OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
May 14, 2025
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 – May 14, 2025

DATE: May 7, 2025

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 May 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

SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update – Appendix C

Action Item – Vote to Prior Authorize Alhemo® (Concizumab-mtci), Beqvez™ (Fidanacogene Elaparvovec), Hympavzi™ (Marstacimab-hncq), and Qfitlia™ (Fitusiran) and Update the Approval Criteria for the Hemophilia Medications – Appendix D

Action Item – Vote to Prior Authorize Adzynma (ADAMTS13, Recombinant-krhn) and Alvaiz® (Eltrombopag) – Appendix E

Action Item – Vote to Prior Authorize Journavx™ (Suzetrigine) – Appendix F

Action Item – Vote to Prior Authorize Xolremdi® (Mavorixafor) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers – Appendix G

Action Item – Vote to Prior Authorize Ocrevus Zunovo™ (Ocrelizumab/Hyaluronidase-ocsq) and Update the Approval Criteria for the Multiple Sclerosis (MS) Medications – Appendix H

Action Item – Vote to Prior Authorize Agamree® (Vamorolone) and Duvyzat™ (Givinostat) and Update the Approval Criteria for the Muscular Dystrophy Medications – Appendix I

Action Item – Annual Review of Spinal Muscular Atrophy (SMA) Medications – Appendix J

Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Axtle™ (Pemetrexed), Bizengri® (Zenocutuzumab-zbco), Imdelltra™ (Tarlatamab-dlle), Lazcluze™ (Lazertinib), and Tecentriq Hybreza™ (Atezolizumab/Hyaluronidase-tqjs) – Appendix K

Annual Review of Botulinum Toxins and 30-Day Notice to Prior Authorize Daxxify® (DaxibotulinumtoxinA-lanm) – Appendix L

Annual Review of Anti-Diabetic Medications and Kerendia® (Finerenone) and 30-Day Notice to Prior Authorize Brynovin™ (Sitagliptin Oral Solution), Glimepiride 3mg Tablet, Merilog™ (Insulin Aspart-szjj), Metformin 750mg Tablet, and Zituvimet™ XR (Sitagliptin/Metformin) – Appendix M

Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Onyda™ XR [Clonidine Extended-Release (ER) Oral Suspension] – Appendix N

30-Day Notice to Prior Authorize Sofdra™ (Sofpironium 12.45% Topical Gel) – Appendix O

Annual Review of Age-Related Macular Degeneration (AMD) Medications and 30-Day Notice to Prior Authorize Enzeevu™ (Aflibercept-abzv), Opuviz™ (Aflibercept-yszy), and Yesafili™ (Aflibercept-jbvf) – Appendix P

Annual Review of Parkinson's Disease (PD) Medications and 30-Day Notice to Prior Authorize Crexont® [Carbidopa/Levodopa Extended-Release (ER) Capsule], Onapgo™ (Apomorphine Injection for Continuous Infusion), and Vyalev™ (Foscarbidopa/Foslevodopa Injection for Continuous Infusion) – Appendix Q

Annual Review of Primary Immunoglobulin A Nephropathy (IgAN) Medications and 30-Day Notice to Prior Authorize Vanrafia™ (Atrasentan) – Appendix R

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – May 14, 2025 @ 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
Mr. Kenneth Foster –	participating in person
Dr. Bret Haymore –	participating in person
Dr. Craig Kupiec –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person
Dr. Edna Patatanian –	participating in person
Dr. Beth Walton –	participating in person
Dr. Jennifer Weakley –	participating in person

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https://oklahoma.zoom.us/webinar/register/WN_94lCoSe9Ty2msgsLMqg2Ww
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: 958 2294 2095
Passcode: 65079339

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.

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. April 9, 2025 DUR Board Meeting Minutes
   B. April 9, 2025 DUR Board Recommendations Memorandum
   C. Correspondence

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

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

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

5. **SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update – See Appendix C**
   A. SoonerPsych Prescriber Mailing Summary
   B. SoonerPsych Trends
   C. Pediatric SoonerPsych Antipsychotic Monitoring Program Prescriber Mailing Summary
   D. Pediatric SoonerPsych Trends
   E. Conclusions

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

6. **Action Item – Vote to Prior Authorize Alhemo® (Concizumab-mtci), Beqvez™ (Fidanacogene Elaparvovec), Hympavzi™ (Marstacimab-hncq), and Qfitlia™ (Fitusiran) and Update the Approval Criteria for the Hemophilia Medications – See Appendix D**
   A. Market News and Updates
   B. Product Summaries
   C. Oklahoma Health Care Authority Recommendations

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

7. **Action Item – Vote to Prior Authorize Adzynma (ADAMTS13, Recombinant-krhn) and Alvaiz® (Eltrombopag)– See Appendix E**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

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

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

9. **Action Item – Vote to Prior Authorize Xolremdi® (Mavorixafor) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers – See Appendix G**
   A. Market News and Updates
   B. Xolremdi® (Mavorixafor) Product Summary
   C. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Ocrevus Zunovo™ (Ocrelizumab/ Hyaluronidase-ocsq) and Update the Approval Criteria for the Multiple Sclerosis (MS) Medications – See Appendix H**
    A. Market News and Updates
    B. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Agamree® (Vamorolone) and Duvyzat™ (Givinostat) and Update the Approval Criteria for the Muscular Dystrophy Medications – See Appendix I**
    A. Market News and Updates
    B. Product Summaries

C. College of Pharmacy Recommendations

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

12. Action Item – Annual Review of Spinal Muscular Atrophy (SMA) Medications – See Appendix J

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

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

13. Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Axtle™ (Pemetrexed), Bizengri® (Zenocutuzumab-zbco), Imdelltra™ (Tarlatamab-dlle), Lazcluze™ (Lazertinib), and Tecentriq Hybreza™ (Atezolizumab/Hyaluronidase-tqjs) – See Appendix K

A. Current Prior Authorization Criteria
B. Utilization of Lung Cancer Medications
C. Prior Authorization of Lung Cancer Medications
D. Market News and Updates
E. Product Summaries
F. Cost Comparison: Pemetrexed Products
G. College of Pharmacy Recommendations
H. Utilization Details of Lung Cancer Medications

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

14. Annual Review of Botulinum Toxins and 30-Day Notice to Prior Authorize Daxxify® (DaxibotulinumtoxinA-lanm) – See Appendix L

A. Current Prior Authorization Criteria
B. Utilization of Botulinum Toxins
C. Prior Authorization of Botulinum Toxins
D. Market News and Updates
E. Daxxify® (DaxibotulinumtoxinA-lanm) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Botulinum Toxins

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

15. Annual Review of Anti-Diabetic Medications and Kerendia® (Finerenone) and 30-Day Notice to Prior Authorize Brynovin™ (Sitagliptin Oral Solution), Glimepiride 3mg Tablet, Metformin 750mg Tablet, Merilog™ (Insulin Aspart-szjj), and Zituvimet™ XR [Sitagliptin/Metformin Extended-Release (ER)] – See Appendix M

A. Current Prior Authorization Criteria
B. Utilization of Anti-Diabetic Medications and Kerendia® (Finerenone)

C. Prior Authorization of Anti-Diabetic Medications and Kerendia® (Finerenone)
D. Market News and Updates
E. Cost Comparisons
F. College of Pharmacy Recommendations
G. Utilization Details of Anti-Diabetic Medications and Kerendia® (Finerenone)

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

16. **Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Onyda™ XR [Clonidine Extended-Release (ER) Oral Suspension] – See Appendix N**

A. Current Prior Authorization Criteria
B. Utilization of ADHD and Narcolepsy Medications
C. Prior Authorization of ADHD and Narcolepsy Medications
D. Oklahoma Resources
E. Market News and Updates
F. Onyda™ XR (Clonidine ER Suspension) Product Summary
G. College of Pharmacy Recommendations
H. Utilization Details of ADHD and Narcolepsy Medications

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

17. **30-Day Notice to Prior Authorize Sofdra™ (Sofpironium 12.45% Topical Gel) – See Appendix O**

A. Introduction
B. Sofdra™ (Sofpironium 12.45% Topical Gel) Product Summary
C. College of Pharmacy Recommendations

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

18. **Annual Review of Age-Related Macular Degeneration (AMD) Medications and 30-Day Notice to Prior Authorize Enzeevu™ (Aflibercept-abzv), Opuviz™ (Aflibercept-yszy), and Yesafili™ (Aflibercept-jbvf) – See Appendix P**

A. Current Prior Authorization Criteria
B. Utilization of AMD Medications
C. Prior Authorization of AMD Medications
D. Market News and Updates
E. Cost Comparison: Aflibercept Biosimilars
F. College of Pharmacy Recommendations
G. Utilization Details of AMD Medications

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

19. **Annual Review of Parkinson's Disease (PD) Medications and 30-Day Notice to Prior Authorize Crexont® [Carbidopa/Levodopa Extended-Release (ER) Capsule], Onapgo™ (Apomorphine Injection for Continuous Infusion), and Vyalev™ (Foscarbidopa/Foslevodopa Injection for Continuous Infusion) – See Appendix Q**

A. Current Prior Authorization Criteria
B. Utilization of PD Medications
C. Prior Authorization of PD Medications
D. Market News and Updates
E. Product Summaries
F. Cost Comparison: Oral Carbidopa/Levodopa Products
G. College of Pharmacy Recommendations
H. Utilization Details of PD Medications

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

20. Annual Review of Primary Immunoglobulin A Nephropathy (IgAN) Medications and 30-Day Notice to Prior Authorize Vanrafia™ (Atrasentan) – See Appendix R

A. Current Prior Authorization Criteria
B. Utilization of Primary IgAN Medications
C. Prior Authorization of Primary IgAN Medications
D. Market News and Updates
E. Vanrafia™ (Atrasentan) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Primary IgAN Medications

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

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

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

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

A. Antiviral Medications
B. Atypical Antipsychotic Medications
C. Genitourinary and Gynecologic Cancer Medications
D. Various Special Formulations

*Future product and class reviews subject to change.

23. 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.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING APRIL 9, 2025

DUR BOARD MEMBERS:	PRESENT	ABSENT
Kenneth Foster, MHS, PA-C	X	
Megan A. Hanner, D.O.	X	
Bret Haymore, M.D.; Chairman	X	
T. Craig Kupiec II, M.D., MSPH	X	
Lee Muñoz, D.Ph.	X	
James Osborne, Pharm.D.		X
Edna Patatanian, Pharm.D., FASHP; Vice Chairwoman	X	
Beth Walton, Pharm.D.	X	
Jennifer Weakley, M.D., DipABLM	X	

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Michaela DeRemer, Pharm.D., MBA, BCPS; Clinical Pharmacist	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	
Chinemerem Opara, Pharm.D.; Pharmacy Resident	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: Tad Autry, Pharm.D., BCPS, BCOP		X
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	
Visiting Pharmacy Student(s): Alissa Volcik	X	
Dayton Wickham	X	
Shelby Little	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Melody Anthony, Interim State Medicaid Director		X
Mark Brandenburg, M.D., MSC; Medical Director	X	
Ellen Buettner; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director		X
Ryan Gillett, J.D.; Deputy General Counsel	X	

Conner Mulvaney, J.D.; Deputy General Counsel		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Chief Medical Officer		X
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Sharon Smith, Pharm.D.; Clinical Pharmacist	X	
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
Toney Welborn, M.D., MPH, MS; Medical Director		X

OTHERS PRESENT:	
Todd Ness, AbbVie	Saurabh Patel, AbbVie
Kim Greenberg, Acadia Pharmaceuticals	John Bullard, Alexion
Lisa Dunn, Amgen	Mike Sullivan, Amgen
Tina Hartmann, Arcutis	Brett Stephenson, Arcutis
Stormy Cameron, Artia Solutions	Jen Golwyn, Ascendis Pharma
Ronnie DePue, Axsome	Jay Mehtq, Axsome
Dan O'Donnell, Axsome	Jay Milton, Bayer
Lee Stout, Chiesi	Lindsey Baker, Genentech
Rhonda Clark, Indivior	Justin Alberts, ITF Therapeutics
Jason Dickerson, Jazz Pharmaceuticals	Scott Burns, Johnson & Johnson
Clare Choi, Lifescan	Brent Parker, Merck
Ray Kong, Neurocrine	Ginger Papesh, Novo Nordisk
Allison Scott, Orchard Therapeutics	Richard Junk, Organon
Dan Sheehan, Pfizer	Pam Storey, PTC Therapeutics
Lauren Warn, PTC Therapeutics	Dana Pipkin, Sarepta Therapeutics
Jim Semans, SK Life Science	Dave Miley, Teva Pharmaceuticals
John Omick, Travere	Brent Fushimi, UCB
Taha Khan, Vertex	Roberto Pedraza, Vertex
Amy Akins, Little Hercules Foundation	Brian Denger, Parent Project MD
Irene Chung, Aetna	Kristen Winters, Centene
Deidra Williams, Humana	

PRESENT FOR PUBLIC COMMENT:	
Jay Mehtq, Axsome	Brett Stephenson, Arcutis
Justin Alberts, ITF Therapeutics	

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. 8 JAY MEHTQ

2B: AGENDA ITEM NO. 13 BRETT STEPHENSON

2C: AGENDA ITEM NO. 17 JUSTIN ALBERTS

ACTION: NONE REQUIRED

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

3A: MARCH 12, 2025 DUR MINUTES

Materials included in agenda packet; presented by Dr. Haymore

Dr. Muñoz moved to approve; seconded by Dr. Walton
ACTION: MOTION CARRIED

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

<u>AGENDA ITEM NO. 5:</u> SPRING PIPELINE UPDATE
5A: SPRING PIPELINE UPDATE
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 6:</u> VOTE TO PRIOR AUTHORIZE PANTOPRAZOLE IN 0.9% SODIUM CHLORIDE (NACL) FOR INTRAVENOUS (IV) INJECTION AND UPDATE THE APPROVAL CRITERIA FOR THE ANTI-ULCER MEDICATIONS
6A: MARKET NEWS AND UPDATES
6B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 7:</u> VOTE TO PRIOR AUTHORIZE ENTRESTO® SPRINKLE (SACUBITRIL/VALSARTAN ORAL PELLETS) AND UPDATE THE APPROVAL CRITERIA FOR THE HEART FAILURE (HF) MEDICATIONS
7A: MARKET NEWS AND UPDATES
7B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Walton moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 8:</u> VOTE TO PRIOR AUTHORIZE SYMBRAVO® (MELOXICAM/RIZATRIPTAN) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTI-MIGRAINE MEDICATIONS
8A: MARKET NEWS AND UPDATES
8B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 9:</u> VOTE TO PRIOR AUTHORIZE CTEXLI™ (CHENODIOL), IQIRVO® (ELAFIBRANOR), AND LIVDELZI® (SELADELPAR) AND UPDATE THE APPROVAL CRITERIA FOR THE CHOLESTATIC LIVER DISEASE MEDICATIONS
9A: MARKET NEWS AND UPDATES
9B: PRODUCT SUMMARIES
9C: 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

<u>AGENDA ITEM NO. 10:</u> VOTE TO PRIOR AUTHORIZE KEBILIDI™ ELADOCAGENE EXUPARVOVEC-TNEQ)

10A: MARKET NEWS AND UPDATES
10B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: VOTE TO PRIOR AUTHORIZE CRENESSITY™ (CRINECERFONT)
11A: MARKET NEWS AND UPDATES
11B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: VOTE TO PRIOR AUTHORIZE AUCATZYL® (OBECABTAGENE AUTOLEUCEL), DANZITEN™ (NILOTINIB), GRAFAPEX™ (TREOSULFAN), REVUFORJ® (REVUMENIB), AND RYTELO™ (IMETELSTAT) AND UPDATE THE APPROVAL CRITERIA FOR THE LEUKEMIA AND LYMPHOMA MEDICATIONS
12A: MARKET NEWS AND UPDATES
12B: PRODUCT SUMMARIES
12C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Sinko
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: ANNUAL REVIEW OF TOPICAL ACNE, PSORIASIS, AND ROSACEA PRODUCTS
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF TOPICAL ACNE, PSORIASIS, AND ROSACEA PRODUCTS
13C: PRIOR AUTHORIZATION OF TOPICAL ACNE, PSORIASIS, AND ROSACEA PRODUCTS
13D: MARKET NEWS AND UPDATES
13E: COLLEGE OF PHARMACY RECOMMENDATIONS
13F: UTILIZATION DETAILS OF TOPICAL ACNE, PSORIASIS, AND ROSACEA PRODUCTS
Materials included in agenda packet; presented by Dr. Wilson
Regarding the atopic dermatitis approval criteria for Vtama® (tapinarof), Dr. Haymore recommended adding allergist and immunologist to criteria 3 as specialists that can prescribe or consult based on clinical practice. Regarding the approval criteria for Zoryve® (roflumilast 0.15% cream) for atopic dermatitis, Dr. Kupiec recommended the removal of criteria 3 (specialist requirement) based on clinical practice.
Dr. Muñoz moved to amend the approval criteria; seconded by Dr. Walton
The DUR Board voted on the amended criteria.
Dr. Kupiec moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: ANNUAL REVIEW OF MOLLUSCUM CONTAGIOSUM MEDICATIONS
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF MOLLUSCUM CONTAGIOSUM MEDICATIONS
14C: PRIOR AUTHORIZATION OF MOLLUSCUM CONTAGIOSUM MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: COLLEGE OF PHARMACY RECOMMENDATIONS

14F: UTILIZATION DETAILS OF MOLLUSCUM CONTAGIOSUM MEDICATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 15: ANNUAL REVIEW OF GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)
15C: PRIOR AUTHORIZATION OF GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)
15D: MARKET NEWS AND UPDATES
15E: COLLEGE OF PHARMACY RECOMMENDATIONS
15F: UTILIZATION DETAILS OF GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)
Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Dr. Walton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 16: ANNUAL REVIEW OF HEMOPHILIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ALHEMO® (CONCIZUMAB-MTCI), BEQVEZ™ (FIDANACOGENE ELAPARVOVEC), HYMPAVZI™ (MARSTACIMAB-HNCQ) AND QFITLIA™ (FITUSIRAN)
16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF HEMOPHILIA MEDICATIONS
16C: PRIOR AUTHORIZATION OF HEMOPHILIA MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: PRODUCT SUMMARIES
16F: OKLAHOMA HEALTH CARE AUTHORITY RECOMMENDATIONS
16G: UTILIZATION DETAILS OF HEMOPHILIA MEDICATIONS
Materials included in agenda packet; presented by Dr. Ratterman
ACTION: NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY

AGENDA ITEM NO. 17: ANNUAL REVIEW OF MUSCULAR DYSTROPHY MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AGAMREE® (VAMOROLONE) AND DUVYZAT™ (GIVINOSTAT)
17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF MUSCULAR DYSTROPHY MEDICATIONS
17C: PRIOR AUTHORIZATION OF MUSCULAR DYSTROPHY MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: PRODUCT SUMMARIES
17F: COLLEGE OF PHARMACY RECOMMENDATIONS
17G: UTILIZATION DETAILS OF MUSCULAR DYSTROPHY MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY

AGENDA ITEM NO. 18: ANNUAL REVIEW OF MULTIPLE SCLEROSIS (MS) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE OCREVUS ZUNOVO™ (OCRELIZUMAB/HAYLURONIDASE-OCSQ)
18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF MS MEDICATIONS
18C: PRIOR AUTHORIZATION OF MS MEDICATIONS
18D: MARKET NEWS AND UPDATES

18E: OCREVUS ZUNOVO™ (OCRELIZUMAB/HYALURONIDASE-OCSQ) PRODUCT SUMMARY
18F: COLLEGE OF PHARMACY RECOMMENDATIONS
18G: UTILIZATION DETAILS OF MS MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY

AGENDA ITEM NO. 19: ANNUAL REVIEW OF GRANULOCYTE COLONGY-STIMULATING FACTORS (G-CSFS) AND STEM CELL MOBILIZERS AND 30-DAY NOTICE TO PRIOR AUTHORIZE XOLREMDI® (MAVORIXAFOR)
19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF G-CSFS AND STEM CELL MOBILIZERS
19C: PRIOR AUTHORIZATION OF G-CSFS AND STEM CELL MOBILIZERS
19D: MARKET NEWS AND UPDATES
19E: COLLEGE OF PHARMACY RECOMMENDATIONS
19F: UTILIZATION DETAILS OF G-CSFS AND STEM CELL MOBILIZERS
Materials included in agenda packet; presented by Dr. DeRemer
ACTION: NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY

AGENDA ITEM NO. 20: 30-DAY NOTICE TO PRIOR AUTHORIZE JOURNAVX™ (SUZETRIGINE)
20A: JOURNAVX™ (SUZETRIGINE) PRODUCT SUMMARY
20B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY

AGENDA ITEM NO. 21: ANNUAL REVIEW OF THROMBOCYTOPENIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ADZYNMA (ADAMTS13, RECOMBINANT-KRHN) AND ALVAIZ® (ELTROMBOPAG)
21A: CURRENT PRIOR AUTHORIZATION CRITERIA
21B: UTILIZATION OF THROMBOCYTOPENIA MEDICATIONS
21C: PRIOR AUTHORIZATION OF THROMBOCYTOPENIA MEDICATIONS
21D: MARKET NEWS AND UPDATES
21E: PRODUCT SUMMARIES
21F: COLLEGE OF PHARMACY RECOMMENDATIONS
21G: UTILIZATION DETAILS OF THROMBOCYTOPENIA MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY

AGENDA ITEM NO. 22: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Non-presentation item; materials included in agenda packet by Dr. Wilson
ACTION: NONE REQUIRED

AGENDA ITEM NO. 23: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
23A: ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
23B: ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATONS
23C: BOTULINUM TOXINS
23D: PARKINSON'S DISEASE MEDICATIONS
23E: SPINAL MUSCULAR ATROPHY (SMA) MEDICATIONS
*Future product and class reviews subject to change.
Non-presentation item; materials included in agenda packet by Dr. Adams

ACTION: NONE REQUIRED

AGENDA ITEM NO. 24: ADJOURNMENT

The meeting was adjourned at 6:02pm.

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

Memorandum

Date: April 11, 2025

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

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

Subject: DUR Board Recommendations from Meeting on April 9, 2025

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Spring Pipeline Update

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Pantoprazole in 0.9% Sodium Chloride (NaCl) for Intravenous (IV) Injection and Update the Approval Criteria for the Anti-Ulcer Medications

MOTION CARRIED by unanimous approval.

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

1. Prior authorization of pantoprazole in 0.9% NaCl for IV injection and placement into Special PA Tier with the following criteria; and
2. Moving Dexilant® (dexlansoprazole) from Tier-1 to Tier-2 based on net costs; and
3. Moving Carafate® (sucralfate) suspension from Tier-1 to the Special PA Tier with additional criteria based on net costs; and

4. Removing esomeprazole strontium and Aciphex® sprinkles (rabeprazole) due to product discontinuations; and
~~5. Updating Tagamet® (cimetidine tablets) criteria to allow for a clinical exception for a diagnosis of molluscum contagiosum; and~~
6. Updating Pylera® (bismuth subcitrate potassium/metronidazole/ tetracycline), Talicia® (omeprazole/amoxicillin/rifabutin), Voquezna® (vonoprazan fumarate) tablets, Voquezna® Dual Pak® (vonoprazan fumarate/amoxicillin trihydrate) and Voquezna® Triple Pak® (vonoprazan fumarate/amoxicillin trihydrate/clarithromycin) criteria based on American College of Gastroenterology (ACG) guideline recommendations.

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
~~**dexlansoprazole (Dexilant® caps)**~~	**dexlansoprazole (Dexilant® caps)**	esomeprazole (Nexium® I.V.)	bismuth subcitrate potassium/metronidazole/ tetracycline (Pylera® caps)
esomeprazole (Nexium® caps)	pantoprazole (Protonix® I.V.)	~~**esomeprazole strontium caps**~~	cimetidine (Tagamet® tabs)
esomeprazole (Nexium® packet) – **Brand Preferred**		omeprazole (Prilosec® susp, powder)	esomeprazole kit (ESOMEP-EZS™)
lansoprazole (Prevacid® caps)		pantoprazole (Protonix® susp)	famotidine (Pepcid® susp)
lansoprazole ODT (Prevacid® ODT) – **Brand Preferred**		~~**rabeprazole (Aciphex® sprinkles)**~~	glycopyrrolate (Glycate® tabs)
omeprazole (Prilosec® caps)			glycopyrrolate ODT (Dartisla® ODT)
pantoprazole (Protonix® tabs)			lansoprazole/amoxicillin/ clarithromycin (PrevPac®)
rabeprazole (Aciphex® tabs)			nizatidine (Axid® caps & soln)
~~**sucralfate (Carafate® susp)**~~			omeprazole/amoxicillin/ rifabutin (Talicia® caps)
sucralfate (Carafate® tabs)			omeprazole/sodium bicarbonate (Konvomep® for oral suspension)
			omeprazole/sodium bicarbonate (Zegrid® caps & pack)
			pantoprazole in 0.9% NaCl for IV injection
			sucralfate (Carafate® susp)
			vonoprazan (Voquezna® tabs)

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA+**
			vonoprazan fumarate/ amoxicillin trihydrate (Voquezna® Dual Pak®)
			vonoprazan fumarate/ amoxicillin trihydrate/ clarithromycin (Voquezna® Triple Pak®)

*Special formulations including ODTs, granules, suspension, sprinkle capsules, and solution for IV require special reasoning for use.
+Individual criteria specific to each product applies.
caps = capsules; IV = intravenous; ODT = orally disintegrating tablet; NaCl = sodium chloride; PA = prior authorization; soln = solution; susp = suspension; tabs = tablet

Pantoprazole in 0.9% NaCl for Intravenous (IV) Injection Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Tier-2 Protonix® I.V. (pantoprazole) must be provided.

Carafate (Sucralfate Suspension) Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use the tablet formulation, which is available without prior authorization, must be provided.

Tagamet® (Cimetidine Tablets) Approval Criteria:

~~1. An FDA approved diagnosis; and~~
2. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided.~~; or~~
~~3. A clinical exception will apply for a diagnosis of molluscum contagiosum in which Tagamet® (cimetidine) tablets will be approved.~~

Pylera® (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline Capsule) Approval Criteria:

1. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and

~~3. A patient-specific, clinically significant reason why the member cannot use the individual components [bismuth subsalicylate, metronidazole, and tetracycline plus a histamine type 2 receptor (H2) antagonist], must be provided; and~~
~~4. A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection (e.g., proton pump~~

~~inhibitor/H2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and~~

5. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori infection* (e.g., omeprazole, amoxicillin, and rifabutin ~~clarithromycin~~), which are available without prior authorization, must be provided; and
6. A quantity limit of 120 capsules per 10 days will apply.

Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsules) Approval Criteria:

1. An FDA approved indication for the treatment of *Helicobacter pylori* (*H. pylori*) infection ~~diagnosis~~; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components of ~~other~~ triple-therapy treatments for *H. pylori* infection ~~regimens approved for the same diagnosis~~ (e.g., omeprazole, amoxicillin, and rifabutin ~~clarithromycin~~), which are available without prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use the individual components of potassium-competitive acid blocker (PCAB) dual therapy (e.g., vonoprazan fumarate and amoxicillin) must be provided; and
5. A quantity limit of 168 capsules per 14 days will apply.

Voquezna® (Vonoprazan Fumarate) Approval Criteria [Erosive and Non-Erosive Esophagitis Diagnosis]:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
4. A quantity limit of 30 tablets per 30 days will apply.

Voquezna® (Vonoprazan Fumarate), Voquezna® Dual Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate), and Voquezna® Triple Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate/Clarithromycin) Approval Criteria [*Helicobacter pylori* (*H. pylori*) Diagnosis]:

1. An FDA approved indication for the treatment of *H. pylori* infection; 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 individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and

~~4. A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended~~

~~concomitant therapy for *H. pylori* infection (e.g., proton pump inhibitor/H2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and~~

5. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and rifabutin ~~clarithromycin~~), which are available without prior authorization, must be provided; and
6. For the Voquezna® Dual Pak® and Voquezna® Triple Pak®, a patient-specific, clinically significant reason why the member cannot use the individual components of the product requested must be provided; and
7. A quantity limit of 112 tablets/capsules per 14 days will apply.

Recommendation 4: Vote to Prior Authorize Entresto® Sprinkle (Sacubitril/Valsartan) and Update the Approval Criteria for the Heart Failure (HF) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Entresto® Sprinkle (sacubitril/valsartan) with the following criteria (shown in red):

Entresto® Sprinkle (Sacubitril/Valsartan) Approval Criteria:

1. An FDA approved diagnosis of symptomatic heart failure with systemic left ventricular systolic dysfunction; and
2. Member must be 1 to 10 years of age; and
3. Member must weigh <50kg; and
4. A recent weight (within the last 3 months) must be provided on the prior authorization request to ensure proper weight-based dosing and to authorize the appropriate amount of drug required according to package labeling; and
5. A quantity limit of 240 capsules per 30 days will apply.

The College of Pharmacy also recommends updating the approval criteria for Corlanor® (ivabradine) based on clinical practice and the American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Rhythm Society Clinical Practice Guidelines for the Management of Adult Patients with Supraventricular Tachycardia and recommends updating the approval criteria for Furoscix® (furosemide on-body infusor) based on the FDA-approved updates to the package labeling, the FDA-approved expanded indication, and clinical practice (changes shown in red):

Corlanor® (Ivabradine) Approval Criteria:

1. ~~An FDA approved indication~~ A diagnosis of 1 of the following:
   a. To reduce the risk of hospitalization for worsening heart failure (HF) in adult members with stable, symptomatic chronic HF with reduced left ventricular ejection fraction (LVEF); or

b. For the treatment of stable, symptomatic HF due to dilated cardiomyopathy (DCM) in members 6 months of age and older; ~~and~~ or
c. For the treatment of inappropriate sinus tachycardia (IST); and

2. For a diagnosis of worsening HF in adults:
   a. Prescriber must verify that the member has LVEF ≤35%; and
   b. Prescriber must verify that the member is in sinus rhythm with a resting heart rate ≥70 beats per minute (bpm); and
   c. Member must be on maximal/maximally tolerated doses of beta blockers or have a contraindication to beta blockers; and
3. For a diagnosis of DCM in members 6 months of age or older:
   a. Prescriber must verify that the member has LVEF ≤45%; and
   b. Prescriber must verify that the member is in sinus rhythm with a resting heart rate (HR) as follows:
      i. Age 6 to 12 months, HR ≥105 bpm; or
      ii. Age 1 to 3 years, HR ≥95 bpm; or
      iii. Age 3 to 5 years, HR ≥75 bpm; or
      iv. Age 5 to 18 years, HR ≥70 bpm; and
   c. Prescriber must verify that dose titration will be followed according to package labeling; and
   d. 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
4. Authorization of Corlanor® solution for members >40kg requires a patient-specific, clinically significant reason why Corlanor® tablets cannot be used; and
5. For Corlanor® tablets, a quantity limit of 60 tablets per 30 days will apply; and
6. For Corlanor® solution, a quantity limit of 280mL (56 ampules) per 28 days will apply.

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

1. An FDA approved indication for the treatment of ~~congestion due to fluid overload~~ edema in members with ~~New York Heart Association (NYHA) Class II-III~~ chronic heart failure or chronic kidney disease (CKD), including nephrotic syndrome; and
2. Member must be 18 years of age or older; and
3. Furoscix® must be prescribed by, or in consultation with, a cardiologist, nephrologist, or a provider trained in managing acute decompensated heart failure (ADHF) or CKD; and
4. Member is currently showing signs of ~~fluid overload~~ edema; and
5. Member has been ~~stable~~ established on maintenance therapy with and is refractory to a dose escalation with at least 1 of the following loop diuretics, at maximally ~~indicated~~ tolerated doses:
   a. Bumetanide oral tablets; or
   b. Furosemide oral tablets; or

c. Torsemide oral tablets; and

6. Prescriber must verify the member will discontinue oral diuretics during the treatment with Furoscix® and will transition back to oral diuretic maintenance therapy when practical; and
7. Prescriber must verify the member is stable and suitable for at-home treatment with Furoscix®, as determined by:
   a. Oxygen saturation ≥90% on exertion; and
   b. Respiratory rate <24 breaths per minute; and
   c. Resting heart rate <100 beats per minute; and
   d. Systolic blood pressure >100mmHg; and
8. Member must have an adequate environment for at-home administration, ~~and~~ have been trained on the proper use of Furoscix®, and be able to detect and respond to the device alarms; and
9. ~~Member must have a creatinine clearance (CrCl) >30mL/min or an estimated glomerular filtration rate (eGFR) >20mL/min/1.73m^2 and no evidence of acute renal failure; and~~
10. Member must not have any contraindications for use of Furoscix® including anuria~~,~~ or hepatic cirrhosis~~, or ascites~~; and
11. Member must not have ~~acute pulmonary edema or other~~ conditions that require immediate hospitalization; and
12. Approvals will be issued per incident of fluid overload; and
13. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of fluid overload.

Recommendation 5: Vote to Prior Authorize Symbravo® (Meloxicam/ Rizatriptan) and Update the Approval Criteria for the Anti-Migraine Medications

MOTION CARRIED by unanimous approval.

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

1. Updating the criteria for the Tier 2 and Tier 3 medications; and
2. Moving Treximet® (sumatriptan/naproxen) to Tier-2 from Tier 3; and
3. Moving Migranal® (dihydroergotamine nasal spray) and Imitrex® (sumatriptan nasal spray) from Special PA to Tier 3; and
4. Moving Imitrex® (sumatriptan autoinjector pen) and Imitrex® (sumatriptan vial) from Special PA Tier to Tier 3 but leaving Imitrex® STATdose System (sumatriptan injection) in the Special PA Tier; and
5. Adding Symbravo® (meloxicam/rizatriptan) to the Special PA Tier with the following additional criteria; and
6. Updating the approval criteria for Reyvow® (lasmiditan), 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 injection (D.H.E. 45®)
naratriptan tablet (Amerge®)	**sumatriptan/ naproxen tablet (Treximet®)**	**DHE nasal spray (Migranal®)**	~~**DHE nasal spray (Migranal®)**~~
rizatriptan tablet, ODT (Maxalt®, Maxalt MLT®)		~~**sumatriptan/ naproxen tablet (Treximet®)**~~	DHE nasal spray (Trudhesa®)
sumatriptan tablet (Imitrex®)		**sumatriptan autoinjector pen and vial (Imitrex®)**	ergotamine sublingual tablet (Ergomar®)
zolmitriptan tablet, ODT (Zomig®, Zomig-ZMT®)		**sumatriptan nasal spray (Imitrex®)**	lasmiditan tablet (Reyvow®)
			meloxicam/rizatriptan (Symbravo®)
			rimegepant ODT (Nurtec® ODT)
			rizatriptan film (RizaFilm®)
			~~**sumatriptan injection (Imitrex®)**~~
			sumatriptan injection (Imitrex® STATdose System)
			sumatriptan injection (Zembrace® SymTouch®)
			sumatriptan nasal powder (Onzetra® Xsail®)
			~~**sumatriptan nasal spray (Imitrex®)**~~
			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 Tier-2 Approval Criteria:

1. A trial of ~~all available~~ 2 Tier-1 products with inadequate response or a patient-specific, clinically significant reason why a Tier-1 product is not appropriate for the member must be provided; or
2. Documented adverse effect(s) to all available Tier-1 products; or
3. Previous success with a Tier-2 product within the last 60 days.

Anti-Migraine Medications Tier-3 Approval Criteria:

1. A trial of ~~all available~~ 3 Tier-1 and Tier-2 products with inadequate response or a patient-specific, clinically significant reason why a lower tiered product is not appropriate for the member must be provided; or
2. Documented adverse effect(s) to all available Tier-1 and Tier-2 products; or
3. Previous success with a Tier-3 product within the last 60 days.~~; and~~
~~4. Use of any non-oral formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation.~~

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 D.H.E. 45® [dihydroergotamine (DHE) injection] or Trudhesa® (DHE nasal spray) will require a patient-specific, clinically significant reason why the member cannot use Migranal® (DHE nasal spray), and lower-tiered triptan medications.
~~3. Use of Migranal® (DHE nasal spray) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications.~~
4. 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 calcitonin gene-related peptide (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.

5. Use of Reyvow® (lasmiditan)~~, 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
    a. Reyvow®~~, Ubrelvy®, and Zavzpret™~~ will not be approved for concurrent use with a prophylactic CGRP inhibitor.
6. Use of RizaFilm® (rizatriptan film) will require a patient-specific, clinically significant reason why the member cannot use the ODT formulation and lower-tiered triptan medications.
7. ~~Use of any non-oral sumatriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.~~
8. 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).
9. Use of Ubrelvy® (ubrogepant) or Zavzpret™ (zavegepant nasal spray) will require a patient-specific, clinically significant reason why the member cannot use triptan medications, Nurtec® ODT (rimegepant), and Reyvow® (lasmiditan); and
    a. Ubrelvy® and Zavzpret™ will not be approved for concurrent use with a prophylactic CGRP inhibitor.
10. Use of Imitrex® STATdose System (sumatriptan injection), Onzetra® Xsail® (sumatriptan nasal powder), 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.
11. 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 also recommends updating the approval criteria for the calcitonin gene-related peptide (CGRP) therapies to be consistent with clinical practice and to be in line with current guideline recommendations (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
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
      ~~i. For episodic migraine, member must have had a history of migraines for a duration of 12 months or longer; and~~
4. Member has been evaluated for all of the following, ~~red flags or possible indicators of secondary headache,~~ 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. Migraine headache exacerbation secondary to other medication therapies or conditions have been ruled out and/or treated. This includes, but is not limited to:~~
   ~~a. Hormone replacement therapy or hormone-based contraceptives; and~~
   ~~b. Chronic insomnia; and~~
   ~~c. Obstructive sleep apnea; and~~

~~6. The member has failed medical migraine preventive therapy with at least 2¥ agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects). within the last 365 days. [¥The manufacturers of Ajovy® and Emgality® have currently provided a supplemental rebate to be the preferred calcitonin gene-related peptide (CGRP) inhibitor(s) and require a trial with 2 other migraine preventative therapies; however, Ajovy® and Emgality® will follow the original criteria and require trials with 3 other migraine preventative therapies if the manufacturers choose not to participate in supplemental rebates.] This includes, but is not limited to:~~
   ~~a. Select antihypertensive therapy (e.g., beta-blocker therapy); or~~
   ~~b. Select anticonvulsant therapy; or~~
   ~~c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and~~

~~7. Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-~~

~~prescription medications known to cause MOH includes, but is not limited to:~~

~~a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and~~

~~b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and~~

~~c. Opioids (≥10 days/month for >3 months); and~~

~~d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and~~

~~e. Ergotamine-containing medications (≥10 days/month for >3 months); and~~

~~f. Triptans (≥10 days/month for >3 months); and~~

~~8. Member is not taking any medications that are likely to be the cause of the headaches; and~~

9. 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

~~10. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and~~

11. Prescriber must verify member has been counseled on appropriate use, storage of the medication, and administration technique; and
12. 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
13. 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 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.

Emgality® (Galcanezumab-gnlm) Approval Criteria [Episodic Cluster Headache Diagnosis]:

1. An FDA approved indication for the treatment of episodic cluster headache in adults; and
2. Member must be 18 years of age or older; and

3. Member has a diagnosis of episodic cluster headache as defined by the International Headache Society (IHS) International Classification of Headache Disorders (ICHD) guideline and meets the following criteria:
    a. Member has a history of episodic cluster headache with at least 2 cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of ≥3 months; and
4. Member has been evaluated for red flags or possible indicators of secondary headache, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated; and
5. ~~Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:~~
    a. ~~Decongestants (alone or in combination products) (≥10 days/month for >3 months); and~~
    b. ~~Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and~~
    c. ~~Opioids (≥10 days/month for >3 months); and~~
    d. ~~Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and~~
    e. ~~Ergotamine-containing medications (≥10 days/month for >3 months); and~~
    f. ~~Triptans (≥10 days/month for >3 months); and~~
6. ~~Member has failed prophylactic therapy with at least 1 other medication (e.g., verapamil, select anticonvulsants, corticosteroids); and~~
7. Member will not use Emgality® concurrently with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
8. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
9. Initial approvals will be for the duration of 3 months. Continuation approvals will be granted until the end of the cluster period if the prescriber documents that the member is responding well to treatment as indicated by a reduction in cluster headache attack frequency; and
10. A quantity limit of (3) 100mg/mL syringes per 30 days will apply.

Nurtec® ODT (Rimegepant)*, Qulipta® (Atogepant), and Vyepti® (Eptinezumab-jjmr) Approval Criteria:

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

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 (*Nurtec® ODT is only FDA approved for the preventive treatment of episodic migraines.); and
        ~~i. For episodic migraine, member must have had a history of migraines for a duration of 12 months or longer; and~~
4. Member has been evaluated for all of the following, ~~red flags or possible indicators of secondary headache,~~ 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. Migraine headache exacerbation secondary to other medication therapies or conditions have been ruled out and/or treated. This includes, but is not limited to:~~
~~a. Hormone replacement therapy or hormone-based contraceptives; and~~
~~b. Chronic insomnia; and~~
~~c. Obstructive sleep apnea; and~~

~~6. The member has failed medical migraine preventive therapy with at least 3 agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects). within the last 365 days. This includes, but is not limited to:~~
~~a. Select antihypertensive therapy (e.g., beta-blocker therapy); or~~
~~b. Select anticonvulsant therapy; or~~
~~c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and~~

~~7. Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:~~
~~a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and~~
~~b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and~~
~~c. Opioids (≥10 days/month for >3 months); and~~
~~d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and~~

~~e. Ergotamine-containing medications (≥10 days/month for >3 months); and~~
~~f. Triptans (≥10 days/month for >3 months); and~~

~~8. Member is not taking any medications that are likely to be the cause of the headaches; and~~

9. 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

~~10. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and~~

11. For Vyepti®, prescriber must verify the medication will be prepared and administered according to the Vyepti® package labeling; and
12. For Qulipta® (atogepant) and Vyepti® (eptinezumab-jjmr), a patient-specific, clinically significant reason (beyond convenience) why member cannot use Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), ~~or~~ and Emgality® (galcanezumab-gnlm) must be provided ~~(members currently taking Nurtec® ODT for acute migraine treatment are not exempt from this criteria requirement)~~; and
13. For Nurtec® ODT (rimegepant), a patient-specific, clinically significant reason (beyond convenience) why member cannot use 2* of the preferred CGRP inhibitors [i.e., Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), Emgality® (galcanezumab-gnlm)] must be provided (members currently taking Nurtec® ODT for acute migraine treatment are not exempt from this criteria requirement; *the manufacturer of Nurtec® ODT has currently provided a supplemental rebate to only require 2 preferred injectable CGRP inhibitors; however, Nurtec® ODT will follow the original criteria and require a reason why the member cannot use all preferred CGRP inhibitors if the manufacturer chooses not to participate in supplemental rebates); and
14. For consideration of Vyepti® at the maximum recommended dosing (300mg every 3 months), a patient-specific, clinically significant reason why other available CGRP inhibitors for migraine prophylaxis are not appropriate for the member must be provided; and
15. 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
16. Quantity limits will apply based on FDA-approved dosing:
    a. For Nurtec® ODT, a quantity limit of 16 orally disintegrating tablets (ODTs) per 30 days will apply; and
    b. For Qulipta®, a quantity limit of 30 tablets per 30 days will apply; and
    c. For Vyepti®, a quantity limit of 3 vials per 90 days will apply.

Recommendation 6: Vote to Prior Authorize Ctexli™ (Chenodiol), Iqirvo® (Elafibranor), and Livdelzi® (Seladelpar) and Update the Approval Criteria for the Cholestatic Liver Disease and Bile Acid Disorder Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Ctexli™ (chenodiol), Iqirvo® (elafibranor), and Livdelzi® (seladelpar) with the following criteria (shown in red):

Ctexli™ (Chenodiol) Approval Criteria:

1. An FDA approved diagnosis of cerebrotendinous xanthomatosis (CTX); and
    a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the CYP27A1 gene (results of genetic testing must be submitted); and
2. Member must be 16 years of age or older; and
3. Must be prescribed by a neurologist, geneticist, or other specialist with expertise in the treatment of CTX (or an advanced care practitioner with a supervising physician who is a neurologist, geneticist, or other specialist with expertise in the treatment of CTX); and
4. Prescriber must agree to obtain baseline liver transaminase, including alanine aminotransferase (ALT) and aspartate aminotransferase (AST), and total bilirubin levels prior to initiating treatment; and
5. Prescriber must agree to monitor liver transaminase and total bilirubin levels yearly and as clinically indicated and will interrupt or discontinue treatment with Ctexli™, if appropriate, per package labeling; and
6. Member must not be using bile acid sequestering agents (e.g., cholestyramine, colestipol) or aluminum-based antacids concomitantly with Ctexli™; and
7. Initial approvals will be for a duration of 3 months. After 3 months of treatment, subsequent approvals (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by a reduction in cholestanol or bile alcohol levels or documentation of other clinical improvements; and
8. A quantity limit of 90 tablets per 30 days will apply.

Iqirvo® (Elafibranor) 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. Iqirvo® must be taken in combination with UDCA; or
    a. For Iqirvo® 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. Muscle pain or myopathy at baseline and periodically during treatment; and
9. Fracture risk and bone health; and
10. Liver function tests at baseline and thereafter; and
11. Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy, must agree to use effective non-hormonal contraception (or add a barrier method when using hormonal contraception), and must not be breastfeeding during treatment and for 3 weeks following the last dose of Iqirvo®; and
12. A quantity limit of 30 tablets per 30 days will apply; and
13. 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.

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
9. Liver function tests at baseline and thereafter; and
10. Member must not be taking OAT3 inhibitors (e.g., probenecid) or strong CYP2C9 inhibitors concurrently with Livdelzi®; and
11. A patient-specific, clinically significant reason why the member cannot use Iqirvo® (elafibranor) must be provided; and
12. A quantity limit of 30 capsules per 30 days will apply; and
13. 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.

