Familial chylomicronemia score ≥10; or
        iii. North American familial chylomicronemia syndrome score ≥45; or
        iv. History of clinical signs and symptoms associated with FCS (i.e., pancreatitis and/or abdominal pain, eruptive xanthomas, lipemia retinalis, lipemic plasma) and a diagnosis of multifactorial chylomicronemia syndrome (MCS) has been ruled out; and
3. Member must be 18 years of age or older; and
4. Must be prescribed by, or in consultation with, a cardiologist, an endocrinologist, or a specialist with expertise in the treatment of disorders related to severe hypertriglyceridemia; and
5. Prescriber must verify the member is on a low-fat diet of ≤20g of fat per day and will continue the low-fat diet while on treatment with Tryngolza®; and
6. Member or caregiver ~~has been~~ will be trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tryngolza®; and
7. A patient specific, clinically significant reason why the member cannot use Redemplo® (plozasiran) must be provided; and
8. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment, as indicated by a reduction in fasting triglyceride levels, decreased episodes of acute pancreatitis, and/or other documentation of a positive clinical response to therapy. Subsequent approvals will be for the duration of 1 year.

Additionally, the College of Pharmacy recommends updating the approval criteria for Evkeeza® (evinacumab-dgnb), Leqvio® (inclisiran), Nexletol® (bempedoic acid), Nexlizet® (bempedoic acid/ezetimibe), Praluent®

(alirocumab), and Repatha® (evolocumab) based on the new FDA approved label expansions and clinical practice (changes shown in red):

Evkeeza® (Evinacumab-dgnb) Approval Criteria:

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

Leqvio® (Inclisiran) Approval Criteria:

1. An FDA approved indication as an adjunct to diet and exercise ~~statin therapy~~ for the treatment of 1 of the following:

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

2. Member must be 18 years of age or older; and
3. Documented trial of all of the following for at least 12 weeks in duration each:
    a. High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy; and
    b. Ezetimibe; and
    c. Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®); and
4. Members with statin intolerance must meet 1 of the following:
    a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C must be provided); and
6. Leqvio® must be administered by a health care professional. Approvals will not be granted for self-administration; and
    a. Prior authorization requests must indicate how Leqvio® will be administered (e.g., prescriber, pharmacist, home health care provider); and
        i. Leqvio® must be shipped to the facility where the member is scheduled to receive treatment; or
        ii. Prescriber must verify the member has been counseled on the proper storage of Leqvio®; and

7. Initial approvals will be for the duration of 6 months. Continued authorization at that time will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of this medication, and compliance will be checked at that time and every 6 months thereafter for continued approval.

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

1. An FDA approved indication of 1 of the following:
    a. As an adjunct to diet and exercise, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies or alone when concomitant LDL-C lowering therapies are not possible to reduce LDL-C in those with heterozygous familial hypercholesterolemia (HeFH). HeFH must be confirmed by 1 of the following:
        i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. Both of the following:
            1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
            2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
        iii. Dutch Lipid Clinic Network Criteria score of >8; or
    b. As an adjunct to diet and exercise, in combination with other LDL-C lowering therapies or alone when concomitant LDL-C lowering therapies are not possible to reduce LDL-C in those with primary hyperlipidemia; and
        i. Member's untreated LDL-C level must be ≥190mg/dL; and
        ii. Current LDL-C level is ≥100mg/dL; and
    c. To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, and coronary revascularization) in ~~those~~ adults at increased risk for these events who are unable to take recommended statin therapy; and ~~with 1 of the following:~~
        ~~i. High risk for a cardiovascular disease (CVD) event without established atherosclerotic CVD (ASCVD); or~~
        ~~ii. Established ASCVD; and~~
        iii. Supporting diagnoses/conditions/risk factors ~~and dates of occurrences must be submitted~~ signifying increased risk of major adverse CV events must be submitted; and
2. Member must be 18 years of age or older; and
3. Member must be on a stable dose of maximally tolerated statin therapy for at least 4 weeks (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and

a. LDL-C levels should be included following at least 4 weeks of treatment; and
b. Member must not be taking simvastatin at doses >20mg or pravastatin at doses >40mg due to drug interactions with Nexletol® and Nexlizet®; and

4. Members with statin intolerance must meet 1 of the following:
   a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
   b. An FDA labeled contraindication to all statins; or
   c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
   d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
6. A quantity limit of 30 tablets per 30 days will apply; and
7. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Praluent® (Alirocumab) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
      i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles know to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
      ii. Both of the following:
         1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
         2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
      iii. Dutch Lipid Clinic Network Criteria score of >8; or
   b. Homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:
      i. Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
      ii. An untreated LDL >500mg/dL and at least 1 of the following:
         1. Documented evidence of definite HeFH in both parents; or

2. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; or

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

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

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

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

Repatha® (Evolocumab)] Approval Criteria:

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

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

Recommendation 14: Vote to Prior Authorize Coxanto® (Oxaprozin 300mg Capsule), Ibuprofen 300mg Tablet, Vyscoxa™ (Celecoxib Oral Suspension), and Xifyrm™ (Meloxicam Injection) and Update the Approval Criteria for the Systemic Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

MOTION CARRIED by unanimous approval.

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

1. Prior authorization and placement of Coxanto® (oxaprozin 300mg capsule), ibuprofen 300mg tablet, Vyscoxa™ (celecoxib oral suspension), and Xifyrm™ (meloxicam injection) into the Special PA Tier with the additional criteria listed below; and
2. Moving EC-Naprosyn® (naproxen) 375mg tablet from Tier-1 to Tier-2; and
3. Moving Feldene® (piroxicam) from Tier-2 to Tier-1 based on net cost.

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
celecoxib (Celebrex®) caps	diclofenac ER (Voltaren® XR)	celecoxib (Elyxyb®) oral solution
diclofenac potassium (Cataflam®)	diclofenac sodium/ misoprostol (Arthrotec®)	**celecoxib (Vyscoxa™) susp**
diclofenac sodium (Voltaren®) 50mg & 75mg tabs	diclofenac sodium (Voltaren®) 25mg tabs	diclofenac epolamine (generic Flector® Patch)
diclofenac sodium 1% (Voltaren® Gel)	diflunisal 500mg tabs	diclofenac potassium (Cambia®) powder pack
etodolac (Lodine®) tabs	etodolac ER (Lodine® XL)	diclofenac potassium (Lofena™) tabs
ibuprofen (Motrin®) **400mg, 600mg, & 800mg tabs**	flurbiprofen (Ansaid®)	diclofenac potassium (Zipsor®) caps
indomethacin (Indocin®) caps	indomethacin (Indocin® SR) ER caps	diclofenac sodium (Pennsaid®) topical drops
meloxicam (Mobic®)	mefenamic acid (Ponstel®)	diflunisal (Dolobid™) 250mg and 375mg tabs
nabumetone (Relafen®)	naproxen DR (EC-Naprosyn®) ~~**500mg tab**~~	fenoprofen (Nalfon®)
naproxen* (Naprosyn®)	naproxen sodium (Anaprox®) 275mg & 550mg tabs	ibuprofen (Caldolor®) inj
~~**naproxen DR (EC-Naprosyn®) 375mg tab**~~	oxaprozin (Daypro®) **600mg tabs**	**ibuprofen (Motrin®) 300mg tabs**
piroxicam (Feldene®)	~~**piroxicam (Feldene®)**~~	ibuprofen/acetaminophen (Combogesic® IV) inj+
sulindac (Clinoril®)		ibuprofen/famotidine (Duexis®)
		indomethacin (Indocin®) supp & susp
		ketoprofen (Orudis®) caps
		ketoprofen ER (Oruvail®)
		ketorolac tromethamine (Sprix®) nasal spray
		meclofenamate (Meclomen®)

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
		meloxicam (Vivlodex®) caps
		meloxicam (Xifyrm™) inj⁺
		nabumetone 1,000mg (Relafen DS®)
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)
		oxaprozin (Coxanto®) 300mg caps
		tolmetin (Tolectin®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Naproxen oral suspension is available without prior authorization for members 12 years of age and younger. Members older than 12 years of age require a reason why a special formulation product is needed in place of the regular tablet formulation.
⁺Unique criteria applies.
caps = capsules; DR = delayed-release; ER = extended-release; EC = enteric-coated; inj = injection; ODT = orally disintegrating tablet; PA = prior authorization; supp = suppository; susp = suspension; tabs = tablets

NSAIDs Special Prior Authorization (PA) Approval Criteria:

1. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or
2. Previous use of at least 2 Tier-1 NSAID products (from different product lines); and
3. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product; and
4. Additionally, use of Coxanto® (oxaprozin) 300mg capsule will require a patient-specific, clinically significant reason why the member cannot use generic oxaprozin 600mg tablets, which can be split to achieve the requested dose, must be provided; and
5. Additionally, use of Dolobid™ (diflunisal) 250mg or 375mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic diflunisal 500mg tablets; and
6. Additionally, use of Elyxyb® (celecoxib oral solution) will require a diagnosis of acute migraine treatment in adults 18 years of age and older and a patient-specific, clinically significant reason why the member cannot use Cambia® (diclofenac potassium powder); and
7. Additionally, use of ibuprofen 300mg tablets will require a patient-specific, clinically significant reason why the member cannot use all Tier-1 strengths of ibuprofen tablets and all other lower-tiered NSAIDs; and
8. Additionally, use of Lofena™ (diclofenac potassium) will require a patient-specific, clinically significant reason why the member cannot use all other available generic diclofenac products; and

9. Additionally, use of Vyscoxa™ (celecoxib oral suspension) will require a patient-specific, clinically significant reason why the member cannot use Tier-1 celecoxib capsules, which can be opened and sprinkled on applesauce for members with difficulties swallowing, must be provided.

Xifyrm™ (Meloxicam Injection) Approval Criteria:

1. An FDA approved diagnosis of management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics; and
2. Member must be 18 years of age or older; and
3. Member must be well hydrated before administration to reduce the risk of renal toxicity; and
4. Should be used for the shortest duration consistent with individual patient treatment goals; and
5. A patient-specific, clinically significant reason the member cannot use oral meloxicam tablets or other Tier-1 NSAID products must be provided; and
6. A quantity limit of 3 vials per 3 days will apply; and
7. For consideration of a longer duration of use, a patient-specific, clinically significant reason why the member cannot transition to an oral Tier-1 NSAID product must be provided, along with the anticipated duration of treatment.

Recommendation 15: Vote to Prior Authorize Zepbound® (Tirzepatide) and Update the Approval Criteria for the Adiposity-Based Chronic Disease (ABCD) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Zepbound® (tirzepatide) with the following criteria, including updates to the diet and exercise criteria in #9 for clarity and updates to #11 to update the 4-week approvals to 8 weeks to relieve logistical challenges of delays in the titration process as recommended by and approved unanimously by the DUR Board (shown in red):

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

1. An FDA approved indication of moderate to severe OSA in members with obesity; and
   a. Zepbound® will not be approved for obese members in the absence of OSA; and
2. Member must be 18 years of age or older; and
3. Member must have moderate-to-severe OSA defined as an apnea-hypopnea index (AHI) ≥15 determined by a polysomnography (PSG) or home sleep apnea testing (HSAT) with a technically adequate device (AHI value must be provided); and
4. Member has a body mass index (BMI) ≥30kg/m^2; and

5. Member must not have central or mixed sleep apnea; and
6. Member does not have type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM); and
7. Member has a hemoglobin A1C (HbA1c) <6.5%; and
8. Member will not be using Zepbound® in combination with other tirzepatide-containing products or any other glucagon-like peptide-1 (GLP-1) receptor agonist; and
9. Zepbound® must be used in conjunction with behavioral changes and/or a reduced calorie diet [clinical documentation (e.g., office notes) of ~~member's diet and exercise program~~ this discussion with the member must be included with the request]; and
10. For Zepbound® vials or KwikPen®, a patient-specific, clinically significant reason why the member cannot use the pen formulation must be provided (Zepbound® pens are preferred over the vials and KwikPen®); and
11. Initial approvals will be for the titration period to allow initial and escalation dosing. A separate prior authorization request must be submitted for each dose; and
    a. Approvals will be for ~~4~~ 8 weeks at a time to allow for proper dose escalation; and
    b. An additional ~~4~~ 8 weeks for each dose may be approved for those who experience intolerable adverse effects during dose escalation with proper documentation; and
    c. Members who cannot tolerate dose escalation to at least 5mg after an additional ~~4~~ 8-week approval will not be approved for continuation; and
12. Subsequent approvals for the maintenance dose (5mg to 15mg) will be approved for 1 year if the prescriber documents the following:
    a. Member is tolerating maintenance dosing and adherent to therapy; and
    b. Clinical improvement of OSA (e.g., patient-reported improvement in daytime sleepiness, partner-reported reduction of snoring episodes or pauses in breathing, reduction of AHI events); and
    c. Member has not developed T1DM or T2DM; and
    d. Member is continuing a reduced calorie diet and increased physical activity in conjunction with Zepbound®; and
13. A quantity limit of 4 pens or vials (2mL) per 28 days or 1 KwikPen® (2.4mL) per 28 days will apply; and
14. Zepbound® should be discontinued in members who cannot tolerate at least the 5mg once weekly maintenance dosing.

Additionally, the College of Pharmacy recommends the following changes to the Wegovy® (semaglutide) approval criteria based on the new FDA approved indication and formulation, including updates to the diet and exercise criteria for clarity and updates to #10 to update the 4-week approvals to 8 weeks to relieve logistical challenges of delays in the titration process as

recommended by and approved unanimously by the DUR Board, and recommends updating the Rezdiffra® (resmetirom) approval criteria based on net costs (changes shown in red):

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

1. An FDA approved indication of noncirrhotic MASH; and
   a. Wegovy® will not be approved for obese members in the absence of MASH; and
2. Member must be 18 years of age or older; and
3. Member must have moderate-to-advanced liver fibrosis (e.g., stage F2 or F3) confirmed by at least 1 of the following (results of the selected test must be submitted with the request):
   a. FibroScan with vibration controlled transient elastography (VCTE) ≥8kPa and controlled attenuation parameter (CAP) ≥280dB/min; or
   b. Enhanced Liver Fibrosis (ELF) biochemical test score ≥9; or
   c. Liver biopsy showing stage F2 or F3 fibrosis with MASH; and
4. Member must not have chronic liver disease other than metabolic dysfunction-associated steatotic liver disease (MASLD); and
5. Member does not have type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM); and
6. Wegovy® must be used in conjunction with diet and exercise [clinical documentation (e.g., office notes) of ~~member's diet and exercise program~~ this discussion with the member must be included with the request]; and
7. Prescriber must attest that metabolic comorbidities are being appropriately managed, including treatment for all of the following, if applicable:
   a. T2DM; and
   b. Dyslipidemia; and
   c. Hypertension; and
8. Member will not be using Wegovy® in combination with other semaglutide-containing products or any other glucagon-like peptide-1 (GLP-1) receptor agonist; and
9. Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist (or an advanced care practitioner with a supervising physician who is a gastroenterologist or hepatologist); and
10. Initial approvals will be for the titration period to allow initial and escalation dosing. A separate prior authorization request must be submitted for each dose; and
    a. Approvals will be for ~~4~~ 8 weeks at a time to allow for proper dose escalation; and
    b. An additional ~~4~~ 8 weeks for each dose may be approved for those who experience intolerable adverse effects during dose escalation with proper documentation; and

c. Members who cannot tolerate dose escalation after an additional ~~4~~ 8 week approval will not be approved for continuation; and

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

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

1. An FDA approved indication to reduce the risk of major adverse cardiovascular (CV) events in members with established CV disease (CVD) and either obesity or overweight; and
    a. Wegovy® will not be approved for obese or overweight members in the absence of established CVD; and
2. Member must be 45 years of age or older; and
3. Member must have established CVD with a history of 1 of the following (documentation must be submitted with the request):
    a. Previous myocardial infarction; or
    b. Previous stroke; or
    c. Symptomatic peripheral arterial disease confirmed by 1 of the following:
        i. Intermittent claudication with ankle-brachial index <0.85 at rest; or
        ii. Peripheral arterial revascularization procedure; or
        iii. Amputation due to atherosclerotic disease; and
4. Member has a body mass index (BMI) ≥27kg/m^2; and
5. Member does not have type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM); and
6. Member has a hemoglobin A1C (HbA1c) <6.5%; and
7. Member will not be using Wegovy® in combination with other semaglutide-containing products or any other glucagon-like peptide-1 (GLP-1) receptor agonist; and
8. Member is currently receiving guideline-directed management and therapy (GDMT) for CVD (e.g., antihypertensives, lipid-lowering agents, antiplatelets), as documented in the member's pharmacy claims history, unless contraindicated; and
9. Wegovy® must be used in conjunction with diet and exercise [clinical documentation (e.g., office notes) of ~~member's diet and exercise program~~ this discussion with the member must be included with the request]; and

10. Initial approvals will be for the titration period to allow initial and escalation dosing. A separate prior authorization request must be submitted for each dose; and
    a. Approvals will be for ~~4~~ 8 weeks at a time to allow for proper dose escalation; and
    b. An additional ~~4~~ 8 weeks for each dose may be approved for those who experience intolerable adverse effects during dose escalation with proper documentation; and
    c. Members who cannot tolerate dose escalation after an additional ~~4~~ 8 week approval will not be approved for continuation; and
11. Subsequent approvals for the maintenance dose (1.7mg or 2.4mg for the injection and 25mg for the tablets) will be approved for 1 year if the prescriber documents the following:
    a. Member is tolerating maintenance dosing; and
    b. Member has not developed T1DM or T2DM; and
    c. Member is continuing all of the following in conjunction with Wegovy®:
        i. Reduced calorie diet; and
        ii. Increased physical activity; and
        iii. GDMT for CVD where applicable; and
12. A quantity limit of 4 pens per 28 days or 30 tablets per 30 days will apply; and
13. Wegovy® should be discontinued in members who cannot tolerate at least the 1.7mg once weekly maintenance dosing.

Rezdiffra® (Resmetirom) Approval Criteria:

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

    c. Hypertension; and
7. Member must not be taking strong CYP2C8 inhibitors (e.g., gemfibrozil) or OATP1B1/OATP1B3 inhibitors (e.g., cyclosporine) concurrently with Rezdiffra; and
8. If member is taking a moderate CYP2C8 inhibitor (e.g., clopidogrel) concurrently with Rezdiffra®, prescriber must agree to reduce the dose as required in the package labeling; and
9. If the member is taking a statin, prescriber must agree to adjust the statin dosage (when necessary) and monitor for statin-related adverse reactions; and
10. A trial of Wegovy® (semaglutide injection) at maintenance dosing for at least 3 months (unless contraindicated) that did not provide an adequate response; and
    a. If combination therapy of Rezdiffra® with Wegovy® is being requested, a patient-specific, clinically significant reason why the member requires combination therapy must be provided; and
11. Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist (or an advanced care practitioner with a supervising physician who is a gastroenterologist or hepatologist); and
12. Initial approvals will be for the duration of 6 months. Subsequent approvals (for the duration of 1 year) will be approved if the prescriber documents the member is tolerating and responding well to the medication; and
13. A quantity limit of 30 tablets per 30 days will apply.

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

Imcivree® (Setmelanotide) Approval Criteria:

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

pathogenic or likely pathogenic (results of genetic testing must be submitted); and

b. Clinical features of BBS supported by detailed clinical documentation of each feature (medical records/clinical documentation of each feature must be submitted), as follows:
    i. Four primary features (i.e., rod-cone dystrophy, polydactyly, obesity, learning disabilities, hypogonadotropic hypogonadism and/or genitourinary anomalies, renal anomalies); or
    ii. Three of the primary features previously listed in 3.b.i. plus 2 secondary features [i.e., speech disorder/delay, strabismus/cataracts/astigmatism, brachydactyly/syndactyly, developmental delay, poor coordination/imbalance, mild spasticity (especially lower limbs), diabetes mellitus, dental crowding/hypodontia/small roots/high arched palate, left ventricular hypertrophy/congenital heart disease, hepatic fibrosis]; and

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

documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; or

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

Recommendation 16: Vote to Prior Authorize Levofloxacin Ophthalmic Solution and Update the Approval Criteria for the Ophthalmic Antibiotic Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes within the Ophthalmic Antibiotic Medications Product Based Prior Authorization (PBPA) category (changes noted in red in the following tier chart):

1. The prior authorization of levofloxacin ophthalmic solution with placement into Tier-2 based on net cost; and
2. Designating Zylet® (tobramycin/loteprednol ophthalmic solution) as brand preferred based on the approval of first-time generic products and based on net costs.

Ophthalmic Antibiotic Medications: Liquids		
Tier-1	**Tier-2**	**Tier-3**
azithromycin (Azasite®)	gatifloxacin (Zymaxid®)	
besifloxacin (Besivance®)	**levofloxacin (Quixin®)**	
ciprofloxacin (Ciloxan®)	neomycin/polymyxin B/ gramicidin (Neosporin®)	
gentamicin (Gentak®)	sulfacetamide sodium (Bleph-10®)	
moxifloxacin (Vigamox®)		
ofloxacin (Ocuflox®)		
polymyxin B/ trimethoprim (Polytrim®)		
tobramycin (Tobrex®)		

Ophthalmic Antibiotic Medications: Ointments	
Tier-1	**Tier-2**
bacitracin/polymyxin B (AK-Poly-Bac®, Polycin®)	bacitracin (AK-Tracin®)
ciprofloxacin (Ciloxan®)	sodium sulfacetamide (Bleph-10®)
erythromycin (Ilotycin™, Romycin®)	
neomycin/polymyxin B/bacitracin (Neosporin®)	
tobramycin (Tobrex®)	

Ophthalmic Antibiotic/Steroid Combination Products	
Tier-1	**Tier-2**

bacitracin/polymyxin B/neomycin/ hydrocortisone (Neo-Polycin® HC) oint	neomycin/polymyxin B/hydrocortisone (Cortisporin®) susp
neomycin/polymyxin B/ dexamethasone (Maxitrol®) oint & susp	
sulfacetamide/prednisolone 10%/0.23% solution	
tobramycin/dexamethasone 0.3%/0.1% (Tobradex®) oint & susp	
tobramycin/dexamethasone 0.3%/0.05% (Tobradex® ST) susp	
tobramycin/loteprednol (Zylet®) susp **– Brand Preferred**	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
HC= hydrocortisone; oint= ointment; susp= suspension

Recommendation 17: Vote to Prior Authorize Estradiol 0.06% Gel (Generic EstroGel®) and Lynkuet™ (Elinzanetant) and Update the Approval Criteria for the Vasomotor Symptom (VMS) Medications

MOTION CARRIED by unanimous approval.

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

Lynkuet® (Elinzanetant) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms (VMS) due to menopause; and
2. Prescriber must verify the following:
   a. Member will not use strong CYP3A4 inhibitors (e.g., clarithromycin, grapefruit juice, itraconazole, ketoconazole) or moderate/strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort) concomitantly with Lynkuet®; and
   b. Liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be assessed prior to the initiation of Lynkuet®, and member will not start treatment with Lynkuet® if labs are ≥2 times the upper limit of normal; and
   c. Follow-up evaluations of LFTs will be done 3 months after initiation of therapy; and
3. A patient-specific, clinically significant reason why the member cannot use menopausal hormone therapy must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use other guideline supported non-hormonal therapy for VMS (e.g., gabapentin, paroxetine, venlafaxine) must be provided; and
5. A quantity limit of 60 capsules per 30 days will apply.

The College of Pharmacy also recommends updating the approval criteria for Veozah® (fezolinetant) based on the FDA approved label updates (changes shown in red):

Veozah® (Fezolinetant) Approval Criteria:

1. An FDA approved ~~diagnosis~~ indication for the treatment of moderate-to-severe vasomotor symptoms (VMS) due to menopause; and
2. Prescriber must verify the following:
   a. Member ~~must~~ will not use CYP1A2 inhibitors (e.g., cimetidine, ciprofloxacin, ethinyl estradiol, fluvoxamine, mexiletine) concomitantly with Veozah®; and
   b. Member ~~must~~ does not have a history of severe renal impairment, end-stage renal disease, or cirrhosis; and
   c. ~~Prescriber must verify~~ ~~b~~Baseline renal function has been assessed and member ~~must have~~ has an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2; and
   ~~d. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to the initiation of Veozah®, every 3 months for the first 9 months of treatment, and as clinically indicated thereafter; and~~
   e. Liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be assessed prior to the initiation of Veozah®, and member will not start treatment with Veozah® if labs are ≥2 times the upper limit of normal; and
   f. Follow up evaluations of LFTs will be done monthly for the first 3 months of treatment, then at 6 months, and 9 months of treatment, and as clinically indicated thereafter; and
   g. Member will be counseled to discontinue Veozah® immediately and seek medical attention if they experience signs or symptoms that may suggest liver injury (i.e., new onset fatigue, nausea, vomiting, pruritus, jaundice, pale feces, dark urine, or right upper quadrant pain); and
3. A patient-specific, clinically significant reason why the member cannot use menopausal hormone therapy must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use other guideline supported non-hormonal therapy for VMS (e.g., gabapentin, paroxetine, venlafaxine) must be provided; and
5. A quantity limit of 30 tablets per 30 days will apply.

Finally, the College of Pharmacy recommends the prior authorization of estradiol 0.06% gel (generic EstroGel®) with the following criteria based on net cost (shown in red):

Estradiol 0.06% Gel (Generic EstroGel®) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of moderate to severe vasomotor symptoms due to menopause; or

   b. Treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause; and
2. Member must not have any contraindications for use of estradiol 0.06% gel; and
3. A patient-specific, clinically significant reason why other topical estradiol formulations (e.g., Divigel®) are not appropriate for the member must be provided; and
4. Members older than 65 years of age will generally not be approved without supporting information; and
5. Approvals will be for the duration of 6 months to ensure the need for continued therapy is reassessed periodically and the medication is being used for the shortest duration possible; and
6. Brand name EstroGel® is not a covered product; and
7. A quantity limit of 37.5 grams per 30 days will apply.

Recommendation 18: Vote to Prior Authorize MoviPrep® [Polyethylene Glycol 3350 (PEG 3350)/Sodium Sulfate/Sodium Chloride/ Potassium Chloride/Sodium Ascorbate/Ascorbic Acid for Oral Solution] and Update the Approval Criteria for the Bowel Preparation Medications

MOTION CARRIED by unanimous approval.

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

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

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

Recommendation 19: Vote to Prior Authorize Aceon® (Perindopril), Arbli™ (Losartan Oral Suspension), Bisoprolol Fumarate 2.5mg Tablet, Hemiclor™ (Chlorthalidone 12.5mg Tablet), Inzirqo™ [Hydrochlorothiazide (HCTZ) Oral Suspension], Javadin™ (Clonidine Oral Solution), Lopressor® (Metoprolol Tartrate Oral Solution), and Univasc® (Moexipril) and Update the Approval Criteria for the Antihypertensive Medications

MOTION CARRIED by unanimous approval.

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

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

Angiotensin I Converting Enzyme Inhibitors (ACEIs)		
Tier-1	**Tier-2**	**Special PA**
benazepril (Lotensin®)	captopril (Capoten®)	enalapril oral solution (Epaned®)
enalapril (Vasotec®)	**moexipril (Univasc®)**	lisinopril oral solution (Qbrelis®)
enalaprilat (Vasotec® IV)	**perindopril (Aceon®)**	

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

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

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

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

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

Antihypertensive Medications Special Prior Authorization (PA) Approval Criteria:

1. **Angiotensin I Converting Enzyme Inhibitors (ACEIs):**

~~a. Epaned® (Enalapril Solution) Approval Criteria:~~

~~i. An age restriction of 7 years or older will apply with the following criteria:~~

~~1. A patient-specific, clinically significant reason why the member cannot use the oral tablet formulation in place of the oral solution formulation, even when the tablets are crushed or used to prepare an oral suspension, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and~~

~~2. Clinical exceptions for the age restriction (younger than the FDA-approved age) may be considered; and~~

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

b. Epaned® (Enalapril Solution) and Qbrelis® (Lisinopril Oral Solution) Approval Criteria:

i. A patient-specific, clinically significant reason why the member cannot use the ~~lisinopril~~ oral tablets in place of the oral solution formulation, even when the tablets are crushed, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and

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

iii. A quantity limit of 300mL per 60 days will apply. For members who require doses exceeding this quantity limit, a quantity limit override may be approved with the submission of supporting clinical documentation.

2. Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products:

a. Arbli™ (Losartan Oral Suspension) Approval Criteria:

i. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the oral tablet formulation in place of the oral suspension, even when the tablets are split or crushed, must be provided (e.g., dose stabilized inpatient, clinically indicated dose cannot be achieved with available tablet formulations); and

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

iii. A quantity limit of 330mL per 33 days will apply.

b. Valsartan ~~4mg/mL~~ Oral Solution Approval Criteria:

~~i. An FDA-approved diagnosis of 1 of the following:~~

1. ~~Hypertension in adults and pediatric members 6 years of age and older; or~~
2. ~~Heart failure; or~~
3. ~~Post-myocardial infarction; and~~

ii. A patient specific, clinically significant, reason why the member cannot use the oral ~~valsartan~~ tablets or the oral suspension prepared from the tablets must be provided (i.e., dose was stabilized inpatient); and

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

iv. A quantity limit of 360mL per 36 days will apply.

~~**3. ACEI/Hydrochlorothiazide (HCTZ) Combination Products:**~~

~~**a. Monopril-HCT® (Fosinopril/HCTZ) Approval Criteria:**~~

~~i. A patient-specific, clinically significant reason why the member cannot use the individual components separately must be provided.~~

4. Calcium Channel Blockers (CCBs):

~~**a. Cardizem® CD (Diltiazem CD 360mg Capsules) Approval Criteria:**~~

~~i. A patient-specific, clinically significant reason why the member cannot use (2) 180mg Cardizem® CD (diltiazem CD) capsules must be provided.~~

b. Conjupri® (Levamlodipine Tablets) Approval Criteria:

i. A patient-specific, clinically significant reason why the member cannot use amlodipine oral tablets, which are available without prior authorization, must be provided.

c. Katerzia® (Amlodipine Oral Suspension) and Norliqva® (Amlodipine Oral Solution) Approval Criteria:

~~i. An FDA approved diagnosis of 1 of the following:~~

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

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

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

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

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

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

Bisoprolol Fumarate 2.5mg Tablet Approval Criteria:

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

Hemiclor™ (Chlorthalidone 12.5mg Tablet) Approval Criteria:

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

Inzirqo™ (Hydrochlorothiazide Oral Suspension) Approval Criteria:

1. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the oral tablet formulation available without prior authorization, even when the tablets are crushed or split, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved with available tablet formulations); and
2. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
3. A quantity limit of 240mL per 30 days will apply. For members who require doses that exceed this quantity limit, a quantity limit override may be approved with the submission of supporting clinical documentation.

Lopressor® (Metoprolol Tartrate Oral Solution) Approval Criteria:

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

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

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

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

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

Tryvio™ (Aprocitentan) Approval Criteria:

1. An FDA approved diagnosis of hypertension; and
2. Member has a reported systolic blood pressure of ≥140mmHg confirmed on at least 2 separate blood pressure readings on 2 separate occasions within the last month (documentation of blood pressure readings with dates must be submitted); and
3. Prescriber must rule out other causes of elevated blood pressure including:
   a. Inaccurate readings due to faulty or inappropriate equipment (i.e., cuff size) or improper technique; and
   b. White coat hypertension; and
   c. Prescription non-adherence. Compliance with antihypertensive medications will be evaluated prior to initiation of Tryvio™; and
4. Member must be currently on at least 3 antihypertensive medications at optimal (or maximally tolerated) doses for at least 4 weeks prior to systolic blood pressure reading of ≥140mmHg; and
5. Member must have tried at least 6 different classes of medications, including a diuretic, in the past 12 months that did not yield adequate blood pressure control. Medications can include, but are not limited to, angiotensin I converting enzyme inhibitors (ACEIs), angiotensin II receptor blockers (ARBs), calcium channel blockers (CCBs), direct renin inhibitors (DRIs), beta blockers, alpha blockers, alpha agonists, or diuretics; and
6. Female members of reproductive potential must not be pregnant or breastfeeding during treatment with Tryvio™ and must be willing to

use an effective method of contraception during treatment and for 1 month after discontinuing Tryvio™; and
7. Female members of reproductive potential must have a negative pregnancy test prior to initiation of Tryvio™ and ~~must agree to take pregnancy tests monthly during treatment and for 1 month after discontinuing Tryvio™~~ if pregnancy occurs during therapy, Tryvio™ must be discontinued immediately; and
8. ~~Member, pharmacy, and provider must be registered under the Tryvio™ Risk Evaluation and Mitigation Strategy (REMS) program; and~~
9. Member must not have elevated aminotransferases >3 times the upper limit of normal (ULN) or moderate to severe hepatic impairment (Child Pugh class B or C); and
10. Prescriber must attest that they will monitor liver transaminase levels during treatment and discontinue Tryvio™ if a sustained, unexplained, clinically relevant elevation occurs or if elevations occur with an increase in bilirubin that is >2 times the ULN; and
11. Member must not have severe anemia prior to initiation of aprocitentan; and
12. A quantity limit of 30 tablets per 30 days will apply; and
13. Initial approvals will be for the duration of 3 months. After 3 months, compliance with all antihypertensive medications, including aprocitentan, will be evaluated and the provider must provide documentation that the member has had a positive response to treatment, including a decrease in blood pressure. Inadequate compliance or a lack of positive response will result in denial of continuation. Subsequent approvals will be for 1 year.

Recommendation 20: Fiscal Year 2025 Annual Review of Cholestatic Liver Disease and Bile Acid Disorder Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Bylvay® (odevixibat) approval criteria based on recent FDA approvals and to be consistent across both indications for the baseline serum bile acid levels (changes shown in red):

Bylvay® (Odevixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:
1. An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and
   a. Diagnosis must be confirmed by genetic testing identifying a pathogenic variant in either the *JAG1* or *NOTCH2* genes (results of genetic testing must be submitted); and
2. Member must be 12 months of age or older; and
3. Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS

(or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and

4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following, unless contraindicated:
   a. Cholestyramine; or
   b. Rifampin; or
   c. Sertraline; or
   d. Naltrexone; and
5. Member must have elevated serum bile acid concentration ~~>3x~~ >1x the upper limit of normal (ULN) for age at baseline; and
6. Members with a history of liver transplantation will generally not be approved for Bylvay®; and
7. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
8. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
9. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Bylvay®; and
10. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
11. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Bylvay® (Odevixibat) Approval Criteria [Progressive Familial Intrahepatic Cholestasis (PFIC) Diagnosis]:

1. An FDA approved indication for the treatment of pruritus in members with PFIC; and
   a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the *ATP8B1, ABCB11, or ABCB4* genes (results of genetic testing must be submitted); and
2. Member must be 3 months of age or older; and
3. Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and

4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration ~~≥100micromol/L~~ >1x the upper limit of normal (ULN) for age at baseline; and
6. Prescriber must verify member does not have known pathologic variants of the *ABCB11* gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and
7. Members with a history of liver transplantation will generally not be approved for Bylvay®; and
8. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
9. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
10. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Bylvay®; and
11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. Initial approvals will be for 40mcg/kg/day for a duration of 3 months. After 3 months of treatment, further approval may be granted at the 40mcg/kg/day dose if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate; or
13. Dose increases to 80mcg/kg/day (for 3 months) and 120mcg/kg/day (for 3 months) may be approved if there is no improvement in pruritus after 3 months of treatment with the lower dose(s). Further approval may be granted if the prescriber documents the member is responding well to treatment at the current dose and is still not a candidate for surgical intervention; and
14. If there is no improvement in pruritus after 3 months of treatment with the maximum 120mcg/kg/day dose, further approval of Bylvay® will not be granted.

The College of Pharmacy also recommends updating the Livmarli® (maralixibat) approval criteria based on recent FDA approvals (changes shown in red):

Livmarli® (Maralixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic variant in the *JAG1* or *NOTCH2* genes (results of genetic testing must be submitted); and
2. Member must be 3 months of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have evidence of cholestasis demonstrated by ≥1 of the following:
    a. Total serum bile acid >3x upper limit of normal (ULN) for age; or
    b. Conjugated bilirubin >1mg/dL; or
    c. Fat soluble vitamin deficiency otherwise unexplainable; or
    d. Gamma-glutamyl transferase (GGT) >3x ULN for age; or
    e. Intractable pruritus explainable only by liver disease; and
6. Members with a history of liver transplantation will not generally be approved for Livmarli®; and
7. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
8. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
9. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Livmarli®; and
10. Prescriber must verify the member and/or member's caregiver has been counseled on appropriate storage, dosing, and administration of Livmarli®, including the use of a calibrated oral dosing dispenser for accurate measurement; and
11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and

12. Requests must be for an appropriate formulation for the member's weight, including:
    a. Solution: The request must be for the 9.5mg/mL solution; ~~and~~ or
    b. Tablet: The member must weigh ≥25kg. Additionally, members weighing 25-43kg must have already completed dosing titration using the oral solution; and
13. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Livmarli® (Maralixibat) Approval Criteria [Progressive Familial Intrahepatic Cholestasis (PFIC) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with PFIC; and
    a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the *ATP8B1, ABCB11, ABCB4, TJP2, or MYO5B* genes (results of genetic testing must be submitted); and
2. Member must be 12 months of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration >3x the upper limit of normal (ULN) for age at baseline; and
6. Prescriber must verify member does not have known pathologic variants of the *ABCB11* gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and
7. Members with a history of liver transplantation will generally not be approved for Livmarli®; and
8. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
9. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
10. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and

international normalized ratio (INR) at baseline and during treatment with Livmarli®; and

11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. Requests must be for an appropriate formulation for the member's weight, including:
    a. Solution: The request must be for the 19mg/mL solution; ~~and~~ or
    b. Tablet: The member must weigh ≥25kg. Additionally, members weighing 25-32kg must have already completed dosing titration using the oral solution; and
13. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Next, the College of Pharmacy recommends updating the Livdelzi® (seladelpar) approval criteria based on net cost (changes shown in red):

Livdelzi® (Seladelpar) Approval Criteria:

1. An FDA approved diagnosis of primary biliary cholangitis (PBC); and
2. Member must be 18 years of age or older; and
3. Member must have elevated alkaline phosphatase (ALP) ≥1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤2 times the ULN at baseline; and
4. Must be prescribed by a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC); and
5. Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year (unless intolerance is documented) with inadequate improvement in liver function tests; and
    a. Prescriber must confirm proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and member compliance with UDCA; and
6. Livdelzi® must be taken in combination with UDCA; or
    a. For Livdelzi® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and
7. Member must not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy); and
8. Prescriber must agree to monitor all of the following:
    a. Fracture risk and bone health; and
    b. Liver function tests at baseline and thereafter; and

9. Member must not be taking OAT3 inhibitors (e.g., probenecid) or strong CYP2C9 inhibitors concurrently with Livdelzi®; and
10. ~~A patient-specific, clinically significant reason why the member cannot use Iqirvo® (elafibranor) must be provided; and~~
11. A quantity limit of 30 capsules per 30 days will apply; and
12. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests.

Lastly, the College of Pharmacy also recommends removing SoonerCare coverage and the approval criteria for Ocaliva® (obeticholic acid) based on its withdrawal from the market (changes shown in red):

~~Ocaliva® (Obeticholic Acid) Approval Criteria:~~

~~1. An FDA approved diagnosis of primary biliary cholangitis (PBC); and~~
~~2. Member must be 18 years of age or older; and~~
~~3. Member must have elevated alkaline phosphatase (ALP) ≥1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤2 times the ULN at baseline; and~~
~~4. Must be prescribed by a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC); and~~
~~5. Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year (unless intolerance is documented) with inadequate improvement in liver function tests; and~~
~~a. Prescriber must confirm proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and member compliance with UDCA; and~~
~~6. Ocaliva® must be taken in combination with UDCA; or~~
~~a. For Ocaliva® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and~~
~~7. Member must not have any of the following:~~
~~a. Decompensated cirrhosis (e.g., Child-Pugh class B or C) or a prior decompensation event; or~~
~~b. Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia); or~~
~~c. Complete biliary obstruction; and~~
~~8. Prescriber must agree to monitor liver tests frequently and to discontinue Ocaliva® if there is any evidence of liver disease progression while on treatment; and~~

9. ~~Initial approvals will be for a dose of 5mg once daily for a duration of 3 months. After 3 months of treatment, information regarding efficacy must be submitted; and~~
    a. ~~If an adequate improvement in liver function tests is not achieved with the 5mg dose, a dose of 10mg once daily may be approved for a duration of 3 months; and~~
10. ~~Subsequent approvals (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests; and~~
11. ~~A quantity limit of 1 tablet per day will apply.~~

Recommendation 21: Fiscal Year 2025 Annual Review of Anticonvulsants

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Banzel® (rufinamide), Briviact® (brivaracetam), Eprontia® (topiramate oral solution), Fycompa® (perampanel), and Qudexy® XR (topiramate ER) approval criteria based on net costs and clinical practice (changes shown in red):

Banzel® (Rufinamide) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); and
2. Initial prescription must be written by, or in consultation with, a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. ~~Authorization of generic rufinamide (in place of brand Banzel®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and~~
5. Members currently stable on Banzel® (rufinamide) and who have a seizure diagnosis will be approved for continuation of therapy.

Briviact® (Brivaracetam) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Initial prescription must be prescribed by, or in consultation with, a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. Members currently stable on Briviact® and who have a seizure diagnosis will be approved for continuation of therapy; and
5. For Briviact® oral solution, an age restriction of 12 years of age and younger will apply. Members older than 12 years of age will require a patient-specific, clinically significant reason why the member cannot take the oral tablet formulation; and

6. Authorization of generic brivaracetam (in place of brand Briviact®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
7. Approval length for Briviact® intravenous (IV) will be for a maximum of 7 days of therapy. Further approval may be granted if the prescriber documents an ongoing need for Briviact® IV therapy over Briviact® oral formulations.

Eprontia® (Topiramate Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
   b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
   c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use topiramate tablets and sprinkle capsules must be provided; and
3. Authorization of generic topiramate oral solution (in place of brand Eprontia®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
4. An age restriction of 11 years of age and younger will apply. Members older than 11 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
5. A quantity limit of 473mL per 29 days will apply.

Fycompa® (Perampanel) Approval Criteria:

1. An FDA approved indication of the treatment of partial-onset seizures with or without secondarily generalized seizures or adjunctive therapy in the treatment of primary generalized tonic-clonic (PGTC) seizures; and
2. Initial prescription must be written by, or in consultation with, a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. For Fycompa® oral suspension, a patient-specific, clinically significant reason why Fycompa® oral tablets cannot be used must be provided; and
5. Authorization of generic perampanel (in place of brand Fycompa®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
6. Members currently stable on Fycompa® and who have a seizure diagnosis will be approved for continuation of therapy.

Qudexy® XR [Topiramate Extended-Release (ER)] Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
   b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
   c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation, Topamax® (topiramate), must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use brand name Trokendi XR® (topiramate ER) must be provided; and
4. Members currently stable on Qudexy® XR and who have a seizure diagnosis will be approved for continuation of therapy; and
5. A quantity limit of 30 capsules per 30 days will apply on the lower strength capsules (25mg, 50mg, and 100mg) and 60 capsules per 30 days on the higher strength capsules (150mg and 200mg).

Additionally, the College of Pharmacy recommends the following changes to Aptiom® (eslicarbazepine), Felbatol® (felbamate), Fintepla® (fenfluramine), Sabril® (vigabatrin), and Xcopri® (cenobamate) approval criteria to be consistent with the other anticonvulsant medications regarding stability (changes shown in red):

Aptiom® (Eslicarbazepine) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Member must not currently be taking oxcarbazepine (concurrent use is contraindicated); and
3. A patient-specific, clinically significant reason why the member cannot use oxcarbazepine must be provided; and
4. Members currently stable on Aptiom® and who have a seizure diagnosis will be approved for continuation of therapy; and
5. A quantity limit of 30 tablets per 30 days will apply on the lower strength tablets (200mg and 400mg) and 60 tablets per 30 days on the higher strength tablets (600mg and 800mg).

Felbatol® (Felbamate) Approval Criteria:

1. Initial prescription must be written by, or in consultation with, a neurologist; and
2. Member must have failed therapy with at least 3 other anticonvulsants; and
3. Members currently stable on Felbatol® and who have a seizure diagnosis will be approved for continuation of therapy.

Fintepla® (Fenfluramine) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Dravet syndrome; or

b. Lennox-Gastaut syndrome (LGS); and
2. Member must be 2 years of age or older; and
3. Initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must not be taking monoamine oxidase inhibitors within 14 days of administration of Fintepla®; and
5. Prescriber must verify the member's blood pressure will be monitored; and
6. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Fintepla® therapy and throughout treatment; and
7. Member must meet 1 of the following:
   a. For a diagnosis of Dravet syndrome, the member must have failed or be inadequately controlled with at least 2 other anticonvulsants; or ~~and~~
   b. For a diagnosis of LGS, the member must have failed or be inadequately controlled with at least 3 other anticonvulsants; or ~~and~~
   c. Members currently stable on Fintepla® and who have a diagnosis of Dravet syndrome or LGS will be approved for continuation of therapy; and
8. Pharmacy and provider must be certified in the Fintepla® Risk Evaluation and Mitigation Strategy (REMS) program; and
9. Member must be enrolled in the Fintepla® REMS program; and
10. 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
11. Prescriber must verify that dose titration and maximum maintenance dose will be followed according to package labeling based on member weight and concomitant medications; and
12. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication; and
13. A quantity limit of 360mL per 30 days will apply.

Sabril® (Vigabatrin) Approval Criteria:

1. An FDA approved diagnosis of refractory complex seizures in adults and pediatric members 2 years of age or older, or infantile spasms in children 1 month to 2 years of age; and
2. Authorization of generic vigabatrin (in place of brand Sabril®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
3. Members with refractory complex seizures must have previous trials of at least 3 other anticonvulsants; or
4. Prescription must be written by, or in consultation with, a neurologist; and

5. Members currently stable on Sabril® and who have a seizure diagnosis will be approved for continuation of therapy; and
6. Member, prescriber, and pharmacy must all register in the Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy.

Xcopri® (Cenobamate) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Initial prescription must be written by, or in consultation with, a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. Members currently stable on Xcopri® and who have a seizure diagnosis will be approved for continuation of therapy.

Recommendation 22: Fiscal Year 2025 Annual Review of Insomnia Medications

MOTION CARRIED by unanimous approval.

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

1. Moving Dalmane® (flurazepam) from Tier-1 to the Special PA Tier based on net costs; and
2. Moving Belsomra® (suvorexant) from Tier-3 to Tier-1 based on net costs; and
3. Moving ProSom® (estazolam) from Tier-1 to Tier-2 based on net costs; and
4. Creating specific criteria for the Special PA Tier for clarity.

Insomnia Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
~~**estazolam (ProSom®)**~~	**estazolam (ProSom®)**	lemborexant (Dayvigo®)	daridorexant (Quviviq®)
eszopiclone (Lunesta®)	zolpidem ER (Ambien® CR)	~~**suvorexant (Belsomra®)**~~	doxepin (Silenor®)
~~**flurazepam (Dalmane®)**~~			**flurazepam (Dalmane®)**
ramelteon (Rozerem®)			quazepam (Doral®)
suvorexant (Belsomra®)			tasimelteon (Hetlioz®, Hetlioz LQ®)+
temazepam (Restoril®) 15mg and 30mg			temazepam (Restoril®) 7.5mg and 22.5mg
triazolam (Halcion®)			zolpidem 7.5mg capsule

zaleplon (Sonata®)			zolpidem SL tablets (Edluar®)
zolpidem (Ambien®)			zolpidem SL tablets (Intermezzo®)

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).
~~*Medications in the Special PA Tier, including unique dosage formulations, require a special reason for use in place of lower-tiered medications.~~
†Individual criteria specific to tasimelteon applies.
ER = extended-release; PA = prior authorization; SL = sublingual

Insomnia Medications Special Prior Authorization (PA) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why all lower-tiered medications are not appropriate for the member must be provided; and
3. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and
4. Approvals will be granted for the duration of 6 months.

Recommendation 23: 30-Day Notice to Prior Authorize Cardamyst™ (Etripamil Nasal Spray)

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

Recommendation 24: Fiscal Year 2025 Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize Brekiya® [Dihydroergotamine (DHE) Autoinjector]

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

Recommendation 25: Fiscal Year 2025 Annual Review of Pulmonary Hypertension Medications and 30-Day Notice to Prior Authorize Yutrepia™ (Treprostinil Powder for Inhalation)

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

Recommendation 26: Fiscal Year 2025 Annual Review of Crenessity® (Crinecerfont)

NO ACTION REQUIRED.

Recommendation 27: Fiscal Year 2025 Annual Review of Kebilidi™ (Eladocagene Exuparvovec-tneq)

NO ACTION REQUIRED.

Recommendation 28: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

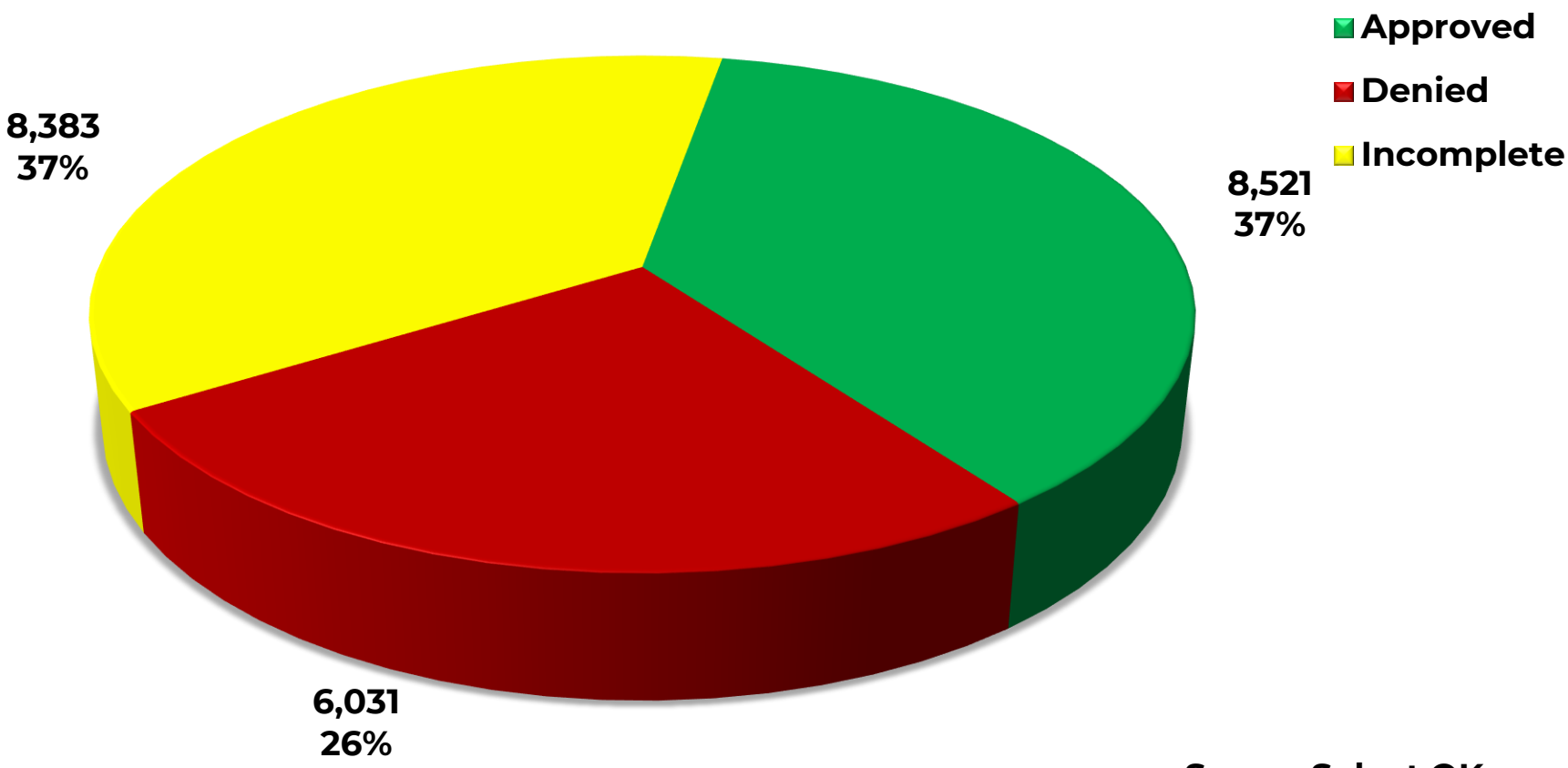
NO ACTION REQUIRED.

Recommendation 29: Future Business

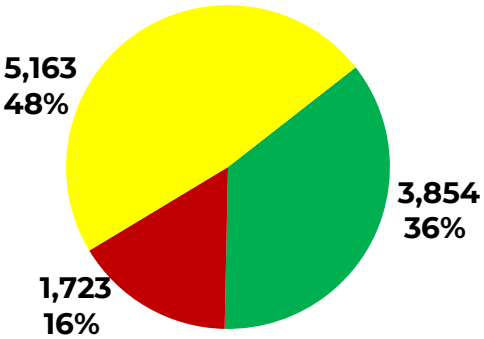
NO ACTION REQUIRED.

Appendix B

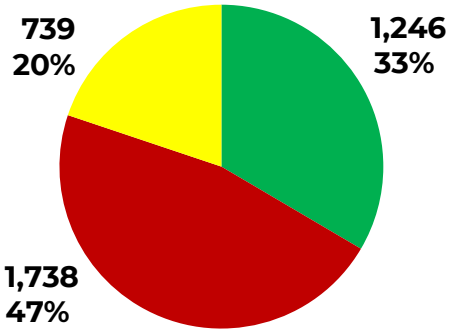
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: FEBRUARY 2026



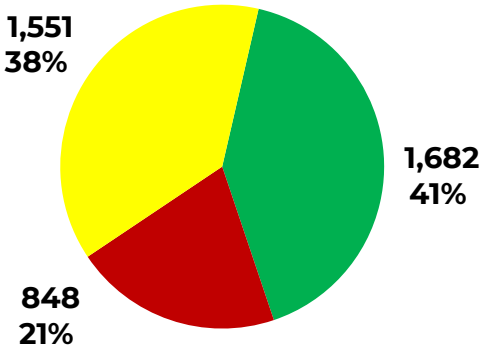
SoonerCare FFS



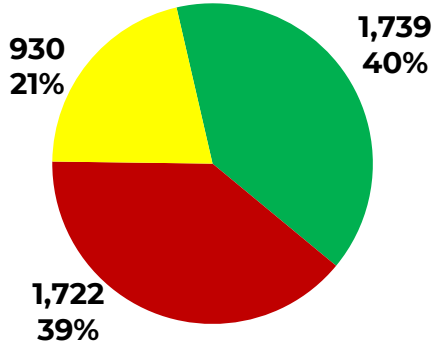
SoonerSelect Aetna



SoonerSelect Humana

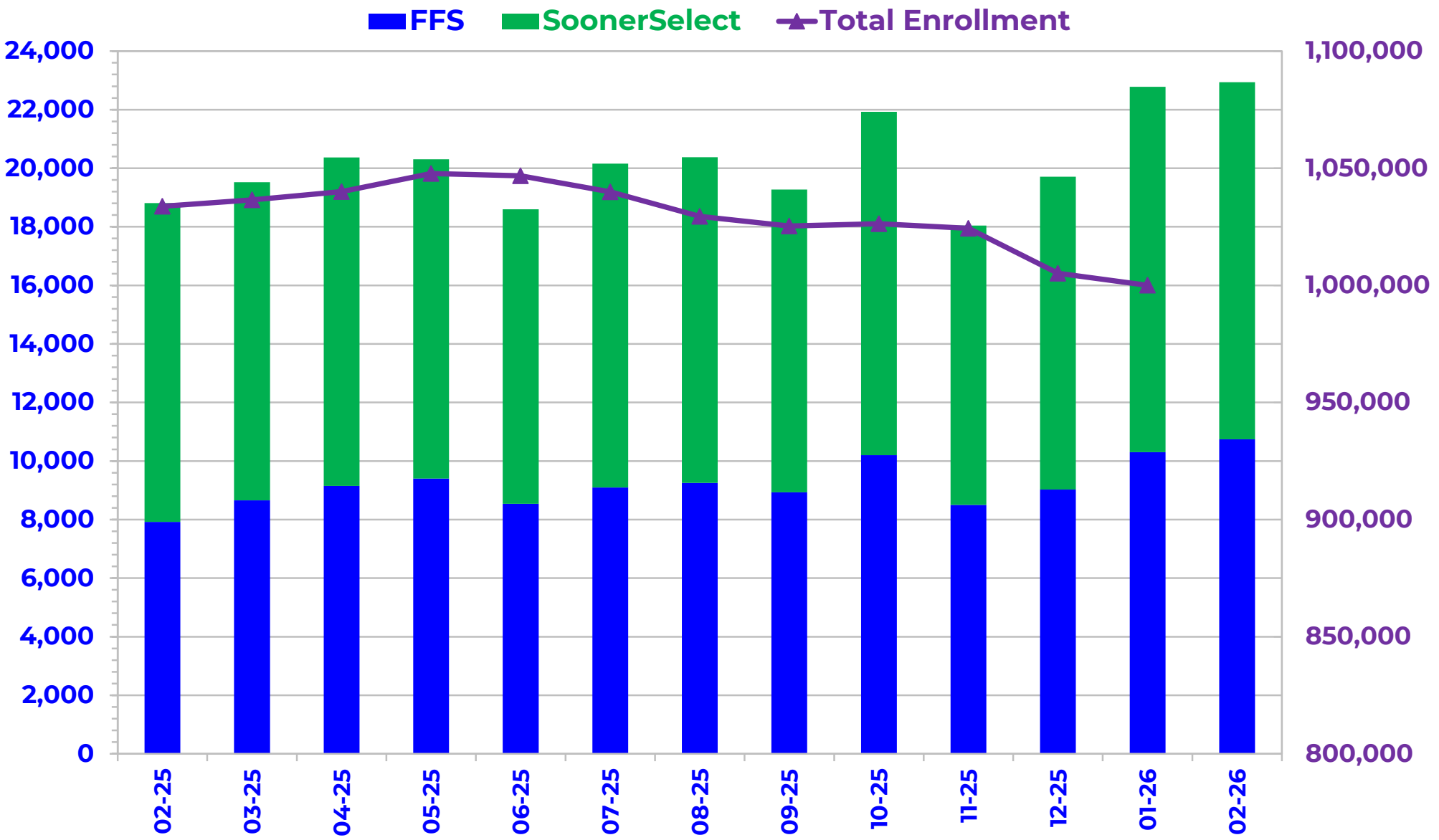


SoonerSelect OK Complete Health



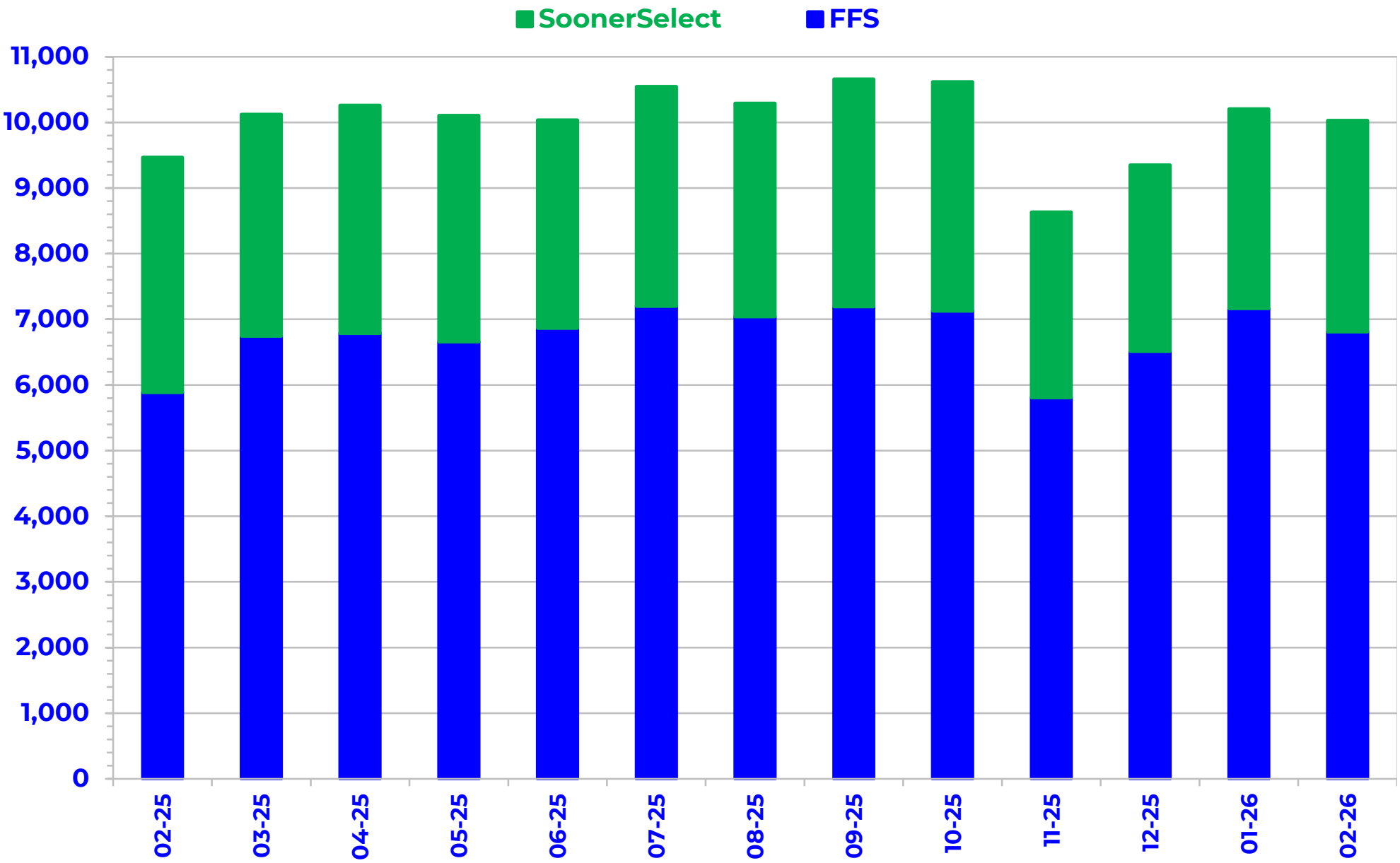
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: FEBRUARY 2025 – FEBRUARY 2026



SoonerCare FFS Prior Authorization Activity

2/1/2026 Through 2/28/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	4	0	2	2	0
Amphetamines	904	471	89	344	352
Analgesics - Anti-Inflammatory	258	81	43	134	328
Analgesics - Nonnarcotic	13	0	0	13	0
Analgesics - Opioid	416	149	38	229	124
Androgens - Anabolic	80	15	18	47	326
Anorectal and Related Products	10	1	2	7	42
Antacids	1	0	0	1	0
Anthelmintics	7	3	0	4	22
Anti-Infective Agents - Misc.	27	4	8	15	14
Anti-Obesity Agents	372	30	201	141	65
Antianginal Agents	1	0	0	1	0
Antianxiety Agents	31	3	2	26	298
Antiarrhythmics	2	0	0	2	0
Antiasthmatic and Bronchodilator Agents	586	105	103	378	467
Antibiotics	29	13	3	13	207
Anticoagulants	22	3	1	18	304
Anticonvulsants	255	113	18	124	374
Antidepressants	314	76	42	196	422
Antidiabetics	1,662	542	286	834	368
Antidiarrheal/Probiotic Agents	1	0	1	0	0
Antidotes and Specific Antagonists	6	2	0	4	359
Antiemetics	19	0	6	13	0
Antifungals	3	1	0	2	53
Antihistamines	25	4	7	14	275
Antihyperlipidemics	80	17	14	49	298
Antihypertensives	20	5	2	13	735
Antineoplastics and Adjunctive Therapies	222	144	8	70	177
Antiparkinson and Related Therapy Agents	10	0	2	8	0
Antipsychotics/Antimanic Agents	405	128	48	229	347
Antivirals	17	2	5	10	44
Attention-deficit/hyperactivity Disorder (ADHD) Agents	290	191	16	83	934
Beta Blockers	16	1	0	15	39
Calcium Channel Blockers	16	4	1	11	827
Cardiovascular Agents - Misc.	86	34	6	46	461
Chemicals	1	0	1	0	0
Contraceptives	29	17	0	12	443
Corticosteroids	9	2	0	7	192
Cough/Cold/Allergy	3	1	1	1	360
Dermatologicals	537	124	130	283	221
Diagnostic Products	37	16	0	21	150
Digestive Aids	11	4	1	6	359
Diuretics	9	5	0	4	652
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	6	1	1	4	360
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	206	103	19	84	240
Estrogens	8	2	2	4	360
Gastrointestinal Agents - Misc.	390	110	84	196	240
Genitourinary Agents - Misc.	10	5	2	3	444

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Gout Agents	8	2	1	5	360
Hematological Agents - Misc.	17	8	0	9	298
Hematopoietic Agents	44	10	7	27	180
Histamine H3-Receptor Antagonist/Inverse Agonists	4	1	1	2	157
Hypnotics/Sedatives/Sleep Disorder Agents	84	5	19	60	320
Laxatives	24	8	2	14	189
Medical Devices and Supplies	317	43	82	192	301
Migraine Products	535	146	137	252	256
Minerals and Electrolytes	7	2	1	4	183
Miscellaneous Therapeutic Classes	61	28	7	26	307
Multivitamins	3	1	0	2	357
Musculoskeletal Therapy Agents	54	9	9	36	225
Nasal Agents - Systemic and Topical	11	2	1	8	224
Neuromuscular Agents	110	47	24	39	335
Nutrients	1	0	1	0	0
Ophthalmic Agents	63	11	9	43	260
Other*	60	29	4	27	226
Otic Agents	38	7	4	27	14
Passive Immunizing and Treatment Agents	10	0	0	10	0
Progestins	11	2	2	7	360
Psychotherapeutic and Neurological Agents - Misc.	242	75	43	124	254
Respiratory Agents - Misc.	30	16	1	13	325
Stimulants - Misc.	206	102	21	83	343
Thyroid Agents	13	6	4	3	669
Ulcer Drugs/Antispasmodics/Anticholinergics	172	25	16	131	721
Urinary Antispasmodics	64	5	20	39	360
Vaginal and Related Products	5	0	0	5	0
Vasopressors	1	0	1	0	0
Vitamins	54	3	45	6	278
Total	**9,715**	**3,125**	**1,675**	**4,915**	
Overrides					
Brand	16	11	1	4	327
Compound	14	11	1	2	17
Diabetic Supplies	2	2	0	0	238
Dosage Change	146	136	0	10	15
High Dose	2	1	0	1	360
Lost/Broken Rx	50	39	6	5	18
MAT Override	9	4	1	4	84
NDC vs Age	134	98	14	22	403
NDC vs Sex	12	11	1	0	334
Nursing Home Issue	85	80	1	4	15
Opioid MME Limit	74	22	2	50	122
Opioid Quantity	23	13	0	10	175
Other	52	37	0	15	21
Quantity vs Days Supply	351	233	11	107	332
STBS/STBSM	15	6	7	2	64
Step Therapy Exception	8	2	3	3	359
Third Brand Request	32	23	0	9	29
Overrides Total	**1,025**	**729**	**48**	**248**	
Total Regular PAs + Overrides	**10,740**	**3,854**	**1,723**	**5,163**	

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

Denial Reasons	
Unable to verify required trials.	4,608
Does not meet established criteria.	1,759
Lack required information to process request.	656
Other PA Activity	
Duplicate Requests	1,361
Letters	53,169
No Process	1
Helpdesk Initiated Prior Authorizations	355
PAs Missing Information	377
Pharmacotherapy	73
Changes to Existing PAs	707

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

SoonerSelect Aetna Prior Authorization Activity

2/1/2026 Through 2/28/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	1	0	0
Amphetamines	296	170	111	15	364
Analgesics - Anti-Inflammatory	106	64	32	10	356
Analgesics - Nonnarcotic	3	0	2	1	0
Analgesics - Opioid	122	61	35	26	181
Androgens - Anabolic	68	10	57	1	365
Anorectal and Related Products	6	0	6	0	0
Anorexiants Non-Amphetamine	1	0	0	1	0
Anthelmintics	6	4	2	0	19
Antianxiety Agents	30	9	6	15	286
Antiarrhythmics	1	1	0	0	181
Antiasthmatic and Bronchodilator Agents	174	57	91	26	291
Antibiotics	13	1	2	10	7
Anticoagulants	11	2	1	8	273
Anticonvulsants	54	14	14	26	290
Antidepressants	200	55	75	70	597
Antidiabetics	542	134	304	104	318
Antidiarrheal/Probiotic Agents	1	0	1	0	0
Antiemetics	20	2	4	14	19
Antifungals	2	1	0	1	89
Antihistamines	13	3	9	1	609
Antihyperlipidemics	32	5	17	10	235
Antihypertensives	21	1	3	17	365
Anti-Infective Agents - Misc.	9	2	4	3	28
Antineoplastics and Adjunctive Therapies	24	8	3	13	342
Anti-Obesity Agents	209	16	181	12	84
Antiparkinson and Related Therapy Agents	10	0	4	6	0
Antipsychotics/Antimanic Agents	164	67	61	36	328
Antivirals	5	2	2	1	112
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	91	73	13	5	824
Beta Blockers	27	2	1	24	365
Calcium Channel Blockers	14	1	2	11	1,096
Cardiovascular Agents - Misc.	39	21	15	3	380
Chemicals	1	0	0	1	0
Contraceptives	27	1	21	5	365
Corticosteroids	9	7	2	0	296
Cough/Cold/Allergy	2	1	0	1	30
Dermatologicals	333	112	168	53	244
Diagnostic Products	53	19	18	16	396
Digestive Aids	2	1	0	1	365
Diuretics	28	5	1	22	198
Endocrine and Metabolic Agents - Misc.	38	19	17	2	231
Estrogens	10	8	2	0	602
Gastrointestinal Agents - Misc.	85	32	46	7	269
General Anesthetics	1	1	0	0	24
Genitourinary Agents - Misc.	3	2	1	0	103

*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
Gout Agents	3	0	0	3	0
Hematological Agents - Misc.	13	6	2	5	242
Hematopoietic Agents	13	1	11	1	365
Hypnotics/Sedatives/Sleep Disorder Agents	39	10	20	9	264
Laxatives	22	4	8	10	177
Local Anesthetics - Parenteral	1	1	0	0	24
Medical Devices and Supplies	92	21	49	22	435
Migraine Products	195	66	124	5	230
Minerals and Electrolytes	16	3	0	13	251
Miscellaneous Therapeutic Classes	39	32	3	4	304
Musculoskeletal Therapy Agents	44	0	18	26	0
Nasal Agents - Systemic and Topical	16	0	12	4	0
Neuromuscular Agents	8	5	1	2	299
Ophthalmic Agents	30	8	16	6	214
Other	14	3	0	11	304
Otic Agents	24	1	23	0	89
Psychotherapeutic and Neurological Agents - Misc.	26	9	13	4	205
Respiratory Agents - Misc.	2	2	0	0	273
Stimulants - Misc.	87	59	23	5	365
Thyroid Agents	1	0	0	1	0
Ulcer Drugs/Antispasmodics/Anticholinergics	62	10	25	27	220
Urinary Antispasmodics	12	3	9	0	365
Vaccines	1	1	0	0	181
Vaginal and Related Products	2	0	1	1	0
Vasopressors	1	0	0	1	0
Vitamins	53	7	45	1	316
****Total**	**3,723**	**1,246**	**1,738**	**739**	

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

Overrides					
Brand	2	2	0	0	365
Other	817	78	0	739	365
Quantity Level Limit	30	30	0	0	406
Refill Too Soon	3	3	0	0	29
Step Therapy Met	2	2	0	0	30
Overrides Total	**854**	**115**	**0**	**739**	

Denial Reason	
Benefit	120
Experimental/Investigational	164
Lack Required Infomation to Process Request	139
Medical Necessity	1,315
Other PA Activity	
Duplicate Requests	19
Letters	4,735
No Process	375
Changes to existing PAs	0
PAs missing info	31

*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

2/1/2026 Through 2/28/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	0	1	0
Amphetamines	15	2	2	11	274
Analgesics - Anti-Inflammatory	79	60	4	15	340
Analgesics - Nonnarcotic	7	0	0	7	0
Analgesics - Opioid	102	45	37	20	217
Androgens - Anabolic	61	19	28	14	226
Anorectal and Related Products	5	0	0	5	0
Antacids	1	0	0	1	0
Anthelmintics	4	3	0	1	365
Antianxiety Agents	1	0	0	1	0
Antiasthmatic and Bronchodilator Agents	147	58	47	42	238
Antibiotics	7	1	0	6	365
Anticoagulants	4	0	2	2	0
Anticonvulsants	12	7	0	5	426
Antidepressants	52	21	7	24	516
Antidiabetics	325	118	126	81	256
Antiemetics	6	0	2	4	0
Antifungals	2	2	0	0	365
Antihistamines	6	1	0	5	365
Antihyperlipidemics	22	11	4	7	279
Antihypertensives	1	0	0	1	0
Anti-Infective Agents - Misc.	1	1	0	0	365
Antimyasthenic/Cholinergic Agents	1	1	0	0	365
Antineoplastics and Adjunctive Therapies	48	36	0	12	220
Anti-Obesity Agents	231	38	96	97	64
Antiparkinson and Related Therapy Agents	1	1	0	0	365
Antipsychotics/Antimanic Agents	14	5	0	9	268
Antivirals	5	2	2	1	193
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	14	7	0	7	685
Beta Blockers	1	0	0	1	0
Calcium Channel Blockers	1	0	0	1	0
Cardiovascular Agents - Misc.	34	14	1	19	373
Chemicals	2	0	0	2	0
Contraceptives	59	43	4	12	299
Corticosteroids	7	3	1	3	228
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	199	112	19	68	263
Diagnostic Products	17	8	6	3	269
Digestive Aids	3	1	0	2	183
Diuretics	1	1	0	0	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	4	1	1	2	91
Endocrine and Metabolic Agents - Misc.	48	28	8	12	252
Estrogens	8	3	0	5	226
Gastrointestinal Agents - Misc.	110	58	32	20	233
Gout Agents	14	1	1	12	911
Hematological Agents - Misc.	7	5	0	2	310

*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	8	1	7	242
Histamine H3-Receptor Antagonist/Inverse Agonists	1	0	0	1	0
Hypnotics/Sedatives/Sleep Disorder Agents	7	0	0	7	0
Laxatives	6	3	1	2	304
Medical Devices and Supplies	15	3	1	11	822
Migraine Products	164	93	58	13	179
Minerals and Electrolytes	2	0	0	2	0
Miscellaneous Therapeutic Classes	9	6	0	3	227
Multivitamins	2	1	0	1	365
Musculoskeletal Therapy Agents	33	14	7	12	335
Nasal Agents - Systemic and Topical	2	1	1	0	0
Neuromuscular Agents	40	22	4	14	305
Nutrients	1	1	0	0	365
Ophthalmic Agents	48	14	10	24	283
Other	20	2	0	18	273
Passive Immunizing and Treatment Agents	1	0	0	1	0
Psychotherapeutic and Neurological Agents - Misc.	35	20	0	15	244
Respiratory Agents - Misc.	9	5	0	4	329
Stimulants - Misc.	10	4	0	6	365
Ulcer Drugs/Antispasmodics/Anticholinergics	17	1	0	16	183
Urinary Antispasmodics	17	3	10	4	578
Vaginal and Related Products	1	0	0	1	0
Vasopressors	1	0	0	1	0
Vitamins	75	5	0	70	83
Total	**2,223**	**923**	**523**	**777**	
Overrides					
High Dose	1	1	0	0	365
Ingredient Duplication	158	90	41	27	198
NDC vs Age	486	308	19	159	232
NDC vs Sex	1	0	0	1	0
Opioid MME Limit	6	3	3	0	182
Opioid Quantity	4	4	0	0	378
Other	197	65	59	73	119
Quantity vs Days Supply	217	136	28	53	236
STBS/STBSM	511	14	97	400	11
Step Therapy Exception	277	138	78	61	186
Overrides Total	**1,858**	**759**	**325**	**774**	
Total Regular PAs + Overrides	**4,081**	**1,682**	**848**	**1,551**	
Denial Reasons					
Alternatives Not Met					298
Medical Necessity					550

*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

2/1/2026 Through 2/28/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	395	222	111	62	1,087
Analgesics - Anti-Inflammatory	134	75	34	25	996
Analgesics - Nonnarcotic	10	1	6	3	14
Analgesics - Opioid	322	107	139	76	271
Androgens - Anabolic	78	6	51	21	1,095
Anorectal and Related Products	6	0	2	4	0
Anthelmintics	1	0	0	1	0
Antianxiety Agents	34	7	23	4	587
Antiarrhythmics	1	1	0	0	318
Antiasthmatic and Bronchodilator Agents	263	91	141	31	633
Antibiotics	16	5	4	7	149
Anticoagulants	4	0	3	1	0
Anticonvulsants	48	16	24	8	891
Antidepressants	164	59	84	21	1,026
Antidiabetics	690	318	242	130	907
Antidiarrheal/Probiotic Agents	2	0	1	1	0
Antidotes and Specific Antagonists	1	0	0	1	0
Antiemetics	27	9	2	16	319
Antihistamines	19	6	5	8	1,095
Antihyperlipidemics	23	4	13	6	1,095
Antihypertensives	2	1	1	0	1,095
Anti-Infective Agents - Misc.	13	1	5	7	365
Antineoplastics and Adjunctive Therapies	91	45	16	30	583
Anti-Obesity Agents	201	18	124	59	411
Antiparkinson and Related Therapy Agents	3	3	0	0	1,095
Antipsychotics/Antimanic Agents	172	66	69	37	1,030
Antivirals	14	5	3	6	426
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	135	88	25	22	1,074
Beta Blockers	6	4	1	1	716
Calcium Channel Blockers	8	3	3	2	576
Cardiovascular Agents - Misc.	42	16	12	14	974
Contraceptives	28	12	13	3	602
Corticosteroids	12	4	4	4	238
Cough/Cold/Allergy	2	0	0	2	0
Dermatologicals	306	101	139	66	470
Diagnostic Products	35	21	9	5	956
Digestive Aids	2	2	0	0	713
Diuretics	5	2	1	2	1,095
Endocrine and Metabolic Agents - Misc.	55	15	29	11	853
Estrogens	14	4	7	3	516
Gastrointestinal Agents - Misc.	96	29	49	18	855
Genitourinary Agents - Misc.	7	0	2	5	0
Gout Agents	4	2	2	0	638
Hematological Agents - Misc.	12	9	2	1	659
Hematopoietic Agents	30	7	9	14	474

*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
Hypnotics/Sedatives/Sleep Disorder Agents	28	5	14	9	285
Laxatives	21	5	5	11	331
Medical Devices and Supplies	130	86	26	18	999
Migraine Products	132	48	69	15	699
Minerals and Electrolytes	1	0	0	1	0
Miscellaneous Therapeutic Classes	16	13	2	1	687
Multivitamins	4	2	1	1	1,095
Musculoskeletal Therapy Agents	34	16	12	6	372
Nasal Agents - Systemic and Topical	10	4	4	2	311
Neuromuscular Agents	16	11	3	2	349
Ophthalmic Agents	33	12	10	11	360
Other	19	5	3	11	425
Otic Agents	20	1	14	5	365
Passive Immunizing and Treatment Agents	5	0	1	4	0
Progestins	1	0	0	1	0
Psychotherapeutic and Neurological Agents - Misc.	33	9	14	10	884
Respiratory Agents - Misc.	8	5	3	0	866
Stimulants - Misc.	154	91	35	28	818
Thyroid Agents	15	10	1	4	751
Ulcer Drugs/Antispasmodics/Anticholinergics	47	14	15	18	776
Urinary Antispasmodics	24	5	12	7	711
Vaccines	1	0	1	0	0
Vaginal and Related Products	4	1	1	2	365
Vitamins	102	11	66	25	1,095
****Total**	**4,391**	**1,739**	**1,722**	**930**	

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

Denial Reasons	
Medical Necessity	1,721
Benefit	1

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

Appendix C

Spring 2026 Pipeline Update

Oklahoma Health Care Authority
March 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.

Cytisinicline[1,2,3,4,5,6,7]

Anticipated Indication(s): Smoking cessation treatment

Clinical Trial(s): In September 2025, the FDA accepted the New Drug Application (NDA) for cytisinicline for the treatment of smoking cessation in adults. The application was supported by safety and efficacy data from 2 Phase 3 clinical trials, ORCA-2 and ORCA-3. Both trials were multicenter, double-blind, randomized, placebo-controlled trials. The trials randomized adult smokers (ORCA-2: N=810 and ORCA-3: N=792) to 1 of 3 groups (cytisinicline 3mg dosed 3 times daily for 6 weeks or 12 weeks or placebo for 12 weeks). All groups were monitored 24 weeks post randomization and received standard behavioral support for the duration of the trial. The primary endpoint for both trials was continuous smoking abstinence measured during the last 4 weeks of treatment, which was verified by weekly expired carbon monoxide measurements of less than 10 parts per million. In ORCA-2, the smoking abstinence rate in the 12-week treated group was 32.6% versus 7.0% in the placebo group with the 12-week treated group having 6.3 times higher odds of quitting smoking than those who received placebo (P<0.0001). The 6-week treated group had similar results with a 25.3% smoking abstinence rate in the treated group versus 4.4% in placebo group, with the 6-week treated group having 8 times higher odds of quitting smoking than those in the placebo group (P<0.0001). ORCA-3 showed similar results with both the 6- and 12-week cytisinicline treatment groups demonstrating a statistically significantly better quit rate than placebo with an odds ratio of 2.85 and 4.40, respectively (P<0.0001). Additionally, those in the cytisinicline

treated groups had higher continuous smoking cessation rates after 24 weeks.

Place in Therapy: Cytisinicline is a plant-based alkaloid that is structurally similar to nicotine. It selectively binds to nicotinic acetylcholine receptors, which are thought to help treat nicotine addiction by reducing the severity of nicotine withdrawal symptoms and by reducing the reward and satisfaction associated with smoking through antagonistic properties. Current treatment options for smoking cessation include nicotine replacement therapy (NRT), bupropion, and varenicline. Cytisinicline is most like varenicline as they both are partial agonists of nicotinic acetylcholine receptors. Based on the clinical trials, cytisinicline dosing is 3mg 3 times daily for either 6 or 12 weeks whereas varenicline dosing is 1mg twice daily for up to 24 weeks (after an initial titration period). Cytisinicline has a similar side effect profile to varenicline; however, it has less gastrointestinal side effects which are common with varenicline (~30%). Additionally, cytisinicline is being studied for nicotine e-cigarette smoking cessation.

Projected FDA Decision: 06/20/2026

SoonerCare Impact: During fiscal year 2025 (07/01/2024 to 06/30/2025), there were 13,947 paid claims for smoking cessation products for 6,798 unique members, which accounted for a total cost of $771,253.92 and an average cost per claim of $55.30.

Baxdrostat[8,9,10]

Anticipated Indication(s): Treatment of adult patients with hard-to-control (uncontrolled or treatment resistant) hypertension (HTN) as an add-on to other antihypertensive medications when these do not provide adequate lowering of blood pressure

Clinical Trial(s): In December 2025, the FDA accepted the NDA for baxdrostat. The application was supported by data in the BaxHTN Phase 3 clinical trial, which was a multicenter, randomized, double-blind, placebo-controlled trial. The trial enrolled 794 adult patients with hard-to-control HTN, which was defined as a mean seated systolic blood pressure (SBP) of 140mmHg to 170mmHg despite treatment with maximally tolerated doses of either 2 antihypertensives medications, for those with uncontrolled HTN, or 3 or more medications, for those with resistant HTN. After a 2-week single-blind run-in period where patients received placebo in addition to their stable background medications, those who had a SBP ≥135mmHg and had good adherence to their antihypertensive therapy underwent randomization. Patients were randomized 1:1:1 to 1mg baxdrostat, 2mg baxdrostat, or placebo once daily. The primary efficacy endpoint was the change in the seated SBP from baseline to week 12, as assessed for each baxdrostat group as compared

with placebo. At week 12, the 1mg and 2mg baxdrostat treatment groups had a change from baseline in the least-squares mean seated SBP of -14.5mmHg [95% confidence interval (CI): -16.5, -12.5] and -15.7mmHg (95% CI: -17.6, -13.7), respectively, as compared with a change of -5.8mmHg (95% CI: -7.9, -3.8) in the placebo group. The estimated treatment difference relative to placebo was -8.7mmHg (95% CI: -11.5, -5.8; P<0.001) for 1mg baxdrostat and -9.8mmHg (95% CI: -12.6, -7.0; P<0.001) for 2mg baxdrostat.

Place in Therapy: High aldosterone levels are thought to be a key driver of hard-to-control HTN. Mineralocorticoid receptor antagonists (i.e., spironolactone, eplerenone) currently on the market work by blocking the action of aldosterone, but they are underused because of dose-dependent adverse effects. Baxdrostat is a highly selective, potent aldosterone synthase inhibitor, that was shown in clinical trials to lower aldosterone levels without affecting cortisol levels. It has a long half-life and is dosed once daily. If approved, it would be the first aldosterone synthase inhibitor on the market and would compete with spironolactone and eplerenone, as well as Tryvio™ (aprocitentan), which was recently approved for treatment resistant HTN.

Projected FDA Decision: 2nd quarter of 2026

SoonerCare Impact: During fiscal year 2025, there were 440,151 paid claims for antihypertensive medications for 96,012 unique members, which accounted for a total cost of $6,700,918.42 and an average cost per claim of $15.20.

Atacicept[11,12,13]

Anticipated Indication(s): Immunoglobulin A nephropathy (IgAN)

Clinical Trial(s): In January 2026, the FDA accepted the biologics license application (BLA) for atacicept. The BLA, submitted under the accelerated approval pathway, was supported by data from the interim analysis of the ORIGIN 3 clinical trial which is an ongoing, multicenter, double-blind, randomized, placebo-controlled trial. Patients eligible for the study were 18 years of age or older with IgAN confirmed by a kidney biopsy. Other key inclusion criteria included a 24-hour urinary protein to creatinine ratio (UPCR) ≥1g/g, an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2, treatment with a stable renin-angiotensin system (RAS) inhibitor for ≥12 weeks, and a blood pressure of ≤150/90mmHg. A total of 203 patients were included in the prespecified interim analysis with 106 patients in the atacicept group and 97 in the placebo group. The primary efficacy end point was the change from baseline at week 36 in the UPCR. The results showed, at week 36, the percentage reduction from baseline in the 24-hour UPCR was 45.7% in the atacicept group and 6.8% in the placebo group with a geometric mean between-group difference of 41.8% (95% CI: 28.9%, 52.3%; P<0.001).

Place in Therapy: Atacicept is an investigational recombinant fusion protein that contains the soluble transmembrane activator and calcium-modulating cyclophilin ligand interactor (TACI) receptor that binds to the cytokines B-cell activating factor (BAFF) and A PRoliferation-Inducing Ligand (APRIL). These cytokines are members of the tumor necrosis factor family that promote B-cell survival and autoantibody production associated with IgAN. Atacicept would be the second medication to target APRIL and the first to target BAFF. By blocking APRIL/BAFF, atacicept would be another therapy to help manage the IgAN-specific drivers of nephron loss. If approved, atacicept will be available in an auto-injector for at-home self-administration for once-weekly subcutaneous (sub-Q) injection. Other medications that are currently FDA approved for IgAN include Fabhalta® (iptacopan), Filspari® (sparsentan), Tarpeyo® [budesonide delayed-release (DR) capsule], Vanrafia® (atrasentan), and Voyxact® (sibeprenlimab-szsi).

Projected FDA Decision: 07/07/2026

SoonerCare Impact: During fiscal year 2025, there were 23 paid claims for IgAN medications for 8 unique members, which accounted for a total cost of $317,561.35 and an average cost per claim of $13,807.02.

Pipeline Table[14,15,16]

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
insulin icodec	Novo Nordisk	T2DM	sub-Q	BLA	03/2026
reproxalap	Aldeyra	DED	OPH	NDA	03/16/2026
linerixibat	GSK	Cholestatic pruritus	PO	NDA; OD	03/24/2026
marnetegragene autotemcel (Kresladi™)	Rocket	Leukocyte adhesion deficiency-I	IV	BLA; Fst Trk; OD	03/28/2026
tividenofusp alfa	Denali	MPS II	IV	BLA; Brk Thru; Fst Trk; OD	04/05/2026
doravirine/ islatravir	Merck	HIV-1 infection treatment	PO	NDA	04/18/2026
nimodipine	Grace	Subarachnoid hemorrhage	IV	505(b)(2) NDA; Fst Trk; OD	04/23/2026
brimonidine tartrate 0.35% (once daily)	Ocuvex	Glaucoma/ocular HTN	OPH	505(b)(2) NDA	05/2026

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
dexmethyl-phenidate IR/ER formulation	Cingulate	ADHD	PO	505(b)(2) NDA	05/31/2026
ensitrelvir	Shionogi	COVID-19 post-exposure prophylaxis	PO	NDA; Fst Trk	06/16/2026
cytisinicline	Achieve Life Sciences	Smoking cessation	PO	NDA; Brk Thru	6/20/2026
sirolimus/ pegadricase	Sobi	Gout	IV	BLA; Fst Trk	06/27/2026
veligrotug	Viridian	Thyroid eye disease	IV	BLA; Brk Thru; PR	06/30/2026
anifrolumab-fnia (Saphnelo®) SC	AstraZeneca	SLE	sub-Q	BLA	2Q 2026
baxdrostat	AstraZeneca	HTN (resistant or uncontrolled)	PO	NDA; PR	2Q 2026
orforglipron	Eli Lilly	Obesity or overweight (adults)	PO	NDA; CNPV	2Q 2026
zidebactam/ cefepime (Zaynich®)	Wockhardt	UTI (complicated)	IV	NDA; Fst Trk; PR	2Q 2026
bulevirtide 10mg	Gilead	Chronic HDV treatment	sub-Q	BLA; Brk Thru; OD	1H 2026
dalnacogene ponparvovec	Belief BioMed	Hemophilia B	IV	BLA	1H 2026
DB-OTO	Regeneron	Congenital hearing loss (otoferlin gene variants)	Intra-cochlear infusion	BLA; CNPV; Fst Trk; OD	1H 2026
oxylanthanum carbonate (Renazorb)	Unicycive	Hyperphospha-temia (in patients with CKD on dialysis)	PO	505(b)(2) NDA	1H 2026
SVP-rapamycin/ pegsiticase	Sobi	Gout	IV	NDA	1H 2026
tebipenem HBr	GSK; Spero	UTI (complicated)	PO	NDA; Fst Trk	1H 2026
icotrokinra	Janssen	Plaque psoriasis	PO	NDA	07/2026
atacicept	Vera, Bristol Myers Squibb	IgA Nephropathy	sub-Q	NDA; Brk Thru; OD; PR	07/07/2026
dexmethyl-phenidate	Cingulate	ADHD	PO	NDA	08/06/2026
tavapadon	Abbvie	Parkinson's disease	PO	NDA	09/2026

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
denecimig (Mim8)	Novo Nordisk	Hemophilia A	sub-Q	BLA	09/29/2026
insulin efsitora alfa	Eli Lilly	T2DM	sub-Q	BLA	3Q 2026
apixaban oral dissolving film (TAH3311)	Taho	Thrombotic disorders	PO	505(b)(2) NDA	3Q 2026
beclometha-sone/formoterol/ glycopyrrolate	Chiesi	Asthma	Inhaled	NDA	3Q 2026
denecimig	Novo Nordisk	Hemophilia A	sub-Q	BLA; OD	3Q 2026
pariglasgene brecaparvovec (DTX401)	Ultragenyx	Glycogen storage disease (type 1a)	IV	BLA; Fst Trk; OD	3Q 2026
doruxapapo-gene ralaplasmid (INO-3107)	Inovio	Respiratory papillomatosis	IM	BLA; Brk Thru; OD	10/30/2026
centanafadine	Otsuka	ADHD	PO	NDA	11/2026
cagrilintide/ semaglutide	Novo Nordisk	Obesity	sub-Q	NDA	12/2026
lorundrostat	Mineralys	HTN (uncontrolled or resistant)	PO	NDA	4Q 2026
olanzapine long-acting injection	Teva	Schizophrenia	sub-Q	505(b)(2) NDA	4Q 2026
adrabetadex	Mandos	Niemann-Pick disease type C	Intra-thecal	NDA; Brk Thru; OD	2H 2026
bezuclastinib	Cogent	Mastocytosis (nonadvanced, systemic)	PO	NDA; Brk Thru	2H 2026
imsidolimab	Vanda	GPP	IV; sub-Q	BLA; OD	2H 2026
molgramostim	Savara	Acute pulmonary alveolar proteinosis	Inhaled	BLA; Brk Thru; Fst Trk; OD	2H 2026
rusfertide	Takeda	Polycythemia vera	sub-Q	NDA; Brk Thru; Fst Trk; OD	2H 2026
lorecivivint	Biosplice	Osteoarthritis (knee)	Intra-articular	NDA	01/2027
quadrivalent influenza mRNA vaccine (mRNA-1010)	Moderna	Seasonal influenza vaccination	IM	BLA	01/2027

*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.
ADHD = attention deficit hyperactivity disorder; Admin = administration; BLA = biologic license application; Brk Thru = breakthrough; CKD = chronic kidney disease; CNPV = Commissioner's National Priority Voucher;

DED = dry eye disease; Fst Trk = fast track; GPP = generalized pustular psoriasis; GSK = GlaxoSmithKline; H = half; HDV = hepatitis D virus; HIV = Human Immunodeficiency Virus; HTN = hypertension; IgA = immunoglobulin A; IN = intranasal; IV = intravenous; MPS II = mucopolysaccharidosis II; NDA = new drug application; OD = orphan drug; OPH = ophthalmic; PR = priority review; PO = by mouth; Q = quarter; SLE = systemic lupus erythematosus; sub-Q = subcutaneous; T2DM = type 2 diabetes mellitus; UTI = urinary tract infection

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Appendix D

Vote to Prior Authorize Yutrepia™ (Treprostinil Powder for Inhalation) and Update the Approval Criteria for the Pulmonary Hypertension Medications

Oklahoma Health Care Authority
March 2026

Market News and Updates[1,2,3]

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

- **April 2025:** The FDA determined that the Risk Evaluation and Mitigation Strategies (REMS) program for the macitentan-containing products, Opsynvi® and Opsumit®, was no longer necessary to ensure the benefits of use outweigh the risk of embryo-fetal toxicity. This decision was supported by the evaluation of long-term human fetal outcomes of those exposed to the endothelial receptor antagonist (ERA) class from 2001 to 2024. The FDA concluded that *Boxed Warnings* in the labeling were sufficient to convey the potential safety risks of fetal harm.
- **May 2025:** The FDA approved the prostacyclin dry-powder formulation, Yutrepia™ (treprostinil powder for inhalation), for the treatment of adults with pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD) to improve exercise tolerability.
- **October 2025:** The FDA approved an update to the package labeling for Winrevair™ (sotatercept-csrk) based on data from the Phase 3 ZENITH trial. The labeling now describes the specific clinically worsening events for which Winrevair™ is indicated to reduce the risk of hospitalization for PAH, lung transplantation, and death.

Yutrepia™ (Treprostinil Powder for Inhalation) Product Summary[4]

Therapeutic Class: Prostacyclin mimetic

Indication(s): Treatment of PAH and PH-ILD to improve exercise tolerability

How Supplied: 26.5mcg, 53mcg, 79.5mcg, and 106mcg capsules containing powder for inhalation

Dosing and Administration:

- Yutrepia™ capsules should only be administered via inhalation and used only with the supplied inhaler.

- For treprostinil-naïve patients, initial dosing should be 26.5mcg 3 to 5 times per day, with each dose delivered in 2 breaths, based on patient response.
- See full *Prescribing Information* for initial dosing in patients transitioning from treprostinil inhalation solution.
- In treprostinil-naïve patients and those transitioning from treprostinil inhalation solution, the initial dose can be titrated by 26.5mcg per dose each week as tolerated; target maintenance dosing is 79.5 to 106mcg 4 times daily.
- Doses above 848mcg per day have not been studied in patients with PAH.

Efficacy: Yutrepia™ was approved by the FDA through the 505(b)(2) regulatory pathway. The safety and tolerability of Yutrepia™ were evaluated in INSPIRE a Phase 3, open-label, multicenter trial that included patients naïve to treprostinil and those transitioning from nebulized treprostinil.

Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days	Cost Per Year
Yutrepia™ (treprostinil inh pow) 106mcg	**$228.38**	**$25,578.56***	**$332,521.28**
Tyvaso DPI® (treprostinil inh pow) 64mcg	$226.00	$25,312.00⁺	$329,056.00
Tyvaso® (treprostinil inh sol) 1.74mg/2.9mL	$288.74	$23,445.69ᵅ	$304,793.97
Remodulin® (treprostinil inj) 10mg/mL	$544.80	$15,254.40ᵝ	$198,307.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
DPI = dry powder inhaler; inh = inhalation, inj = injection, pow = powder, sol = solution
Unit = capsule, cartridge, mL
*Cost per 28 days is based on the upper limit of the target dose range of 106mcg inhaled 4 times daily.
⁺Cost per 28 days is based on the upper limit of the target dose range of 64mcg inhaled 4 times daily.
ᵅCost per 28 days is based on use of 1 ampule per day divided 4 times daily.
ᵝCost per 28 days is based on the upper limit of the target dose range of 80ng/kg/min by continuous intravenous or subcutaneous infusion for an 80kg patient.

Recommendations

The College of Pharmacy recommends the prior authorization of Yutrepia™ (treprostinil powder for inhalation) with criteria similar to Tyvaso DPI® (treprostinil powder for inhalation) and recommends updating the Tyvaso DPI® criteria for clarity and based on clinical practice (changes shown in red):

Tyvaso DPI® (Treprostinil Powder for Inhalation) and Yutrepia™ (Treprostinil Powder for Inhalation) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Pulmonary arterial hypertension (PAH); or
   b. Pulmonary hypertension associated with interstitial lung disease (PH-ILD); and

i. Diagnosis of PH-ILD must be confirmed by right-sided heart catheterization; and

2. Medical supervision by a pulmonary specialist or cardiologist; and
3. For a diagnosis of PAH:
   a. Member must have previous failed trials of at least 1 of each of the following categories or have a contraindication to use of all alternatives:
      i. Revatio® (sildenafil) or Adcirca® (tadalafil); and
      ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
~~4. A patient-specific, clinically significant reason (beyond convenience) why Tyvaso® (treprostinil inhalation solution) and Remodulin® (treprostinil injection), which are available without a prior authorization, are not appropriate for the member must be provided; and~~
~~5. For a diagnosis of PH-ILD, a patient-specific, clinically significant reason (beyond convenience) why Tyvaso® (treprostinil inhalation solution), which is available without a prior authorization, is not appropriate for the member must be provided.~~

The College of Pharmacy also recommends updating the Opsynvi® (macitentan) and Opsumit® (macitentan/tadalafil) approval criteria based on the discontinuation of the REMS program (changes shown in red):

Opsumit® (Macitentan) and Opsynvi® (Macitentan/Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must have previous failed trials of at least 1 medication in each of the following categories or have a contraindication to use of all alternatives:
   a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. Requests for Opsynvi® will also require a patient-specific, clinically significant reason why the member cannot use Opsumit® in combination with generic sildenafil or tadalafil; and
~~5. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Opsumit® Risk Evaluation and Mitigation Strategy (REMS) program or the Macitentan-Containing Products REMS program; and~~
6. Female members of reproductive potential must have a negative pregnancy test prior to initiation of Opsumit® or Opsynvi® and, if pregnancy occurs during therapy, Opsumit® or Opsynvi® must be discontinued immediately; and
7. A quantity limit of 30 tablets per 30 days will apply.

Lastly, the College of Pharmacy recommends updating the Uptravi® (selexipag) and Winrevair™ (sotatercept-csrk) based on clinical practice (changes shown in red):

Uptravi® (Selexipag) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. ~~Member must be 18 years of age or older; and~~
3. Member must have previous failed trials of at least 1 medication in each of the following categories (alone or in combination) or have a contraindication to use of all alternatives:
   a. Adcirca® (tadalafil), Adempas® (riociguat), or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
4. Medical supervision by a pulmonary specialist or cardiologist; and
5. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and
6. A quantity limit of 2 tablets daily will apply for all strengths with an upper dose limit of 1,600mcg twice daily.

Winrevair™ (Sotatercept-csrk) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. ~~Member must be 18 years of age or older; and~~
3. Member is currently taking PAH medications from at least 2 of the following categories for ≥90 days or has a contraindication to use of all alternatives:
   a. Phosphodiesterase-5 (PDE-5) inhibitor (e.g., sildenafil, tadalafil) or soluble guanylate cyclase stimulator (e.g., riociguat); or
   b. Endothelin-receptor antagonist (e.g., ambrisentan, bosentan); or
   c. Prostacyclin analogue or receptor agonist (e.g., epoprostenol, treprostinil); and
4. Prescriber must verify that Winrevair™ will be used concurrently with member's current PAH therapies; and
5. Medical supervision by a pulmonary specialist and/or cardiologist; and
6. Prescriber must confirm the member or caregiver has been trained by a health care professional on the preparation, subcutaneous (sub-Q) administration, and proper storage of Winrevair™; and
7. Prescriber must agree to monitor hemoglobin and platelet counts prior to each dose for the first 5 doses and periodically thereafter; and
8. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during therapy and for at least 4 months after the last dose; and

9. 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
10. A quantity limit of 1 kit every 3 weeks will apply.
    a. Members requiring (2) 45mg or (2) 60mg vials based on their body weight will not be approved for multiple 1-vial kits but should use the 2-vial kits to achieve the dose required.

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[3] Merck. U.S. FDA Approves Updated Indication for Winrevair™ (Sotatercept-csrk) in Adults with Pulmonary Arterial Hypertension (PAH WHO Group 1 Pulmonary Hypertension) Based on Phase 3 ZENITH Study. Available online at: https://www.merck.com/news/u-s-fda-approves-updated-indication-for-winrevair-sotatercept-csrk-in-adults-with-pulmonary-arterial-hypertension-pah-who-group-1-pulmonary-hypertension-based-on-phase-3-zenith-study/. Issued 10/27/2025. Last accessed 02/25/2026.
[4] Yutrepia™ (Treprostinil) Inhalation Powder, for Oral Inhalation Prescribing Information. Liquidia Corporation. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/213005s000lbl.pdf. Last revised 05/25/2025. Last accessed 02/16/2026.

Appendix E

Vote to Prior Authorize Brekiya® [Dihydroergotamine (DHE) Autoinjector] and Update the Approval Criteria for the Anti-Migraine Medications

Oklahoma Health Care Authority
March 2026

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

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

- **May 2025:** The FDA approved Brekiya® (DHE autoinjector) for the acute treatment of migraine with or without aura and of acute cluster headaches (HA) in adults. This is the first DHE autoinjector approved by the FDA. DHE was previously FDA approved as a nasal spray (i.e., Migranal®) and as an injectable solution in ampules (i.e., D.H.E. 45®).
- **August 2025:** The FDA approved an age expansion for Ajovy® (fremanezumab-vfrm) for the preventative treatment of episodic migraine to include pediatric patients 6 to 17 years of age who weigh ≥45kg. The approval was based on the results of the Phase 3 SPACE trial, which showed Ajovy® significantly reduced monthly migraine days (-2.5 vs. -1.4; P=0.0210) and monthly HA days (-2.6 vs. -1.5; P=0.0172) in pediatric patients over 12 weeks compared to placebo, with a safety profile consistent with that observed in the adult population.

News:

- **November 2025:** Eli Lilly announced they are discontinuing Reyvow® (lasmiditan tablets) based on a business decision.

Cost Comparison: DHE Products[7,8]

Product	Cost Per mL	Cost Per Month	Cost Per Year
Brekiya® (DHE 1mg/mL autoinjector)	**$875.00**	**$21,000.00**[α]	**$273,000.00**
DHE 1mg/mL injection (generic D.H.E. 45®)	$57.08	$1,369.92[α]	$17,808.96
DHE 4mg/mL nasal spray (generic Migranal®)	$30.12	$240.96[+]	$3,132.48

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), Specialty Pharmaceutical Allowable Costs (SPAC), or State Maximum Allowable Costs (SMAC).
DHE = dihydroergotamine
[α]Cost per month is based on the maximum FDA approved dose of 3mg in a 24-hour period with no more than 6mg (6 doses) in a total week.
[+]Cost per month is based on the maximum FDA approved dose of 4mg in a 7-day period. Please note each vial is 4mg/mL but only delivers 2mg of DHE after being primed; therefore, to achieve the maximum dose per month 8 vials will be needed.

Recommendations

The College of Pharmacy recommends the following changes to the current Anti-Migraine Medications Product Based Prior Authorization (PBPA) category based on the new FDA approval, product discontinuation, and net costs (changes shown in red):

1. Prior authorization of Brekiya® (DHE autoinjector) and placement into the Special PA Tier with the following additional criteria; and
2. Updating the approval criteria for Ubrelvy® (ubrogepant) and Zavzpret™ (zavegepant nasal spray).