Next, the College of Pharmacy recommends updating the Ocaliva® (obeticholic acid) approval criteria based on the FDA's safety alerts and to be consistent with the criteria for other primary biliary cholangitis (PBC) medications (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. The prescriber must also confirm all of the following:~~
    ~~a. PBC is not caused by a superimposed liver disease; and~~

~~b. If the member has a superimposed liver disease, it is being adequately treated; and~~
~~c. Proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and patient compliance with UDCA; and~~

7. 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
8. 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
9. 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
10. 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
11. 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
12. A quantity limit of 1 tablet per day will apply.

The College of Pharmacy also recommends updating the Livmarli® (maralixibat) approval criteria based on the new FDA approved age expansion for the progressive familial intrahepatic cholestasis (PFIC) indication and to be consistent with the recent label updates regarding the recommended formulation for each indication (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. The request must be for the 9.5mg/mL 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 ~~5 years~~ 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. The request must be for the 19mg/mL 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.

Lastly, the College of Pharmacy also recommends updating the Cholbam® (cholic acid) approval criteria to be consistent with other medications in this category (changes shown in red):

Cholbam® (Cholic Acid) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of bile acid synthesis disorders due to single enzyme defects (SEDs); ~~or~~ and
        i. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic or likely pathogenic variants in the *AKR1D1, AMACR, BAAT, CYP7A1, CYP7B1, CYP27A1, DHCR7, HSD3B7,* or *SLC27A5* gene, or other gene with significant supporting evidence of pathogenicity (results of genetic testing must be submitted); or
    b. Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption; and
        i. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic or likely pathogenic variants in the *PEX1, PEX2, PEX3, PEX5, PEX6, PEX10, PEX11B, PEX12, PEX13, PEX14, PEX16, PEX19,* or *PEX26* gene (results of genetic testing must be submitted); and
2. Treatment with Cholbam® should be initiated and monitored by a hepatologist, ~~or~~ pediatric gastroenterologist, or other specialist with expertise in the treatment of SEDs or PDs; and
3. The prescriber must verify that AST, ALT, GGT, alkaline phosphatase, bilirubin, and INR will be monitored every month for the first 3 months, every 3 months for the next 9 months, every 6 months during the next 3 years, and annually thereafter; and
4. Cholbam® should be discontinued if liver function does not improve within 3 months of starting treatment, if complete biliary obstruction develops, or if there are persistent clinical or laboratory indicators of worsening liver function or cholestasis; and
5. Initial approvals will be for the duration of 3 months to monitor for compliance and liver function tests; and
6. Continuation approvals will be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests; and
7. A quantity limit of 120 capsules per 30 days will apply. Quantity limit requests will be based on the member's recent weight taken within the last 30 days.

Recommendation 7: Vote to Prior Authorize Kebilidi™ (Eladocagene Exuparvovec-tneq)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Kebilidi™ (eladocagene exuparvovec-tneq) with the following criteria (shown in red):

Kebilidi™ (Eladocagene Exuparvovec-tneq) Approval Criteria:

1. An FDA approved diagnosis of aromatic L-amino acid decarboxylase (AADC) deficiency; and
2. Diagnosis must be confirmed by
   a. Genetic testing confirming biallelic pathogenic or likely pathogenic mutations in the *DDC* gene (results of genetic testing must be submitted); and
   b. Functional confirmation with measured diagnostic variations in AADC enzyme activity in plasma and/or levels of neurotransmitter metabolites in cerebrospinal fluid (CSF) (results of testing must be submitted); and
3. Member must be 16 months of age or older; and
4. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to Kebilidi™ administration; and
5. Must be prescribed by a neurologist, neurosurgeon, or a specialist with expertise in the treatment of AADC deficiency; and
6. Prescriber must verify the member has confirmed skull maturity as assessed by neuroimaging; and
7. Must be administered by intraputaminal infusion in a medical center that specializes in stereotactic neurosurgery in addition to the preparation and infusion of Kebilidi™; and
8. Must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment, and the facility must be capable of adhering to the storage, handling, and preparation requirements as described in the package labeling; and
9. Must only be administered using an FDA-authorized cannula for intraparenchymal infusion (e.g., ClearPoint® SmartFlow® Neuro Cannula); and
10. Approvals will be for 1 treatment per member per lifetime.

Recommendation 8: Vote to Prior Authorize Crenessity™ (Crinecerfont)

MOTION CARRIED by unanimous approval.

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

Crenessity™ (Crinecerfont) Approval Criteria:

1. An FDA approved indication as adjunctive treatment to glucocorticoid replacement to control androgens in members with classic congenital adrenal hyperplasia (CAH); and
2. A diagnosis of classic CAH due to 21-hydroxylase deficiency (21-OHD) must be confirmed by 1 of the following (results of the selected test must be submitted with the request):
   a. Elevated 17-hydroxyprogesterone (17-OHP); or
   b. Elevated 17-OHP following a cosyntropin stimulation test; or

c. Genetic testing identifying biallelic pathogenic variants in the *CYP21A2* gene; or
d. Positive newborn screening with confirmatory second-tier testing; or
e. Submitted historical documentation confirming the diagnosis; and

3. Member must be 4 years of age or older and weigh ≥10kg; and
   a. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
4. Crenessity™ must be prescribed by, or in consultation with, an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
5. Prescriber must verify that member will continue glucocorticoid replacement therapy concomitantly with Crenessity™ and the member will be monitored for signs of acute adrenal insufficiency or adrenal crisis; and
6. For the oral solution, members weighing ≥55kg (or ≥20kg if on concomitant CYP3A4 inducers) will require a patient-specific, clinically significant reason why the capsule formulation cannot be used; and
7. A quantity limit of 60 capsules or 60mL per 30 days will apply; and
   a. For members who require increased doses above 100mg twice daily, a quantity limit override may be approved with documentation that the member is taking a strong or moderate CYP3A4 inducer (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone) concomitantly with Crenessity™; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents that the member is responding well to therapy as indicated by a decrease in glucocorticoid daily dose from baseline or a decrease in serum androstenedione levels from baseline. Subsequent approvals will be for the duration of 1 year.

Recommendation 9: Vote to Prior Authorize Aucatzyl® (Obecabtagene Autoleucel), Danziten™ (Nilotinib), Grafapex™ (Treosulfan), Revuforj® (Revumenib), and Rytelo® (Imetelstat) and Update the Approval Criteria for the Leukemia and Lymphoma Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Aucatzyl® (obecabtagene autoleucel), Danziten™ (nilotinib), Grafapex™ (treosulfan), Revuforj® (revumenib), and Rytelo® (imetelstat) with the following criteria (shown in red):

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.

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.

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.

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.

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).

Next, the College of Pharmacy recommends updating the approval criteria for Besponsa® (inotuzumab ozogamicin), Breyanzi® (lisocabtagene

maraleucel), Calquence® (acalabrutinib), Epkinly™ (epcoritamab-bysp), and Scemblix® (asciminib) based on recent FDA approvals (changes shown in red)

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

1. Diagnosis of relapsed or refractory CD22-positive B-cell precursor ALL; and
2. Member must be 1 year of age or older.
3. ~~Diagnosis of ALL; and~~
4. ~~Member must have 1 of the following:~~
   a. ~~Relapsed/refractory Philadelphia chromosome negative (Ph-) ALL; or~~
   b. ~~Relapsed/refractory Philadelphia chromosome positive (Ph+) ALL who are intolerant/refractory to ≥2 tyrosine kinase inhibitors (TKIs); and~~
5. ~~As a single agent only.~~

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 [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.

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).

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.

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.

The College of Pharmacy also recommends updating the approval criteria for Adcetris® (brentuximab vedotin), Blincyto® (blinatumomab), and Iclusig® (ponatinib) based on recent FDA approvals and National Comprehensive Cancer Network (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
   ~~c. In members who have transformed to DLBCL from follicular lymphoma or marginal zone lymphoma and received ≥2 lines of therapy for indolent or transformed disease; 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 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.

~~3. Diagnosis of ALL; and~~

~~4. Member must have 1 of the following:~~

~~a. Relapsed/refractory Philadelphia chromosome negative (Ph-) ALL; or~~

~~b. Relapsed/refractory Philadelphia chromosome positive (Ph+) ALL after failure of 2 tyrosine kinase inhibitors (TKIs); or~~

~~c. Ph- ALL as consolidation in adolescent/young adult or members 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; and~~

~~5. As a single agent.~~

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.

~~d. Induction/consolidation with hyperfractionated cyclophosphamide, vincristine sulfate, doxorubicin hydrochloride (Adriamycin®), and dexamethasone (HyperCVAD); or~~

~~e. Maintenance therapy post-hematopoietic stem cell transplantation; or~~

The College of Pharmacy also recommends updating the approval criteria for Asparlas® (calaspargase pegol-mknl) and Oncaspar® (pegaspargase),

Beleodaq® (belinostat), Bosulif® (bosutinib), Columvi™ (glofitamab-gxbm), Copiktra® (duvelisib), Folotyn® (pralatrexate), Gazyva® (obinutuzumab), Idhifa® (enasidenib), Imbruvica® (ibrutinib), Istodax® (romidepsin), Jaypirca® (pirtobrutinib), Monjuvi® (tafasitamab-cxix), Poteligeo® (mogamulizumab-kpkc), Sprycel® (dasatinib), Tasigna® (nilotinib), Tazverik® (tazemetostat), Venclexta® (venetoclax), Zevalin® (ibritumomab tiuxetan), Zydelig® (idelalisib), and Zynlonta® (loncastuximab tesirine-lpyl) based on NCCN recommendations (changes shown in red):

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 ~~nasal disease~~ 1 of the following~~; and~~:
    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.

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.

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

~~1. Relapsed/refractory Ph+ ALL; and~~
    ~~a. As a single agent; or~~
    ~~b. In combination with an induction regimen not previously given; and~~
~~2. E255K/V, F317L/VI/C, F359V/C/I, T315A, or Y253H mutations.~~
3. Diagnosis of Ph+ ALL; and
4. 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

5. Member does not have any of the following mutations of BCR-ABL1: T315I, V299L, G250E, or F317L.

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 [Peripheral T-Cell Lymphomas (PTCL) Diagnosis]:

1. Diagnosis of PTCL; and
2. As a single agent or in combination with romidepsin.

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. As a single agent in relapsed/refractory disease; or~~
~~3. In combination with acalabrutinib, bendamustine, chlorambucil, ibrutinib, or venetoclax for first-line therapy; and~~

4. 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
5. 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
6. When obinutuzumab is used in combination with venetoclax, maximum approval duration of obinutuzumab will be 6 treatment cycles.

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.

Idhifa® (Enasidenib) 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. Unable to tolerate intensive induction chemotherapy; and
c. As a single agent; and
d. Isocitrate dehydrogenase-2 (IDH2) mutation; or

2. Relapsed/refractory AML; and
   a. IDH2 mutation; and
   b. As a single agent.

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 ~~bendamustine,~~ 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 ~~high-dose therapy~~ CAR T-cell therapy or has no intention to proceed to transplant.

~~**Imbruvica® (Ibrutinib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:**~~

~~1. Diagnosis of grade 1 or 2 FL; and~~
~~2. As subsequent therapy (third-line or greater) for histologic transformation to non-germinal center diffuse large B-cell lymphoma (DLBCL).~~

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 [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. ~~Has received ≥2 lines of systemic therapy, including a Bruton's kinase (BTK) inhibitor and a BCL-2 inhibitor.~~
3. As second-line or subsequent therapy following resistance or intolerance to prior covalent Bruton's kinase (BTK) inhibitor and a BCL-2 inhibitor; or
4. Demonstrates histologic (Richter) transformation to diffuse large B-cell lymphoma (DLBCL).

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.

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.

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 [Soft Tissue Sarcoma – Gastrointestinal Stromal Tumors (GIST) Diagnosis]:

1. Diagnosis of soft tissue sarcoma – GIST; and

~~2. Member must have all of the following:~~
   ~~a. Progressive disease and failed imatinib, sunitinib, or regorafenib; and~~
   ~~b. PDGFRA D842V mutation.~~
3. Used for gross residual disease (R2 resection), unresectable primary disease, tumor rupture, or recurrent/metastatic disease; and
4. Used as second-line therapy as single agent; and
5. Member has progressive disease after treatment with avapritinib; and
6. 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 [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 [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.

~~4. *EZH2* mutation detected; and~~

~~5. Member must have received 2 lines of therapy or as subsequent therapy with no satisfactory alternative treatment options.~~

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.

Zevalin® (Ibritumomab Tiuxetan) Approval Criteria [~~Follicular Lymphoma (FL) (Grade 1-2)~~ Lymphoma Diagnosis]:

~~1. Diagnosis of FL (grade 1-2); and~~

~~2. As a single agent; and~~

3. Diagnosis of low grade B-cell non-Hodgkin's lymphoma (NHL) or follicular lymphoma; and
4. 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
5. Used in combination with rituximab; and
6. 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.

~~**Zevalin® (Ibritumomab Tiuxetan) Approval Criteria [Follicular Lymphoma (FL) or Marginal Zone Lymphoma (MZL) Transformed to Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:**~~

~~1. Diagnosis of FL or MZL transformed to DLBCL; and~~

~~2. As a single agent; and~~

~~3. Member meets 1 of the following:~~

~~a. Minimal or no chemotherapy prior to histologic transformation to DLBCL (FISH for MYC and BCL2 and/or BCL6 must show no translocation) and have partial response, no response, or progressive disease after chemoimmunotherapy; or~~

~~b. Member must have received ≥2 prior therapies of chemoimmunotherapy for indolent or transformed 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.

~~**Zydelig® (Idelalisib) 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; and~~
~~3. Refractory to both alkylator and rituximab therapy.~~

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. ~~If previous CD19-directed therapy was used, patient must have a biopsy that shows CD19 protein expression after completion of the CD19-directed therapy; and~~
4. A patient-specific, clinically significant reason why tafasitamab in combination with lenalidomide is not appropriate for the member must be provided.

Lastly, the College of Pharmacy recommends removal of SoonerCare coverage and of the approval criteria for Aliqopa® (copanlisib), Arzerra® (ofatumumab), Lumoxiti® (moxetumomab pasudotox-tdfk), and Synribo® (omacetaxine) based on product discontinuations or withdrawn indications (changes shown in red):

~~**Aliqopa® (Copanlisib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:**~~

~~1. Diagnosis of relapsed/refractory FL; and~~
~~2. Member must have failed at least 2 prior systemic therapies; and~~
~~3. Members who are new to treatment with Aliqopa® will not generally be approved.~~

~~**Arzerra® (Ofatumumab) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:**~~

~~1. For first-line treatment of CLL/SLL in combination with chlorambucil or bendamustine; or~~
~~2. Relapsed/refractory disease as a single agent or in combination with fludarabine and cyclophosphamide; or~~
~~3. Maintenance therapy as second-line extended dosing following complete or partial response to relapsed/refractory therapy (maximum 2 years).~~

~~**Arzerra® (Ofatumumab) Approval Criteria [Waldenström's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma Diagnosis]:**~~

~~1. For previously treated disease that does not respond to primary therapy or for progressive or relapsed disease; and~~
~~2. Member is rituximab-intolerant; and~~
~~3. As a single agent or combination therapy.~~

~~**Lumoxiti® (Moxetumomab Pasudotox-tdfk) Approval Criteria [Hairy Cell Leukemia (HCL) Diagnosis]:**~~

~~1. Treatment of relapsed or refractory HCL in adults; and~~
~~2. Member has received ≥2 prior systemic therapies, including treatment with a purine nucleoside analog (PNA); and~~
~~3. Creatinine clearance (CrCl) ≥30mL/min/1.73m^2; and~~
~~4. As a single agent.~~

~~**Synribo® (Omacetaxine) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:**~~

~~1. Member must have 1 of the following:~~
~~a. Primary treatment of advanced phase CML with disease progression to accelerated phase; or~~
~~b. Post-hematopoietic stem cell transplant in members who have relapsed; or~~
~~c. T315I mutation; or~~
~~d. Members who are intolerant or resistant to ≥2 tyrosine kinase inhibitors (TKIs); and~~
~~2. As a single agent.~~

Recommendation 10: Annual Review of Topical Acne, Psoriasis, and Rosacea Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for Vtama® (tapinarof) and Zoryve® (roflumilast) based on the recent FDA approved indications for AD with the following criteria, including the addition of allergist and immunologist as specialists included in criteria #3 for Vtama® for the atopic dermatitis indication and removing the specialist requirement

(criteria #3) for Zoryve® 0.15% cream for atopic dermatitis as recommended by and approved unanimously by the DUR Board (shown in red):

Vtama® (Tapinarof) Approval Criteria [Atopic Dermatitis Diagnosis]:

1. An FDA approved diagnosis of atopic dermatitis; and
2. Member must be 2 years of age or older; and
3. Must be prescribed by, or in consultation with, an allergist, dermatologist, or immunologist (or an advanced care practitioner with a supervising physician who is an allergist, dermatologist, or immunologist); and
4. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); and
    b. 1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
    c. Eucrisa® (crisaborole); and
5. Initial approvals will be for the duration of 2 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
6. A quantity limit of 60 grams per 30 days will apply.

Zoryve® (Roflumilast 0.15% Cream) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis; and
2. Member must be 6 years of age or older; and
3. ~~Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and~~
4. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); and
    b. 1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
    c. Eucrisa® (crisaborole); and
5. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
6. A quantity limit of 60 grams per 30 days will apply.

Next, the College of Pharmacy recommends updating the approval criteria regarding the topical erythromycin products based on net costs with the following changes (shown in red):

Erythromycin 2% Swabs ~~and 2% Topical Gel~~ Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use erythromycin 2% topical gel or solution must be provided; and
2. Member must be 20 years of age or younger.

Brimonidine 0.33% Topical Gel (Generic Mirvaso®) Approval Criteria:

1. An FDA approved diagnosis of persistent (non-transient) facial erythema of rosacea; and
2. Member must be 18 to 20 years of age; and
3. A patient-specific, clinically significant reason why the member cannot utilize clindamycin topical solution (generic), metronidazole topical gel and cream 0.75%, erythromycin topical 2% gel or solution, oral isotretinoin medications, or other generically available preferred oral or topical antibiotic products; and
4. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
5. Brand name Mirvaso® is not a covered product; and
6. A quantity limit of 30 grams per 30 days will apply.

Winlevi® (Clascoterone 1% Cream) Approval Criteria:

1. An FDA approved diagnosis of acne vulgaris; and
2. Member must be 12 to 20 years of age; and
3. A patient-specific, clinically significant reason why the member cannot use erythromycin 2% topical gel or solution, clindamycin 1% solution, benzoyl peroxide, preferred tazarotene formulations, oral isotretinoin medications, and other generically available preferred oral or topical antibiotic products must be provided; and
4. A quantity limit of 60 grams per 30 days will apply.

Lastly, the College of Pharmacy recommends updating the approval criteria for the topical tazarotene products based on the FDA approval of generic tazarotene 0.05% cream and net costs with the following changes (shown in red):

Tazorac® (Tazarotene Cream and Gel) Approval Criteria:

1. An FDA approved diagnosis of acne vulgaris or plaque psoriasis; and
2. Female members must not be pregnant and must be willing to use an effective method of contraception during treatment; and
3. For the diagnosis of acne vulgaris, the following must be met:
    a. Member must be 20 years of age or younger; and
    b. Tazarotene 0.1% cream will not require prior authorization for members 20 years of age or younger; and
4. Tazarotene 0.05% cream, 0.05% gel, and tazarotene 0.1% gel will require a patient specific, clinically significant reason why the member cannot use tazarotene 0.1% cream, which is available without prior authorization for members 20 years of age and younger; and
5. A quantity limit of 100 grams per 30 days will apply.

Recommendation 11: Annual Review of Molluscum Contagiosum Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Ycanth™ (cantharidin 0.7% solution) and Zelsumvi™ (berdazimer 10.3% gel) approval criteria for clarity and based on clinical practice and prior discussion with the DUR Board (changes shown in red):

Ycanth™ (Cantharidin 0.7% Solution) Approval Criteria:

1. An FDA approved indication for the treatment of molluscum contagiosum lesions; and
2. Member must be 2 years of age or older; and
3. Member must meet 1 of the following:
    a. Is immunocompromised; or
    b. Is experiencing itching or pain; or
    c. Has concomitant bacterial infection; or
    d. Has concomitant atopic dermatitis; or
    e. There is concern for contagion (e.g., siblings, daycare) and the spread of lesions cannot be reasonably prevented using good hygiene or covered using a bandage; and
4. Prescriber must attest that it has been at least 6 months since the onset of the current infection unless the member is experiencing severe symptoms; and
5. Unless contraindicated, member must have a trial of: ~~at least 1 of the following procedures or medications for the removal of molluscum contagiosum lesions in the last 6 months,~~
    a. At least 1 of the following physical removal procedures:
        i. Cryotherapy; or
        ii. Curettage; or
        iii. Laser therapy; and
    b. At least 1 of the following medications:
        i. Potassium hydroxide; or
        ii. Salicylic acid; or
        ~~iii. Cimetidine; or~~
        iv. Other pharmacological treatment for removal of molluscum contagiosum lesions (supporting evidence must be provided with the request); and
6. Member must not have lesions exclusively on genitals or around eyes; and
7. Ycanth™ must be dispensed to and administered by a health care professional (HCP) trained in the administration of Ycanth™. Approvals will not be granted for self-administration. Requests must indicate who will administer Ycanth™ and in what setting; and

8. Prescriber must attest that the member or caregiver has been counseled to wash off lesions treated with Ycanth™ with soap and water 24 hours after application and to avoid skin contact with water, including bathing, prior to the 24-hour mark; and
9. Prescriber must attest that the member or caregiver has been counseled on all precautions prior to and during treatment with Ycanth™ that are listed in the package labeling, including avoiding contact with the eyes and mouth and avoiding close contact with open flames, even after the medication has dried; and
10. Approvals will be for a maximum of 12 weeks of therapy; and
11. A quantity limit of 2 applicators every 3 weeks for a maximum of 4 applications will apply; and
12. Reauthorization is not permitted. A new prior authorization request must be submitted, and the member must meet all initial approval criteria for each molluscum contagiosum infection.

Zelsuvmi™ (Berdazimer 10.3% Gel) Approval Criteria:

1. An FDA approved indication for the treatment of molluscum contagiosum lesions; and
2. Member must be 1 year of age or older; and
3. Member must meet 1 of the following:
    a. Is immunocompromised; or
    b. Is experiencing itching or pain; or
    c. Has concomitant bacterial infection; or
    d. Has concomitant atopic dermatitis; or
    e. There is concern for contagion (e.g., siblings, daycare) and the spread of lesions cannot be reasonably prevented using good hygiene or covered using a bandage;
4. Prescriber must attest that it has been at least 6 months since the onset of the current infection unless the member is experiencing severe symptoms; and
5. Unless contraindicated, member must have a trial of: ~~at least 1 of the following procedures or medications for the removal of molluscum contagiosum lesions in the last 6 months,~~
    a. At least 1 of the following physical removal procedures:
        i. Cryotherapy; or
        ii. Curettage; or
        iii. Laser therapy; and
    b. At least 1 of the following medications:
        i. Potassium hydroxide; or
        ii. Salicylic acid; or
        ~~iii. Cimetidine; or~~
        iv. Other pharmacological treatment for removal of molluscum contagiosum lesions (supporting evidence must be provided with the request); and

6. Member must not have lesions exclusively on genitals or around eyes; and
7. Prescriber must attest that the member or caregiver has been counseled on and demonstrates understanding of the proper storage and preparation of Zelsuvmi™; and
8. Prescriber must attest that the member or caregiver has been counseled on and has demonstrated understanding of the proper administration of Zelsuvmi™, including the medication's drying time and avoiding contact with the eyes, mouth, and genital areas; and
9. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use Ycanth™ (cantharidin) must be provided; and
10. Approvals will be for a maximum of 12 weeks of therapy; and
11. A quantity limit of 1 carton (14-gram tube of Zelsuvmi™ and 17 gram tube of hydrogel) every 30 days for a maximum of 3 cartons will apply; and
12. Reauthorization is not permitted. A new prior authorization request must be submitted, and the member must meet all initial approval criteria for each molluscum contagiosum infection.

Recommendation 12: Annual Review of Growth Hormone Products and Voxzogo® (Vosoritide)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for adult dosing of growth hormone to be consistent with clinical practice with the following changes (shown in red):

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) ~~between -2 and~~ ≤ +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 ~~between -2 and~~ ≤ +2.

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 ~~between -2 and~~ ≤ +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 ~~between -2 and~~ ≤ +2.

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 ~~between -2 and~~ ≤ +2.

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 ~~between -2 and~~ ≤ +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.

Next, the College of Pharmacy recommends updating the approval criteria for Serostim® (somatropin) to be more consistent with the FDA approved labeling and dosing with the following changes (shown in red):

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 ~~4~~ 8 weeks of therapy will be approved to complete 12 weeks of treatment; and
   b. Subsequent follow up evaluations will be required every ~~4~~ 12 weeks to assess response and compliance. The member may receive ~~another 4 weeks of therapy for~~ up to a maximum of ~~12~~ 48 weeks continuous therapy.
3. Discontinuation Criteria:

a. Completion of ~~the FDA approved 12~~ 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.

Recommendation 13: Annual Review of Hemophilia Medications and 30-Day Notice to Prior Authorize Alhemo® (Concizumab-mtci), Beqvez™ (Fidanacogene Elaparvovec-dzkt), Hympavzi™ (Marstacimab-hncq), and Qfitlia™ (Fitusiran)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY 2025.

Recommendation 14: Annual Review of Muscular Dystrophy Medications and 30-Day Notice to Prior Authorize Agamree® (Vamorolone) and Duvyzat™ (Givinostat)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY 2025.

Recommendation 15: Annual Review of Multiple Sclerosis (MS) Medications and 30-Day Notice to Prior Authorize Ocrevus Zunovo™ (Ocrelizumab/Hyaluronidase-ocsq)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY 2025.

Recommendation 16: Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers and 30-Day Notice to Prior Authorize Xolremdi® (Mavorixafor)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY 2025.

Recommendation 17: 30-Day Notice to Prior Authorize Journavx™ (Suzetrigine)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY 2025.

Recommendation 18: Annual Review of Thrombocytopenia Medications and 30-Day Notice to Prior Authorize Adzynma (ADAMTS13, Recombinant-krhn) and Alvaiz® (Eltrombopag)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY 2025.

Recommendation 19: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 20: Future Business

NO ACTION REQUIRED.

April 4, 2025

Oklahoma Health Care Authority
Drug Utilization Review Board

To the Board;

My name is Brian Denger and I work in Community Engagement for Parent Project Muscular Dystrophy, a volunteer health organization focused on improving outcomes for those affected by Duchenne muscular dystrophy. I also have an adult son who has Duchenne muscular dystrophy. Supporting Patrick and individuals who live with Duchenne muscular dystrophy is the reason for writing the Oklahoma Drug Utilization Review Board (DURB). I strongly recommend the DUR update the Prior Approval and Approval criteria as recommended by the College of Pharmacy for Duchenne muscular dystrophy agents; Agamree, Duvyzat, Elevidys, and Emflaza.

Duchenne muscular dystrophy (DMD) is an extraordinarily complex, progressive, degenerative muscle wasting disorder. Based on the advice of his expert clinical team, Patrick is treated with several drugs and therapies for his condition, including Exondys-51 (Exondys) as he has an amenable gene variant. His experience with Exondys serves as an appropriate comparator to provide access to DMD therapies to individuals living with DMD. His primary care is provided by an interdisciplinary team of DMD experts at Kennedy Krieger Institute (KKI) in Baltimore, MD. Patrick's KKI neurologist is a leading clinician/scientist in the muscular dystrophy field who is the Primary Investigator on over a dozen clinical trials for DMD and other neuromuscular disorders. On her recommendation Patrick decided to initiate use of Exondys-51.

My son, now 30 years old, has been treated with Exondys-51 since December 2016. I often read that the clinical benefit of Exondys-51 is "marginal" as the drug only produces small amount of dystrophin protein. For patients with DMD, marginal benefit changes the natural history of disease progression. Preservation of function not only translates to continued ability yet delays the deleterious effects of disease progression which can increase survival. We are fortunate that Patrick is experiencing both.

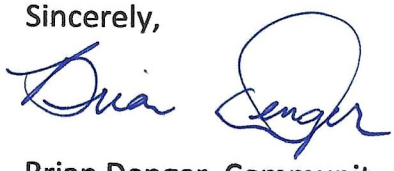
Patrick is self-employed as an online streamer, independently feeds himself and uses his computers and cell phone without assistance. (My wife and I provide appropriate support, as needed with his activities of daily living.) Exondys-51 also slows the

progression of pulmonary decline. My son's Forced Vital Capacity is still in 30% range. He uses a Cough Assist to maintain healthy chest wall and respiratory muscles and began limited nighttime ventilatory support (Bi-Pap) beginning the end of 2019. He has no pulmonary deficiency symptoms. I'm not sure you realize the significance, especially for a man his age with DMD.

Recognizing that each person with DMD is unique and that the same interventions may lead to different results, providing a therapy that may help preserve function and survival to patients who have few viable alternatives is appropriate and vital. Patrick's example of continued independence bolsters my argument. Early treatment with Elevidys may significantly extend the time a treated individual is able to walk and may preserve upper body ability. Access to Agamree and Emflaza may decrease patient burden often experience using Prednisone. Similarly, Duvyzat has been shown to preserve physical ability for patients in clinical trials and offers another option for families to slow the progress of weakness. Agamree, Emflaza, and Duvyzat may also delay the time to loss of ambulation. In addition to increasing a child's ability to participate in similar activities as their unaffected peers, later walking allows the trunk muscles to fully develop, eliminating the need for spinal intervention for scoliosis and helps in preserving upper body and limb function. The importance of upper body ability for selfcare and the use of computers and communication devices makes a significant difference for affected individuals regarding quality of life and independence. Replacing that independence with a team of state-funded personal care attendants to get him up, prepare him for work (if still possible) and assist him throughout the day becomes the alternative. As a former member on the Boards of Directors for local organizations that supported people with that level of need, I'm fully aware of the expense and the difficulty in obtaining staff to meet those obligations.

My request is that the DUR votes to update coverage and approval policies as recommended by the College of Pharmacy for Agamree, Duvyzat, Elevidys, and Emflaza for Oklahoma Medicaid covered DMD patients who meet the FDA label criteria. Thank you for considering my request.

Sincerely,



Brian Denger, Community Engagement
Parent Project Muscular Dystrophy

Dear Pharmacy Review Board,

I am submitting a formal comment regarding the upcoming review of disease modifying treatments for Spinal Muscular Atrophy - Zolgensma (onasemnogene abeparvovec), Evrysdi (risdiplam), and Spinraza (nusinersen).

First of all, thank you to all on the board who have been instrumental in providing coverage for these treatment options for Oklahoman's with SMA. We have watched this previously rapidly fatal disease become mostly an afterthought, as the children treated after identification with newborn screening (and prior to onset of symptoms) have almost all gone on to have essentially normal physical development and strength through their early childhood. This has not only saved millions of healthcare dollars, but also given these beautiful children and their families the opportunity of a 'normal life'.

However, with the knowledge gained after 7 years of 'real-life' experience with these drugs, it is apparent that there are a very small number of patients who do not respond as robustly as expected. Although these children clearly do not have the same clinical progression of severe untreated SMA, they do continue to have at least moderate delays in their development, low muscle tone, and swallowing/respiratory difficulties that place them at high risk for complications such as aspiration and pneumonia.

There has been a push in the muscular dystrophy community nationwide to start "dual therapy" for these children, offering them the benefits of SMN2 gene upregulation with risdiplam or nusinersen, even if they have already received onasemnogene abeparvovec (which provides support through the SMN1 gene). Thus far, studies have been completed that show that combination therapy is safe, with efficacy studies ongoing or being planned for the near future.

I have three patients who currently receive dual therapy and all appear to have seen a benefit with the second drug added.

I would like all reviews of the SMA treatments to include the possibility for dual therapy, only in very select patients who are deemed to have significant symptoms of SMA, despite therapy with onasemnogene abeparvovec. In my experience so far, this would apply to <10% of all of those treated and I would be happy to help draft specific criteria that could be used for authorization only in those that would specifically benefit from treatment.

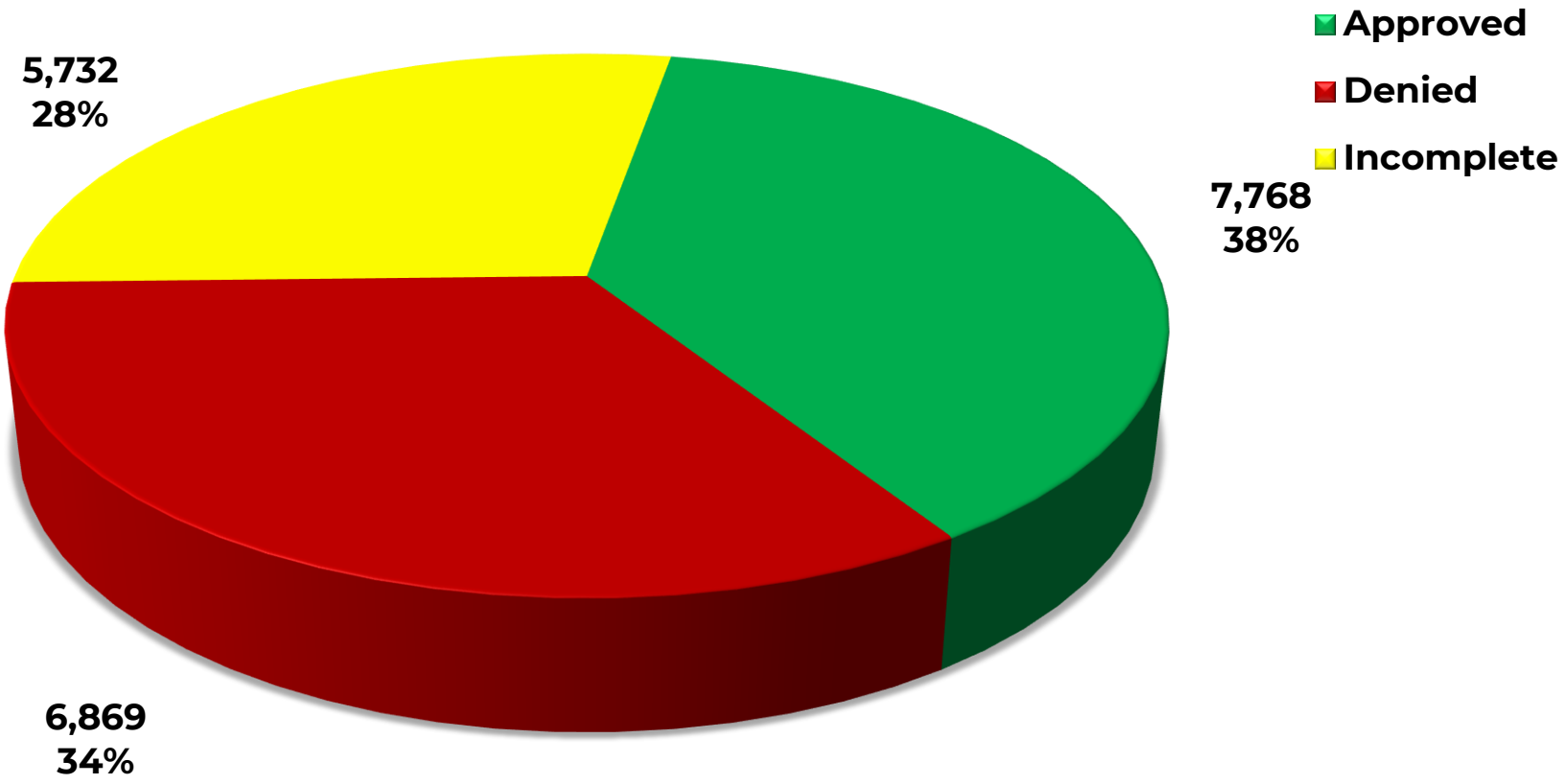
Thank you for your consideration,

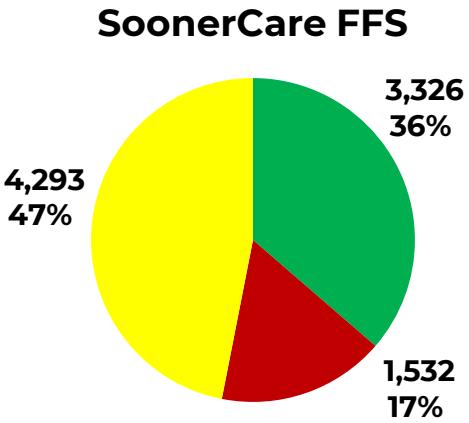
Jennifer Norman, MD

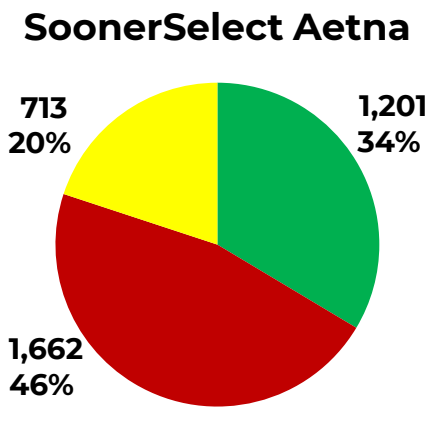
INTEGRIS Pediatric Neurology

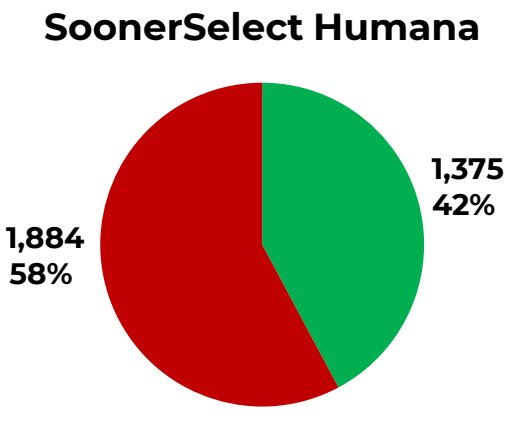
Appendix B

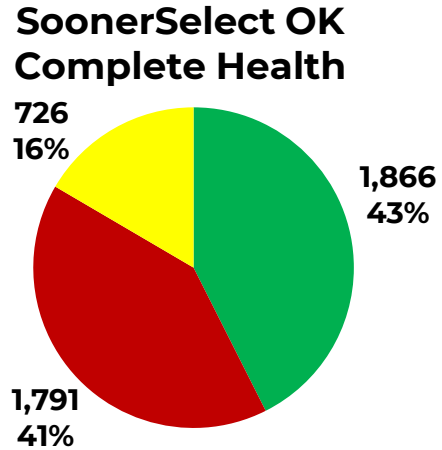
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: APRIL 2025





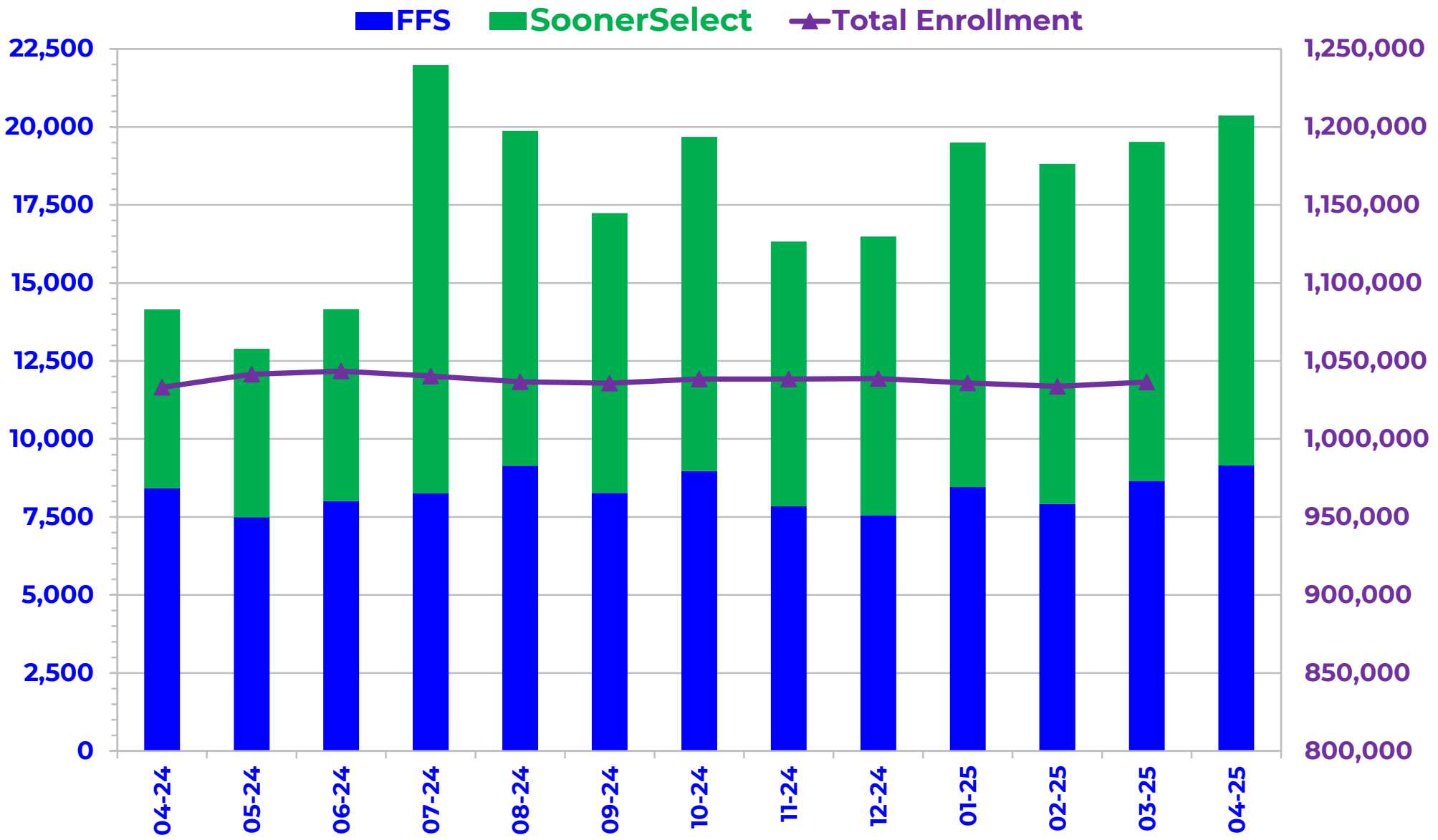






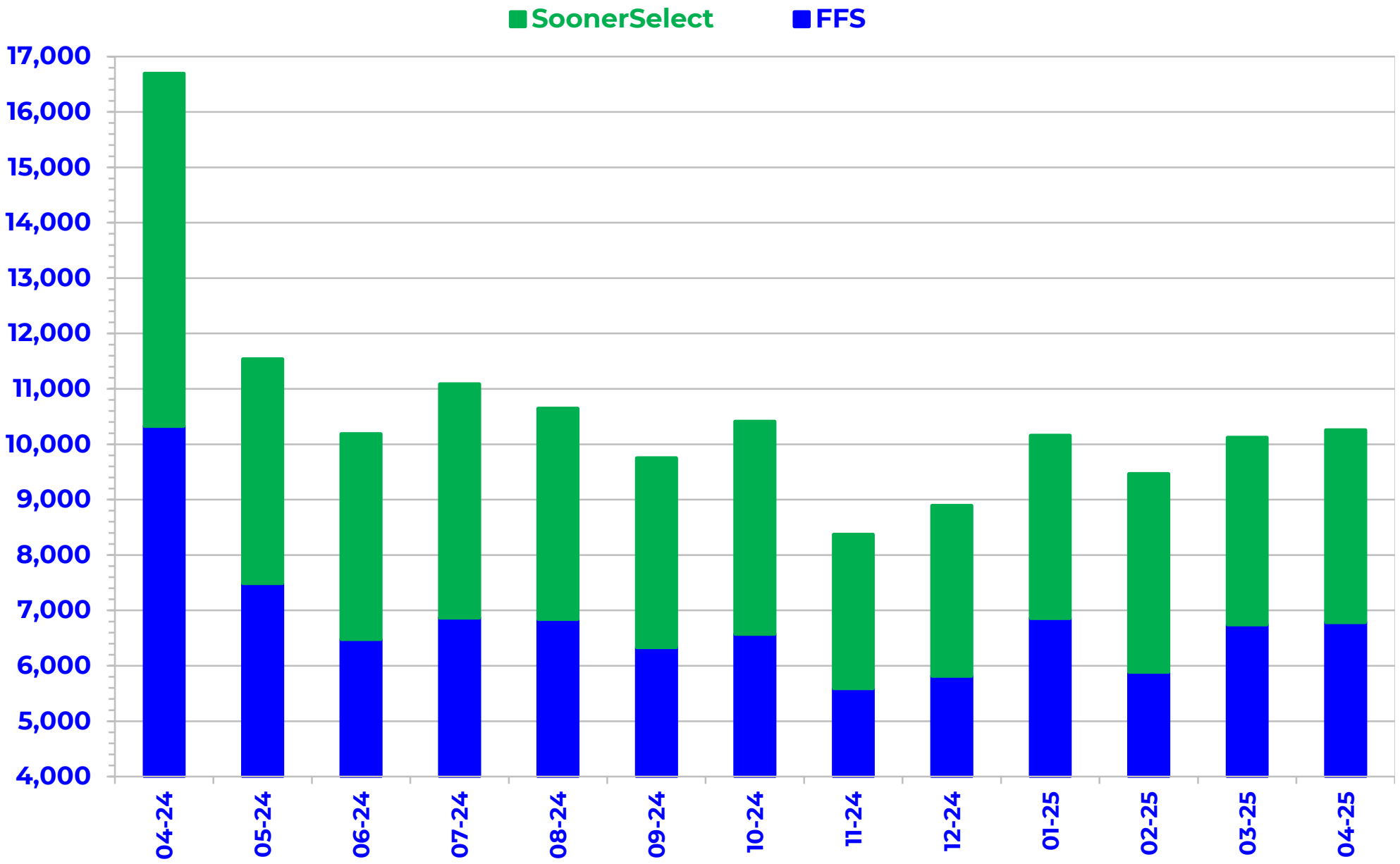
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: APRIL 2024 – APRIL 2025