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
eletriptan tablet (Relpax®)	frovatriptan tablet (Frova®)	almotriptan tablet (Axert®)	**DHE autoinjector (Brekiya®)**
naratriptan tablet (Amerge®)	sumatriptan/ naproxen tablet (Treximet®)	DHE nasal spray (Migranal®)	DHE injection (D.H.E. 45®)
rizatriptan tablet, ODT (Maxalt®, Maxalt MLT®)		sumatriptan autoinjector pen and vial (Imitrex®)	ergotamine sublingual tablet (Ergomar®)
sumatriptan tablet (Imitrex®)		sumatriptan nasal spray (Imitrex®)	lasmiditan tablet (Reyvow®)
zolmitriptan tablet, ODT (Zomig®, Zomig-ZMT®)			meloxicam/rizatriptan (Symbravo®)
			rimegepant ODT (Nurtec® ODT)
			sumatriptan injection (Imitrex® STATdose System)
			sumatriptan injection (Zembrace® SymTouch®)
			sumatriptan nasal spray (Tosymra®)
			ubrogepant tablet (Ubrelvy®)
			zavegepant nasal spray (Zavzpret™)
			zolmitriptan nasal spray (Zomig® nasal spray)

*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).
DHE = dihydroergotamine; ODT = orally disintegrating tablet; PA = prior authorization

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of Ergomar® (ergotamine sublingual tablets) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications; and
    a. Member must not have any of the contraindications for use of Ergomar® (e.g., coadministration with a potent CYP3A4 inhibitor, women who are or may become pregnant, peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic or renal function, sepsis, hypersensitivity to any of the components); and
    b. A quantity limit of 20 tablets per 28 days will apply.
2. Use of Brekiya® [dihydroergotamine (DHE) autoinjector] or D.H.E. 45® ~~[dihydroergotamine~~ (DHE~~)~~ injection)~~]~~ will require a patient-specific, clinically significant reason why the member cannot use Migranal® (DHE nasal spray) and lower-tiered triptan medications.
3. Nurtec® ODT (rimegepant) Approval Criteria [Migraine Diagnosis (Acute Treatment)]⁺:
    a. Member must have failed therapy with at least 2* triptan medications or a patient-specific, clinically significant reason why a triptan is not appropriate for the member must be provided; and
    b. Nurtec® ODT will not be approved for concurrent use with a prophylactic CGRP inhibitor; and
    c. A quantity limit of 8 orally disintegrating tablets (ODTs) per 30 days will apply.

    *The manufacturer of Nurtec® ODT has currently provided a supplemental rebate to require a trial with 2 triptan medications and to be the preferred CGRP product for acute treatment over Reyvow®, Ubrelvy®, and Zavzpret™; however, Nurtec® ODT will follow the same criteria as Reyvow®, Ubrelvy®, and Zavzpret™ if the manufacturer chooses not to participate in supplemental rebates.

    ⁺Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Qulipta® and Vyepti® approval criteria.
4. Use of Reyvow® (lasmiditan) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
    a. Reyvow® will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor
5. Use of Symbravo® (meloxicam/rizatriptan) will require a patient-specific, clinically significant reason why the member cannot use Treximet® (sumatriptan/naproxen) and a different combination of a lower-tiered triptan medication in combination with a non-steroidal anti-inflammatory drug (NSAID) (i.e., rizatriptan with ibuprofen).
6. Use of Ubrelvy® (ubrogepant) or Zavzpret™ (zavegepant nasal spray) will require a patient-specific, clinically significant reason why the

member cannot use triptan medications~~,~~ and Nurtec® ODT (rimegepant)~~, and Reyvow® (lasmiditan)~~; and
    a. Ubrelvy® and Zavzpret™ will not be approved for concurrent use with a prophylactic CGRP inhibitor.
7. Use of Imitrex® STATdose System (sumatriptan injection), Tosymra® (sumatriptan nasal spray), or Zembrace® SymTouch® (sumatriptan injection) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.
8. Use of any non-oral zolmitriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.

Additionally, the College of Pharmacy recommends updating the approval criteria for Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), and Emgality® (galcanezumab-gnlm) based on the FDA age expansion for Ajovy® (changes shown in red):

Aimovig® (Erenumab-aooe), Ajovy® (Fremanezumab-vfrm), and Emgality® (Galcanezumab-gnlm) Approval Criteria [Migraine Diagnosis]:

1. An FDA approved indication for the preventive treatment of migraine ~~in adults~~; and
2. Member must be 18 years of age or older;~~ and~~ or
    a. For Ajovy®, pediatric members must be 6 to 17 years of age, weigh at least 45kg, and have a diagnosis of episodic migraine, as defined below; and
3. Member has documented chronic migraine or episodic migraine headaches:
    a. Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month for more than 3 months; or
    b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months; and
4. Member has been evaluated for all of the following, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated:
    a. Red flags; and
    b. Possible indicators of secondary headache; and
    c. Medication overuse; and
5. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
6. Prescriber must verify member has been counseled on appropriate use, storage of the medication, and administration technique; and

7. Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and
8. Quantity limits will apply based on FDA-approved dosing:
    a. For Aimovig®, a quantity limit of 1 syringe or autoinjector per 30 days will apply; and
    b. For Ajovy® prefilled syringe and autoinjector, a quantity limit of 1 syringe or 1 autoinjector per 30 days will apply. Requests for quarterly dosing (675mg every 3 months) will be approved for adults only for a quantity limit override upon meeting Ajovy® approval criteria; and
    c. For Emgality®, a quantity limit of 1 syringe or pen per 30 days will apply. Requests for an initial loading dose (240mg administered as 2 consecutive 120mg injections) will be approved for a quantity limit override upon meeting Emgality® approval criteria.

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[1] Amneal. Amneal Receives FDA Approval for Brekiya® (Dihydroergotamine Mesylate) Injection for the Acute Treatment of Migraine and Cluster Headaches in Adults. Available online at: https://investors.amneal.com/news/press-releases/press-release-details/2025/Amneal-Receives-U-S--FDA-Approval-for-Brekiya-dihydroergotamine-mesylate-injection-for-the-Acute-Treatment-of-Migraine-and-Cluster-Headaches-in-Adults/default.aspx. Issued 05/15/2025. Last access 02/09/2026.
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[3] Teva Pharmaceutical Industries Ltd. FDA Approves Expanded Indication for Ajovy® (Fremanezumab-vfrm), the First Anti-CGRP Preventative Treatment for Pediatric Episodic Migraine. Available online at: https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2025/FDA-Approves-Expanded-Indication-for-AJOVY-fremanezumab-vfrm-The-First-Anti-CGRP-Preventive-Treatment-for-Pediatric-Episodic-Migraine/default.aspx. Issued 08/06/2025. Last accessed 02/09/2026.
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[7] Dihydroergotamine Injection Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=40b9ba9e-436e-444e-b078-01b12bb57ea7. Last revised 02/25/2025. Last accessed 02/09/2026.
[8] Dihydroergotamine Nasal Spray Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=65f8c60d-9213-48ac-8233-acc5d44548f4. Last revised 01/07/2026. Last accessed 02/09/2026.

Appendix F

Vote Prior Authorize Cardamyst™ (Etripamil Nasal Spray)

Oklahoma Health Care Authority
March 2026

Market News and Updates[1]

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

- **December 2025:** The FDA approved Cardamyst™ (etripamil nasal spray) as the first self-administered, on-demand therapy for the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults.

Cardamyst™ (Etripamil Nasal Spray) Product Summary[2,3]

Therapeutic Class: Non-dihydropyridine calcium channel blocker

Indication(s): Conversion of acute symptomatic episodes of PSVT to sinus rhythm in adults

How Supplied: Nasal spray device containing 2 sprays, which is a total dose of 70mg of etripamil

Dosing and Administration:

- One spray (35mg) should be administered into each nostril for a total dose of 70mg as soon as possible after PSVT onset.
- A second dose of 70mg may be administered if symptoms persist for more than 10 minutes after the first dose.
- The maximum dose is 140mg in a 24-hour period.
- If symptoms do not improve within 20 minutes of a second dose, patients and caregivers should contact a heath care provider or seek emergency medical attention.

Efficacy: The safety and efficacy of Cardamyst™ were evaluated in RAPID, a randomized, double-blind, placebo-controlled, multicenter, event-driven Phase 3 clinical trial.

- Key Inclusion Criteria:
  - History of PSVT with sustained, symptomatic episodes ≥20 minutes as documented by electrocardiogram (ECG)
  - 18 years of age or older
- Intervention(s): Patients were randomized 1:1 to Cardamyst™ or placebo to administer intranasally in a medically unsupervised setting; patients could self-administer a second dose if symptoms did not resolve after the first dose.

- Primary Endpoint(s): Time-to-conversion of confirmed PSVT to sinus rhythm for at least 30 seconds within 30 minutes of the first dose
- Results:
  - 255/692 randomized patients perceived an episode of PSVT and self-administered the intervention
  - 72% (184/255) episodes were confirmed by blinded adjudication as PSVT
  - 64% of participants who received Cardamyst™ met the primary endpoint compared to 31% for placebo, with a hazard ratio of 2.6 [95% confidence interval (CI): 1.7, 4.2; P<0.001].
  - Median time-to-conversion was 17.2 minutes (95% CI: 12.4, 26.5) for Cardamyst™ compared to 53.5 minutes (95% CI: 38.7, 87.3) with placebo.

Cost: The Wholesale Acquisition Cost (WAC) of Cardamyst™ is $824.50 per 70mg nasal spray device, with each package containing 2 devices, resulting in an estimated cost of $1,649 per treatment course based on the maximum FDA-approved dosing regimen of up to 140mg in a 24-hour period.

Recommendations

The College of Pharmacy recommends the prior authorization of Cardamyst™ (etripamil nasal spray) with the following criteria (shown in red):

Cardamyst™ (Etripamil Nasal Spray) Approval Criteria:

1. An FDA approved indication of the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm; and
2. Member must 18 years of age or older; and
3. Member must not have any of the contraindications for use of Cardamyst™, including:
   a. Hypersensitivity to Cardamyst™ or any of its components; and
   b. New York Heart Association (NYHA) Class II to IV heart failure; and
   c. Wolff-Parkinson-White (WPW), Lown-Ganong-Levine (LGL) syndromes, or manifest pre-excitation (delta wave) on a 12-lead electrocardiogram (ECG); and
   d. Sick sinus syndrome without a permanent pacemaker; and
   e. Second degree atrioventricular (AV) Mobitz 2 block or higher degree of AV block; and
4. Prescriber must verify the member or caregiver will be counseled on all of the following:
   a. PSVT symptoms; and

   b. Timing of Cardamyst™ administration in relation to the onset of the PSVT episode; and
   c. The proper storage and administration of Cardamyst™; and
   d. When to contact a health care provider or seek emergency medical attention; and
5. Prescriber must verify members with a history of hypotensive episodes or those at increased risk for hemodynamic instability will be monitored appropriately when initiating Cardamyst™; and
6. Must be prescribed by, or in consultation with, a cardiologist or a specialist with expertise in the treatment of PSVT; and
7. Approvals will be for up to 6 cartons (i.e., 12 nasal spray devices) per year; and
   a. A quantity limit of 1 carton (i.e., 2 nasal spray devices) per 30 days will apply; or
   b. For requests exceeding the quantity limit, clinical documentation (i.e., recent office notes) supporting the need for additional supply must be provided for consideration of a quantity limit override; and
8. Subsequent approvals may be granted if the prescriber documents the member has responded well to treatment and continues to require treatment with Cardamyst™.

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[1] Milestone Pharmaceuticals. Milestone Receives FDA Approval of Cardamyst™ (Etripamil) as First and Only Self-Administered Nasal Spray for Adults with Paroxysmal Supraventricular Tachycardia (PSVT). Available online at: https://investors.milestonepharma.com/news-releases/news-release-details/milestone-receives-fda-approval-cardamysttm-etripamil-first-and. Issued 12/15/2025. Last accessed 02/25/2026.

[2] Cardamyst™ (Etripamil) Prescribing Information. Milestone Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218571s000lbl.pdf. Last revised 12/2025. Last accessed 02/25/2026.

[3] Stambler BS, Camm AJ, Alings M, et al. Self-administered Intranasal Etripamil Using a Symptom-prompted, Repeat-dose Regimen for Atrioventricular-nodal-dependent Supraventricular Tachycardia (RAPID): A Multicentre Randomized Trial. *Lancet* 2023; 402: 118-128. doi: 10.1016/S0140-6736(23)00776-6.

Appendix G

Fiscal Year 2025 Annual Review of Hemophilia Medications

Oklahoma Health Care Authority
March 2026

Current Prior Authorization Criteria

Adynovate®, Afstyla®, Eloctate®, and Esperoct® Approval Criteria:

1. An FDA approved indication; and
2. Requested medication must be prescribed by a hematologist specializing in rare bleeding disorders or a mid-level practitioner with a supervising physician that is a hematologist specializing in rare bleeding disorders; and
3. A patient-specific, clinically significant reason why the member cannot use the following must be provided:
    a. Hemophilia A: Advate®, Altuviiio®, Jivi®, or current factor VIII replacement product; or
    b. Hemophilia B: Alprolix®, Benefix®, Idelvion®, Rebinyn®, or current factor IX replacement product; and
4. A half-life study must be performed to determine the appropriate dose and dosing interval; and
5. Initial approvals will be for the duration of the half-life study. If the half-life study shows significant benefit in prolonged half-life, subsequent approvals will be for the duration of 1 year.

Alhemo® (Concizumab-mtci) Approval Criteria:

1. An FDA approved diagnosis of hemophilia A or B with inhibitors; and
2. Member must be 12 years of age or older; and
3. Member's recent weight (taken within the past 3 months) must be provided and must be ≥25kg; and
4. Member must not be undergoing immune tolerance induction (ITI); and
5. Member must not have a history of or be at high risk for thromboembolic events; and
6. Female members of reproductive potential must meet the following:
    a. Must not be pregnant; or
        i. If member is pregnant or becomes pregnant during treatment, the risk to the fetus must be weighed against the benefit to the mother; and
    b. Must agree to use effective birth control during treatment and for at least 7 weeks after the last dose; and

7. Prescriber must agree the member will not be continuing on other prophylactic therapies; and
8. Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
9. Prescriber must verify that the member or caregiver has been trained on the subcutaneous administration and counseled on the storage of Alhemo®; and
10. Prescriber must verify that the member has been counseled on the potential risk of thrombosis and use of bypassing agents at the lowest possible dose for breakthrough bleeding episodes based on severity and location of bleed; and
11. Requests must be for an FDA approved dosing regimen as outlined in the package labeling; and
12. Initial approvals will be for 3 months for the loading dose of 1mg/kg on day 1 and 0.2mg/kg daily until individualization of the maintenance dose has been achieved. Subsequent approvals will be the duration of 1 year if there is documentation of clinical effectiveness.

Coagadex® [Coagulation Factor X (Human)] Approval Criteria:

1. An FDA approved indication; and
2. Coagadex® must be prescribed by a hematologist specializing in rare bleeding disorders or a mid-level practitioner with a supervising physician that is a hematologist specializing in rare bleeding disorders; and
3. A half-life study must be performed to determine the appropriate dose and dosing interval; and
4. Initial approvals will be for the duration of the half-life study and immediate needs. After a half-life study is performed and appropriate dose and interval is determined, subsequent approvals will be for the duration of 1 year.

Corifact® [Factor XIII Concentrate (Human)] and Tretten® [Coagulation Factor XIII A-Subunit (Recombinant)] Approval Criteria:

1. An FDA approved indication; and
2. Corifact® or Tretten® must be prescribed by a hematologist specializing in rare bleeding disorders or a mid-level practitioner with a supervising physician that is a hematologist specializing in rare bleeding disorders; and
3. A half-life study must be performed to determine the appropriate dose and dosing interval; and
4. Initial approvals will be for the duration of the half-life study and immediate needs. After a half-life study is performed and appropriate

dose and interval is determined, subsequent approvals will be for the duration of 1 year.

Feiba® (Anti-Inhibitor Coagulation Complex) Approval Criteria:

1. Member must be diagnosed with hemophilia A or B with an inhibitor; and
    a. For a diagnosis of hemophilia A with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Alhemo® (concizumab-mtci), Hemlibra® (emicizumab-kxwh), or Qfitlia™ (fitusiran) for prophylaxis therapy must be provided; or
    b. For a diagnosis of hemophilia B with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Alhemo® (concizumab-mtci) or Qfitlia™ (fitusiran) for prophylaxis therapy must be provided; and
2. Feiba® must be prescribed by a hematologist specializing in rare bleeding disorders practicing in a federally recognized Hemophilia Treatment Center (HTC) or a mid-level practitioner under the supervision of a physician at an HTC.

Hemgenix® (Etranacogene Dezaparvovec-drlb) Approval Criteria:

1. Diagnosis of severe or moderately severe congenital, X-linked, hemophilia B; and
2. Member must not have a history of an inhibitor or a recent positive screening, defined as ≥0.6 Bethesda units, prior to administration of etranacogene dezaparvovec-drlb; and
3. Member must not have an AAV5 neutralizing antibody titer >700; and
4. Member must be a male 18 years of age or older; and
5. Member must be on prophylactic therapy with continued frequent breakthrough bleeding episodes or has experienced a life-threatening bleeding episode; and
6. Member must have had >150 previous exposure days of treatment with factor IX; and
7. Member must not have active hepatitis B or C; and
8. Members with human immunodeficiency virus (HIV) must be controlled with antiviral therapy; and
9. Member must not have received prior treatment with any gene therapy for hemophilia B; and
10. Prescriber must perform baseline liver health assessment including:
    a. Enzyme testing (ALT, AST, ALP); and
    b. Hepatic ultrasound; and
11. Member's recent weight must be provided (taken within the last month) to ensure appropriate dosing; and

12. Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
13. Must be administered in a clinical setting and monitoring performed for at least 3 hours post-infusion; and
14. Prescriber must monitor liver enzymes weekly for 3 months following administration of etranacogene dezaparvovec-drlb and continue monitoring until liver enzymes return to baseline; and
    a. Prescriber must agree to begin corticosteroids if indicated; and
15. Approvals will be for 1 dose per member per lifetime.

Hemlibra® (Emicizumab-kxwh) Approval Criteria:

1. Member must have a diagnosis of hemophilia A; and
2. Hemlibra® must be prescribed by a hematologist specializing in rare bleeding disorders practicing in a federally recognized Hemophilia Treatment Center (HTC) or a mid-level practitioner under the supervision of a physician at an HTC.; and
3. Prescriber must be able to monitor appropriate blood clotting tests and levels utilizing testing which accounts for the interaction of Hemlibra® and blood factors by following the Medical and Scientific Advisory Council (MASAC) guidance; and
4. For members with hemophilia A with an inhibitor to factor VIII:
    a. A treatment plan must be developed to address breakthrough bleeds and procedures. Prescriber must counsel member and/or caregiver on the risks of utilizing Feiba® for breakthrough bleeding while on Hemlibra®, and member should be monitored closely if any bypassing agent is given; or
5. For members without an inhibitor and having severe hemophilia A or those with moderate hemophilia A presenting as severe:
    a. A treatment plan must be made to address breakthrough bleeds and procedures; and
    b. Routine lab screenings must occur for factor VIII inhibitor while using Hemlibra® since this would change the treatment plan for bleeds and procedures; and
6. Prescriber must agree the member will not be continuing other prophylactic therapies; and
7. First dose must be given in a health care facility; and
8. In order to calculate appropriate dosing, the member's recent weight must be provided and been taken within the last 3 months; and
9. Initial approvals will be for 3 months of therapy. Subsequent approvals will be for the duration of 1 year, if there has been a decrease in the member's spontaneous bleeding episodes since initiating Hemlibra® treatment.

Hympavzi® (Marstacimab-hncq) Approval Criteria:

1. A diagnosis of moderately severe to severe hemophilia A (FVIII <2%) without inhibitors or moderately severe to severe hemophilia B (FIX activity <2%) without inhibitors; and
2. Member must be 12 years of age or older and weigh at least 35kg; and
3. Member must not have a current inhibitor or documented history of an inhibitor; and
4. For females of reproductive potential:
    a. Member must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
    b. Member must be willing to use effective contraception during and after treatment for at least 2 months after the last dose; and
5. Member must not have uncontrolled human immunodeficiency virus (HIV) as shown by CD4+ counts ≤200cells/mm3; and
6. Prescriber must agree the member will not be continuing other prophylactic therapies; and
7. Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
8. Prescriber must verify that the member or caregiver has been trained on the subcutaneous administration and counseled on the storage of Hympavzi®; and
9. Prescriber must verify that the member has been counseled on the use of factor replacement therapy at the lowest possible dose for breakthrough bleeding episodes; and
10. Initial approvals will be for 3 months of therapy. Subsequent approvals will be the duration of 1 year if there is documentation of clinical effectiveness; and
11. Approvals will be for 300mg loading dose followed by 150mg weekly doses. Approvals may be granted for dose escalation to 300mg weekly when the following are met:
    a. Member weighs ≥50kg; and
    b. There have been ≥2 spontaneous bleeding episodes which were treated with factor replacement therapy in the last 6 months despite compliance; and
    c. Absence of inhibitor development.

NovoSeven® RT [Coagulation Factor VIIa (Recombinant)] Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Hemophilia A or B with inhibitors; or
        i. For a diagnosis of hemophilia A with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Alhemo® (concizumab-mtci), Hemlibra® (emicizumab-

kxwh), or Qfitlia™ (fitusiran) for prophylaxis therapy must be provided; or

ii. For a diagnosis of hemophilia B with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Alhemo® (concizumab-mtci) or Qfitlia™ (fitusiran) for prophylaxis therapy must be provided; or

b. Congenital factor VII deficiency; or
c. Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets; or
d. Acquired hemophilia; and

2. NovoSeven® RT must be prescribed by a hematologist specializing in rare bleeding disorders practicing in a federally recognized Hemophilia Treatment Center (HTC) or a mid-level practitioner under the supervision of a physician that is a hematologist specializing in rare bleeding disorders at an HTC.

Obizur® [Antihemophilic Factor (Recombinant), Porcine Sequence] Approval Criteria:

1. An FDA approved indication; and
2. Obizur® must be prescribed by a hematologist specializing in rare bleeding disorders or a mid-level practitioner with a supervising physician that is a hematologist specializing in rare bleeding disorders; and
3. A patient-specific, clinically significant reason why the member cannot use Feiba® (anti-inhibitor coagulant complex) or NovoSeven® RT [coagulation factor VIIa (recombinant)] must be provided; and
4. A half-life study must be performed to determine the appropriate dose and dosing interval; and
5. Initial approvals will be for the duration of the half-life study. After a half-life study is performed and appropriate dose and interval is determined, subsequent approvals will be for the duration of 1 year.

Qfitlia™ (Fitusiran) Approval Criteria:

1. A diagnosis of severe hemophilia A or B, with or without factor inhibitors; and
2. Member must be 12 years of age or older; and
3. Member must not have a history of or be at high risk for thromboembolic events; and
4. Member must not have clinically significant liver disease; and
5. Member must not have active hepatitis C; and
6. Member must not have an acute or chronic hepatitis B infection; and
7. Members with human immunodeficiency virus (HIV) must be controlled with antiviral therapy as shown by CD4+ counts ≤200cells/mm^3 or viral load ≥20 copies/mL; and

8. In a member with a history of symptomatic gallbladder disease, a reason why the member cannot use other available treatments must be provided; and
9. Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
10. Prescriber must agree the member will not be continuing other prophylactic therapies for longer than 7 days after initiation of fitusiran; and
11. Prescriber must agree to perform an FDA-cleared test for antithrombin activity at weeks 4, 12, 20, and 24 and adjust the dosing as outlined in the package labeling; and
12. Prescriber must agree to perform baseline liver tests prior to initiation of fitusiran and monthly for at least 6 months and after any dose increase; and
13. Prescriber must verify that the member or caregiver has been trained on the subcutaneous administration and counseled on the storage of fitusiran; and
14. Prescriber must verify that the member has been counseled on the use of factor replacement therapy or bypassing agent as outlined in the prescribing information for breakthrough bleeding episodes; and
15. Initial approvals will be for 3 months of therapy. Subsequent approvals will be the duration of 1 year if there is documentation of clinical effectiveness.

Roctavian® (Valoctocogene Roxaparvovec-rvox) Approval Criteria:

1. An FDA approved diagnosis of severe congenital (or X-linked) hemophilia A; and
2. Member must be a male 18 years of age or older; and
3. Member must not have a history of or a recent positive screening of an inhibitor defined as ≥0.6 Bethesda units; and
4. Member must be on prophylactic therapy with continued frequent breakthrough bleeding episodes or has experienced a life-threatening bleeding episode; and
5. Member must not have acute infections; and
6. Member must not have chronic active infections such as Hepatitis B or C; and
7. Member must not have uncontrolled human immunodeficiency virus (HIV) as shown by CD4+ counts ≤200u/L; and
8. Member must not be taking efavirenz; and
9. Member must not have antibodies to AAV5; and
10. Member must not have an of the following:
    a. Significant liver fibrosis:

        i. Defined as ≥3 as rated on a scale of 0-4 on the METAVIR scoring system or equivalent grade on an alternative scale; and
        ii. Measured by ultrasound and elastography or laboratory assessments; or
    b. Liver cirrhosis; or
    c. Significant liver dysfunction with any of the following abnormal lab results:
        i. ALT (alanine aminotransferase) >1.25x upper limit of normal (ULN); or
        ii. AST (aspartate aminotransferase) >1.25x ULN; or
        iii. GGT (gamma-glutamyltransferase) >1.25x ULN; or
        iv. Total bilirubin >1.25x ULN; or
        v. Alkaline phosphatase >1.25x ULN; or
        vi. INR (international normalized ratio) ≥1.4; and
11. Must be prescribed by a hematologist practicing in a federally recognized hemophilia treatment center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
12. Prescriber must counsel member to not donate semen, and if member is of reproductive potential then their female partners must agree to prevent or postpone pregnancy for 6 months after treatment with valoctocogene roxaparvovec-rvox; and
13. Valoctocogene roxaparvovec-rvox must be administered in an appropriate clinical setting and member must be monitored for at least 3 hours post infusion; and
14. Prescriber must follow liver enzymes weekly for 26 weeks, every 1 to 2 weeks for weeks 26 through 52, every 3 months in the second year and every 6 months thereafter; and
15. Prescriber agrees to start corticosteroids (or other immunosuppressives if corticosteroids are contraindicated) as outlined in the package labeling; and
16. Prescriber agrees to monitor factor VIII levels weekly for 26 weeks, every 1 to 2 weeks for weeks 26 through 52, every 3 months in the second year and every 6 months thereafter; and
17. Approvals will be for 1 treatment per member per lifetime.

Sevenfact® [Coagulation Factor VIIA (Recombinant)-jncw] Approval Criteria:

1. An FDA approved diagnosis; and
    a. For a diagnosis of hemophilia A with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Alhemo® (concizumab-mtci), Hemlibra® (emicizumab-kxwh), or Qfitlia™ (fitusiran) for prophylaxis therapy must be provided; or

b. For a diagnosis of hemophilia B with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Alhemo® (concizumab-mtci) or Qfitlia™ (fitusiran) for prophylaxis therapy must be provided; and

2. Sevenfact® must be prescribed by a hematologist specializing in rare bleeding disorders practicing in a federally recognized Hemophilia Treatment Center (HTC) or a mid-level practitioner under the supervision of a physician at an HTC.

Standards-of-Care for Pharmacies Providing Factor Replacement Products can be found on the Oklahoma Health Care Authority (OHCA) website on the Pharmacy Prior Authorization (PA) page in the Hemophilia Therapeutic Category at https://oklahoma.gov/ohca/pa.

Utilization of Hemophilia Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	122	916	$24,905,402.95	$27,189.30	$1,209.53	5,665,569	20,591
Aetna	19	49	$1,168,343.24	$23,843.74	$992.65	316,440	1,177
Humana	10	33	$1,415,925.66	$42,906.84	$1,824.65	476,756	776
OCH	9	23	$512,544.29	$22,284.53	$865.78	49,659	592
2024 Total	**128**	**1,021**	**$28,002,216.14**	**$27,426.26**	**$1,210.33**	**6,508,424**	**23,136**
Fiscal Year 2025							
FFS	59	402	$12,907,286.75	$32,107.68	$1,379.72	2,363,996	9,355
Aetna	29	221	$6,992,907.60	$31,642.12	$1,272.13	2,038,100	5,497
Humana	27	159	$6,920,482.54	$43,525.05	$1,957.15	2,128,891	3,536
OCH	18	114	$2,659,180.39	$23,326.14	$1,043.63	420,710	2,548
2025 Total	**118**	**896**	**$29,479,857.28**	**$32,901.63**	**$1,408.09**	**6,951,696**	**20,936**
% Change	**-7.80%**	**-12.20%**	**5.30%**	**20.00%**	**16.30%**	**6.80%**	**-9.50%**
Change	**-10**	**-125**	**$1,477,641.14**	**$5,475.37**	**$197.76**	**443,272**	**-2,200**

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

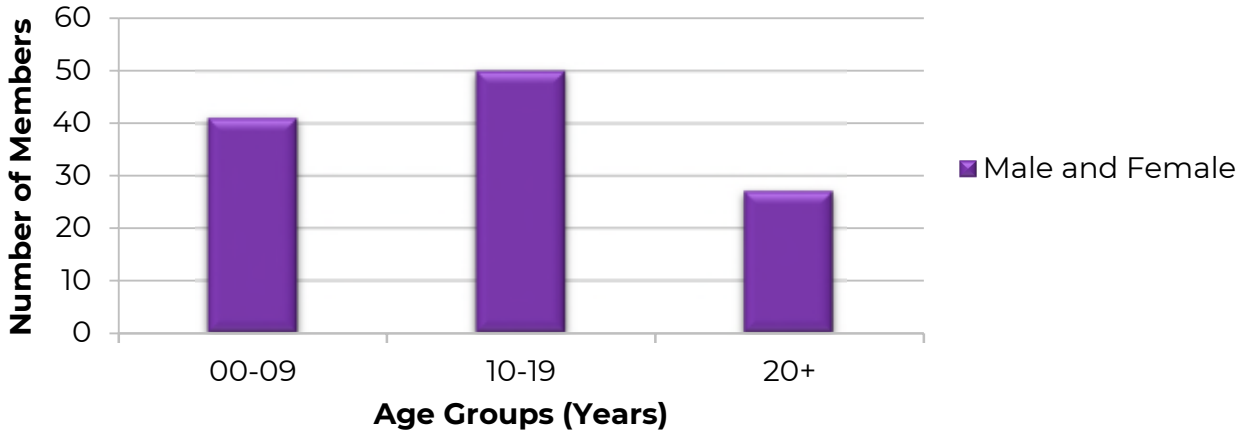
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	+Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	11	22	$50,700.01	$2,304.55	2
Aetna	0	0	$0.00	$0.00	0
Humana	1	2	$9,720.00	$4,860.00	2
OCH	0	0	$0.00	$0.00	0
2024 Total	**12**	**24**	**$60,420.01**	**$2,517.50**	**2**
Fiscal Year 2025					
FFS	10	33	$329,837.75	$9,995.08	3.3
Aetna	2	2	$5,738.41	$2,869.21	1
Humana	6	24	$120,903.69	$5,037.65	4
OCH	2	2	$5,100.55	$2,550.28	1
2025 Total	**20**	**61**	**$461,580.40**	**$7,566.89**	**3.05**
% Change	**66.67%**	**154.17%**	**663.95%**	**200.57%**	**52.50%**
Change	**8**	**37**	**$401,160.39**	**$5,049.39**	**1.05**

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

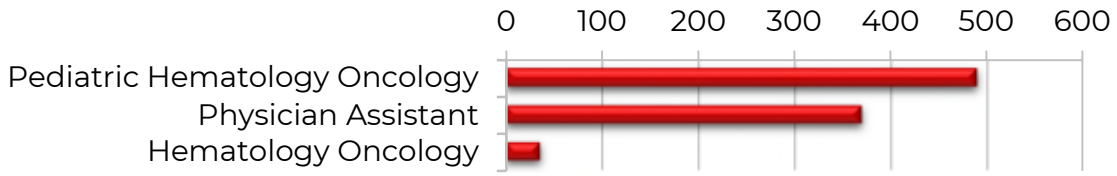
- Aggregate drug rebates collected during fiscal year 2025 for the hemophilia medications totaled $5,569,328.38.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Hemophilia 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.

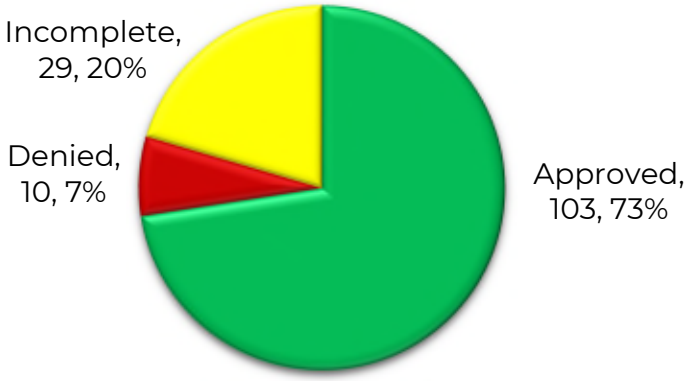
Top Prescriber Specialties of Hemophilia Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Hemophilia Medications

There were 142 prior authorization requests submitted for hemophilia medications during fiscal year 2025. The following chart shows the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	70	76%	21	23%	1	1%	**92**
Aetna	17	77%	2	9%	3	14%	**22**
Humana	6	60%	0	0%	4	40%	**10**
OCH	10	56%	6	33%	2	11%	**18**
Total	**103**	**73%**	**29**	**20%**	**10**	**7%**	**142**

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

Market News and Updates[1,2,3,4,5,6,7]

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

- **July 2025:** The FDA approved Alhemo® (concizumab-mtci) for an expanded indication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A or B without inhibitors. Previously, Alhemo® was only approved for hemophilia A or B with inhibitors.

The label expansion was based on the Phase 3a explorer8 clinical trial. Patients were randomized in a 1:2 ratio where group 1 included patients receiving no prophylaxis and continued on-demand treatment and group 2 received Alhemo® prophylaxis. The primary outcome was the number of treated bleeding episodes, measured by annualized bleeding rate (ABR). For patients with hemophilia A without inhibitors, the mean ABR was 19.3 vs. 2.7 for group 1 and group 2, respectively ($P<0.0001$). For patients with hemophilia B without inhibitors, the mean ABR was 14.8 vs. 3.1 for group 1 and group 2, respectively ($P<0.0001$).

News:

- **December 2025:** An analysis of Hemgenix® (etranacogene dezaparvovec-drlb) was published for the 5-year follow-up of the open-label Phase 3 trial. The ABR for the 6-month lead in period prior to patients receiving the gene therapy was 4.16. The ABR for months 7 through 60 after receiving gene therapy was 1.52. The factor IX (FIX) level remained stable at 5 years with the mean of 36.1 international units per deciliter (IU/dL). This factor IX level is considered mild hemophilia B (5%-49%).

Pipeline:

- **Denecimig (Mim8):** Denecimig is a fully human bispecific immunoglobulin G4 (IgG4) antibody which mimics the function of activated factor VIII (FVIIIa) by bringing together activated factor IX (FIXa) and factor X (FX). It has been studied in the FRONTIER clinical program. FRONTIER2 was a Phase 3 clinical trial for adults and adolescents 12 years of age and older with hemophilia A with or without inhibitors. Patients were randomized to receive denecimig prophylactically weekly or monthly or to continue on-demand standard-of-care treatments. Patients were also grouped by their prior treatment regimen of on-demand treatment or clotting factor concentrate prophylaxis. The primary endpoint was the number of treated bleeding episodes. In the weekly denecimig group, 86% of patients had 0 treated bleeds over 26 weeks for those using on-demand treatment prior to the beginning of the trial and 67% had 0 treated bleeds for those using factor concentrate prophylactically prior to the beginning of the trial. In the monthly denecimig group, 91% of patients previously using on-demand treatment and 63% of patients previously using factor concentrate prophylaxis had 0 treated bleeds over 26 weeks. No thromboembolic events were reported, and most adverse events were mild. In September 2025, Novo Nordisk announced a Biologics License Application (BLA) had been submitted to the FDA, with a decision expected in the second half of 2026.

- **Marstacimab-hncq (Hympavzi™):** Marstacimab, an anti-tissue factor pathway inhibitor (TFPI) monoclonal antibody, is FDA approved in adults and adolescents with hemophilia A or B without inhibitors. Pfizer has conducted several clinical trials, 1 of which was a Phase 3 trial, BASIS. This clinical trial was in patients with hemophilia A or B with or without inhibitors and had 2 cohorts. Cohort 1 included patients without inhibitors, and Cohort 2 included patients with inhibitors. In Cohort 2, patients had a 6-month observation period where they received either on-demand treatments or routine prophylaxis followed by a 12-month treatment phase where patients received a loading dose of 300mg then once weekly doses of 150mg of marstacimab. Dose escalation was allowed at the investigator's discretion. The primary endpoint was ABR. Of the 60 study participants, 57 received on-demand treatments prior to the study. The ABR during the observation period was 19.8 and decreased to 1.4 (P<0.0001) during the treatment period. For the 3 participants on prophylactic therapy during the observational period, there was a numerical decrease in the ABR for treated bleeding episodes from 7.61 during the observational period to 1.03 during the treatment period. On February 6, 2026, Pfizer announced the FDA has accepted and granted Priority Review for a supplemental BLA (sBLA) to expand the approved indication to include patients 6 years of age and older with hemophilia A or B with inhibitors and patients 6 to 11 years of age without inhibitors. The FDA has set a Prescription Drug User Fee Act (PDUFA) date in the second quarter of 2026.

Recommendations

The Oklahoma Health Care Authority recommends updating the approval criteria for Alhemo® (concizumab-mtci) based on the new FDA approved label expansion (changes shown in red):

Alhemo® (Concizumab-mtci) Approval Criteria:

1. ~~An FDA approved~~ A diagnosis of 1 of the following:
   a. Hemophilia A or B with inhibitors; ~~and~~ or
   b. Severe hemophilia A (factor VIII ≤1%) without inhibitors; or
   c. Moderately severe or severe hemophilia B (factor XI ≤2%); and
2. Member must be 12 years of age or older; and
3. Member's recent weight (taken within the past 3 months) must be provided and must be ≥25kg; and
4. Member must not be undergoing immune tolerance induction (ITI); and
5. For members without an inhibitor, a patient-specific, clinically significant reason why continuing the member's current prophylaxis therapy is not appropriate must be provided; and

6. Member must not have a history of or be at high risk for thromboembolic events; and
7. Female members of reproductive potential must meet the following:
    a. Must not be pregnant; or
        i. If member is pregnant or becomes pregnant during treatment, the risk to the fetus must be weighed against the benefit to the mother; and
    b. Must agree to use effective birth control during treatment and for at least 7 weeks after the last dose; and
8. Prescriber must agree the member will not be continuing on other prophylactic therapies; and
9. Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
10. Prescriber must verify that the member or caregiver has been trained on the subcutaneous administration and counseled on the storage of Alhemo®; and
11. Prescriber must verify that the member has been counseled on the potential risk of thrombosis; and
12. Prescriber must verify the member has been counseled on the use of bypassing agents or factor concentrate at the lowest possible dose for breakthrough bleeding episodes based on severity and location of bleed; and
13. Requests must be for an FDA approved dosing regimen as outlined in the package labeling; and
14. Initial approvals will be for 3 months for the loading dose of 1mg/kg on day 1 and 0.2mg/kg daily until individualization of the maintenance dose has been achieved. Subsequent approvals will be the duration of 1 year if there is documentation of clinical effectiveness.

Utilization Details of Hemophilia Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HEMLIBRA PRODUCTS						
HEMLIBRA INJ 60MG/0.4ML	174	27	$3,580,023.00	$20,574.84	6.44	12.14%
HEMLIBRA INJ 105MG/0.7ML	107	19	$4,201,835.83	$39,269.49	5.63	14.25%
HEMLIBRA INJ 150MG/ML	86	12	$4,211,050.86	$48,965.71	7.17	14.28%
HEMLIBRA INJ 30MG/ML	79	15	$733,365.55	$9,283.11	5.27	2.49%
HEMLIBRA SOL 12MG/0.4ML	25	7	$93,462.07	$3,738.48	3.57	0.32%
HEMLIBRA INJ 300MG/2ML	18	4	$1,756,675.38	$97,593.08	4.5	5.96%
SUBTOTAL	**489**	**84**	**$14,576,412.69**	**$29,808.61**	**5.82**	**49.45%**
ADVATE PRODUCTS						
ADVATE INJ 2,000U	19	7	$543,473.99	$28,603.89	2.71	1.84%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ADVATE INJ 4,000U	19	3	$989,103.30	$52,058.07	6.33	3.36%
ADVATE INJ 3,000U	13	6	$435,324.84	$33,486.53	2.17	1.48%
ADVATE INJ 1,500U	13	6	$350,077.52	$26,929.04	2.17	1.19%
ADVATE INJ 1,000U	6	4	$89,966.03	$14,994.34	1.5	0.31%
ADVATE INJ 500U	5	1	$38,491.76	$7,698.35	5	0.13%
ADVATE INJ 250U	3	1	$11,074.58	$3,691.53	3	0.04%
SUBTOTAL	**78**	**28**	**$2,457,512.02**	**$31,506.56**	**2.79**	**8.34%**
ALPROLIX PRODUCTS						
ALPROLIX INJ 2,000U	26	4	$594,166.09	$22,852.54	6.5	2.02%
ALPROLIX INJ 3,000U	20	3	$581,924.40	$29,096.22	6.67	1.97%
ALPROLIX INJ 1,000U	10	2	$177,433.27	$17,743.33	5	0.60%
ALPROLIX INJ 500U	7	4	$48,482.44	$6,926.06	1.75	0.16%
ALPROLIX INJ 4,000U	6	3	$251,665.05	$41,944.18	2	0.85%
ALPROLIX INJ 250U	6	2	$13,401.55	$2,233.59	3	0.05%
SUBTOTAL	**75**	**18**	**$1,667,072.80**	**$22,227.64**	**4.17**	**5.65%**
ALTUVIIIO PRODUCTS						
ALTUVIIIO INJ 3,000U	29	5	$1,570,325.81	$54,149.17	5.8	5.33%
ALTUVIIIO INJ 2,000U	10	2	$317,903.50	$31,790.35	5	1.08%
ALTUVIIIO INJ 4,000U	5	3	$159,254.44	$31,850.89	1.67	0.54%
ALTUVIIIO INJ 1,000U	3	2	$91,573.29	$30,524.43	1.5	0.31%
ALTUVIIIO INJ 500U	1	1	$6,315.81	$6,315.81	1	0.02%
ALTUVIIIO INJ 250U	1	1	$12.00	$12.00	1	0.00%
SUBTOTAL	**49**	**14**	**$2,145,384.85**	**$43,783.36**	**3.5**	**7.28%**
WILATE PRODUCTS						
WILATE INJ 1,000-1,000U	21	6	$538,614.60	$25,648.31	3.5	1.83%
WILATE INJ 500-500U	14	1	$126,321.14	$9,022.94	14	0.43%
SUBTOTAL	**35**	**7**	**$664,935.74**	**$18,998.16**	**5**	**2.26%**
HUMATE-P PRODUCTS						
HUMATE-P SOL 1,000-2,400U	13	8	$79,745.03	$6,134.23	1.63	0.27%
HUMATE-P SOL 500-1,200U	10	8	$32,453.06	$3,245.31	1.25	0.11%
HUMATE-P SOL 250-600U	2	2	$3,840.88	$1,920.44	1	0.01%
SUBTOTAL	**25**	**18**	**$116,038.97**	**$4,641.56**	**1.39**	**0.39%**
NUWIQ PRODUCTS						
NUWIQ KIT 1,000U	10	9	$33,946.87	$3,394.69	1.11	0.12%
NUWIQ KIT 500U	9	8	$14,722.40	$1,635.82	1.13	0.05%
NUWIQ KIT 250U	2	2	$1,341.12	$670.56	1	0.00%
NUWIQ KIT 2,000U	1	1	$5,167.56	$5,167.56	1	0.02%
SUBTOTAL	**22**	**20**	**$55,177.95**	**$2,508.09**	**1.1**	**0.19%**
NOVOSEVEN PRODUCTS						
NOVOSEVEN RT INJ 1MG	10	2	$217,636.10	$21,763.61	5	0.74%
NOVOSEVEN RT INJ 5MG	4	3	$189,717.64	$47,429.41	1.33	0.64%
NOVOSEVEN RT INJ 8MG	4	2	$182,517.64	$45,629.41	2	0.62%
NOVOSEVEN RT INJ 2MG	2	2	$35,186.41	$17,593.21	1	0.12%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**20**	**9**	**$625,057.79**	**$31,252.89**	**2.22**	**2.12%**
KOVALTRY PRODUCTS						
KOVALTRY INJ 2,000U	11	6	$69,861.43	$6,351.04	1.83	0.24%
KOVALTRY INJ 3,000U	6	3	$22,510.61	$3,751.77	2	0.08%
KOVALTRY INJ 1,000U	2	1	$5,175.79	$2,587.90	2	0.02%
KOVALTRY INJ 500U	1	1	$2,308.53	$2,308.53	1	0.01%
SUBTOTAL	**20**	**11**	**$99,856.36**	**$4,992.82**	**1.82**	**0.34%**
SEVENFACT PRODUCTS						
SEVENFACT INJ 5MG	13	2	$4,265,083.33	$328,083.33	6.5	14.47%
SUBTOTAL	**13**	**2**	**$4,265,083.33**	**$328,083.33**	**6.5**	**14.47%**
ESPEROCT PRODUCTS						
ESPEROCT INJ 3,000U	9	1	$782,684.99	$86,965.00	9	2.65%
ESPEROCT INJ 4,000U	3	1	$224,581.23	$74,860.41	3	0.76%
ESPEROCT INJ 2,000U	1	1	$45,978.13	$45,978.13	1	0.16%
SUBTOTAL	**13**	**3**	**$1,053,244.35**	**$81,018.80**	**4.33**	**3.57%**
JIVI PRODUCTS						
JIVI INJ 3,000U	7	2	$472,228.48	$67,461.21	3.5	1.60%
JIVI INJ 2,000U	3	2	$177,006.23	$59,002.08	1.5	0.60%
JIVI INJ 1,000U	1	1	$21,183.99	$21,183.99	1	0.07%
SUBTOTAL	**11**	**5**	**$670,418.70**	**$60,947.15**	**2.2**	**2.27%**
VONVENDI PRODUCTS						
VONVENDI INJ 1,300U	7	1	$211,655.02	$30,236.43	7	0.72%
VONVENDI INJ 650U	2	1	$37,742.42	$18,871.21	2	0.13%
SUBTOTAL	**9**	**2**	**$249,397.44**	**$27,710.83**	**4.5**	**0.85%**
ALPHANATE PRODUCTS						
ALPHANATE INJ 2,000U	4	2	$113,807.72	$28,451.93	2	0.39%
ALPHANATE INJ 1,500U	2	1	$16,584.82	$8,292.41	2	0.06%
ALPHANATE INJ 500U	1	1	$1,260.91	$1,260.91	1	0.00%
ALPHANATE INJ 250U	1	1	$599.41	$599.41	1	0.00%
SUBTOTAL	**8**	**5**	**$132,252.86**	**$16,531.61**	**1.6**	**0.45%**
RIXUBIS PRODUCTS						
RIXUBIS INJ 1,000U	4	2	$7,371.30	$1,842.83	2	0.03%
RIXUBIS INJ 3,000U	3	2	$30,943.84	$10,314.61	1.5	0.10%
RIXUBIS INJ 2,000U	1	1	$6,991.84	$6,991.84	1	0.02%
SUBTOTAL	**8**	**5**	**$45,306.98**	**$5,663.37**	**1.6**	**0.15%**
FEIBA PRODUCTS						
FEIBA INJ 2,500U	5	1	$417,464.47	$83,492.89	5	1.42%
SUBTOTAL	**5**	**1**	**$417,464.47**	**$83,492.89**	**5**	**1.42%**
KOATE PRODUCTS						
KOATE INJ 1,000U	5	1	$103,093.67	$20,618.73	5	0.35%
SUBTOTAL	**5**	**1**	**$103,093.67**	**$20,618.73**	**5**	**0.35%**
ADYNOVATE PRODUCTS						
ADYNOVATE INJ 2,000U	2	1	$33,298.04	$16,649.02	2	0.11%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ADYNOVATE INJ 1,000U	1	1	$2,190.17	$2,190.17	1	0.01%
ADYNOVATE INJ 3,000U	1	1	$37,557.33	$37,557.33	1	0.13%
SUBTOTAL	**4**	**3**	**$73,045.54**	**$18,261.39**	**1.33**	**0.25%**
REBINYN PRODUCTS						
REBINYN SOL 500U	3	1	$22,845.59	$7,615.20	3	0.08%
REBINYN SOL 1,000U	1	1	$9,428.95	$9,428.95	1	0.03%
SUBTOTAL	**4**	**2**	**$32,274.54**	**$8,068.64**	**2**	**0.11%**
FIBRYGA PRODUCTS						
FIBRYGA INJ 1GM	2	2	$10,142.82	$5,071.41	1	0.03%
SUBTOTAL	**2**	**2**	**$10,142.82**	**$5,071.41**	**1**	**0.03%**
BENEFIX PRODUCTS						
BENEFIX INJ 3,000U	1	1	$20,683.41	$20,683.41	1	0.07%
SUBTOTAL	**1**	**1**	**$20,683.41**	**$20,683.41**	**1**	**0.07%**
TOTAL	**896**	**118***	**$29,479,857.28**	**$32,901.63**	**7.59**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; RT = recombinant; SOL = solution; U = units
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J7189 FACTOR VIIA RT	21	3	$312,171.47	$14,865.31	7
J7170 EMICIZUMAB-KXWH	20	3	$98,277.49	$4,913.87	6.67
J7187 VWF COMPLEX	9	5	$13,403.20	$1,489.24	1.8
J7192 FACTOR VIII RT	6	5	$21,687.05	$3,614.51	1.2
J7186 FACTOR VIII VWF COMPLEX	4	3	$4,241.19	$1,060.30	1.33
J7198 ANTI-INHIBITOR	1	1	$11,800.00	$11,800.00	1
TOTAL	**61**	**20**	**$461,580.40**	**$7,566.89**	**3.05**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
RT = recombinant; VWF = von Willebrand factor
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[1] Novo Nordisk. FDA approves Alhemo® as Once-Daily Prophylactic Treatment to Prevent or Reduce the Frequency of Bleeding Episodes for Adults and Children 12 Years of Age and Older with Hemophilia A or B (HA/HB) Without Inhibitors. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/fda-approves-alhemo-as-once-daily-prophylactic-treatment-to-prevent-or-reduce-the-frequency-of-bleeding-episodes-for-adults-and-children-12-years-of-age-and-older-with-hemophilia-a-or-b-hahb-without-inhibitors-302519177.html. Issued 07/31/2025. Last accessed 02/02/2026.

[2] Chowdary P, Angchaisuksiri P, Apte S, et al. Concizumab Prophylaxis in People with Haemophilia A or Haemophilia B Without Inhibitors (explorer8): A Prospective, Multicentre, Open-Label, Randomised, Phase 3a Trial. *Lancet Haematol* 2024; 11:E891-E904. doi: 10.1016/S2352-3026(24)00307-7.

[3] Pipe S, Miesbach W, Recht M, et al. Final Analysis of a Study of Etranacogene Dezaparvovec for Hemophilia B. *N Engl J Med* 2025; 394:463-474. doi: 10.1056/NEJMoa2514332.

[4] Lentz S, Abraham A, Ay C, et al. Mim8 Prophylaxis in Adults and Adolescents with Hemophilia A: 52-Week Efficacy and Safety Outcomes from the Phase 3 FRONTIER2 Study. *Blood* 2025; 146 (Supplement 1):537. doi: 10.1182/blood-2025-537.

[5] Novo Nordisk. Novo Nordisk Submits Biologics License Application (BLA) to FDA for Mim8; An Investigational, Prophylaxis Treatment for People Living with Hemophilia A with or without Inhibitors. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/novo-nordisk-submits-biologics-license-application-bla-to-fda-for-mim8-an-investigational-prophylaxis-treatment-for-people-living-with-hemophilia-a-with-or-without-inhibitors-302568838.html. Issued 09/29/2025. Last accessed 02/10/2026.

[6] Matino D, Acharya S, Taylor C, et al. Efficacy and Safety of Marstacimab Prophylaxis in Hemophilia A/B With Inhibitors: Results from the Phase 3 BASIS Trial. *Blood* 2025; 146(14):1654-1663. doi: 10.1182/blood.2025031065.

[7] Pfizer. FDA Grants Priority Review for Hympavzi® (Marstacimab) sBLA for the Treatment of Two Hemophilia A or B Patient Populations with Significant Medical Need. *Morningstar*. Available online at: https://www.morningstar.com/news/business-wire/20260205107500/fda-grants-priority-review-for-hympavzi-marstacimab-sbla-for-the-treatment-of-two-hemophilia-a-or-b-patient-populations-with-significant-medical-need. Issued 02/06/2026. Last accessed 02/10/2026.

Appendix H

Fiscal Year 2025 Annual Review of Muscular Dystrophy Medications

Oklahoma Health Care Authority
March 2026

Current Prior Authorization Criteria

Agamree® (Vamorolone Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be 2 years of age or older; and
3. Agamree® must be prescribed by, or in consultation with, a prescriber who specializes in the treatment of DMD; and
4. Member must have a minimum 6-month trial of prednisone that resulted in inadequate effects or intolerable adverse effects that are not expected to occur with Agamree® or a patient specific, clinically significant reason why the member cannot use prednisone must be provided; and
5. A patient specific, clinically significant reason why the member cannot use brand name Emflaza® (deflazacort) must be provided; and
6. Prescriber must verify the member has a baseline eye examination; and
7. The member's recent weight must be provided in order to authorize the appropriate amount of drug required according to the package labeling; and
8. For continued authorization, an updated weight must be provided, and the member must have had a repeat eye exam with results that are acceptable to the prescriber; and
9. A quantity limit of 300mL per 40 days will apply.

Amondys 45 (Casimersen), Exondys 51 (Eteplirsen), Viltepso® (Viltolarsen), and Vyondys 53 (Golodirsen) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD); and
2. Member must have a confirmed mutation of the *DMD* gene that is amenable to exon skipping for the requested medication (results of genetic testing must be submitted); and
3. Member must not have previously received Elevidys (delandistrogene moxeparvovec-rokl); and
4. Must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising

physician who is a neurologist or specialist with expertise in the treatment of DMD); and
5. Prescriber must verify the member's renal function will be appropriately assessed prior to initiation of therapy and monitored during treatment; and
6. Member must be on a stable dose of a corticosteroid (at least 3 months in duration) or a patient-specific, clinically significant reason why corticosteroids are not appropriate for the member must be provided; and
7. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
    a. 6-minute walk test (6MWT); or
    b. Forced vital capacity percent predicted (FVCpp); and
8. The requested exon-skipping therapy will not be approved for concurrent use with any other exon-skipping therapies for DMD; and
9. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and
10. Subsequent approvals will be for the duration of 1 year. For yearly approvals, the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; 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.

Duvyzat™ (Givinostat Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be 6 years of age or older; and
3. Must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and
4. Member must be on a stable dose of a corticosteroid (at least 3 months in duration) or a patient-specific, clinically significant reason why corticosteroids are not appropriate for the member must be provided; and
5. Prescriber must verify platelet counts and triglycerides have been evaluated at baseline, and levels are acceptable to the prescriber; and

6. Prescriber must agree to monitor member for adverse reactions such as a decrease in platelet counts, increase in triglycerides, or moderate to severe diarrhea and agree to modify the dose based on the package labeling recommendations, if needed; and
7. If member has underlying cardiac disease or is taking concomitant medications that cause QT prolongation, prescriber must agree to obtain an electrocardiogram (ECG) before initiating treatment with Duvyzat™, during concomitant use, and as clinically indicated; and
8. Approvals will be for the duration of 1 year. For each subsequent approval, the prescriber must document the member is tolerating and benefiting from treatment, as indicated by improvement, stabilization, or a slower progression of disease compared to the typical DMD progression (i.e., improved functional tests, strength, or pulmonary function test); and
9. The member's recent weight must be provided in order to authorize the appropriate amount of drug required according to the package labeling; and
10. A quantity limit of 420mL per 35 days will apply.

Elevidys (Delandistrogene Moxeparvovec-rokl) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be at least 4 years of age; and
3. Elevidys must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and
4. Member's baseline anti-AAVrh74 total binding antibody titers must be <1:400; and
5. Member must not have any deletion in exon 8 and/or exon 9 in the *DMD* gene; and
6. If the member has a deletion in the *DMD* gene in exon 1 to 17 and/or exons 59 to 71, the prescriber must verify the member will be monitored for a severe immune-mediated myositis reaction; and
7. Member must not have any active infections and if the member does have an active infection, the prescriber must verify Elevidys infusion will be postponed until infection has resolved; and
8. Prescriber must verify the member will initiate a corticosteroid regimen 1 day prior to the infusion of Elevidys and continue for a minimum of 60 days to reduce the risk of an immune response as specified in the package labeling; and
9. Prescriber must verify liver function tests (LFTs) (e.g., GGT, total bilirubin) will be performed prior to Elevidys administration and will be

monitored weekly for the first 3 months following Elevidys infusion then as clinically indicated; and
10. Prescriber must verify troponin-I will be monitored before the Elevidys infusion and weekly for the first month following infusion then as clinically indicated; and
11. Prescriber must verify that platelet counts will be monitored before the Elevidys infusion and weekly for the first 2 weeks following infusion then as clinically indicated; and
12. Member will not be approved for concomitant treatment with exon skipping therapy (e.g., Amondys 45, Exondys 51, Viltepso®, Vyondys 53) following Elevidys infusion (current authorizations for exon skipping therapy will be discontinued upon Elevidys approval); and
13. Member's current weight (kg) taken within the past 6 months must be provided on the request to ensure accurate weight-based dosing according to package labeling; and
14. Approvals will be for 1 dose per member per lifetime.

Emflaza® (Deflazacort) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be 2 years of age or older; and
3. Emflaza® must be prescribed by, or in consultation with, a prescriber who specializes in the treatment of DMD; and
4. Member must have a minimum 6-month trial of prednisone that resulted in inadequate effects or intolerable adverse effects that are not expected to occur with Emflaza® or a patient specific, clinically significant reason why the member cannot use prednisone must be provided; and
5. For Emflaza® suspension, a patient-specific, clinically significant reason why the member cannot use the tablet formulation in the place of oral suspension even when the tablets are crushed must be provided; and
6. Emflaza® is brand preferred. Requests for generic deflazacort will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
7. Prescriber must verify the member has had a baseline eye examination; and
8. The member's recent weight must be provided in order to authorize the appropriate amount of drug required according to package labeling; and
9. For continued authorization, an updated weight must be provided, and the member must have had a repeat eye exam with results that are acceptable to the prescriber; and

10. For the tablets, a quantity limit of 30 tablets per 30 days will apply, and for the suspension, a quantity limit of 39mL (3 bottles) per 30 days will apply. Quantity limit override requests will be approved as appropriate based on the member's recent weight taken within the last 30 days.

Utilization of Muscular Dystrophy Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

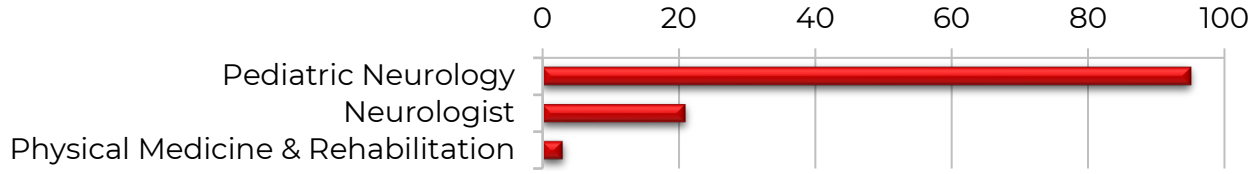
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	11	105	$11,640,891.00	$110,865.63	$3,908.96	13,585	2,978
Aetna	1	3	$46,081.65	$15,360.55	$512.02	90	90
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	1	2	$51,222.82	$25,611.41	$914.69	64	56
2024 Total	**11**	**110**	**$11,738,195.47**	**$106,710.87**	**$3,757.42**	**13,739**	**3,124**
Fiscal Year 2025							
FFS	9	100	$10,847,386.22	$108,473.86	$3,903.34	15,887	2,779
Aetna	3	19	$3,562,270.55	$187,487.92	$7,881.13	605	452
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	0	0	$0.00	$0.00	$0.00	0	0
2025 Total	**12**	**119**	**$14,409,656.77**	**$121,089.55**	**$4,459.81**	**16,492**	**3,231**
% Change	**9.09%**	**8.18%**	**22.76%**	**13.47%**	**18.69%**	**20.04%**	**3.43%**
Change	**1**	**9**	**$2,671,461.30**	**$14,378.68**	**$702.39**	**2,753**	**107**

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

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

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

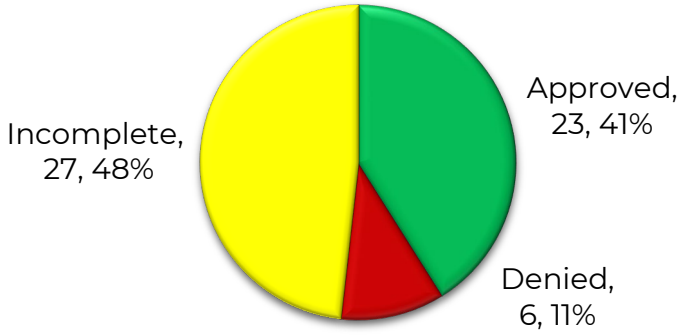
Top Prescriber Specialties of Muscular Dystrophy Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Muscular Dystrophy Medications

There were 56 prior authorization requests submitted for muscular dystrophy medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	21	42%	25	50%	4	8%	**50**
Aetna	2	33%	2	33%	2	33%	**6**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	0	N/A	0	N/A	0	N/A	**0**
Total	**23**	**41%**	**27**	**48%**	**6**	**11%**	**56**

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

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

Anticipated Patent Expiration(s):

- Vyondys 53 (golodirsen injection): June 2028
- Amondys 45 (casimersen injection): November 2030
- Viltepso® (viltolarsen injection): April 2034
- Exondys 51 (eteplirsen injection): March 2034
- Duvyzat™ (givinostat suspension): October 2036
- Agamree® (vamorolone suspension): July 2040

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

- **November 2025:** The FDA approved labeling updates for Elevidys (delandistrogene moxeparvovec-rokl) following reports of fatal acute liver failure in 2 non-ambulatory patients treated with Elevidys. The labeling updates included:
  - The addition of a *Boxed Warning* describing the risk of serious liver injury and acute liver failure, including fatal outcomes

- Limiting the indication to ambulatory patients with Duchenne muscular dystrophy (DMD) who are 4 years of age and older with a confirmed mutation in the *DMD* gene
- Removal of the indication for non-ambulatory patients with DMD
- Addition of a *Limitations of Use* statement to guide clinical decision-making, which included recommendations that Elevidys should not be used in patients with preexisting liver impairment, recent vaccinations, or recent/active infections
- Updates to the *Dosage and Administration* section including recommendations that patients maintain proximity to an appropriate health care facility for at least 2 months following the Elevidys infusion, information on how to modify the corticosteroid regimen based on liver function abnormalities following Elevidys infusion, and when to obtain consultation with a specialist (e.g., gastroenterologist or hepatologist)
- Updates to the *Warnings and Precautions*, *Adverse Reactions*, *Use in Specific Populations*, *Clinical Studies*, and *Patient Counseling Information* sections and a new *Medication Guide* for patients and caregivers

- **April 2025:** The FDA approved Jaythari® (deflazacort), which is a branded generic of Emflaza® (deflazacort). It is available in 6mg, 18mg, 30mg, and 36mg tablets.
- **November 2025:** The FDA approved Jaythari® (deflazacort) in a 22.75mg/mL oral suspension according to the FDA's National Drug Code Directory.

News:

- **December 2025:** Upsher-Smith announced the launch of Kymbee™ (deflazacort) tablets, which is another branded generic of Emflaza® (deflazacort). It is available in 6mg, 18mg, 30mg, and 36mg tablets.
- **December 2025:** The U.S. Department of Health and Human Services (HHS) added DMD and metachromatic leukodystrophy (MLD) to the Recommended Uniform Screening Panel (RUSP), which is a list of conditions the HHS recommends for universal newborn screening. Each state chooses whether to adopt each screening. Currently, DMD and MLD are not on the Oklahoma Newborn Screening Panel.
- **February 2026:** Aucta Pharmaceuticals announced the launch of Pyquvi™ (deflazacort) 22.75mg/mL oral suspension, another branded generic of Emflaza®.

Pipeline:

- **Ataluren:** Ataluren is an investigational protein restoration therapy designed to enable the formation of a functioning protein in patients with genetic disorders caused by a nonsense mutation. In February

2026, PTC Therapeutics announced they withdrew the New Drug Application (NDA) for ataluren following the FDA's feedback. According to the company, the FDA indicated the data submitted was unlikely to meet the FDA's threshold on evidence of effectiveness to support the approval of ataluren.

- **Delpacibart Zotadirsen (Del-zota):** Del-zota is designed to deliver phosphorodiamidate morpholino oligomers (PMO) to skeletal muscle and heart tissue to specifically skip exon 44 of the dystrophin gene to enable dystrophin production in patients with DMD. The results of the EXPLORE44 and EXPLORE44-open label extension trials showed significant functional improvements compared to the natural history cohorts. Additionally, del-zota showed increased dystrophin production by 25% and reduced creatine kinase levels by over 80%. In October 2025, Avidity Biosciences announced a biologics license application (BLA) submission will likely occur in the first quarter of 2026 for del-zota.
- **Deramiocel:** Deramiocel is an investigational biologic consisting of allogeneic cardiosphere-derived cells (CDCs) which exhibit immunomodulatory, antifibrotic, and regenerative properties. It is being studied for the treatment of the cardiomyopathy associated with DMD. In July 2025, the FDA issued a complete response letter (CRL) citing the BLA does not meet the statutory requirement for substantial evidence of effectiveness and the need for additional clinical data. In January 2026, Capricor Therapeutics, the manufacturer of deramiocel, announced that the FDA has requested the HOPE-3 clinical trial report and supporting data to address the CRL. The FDA did not request any additional clinical trials or new patient data as part of the request. Capricor Therapeutics plans to submit the updated material to the FDA in February 2026 with hopes a new Prescription Drug User Fee Act (PDUFA) target action date will be assigned.

Recommendations

The College of Pharmacy recommends updating the approval criteria for Elevidys (delandistrogene moxeparvovec-rokl) based on the FDA label updates (changes shown in red):

Elevidys (Delandistrogene Moxeparvovec-rokl) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be at least 4 years of age; and
3. Prescriber must attest the member is ambulatory and the results of 1 of the following tests must be submitted:
    a. North Star Ambulatory Assessment (NSAA); or
    b. 6-minute walk test (6MWT); or
    c. 10-meter walk test (10mWT); or
    d. Ascend 4 Steps; or
    e. Time to Rise (TTR); or
    f. 100-meter timed test; and
4. Elevidys must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and
5. Member's baseline anti-AAVrh74 total binding antibody titers must be <1:400; and
6. Member must not have any deletion in exon 8 and/or exon 9 in the *DMD* gene; and
7. If the member has a deletion in the *DMD* gene in exon 1 to 17 and/or exons 59 to 71, the prescriber must verify the member will be monitored for a severe immune-mediated myositis reaction; and
8. Member must not have preexisting liver impairment [defined as gamma-glutamyl transferase (GGT) >2x upper limit of normal (ULN) or total bilirubin >ULN not due to Gilbert's syndrome] or active hepatic viral infection due to the high risk of acute serious liver injury and acute liver failure; and
9. Member must not receive any vaccinations within 4 weeks of Elevidys infusion; and
10. Member must not have any active or recent infections (within 4 weeks of Elevidys infusion) and if the member does have an active or recent infection (within 4 weeks of Elevidys infusion), the prescriber must verify Elevidys infusion will be postponed ~~until infection has resolved~~; and
11. Prescriber must confirm the member has been instructed to maintain proximity to an appropriate health care facility, as determined by the

health care provider, for at least 2 months following the Elevidys infusion; and

12. Prescriber must verify the member will initiate a corticosteroid regimen 1 day prior to the infusion of Elevidys and continue for a minimum of 60 days to reduce the risk of an immune response as specified in the package labeling; and
13. Prescriber must verify liver function tests (LFTs) (e.g., GGT, total bilirubin) will be performed prior to Elevidys administration and will be monitored weekly for the first 3 months following Elevidys infusion then as clinically indicated; and
14. Prescriber must confirm the oral corticosteroid regimen will be modified according to the package labeling for members with liver function abnormalities following Elevidys infusion and prompt consultation with a specialist (i.e., gastroenterologist or hepatologist) will occur if acute serious liver injury or impending acute liver failure is suspected; and
15. Prescriber must verify troponin-I will be monitored before the Elevidys infusion and weekly for the first month following infusion then as clinically indicated; and
16. Prescriber must verify that platelet counts will be monitored before the Elevidys infusion and weekly for the first 2 weeks following infusion then as clinically indicated; and
17. Prescriber must verify the member and/or caregiver will be given a copy of the Elevidys medication guide and it will be reviewed with the member and/or caregiver including when to contact their health care provider; and
18. Member will not be approved for concomitant treatment with exon skipping therapy (e.g., Amondys 45, Exondys 51, Viltepso®, Vyondys 53) following Elevidys infusion (current authorizations for exon skipping therapy will be discontinued upon Elevidys approval); and
19. Member's current weight (kg) taken within the past 6 months must be provided on the request to ensure accurate weight-based dosing according to package labeling; and
20. Approvals will be for 1 dose per member per lifetime.

The College of Pharmacy also recommends updating the approval criteria for Emflaza® (deflazacort) based on the FDA approval of the branded generics Jaythari® (deflazacort), Kymbee™ (deflazacort), and Pyquvi™ (deflazacort) and net cost (changes shown in red):

Emflaza® (Deflazacort), Jaythari® (Deflazacort), Kymbee™ (Deflazacort), and Pyquvi™ (Deflazacort) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be 2 years of age or older; and
3. ~~Emflaza®~~ Deflazacort must be prescribed by, or in consultation with, a prescriber who specializes in the treatment of DMD; and
4. Member must have a minimum 6-month trial of prednisone that resulted in inadequate effects or intolerable adverse effects that are not expected to occur with ~~Emflaza®~~ deflazacort or a patient specific, clinically significant reason why the member cannot use prednisone must be provided; and
5. For ~~Emflaza®~~ deflazacort suspension, a patient-specific, clinically significant reason why the member cannot use the tablet formulation in the place of oral suspension even when the tablets are crushed must be provided; and
6. Emflaza® is brand preferred. Requests for generic deflazacort including branded generics, Jaythari®, Kymbee™, and Pyquvi™, will require a patient-specific, clinically significant reason why the member cannot use the brand Emflaza® formulation; and
7. Prescriber must verify the member has had a baseline eye examination; and
8. The member's recent weight must be provided in order to authorize the appropriate amount of drug required according to package labeling; and
9. For continued authorization, an updated weight must be provided, and the member must have had a repeat eye exam with results that are acceptable to the prescriber; and
10. For the tablets, a quantity limit of 30 tablets per 30 days will apply, and for the suspension, a quantity limit of 39mL (3 bottles) per 30 days will apply. Quantity limit override requests will be approved as appropriate based on the member's recent weight taken within the last 30 days.

Finally, the College of Pharmacy also recommends updating the exon skipping therapies approval criteria based on clinical practice (changes shown in red):

Amondys 45 (Casimersen), Exondys 51 (Eteplirsen), Viltepso® (Viltolarsen), and Vyondys 53 (Golodirsen) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD); and

2. Member must have a confirmed mutation of the *DMD* gene that is amenable to exon skipping for the requested medication (results of genetic testing must be submitted); and
3. Member must not have previously received Elevidys (delandistrogene moxeparvovec-rokl); and
4. Must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and
5. Prescriber must verify the member's renal function will be appropriately assessed prior to initiation of therapy and monitored during treatment; and
6. Member must be on a stable dose of a corticosteroid (at least 3 months in duration) or a patient-specific, clinically significant reason why corticosteroids are not appropriate for the member must be provided; and
7. ~~A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:~~
   a. ~~6-minute walk test (6MWT); or~~
   b. ~~Forced vital capacity percent predicted (FVCpp); and~~
8. The requested exon-skipping therapy will not be approved for concurrent use with any other exon-skipping therapies for DMD; and
9. ~~Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and~~
10. ~~Subsequent approvals will be for the duration of 1 year. For yearly approvals, the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and~~
11. Approvals will be for the duration of 1 year. For each subsequent approval, the prescriber must document the member is tolerating and benefiting from treatment, as indicated by improvement, stabilization, or a slower progression of disease compared to the typical DMD progression (i.e., improved functional tests, strength, or pulmonary function test); and
12. 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.

Utilization Details of Muscular Dystrophy Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
AMONDYS 45 INJ 50MG/ML	26	3	$4,048,251.16	$155,701.97	8.67
VYONDYS 53 INJ 100MG/2ML	24	3	$2,624,299.84	$109,345.83	8
EMFLAZA TAB 30MG	14	1	$215,047.70	$15,360.55	14
AGAMREE SUS 40MG/ML†	14	3	$84,143.48	$6,010.25	4.67
EXONDYS 51 SOL 500MG/10ML	13	1	$435,350.93	$33,488.53	13
EXONDYS 51 SOL 100MG/2ML	12	1	$230,536.92	$19,211.41	12
EMFLAZA TAB 36MG	8	1	$142,210.16	$17,776.27	8
DUVYZAT SUS 8.86MG	3	1	$229,793.73	$76,597.91	3
ELEVIDYS 28 x 10ML KIT	1	1	$3,200,011.44	$3,200,011.44	1
ELEVIDYS 70 X 10ML KIT	1	1	$3,200,011.41	$3,200,011.41	1
TOTAL	**119**	**12***	**$14,409,656.77**	**$121,089.55**	**9.92**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†These claims include 2 members for whom SoonerCare was not the primary payer; therefore, the reimbursed amount is not a true reflection of the cost of the medication for SoonerCare.
INJ = injection; SOL = solution; SUS = suspension; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix I

Fiscal Year 2025 Annual Review of Leukemia and Lymphoma Medications and 30-Day Notice to Prior Authorize Komzifti™ (Ziftomenib), Lymphir™ (Denileukin Diftitox-cxdl), Lunsumio VELO™ (Mosunetuzumab-axgb), Nilotinib D-Tartrate, and Phyrago™ (Dasatinib)

Oklahoma Health Care Authority
March 2026

Current Prior Authorization Criteria

Utilization data for Ayvakit® (avapritinib) and approval criteria for indications other than leukemia and lymphoma can be found in the January 2026 DUR Board packet. Ayvakit® is reviewed annually with the gastrointestinal cancer medications. Utilization data for Keytruda® (pembrolizumab), Opdivo® (nivolumab), and Zelboraf® (vemurafenib) and approval criteria for indications other than leukemia and lymphoma can be found in the December 2025 DUR Board packet. These medications are reviewed annually with the skin cancer medications. Utilization data for Xalkori® (crizotinib) and approval criteria for indications other than leukemia and lymphoma can be found in the May 2025 DUR Board packet. Xalkori® (crizotinib) is reviewed annually with the lung cancer medications. Utilization data for Xpovio® (selinexor) and approval criteria for indications other than leukemia and lymphoma can be found in the November 2025 DUR Board packet. Xpovio® (selinexor) is reviewed annually with the multiple myeloma medications.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Adult T-Cell Leukemia/Lymphoma (ATLL) Diagnosis]:

1. Diagnosis of ATLL; and
2. CD30+ disease; and
3. Member meets 1 of the following:
    a. In combination with cyclophosphamide, doxorubicin, and prednisone (CHP) in nonresponders to first-line therapy for chronic/smoldering subtype; or
    b. In combination with CHP for first-line therapy for acute or lymphoma subtype; or
    c. In combination with CHP for continued treatment in responders to first-line therapy for acute or lymphoma subtype; or
    d. As a single agent in members who have received ≥1 line of therapy.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL), Primary Cutaneous Diagnosis]:

1. Diagnosis of primary cutaneous ALCL; and
2. As a single agent in members with multifocal lesions or regional nodes either as primary treatment or in relapsed/refractory disease; or
3. In combination with cyclophosphamide, doxorubicin, and prednisone (CHP) for primary treatment or relapsed/refractory disease with regional nodes.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL), Systemic Diagnosis]:

1. Diagnosis of systemic ALCL; and
2. In previously untreated disease in combination with cyclophosphamide, doxorubicin, and prednisone (CHP); or
3. In members who have received ≥1 line of therapy as a single agent.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Classical Hodgkin Lymphoma (cHL) Diagnosis]:

1. Diagnosis of cHL; and
2. For members 18 years of age or older:
    a. In previously untreated Stage III or IV disease in combination with doxorubicin, vinblastine, and dacarbazine; or
    b. In relapsed/refractory disease after failure of ≥2 multi-agent chemotherapy regimens in non-autologous stem cell transplant (SCT) candidates or after failure of autologous SCT as a single-agent; or
    c. In relapsed/refractory disease if not previously used in combination with nivolumab, bendamustine, or multi-agent chemotherapy; or
    d. Consolidation following autologous SCT in members at high risk of relapse or progression; or
3. For members 2 to 21 years of age:
    a. Diagnosis of previously untreated cHL; and
    b. Stage IIB with bulky disease, Stage IIIB, or Stage IV per Ann Arbor staging system; and
    c. Used in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide (AVE-PC); and
    d. Maximum of (5) 21-day cycles will be approved.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) or High Grade Lymphoma Diagnosis]:

1. Diagnosis of DLBCL or high grade lymphoma; and
2. As a single agent; and
    a. CD30+ disease; and

   b. For DLBCL relapsed/refractory disease in non-autologous stem cell transplant (SCT) candidates or non-candidates for chimeric antigen receptor (CAR) T-cell therapy; or
3. Used in combination with lenalidomide and a rituximab product; and
   a. CD30+ disease; and
   b. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
   c. Ineligible for autologous hematopoietic stem cell transplantation (HSCT) or CAR T-cell therapy; or
4. Used in combination with nivolumab; and
   a. CD30+ disease; and
   b. Relapsed or refractory primary mediastinal large B-cell lymphoma.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Peripheral T-Cell Lymphoma (PTCL) Diagnosis]:
1. Diagnosis of PTCL; and
2. Treatment of previously untreated CD30+ disease in combination with cyclophosphamide, doxorubicin, and prednisone (CHP); or
3. In members who have received ≥1 line of therapy as a single agent.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:
1. Diagnosis of MF/SS; and
2. As a single agent as primary treatment or in relapsed/refractory disease.

Adcetris® (Brentuximab Vedotin) Approval Criteria [T-Cell Lymphoma, Extranodal NK/T-Cell Lymphoma, Nasal Type Diagnosis]:
1. Diagnosis of T-cell lymphoma, extranodal NK/T-cell lymphoma, nasal type; and
2. CD30+ disease; and
3. As a single agent; and
4. Relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen not previously used.

Asparlas® (Calaspargase Pegol-mknl) and Oncaspar® (Pegaspargase) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:
1. Diagnosis of ALL; and
2. Used as a component of multi-agent chemotherapy; and
3. For Asparlas®, a patient-specific, clinically significant reason why the member cannot use Oncaspar® (pegaspargase) must be provided; and
4. For Asparlas®, member must be 1 month to 21 years of age.

Asparlas® (Calaspargase Pegol-mknl) and Oncaspar® (Pegaspargase) Approval Criteria [Extranodal NK/T-Cell Lymphoma Diagnosis]:
1. Diagnosis of NK/T-cell lymphoma; and

2. Member has 1 of the following:
    a. Used as induction therapy for nasal or extranasal disease; or
    b. Used as additional therapy in members with a positive biopsy following a partial or no response to induction therapy; and
3. For Asparlas®, a patient-specific, clinically significant reason why the member cannot use Oncaspar® (pegaspargase) must be provided; and
4. For Asparlas®, member must be 1 month to 21 years of age.

Aucatzyl® (Obecabtagene Autoleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of B-cell precursor ALL; and
2. Disease is relapsed or refractory; and
3. Member has not received any prior CD19-directed CART product; and
4. Approvals will be for 1 split dose infusion per member per lifetime.

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

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

Beleodaq® (Belinostat) Approval Criteria [Adult T-Cell Leukemia/ Lymphoma (ATLL) Diagnosis]:

1. Diagnosis of ATLL; and
2. As a single agent in relapsed/refractory disease.

Beleodaq® (Belinostat) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL), Primary Cutaneous Diagnosis]:

1. Diagnosis of ALCL, primary cutaneous; and
2. As a single agent for primary treatment or relapsed refractory with multifocal lesions, or cutaneous ALCL with regional nodes.

Beleodaq® (Belinostat) Approval Criteria [Peripheral T-Cell Lymphoma (PTCL) Diagnosis]:

1. Diagnosis of PTCL; and
2. As a single agent for initial palliative intent or in relapsed/refractory disease.

Beleodaq® (Belinostat) Approval Criteria [T-Cell Lymphoma, Extranodal NK/T-Cell Lymphoma, Nasal Type Diagnosis]:

1. Diagnosis of T-cell lymphoma, extranodal NK/T-cell lymphoma, nasal type; and
2. As a single agent; and

3. Relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen (asparaginase-based) not previously used.

Besponsa® (Inotuzumab Ozogamicin) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of released or refractory CD22-positive B-cell precursor ALL; and
2. Member must be 1 year of age or older.

Blincyto® (Blinatumomab) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of Philadelphia chromosome negative (Ph-) ALL; and
    a. Member must be 1 month of age or older; and
    b. Used in 1 of the following settings:
        i. As consolidation therapy as a component of multiphase chemotherapy; or
        ii. As consolidation in adolescents/young adults or adults younger than 65 years of age without substantial comorbidity with persistent or late clearance minimal residual disease positive (MRD+) following a complete response to induction; or
        iii. As maintenance therapy in combination with mercaptopurine, vincristine, methotrexate, and prednisone (POMP) as a component of maintenance; or
        iv. For management of relapsed/refractory Ph- ALL; or
2. Diagnosis of Philadelphia chromosome positive (Ph+) ALL; and
    a. Member must be 1 month of age or older; and
    b. Used in 1 of the following settings:
        i. In combination with a tyrosine kinase inhibitor (TKI) as frontline consolidation if not a candidate for multiagent chemotherapy; or
        ii. With or without a TKI as consolidation in adolescents/young adults or adults younger than 65 years of age without substantial comorbidity with persistent or late clearance MRD+ following a complete response to induction; or
        iii. As maintenance therapy in combination with POMP as a component of maintenance if refractory to TKIs; or
        iv. For management of relapsed/refractory Ph+ ALL after failure of 2 TKIs.

Bosulif® (Bosutinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of Ph+ ALL; and
2. Member must have 1 of the following:

a. Upfront therapy (including induction and consolidation) in combination with multi-agent chemotherapy or as a single agent; or
b. Maintenance therapy including:
    i. As a single agent if unfit for additional therapies; or
    ii. As a single agent if previously received blinatumomab plus a tyrosine kinase inhibitor (TKI); or
    iii. In combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
    iv. Post-hematopoietic stem cell transplant; or
c. Relapsed/refractory disease as a single agent or in combination with multi-agent chemotherapy; and

3. Member does not have any of the following mutations of BCR-ABL1: T315I, V299L, G250E, or F317L.

Bosulif® (Bosutinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Diagnosis of chronic, accelerated, or blast phase CML; and
2. Newly diagnosed or resistant/intolerant to other tyrosine kinase inhibitors (TKIs).

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy including a Burton tyrosine kinase (BTK) inhibitor and a B cell lymphoma-2 (BCL-2) inhibitor; and
3. Member does not have primary central nervous system (CNS) lymphoma; and
4. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
5. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of FL; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
3. Member does not have primary central nervous system (CNS) lymphoma; and

4. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
5. A patient-specific, clinically significant reason why Kymriah® (tisagenlecleucel) or Yescarta® (axicabtagene ciloleucel) are not appropriate for the member must be provided; and
6. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Large B-Cell Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma; and
    a. One of the following:
        i. Refractory disease to frontline chemoimmunotherapy; or
        ii. Relapse within 12 months of frontline chemoimmunotherapy; or
        iii. Relapse after frontline chemoimmunotherapy and member is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidity or age; or
        iv. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
2. Member does not have primary central nervous system (CNS) lymphoma; and
3. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
4. A patient-specific, clinically significant reason why Kymriah® (tisagenlecleucel) or Yescarta® (axicabtagene ciloleucel) are not appropriate for the member must be provided; and
5. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. Diagnosis of MCL; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy including a Bruton tyrosine kinase (BTK) inhibitor; and
3. Member does not have primary central nervous system (CNS) lymphoma; and
4. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply

with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
5. A patient-specific, clinically significant reason why Tecartus® (brexucabtagene autoleucel) is not appropriate for the member must be provided; and
6. Approvals will be for 1 dose per member per lifetime.

Brukinsa® (Zanubrutinib) Approval Criteria [Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) Diagnosis]:
1. Diagnosis of CLL/SLL.

Brukinsa® (Zanubrutinib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:
1. Diagnosis of FL; and
2. Third line or subsequent therapy for no response, relapsed, or progressive disease; and
3. Used in combination with obinutuzumab.

Brukinsa® (Zanubrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:
1. Diagnosis of MCL in adult members; and
2. Member must have received at least 1 prior therapy.

Brukinsa® (Zanubrutinib) Approval Criteria [Marginal Zone Lymphoma (MZL) Diagnosis]:
1. Diagnosis of MZL in adult members; and
2. Member must have received at least 1 prior anti-CD20 monoclonal antibody-based therapy.

Brukinsa® (Zanubrutinib) Approval Criteria [Waldenström's Macroglobulinemia (WM) Diagnosis]:
1. Diagnosis of WM in adult members; and
2. Used as primary or subsequent therapy.

Calquence® (Acalabrutinib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:
1. Diagnosis of CLL/SLL; and
2. Used as a single agent; or
3. In combination with obinutuzumab.

Calquence® (Acalabrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:
1. Diagnosis of MCL; and
    a. Used after at least 1 prior line of therapy; and
    b. As a single agent; or
2. Diagnosis of previously untreated MCL; and

a. Used in combination with bendamustine and rituximab; and
b. Member is ineligible for autologous hematopoietic stem cell transplantation (HSCT).

Columvi™ (Glofitamab-gxbm) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including large B-cell lymphoma (LBCL) arising from follicular lymphoma; and
   a. Has received ≥2 lines of systemic therapy; and
   b. Will receive a single dose of obinutuzumab for pre-treatment purposes; or
2. Diagnosis of DLBCL; and
   a. As second-line and subsequent therapy in combination with GemOx (gemcitabine and oxaliplatin; and
   b. Member is not a candidate for CAR T-cell therapy or has no intention to proceed to transplant; and
   c. Will receive a single dose of obinutuzumab for pre-treatment purposes.

Copiktra® (Duvelisib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of relapsed/refractory CLL/SLL; and
2. Progression of disease following 2 or more lines of systemic therapy; and
3. As a single agent.

Copiktra® (Duvelisib) Approval Criteria [Peripheral T-Cell Lymphomas (PTCL) Diagnosis]:

1. Diagnosis of PTCL; and
2. As a single agent or in combination with romidepsin.

Danziten® (Nilotinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Diagnosis of CML; and
2. Member must have 1 of the following:
   a. Newly diagnosed chronic, accelerated, or blast phase CML; or
   b. Philadelphia chromosome positive (Ph+) CML chronic phase (CP) resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy; or
   c. Post-hematopoietic stem cell transplant; and
3. A patient-specific, clinically significant reason the member cannot use Tasigna® (nilotinib) must be provided.

Daurismo® (Glasdegib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly-diagnosed AML; and
2. Member meets 1 of the following:
    a. Member is 75 years of age or older; or
    b. If the member is younger than 75 years of age, must be unable to tolerate intensive induction chemotherapy; and
3. In combination with low-dose cytarabine (LDAC).

Epkinly™ (Epcoritamab-bysp) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory follicular lymphoma (FL) or diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from indolent lymphomas and/or high-grade B-cell lymphomas; and
2. Has received ≥2 lines of systemic therapy.

Folotyn® (Pralatrexate) Approval Criteria [Adult T-Cell Leukemia/ Lymphoma (ATLL) Diagnosis]:

1. Diagnosis of ATLL; and
2. As a single agent in relapsed/refractory disease.

Folotyn® (Pralatrexate) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL), Primary Cutaneous Diagnosis]:

1. Diagnosis of primary cutaneous ALCL; and
2. As a single agent in members with multifocal lesions or regional nodes either as primary treatment or in relapsed/refractory disease.

Folotyn® (Pralatrexate) Approval Criteria [Peripheral T-Cell Lymphoma (PTCL) Diagnosis]:

1. Diagnosis of PTCL; and
2. As a single agent in relapsed/refractory disease.

Folotyn® (Pralatrexate) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. Diagnosis of MF/SS; and
2. As a single agent as primary treatment or in relapsed/refractory disease.

Folotyn® (Pralatrexate) Approval Criteria [T-Cell Lymphoma, Extranodal NK/T-Cell Lymphoma, Nasal Type Diagnosis]:

1. Diagnosis of T-cell lymphoma, extranodal NK/T-cell lymphoma, nasal type; and
2. As a single agent; and
3. Relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen (asparaginase-based) not previously used.

Gazyva® (Obinutuzumab) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. First-line therapy in 1 of the following settings:
    a. Without del(17p)/TP53 mutation: Used as a single agent or in combination with acalabrutinib, bendamustine, chlorambucil, ibrutinib, or venetoclax; or
    b. With del(17p)/TP53 mutation: Used as a single agent or in combination with acalabrutinib or venetoclax; or
3. Relapsed/refractory disease in 1 of the following settings:
    a. Without del(17p)/TP53 mutation: Used as a single agent or in combination with venetoclax; or
    b. With del(17p)/TP53 mutation: Used in combination with venetoclax; and
4. When obinutuzumab is used in combination with venetoclax, maximum approval duration of obinutuzumab will be 6 treatment cycles.

Gazyva® (Obinutuzumab) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. Diagnosis of relapsed or refractory DLBCL not otherwise specified, including large B-cell lymphoma (LBCL) arising from follicular lymphoma; and
2. Used as lymphoid depletion pretreatment prior to glofitamab; and
3. Member must meet criteria for glofitamab; and
4. Dosing will be 1,000mg as a single dose 7 days prior to start of glofitamab.

Gazyva® (Obinutuzumab) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of FL; and
2. Grade 1 or 2 members with Stage I (≥7cm), contiguous Stage II (≥7cm), noncontiguous Stage II, Stage III, or Stage IV members (first, second, or subsequent therapy); and
    a. In combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP), cyclophosphamide, vincristine, and prednisone (CVP), or bendamustine; and
    b. When used for maintenance therapy, a total of 12 doses will be approved; or
3. As second line as a single agent therapy; or
4. Third line or subsequent therapy for FL in members with no response, relapsed, or progressive disease; and
    a. Used in combination with zanubrutinib.

Gazyva® (Obinutuzumab) Approval Criteria [Gastric or Nongastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma, Nodal or Splenic Marginal Zone Lymphoma (MZL) Diagnosis]:

1. Diagnosis of gastric or nongastric MALT lymphoma, nodal or splenic MZL; and
2. As second-line or subsequent therapy in combination with bendamustine or lenalidomide; or
3. Maintenance therapy as second-line consolidation or extended dosing in rituximab-refractory members treated with obinutuzumab and bendamustine for a total of 12 doses.

Grafapex™ (Treosulfan) Approval Criteria [Acute Myeloid Leukemia (AML) or Myelodysplastic Syndromes (MDS) Diagnosis]:

1. Diagnosis of AML or MDS; and
2. Used in combination with fludarabine as preparative regimen prior to allogenic hematopoietic stem cell transplantation (HSCT); and
3. Member is 1 year of age or older; and
4. Member's recent body surface area (BSA) must be provided.

Iclusig® (Ponatinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of Ph+ ALL; and
2. Used in 1 of the following settings:
    a. Newly diagnosed Ph+ ALL; and
        i. Used in combination with chemotherapy; or
        ii. Used in combination with corticosteroids or as single agent in those unfit for chemotherapy; or
    b. Maintenance therapy either as a single agent or in combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
    c. Relapsed/refractory disease either as a single agent, in combination with chemotherapy not previously given, or in patients with T315I mutations.

Iclusig® (Ponatinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Diagnosis of CML; and
2. Member must have 1 of the following:
    a. T315I mutation; or
    b. Intolerant or resistant to ≥2 tyrosine kinase inhibitors (TKIs); or
    c. Post-hematopoietic stem cell transplantation in patients with prior accelerated or blast phase prior to transplant or who have relapsed.

Idhifa® (Enasidenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly diagnosed AML; and
    a. Unable to tolerate intensive induction chemotherapy; and
    b. As a single agent; and
    c. Isocitrate dehydrogenase-2 (IDH2) mutation; or
2. Relapsed/refractory AML; and
    a. IDH2 mutation; and
    b. As a single agent.

Imbruvica® (Ibrutinib) Approval Criteria [B-Cell Lymphomas Diagnosis]:

1. Diagnosis of B-cell lymphoma [including diffuse large B-cell lymphomas, human immunodeficiency virus (HIV)-related B-cell lymphomas, post-transplant lymphoproliferative disorders, and high-grade B-cell lymphoma]; and
2. As second-line or subsequent therapy.

Imbruvica® (Ibrutinib) Approval Criteria [Chronic Graft-Versus-Host Disease (cGVHD) Diagnosis]:

1. Diagnosis of cGVHD; and
2. Failure of 1 or more lines of therapy; and
3. Member must be 1 year of age or older; and
4. For members younger than 12 years of age:
    a. The member's current body surface area (BSA) must be provided; and
    b. Requests for use of the 70mg capsule formulation will require a patient-specific, clinically significant reason why the member cannot use the 70mg/mL oral suspension formulation.

Imbruvica® (Ibrutinib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. As first-line or subsequent therapy; and
3. As a single agent or in combination with rituximab, obinutuzumab, or venetoclax.

Imbruvica® (Ibrutinib) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis or Acquired Immunodeficiency Syndrome (AIDS)-Related B-Cell Lymphoma Diagnosis]:

1. Diagnosis of non-germinal center DLBCL; and
2. As second-line or subsequent therapy; and
3. Member is not a candidate for CAR T-cell therapy or has no intention to proceed to transplant.

Imbruvica® (Ibrutinib) Approval Criteria [Gastric or Nongastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma, Nodal or Splenic Marginal Zone Lymphoma (MZL) Diagnosis]:

1. Diagnosis of gastric or nongastric MALT lymphoma, nodal or splenic MZL; and
2. As second-line or subsequent therapy for refractory or progressive disease.

Imbruvica® (Ibrutinib) Approval Criteria [Hairy Cell Leukemia (HCL) Diagnosis]:

1. Diagnosis of HCL; and
2. As third-line or subsequent therapy for refractory or progressive disease.

Imbruvica® (Ibrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. Diagnosis of MCL; and
2. As second-line or subsequent therapy; or
3. Used in combination with rituximab prior to induction therapy; or
4. Used as a component of aggressive induction therapy; or
5. Used as maintenance therapy following aggressive induction therapy or hematopoietic stem cell transplant (HSCT).

Imbruvica® (Ibrutinib) Approval Criteria [Post-Transplantation Lymphoproliferative Disorders Diagnosis]:

1. Diagnosis of post-translation lymphoproliferative disorder; and
2. As second-line or subsequent therapy in members with partial response, persistent, or progressive disease; and
3. Non-germinal center B-cell type.

Imbruvica® (Ibrutinib) Approval Criteria [Primary Central Nervous System (CNS) Lymphoma Diagnosis]:

1. Diagnosis of primary CNS lymphoma; and
2. Member is not a candidate for or is intolerant to high-dose methotrexate according to the prescriber; or
3. As second-line or subsequent therapy for refractory or progressive disease.

Imbruvica® (Ibrutinib) Approval Criteria [Waldenström's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma Diagnosis]:

1. Diagnosis of WM/lymphoplasmacytic lymphoma; and
2. As first-line or subsequent therapy; and
3. As a single agent or in combination with rituximab.

Imkeldi (Imatinib Oral Solution) Approval Criteria:

1. An FDA approved diagnosis; and

2. A patient-specific, clinically significant reason why the member cannot use imatinib tablets, which are available without a prior authorization, must be provided. Imatinib tablets may be dispersed in a glass of water or apple juice to form a suspension for members who cannot swallow the film-coated tablets.

Inqovi® (Decitabine/Cedazuridine) Approval Criteria [Myelodysplastic Syndromes (MDS) Diagnosis]:

1. Diagnosis of MDS (intermediate-1, intermediate-2, or high risk) in adults including previously treated and untreated, de novo, and secondary MDS with the 1 of the following subtypes:
    a. Refractory anemia; or
    b. Refractory anemia with ring sideroblasts; or
    c. Refractory anemia with excess blasts; or
    d. Chronic myelomonocytic leukemia (CMML).

Istodax® (Romidepsin) and Romidepsin 27.5mg/5.5mL Vial Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL), Primary Cutaneous Diagnosis]:

1. Diagnosis of primary cutaneous ALCL; and
2. As a single agent in members with multifocal lesions or regional nodes either as primary treatment or in relapsed/refractory disease.

Istodax® (Romidepsin) and Romidepsin 27.5mg/5.5mL Vial Approval Criteria [Peripheral T-Cell Lymphoma (PTCL) Diagnosis]:

1. Diagnosis of PTCL; and
2. As a single agent in initial palliative intent or relapsed/refractory disease; or
3. As second-line and subsequent therapy in combination with duvelisib.

Istodax® (Romidepsin) and Romidepsin 27.5mg/5.5mL Vial Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. Diagnosis of MF/SS; and
2. As a single agent as primary treatment or in relapsed/refractory disease.

Istodax® (Romidepsin) and Romidepsin 27.5mg/5.5mL Vial Approval Criteria [T-Cell Lymphoma, Extranodal NK/T-Cell Lymphoma, Nasal Type Diagnosis]:

1. Diagnosis of T-cell lymphoma, extranodal NK/T-cell lymphoma, nasal type; and
2. As a single agent; and
3. Relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen (asparaginase-based) not previously used.

Jaypirca® (Pirtobrutinib) Approval Criteria [Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. As second-line or subsequent therapy following resistance or intolerance to prior covalent Bruton's kinase (BTK) inhibitor and a BCL-2 inhibitor; or
3. Demonstrates histologic (Richter) transformation to diffuse large B-cell lymphoma (DLBCL).

Jaypirca® (Pirtobrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. Diagnosis of MCL; and
2. Relapsed or refractory disease after ≥2 lines of systemic therapy; and
3. Previous treatment must have included a Bruton's tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, zanubrutinib).

Keytruda® (Pembrolizumab) Approval Criteria [Classical Hodgkin Lymphoma (cHL) Diagnosis]:

1. Diagnosis of cHL; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)]; and
3. For adult members:
    a. Diagnosis of relapsed or refractory cHL and member does not have lymphocyte-predominant Hodgkin lymphoma; and
        i. Used as a single agent; or
        ii. Used in second-line or subsequent systemic therapy in combination with gemcitabine, vinorelbine, and liposomal doxorubicin (GVD) or ifosfamide, carboplatin, and etoposide (ICE); or
4. For pediatric members:
    a. Used as a single agent; and
    b. Diagnosis of refractory cHL; or
    c. Relapsed disease after ≥2 therapies; or
    d. Decrease in cardiac function is observed.

Keytruda® (Pembrolizumab) Approval Criteria [Primary Mediastinal Large B-cell Lymphoma (PMBCL) Diagnosis]:

1. Diagnosis of PMBCL in adult or pediatric members; and
2. Member must have refractory disease or pembrolizumab must be used in members who have relapsed after 2 or more prior lines of therapy; and
3. Authorizations will not be granted for members who require urgent cytoreduction; and
4. Member has not previously failed other PD-1 inhibitors [e.g., Opdivo® (nivolumab)].

Kymriah® (Tisagenlecleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Members must meet all of the following:
    a. B-cell precursor ALL; and
    b. Member must be 25 years of age or younger; and
    c. Refractory or in second or later relapse:
        i. Philadelphia chromosome negative (Ph-) ALL: Must be refractory or with ≥2 relapses; or
        ii. Philadelphia chromosome positive (Ph+) ALL: Must have failed ≥2 tyrosine kinase inhibitors (TKIs); and
    d. Therapies to consider prior to tisagenlecleucel if appropriate: Clinical trial, multi-agent chemotherapy with or without hematopoietic cell transplantation (HCT), blinatumomab (category 1 recommendation), and inotuzumab (category 1 recommendation); and
2. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells, must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities, and must comply with the Kymriah® Risk Evaluation and Mitigation Strategy (REMS) requirements; and
3. Approvals will be for 1 dose per member per lifetime.

Kymriah® (Tisagenlecleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma [including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and
2. Relapsed/refractory disease; and
3. Member must be 18 years of age or older; and
4. Member must not have primary central nervous system lymphoma; and
5. Member must have had ≥2 lines of therapy; and
6. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells, must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities, and must comply with the Kymriah® Risk Evaluation and Mitigation Strategy (REMS) requirements; and
7. Approvals will be for 1 dose per member per lifetime.

Lunsumio™ (Mosunetuzumab-axgb) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of FL; and
2. Relapsed or refractory disease after ≥2 lines of systemic therapy.

Monjuvi® (Tafasitamab-cxix) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. Diagnosis of DLBCL in adult members; and
2. Relapsed or refractory disease; and
3. Used in combination with lenalidomide; and
4. Member is not eligible for autologous stem cell transplant and not a candidate for CAR T-cell therapy.

Onureg® (Azacitidine) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Diagnosis of AML; and
2. Used as maintenance therapy in members who have achieved first complete remission (CR) or complete remission with incomplete blood count recover (CRi) following intensive induction chemotherapy; and
3. Member is unable to complete intensive curative therapy.

Opdivo® (Nivolumab) Approval Criteria [Hodgkin Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory classical Hodgkin lymphoma and member does not have lymphocyte-predominant Hodgkin lymphoma; and
2. Nivolumab must be used in 1 of the following settings:
    a. As a single-agent; or
    b. In combination with doxorubicin, vinblastine, and dacarbazine (AVD) for primary systemic therapy in stage III-IV disease or together with involved-site radiation therapy (ISRT) for state I-II (unfavorable) disease; or
    c. In combination with ISRT plus brentuximab vedotin or as a single agent for primary systemic therapy in members who are not a candidate for anthracyclines; or
    d. In combination with brentuximab vedotin or ifosfamide, carboplatin, and etoposide (ICE) as second line or subsequent therapy after failure of autologous stem cell transplant (SCT), allogeneic SCT, or those who are transplant-ineligible; and
3. Member has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)].

Polivy® (Polatuzumab Vedotin-piiq) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) or High-Grade B-Cell Lymphoma Diagnosis]:

1. Previously untreated DLBCL not otherwise specified or high-grade B-cell lymphoma; and
    a. Has an International Prognostic Index score of ≥2; and
    b. Used in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP); or
2. Relapsed/refractory DLBCL not otherwise specified or high-grade B-cell lymphoma; and

a. Member is not a candidate or has no intention to proceed to hematopoietic stem cell transplant.

Poteligeo® (Mogamulizumab-kpkc) Approval Criteria [Adult T-Cell Leukemia/Lymphoma (ATLL) Diagnosis]:

1. Diagnosis of ATLL; and
2. As a single-agent in relapsed/refractory disease.

Poteligeo® (Mogamulizumab-kpkc) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. Diagnosis of MF/SS; and
2. As a single-agent as primary treatment (does not include Stage IA) or in relapsed/refractory disease.

Purixan® (Mercaptopurine Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of acute lymphoblastic leukemia (ALL); and
2. An age restriction for members older than 10 years of age applies. Purixan® does not require prior authorization for members 10 years of age and younger; and
3. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

Revuforj® (Revumenib) Approval Criteria [Acute Leukemia Diagnosis]:

1. Diagnosis of acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL); and
2. Disease is relapsed or refractory; and
3. Leukemia is positive for a lysine methyltransferase 2A gene (KMT2A) translocation; and
4. Member is 1 year of age or older; and
5. Member's recent weight (kg) must be provided; and
    a. For members weighing <40kg, the member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug.

Rezlidhia® (Olutasidenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Diagnosis of relapsed/refractory AML; and
    a. As a single agent; and
    b. Isocitrate dehydrogenase-1 (IDH1) mutation.

Rylaze® [Asparaginase *Erwinia Chrysanthemi* (Recombinant)-rywn] Approval Criteria [Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma Diagnosis]:

1. Diagnosis of ALL or lymphoblastic lymphoma; and
2. Used as a component of multi-agent chemotherapy; and

3. Member has a documented hypersensitivity to *Escherichia coli*-derived asparagine-deprivation product.

Rytelo® (Imetelstat) Approval Criteria [Myelodysplastic Syndromes (MDS) Diagnosis]:

1. Diagnosis of low- to intermediate-1 risk MDS; and
2. Experiencing transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks; and
3. Have not responded, have lost response, or are ineligible for erythropoiesis-stimulating agents (ESAs).