SoonerCare FFS Prior Authorization Activity

4/1/2025 Through 4/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	6	0	1	5	0
Amebicides	1	0	0	1	0
Amphetamines	607	398	13	196	351
Analgesics - Anti-Inflammatory	219	90	24	105	305
Analgesics - Nonnarcotic	16	1	6	9	14
Analgesics - Opioid	280	103	24	153	128
Androgens - Anabolic	76	18	18	40	349
Anorexiants Non-Amphetamine	1	0	1	0	0
Antacids	1	1	0	0	361
Anthelmintics	18	5	1	12	18
Anti-Infective Agents - Misc.	36	14	6	16	234
Anti-Obesity Agents	99	6	74	19	27
Antianginal Agents	3	2	0	1	358
Antianxiety Agents	26	1	2	23	358
Antiarrhythmics	2	0	0	2	0
Antiasthmatic and Bronchodilator Agents	592	97	116	379	307
Antibiotics	26	6	4	16	206
Anticoagulants	9	0	0	9	0
Anticonvulsants	203	88	15	100	345
Antidepressants	219	44	39	136	299
Antidiabetics	1,531	418	315	798	350
Antidotes and Specific Antagonists	3	2	0	1	360
Antiemetics	19	2	2	15	358
Antifungals	4	0	2	2	0
Antihistamines	18	3	7	8	360
Antihyperlipidemics	80	14	34	32	317
Antihypertensives	16	3	1	12	360
Antimalarials	2	1	0	1	89
Antimyasthenic/Cholinergic Agents	3	1	0	2	360
Antineoplastics and Adjunctive Therapies	167	112	6	49	175
Antiparkinson and Related Therapy Agents	12	0	6	6	0
Antipsychotics/Antimanic Agents	371	106	53	212	340
Antivirals	32	10	2	20	56
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	231	148	18	65	354
Beta Blockers	11	3	1	7	258
Calcium Channel Blockers	15	2	1	12	358
Cardiovascular Agents - Misc.	132	63	19	50	331
Chemicals	1	0	0	1	0
Contraceptives	48	17	7	24	331
Corticosteroids	14	3	1	10	360
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	462	126	133	203	222
Diagnostic Products	41	23	2	16	139
Dietary Products/Dietary Management Products	1	0	0	1	0
Digestive Aids	11	9	0	2	351
Diuretics	4	2	0	2	359
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	1	0	0	360
Emergency PA	0	0	0	0	0

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Endocrine and Metabolic Agents - Misc.	145	75	19	51	220
Estrogens	10	2	1	7	360
Gastrointestinal Agents - Misc.	333	84	76	173	254
Genitourinary Agents - Misc.	3	1	2	0	347
Gout Agents	2	2	0	0	359
Hematological Agents - Misc.	7	4	1	2	359
Hematopoietic Agents	61	21	9	31	133
Histamine H3-receptor Antagonist/Inverse Agonists	1	0	0	1	0
Hypnotics/Sedatives/Sleep Disorder Agents	73	6	13	54	237
Laxatives	27	12	2	13	274
Medical Devices and Supplies	297	58	56	183	287
Migraine Products	324	64	85	175	257
Minerals and Electrolytes	9	4	0	5	270
Miscellaneous Therapeutic Classes	49	23	8	18	338
Multivitamins	4	3	0	1	250
Musculoskeletal Therapy Agents	39	7	3	29	168
Nasal Agents - Systemic and Topical	21	4	6	11	153
Neuromuscular Agents	86	41	27	18	299
Ophthalmic Agents	88	22	18	48	215
Other*	45	13	4	28	206
Otic Agents	28	0	8	20	0
Passive Immunizing and Treatment Agents	2	0	0	2	0
Progestins	2	1	0	1	360
Psychotherapeutic and Neurological Agents - Misc.	231	80	52	99	205
Respiratory Agents - Misc.	15	9	1	5	318
Stimulants - Misc.	252	94	29	129	329
Thyroid Agents	11	2	3	6	359
Toxoids	1	1	0	0	360
Ulcer Drugs/Antispasmodics/Anticholinergics	61	11	14	36	264
Urinary Antispasmodics	44	7	9	28	359
Vaccines	3	1	2	0	360
Vaginal and Related Products	2	0	1	1	0
Vitamins	42	3	30	9	268
Total	**7,989**	**2,598**	**1,433**	**3,958**	
Overrides					
Brand	25	13	1	11	318
Compound	21	17	1	3	13
Dosage Change	184	166	0	18	16
Ingredient Duplication	2	0	0	2	0
Lost/Broken Rx	64	57	4	3	19
MAT Override	17	10	2	5	127
NDC vs Age	165	96	26	43	293
NDC vs Sex	23	15	4	4	253
Nursing Home Issue	42	38	0	4	12
Opioid MME Limit	96	18	12	66	136
Opioid Quantity	20	13	0	7	203
Other	50	33	9	8	18
Quantity vs Days Supply	386	215	36	135	271
STBS/STBSM	21	11	1	9	95
Step Therapy Exception	6	2	2	2	359

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Stolen	9	7	0	2	18
Third Brand Request	31	17	1	13	24
Overrides Total	**1,162**	**728**	**99**	**335**	
Total Regular PAs + Overrides	**9,151**	**3,326**	**1,532**	**4,293**	

Denial Reasons	
Unable to verify required trials.	3,681
Does not meet established criteria.	1,559
Lack required information to process request.	584
Other PA Activity	
Duplicate Requests	1,150
Letters	39,245
No Process	1
Helpdesk Initiated Prior Authorizations	391
PAs Missing Information	310
Pharmacotherapy	58
Changes to Existing PAs	538

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

SoonerSelect Aetna Prior Authorization Activity

4/1/2025 Through 4/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc	1	0	1	0	0
Amphetamines	244	194	12	38	363
Analgesics - Anti-Inflammatory	128	84	32	12	356
Analgesics - Nonnarcotic	11	1	10	0	365
Analgesics - Opioid	167	83	56	28	216
Androgens - Anabolic	60	12	46	2	365
Anorectal and Related Products	1	1	0	0	42
Anorexiants Non-Amphetamine	1	1	0	0	183
Anthelmintics	8	3	5	0	22
Antianxiety Agents	21	5	9	7	305
Antiarrhythmics	3	1	1	1	198
Antiasthmatic and Bronchodilator Agents	227	22	154	51	303
Antibiotics	23	4	6	13	144
Anticoagulants	5	1	0	4	365
Anticonvulsants	35	9	12	14	365
Antidepressants	178	51	70	57	312
Antidiabetics	562	137	323	102	325
Antiemetics	5	2	2	1	228
Antihistamines	39	8	27	4	391
Antihyperlipidemics	34	4	16	14	296
Antihypertensives	18	1	6	11	365
Anti-Infective Agents - Misc.	13	8	2	3	104
Antineoplastics and Adjunctive Therapies	25	7	0	18	249
Anti-Obesity Agents	80	1	76	3	28
Antiparkinson and Related Therapy Agents	8	2	2	4	228
Antipsychotics/Antimanic Agents	161	45	75	41	335
Antivirals	5	1	4	0	84
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	93	61	28	4	362
Beta Blockers	27	2	0	25	365
Calcium Channel Blockers	13	2	3	8	365
Cardiovascular Agents - Misc.	26	10	13	3	342
Contraceptives	13	5	7	1	365
Corticosteroids	32	13	9	10	318
Cough/Cold/Allergy	1	0	1	0	0
Dermatologicals	283	101	146	36	240
Diagnostic Products	44	18	9	17	304
Dietary Products/Dietary Management Products	4	4	0	0	364
Digestive Aids	2	2	0	0	365
Diuretics	11	1	0	10	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	0	2	0	0
Endocrine and Metabolic Agents - Misc.	24	16	3	5	243
Estrogens	16	9	4	3	365
Gastrointestinal Agents - Misc.	95	29	56	10	260
General Anesthetics	3	1	2	0	142
Genitourinary Agents - Misc.	3	1	0	2	183
Gout Agents	3	0	0	3	0
Hematological Agents - Misc.	1	1	0	0	365
Hematopoietic Agents	11	8	3	0	311

*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	19	4	9	6	206
Laxatives	21	2	14	5	91
Local Anesthetics-Parenteral	4	3	1	0	66
Medical Devices and Supplies	84	23	51	10	365
Migraine Products	205	36	157	12	164
Minerals and Electrolytes	14	6	2	6	160
Miscellaneous Therapeutic Classes	30	23	6	1	328
Multivitamins	3	1	2	0	365
Musculoskeletal Therapy Agents	51	17	11	23	235
Nasal Agents - Systemic and Topical	19	0	12	7	0
Neuromuscular Agents	34	13	14	7	148
Nutrients	3	3	0	0	197
Ophthalmic Agents	35	2	23	10	288
Other	7	2	3	2	228
Otic Agents	18	2	16	0	22
Pharmaceutical Adjuvants	1	1	0	0	91
Progestins	5	5	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	36	14	18	4	210
Respiratory Agents - Misc.	3	2	1	0	256
Stimulants - Misc.	88	58	18	12	325
Thyroid Agents	5	0	4	1	0
Ulcer Drugs/Antispasmodics/Anticholinergics	55	6	9	40	304
Urinary Antispasmodics	18	2	16	0	365
Vaccines	1	0	1	0	0
Vaginal and Related Products	3	0	2	1	0
Vitamins	44	4	39	1	365
****Total**	**3,576**	**1,201**	**1,662**	**713**	

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

Overrides					
Brand	1	1	0	0	365
Other	715	2	0	713	365
Quantity Level Limit	30	30	0	0	261
Overrides Total	**746**	**33**	**0**	**713**	

Denial Reason	
Benefit	91
Experimental/Investigational	205
Lack Required Infomation to Process Request	66
Medical Necessity	1,299
Other	1
Other PA Activity	
Duplicate Requests	17
Letters	4,425
No Process	288
Changes to existing PAs	0
Helpdesk initiated PA	1
PAs missing info	75

*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

4/1/2025 Through 4/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	2	1	1	0	92
Amebicides	1	1	0	0	365
Amphetamines	4	0	4	0	0
Analgesics - Anti-Inflammatory	54	41	13	0	360
Analgesics - Nonnarcotic	6	1	5	0	365
Analgesics - Opioid	66	40	26	0	217
Androgens - Anabolic	49	15	34	0	216
Anthelmintics	3	0	3	0	0
Antianxiety Agents	1	1	0	0	365
Antiasthmatic and Bronchodilator Agents	197	44	153	0	220
Antibiotics	9	3	6	0	341
Anticonvulsants	15	9	6	0	324
Antidepressants	44	23	21	0	270
Antidiabetics	222	73	149	0	245
Antidiarrheal/Probiotic Agents	1	1	0	0	365
Antiemetics	5	0	5	0	0
Antihyperlipidemics	27	8	19	0	104
Anti-Infective Agents - Misc.	4	4	0	0	365
Antineoplastics and Adjunctive Therapies	48	40	8	0	247
Anti-Obesity Agents	72	5	67	0	127
Antiparkinson and Related Therapy Agents	2	2	0	0	364
Antivirals	6	4	2	0	67
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	15	7	8	0	284
Beta Blockers	2	1	1	0	365
Calcium Channel Blockers	1	0	1	0	0
Cardiovascular Agents - Misc.	29	16	13	0	330
Contraceptives	22	13	9	0	241
Corticosteroids	2	1	1	0	183
Dermatologicals	153	56	97	0	237
Diagnostic Products	51	47	4	0	327
Digestive Aids	1	0	1	0	0
Diuretics	3	3	0	0	365
Endocrine and Metabolic Agents - Misc.	42	20	22	0	218
Estrogens	6	1	5	0	183
Gastrointestinal Agents - Misc.	93	40	53	0	181
Genitourinary Agents - Misc.	3	2	1	0	274
Gout Agents	6	1	5	0	122
Hematological Agents - Misc.	7	3	4	0	334
Hematopoietic Agents	14	6	8	0	171
Histamine H3-Receptor Antagonist/Inverse Agonists	2	2	0	0	182
Hypnotics/Sedatives/Sleep Disorder Agents	20	0	20	0	0
Laxatives	1	0	1	0	0
Migraine Products	102	58	44	0	268
Minerals and Electrolytes	2	0	2	0	0
Miscellaneous Therapeutic Classes	8	6	2	0	274

*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
Multivitamins	2	2	0	0	365
Musculoskeletal Therapy Agents	17	8	9	0	339
Neuromuscular Agents	29	22	7	0	331
Ophthalmic Agents	21	8	13	0	310
Other	4	0	4	0	0
Otic Agents	2	0	2	0	0
Psychotherapeutic and Neurological Agents - Misc.	29	15	14	0	193
Respiratory Agents - Misc.	8	6	2	0	228
Stimulants - Misc.	16	8	8	0	351
Thyroid Agents	1	0	1	0	0
Ulcer Drugs/Antispasmodics/Anticholinergics	15	4	11	0	243
Urinary Antispasmodics	10	1	9	0	91
Vitamins	54	3	51	0	36
Total	**1,631**	**676**	**955**	**0**	
Overrides					
High Dose	1	0	1	0	0
Ingredient Duplication	141	78	63	0	230
NDC vs Age	400	283	117	0	262
Opioid MME Limit	6	3	3	0	243
Opioid Quantity	9	9	0	0	340
Other	167	73	94	0	162
Quantity vs Days Supply	180	107	73	0	247
STBS/STBSM	431	20	411	0	16
Step Therapy Exception	293	126	167	0	382
Overrides Total	**1,628**	**699**	**929**	**0**	
Total Regular PAs + Overrides	**3,259**	**1,375**	**1,884**	**0**	
Denial Reasons					
Benefit					860
Medical Necessity					1,024

*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

4/1/2025 Through 4/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	366	267	35	64	227
Analgesics - Anti-Inflammatory	116	62	38	16	350
Analgesics - Nonnarcotic	6	0	6	0	0
Analgesics - Opioid	324	112	158	54	227
Androgens - Anabolic	61	15	43	3	360
Anorectal and Related Products	1	0	1	0	0
Anorexiants Non-Amphetamine	4	0	4	0	0
Anthelmintics	3	0	3	0	0
Antianxiety Agents	19	6	11	2	278
Antiasthmatic and Bronchodilator Agents	317	110	159	48	296
Antibiotics	17	10	7	0	244
Anticoagulants	1	0	1	0	0
Anticonvulsants	48	28	15	5	348
Antidepressants	148	47	71	30	337
Antidiabetics	709	320	291	98	342
Antiemetics	17	5	2	10	250
Antifungals	8	4	4	0	319
Antihistamines	33	6	19	8	349
Antihyperlipidemics	30	7	19	4	255
Antihypertensives	4	2	2	0	312
Anti-Infective Agents - Misc.	9	4	5	0	277
Antineoplastics and Adjunctive Therapies	86	49	10	27	217
Anti-Obesity Agents	91	3	82	6	280
Antiparkinson and Related Therapy Agents	2	2	0	0	365
Antipsychotics/Antimanic Agents	151	74	58	19	357
Antivirals	7	3	2	2	271
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	93	41	38	14	337
Beta Blockers	7	5	1	1	260
Calcium Channel Blockers	3	2	1	0	365
Cardiovascular Agents - Misc.	34	16	15	3	365
Chemicals	1	0	0	1	0
Contraceptives	14	0	11	3	0
Corticosteroids	3	1	0	2	245
Cough/Cold/Allergy	6	4	1	1	268
Dermatologicals	380	126	182	72	236
Diagnostic Products	31	10	20	1	297
Diuretics	3	2	1	0	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	77	30	42	5	326
Estrogens	14	2	11	1	220
Gastrointestinal Agents - Misc.	100	27	54	19	246
Genitourinary Agents - Misc.	2	0	2	0	0
Gout Agents	3	0	3	0	0
Hematological Agents - Misc.	15	4	8	3	250
Hematopoietic Agents	38	12	14	12	171
Histamine H3-Receptor Antagonist/Inverse Agonists	4	0	1	3	0
Hypnotics/Sedatives/Sleep Disorder Agents	29	12	9	8	268
Laxatives	9	3	6	0	365

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Medical Devices and Supplies	132	69	48	15	366
Migraine Products	175	57	92	26	256
Minerals and Electrolytes	1	1	0	0	0
Miscellaneous Therapeutic Classes	22	12	6	4	232
Multivitamins	6	2	4	0	272
Musculoskeletal Therapy Agents	25	11	11	3	282
Nasal Agents - Systemic and Topical	18	2	11	5	316
Neuromuscular Agents	27	11	6	10	355
Ophthalmic Agents	43	11	19	13	314
Other	48	13	7	28	250
Otic Agents	27	3	17	7	366
Passive Immunizing and Treatment Agents	2	2	0	0	180
Pharmaceutical Adjuvants	3	1	2	0	180
Progestins	13	4	7	2	272
Psychotherapeutic and Neurological Agents - Misc.	59	24	29	6	255
Respiratory Agents - Misc.	7	6	1	0	295
Stimulants - Misc.	273	188	35	50	251
Thyroid Agents	9	1	6	2	365
Ulcer Drugs/Antispasmodics/Anticholinergics	21	4	13	4	309
Urinary Antispasmodics	20	10	6	4	292
Vaccines	1	0	1	0	0
Vaginal and Related Products	5	0	3	2	0
Vitamins	1	1	0	0	254
****Total**	**4,383**	**1,866**	**1,791**	**726**	

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

Denial Reasons	
Benefit	116
Medical Necessity	1,675

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

Appendix C

SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update

Oklahoma Health Care Authority
May 2025

SoonerPsych Prescriber Mailing Summary

The SoonerPsych program is an educational quarterly mailing to prescribers of atypical antipsychotic (AAP) medications. Each mailing includes a gauge showing prescribers how their prescribing compares to other SoonerCare prescribers of these medications and how their prescribing potentially differs from evidence-based recommendations. Each mailing also includes an informational page with evidence-based material related to the mailing topics. Mailing topics are comprised of 4 modules: adherence, diagnosis, metabolic monitoring, and poly-pharmacy as defined below.

The SoonerPsych program has been using a "report card" format since April 2014. Beginning in April 2016, educational letters were sent to a consistent cohort of prescribers with all modules included in each mailing. The mailing cohort list is updated approximately every 2 years, and cohort prescribers receive 4 letters per year to more completely summarize their SoonerCare members taking these medications and to facilitate more conveniently following changes and improvements in their patients and prescribing patterns over time. The mailing list was last updated in January 2024, and inclusion criteria required the prescriber to have at least 7 SoonerCare members taking AAP medications.

Effective January 2017, data collection was expanded from a previous research-based approach to include additional diagnosis fields and monitoring fields (lipids and glucose) in order to provide a more clinically meaningful description for prescribers. The following list defines the terms used for prescriber comparison within each module of the current SoonerPsych mailing:

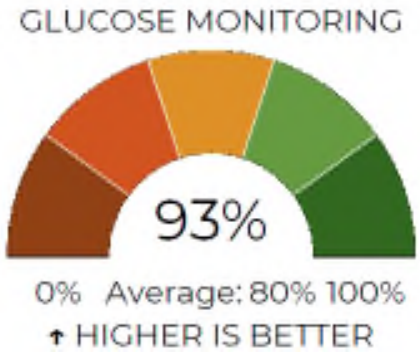
- **Medication Adherence:** Members are considered adherent when their proportion of days covered (PDC), as calculated from pharmacy claims history for AAP medications, is ≥80%. The prescriber adherence gauge shows the percentage of members receiving AAP medications who are adherent during the most recent 12-month period.
- **Target Diagnosis:** Diagnoses with a strong indication for prescribing an AAP medication include: schizophrenia, bipolar disorder, delusional disorders, other nonorganic psychoses, autism spectrum disorder, mood disorder, obsessive-compulsive disorder, and severe depression with or

without psychotic features. The prescriber diagnosis gauge shows the percentage of members receiving AAP medications who had ≥1 medical claim for 1 of the above diagnoses within the most recent 12-month period.

- **Metabolic Monitoring:** Metabolic monitoring includes both lipid and glucose monitoring. Lipid monitoring is recommended for members receiving AAP medications and with a diagnosis of hyperlipidemia. Glucose monitoring is recommended for all members receiving AAP medications. The prescriber metabolic monitoring gauges show the percentage of members receiving AAP medications whose most recent 12-month medical claims history includes the recommended lipid and glucose testing.
- **Poly-Pharmacy:** Poly-pharmacy is defined as having a pharmacy claims history which includes concurrent use of 2 or more AAP medications for >90 days. The prescriber poly-pharmacy gauge shows the percentage of members receiving AAP medications whose most recent 6-month history included poly-pharmacy.

SoonerPsych Example Gauge

Each gauge includes the individual prescriber's performance in relation to the specific module, the average performance of other SoonerCare prescribers for comparison, and a statement summarizing the improvement metric for the specific module. The following is an example of one of the gauges included in the mailings.

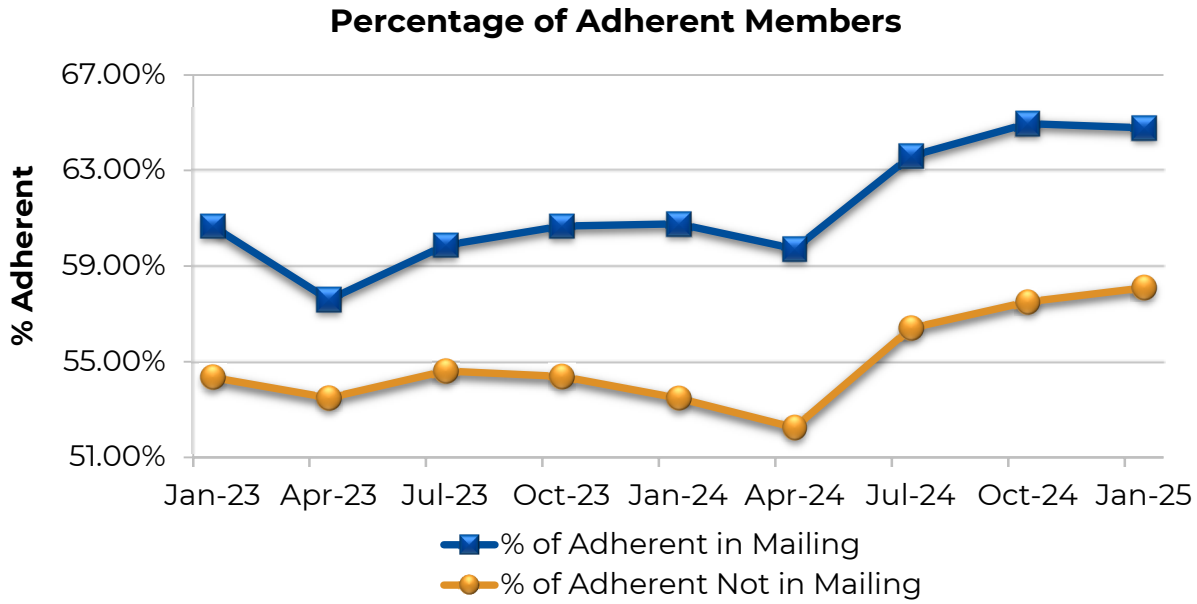


SoonerPsych Trends

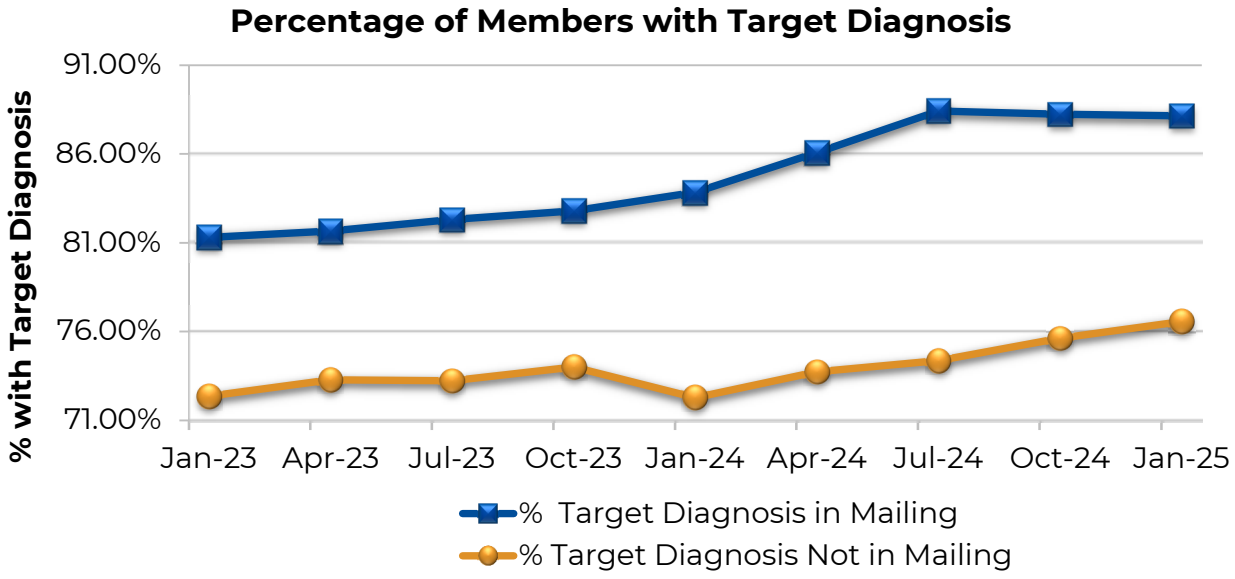
The following graphs show the SoonerPsych trends for medication adherence, diagnosis, metabolic monitoring, and poly-pharmacy from January 2023 to January 2025. Members whose prescribers were included in the SoonerPsych mailings are designated separately from those members whose prescribers were not included in the mailings. It is important to note that the SoonerPsych data has been adjusted for outliers, based on input from the Drug Utilization Review (DUR) Board, to show a more meaningful

comparison of prescribers included in the mailing and prescribers not included in the mailing.

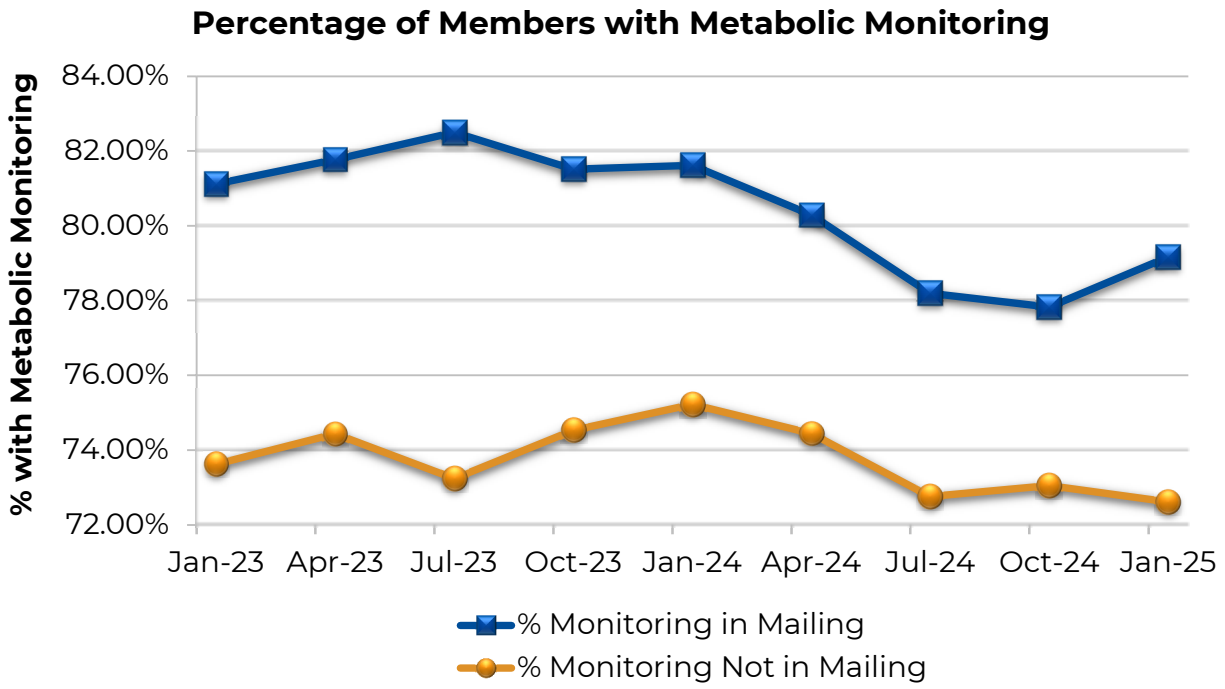
The following graph shows the SoonerPsych trends for the percentage of adherent members. Members are considered adherent if their PDC was ≥80%. Please note, the vertical axis starts at 51% of members in order to reflect small changes.



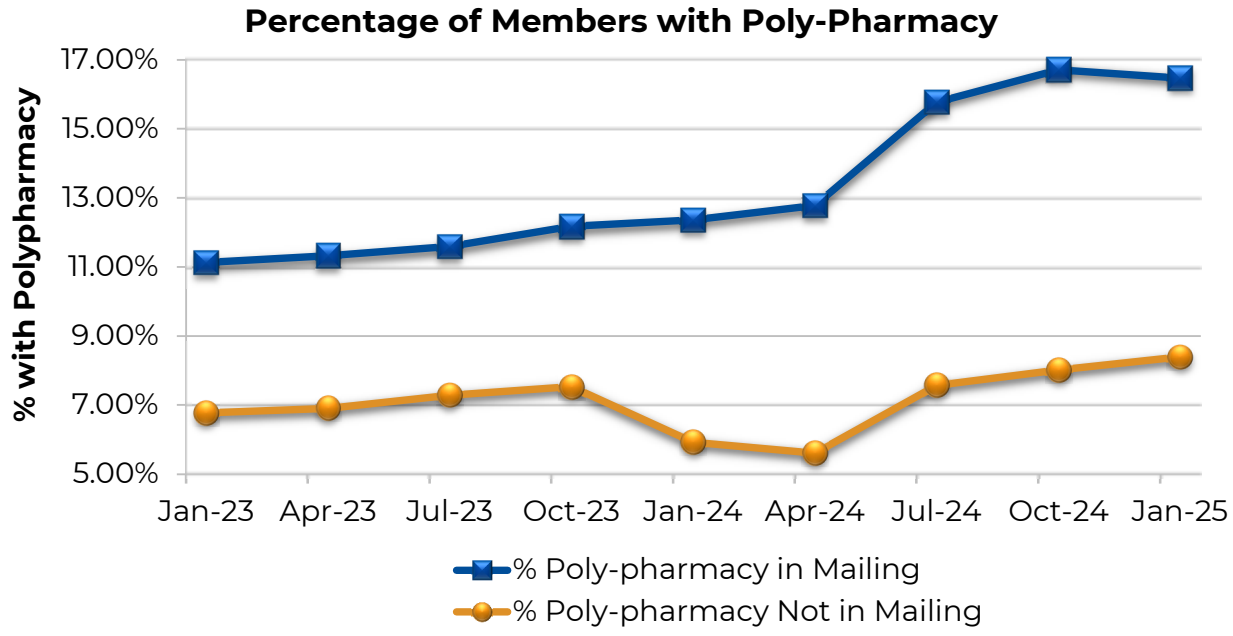
The following graph shows the SoonerPsych trends for the percentage of members having a diagnosis with a strong indication for prescribing an AAP medication. Please note, the vertical axis starts at 71% of members in order to reflect small changes.



The following graph shows the SoonerPsych trends for the percentage of members who received the recommended metabolic monitoring while on an AAP medication. Please note, the vertical axis starts at 72% of members in order to reflect small changes.



The following graph shows the SoonerPsych trends for the percentage of members with poly-pharmacy. Please note, the vertical axis starts at 5.0% of members in order to reflect small changes, and a lower percentage is a better outcome, indicating less prescribing of concomitant AAP medications.



Pediatric SoonerPsych Antipsychotic Monitoring Program Prescriber Mailing Summary

The Oklahoma Health Care Authority (OHCA) is also responsible for establishing and maintaining an additional program to monitor and manage appropriate utilization of AAP medications specifically for children, including children in the foster care system, as part of a requirement by the Centers for Medicare and Medicaid Services (CMS). To accomplish these purposes, the College of Pharmacy developed the Pediatric SoonerPsych program in October 2019. Pediatric SoonerPsych is updated twice per year and includes prescribers caring for pediatric members receiving AAP medications. Historically, specific prescriber focus has alternated on a semi-annual basis between all children and those children in the foster care system. With the transition to a managed care model, the number of pediatric foster care members in the fee-for-service population has decreased dramatically. Since June 2024, prescriber focus has been all pediatric members but with special attention given to highlight members in the foster care system. Pediatric SoonerPsych evaluates prescribing patterns and medical claims across 4 topics as previously described: medication adherence, target diagnosis, metabolic monitoring, and poly-pharmacy.

Pediatric SoonerPsych inclusion criteria is limited to prescribers whose prescribing of AAP medications for pediatric SoonerCare members varies significantly when compared to other SoonerCare prescribers in 1 or more of the 4 topics listed above.

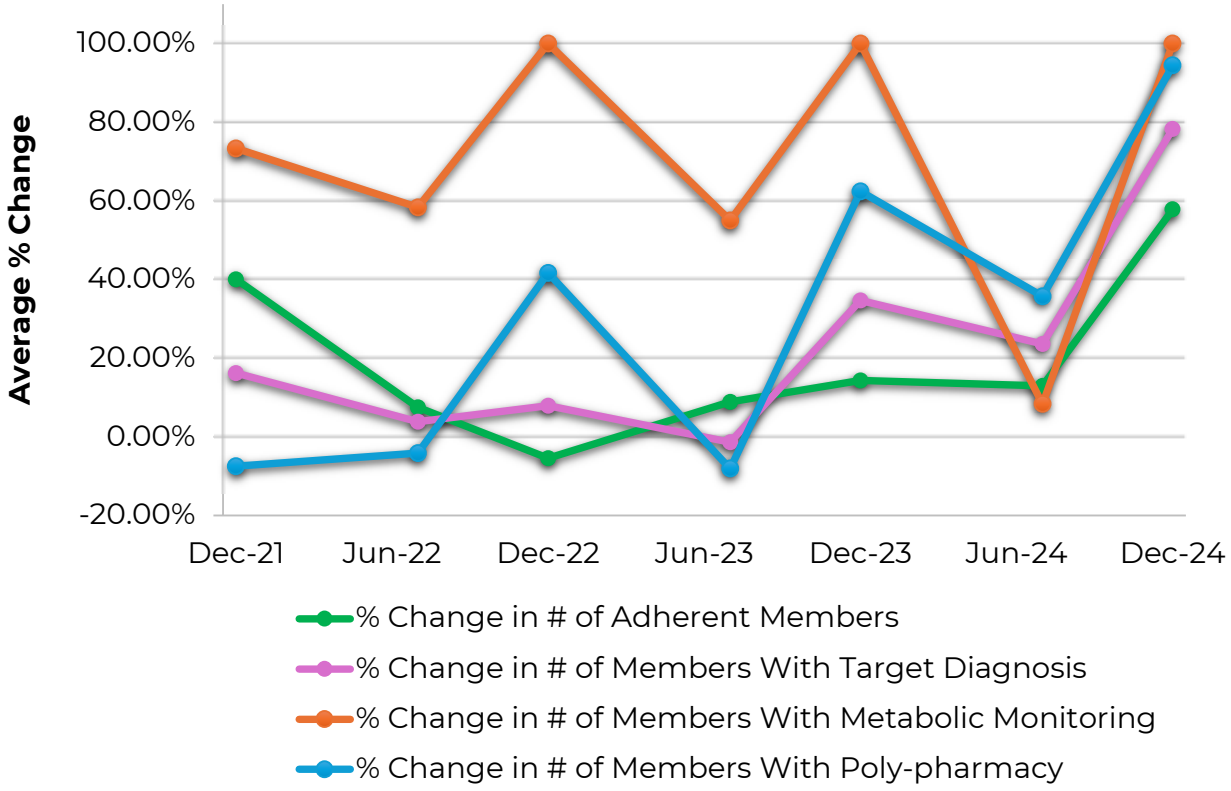
Prescribers receive an educational mailing and member list if they are the last prescriber of record for an AAP medication and are in the most concerning cohort of prescribers. Following receipt of the Pediatric SoonerPsych mailings, prescribers are offered a virtual or in-person visit by an academic detailing (AD) pharmacist and they are encouraged to utilize several other resources. Historically, those resources have included consultation with an OHCA child psychiatrist and participation in the pediatric psychiatry Project ECHO (Extension for Community Health Care Outcomes) for medical education and care management and in the Oklahoma Child and Adolescent Psychiatry and Mental Health Access Program (OKCAPMAP). Additional services through OHCA Care Management and Behavioral Health Care Management have also been encouraged. Historically, prescribers meeting criteria for pediatric members received mailings and educational offerings each December, and prescribers meeting criteria for pediatric members in the foster care system received mailings and educational offerings each June. Since June 2024, prescribers receive these offerings in both June and December.

Pediatric SoonerPsych Trends

Across all topics, an overall trend towards more evidence-based prescribing has been observed. However, improvement in the area of adherence has historically proved difficult to measure with certainty. The Pediatric SoonerPsych educational materials emphasize the appropriate use of antipsychotic medications only within the clinical setting of appropriate diagnoses. Lowering the dose and/or frequency (i.e., tapering) of these medications with eventual discontinuation is suggested for members who do not meet diagnostic criteria. With this in mind, some intentional medication tapering may be represented as poor adherence.

The following graph shows the Pediatric SoonerPsych trends for the average percentage change during the 6-month post-AD period in number of adherent members, members with target diagnoses, members with recommended metabolic monitoring, and members with poly-pharmacy. Please note, the vertical axis starts at -20%, and a higher percentage change is a better outcome. To date, nearly 110 prescribers have received the Pediatric SoonerPsych mailings, AD, and additional program resources. Each of the prescribers met inclusion criteria for 1 to 6 cohorts, with an average of 2.6 cohort inclusions per prescriber in the 8 mailings from 2021 to 2024.

Pediatric SoonerPsych Trends: Average Percentage Change



Conclusions

Recent SoonerPsych trends comparing January 2023 through January 2025 indicate overall improvements in the percentage of adherent members and the percentage of members with a target diagnosis. Adherence improvements were similar to the improvements demonstrated by prescribers not in the mailings. Diagnosis improvements exceeded the improvements of prescribers not in the mailing. The percentage of members with metabolic monitoring has decreased slightly. However, the trend has been recently improving. The percentage of members with poly-pharmacy increased for members whose prescribers received the SoonerPsych mailings compared to those not included in the mailings. While the poly-pharmacy trend appears to have stabilized, the trend worsened during 2024. As noted above, prescriber data has been adjusted for outliers since 2019. Continuing to adjust the data for outliers and following the results of the new prescriber list over time may provide more opportunities for additional prescriber-specific interventions. Overall, results indicate consistently receiving evidence-based educational mailings reminds prescribers of evidence-based practices and reduces some potentially inappropriate prescribing. Recent changes to the mailing format (including all modules in each mailing, mailing to consistent prescribers, and updating the prescriber mailing list), as well as expanding the data collection process and adjusting the data for outliers, are intended to sustain improvements and reduce waning interventions. The College of Pharmacy will continue to work with OHCA to improve educational mailings with the goal of improving the quality of care for SoonerCare members utilizing AAP medications.

Since the Pediatric SoonerPsych program initiation, trends indicate overall improvements in the areas of diagnosis, metabolic monitoring, and poly-pharmacy. Improvements in the area of adherence are consistently difficult to determine, owing to the likely co-occurrences of true poor adherence and intentional tapering. The greatest improvements continue to be seen in the area of metabolic monitoring, and more recently, poly-pharmacy. Overall results indicate the Pediatric SoonerPsych focused mailing and educational offerings are likely leading to improvements in antipsychotic medication management resulting in a lower risk of overprescribing and increased rates of recommended metabolic monitoring. The College of Pharmacy will continue to work with OHCA to identify prescribers who may benefit from Pediatric SoonerPsych activities with the goal of promoting evidence-based use of antipsychotic medications for pediatric members.

Future results of the SoonerPsych and Pediatric SoonerPsych activities will be reviewed with the DUR Board as they become available.

Appendix D

Vote to Prior Authorize Alhemo® (Concizumab-mtci), Beqvez™ (Fidanacogene Elaparvovec-dzkt), Hympavzi™ (Marstacimab-hncq), and Qfitlia™ (Fitusiran) and Update the Approval Criteria for the Hemophilia Medications

Oklahoma Health Care Authority
May 2025

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

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

- **April 2024:** The FDA approved Beqvez™ (fidanacogene elaparvovec-dzkt), an adeno-associated virus vector-based gene therapy for the treatment of adults with hemophilia B.
- **October 2024:** The FDA approved Hympavzi™ (marstacimab-hncq), a tissue factor pathway inhibitor (TFPI) antagonist, for routine prophylaxis in adolescents and adults with hemophilia A or B without inhibitors.
- **December 2024:** The FDA approved Alhemo® (concizumab-mtci), a TFPI antagonist, for routine prophylaxis in adolescents and adults with hemophilia A or B with inhibitors.
- **March 2025:** The FDA approved Qfitlia™ (fitusiran), an antithrombin small interfering ribonucleic acid (siRNA), for the routine prophylaxis in adolescents and adults with hemophilia A or B, with or without factor inhibitors.

News:

- **February 2025:** Pfizer announced it will stop the commercialization of Beqvez™ (fidanacogene elaparvovec-dzkt). The lack of demand was 1 of the reasons for this decision. Some product is still available for dosing currently.

Guideline Update(s):

- **The National Bleeding Disorders Foundation's Medical and Scientific Advisory Council (MASAC):** The MASAC recommends the use of prophylaxis for people with severe hemophilia, including those with inhibitors, and prophylaxis should be considered in those with mild to moderate hemophilia with a severe phenotype. Prophylaxis should be considered early to prevent complications. The types of prophylaxis therapy include factor replacement, bypassing agents where appropriate, or non-factor replacements. The MASAC does not recommend 1 prophylaxis therapy type over another.

- **World Federation of Hemophilia (WFH):** The WFH recommends patients with a severe phenotype of hemophilia use prophylaxis therapy with early initiation to maintain better musculoskeletal health, including joints, and to promote a better quality of life. The WFH does not recommend 1 type of prophylaxis therapy over another.

Beqvez™ (Fidanacogene Elaparvovec-dzkt) Product Summary[8,9]

Therapeutic Class: Adeno-associated virus vector-based gene therapy

Indication(s): Treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency) who:
- Currently use factor IX prophylaxis therapy, or
- Have current or historical life-threatening hemorrhage, or
- Have repeated, serious spontaneous bleeding episodes, and
- Do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test

How Supplied:
- Single dose vials containing 1mL of $1x10^{13}$ vector genomes (vg)
- The vials are packaged in kits based on the patient's dose weight.

Dosing and Administration:
- Single-dose one-time intravenous infusion.
- The recommended dose of Beqvez™ is $5x10^{11}$ vg/kg of body weight based on the patient's body mass index (BMI) in kg/m^2.
  - For patients with a BMI >30kg/m^2 the dose is based on adjusted body weight.
- See the full *Prescribing Information* for calculations to determine the patient's required dose.

Efficacy: Pfizer conducted a Phase 3 open-label clinical trial, Benegene-2, with fidanacogene elaparvovec. The trial was conducted in adult males 18 to 65 years of age with hemophilia B categorized as moderately severe to severe (≤2% factor IX levels). There were 45 participants who were dosed with the gene therapy. The primary endpoint was met, which was noninferiority of annualized bleed rate (ABR) following treatment with fidanacogene elaparvovec when compared to prophylaxis during a lead-in period. The ABR during the lead-in period was 4.42 compared to 1.28 after the gene therapy which was a 71% decrease. The mean factor IX activity was 26.9% at month 15 post-gene therapy dosing. Glucocorticoids were given to 28 of the trial participants due to increased aminotransferase levels or decreased factor IX levels (or both).

Cost: The Wholesale Acquisition Cost (WAC) of Beqvez™ is $3,500,000 per 1-time treatment.

Alhemo® (Concizumab-mtci) Product Summary[10,11]

Therapeutic Class: TFPI antagonist

Indication(s): 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 with inhibitors or hemophilia B with inhibitors

How Supplied:

- 60mg/1.5mL (40mg/mL) single-patient-use prefilled pen
- 150mg/1.5mL (100mg/mL) single-patient-use prefilled pen
- 300mg/3mL (100mg/mL) single-patient-use prefilled pen

Dosing and Administration:

- Alhemo® should be administered by subcutaneous (sub-Q) injection in the abdomen or thigh
- Day 1: Loading dose of 1mg/kg
- Day 2: 0.2mg/kg once daily until individualization of maintenance dose is obtained
  - 4 weeks after initiation, measure concizumab plasma concentration by concizumab enzyme-linked immunosorbent assay (ELISA)
- Once results are available, the dose should be adjusted as follows:
  - <200ng/mL: Adjust to a once-daily dose of 0.25mg/kg
  - 200 to 4,000ng/mL: Continue once-daily dose of 0.2mg/kg
  - >4,000ng/mL: Adjust to a once-daily dose of 0.15mg/kg
- Additional plasma concentrations measurements should be performed at routine clinical follow ups to maintain levels above 200ng/mL.

Efficacy: The FDA approval of Alhemo® was supported by the results from the Phase 3 explorer7 multicenter, open-label clinical trial. There were 133 males with hemophilia A or B with inhibitors enrolled and assigned to receive either on-demand treatment with bypassing agents or prophylaxis with concizumab. The trial was temporarily paused after the report of a non-fatal thromboembolic event in 3 participants receiving concizumab. The trial was resumed after an investigation, and implementation of risk-mitigation measures were put into place. No thromboembolic events were reported after the trial was restarted. The primary endpoint measured the ABR, which was 1.7 in the concizumab arm vs. 11.8 in the on-demand or no prophylaxis arm, an 86% decrease.

Hympavzi™ (Marstacimab-hncq) Product Summary[12,13]

Therapeutic Class: TFPI antagonist

Indication(s): 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 (congenital factor VIII deficiency) without factor VIII inhibitors, or hemophilia B (congenital factor IX deficiency) without factor IX inhibitors

How Supplied: 150mg/mL single-dose prefilled syringe or pen

Dosing and Administration:

- Loading dose: 300mg sub-Q
- Maintenance dose: 1 week after loading dose; start maintenance dose at 150mg every week

Efficacy: Pfizer conducted an open-label, multicenter Phase 3 clinical trial, BASIS, in adult and adolescent males with hemophilia A or B without inhibitors. There were 116 participants ranging in age from 13-66 years enrolled in the trial. Prior to enrollment, 33 patients had used on-demand treatment with factor replacement while 83 had received routine prophylaxis with factor replacement therapy. The primary endpoint was ABR which decreased by 91.6% in those previously using on-demand treatment and 35.2% in those receiving prophylaxis. No deaths or thromboembolic events were reported during the study or its long-term extension.

Qfitlia™ (Fitusiran) Product Summary[14,15]

Therapeutic Class: siRNA therapeutic antithrombin (AT) antagonist

Indication(s): 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 with or without factor VIII or IX inhibitors

How Supplied:

- 50mg/0.5mL in a single-dose prefilled pen
- 20mg/0.2mL in a single-dose vial

Dosing and Administration:

- The recommended starting dose of Qfitlia™ is 50mg sub-Q once every 2 months.
- The dose and/or dosing interval should be adjusted, if needed, to maintain AT activity between 15-35%.
- AT activity should be measured using an FDA-cleared test at weeks 4, 12, 20, and 24 following the starting dose and after any dose modification.

        - If any AT activity is <15%, a dose reduction is required. The lower dose should be initiated 3 months after the prior dose. AT measurements should be restarted after a dose reduction.
        - If any AT activity is >35% after 6 months, or if the patient has not achieved satisfactory bleed control, dose escalation should be considered. AT measurements should be restarted after a dose escalation.
    - See the full *Prescribing Information* for dose modifications based on AT activity levels.

Efficacy: Sanofi conducted 3 Phase 3 trials with fitusiran, ATLAS-INH, ATLAS-A/B, and ATLAS-PPX. The ATLAS-INH trial was a randomized open-label trial in patients with severe hemophilia A or B with inhibitors. Patients were randomized to receive either on-demand treatment with bypassing agents or 80mg of fitusiran monthly for 9 months. The ABR decreased by 73% in the fitusiran treatment group when compared to the on-demand group. The ATLAS-A/B trial was a randomized open-label trial in patients with severe hemophilia A or B without inhibitors. The participants were randomized to either use on-demand appropriate factor replacement or 80mg of fitusiran monthly and were followed for 9 months. The ABR was reduced by 71% in the fitusiran group compared to the group receiving on-demand treatment. ATLAS-PPX was an open-label multicenter trial in males 12 years of age and older with severe hemophilia A or B with or without inhibitors who had previously received prophylaxis. Patients continued on their previous prophylaxis treatment for 6 months and were then switched to fitusiran 80mg sub-Q once a month for 7 months. The primary endpoint, ABR, decreased in the fitusiran groups by 79.7% and 46.4% compared to the bypassing agent and clotting factor concentration groups, respectively. Suspected or confirmed thromboembolic events occurred in 2.6% of trial participants while using fitusiran 80mg once monthly. Based on this data, a dose of 80mg once monthly has not been approved by the FDA or recommended for use.

Cost Comparison

Product	FDA Approved Indication	Cost Per Month	Cost Per Year
Alhemo® (concizumab-mtci)	**A & B w/ inhibitors**	**$103,200.00**	**$1,255,600.00μ**
Hympavzi™ (marstacimab-hncq)	**A & B w/o inhibitors**	**$61,200.00**	**$795,600.00∞**
Qfitlia™ (fitusiran)	**A & B all**	**$80,700.00**	**$968,400.00˚**
Feiba® (anti-inhibitor coagulant complex)	A & B w/ inhibitors	$305,617.50	$3,708,159.00Ω
Advate® [antihemophilic factor (recombinant)]	A	$93,480.00	$1,134,224.00±
Hemlibra® (emicizumab-kxwh)	A all	$62,380.80	$810,950.40α
Alprolix® [coagulation factor IX (recombinant), Fc fusion protein]	B	$70,900.00	$921,700.00β

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC), Specialty Pharmaceutical Acquisition Cost (SPAC).
μCost is based on the FDA approved dosing of 0.2mg/kg daily for a 100kg patient, assuming no dose change after 4-week labs.
∞Cost is based on the FDA approved dosing of 150mg every week for a 100kg patient.
˚Cost is based on the FDA approved dosing of 50mg every 2 months
ΩCost is based on the FDA approved dosing of 85U/kg every other day for a 100kg patient.
±Cost is based on the FDA approved dosing of 40U/kg every other day for a 100kg patient.
αCost is based on the FDA approved dosing 1.5mg/kg every week for a 100kg patient.
βCost is based on the FDA approved dosing of 50U/kg every week for a 100kg patient.

Recommendations

The Oklahoma Health Care Authority recommends the prior authorization of Alhemo® (concizumab-mtci), Beqvez™ (fidanacogene elaparvovec-dzkt), Hympavzi™ (marstacimab-hncq), and Qfitlia™ (fitusiran) with the following criteria (shown in red):

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.

Beqvez™ (Fidanacogene Elaparvovec-dzkt) Approval Criteria:

1. A diagnosis of severe or moderately severe congenital, X-linked, hemophilia B (FIX ≤2%); and
2. Member must be a male 18 years of age or older; and
3. Member must not have a history of an inhibitor, or a recent positive screening defined as ≥0.6 Bethesda units prior to administration of fidanacogene elaparvovec-dzkt; and
4. Member must not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test; 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 >50 previous exposure days of treatment with factor IX; and
7. Member must not have any of the following:
    a. Current liver-related coagulopathy; or
    b. Hypoalbuminemia; or
    c. Persistent jaundice; or
    d. Cirrhosis; or
    e. Portal hypertension; or
    f. Splenomegaly; or
    g. Hepatic encephalopathy; or

    h. Hepatic fibrosis; or
    i. Active viral hepatitis; and
8. Members with human immunodeficiency virus (HIV) must not be uncontrolled with antiviral therapy as shown by CD4+ counts ≤200cells/mm^3 or viral load ≥20 copies/mL; and
9. Member must not have received prior treatment with any gene therapy for hemophilia B; and
10. Provider must perform a liver health assessment including:
    a. Enzyme testing (ALT, AST, ALP); and
    b. Hepatic ultrasound and elastography; and
11. Member's recent weight must be provided (taken within the last month) to ensure appropriate dosing; and
12. Prescriber must counsel member not to 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 fidanacogene elaparvovec-dzkt; and
13. 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
14. Fidanacogene elaparvovec-dzkt must be administered in an appropriate clinical setting and member must be monitored for at least 3 hours post infusion; and
15. Prescriber agrees to monitor liver enzymes and the factor IX activity level following administration of fidanacogene elaparvovec-dzkt per the package labeling as follows:
    a. Weeks 1 through 16: once to twice weekly; and
    b. Weeks 17 and 18: weekly; and
    c. Weeks 19 through 52: at weeks 24, 32, 42, and 52; and
    d. Years 2 and 3: quarterly; and
    e. Years 4 through 6: twice yearly; and
    f. Yearly thereafter; and
16. Prescriber agrees to start corticosteroids as indicated in the package labeling based on liver enzyme results and the factor IX activity level; and
17. Approvals will be for 1 treatment per member per lifetime.

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/mm^3; 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.

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 not be uncontrolled 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.

Additionally, the Oklahoma Health Care Authority recommends updating the approval criteria for Feiba® (anti-inhibitor coagulation complex), NovoSeven® RT [coagulation factor VIIa (recombinant)] and Sevenfact® [coagulation factor VIIA (recombinant)-jncw] with the following based on net costs (changes shown in red):

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; ~~and~~ 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 ~~with a supervising~~ under the supervision of a physician ~~that is a hematologist specializing in rare bleeding disorders~~ at an HTC.

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 ~~with a supervising~~ under the supervision of a physician ~~that is a hematologist specializing in rare bleeding disorders~~ at an HTC.

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 ~~with a supervising~~

under the supervision of a physician ~~that is a hematologist specializing in rare bleeding disorders~~ at an HTC.

Finally, the Oklahoma Health Care Authority recommends updating the approval criteria for Hemlibra® (emicizumab-kxwh) with the following based on guidelines (changes shown in red):

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 ~~with a supervising~~ under the supervision of a physician ~~that is a hematologist specializing in rare bleeding disorders~~ 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. Member's current prophylaxis therapy is not adequate to prevent spontaneous bleeding episodes, or the member is unable to maintain venous access for prophylactic infusions; and~~
    b. Treatment plan must be made to address breakthrough bleeds and procedures; and
    c. 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.

[1] U.S. Food and Drug Administration (FDA). FDA BLA Approval Letter. Available online at: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/beqvez. Issued 04/25/2024. Last accessed 04/10/2025.
[2] U.S. FDA. FDA Approves New Treatment for Hemophilia A or B. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-hemophilia-or-b. Issued 10/11/2024. Last accessed 04/10/2025.
[3] U.S. FDA. FDA Approves Drug to Prevent or Reduce the Frequency of Bleeding Episodes for Patients with Hemophilia A with Inhibitors or Hemophilia B with Inhibitors. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-drug-prevent-or-reduce-frequency-bleeding-episodes-patients-hemophilia-inhibitors-or. Issued 12/20/2024. Last accessed 04/10/2025.
[4] U.S. FDA. FDA Approves Novel Treatment for Hemophilia A or B, With or Without Factor Inhibitors. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-novel-treatment-hemophilia-or-b-or-without-factor-inhibitors. Issued 03/28/2025. Last accessed 03/31/2025.
[5] Pfizer. Pfizer Stops Commercialization of Hemophilia Gene Therapy Beqvez™. Available online at: https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-says-it-will-end-global-development-gene-therapy-beqvez-nikkei-reports-2025-02-20/. Issued 02/21/2025. Last accessed 04/10/2025.
[6] National Bleeding Disorder Foundation. MASAC Document 267 - MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B With and Without Inhibitors. Available online at: https://www.bleeding.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-267-masac-recommendation-concerning-prophylaxis-for-hemophilia-a-and-b-with-and-without-inhibitors. Issued 04/27/2022. Last accessed 04/10/2025.
[7] Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd Edition. Chapter 6 Prophylaxis in Hemophilia. *Haemophilia* 2020; 26(6):1-158. doi: 10.1111/hae.14046.
[8] Beqvez™ (Fidanacogene Elaparvovec) Prescribing Information. Pfizer. Available online at: https://www.fda.gov/media/178140/download?attachment. Last revised 12/2024. Last accessed 04/10/2025.
[9] Cuker A, Kavakli K, Frenzel L, et.al. Gene Therapy with Fidanacogene Elaparvovec in Adults with Hemophilia B. *N Engl J Med* 2024; 391:1108-1118. doi: 10.1056/NEJMoa2302982.
[10] Alhemo® (Concizumab-mtci) Prescribing Information. Novo Nordisk. Available online at: https://www.novo-pi.com/alhemo.pdf. Last revised 12/2024. Last accessed 04/10/2025.
[11] Matsushita T, Shapiro A, Abraham A, et al. Phase 3 Trial of Concizumab in Hemophilia with Inhibitors. *N Engl J Med* 2023; 389:783-794. doi: 10.1056/NEJMoa2216455.
[12] Hympavzi™ (Marstacimab-hncq) Prescribing Information. Pfizer. Available online at: https://labeling.pfizer.com/ShowLabeling.aspx?id=20916. Last revised 10/2024. Last accessed 04/10/2025.
[13] Matino D, Acharya S, Palladino A, et.al. Efficacy and Safety of the Anti-Tissue Factor Pathway Inhibitor Marstacimab in Participants with Severe Hemophilia without Inhibitors: Results from the Phase 3 Basis Trial. *Blood* 2023; 142(1): 285. doi: 10.1182/blood-2023-181263.
[14] Qfitlia™(Fitusiran) Prescribing Information. Sanofi. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219019s000lbl.pdf. Last revised 03/2025. Last accessed 04/10/2025.
[15] Kenet G, Nolan B, et. al. Fitusiran Prophylaxis in People with Hemophilia A or B Who Switched From Prior BPA/CFC Prophylaxis: The ATLAS-PPX Trial. *Blood* 2024; 143(22): 2256–2269. doi: 10.1182/blood.2023021864.

Appendix E

Vote to Prior Authorize Adzynma (ADAMTS13, Recombinant-krhn) and Alvaiz® (Eltrombopag)

Oklahoma Health Care Authority
May 2025

Market News and Updates[1,2]

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

- **November 2023:** The FDA approved Adzynma (ADAMTS13, recombinant-krhn), the first recombinant protein product indicated for prophylactic or on-demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP). cTTP is a rare and life-threatening disorder caused by biallelic pathogenic mutations in the *ADAMTS13* gene leading to deficiencies in the ADAMTS13 enzyme that regulates blood clotting. Patients with cTTP may experience severe bleeding episodes, stroke, and damage to vital organs. Historic treatment for cTTP has been with prophylactic plasma-based therapies to replenish the absent or low ADAMTS13 enzyme.
- **November 2023:** The FDA approved Alvaiz® (eltrombopag) oral tablets for the treatment of thrombocytopenia in adult and pediatric patients 6 years of age and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy; thrombocytopenia in adult patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy; and severe aplastic anemia in adults who have had an insufficient response to immunosuppressive therapy. Alvaiz® was approved for a New Drug Application (NDA) under the 505(b)2 pathway based on adequate and well-controlled studies of Promacta® (eltrombopag) in adult and pediatric patients 6 years of age and older.

Adzynma (ADAMTS13, Recombinant-krhn) Product Summary[3]

Therapeutic Class: Human recombinant A disintegrin and metalloproteinase with thrombospondin motifs 13 (rADAMTS13)

Indication(s): Prophylactic or on demand ERT in adult and pediatric patients with cTTP

How Supplied: Lyophilized powder in single-dose vials containing nominally 500 or 1,500 international units (IU)

Dosing and Administration:

- Prophylactic Therapy:
  - 40 IU/kg of body weight once every other week via intravenous (IV) infusion
  - The prophylaxis dosing frequency may be adjusted to 40 IU/kg of body weight once weekly based on prior prophylactic dosing regimen or clinical response.
- On-Demand Therapy:
  - Administer IV at a rate of 2-4mL per minute:
    - Day 1: 40 IU/kg of body weight
    - Day 2: 20 IU/kg body weight
    - Day 3 and beyond until 2 days after acute event is resolved: 15 IU/kg of body weight

Efficacy: The safety and efficacy of Adzynma was studied in a global, prospective, randomized, active-controlled, open-label 2-period crossover trial followed by a single-arm continuation period. Adzynma was compared to plasma-based therapies for prophylactic and on-demand ERT in patients with cTTP.

- Key Inclusion Criteria:
  - Confirmed diagnosis of severe hereditary ADAMTS13 deficiency (confirmed by genetic testing and ADAMTS13 activity <10%)
  - Prophylactic Cohort Only:
    - No severe thrombotic thrombocytopenic purpura (TTP) signs [platelet count <100,000/mcL and elevation of lactate dehydrogenase (LDH) >2x the upper limit of normal (ULN)] at screening
    - Currently on a prophylactic dosing regimen or has a documented history of ≥1 TTP event and an ability to tolerate standard of care prophylactic dosing
- Prophylactic ERT:
  - Intervention(s):
    - 46 patients were randomized to receive 6 months of treatment of 40 IU/kg of Adzynma or plasma-based therapies in Period 1. In Period 2, patients were crossed over to the other treatment for 6 months. A total of 35 patients entered Period 3 for the 6-month single-arm trial of Adzynma.
  - Endpoint(s):
    - Incidence of acute TTP events, subacute TTP events, and TTP manifestations
      - Acute TTP events were defined as a drop in platelet count (≥50% of baseline or a platelet count <100,000/mcL) and an elevation of LDH (>2x baseline or ULN).

        - Subacute TTP events were defined as a thrombocytopenia event or a microangiopathic hemolytic anemia event and organ-specific signs and symptoms including but not limited to renal dysfunction events, neurological symptoms events, fever, fatigue/ lethargy, and/or abdominal pain.
        - TTP manifestations were defined as thrombocytopenia events, microangiopathic hemolytic anemia events, renal dysfunction, neurological symptoms, and abdominal pain.
    - Results:
        - No patients receiving Adzynma had an acute TTP event throughout the trial, including Period 3 (with a median duration of exposure to Adzynma of 14 months for patients 12 to <18 years of age and patients ≥18 years of age; and 4 months and 1 month in patients 6 to <12 years of age and in patients <6 years of age, respectively).
        - One acute TTP event occurred in a patient receiving fresh frozen plasma (FFP) prophylactically during Period 1.
        - No subacute TTP events were reported in patients receiving Adzynma during Periods 1 and 2. In Period 3, 2 patients receiving Adzynma prophylaxis had 2 subacute events, of which 1 was treated with 4 supplemental doses, 2 of FFP and 2 of Adzynma.
        - 4 patients receiving plasma-based therapies had 5 subacute TTP events in Periods 1 and 2. A total of 7 supplemental doses were given to 3 of these patients as follows: 2 of factor VIII/von Willebrand factor (VWF) concentrate, 1 of FFP, and 4 of Adzynma.
- On-Demand ERT:
    - Intervention(s):
        - A total of 5 patients enrolled in the on-demand cohort, where 2 were randomized to Adzynma and 3 were randomized to plasma-based therapies.
    - Primary Endpoint(s):
        - Proportion of acute TTP events responding to Adzynma in both the prophylactic and on-demand cohorts throughout the duration of the study
    - Results:
        - There were 6 acute TTP events observed in the on-demand trial. All 6 events resolved after treatment with either Adzynma or plasma-based therapies.

Cost: The Wholesale Acquisition Cost (WAC) of Adzynma is $3.38 per IU. For a member weighing 80kg using every other week dosing, this would result in an estimated cost of $21,632 per 28 days or $281,216 per year for prophylactic dosing. For a member weighing 80kg using on-demand dosing for a 4-day event, this would result in an estimated cost of $32,448.

Alvaiz® (Eltrombopag) Product Summary[4,5]

Therapeutic Class: Thrombopoietin receptor agonist

Indication(s):

- Treatment of thrombocytopenia in adult and pediatric patients 6 years of age and older with persistent or chronic ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
  - Alvaiz® should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.
- Treatment of thrombocytopenia in adult patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy
  - Alvaiz® should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy.
- Treatment of adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.
- **Limitation(s) of Use:**
  - Alvaiz® is not indicated for the treatment of patients with myelodysplastic syndrome (MDS).
  - Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.

How Supplied: 9mg, 18mg, 36mg, and 54mg oral tablets

Dosing and Administration:

- Alvaiz® is not substitutable with other eltrombopag products on a mg per mg basis.
- Alvaiz® should be taken without a meal or with a meal low in calcium (≤50mg) and at least 2 hours before or 4 hours after any medications or products containing polyvalent cations, such as antacids, calcium-rich foods, and mineral supplements.

- Persistent or Chronic ITP:
  - Alvaiz® should be initiated at 36mg orally once daily for most adult and pediatric patients 6 years of age and older with a maximum dose of 54mg per day.
  - The dose should be adjusted to maintain a platelet count ≥50x10^9/L.
  - Alvaiz® should not be used to normalize platelet counts.
- Chronic Hepatitis C-Associated Thrombocytopenia:
  - Alvaiz® should be initiated at 18mg orally once daily for all patients with a maximum dose of 72mg per day.
  - The dose should be adjusted to achieve target platelet count required to initiate antiviral therapy.
- Refractory Severe Aplastic Anemia:
  - Alvaiz® should be initiated at 36mg orally once daily with a maximum dose of 108mg per day.
  - The dose should be adjusted to maintain a platelet count ≥50x10^9/L.
- See the full *Prescribing Information* for initial dose modifications for patients with hepatic impairment and patients of East-/Southeast-Asian ancestry and dose adjustments based on platelet counts for each indication.

Efficacy: The efficacy of Alvaiz® has been established based on adequate and well-controlled studies of Promacta® (eltrombopag olamine) in adult and pediatric patients 6 years of age and older with persistent or chronic ITP, adult patients with chronic hepatitis C-associated thrombocytopenia, and adult patients with refractory severe aplastic anemia. Based on bioavailability studies conducted with Alvaiz®, it was found that Alvaiz® is not bioequivalent with Promacta® on a mg per mg basis.

Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days	Cost Per Year
Alvaiz® (eltrombopag) 54mg tablet	**$622.92**	**$37,375.20***	**$448,502.40***
Promacta® (eltrombopag) 75mg tablet	$708.16	$42,489.60⁺	$509,875.20⁺

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost based on the FDA approved maximum dose for refractory severe aplastic anemia of 108mg/day.
⁺Cost based on the FDA approved maximum dose for refractory severe aplastic anemia of 150mg/day.

Recommendations

The College of Pharmacy recommends the prior authorization of Adzynma (ADAMTS13, recombinant-krhn) and Alvaiz® (eltrombopag) with the following criteria (shown in red):

Adzynma (ADAMTS13, Recombinant-krhn) Approval Criteria:

1. An FDA approved diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) confirmed by:
    a. Molecular genetic testing confirming biallelic pathogenic variants in the *ADAMTS13* gene (results of genetic testing must be submitted); and
    b. ADAMTS13 activity testing showing <10% of normal ADAMTS13 activity (results of activity testing must be submitted); and
2. Member's recent weight (within the last 3 weeks) must be provided in order to ensure appropriate dosing in accordance with the package labeling; and
3. For prophylactic therapy, member has a history of ≥1 documented TTP event or is currently receiving prophylactic therapy; and
4. Must be prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the treatment of cTTP; and
5. For prophylactic enzyme replacement therapy (ERT):
    a. Initial approvals will be for the duration of 6 months. Subsequent approvals, for the durations of 1 year, may be granted if the prescriber attests that the member is tolerating and responding well to treatment (e.g., improvement in acute and subacute TTP events, TTP manifestations, other clinical symptoms associated with TTP); and
6. For on-demand ERT:
    a. Approvals will be for 1 month; and
    b. If additional days are needed, requests should specify that the acute event has not resolved.

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.

Alvaiz® (Eltrombopag) Approval Criteria [Chronic Hepatitis C-Associated Thrombocytopenia Diagnosis]:

1. Member must have diagnosis of chronic hepatitis C-associated thrombocytopenia; and
2. Member must have a platelet count of $<75 \times 10^9/L$; and
3. Member must be 18 years of age or older; and
4. Member must not have a recent diagnosis of myelodysplastic syndromes; and
5. Member must be initiating interferon-based therapy (regimen must be provided); and
6. 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
7. Prescriber must verify that members will receive baseline and follow-up ocular examinations as recommended in the package labeling; and
8. Prescriber must agree to monitor hepatic function prior to and during treatment with Alvaiz® and concomitant hepatitis C therapy; and
9. Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of hepatitis C-associated thrombocytopenia; and
10. Continuation requests will not be approved once antiviral therapy has been discontinued; and
11. Quantity limits will apply based on FDA-approved dosing, up to a maximum of 72mg per day, as follows:
    a. 9mg strength: 30 tablets per 30 days; or
    b. 18mg strength: 120 tablets per 30 days; or
    c. 36mg strength: 60 tablets per 30 days; or
    d. 54mg strength: 30 tablets per 30 days.

Alvaiz® (Eltrombopag) Approval Criteria [Refractory Severe Aplastic Anemia Diagnosis]:

1. Member must have diagnosis of refractory severe aplastic anemia; and
2. Member must have a platelet count of ≤30 x 10^9/L; and
3. Member must not have a diagnosis of Fanconi anemia; and
4. Member must be 18 years of age or older; and
5. Member must not have a recent diagnosis of myelodysplastic syndromes; and
6. Member must have a documented trial of immunosuppressive therapy; 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 verify that members will receive baseline and follow-up ocular examinations as recommended in the package labeling; and
9. Prescriber must agree to monitor hepatic function prior to and during treatment with Alvaiz®; and
10. Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of aplastic anemia; and
11. Quantity limits will apply based on FDA-approved dosing, up to a maximum of 108mg per day as follows:
    a. 9mg strength: 30 tablets per 30 days; or
    b. 18mg strength: 120 tablets per 30 days; or
    c. 36mg and 54mg strengths: 60 tablets per 30 days.

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[1] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for Patients with Rare Inherited Blood Clotting Disorder. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-patients-rare-inherited-blood-clotting-disorder. Issued 11/09/2023. Last accessed 04/17/2025.

[2] Alvaiz® (Eltrombopag) – New Drug Approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_alvaiz_2023-1201.pdf. Issued 11/29/2023. Last accessed 04/17/2025.

[3] Adzynma (ADAMTS13, Recombinant-krhn) Prescribing Information. Takeda Pharmaceuticals. Available online at: https://www.fda.gov/media/173756/download. Last revised 11/2023. Last accessed 04/17/2025.

[4] Alvaiz® (Eltrombopag) Prescribing Information. Teva Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216774s000lbl.pdf. Last revised 11/2023. Last accessed 04/17/2025.

[5] U.S. FDA. Drugs@FDA. Drug Approval Package: Alvaiz®: Clinical Pharmacology Review. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/216774Orig1s000ClinPharmR.pdf. Issued 09/02/2022. Last accessed 04/17/2025.

Appendix F

Vote to Prior Authorize Journavx™ (Suzetrigine)

Oklahoma Health Care Authority
May 2025

Market News and Updates[1,2]

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

- **January 2025:** The FDA approved Journavx™ (suzetrigine), an oral, non-opioid analgesic used to treat moderate to severe acute pain in adults. Journavx™ is a selective blocker of the $Na_V1.8$ voltage-gated sodium channel, which is expressed in the peripheral sensory neurons, where its role is to transmit pain signals to the spinal cord and brain.

Journavx™ Product Summary[3]

Therapeutic Class: Sodium channel blocker

Indication(s): Treatment of moderate to severe acute pain in adults

How Supplied: 50mg oral tablet

Dosing and Administration:

- The recommended starting dose of Journavx™ is 100mg on an empty stomach at least 1 hour before or 2 hours after food to avoid a delay in the onset of action.
- Starting 12 hours after the initial dose, the recommended dose is 50mg of Journavx™ orally every 12 hours with or without food.
- Journavx™ should be used for the shortest duration to meet individual treatment goals for the patient; however, Journavx™ has not been studied beyond 14 days.
- Food or drink containing grapefruit should be avoided during treatment with Journavx™.
- Refer to the full *Prescribing Information* for the recommended dosage in patients with hepatic impairment, dosage modifications for concomitant use of CYP3A4 inhibitors, and recommendations regarding missed doses.

Efficacy: The safety and efficacy of Journavx™ were studied in 2 randomized, double-blind, placebo and active-controlled trials of acute pain, 1 following full abdominoplasty (Trial 1) and the other following bunionectomy (Trial 2).

- Key Inclusion Criteria:
  - Moderate to severe pain on the verbal categorical rating system (VRS) and a pain score of ≥4 on the 11-point numerical pain rating scale (NPRS)

        - Within 4 hours after the abdominoplasty completion; or
        - During the 9-hour period after discontinuation of regional anesthesia following bunionectomy
- Intervention: Patients were randomized to receive Journavx™, placebo, or hydrocodone/acetaminophen (APAP) for 48 hours.
    - Rescue pain relief was allowed with ibuprofen 400mg every 6 hours, as needed.
- Primary Outcomes:
    - Time-weighted sum of the pain intensity difference from 0 to 48 hours (SPID48) in the Journavx™ group compared to placebo and to the hydrocodone/APAP group
- Results:
    - Trial 1: The least squares (LS) mean for the Journavx™ group was 118.4 compared to 70.1 in the placebo group [LS mean difference: 48.4; 95% confidence interval (CI): 33.6, 63.1; P<0.0001] and 111.8 in the hydrocodone/APAP group (LS mean difference: 6.6; 95% CI: -5.4, 18.7).
    - Trial 2: The LS mean for the Journavx™ group was 99.9 compared to 70.6 in the placebo group (LS mean difference: 29.3; 95% CI: 14.0, 44.6; P<0.0002) and 120.1 in the hydrocodone/APAP group (LS mean difference: -20.2; 95% CI: -32.7, -7.7).

Cost Comparison

Product	Cost Per Tablet	Cost Per Treatment Course
Journavx™ 50mg tablet	**$15.50**	**$449.50***
hydrocodone/APAP 5mg/325mg tablet	$0.12	$13.44⁺
ibuprofen 400mg tablet	$0.04	$4.48α

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).
APAP = acetaminophen
*Cost per treatment course is based on the FDA approved dosing of 2 tablets once, then 1 tablet every 12 hours for 14 days.
⁺Cost per treatment course is based on the FDA approved dosing of 1 to 2 tablets every 4 to 6 hours as needed for pain with a maximum of 8 tablets per day for 14 days.
αCost per treatment course is based on the FDA approved dosing of 1 tablet every 4 to 6 hours as needed with a maximum of 3,200mg per day for 14 days.

Recommendations

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

Journavx™ (Suzetrigine) Approval Criteria:

1. An FDA approved diagnosis of moderate to severe acute pain; and
2. Member must be 18 years of age or older; and
3. The underlying cause of the acute pain must be provided; and
4. Member must have a current numeric pain rating scale (NPRS) score ≥4 (NPRS score must be provided on the request); and
5. Member must not be taking any strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, clarithromycin); and
6. Member must not have severe hepatic impairment (Child-Pugh class C); and
7. If member is using hormonal contraceptives containing progestins, other than levonorgestrel and norethindrone, prescriber must confirm the member has been counseled to use an additional nonhormonal contraceptive method or an alternative hormonal contraceptive during treatment with Journavx™ and 28 days after Journavx™ discontinuation; and
8. A patient specific, clinically significant reason why the member cannot use other non-opioid pain relievers, including acetaminophen and a non-steroidal anti-inflammatory drug (NSAID), must be provided; and
9. Journavx™ will not be approved for concurrent use with an opioid; and
10. A quantity limit of 30 tablets for a 14-day supply will apply. The use of Journavx™ for acute pain has not been studied for longer than 14 days. Journavx™ will not be approved for use beyond 14 days or for chronic pain.

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[1] U.S. Food and Drug Administration (FDA). FDA Approves Novel Non-Opioid Treatment for Moderate to Severe Acute Pain. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-novel-non-opioid-treatment-moderate-severe-acute-pain. Issued 01/30/2025. Last accessed 04/15/2025.

[2] Vertex Pharmaceuticals. Vertex Announces FDA Approval of Journavx™ (Suzetrigine), a First-in-Class Treatment for Adults with Moderate-to-Severe Acute Pain. Available online at: https://investors.vrtx.com/news-releases/news-release-details/vertex-announces-fda-approval-journavxtm-suzetrigine-first-class. Issued 01/30/2025. Last accessed 04/15/2025.

[3] Journavx™ (Suzetrigine) Tablet Prescribing Information. Vertex Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219209s000lbl.pdf. Last revised 01/2025. Last accessed 04/15/2025.

Appendix G

Vote to Prior Authorize Xolremdi® (Mavorixafor) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers

Oklahoma Health Care Authority
May 2025

Market News and Updates[1]

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

- **April 2024:** The FDA approved Xolremdi® (mavorixafor) for warts, hypogammaglobulinemia, infections, and myelokathexis (WHIM) syndrome, a rare genetic disease that reduces the number of circulating mature neutrophils and lymphocytes. Xolremdi® is the first FDA-approved medication for WHIM syndrome.

Xolremdi® (Mavorixafor) Product Summary[2,3]

Therapeutic class: CXC chemokine receptor 4 (CXCR4) antagonist

Indication(s): To increase the number of circulating mature neutrophils and lymphocytes in patients 12 years of age and older with WHIM syndrome

How Supplied: 100mg capsule

Dosing and Administration:

- Weight >50kg: 400mg orally once daily
- Weight ≤50kg: 300mg orally once daily
- Xolremdi® should be administered on an empty stomach after an overnight fast and at least 30 minutes before food.
- Doses may be reduced by steps of 100mg due to adverse effects or drug-drug interactions with strong or moderate CYP3A4 inhibitors or P-gp inhibitors, but not to a dose less than 200mg.

Efficacy: The efficacy of Xolremdi® was evaluated in the randomized, double-blind, placebo-controlled portion of the Phase 3 4WHIM trial that included 31 patients.

- Key Inclusion Criteria:
  - ≥12 years of age
  - Confirmed *CXCR4* gene variant consistent with WHIM syndrome
  - Absolute neutrophile count (ANC) ≤400 cells/mcL
- Key Exclusion Criteria:
  - Active infection (excluding warts)

    - Plerixafor within the last 6 months
    - Chronic or prophylactic antibiotics in the last 4 weeks
    - Chronic or prophylactic G-CSF, granulocyte-macrophage colony stimulating factors (GM-CSF), or systemic glucocorticoid in the last 2 weeks
- Interventions:
    - Randomized 1:1 to Xolremdi® once daily or placebo for 52 weeks.
- Primary Endpoint(s):
    - Effect of Xolremdi® on ANC time above threshold (TAT_{ANC}) of 500 cells/mcL over a 24-hour period
- Results:
    - At week 52, the least squares mean TAT_{ANC} was 15.0 hours [95% confidence interval (CI): 11.2, 18.9)] in the Xolremdi® group (n=14) compared to 2.8 hours (95% CI: 0.0, 5.9) in the placebo group (n=17) (P<0.001, 5.3-fold increase).
    - Annualized infection rates were 60% lower with Xolremdi® compared to placebo (P=0.007).

Cost: The Wholesale Acquisition Cost (WAC) of Xolremdi® is $363.80 per 100mg capsule, resulting in an estimated cost of $43,656 per 30 days and $523,872 per year based on the FDA-approved dosing of 400mg orally once daily for a patient weighing >50kg.

Recommendations

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

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 in 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. Prescriber 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.

The College of Pharmacy also recommends removing the prior authorization for Nyvepria® (pegfilgrastim-apgf) as a medical benefit only 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® 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.

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.

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[1] U.S. Food and Drug Administration (FDA). FDA Approves First Drug for WHIM Syndrome, a Rare Disorder That Can Lead to Recurrent, Life-threatening Infections. Available online: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-drug-whim-syndrome-rare-disorder-can-lead-recurrent-life-threatening-infections. Issued 04/30/2024. Last accessed 04/17/2025.
[2] Badolato R, Alsina L, Azar A, et al. A Phase 3 Randomized Trial of Mavorixafor, a CXCR4 Antagonist, for WHIM Syndrome. *Blood* 2024; 144(1): 35-45. doi: 10.1182/blood.2023022658.
[3] Xolremdi® (Mavorixafor) Prescribing Information. X4 Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218709s000lbl.pdf. Last revised 04/26/2024. Last accessed 04/17/2025.

Appendix H

Vote to Prior Authorize Ocrevus Zunovo™ (Ocrelizumab/Hyaluronidase-ocsq) and Update the Approval Criteria for the Multiple Sclerosis (MS) Medications

Oklahoma Health Care Authority
May 2025

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

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

- **June 2024:** The FDA updated the labeling for all sphingosine 1-phosphate (S1P) receptor modulators, including Gilenya®, Mayzent®, Ponvory®, Tascenso ODT®, and Zeposia®, to include information on the risks of cutaneous malignancy, macular edema, and progressive multifocal leukoencephalopathy (PML) associated with S1P receptor modulator use. The new labeling included updates to *Assessments Prior to First Initiating* and the *Warnings and Precautions* sections of the package labeling for each product. These updates are based on information from the post marketing setting. Additionally, Ponvory®'s label was updated to remove the drug interactions with strong CYP3A4 and UGT1A1 inducers. Based on post marketing trials conducted it was determined that coadministration with strong CYP3A4 and UGT1A1 inducers did not show a clinically significant reduction in ponesimod exposure.
- **September 2024:** The FDA approved Ocrevus Zunovo™ (ocrelizumab/hyaluronidase-ocsq) for the treatment of relapsing forms of multiple sclerosis (RMS), including relapsing-remitting multiple sclerosis (RRMS) and active, or relapsing secondary progressive multiple sclerosis (SPMS), as well as clinically isolated syndrome (CIS) and primary progressive multiple sclerosis (PPMS) in adults, making it the first and only twice a year subcutaneous (sub-Q) injection approved for both RMS and PPMS. Ocrevus® was originally FDA approved in 2017 as an intravenous (IV) formulation that is administered over 2 to 3.5 hours by a health care professional and requires 2 loading doses followed by a maintenance dose every 6 months. Ocrevus Zunovo™ is also recommended to be administered by a health care professional but is given over 10 minutes as a sub-Q injection every 6 months with no loading doses required. The approval of Ocrevus Zunovo™ was based on data from the Phase 3 OCARINA II trial that evaluated the pharmacokinetics, safety, and clinical and radiological efficacy of the

sub-Q formulation compared to the IV formulation. Ocrevus Zunovo™ was found to be non-inferior to Ocrevus® IV and showed no clinically significant difference in the levels of ocrelizumab in the blood as well as consistent control of clinical and radiological disease activity through 48 weeks. Additionally, the safety profile of Ocrevus Zunovo™ was consistent with the safety profile of the IV formulation, with the exception of injection site reactions, which was the most common adverse effect that was seen with the new sub-Q formulation. The Wholesale Acquisition Cost of Ocrevus Zunovo™ is $1,794.87 per mL, resulting in an estimated cost of $41,282.01 every 6 months.

- **January 2025:** The FDA announced the addition of a *Boxed Warning* for glatiramer acetate products about the risk of rare but serious allergic reactions which can occur any time following initiation of therapy. An investigation found that patients using glatiramer acetate reported anaphylaxis associated with therapy with 19 cases reporting anaphylaxis more than 1 year after starting therapy with glatiramer acetate.

Recommendations

The College of Pharmacy recommends the prior authorization of Ocrevus Zunovo™ (ocrelizumab/hyaluronidase-ocsq) with criteria similar to the Ocrevus® (ocrelizumab) approval criteria (changes shown in red):

Ocrevus® (Ocrelizumab) and Ocrevus Zunovo™ (Ocrelizumab/ Hyaluronidase-ocsq) Approval Criteria:

1. An FDA approved diagnosis of primary progressive forms of multiple sclerosis (MS) or relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease modifying therapies; and
4. Ocrevus® and Ocrevus Zunovo™ must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion/injection reactions. Approvals will not be granted for self-administration. Prior authorization requests must indicate how the requested product ~~Ocrevus®~~ will be administered; and
    a. Ocrevus® and Ocrevus Zunovo™ must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or

b. Ocrevus® and Ocrevus Zunovo™ must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of the requested product ~~Ocrevus®~~; and

5. Prescriber must confirm that member will be monitored appropriately per package labeling ~~for 1 hour~~ after each infusion or injection; and
6. Prescriber must verify hepatitis B virus (HBV) testing has been performed prior to initiating ocrelizumab ~~Ocrevus®~~ therapy and member does not have active HBV; and
7. Verification from the prescriber that member has no active infection(s); and
8. Verification from the prescriber that female members are not currently pregnant and will use contraception while receiving ocrelizumab ~~Ocrevus®~~ therapy and for 6 months after the last dose ~~infusion~~ of ocrelizumab ~~Ocrevus®;~~ and
9. Approvals will be for the duration of 1 year, and compliance will be checked for continued approval.

Additionally, the College of Pharmacy recommends updating the Copaxone® (glatiramer acetate) approval criteria based on the FDA's safety alert and updating the approval criteria for Gilenya® (fingolimod), Mayzent® (siponimod), Ponvory® (ponesimod), Tascenso ODT® [fingolimod orally disintegrating tablet (ODT)], and Zeposia® (ozanimod) based on the FDA safety-related label changes and to be consistent with clinical practice and the other MS medications (changes shown in red):

Copaxone® (Glatiramer Acetate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must verify that the member has no history of hypersensitivity reactions, including anaphylaxis, to glatiramer acetate and verify that the member has been counseled on the symptoms of anaphylaxis and instructed to seek immediate medical care should anaphylaxis symptoms occur; and
5. Approvals for the 40mg strength of Copaxone® will require a patient-specific, clinically significant reason why the member cannot use the 20mg strength; and

6. Approvals for the generic formulation of either strength of Copaxone®, including Glatopa®, will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
7. Compliance will be checked for continued approval every 6 months.

Gilenya® (Fingolimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; and
   ~~a. Member has experienced at least 1 relapse in the previous 12 months or is transitioning from existing MS therapy; and~~
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must confirm that member will be observed in the prescriber's office for signs and symptoms of bradycardia for 6 hours after the first dose; and
5. Member must not have any contraindications for use of Gilenya® including:
   a. Myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; and
   b. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and
   c. Baseline QTc interval ≥500msec; and
   d. Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs; and
6. Verification from the prescriber that all baseline assessments have been completed prior to initiating Gilenya® as per package labeling, including:
   a. Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring; and
   b. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
   c. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
   d. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and
   e. Skin examination and verification that member will be monitored throughout therapy; and

f. Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Gilenya®; and

7. Verification from the prescriber that member has no active infection(s); and
8. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
~~9. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
~~10. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
11. 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 effective contraception during treatment with Gilenya® and for at least 2 months after discontinuing treatment; and
12. Compliance will be checked for continued approval every 6 months.

Mayzent® (Siponimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Member must have been assessed for CYP2C9 genotype:
    a. Members with a CYP2C9*3/*3 genotype will not generally be approved; or
    b. Members with a CYP2C9*1/*3 or *2/*3 genotype will not be approved for doses exceeding 1mg per day; or
    c. All other genotypes CYP2C9 *1/*1, *1/*2, or *2/*2 will be approved for 2mg per day; and
5. Member must not have any contraindication for use of siponimod including:
    a. CYP2C9*3/*3 genotype; or
    b. Experienced myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or Class III/IV HF in the last 6 months; or
    c. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and

6. Verification from the prescriber that all baseline assessments have been completed prior to initiating Mayzent® as per package labeling, including:
    a. Member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present; and
    b. Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring; and
    c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
    d. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
    e. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and
    f. Skin examination and verification that member will be monitored throughout therapy; and
    g. Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Mayzent®; and
7. Member must not have received prior treatment with alemtuzumab; and
8. Verification from the prescriber that member has no active infection(s); and
9. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
~~10. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
~~11. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
~~12. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~
~~13. Verification from the prescriber that the member has been assessed for medications and conditions that cause reduction in heart rate (HR) or AV conduction delays and that the member will be followed with appropriate monitoring per package labeling; and~~
~~14. Verification from the prescriber that the member has been assessed for previous confirmed history of chickenpox or vaccination against varicella. Members without history of chickenpox or varicella vaccination should receive a full course of varicella vaccine prior to commencing treatment with Mayzent®; and~~

15. Verification from the prescriber that members with sinus bradycardia (HR <55 beats per minute), first- or second-degree AV block (Mobitz type I), or a history of HF or MI will be monitored following the first dose for a minimum of 6 hours; and
16. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
17. Female members of reproductive potential must be willing to use effective contraception during treatment with Mayzent® and for at least 10 days after discontinuing treatment; and
18. Member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; and
19. Compliance will be checked for continued approval every 6 months; and
20. Quantity limits according to package labeling will apply.

Ponvory® (Ponesimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must confirm that members with sinus bradycardia (HR <55 beats per minute), first- or second-degree AV block (Mobitz type I), or a history of HF or MI will be monitored following the first dose for a minimum of 4 hours; and
5. Member must not have any contraindications for use of Ponvory® including:
    a. Myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or
    b. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and
6. Verification from the prescriber that all baseline assessments have been completed prior to initiating Ponvory® as per package labeling, including:
    a. Member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present; and
    b. Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring

c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
d. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
e. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and
f. Skin examination and verification that member will be monitored throughout therapy; and
g. Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Ponvory®; and

7. Member must not have received prior treatment with alemtuzumab; and
~~8. Member must not be concurrently using strong CYP3A4 and UGT1A1 inducers (e.g., rifampin, phenytoin, carbamazepine); and~~
9. Verification from the prescriber that the member has no active infection(s); and
10. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
~~11. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
~~12. Verification from the prescriber that the member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Ponvory®; and~~
~~13. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
14. Verification from the prescriber that the member's blood pressure will be monitored during treatment with Ponvory®; and
~~15. Verification from the prescriber that the member has undergone an ophthalmic evaluation prior to starting therapy with Ponvory® and the member will be monitored for changes in vision throughout therapy; and~~
~~16. Verification from the prescriber that the member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring per package labeling; and~~
~~17. Verification from the prescriber that the member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Ponvory®; and~~

18. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
19. Female members of reproductive potential must be willing to use effective contraception during treatment with Ponvory® and for at least 1 week after discontinuing treatment; and
20. Member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; and
21. Compliance will be checked for continued approval every 6 months; and
22. A quantity limit of 30 tablets per 30 days will apply for the 20mg tablet. A quantity limit of 14 tablets per 14 days will apply for the Ponvory® starter pack.

Tascenso ODT® [Fingolimod Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
~~3. Member must have had at least 1 relapse in the previous 12 months; and~~
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. Prescriber must confirm that member will be observed in the prescriber's office for signs and symptoms of bradycardia for 6 hours after the first dose; and
6. Member must not have any contraindications for use of Tascenso ODT® including:
    a. Myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; and
    b. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and
    c. Baseline QTc interval ≥500msec; and
    d. Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs; and
7. Verification from the prescriber that all baseline assessments have been completed prior to initiating Tascenso ODT® as per package labeling, including:
    a. Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring; and

b. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
c. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
d. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and
e. Skin examination and verification that member will be monitored throughout therapy; and
f. Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Tascenso ODT®; and

8. Verification from the prescriber that member has no active infection(s); and
9. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
~~10. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
~~11. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
12. 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 effective contraception during treatment with Tascenso ODT® and for at least 2 months after discontinuing treatment; and
13. A patient-specific, clinically significant reason why the member cannot use Gilenya® (fingolimod) capsules must be provided; and
14. Compliance will be checked for continued approval every 6 months.