Scemblix® (Asciminib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Diagnosis of Philadelphia chromosome positive (Ph+) CML in chronic phase; and
    a. Used in the first line setting; or
    b. Previously treated with ≥2 or more tyrosine kinase inhibitors (TKIs); or
    c. Frontline or subsequent therapy in patients with the T315I mutation.

Sprycel® (Dasatinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of Ph+ ALL; and
2. Member must have 1 of the following:
    a. Upfront therapy (including induction and consolidation) in combination with multi-agent chemotherapy or as a single agent; or
    b. Maintenance therapy including:
        i. As a single agent if unfit for additional therapies; or
        ii. As a single agent if member previously received blinatumomab plus a tyrosine kinase inhibitor (TKI); or
        iii. In combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
        iv. Post-hematopoietic stem cell transplantation; or
    c. Relapsed/refractory disease as a single agent or in combination with multi-agent chemotherapy; and
3. Member does not have the following mutations of BCR-ABL1: T315I/A, F317L/V/I/C, or V299L.

Sprycel® (Dasatinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Diagnosis of CML; and
2. Member must have 1 of the following:
    a. Chronic, accelerated, or blast phase CML; or

b. Post-hematopoietic stem cell transplantation.

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

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

Tasigna® (Nilotinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of Ph+ ALL; and
2. Member must have 1 of the following:
    a. Upfront therapy (including induction and consolidation) in combination with multi-agent chemotherapy or as a single agent; or
    b. Maintenance therapy including:
        i. As a single agent if unfit for additional therapies; or
        ii. As a single agent if member previously received blinatumomab plus a tyrosine kinase inhibitor (TKI); or
        iii. In combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
        iv. Post-hematopoietic stem cell transplant; or
    c. Relapsed/refractory disease as a single agent or in combination with multi-agent chemotherapy; and
3. Member does not have the following mutations of BCR-ABL1: T315I, Y253H, E255K/V, F359V/C/I or G250E.

Tasigna® (Nilotinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Diagnosis of CML; and
2. Member must have 1 of the following:
    a. Newly diagnosed chronic, accelerated, or blast phase CML; or
    b. Philadelphia chromosome positive (Ph+) CML chronic phase (CP) resistant or intolerant to prior tyrosine kinase inhibitor (TKI) therapy; or
    c. Post-hematopoietic stem cell transplantation.

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

1. Diagnosis of soft tissue sarcoma – GIST; and

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

Tazverik® (Tazemetostat) Approval Criteria [Epitheloid Sarcoma Diagnosis]:

1. Diagnosis of metastatic or locally advanced epithelioid sarcoma; and
2. Member is not eligible for complete resection; and
3. Member must be 16 years of age or older.

Tazverik® (Tazemetostat) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of FL; and
2. Treatment of adult members with relapsed/refractory disease; and
3. Must meet 1 of the following:
    a. Subsequent therapy and EZH2 mutation positive after 2 or more prior systemic therapies; or
    b. Second line therapy irrespective of EZH2 mutation status for older or infirm members with indications for treatment where other options are not expected to be tolerable; or
    c. Third line and/or subsequent therapy (and not previously given) irrespective of EZH2 mutation status in members with indications for treatment.

Tecartus® (Brexucabtagene Autoleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of ALL; and
2. Relapsed or refractory disease; and
3. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
4. Approvals will be for 1 dose per member per lifetime.

Tecartus® (Brexucabtagene Autoleucel) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. Diagnosis of MCL; and
2. Relapsed or refractory disease; and
3. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply

with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
4. Approvals will be for 1 dose per member per lifetime.

Tibsovo® (Ivosidenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly diagnosed AML; and
    a. Member meets 1 of the following:
        i. Member is 75 years of age or older; or
        ii. If the member is younger than 75 years of age, must be unable to tolerate intensive induction chemotherapy; and
    b. As a single agent or in combination with azacitidine; and
    c. Isocitrate dehydrogenase-1 (IDH1) mutation; or
2. Relapsed/refractory AML; and
    a. As a single agent; and
    b. IDH1 mutation.

Tibsovo® (Ivosidenib) Approval Criteria [Cholangiocarcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic cholangiocarcinoma; and
2. An isocitrate dehydrogenase-1 (IDH1) mutation; and
3. Member has received prior treatment for this diagnosis.

Tibsovo® (Ivosidenib) Approval Criteria [Myelodysplastic Syndromes (MDS) Diagnosis]:

1. Diagnosis of relapsed or refractory MDS; and
2. Presence of isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test.

Vanflyta® (Quizartinib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly diagnosed AML; and
2. Disease is positive for FLT3 internal tandem duplication (FLT3-ITD) as detected by an FDA-approved test; and
3. Will be used in 1 of the following settings:
    a. In combination with standard anthracycline and cytarabine-based induction; or
    b. In combination with standard cytarabine-based consolidation; or
    c. As maintenance therapy following standard anthracycline and cytarabine-based induction and cytarabine-based consolidation.

Venclexta® (Venetoclax) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Diagnosis of AML; and
2. Member meets 1 of the following:
    a. Member is 75 years of age or older; or

   b. If the member is younger than 75 years of age, must be unable to tolerate intensive induction chemotherapy; and
3. As first-line therapy or in relapsed/refractory disease; and
4. In combination with azacitidine, decitabine, or low-dose cytarabine (LDAC).

Venclexta® (Venetoclax) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. As first-line therapy in combination with obinutuzumab for a maximum duration of 12 months; or
3. As first-line therapy in combination with ibrutinib; or
4. Relapsed/refractory disease in combination with obinutuzumab, rituximab, or as a single agent.

Venclexta® (Venetoclax) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. Diagnosis of MCL; and
2. As second-line or subsequent therapy; and
3. As a single agent.

Xalkori® (Crizotinib) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL) Diagnosis]:

1. Members 1 year of age or older:
   a. Diagnosis of systemic ALCL that is anaplastic lymphoma kinase (ALK)-positive; and
   b. Relapsed or refractory disease; and
2. As a single agent.

Xospata® (Gilteritinib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Diagnosis of relapsed/refractory AML; and
2. FMS-related tyrosine kinase 3 (FLT3) mutation; and
3. As a single agent.

Xpovio® (Selinexor) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. Diagnosis of relapsed/refractory DLBCL, not otherwise specified, including DLBCL arising from follicular lymphoma; and
2. Member has received ≥2 prior lines of systemic therapy.

Yescarta® (Axicabtagene Ciloleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma [including diffuse large B cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and
2. Member must be 18 years of age or older; and
3. Relapsed or refractory disease used in 1 of the following settings:
    a. After 2 or more lines of therapy; or
    b. After 1 line of therapy, if member is refractory to first-line chemotherapy or relapses within 12 months of first-line chemotherapy; and
4. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
5. For large B-cell lymphoma (including DLBCL, high grade B-cell lymphoma, and DLBCL arising from FL), member must not have primary central nervous system lymphoma; and
6. Approvals will be for 1 dose per member per lifetime.

Zelboraf® (Vemurafenib) Approval Criteria [Hairy Cell Leukemia (HCL) Diagnosis]:

1. Diagnosis of HCL; and
2. Used in 1 of the following settings:
    a. As a single agent; and
        i. Disease progression following failure of purine analog therapy (i.e., pentostatin, cladribine); or
    b. In combination with rituximab or obinutuzumab for patients who are not candidates for purine analogs.

Zevalin® (Ibritumomab Tiuxetan) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of low grade B-cell non-Hodgkin's lymphoma (NHL) or follicular lymphoma; and
2. Used in 1 of the following settings:
    a. Relapsed/refractory disease; or
    b. Previously untreated follicular NHL achieving partial or complete response to first-line chemotherapy; and
3. Used in combination with rituximab; and
4. Members who are new to treatment will not generally be approved as Zevalin® is not recommended by the National Comprehensive Cancer Network (NCCN). Requests for Zevalin® must indicate the rationale for treatment and must be reviewed by an oncology specialist prior to approval.

Zolinza® (Vorinostat) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. Diagnosis of MF/SS; and
2. As a single agent as primary treatment or in relapsed/refractory disease.

Zydelig® (Idelalisib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL) Diagnosis]:

1. Diagnosis of CLL; and
2. Relapsed/refractory disease; and
3. Used as subsequent therapy after prior treatment with Bruton tyrosine kinase (BTK) inhibitor- and venetoclax-based regimens; and
4. In combination with rituximab; or
5. As a single agent.

Zynlonta® (Loncastuximab Tesirine-lpyl) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified, or DLBCL arising from low grade lymphoma, or high-grade B-cell lymphoma; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
3. A patient-specific, clinically significant reason why tafasitamab in combination with lenalidomide is not appropriate for the member must be provided.

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 Leukemia and Lymphoma Medications: Fiscal Year 2025

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

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	238	1,309	$11,856,104.95	$9,057.38	$304.49	64,078	38,937
Aetna	21	48	$313,153.60	$6,524.03	$251.93	1,991	1,243
Humana	27	62	$810,302.92	$13,069.40	$437.53	3,397	1,852
OCH	25	60	$355,112.06	$5,918.53	$206.10	2,204	1,723
2024 Total	**250**	**1,479**	**$13,334,673.53**	**$9,016.01**	**$304.76**	**71,670**	**43,755**
Fiscal Year 2025							
FFS	159	717	$7,304,669.79	$10,187.82	$341.75	36,609	21,374
Aetna	43	199	$1,801,984.47	$9,055.20	$315.14	11,169	5,718
Humana	53	284	$2,658,034.99	$9,359.28	$322.97	14,778	8,230
OCH	51	240	$1,867,361.34	$7,780.67	$271.89	11,606	6,868
2025 Total	**262**	**1,440**	**$13,632,050.59**	**$9,466.70**	**$323.11**	**74,162**	**42,190**
% Change	**4.80%**	**-2.60%**	**2.20%**	**5.00%**	**6.00%**	**3.50%**	**-3.60%**
Change	**12**	**-39**	**$297,377.06**	**$450.69**	**$18.35**	**2,492**	**-1,565**

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

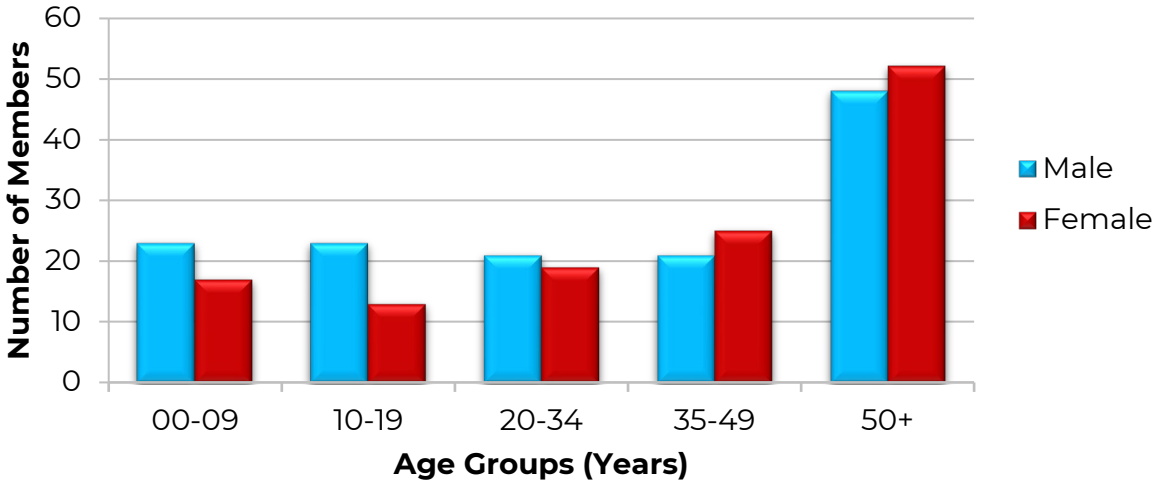
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	65	443	$5,758,756.32	$12,999.45	6.82
Aetna	3	6	$145,662.00	$24,277.00	2
Humana	1	1	$30,795.20	$30,795.20	1
OCH	3	17	$273,847.78	$16,108.69	5.67
2024 Total	**67**	**467**	**$6,209,061.30**	**$13,295.63**	**6.97**
Fiscal Year 2025					
FFS	31	237	$3,222,142.05	$13,595.54	7.65
Aetna	17	77	$1,239,067.52	$16,091.79	4.53
Humana	18	114	$778,669.44	$6,830.43	6.33
OCH	14	206	$3,222,182.29	$15,641.66	14.71
2025 Total	**75**	**634**	**$8,462,061.30**	**$13,347.10**	**8.45**
% Change	**11.94%**	**35.76%**	**36.29%**	**0.39%**	**21.23%**
Change	**8**	**167**	**$2,253,000.00**	**$51.47**	**1.48**

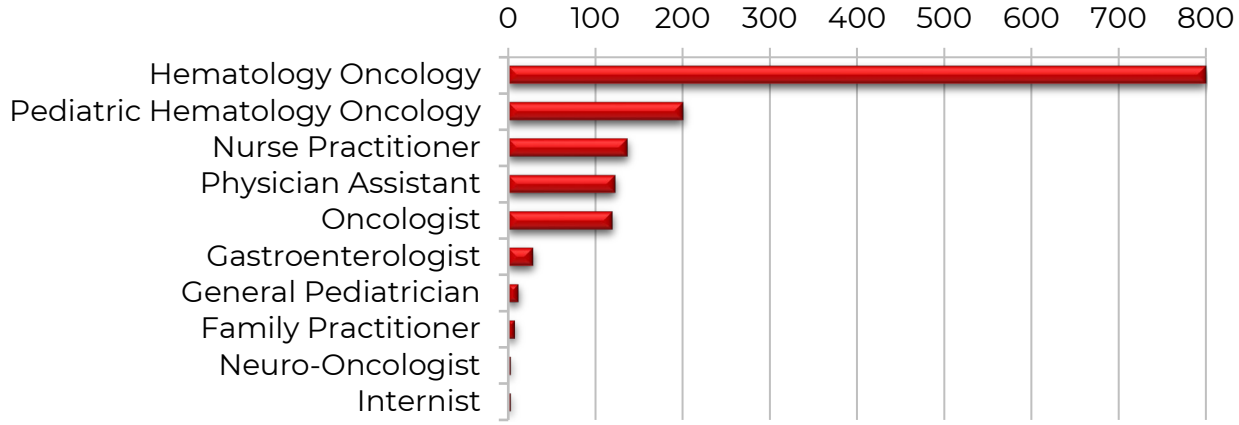
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective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

- Aggregate drug rebates collected during fiscal year 2025 for leukemia and lymphoma medications totaled $11,816,617.62.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Leukemia and Lymphoma Medications: Pharmacy Claims (All Plans)



Top Prescriber Specialties of Leukemia and Lymphoma Medications by Number of Claims: Pharmacy Claims (All Plans)

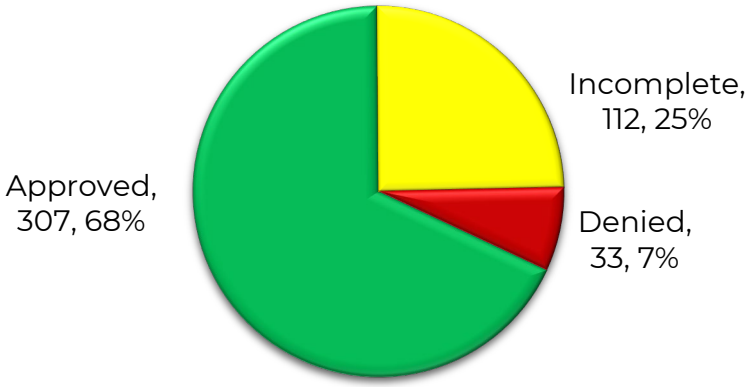


Prior Authorization of Leukemia and Lymphoma Medications

There were 452 prior authorization requests submitted for leukemia and lymphoma medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

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

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	233	67%	100	29%	13	4%	**346**
Aetna	20	50%	9	23%	11	28%	**40**
Humana	24	92%	0	0%	2	8%	**26**
OCH	30	75%	3	8%	7	18%	**40**
Total	**307**	**68%**	**112**	**25%**	**33**	**7%**	**452**

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

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23]

Anticipated Patent Expiration(s):

- Beleodaq® (belinostat): October 2027
- Zolinza® (vorinostat): March 2028
- Onureg® (azacitidine): June 2030
- Vanflyta® (quizartinib): September 2033
- Venclexta® (venetoclax): September 2033
- Zydelig® (idelalisib): September 2033
- Iclusig® (ponatinib): December 2033
- Bosulif® (bosutinib): August 2034
- Idhifa® (enasidenib): September 2034
- Copiktra® (duvelisib): April 2035
- Daurismo® (glasdegib): April 2036
- Calquence® (acalabrutinib): July 2036
- Xospata® (gilteritinib): July 2036
- Imbruvica® (ibrutinib): September 2036
- Revuforj® (revumenib): June 2037
- Tazverik® (tazemetostat): May 2038
- Rytelo® (imetelstat): June 2039
- Tibsovo® (ivosidenib): June 2039
- Rezlidhia® (olutasidenib): November 2039

- Danziten® (nilotinib): February 2040
- Scemblix® (asciminib): May 2040
- Phyrago™ (dasatinib): January 2041
- Inqovi® (decitabine/cedazuridine): February 2041
- Jaypirca® (pirtobrutinib): September 2041
- Brukinsa® (zanubrutinib): January 2043
- Komzifti™ (ziftomenib): July 2044

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

- **December 2023:** The FDA approved Phyrago™ (dasatinib) for the treatment of multiple indications for adults with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) or Ph+ acute lymphoblastic leukemia (ALL). In August 2025, the FDA approved additional indications for the treatment of pediatric patients 1 year of age and older with Ph+ ALL or Ph+ CML. Cycle Pharma announced the commercial United States launch of Phyrago™ in October 2025. Phyrago™ was FDA approved through the 505(b)(2) pathway based primarily on the existing safety and efficacy data of Sprycel® (dasatinib). Unlike Sprycel®, Phyrago™ may be administered concomitantly with proton pump inhibitors (PPIs) or histamine-2 (H_2) receptor antagonists.
- **August 2024:** The FDA approved Lymphir™ (denileukin diftitox-cxdl) for the treatment of adult patients with relapsed or refractory Stage I-III cutaneous T-cell lymphoma (CTCL) after at least 1 prior systemic therapy. The manufacturer announced the commercial launch of Lymphir™ in December 2025.
- **February 2025:** The FDA approved Nilotinib D-Tartrate capsules through the 505(b)(2) approval pathway based primarily on the existing safety and efficacy data of Tasigna® (nilotinib). Nilotinib D-Tartrate is indicated for the treatment of adult patients with newly diagnosed Ph+ CML in chronic phase and for the treatment of adult patients with chronic phase and accelerated phase Ph+ CML resistant to or intolerant to prior therapy that included imatinib. It is available as oral capsules containing nilotinib d-tartrate in the equivalent of 50mg, 150mg, and 200mg of nilotinib.
- **June 2025:** The FDA approved a new indication for Monjuvi® (tafasitamab-cxix), in combination with lenalidomide and rituximab, for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).
- **June 2025:** The FDA announced the removal of the Risk Evaluation and Mitigation Strategies (REMS) programs for all currently approved bispecific B-cell maturation antigen (BCMA)- and CD19-directed autologous chimeric antigen receptor (CAR) T-cell immunotherapies, including Breyanzi® (lisocabtagene maraleucel), Kymriah® (tisagenlecleucel), Tecartus® (brexucabtagene autoleucel), and

Yescarta® (axicabtagene ciloleucel). The FDA determined that the REMS were no longer necessary to ensure that the benefits of these therapies outweigh their risks and to minimize the burden on the health care delivery system.

- **October 2025:** The FDA approved a new indication for Gazyva® (obinutuzumab) for the treatment of adult patients with active lupus nephritis who are receiving standard therapy.
- **October 2025:** The FDA approved a new indication for Revuforj® (revumenib) for the treatment of relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (*NPM1*) mutation in adult and pediatric patients 1 year of age and older who have no satisfactory alternative treatment options.
- **November 2025:** The FDA approved Komzifti™ (ziftomenib) for the treatment of adult patients with relapsed or refractory AML with a susceptible *NPM1* mutation who have no satisfactory alternative treatment options.
- **November 2025:** The FDA approved a new indication for Epkinly™ (epcoritamab-bysp), in combination with lenalidomide and rituximab, for the treatment of adult patients with relapsed or refractory FL.
- **December 2025:** The FDA granted traditional approval and an updated indication for Jaypirca® (pirtobrutinib) for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have previously been treated with a covalent Bruton tyrosine kinase (BTK) inhibitor.
- **December 2025:** The FDA approved a new indication for Breyanzi® (lisocabtagene maraleucel) for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least 2 prior lines of systemic therapy.
- **December 2025:** The FDA granted accelerated approval to Lunsumio VELO™ (mosunetuzumab-axgb), a new subcutaneous (sub-Q) formulation of mosunetuzumab-axgb, for the treatment of adult patients with relapsed or refractory FL after 2 or more lines of systemic therapy.
- **February 2026:** The FDA approved an updated label for Yescarta® (axicabtagene ciloleucel) to remove the previous *Limitations of Use* which specified that it was not indicated for the treatment of patients with primary central nervous system (CNS) lymphoma.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for ALL:
  - Allow for the use of blinatumomab in combination with a tyrosine kinase inhibitor (TKI) for frontline consolidation or induction if the patient is not a candidate for multi-agent chemotherapy

    - Allow for the use of ponatinib in combination with blinatumomab for Ph+ ALL
- The NCCN guidelines for B-cell lymphomas:
    - Allow for the use of ibrutinib in patients with B-cell lymphoma [including diffuse large B-cell lymphomas, human immunodeficiency virus (HIV)-related B-cell lymphomas, post-transplant lymphoproliferative disorders, and high-grade B-cell lymphoma] who are not candidates for CAR T-cell therapy or have no intention of proceeding to transplant
    - Removed recommendations for use of ibrutinib in patients with gastric or nongastric mucosa-associated lymphoid tissue (MALT) lymphoma, nodal or splenic MZL diagnosis
    - Allow for the combination of brentuximab and nivolumab; however, the recommendation is based on a lower level of evidence.
- The NCCN guidelines for multiple myeloma allow for the use of venetoclax in combination with daratumumab or daratumumab/ hyaluronidase-fihj in multiple myeloma and light chain amyloidosis for patients with t(11;14) translocation.
- The NCCN guidelines for CLL/SLL allow for the use of venetoclax in combination with acalabrutinib with or without obinutuzumab as first line therapy.
- The NCCN guidelines for T-cell lymphomas allow for the use of mogamulizumab-kpkc, used in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) in members with no intention to proceed to transplant.

Komzifti™ (Ziftomenib) Product Summary[24]

Therapeutic Class: Menin inhibitor

Indication(s): Treatment of adult patients with relapsed or refractory AML with a susceptible *NPM1* mutation who have no satisfactory alternative treatment options

How Supplied: 200mg oral capsules

Dosing and Administration: The recommended dose is 600mg orally once daily, continued until disease progression or unacceptable toxicity.

Cost: The Wholesale Acquisition Cost (WAC) is $538.89 per capsule which results in an estimated cost of $48,500.10 per month or $582,001.20 per year based on recommended dosing.

Lunsumio VELO™ (Mosunetuzumab-axgb) Product Summary[25]

Therapeutic Class: Bispecific CD20-directed CD3 T-cell engager

Indication(s): Treatment of adult patients with relapsed or refractory FL after 2 or more lines of systemic therapy

- This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

How Supplied:

- 5mg/0.5mL solution in a single-dose vial (SDV)
- 45mg/mL solution in an SDV

Dosing and Administration:

- Administered in 21-day treatment cycles by sub-Q injection
- Cycle 1: 5mg on day 1, 45mg on day 8, and 45mg on day 15
- Cycle 2 (and subsequent cycles): 45mg on day 1

Cost: The WAC is $3,227.37 for the 5mg vial and $29,046.35 for the 45mg vial. This would result in a cost of $61,320.07 for the first cycle and $29,046.35 for the second and subsequent cycles based on recommended dosing. This results in an estimated cost of $526,061.67 for a year of treatment.

Lymphir™ (Denileukin Diftitox-cxdl) Product Summary[26]

Therapeutic Class: Interleukin-2 (IL-2)-receptor-directed cytotoxin

Indication(s): Treatment of adult patients with relapsed or refractory Stage I-III CTCL after at least 1 prior systemic therapy

How Supplied: Lyophilized powder in a 300mcg SDV

Dosing and Administration: The recommended dose is 9mcg/kg administered as an intravenous (IV) infusion over 60 minutes on days 1-5 of a 21-day treatment cycle, continued until disease progression or unacceptable toxicity.

Cost: The WAC is $3,630 per vial. For a member weighing 75kg, this would result in an estimated cost of $54,450 per cycle or $925,650 per year based on recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Komzifti™ (ziftomenib) and Lymphir™ (denileukin diftitox-cxdl), with the following criteria (shown in red):

Komzifti™ (Ziftomenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Diagnosis of AML; and
2. Disease is relapsed or refractory; and
3. Disease is positive for a susceptible nucleophosmin 1 (*NPM1*) mutation; and
4. Member has no satisfactory alternative treatment options; and
5. Member is 18 years of age or older.

Lymphir™ (Denileukin Diftitox-cxdl) Approval Criteria [Cutaneous T-Cell Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory stage I-III cutaneous T-cell lymphoma; and
2. Member must be 18 years of age or older; and
3. Expression of CD25 on ≥20% of malignant cells by immunohistochemistry (IHC); and
4. Has received at least 1 prior systemic therapy.

Next, the College of Pharmacy recommends the prior authorization of Nilotinib D-Tartrate, Lunsumio VELO™ (mosunetuzumab-axgb), and Phyrago™ (dasatinib) with criteria similar to Danziten® (nilotinib tartrate), Lunsumio™ (mosunetuzumab-axgb), and Sprycel® (dasatinib), respectively (changes shown in red):

Danziten® (Nilotinib Tartrate) and Nilotinib D-Tartrate Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Diagnosis of CML; and
2. Member must have 1 of the following:
    a. Newly diagnosed chronic, accelerated, or blast phase CML; or
    b. Philadelphia chromosome positive (Ph+) CML chronic phase (CP) resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy; or
    c. Post-hematopoietic stem cell transplant; and
3. A patient-specific, clinically significant reason the member cannot use Tasigna® (nilotinib) must be provided.

Lunsumio™ (Mosunetuzumab-axgb) and Lunsumio VELO™ (Mosunetuzumab-axgb) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of FL; and
2. Relapsed or refractory disease after ≥2 lines of systemic therapy.

Phyrago™ (Dasatinib) and Sprycel® (Dasatinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of Ph+ ALL; and
2. Member must have 1 of the following:
    a. Upfront therapy (including induction and consolidation) in combination with multi-agent chemotherapy or as a single agent; or
    b. Maintenance therapy including:
        i. As a single agent if unfit for additional therapies; or
        ii. As a single agent if member previously received blinatumomab plus a tyrosine kinase inhibitor (TKI); or
        iii. In combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
        iv. Post-hematopoietic stem cell transplantation; or
    c. Relapsed/refractory disease as a single agent or in combination with multi-agent chemotherapy; and
3. Member does not have the following mutations of BCR-ABL1: T315I/A, F317L/V/I/C, or V299L; and
4. For Phyrago™, a patient-specific, clinically significant reason why the member cannot use generic dasatinib (Sprycel®) must be provided.

Phyrago™ (Dasatinib) and Sprycel® (Dasatinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Diagnosis of CML; and
2. Member must have 1 of the following:
    a. Chronic, accelerated, or blast phase CML; or
    b. Post-hematopoietic stem cell transplantation; and
3. For Phyrago™, a patient-specific, clinically significant reason why the member cannot use generic dasatinib (Sprycel®) must be provided.

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

1. Diagnosis of soft tissue sarcoma – GIST; and
2. Used for gross residual disease (R2 resection), unresectable primary disease, tumor rupture, or recurrent/metastatic disease; and
3. Used as second-line therapy as single agent; and
4. Member has progressive disease after treatment with avapritinib; and
5. PDGFRA exon 18 mutations that are insensitive to imatinib (including D842V); and
6. For Phyrago™, a patient-specific, clinically significant reason why the member cannot use generic dasatinib (Sprycel®) must be provided.

Next, the College of Pharmacy recommends updating the approval criteria for Epkinly® (epcoritamab-bysp), Gazyva® (obinutuzumab), Jaypirca® (pirtobrutinib), Monjuvi® (tafasitamab-cxix), and Revuforj® (revumenib) based on recent FDA approvals (changes shown in red):

Epkinly® (Epcoritamab-bysp) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. Diagnosis of relapsed or refractory ~~follicular lymphoma (FL) or diffuse large B-cell lymphoma~~ ~~(~~DLBCL~~)~~ not otherwise specified, including DLBCL arising from indolent lymphomas and/or high-grade B-cell lymphomas; and
2. Has received ≥2 lines of systemic therapy.

Epkinly® (Epcoritamab-bysp) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of relapsed or refractory FL; and
2. Used in 1 of the following settings:
    a. Has received ≥2 lines of systemic therapy; and
        i. Used as a single agent; or
    b. Has received ≥ 1 line of systemic therapy; and
        i. Used in combination with lenalidomide and rituximab.

Gazyva® (Obinutuzumab) Approval Criteria [Lupus Nephritis (LN) Diagnosis]:

1. An FDA approved indication for the treatment of active LN in members who are receiving standard therapy; and
2. Member must be 18 years of age or older; 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. Azathioprine; or
    c. Mycophenolate; or
    d. Cyclophosphamide; or
    e. Hydroxychloroquine/chloroquine; and
4. Will not be approved for combination use with other biologic therapies (e.g., anifrolumab, belimumab).

Jaypirca® (Pirtobrutinib) Approval Criteria [Chronic Lymphocytic/Small Lymphocytic Lymphoma (CLL/SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
~~2. As second-line or subsequent therapy following resistance or intolerance to prior covalent Bruton's kinase (BTK) inhibitor and a BCL-2 inhibitor; or~~
3. Disease is relapsed or refractory; and

4. Previously treated with a covalent Bruton's kinase (BTK) inhibitor or a BCL-2 inhibitor; or
5. Demonstrates histologic (Richter) transformation to diffuse large B-cell lymphoma (DLBCL).

Monjuvi® (Tafasitamab-cxix) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of classic FL; and
2. Member must be 18 years of age or older; and
3. Used as second line or later line of therapy (no response, relapsed, or progressive disease); and
4. Used in combination with lenalidomide and rituximab; and
5. Member has received at least 1 prior systemic therapy including an anti-CD20 monoclonal antibody.

Revuforj® (Revumenib) Approval Criteria [Acute Leukemia Diagnosis]:

1. Diagnosis of acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL); and
2. Disease is relapsed or refractory; and
3. Must meet 1 of the following:
    a. Leukemia is positive for a lysine methyltransferase 2A gene (KMT2A) translocation; ~~and~~ or
    b. Susceptible nucleophosmin 1 (*NPM1*) mutation with no satisfactory alternative treatment options; and
4. Member is 1 year of age or older; and
5. Member's recent weight (kg) must be provided; and
    a. For members weighing <40kg, the member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug.

Next, the College of Pharmacy recommends updating the approval criteria for Breyanzi® (lisocabtagene maraleucel), Kymriah® (tisagenlecleucel), Tecartus® (brexucabtagene autoleucel), and Yescarta® (axicabtagene ciloleucel) based on the removal of the REMS requirements, other FDA approvals, and net costs (changes shown in red):

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy including a Burton tyrosine kinase (BTK) inhibitor and a B cell lymphoma-2 (BCL-2) inhibitor; and
3. Member does not have primary central nervous system (CNS) lymphoma; and

4. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
5. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Follicular Lymphoma Diagnosis]:

1. Diagnosis of FL; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
3. Member does not have primary central nervous system (CNS) lymphoma; and
4. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
5. ~~A patient-specific, clinically significant reason why Kymriah® (tisagenlecleucel) or Yescarta® (axicabtagene ciloleucel) are not appropriate for the member must be provided; and~~
6. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Large B Cell Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma; and
    a. One of the following:
        i. Refractory disease to frontline chemoimmunotherapy; or
        ii. Relapse within 12 months of frontline chemoimmunotherapy; or
        iii. Relapse within 12 months of frontline chemoimmunotherapy and member is not eligible for hematopoetic stem cell transplantation (HSCT) due to comorbidity or age; or
        iv. Relapse or refractory disease after 2 or more lines of systemic therapy; and
2. Member does not have primary central nervous system (CNS) lymphoma; and
3. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and

~~4. A patient-specific, clinically significant reason why Kymriah® (tisagenlecleucel) or Yescarta® (axicabtagene) is not appropriate for the member must be provided.~~
5. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. Diagnosis of MCL; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy including a Bruton tyrosine kinase (BTK) inhibitor; and
3. Member does not have primary central nervous system (CNS) lymphoma; and
4. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
~~5. A patient-specific, clinically significant reason why Tecartus® (brexucabtagene autoleucel) is not appropriate for the member must be provided; and~~
6. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Marginal Zone Lymphoma (MZL) Diagnosis]:

1. Diagnosis of MZL; and
2. Disease is relapsed or refractory; and
3. Member has received at least 2 prior lines of systemic therapy; and
4. Health care facilities must be a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities; and
5. Approvals will be for 1 dose per member per lifetime.

Kymriah® (Tisagenlecleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Members must meet all of the following:
    a. B-cell precursor ALL; and
    b. Member must be 25 years of age or younger; and
    c. Refractory or in second or later relapse:
        i. Philadelphia chromosome negative (Ph-) ALL: Must be refractory or with ≥2 relapses; or
        ii. Philadelphia chromosome positive (Ph+) ALL: Must have failed ≥2 tyrosine kinase inhibitors (TKIs); and
    d. Therapies to consider prior to tisagenlecleucel if appropriate: Clinical trial, multi-agent chemotherapy with or without

hematopoietic cell transplantation (HCT), blinatumomab (category 1 recommendation), and inotuzumab (category 1 recommendation); and

2. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities~~, and must comply with the Kymriah Risk Evaluation and Mitigation Strategy (REMS) requirements~~; and
3. Approvals will be for 1 dose per member per lifetime.

Kymriah® (Tisagenlecleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma [including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and
2. Relapsed/refractory disease; and
3. Member must be 18 years of age or older; and
4. Member must not have primary central nervous system lymphoma; and
5. Member must have had ≥2 lines of therapy; and
6. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities~~, and must comply with the Kymriah Risk Evaluation and Mitigation Strategy (REMS) requirements~~; and
7. Approvals will be for 1 dose per member per lifetime.

Tecartus® (Brexucabtagene Autoleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of acute lymphoblastic leukemia (ALL); and
2. Relapsed or refractory disease; and
3. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
4. Approvals will be for 1 dose per member per lifetime.

Tecartus® (Brexucabtagene Autoleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of mantle cell lymphoma; and
2. Relapsed or refractory disease; and
3. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and

neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
4. Approvals will be for 1 dose per member per lifetime.

Yescarta® (Axicabtagene Ciloleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma [including diffuse large B cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and
2. Member must be 18 years of age or older; and
3. Relapsed or refractory disease used in 1 of the following settings; and
    a. After 2 or more lines of therapy; or
    b. After 1 line of therapy, if member is refractory to first-line chemotherapy or relapses within 12 months of first-line chemotherapy; and
4. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~;~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
~~5. For large B-cell lymphoma (including DLBCL, high grade B-cell lymphoma, and DLBCL arising from FL), member must not have primary central nervous system lymphoma.~~
6. Approvals will be for 1 dose per member per lifetime.

The College of Pharmacy also recommends updating the approval criteria for Adcetris® (brentuximab vedotin), Blincyto® (blinatumomab), Calquence® (acalabrutinib), Iclusig® (ponatinib), Imbruvica® (ibrutinib), Poteligeo® (mogamulizumab-kpkc), and Venclexta® (venetoclax) based on NCCN recommendations (changes shown in red):

Adcetris® (Brentuximab Vedotin) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) or High Grade Lymphoma Diagnosis]:

1. Diagnosis of DLBCL or high grade lymphoma; and
2. As a single agent; and
    a. CD30+ disease; and
    b. For DLBCL relapsed/refractory disease in non-autologous stem cell transplant (SCT) candidates or non-candidates for chimeric antigen receptor (CAR) T-cell therapy; or
3. Used in combination with lenalidomide and a rituximab product; and
    a. CD30+ disease; and
    b. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
    c. Ineligible for autologous hematopoietic stem cell transplantation (HSCT) or CAR T-cell therapy.~~; or~~

~~4. Used in combination with nivolumab; and~~
   ~~a. CD30+ disease; and~~
   ~~b. Relapsed or refractory primary mediastinal large B-cell lymphoma.~~

Blincyto® (Blinatumomab) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of Philadelphia chromosome negative (Ph-) ALL; and
   a. Member must be 1 month of age or older; and
   b. Used in 1 of the following settings:
      i. As consolidation therapy as a component of multiphase chemotherapy; or
      ii. As consolidation in adolescents/young adults or adults younger than 65 years of age without substantial comorbidity with persistent or late clearance minimal residual disease positive (MRD+) following a complete response to induction; or
      iii. As maintenance therapy in combination with mercaptopurine, vincristine, methotrexate, and prednisone (POMP) as a component of maintenance; or
      iv. For management of relapsed/refractory Ph- ALL; or
2. Diagnosis of Philadelphia chromosome positive (Ph+) ALL; and
   a. Member must be 1 month of age or older; and
   b. Used in 1 of the following settings:
      i. In combination with a tyrosine kinase inhibitor (TKI) as either frontline consolidation or induction if not a candidate for multiagent chemotherapy; or
      ii. With or without a TKI as consolidation in adolescents/young adults or adults younger than 65 years of age without substantial comorbidity with persistent or late clearance MRD+ following a complete response to induction; or
      iii. As maintenance therapy in combination with POMP as a component of maintenance if refractory to TKIs; or
      iv. For management of relapsed/refractory Ph+ ALL after failure of 2 TKIs.

Calquence® (Acalabrutinib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. Used as a single agent; or
3. In combination with obinutuzumab and/or venetoclax.

Iclusig® (Ponatinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of Ph+ ALL; and
2. Used in 1 of the following settings:

a. Newly diagnosed Ph+ ALL; and
    i. Used in combination with chemotherapy; or
    ii. Used in combination with blinatumomab; or
    iii. Used in combination with corticosteroids or as single agent in those unfit for chemotherapy; or
b. Maintenance therapy either as a single agent or in combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
c. Relapsed/refractory disease either as a single agent, in combination with chemotherapy not previously given, or in patients with T315I mutations.

Imbruvica® (Ibrutinib) Approval Criteria [B-Cell Lymphomas Diagnosis]:

1. Diagnosis of B-cell lymphoma [including diffuse large B-cell lymphomas, human immunodeficiency virus (HIV)-related B-cell lymphomas, post-transplant lymphoproliferative disorders, and high-grade B-cell lymphoma]; and
2. As second-line or subsequent therapy; and
3. Member is not a candidate for CAR T-cell therapy or has no intention to proceed to transplant.

~~**Imbruvica® (Ibrutinib) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis or Acquired Immunodeficiency Syndrome (AIDS)-Related B-Cell Lymphoma Diagnosis]:**~~

~~1. Diagnosis of non-germinal center DLBCL; and~~
~~2. As second-line or subsequent therapy; and~~
~~3. Member is not a candidate for CAR T-cell therapy or has no intention to proceed to transplant.~~

~~**Imbruvica® (Ibrutinib) Approval Criteria [Gastric or Nongastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma, Nodal or Splenic Marginal Zone Lymphoma (MZL) Diagnosis]:**~~

~~1. Diagnosis of gastric or nongastric MALT lymphoma, nodal or splenic MZL; and~~
~~2. As second-line or subsequent therapy for refractory or progressive disease.~~

Poteligeo® (Mogamulizumab-kpkc) Approval Criteria [Adult T-Cell Leukemia/Lymphoma (ATLL) Diagnosis]:

1. Diagnosis of ATLL; and
2. Used in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP); and
    a. No intention to proceed to transplant; or
3. As a single-agent in relapsed/refractory disease.

Venclexta® (Venetoclax) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. As first-line therapy in combination with acalabrutinib and/or obinutuzumab for a maximum duration of 12 months; or
3. As first-line therapy in combination with ibrutinib; or
4. Relapsed/refractory disease in combination with obinutuzumab, rituximab, or as a single agent.

Venclexta® (Venetoclax) Approval Criteria [Systemic Light Chain Amyloidosis Diagnosis]

1. Diagnosis of relapsed/refractory systemic light chain amyloidosis; and
2. Presence of t(11;14) translocation; and
3. Be used as a single agent; or
4. In combination with dexamethasone; or
5. In combination with daratumumab

Venclexta® (Venetoclax) Approval Criteria [Multiple Myeloma Diagnosis]

1. Diagnosis of relapsed or progressive multiple myeloma and
2. Presence of t(11;14) translocation; and
3. In combination with dexamethasone; or
4. In combination with dexamethasone and daratumumab; or
5. In combination with dexamethasone and either bortezomib, carfilzomib, or ixazomib

Utilization Details of Leukemia and Lymphoma Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MERCAPTOPURINE PRODUCTS						
MERCAPTOPURINE TAB 50MG	299	67	$14,145.27	$47.31	4.46	0.10%
PURIXAN SUS 20MG/ML	68	19	$85,085.25	$1,251.25	3.58	0.62%
MERCAPTOPURINE SUS 20MG/ML	20	12	$22,325.95	$1,116.30	1.67	0.16%
SUBTOTAL	**387**	**98**	**$121,556.47**	**$314.10**	**3.95**	**0.89%**
DASATINIB PRODUCTS						
DASATINIB TAB 100MG	94	18	$946,007.76	$10,063.91	5.22	6.94%
SPRYCEL TAB 100MG	81	21	$1,386,747.33	$17,120.34	3.86	10.17%
SPRYCEL TAB 50MG	37	7	$371,064.13	$10,028.76	5.29	2.72%
DASATINIB TAB 50MG	30	9	$155,947.99	$5,198.27	3.33	1.14%
DASATINIB TAB 20MG	10	3	$55,998.39	$5,599.84	3.33	0.41%
SPRYCEL TAB 80MG	8	1	$146,061.92	$18,257.74	8	1.07%
SPRYCEL TAB 70MG	5	2	$50,675.70	$10,135.14	2.5	0.37%
SPRYCEL TAB 20MG	4	2	$40,540.64	$10,135.16	2	0.30%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DASATINIB TAB 70MG	4	3	$17,820.07	$4,455.02	1.33	0.13%
DASATINIB TAB 80MG	3	1	$20,196.42	$6,732.14	3	0.15%
SPRYCEL TAB 140MG	1	1	$18,257.74	$18,257.74	1	0.13%
DASATINIB TAB 140MG	1	1	$12,491.90	$12,491.90	1	0.09%
SUBTOTAL	**278**	**69**	**$3,221,809.99**	**$11,589.24**	**4.03**	**23.63%**
IMATINIB PRODUCTS						
IMATINIB MES TAB 400MG	137	27	$11,962.87	$87.32	5.07	0.09%
IMATINIB MES TAB 100MG	29	7	$1,731.72	$59.71	4.14	0.01%
SUBTOTAL	**166**	**34**	**$13,694.59**	**$82.50**	**4.88**	**0.10%**
VENETOCLAX PRODUCTS						
VENCLEXTA TAB 100MG	63	20	$489,368.99	$7,767.76	3.15	3.59%
VENCLEXTA TAB 50MG	17	8	$16,509.57	$971.15	2.13	0.12%
VENCLEXTA TAB START PK	5	5	$16,823.76	$3,364.75	1	0.12%
VENCLEXTA TAB 10MG	2	1	$1,453.70	$726.85	2	0.01%
SUBTOTAL	**87**	**34**	**$524,156.02**	**$6,024.78**	**2.56**	**3.85%**
ZANUBRUTINIB PRODUCTS						
BRUKINSA CAP 80MG	86	16	$1,121,451.31	$13,040.13	5.38	8.23%
SUBTOTAL	**86**	**16**	**$1,121,451.31**	**$13,040.13**	**5.38**	**8.23%**
ACALABRUTINIB PRODUCTS						
CALQUENCE TAB 100MG	78	15	$1,151,746.39	$14,765.98	5.2	8.45%
SUBTOTAL	**78**	**15**	**$1,151,746.39**	**$14,765.98**	**5.2**	**8.45%**
IBRUTINIB PRODUCTS						
IMBRUVICA TAB 420MG	48	5	$798,617.24	$16,637.86	9.6	5.86%
IMBRUVICA TAB 280MG	14	2	$231,245.32	$16,517.52	7	1.70%
IMBRUVICA CAP 140MG	13	2	$312,291.88	$24,022.45	6.5	2.29%
SUBTOTAL	**75**	**9**	**$1,342,154.44**	**$17,895.39**	**8.33**	**9.85%**
NILOTINIB PRODUCTS						
TASIGNA CAP 150MG	54	9	$1,122,857.22	$20,793.65	6	8.24%
TASIGNA CAP 200MG	20	5	$359,725.06	$17,986.25	4	2.64%
SUBTOTAL	**74**	**14**	**$1,482,582.28**	**$20,034.90**	**5.29**	**10.88%**
PONATINIB PRODUCTS						
ICLUSIG TAB 30MG	20	5	$404,422.48	$20,221.12	4	2.97%
ICLUSIG TAB 15MG	17	6	$402,448.47	$23,673.44	2.83	2.95%
ICLUSIG TAB 45MG	13	4	$287,479.33	$22,113.79	3.25	2.11%
ICLUSIG TAB 10MG	5	3	$111,503.55	$22,300.71	1.67	0.82%
SUBTOTAL	**55**	**18**	**$1,205,853.83**	**$21,924.62**	**3.06**	**8.85%**
BOSUTINIB PRODUCTS						
BOSULIF TAB 400MG	22	3	$456,976.65	$20,771.67	7.33	3.35%
BOSULIF TAB 100MG	22	2	$335,824.24	$15,264.74	11	2.46%
SUBTOTAL	**44**	**5**	**$792,800.89**	**$18,018.20**	**8.8**	**5.82%**
ASCIMINIB PRODUCTS						
SCEMBLIX TAB 40MG	30	10	$655,541.17	$21,851.37	3	4.81%
SCEMBLIX TAB 100MG	4	2	$152,692.95	$38,173.24	2	1.12%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**34**	**12**	**$808,234.12**	**$23,771.59**	**2.83**	**5.93%**
AZACITIDINE PRODUCTS						
ONUREG TAB 300MG	11	3	$287,862.03	$26,169.28	3.67	2.11%
ONUREG TAB 200MG	10	1	$142,052.06	$14,205.21	10	1.04%
SUBTOTAL	**21**	**4**	**$429,914.09**	**$20,472.10**	**5.25**	**3.15%**
ENASIDENIB PRODUCTS						
IDHIFA TAB 100MG	16	4	$566,487.43	$35,405.46	4	4.16%
IDHIFA TAB 50MG	4	1	$136,023.64	$34,005.91	4	1.00%
SUBTOTAL	**20**	**5**	**$702,511.07**	**$35,125.55**	**4**	**5.15%**
DECITABINE/CEDAZURIDINE PRODUCTS						
INQOVI TAB 35-100MG	9	3	$76,517.07	$8,501.90	3	0.56%
SUBTOTAL	**9**	**3**	**$76,517.07**	**$8,501.90**	**3**	**0.56%**
IVOSIDENIB PRODUCTS						
TIBSOVO TAB 250MG	6	2	$201,953.91	$33,658.99	3	1.48%
SUBTOTAL	**6**	**2**	**$201,953.91**	**$33,658.99**	**3**	**1.48%**
TAZEMETOSTAT PRODUCTS						
TAZVERIK TAB 200MG	5	1	$102,722.05	$20,544.41	5	0.75%
SUBTOTAL	**5**	**1**	**$102,722.05**	**$20,544.41**	**5**	**0.75%**
QUIZARTINIB PRODUCTS						
VANFLYTA TAB 17.7MG	5	1	$47,510.89	$9,502.18	5	0.35%
SUBTOTAL	**5**	**1**	**$47,510.89**	**$9,502.18**	**5**	**0.35%**
REVUMENIB PRODUCTS						
REVUFORJ TAB 110MG	3	1	$118,530.73	$39,510.24	3	0.87%
REVUFORJ TAB 160MG	2	1	$79,022.82	$39,511.41	2	0.58%
SUBTOTAL	**5**	**2**	**$197,553.55**	**$39,510.71**	**2.5**	**1.45%**
GILTERITINIB PRODUCTS						
XOSPATA TAB 40MG	3	2	$77,306.41	$25,768.80	1.5	0.57%
SUBTOTAL	**3**	**2**	**$77,306.41**	**$25,768.80**	**1.5**	**0.57%**
VORINOSTAT PRODUCTS						
ZOLINZA CAP 100MG	2	1	$10,021.22	$5,010.61	2	0.07%
SUBTOTAL	**2**	**1**	**$10,021.22**	**$5,010.61**	**2**	**0.07%**
TOTAL	**1,440**	**262***	**$13,632,050.59**	**$9,466.70**	**5.5**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; MES = mesylate; START PK = starter pack; SUS = suspension; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BLINATUMOMAB J9039	204	20	$722,759.66	$3,542.94	10.2
ASPARAGINASE, RECOMB J9021	136	8	$2,127,548.41	$15,643.74	17
BRENTUXIMAB VEDOTIN J9042	109	12	$2,244,640.38	$20,593.03	9.08
OBINUTUZUMAB J9301	76	16	$513,069.44	$6,750.91	4.75
CALASPARGASE PEGOL J9118	37	12	$564,110.05	$15,246.22	3.08
POLATUZUMAB VEDOTIN-PIIQ J9309	37	7	$493,941.40	$13,349.77	5.29
MOSUNETUZUMAB-AXGB J9350	11	1	$210,415.50	$19,128.68	11
MOGAMULIZUMAB-KPKC J9204	9	1	$204,463.20	$22,718.13	9
INOTUZUMAB OZOGAMICIN J9229	6	3	$125,704.80	$20,950.80	2
PEGASPARGASE J9266	3	2	$81,155.92	$27,051.97	1.5
BREXUCABTAGENE AUTOLEUCEL Q2053	2	2	$671,817.94	$335,908.97	1
TAFASITAMAB-CXIX J9349	2	1	$13,297.70	$6,648.85	2
AXICABTAGENE CILOLEUCEL Q2041	1	1	$489,136.90	$489,136.90	1
TISAGENLECLEUCEL Q2042	1	1	$0.00	$0.00	1
TOTAL	**634**	**75**	**$8,462,061.30**	**$13,347.10**	**8.45**

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

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Appendix J

30-Day Notice to Prior Authorize Fesilty™ (Fibrinogen, Human-chmt)

Oklahoma Health Care Authority
March 2026

Introduction[1,2,3,4,5,6]

Congenital fibrinogen disorders (CFDs) are a heterogeneous group of rare inherited abnormalities of blood coagulation that result from monoallelic or biallelic mutations in *FGA*, *FGB,* and *FGG* genes. CFDs are classified into 2 categories of either quantitative or qualitative disorders. Quantitative disorders include afibrinogenemia and hypofibrinogenemia, and qualitative disorders include dysfibrinogenemia and hypodysfibrinogenemia. In afibrinogenemia, most patients suffer from major bleeding, but a minority can either experience minor bleeding or be asymptomatic, and some patients may develop arterial or venous thromboembolism in the presence or absence of fibrinogen replacement. In hypofibrinogenemia, the bleeding phenotype is generally well correlated with the fibrinogen level, with most patients with fibrinogen levels >1g/L being asymptomatic. In dysfibrinogenemia, the bleeding phenotype is usually mild but may be of concern in women of childbearing age. Some fibrinogen variants significantly increase the thrombotic risk, resulting in a strong positive family history and thrombotic events. Hypodysfibrinogenemia is often symptomatic with severe bleeding and is more likely to lead to thrombosis compared with dysfibrinogenemia.

The prevalence of CFDs is estimated to be 1 to 9 in 1,000,000 people with hypo- and dysfibrinogenemia being more common, but the exact prevalence is unknown. CFDs can be discovered at any age, but afibrinogenemia usually manifests early in childhood, often in the neonatal period. Initial laboratory diagnosis of CFDs should include activated partial thromboplastin time (APTT) and prothrombin time (PT), functional assessment of the fibrinogen level, and an antigenic measurement, and the diagnosis can be confirmed based on the fibrinogen levels through functional and immunological assays. Genetic testing can be performed in order to confirm the diagnosis and the specific phenotype.