Zeposia® (Ozanimod) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following in adults:
   a. Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; or
   b. Moderately to severely active ulcerative colitis (UC); and
2. For the diagnosis of MS:
   a. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
   b. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
3. Member must not have any contraindications for use of Zeposia® including:

a. Experienced myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or
b. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; or
c. Have severe untreated sleep apnea; or
d. Concurrent use of monoamine oxidase inhibitors (MAOIs); and

4. Verification from the prescriber that all baseline assessments have been completed prior to initiating Zeposia® as per package labeling, including:
   a. Member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present; and
   b. Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring; and
   c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
   d. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
   e. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and
   f. Skin examination and verification that member will be monitored throughout therapy; and
   g. Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Zeposia®; and
5. Member must not have received prior treatment with alemtuzumab; and
6. Verification from the prescriber that member has no active infection(s); and
7. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
8. Member must not be concurrently using strong CYP2C8 inhibitors/ inducers ~~or breast cancer resistance protein (BCRP) inhibitors~~; and
9. Verification from the prescriber that member has no active infection(s); and
10. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~

~~11. Prescriber must conduct an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Zeposia®; and~~
~~12. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
~~13. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~
~~14. Verification from the prescriber that the member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and that the member will be followed with appropriate monitoring per package labeling; and~~
~~15. Verification from the prescriber that the member has been assessed for previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Zeposia®; and~~
16. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
17. Female members of reproductive potential must be willing to use effective contraception during treatment with Zeposia® and for at least 3 months after discontinuing treatment; and
18. For the diagnosis of MS, member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; or
19. For the diagnosis of UC, member must have had an inadequate response, loss of response, or intolerance to oral aminosalicylates, corticosteroids, immunomodulators (e.g., 6-mercaptopurine, azathioprine), and a biologic [e.g., tumor necrosis factor (TNF) blocker]. Tier structure applies; and
20. Compliance will be checked for continued approval every 6 months; and
21. A quantity limit of 30 capsules per 30 days will apply.

Finally, the College of Pharmacy recommends updating the Briumvi® (ublituximab-xiiy), Kesimpta® (ofatumumab), and Mavenclad® (cladribine), approval criteria to be consistent with clinical practice and the other MS medications (changes shown in red):

Briumvi® (Ublituximab-xiiy) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and

2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
~~3. Member must have had at least 1 relapse in the previous 12 months; and~~
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. Briumvi® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Briumvi® will be administered; and
    a. Briumvi® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Briumvi® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of Briumvi®; and
6. Prescriber must confirm that member will be monitored for 1 hour following the first 2 infusions and as indicated for subsequent infusions; and
7. Prescriber must verify hepatitis B virus (HBV) testing has been performed prior to initiating Briumvi® therapy and member does not have active HBV; and
8. Verification from the prescriber that member has no active infection(s); and
9. Verification from the prescriber that female members are not currently pregnant and will use contraception while receiving Briumvi® therapy and for 6 months after the last infusion of Briumvi®; and
10. Approvals will be for the duration of 1 year, and compliance will be checked for continued approval.

Kesimpta® (Ofatumumab) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
~~3. Member must have had at least 1 relapse in the previous 12 months; and~~
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. The prescriber must verify Hepatitis B virus (HBV) screening is performed before the first dose of Kesimpta® and the member does not have an active HBV infection; and

6. Prescriber must agree to monitor quantitative serum immunoglobulin level before, during, and after discontinuation of treatment with Kesimpta® until B-cell repletion; and
7. Prescriber must verify the member has no active infection(s); and
8. Prescriber must verify the first injection of Kesimpta® will be administered by a health care professional prepared to manage injection-related adverse reactions; and
9. Kesimpta® must be shipped via cold chain supply and the member or member's caregiver must be trained on the proper storage and subcutaneous (sub-Q) administration of Kesimpta®; and
10. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of treatment with Kesimpta®; and
11. Female members of reproductive potential must use an effective method of contraception during treatment and for 6 months after stopping Kesimpta®; and
12. A quantity limit of 1 syringe or prefilled Sensoready® Pen per month will apply. Initial dosing titration will be approved for a quantity limit override upon meeting Kesimpta® approval criteria; and
13. Compliance will be checked for continued approval every 6 months.

Mavenclad® (Cladribine) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include relapsing remitting disease and active secondary progressive disease, in adults; and
2. Requests for use in patients with clinically isolated syndrome (CIS) will not generally be approved; and
3. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
~~4. Member must have had at least 1 relapse in the previous 12 months; and~~
5. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
6. Member must have had an inadequate response to 2 or more medications indicated for the treatment of MS; and
7. Prescriber must confirm that the member does not have any contraindications for use of cladribine; and
8. Prescriber must confirm member does not have an active malignancy; and
9. Prescriber must confirm that female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
10. Prescriber must attest that female and male members of reproductive potential plan to use effective contraception during cladribine dosing and for 6 months after the last dose in each treatment course; and

11. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
12. Verification from the prescriber that member has no active infection(s); and
13. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
14. 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
15. Quantity limits according to package labeling will apply; and
16. Approvals will be for 1 year of therapy (1 treatment course/2 cycles) at a time. Lifetime approval duration will be limited to a maximum of 2 treatment courses according to package labeling.

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[1] U.S. Food and Drug Administration (FDA). Zeposia® Supplement Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/209899Orig01s013,s014ltr.pdf. Issued 06/05/2024. Last accessed 04/17/2025.
[2] U.S. FDA. Ponvory® Supplement Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/213498Orig1s005,s006ltr.pdf. Issued 06/05/2024. Last accessed 04/17/2025.
[3] Ponvory® (Ponesimod) Prescribing Information. Janssen Pharmaceuticals. Available online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/213498s005s006lbl.pdf. Last revised 06/2024. Last accessed 04/17/2025.
[4] Genentech. FDA Approves Ocrevus Zunovo™ as the First and Only Twice-A-Year 10-Minute Subcutaneous Injection for People with Relapsing and Progressive Multiple Sclerosis. Available online at: https://www.gene.com/media/press-releases/15036/2024-09-13/fda-approves-ocrevus-zunovo-as-the-first. Issued 09/13/2024. Last accessed 04/17/2025.
[5] Ocrevus Zunovo™ (Ocrelizumab/Hyaluronidase-ocsq) Prescribing Information. Genentech. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761371s000lbl.pdf. Last revised 09/2024. Last accessed 04/17/2025.
[6] Ocrevus® (Ocrelizumab) Prescribing Information. Genentech. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761053s035lbl.pdf. Last revised 06/2024. Last accessed 04/17/2025.
[7] U.S. FDA. FDA adds Boxed Warning About a Rare but Serious Allergic Reaction Called Anaphylaxis with the Multiple Sclerosis Medicine Glatiramer Acetate (Copaxone®, Glatopa®). Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-about-rare-serious-allergic-reaction-called-anaphylaxis-multiple-sclerosis. Last revised 01/30/2025. Last accessed 04/17/2025.

Appendix I

Vote to Prior Authorize Agamree® (Vamorolone) and Duvyzat™ (Givinostat) and Update the Approval Criteria for the Muscular Dystrophy Medications

Oklahoma Health Care Authority
May 2025

Market News and Updates[1,2,3]

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

- **October 2023:** The FDA approved Agamree® (vamorolone) for the treatment of Duchenne muscular dystrophy (DMD) in children and adults 2 years of age and older.
- **March 2024:** The FDA approved Duvyzat™ (givinostat) for the treatment of DMD in patients 6 years of age and older.
- **June 2024:** The FDA expanded the approval of Elevidys (delandistrogene moxeparvovec-rokl) for the treatment of DMD to both ambulatory and non-ambulatory patients 4 years of age and older with a confirmed mutation in the *DMD* gene. The previous approval was under accelerated approval for ambulatory patients 4 through 5 years of age. The FDA update has given Elevidys traditional approval in ambulatory patients and accelerated approval in non-ambulatory patients. The traditional approval in ambulatory patients was supported by the results of 2 double-blind, placebo-controlled trials and 2 open-label trials, which enrolled 218 male patients with DMD. Although Elevidys failed to meet its primary endpoint of improvement versus placebo in North Star Ambulatory Assessment (NSAA), the FDA stated approval of Elevidys was based on the "totality of evidence" including the improvement in secondary and exploratory endpoints which included improvements in time to rise (TTR) from the floor, 10-meter walk/run (10MWR), time to ascend 4 steps, and creatine kinase levels. The accelerated approval for non-ambulatory patients was based on the clinical trials in ambulatory patients and the evidence that Elevidys increases the levels of micro-dystrophin, which the FDA determined is "reasonably likely to predict clinical benefit in the non-ambulatory population." A confirmatory trial is currently underway in non-ambulatory patients.

Agamree® (Vamorolone) Product Summary[4,5,6]

Therapeutic Class: Corticosteroid

Indication(s): Treatment of DMD in patients 2 years of age and older

How Supplied: 40mg/mL oral suspension

Dosing and Administration:

- The recommended dose is 6mg/kg taken orally once daily preferably with a meal.
- The maximum daily dose is 300mg for patients weighing >50kg.

Efficacy: The safety and efficacy of Agamree® were studied in the Phase 2b VISION-DMD study, a randomized, double-blind, parallel-group, placebo-, and active-controlled 24-week clinical trial.

- Key Inclusion Criteria:
  - Boys ≥4 to <7 years of age
  - Genetically confirmed DMD
  - Not previously treated with a corticosteroid
  - Patients were ambulatory
- Intervention: 121 patients were randomized to Agamree® 6mg/kg/day, Agamree® 2mg/kg/day, prednisone 0.75mg/kg/day, or placebo for 24 weeks
  - After 24 weeks, patients on prednisone or placebo received Agamree® (either dose) for 20 weeks.
- Primary Outcome and Results: Change from baseline to week 24 in the Time to Stand Test (TTSTAND) velocity for Agamree® compared to placebo.
  - The difference in TTSTAND velocity vs. placebo in the 6mg/kg/day group was 0.060 rises per second [95% confidence interval (CI): 0.023, 0.098; P=0.002].
  - The difference in TTSTAND velocity vs. placebo in the 2mg/kg/day group was 0.045 rises per second (95% CI: 0.008, 0.082; P=0.017).
- Safety:
  - Participants reporting at least 1 treatment emergent adverse event (TEAE) was similar between groups (placebo group, 73.9%; prednisone group, 83.9%; Agamree®, 2mg/kg per day group, 83.3%; Agamree®, 6mg/kg per day group, 89.3%).
  - Height percentile declined in the prednisone group, but not the Agamree® group (change from baseline [standard deviation (SD)]: prednisone -1.88 [8.81] percentile vs. Agamree®, 6mg/kg per day, +3.86 [6.16] percentile; P=0.02)
  - Bone turnover markers declined with prednisone but not with Agamree®.
  - Boys with DMD at baseline showed low adrenocorticotropic hormone (ACTH)-stimulated cortisol and high incidence of adrenal insufficiency. All 3 treatments led to increased adrenal insufficiency.

Cost Comparison:

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Agamree® 40mg/mL sus	**$100.70**	**$18,126.00**	**$217,512.00***
Emflaza® (deflazacort) 22.75mg/mL sus	$518.52	$24,888.96	$298,667.52⁺
deflazacort 22.75mg/mL sus (generic)	$466.66	$22,399.68	$268,796.16⁺
Emflaza® (deflazacort) 36mg tablet	$592.28	$17,768.40	$213,220.80ᵅ
deflazacort 36 mg tablet (generic)	$473.82	$14,214.60	$170,575.20ᵅ
prednisone 10mg tablet (generic)	$0.06	$5.40	$64.80ᵝ

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).
sus = suspension; Unit = mL or tablet
*Cost is based on the FDA approved dosing of 6mg/kg/day for a 40kg patient.
⁺Cost is based on the FDA approved dosing of 0.9mg/kg/day (rounded up to the nearest tenth of a mL) for a 40kg patient.
ᵅCost is based on the FDA approved dosing of 0.9mg/kg/day (round up to nearest possible tablet size) for a 40kg patient.
ᵝCost is based on the guideline recommended dose of prednisone for DMD of 0.75mg/kg/day for a 40kg patient.

Duvyzat™ (Givinostat) Product Summary[7,8]

Therapeutic Class: Histone deacetylase inhibitor

Indication(s): Treatment of DMD in patients 6 years of age and older

How Supplied: 8.86mg/mL oral suspension

Dosing and Administration:

- Baseline platelet counts and triglycerides should be obtained and evaluated prior to the initiation of Duvyzat™.
- Patients with a platelet count <150 x 10^9/L should not be initiated on Duvyzat™.
- The recommended dose of Duvyzat™ is based on actual body weight (see Figure 1 below for dosing) and administered orally twice daily with food.
- Dosage modifications may be needed for decreased platelet counts, diarrhea, increased triglycerides, or QTc prolongation. See full *Prescribing Information* for modifications.

Figure 1: Recommended Dosage of Duvyzat™		
Actual Body Weight (kg)	**Dosage (mg) BID**	**Oral Suspension Volume (mL) BID**
10 to <20	22.2	2.5
20 to <40	31	3.5
40 to <60	44.3	5
60+	53.2	6

BID = twice daily

Efficacy: The safety and efficacy of Duvyzat™ were studied in the Phase 3 EPIDYS trial, a randomized, double-blind, placebo-controlled, 18-month clinical trial.

- Key Inclusion Criteria:
  - Ambulatory boys ≥6 years of age
  - Genetically confirmed DMD
  - Completed two 4-stair climb assessments with a mean of ≤8 seconds and a time-to-rise of ≥3 seconds but <10 seconds
  - Received stable systemic corticosteroids for ≥6 months (with a reasonable expectation that corticosteroid dose and regimen would not change over the duration of the study)
- Key Exclusion Criteria:
  - Any surgery or medication change in the previous 3 months that could affect muscle strength or function
  - Exposure to any dystrophin restoration product (i.e., exon-skipping) within 6 months prior to the start of the study
- Intervention: 179 patients were randomized 2:1 to received Duvyzat™ or placebo twice daily, in addition to corticosteroids for 72 weeks
- Primary Outcome: Change from baseline to 72 weeks in 4-stair climb for Duvyzat™ vs. placebo
- Primary Result: The mean change from baseline in the Duvyzat™ group was 1.25 seconds (s) versus 3.03s in the placebo group (least squares mean difference: -1.78s; 95% CI: -3.46, -0.11; P=0.037).

Cost: The Wholesale Acquisition Cost (WAC) of Duvyzat™ is $273.54 per mL which results in a cost of $98,474.40 for a 30-day supply or $1,181,692.80 per year at the maximum dose for a patient weighing ≥60kg.

Recommendations

The College of Pharmacy recommends the prior authorization of Agamree® (vamorolone) and Duvyzat™ (givinostat) with the following criteria (shown in red):

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.

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.

The College of Pharmacy also recommends updating the approval criteria for Elevidys (delandistrogene moxeparvovec-rokl) based on the new FDA approved expanded indication (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 ~~through 5 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 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
9. 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
10. 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

11. 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
12. 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
13. 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
14. Member's current weight (kg) taken within the past ~~3 weeks~~ 6 months must be provided on the request to ensure accurate weight-based dosing according to package labeling; and
15. Approvals will be for 1 dose per member per lifetime.

Lastly, the College of Pharmacy recommends updating the approval criteria for Emflaza® (deflazacort) to be consistent with clinical practice (changes shown in red):

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. ~~A patient-specific, clinically significant reason why the member cannot use prednisone even when the tablets are crushed must be provided; and~~
6. ~~Patients already established on deflazacort via the ACCESS DMD Program must also document a patient-specific, clinically significant reason why the member cannot use prednisone even when the tablets are crushed; and~~
7. 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
8. 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

9. Prescriber must verify the member has had a baseline eye examination; and
10. The member's recent weight must be provided in order to authorize the appropriate amount of drug required according to package labeling; and
11. 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
12. 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.

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[1] Santhera Pharmaceuticals. Santhera Receives U.S. FDA Approval of Agamree® (Vamorolone) for the Treatment of Duchenne Muscular Dystrophy. Available online at: https://www.santhera.com/assets/files/press-releases/2023-10-27_FDA-approval_e_final.pdf. Issued 10/27/2023. Last accessed 04/18/2025.

[2] U.S. Food and Drug Administration (FDA). FDA Approves Nonsteroidal Treatment for Duchenne Muscular Dystrophy. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-nonsteroidal-treatment-duchenne-muscular-dystrophy. Issued 03/21/2024. Last accessed 04/18/2025.

[3] U.S. FDA. FDA Expands Approval of Gene Therapy for Patients with Duchenne Muscular Dystrophy. Available online at: https://www.fda.gov/news-events/press-announcements/fda-expands-approval-gene-therapy-patients-duchenne-muscular-dystrophy. Issued 06/20/2024. Last accessed 04/18/2025.

[4] Agamree® (Vamorolone) Prescribing Information. Catalyst Pharmaceuticals, Inc. Available online at: https://agamreehcp.com/wp-content/uploads/sites/2/2024/10/AGAMREE-PI-06-2024-1.pdf. Last revised 06/2024. Last accessed 04/18/2025.

[5] Guglieri M, Clemens P, Perlman S, et al. Efficacy and Safety of Vamorolone vs Placebo and Prednisone Among Boys with Duchenne Muscular Dystrophy: A Randomized Clinical Trial. *JAMA Neurol* 2022; 79(10): 1005-1014. doi: 10.1001/jamaneurol.2022.2480.

[6] Gloss D, Moxley R, Ashwal S, et al. Practice Guideline Update Summary: Corticosteroid Treatment of Duchenne Muscular Dystrophy. *Neurology* 2016; 86(5): 465-472. doi: 10.1212/WNL.0000000000002337.

[7] Duvyzat™ (Givinostat) Prescribing Information. ITF Therapeutics, LLC. Available online at: https://itftherapeutics.com/documents/PI.pdf. Last revised 11/2024. Last accessed 04/18/2025.

[8] Mercuri E, Vilchez J, Boespflug-Tanguy O, et al. Safety and Efficacy of Givinostat in Boys with Duchenne Muscular Dystrophy (EPIDYS): A Multicentre, Randomized, Double-blind, Placebo-controlled, Phase 3 Trial. *Lancet Neurol* 2024; 23:393-403. doi: 10.1016/S1474-4422(24)00036-X.

Appendix J

Fiscal Year 2024 Annual Review of Spinal Muscular Atrophy (SMA) Medications

Oklahoma Health Care Authority
May 2025

Current Prior Authorization Criteria

Evrysdi® (Risdiplam) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA); and
2. Molecular genetic testing to confirm biallelic pathogenic variants in the *survival motor neuron 1* (*SMN1*) gene; and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Evrysdi® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. Prescriber must agree to evaluate member's liver function prior to initiating Evrysdi® and must verify the member does not have severe hepatic impairment (Child-Pugh C); and
6. Pharmacy must confirm Evrysdi® will be constituted to an oral solution by a pharmacist prior to dispensing and must confirm Evrysdi® will be shipped via cold chain supply to adhere to the storage and handling requirements in the package labeling; and
7. Prescriber must confirm the member or caregiver has been counseled on the proper storage of Evrysdi® and has been instructed on how to prepare the prescribed daily dose of Evrysdi® prior to administration of the first dose; and
8. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
9. Female members of reproductive potential must be willing to use effective contraception during treatment with Evrysdi® and for at least 1 month after the last dose; and
10. Prescriber must verify male members of reproductive potential have been counseled on the potential effects on fertility and the potential of compromised male fertility is acceptable; and
11. Member will not be approved for concomitant treatment with Spinraza® (nusinersen); and
12. Member must not have previously received treatment with Zolgensma® (onasemnogene abeparvovec-xioi); and

13. A baseline assessment must be provided using a functionally appropriate exam [e.g., Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), Hammersmith Functional Motor Scale Expanded (HFMSE), Hammersmith Infant Neurological Exam (HINE), Upper Limb Module (ULM) Test]; and
14. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is compliant with Evrysdi® and responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pre-treatment baseline status using the same exam as performed at baseline assessment; and
15. Member's recent weight must be provided to ensure accurate dosing in accordance with package labeling; and
16. A quantity limit of 240mL per 36 days will apply.

Spinraza® (Nusinersen) Approval Criteria:

1. Diagnosis of spinal muscular atrophy (SMA):
    a. Type 1; or
    b. Type 2; or
    c. Type 3 with symptoms; and
2. Molecular genetic testing to confirm biallelic pathogenic variants in the *survival motor neuron 1* (*SMN1*) gene; and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Spinraza® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. Member must not have previously received treatment with Zolgensma® (onasemnogene abeparvovec-xioi); and
6. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam); and
7. Prescriber must verify platelet count, coagulation laboratory testing, and quantitative spot urine protein testing have been assessed at baseline, levels are acceptable to the prescriber, and levels will be monitored prior to each dose; and
8. Spinraza® must be administered in a health care facility by a specialist experienced in performing lumbar punctures; and
    a. Spinraza® must be shipped to the facility where the member is scheduled to receive treatment; and
9. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
    a. Hammersmith Infant Neurological Exam (HINE); or

   b. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); or
   c. Upper Limb Module (ULM) Test; or
   d. Hammersmith Functional Motor Scale Expanded (HFMSE); and
10. 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:
    a. HINE; or
    b. CHOP-INTEND; or
    c. ULM Test; or
    d. HFMSE; and
11. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and
    a. Only (1) 5mL vial of Spinraza® is to be dispensed prior to each scheduled procedure for administration.

Zolgensma® (Onasemnogene Abeparvovec-xioi) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA) in pediatric members younger than 2 years of age; and
2. Member must have reached full-term gestational age prior to Zolgensma® infusion; and
3. Molecular genetic testing to confirm biallelic mutations in the *survival motor neuron 1* (*SMN1*) gene; and
4. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
5. Zolgensma® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
6. Member must have baseline anti-AAV9 antibody titers ≤1:50; and
7. Prescriber must agree to monitor liver function tests, platelet counts, and troponin-I at baseline and as directed by the package labeling; and
8. Prescriber must agree to administer systemic corticosteroids starting 1 day prior to the Zolgensma® infusion and continuing as recommended in the package labeling based on member's liver function; and
9. Zolgensma® must be shipped to the facility where the member is scheduled to receive treatment and must adhere to the storage and handling requirements in the package labeling; and
10. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam) or Spinraza® (nusinersen) following Zolgensma® infusion

(current authorizations for risdiplam or nusinersen will be discontinued upon Zolgensma® approval); and

11. Member's recent weight must be provided to ensure accurate dosing in accordance with package labeling; and
12. Only 1 Zolgensma® infusion will be approved per member per lifetime.

Utilization of SMA Medications: Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	28	213	$11,321,820.64	$53,154.09	$1,718.55	26,688	6,588
2023 Total	**28**	**213**	**$11,321,820.64**	**$53,154.09**	**$1,718.55**	**26,688**	**6,588**
Fiscal Year 2024							
FFS	26	172	$8,607,137.96	$50,041.50	$1,872.75	23,076	4,596
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	2	8	$141,059.91	$17,632.49	$796.95	880	177
OCH	1	3	$76,926.21	$25,642.07	$1,068.42	480	72
2024 Total	**26**	**183**	**$8,825,124.08**	**$48,224.72**	**$1,821.49**	**24,436**	**4,845**
% Change	**-7.10%**	**-14.10%**	**-22.05%**	**-9.27%**	**5.99%**	**-8.40%**	**-26.50%**
Change	**-2**	**-30**	**-$2,496,696.56**	**$4,929.37**	**$102.94**	**-2,252**	**-1,743**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Fiscal Year Comparison: Medical Claims (All Plans)

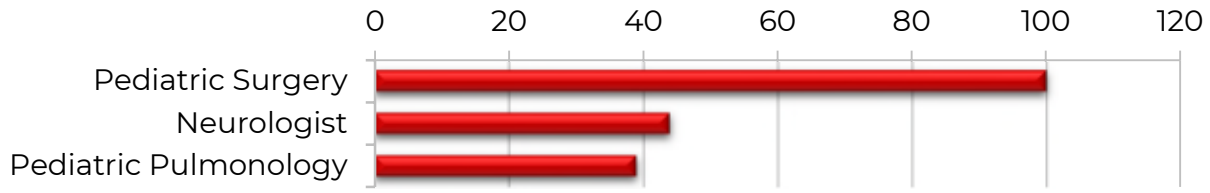
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	1	3	$388,237.20	$129,412.40	3
2023 Total	**1**	**3**	**$388,237.20**	**$129,412.40**	**3**
Fiscal Year 2024					
FFS	2	6	$822,739.20	$137,123.20	3
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**2**	**6**	**$822,739.20**	**$137,123.20**	**3**
% Change	**100.00%**	**100.00%**	**111.92%**	**5.96%**	**0.00%**
Change	**1**	**3**	**$454,502.00**	**$7,710.80**	**0**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

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

- Due to the limited number of members utilizing SMA medications during fiscal year 2024, detailed demographic information could not be provided.

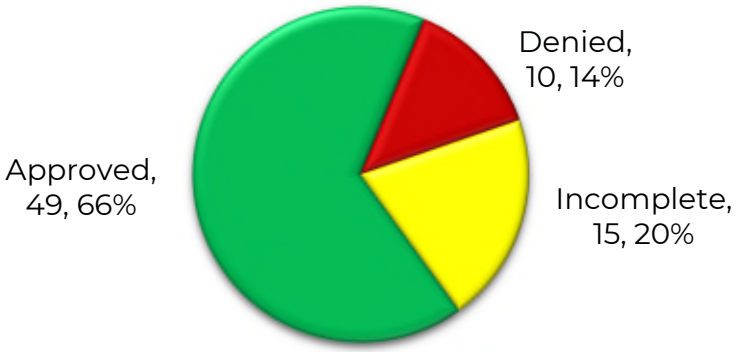
Top Prescriber Specialties of SMA Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of SMA Medications

There were 74 prior authorization requests submitted for SMA medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	48	66%	15	20%	10	14%	**73**
Aetna	0	N/A	0	N/A	0	N/A	**0**
Humana	1	100%	0	0%	0	0%	**1**
OCH	0	N/A	0	N/A	0	N/A	**0**
Total	**49**	**66%**	**15**	**20%**	**10**	**14%**	**74**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

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

Anticipated Patent Expiration(s):

- Spinraza® (nusinersen) injection: September 2035
- Evrysdi® (risdiplam) for oral solution: October 2038
- Evrysdi® (risdiplam) tablet: April 2041

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

- **February 2025:** The FDA approved a 5mg oral tablet formulation of Evrysdi® (risdiplam) for the treatment of SMA, which may be utilized as an alternative to the Evrysdi® oral solution, for patients 2 years of age and older who weigh ≥20kg. Infants and pediatric patients younger than 2 years of age and weighing <20kg should use the oral solution formulation per package labeling.
- **February 2025:** The FDA approved updates to the Zolgensma® (onasemnogene abeparvovec-xioi) package labeling to include infusion-related reactions in the *Warnings and Precautions* section. Additionally, the label update removes the previous recommendations for monitoring troponin-1 levels before and after infusion of Zolgensma® and now states that clinicians can consider cardiac evaluation and consulting a cardiologist as needed if elevations in cardiac troponin-1 levels occur following Zolgensma® infusions.

News:

- **May 2024:** Results of the open-label JEWELFISH trial indicated that, over 24 months, the safety profile of Evrysdi® (risdiplam) in patients who have been previously treated with other therapies [e.g., Spinraza® (nusinersen), Zolgensma® (onasemnogene abeparvovec-xioi), investigative therapies] was consistent with existing safety data for treatment-naïve patients. The patient population included a total of 173 patients with SMA of whom 76 were previously treated with Spinraza® and 14 were previously treated with Zolgensma®. Of note, this open-label trial was not designed to evaluate efficacy endpoints and did not contain a control-group.

Pipeline:

- **Apitegromab:** In March 2025, Scholar Rock announced that the FDA accepted its Biologics License Application (BLA) for apitegromab, an investigational treatment for SMA. If approved, apitegromab will be the first muscle-targeted treatment approved for SMA. The BLA submission is supported by the positive results of the Phase 3 SAPPHIRE trial, including statistically significant and clinically meaningful motor function improvement in patients with SMA receiving apitegromab as compared to placebo; both groups received chronic dosing of either

nusinersen or risdiplam. The Prescription Drug User Fee Act (PDUFA) date is currently September 22, 2025.

- **Higher Dose Spinraza®:** In January 2025, Biogen Inc. announced that the FDA accepted its supplemental New Drug Application (sNDA) for a higher dose regimen of Spinraza® (nusinersen) for the treatment of SMA. The higher dose regimen consists of a more rapid loading dose regimen consisting of 2 doses of 50mg intrathecally 14 days apart followed by a maintenance regimen of 28mg intrathecally every 4 months. This application was supported by the positive results of the Phase 2/3 randomized, controlled, dose-escalating DEVOTE trial, which showed benefits in the safety, tolerability, pharmacokinetics, and efficacy of this higher dosing regimen in treatment-naïve patients and patients previously treated with the currently FDA-approved Spinraza® dosing regimen. Spinraza® was initially FDA approved in 2016, and the current dosing regimen includes (4) 12mg loading doses followed by maintenance dosing of 12mg intrathecally every 4 months. The PDUFA date for the higher dose regimen is currently September 22, 2025.
- **OAV-101 IT:** In March 2025, Novartis reported results from the Phase 3 clinical trial, STEER, that included a total of 126 patients between 2 and 18 years of age with SMA who were able to sit but had never walked independently. The trial demonstrated OAV-101 IT (an intrathecal version of Zolgensma®) led to a statistically significant improvement on the Hammersmith Functional Motor Scale Expanded (HFMSE) of 2.39 points (N=75) compared to 0.51 points (N=51) in the sham control arm (P=0.0074). Novartis plans to include this trial, along with other completed trials for OAV-101 IT, in an application to the FDA in 2025.

Recommendations

The College of Pharmacy recommends updating the Evrysdi® (risdiplam) approval criteria to include the prior authorization of the Evrysdi® (risdiplam) tablet formulation and to be consistent with other criteria that require genetic testing (changes shown in red):

Evrysdi® (Risdiplam) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA); and
2. Molecular genetic testing to confirm biallelic pathogenic variants in the *survival motor neuron 1 (SMN1)* gene (results of genetic testing must be submitted); and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Evrysdi® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a

supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and

5. For the tablet formulation, the member must be 2 years of age or older and weigh ≥20kg (recent weight measured within the last 3 months must be submitted); and
6. Prescriber must agree to evaluate member's liver function prior to initiating Evrysdi® and must verify the member does not have severe hepatic impairment (Child-Pugh C); and
7. Pharmacy must confirm Evrysdi® oral solution will be constituted ~~to an oral solution~~ by a pharmacist prior to dispensing and must confirm Evrysdi® oral solution will be shipped via cold chain supply to adhere to the storage and handling requirements in the Evrysdi® *Prescribing Information*; and
8. Prescriber must confirm the member or caregiver has been counseled on the proper storage of Evrysdi® and has been instructed on how to prepare the prescribed daily dose of Evrysdi® formulations prior to administration of the first dose; and
9. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
10. Female members of reproductive potential must be willing to use effective contraception during treatment with Evrysdi® and for at least 1 month after the last dose; and
11. Prescriber must verify male members of reproductive potential have been counseled on the potential effects on fertility and the potential of compromised male fertility is acceptable; and
12. Member will not be approved for concomitant treatment with Spinraza® (nusinersen); and
13. Member must not have previously received treatment with Zolgensma® (onasemnogene abeparvovec-xioi); and
14. A baseline assessment must be provided using a functionally appropriate exam [e.g., Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), Hammersmith Functional Motor Scale Expanded (HFMSE), Hammersmith Infant Neurological Exam (HINE), Upper Limb Module (ULM) Test]; and
15. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is compliant with Evrysdi® and responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pre-treatment baseline status using the same exam as performed at baseline assessment; and
16. Member's recent weight must be provided to ensure accurate dosing in accordance with Evrysdi® *Prescribing Information*; and
17. For the oral solution, ~~A~~ a quantity limit of 240mL per 36 days will apply~~.~~ and for the tablets, a quantity limit of 30 tablets per 30 days will apply.

The College of Pharmacy also recommends updating the Spinraza® (nusinersen) approval criteria to be consistent with other criteria that require genetic testing (changes shown in red):

Spinraza® (Nusinersen) Approval Criteria:

1. Diagnosis of spinal muscular atrophy (SMA):
   a. Type 1; or
   b. Type 2; or
   c. Type 3 with symptoms; and
2. Molecular genetic testing to confirm biallelic pathogenic variants in the *survival motor neuron 1* (*SMN1*) gene (results of genetic testing must be submitted); and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Spinraza® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. Member must not have previously received treatment with Zolgensma® (onasemnogene abeparvovec-xioi); and
6. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam); and
7. Prescriber must verify platelet count, coagulation laboratory testing, and quantitative spot urine protein testing have been assessed at baseline, levels are acceptable to the prescriber, and levels will be monitored prior to each dose; and
8. Spinraza® must be administered in a health care facility by a specialist experienced in performing lumbar punctures; and
   a. Spinraza® must be shipped to the facility where the member is scheduled to receive treatment; and
9. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
   a. Hammersmith Infant Neurological Exam (HINE); or
   b. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); or
   c. Upper Limb Module (ULM) Test; or
   d. Hammersmith Functional Motor Scale Expanded (HFMSE); and
10. 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:

    a. HINE; or
    b. CHOP-INTEND; or
    c. ULM Test; or
    d. HFMSE; and
11. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and
    a. Only (1) 5mL vial of Spinraza® is to be dispensed prior to each scheduled procedure for administration.

Lastly, the College of Pharmacy recommends updating the Zolgensma® (onasemnogene abeparvovec-xioi) approval criteria based on the updates to the package labeling and to be consistent with other criteria that require genetic testing (changes shown in red):

Zolgensma® (Onasemnogene Abeparvovec-xioi) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA) in pediatric members younger than 2 years of age; and
2. Member must have reached full-term gestational age prior to Zolgensma® infusion; and
3. Molecular genetic testing to confirm biallelic mutations in the *survival motor neuron 1* (*SMN1*) gene (results of genetic testing must be submitted); and
4. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
5. Zolgensma® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
6. Member must have baseline anti-AAV9 antibody titers ≤1:50; and
7. Prescriber must agree to monitor liver function tests~~,~~ and platelet counts~~, and troponin I~~ at baseline and as directed by the package labeling; and
8. Prescriber must agree to administer systemic corticosteroids starting 1 day prior to the Zolgensma® infusion and continuing as recommended in the package labeling based on member's liver function; and
9. Zolgensma® must be shipped to the facility where the member is scheduled to receive treatment and must adhere to the storage and handling requirements in the package labeling; and
10. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam) or Spinraza® (nusinersen) following Zolgensma® infusion (current authorizations for risdiplam or nusinersen will be discontinued upon Zolgensma® approval); and

11. Member's recent weight must be provided to ensure accurate dosing in accordance with package labeling; and
12. Only 1 Zolgensma® infusion will be approved per member per lifetime.

Utilization Details of SMA Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
RISDIPLAM PRODUCTS					
EVRYSDI SOL 0.75MG/ML	159	17	$3,457,793.57	9.35	$21,747.13
SUBTOTAL	**159**	**17**	**$3,457,793.57**	**9.35**	**$21,747.13**
NUSINERSEN PRODUCTS					
SPINRAZA INJ 12MG/5ML	23	8	$3,045,286.15	2.88	$132,403.75
SUBTOTAL	**23**	**8**	**$3,045,286.15**	**2.88**	**$132,403.75**
ONASEMNOGENE ABEPARVOVEC-XIOI PRODUCTS					
ZOLGENSMA INJ 2x5.5ML/1x8.3ML KIT	1	1	$2,322,044.36	1	$2,322,044.36
SUBTOTAL	**1**	**1**	**$2,322,044.36**	**1**	**$2,322,044.36**
TOTAL	**183**	**26***	**$8,825,124.08**	**7.04**	**$48,224.72**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; SOL = solution
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/302024 are available for the SoonerSelect plans

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
NUSINERSEN INJ (J2326)	6	2	$822,739.20	3	$137,123.20
TOTAL	**6**	**2**	**$822,739.20**	**3**	**$137,123.20**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

[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 03/2025. Last accessed 04/17/2025.
[2] Evrysdi® (Risdiplam) Prescribing Information. Genentech. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219285s000lbl.pdf. Last revised 02/2025. Last accessed 04/17/2025.
[3] Zolgensma® (Onasemnogene abeparvovec-xioi) Prescribing Information. Novartis. Available online at: https://www.fda.gov/media/126109/download?attachment. Last revised 02/2025. Last accessed 04/17/2025.
[4] Chiriboga CA, Bruno C, Duong T, et al. JEWELFISH: 24-Month Results from an Open-Label Study in Non-Treatment-Naïve Patients with SMA Receiving Treatment with Risdiplam. *J Neurol*. 2024; 271(8):4871-4884. doi:10.1007/s00415-024-12318-z
[5] Scholar Rock. FDA Grants Priority Review for Biologics License Application (BLA) and EMA Accepts Marketing Authorization Application (MAA) for Apitegromab as a Treatment for Spinal Muscular Atrophy. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20250325289782/en/FDA-Grants-Priority-Review-for-Biologics-License-Application-BLA-and-EMA-Accepts-Marketing-Authorisation-Application-MAA-for-Apitegromab-as-a-Treatment-for-Spinal-Muscular-Atrophy. Issued 03/25/2025. Last accessed 04/17/2025.
[6] Biogen Inc. Biogen Reports Fourth Quarter and Full Year 2024 Results and Provides Full Year 2025 Financial Guidance. Available online at: https://investors.biogen.com/static-files/a4eadd7a-6e77-4110-8289-94816df02324. Issued 02/12/2025. Last accessed 04/17/2025.
[7] Biogen Inc. New Higher Dose Nusinersen Efficacy and Safety Data Presented at World Muscle Society Congress, Highlight Potential to Maximize Benefit of Nusinersen in SMA. Available online at: https://investors.biogen.com/news-releases/news-release-details/new-higher-dose-nusinersen-efficacy-and-safety-data-presented. Issued 10/08/2024. Last accessed 04/17/2025.
[8] Novartis. New Novartis Phase III Data Demonstrate Meaningful Efficacy and Safety Results of Intrathecal Onasemnogene Abeparvovec in Board Patient Populations with SMA. Available online at: https://www.novartis.com/news/media-releases/new-novartis-phase-iii-data-demonstrate-meaningful-efficacy-and-safety-results-intrathecal-onasemnogene-abeparvovec-broad-patient-population-sma. Issued 03/19/2025. Last accessed 04/17/2025.

Appendix K

Fiscal Year 2024 Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Axtle™ (Pemetrexed), Bizengri® (Zenocutuzumab-zbco), Imdelltra™ (Tarlatamab-dlle), Lazcluze™ (Lazertinib), and Tecentriq Hybreza™ (Atezolizumab/ Hyaluronidase-tqjs)

Oklahoma Health Care Authority
May 2025

Current Prior Authorization Criteria

Utilization data for Braftovi® (encorafenib), Keytruda® (pembrolizumab), Libtayo® (cemiplimab-rwlc), Mekinist® (trametinib), Mektovi® (binimetinib), Opdivo® (nivolumab), Tafinlar® (dabrafenib), Yervoy® (ipilimumab), and Zelboraf® (vemurafenib) and approval criteria for indications other than lung cancer can be found in the December 2024 Drug Utilization Review (DUR) Board packet. These medications and criteria are reviewed annually with the skin cancer medications. Utilization data for Cyramza® (ramucirumab) and approval criteria for indications other than lung cancer can be found in the January 2025 DUR Board packet. Cyramza® is reviewed annually with the gastrointestinal cancer medications. Utilization data for Enhertu® (fam-trastuzumab deruxtecan-nxki) and approval criteria for indications other than lung cancer can be found in the September 2024 DUR Board packet. Enhertu® is reviewed annually with the breast cancer medications.

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

1. Diagnosis of recurrent or metastatic NSCLC; and
    a. Anaplastic lymphoma kinase (ALK) positivity; and
    b. First-line or recurrent setting; and
    c. As a single agent only; or
2. Diagnosis of resected NSCLC (tumors ≥4cm or node positive); and
    a. ALK positivity; and
    b. Used as adjuvant treatment; and
    c. As a single agent only.

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

1. Diagnosis of metastatic NSCLC; and
2. Anaplastic lymphoma kinase (ALK) positivity; and
3. As a single agent.

Augtyro™ (Repotrectinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. ROS1-positive; and
3. Used as a single agent.

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

1. Diagnosis of metastatic NSCLC; and
2. *BRAF* V600E mutation; and
3. Used in combination with binimetinib.

Cosela® (Trilaciclib) Approval Criteria [Extensive-Stage Small Cell Lung Cancer (ES-SCLC) Diagnosis]:

1. Diagnosis of ES-SCLC; and
2. Member is undergoing myelosuppressive chemotherapy with 1 of the following:
    a. Platinum (carboplatin or cisplatin) and etoposide-containing regimen; or
    b. Topotecan-containing regimen.

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

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

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Unresectable or metastatic NSCLC; and
2. Disease is human epidermal growth factor receptor 2 (HER2)-positive; and
3. Member must have received a prior systemic therapy.

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

1. Diagnosis of advanced or metastatic NSCLC; and
2. Tumor exhibits an epidermal growth factor receptor (EGFR) exon 20 insertion mutation; and
3. Disease has progressed on or after platinum-based chemotherapy; and
4. As a single agent; and

5. Members who are new to treatment with Exkivity® will generally not be approved.

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

1. Diagnosis of NSCLC in adults; and
2. Recurrent, advanced, or metastatic disease; and
3. Rearranged during transfection (RET) fusion-positive tumor; and
4. As a single agent.

Gavreto® (Pralsetinib) Approval Criteria [Thyroid Cancer Diagnosis]:

1. Adult and pediatric members 12 years of age and older; and
2. Diagnosis of advanced or metastatic disease with:
    a. RET fusion-positive thyroid cancer requiring systemic therapy and member is radioactive iodine-refractory (if radioactive iodine is appropriate); and
3. As a single agent.

Gilotrif® (Afatinib) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Diagnosis of head and neck cancer; and
2. Disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin); and
3. Non-nasopharyngeal cancer must be 1 of the following:
    a. Newly diagnosed T4b, any N, M0 disease, unresectable nodal disease with no metastases, or for members who are unfit for surgery and have a performance status (PS) of 3; or
    b. Metastatic (M1) disease at initial presentation, recurrent/persistent disease with distant metastases, or unresectable locoregional recurrence or second primary with prior radiation therapy (RT) and PS of 0 to 2; or
    c. Unresectable locoregional recurrence without prior RT and PS of 3; and
4. As a single agent only.

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

1. Diagnosis of metastatic NSCLC; and
2. For first-line therapy, meeting the following:
    a. Epidermal growth factor receptor (EGFR) mutation detected; and
    b. As a single agent only; or
3. For second-line therapy, meeting the following:
    a. Progressed following platinum-based chemotherapy; and
    b. As a single agent or in combination with cetuximab in members with a known sensitizing EGFR mutation who are T790M negative.

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

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

Imfinzi® (Durvalumab) Approval Criteria [Extensive-Stage Small Cell Lung Cancer (ES-SCLC) Diagnosis]:

1. Diagnosis of ES-SCLC; and
2. In combination with etoposide and either cisplatin or carboplatin followed by single agent maintenance.

Imfinzi® (Durvalumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of unresectable HCC; and
2. Used in combination with tremelimumab-actl; or
3. As a single agent.

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

1. Diagnosis of unresectable stage II or III NSCLC; and
    a. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; or
2. Diagnosis of metastatic NSCLC; and
    a. No epidermal growth factor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
    b. Used in combination with tremelimumab-actl and platinum-based chemotherapy.

Imjudo® (Tremelimumab-actl) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of unresectable HCC; and
2. Used in combination with durvalumab; and
3. Will be approved for a maximum of 1 dose per treatment plan per member.

Imjudo® (Tremelimumab-actl) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. No epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS1 mutations; and
3. Used in combination with durvalumab and platinum-based chemotherapy; and
4. Will be approved for a maximum of 5 doses per treatment plan per member.

Keytruda® (Pembrolizumab) 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) 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. As a single agent for disease progression on or after platinum-containing chemotherapy (e.g., 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*; and
            1. *Examples of drugs for EGFR-mutation-positive tumors: osimertinib, erlotinib, afatinib, or gefitinib; or*
        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*; and
            1. *Examples of drugs for ALK-mutation-positive tumors: crizotinib, ceritinib, or alectinib*.

Keytruda® (Pembrolizumab) 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) 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)].

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

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
2. Presence of KRAS G12C mutation in tumor or plasma specimen as determined by an FDA approved test; and
3. Member has received at least 1 prior systemic therapy; and
4. As a single agent.

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.

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

1. Diagnosis of metastatic NSCLC; and
2. Tumor expresses anaplastic lymphoma kinase (ALK) translocation; and

3. As a single agent as first-line therapy; or
4. As a single agent as second-line therapy following disease progression on either alectinib or ceritinib; or
5. As a single agent as third-line or greater therapy following disease progression on crizotinib and 1 other ALK inhibitor (i.e., ceritinib, alectinib).

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

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Presence of *KRAS G12C* mutation; and
3. Disease has progressed on at least 1 prior systemic therapy; and
4. As a single agent.

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

1. Diagnosis of refractory or metastatic disease; and
2. BRAF V600E or V600K mutation; and
    a. Trametinib is not indicated for wild-type BRAF NSCLC; and
3. In combination with dabrafenib.

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

1. Diagnosis of metastatic NSCLC; and
2. *BRAF* V600E mutation; and
3. Used in combination with encorafenib.

Opdivo® (Nivolumab) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of malignant pleural mesothelioma that cannot be surgically removed; and
2. Used as first-line therapy; and
3. Used in combination with ipilimumab.

Opdivo® (Nivolumab) 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. Used in combination with Yervoy® (ipilimumab) and 2 cycles of platinum-doublet chemotherapy; and
    b. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
    c. 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.

Opdivo® (Nivolumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of SCLC; and
2. Member meets 1 of the following:
    a. Disease relapsed within 6 months of initial chemotherapy; or
    b. Disease progression on initial chemotherapy; and
3. As a single agent; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)].

Pemfexy® (Pemetrexed; J9304) and Pemrydi RTU® (Pemetrexed; J9324) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use Alimta® (pemetrexed; J9305), pemetrexed ditromethamine (J9323), and other preferred pemetrexed 25mg/mL solution products (J9294 - Hospira, J9296 - Accord, J9297 – Sandoz, J9314 – Teva, J9322 - Bluepoint) that do not require prior authorization must be provided.

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

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
2. Rearranged during transfection (RET) fusion-positive tumor; and
3. As a single agent.

Retevmo® (Selpercatinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of locally advanced or metastatic solid tumor; and
2. Member must be 2 years of age or older; and
3. Rearranged during transfection (RET) gene fusion; and
    a. Disease has progressed on or following prior systemic treatment; or
    b. There are no satisfactory alternative treatment options; and
4. As a single agent.