Current treatment for CFDs includes fibrinogen replacement therapy to restore and maintain normal fibrinogen levels, including fresh frozen plasma (FFP), cryoprecipitates, or fibrinogen concentrates such as RiaSTAP® or Fibryga®. Fibrinogen concentrates are typically the best option, as they have a faster onset, greater dosing flexibility, are easier to administer, and are safer,

as they are less likely to be contaminated with viruses than FFP and cryoprecipitate. Depending on the patient's needs, treatment can be given weekly or bi-weekly as primary prophylaxis, secondary prophylaxis, or as on-demand treatment. Primary prophylaxis is essential for pregnant women to avoid miscarriage. In some patients, fibrinogen replacement therapy could provoke thromboembolic complications, and these patients should receive anticoagulant therapy with their treatment.

In December 2025, the U.S. Food and Drug Administration (FDA) approved Fesilty™ (fibrinogen, human-chmt) for the treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency, including hypo- or afibrinogenemia.

Fesilty™ (Fibrinogen, Human-chmt) Product Summary[7,8]

Therapeutic Class: Human blood coagulation factor

Indication(s): Treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency, including hypo- or afibrinogenemia

- **Limitation(s) of Use:** Fesilty™ is not indicated for dysfibrinogenemia.

How Supplied: Sterile, lyophilized, white powder for solution for intravenous (IV) injection

- Fesilty™ is supplied in a kit containing 1 single-dose vial containing nominally 1 gram of human fibrinogen, (1) 50mL vial of sterile water for injection, and 1 sterile transfer system.
- The actual amount of fibrinogen in milligrams per vial is printed on the vial label and carton.

Dosing and Administration:

- Fesilty™ is for IV use after reconstitution only.
- The dose of Fesilty™ should be calculated in mg of fibrinogen per kg of body weight (BW) for each patient individually based on age, location and extent of the bleeding, plasma level of fibrinogen (mg/dL), and clinical condition of the patient.
- See the full *Prescribing Information* for calculations based on age when the baseline fibrinogen level is known and frequency and duration of dosing.
- When the baseline plasma fibrinogen level is not known, the recommended dose is 70mg/kg BW for patients of all ages.
- The target plasma fibrinogen level is 100mg/dL for minor bleeding and 150mg/dL for major bleeding.

Efficacy: The efficacy of Fesilty™ for on-demand treatment (ODT) and on-demand prophylaxis (ODP) was studied in an open-label, single arm,

multicenter trial in 36 pediatric and adult patients with congenital hypo- or afibrinogenemia.

- Key Inclusion Criteria:
  - Known congenital afibrinogenemia or severe congenital hypofibrinogenemia
  - Plasma fibrinogen activity ≤0.5g/L and antigen ≤0.5g/L
- Key Exclusion Criteria:
  - Known dysfibrinogenemia phenotype or bleeding disorders other than CFD
  - History of esophageal variceal bleeding
  - Thrombotic event ≤6 months before enrollment
  - Inhibitory antibodies to fibrinogen
  - Treatment with fibrinogen-containing product or concomitant medication relevantly interacting with the coagulation system ≤2 weeks before study drug administration
- Intervention(s): All patients were given Fesilty™ as a single or repetitive IV infusion(s) for ODP/ODT of bleeding events.
  - The dose given was based on individual BW and fibrinogen levels.
  - The mean dose for 175 bleeding events was 70.1mg/kg for adults and 75.8mg/kg for pediatric patients.
- Endpoint(s):
  - Overall hemostatic response (OHR) based on a 4-point scale assessed by the investigator as excellent, good, moderate, or none
    - Good and excellent ratings were classified as successful
  - Mean change in maximum clot firmness (MCF) at 1 hour after infusion
- Results:
  - A total of 175 bleeding events (122 minor and 53 major) were treated with Fesilty™, with the majority being in adults (92 events) and a mean of 4.9 bleeding events per patient.
  - OHR was considered successful in 98.9% of adult patients and 100% of pediatric patients.
    - OHR was reported as excellent in 150 bleeding events (86%), good in 23 events (13%), and moderate in 2 events (1%).
  - The mean change in MCF was 10.76mm at 1 hour after Fesilty™ infusion.

Cost: Cost information for Fesilty™ is not yet available.

Recommendations

The College of Pharmacy recommends the prior authorization of Fesilty™ (fibrinogen, human-chmt) with the following criteria (shown in red):

Fesilty™ (Fibrinogen, Human-chmt) Approval Criteria:

1. An FDA approved diagnosis of congenital fibrinogen deficiency, including afibrinogenemia or hypofibrinogenemia; and
2. Member must not have dysfibrinogenemia; and
3. Documented plasma fibrinogen activity ≤0.5g/L and antigen ≤0.5g/L; and
4. Fesilty™ must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of congenital fibrinogen deficiency; and
5. A patient-specific, clinically significant reason why the member cannot use RiaSTAP® [fibrinogen concentrate (human)] or Fibryga® [fibrinogen (human)], which are available without prior authorization, must be provided; and
6. Fesilty™ will not be used concomitantly with RiaSTAP® or Fibryga®; and
7. Fesilty™ will be used for the treatment of acute bleeding or for the perioperative management of bleeding; and
8. Approval lengths will be based on duration of need.

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Appendix K

30-Day Notice to Prior Authorize Waskyra™ (Etuvetidigene Autotemcel)

Oklahoma Health Care Authority
March 2026

Introduction[1,2,3]

Wiskott-Aldrich Syndrome (WAS) results from rare, X-linked mutations in the *WAS* gene, with an estimated incidence of 1 in 100,000 male live births. More than 300 *WAS* gene mutations have been identified. Clinical presentation typically includes immunodeficiency, microthrombocytopenia, eczema, and increased susceptibility to autoimmunity and malignancies. Phenotypes correspond to the level of retained functionality of the WAS protein (WASP), which is key to actin polymerization in hematopoietic stem cells. Reduced, truncated, or absent WASP expression disrupts cell signaling, cell motility, and immune synapse formations.

Milder phenotypes are typically categorized as X-linked thrombocytopenia (XLT) or X-linked neutropenia (XLN), and treatment consists of supportive care of the presenting symptoms, including but not limited to immunoglobulin replacement therapy or platelet transfusions. Patients with the milder phenotypes are anticipated to have life expectancies similar to the normal male population. More severe phenotypes, or "classic" WAS, often result in premature death from infections, hemorrhage, or malignancies if left untreated by hematopoietic stem cell transplantation (HSCT).

In December 2025, the Food and Drug Administration (FDA) approved Waskyra™ (etuvetidigene autotemcel) as the first gene therapy for the treatment of WAS in adults and pediatric patients 6 months of age and older. Waskyra™ is manufactured from the patient's own CD34+ hematopoietic stem cells by transducing them with a lentiviral vector containing a functional copy of the *WAS* gene.

Waskyra™ (Etuvetidigene Autotemcel) Product Summary[4,5]

Therapeutic Class: Autologous hematopoietic stem cell-based gene therapy

Indication(s): Treatment of WAS in patients with a mutation in the *WAS* gene for whom HSCT is appropriate and no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available

How Supplied: 1 to 8 infusion bags overall containing a suspension of 2 to 11.4 x 10^6 cells/mL (1.9 to 11.4 x 10^6 CD34+ cells/mL) in a cryopreservative solution

Dosing and Administration:

- Dosing is based on the number of CD34+ cells in the infusion bag(s) per kg of body weight at the time of infusion
  - Minimum recommended dose is 7 x 10^6 CD34+ cells/kg
- Patients are required to undergo hematopoietic stem and progenitor cells (HSPC) mobilization followed by apheresis to obtain CD34+ cells for Waskyra™ manufacturing
- Reduced intensity conditioning is required before infusion of Waskyra™

Efficacy: The safety and efficacy of Waskyra™ were evaluated in a prospective, open-label, single-arm, multicenter clinical trial (N=8); an on-going, open-label, single-arm, multicenter trial (N=10); an expanded access program (N=3); and a Compassionate Use Program (N=6).

- Key Inclusion Criteria:
  - Diagnosis of WAS confirmed by *WAS* gene mutation and at least 1 of the following:
    - Severe *WAS* mutation
    - Absence of WASP expression
    - Severe clinical score (Zhu clinical score ≥3)
  - No HLA-matched sibling donor
  - Negative search for matched unrelated donor (10/10) or an adequate unrelated cord blood donor (5-6/6) within 4 to 6 months
- Intervention(s): Waskyra™ compared to 12-month pre-treatment outcomes
- Primary Endpoint(s):
  - Rate of severe infections during the 6- to 18-month period after Waskyra™ infusion compared with the 12-month pretreatment period
  - Rate of moderate or severe bleeding episodes during the 12-month period after Waskyra™ infusion compared with the 12-month pre-treatment period
- Results:
  - The rate of severe infections decreased from 2 infections per patient year observation (PYO) [95% confidence interval (CI): 1.5, 2.61] during the 12-month pre-treatment period to 0.2 infections per PYO (95% CI: 0.04, 0.40) during the 6- to 18-month post-treatment period.
  - The rate of moderate and severe bleeding events decreased from 2 events per PYO (95% CI: 1.5, 2.61) during the 12-month pre-treatment period to 0.8 events per PYO (95% CI: 0.49, 1.22) during the 12-month post-treatment period.

Cost: The Wholesale Acquisition Cost (WAC) of Waskyra™ is not currently available to allow for a cost analysis.

Recommendations

The College of Pharmacy recommends the prior authorization of Waskyra™ (etuvetidigene autotemcel) with the following criteria (shown in red):

Waskyra™ (Etuvetidigene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of Wiskott-Aldrich Syndrome (WAS); and
2. Diagnosis must be confirmed by molecular genetic testing confirming a mutation in the *WAS* gene (results of genetic testing must be submitted) and at least 1 of the following:
    a. Severe *WAS* mutation as indicated by molecular genetic testing; or
    b. Absence of WAS protein (WASP) expression in hematopoietic cells; or
    c. Severe Zhu clinical score of ≥3; and
3. Member must be male; and
4. Member must be 6 months of age or older; and
5. Must be prescribed by a geneticist, hematologist/oncologist, immunologist, or other specialist with expertise in the treatment of WAS and the administration of Waskyra™; and
6. Member must not have a known and available human leukocyte antigen (HLA)-matched related stem cell donor; and
7. Member must not have any contraindications to the use of Waskyra™, including:
    a. Hypersensitivity to the active substance or to any of the excipients; and
    b. Previous treatment with hematopoietic stem cell transplantation (HSCT) within 6 months prior to screening or HSCT with evidence of residual donor cell; and
    c. Previous treatment with hematopoietic stem cell gene therapy; and
    d. Contraindications to the mobilization and the conditioning regimen; and
8. Prescriber must verify the member is eligible to undergo HSCT (i.e., HSCT must be appropriate for a member to be treated with Waskyra™); and
9. Prescriber must verify the member will be monitored for signs and symptoms of the following:
    a. Cytopenia for at least 8 weeks after treatment; and
    b. Engraftment failure after treatment; and
    c. Hepatic veno-occlusive diseases, including assessment of liver function tests for 1 month after infusion; and
    d. Infection before and after treatment with Waskyra™; and

10. Waskyra™ must be administered at a Waskyra™ qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific dose from receipt to storage to administration; and
11. Approvals will be for 1 dose per member per lifetime.

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Appendix L

Fiscal Year 2025 Annual Review of Growth-Related Disorder Medications and 30-Day Notice to Prior Authorize Daybue® Stix (Trofinetide Packet), Palsonify™ (Paltusotine), Vykat™ XR [Diazoxide Choline Extended-Release (ER)], and Yuviwel® (Navepegritide)

Oklahoma Health Care Authority
March 2026

Current Prior Authorization Criteria

Growth Hormone Products	
Tier-1*	**Tier-2**
Genotropin® (somatropin) (Pfizer) - Cartridge, MiniQuick	**Humatrope®** (somatropin) (Eli Lilly) - Vial, Cartridge Kit
	ᵗNgenla® (somatrogon-ghla) (Pfizer) - Pen
	Norditropin® (somatropin) (Novo Nordisk) - FlexPro® Pen
	Nutropin® and Nutropin AQ® (somatropin) (Genentech) - Vial, Pen Cartridge, NuSpin®
	Omnitrope® (somatropin) (Sandoz) - Vial, Cartridge
	Saizen® (somatropin) (EMD Serono) - Vial, click.easy®
	ᵗSerostim® (somatropin) (EMD Serono) - Vial
	ᵗSkytrofa® (lonapegsomatropin-tcgd) (Ascendis) - Cartridge
	ᵗSogroya® (somapacitan-beco) (Novo Nordisk) - Pen
	Zomacton® and Zoma-Jet® (somatropin) (Ferring) - Vial, Injection Device

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).
*Supplementally rebated product(s)
ᵗAdditional approval criteria applies.

Growth Hormone Covered Indications *(prior to epiphyseal closure)**:

1. Growth hormone deficiency (GHD) of 1 of the following types:
    a. Classic GHD as determined by childhood GH stimulation tests; or
    b. Panhypopituitarism; or
    c. Hypoglycemia with evidence for GHD; or
    d. Neurosecretory dysfunction; or

e. Other evidence for GHD submitted for panel review and decision; or
2. Short stature associated with Prader-Willi syndrome; or
3. Short stature associated with Noonan syndrome; or
4. Short stature associated with chronic renal insufficiency (pre-transplantation); or
5. Growth failure in children born small for gestational age (SGA) who fail to manifest catch-up growth by 2 years of age; or
6. Idiopathic short stature (ISS) in children with height ≥2.25 SD below the mean for age and gender and who are unlikely to catch up in height; or
7. Turner syndrome or 45X, 46XY mosaicism; or
8. Short-stature homeobox-containing gene (SHOX) deficiency with genetic evidence for SHOX deficiency.

*Please refer to the complete prior authorization criteria for each indication, listed below.

Growth Hormone Tier-2 Approval Criteria:

1. Documented allergic reaction to non-active components of all available Tier-1 products; or
2. A clinical exception applies to members with a diagnosis of acquired immunodeficiency syndrome (AIDS) wasting syndrome, in which case Serostim® can be used, regardless of its current Tier status.

Discontinuation of Therapy or Transition to Adult Therapy Criteria:

1. Failure to show improvement in height percentile on growth chart after 1 year of treatment; or
2. Growth velocity <2.5cm/year unless associated with another growth-limiting and treatable medical condition (i.e., hypothyroidism); or
3. Epiphyseal closure; or
4. Covered height has been reached:
   a. 152.4cm (60 inches) for girls; or
   b. 165.1cm (65 inches) for boys; or
   c. The covered height does not apply for members with a diagnosis of growth hormone deficiency (GHD) or panhypopituitarism; or
5. Inadequate compliance; or
6. Significant adverse effects.

Growth Hormone Dosing (*doses must be individualized and titrated*):

1. Children: 22 to 100mcg/kg/day according to current pediatric guidelines; or
2. Adults:
   a. Initial Dosing: 0.1 to 0.5mg per day – Doses should be evaluated and titrated at 1- to 2-month intervals targeting an insulin-like growth factor 1 (IGF-1) level within the age-adjusted reference range

provided by the laboratory utilized [IGF-1 standard deviation score (SDS) ≤ +2]. In general, younger patients may require higher doses than older patients. The following **initial** doses are suggested by the current American Association of Clinical Endocrinologists/American College of Endocrinology (AACE/ACE) guidelines, but these doses should be titrated based on IGF-1 levels:
    i. Age <30 years: 0.4 to 0.5mg per day (may be higher for patients transitioning from pediatric treatment); or
    ii. Age 30-60 years: 0.2 to 0.3mg per day; or
    iii. Age >60 years: 0.1 to 0.2mg per day; and
b. Transition Dosing: In patients transitioning from pediatric to adult dosing, resuming GH doses at 50% of the dose last used in childhood is suggested, as they tend to be more tolerant of higher doses.

Growth Hormone Deficiency (GHD) Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years of age or older (unless hypoglycemia is present); and
    b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    c. Member must meet at least 1 of the following:
        i. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; or
        ii. Member must have evidence of delayed bone age (undefined delay); and
    d. Member must have open epiphyses; and
    e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
    f. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available; and
    g. There must be no contributing medical conditions (e.g., cystic fibrosis, malnutrition, psychosocial deprivation); and
    h. Member must have suboptimal response of ≤10ng/mL on 2 of the following provocative growth hormone stimulation tests, using the highest level per date of testing. (Stimulation tests are always required for approval unless hypoglycemia is observed, in which case a random low glucose level and low growth hormone level would be acceptable):
        i. Propranolol with exercise; or
        ii. Levodopa; or

iii. Insulin hypoglycemia test; or
iv. Arginine HCl infusion; or
v. Clonidine; or
vi. Glucagon (not approved for use in children); or

i. If hypoglycemia is present and member is growth hormone deficient, request may be approved for 6 months (other criteria above is not applicable). If the member has hypoglycemia, a low glucose level must be submitted along with additional evidence of GHD such as:
    i. Low insulin-like growth factor 1 (IGF-1), random growth hormone level, or suboptimal growth hormone stimulation tests; or
    ii. MRI evidence of congenital anomaly which includes pituitary damage or absence; or
    iii. Other pituitary hormones also being replaced (e.g., thyroid, cortisol).

2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations; or
    b. Adult Dosing: Members with this diagnosis may transition to adult dosing (see "Growth Hormone Dosing" section above for recommendations for adult and transition dosing) after 1 or both of the following:
        i. Epiphyseal closure; or
        ii. GV <2.5cm/year; and
        iii. If either of the above have occurred and the member has not yet transitioned to adult dosing, may be approved short term (3 months) to allow time for transition to adult dosing.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. GV should not be <2.5cm/year if not on adult dosing; and
    e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be ≤ +2.

Idiopathic Short Stature Approval Criteria:

1. Initial Approval:
    a. Member must be 8 years of age or older; and

b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
c. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
d. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
e. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
f. Member's growth chart and parental heights must be provided; and
    i. If the form is completed, a growth chart is not required; and
    ii. Parental heights are not always available.

2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations. Treatment may continue until 1 of the following:
        i. Epiphyseal closure; or
        ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
    b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Epiphyses are open; and
    e. GV should not be <2.5cm/year.

Neurosecretory Dysfunction Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years of age or older; and
    b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    c. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and

d. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
e. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
f. Member's growth chart and parental heights must be provided; and
    i. If the form is completed, a growth chart is not required; and
    ii. Parental heights are not always available; and
g. Member's serum insulin-like growth factor 1 (IGF-1) must be below the mean for member's age; and
    i. Note: Children with profoundly low GV, who are at risk for growth hormone deficiency due to CNS radiation or other organic causes, termed neurosecretory dysfunction, may demonstrate "normal" responses to provocative tests, often for several years, but often benefit from growth hormone therapy.
h. Growth hormone stimulation testing is required; however, growth hormone levels may be normal.

2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations; or
    b. Adult Dosing: Members with this diagnosis may transition to adult dosing (see "Growth Hormone Dosing" section above for recommendations for adult and transition dosing) after 1 of the following:
        i. Epiphyseal closure; or
        ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
        iv. If any of the above have occurred and the member has not yet transitioned to adult dosing, may be approved short term (3 months) to allow time for transition to adult dosing.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. GV should not be <2.5cm/year if not on adult dosing; and
    e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be ≤ +2.

Panhypopituitarism Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years of age or older (unless hypoglycemia is present); and
    b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    c. Member must meet at least 1 of the following:
        i. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; or
        ii. Member must have evidence of delayed bone age (undefined delay); and
    d. Member must have open epiphyses; and
    e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
        i. For members with secondary panhypopituitarism due to tumor, trauma, or surgery 12 months post trauma or surgery, approval may be granted if no evidence of tumor recurrence and growth has not restarted. The member must still meet all the other criteria; however, authorization would not require height ≥2.25 SD below the mean in these circumstances; and
    f. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available; and
    g. Member must have a history of pituitary or hypothalamic injury due to tumor, trauma, surgery, documented whole brain radiation, irradiation, hemorrhage or infarction, or a congenital anomaly; and
        i. Deficiency in ≥3 pituitary hormones and insulin-like growth factor 1 (IGF-1) ≥2.5 SD below the mean for member's age; or
        ii. No deficiency, or deficiency in <3 pituitary hormones, and IGF-1 <50th percentile and subnormal response of 10ng/mL or less on at least 2 provocative growth hormone stimulation tests, using the highest level per date of testing. (Stimulation tests are always required for approval unless hypoglycemia is observed, in which case a random low glucose level and low growth hormone level would be acceptable); or
    h. If member has MRI evidence of pituitary stalk agenesis, empty sella, or ectopic posterior pituitary "bright spot", member is exempt from height requirement (*criteria letter e listed above*); and
        i. If they lack the hormones testosterone, luteinizing hormone (LH), or follicle-stimulating hormone (FSH) then an MRI is not required; or

i. If hypoglycemia is present and member is growth hormone deficient: request may be approved for 6 months (other criteria above is not applicable). If the member has hypoglycemia, a low glucose level must be submitted along with additional evidence of GHD such as:
    i. Low IGF-1, random growth hormone level, or suboptimal growth hormone stimulation tests; or
    ii. MRI evidence of congenital anomaly which includes pituitary damage or absence; or
    iii. Other pituitary hormones also being replaced (e.g., thyroid, cortisol).

2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations; or
    b. Adult Dosing: Members with this diagnosis may transition to adult dosing (see "Growth Hormone Dosing" section above for recommendations for adult and transition dosing) after 1 or both of the following:
        i. Epiphyseal closure; or
        ii. GV <2.5cm/year; and
        iii. If either of the above have occurred and the member has not yet transitioned to adult dosing, may be approved short term (3 months) to allow time for transition to adult dosing.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. GV should not be <2.5cm/year if not on adult dosing; and
    e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be ≤ +2.

Short Stature Associated with Chronic Renal Insufficiency (Pre-Transplantation) Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years of age or older; and
    b. Member's estimated creatinine clearance (CrCl) must be <50mL/min; and
    c. Member must not be post-kidney transplant; and
    d. Growth hormone therapy must be prescribed by an endocrinologist or pediatric nephrologist (or an advanced care

practitioner with a supervising physician who is an endocrinologist or pediatric nephrologist); and
    e. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available; and
    f. Members meeting the above criteria are exempt from height requirements.
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or growth velocity (GV) is <2.5cm/year, therapy should be discontinued.
3. Dosing:
    a. Pediatric Dosing: Standard dosing applies for members receiving pediatric dosing (0.05mg/kg/day). Treatment may continue until 1 of the following:
        i. Renal transplantation; or
        ii. Epiphyseal closure; or
        iii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
        iv. GV <2.5cm/year; and
    b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
    a. Member is still pre-transplant; and
    b. Medications and dosing should be appropriate; and
    c. Member should have had a recent office visit with new information regarding heights; and
    d. Member should be compliant; and
    e. Epiphyses are open; and
    f. GV should not be <2.5cm/year.

Short Stature Associated with Noonan Syndrome Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years or older; and
    b. Member must have a chromosome analysis confirming the diagnosis of Noonan syndrome; and
    c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist).
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or growth velocity (GV) is <2.5cm/year, therapy should be discontinued.

3. Dosing:
    a. Pediatric Dosing: Standard dosing applies for members receiving pediatric dosing (up to 0.066mg/kg/day). Treatment should continue until 1 of the following:
        i. Epiphyseal closure; or
        ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year.
    b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Epiphyses should be open; and
    e. GV should not be <2.5cm/year.

Short Stature Associated with Prader-Willi Syndrome (PWS) Approval Criteria:

1. Initial Approval:
    a. Member must have a chromosome analysis confirming the diagnosis of PWS; and
    b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    c. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available.
2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: 0.5-1mg/m^2/day or 0.24mg/kg/week. Treatment should continue until 1 of the following:
        i. Epiphyseal closure; or
        ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
    b. Adult Dosing: After attainment of adult height, adults with PWS may be considered for adult dosing if evidence is submitted documenting adult growth hormone deficiency [e.g., low insulin-like growth factor 1 (IGF-1) level and GH stimulation testing].
4. Continuation Approval:

a. Medications and dosing should be appropriate; and
b. Member should have had a recent office visit with new information regarding heights provided; and
c. Member should be compliant; and
d. GV should not be <2.5cm/year; and
e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be ≤ +2.

Short Stature Associated with Short Stature Homeobox-Containing Gene (SHOX) Deficiency Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years or older; and
    b. Member must have a chromosome analysis confirming the diagnosis of SHOX deficiency; and
    c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    d. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
    e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
    f. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
    g. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available; and
    h. Member must have a normal endocrine screen; and
    i. Member must have no evidence of growth hormone deficiency or insensitivity, tumor activity, diabetes mellitus, history of impaired glucose tolerance, or other serious illness known to interfere with growth.
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:
    a. <u>Pediatric Dosing:</u> Standard dosing applies for members receiving pediatric dosing (up to 0.05mg/kg/day). Treatment should continue until 1 of the following:
        i. Epiphyseal closure; or
        ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches]; or
        iii. GV <2.5cm/year; and

b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.

4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Epiphyses should be open; and
    e. GV should not be <2.5cm/year.

Short Stature Associated with Turner Syndrome or 45,X/46,XY Mosaicism Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years of age or older; and
    b. Member must have a chromosome analysis confirming the diagnosis of Turner syndrome in females or 45,X/46,XY mosaicism in males; and
    c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist).
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or growth velocity (GV) is <2.5cm/year, therapy should be discontinued.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations. Treatment should continue until 1 of the following:
        i. Epiphyseal closure; or
        ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
    b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Epiphyses should be open; and
    e. GV should not be <2.5cm/year.

Small for Gestational Age (SGA) Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years or age or older; and
    b. Documentation of birth weight <2,500 grams at gestational age of more than 37 weeks or birth weight or length below the 3rd percentile for gestational age; and
    c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    d. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
    e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
    f. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
    g. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required
        ii. Parental heights are not always available.
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations. Treatment should continue until 1 of the following:
        i. Epiphyseal closure; or
        ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
    b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Epiphyses should be open; and
    e. GV should not be <2.5cm/year.

Daybue® (Trofinetide) Approval Criteria:

1. A diagnosis of typical Rett syndrome confirmed by all of the following:

a. Prescriber must verify all clinical diagnostic criteria are met supporting a diagnosis of typical Rett syndrome including:
    i. A period of regression followed by recovery or stabilization; and
    ii. Partial or complete loss of acquired purposeful hand skills; and
    iii. Partial or complete loss of acquired spoken language; and
    iv. Gait abnormalities (impaired/dyspraxic or absence of ability); and
    v. Stereotypic hand movements (e.g., hand wringing/squeezing, clapping/tapping, mouthing, washing/rubbing automatisms); and
    vi. Lack of brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection causing neurological problems; and
    vii. Lack of grossly abnormal psychomotor development in the first 6 months of life; and
b. Genetic testing documenting a disease-causing mutation in the *MECP2* gene; and

2. Member must be 2 years of age or older; and
3. Daybue® must be prescribed by a geneticist, neurologist, or other specialist with expertise in the treatment of Rett syndrome; and
4. Prescriber must agree to counsel members and caregivers on the risks of diarrhea, weight loss, and vomiting (including aspiration and aspiration pneumonia) associated with Daybue®, and will monitor appropriately for these adverse effects; and
5. Prescriber must agree to counsel members and caregivers on proper storage and administration of Daybue®, including the use of a calibrated device for measuring each dose; and
6. Prescriber must verify the member does not have severe renal impairment; and
    a. If the member has moderate renal impairment, the prescriber must agree to reduce the dose as required in the package labeling; and
7. Member's current weight (kg) taken within the past 3 weeks must be provided on initial and subsequent prior authorization requests to ensure accurate weight-based dosing according to package labeling; and
8. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for a duration of 1 year; and
9. A quantity limit of 3,600mL per 30 days will apply.

Insulin-Like Growth Factor-1 (IGF-1) Analog Medications: Increlex® [Mecasermin (rDNA Origin) Injection] Approval Criteria:

1. Therapy initiated by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
2. Diagnosis of primary IGF-1 deficiency with all of the following:
   a. Height >3 standard deviations (SD) below the mean; and
   b. Basal IGF-1 >3 SD below the mean; and
   c. Normal or elevated growth hormone (GH); and
3. Documentation of mutation in GH receptor (GHR) or mutation in post-GHR signaling pathway or IGF-1 gene defects (Laron Syndrome); and
4. IGF-1 analog medications will not be approved for use in secondary IGF-1 deficiencies related to GH deficiency, malnutrition, hypothyroidism, or chronic steroid therapy.

Mycapssa® (Octreotide) Approval Criteria:

1. An FDA approved indication for long-term maintenance treatment in members with acromegaly who have responded to and tolerated treatment with octreotide or lanreotide; and
2. Member has elevated insulin-like growth factor-1 (IGF-1) levels for age and/or gender; and
3. Member has a documented trial with injectable octreotide or lanreotide, and the prescriber must verify that the member responded to and tolerated treatment with octreotide or lanreotide; and
4. A patient-specific, clinically significant reason why the member cannot continue treatment with injectable octreotide or lanreotide must be provided; and
5. Must be prescribed by, or in consultation with, an endocrinologist; and
6. Prescriber must document that the member has had an inadequate response to surgery or is not a candidate for surgery; and
7. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member's IGF-1 level has decreased or normalized since initiating treatment; and
8. A quantity limit of 120 capsules per 30 days will apply.

Ngenla® (Somatrogon-ghla) Approval Criteria:

1. Member must have a confirmed diagnosis of growth hormone deficiency (GHD) or panhypopituitarism meeting the initial growth hormone approval criteria (listed under "Initial Approval") for the member's specific diagnosis; and
2. Member must be 3 years of age or older; and
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and

4. Prescriber must verify the member has been counseled on proper administration and storage of Ngenla®; and
5. Initial approvals will be for the 0.66mg/kg dose recommended in package labeling; and
6. Initial approvals will be for the duration of 6 months. For additional approval consideration:
    a. Dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Growth velocity should not be <2.5cm/year; and
    e. Prescriber must verify member still has open epiphyses; and
7. Ngenla® will not be approved following epiphyseal closure. Ngenla® is contraindicated in children with closed epiphyses.

Serostim® (Somatropin) Approval Criteria:

1. Initial Approval:
    a. An FDA approved diagnosis of human immunodeficiency virus (HIV)-associated wasting; and
    b. Member must be receiving optimal antiretroviral treatment; and
    c. Member must have an unintentional weight loss of >10% if baseline pre-morbid weight was <120% of ideal body weight (IBW) or unintentional weight loss of >20% if baseline pre-morbid weight was >120% of IBW; and
    d. Member must not have a reversible cause of weight loss such as infection, gastrointestinal (GI) bleed/obstruction, or malnutrition; and
    e. Member is receiving aggressive nutritional intake or supplementation; and
    f. Member must not have an active malignancy (except localized Kaposi's sarcoma); and
    g. Member has failed a trial of megestrol acetate and/or dronabinol; and
    h. Male members must have been evaluated for testosterone deficiency and treated as needed; and
    i. Approvals will be for 4 weeks initially and a quantity limit of 28 vials per 28 days will apply.
2. Continuation Approval:
    a. At 4 weeks, member must be evaluated for response to therapy (weight gain), side effects, and compliance. If member's response and compliance are appropriate, another 8 weeks of therapy will be approved to complete 12 weeks of treatment; and

b. Subsequent follow up evaluations will be required every 12 weeks to assess response and compliance. The member may receive up to a maximum of 48 weeks continuous therapy.

3. Discontinuation Criteria:
   a. Completion of 48 weeks duration of therapy; or
   b. Treatment failure measured by no weight gain despite 8 weeks of therapy, or continued/resumed weight loss at any time following 8 weeks of therapy when other potential causes have resolved or ruled out; or
   c. Member noncompliance; or
   d. Adverse effects that are refractory to dose reduction; or
   e. New or progressive Kaposi's sarcoma; or
   f. Member weight exceeds 110% of pre-morbid weight.

Signifor® LAR (Pasireotide) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Members with acromegaly who have had an inadequate response to surgery or for whom surgery is not an option; or
   b. Members with Cushing's disease from a pituitary tumor for whom pituitary surgery is not an option or has not been curative; and
2. For a diagnosis of acromegaly, the member must have a documented trial with long-acting octreotide or lanreotide depot with an inadequate response or have a patient-specific, clinically significant reason why the other long-acting release (LAR) somatostatin analogs (SSAs) are not appropriate for the member; and
3. Must be prescribed by, or in consultation with, an endocrinologist; and
4. Must be administered by a health care professional; and
5. Prescriber must document that the member has had an inadequate response to surgery or is not a candidate for surgery; and
6. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored when starting treatment and periodically thereafter; and
7. Authorizations will be for the duration of 12 months; and
8. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Skytrofa® (Lonapegsomatropin-tcgd) Approval Criteria:

1. Member must have a confirmed diagnosis of growth hormone deficiency (GHD) or panhypopituitarism meeting the initial growth hormone approval criteria (listed under "Initial Approval") for the member's specific diagnosis; and
2. Member's weight must be ≥11.5kg; and
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and

4. Prescriber must verify the member has been counseled on proper administration and storage of Skytrofa®; and
5. Initial approvals will be for the 0.24mg/kg weekly dose, using the specific dose recommended in the package labeling; and
6. Initial approvals will be for the duration of 6 months. For additional approval consideration:
    a. Dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Growth velocity should not be <2.5cm/year; and
    e. Prescriber must verify member still has open epiphyses; and
7. Skytrofa® will not be approved following epiphyseal closure. Skytrofa® is contraindicated in children with closed epiphyses.

Sogroya® (Somapacitan-beco) Approval Criteria:

1. Member must have a confirmed diagnosis of 1 of the following:
    a. Pediatric growth hormone deficiency (GHD) or panhypopituitarism meeting all the "Initial Approval" criteria for the member's specific diagnosis; or
    b. Adult GHD confirmed by 1 of the following:
        i. Insulin tolerance test (ITT) or glucagon test with a peak growth hormone (GH) response <3ng/mL; or
        ii. ≥3 pituitary hormone deficiencies and insulin like growth factor-1 (IGF-1) standard deviation score (SDS) <-2.0; and
2. Member must be 2.5 years of age or older; and
3. Sogroya® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
4. Member's baseline IGF-1 level and SDS must be provided; and
5. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and
6. Prescriber must verify the member does not have active malignancy or active proliferative or severe non-proliferative diabetic retinopathy; and
7. Prescriber must verify the member has been counseled on proper administration and storage of Sogroya®; and
8. Approval quantity will be based on the FDA approved dosing in accordance with the package labeling; and
9. Initial approvals will be for the duration of 6 months. For additional approval consideration:
    a. Dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and

    d. Growth velocity should not be <2.5cm/year if not on adult dosing; and
    e. For members on adult dosing, recent IGF-1 level and SDS should be submitted and SDS should be ≤ +2; and
    f. For members initially approved as adults, the prescriber must verify the member is responding well to treatment as demonstrated by a reduction in truncal fat percentage or normalization of IGF-1 level (IGF-1 SDS of -0.5 to 1.75); and
10. A maximum approved dose of 8mg per week will apply for members with adult GHD.

Voxzogo® (Vosoritide) Approval Criteria:

1. Member must have an FDA approved indication of achondroplasia; and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic mutation in the *FGFR3* gene; and
2. Prescriber must verify member has open epiphyses; and
3. The member's baseline height and growth velocity (GV) must be provided; and
4. Voxzogo® must be prescribed by a geneticist, endocrinologist, or other specialist with expertise in the treatment of achondroplasia; and
5. Member's recent weight (taken within the past 3 weeks) must be provided in order to ensure appropriate dosing in accordance with the package labeling; and
6. Prescriber must verify the member or member's caregiver has been counseled on proper administration and storage of Voxzogo®, including the need for adequate food and fluid intake prior to each dose; and
7. A quantity limit of 30 vials per 30 days will apply; and
8. Initial and subsequent approvals will be for the duration of 6 months. For additional approval consideration:
    a. Member's current height must be provided and must demonstrate an improvement in GV from baseline; and
    b. Member's recent weight must be provided and dosing must be appropriate; and
    c. Member should be compliant; and
    d. Prescriber must verify member still has open epiphyses; and
9. Voxzogo® will not be approved following epiphyseal closure.

Utilization of Growth-Related Disorder Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	694	4,008	$15,332,089.60	$3,825.37	$122.10	121,969	125,566
Aetna	80	204	$1,113,417.51	$5,457.93	$189.68	2,685	5,870
Humana	83	182	$680,794.97	$3,740.63	$131.71	2,989	5,169
OCH	132	296	$1,167,496.29	$3,944.24	$133.40	4,190	8,752
2024 Total	**757**	**4,690**	**$18,293,798.37**	**$3,900.60**	**$125.85**	**131,833**	**145,357**
Fiscal Year 2025							
FFS	385	2,266	$9,152,952.97	$4,039.26	$132.39	96,022	69,135
Aetna	139	871	$4,133,727.26	$4,745.96	$163.00	12,872	25,360
Humana	152	956	$3,639,129.10	$3,806.62	$124.89	15,949	29,139
OCH	198	1,380	$5,313,604.46	$3,850.44	$131.17	23,473	40,509
2025 Total	**766**	**5,473**	**$22,239,413.79**	**$4,063.48**	**$135.49**	**148,316**	**164,143**
% Change	**1.20%**	**16.70%**	**21.60%**	**4.20%**	**7.70%**	**12.50%**	**12.90%**
Change	**9**	**783**	**$3,945,615.42**	**$162.88**	**$9.64**	**16,483**	**18,786**

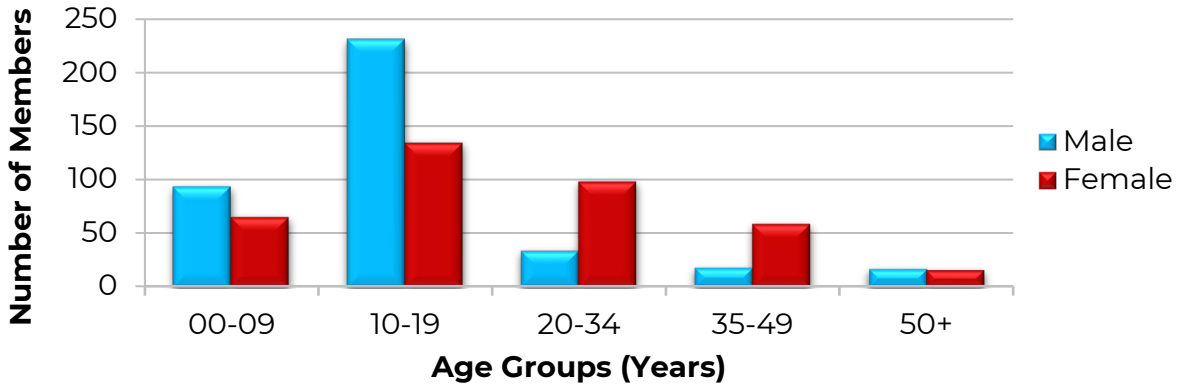
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective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

Comparison of Fiscal Years: Medical Claims (All Plans)

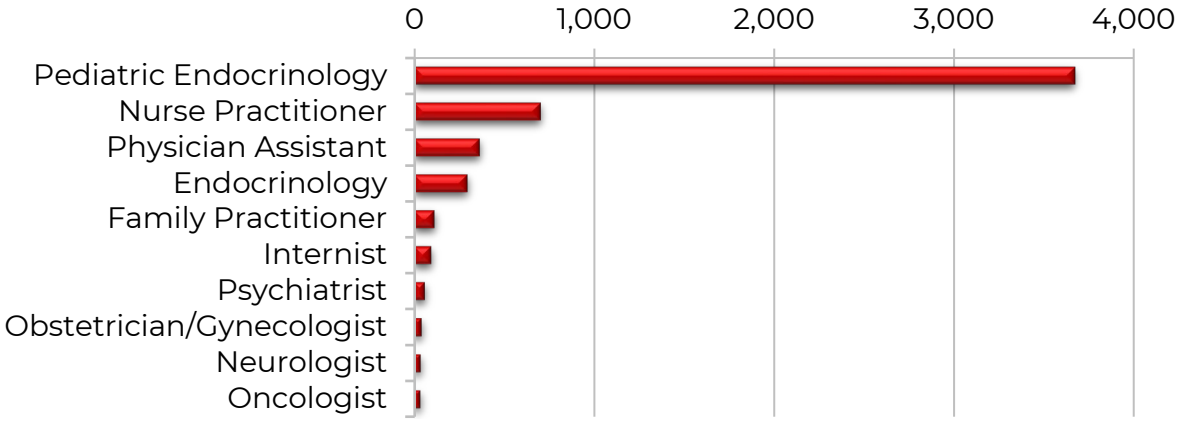
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	67	212	$941,739.94	$4,442.17	3.16
Aetna	3	6	$34,868.80	$5,811.47	2
Humana	1	2	$11,625.60	$5,812.80	2
OCH	1	2	$12,568.80	$6,284.40	2
2024 Total	**67**	**222**	**$1,000,803.14**	**$4,508.12**	**3.31**
Fiscal Year 2025					
FFS	35	97	$296,495.68	$3,056.66	2.77
Aetna	11	54	$258,583.20	$4,788.58	4.91
Humana	5	19	$86,090.00	$4,531.05	3.8
OCH	14	55	$176,979.20	$3,217.80	3.93
2025 Total	**60**	**225**	**$818,148.08**	**$3,636.21**	**3.75**
% Change	**-10.45%**	**1.35%**	**-18.25%**	**-19.34%**	**13.29%**
Change	**-7**	**3**	**-$182,655.06**	**-$871.91**	**0.44**

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

Demographics of Members Utilizing Growth-Related Disorder Medications: Pharmacy Claims (All Plans)



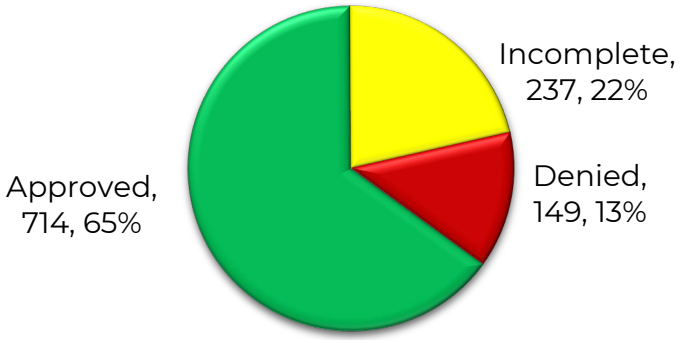
Top Prescriber Specialties of Growth-Related Disorder Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Growth-Related Disorder Medications

There were 1,100 prior authorization requests submitted for growth-related disorder medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	516	65%	207	26%	75	9%	**798**
Aetna	66	76%	10	11%	11	13%	**87**
Humana	61	84%	0	0%	12	16%	**73**
OCH	71	50%	20	14%	51	36%	**142**
Total	**714**	**65%**	**237**	**22%**	**149**	**13%**	**1,100**

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

Market News and Updates[1,2,3,4,5,6,7,89,10]

Anticipated Patent Expiration(s):

- Signifor® LAR (pasireotide): May 2028
- Vykat™ XR (diazoxide choline ER): November 2035
- Mycapssa® (octreotide): December 2040
- Daybue® (trofinetide): July 2042
- Voxzogo® (vosoritide): July 2042
- Palsonify™ (paltusotine): March 2044

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

- **March 2025:** The FDA approved Vykat™ XR (diazoxide choline ER) for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS).
- **July 2025:** The FDA approved Skytrofa® (lonapegsomatropin-tcgd) for a new indication for the replacement of endogenous growth hormone in adults with GHD. Previously, Skytrofa® was only FDA approved for use in pediatric patients.
- **September 2025:** The FDA approved Palsonify™ (paltusotine) for the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option.
- **December 2025:** The FDA approved Daybue® Stix (trofinetide) for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older. This is a new formulation of trofinetide available as powder packets in 5,000mg, 6,000mg, and 8,000mg strengths. The powder contained in the packets must be dissolved in cold to room temperature water or a water-based beverage (e.g., juice, tea, lemonade, limeade, liquid hydration) to form an oral solution prior to administration. The recommended dosing for Daybue® Stix is the same as the recommended dosing for Daybue® (trofinetide) oral solution, which is available in 450mL bottle. The cost of Daybue Stix is $612.28 for each 5,000mg packet, $734.73 for each 6,000mg packet, or $979.64 for each 8,000mg packet.

- **February 2026:** The FDA approved Yuviwel® (navepegritide) to increase linear growth in pediatric patients 2 years of age and older with achondroplasia with open epiphyses.
- **February 2026:** The FDA approved Sogroya® (somapacitan-beco) for 3 new pediatric indications for treatment of patients 2.5 years of age and older with: short stature born small for gestational age (SGA) and with no catch-up growth by 2 years of age, growth failure associated with Noonan syndrome (NS), and idiopathic short stature (ISS).

Pipeline:

- **Oclaiz™ (CAM2029):** CAM2029 is a long-acting subcutaneous (sub-Q) depot formulation of octreotide that is in development for the treatment of acromegaly. If approved, the manufacturer plans for the product to be available in an autoinjector for self-administration. In January 2026, Camurus announced the FDA has accepted the resubmission of the New Drug Application (NDA) for CAM2029 and has assigned a PDUFA date of June 10, 2026.

Palsonify™ (Paltusotine) Product Summary[11]

Therapeutic Class: Somatostatin receptor agonist

Indication(s): Treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option

How Supplied: 20mg and 30mg oral tablets

Dosing and Administration:

- The recommended initial dosage is 40mg [(2) 20mg tablets] once daily.
- Palsonify™ should be taken orally once daily with water on an empty stomach, at least 6 hours after a meal (e.g., after overnight fasting) and at least 1 hour before the next meal.
- During the initiation period, the dose may temporarily be reduced to 20mg once daily if needed, based on tolerability. Once adverse reactions have resolved, the 40mg once daily dose should be resumed.
- After 2 to 4 weeks on the 40mg once daily dose, the dose may be titrated to 60mg once daily based on insulin-like growth factor 1 (IGF-1) levels.
- Additional dosage modifications may be required for drug interactions, including concomitant use with strong or moderate CYP3A4 inducers or proton pump inhibitors (PPIs).

Efficacy: The efficacy of Palsonify™ was evaluated in 2 randomized, double-blind, parallel group, placebo-controlled studies (Study 1 and Study 2). Study 1 enrolled 111 patients while Study 2 enrolled 58 patients.

- Key Inclusion Criteria:
  - Study 1:
    - 18 years of age or older
    - Confirmed diagnosis of acromegaly
    - Biochemically uncontrolled at time of randomization (including patients who were treatment-naïve, off acromegaly medications for at least 4 months before screening, or washed out of treatment during screening)
  - Study 2:
    - 18 years of age or older
    - Confirmed diagnosis of acromegaly
    - Previously biochemically controlled on a stable, effective dose of octreotide or lanreotide depot injections for at least 12 weeks
- Intervention:
  - In both studies, patients were randomized 1:1 to receive paltusotine or placebo once daily. In Study 2, the first dose of the study drug was administered when the patient's next dose of octreotide or lanreotide was due.
- Primary Endpoint(s):
  - Study 1: Proportion of patients achieving biochemical control, defined as IGF-1 level ≤1x upper limit of normal (ULN) at week 24
  - Study 2: Proportion of patients with biochemical response maintenance, defined as IGF-1 ≤1x ULN at week 36
- Results:
  - Study 1: Biochemical control was achieved by 56% of patients who received paltusotine compared to 5% of patients who received placebo (P<0.0001).
  - Study 2: Biochemical response was maintained in 83% of patients who received paltusotine compared to 4% of patients who received placebo (P<0.0001).

Cost Comparison:

Product	Cost Per Unit	Cost Per Month⁺	Cost Per Year
Palsonify™ (paltusotine) 30mg tablet	**$402.75**	**$24,165.00**	**$289,980.00**
Signifor® LAR (pasireotide) 60mg vial	$21,758.90	$21,758.90	$282,865.70
Mycapssa® (octreotide DR) 20mg capsule	$126.16	$15,139.20	$181,670.40
octreotide acetate ER 20mg vial (generic)	$3,983.40	$7,966.80	$103,568.40
lanreotide acetate depot 120mg/0.5mL PFS (generic)	$8,493.12	$4,246.56	$55,205.28

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 month based on the maximum FDA approved dose for each product: 60mg daily for Palsonify™, 60mg every 4 weeks for Signifor® LAR, 80mg daily for Mycapssa®, 40mg every 4 weeks for octreotide ER, and 120mg every 4 weeks for lanreotide depot
Unit = each capsule, tablet, vial, or mL
DR = delayed-release; ER = extended-release; PFS = prefilled syringe

Vykat™ XR (Diazoxide Choline ER) Product Summary[12,13]

Indication(s): Treatment of hyperphagia in adults and pediatric patients 4 years of age and older with PWS

How Supplied: 25mg, 75mg, and 150mg extended-release tablets

Dosing and Administration:

- Administered orally once daily based on weight:

Weight	Recommended Once Daily Dosage			
	Starting Dosage Weeks 1 and 2	Titration Dosage Weeks 3 and 4	Titration Dosage Weeks 5 and 6	Target Maintenance Dosage
20kg to <30kg	25mg	50mg	75mg	100mg
30kg to <40kg	75mg	150mg	150mg	150mg
40kg to <65kg	75mg	150mg	225mg	225mg
65kg to <100kg	150mg	225mg	300mg	375mg
100kg to <135kg	150mg	300mg	375mg	450mg
≥135kg	150mg	300mg	450mg	525mg

- Tablets should be swallowed whole and should not be split, crushed, or chewed.
- Vykat™ XR should not be substituted with diazoxide oral suspension because the pharmacokinetic profiles are different.
- Prior to initiating treatment, fasting plasma glucose and hemoglobin A1C (HbA1c) should be tested, and blood glucose should be optimized in patients who have hyperglycemia.
- Treatment with Vykat™ XR may need to be interrupted, or the dosage may need to be reduced due to elevations in fasting glucose or HbA1c or if fluid overload occurs.
- Dosage reductions are also necessary for concomitant use with strong CYP1A2 inhibitors.

Efficacy: The efficacy of Vykat™ XR was evaluated primarily in a 16-week, double-blind, placebo-controlled, randomized withdrawal study period which followed an open-label study period. A total of 77 patients, who had received diazoxide choline ER for a mean duration of 3.3 years (range: 2.5 to 4.5 years) during the initial open-label study period, were included in the randomized withdrawal study.

- <u>Key Inclusion Criteria:</u>
  - Genetically confirmed diagnosis of PWS
  - Presence of hyperphagia
- <u>Intervention:</u>
  - Patients were randomized 1:1 to continue their current dose of diazoxide choline ER or to receive placebo for 16 weeks

- Primary Endpoint:
  - Change from baseline in the hyperphagia questionnaire for clinical trials (HQ-CT) total score at week 16 (score ranges from 0 to 36, with higher scores indicating greater overall severity of hyperphagic and food-related behaviors)
- Results:
  - At week 16, the HQ-CT total score least squares mean change from baseline was 2.6 in the diazoxide choline ER group vs. 7.6 in the placebo group [difference: -5.0; 95% confidence interval (CI): -8.1, -1.8; P=0.0022], indicating that there was statistically significant worsening of hyperphagia in the placebo group when compared to the group which continued use of diazoxide choline ER.

Cost: The Wholesale Acquisition Cost (WAC) is $152.44 for each 25mg tablet, $457.32 for each 75mg tablet, and $914.64 for each 150mg tablet. For a member weighing 40kg using the target maintenance dose of 225mg once daily, this would result in an estimated cost of $41,158.80 per month or $493,905.60 per year. For a member weighing ≥135kg using the maximum target maintenance dose of 525mg once daily, this would result in an estimated cost of $96,037.20 per month or $1,152,446.40 per year.