Retevmo® (Selpercatinib) Approval Criteria [Thyroid Cancer Diagnosis]:

1. Adult and pediatric members 2 years of age and older; and
2. As a single agent; and
3. Diagnosis of advanced or metastatic disease with either:
    a. Rearranged during transfection (RET)-mutant medullary thyroid cancer (MTC) requiring systemic therapy; or
    b. RET fusion-positive thyroid cancer requiring systemic therapy and member is radioactive iodine-refractory (if radioactive iodine is appropriate).

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

1. Diagnosis of metastatic NSCLC; and
2. *ROS1*-positive; and
3. As a single agent.

Rozlytrek® (Entrectinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of solid tumors; and
2. Member must be older than 1 month of age; and
3. Neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion without a known acquired resistance mutation; and
4. Metastatic or not a surgical candidate; and
5. Progressed following treatment or have no satisfactory alternative therapy.
6. As a single agent.

Rybrevant® (Amivantamab-vmjw) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Tumor exhibits epidermal growth factor receptor (EGFR) exon 20 insertion mutations; and
    a. As first-line therapy in combination with carboplatin and pemetrexed; or
    b. As a single agent in disease that has progressed on or after platinum-based chemotherapy; or
3. Tumor exhibits EGFR exon 19 deletion or exon 21 L858R mutations; and

a. As subsequent therapy in combination with carboplatin and pemetrexed after progression on osimertinib.

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

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
2. Mesenchymal-epithelial transition (MET) exon 14 skipping positive tumor; and
3. As a single agent.

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

1. Diagnosis of refractory or metastatic disease; and
2. BRAF V600E or V600K mutation; and
   a. Not indicated for wild-type BRAF NSCLC; and
3. As a single agent or in combination with trametinib.

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

1. Diagnosis of NSCLC; and
   a. As adjuvant therapy following tumor resection in members with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations; and
   b. As a single agent; or
2. Diagnosis of metastatic NSCLC; and
   a. EGFR T790M mutation-positive disease; or
   b. EGFR exon 19 deletions or exon 21 L858R mutations; and
   c. As a single agent; or
3. Diagnosis of locally advanced or metastatic non-squamous NSCLC; and
   a. Used as first-line treatment; and
   b. EGFR exon 19 deletions or exon 21 L858R mutations; and
   c. Used in combination with pemetrexed and platinum-based (cisplatin or carboplatin) chemotherapy.

Tarceva® (Erlotinib) Approval Criteria [Bone Cancer – Chordoma Diagnosis]:

1. Diagnosis of bone cancer – chordoma; and
2. Recurrent disease; and
3. As a single agent only.

Tarceva® (Erlotinib) Approval Criteria [Kidney Cancer Diagnosis]:

1. Diagnosis of kidney cancer; and
2. Non-clear cell histology; and
3. Relapsed disease or surgically unresectable stage IV disease; and
4. As a single agent only.

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

1. Diagnosis of NSCLC; and
2. Recurrent or metastatic disease; and
3. Epidermal growth factor receptor (EGFR) mutation detected; and
4. As a single agent only.

Tarceva® (Erlotinib) Approval Criteria [Pancreatic Adenocarcinoma Diagnosis]:

1. Diagnosis of pancreatic adenocarcinoma; and
2. ECOG performance status of 0 or 1; and
3. Locally advanced, unresectable disease or metastatic disease; and
4. In combination with gemcitabine.

Tecentriq® (Atezolizumab) Approval Criteria [Alveolar Soft Part Sarcoma (ASPS) Diagnosis]:

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

Tecentriq® (Atezolizumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of advanced unresectable or metastatic disease; and
2. Used in combination with bevacizumab; and
3. Member has not received prior systemic therapy.

Tecentriq® (Atezolizumab) Approval Criteria [Melanoma Diagnosis]:

1. Unresectable or metastatic disease; and
2. BRAF V600 mutation-positive; and
3. In combination with cobimetinib and vemurafenib.

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

1. Diagnosis of non-squamous NSCLC:
    a. First-line therapy for metastatic disease; and
    b. Member does not have epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), *ROS1*, *BRAF*, MET exon 14 skipping, or rearranged during transfection (RET) mutations; and
    c. Used in combination with bevacizumab, paclitaxel, and carboplatin (maximum of 6 cycles) or in combination with paclitaxel (protein bound) and carboplatin; and
    d. Atezolizumab and bevacizumab may be continued after the above combination in members without disease progression (applies to the bevacizumab/paclitaxel/carboplatin regimen); or
2. Diagnosis of NSCLC:
    a. For first-line therapy for metastatic disease:

i. As a single agent; and
ii. Member does not have EGFR, ALK, *ROS1*, *BRAF*, MET exon 14 skipping, or RET mutations; and
iii. High programmed death ligand-1 (PD-L1) expression determined by 1 of the following:
1. PD-L1 stained ≥50% of tumor cells (TC≥50%); or
2. PD-L1 stained tumor-infiltrating immune cells (IC) covering ≥10% of the tumor area (IC≥10%); or

b. For subsequent therapy for metastatic disease:
i. As a single agent only; or

3. Diagnosis of stage II or III3A NSCLC; and
a. Member has undergone resection and completed platinum-based chemotherapy; and
b. PD-L1 expression of ≥1% of TC.

Tecentriq® (Atezolizumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of SCLC; and
2. First-line therapy; and
3. Extensive-stage disease; and
4. In combination with carboplatin and etoposide.

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

1. Diagnosis of advanced, metastatic, or unresectable NSCLC; and
2. Mesenchymal-epithelial transition (MET) exon 14 skipping positive tumor; and
3. As a single agent.

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

1. Diagnosis of metastatic NSCLC; and
2. Member has not received prior epidermal growth factor receptor (EGFR) therapy for metastatic disease; and
3. Members must meet 1 of the following:
a. EGFR exon 19 deletion; or
b. Exon 21 L858R substitution mutation; and
4. 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.

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

1. Diagnosis of metastatic NSCLC; and
2. First-line or subsequent therapy; and
3. Anaplastic lymphoma kinase (ALK) or *ROS1*-positive; or
4. MET amplification; and
5. As a single agent only.

Xalkori® (Crizotinib) Approval Criteria [Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT) Diagnosis]:

1. Diagnosis of soft tissue sarcoma – IMT; and
2. Member must be 1 year of age or older; and
3. Anaplastic lymphoma kinase (ALK) positive; and
4. Used as a single agent only.

Yervoy® (Ipilimumab) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of malignant pleural mesothelioma that cannot be surgically removed; and
2. Used as first-line therapy; and
3. Used in combination with nivolumab.

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:
        i. Used in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy; and
        ii. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
        iii. Expresses programmed death ligand 1 (PD-L1) ≥1%.

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

1. Refractory or metastatic disease; and
2. BRAF V600E or V600K mutation; and
    a. Not indicated for wild-type BRAF NSCLC; and
3. As a single agent.

Zepzelca® (Lurbinectedin) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of metastatic SCLC; and
2. Used following disease progression on or after platinum-based chemotherapy.

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

1. Diagnosis of metastatic NSCLC; and
2. Anaplastic lymphoma kinase (ALK) positivity; and
3. As a single agent only.

Zykadia® (Ceritinib) Approval Criteria [Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT) with Anaplastic Lymphoma Kinase (ALK) Translocation Diagnosis]:

1. Diagnosis of soft tissue sarcoma – IMT; and
2. ALK positivity; and
3. As a single agent only.

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 Lung Cancer Medications: Fiscal Year 2024

The following utilization data includes medications indicated for lung cancer; however, the data does not differentiate between lung cancer 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 2023							
FFS	24	162	$2,610,914.88	$16,116.76	$537.23	18,420	4,860
2023 Total	**24**	**162**	**$2,610,914.88**	**$16,116.76**	**$537.23**	**18,420**	**4,860**
Fiscal Year 2024							
FFS	25	160	$2,665,006.31	$16,656.29	$558.94	18,622	4,768
Aetna	3	7	$140,326.35	$20,046.62	$668.22	690	210
Humana	4	12	$221,844.58	$18,487.05	$616.23	2,040	360
OCH	3	4	$84,136.28	$21,034.07	$701.14	150	120
2024 Total	**27**	**183**	**$3,111,313.52**	**$17,001.71**	**$570.05**	**21,502**	**5,458**
% Change	**12.50%**	**13.00%**	**19.20%**	**5.50%**	**6.10%**	**16.70%**	**12.30%**
Change	**3**	**21**	**$500,398.64**	**$884.95**	**$32.82**	**3,082**	**598**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	175	1,133	$7,015,440.27	$6,191.92	6.47
2023 Total	**175**	**1,133**	**$7,015,440.27**	**$6,191.92**	**6.47**
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	**147**	**929**	**$6,006,654.18**	**$6,465.72**	**6.32**
% Change	**-16.00%**	**-18.01%**	**-14.38%**	**4.42%**	**-2.32%**
Change	**-28**	**-204**	**-$1,008,786.09**	**$273.80**	**-0.15**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

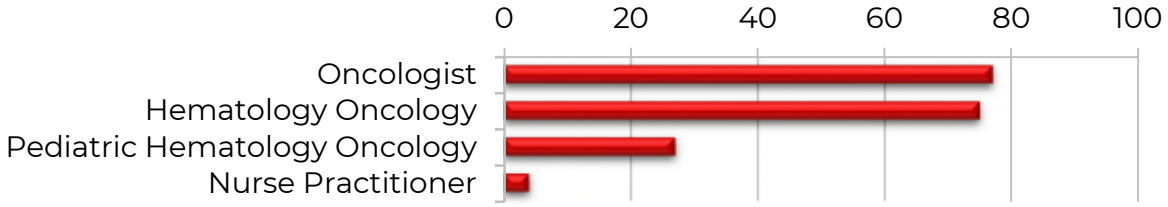
- Aggregate drug rebates collected during fiscal year 2024 for lung cancer medications totaled $3,222,637.04.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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

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

- Due to the limited number of members utilizing lung cancer medications during fiscal year 2024, detailed demographic information could not be provided.

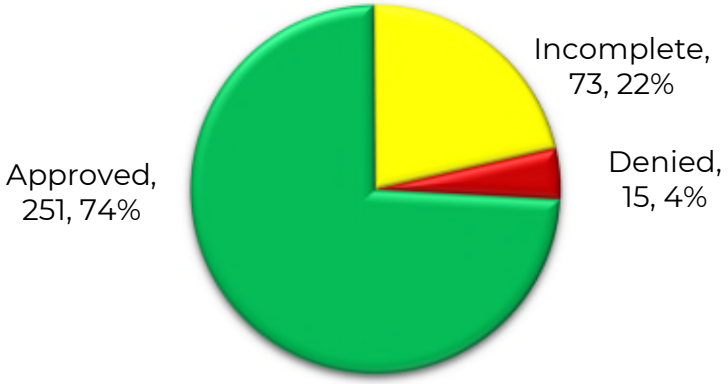
Top Prescriber Specialties of Lung Cancer Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Lung Cancer Medications

There were 339 prior authorization requests submitted for lung cancer medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	239	74%	71	22%	14	4%	**324**
Aetna	1	33%	2	67%	0	0%	**3**
Humana	9	90%	0	0%	1	10%	**10**
OCH	2	100%	0	0%	0	0%	**2**
Total	**251**	**74%**	**73**	**22%**	**15**	**4%**	**339**

FFS = fee-for-service; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

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]

Anticipated Patent Expiration(s):

- Vizimpro® (dacomitinib): May 2028
- Xalkori® (crizotinib): November 2029
- Zepzelca® (lurbinectedin): December 2029
- Tepmetko® (tepotinib): March 2030
- Gilotrif® (afatinib): January 2031
- Zykadia® (ceritinib): February 2032
- Tagrisso® (osimertinib): January 2035
- Alecensa® (alectinib): April 2035
- Tabrecta® (capmatinib): July 2035
- Alunbrig® (brigatinib): November 2035
- Pemfexy® (pemetrexed): February 2036
- Augtyro (repotrectinib): July 2036
- Krazati® (adagrasib): May 2037
- Rozlytrek® (entrectinib): July 2038
- Lorbrena® (lorlatinib): October 2038
- Retevmo® (selpercatinib): October 2038
- Gavreto® (pralsetinib): April 2039
- Lumakras® (sotorasib): September 2040
- Cosela® (trilaciclib): November 2040
- Lazcluze™ (lazertinib): August 2041

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

- **May 2024:** The FDA granted accelerated approval to Imdelltra™ (tarlatamab-dlle) for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.
- **June 2024:** The FDA granted accelerated approval to Augtyro™ (repotrectinib) for a new indication for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and that have progressed following treatment or have no satisfactory alternative therapy.
- **June 2024:** The FDA approved Imfinzi® (durvalumab) for a new indication, in combination with carboplatin and paclitaxel followed by durvalumab as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).
- **June 2024:** The FDA granted accelerated approval to Krazati® (adagrasib) for a new indication, in combination with cetuximab, for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic colorectal cancer (CRC), as determined by an FDA-

approved test, who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

- **June 2024:** The FDA approved pemetrexed for injection, 100mg and 500mg, through the 505(b)(2) pathway based on prior studies utilizing Alimta® (pemetrexed). In December 2024, a supplemental New Drug Application (sNDA) was approved allowing the addition of the proprietary name, Axtle™, to the package labeling. Axtle™ is supplied as a lyophilized powder for reconstitution in 100mg or 500mg single-dose vials (SDVs).
- **August 2024:** The FDA approved Imfinzi® (durvalumab) for a new indication, in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by single-agent durvalumab as adjuvant treatment after surgery for adults with resectable (tumors ≥4cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.
- **August 2024:** The FDA approved Lazcluze™ (lazertinib), in combination with Rybrevant® (amivantamab-vmjw), for the first-line treatment of locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test. The FDA also approved this as a new indication for Rybrevant®.
- **September 2024:** The FDA approved Tecentriq Hybreza™ (atezolizumab/hyaluronidase-tqjs) for subcutaneous (sub-Q) injection for all of the adult indications as the intravenous (IV) formulation of Tecentriq® (atezolizumab), including for NSCLC, small cell lung cancer (SCLC), hepatocellular carcinoma (HCC), melanoma, and alveolar soft part sarcoma (ASPS).
- **September 2024:** The FDA approved Rybrevant® (amivantamab-vmjw) for a new indication, in combination with carboplatin and pemetrexed, the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor.
- **September 2024:** The FDA approved Tagrisso® (osimertinib) for a new indication for the treatment of adult patients with locally advanced, unresectable (stage III) NSCLC whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- **December 2024:** The FDA granted accelerated approval to Bizengri® (zenocutuzumab-zbco) for the treatment of adults with advanced, unresectable or metastatic NSCLC or pancreatic adenocarcinoma

harboring a neuregulin 1 (*NRG1*) gene fusion with disease progression on or after prior systemic therapy.

- **December 2024:** The FDA approved Imfinzi® (durvalumab) for a new indication, as a single agent, for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
- **January 2025:** The FDA approved Lumakras® (sotorasib) for a new indication, in combination with panitumumab, for the treatment of adult patients with KRAS G12C-mutated metastatic CRC, as determined by an FDA approved-test, who have received prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
- **March 2025:** The FDA approved Imfinzi® (durvalumab) for a new indication, in combination with gemcitabine and cisplatin, as neoadjuvant treatment, followed by single agent durvalumab as adjuvant treatment following radical cystectomy, for the treatment of adult patients with muscle invasive bladder cancer.

News:

- **July 2024:** The FDA's previous accelerated approval for Exkivity® (mobocertinib) has been withdrawn. Takeda, the former manufacturer of Exkivity®, requested the voluntary withdrawal of the accelerated approval because the required postmarketing trial did not verify a clinical benefit of the medication.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for colon cancer and rectal cancer recommend the use of sotorasib or adagrasib in combination with cetuximab or panitumumab for patients with KRAS G12C mutation positive disease. Additionally, sotorasib or adagrasib may be used as a single agent for patients who are unable to tolerate an epidermal growth factor receptor (EGFR) inhibitor due to toxicity.
- The NCCN guidelines for kidney cancer recommend erlotinib, when used in combination with bevacizumab, for patients with advanced papillary renal cell carcinoma with non-clear cell histology that is relapsed or surgically unresectable stage IV disease.

Bizengri® (Zenocutuzumab-zbco) Product Summary[22]

Therapeutic Class: Bispecific human epidermal growth factor receptor 2 (HER2)- and human epidermal growth factor receptor 3 (HER3)-directed antibody

Indication(s):

- Treatment of adults with advanced, unresectable or metastatic NSCLC harboring a neuregulin 1 (*NRG1*) gene fusion with disease progression on or after prior systemic therapy; or
- Treatment of adults with advanced, unresectable or metastatic pancreatic adenocarcinoma harboring a *NRG1* gene fusion with disease progression on or after prior systemic therapy.
- These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

How Supplied: 375mg/18.75mL (20mg/mL) solution in a SDV

Dosing and Administration:

- Recommended dose is 750mg as an IV infusion every 2 weeks
- Should be continued until disease progression or unacceptable toxicity

Cost: The Wholesale Acquisition Cost (WAC) is $633.33 per mL, resulting in a cost of $47,499.75 per 28 days or $617,496.75 per year based on the recommended dosing.

Imdelltra™ (Tarlatamab-dlle) Product Summary[23]

Therapeutic Class: Bispecific delta-like ligand 3 (DLL3)-directed CD3 T-cell engager

Indication(s): Treatment of adult patients with ES-SCLC with disease progression on or after platinum-based chemotherapy

- This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

How Supplied: Lyophilized powder in a 1mg or 10mg SDV

Dosing and Administration: Administered as a 1-hour IV infusion according to the following schedule:

- Cycle 1 (Step-Up Dosing): 1mg on day 1, 10mg on day 8, 10mg on day 15
- Cycle 2 (and Subsequent Cycles): 10mg on day 1 and day 15

- Patients should be observed following Imdelltra™ infusion due to the risk of cytokine release syndrome (CRS) and neurologic toxicity, including immune effector cell-associated neurotoxicity (ICANS). See the full *Prescribing Information* for the recommended monitoring time for each cycle. Additionally, patients should remain within 1-hour of an appropriate health care setting for a total of 48 hours from the start of the infusion and be accompanied by a caregiver following the first 2 doses of cycle 1.
- Following step-up dosing, biweekly dosing should continue until disease progression or unacceptable toxicity.

Cost: The WAC is $1,500 for the 1mg SDV and $15,000 for the 10mg SDV. The cost of cycle 1 would be $31,500. Subsequent cycles would result in a cost of $30,000 per 28 days or $390,000 per year based on the recommended dosing.

Lazcluze™ (Lazertinib) Product Summary[24]

Therapeutic Class: Kinase inhibitor

Indication(s): First-line-treatment, in combination with amivantamab, of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test

How Supplied: 80mg and 240mg oral tablets

Dosing and Administration: Recommended dose is 240mg once daily with or without food, given in combination with amivantamab, until disease progression or unacceptable toxicity

Cost: The WAC is $606.60 per 240mg tablet, resulting in a cost of $18,198.00 per 30 days or $218,376.00 per year based on the recommended dosing.

Tecentriq Hybreza™ (Atezolizumab/ Hyaluronidase-tqjs) Product Summary[25]

Therapeutic Class: Combination of atezolizumab, a programmed death-ligand 1 (PD-L1) blocking antibody, and hyaluronidase, an endoglycosidase

Indication(s): Indicated for all of the same adult indications as the IV formulation of atezolizumab, including indications for NSCLC, SCLC, HCC, melanoma, and ASPS

How Supplied: 1,875mg atezolizumab/30,000 units hyaluronidase per 15mL (125mg/2,000 units per mL) solution in a SDV

Dosing and Administration:

- The recommended dose is 15mL (1,875mg atezolizumab and 30,000 units hyaluronidase) administered sub-Q into the thigh over approximately 7 minutes every 3 weeks.
- Tecentriq Hybreza™ must be administered by a health care professional.
- Please refer to the full *Prescribing Information* for indication-specific recommendations, including the duration of treatment, timing of administration relative to other medications, and other administration details.

Cost: The WAC is $750.12 per mL, resulting in a cost of $11,251.80 per 21 days or $191,280.60 per year based on the recommended dosing.

Cost Comparison: Pemetrexed Products

Product	Cost Per 10mg	Cost Per 21 Days*	Cost Per Year
Axtle™ (pemetrexed) (J9292)	**$79.00**	**$7,110.00**	**$120,870.00**
Pemrydi RTU® (pemetrexed) (J9324)	$81.06	$7,295.40	$124,021.80
Pemfexy® (pemetrexed) (J9304)	$46.35	$4,171.50	$70,915.50
pemetrexed (Hospira) (J9294)	$3.86	$347.40	$5,905.80
pemetrexed (Alimta® generic) (J9305)	$3.77	$339.30	$5,768.10
pemetrexed (Sandoz) (J9297)	$1.74	$156.60	$2,662.20

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS).
*Cost per 21 days based on a dose of 500mg/m^2 every 3 weeks for a member with a body surface area (BSA) of 1.73m^2 (using a total of 900mg per dose)

Recommendations

The College of Pharmacy recommends the prior authorization of Bizengri® (zenocutuzumab-zbco), Imdelltra™ (tarlatamab-dlle), and Lazcluze™ (lazertinib) based on recent FDA approval with the following criteria (shown in red):

Bizengri® (Zenocutuzumab-zbco) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of advanced, unresectable or metastatic NSCLC; and
2. Neuregulin 1 (*NRG1*) gene fusion-positive; and
3. Disease progression on or after prior systemic therapy; and
4. Used as single agent.

Bizengri® (Zenocutuzumab-zbco) Approval Criteria [Pancreatic Cancer Diagnosis]:

1. Diagnosis of advanced, unresectable or metastatic pancreatic adenocarcinoma; and
2. Neuregulin 1 (*NRG1*) gene fusion-positive; and
3. Disease progression on or after prior systemic therapy; and
4. Used as single agent.

Imdelltra™ (Tarlatamab-dlle) Approval Criteria [Extensive Stage Small Cell Lung Cancer (ES-SCLC) Diagnosis]:

1. Diagnosis of ES-SCLC; and
2. Member has disease progression on or after platinum-based chemotherapy; and
3. Healthcare facilities must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities.

Lazcluze™ (Lazertinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Tumor exhibits epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations; and
3. Used as first-line treatment in combination with amivantamab.

Next, the College of Pharmacy also recommends the prior authorization of Tecentriq Hybreza™ (atezolizumab/hyaluronidase-tqjs) with criteria similar to Tecentriq® (atezolizumab) with the following changes (shown in red):

Tecentriq® (Atezolizumab) and Tecentriq Hybreza™ (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Alveolar Soft Part Sarcoma (ASPS) Diagnosis]:

1. Diagnosis of unresectable or metastatic ASPS; and
2. Member must be 2 years of age or older for Tecentriq®; or
3. Member must be 18 years of age or older for Tecentriq Hybreza™.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza™ (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of advanced unresectable or metastatic HCC disease; and
2. Used in combination with bevacizumab; and
3. Member has not received prior systemic therapy; and
4. Member must be 18 years of age or older.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza™ (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Melanoma Diagnosis]:

1. Unresectable or metastatic disease; and
2. BRAF V600 mutation-positive; and

3. In combination with cobimetinib and vemurafenib; and
4. Member must be 18 years of age or older.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza™ (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of non-squamous NSCLC; and
    a. First-line therapy for metastatic disease; and
    b. The member does not have epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), ROS1, BRAF, MET exon 14 skipping mutation, or RET mutations; and
    c. Used in combination with bevacizumab, paclitaxel, and carboplatin (maximum of 6 cycles) or in combination with paclitaxel (protein bound) and carboplatin; and
    d. Atezolizumab and bevacizumab may be continued after the above combination in members without disease progression (applies to the bevacizumab/paclitaxel/carboplatin regimen); or
2. Diagnosis of NSCLC; and
    a. For first-line therapy for metastatic disease:
        i. Used as a single-agent; and
        ii. Member does not have epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), ROS1, BRAF, MET exon 14 skipping, or RET mutations; and
        iii. High programmed death ligand-1 (PD-L1) expression determined by 1 of the following:
            1. PD-L1 stained ≥50% of tumor cells (TC≥50%); or
            2. PD-L1 stained tumor-infiltrating immune cells (IC) covering ≥10% of the tumor area (IC≥10%); or
    b. For subsequent therapy for metastatic disease, meets the following:
        i. Used as a single-agent only; or
3. Diagnosis of stage II or IIIA NSCLC; and
    a. Member has undergone resection and completed platinum-based chemotherapy; and
    b. PD-L1 expression of ≥1% of tumor cells; and
4. Member must be 18 years of age or older.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza™ (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of SCLC; and
2. First-line therapy; and
3. Extensive-stage disease; and

4. Atezolizumab must be used in combination with carboplatin and etoposide; and
5. Member must be 18 years of age or older.

The College of Pharmacy also recommends the prior authorization of Axtle™ (pemetrexed) with criteria similar to Pemfexy® (pemetrexed) and Pemrydi RTU® (pemetrexed) based on net costs (changes shown in red):

Axtle™ (Pemetrexed; J9292), Pemfexy® (Pemetrexed; J9304), and Pemrydi RTU® (Pemetrexed; J9324) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use Alimta® (pemetrexed; J9305), pemetrexed ditromethamine (J9323), and other preferred pemetrexed 25mg/mL solution products (J9294 - Hospira, J9296 - Accord, J9297 – Sandoz, J9314 - Teva, J9322 - Bluepoint) that do not require prior authorization must be provided.

Next, the College of Pharmacy recommends updating the Augtyro™ (repotrectinib), Imfinzi® (durvalumab), Rybrevant® (amivantamab-vmjw), and Tagrisso® (osimertinib) approval criteria based on new FDA approvals (changes shown in red):

Augtyro™ (Repotrectinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of solid tumor(s) that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion; and
2. Locally advanced or metastatic or where surgical resection is likely to result in severe morbidity; and
3. Member must be 12 years of age or older; and
4. Progressed following treatment or have no satisfactory alternative therapy; and
5. Used as a single agent.

Imfinzi® (Durvalumab) Approval Criteria [Bladder Cancer Diagnosis]:

1. Diagnosis of muscle invasive bladder cancer; and
2. Used in combination with gemcitabine and cisplatin as neoadjuvant treatment for 4 cycles; and
3. Followed by single-agent adjuvant treatment following radical cystectomy for up to 8 additional cycles.

Imfinzi® (Durvalumab) Approval Criteria [Endometrial Cancer Diagnosis]:

1. Diagnosis of primary advanced (FIGO measurable stage III/newly diagnosed stage IV) or recurrent endometrial cancer; and
2. Mismatch repair deficient (dMMR); and
3. Used in combination with carboplatin and paclitaxel followed by single-agent maintenance.

Imfinzi® (Durvalumab) Approval Criteria [Limited-Stage Small Cell Lung Cancer (LS-SCLC) Diagnosis]:

1. Diagnosis of LS-SCLC; and
2. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; and
3. Used as single agent.

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

1. Diagnosis of resectable (tumors ≥4cm and/or node positive) NSCLC; and
    a. Used in combination with platinum-containing chemotherapy as neoadjuvant treatment before surgery, followed by single agent durvalumab as adjuvant treatment after surgery; and
    b. No epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements; or
2. Diagnosis of unresectable stage II or III non-small cell lung cancer (NSCLC); and
    a. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; or
3. Diagnosis of metastatic NSCLC; and
    a. No EGFR mutation or ALK genomic tumor aberrations; and
    b. Used in combination with tremelimumab-actl and platinum-based chemotherapy.

Rybrevant® (Amivantamab-vmjw) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Tumor exhibits epidermal growth factor receptor (EGFR) exon 20 insertion mutations; and
    a. As first-line therapy in combination with carboplatin and pemetrexed; or
    b. As a single agent in disease that has progressed on or after platinum-based chemotherapy; or
3. Tumor exhibits EGFR exon 19 deletion or exon 21 L858R mutations; and
    a. As first-line therapy in combination with lazertinib; or
    b. As subsequent therapy in combination with carboplatin and pemetrexed after progression on ~~osimertinib~~ an EGFR tyrosine kinase inhibitor.

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

1. Diagnosis of NSCLC; and

   a. As adjuvant therapy following tumor resection in members with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations; and
   b. As a single agent; or
2. Diagnosis of locally advanced, unresectable (stage III) NSCLC; and
   a. EGFR exon 19 deletions or exon 21 L858R mutations; and
   b. As single agent; and
   c. Disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy; or
3. Diagnosis of metastatic NSCLC; and
   a. EGFR T790M mutation-positive disease; or
   b. EGFR exon 19 deletions or exon 21 L858R mutations; and
   c. As a single agent; or
4. Diagnosis of locally advanced or metastatic non-squamous NSCLC; and
   a. Used as first-line treatment; and
   b. EGFR exon 19 deletions or exon 21 L858R mutations; and
   c. Used in combination with pemetrexed and platinum-based (cisplatin or carboplatin) chemotherapy.

Next, the College of Pharmacy recommends updating the Krazati® (adagrasib) and Lumakras® (sotorasib) approval criteria based on new FDA approvals and NCCN guideline recommendations (changes shown in red):

Krazati® (Adagrasib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic CRC; and
2. Presence of KRAS G12C mutation; and
3. Member has received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
4. Used in combination with cetuximab or panitumumab; or
   a. Used as a single agent if unable to tolerate epidermal growth factor receptor (EGFR) inhibitor due to toxicity.

Lumakras® (Sotorasib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of metastatic CRC; and
2. Presence of KRAS G12C mutation; and
3. Member has received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
4. Used in combination with cetuximab or panitumumab; or
   a. Used as a single agent if unable to tolerate epidermal growth factor receptor (EGFR) inhibitor due to toxicity.

Next, the College of Pharmacy recommends updating the approval criteria for Tarceva® (erlotinib) based on NCCN guideline recommendations (changes shown in red):

Tarceva® (Erlotinib) Approval Criteria [Kidney Cancer Diagnosis]:

1. Diagnosis of ~~kidney cancer~~ advanced papillary renal cell carcinoma; and
2. Non-clear cell histology; and
3. Relapsed disease or surgically unresectable stage IV disease; and
4. ~~As a single agent only.~~
5. Used in combination with bevacizumab.

Lastly, the College of Pharmacy recommends removing the approval criteria and SoonerCare coverage for Exkivity® (mobocertinib) based on the withdrawal of its accelerated approval (changes shown in red):

~~**Exkivity® (Mobocertinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:**~~

~~1. Diagnosis of advanced or metastatic NSCLC; and~~
~~2. Tumor exhibits an epidermal growth factor receptor (EGFR) exon 20 insertion mutation; and~~
~~3. Disease has progressed on or after platinum-based chemotherapy; and~~
~~4. As a single agent; and~~
~~5. Members who are new to treatment with Exkivity® will generally not be approved.~~

Utilization Details of Lung Cancer Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OSIMERTINIB PRODUCTS						
TAGRISSO TAB 80MG	52	9	$851,631.20	$16,377.52	5.78	27.37%
TAGRISSO TAB 40MG	10	2	$181,464.74	$18,146.47	5	5.83%
SUBTOTAL	**62**	**11**	**$1,033,095.94**	**$16,662.84**	**5.64**	**33.20%**
ALECTINIB PRODUCTS						
ALECENSA CAP 150MG	50	5	$896,951.27	$17,939.03	10	28.83%
SUBTOTAL	**50**	**5**	**$896,951.27**	**$17,939.03**	**10**	**28.83%**
SELPERCATINIB PRODUCTS						
RETEVMO CAP 80MG	25	2	$421,702.96	$16,868.12	12.5	13.55%
RETEVMO CAP 40MG	13	1	$284,262.67	$21,866.36	13	9.14%
SUBTOTAL	**38**	**3**	**$705,965.63**	**$18,578.04**	**12.67**	**22.69%**
ERLOTINIB PRODUCTS						
ERLOTINIB TAB 100MG	8	2	$1,829.58	$228.70	4	0.06%
ERLOTINIB TAB 150MG	2	1	$652.82	$326.41	2	0.02%
SUBTOTAL	**10**	**3**	**$2,482.40**	**$248.24**	**3.33**	**0.08%**
ADAGRASIB PRODUCTS						
KRAZATI TAB 200MG	8	2	$172,406.03	$21,550.75	4	5.54%
SUBTOTAL	**8**	**2**	**$172,406.03**	**$21,550.75**	**4**	**5.54%**
SOTORASIB PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LUMAKRAS TAB 320MG	8	2	$162,962.58	$20,370.32	4	5.24%
SUBTOTAL	**8**	**2**	**$162,962.58**	**$20,370.32**	**4**	**5.24%**
MOBOCERTINIB PRODUCTS						
EXKIVITY CAP 40MG	2	1	$53,518.82	$26,759.41	2	1.72%
SUBTOTAL	**2**	**1**	**$53,518.82**	**$26,759.41**	**2**	**1.72%**
ENTRECTINIB PRODUCTS						
ROZLYTREK CAP 200MG	2	1	$40,100.80	$20,050.40	2	1.29%
SUBTOTAL	**2**	**1**	**$40,100.80**	**$20,050.40**	**2**	**1.29%**
AFATINIB PRODUCTS						
GILOTRIF TAB 20MG	2	1	$22,245.54	$11,122.77	2	0.71%
SUBTOTAL	**2**	**1**	**$22,245.54**	**$11,122.77**	**2**	**0.71%**
CAPMATINIB PRODUCTS						
TABRECTA TAB 200MG	1	1	$21,584.51	$21,584.51	1	0.69%
SUBTOTAL	**1**	**1**	**$21,584.51**	**$21,584.51**	**1**	**0.69%**
TOTAL	**183**	**27***	**$3,111,313.52**	**$17,001.71**	**6.78**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PEMETREXED J9305	326	45	$90,024.62	$276.15	7.24
ATEZOLIZUMAB J9022	254	48	$2,642,607.60	$10,403.97	5.29
DURVALUMAB J9173	238	49	$2,504,297.04	$10,522.26	4.86
LURBINECTEDIN J9223	48	9	$427,446.22	$8,905.13	5.33
PEMETREXED J9294	39	5	$13,922.70	$356.99	7.8
TREMELIMUMAB-ACTL J9347	12	8	$306,361.50	$25,530.13	1.5
PEMETREXED J9296	6	3	$2,898.00	$483.00	2
TRILACICLIB J1448	5	1	$15,600.00	$3,120.00	5
AMIVANTAMAB-VMJW J9061	1	1	$3,496.50	$3,496.50	1
TOTAL	**929**	**147**	**$6,006,654.18**	**$6,465.72**	**6.32**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 04/2025. Last accessed 04/11/2025.
[2] U.S. FDA. FDA Grants Accelerated Approval to Tarlatamab-dlle for Extensive Stage Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-tarlatamab-dlle-extensive-stage-small-cell-lung-cancer. Issued 05/16/2024. Last accessed 04/11/2025.
[3] U.S. FDA. FDA Grants Accelerated Approval to Repotrectinib for Adult and Pediatric Patients with NTRK Gene Fusion-Positive Solid Tumors. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-repotrectinib-adult-and-pediatric-patients-ntrk-gene-fusion-positive. Issued 06/13/2024. Last accessed 04/11/2025.
[4] U.S. FDA. FDA Approves Durvalumab with Chemotherapy for Mismatch Repair Deficient Primary Advanced or Recurrent Endometrial Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-durvalumab-chemotherapy-mismatch-repair-deficient-primary-advanced-or-recurrent. Issued 06/14/2024. Last accessed 04/11/2025.
[5] U.S. FDA. FDA Grants Accelerated Approval to Adagrasib with Cetuximab for KRAS G12C-Mutated Colorectal Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-adagrasib-cetuximab-kras-g12c-mutated-colorectal-cancer. Issued 06/21/2024. Last accessed 04/11/2025.
[6] U.S. FDA. NDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/210661Orig1s000ltr.pdf. Issued 06/28/2024. Last accessed 04/11/2025.
[7] U.S. FDA. Supplemental Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/210661Orig1s001ltr.pdf. Issued 12/02/2024. Last accessed 04/11/2025.
[8] Axtle™ (Pemetrexed) Prescribing Information. Avyxa Pharma, LLC. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/210661s001lbl.pdf. Last revised 12/2024. Last accessed 04/11/2025.
[9] U.S. FDA. FDA Approves Neoadjuvant/Adjuvant Durvalumab for Resectable Non-Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-neoadjuvantadjuvant-durvalumab-resectable-non-small-cell-lung-cancer. Issued 08/15/2024. Last accessed 04/11/2025.
[10] U.S. FDA. FDA Approves Lazertinib with Amivantamab-vmjw for Non-Small Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-lazertinib-amivantamab-vmjw-non-small-lung-cancer. Issued 08/19/2024. Last accessed 04/11/2025.
[11] U.S. FDA. FDA Approves Atezolizumab and Hyaluronidase-tqjs for Subcutaneous Injection. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-atezolizumab-and-hyaluronidase-tqjs-subcutaneous-injection. Issued 09/12/2024. Last accessed 04/11/2025.
[12] U.S. FDA. FDA Approves Amivantamab-vmjw with Carboplatin and Pemetrexed for Non-Small Cell Lung Cancer with EGFR Exon 19 Deletions or L858R Mutations. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-amivantamab-vmjw-carboplatin-and-pemetrexed-non-small-cell-lung-cancer-egfr-exon-19. Issued 09/19/2024. Last accessed 04/11/2025.
[13] U.S. FDA. FDA Approves Osimertinib for Locally Advanced, Unresectable (Stage III) Non-Small Cell Lung Cancer Following Chemoradiation Therapy. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-osimertinib-locally-advanced-unresectable-stage-iii-non-small-cell-lung-cancer. Issued 09/25/2024. Last accessed 04/11/2025.
[14] U.S. FDA. FDA Grants Accelerated Approval to Zenocutuzumab-zbco for Non-Small Cell Lung Cancer and Pancreatic Adenocarcinoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-zenocutuzumab-zbco-non-small-cell-lung-cancer-and-pancreatic. Issued 12/04/2024. Last accessed 04/11/2025.
[15] U.S. FDA. FDA Approves Durvalumab for Limited-Stage Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-durvalumab-limited-stage-small-cell-lung-cancer. Issued 12/04/2024. Last accessed 04/11/2025.

[16] U.S. FDA. FDA Approves Sotorasib with Panitumumab for KRAS G12C-Mutated Colorectal Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-sotorasib-panitumumab-kras-g12c-mutated-colorectal-cancer. Issued 01/16/2025. Last accessed 04/11/2025.
[17] U.S. FDA. FDA Approves Durvalumab for Muscle Invasive Bladder Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-durvalumab-muscle-invasive-bladder-cancer. Issued 03/28/2025. Last accessed 04/11/2025.
[18] U.S. FDA. Takeda Pharmaceuticals U.S.A., Inc.; Withdrawal of Approval of New Drug Application for Exkivity® (Mobocertinib Succinate) Capsule, Equivalent to 40 Milligrams Base. *Federal Register*. Available online at: https://www.federalregister.gov/documents/2024/07/15/2024-15371/takeda-pharmaceuticals-usa-inc-withdrawal-of-approval-of-new-drug-application-for-exkivity. Issued 07/15/2024. Last accessed 04/11/2025.
[19] National Comprehensive Cancer Network (NCCN). Colon Cancer Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Last revised 04/24/2025. Last accessed 04/29/2025.
[20] NCCN. Rectal Cancer Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Last revised 03/31/2025. Last accessed 04/29/2025.
[21] NCCN. Kidney Cancer Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Last revised 01/09/2025. Last accessed 04/29/2025.
[22] Bizengri® (Zenocutuzumab-zbco) Prescribing Information. Merus US, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761352s001lbl.pdf. Last revised 12/2024. Last accessed 04/11/2025.
[23] Imdelltra™ (Tarlatamab-dlle) Prescribing Information. Amgen, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761344s000lbl.pdf. Last revised 05/2024. Last accessed 04/11/2025.
[24] Lazcluze™ (Lazertinib) Prescribing Information. Janssen Biotech, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/219008s000lbledt.pdf. Last revised 08/2024. Last accessed 04/11/2025.
[25] Tecentriq Hybreza™ (Atezolizumab/Hyaluronidase-tqjs) Prescribing Information. Genentech, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761347s000lbl.pdf. Last revised 09/2024. Last accessed 04/11/2025.

Appendix L

Fiscal Year 2024 Annual Review of Botulinum Toxins and 30-Day Notice to Prior Authorize Daxxify® (DaxibotulinumtoxinA-lanm)

Oklahoma Health Care Authority
May 2025

Current Prior Authorization Criteria

Botulinum Toxins Approval Criteria:

1. For approval of Myobloc® or Xeomin®, a patient-specific, clinically significant reason the member cannot use Botox® or Dysport® must be provided; and
2. Cosmetic indications will not be covered; and
3. A diagnosis of chronic migraine (tension headaches are not a covered diagnosis), neurogenic detrusor overactivity, and non-neurogenic overactive bladder will require manual review (see specific criteria below); and
4. The following indications have been determined to be appropriate and are covered:
    a. Spasticity associated with:
        i. Cerebral palsy; or
        ii. Paralysis; or
        iii. Generalized weakness/incomplete paralysis; or
        iv. Larynx; or
        v. Anal fissure; or
        vi. Esophagus (achalasia and cardiospasms); or
        vii. Eye and eye movement disorders; or
    b. Cervical dystonia.

Botox® (OnabotulinumtoxinA) Approval Criteria [Chronic Migraine Diagnosis*]:

1. FDA indications are met:
    a. Member is 18 years of age or older; and
    b. Member has documented chronic migraine headaches:
        i. Frequency of ≥15 headache days per month with ≥8 migraine days per month and occurring for >3 months; and
        ii. Headache duration of ≥4 hours per day; and
2. Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes, but is not limited to:
    a. Increased intracranial pressure (e.g., tumor, pseudotumor cerebri, central venous thrombosis); and

    b. Decreased intracranial pressure (e.g., post-lumbar puncture headache, dural tear after trauma); and
3. Migraine headache exacerbation secondary to other medical conditions or medication therapies have been ruled out and/or treated. This includes, but is not limited to:
    a. Hormone replacement therapy or hormone-based contraceptives; and
    b. Chronic insomnia; and
    c. Obstructive sleep apnea; and
4. Member has no contraindications to Botox® injections; and
5. The member has failed medical migraine preventative therapy, including ≥2 agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects) within the last 365 days. This includes, but is not limited to:
    a. Select antihypertensive therapy (e.g., beta blockers); or
    b. Select anticonvulsant therapy; or
    c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and
6. Member is not frequently taking medications which are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
    a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and
    b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
    c. Opioids (≥10 days/month for >3 months); and
    d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
    e. Ergotamine-containing medications (≥10 days/month for >3 months); and
    f. Triptans (≥10 days/month for >3 months); and
7. Member is not taking any medications that are likely to be the cause of the headaches; and
8. Member must have been evaluated within the last 6 months by a neurologist for chronic migraine headaches and Botox® recommended as treatment (not necessarily prescribed or administered by a neurologist); and
9. Prescriber must verify that other aggravating factors that are contributing to the development of chronic migraine headaches are being treated when applicable (e.g., smoking); and

10. Member will not use the requested medication concurrently with a calcitonin gene-related peptide (CGRP) inhibitor for the prevention of migraine headaches.

Botox® (OnabotulinumtoxinA) Approval Criteria [Neurogenic Detrusor Overactivity (NDO) Diagnosis*]:

1. Diagnosis of 1 of the following:
    a. Urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury, multiple sclerosis] in adult members; or
    b. NDO in pediatric members; and
2. Underlying pathological dysfunction subtype confirmed by:
    a. Urodynamic studies to determine pathology and serve to provide objective evidence of bladder and external sphincter function; and
    b. A diary of fluid intake, incontinence, voiding, and catheterization times and amounts to provide a record of actual occurrences; and
3. Member must have a clinically significant reason why anticholinergic medications are no longer an option for the member; and
4. Member must be 5 years of age or older and have adequate hand function and sufficient cognitive ability to know when the bladder needs emptying and to self-catheterize, or have a caregiver able to catheterize the member when necessary; and
5. Botox® must be administered by a urologist.

Botox® (OnabotulinumtoxinA) Approval Criteria [Non-Neurogenic Overactive Bladder Diagnosis*]:

1. Member must have severe disease (≥5 urinary incontinence episodes per day on medication) and specific pathology determined via urodynamic studies; and
2. Member must have participated in behavioral therapy for ≥12 weeks that did not yield adequate clinical results; and
3. Member must have had compliant use of ≥3 anti-muscarinic or beta-3 adrenoceptor agonist medications for ≥12 weeks each, alone or in combination with behavioral therapy, that did not yield adequate clinical results. One of those trials must have been an extended-release formulation; and
4. Member must be 18 years of age or older and have adequate hand function and sufficient cognitive ability to know when the bladder needs emptying and to self-catheterize, or have a caregiver able to catheterize the member when necessary; and
5. Botox® must be administered by a urologist.

***Other botulinum toxins will not be approved for this diagnosis**

Utilization of Botulinum Toxins: Fiscal Year 2024

Fiscal Year 2024 Utilization: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	0	0	$0.00	$0.00	$0.00	0	0
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	16	16	$20,470.56	$1,279.41	$14.34	16	1,428
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**16**	**16**	**$20,470.56**	**$1,279.41**	**$14.34**	**16**	**1,428**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.
Please note: There were no paid pharmacy claims during fiscal year 2024 to allow for a fiscal year comparison.