Yuviwel® (Navepegritide) Product Summary[14,15]

Therapeutic Class: C type natriuretic peptide (CNP) analog

Indication(s): To increase linear growth in pediatric patients 2 years of age and older with achondroplasia with open epiphyses

- This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

How Supplied: Supplied as a carton containing 4 kits; each kit contains:

- 1 single-dose vial (SDV) containing navepegritide as a lyophilized powder (1.3mg, 2.8mg, or 5.5mg)
- 1 prefilled diluent syringe containing 0.8mL or 1.1mL of sterile water for injection, USP
- 2 single use preparation needles (21 gauge)
- 1 single use injection syringe
- 1 single use injection needle (30 gauge)

Dosing and Administration:

- Dosing is based on body weight according to the following recommendations:

Body Weight	Weekly Dose	Injection Volume	Vial Strength for Reconstitution
8-9.9kg	0.88mg	0.4mL	1.3mg
10-13.4kg	1.2mg	0.55mL	
13.5-17.5kg	1.6mg	0.35mL	2.8mg
17.6-23kg	2.1mg	0.45mL	
23.1-30.5kg	2.8mg	0.6mL	
30.6-41.2kg	3.6mg	0.65mL	5.5mg
41.3-55.9kg	5mg	0.9mL	
56-73.5kg	6.6mg	1.2mL (use 2 kits; administer 0.6mL from each kit)	
73.6-90kg	8.8mg	1.6mL (use 2 kits; administer 0.8mL from each kit)	

- The concentration of navepegritide is 2.2mg/mL in a reconstituted 1.3mg vial; 4.6mg/mL in a reconstituted 2.8mg vial; and 5.5mg/mL in a reconstituted 5.5mg vial.
- Yuviwel® is administered once weekly by subcutaneous (sub-Q) injection into the abdominal region (2 inches from the belly button) or thighs. If a caregiver is administering Yuviwel®, sub-Q injection into the buttocks or back of the upper arm is also acceptable. Injection sites should be rotated.
- Yuviwel® should be discontinued upon confirmation of no further growth potential, indicated by closure of epiphyses.

Efficacy: The efficacy of Yuviwel® was evaluated primarily in a 52-week, randomized, double-blind, placebo-controlled trial which was followed by a single-arm 52-week open label extension (OLE) period. The trial enrolled a total of 84 patients, of which 57 received navepegritide and 27 received placebo.

- Key Inclusion Criteria:
  - Genetically confirmed diagnosis of achondroplasia
  - 2 to 11 years of age at time of screening
  - Naïve to treatment with growth-promoting agents
  - Open epiphyses
- Intervention:
  - Patients were randomized 2:1 to receive navepegritide or placebo once weekly for 52 weeks
- Primary Endpoint:
  - Annualized growth velocity (AGV) (cm/year) at week 52

- Results:
  - At week 52, the AGV was 5.9cm/year in the navepegritide group vs. 4.4cm/year in the placebo group [treatment difference: 1.5cm/year; 95% confidence interval (CI): 1.0, 1.9; P<0.0001].

Cost: The cost of Yuviwel® is not yet available.

Recommendations

The College of Pharmacy recommends the prior authorization of Palsonify™ (paltusotine), Vykat™ XR (diazoxide choline ER), and Yuviwel® (navepegritide) with the following criteria (shown in red):

Palsonify™ (Paltusotine) Approval Criteria:

1. An FDA approved diagnosis of acromegaly confirmed by 1 of the following:
   a. Serum growth hormone (GH) level >1ng/mL after a 2-hour oral glucose tolerance test (OGTT); or
   b. Elevated insulin-like growth factor 1 (IGF-1) (above the age and gender adjusted normal range); and
2. Member has had an inadequate response to surgery or is not a candidate for surgery; and
3. Member must be 18 years of age or older; and
4. Member must have a documented trial with long-acting injectable octreotide or lanreotide depot, which do not require prior authorization, with an inadequate response or a patient-specific, clinically significant reason why both of these are not appropriate for the member must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Mycapssa® (octreotide) and Signifor® LAR (pasireotide) must be provided; and
6. Must be prescribed by, or in consultation with, an endocrinologist; and
7. Initial approvals will be for the duration of 6 months. Reauthorization (for the duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment.

Vykat™ XR [Diazoxide Choline Extended-Release (ER)] Approval Criteria:

1. An FDA approved diagnosis of Prader-Willi syndrome (PWS) confirmed by chromosome analysis (results of genetic testing must be submitted); and
2. Member must be 4 years of age or older; and
3. Prescriber must confirm member has moderate to severe hyperphagia related to PWS; and
4. Must be prescribed by a geneticist, endocrinologist, psychiatrist, or other specialist with expertise in the treatment of PWS; and

5. The member's caregiver has implemented and intends to continue strategies to establish a food-secure environment (e.g., locked food storage); and
6. Prescriber must confirm the member is able to successfully swallow the number of tablets necessary to achieve the target maintenance dose; and
7. Prescriber must confirm the member does not have hepatic impairment or renal impairment; and
8. Fasting plasma glucose and HbA1c must be evaluated prior to initiating treatment with Vykat™ XR; and
    a. For members with hyperglycemia, the prescriber must confirm the member's blood glucose has been optimized prior to initiating treatment; and
    b. Prescriber must agree to monitor blood glucose and HbA1c periodically during treatment; and
9. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Vykat™ XR, and agrees to modify the dose, if necessary; and
10. Member's recent weight (taken within the past month) must be provided to authorize the appropriate amount of drug required according to package labeling; and
11. Initial approvals will be for the duration of 6 months; and
12. Subsequent approvals (for the duration of 6 months) require all the following to be met:
    a. Prescriber must verify the member is tolerating and responding well to the medication as demonstrated by an improvement in hyperphagic symptoms; and
    b. Member has been adherent to therapy; and
    c. Member's recent weight (taken within the past month) must be provided to ensure the requested dose is still appropriate for member's weight.

Yuviwel® (Navepegritide) Approval Criteria:

1. Member must have an FDA approved indication of achondroplasia; and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic mutation in the *FGFR3* gene; and
2. Member must be 2 years of age or older; and
3. Prescriber must verify member has open epiphyses; and
4. The member's baseline height (cm) and growth velocity (GV) (cm/year) must be provided; and
5. Yuviwel® must be prescribed by a geneticist, endocrinologist, or other specialist with expertise in the treatment of achondroplasia; and

6. Member's recent weight (taken within the past 3 weeks) must be provided in order to ensure appropriate dosing per package labeling; and
7. Prescriber must verify the member or member's caregiver has been counseled on proper administration and storage of Yuviwel®; and
8. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use Voxzogo® (vosoritide) must be provided; and
9. A quantity limit of 4 kits per 28 days will apply; or
    a. For members weighing ≥56kg, a quantity limit override will be approved for 8 kits per 28 days; and
10. Initial and subsequent approvals will be for the duration of 6 months. For additional approval consideration:
    a. Member's current height must be provided and must demonstrate an improvement in GV from baseline; and
    b. Member's recent weight must be provided and dosing must be appropriate; and
    c. Member should be compliant; and
    d. Prescriber must verify member still has open epiphyses; and
11. Yuviwel® will not be approved following epiphyseal closure.

Additionally, the College of Pharmacy recommends the prior authorization of Daybue® Stix (trofinetide packet) with criteria similar to Daybue® (trofinetide oral solution) with the following changes (shown in red):

Daybue® (Trofinetide Oral Solution) and Daybue® Stix (Trofinetide Packet) Approval Criteria:

1. A diagnosis of typical Rett syndrome confirmed by all of the following:
    a. Prescriber must verify all clinical diagnostic criteria are met supporting a diagnosis of typical Rett syndrome including:
        i. A period of regression followed by recovery or stabilization; and
        ii. Partial or complete loss of acquired purposeful hand skills; and
        iii. Partial or complete loss of acquired spoken language; and
        iv. Gait abnormalities (impaired/dyspraxic or absence of ability); and
        v. Stereotypic hand movements (e.g., hand wringing/squeezing, clapping/tapping, mouthing, washing/rubbing automatisms); and
        vi. Lack of brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection causing neurological problems; and

vii. Lack of grossly abnormal psychomotor development in the first 6 months of life; and

b. Genetic testing documenting a disease-causing mutation in the *MECP2* gene; and

2. Member must be 2 years of age or older; and
3. Daybue® must be prescribed by a geneticist, neurologist, or other specialist with expertise in the treatment of Rett syndrome; and
4. Prescriber must agree to counsel members and caregivers on the risks of diarrhea, weight loss, and vomiting (including aspiration and aspiration pneumonia) associated with Daybue®, and will monitor appropriately for these adverse effects; and
5. Prescriber must agree to counsel members and caregivers on proper storage and administration of Daybue®, including the use of a calibrated device for measuring each dose; and
6. Prescriber must verify the member does not have severe renal impairment; and
   a. If the member has moderate renal impairment, the prescriber must agree to reduce the dose as required in the package labeling; and
7. Member's current weight (kg) taken within the past 3 weeks must be provided on initial and subsequent prior authorization requests to ensure accurate weight-based dosing according to package labeling; and
8. Requests for Daybue® Stix packets will require a patient-specific, clinically significant reason why the member cannot use Daybue® oral solution; and
9. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for a duration of 1 year; and
10. The following quantity limits will apply:
    a. Oral Solution: A quantity limit of 3,600mL per 30 days will apply; or
    b. Packets: A quantity limit of 60 packets per 30 days will apply.

Next, the College of Pharmacy recommends updating the approval criteria for Skytrofa® (lonapegsomatropin-tcgd) and Sogroya® (somapacitan-beco) based on new FDA approved indications with the following changes (shown in red):

Skytrofa® (Lonapegsomatropin-tcgd) Approval Criteria:

1. Member must have a confirmed diagnosis of 1 of the following:
   a. Pediatric growth hormone deficiency (GHD) or panhypopituitarism meeting the initial growth hormone approval criteria (listed under "Initial Approval") for the member's specific diagnosis; ~~and~~ or

b. Adult GHD confirmed by 1 of the following:
    i. Insulin tolerance test (ITT) with peak growth hormone (GH) response <5ng/mL; or
    ii. Glucagon stimulation test (GST) with peak growth hormone (GH) response as follows:
        1. Member's recent body mass index (BMI) must be provided; and
        2. If BMI is ≤30kg/m^2: Peak GH response is ≤3ng/mL; or
        3. If BMI is >30kg/m^2: Peak GH response is ≤1ng/mL; or
    iii. ≥3 other pituitary hormone deficiencies (e.g., adrenal, thyroid, gonadal, vasopressin) with insulin-like growth factor-1 (IGF-1) standard deviation score (SDS) <-2.0; and
2. Member's weight must be ≥11.5kg; and
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and
4. Prescriber must verify the member has been counseled on proper administration and storage of Skytrofa®; and
5. Initial approvals will be as follows:
    a. For pediatric members, initial approvals will be for the 0.24mg/kg weekly dose, using the specific dose recommended in the package labeling; ~~and~~ or
    b. For adult members, initial approvals will be for 0.7mg, 1.4mg, or 2.1mg per week depending on the member's age and oral estrogen use per package labeling; and
6. Initial approvals will be for the duration of 6 months. For additional approval consideration:
    a. Dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Growth velocity should not be <2.5cm/year if not on adult dosing; and
    ~~e. Prescriber must verify member still has open epiphyses; and~~
    f. For members on adult dosing, recent IGF-1 level and SDS should be submitted and SDS should be ≤ +2; and
    g. For members initially approved as adults, the prescriber must verify the member is responding well to treatment as demonstrated by a reduction in truncal fat percentage or normalization of IGF-1 level (IGF-1 SDS of -0.5 to 1.75); and
~~7. Skytrofa® will not be approved following epiphyseal closure. Skytrofa® is contraindicated in children with closed epiphyses.~~
8. A maximum approved dose of 6.3mg per week will apply for members with adult GHD.

Sogroya® (Somapacitan-beco) Approval Criteria:

1. Member must have a confirmed diagnosis of 1 of the following:
    a. Pediatric growth hormone deficiency (GHD) or panhypopituitarism meeting all the "Initial Approval" criteria for the member's specific diagnosis; or
    b. Adult GHD confirmed by 1 of the following:
        i. Insulin tolerance test (ITT) or glucagon test with a peak growth hormone (GH) response <3ng/mL; or
        ii. ≥3 pituitary hormone deficiencies and insulin like growth factor-1 (IGF-1) standard deviation score (SDS) <-2.0; ~~and~~ or
    c. Idiopathic short stature (ISS) meeting all the "Initial Approval" criteria; or
    d. Noonan syndrome (NS) meeting all the "Initial Approval" criteria; or
    e. Small for gestational age (SGA) meeting all the "Initial Approval" criteria; and
2. Member must be 2.5 years of age or older; and
3. Sogroya® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
4. Member's baseline IGF-1 level and SDS must be provided; and
5. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and
6. Prescriber must verify the member does not have active malignancy or active proliferative or severe non-proliferative diabetic retinopathy; and
7. Prescriber must verify the member has been counseled on proper administration and storage of Sogroya®; and
8. Approval quantity will be based on the FDA approved dosing in accordance with the package labeling; and
9. Initial approvals will be for the duration of 6 months. For additional approval consideration:
    a. Dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Growth velocity should not be <2.5cm/year if not on adult dosing; and
    e. For members on adult dosing, recent IGF-1 level and SDS should be submitted and SDS should be ≤ +2; and
    f. For members initially approved as adults, the prescriber must verify the member is responding well to treatment as demonstrated by a reduction in truncal fat percentage or normalization of IGF-1 level (IGF-1 SDS of -0.5 to 1.75); and
10. A maximum approved dose of 8mg per week will apply for members with adult GHD.

Lastly, the College of Pharmacy recommends updating the initial approval criteria for growth hormone for a diagnosis of ISS to be consistent with the FDA approved age range for Sogroya® (changes shown in red):

Idiopathic Short Stature Approval Criteria:

1. Initial Approval:
    a. Member must be ~~8~~ 2.5 years of age or older; and
    b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    c. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
    d. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
    e. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
    f. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available.
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations. Treatment may continue until 1 of the following:
        i. Epiphyseal closure; or
        ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
    b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Epiphyses are open; and
    e. GV should not be <2.5cm/year.

Utilization Details of Growth-Related Disorder Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GROWTH HORMONE (GH) PRODUCTS						
TIER-1 GH PRODUCTS						
GENOTROPIN INJ 5MG	1,145	149	$4,429,881.19	$3,868.89	7.68	19.92%
GENOTROPIN INJ 12MG	1,099	139	$7,646,727.86	$6,957.90	7.91	34.38%
GENOTROPIN INJ 0.6MG	251	42	$579,111.54	$2,307.22	5.98	2.60%
GENOTROPIN INJ 0.8MG	230	32	$779,497.30	$3,389.12	7.19	3.51%
GENOTROPIN INJ 1MG	218	36	$922,578.94	$4,232.01	6.06	4.15%
GENOTROPIN INJ 1.2MG	147	22	$752,816.79	$5,121.20	6.68	3.39%
GENOTROPIN INJ 0.2MG	144	18	$116,557.10	$809.42	8	0.52%
GENOTROPIN INJ 1.4MG	123	24	$699,503.08	$5,687.02	5.13	3.15%
GENOTROPIN INJ 0.4MG	114	21	$207,822.52	$1,823.00	5.43	0.93%
GENOTROPIN INJ 1.6MG	105	17	$691,784.45	$6,588.42	6.18	3.11%
GENOTROPIN INJ 2MG	81	16	$729,297.54	$9,003.67	5.06	3.28%
GENOTROPIN INJ 1.8MG	69	16	$535,862.73	$7,766.13	4.31	2.41%
TIER-1 SUBTOTAL	**3,726**	**423***	**$18,091,441.04**	**$4,855.46**	**8.81**	**81.35%**
TIER-2 GH PRODUCTS+						
DAILY GH PRODUCTS						
NORDITROPIN INJ 15MG/1.5ML	131	20	$664,005.37	$5,068.74	6.55	2.99%
NORDITROPIN INJ 10MG/1.5ML	118	13	$428,431.29	$3,630.77	9.08	1.93%
OMNITROPE INJ 5MG/1.5ML	22	3	$70,893.21	$3,222.42	7.33	0.32%
SEROSTIM INJ 6MG	8	1	$82,759.88	$10,344.99	8	0.37%
NUTROPIN AQ INJ 10MG/2ML	5	1	$12,610.55	$2,522.11	5	0.06%
NORDITROPIN INJ 5MG/1.5ML	5	2	$6,601.80	$1,320.36	2.5	0.03%
OMNITROPE INJ 10MG/1.5ML	1	1	$3,748.26	$3,748.26	1	0.02%
DAILY GH SUBTOTAL	**290**	**39***	**$1,269,050.36**	**$4,376.04**	**7.44**	**5.71%**
WEEKLY GH PRODUCTS						
SKYTROFA INJ 7.6MG	35	7	$302,286.10	$8,636.75	5	1.36%
SOGROYA INJ 15MG/1.5ML	23	4	$197,767.86	$8,598.60	5.75	0.89%
SOGROYA INJ 10MG/1.5ML	23	4	$106,963.00	$4,650.57	5.75	0.48%
SKYTROFA INJ 6.3MG	15	4	$112,908.69	$7,527.25	3.75	0.51%
SKYTROFA INJ 5.2MG	14	3	$70,523.20	$5,037.37	4.67	0.32%
SKYTROFA INJ 11MG	14	2	$152,486.70	$10,891.91	7	0.69%
SKYTROFA INJ 9.1MG	13	2	$117,917.46	$9,070.57	6.5	0.53%
SKYTROFA INJ 3MG	10	1	$29,516.92	$2,951.69	10	0.13%
NGENLA INJ 60MG/1.2ML	5	1	$54,837.05	$10,967.41	5	0.25%
SKYTROFA INJ 4.3MG	4	2	$16,993.96	$4,248.49	2	0.08%
SKYTROFA INJ 13.3MG	1	1	$12,766.05	$12,766.05	1	0.06%
SOGROYA INJ 5MG/1.5ML	1	1	$1,476.86	$1,476.86	1	0.01%
WEEKLY GH SUBTOTAL	**158**	**23***	**$1,176,443.85**	**$7,445.85**	**6.87**	**5.29%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-2 GH SUBTOTAL	**448**	**61***	**$2,445,494.21**	**$5,458.69**	**7.34**	**11.00%**
GH SUBTOTAL	**4,174**	**472***	**$20,536,935.25**	**$4,920.20**	**8.84**	**92.34%**
ACROMEGALY PRODUCTS						
BROMOCRIPTINE PRODUCTS						
BROMOCRIPTINE TAB 2.5MG	417	89	$33,436.68	$80.18	4.69	0.15%
BROMOCRIPTINE CAP 5MG	207	37	$38,679.12	$186.86	5.59	0.17%
SUBTOTAL	**624**	**126**	**$72,115.80**	**$115.57**	**4.95**	**0.32%**
CABERGOLINE PRODUCTS						
CABERGOLINE TAB 0.5MG	543	161	$14,920.60	$27.48	3.37	0.07%
SUBTOTAL	**543**	**161**	**$14,920.60**	**$27.48**	**3.37**	**0.07%**
OCTREOTIDE PRODUCTS						
OCTREOTIDE INJ 50MCG/ML SYR	18	4	$5,126.94	$284.83	4.5	0.02%
OCTREOTIDE INJ 100MCG VIAL	15	5	$3,648.10	$243.21	3	0.02%
OCTREOTIDE INJ 50MCG/ML VIAL	6	3	$826.85	$137.81	2	0.00%
OCTREOTIDE INJ 1,000MCG/5ML VIAL	5	3	$2,279.59	$455.92	1.67	0.01%
OCTREOTIDE INJ 100MCG SYR	3	1	$1,241.31	$413.77	3	0.01%
SANDOSTATIN LAR KIT 20MG	1	1	$4,103.25	$4,103.25	1	0.02%
SANDOSTATIN INJ 50MCG/ML	1	1	$576.05	$576.05	1	0.00%
SUBTOTAL	**49**	**18**	**$17,802.09**	**$363.31**	**2.72**	**0.08%**
LANREOTIDE PRODUCTS						
SOMATULINE INJ 60MG/0.2ML	24	2	$67,662.24	$2,819.26	12	0.30%
SOMATULINE INJ 120MG/0.5ML	13	1	$72,530.13	$5,579.24	13	0.33%
SUBTOTAL	**37**	**3**	**$140,192.37**	**$3,788.98**	**12.33**	**0.63%**
PASIREOTIDE PRODUCTS						
SIGNIFOR LAR INJ 60MG	10	1	$196,471.28	$19,647.13	10	0.88%
SUBTOTAL	**10**	**1**	**$196,471.28**	**$19,647.13**	**10**	**0.88%**
ACROMEGALY SUBTOTAL	**1,263**	**287***	**$441,502.14**	**$349.57**	**4.4**	**1.99%**
OTHER GROWTH-RELATED DISORDER PRODUCTS						
DAYBUE SOL 200MG/ML	25	7	$913,924.89	$36,557.00	3.57	4.11%
VOXZOGO INJ 0.56MG	11	1	$347,051.51	$31,550.14	11	1.56%
OTHER SUBTOTAL	**36**	**8***	**$1,260,976.40**	**$35,027.12**	**4.5**	**5.67%**
TOTAL	**5,473**	**766***	**$22,239,413.79**	**$4,063.48**	**7.14**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Claims for Tier-2 GH products largely consist of claims for which SoonerCare is not the primary payer; therefore, the reimbursed amount included in the above data is not a true reflection of the cost of the medication for SoonerCare.
CAP = capsule; INJ = injection; SOL = solution; SYR = syringe; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LANREOTIDE INJ J1930	84	19	$467,435.63	$5,564.71	4.42
OCTREOTIDE INJ J2354	77	36	$0.00	$0.00	2.14
OCTREOTIDE DEPOT INJ J2353	38	8	$236,448.45	$6,222.33	4.75
LANREOTIDE (CIPLA) INJ J1932	26	5	$114,264.00	$4,394.77	5.2
TOTAL	**225**	**60**	**$818,148.08**	**$3,636.21**	**3.75**

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

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Appendix M

Fiscal Year 2025 Annual Review of Glaucoma Medications and the 30-Day Notice to Prior Authorize Zolymbus™ (Bimatoprost 0.01% Gel)

Oklahoma Health Care Authority
March 2026

Current Prior Authorization Criteria

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
Alpha-2 Adrenergic Agonists		
brimonidine (Alphagan® 0.2%)	apraclonidine (Iopidine® 0.5%, 1%)	brimonidine (Alphagan-P® 0.15%)
brimonidine (Alphagan® P 0.1%) – **Brand Preferred**		
brimonidine/timolol (Combigan® 0.2%/0.5%) – **Brand Preferred**		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		
Beta-Blockers		
betaxolol (Betoptic-S® 0.25%)	betaxolol (Betoptic® 0.5%)	timolol maleate (Istalol® 0.5%)
brimonidine/timolol (Combigan® 0.2%/0.5%) – **Brand Preferred**	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	timolol maleate (Timoptic® in Ocudose® 0.25%, 0.5%)
carteolol (Ocupress® 1%)	timolol (Betimol® 0.5%)	
dorzolamide/timolol (Cosopt® 22.3/6.8mg/mL)	timolol maleate (Timoptic-XE® 0.25%, 0.5%)	
levobunolol (Betagan® 0.5%)		
timolol maleate (Timoptic® 0.25%, 0.5%)		
Carbonic Anhydrase Inhibitors		
acetazolamide (Diamox® 500mg caps; 125mg, 250mg tabs)+	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	methazolamide (Neptazane® 25mg, 50mg tabs)+
brinzolamide (Azopt® 1%) – **Brand Preferred**		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
dorzolamide (Trusopt® 2%)		
dorzolamide/timolol (Cosopt® 22.3/6.8mg/mL)		
Cholinergic Agonists/Cholinesterase Inhibitors		
pilocarpine (Isopto® Carpine 1%, 2%, 4%)		
Prostaglandin Analogs		
bimatoprost (Lumigan® 0.01%)	bimatoprost (Lumigan® 0.03%)	latanoprost (Iyuzeh™ 0.005%)
latanoprost (Xalatan® 0.005%)		latanoprostene bunod (Vyzulta® 0.024%)
netarsudil/latanoprost (Rocklatan®)		
tafluprost (Zioptan® 0.0015%) – **Brand Preferred**		
travoprost (Travatan-Z® 0.004%) – **Brand Preferred**		
Rho Kinase Inhibitors		
netarsudil (Rhopressa® 0.02%)		
netarsudil/latanoprost (Rocklatan®)		

*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).
†Indicates available oral medications.
Please note: Combination products are included in both applicable pharmaceutical classes; therefore, combination products are listed twice in the tier chart.
caps = capsules; PA = prior authorization; tabs = tablets

Glaucoma Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have documented, recent (within the last 120 days) trials with at least 3 Tier-1 medications for a minimum of 4 weeks duration each. Tier-1 trials may be from any pharmacologic class; or
3. Approvals may be granted if there is a documented adverse effect, drug interaction, or contraindication to all Tier-1 medications; or
4. Approvals may be granted if there is a unique FDA approved indication not covered by all Tier-1 medications; and
5. Member must have had a comprehensive, dilated eye exam within the last 365-day period as recommended by the National Institutes of Health; and
6. Approvals will be for the duration of 1 year.

Glaucoma Medications Special Prior Authorization (PA) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 or Tier-2 medication must be provided; or
3. Approvals may be granted if there is a documented adverse effect, drug interaction, or contraindication to all Tier-1 and Tier-2 medications; or
4. Approvals may be granted if there is a unique FDA approved indication not covered by all Tier-1 and Tier-2 medications; and
5. Member must have had a comprehensive, dilated eye exam within the last 365-day period as recommended by the National Institutes of Health; and
6. Approvals will be for the duration of 1 year.

Durysta® (Bimatoprost Intracameral Implant) Approval Criteria:

1. An FDA approved indication to reduce intraocular pressure (IOP) in members with open-angle glaucoma (OAG) or ocular hypertension (OHT); and
2. Member must be 18 years of age or older; and
3. Durysta® must be prescribed by, or in consultation with, an ophthalmologist; and
4. A patient-specific, clinically significant reason why the member requires Durysta® and cannot utilize ophthalmic preparations, such as solution or suspension, to treat OAG or OHT must be provided; and
5. The affected eye has not received prior treatment with Durysta®; and
6. Member has no contraindications to Durysta®; and
7. A quantity limit of (1) Durysta® 10mcg implant per eye per lifetime will apply.

iDose® TR (Travoprost Intracameral Implant) Approval Criteria:

1. An FDA approved indication to reduce intraocular pressure (IOP) in members with open-angle glaucoma (OAG) or ocular hypertension (OHT); and
2. Member must be 18 years of age or older; and
3. iDose® TR must be prescribed by, or in consultation with, an ophthalmologist; and
4. A patient-specific, clinically significant reason why the member requires iDose® TR and cannot utilize ophthalmic preparations, such as solution or suspension, to treat OAG or OHT must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Durysta® (bimatoprost intracameral implant) must be provided; and
6. The affected eye has not received prior treatment with iDose® TR; and
7. Member has no contraindications to iDose® TR; and

8. A quantity limit of (1) iDose® TR 75mcg implant per eye per lifetime will apply.

Utilization of Glaucoma Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	2,355	9,386	$684,139.37	$72.89	$1.69	135,480	404,752
Aetna	202	390	$27,808.32	$71.30	$1.67	6,039	16,610
Humana	270	484	$27,549.67	$56.92	$1.39	7,959	19,776
OCH	170	297	$18,903.52	$63.65	$1.58	4,778	12,001
2024 Total	**2,566**	**10,557**	**$758,400.88**	**$71.84**	**$1.67**	**154,255**	**453,139**
Fiscal Year 2025							
FFS	1,384	5,865	$455,719.54	$77.70	$1.82	76,717	250,894
Aetna	476	1,581	$107,576.80	$68.04	$1.54	28,738	69,678
Humana	617	2,120	$152,462.18	$71.92	$1.64	38,783	92,997
OCH	461	1,453	$93,340.90	$64.24	$1.39	28,967	67,380
2025 Total	**2,727**	**11,019**	**$809,099.42**	**$73.43**	**$1.68**	**173,204**	**480,949**
% Change	**6.30%**	**4.40%**	**6.70%**	**2.20%**	**0.60%**	**12.30%**	**6.10%**
Change	**161**	**462**	**$50,698.54**	**$1.59**	**$0.01**	**18,949**	**27,810**

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

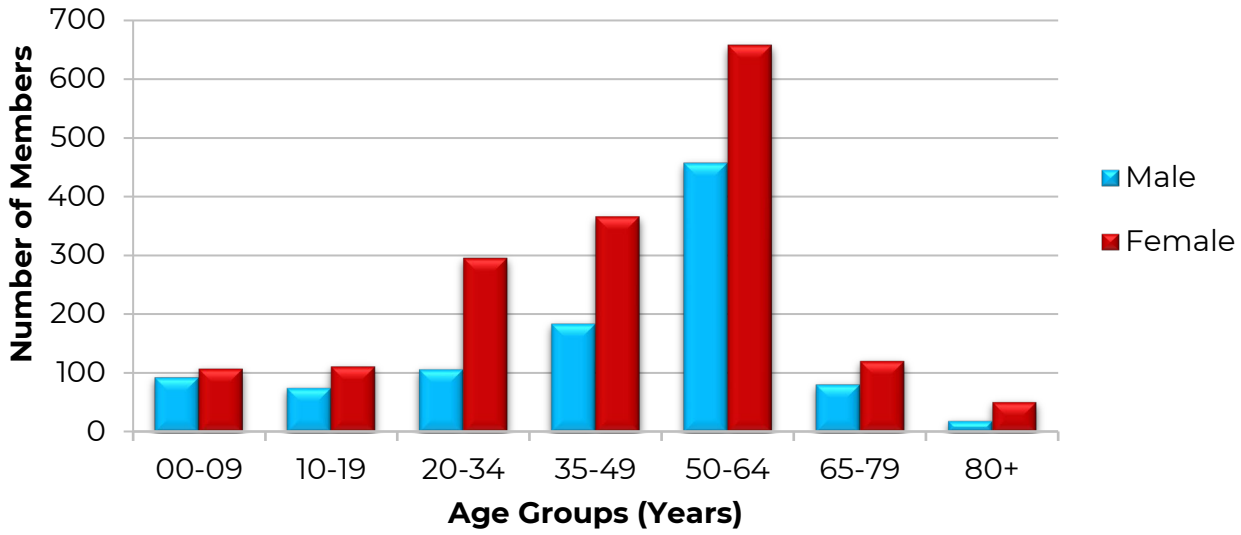
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2025					
FFS	0	0	$0.00	$0.00	0
Aetna	2	3	$4,356.47	$1,452.16	1.5
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2025 Total	**2**	**3**	**$4,356.47**	**$1,452.16**	**1.5**

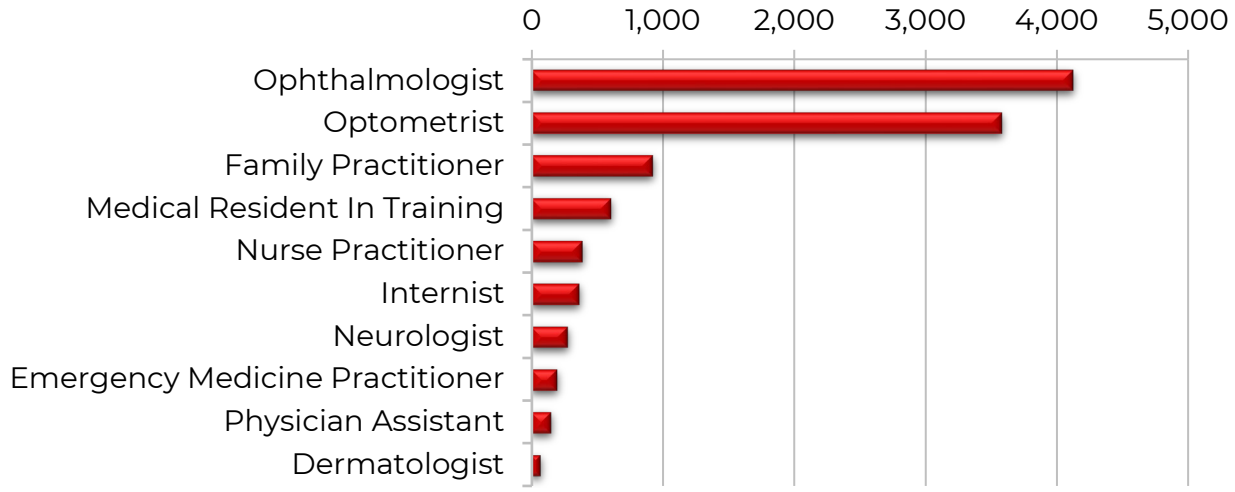
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: There were no paid medical claims during fiscal year 2024 to allow for a fiscal year comparison.

- Aggregate drug rebates collected during fiscal year 2025 for the glaucoma medications totaled $812,703.53.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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



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

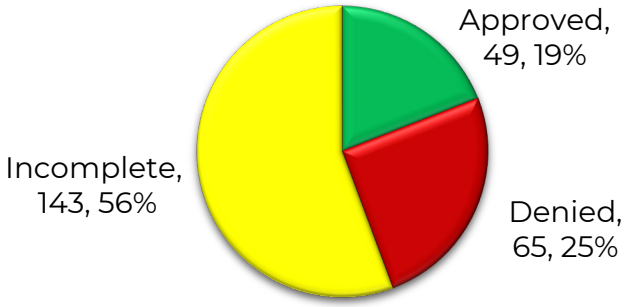


[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Prior Authorization of Glaucoma Medications

There were 257 prior authorization requests submitted for glaucoma medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	20	14%	94	68%	25	18%	**139**
Aetna	6	21%	15	52%	8	28%	**29**
Humana	4	17%	0	0%	19	83%	**23**
OCH	19	29%	34	52%	13	20%	**66**
Total	**49**	**19%**	**143**	**56%**	**65**	**25%**	**257**

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

Market News and Updates[1,2,3,4,5,6,7]

Anticipated Patent Expiration(s):

- Lumigan® (bimatoprost 0.01% solution): June 2027
- Vyzulta® (latanoprostene bunod 0.024%): February 2029
- Zioptan® (tafluprost 0.0015%): May 2029
- Simbrinza® (brinzolamide/brimonidine 0.2%/1%): October 2030
- iDose® TR (travoprost intracameral 75mcg implant): February 2031
- Iyuzeh™ (latanoprost 0.005%): July 2031
- Rhopressa® (netarsudil 0.02%): March 2034
- Rocklatan® (netarsudil/latanoprost 0.02%/0.005%): March 2034
- Durysta® (bimatoprost intracameral 10mcg implant): October 2034
- Zolymbus™ (bimatoprost 0.01% gel): June 2036

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

- **September 2025:** The FDA approved Zolymbus™ (bimatoprost ophthalmic 0.01% gel) for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT). It was approved through the 505(b)(2) pathway

and was found to be non-inferior to bimatoprost 0.01% solution during a 12-week trial. Zolymbus™ is preservative free and is administered once daily. The cost information for Zolymbus™ (bimatoprost ophthalmic 0.01% gel) is currently not available.

- **January 2026:** The FDA approved a supplemental New Drug Application (sNDA) for iDose® TR (travoprost) to allow for re-administration of iDose® TR in patients who maintain a healthy cornea, as defined by corneal endothelial cell density parameters. The long-term safety data showed no clinically significant corneal endothelial cell loss observed through 3 years across clinical trials. Additionally, the data from the iDose® TR exchange trial showed a second administration and removal of iDose® TR implant was safe and well tolerated, over a 12-month evaluation period.

Pipeline:

- **NCX 470 (Bimatoprost Grenod):** NCX 470 is a nitric oxide donating bimatoprost eye drop being studied for the treatment of patients with OAG or OHT. In December 2025, Nicox, the manufacturer of NCX 470, announced all clinical trial data and long-term stability data have been analyzed, and they are planning to submit a New Drug Application (NDA) to the FDA in the first half of 2026.

Recommendations

The College of Pharmacy recommends the following changes to the current Glaucoma Medications Product Based Prior Authorization (PBPA) category based on the new FDA approval and net costs (changes shown in red):

1. The prior authorization of Zolymbus™ (bimatoprost 0.01% gel) and placement into the Special PA Tier; and
2. Moving Betimol® (timolol 0.5%) from Tier-2 to the Special PA Tier; and
3. Moving Istalol® (timolol maleate 0.5%) from the Special PA Tier to Tier-2.

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
Alpha-2 Adrenergic Agonists		
brimonidine (Alphagan® 0.2%)	apraclonidine (Iopidine® 0.5%, 1%)	brimonidine (Alphagan-P® 0.15%)
brimonidine (Alphagan® P 0.1%) – **Brand Preferred**		
brimonidine/timolol (Combigan® 0.2%/0.5%) – **Brand Preferred**		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		
Beta-Blockers		

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
betaxolol (Betoptic-S® 0.25%)	betaxolol (Betoptic® 0.5%)	**timolol (Betimol® 0.5%)**
brimonidine/timolol (Combigan® 0.2%/0.5%) – **Brand Preferred**	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	~~**timolol maleate (Istalol® 0.5%)**~~
carteolol (Ocupress® 1%)	~~**timolol (Betimol® 0.5%)**~~	timolol maleate (Timoptic® in Ocudose® 0.25%, 0.5%)
dorzolamide/timolol (Cosopt® 22.3/6.8mg/mL)	**timolol maleate (Istalol® 0.5%)**	
levobunolol (Betagan® 0.5%)	timolol maleate (Timoptic-XE® 0.25%, 0.5%)	
timolol maleate (Timoptic® 0.25%, 0.5%)		
Carbonic Anhydrase Inhibitors		
acetazolamide (Diamox® 500mg caps; 125mg, 250mg tabs)+	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	methazolamide (Neptazane® 25mg, 50mg tabs)+
brinzolamide (Azopt® 1%) – **Brand Preferred**		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		
dorzolamide (Trusopt® 2%)		
dorzolamide/timolol (Cosopt® 22.3/6.8mg/mL)		
Cholinergic Agonists/Cholinesterase Inhibitors		
pilocarpine (Isopto® Carpine 1%, 2%, 4%)		
Prostaglandin Analogs		
bimatoprost (Lumigan® 0.01%)	bimatoprost (Lumigan® 0.03%)	**bimatoprost gel (Zolymbus™ 0.01%)**
latanoprost (Xalatan® 0.005%)		latanoprost (Iyuzeh™ 0.005%)
netarsudil/latanoprost (Rocklatan®)		latanoprostene bunod (Vyzulta® 0.024%)
tafluprost (Zioptan® 0.0015%) – **Brand Preferred**		
travoprost (Travatan-Z® 0.004%) – **Brand Preferred**		
Rho Kinase Inhibitors		
netarsudil (Rhopressa® 0.02%)		

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
netarsudil/latanoprost (Rocklatan®)		

*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).
†Indicates available oral medications.
Please note: Combination products are included in both applicable pharmaceutical classes; therefore, combination products are listed twice in the tier chart.
caps = capsules; PA = prior authorization; tabs = tablets

The College of Pharmacy also recommends updating the prior authorization criteria for iDose® TR (travoprost intracameral implant) based on the FDA label update (changes shown in red):

iDose® TR (Travoprost Intracameral Implant) Approval Criteria:

1. An FDA approved indication to reduce intraocular pressure (IOP) in members with open-angle glaucoma (OAG) or ocular hypertension (OHT); and
2. Member must be 18 years of age or older; and
3. iDose® TR must be prescribed by, or in consultation with, an ophthalmologist; and
4. A patient-specific, clinically significant reason why the member requires iDose® TR and cannot utilize ophthalmic preparations, such as solution or suspension, to treat OAG or OHT must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Durysta® (bimatoprost intracameral implant) must be provided; and
6. ~~The affected eye has not received prior treatment with iDose® TR; and~~
7. Member has no contraindications to iDose® TR; and
8. A quantity limit of (1) iDose® TR 75mcg implant per eye per ~~lifetime~~ year will apply; and
9. For reauthorization, the prescriber must verify the member is an appropriate candidate for re-administration of iDose® TR based on corneal endothelial cell density parameters defined in the package labeling.

Utilization Details of Glaucoma Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
LATANOPROST SOL 0.005%	3,625	1,110	$57,971.19	$15.99	3.27	7.16%
BRIMONIDINE SOL 0.2% OP	1,284	541	$19,890.91	$15.49	2.37	2.46%
DORZOL/TIMOL SOL 22.3-6.8MG/ML	1,270	432	$27,445.79	$21.61	2.94	3.39%
TIMOLOL MAL SOL 0.5% OP	1,213	535	$20,619.27	$17.00	2.27	2.55%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ACETAZOLAMIDE TAB 250MG	652	225	$15,710.53	$24.10	2.9	1.94%
ACETAZOLAMIDE CAP 500MG ER	482	159	$14,216.13	$29.49	3.03	1.76%
LUMIGAN SOL 0.01% OP	438	161	$209,904.86	$479.23	2.72	25.94%
COMBIGAN SOL 0.2%/0.5%	359	117	$122,210.84	$340.42	3.07	15.10%
DORZOLAMIDE SOL 2% OP	326	119	$7,694.91	$23.60	2.74	0.95%
TRAVATAN Z DRO 0.004%	202	51	$72,445.24	$358.64	3.96	8.95%
ACETAZOLAMIDE TAB 125MG	179	61	$3,416.94	$19.09	2.93	0.42%
SIMBRINZA SUS 1%/0.2%	164	58	$37,625.34	$229.42	2.83	4.65%
RHOPRESSA SOL 0.02%	161	48	$66,445.55	$412.71	3.35	8.21%
ALPHAGAN P SOL 0.1% OP	131	39	$34,495.78	$263.33	3.36	4.26%
ROCKLATAN DRO 0.02%/0.005%	92	25	$38,460.82	$418.05	3.68	4.75%
TIMOLOL MAL SOL 0.25% OP	81	55	$1,313.02	$16.21	1.47	0.16%
AZOPT SUS 1% OP	49	11	$18,669.82	$381.02	4.45	2.31%
BRIMO/TIMOL SOL 0.2%/0.5%	25	14	$1,936.24	$77.45	1.79	0.24%
ZIOPTAN DRO 0.0015%	21	4	$5,559.05	$264.72	5.25	0.69%
PILOCARPINE SOL 1% OP	17	11	$932.84	$54.87	1.55	0.12%
TRAVOPROST DRO 0.004%	9	4	$590.62	$65.62	2.25	0.07%
PILOCARPINE SOL 2% OP	8	3	$485.00	$60.63	2.67	0.06%
PILOCARPINE SOL 4% OP	4	1	$231.05	$57.76	4	0.03%
BETOPTIC-S SUS 0.25% OP	4	1	$1,673.36	$418.34	4	0.21%
SUBTOTAL	**10,796**	**3,785**	**$779,945.10**	**$72.24**	**2.85**	**96.40%**
TIER-2 PRODUCTS						
TIMOLOL GEL SOL 0.5% OP	65	37	$4,387.94	$67.51	1.76	0.54%
DORZOL/TIMOL SOL 2%-0.5% PF	42	6	$3,733.52	$88.89	7	0.46%
BIMATOPROST SOL 0.03% OP	26	9	$1,960.58	$75.41	2.89	0.24%
TIMOLOL HEMI SOL 0.5% OP	5	4	$728.49	$145.70	1.25	0.09%
TIMOLOL GEL SOL 0.25% OP	2	2	$238.65	$119.33	1	0.03%
SUBTOTAL	**140**	**58**	**$11,049.18**	**$78.92**	**2.41**	**1.37%**
SPECIAL PA PRODUCTS						
VYZULTA SOL 0.024%	31	8	$11,956.83	$385.70	3.88	1.48%
BRIMONIDINE SOL 0.15% OP	22	5	$2,203.29	$100.15	4.4	0.27%
METHAZOLAMIDE TAB 50MG	19	5	$1,816.55	$95.61	3.8	0.22%
METHAZOLAMIDE TAB 25MG	6	1	$676.06	$112.68	6	0.08%
IYUZEH DRO 0.005%	4	2	$1,245.73	$311.43	2	0.15%
ALPHAGAN P SOL 0.15% OP	1	1	$206.68	$206.68	1	0.03%
SUBTOTAL	**83**	**22**	**$18,105.14**	**$218.13**	**3.77**	**2.24%**
TOTAL	**11,019**	**2,727***	**$809,099.42**	**$73.43**	**4.04**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
BRIMO = brimonidine; CAP = capsule; DORZOL= dorzolamide; DRO = drop; ER = extended-release; HEMI = hemihydrate; MAL = maleate; OP = ophthalmic; PA = prior authorization; PF = preservative free; SOL = solution; SUS = suspension; TAB = tablet; TIMOL = timolol
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS[+]	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
DURYSTA (J7351)	3	2	$4,356.47	$1,452.16	1.5
TOTAL	**3**	**2**	**$4,356.47**	**$1,452.16**	**1.5**

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

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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 02/2026. Last accessed 02/23/2026.
[2] Zolymbus™ (Bimatoprost)—New Drug Approval. *OptumRx®*. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/drug-approvals/drugapproval-zolymbus-091125.pdf. Issued 09/09/2025. Last accessed 02/23/2026.
[3] U.S. FDA. Zolymbus™ (Bimatoprost) Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/217307Orig1s000ltr.pdf. Issued 09/09/2025. Last accessed 02/23/2026.
[4] Zolymbus™ (Bimatoprost) Prescribing Information. Thea Pharma Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/217307s000lbl.pdf. Last revised 09/2025. Last accessed 02/23/2026.
[5] Glaukos. Glaukos Announces US FDA Approval of NDA Supplement Allowing for Re-Administration of iDose® TR. Available online at: https://investors.glaukos.com/news/news-details/2026/Glaukos-Announces-US-FDA-Approval-of-NDA-Supplement-Allowing-for-Re-Administration-of-iDose-TR/default.aspx. Issued 01/28/2026. Last accessed 02/23/2026.
[6] iDose® TR (Travoprost Intracameral Implant) Prescribing Information. Glaukos Corp. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/218010s004lbl.pdf. Last revised 01/2026. Last accessed 02/23/2026.
[7] Nicox. Nicox Completes NCX 470 New Drug Application Key Data Generation for Submission as Planned in H1 2026. Available online at: https://www.nicox.com/wp-content/uploads/EN_NCX470NDADataGenerationDecember2025_FINAL.pdf. Issued 12/16/2025. Last accessed 02/23/2026.

Appendix N

Fiscal Year 2025 Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers and 30-Day Notice to Prior Authorize Nypozi™ (Filgrastim-txid)

Oklahoma Health Care Authority
March 2026

Current Prior Authorization Criteria

Aphexda® (Motixafortide) Approval Criteria:

1. An FDA approved indication for use in combination with filgrastim to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in members with multiple myeloma (MM); and
2. Member must have an oncology diagnosis of MM. This medication is not covered for the diagnosis of leukemia; and
3. Aphexda® must be prescribed by an oncologist; and
4. Member must be 18 years of age or older; and
5. Aphexda® must be given in combination with the granulocyte-colony stimulating factor (G-CSF) filgrastim per package labeling; and
6. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use generic plerixafor must be provided; and
7. The following dosing restrictions will apply (current body weight in kilograms is required):
    a. Recommended dose is 1.25mg/kg actual body weight by subcutaneous injection 10 to 14 hours prior to initiation of apheresis; and
    b. A second dose of Aphexda® can be administered 10 to 14 hours prior to a third apheresis if necessary; and
8. Approvals will be for 2 cycles for the duration of 2 months.

Mozobil® (Plerixafor) Approval Criteria:

1. An FDA approved indication for use in combination with filgrastim to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in members with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM); and
2. Member must have an oncology diagnosis of NHL or MM. This medication is not covered for the diagnosis of leukemia; and
3. Mozobil® must be prescribed by an oncologist; and
4. Member must be 18 years of age or older; and

5. Mozobil® must be used in combination with the granulocyte-colony stimulating factor (G-CSF) filgrastim per package labeling; and
6. The following dosing restrictions will apply (current body weight in kilograms is required):
    a. Recommended dose is 0.24mg/kg (maximum dose is 40mg/day) administered 11 hours prior to apheresis for up to 4 consecutive days; or
    b. For members with renal impairment (creatinine clearance ≤50mL/min), the recommended dose is 0.16mg/kg (maximum dose is 27mg/day); and
7. Approvals will be for 2 cycles for the duration of 2 months.

Neulasta® (Pegfilgrastim), Stimufend® (Pegfilgrastim-fpgk), and Udenyca® (Pegfilgrastim-cbqv) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fulphila® (pegfilgrastim-jmdb), Fylnetra® (pegfilgrastim-pbbk), Neulasta® Onpro® (pegfilgrastim), Nyvepria® (pegfilgrastim-apgf), or Ziextenzo® (pegfilgrastim-bmez) 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. Neulasta® Onpro® (pegfilgrastim) and Nyvepria® (pegfilgrastim-apgf) will be covered as a medical only benefit without prior authorization.

Nivestym® (Filgrastim-aafi) and Releuko® (Filgrastim-ayow) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Granix® (tbo-filgrastim), Neupogen® (filgrastim), or Zarxio® (filgrastim-sndz) 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.

Rolvedon® (Eflapegrastim-xnst) and Ryzneuta® (Efbemalenograstim Alfa-vuxw) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fulphila® (pegfilgrastim-jmdb), Fylnetra® (pegfilgrastim-pbbk), Neulasta® Onpro® (pegfilgrastim), Nyvepria® (pegfilgrastim-apgf), or Ziextenzo® (pegfilgrastim-bmez) must be provided; and

3. Neulasta® Onpro® (pegfilgrastim) and Nyvepria® (pegfilgrastim-apgf) will be covered as a medical only benefit without prior authorization.

Xolremdi® (Mavorixafor) Approval Criteria:

1. An FDA approved diagnosis of warts, hypogammaglobulinemia, infections, and myelokathexis (WHIM) syndrome; and
    a. Diagnosis must be confirmed by the presence of a pathogenic or likely pathogenic genotypic variant of the *CXCR4* gene (results of genetic testing must be submitted); and
2. Member must be 12 years of age or older; and
3. Must be prescribed by, or consultation with, a hematologist, immunologist, or other specialist with expertise in treatment of WHIM syndrome (or an advanced care practitioner with a supervising physician who is a hematologist, immunologist, or other specialist with expertise in treatment of WHIM syndrome); and
4. The member's recent weight (within the last 3 months) must be provided with the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
5. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must be willing to use an effective method of contraception during treatment and for at least 3 weeks after discontinuing treatment; and
6. Female members must not be breastfeeding during treatment and for at least 3 weeks after discontinuation of treatment; and
7. Prescriber must agree to counsel the member on proper administration, including taking Xolremdi® on an empty stomach after an overnight fast and at least 30 minutes before food; and
8. Prescriber must verify the member does not have severe renal impairment [creatinine clearance (CrCl) 15-30mL/min] or end-stage renal disease (CrCl <15mL/min); and
9. Provider must verify the member does not have moderate or severe hepatic impairment (Child-Pugh B or C); and
10. Prescriber must evaluate the potential for drug interactions, including the need for dose adjustments or increased monitoring of Xolremdi® or the concomitant medication(s), according to package labeling, before initiating and throughout treatment with Xolremdi®; and
11. Prescriber must verify that any modifiable risk factors for QTc prolongation (e.g., hypokalemia, hypomagnesemia) are corrected prior to initiation of therapy; and
12. Prescriber must agree to perform and monitor electrocardiogram (ECG) at baseline and as clinically indicated, thereafter, for patients with risk factors for QTc prolongation (e.g., receiving concomitant

medications with known potential to prolong the QTc interval or concomitant medications that increase Xolremdi® exposure); and

13. For members who are using Xolremdi® concomitantly with other medications that are known to increase Xolremdi® exposure and/or prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval] the prescriber must agree to monitor the member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures) and evaluate the need for a dose reduction based on clinical response; and
14. A quantity limit of 120 capsules per 30 days will apply; and
15. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment as indicated by 1 of the following:
    a. Documentation of sustained improvement in absolute neutrophil count (ANC) and/or absolute lymphocyte count (ALC) is provided; or
    b. If the member does not show a sustained improvement in ANC and/or ALC, a clinical rationale for continuation of treatment must be provided for reauthorization.