Comparison of Fiscal Years: Medical Claims (All Plans)

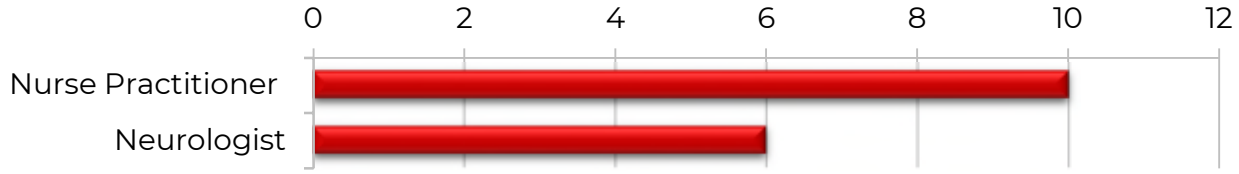
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	422	863	$1,214,130.92	$1,406.87	2.05
2023 Total	**422**	**863**	**$1,214,130.92**	**$1,406.87**	**2.05**
Fiscal Year 2024					
FFS	371	651	$884,656.53	$1,358.92	1.75
Aetna	10	10	$9,855.60	$985.56	1
Humana	2	2	$1,278.00	$639.00	1
OCH	11	11	$13,536.00	$1,230.55	1
2024 Total	**386**	**674**	**$909,326.13**	**$1,349.15**	**1.75**
% Change	**-8.53%**	**-21.90%**	**-25.10%**	**-4.10%**	**-14.63%**
Change	**-36**	**-189**	**-$304,804.79**	**-$57.72**	**-0.30**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Demographics of Members Utilizing Botulinum Toxins: Pharmacy Claims (All Plans)

- Due to the limited number of members utilizing botulinum toxins during fiscal year 2024, detailed demographic information could not be provided.

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



Prior Authorization of Botulinum Toxins

There were 955 prior authorization requests submitted for botulinum toxins during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	518	58%	135	15%	233	26%	**886**
Aetna	0	0%	3	100%	0	0%	**3**
Humana	36	55%	0	0%	29	45%	**65**
OCH	1	100%	0	0%	0	0%	**1**
Total	**555**	**58%**	**138**	**15%**	**262**	**27%**	**955**

FFS = fee-for-service; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans

Market News and Updates[1,2,3]

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

- **August 2023:** The FDA approved Daxxify® (daxibotulinumtoxinA-lanm) for the treatment of cervical dystonia. Previously, Daxxify® was only FDA approved to temporarily improve moderate to severe glabellar lines, a cosmetic indication. Daxxify® was not covered by SoonerCare until the manufacturer entered into a federal drug rebate agreement effective October 1, 2024. Daxxify® is the first botulinum toxin type A (BoNTA) to be formulated with a proprietary peptide technology that helps eliminate the need for animal or human components.

Guideline Update(s):

- **American Headache Society (AHS):**
  - In March 2024, the AHS issued a position statement update regarding the use of calcitonin gene-related peptide (CGRP) targeting therapies. The key updates included:
    - CGRP-targeting therapies are considered a first-line option for migraine prevention.
    - All therapies previously recommended by the AHS as first-line preventive options are still considered first-line options which include onabotulinumtoxinA. Additionally, candesartan was added.
    - CGRP-targeting therapies have additional evidence supporting their use that previous therapies do not, including responder rates, efficacy in patients with multiple prior treatment failures, efficacy in those with acute medication overuse, and those who do and do not have aura.
    - Cost considerations should include not only the direct cost of treatments, but also the indirect costs of health care utilization and acute therapies, as well as socioeconomic costs for those who are disabled by migraines.
- **American Urological Association (AUA):**
  - According to the AUA Neurogenic Lower Urinary Tract Dysfunction (NLUTD) 2021 Guidelines, optional studies in patients with NLUTD include a voiding/catheterization diary, pad test, and non-invasive uroflow.

Daxxify® (DaxibotulinumtoxinA-lanm) Product Summary[4]

Therapeutic Class: Acetylcholine release inhibitor and neuromuscular-blocking agent

Indication(s): Treatment of cervical dystonia in adult patients

- Please Note: Daxxify® is also FDA approved for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients; however, that indication is considered cosmetic and will not be covered by SoonerCare.

How Supplied: Sterile lyophilized powder in 50-unit or 100-unit single-dose vials (SDVs)

Dosing and Administration:

- The recommended dose for cervical dystonia is 125-250 units given intramuscularly (IM) as a divided dose among affected muscles.

- The potency units for Daxxify® are not interchangeable with other preparations of botulinum toxin products; therefore, units of biological activity of Daxxify® cannot be compared to or converted into units of any other botulinum toxin product.
- Daxxify® should be administered no more frequently than every 3 months for any indication.

Efficacy: The efficacy of Daxxify® was evaluated in a randomized, double-blind, placebo-controlled, multicenter trial.

- Key Inclusion Criteria:
  - Clinical diagnosis of cervical dystonia
  - Baseline Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) total score ≥20, TWSTRS severity score ≥15, TWSTRS disability score ≥3, and TWSTRS pain score ≥1
  - For patients who previously received botulinum toxin treatment, ≥14 weeks have passed since the most recent botulinum toxin injection
- Intervention: 301 patients were randomized 3:3:1 to receive a single dose of 2.5mL of either Daxxify® 125 units, Daxxify® 250 units, or placebo divided amongst the affected muscles
- Primary Outcome: Mean change in the TWSTRS total score from baseline averaged over weeks 4 and 6
- Results: The mean change from baseline in the total TWSTRS score was significantly greater for both dosage groups of Daxxify® compared to placebo.
  - The least squares mean difference from placebo in the Daxxify® 125 units group was -8.4 [95% confidence interval (CI): -12.2, -4.6; P<0.0001].
  - The least squares mean difference from placebo in the Daxxify® 250 units group was -6.6 (95% CI: -10.4, -2.8; P<0.0007).

Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment	Cost Per Year
Daxxify® 100-unit vial	**$2.99**	**$897.00**	**$3,588.00***
Botox® 100-unit vial	$6.48	$1,944.00	$7,776.00⁺
Dysport® 500-unit vial	$1.81	$1,810.00	$7,240.00ᵅ
Myobloc® 10,000-unit vial	$0.13	$1,300.00	$5,200.00ᵝ
Xeomin® 50-unit vial	$5.33	$799.50	$3,198.00ᵘ

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS).

*Cost is based on the max FDA approved dose for cervical dystonia of 250 units every 3 months, assuming the use of (3) 100-unit vials. Daxxify® 50-unit vial is not yet available.

⁺Cost is based on the max FDA approved dose for cervical dystonia of 300 units every 3 months.

ᵅCost is based on the max FDA approved dose for cervical dystonia of 1,000 units every 3 months.

ᵝCost is based on the max FDA approved dose for cervical dystonia of 10,000 units every 3 months.

ᵘCost is based on the max FDA approved dose for cervical dystonia of 120 units every 3 months, assuming the use of 3 full vials.

Recommendations

The College of Pharmacy recommends the prior authorization of Daxxify® (daxibotulinumtoxinA-lanm) with criteria similar to other botulinum toxins and adding the diagnosis of sialorrhea to be consistent with the FDA approved label for botulinum toxins (changes shown in red):

Botulinum Toxins Approval Criteria:

1. For approval of Daxxify®, Myobloc®, or Xeomin®, a patient-specific, clinically significant reason the member cannot use Botox® or Dysport® must be provided; and
2. Cosmetic indications will not be covered; and
3. A diagnosis of chronic migraine (tension headaches are not a covered diagnosis), neurogenic detrusor overactivity, and non-neurogenic overactive bladder will require manual review (see specific criteria below); and
4. The following indications have been determined to be appropriate and are covered:
    a. Spasticity associated with:
        i. Cerebral palsy; or
        ii. Paralysis; or
        iii. Generalized weakness/incomplete paralysis; or
        iv. Larynx; or
        v. Anal fissure; or
        vi. Esophagus (achalasia and cardiospasms); or
        vii. Eye and eye movement disorders; or
    b. Cervical dystonia.
5. Myobloc® or Xeomin® will be covered for a diagnosis of chronic sialorrhea.

Additionally, the College of Pharmacy recommends updating the approval criteria for Botox® (onabotulinumtoxinA) for a diagnosis of chronic migraine to be consistent with the migraine preventive criteria for the calcitonin gene-related peptide (CGRP) inhibitors and current guidelines and based on net cost (changes shown in red):

Botox® (OnabotulinumtoxinA) Approval Criteria [Chronic Migraine Diagnosis*]:

1. FDA indications are met:
    a. Member is 18 years of age or older; and
    b. Member has documented chronic migraine headaches:
        i. Frequency of ≥15 headache days per month with ≥8 migraine days per month and occurring for >3 months; and
        ii. Headache duration of ≥4 hours per day; and

2. 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
~~3. Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes, but is not limited to:~~
    ~~a. Increased intracranial pressure (e.g., tumor, pseudotumor cerebri, central venous thrombosis); and~~
    ~~b. Decreased intracranial pressure (e.g., post-lumbar puncture headache, dural tear after trauma); and~~
~~4. Migraine headache exacerbation secondary to other medical conditions or medication therapies have been ruled out and/or treated. This includes, but is not limited to:~~
    ~~a. Hormone replacement therapy or hormone-based contraceptives; and~~
    ~~b. Chronic insomnia; and~~
    ~~c. Obstructive sleep apnea; and~~
5. Member has no contraindications to Botox® injections; and
6. The member has failed medical migraine preventative therapy, including ≥2 agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects) for oral medications and at least 3 months in duration for injectable medications (or documented adverse effects). ~~within the last 365 days~~. This includes, but is not limited to:
    a. Select antihypertensive therapy (e.g., beta blockers); or
    b. Select anticonvulsant therapy; or
    c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; ~~and~~ or
    d. Select calcitonin gene-related peptide (CGRP) inhibitors (e.g., Aimovig®, Ajovy®, Emgality®); and
~~7. Member is not frequently taking medications which are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:~~
    ~~a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and~~
    ~~b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and~~
    ~~c. Opioids (≥10 days/month for >3 months); and~~

~~d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and~~

~~e. Ergotamine-containing medications (≥10 days/month for >3 months); and~~

~~f. Triptans (≥10 days/month for >3 months); and~~

~~8. Member is not taking any medications that are likely to be the cause of the headaches; and~~

9. Member must have been evaluated within the last 6 months by a neurologist for chronic migraine headaches and Botox® recommended as treatment (not necessarily prescribed or administered by a neurologist); and

~~10. Prescriber must verify that other aggravating factors that are contributing to the development of chronic migraine headaches are being treated when applicable (e.g., smoking); and~~

11. Member will not use the requested medication concurrently with a calcitonin gene-related peptide (CGRP) inhibitor for the prevention of migraine headaches.

Finally, the College of Pharmacy recommends updating the approval criteria for Botox® (onabotulinumtoxinA) for the neurogenic detrusor overactivity (NDO) diagnosis to be consistent with current guidelines (changes shown in red):

Botox® (OnabotulinumtoxinA) Approval Criteria [Neurogenic Detrusor Overactivity (NDO) Diagnosis*]:

1. Diagnosis of 1 of the following:
   a. Urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury, multiple sclerosis] in adult members; or
   b. NDO in pediatric members; and
2. Underlying pathological dysfunction subtype confirmed by:
   a. Urodynamic studies to determine pathology and serve to provide objective evidence of bladder and external sphincter function; and
   ~~b. A diary of fluid intake, incontinence, voiding, and catheterization times and amounts to provide a record of actual occurrences; and~~
3. Member must have a clinically significant reason why anticholinergic medications are no longer an option for the member; and
4. Member must be 5 years of age or older and have adequate hand function and sufficient cognitive ability to know when the bladder needs emptying and to self-catheterize, or have a caregiver able to catheterize the member when necessary; and
5. Botox® must be administered by a urologist.

Utilization Details of Botulinum Toxins: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BOTOX INJ 200 UNIT	16	16	$20,470.56	$1,279.41	1	100%
TOTAL	**16**	**16***	**$20,470.56**	**$1,279.41**	**1**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BOTOX (J0585)	656	374	$892,951.95	$1,361.21	1.75
DYSPORT (J0586)	14	9	$13,550.18	$967.87	1.56
XEOMIN (J0588)	3	2	$1,558.00	$519.33	1.5
TOTAL	**674**	**386**	**$909,326.13**	**$1,349.15**	**1.75**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
+Total number of unduplicated claims.
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

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[1] Meglio, M. FDA Approves Expanded Indication of DaxibotulinumtoxinA to Treat Cervical Dystonia. Available online: https://www.neurologylive.com/view/fda-approves-expanded-indication-daxibotulinumtoxina-treat-cervical-dystonia. Issued 08/15/2023. Last accessed 04/17/2025.
[2] Charles A, Digre K, Goadsby P, et al. Calcitonin Gene-Related Peptide-Targeting Therapies are a First-Line Option for the Prevention of Migraine: An American Headache Society Position Statement Update. *Headache* 2024; 64:333–341. doi: 10.1111/head.14692.
[3] Ginsberg D, Boone T, Cameron A, et al. The AUA/SUFU Guideline on Adult Neurogenic Lower Urinary Tract Dysfunction: Diagnosis and Evaluation. *J Urol* 2021; 206: 1097. doi: 10.1097/JU.0000000000002235.
[4] Daxxify® (DaxibotulinumtoxinA-lanm) Prescribing Information. Revance Therapeutics. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761127s002lbl.pdf. Last revised 08/2023. Last accessed 04/16/2025.

Appendix M

Fiscal Year 2024 Annual Review of Anti-Diabetic Medications and Kerendia® (Finerenone) and 30-Day Notice to Prior Authorize Brynovin™ (Sitagliptin Oral Solution), Glimepiride 3mg Tablet, Merilog™ (Insulin Aspart-szjj), Metformin 750mg Tablet, and Zituvimet™ XR [Sitagliptin/Metformin Extended-Release (ER)]

Oklahoma Health Care Authority
May 2025

Current Prior Authorization Criteria

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

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

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	empagliflozin/ metformin (Synjardy®)		ertugliflozin/ metformin (Segluromet®)
	empagliflozin/ metformin ER (Synjardy® XR)		sotagliflozin (Inpefa®)*
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)			dapagliflozin/ saxagliptin/ metformin ER (Qternmet® XR)
Sulfonylureas			
glimepiride (Amaryl®)			glipizide 2.5mg immediate-release tablet*
glipizide (Glucotrol®)			
glipizide SR (Glucotrol XL®)			
glyburide (Diabeta®)			
glyburide micronized (Micronase®)			
Thiazolidinediones			
pioglitazone (Actos®)		pioglitazone/ glimepiride (Duetact®)	
		pioglitazone/ metformin (Actoplus Met®, Actoplus Met XR®)	
		rosiglitazone (Avandia®)	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria applies.
DPP-4 = dipeptidyl peptidase-4; ER = extended-release; GIP = glucose-dependent insulinotropic polypeptide; GLP-1 = glucagon-like peptide-1; PA = prior authorization; SGLT-2 = sodium-glucose cotransporter-2; soln = solution; SR = sustained-release;
susp = suspension

Anti-Diabetic Medications Tier-2 Approval Criteria:

1. A trial at least 3 months in duration (unless intolerable adverse effects) of metformin titrated up to maximum tolerated dose or a patient-specific, clinically significant reason why a 3-month trial of metformin titrated up to maximum tolerated dose is not appropriate must be provided.
2. For initiation with dual or triple therapy, additional Tier-2 medications may be approved based on current American Association of Clinical

Endocrinologists (AACE) or American Diabetes Association (ADA) guidelines.
3. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-1 medications. Tier structure rules for unique FDA approved indications will apply.

Anti-Diabetic Medications Tier-3 Approval Criteria:

1. Member must have a trial at least 3 months in duration and at recommended dosing (and member must be adherent to therapy) with 1 Tier-2 medication in the same category and have a documented clinical reason why the member cannot continue treatment with the Tier-2 medication.
    a. For members who did not complete a 3 month trial (i.e., due to intolerable adverse effects), the member must have a documented clinical reason why they cannot utilize a different Tier-2 medication in the same category, a Tier-2 medication in a different category, or provide detailed information regarding adverse effects occurring with the Tier-2 medication(s) that are not expected to occur with the requested Tier-3 medication that is in the same category.
    b. For Tier-3 medications that do not have a similar category in Tier-2, a medication from any category in Tier-2 may be used.
2. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-1 and Tier-2 medications. Tier structure rules for unique FDA approved indications will apply.

Anti-Diabetic Medications Special PA Approval Criteria:

1. Member must be currently stabilized on the requested product or have attempted at least 3 other categories of Tier-2 or Tier-3 medications, or have a documented clinical reason why the requested product is necessary for the member; and
2. Use of Adlyxin® (lixisenatide) or Mounjaro® (tirzepatide) will require a patient-specific, clinically significant reason (other than convenience) why the member cannot use all available lower-tiered glucagon-like peptide 1 receptor agonists (GLP-1 agonists); and
3. Use of generic dapagliflozin or dapagliflozin/metformin ER will require a patient-specific, clinically significant reason why they member cannot use brand name Farxiga® (dapagliflozin) or Xigduo® XR (dapagliflozin/metformin ER) and all available lower-tiered sodium-glucose cotransporter-2 (SGLT-2) inhibitors; and
4. Use of glipizide 2.5mg immediate-release tablet will require a patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products including splitting a glipizide 5mg tablet to achieve a 2.5mg dose; and

5. Use of Zituvio™ (sitagliptin) and Zituvimet™ (sitagliptin/metformin) will require a patient-specific, clinically significant reason why the member cannot use all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors).

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

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Humalog® (the brand formulation of Humalog® is preferred).

Afrezza® (Insulin Human Inhalation Powder) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus (DM); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why other rapid-acting injectable insulins are not appropriate must be provided; and
4. For the diagnosis of type 1 DM, the member must use Afrezza® with a long-acting insulin; and
5. Member must not smoke or have chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD).

Basaglar® (Insulin Glargine) Approval Criteria:

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

Fiasp® (Insulin Aspart) Approval Criteria:

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

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

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

Humulin® R U-500 Vials (Insulin Human 500 Units/mL) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use the Humulin® R U-500 KwikPen® (insulin human 500 units/mL), which is available without prior authorization, must be provided.

Inpefa® (Sotagliflozin) Approval Criteria:

1. An FDA approved indication to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure or type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use all other lower tiered SGLT-2 inhibitors that have a similar indication must be provided.

Insulin Degludec U-100 and U-200 (Unbranded Tresiba®) Approval Criteria:

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

Insulin Glargine U-300 (Unbranded Toujeo®) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use brand name Toujeo® (the brand formulation of Toujeo® is preferred); and
3. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or insulin glargine-yfgn (unbranded Semglee®) must be provided, and the member must be using a minimum of 100 units per day.

Kerendia® (Finerenone) Approval Criteria:

1. An FDA approved indication to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult members with chronic kidney disease (CKD) associated with type 2 diabetes mellitus (T2DM); and
2. Member must be receiving a maximum tolerated dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or have a contraindication to use; and
3. A patient specific, clinically significant reason why the member cannot use a sodium-glucose cotransporter-2 (SGLT-2) inhibitor must be provided; and
4. Member must not be receiving concomitant treatment with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir); and
5. Member must not have adrenal insufficiency; and

6. Member must not have severe hepatic impairment (Child Pugh C); and
7. Prescriber must measure serum potassium and eGFR prior to initiation of Kerendia®; and
8. Prescriber must verify serum potassium is not >5.0mEq/L prior to treatment initiation with Kerendia®; and
9. Prescriber must agree to monitor serum potassium levels 4 weeks after a dose adjustment and throughout treatment and adjust the dose accordingly per package labeling; and
10. Initial authorization will be for 4 weeks, after which time serum potassium levels will be required for continued approval; and
11. A quantity limit of 30 tablets per 30 days will apply. The member's eGFR should be provided for initiation of treatment to ensure the correct recommended dose per package labeling. The following initial dose will be approved based on eGFR:
    a. Kerendia® 10mg once daily in members with eGFR 25 to <60mL/min/1.73m^2; or
    b. Kerendia® 20mg once daily in members with eGFR ≥60mL/min/1.73m^2.

Lantidra™ (Donislecel-jujn) Approval criteria:

1. An FDA approved diagnosis of type 1 diabetes mellitus (T1DM); and
2. Member must be 18 years of age or older; and
3. Must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
4. Member must have had T1DM for ≥5 years and has been receiving intensive insulin management defined as:
    a. Self-monitoring of glucose values at least 3 times per day on average; and
    b. Using insulin pump therapy or at least 3 insulin injections per day; and
    c. Under the care of a diabetes specialist with at least 3 evaluations in the past 12 months; and
5. Member is exhibiting 1 of the following despite intensive insulin management efforts:
    a. Hypoglycemic unawareness; or
    b. Two or more episodes of severe hypoglycemia, defined as an event with symptoms consistent with hypoglycemia in which the patient requires the assistance of another person and which is associated with a blood glucose <54mg/dL; or
    c. Two or more hospital visits for diabetic ketoacidosis over the last year; or

    d. Progressive secondary complications of diabetes as defined by retinopathy, nephropathy, or neuropathy despite efforts at optimal glucose control; and
6. Member must receive concomitant immunosuppression. Lantidra™ is contraindicated in adults who have a contraindication to immunosuppression; and
7. Member is T- and B-cell crossmatch assay negative; and
8. Member must not have any of the following:
    a. Severe cardiac disease defined by 1 of the following:
        i. Recent, within the past 6 months, myocardial infarction; or
        ii. Angiographic evidence of non-correctable coronary artery disease; or
        iii. Evidence of ischemia on functional cardiac exam (with a stress echo test recommended for members with a history of ischemic disease); or
        iv. Heart failure > New York Heart Association (NYHA) II; or
        v. History of stroke within the past 6 months; and
    b. Active infections, including hepatitis C, hepatitis B, human immunodeficiency virus (HIV), or tuberculosis; and
    c. History of malignancy except squamous or basal skin cancer; and
    d. Concomitant disease or condition that contradicts the procedure or immunosuppression; and
    e. History of liver disease or renal failure and has not been the recipient of a renal transplant; and
    f. History of a prior portal vein thrombosis excluding thrombosis limited to second- or third-order portal vein branches; and
    g. C-peptide ≥0.3ng/ml following a 5g IV arginine infusion challenge; and
    h. Insulin requirements >0.7IU/kg/day; and
    i. Recent HbA1c >12%; and
9. Female members of reproductive potential must not be pregnant or breastfeeding and must agree to use effective contraception prior to initiation of immunosuppression and thereafter; and
10. Initial approvals will be for 12 months. Reauthorization may be granted if the prescriber documents the member has not achieved independence from exogenous insulin within 1 year of infusion or within 1 year after losing independence from exogenous insulin after a previous infusion; and
    a. Prescriber must verify the member is still receiving concomitant immunosuppression; and
11. Lantidra™ must be administered at a manufacturer approved transplant center; and
12. Approvals will be for a maximum of 3 infusions per member per lifetime.

Rezvoglar™ (Insulin Glargine-aglr) and Semglee® (Insulin Glargine-yfgn) Approval Criteria:

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

Ryzodeg® (Insulin Degludec/Insulin Aspart) Approval Criteria:

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

Soliqua® 100/33 (Insulin Glargine/Lixisenatide) Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or insulin glargine-yfgn (unbranded Semglee®) with an alternative glucagon-like peptide-1 (GLP-1) receptor agonist must be provided; and
3. Current Tier-3 criteria will apply.

Symlin® (Pramlintide) Approval Criteria:

1. An FDA approved diagnosis of type 1 or type 2 diabetes; and
2. Member must be using a basal-bolus insulin regimen; and
3. Member must have failed to achieve adequate glycemic control on basal-bolus insulin regimen or are gaining excessive weight on basal-bolus insulin regimen; and
4. Member must be receiving ongoing care under the guidance of a health care professional; and
5. Members meeting any of the following criteria should not be considered for Symlin® (pramlintide) therapy:
    a. Poor compliance with insulin regimen; or
    b. Poor compliance with self-blood glucose monitoring; or
    c. Hemoglobin A1C (HbA1c) >9%; or
    d. Recurrent severe hypoglycemia requiring assistance in the past 6 months; or
    e. Presence of hypoglycemia unawareness; or
    f. Diagnosis of gastroparesis; or
    g. Required use of medications that stimulate gastrointestinal motility; or

h. Pediatric members 15 years of age or younger.

Toujeo® (Insulin Glargine) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or insulin glargine-yfgn (unbranded Semglee®) must be provided, and the member must be using a minimum of 100 units of insulin glargine per day.

Tresiba® (Insulin Degludec) Approval Criteria:

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

Tzield® (Teplizumab-mzwv) Approval Criteria:

1. An FDA approved diagnosis of stage 2 Type 1 diabetes mellitus (DM). Diagnosis must be confirmed by the following:
    a. Laboratory testing confirming the presence of ≥2 pancreatic islet autoantibodies; and
        i. Documentation must be submitted with results of autoantibody testing; and
    b. Documented evidence of dysglycemia without overt hyperglycemia as demonstrated by an abnormal oral glucose tolerance test (OGTT) meeting 1 of the following:
        i. Fasting plasma glucose ≥100mg/dL and <126mg/dl; or
        ii. 2-hour plasma glucose ≥140 mg/dL and <200mg/dl; or
        iii. 30-, 60-, or 90-minute value on OGTT ≥200mg/dl; and
2. Member must be 8 years of age or older; and
3. Prescriber must confirm that member's clinical history does not suggest a diagnosis of Type 2 DM; and
4. Tzield® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
5. All of the following will be required for initiation of treatment:
    a. Verification that female members of reproductive potential are not pregnant and are currently using reliable contraception; and
    b. Verification that the member has no active infection(s); and
    c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
    d. Liver function tests and verification that levels are acceptable to the prescriber; and
    e. Verification that all age-appropriate vaccinations have been administered prior to treatment; and

f. Prescriber must agree to premedicate the member for the first 5 days of dosing and as needed with a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, an antihistamine, and/or an antiemetic; and

6. Tzield® must be administered by a health care professional. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Tzield® will be administered; and
   a. Tzield® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
   b. Tzield® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of Tzield®; and
7. The member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. A quantity limit of 28mL per 14 days will apply; and
9. Approvals will be for (1) 14-day cycle per member per lifetime.

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

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

Utilization of Anti-Diabetic Medications and Kerendia® (Finerenone): Fiscal Year 2024

Comparison of Fiscal Years: Non-Insulin Anti-Diabetic Medications and Kerendia® (Finerenone): Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	35,804	184,953	$82,889,646.09	$448.17	$8.60	13,727,342	9,640,446
2023 Total	**35,804**	**184,953**	**$82,889,646.09**	**$448.17**	**$8.60**	**13,727,342**	**9,640,446**
Fiscal Year 2024							
FFS	36,509	170,335	$90,922,822.37	$533.79	$10.49	11,535,237	8,671,177
Aetna	4,443	8,741	$4,944,080.59	$565.62	$11.08	590,326	446,337
Humana	5,785	13,782	$7,497,145.59	$543.98	$12.00	783,136	625,003
OCH	4,702	9,368	$4,897,783.52	$522.82	$11.47	548,159	427,060
2024 Total	**39,867**	**202,226**	**$108,261,832.07**	**$535.35**	**$10.65**	**13,456,857**	**10,169,577**
% Change	**11.30%**	**9.30%**	**30.60%**	**19.50%**	**23.80%**	**-2.00%**	**5.50%**
Change	**4,063**	**17,273**	**$25,372,185.98**	**$87.18**	**$2.05**	**-270,485**	**529,131**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

- Aggregate drug rebates collected during fiscal year 2024 for non-insulin anti-diabetic medications and Kerendia® totaled $99,088,073.75.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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

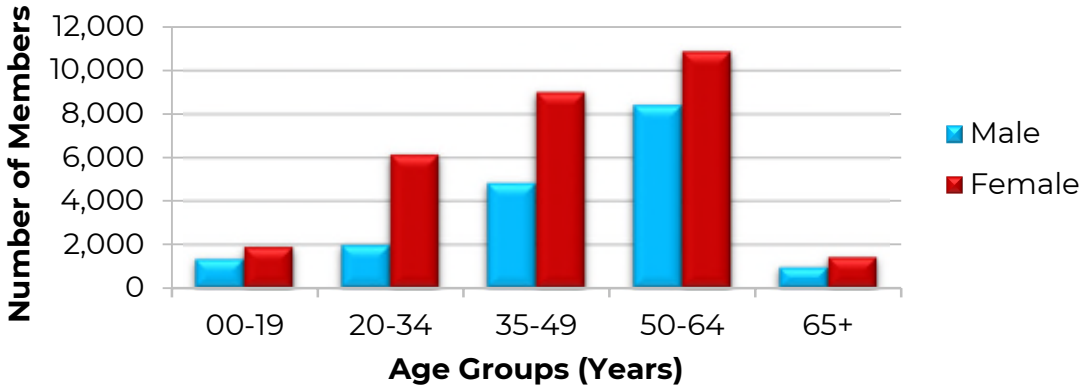
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	15,189	88,454	$52,631,963.95	$595.02	$13.48	1,981,580	3,903,213
2023 Total	**15,189**	**88,454**	**$52,631,963.95**	**$595.02**	**$13.48**	**1,981,580**	**3,903,213**
Fiscal Year 2024							
FFS	14,665	73,093	$31,745,811.57	$434.32	$9.80	1,608,147	3,238,874
Aetna	1,696	3,465	$807,936.47	$233.17	$5.33	79,342	151,451
Humana	1,973	4,262	$1,017,418.85	$238.72	$5.27	95,056	193,052
OCH	1,733	3,571	$838,980.03	$234.94	$5.59	77,907	150,134
2024 Total	**15,441**	**84,391**	**$34,410,146.92**	**$407.75**	**$9.22**	**1,860,452**	**3,733,511**
% Change	**1.70%**	**-4.60%**	**-34.60%**	**-31.50%**	**-31.60%**	**-6.10%**	**-4.30%**
Change	**252**	**-4,063**	**-$18,221,817.03**	**-$187.27**	**-$4.26**	**-121,128**	**-169,702**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

- Aggregate drug rebates collected during fiscal year 2024 for insulin medications totaled $34,329,873.86.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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

Demographics of Members Utilizing Anti-Diabetic Medications and Kerendia® (Finerenone): Pharmacy Claims (All Plans)

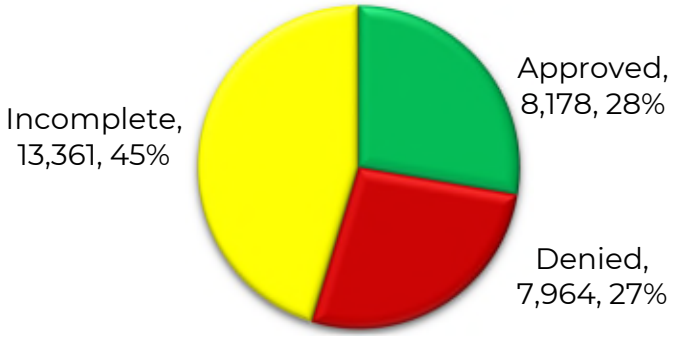


Top Prescriber Specialties of Anti-Diabetic Medications and Kerendia® (Finerenone) by Number of Claims: Pharmacy Claims (All Plans)

Prior Authorization of Anti-Diabetic Medications and Kerendia® (Finerenone)

There were 29,503 prior authorization requests submitted for anti-diabetic medications and Kerendia® during fiscal year 2024. Of the 29,503 total prior authorization requests submitted, 25,048 were for non-insulin anti-diabetic medications and Kerendia® and 4,455 were for insulin products. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	7,205	26%	13,157	48%	6,855	25%	**27,217**
Aetna	494	35%	204	15%	703	50%	**1,401**
Humana	142	43%	0	0%	190	57%	**332**
OCH	337	61%	0	0%	216	39%	**553**
Total	**8,178**	**28%**	**13,361**	**45%**	**7,964**	**27%**	**29,503**

FFS = fee-for-service; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans

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]

Anticipated Patent Expiration(s):

- Kombiglyze® XR [saxagliptin/metformin extended-release (ER) tablet]: July 2025
- Januvia® (sitagliptin tablet): May 2027
- Janumet® XR (sitagliptin/metformin ER tablet): May 2027
- Onglyza® (saxagliptin tablet): November 2028
- Janumet® (sitagliptin/metformin tablet): January 2029
- Actoplus Met® (pioglitazone/metformin tablet): February 2029
- Invokana® (canagliflozin tablet): August 2029
- Invokamet® XR (canagliflozin/metformin ER tablet): August 2029
- Qtern® (dapagliflozin/saxagliptin tablet): December 2029
- Invokamet® (canagliflozin/metformin tablet): July 2030
- Steglatro® (ertugliflozin tablet): July 2030
- Inpefa® (sotagliflozin tablet): October 2030
- Segluromet® (ertugliflozin/metformin tablet): October 2030
- Steglujan® (ertugliflozin/sitagliptin tablet): October 2030
- Farxiga® (dapagliflozin tablet): November 2030
- Jentadueto® (linagliptin/metformin tablet): December 2030
- Bydureon BCise® (exenatide ER autoinjector): April 2031
- Xigduo® XR (dapagliflozin/metformin ER tablet): May 2031
- Tradjenta® (linagliptin tablet): September 2031

- Cycloset® (bromocriptine tablet): April 2032
- Brenzavvy® (bexagliflozin tablet): May 2032
- Ozempic® (semaglutide injection): June 2033
- Jentadueto® XR (linagliptin/metformin ER tablet): September 2033
- Glyxambi® (empagliflozin/linagliptin tablet): October 2034
- Synjardy® (empagliflozin/metformin tablet): November 2034
- Jardiance® (empagliflozin tablet): December 2034
- Synjardy® XR (empagliflozin/metformin ER tablet): December 2034
- Trijardy® XR (empagliflozin/linagliptin/metformin ER tablet): December 2034
- Zituvio™ (sitagliptin tablet): February 2035
- Riomet ER™ (metformin ER oral suspension): May 2035
- Kerendia® (finerenone tablet): July 2035
- Victoza® (liraglutide injection): July 2037
- Rybelsus® (semaglutide tablet): February 2039
- Mounjaro® (tirzepatide injection): June 2039
- Brynovin™ (sitagliptin oral solution): October 2040

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

- **June 2024:** The FDA approved Farxiga® (dapagliflozin) for an age expansion for the treatment of type 2 diabetes mellitus (T2DM) in patients 10 years of age or older. Farxiga® was previously only approved for use in adults.
- **July 2024:** Zydus Lifesciences received FDA approval for a New Drug Application (NDA) for Zituvimet™ XR (sitagliptin/metformin). Zituvimet™ XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM. This combination is also available under the brand name Janumet® XR for the same indication.
- **November 2024:** The FDA approved exenatide injection, which is a generic formulation of Byetta®, indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM. This is the first approval of a generic glucagon-like peptide-1 (GLP-1) receptor agonist.
- **December 2024:** The FDA approved liraglutide injection, which is a generic formulation of Victoza®. Liraglutide is indicated to improve glycemic control in adults and pediatric patients 10 years of age and older with T2DM as an adjunct to diet and exercise.
- **December 2024:** Rybelsus® (semaglutide) was approved for a supplemental New Drug Application (sNDA) to expand the label to include a new dosage formulation called R2. Rybelsus® now has 2 formulations with different strengths, R1 including 3mg, 7mg, and 14mg tablets and R2 including 1.5mg, 4mg, and 9mg tablets. A bioequivalence study was conducted that showed the R2 formulation

was bioequivalent to the R1 formulation with no new safety concerns identified. The prescribing information now states that either formulation can be used but they cannot be used at the same time and are not substitutable on a mg per mg basis. Additionally, there are recommendations for switching between formulation R1 and R2 which can be achieved after the initiation phase.

- **January 2025:** The FDA approved Brynovin™ (sitagliptin oral solution) as an adjunct to diet and exercise to improve glycemic control in adults with T2DM. Sitagliptin is also available as an oral tablet formulation. The Wholesale Acquisition Cost (WAC) for Brynovin™ is not available at this time.
- **January 2025:** Ozempic® (semaglutide) was approved for a new indication to reduce the risk of kidney disease worsening, kidney failure, and death due to cardiovascular disease (CVD) in adults with T2DM and chronic kidney disease (CKD). This approval was based on the results of the FLOW trial which achieved its primary endpoint of a 24% relative risk reduction of kidney disease worsening, kidney failure, and death due to CVD compared to placebo, when added to standard of care therapy. Currently Ozempic® is the only GLP-1 receptor agonist with this indication.
- **February 2025:** The FDA approved Merilog™ (insulin aspart-szjj) for the improvement of glycemic control in adults and pediatric patients with diabetes mellitus. Merilog™ is a rapid-acting insulin that is a biosimilar to Novolog® (insulin aspart) and is the first rapid-acting insulin biosimilar to gain FDA approval. Merilog™ will be available in a 3mL prefilled pen and 10mL vial. The WAC for Merilog™ is not available at this time.

News:

- **January 2023:** Sanofi announced that Adlyxin® will no longer be available in the United States. The discontinuation was stated to be due to business decisions and was not due to safety or efficacy issues.
- **August 2024:** A new formulation of glimepiride, available as a 3mg tablet, is being marketed by LifSa Pharma. Glimepiride is also available as 1mg, 2mg, and 4mg tablets.
- **October 2024:** As of October 28, 2024, Bydureon Bcise® (exenatide ER autoinjector) and Byetta® (exenatide) have been discontinued by AstraZeneca. A generic version of Byetta® was recently approved in November 2024.
- **January 2025:** A new formulation of metformin, available as a 750mg immediate-release tablet, is being marketed by LifSa Pharma. Metformin was previously only available as 500mg, 625mg, 850mg, and 1,000mg tablets in the immediate-release formulation.

- **April 2025:** As of April 2025, the FDA Orange Book lists Qternmet® XR (dapagliflozin/saxagliptin/metformin) as a discontinued product. Additionally, there are no generic equivalents for this product.

Guideline Update(s):

- **American Diabetes Association (ADA) Guideline Update(s):** The ADA released the *Standards of Medical Care in Diabetes 2025*, to include new and updated practice guidelines to care for patients with diabetes and prediabetes. Some notable updates and additions include:
  - Recommendations were added to emphasize the use of antibody-based screening for presymptomatic type 1 diabetes mellitus (T1DM) in those who have a family history or known genetic risk.
  - Recommendations were added to emphasize the importance of selecting glucose-lowering medications that provide sufficient effectiveness and achieve and maintain multiple treatment goals simultaneously, including improving cardiovascular, kidney, weight, and other relevant outcomes, reducing hypoglycemia risk, and considering cost, access, risk for adverse reactions, and individual preferences.
  - Recommendations were revised to explicitly advise on choice of pharmacotherapy for individuals with T2DM and established or high risk of atherosclerotic cardiovascular disease (ASCVD), heart failure (HF), and CKD to improve health outcomes for individuals with these conditions irrespective of hemoglobin A1c.
  - Recommendations were added on the use of GLP-1 receptor agonists with demonstrated benefits in individuals with T2DM, symptomatic HF with preserved ejection fraction, and obesity, and recommendations were added on the use of either a GLP-1 receptor agonist or sodium-glucose cotransporter-2 (SGLT-2) inhibitor with demonstrated benefits in individuals with T2DM and CKD.
  - Consideration should be given for the use of a continuous glucose monitor (CGM) for adults with T2DM on glucose-lowering agents other than insulin.

Pipeline:

- **Orforglipron:** Orforglipron is an investigational, once-daily, non-peptide, oral GLP-1 receptor agonist being studied for the treatment of adults with T2DM and inadequate glycemic control with diet and exercise alone. Results from the ACHIEVE-1 trial showed that orforglipron at doses of 3mg, 12mg, and 36mg met the primary endpoint of A1c reduction from baseline to 40 weeks when compared to placebo. Orforglipron showed statistically significant reductions in A1c of 1.2% for the 3mg and 1.5% for those on 12mg or 36mg versus 0.4%

for those on placebo. Additionally, the overall safety profile of orforglipron was consistent with the GLP-1 receptor agonist class. Eli Lilly stated they are anticipating regulatory submission for the treatment of T2DM in 2026.

- **Semaglutide:** Ozempic® (semaglutide injection) is being studied in the Phase 3b STRIDE trial for the treatment of adults with T2DM and early-stage symptomatic peripheral artery disease (PAD). Results from STRIDE were presented and showed that Ozempic® met its primary endpoint demonstrating a 13% improvement in maximum walking distance [estimated treatment ratio (ETR) vs placebo: 1.13; 95% confidence interval (CI): 1.06, 1.21; P=0.0004] and a clinically meaningful median treatment difference of 26.4 meters (95% CI: 11.8, 40.9) on a 12% incline, compared to placebo at 52 weeks. Additionally, Rybelsus® (semaglutide tablet) is being studied in the Phase 3 SOUL trial for reducing the risk of major adverse cardiovascular events (MACE) in adults with T2DM and ASCVD and/or CKD. Rybelsus® achieved its primary endpoint, with oral semaglutide 14mg demonstrating a 14% reduction in risk of MACE (2% absolute risk reduction at 3 years) compared to placebo (hazard ratio: 0.86; 95% CI: 0.77; 0.96; P=0.0055). The primary endpoint was time from randomization to first occurrence of a major adverse CV event (a composite of CV death, nonfatal myocardial infarction, or nonfatal stroke). An sNDA has been submitted to the FDA for both of these indications with a decision anticipated in 2025.
- **Zimislecel:** Zimislecel is an investigational allogeneic stem cell-derived, insulin-producing islet cell therapy being studied for the treatment of T1DM with impaired hypoglycemic awareness and severe hypoglycemia. Zimislecel is in the Phase 3 portion of the Phase 1/2/3 trial and is currently enrolling patients with enrollment expected to be completed in 2025. Pending the results from the Phase 3 trial, Vertex is anticipating submitting regulatory filings in 2026. Zimislecel was previously granted Regenerative Medicine Advanced Therapy (RMAT) and Fast Track designations from the FDA.

Cost Comparison: Biguanides

Product	Cost Per Tablet	Cost Per Month*	Cost Per Year
metformin 750mg (generic)	**$33.36**	**$2,001.60**	**$24,019.20**
metformin 625mg (generic)	$32.68+	$1,960.80	$23,529.60
metformin 1,000mg (generic)	$0.02	$1.20	$14.40
metformin 500mg (generic)	$0.01	$0.60	$7.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
+Cost per tablet varies per NDC
*Cost per month is based on twice daily dosing for each product

Cost Comparison: DPP-4 Inhibitor and Biguanide Combination Products

Product	Cost Per Tablet	Cost Per Month	Cost Per Year
Zituvimet™ XR (sitaglip/met) 50/1,000mg	**$5.26**	**$315.60***	**$3,787.20**
Jentadueto® XR (linaglip/met) 2.5/1,000mg	$8.44	$506.40⁺	$6,076.80
Jentadueto® (linaglip/met) 2.5/1,000mg	$8.42	$505.20⁺	$6,062.40
Janumet XR® (sitaglip/met) 50/1,000mg	$5.29	$317.40*	$3,808.80
Janumet® (sitaglip/met) 50/1,000mg	$5.28	$316.80*	$3,801.60
Zituvimet™ (sitaglip/met) 50/1,000mg	$5.26	$315.60*	$3,787.20
sitagliptin/metformin 50/1,000mg (generic)	$2.67	$160.20*	$1,922.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
DPP-4 = dipeptidyl peptidase-4; linaglip = linagliptin; met = metformin; sitaglip = sitagliptin
*Cost per month based on the maximum FDA approved dosing of 100mg of sitagliptin and 2,000mg of metformin per day.
⁺Cost per month based on the maximum FDA approved dosing of 5mg of linagliptin and 2,000mg of metformin per day.

Cost Comparison: GIP/GLP-1 Agonists

Product	Cost Per Unit	Cost Per Month	Cost Per Year
exenatide 10mcg/0.04mL inj (generic)	**$322.98**	**$775.15***	**$9,301.82**
liraglutide 18mg/3mL inj (generic)	**$67.74**	**$609.66⁺**	**$7,315.92**
Victoza® (liraglutide) 18mg/3mL inj	$87.48	$787.32⁺	$9,447.84
Trulicity® (dulaglutide) 4.5mg/0.5mL inj	$476.34	$952.68ᵅ	$12,384.84
Ozempic® (semaglutide) 8mg/3mL inj	$321.14	$963.42ᵝ	$12,524.46
Rybelsus® (semaglutide) 14mg tablet	$32.09	$962.70¥	$11,552.40
Mounjaro® (tirzepatide) 15mg/0.5mL inj	$520.73	$1,041.46€	$13,538.98

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).
GIP = glucose-dependent insulinotropic polypeptide; GLP-1 = glucagon-like peptide-1; inj = injection; Unit = mL or tablet
*Cost per month based on the maximum FDA approved dosing of 10mcg twice daily
⁺Cost per month based on the maximum FDA approved dosing of 1.8mg once daily
ᵅCost per month based on the maximum FDA approved dosing of 4.5mg once weekly
ᵝCost per month based on the maximum FDA approved dosing of 2mg once weekly
¥Cost per month based on the maximum FDA approved dosing of 14mg once daily
€Cost per month based on the maximum FDA approved dosing of 15mg once weekly

Cost Comparison: Sulfonylureas

Product	Cost Per Tablet	Cost Per Month*	Cost Per Year
glimepiride 3mg (generic)	**$16.89**	**$506.70**	**$6,080.40**
glimepiride 4mg (generic)	$0.03	$0.90	$10.80
glimepiride 2mg (generic)	$0.03	$0.90	$10.80
glimepiride 1mg (generic)	$0.02	$0.60	$7.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month based on a dose of 1 tablet once daily for each product

Recommendations

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

1. Prior authorization of Brynovin™ (sitagliptin oral solution), glimepiride 3mg tablet, and Zituvimet™ XR (sitagliptin/metformin) and placement into the Special PA Tier with the following additional criteria; and
2. Prior authorization of metformin 750mg tablet and placement into the Special PA Tier; and
3. Moving Byetta® (exenatide) and generic liraglutide to the Special PA Tier with the following additional criteria based on net costs and the discontinuation of brand name Byetta®; and
4. Making Victoza® (liraglutide) brand preferred based on net costs; and
5. Moving Invokana® (canagliflozin), Invokamet® (canagliflozin/metformin), and Invokamet® XR (canagliflozin/metformin ER) to Tier-3 based on net costs; and
6. Removing Adlyxin® (lixisenatide) and Qternmet® XR (dapagliflozin/saxagliptin/metformin ER) based on product discontinuations.