Utilization of G-CSFs and Stem Cell Mobilizers: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	107	294	$786,711.60	$2,675.89	$148.83	1,803	5,286
Aetna	8	14	$48,374.47	$3,455.32	$270.25	100	179
Humana	7	11	$24,380.21	$2,216.38	$123.13	32	198
OCH	9	13	$43,177.46	$3,321.34	$167.35	96	258
2024 Total	**121**	**332**	**$902,643.74**	**$2,718.81**	**$152.45**	**2,031**	**5,921**
Fiscal Year 2025							
FFS	57	139	$327,482.06	$2,355.99	$143.38	738	2,284
Aetna	24	52	$171,518.58	$3,298.43	$210.19	463	816
Humana	21	58	$154,966.64	$2,671.84	$213.45	202	726
OCH	28	88	$239,235.17	$2,718.58	$177.74	415	1346
2025 Total	**119**	**337**	**$893,202.45**	**$2,650.45**	**$172.70**	**1,818**	**5,172**
% Change	**-1.70%**	**1.50%**	**-1.00%**	**-2.50%**	**13.30%**	**-10.50%**	**-12.60%**
Change	**-2**	**5**	**-$9,441.29**	**-$68.36**	**$20.25**	**-213**	**-749**

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

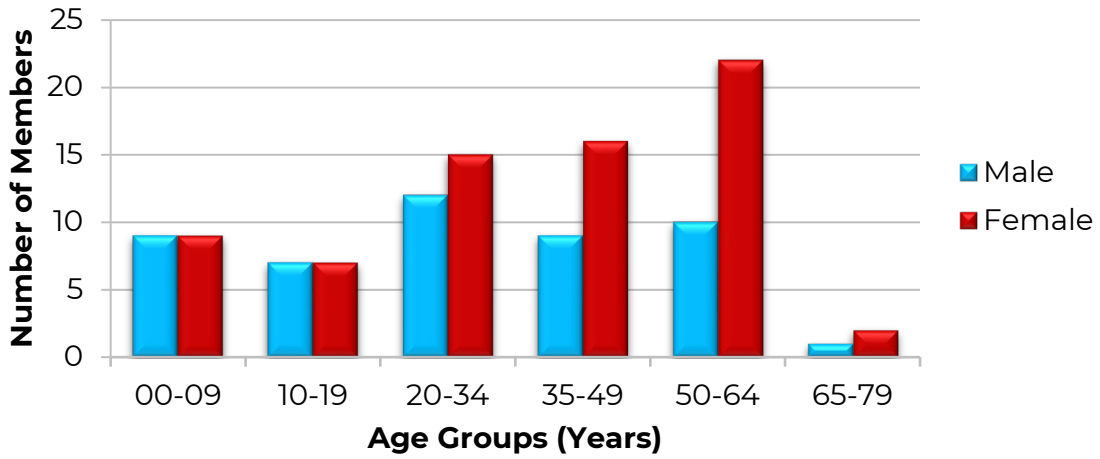
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	312	1,107	$1,675,178.67	$1,513.26	3.55
Aetna	5	19	$21,666.56	$1,140.35	3.8
Humana	11	20	$39,578.16	$1,978.91	1.82
OCH	10	19	$28,237.08	$1,486.16	1.9
2024 Total	**325**	**1,165**	**$1,764,660.47**	**$1,514.73**	**3.58**
Fiscal Year 2025					
FFS	163	495	$489,046.32	$987.97	3.04
Aetna	60	212	$253,735.56	$1,196.87	3.53
Humana	57	159	$219,697.69	$1,381.75	2.79
OCH	60	224	$269,973.15	$1,205.24	3.73
2025 Total	**311**	**1,090**	**$1,232,452.72**	**$1,130.69**	**3.5**
% Change	**-4.31%**	**-6.44%**	**-30.16%**	**-25.35%**	**-2.10%**
Change	**-14**	**-75**	**-$532,207.75**	**-$384.04**	**-7.52%**

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

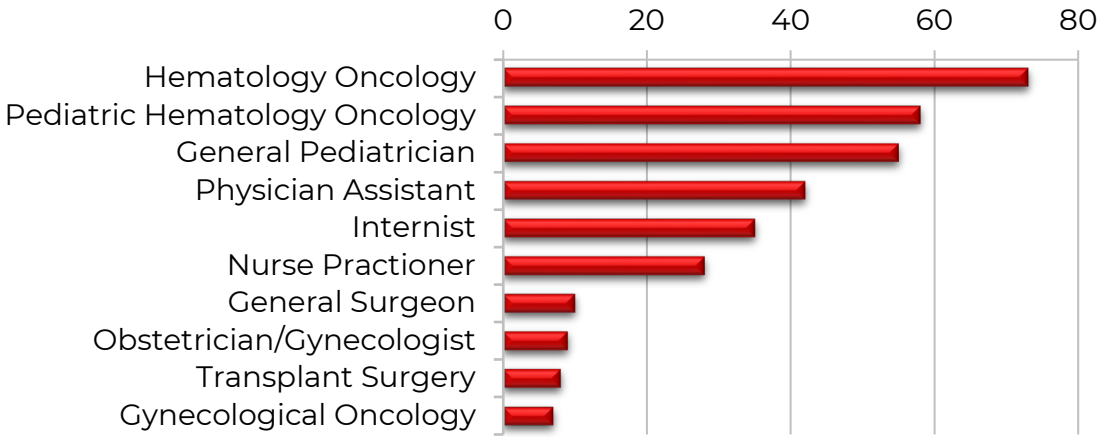
- Aggregate drug rebates collected during fiscal year 2025 for the G-CSFs and stem cell mobilizers totaled $639,672.54.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing G-CSFs and Stem Cell Mobilizers: 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.

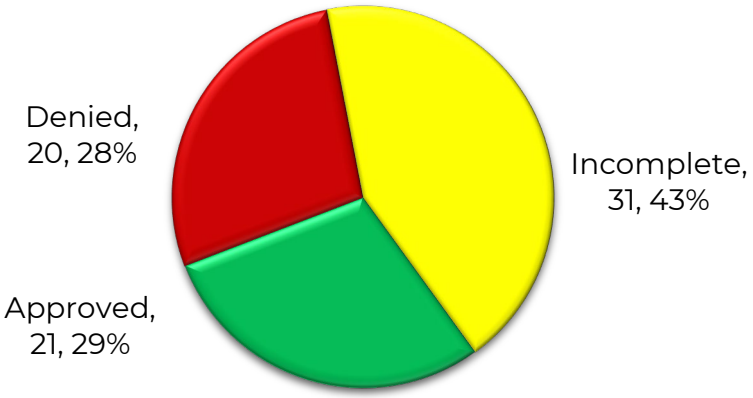
Top Prescriber Specialties of G-CSFs and Stem Cell Mobilizers by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of G-CSFs and Stem Cell Mobilizers

There were 72 prior authorization requests submitted for the G-CSFs and stem cell mobilizers during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	11	24%	26	58%	8	18%	**45**
Aetna	2	29%	2	29%	3	43%	**7**
Humana	6	75%	0	0%	2	25%	**8**
OCH	2	17%	3	25%	7	58%	**12**
Total	**21**	**29%**	**31**	**43%**	**20**	**28%**	**72**

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

Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Aphexda® (motixafortide): September 2030
- Xolremdi® (mavorixafor): December 2038

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

- **June 2024:** The FDA approved Nypozi™ (filgrastim-txid) as a biosimilar to Neupogen® (filgrastim) for the same FDA-approved indications. According to the FDA's National Drug Code (NDC) Directory, Nypozi™, a biosimilar of Neupogen® (filgrastim), began being marketed in September 2025.

Recommendations

The College of Pharmacy recommends the prior authorization of Nypozi™ (filgrastim-txid) with the following criteria (changes shown in red):

Nivestym® (Filgrastim-aafi), Nypozi™ (Filgrastim-txid), and Releuko® (Filgrastim-ayow) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Granix® (tbo-filgrastim), Neupogen® (filgrastim), or Zarxio® (filgrastim-sndz) 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.

The College of Pharmacy also recommends updating the approval criteria for the pegfilgrastim products based on net costs (changes shown in red):

~~**Neulasta® (Pegfilgrastim),**~~ **Nyvepria® (Pegfilgrastim-apgf), Stimufend® (Pegfilgrastim-fpgk), and Udenyca® (Pegfilgrastim-cbqv) Approval Criteria:**

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fulphila® (pegfilgrastim-jmdb), Fylnetra® (pegfilgrastim-pbbk), Neulasta® (pegfilgrastim), Neulasta® Onpro® (pegfilgrastim), ~~Nyvepria® (pegfilgrastim-apgf),~~ or Ziextenzo® (pegfilgrastim-bmez) 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. Neulasta® Onpro® (pegfilgrastim) ~~and Nyvepria® (pegfilgrastim-apgf)~~ will be covered as a medical only benefit without prior authorization.

Lastly, the College of Pharmacy recommends updating the approval criteria for Rolvedon® (elfapegrastim-xnst) and Ryzneuta® (efbemalenograstim alfa-vuxw) based on net costs (changes shown in red):

Rolvedon® (Eflapegrastim-xnst) and Ryzneuta® (Efbemalenograstim Alfa-vuxw) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fulphila® (pegfilgrastim-jmdb), Fylnetra® (pegfilgrastim-pbbk), Neulasta® (pegfilgrastim), Neulasta® Onpro® (pegfilgrastim), ~~Nyvepria® (pegfilgrastim-apgf),~~ or Ziextenzo® (pegfilgrastim-bmez) must be provided; and
3. Neulasta® Onpro® (pegfilgrastim) ~~and Nyvepria® (pegfilgrastim-apgf)~~ will be covered as a medical only benefit without prior authorization.

Utilization Details of G-CSFs and Stem Cell Mobilizers: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FILGRASTIM PRODUCTS						
NEUPOGEN INJ 300MCG/ML	73	13	$370,445.81	$5,074.60	5.62	41.47%
GRANIX INJ 480MCG/0.8ML	19	9	$30,878.26	$1,625.17	2.11	3.46%
NEUPOGEN INJ 480MCG/ML	15	13	$32,596.67	$2,173.11	1.15	3.65%
ZARXIO INJ 480MCG/0.8ML	15	12	$20,459.57	$1,363.97	1.25	2.29%
ZARXIO INJ 300MCG/0.5ML	14	12	$12,387.24	$884.80	1.17	1.39%
NEUPOGEN INJ 300MCG/0.5ML	13	11	$20,940.83	$1,610.83	1.18	2.34%
GRANIX INJ 300MCG/0.5ML	7	6	$7,599.67	$1,085.67	1.17	0.85%
NIVESTYM INJ 300MCG/0.5ML	2	1	$2,650.82	$1,325.41	2	0.30%
NIVESTYM INJ 480MCG/0.8ML	2	1	$2,410.82	$1,205.41	2	0.27%
SUBTOTAL	**160**	**78**	**$500,369.69**	**$3,127.31**	**2.05**	**56.02%**
PEGFILGRASTIM PRODUCTS						
FULPHILA INJ 6MG/0.6ML	158	49	$335,883.13	$2,125.84	3.22	37.60%
FYLNETRA INJ 6MG/0.6ML	18	6	$45,201.38	$2,511.19	3	5.06%
NEULASTA INJ 6MG/0.6ML	1	1	$11,748.25	$11,748.25	1	1.32%
SUBTOTAL	**177**	**56**	**$392,832.76**	**$2,219.39**	**3.16**	**43.98%**
TOTAL	**337**	**119***	**$893,202.45**	**$2,650.45**	**2.83**	**100%**

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

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PEGFILGRASTIM PRODUCTS					
PEGFILGRASTIM-JMDB INJ (Q5108)	505	159	$778,811.22	$1,542.20	3.18
PEGFILGRASTIM INJ (J2506)	271	86	$113,026.20	$417.07	3.15
PEGFILGRASTIM-PBBK INJ (Q5130)	128	39	$284,928.12	$2,226.00	3.28
PEGFILGRASTIM-APGF INJ (Q5122)	4	1	$5,823.36	$1,455.84	4
PEGFILGRASTIM-CBQV (Q5111)	2	1	$2,024.52	$1,012.26	2
SUBTOTAL	**910**	**286**	**$1,184,613.42**	**$1,301.77**	**3.18**
FILGRASTIM PRODUCTS					
FILGRASTIM-SNDZ INJ (Q5101)	99	21	$13,939.18	$140.80	4.7
FILGRASTIM INJ (J1442)	35	8	$14,670.26	$419.15	4.4
TBO-FILGRASTIM INJ (J1447)	26	6	$4,437.00	$170.65	4.3
FILGRASTIM-AAFI INJ (Q5110)	7	1	$907.20	$129.60	7
SUBTOTAL	**167**	**36**	**$33,953.64**	**$203.32**	**4.64**
PLERIXAFOR PRODUCTS					
PLERIXAFOR INJ (J2562)	11	6	$7,879.66	$716.33	1.83
SUBTOTAL	**11**	**6**	**$7,879.66**	**$716.33**	**1.83**
EFLAPEGRASTIM PRODUCTS					
EFLAPEGRASTIM-XNST INJ (J1449)	2	1	$6,006.00	$3,003.00	2
SUBTOTAL	**2**	**1**	**$6,006.00**	**$3,003.00**	**2**
TOTAL	**1,090⁺**	**311***	**$1,232,452.72**	**$1,130.69**	**3.5**

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

[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 02/2026. Last accessed 02/13/2026.
[2] Nypozi™ (Filgrastim-txid) – New Biosimilar Approval. *OptumRx®*. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/drug-approvals/drugapproval_nypozi_2024-0703.pdf. Issued 06/28/2024. Last accessed 02/24/2026.
[3] U.S. FDA. National Drug Code Directory. Available online at: https://www.accessdata.fda.gov/scripts/cder/ndc/. Last accessed 02/13/2026.

Appendix O

Fiscal Year 2025 Annual Review of Dry Eye Disease (DED) Medications and 30-Day Notice to Prior Authorize Tryptyr® (Acoltremon 0.003% Ophthalmic Solution)

Oklahoma Health Care Authority
March 2026

Current Prior Authorization Criteria

Cequa® (Cyclosporine 0.09% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication to increase tear production in members with keratoconjunctivitis sicca (dry eye); and
2. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided; and
4. A quantity limit of 60 single-use vials (1 box) per 30 days will apply.

Eysuvis® (Loteprednol Etabonate 0.25% Ophthalmic Suspension) Approval Criteria:

1. An FDA approved indication for the short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease (DED); and
2. A documented trial of intermittent or regular artificial tear use within the past 3 months; and
3. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine 0.05% ophthalmic emulsion), which is available without a prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use Tier-1 ophthalmic corticosteroids including Lotemax® (loteprednol 0.5% suspension) must be provided; and
5. Member must not have any contraindications to Eysuvis®; and
6. A quantity limit of 8.3mL per 15 days will apply (Eysuvis® for the treatment of DED is not indicated for use beyond 15 days).

Miebo® (Perfluorohexyloctane Ophthalmic Solution) Approval Criteria:

1. An FDA approved diagnosis of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and

4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without a prior authorization, and Xiidra® (lifitegrast ophthalmic solution) must be provided; and
6. A quantity limit of 12mL per 30 days will apply.

Restasis MultiDose® (Cyclosporine 0.05% Ophthalmic Emulsion) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Restasis® in the individual dosage formulation (single-use vials), which is available without a prior authorization, must be provided; and
2. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided.

Tyrvaya® (Varenicline Nasal Spray) Approval Criteria:

1. An FDA approved indication for the treatment of the signs and symptoms of dry eye disease (DED) in members 18 years of age or older; and
2. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
3. Member must have trials with at least 3 over-the-counter (OTC) products for at least 3 days in duration (per product) in the last 30 days that failed to relieve signs and symptoms of DED; and
4. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use all available ophthalmic preparations for the treatment of DED must be provided; and
6. A quantity limit of 8.4mL (2 bottles) per 30 days will apply.

Vevye® (Cyclosporine 0.1% Solution) Approval Criteria:

1. An FDA approved diagnosis of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine ophthalmic emulsion) single-use vials,

which are available without prior authorization, and Xiidra® (lifitegrast ophthalmic solution) must be provided; and
6. A quantity limit of 2mL per 50 days will apply.

Xiidra® (Lifitegrast 5% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication for the treatment of the signs and symptoms of dry eye disease (DED) in members 17 years of age or older; and
2. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
3. Member must have trials with at least 3 over-the-counter (OTC) products for at least 3 days in duration (per trial) in the last 30 days that failed to relieve signs and symptoms of DED; and
4. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
5. A quantity limit of 2 vials per day will apply.

Utilization of DED Medications: Fiscal Year 2025

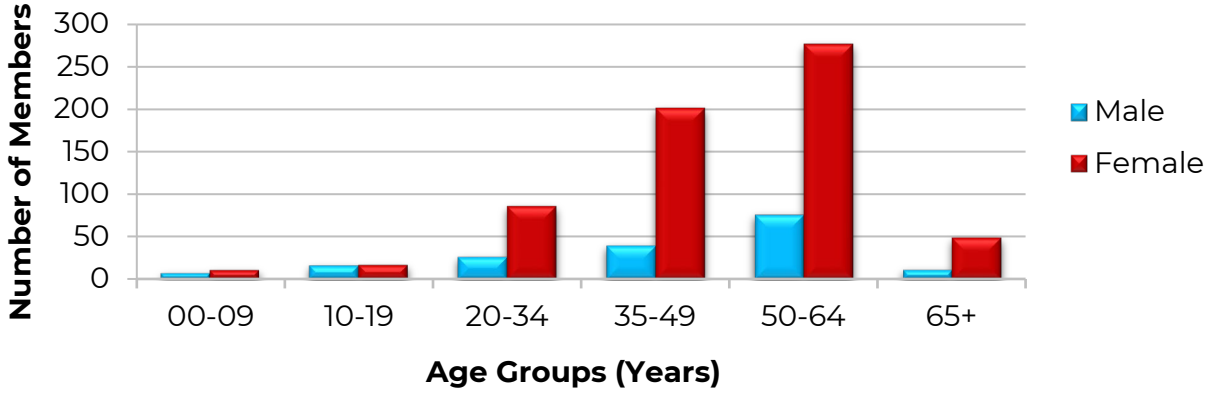
Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	585	1,529	$471,863.75	$308.61	$10.38	85,813	45,468
Aetna	57	75	$17,461.71	$232.82	$7.81	4,238	2,235
Humana	74	116	$32,671.12	$281.65	$9.74	6,630	3,353
OCH	40	57	$20,683.33	$362.87	$12.31	3,091	1,680
2024 Total	**679**	**1,777**	**$542,679.91**	**$305.39**	**$10.29**	**99,773**	**52,736**
Fiscal Year 2025							
FFS	333	948	$267,186.16	$281.84	$9.80	52,261	27,265
Aetna	147	342	$87,978.81	$257.25	$8.57	19,328	10,260
Humana	222	541	$140,212.52	$259.17	$8.63	31,148	16,256
OCH	151	328	$102,178.90	$311.52	$10.12	18,695	10,098
2025 Total	**814**	**2,159**	**$597,556.39**	**$276.77**	**$9.35**	**121,431**	**63,879**
% Change	**19.90%**	**21.50%**	**10.10%**	**-9.40%**	**-9.10%**	**21.70%**	**21.10%**
Change	**135**	**382**	**$54,876.48**	**-$28.62**	**-$0.94**	**21,658**	**11,143**

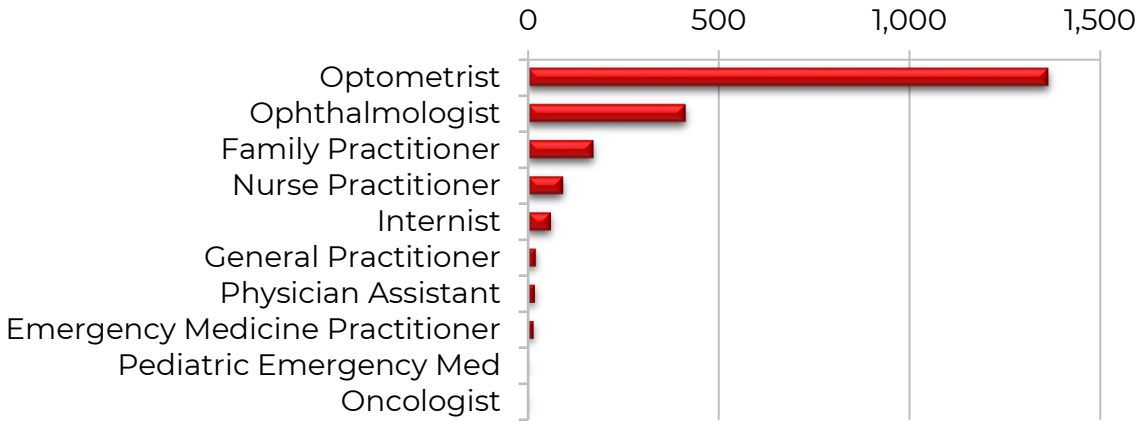
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective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

- Aggregate drug rebates collected during fiscal year 2025 for the DED medications totaled $524,135.64.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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



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

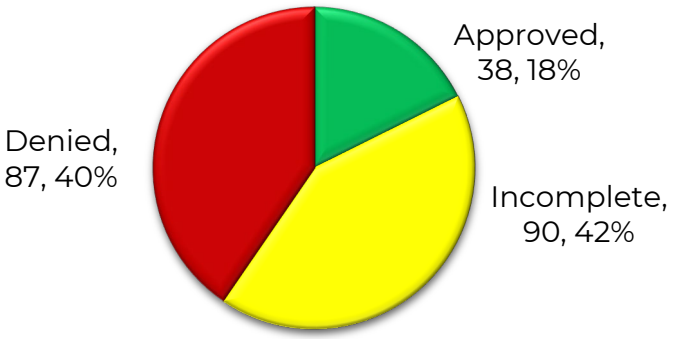


Prior Authorization of DED Medications

There were 215 prior authorization requests submitted for DED medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

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

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	17	8%	69	32%	26	12%	**112**
Aetna	7	3%	14	7%	13	6%	**34**
Humana	8	4%	0	0%	28	13%	**36**
OCH	6	3%	7	3%	20	9%	**33**
Total	**38**	**18%**	**90**	**42%**	**87**	**40%**	**215**

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

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

Anticipated Patent Expiration(s):

- Eysuvis® (loteprednol etabonate 0.25% suspension): May 2033
- Xiidra® (lifitegrast 5% solution): December 3033
- Restasis Multidose® (cyclosporine 0.05% emulsion): May 2034
- Tyrvaya® (varenicline nasal spray): October 2035
- Cequa® (cyclosporine 0.09% solution): February 2037
- Miebo® (perfluorohexyloctane solution): June 2037
- Vevye® (cyclosporine 0.1% solution): April 2042
- Tryptyr® (acoltremon 0.003% ophthalmic solution): December 2042

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

- **May 2025:** The FDA approved Tryptyr® (acoltremon 0.003% ophthalmic solution) for the treatment of the signs and symptoms of DED.

Pipeline:

- **Reproxalap:** Reproxalap 0.25% is an investigational aldehyde inhibitor being studied for the treatment of DED. Reproxalap met the primary endpoint of decreased ocular discomfort in a Phase 3 randomized, double-masked, vehicle-controlled dry eye chamber trial. The Prescription Drug User Fee Act (PDUFA) target date for reproxalap 0.25% was delayed due to the FDA's request for an additional efficacy report. The new PDUFA date is March 16, 2026.

Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) Product Summary[6]

Therapeutic Class: Ophthalmic TRPM8 thermoreceptor agonist

Indication(s): Treatment of the signs and symptoms of DED

How Supplied: One carton contains 60 single dose vials (SDVs), each containing 0.4mL of Tryptyr®. One strip is comprised of 5 SDVs packaged in a foil pouch; the carton contains 12 foil pouches.

Dosing and Administration:

- 1 drop should be instilled in each eye twice daily (approximately 12 hours apart).
- Hands should be washed prior to use.
- The SDVs are for immediate use after opening and can be utilized for both eyes.
- Concomitant eye drops should be administered 5 minutes apart.
- Contact lenses should be removed prior to administration and reinserted 15 minutes later.

Efficacy: The efficacy of Tryptyr® was evaluated in 2 prospective, randomized, multi-center, double-masked, vehicle-controlled, parallel group studies (COMET-2 and COMET-3). Use of artificial tears was not allowed during the studies.

- Key Inclusion Criteria:
  - 30 years of age and older
  - Corneal fluorescein staining score of 2-15
  - Anesthetized Schirmer tear test (2-9mm)
  - Symptom Assessment iN Dry Eye (SANDE) score ≥50
  - Ocular Discomfort Score ≥50
- Intervention(s): Patients were randomized to Tryptyr® or vehicle in a 1:1 ratio and dosed twice a day for 90 days.
- Primary Endpoint(s): An increase of ≥10mm in a 5 minute unanesthetized Schirmer tear test score on day 14
- Results:
  - COMET-2: The primary endpoint was achieved in 42.6% of patients who received Tryptyr® vs. 8.2% of patients who received vehicle [difference: 34.4%; 95% confidence interval (CI): 26.9, 42.0; P<0.01].
  - COMET-3: The primary endpoint was achieved in 53.2% of patients who received Tryptyr® vs. 14.4% of patients who received vehicle (difference: 38.8%; 95% CI: 30.8, 46.8; P<0.01).

Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days	Cost Per Year
Tryptyr® (acoltremon 0.003% sol) vial	**$14.07**	**$844.20***	**$10,130.40**
Miebo® (perfluorohexyloctane sol) multidose vial	$263.80	$3,165.60Δ	$37,987.20
Xiidra® (lifitegrast 5% sol) single-use container	$11.84	$710.40*	$8,524.80
cyclosporine 0.05% emu (generic Restasis®) vial	$1.60	$96.00*	$1,152.00

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 is based on the FDA approved dose of 1 drop twice daily in both eyes.
ΔCost per 30 days is based on the FDA approved dose of 1 drop four times daily in both eyes.
Unit = each vial, mL, or single-use container
emu = emulsion; sol = solution

Recommendations

The College of Pharmacy recommends the prior authorization of Tryptyr® (acoltremon 0.003% ophthalmic solution) with the following criteria (shown in red):

Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication to treat the signs and symptoms of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided; and
7. A quantity limit of 60 single-use vials (1 box) per 30 days will apply.

Additionally, the College of Pharmacy recommends to designate Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials as brand preferred based on net costs with the following criteria (shown in red):

Cyclosporine 0.05% Ophthalmic Emulsion (Generic Restasis® Single-Use Vials) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials must be provided.

Lastly, the College of Pharmacy recommends updating the Cequa® (cyclosporine 0.09% ophthalmic solution), Eysuvis® (loteprednol etabonate 0.25% ophthalmic suspension), Miebo® (perfluorohexyloctane ophthalmic solution), Restasis MultiDose® (cyclosporine 0.05% ophthalmic emulsion), Tyrvaya® (varenicline nasal spray), Vevye® (cyclosporine 0.1% ophthalmic solution), and Xiidra® (lifitegrast 5% ophthalmic solution) approval criteria for clarity and based on net costs (changes shown in red):

Cequa® (Cyclosporine 0.09% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication to increase tear production in members with keratoconjunctivitis sicca (dry eye); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided; and
7. A quantity limit of 60 single-use vials (1 box) per 30 days will apply.

Eysuvis® (Loteprednol Etabonate 0.25% Ophthalmic Suspension) Approval Criteria:

1. An FDA approved indication for the short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. ~~A documented trial of intermittent or regular artificial tear use within the past 3 months; and~~
4. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
5. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
6. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which ~~is~~ are available without a prior authorization, must be provided; and
7. A patient-specific, clinically significant reason why the member cannot use Tier-1 ophthalmic corticosteroids ~~including Lotemax® (loteprednol 0.5% suspension)~~ must be provided; and

8. Member must not have any contraindications to Eysuvis®; and
9. A quantity limit of 8.3mL per 15 days will apply (Eysuvis® for the treatment of DED is not indicated for use beyond 15 days).

Miebo® (Perfluorohexyloctane Ophthalmic Solution) Approval Criteria:

1. An FDA approved diagnosis of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use Tryptyr® (acoltremon ophthalmic solution) and Xiidra® (lifitegrast ophthalmic solution) must be provided; and
7. A quantity limit of 12mL per 30 days will apply.

Restasis MultiDose® (Cyclosporine 0.05% Ophthalmic Emulsion) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® in the individual dosage formulation (single-use vials), which is available without a prior authorization, must be provided; and
2. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided.

Tyrvaya® (Varenicline Nasal Spray) Approval Criteria:

1. An FDA approved indication for the treatment of the signs and symptoms of dry eye disease (DED) in members 18 years of age or older; and
2. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
3. Member must have trials with at least 3 over-the-counter (OTC) products for at least 3 days in duration (per product) in the last 30 days that failed to relieve signs and symptoms of DED; and
4. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and

5. ~~A patient-specific, clinically significant reason why the member cannot use all available ophthalmic preparations for the treatment of DED must be provided; and~~
6. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast ophthalmic solution) must be provided; and
7. A quantity limit of 8.4mL (2 bottles) per 30 days will apply.

Vevye® (Cyclosporine 0.1% Solution) Approval Criteria:

1. An FDA approved diagnosis of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without prior authorization, must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use ~~and~~ Xiidra® (lifitegrast ophthalmic solution) must be provided; and
7. A quantity limit of 2mL per 50 days will apply.

Xiidra® (Lifitegrast 5% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication for the treatment of the signs and symptoms of dry eye disease (DED) in members 17 years of age or older; and
2. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
3. Member must have trials with at least 3 over-the-counter (OTC) products for at least 3 days in duration (per trial) in the last 30 days that failed to relieve signs and symptoms of DED; and
4. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
5. A quantity limit of 2 vials per day will apply.

Utilization Details of DED Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CYCLOSPORINE PRODUCTS						
CYCLOSPORINE EMU 0.05%	1,554	643	$226,575.06	$145.80	2.42	37.92%
RESTASIS EMU 0.05% OP	424	147	$248,031.75	$584.98	2.88	41.51%
CEQUA SOL 0.09%	34	14	$20,296.77	$596.96	2.43	3.40%
VEVYE DRO 0.1%	29	12	$21,739.00	$749.62	2.42	3.64%
RESTASIS MUL EMU 0.05%	2	2	$1,260.46	$630.23	1	0.21%
SUBTOTAL	**2,043**	**818**	**$517,903.04**	**$253.50**	**2.5**	**86.67%**
LIFITEGRAST PRODUCTS						
XIIDRA DRO 5%	78	31	$52,254.21	$669.93	2.52	8.77%
SUBTOTAL	**78**	**31**	**$52,254.21**	**$669.93**	**2.52**	**8.74%**
PERFLUOROHEXYLOCTANE PRODUCTS						
MIEBO DRO 1.3GM/ML	29	13	$22,383.87	$771.86	2.23	3.76%
SUBTOTAL	**29**	**13**	**$22,383.87**	**$771.86**	**2.23**	**3.75%**
LOTEPREDNOL ETABONATE PRODUCTS						
EYSUVIS DRO 0.25%	6	3	$3,024.84	$504.14	2	0.51%
SUBTOTAL	**6**	**3**	**$3,024.84**	**$504.14**	**2**	**0.51%**
VARENICLINE PRODUCTS						
TYRVAYA SOL 0.03MG	3	3	$1,990.43	$663.48	1	0.33%
SUBTOTAL	**3**	**3**	**$1,990.43**	**$663.48**	**1**	**0.33%**
TOTAL	**2,159**	**814**	**$597,556.39**	**$276.77**	**2.65**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
EMU= emulsion; OP=ophthalmic, SOL= solution; DRO= drop, MUL=multidose
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 02/2026. Last accessed 02/24/2026.
[2] Alcon. Alcon Announces FDA Approval of Tryptyr® (Acoltremon Ophthalmic Solution) 0.003% for the Treatment of the Signs and Symptoms of Dry Eye Disease. Available online at: https://investor.alcon.com/news-and-events/press-releases/news-details/2025/Alcon-Announces-FDA-Approval-of-TRYPTYR-acoltremon-ophthalmic-solution-0-003-for-the-Treatment-of-the-Signs-and-Symptoms-of-Dry-Eye-Disease/default.aspx. Issued 05/28/2025. Last accessed 02/16/2026.
[3] National Library of Medicine. A Trial to Assess the Safety and Efficacy of Subjects With Dry Eye Disease. Available online at: https://clinicaltrials.gov/study/NCT06493604?term=NCT06493604&rank=1. Last accessed 02/24/2026.
[4] Aldeyra Therapeutics Pipeline Area. Available online at: https://www.aldeyra.com/pipeline-disease-areas/. Last accessed 02/24/2026.
[5] Aldeyra. Aldeyra Therapeutics Announces PDUFA Extension of the New Drug Application of Reproxalap for the Treatment of Dry Eye Disease. Available online at: https://ir.aldeyra.com/news-releases/news-release-details/aldeyra-therapeutics-announces-pdufa-extension-new-drug. Issued 12/15/2025. Last accessed 02/25/2026.
[6] Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) Prescribing Information. Liquidia Technologies. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/217370s000lbl.pdf. Last revised 05/2025. Last accessed 02/16/2026.

Appendix P

Fiscal Year 2025 Annual Review of Topical Antibiotic Products and 30-Day Notice to Prior Authorize Clindesse® (Clindamycin Phosphate 2% Vaginal Cream)

Oklahoma Health Care Authority
March 2026

Current Prior Authorization Criteria

Topical Antibiotic Products*	
Tier-1	**Tier-2**
gentamicin 0.1% cream (Garamycin®)	mupirocin 2% cream (Bactroban®)
gentamicin 0.1% ointment (Garamycin®)	mupirocin 2% kit (Centany®)
mupirocin 2% ointment (Bactroban®)	neomycin 0.5%/fluocinolone 0.025% cream (Neo-Synalar®)+
	ozenoxacin 1% cream (Xepi®)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
+Unique criteria apply

Topical Antibiotic Products Tier-2 Approval Criteria:

1. A documented 5-day trial of a Tier-1 product within the last 30 days; or
2. Clinical exceptions apply for adverse effects with all Tier-1 products or for a unique indication not covered by Tier-1 products; and
3. Approvals will be for the duration of 10 days.

Neo-Synalar® (Neomycin 0.5%/Fluocinolone 0.025% Cream) Approval Criteria:

1. An FDA approved diagnosis of corticosteroid-responsive dermatoses with secondary infection; and
2. A patient-specific, clinically significant reason why the member cannot use a Tier-1 topical antibiotic in combination with a Tier-1 medium to very-high potency topical corticosteroid must be provided; and
3. Approvals will be for 1 tube for the duration of 7 days.

Nuvessa® (Metronidazole 1.3% Vaginal Gel) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis in non-pregnant women; and
2. A patient-specific, clinically significant reason why the member cannot use MetroGel-Vaginal® 0.75% (metronidazole 0.75% vaginal gel) or generic metronidazole oral tablets must be provided.

Xaciato® (Clindamycin Vaginal Gel) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis; and

2. A patient specific, clinically significant reason why the member cannot use clindamycin 2% vaginal cream, Clindesse® (clindamycin phosphate 2% vaginal cream), and Cleocin® vaginal ovules (clindamycin phosphate 2.5g vaginal suppositories), which are available without a prior authorization, must be provided.

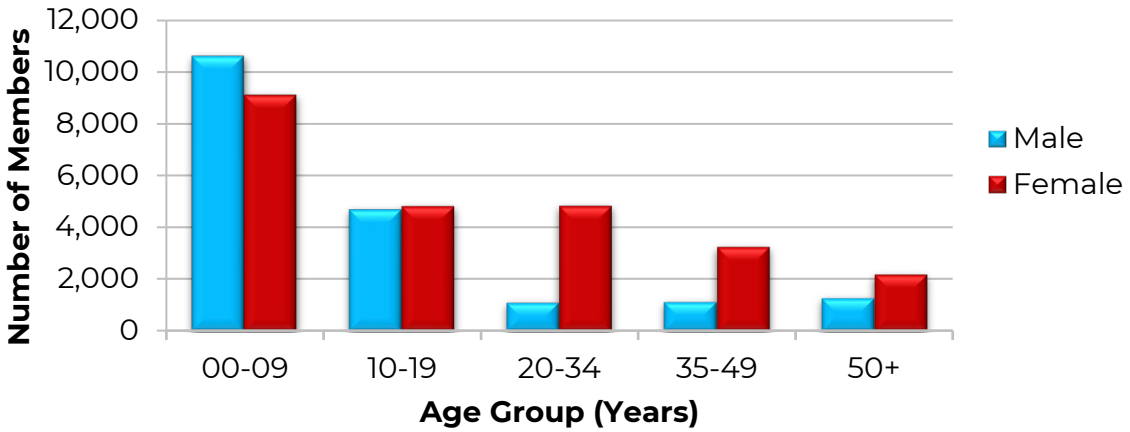
Utilization of Topical Antibiotic Products: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

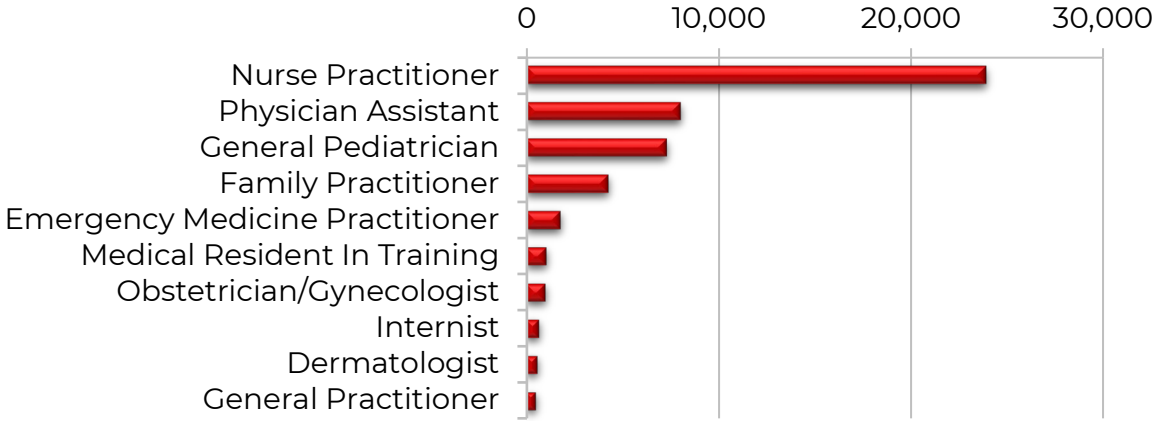
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	36,805	43,172	$810,842.26	$18.78	$1.61	1,195,192	504,657
Aetna	2,543	2,675	$47,110.88	$17.61	$1.60	70,238	29,532
Humana	2,632	2,839	$52,078.58	$18.34	$1.61	72,067	32,380
OCH	2,751	2,891	$52,025.54	$18.00	$1.59	74,314	32,748
2024 Total	**43,537**	**51,577**	**$962,057.26**	**$18.65**	**$1.61**	**1,411,811**	**599,317**
Fiscal Year 2025							
FFS	13,822	16,718	$292,366.57	$17.49	$1.49	439,222	195,849
Aetna	9,463	10,947	$189,747.42	$17.33	$1.56	290,865	121,729
Humana	9,652	11,403	$203,227.37	$17.82	$1.55	296,233	131,479
OCH	10,626	12,367	$221,271.96	$17.89	$1.60	326,516	138,239
2025 Total	**43,062**	**51,435**	**$906,613.32**	**$17.63**	**$1.54**	**1,352,836**	**587,296**
% Change	**-1.10%**	**-0.30%**	**-5.80%**	**-5.50%**	**-4.30%**	**-4.20%**	**-2.00%**
Change	**-475**	**-142**	**-$55,443.94**	**-$1.02**	**-$0.07**	**-58,975**	**-12,021**

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

Demographics of Members Utilizing Topical Antibiotic Products: Pharmacy Claims (All Plans)



Top Prescriber Specialties of Topical Antibiotic Products by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Topical Antibiotic Products

There were 101 prior authorization requests submitted for topical antibiotic products during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	12	24%	32	65%	5	10%	**49**
Aetna	0	0%	17	53%	15	47%	**32**
Humana	0	0%	0	0%	1	100%	**1**
OCH	2	11%	5	26%	12	63%	**19**
Total	**14**	**14%**	**54**	**53%**	**33**	**33%**	**101**

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

Market News and Updates[1]

Anticipated Patent Expiration(s):

- Clindesse® (clindamycin phosphate 2% vaginal cream): December 2026
- Xepi® (ozenoxacin 1% cream): January 2032
- Nuvessa® (metronidazole 1.3% vaginal gel): June 2032
- Xaciato® (clindamycin vaginal gel): September 2036

Recommendations

The College of Pharmacy recommends the prior authorization of Clindesse® (clindamycin phosphate 2% vaginal cream) with the following criteria based on net costs (changes shown in red):

Clindesse® (Clindamycin Phosphate 2% Vaginal Cream) and Xaciato® (Clindamycin 2% Vaginal Gel) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis; and
2. A patient specific, clinically significant reason why the member cannot use Cleocin® (clindamycin 2% vaginal cream)~~, Clindesse® (clindamycin phosphate 2% vaginal cream),~~ and Cleocin® vaginal ovules (clindamycin phosphate 2.5g vaginal suppositories), which are available without a prior authorization, must be provided~~.~~; and
3. Requests for Clindesse® will also require a patient specific, clinically significant reason why the member cannot use Xaciato®.

Utilization Details of Topical Antibiotic Products: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
MUPIROCIN PRODUCTS						
MUPIROCIN OINT 2%	46,950	39,795	$720,250.02	$15.34	1.18	79.44%
SUBTOTAL	**46,950**	**39,795**	**$720,250.02**	**$15.34**	**1.18**	**79.44%**
GENTAMICIN PRODUCTS						
GENTAMICIN OINT 0.1%	312	207	$10,959.42	$35.13	1.51	1.21%
GENTAMICIN CRE 0.1%	267	150	$8,134.26	$30.47	1.78	0.90%
GENTAMICIN POW	1	1	$75.74	$75.74	1	0.01%
SUBTOTAL	**580**	**358**	**$19,169.42**	**$33.05**	**1.62**	**2.11%**
TIER-1 SUBTOTAL	**47,530**	**40,153**	**$739,419.44**	**$15.56**	**1.18**	**81.56%**
TIER-2 PRODUCTS						
MUPIROCIN PRODUCTS						
MUPIROCIN CRE 2%	104	95	$3,457.11	$33.24	1.09	0.38%
TIER-2 SUBTOTAL	**104**	**95**	**$3,457.11**	**$33.24**	**1.09**	**0.38%**
METRONIDAZOLE PRODUCTS						
NO PA REQUIRED						
METRO GEL 0.75% VAG	2,709	2,243	$72,770.58	$26.86	1.21	8.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VANDAZOLE GEL 0.75%	20	19	$804.41	$40.22	1.05	0.09%
SUBTOTAL	**2,729**	**2,262**	**$73,574.99**	**$26.96**	**1.21**	**8.12%**
PA REQUIRED						
NUVESSA GEL 1.3%	3	3	$649.20	$216.40	1	0.07%
SUBTOTAL	**3**	**3**	**$649.20**	**$216.40**	**1**	**0.07%**
METRO SUBTOTAL	**2,732**	**2,265**	**$74,224.19**	**$27.17**	**1.21**	**8.19%**
CLINDAMYCIN PRODUCTS						
NO PA REQUIRED						
CLINDA CRE 2% VAG	887	766	$59,759.99	$67.37	1.16	6.59%
CLINDESSE CRE 2%	149	138	$21,439.58	$143.89	1.08	2.36%
CLEOCIN SUP 100MG	28	26	$7,534.29	$269.08	1.08	0.83%
SUBTOTAL	**1,064**	**930**	**$88,733.86**	**$83.40**	**1.14**	**9.79%**
PA REQUIRED						
XACIATO GEL 2%	5	5	$778.72	$155.74	1	0.09%
SUBTOTAL	**5**	**5**	**$778.72**	**$155.74**	**1**	**0.09%**
CLINDA SUBTOTAL	**1,069**	**935**	**$89,512.58**	**$83.73**	**1.14**	**9.87%**
TOTAL	**51,435**	**43,062***	**$906,613.32**	**$17.63**	**1.19**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CLINDA = clindamycin; CRE = cream; METRO = metronidazole; OINT = ointment; POW = powder; SUP = suppository; VAG = vaginal
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 02/2026. Last accessed 02/25/2026

Appendix Q

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: February 26, 2026

FDA Grants Second Approval under the National Priority Voucher Pilot Program

The FDA issued an approval for the lung cancer drug Hernexeos® (zongertinib) as a part of the new Commissioner's National Priority Voucher (CNPV) pilot program. The application was filed on January 13, 2026.

In the clinical trial data submitted to the FDA, a remarkable 76% of previously untreated patients had a substantial decrease in tumor size, representing a significant improvement from the current standard of care whereby 30-45% of patients are typically expected to demonstrate this response. Lung cancer kills more Americans annually than any other type of cancer, with an estimated 226,650 new diagnoses and 124,730 deaths in 2025, according to the National Cancer Institute. Hernexeos® targets molecular alterations found in a certain subset of non-small cell lung cancers (NSCLC).

Hernexeos® is now approved for adults with unresectable or metastatic non-squamous NSCLC whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations as detected by an FDA-authorized test. In August 2025, Hernexeos® was granted accelerated approval for adults with non-squamous NSCLC with these mutations who had received prior systemic therapy; today's accelerated approval extends this treatment option to patients who have not received prior therapy.

Based on preliminary data, Hernexeos® was proactively granted a national priority voucher by the FDA on November 6, 2025. The CNPV pilot program seeks to expedite approval of applications that address critical national health priorities, such as bringing innovative therapies to the American people, addressing large unmet medical needs, promoting domestic manufacturing, and increasing affordability. A company selected for the program is issued a voucher entitling the company to benefits including enhanced communications and rolling review to allow for a shortened review time.

The FDA granted Hernexeos® Breakthrough Therapy and Priority Review designations. Serious side effects associated with Hernexeos® include hepatotoxicity, left ventricular dysfunction, interstitial lung disease/pneumonitis, and embryofetal toxicity. The most common side effects include diarrhea, rash, hepatotoxicity, fatigue, nausea, musculoskeletal pain, and upper respiratory tract infection. The FDA granted the accelerated approval to Boehringer Ingelheim Pharmaceuticals, Inc.

FDA NEWS RELEASE

For Immediate Release: February 23, 2026

FDA Launches Framework for Accelerating Development of Individualized Therapies for Ultra-Rare Diseases

The FDA issued draft guidance for sponsors seeking approval for targeted individualized therapies by generating substantial evidence of effectiveness and safety when randomized controlled trials are not feasible due to small patient populations.

The draft guidance, issued by the Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research, specifically discusses genome editing and RNA-based therapies such as antisense oligonucleotides but leaves open the potential that this framework may apply to additional tailored therapeutics provided they directly address the underlying specific cause of the disease.

The draft guidance focuses on therapies that target a specific genetic, cellular, or molecular abnormality and are designed to correct or modify the underlying cause of disease. Key criteria include:

- Identifying the disease-causing abnormality
- Demonstrating the therapy targets the root cause or proximate biological pathway
- Relying on well-characterized natural history data in untreated patients
- Confirming successful target drugging or editing
- For traditional approval, therapies should demonstrate improvement in clinical outcomes, disease course, or biomarkers if they are established to predict clinical benefit.

Because genome editing technologies are designed to be highly specific to unique DNA sequences, a product targeting different mutations in a single gene could be included in a single product application and potentially evaluated through the use of master protocols that evaluate these product variations in a single trial. A highly supported “plausible” mechanism of action may then be used to support the addition of other such genome editing product variants, intended to treat patients with mutations that were not included in the clinical trial used to support the original approval.

The FDA recognizes that an adequate and well-controlled clinical investigation in this context will include a small sample size, therefore, investigation results should be sufficiently robust to exclude chance findings. When determining effectiveness, the FDA considers the specific disease, the strength of the evidence, and the challenges of conducting clinical investigations for individualized therapies.

The draft guidance, Considerations for the Use of the Plausible Mechanism Framework to Develop Individualized Therapies that Target Specific Genetic Conditions with Known Biological Cause, is available for public comment. Comments must be submitted within 60 days of publication in the Federal Register at Regulations.gov.

The FDA is committed to advancing safe and effective therapies for rare diseases and ensuring no family is overlooked because their condition is uncommon.

FDA NEWS RELEASE

For Immediate Release: February 12, 2026

FDA Approves First-of-Its-Kind Device to Treat Pancreatic Cancer

The FDA has approved a first-of-its-kind device for the treatment of adult patients with locally advanced pancreatic cancer. Optune Pax®, developed by Novocure, is a portable, non-invasive device that delivers alternating electrical fields, known as tumor treating fields (TTFields), to the abdomen. TTFields work by physically disrupting the rapid cell division that is characteristic of cancer cells, while minimizing damage to healthy tissue. The approval reflects the FDA's unwavering commitment to advancing safe and effective medical devices that address chronic diseases and improve the lives of Americans and is also aligned with the FDA's Home as a Health Care Hub Initiative, which focuses on advancing the development of innovative, patient-centered devices that fit more seamlessly into people's daily lives at home.

According to information published by the National Cancer Institute, pancreatic cancer was expected to result in approximately 67,440 new diagnoses and 51,980 deaths in the United States in 2025. Pancreatic cancer accounts for roughly 3.3% of all new cancer cases but represents a disproportionately large share of cancer deaths due to its late detection, aggressive disease behavior, and limited treatment options.

The therapy is administered through electrically insulated adhesive patches that are placed on the patient's skin and connected to an electric field generator. Device treatment technological parameters are preset by the manufacturer and cannot be adjusted by the patient or physician. Patients are trained on how to use the device, including how to recharge and replace device batteries, connect the device to an external power supply, place the adhesive patches in the appropriate positions on the body, and replace the transducer arrays at least twice per week. The device is designed to be worn with the generator carried in a specially designed bag, allowing patients to receive continuous treatment while going about their normal daily activities.

Optune Pax® was approved through the premarket approval (PMA) pathway, the FDA's most rigorous review process for medical devices. The FDA's approval of Optune Pax® is based on data from a pivotal clinical study conducted under an Investigational Device Exemption. The randomized and controlled study followed adult patients with locally advanced pancreatic cancer for up to 5 years. The results showed that the addition of TTFields to standard of care chemotherapies gemcitabine and nab-paclitaxel (GnP) improved overall survival by approximately 2 months compared to GnP alone. Localized skin reactions were the most common device-related risks

observed in the study. The results of this study formed the basis for the FDA's PMA approval decision.

The FDA granted Breakthrough Device designation for the Optune Pax® device in December 2024. A breakthrough designation is meant to expedite the development and review of devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

FDA NEWS RELEASE

For Immediate Release: February 12, 2026

FDA Intends to Take Action Against Non-FDA-Approved Glucagon-Like Peptide-1 (GLP-1) Drugs

The FDA has announced its intent to take decisive steps to restrict GLP-1 active pharmaceutical ingredients (APIs) intended for use in non-FDA-approved compounded drugs that are being mass-marketed by companies — including Hims & Hers and other compounding pharmacies — as similar alternatives to FDA-approved drugs. These actions are aimed to safeguard consumers from drugs for which the FDA cannot verify quality, safety, or efficacy.

The FDA is also taking steps to combat misleading direct-to-consumer advertising and marketing following warning letters that were sent in the fall of 2025. In promotional materials, companies cannot claim that non-FDA-approved compounded products are generic versions or the same as drugs approved by FDA. They also cannot state compounded drugs use the same active ingredient as the FDA-approved drugs or that compounded drugs are clinically proven to produce results for the patient.

The FDA will use all available compliance and enforcement tools within its authorities to address unsubstantiated claims and associated public health concerns. Entities engaged in the manufacture, distribution, or marketing of unapproved compounded GLP-1 products should be aware that failure to adequately address any violations may result in legal action without further notice, including, without limitation, seizure and injunction.

FDA NEWS RELEASE

For Immediate Release: February 1, 2026

FDA Launches PreCheck Pilot Program to Strengthen Domestic Pharmaceutical Manufacturing

The FDA began accepting requests to participate in the FDA PreCheck pilot program. FDA PreCheck is designed to strengthen the domestic pharmaceutical supply chain by increasing regulatory predictability, facilitating the construction of manufacturing sites in the United States, and streamlining aspects of pharmaceutical manufacturing facility assessments in advance of a specific product application.

The FDA will select an initial cohort of new pharmaceutical manufacturing facilities and begin conducting PreCheck activities in 2026. Facilities will be selected based on overall alignment with national priorities across multiple selection criteria, such as products to be manufactured, phase of facility development, timeline to producing pharmaceutical products for the United States market, and innovation in facility development. Additional priority consideration will be given to facilities producing critical medications for the United States market.

The FDA incorporated extensive industry feedback into the program design based on comments made during the "Onshoring Manufacturing of Drugs and Biological Products" public meeting held on September 30, 2025, and public comments received through Federal Register publication. Industry strongly supported early engagement during facility development and streamlined documentation processes.

FDA PreCheck consists of 2 phases. In Phase 1, the Facility Readiness Phase, selected manufacturers will engage with the FDA for early technical advice before a facility is operational through pre-operational reviews and utilization of a facility-specific Drug Master File to facilitate efficient evaluation of facility-specific elements prior to, and in support of, the submission of a drug application. In Phase 2, the Application Submission Phase, FDA and applicants build upon Phase 1 and engage through pre-submission meetings and inspections to resolve issues and expedite assessments of manufacturing information in a drug application.

Current Drug Shortages Index (as of March 2, 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.

Albuterol Sulfate Solution	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bacitracin Ophthalmic Ointment	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Powder, for Solution	***Currently in Shortage***

Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate 10% Injection	***Currently in Shortage***
Dextrose Monohydrate 5% Injection	***Currently in Shortage***
Dextrose Monohydrate 50% Injection	***Currently in Shortage***
Dextrose Monohydrate 70% Injection	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Meperidine Hydrochloride Injection	***Currently in Shortage***
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***
Peginterferon alfa-2a Injection	***Currently in Shortage***

Penicillin G Benzathine Injection	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Riluzole Oral Suspension	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***