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

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	sitagliptin (Januvia®)		sitagliptin/metformin (Zituvimet™)*
	sitagliptin/ metformin (Janumet®)		**sitagliptin/metformin ER (Zituvimet™ XR)***
	sitagliptin/ metformin ER (Janumet XR®)		**sitagliptin oral solution (Brynovin™)***
DPP-4 Inhibitors/SGLT-2 Inhibitors			
empagliflozin/ linagliptin (Glyxambi®)			dapagliflozin/ saxagliptin (Qtern®)
			ertugliflozin/ sitagliptin (Steglujan®)
Dopamine Agonists			
		bromocriptine (Cycloset®)	
Glinides			
repaglinide (Prandin®)	nateglinide (Starlix®)		
	repaglinide/ metformin (Prandimet®)		
GIP/GLP-1 Agonists			
	dulaglutide (Trulicity®)	exenatide ER autoinjector (Bydureon BCise®)	**exenatide (Byetta®)***
	~~**exenatide (Byetta®)**~~	semaglutide (Ozempic®)	**liraglutide (generic)***
	liraglutide (Victoza®) **– Brand Preferred**	semaglutide (Rybelsus®)	~~**lixisenatide (Adlyxin®)***~~
			tirzepatide (Mounjaro®)*
GLP-1 Agonists/Insulin			
		insulin degludec/ liraglutide (Xultophy® 100/3.6)*	
		insulin glargine/ lixisenatide (Soliqua® 100/33)*	
SGLT-2 Inhibitors			
dapagliflozin (Farxiga®) **– Brand Preferred**	~~**canagliflozin (Invokana®)**~~	**canagliflozin (Invokana®)**	bexagliflozin (Brenzavvy®)
empagliflozin (Jardiance®)	~~**canagliflozin/ metformin (Invokamet®)**~~	**canagliflozin/ metformin (Invokamet®)**	dapagliflozin (generic)*

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	~~**canagliflozin/ metformin ER (Invokamet® XR)**~~	**canagliflozin/ metformin ER (Invokamet® XR)**	dapagliflozin/ metformin ER (generic)*
	dapagliflozin/ metformin ER (Xigduo® XR) – **Brand Preferred**		ertugliflozin (Steglatro®)
	empagliflozin/ metformin (Synjardy®)		ertugliflozin/ metformin (Segluromet®)
	empagliflozin/ metformin ER (Synjardy® XR)		sotagliflozin (Inpefa®)*
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)			~~**dapagliflozin/ saxagliptin/ metformin ER (Qternmet® XR)**~~
Sulfonylureas			
glimepiride (Amaryl®)			**glimepiride 3mg tablet***
glipizide (Glucotrol®)			glipizide 2.5mg immediate-release tablet*
glipizide SR (Glucotrol XL®)			
glyburide (Diabeta®)			
glyburide micronized (Micronase®)			
Thiazolidinediones			
pioglitazone (Actos®)		pioglitazone/ glimepiride (Duetact®)	
		pioglitazone/ metformin (Actoplus Met®, Actoplus Met XR®)	
		rosiglitazone (Avandia®)	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria applies.
DPP-4 = dipeptidyl peptidase-4; ER = extended-release; GIP = gastric inhibitory polypeptide; GLP-1 = glucagon-like peptide-1; PA = prior authorization; SGLT-2 = sodium-glucose cotransporter-2; soln = solution; SR = sustained-release;
susp = suspension

Anti-Diabetic Medications Special PA Approval Criteria:

1. Member must be currently stabilized on the requested product or have attempted at least 3 other categories of Tier-2 or Tier-3 medications, or have a documented clinical reason why the requested product is necessary for the member; and
2. Use of Brynovin™ (sitagliptin oral solution) will require a patient-specific, clinically significant reason why a special formulation is needed and why the member cannot use all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors); and
3. Use of Byetta® (exenatide) ~~Adlyxin® (lixisenatide)~~ or Mounjaro® (tirzepatide) will require a patient-specific, clinically significant reason (other than convenience) why the member cannot use all available lower-tiered glucagon-like peptide 1 receptor agonists (GLP-1 agonists); and
4. Use of generic dapagliflozin or dapagliflozin/metformin ER will require a patient-specific, clinically significant reason why they member cannot use brand name Farxiga® (dapagliflozin) or Xigduo® XR (dapagliflozin/metformin ER) and all available lower-tiered sodium-glucose cotransporter-2 (SGLT-2) inhibitors; and
5. Use of generic liraglutide will require a patient-specific, clinically significant reason why the member cannot use brand name Victoza® (liraglutide); and
6. Use of glimepiride 3mg tablet will require a patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including using the lower strengths of glimepiride to achieve the 3mg dose; and
7. Use of glipizide 2.5mg immediate-release tablet will require a patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products including splitting a glipizide 5mg tablet to achieve a 2.5mg dose; and
8. Use of Zituvio™ (sitagliptin), ~~and~~ Zituvimet™ (sitagliptin/metformin), and Zituvimet™ XR (sitagliptin/metformin ER) will require a patient-specific, clinically significant reason why the member cannot use all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors).

Next, the College of Pharmacy recommends the prior authorization of Merilog™ (insulin aspart-szjj) with the following criteria (shown in red):

Merilog™ (Insulin Aspart-szjj) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Novolog® (insulin aspart) or Fiasp® (insulin aspart) must be provided. Biosimilars and/or reference products are preferred based on

the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Additionally, the College of Pharmacy recommends removing the brand preferred status from Humalog® and removing the prior authorization from Fiasp® (insulin aspart) based on net costs (changes shown in red):

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

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use insulin lispro U-100 (unbranded Humalog® U-100) ~~Humalog® (the brand formulation of Humalog® is preferred).~~

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

1. An FDA approved diagnosis of diabetes mellitus; and
2. Authorization of the 200 units/mL strength requires a patient-specific, clinically significant reason why the member cannot use the 100 units/mL strength ~~(the brand formulation of Humalog® U-100 is preferred)~~.

~~**Fiasp® (Insulin Aspart) Approval Criteria:**~~

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

Finally, the College of Pharmacy recommends updating the Tzield® (teplizumab-mzwv) approval criteria to be consistent with the ADA guidelines and clinical practice (change shown in red):

Tzield® (Teplizumab-mzwv) Approval Criteria:

1. An FDA approved diagnosis of stage 2 Type 1 diabetes mellitus (DM). Diagnosis must be confirmed by the following:
    a. Laboratory testing confirming the presence of ≥2 pancreatic islet autoantibodies; and
        i. Documentation must be submitted with results of autoantibody testing; and
    b. Documented evidence of dysglycemia without overt hyperglycemia as demonstrated by ~~an abnormal oral glucose tolerance test (OGTT) meeting~~ 1 of the following (results of lab testing must be submitted):
        i. Fasting plasma glucose ≥100mg/dL and <126mg/dl; or
        ii. 2-hour plasma glucose ≥140 mg/dL and <200mg/dl; or

iii. Hemoglobin A1c ≥5.7% and <6.5% or ≥10% increase in A1c; or
iv. 30-, 60-, or 90-minute value ~~on OGTT~~ ≥200mg/dl on 2 separate occasions; and

2. Member must be 8 years of age or older; and
3. Prescriber must confirm that member's clinical history does not suggest a diagnosis of Type 2 DM; and
4. Tzield® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
5. All of the following will be required for initiation of treatment:
   a. Verification that female members of reproductive potential are not pregnant and are currently using reliable contraception; and
   b. Verification that the member has no active infection(s); and
   c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
   d. Liver function tests and verification that levels are acceptable to the prescriber; and
   e. Verification that all age-appropriate vaccinations have been administered prior to treatment; and
   f. Prescriber must agree to premedicate the member for the first 5 days of dosing and as needed with a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, an antihistamine, and/or an antiemetic; and
6. Tzield® must be administered by a health care professional. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Tzield® will be administered; and
   a. Tzield® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
   b. Tzield® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of Tzield®; and
7. The member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. A quantity limit of 28mL per 14 days will apply; and
9. Approvals will be for (1) 14-day cycle per member per lifetime.

Utilization Details of Anti-Diabetic Medications and Kerendia® (Finerenone): Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BIGUANIDE PRODUCTS						
TIER-1 PRODUCTS						
METFORMIN TAB 500MG	31,791	12,584	$315,840.41	$9.93	2.53	0.29%
METFORMIN TAB 1,000MG	21,036	7,899	$227,231.98	$10.80	2.66	0.21%
METFORMIN TAB 500MG ER	17,072	7,375	$190,621.58	$11.17	2.31	0.18%
METFORMIN TAB 750MG ER	1,723	757	$21,231.94	$12.32	2.28	0.02%
METFORMIN TAB 850MG	1,294	546	$13,088.85	$10.12	2.37	0.01%
TIER-1 SUBTOTAL	**72,916**	**29,161**	**$768,014.76**	**$10.53**	**2.5**	**0.71%**
SPECIAL PA PRODUCTS						
METFORMIN SOL 500MG/5ML	72	15	$20,359.19	$282.77	4.8	0.02%
METFORMN OSM TAB 1,000 ER	45	29	$1,220.69	$27.13	1.55	0.00%
METFORMN OSM TAB 500MG ER	17	14	$408.17	$24.01	1.21	0.00%
METFORMN MOD TAB 1,000 ER	15	12	$505.07	$33.67	1.25	0.00%
METFORMN MOD TAB 500MG ER	7	4	$390.37	$55.77	1.75	0.00%
METFORMIN TAB 625MG	1	1	$1,972.43	$1,972.43	1	0.00%
GLUMETZA TAB 1,000MG	1	1	$3,220.89	$3,220.89	1	0.00%
SPECIAL PA SUBTOTAL	**158**	**76**	**$28,076.81**	**$177.70**	**2.08**	**0.03%**
BIGUANIDE TOTAL	**73,074**	**29,237**	**$796,091.57**	**$10.89**	**2.5**	**0.74%**
GLP-1/GIP AGONIST PRODUCTS						
TIER-2 PRODUCTS						
TRULICITY INJ 0.75MG/0.5ML	14,705	5,246	$15,746,246.91	$1,070.81	2.8	14.54%
TRULICITY INJ 1.5MG/0.5ML	11,701	4,269	$12,811,221.01	$1,094.88	2.74	11.83%
TRULICITY INJ 3MG/0.5ML	9,177	2,991	$10,493,955.37	$1,143.51	3.07	9.69%
TRULICITY INJ 4.5MG/0.5ML	5,653	1,538	$6,804,831.60	$1,203.76	3.68	6.29%
VICTOZA INJ 18MG/3ML	4,570	1,581	$4,252,460.74	$930.52	2.89	3.93%
BYETTA INJ 5MCG/0.02ML	56	37	$53,003.20	$946.49	1.51	0.05%
BYETTA INJ 10MCG/0.04ML	33	16	$33,435.58	$1,013.20	2.06	0.03%
TIER-2 SUBTOTAL	**45,895**	**15,678**	**$50,195,154.41**	**$1,093.70**	**2.93**	**46.36%**
TIER-3 PRODUCTS						
OZEMPIC INJ 8MG/3ML	4,084	931	$3,759,656.85	$920.58	4.39	3.47%
OZEMPIC INJ 2MG/3ML	4,037	1,903	$3,731,473.37	$924.32	2.12	3.45%
OZEMPIC INJ 4MG/3ML	3,937	1,369	$3,624,443.61	$920.61	2.88	3.35%
RYBELSUS TAB 7MG	245	111	$222,558.24	$908.40	2.21	0.21%
RYBELSUS TAB 14MG	187	51	$162,301.19	$867.92	3.67	0.15%
RYBELSUS TAB 3MG	159	97	$148,769.60	$935.66	1.64	0.14%
BYDUREON BC INJ 2MG/0.85ML	56	24	$46,065.83	$822.60	2.33	0.04%
OZEMPIC INJ 2MG/1.5ML	3	2	$2,724.16	$908.05	1.5	0.00%
TIER-3 SUBTOTAL	**12,708**	**4,488**	**$11,697,992.85**	**$920.52**	**2.83**	**10.81%**
SPECIAL PA PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MOUNJARO INJ 7.5MG/0.5ML	1,162	394	$1,154,722.02	$993.74	2.95	1.07%
MOUNJARO INJ 5MG/0.5ML	1,126	518	$1,129,003.02	$1,002.67	2.17	1.04%
MOUNJARO INJ 2.5MG/0.5ML	979	564	$1,006,455.17	$1,028.04	1.74	0.93%
MOUNJARO INJ 10MG/0.5ML	942	318	$938,719.29	$996.52	2.96	0.87%
MOUNJARO INJ 12.5MG/0.5ML	894	273	$897,040.69	$1,003.40	3.27	0.83%
MOUNJARO INJ 15MG/0.5ML	738	157	$740,700.97	$1,003.66	4.7	0.68%
LIRAGLUTIDE INJ 18MG/3ML	4	4	$3,567.64	$891.91	1	0.00%
SPECIAL PA SUBTOTAL	**5,845**	**2,228**	**$5,870,208.80**	**$1,004.31**	**2.62**	**5.42%**
GLP1/GIP AGONIST TOTAL	**64,448**	**22,394**	**$67,763,356.06**	**$1,051.44**	**2.88**	**62.59%**
SGLT-2 INHIBITOR PRODUCTS						
TIER-1 PRODUCTS						
JARDIANCE TAB 25MG	9,828	3,284	$10,654,631.09	$1,084.11	2.99	9.84%
JARDIANCE TAB 10MG	9,481	3,566	$9,125,023.33	$962.45	2.66	8.43%
FARXIGA TAB 10MG	6,136	2,326	$6,033,310.11	$983.26	2.64	5.57%
FARXIGA TAB 5MG	1,437	598	$1,262,841.63	$878.80	2.4	1.17%
TIER-1 SUBTOTAL	**26,882**	**9,774**	**$27,075,806.16**	**$1,007.21**	**2.75**	**25.01%**
TIER-2 PRODUCTS						
INVOKANA TAB 300MG	152	49	$181,262.00	$1,192.51	3.1	0.17%
INVOKANA TAB 100MG	108	32	$116,568.34	$1,079.34	3.38	0.11%
TIER-2 SUBTOTAL	**260**	**81**	**$297,830.34**	**$1,145.50**	**3.21**	**0.28%**
SPECIAL PA PRODUCTS						
DAPAGLIFLOZIN TAB 5MG	414	250	$242,353.88	$585.40	1.66	0.22%
DAPAGLIFLOZIN TAB 10MG	2,348	1,286	$1,389,351.20	$591.72	1.83	1.28%
STEGLATRO TAB 15MG	29	10	$10,004.07	$344.97	2.9	0.01%
STEGLATRO TAB 5MG	17	2	$5,891.54	$346.56	8.5	0.01%
SPECIAL PA SUBTOTAL	**2,808**	**1,548**	**$1,647,600.69**	**$586.75**	**1.81**	**1.52%**
SGLT-2 INHIBITOR TOTAL	**29,950**	**11,403**	**$29,021,237.19**	**$968.99**	**2.63**	**26.81%**
SULFONYLUREA PRODUCTS						
TIER-1 PRODUCTS						
GLIPIZIDE TAB 10MG	4,018	1,506	$48,638.77	$12.11	2.67	0.04%
GLIPIZIDE TAB 5MG	3,496	1,476	$36,590.73	$10.47	2.37	0.03%
GLIPIZIDE ER TAB 10MG	1,861	771	$42,591.01	$22.89	2.41	0.04%
GLYBURIDE TAB 5MG	1,839	674	$29,301.80	$15.93	2.73	0.03%
GLIMEPIRIDE TAB 4MG	1,729	626	$20,587.79	$11.91	2.76	0.02%
GLIPIZIDE ER TAB 5MG	1,368	643	$21,725.19	$15.88	2.13	0.02%
GLIMEPIRIDE TAB 2MG	1,316	499	$14,258.27	$10.83	2.64	0.01%
GLIMEPIRIDE TAB 1MG	526	230	$4,908.43	$9.33	2.29	0.00%
GLIPIZIDE ER TAB 2.5MG	525	238	$8,917.44	$16.99	2.21	0.01%
GLYBURIDE TAB 2.5MG	365	159	$5,429.59	$14.88	2.3	0.01%
GLYBURIDE TAB 1.25MG	78	29	$1,084.01	$13.90	2.69	0.00%
GLYBURIDE MCR TAB 3MG	23	8	$439.62	$19.11	2.88	0.00%
GLIPIZIDE XL TAB 10MG	21	18	$531.59	$25.31	1.17	0.00%
GLIPIZIDE TAB 2.5MG	14	10	$668.54	$47.75	1.4	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GLYBURIDE MCR TAB 6MG	9	4	$333.30	$37.03	2.25	0.00%
GLYBURIDE MCR TAB 1.5MG	6	4	$147.71	$24.62	1.5	0.00%
GLIPIZIDE XL TAB 2.5MG	1	1	$33.77	$33.77	1	0.00%
SULFONYLUREA TOTAL	**17,195**	**6,896**	**$236,187.56**	**$13.74**	**2.49**	**0.22%**
DPP-4 INHIBITOR PRODUCTS						
TIER-2 PRODUCTS						
JANUVIA TAB 100MG	3,313	1,015	$3,341,527.73	$1,008.61	3.26	3.09%
TRADJENTA TAB 5MG	1,788	362	$941,141.87	$526.37	4.94	0.87%
JANUVIA TAB 50MG	977	312	$939,810.18	$961.93	3.13	0.87%
JANUVIA TAB 25MG	403	145	$339,726.97	$842.99	2.78	0.31%
TIER-2 SUBTOTAL	**6,481**	**1,834**	**$5,562,206.75**	**$858.23**	**3.53**	**5.14%**
TIER-3 PRODUCTS						
ALOGLIPTIN TAB 25MG	32	10	$6,671.40	$208.48	3.2	0.01%
ALOGLIPTIN TAB 12.5MG	19	6	$5,230.35	$275.28	3.17	0.00%
ALOGLIPTIN TAB 6.25MG	4	2	$644.01	$161.00	2	0.00%
TIER-3 SUBTOTAL	**55**	**18**	**$12,545.76**	**$228.10**	**3.06**	**0.01%**
SPECIAL PA PRODUCTS						
ONGLYZA TAB 5MG	59	20	$60,564.69	$1,026.52	2.95	0.06%
SAXAGLIPTIN TAB 5MG	56	18	$6,502.50	$116.12	3.11	0.01%
ONGLYZA TAB 2.5MG	6	4	$9,830.57	$1,638.43	1.5	0.01%
SAXAGLIPTIN TAB 2.5MG	5	3	$584.87	$116.97	1.67	0.00%
SPECIAL PA SUBTOTAL	**126**	**45**	**$77,482.63**	**$614.94**	**2.8**	**0.07%**
DPP-4 INHIBITOR TOTAL	**6,662**	**1,897**	**$5,652,235.14**	**$848.43**	**3.51**	**5.22%**
TZD PRODUCTS						
TIER-1 PRODUCTS						
PIOGLITAZONE TAB 30MG	2,162	744	$35,521.68	$16.43	2.91	0.03%
PIOGLITAZONE TAB 15MG	1,828	714	$27,044.89	$14.79	2.56	0.02%
PIOGLITAZONE TAB 45MG	995	382	$18,171.97	$18.26	2.6	0.02%
TZD TOTAL	**4,985**	**1,840**	**$80,738.54**	**$16.20**	**2.71**	**0.07%**
DPP-4 INHIBITOR/BIGUANIDE COMBINATION PRODUCTS						
TIER-2 PRODUCTS						
JANUMET TAB 50-1,000MG	981	328	$973,629.36	$992.49	2.99	0.90%
JANUMET XR TAB 50-1,000MG	290	89	$253,754.13	$875.01	3.26	0.23%
JENTADUETO TAB 2.5-1,000MG	245	98	$300,092.87	$1,224.87	2.5	0.28%
JANUMET XR TAB 100-1,000MG	239	68	$227,590.47	$952.26	3.51	0.21%
JANUMET TAB 50-500MG	153	46	$132,516.55	$866.12	3.33	0.12%
JANUMET XR TAB 50-500MG	23	8	$9,508.75	$413.42	2.88	0.01%
JENTADUETO TAB 2.5-500MG	4	3	$3,817.25	$954.31	1.33	0.00%
TIER-2 SUBTOTAL	**1,935**	**640**	**$1,900,909.38**	**$982.38**	**3.02**	**1.76%**
TIER-3 PRODUCTS						
ALOG/METFOR TAB 12.5-500MG	3	1	$326.73	$108.91	3	0.00%
OSENI TAB 25-30MG	1	1	$1,234.47	$1,234.47	1	0.00%
TIER-3 SUBTOTAL	**4**	**2**	**$1,561.20**	**$390.30**	**2**	**0.00%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SPECIAL PA PRODUCTS						
SAXA/METFOR TAB 2.5-1,000MG	12	3	$6,731.95	$561.00	4	0.01%
KOMBIGLYZE XR TAB 2.5-1,000MG	6	4	$3,993.91	$665.65	1.5	0.00%
KOMBIGLYZE XR TAB 5-1,000MG	6	2	$6,576.74	$1,096.12	3	0.01%
SAXA/METFOR TAB 5-1,000MG	2	1	$531.60	$265.80	2	0.00%
SPECIAL PA SUBTOTAL	**26**	**10**	**$17,834.20**	**$685.93**	**2.6**	**0.02%**
DPP-4 INHIBITOR/BIGUANIDE COMBINATION TOTAL	**1,965**	**652**	**$1,920,304.78**	**$977.25**	**3.01**	**1.77%**
SGLT-2 INHIBITOR/BIGUANIDE COMBINATION PRODUCTS						
TIER-2 PRODUCTS						
SYNJARDY TAB 12.5-1,000MG	384	140	$436,626.25	$1,137.05	2.74	0.40%
SYNJARDY XR TAB 25-1,000MG	362	130	$450,621.42	$1,244.81	2.78	0.42%
SYNJARDY XR TAB 12.5-1,000MG	326	112	$298,301.01	$915.03	2.91	0.28%
XIGDUO XR TAB 10-1,000MG	276	83	$285,670.73	$1,035.04	3.33	0.26%
XIGDUO XR TAB 5-1,000MG	149	52	$136,145.86	$913.73	2.87	0.13%
SYNJARDY TAB 5-1,000MG	138	56	$160,125.68	$1,160.33	2.46	0.15%
SYNJARDY XR TAB 10-1,000MG	86	32	$108,266.67	$1,258.91	2.69	0.10%
SYNJARDY XR TAB 5-1,000MG	31	12	$27,453.07	$885.58	2.58	0.03%
INVOKAMET TAB 150-1,000MG	20	6	$19,654.28	$982.71	3.33	0.02%
SYNJARDY TAB 5-500MG	19	6	$14,855.30	$781.86	3.17	0.01%
SYNJARDY TAB 12.5-500MG	18	7	$16,898.33	$938.80	2.57	0.02%
XIGDUO XR TAB 5-500MG	16	9	$19,605.46	$1,225.34	1.78	0.02%
XIGDUO XR TAB 10-500MG	7	2	$3,907.49	$558.21	3.5	0.00%
INVOKAMET XR TAB 150-1,000MG	5	1	$6,330.83	$1,266.17	5	0.01%
XIGDUO XR TAB 2.5-1,000MG	5	3	$1,493.27	$298.65	1.67	0.00%
INVOKAMET XR TAB 50-1,000MG	3	2	$2,905.15	$968.38	1.5	0.00%
TIER-2 SUBTOTAL	**1,845**	**653**	**$1,988,860.80**	**$1,077.97**	**2.83**	**1.84%**
SPECIAL PA PRODUCTS						
DAPAGLIF-METFOR TAB 10-1,000MG	31	23	$27,138.75	$875.44	1.35	0.03%
SEGLUROMET TAB 7.5-1,000MG	20	2	$6,899.72	$344.99	10	0.01%
DAPAGLIF-METFOR TAB 5-1,000MG	16	10	$13,387.48	$836.72	1.6	0.01%
SEGLUROMET TAB 2.5-1,000MG	7	1	$1,204.00	$172.00	7	0.00%
SPECIAL PA SUBTOTAL	**74**	**36**	**$48,629.95**	**$657.16**	**2.06**	**0.04%**
SGLT-2 INHIBITOR/BIGUANIDE COMBINATION TOTAL	**1,919**	**689**	**$2,037,490.75**	**$1,061.75**	**2.79**	**1.88%**
SULFONYLUREA/BIGUANIDE COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
GLYB/METFOR TAB 5-500MG	191	61	$3,027.43	$15.85	3.13	0.00%
GLIP/METFOR TAB 5-500MG	119	50	$5,499.74	$46.22	2.38	0.01%
GLIP/METFOR TAB 2.5-500MG	65	38	$3,491.45	$53.71	1.71	0.00%
GLYB/METFOR TAB 2.5-500MG	49	20	$769.82	$15.71	2.45	0.00%
GLIP/METFOR TAB 2.5-250MG	18	6	$537.34	$29.85	3	0.00%
GLYB/METFOR TAB 1.25-250MG	6	2	$125.18	$20.86	3	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SULFONYLUREA/BIGUANIDE COMBINATION TOTAL	**448**	**177**	**$13,450.96**	**$30.02**	**2.53**	**0.01%**
SGLT-2 INHIBITOR/DPP-4 INHIBITOR COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
GLYXAMBI TAB 25-5 MG	307	62	$172,140.90	$560.72	4.95	0.16%
GLYXAMBI TAB 10-5 MG	121	29	$66,145.99	$546.66	4.17	0.06%
TIER-1 SUBTOTAL	**428**	**91**	**$238,286.89**	**$556.75**	**4.7**	**0.22%**
SPECIAL PA PRODUCTS						
STEGLUJAN TAB 15-100MG	9	1	$4,845.44	$538.38	9	0.00%
STEGLUJAN TAB 5-100MG	4	1	$2,229.24	$557.31	4	0.00%
SPECIAL PA SUBTOTAL	**13**	**2**	**$7,074.68**	**$544.21**	**6.5**	**0.01%**
SGLT-2/DPP-4 INHIBITOR COMBINATION TOTAL	**441**	**93**	**$245,361.57**	**$556.38**	**4.74**	**0.23%**
SGLT-2 INHIBITOR/DPP-4 INHIBITOR/BIGUANIDE COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
TRIJARDY XR TAB 25-5-1,000MG	266	59	$154,830.54	$582.07	4.51	0.14%
TRIJARDY XR TAB 12.5-2.5-1,000MG	97	29	$52,935.14	$545.72	3.34	0.05%
TRIJARDY XR TAB 5-2.5-1,000MG	34	13	$13,042.30	$383.60	2.62	0.01%
TRIJARDY XR TAB 10-5-1,000MG	33	9	$25,845.02	$783.18	3.67	0.02%
SGLT-2/DPP-4/BIGUANIDE COMBINATION TOTAL	**430**	**110**	**$246,653.00**	**$573.61**	**3.91**	**0.23%**
ALPHA-GLUCOSIDASE INHIBITOR PRODUCTS						
TIER-1 PRODUCTS						
ACARBOSE TAB 25MG	133	54	$3,951.64	$29.71	2.46	0.00%
ACARBOSE TAB 50MG	65	18	$2,005.13	$30.85	3.61	0.00%
ACARBOSE TAB 100MG	43	19	$2,089.51	$48.59	2.26	0.00%
ALPHA-GLUCOSIDASE INHIBITOR TOTAL	**241**	**91**	**$8,046.28**	**$33.39**	**2.65**	**0.01%**
GLP-1 AGONIST/INSULIN COMBINATION PRODUCTS						
TIER-3 PRODUCTS						
SOLIQUA INJ 100U/33MCG	147	32	$104,761.26	$712.66	4.59	0.10%
XULTOPHY INJ 100U/3.6MCG	40	14	$47,451.56	$1,186.29	2.86	0.04%
GLP-1 AGONIST/INSULIN COMBINATION TOTAL	**187**	**46**	**$152,212.82**	**$813.97**	**4.07**	**0.14%**
FINERENONE PRODUCTS						
KERENDIA TAB 10MG	98	27	$61,254.50	$625.05	3.63	0.06%
KERENDIA TAB 20MG	23	3	$14,383.90	$625.39	7.67	0.01%
FINERENONE TOTAL	**121**	**30**	**$75,638.40**	**$625.11**	**4.03**	**0.07%**
GLINIDE PRODUCTS						
TIER-1 PRODUCTS						
REPAGLINIDE TAB 1MG	44	16	$1,106.61	$25.15	2.75	0.00%
REPAGLINIDE TAB 2MG	26	6	$694.19	$26.70	4.33	0.00%
REPAGLINIDE TAB 0.5MG	18	7	$376.71	$20.93	2.57	0.00%
TIER-1 SUBTOTAL	**88**	**29**	**$2,177.51**	**$24.74**	**3.03**	**0.00%**
TIER-2 PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NATEGLINIDE TAB 120MG	19	7	$764.66	$40.25	2.71	0.00%
NATEGLINIDE TAB 60MG	12	6	$494.97	$41.25	2	0.00%
TIER-2 SUBTOTAL	**31**	**13**	**$1,259.63**	**$40.63**	**2.38**	**0.00%**
GLINIDE TOTAL	**119**	**42**	**$3,437.14**	**$28.88**	**2.83**	**0.00%**
TZD/BIGUANIDE COMBINATION PRODUCTS						
TIER-3 PRODUCTS						
PIOG/METFOR TAB 15-850MG	18	7	$552.57	$30.70	2.57	0.00%
PIOG/METFOR TAB 15-500MG	11	2	$326.81	$29.71	5.5	0.00%
TZD/BIGUANIDE COMBINATION TOTAL	**29**	**9**	**$879.38**	**$30.32**	**3.22**	**0.00%**
DPP-4 INHIBITOR/TZD COMBINATION PRODUCTS						
TIER-3 PRODUCTS						
ALOG/PIOG TAB 25-45MG	5	1	$2,194.95	$438.99	5	0.00%
ALOG/PIOG TAB 25-30MG	2	1	$302.38	$151.19	2	0.00%
DPP-4 INHIBITOR/TZD COMBINATION TOTAL	**7**	**2**	**$2,497.33**	**$356.76**	**3.5**	**0.00%**
AMYLINOMIMETIC PRODUCTS						
SPECIAL PA PRODUCTS						
SYMLNPEN 120 INJ 1,000MCG	4	2	$4,966.28	$1,241.57	2	0.00%
SYMLINPEN 60 INJ 1,000MCG	1	1	$1,047.32	$1,047.32	1	0.00%
AMYLINOMIMETIC TOTAL	**5**	**3**	**$6,013.60**	**$1,202.72**	**1.67**	**0.01%**
TOTAL	**202,226**	**39,867***	**$108,261,832.07**	**$535.35**	**5.07**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members
ALOG = alogliptin; DPP-4 = dipeptidyl peptidase-4; ER, XL, XR = extended-release; GIP = glucose-dependent insulinotropic polypeptide; GLIP = glipizide; GLP-1 = glucagon-like peptide 1; GLYB = glyburide; INJ = injection; MCR = micronized; METFOR = metformin; PIOG = pioglitazone; SAXA = saxagliptin; SGLT-2 = sodium-glucose cotransporter-2; SOL = solution; TZD = thiazolidinedione; TAB = tablet; U = unit
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Utilization Details of Insulin Medication: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INSULIN GLARGINE PRODUCTS						
LANTUS SOLO INJ 100U/ML	26,207	8,618	$9,199,945.02	$351.05	3.04	26.74%
LANTUS INJ 100U/ML	4,227	1,364	$1,351,916.86	$319.83	3.1	3.93%
INSULIN GLARGINE INJ 100U/ML	1,600	882	$335,563.13	$209.73	1.81	0.98%
TOUJEO MAX INJ 300U/ML	606	141	$586,081.17	$967.13	4.3	1.70%
TOUJEO SOLO INJ 300U/ML	368	87	$272,078.27	$739.34	4.23	0.79%
SEMGLEE INJ 100U/ML	288	227	$128,675.26	$446.79	1.27	0.37%
GLARGINE YFGN INJ 100U/ML	259	224	$30,545.68	$117.94	1.16	0.09%
BASAGLAR INJ 100UNIT	199	114	$82,096.84	$412.55	1.75	0.24%
GLARGINE YFGN SOL 100U/ML	33	27	$3,376.52	$102.32	1.22	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INSULIN GLARGINE SOL 100U/ML	15	13	$3,158.67	$210.58	1.15	0.01%
INSULIN GLARINE INJ 300U/ML	6	4	$1,648.92	$274.82	1.5	0.00%
REZVOGLAR INJ 100U/ML	2	1	$203.79	$101.90	2.	0.00%
BASAGLAR INJ TEMPO PEN 100U/ML	2	2	$461.68	$230.84	1	0.00%
INSULIN GLARGINE INJ 300U/ML	1	1	$177.12	$177.12	1	0.00%
SUBTOTAL	**33,813**	**11,705**	**$11,995,928.93**	**$354.77**	**2.89**	**34.86%**
INSULIN ASPART PRODUCTS						
NOVOLOG INJ FLEXPEN	5,565	2,150	$2,719,895.69	$488.75	2.59	7.90%
INSULIN ASPA INJ FLEXPEN	4,595	1,827	$1,273,125.72	$277.07	2.52	3.70%
NOVOLOG INJ 100U/ML	2,942	788	$1,456,699.64	$495.14	3.73	4.23%
NOVOLOG INJ FLEX RELION	2,834	1,166	$365,315.49	$128.90	2.43	1.06%
INSULIN ASP INJ 100U/ML	1,810	594	$618,171.42	$341.53	3.05	1.80%
NOVOLOG INJ RELION	638	229	$137,673.89	$215.79	2.79	0.40%
FIASP INJ FLEXTOUCH	280	61	$211,195.82	$754.27	4.59	0.61%
NOVOLOG INJ PENFILL	218	60	$103,517.09	$474.85	3.63	0.30%
FIASP INJ 100U/ML	69	16	$49,543.77	$718.03	4.31	0.14%
INSULIN ASP INJ PENFILL	65	26	$19,878.25	$305.82	2.5	0.06%
FIASP PENFILL INJ 100U	37	12	$27,590.18	$745.68	3.08	0.08%
FIASP PUMPCART INJ 100U	5	3	$3,911.75	$782.35	1.67	0.01%
SUBTOTAL	**19,058**	**6,932**	**$6,986,518.71**	**$366.59**	**2.75**	**20.30%**
INSULIN LISPRO PRODUCTS						
HUMALOG KWIK INJ 100U/ML	7,894	2,671	$3,928,735.59	$497.69	2.96	11.42%
HUMALOG INJ 100U/ML	4,595	1,104	$2,193,699.98	$477.41	4.16	6.38%
HUMALOG JR INJ 100U/ML	613	169	$244,328.14	$398.58	3.63	0.71%
HUMALOG KWIK INJ 200U/ML	423	81	$813,096.34	$1,922.21	5.22	2.36%
INSULIN LISP INJ JR 100U/ML	332	93	$65,877.95	$198.43	3.57	0.19%
HUMALOG INJ 100U/ML	155	51	$84,185.08	$543.13	3.04	0.24%
LYUMJEV INJ 100U/ML	98	26	$126,117.26	$1,286.91	3.77	0.37%
INSULIN LISP KWIK INJ 100U/ML	92	70	$20,177.76	$219.32	1.31	0.06%
INSULIN LISP INJ 100U/ML	76	48	$6,502.01	$85.55	1.58	0.02%
LYUMJEV KWIK INJ 100U/ML	35	12	$28,383.02	$810.94	2.92	0.08%
LYUMJEV KWIK INJ 200U/ML	18	4	$39,505.78	$2,194.77	4.5	0.11%
ADMELOG INJ 100/ML	13	5	$1,314.03	$101.08	2.6	0.00%
ADMELOG SOLO INJ 100U/ML	8	3	$2,530.07	$316.26	2.67	0.01%
HUMALOG TEMPO INJ 100U/ML	8	3	$1,577.69	$197.21	2.67	0.00%
LYUMJEV TEMPO INJ 100U/ML	1	1	$1,598.61	$1,598.61	1	0.00%
SUBTOTAL	**14,361**	**4,341**	**$7,557,629.31**	**$526.26**	**3.31**	**21.96%**
INSULIN DETEMIR PRODUCTS						
LEVEMIR INJ FLEXPEN 100U/ML	7,097	2,557	$3,274,792.32	$461.43	2.78	9.52%
LEVEMIR INJ 100U/ML	1,514	477	$673,595.81	$444.91	3.17	1.96%
LEVEMIR INJ FLEXTOUCH 100U/ML	46	28	$23,395.35	$508.59	1.64	0.07%
SUBTOTAL	**8,657**	**3,062**	**$3,971,783.48**	**$458.79**	**2.83**	**11.54%**
INSULIN DEGLUDEC PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TRESIBA FLEX INJ 200U/ML	1,308	347	$1,116,461.08	$853.56	3.77	3.24%
TRESIBA FLEX INJ 100U/ML	1,099	376	$587,098.44	$534.21	2.92	1.71%
INS DEGLUDEC FLEX INJ 200U/ML	128	54	$38,785.27	$303.01	2.37	0.11%
INS DEGLUDEC FLEX INJ 100U/ML	113	56	$22,135.85	$195.89	2.02	0.06%
TRESIBA INJ 100/ML	15	7	$7,926.02	$528.40	2.14	0.02%
INSULIN DEGLUDEC INJ 100U/ML	3	3	$390.12	$130.04	1	0.00%
SUBTOTAL	**2,666**	**843**	**$1,772,796.78**	**$664.97**	**3.16**	**5.15%**
REGULAR INSULIN PRODUCTS						
HUMULIN R INJ 100U/ML	494	163	$94,030.94	$190.35	3.03	0.27%
HUMULIN R KWIK INJ 500U/ML	441	109	$554,925.39	$1,258.33	4.05	1.61%
NOVOLIN R INJ 100U/ML	400	163	$77,589.18	$193.97	2.45	0.23%
NOVOLIN R INJ 100U/ML	292	125	$51,659.38	$176.92	2.34	0.15%
NOVOLIN R INJ RELION	226	76	$16,972.52	$75.10	2.97	0.05%
HUMULIN R INJ 500U/ML	32	9	$48,729.89	$1,522.81	3.56	0.14%
AFREZZA POWDER 4-8-12U	5	1	$10,602.83	$2,120.57	5	0.03%
AFREZZA POWDER 12U	2	1	$2,669.98	$1,334.99	2	0.01%
AFREZZA POWDER 8U	1	1	$913.37	$913.37	1	0.00%
SUBTOTAL	**1,893**	**648**	**$858,093.48**	**$453.30**	**2.92**	**2.49%**
REGULAR/NPH INSULIN COMBINATION PRODUCTS						
NOVOLIN INJ FLEX 70/30	414	140	$104,561.62	$252.56	2.96	0.30%
HUMULIN INJ KWIK INJ 70/30	267	92	$134,280.00	$502.92	2.9	0.39%
HUMULIN INJ 70/30	239	83	$59,955.78	$250.86	2.88	0.17%
NOVOLIN 70/30 INJ RELION	239	73	$20,968.78	$87.74	3.27	0.06%
NOVOLIN INJ 70/30	222	89	$67,310.50	$303.20	2.49	0.20%
SUBTOTAL	**1,381**	**477**	**$387,076.68**	**$280.29**	**2.9**	**1.12%**
NPH INSULIN PRODUCTS						
NOVOLIN N INJ 100U	374	184	$54,178.55	$144.86	2.03	0.16%
HUMULIN N KWIK INJ 100U	312	162	$117,479.72	$376.54	1.93	0.34%
HUMULIN N INJ 100U	237	96	$52,471.65	$221.40	2.47	0.15%
NOVOLIN N INJ RELION	199	67	$14,131.83	$71.01	2.97	0.04%
NOVOLIN N INJ 100U	175	66	$39,711.87	$226.92	2.65	0.12%
SUBTOTAL	**1,297**	**575**	**$277,973.62**	**$214.32**	**2.26**	**0.81%**
INSULIN ASPART/NPH COMBINATION PRODUCTS						
NOVOLOG MIX INJ FLEX	351	119	$205,735.26	$586.14	2.95	0.60%
INS ASP PROT INJ FLEX	184	64	$68,881.16	$374.35	2.88	0.20%
NOVOLOG MIX INJ FLEX RELION	123	59	$19,733.84	$160.44	2.08	0.06%
NOVOLOG MIX INJ 70/30	60	22	$41,732.79	$695.55	2.73	0.12%
INSULIN ASP INJ 70/30	27	18	$9,252.59	$342.69	1.5	0.03%
NOVOLOG RELION INJ 70/30	20	5	$2,361.56	$118.08	4	0.01%
SUBTOTAL	**765**	**287**	**$347,697.20**	**$454.51**	**2.67**	**1.01%**
INSULIN GLULISINE PRODUCTS						
APIDRA INJ SOLOSTAR	244	81	$123,532.64	$506.28	3.01	0.36%
APIDRA INJ 100U	57	14	$24,353.80	$427.26	4.07	0.07%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**301**	**95**	**$147,886.44**	**$491.32**	**3.17**	**0.43%**
INSULIN LISPRO/NPH COMBINATION PRODUCTS						
HUMALOG MIX KWIK INJ 75/25	100	34	$58,329.75	$583.30	2.94	0.17%
HUMALOG MIX SUS 75/25	44	11	$24,941.09	$566.84	4	0.07%
HUMALOG MIX KWIK INJ 50/50	30	10	$17,840.43	$594.68	3	0.05%
INSULIN LISP INJ PROT	23	8	$4,493.40	$195.37	2.88	0.01%
HUMALOG MIX INJ 50/50	2	2	$1,157.62	$578.81	1	0.00%
SUBTOTAL	**199**	**65**	**$106,762.29**	**$536.49**	**3.06**	**0.31%**
TOTAL	**84,391**	**15,441***	**$34,410,146.92**	**$407.75**	**5.47**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ASP = aspart; FLEX = FlexPen; GLAR = glargine; INJ = injection; INS = insulin; JR = junior; KWIK = KwikPen; LISP = lispro; POW = powder; PROT = protamine; SOL = solution; SUS = suspension; U = unit
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

[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 04/2025. Last accessed 04/17/2025.
[2] AstraZeneca. Farxiga® Approved in the U.S. for the Treatment of Pediatric Type-2 Diabetes. Available online at: https://www.astrazeneca-us.com/media/press-releases/2024/farxiga-approved-in-the-us-for-the-treatment-of-pediatric-type-two-diabetes.html. Issued 06/12/2024. Last accessed 04/17/2025.
[3] Zydus Lifesciences. Zydus Receives Final Approval from U.S. FDA for Its NDA Zituvimet™ XR (Sitagliptin and Metformin Hydrochloride) Extended-Release Tablets. Available online at: https://zyduslife.com/investor/admin/uploads/21/83/Zydus-receives-final-approval-from-USFDA-for-its-NDA-ZituvimetTM-XR-(sitagliptin-and-metformin-hydrochloride)-extended-release-tablets.pdf. Issued 07/19/2024. Last accessed 04/17/2025.
[4] Amneal Pharmaceuticals. Amneal Resubmits DHE Autoinjector New Drug Application and Receives U.S. FDA Approval of Exenatide, Its First Generic Injectable GLP-1 Agonist. *Businesswire*. Available online at: https://www.businesswire.com/news/home/20241121053036/en/Amneal-Resubmits-DHE-Autoinjector-New-Drug-Application-and-Receives-U.S.-FDA-Approval-of-Exenatide-its-First-Generic-Injectable-GLP-1-Agonist. Issued 11/21/2024. Last accessed 04/17/2025.

[5] U.S. FDA. FDA Approves First Generic of Once-Daily GLP-1 Injection to Lower Blood Sugar in Patients with Type 2 Diabetes. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-once-daily-glp-1-injection-lower-blood-sugar-patients-type-2-diabetes. Issued 12/23/2024. Last accessed 04/17/2025.
[6] Rybelsus® (Semaglutide) Prescribing Information. Novo Nordisk. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/213051Orig1s020,213051Orig1s021lbl.pdf. Last revised 12/2024. Last accessed 04/17/2025.
[7] U.S. FDA. Rybelsus® Supplement Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/213051Orig1s020,213051Orig1s021ltr.pdf. Issued 12/09/2024. Last accessed 04/17/2025.
[8] Nielsen M, Brondsted L, Kankam M, et al. A Bioequivalence Study of Two Formulations of Oral Semaglutide in Healthy Participants. *Diabetes Ther* 2025; 16:269–287. doi: 10.1007/s13300-024-01674-8.
[9] Brynovin™ (Sitagliptin) – New drug approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_brynovin_2025-0117.pdf. Issued 01/16/2025. Last accessed 04/17/2025.
[10] Novo Nordisk. FDA Approves Ozempic® (Semaglutide) As the Only GLP-1 RA to Reduce the Risk of Worsening Kidney Disease and Cardiovascular Death in Adults with Type 2 Diabetes and Chronic Kidney Disease. Available online at: https://www.novonordisk-us.com/media/news-archive/news-details.html?id=915253. Issued 01/28/2025. Last accessed 04/17/2025.
[11] U.S. FDA. FDA Approves First Rapid-Acting Insulin Biosimilar Product for Treatment of Diabetes. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-rapid-acting-insulin-biosimilar-product-treatment-diabetes. Issued 02/14/2025. Last accessed 04/17/2025.
[12] Sanofi – Discontinuation of Adlyxin® (Lixisenatide). *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-withdrawls/drugwithdrawal_adlyxin_2023-0117.pdf. Issued 01/01/2023. Last accessed 04/17/2025.
[13] U.S. FDA. National Drug Code Directory. Available online at: https://dps.fda.gov/ndc. Last accessed 04/17/2025.
[14] U.S. FDA. FDA Drug Shortages: Discontinuations. Available online at: https://dps.fda.gov/drugshortages/discontinuations/exenatide-synthetic-injectable-suspension-extended-release. Issued 10/28/2024. Last accessed 04/17/2025.
[15] American Diabetes Association (ADA). The American Diabetes Association Releases Standards of Care in Diabetes 2025. Available online at: https://diabetes.org/newsroom/press-releases/american-diabetes-association-releases-standards-care-diabetes-2025. Issued 12/09/2024. Last accessed 04/17/2025.
[16] American Diabetes Association Professional Practice Committee. Summary of Revisions: *Standards of Care in Diabetes—2025. Diabetes Care* 2025; 48 (Supplement 1): S6–S13. doi: 10.2337/dc25-Srev.
[17] Eli Lilly. Lilly's Oral GLP-1, Orforglipron, Demonstrated Statistically Significant Efficacy Results and a Safety Profile Consistent with Injectable GLP-1 Medicines in Successful Phase 3 Trial. Available online at: https://investor.lilly.com/news-releases/news-release-details/lillys-oral-glp-1-orforglipron-demonstrated-statistically. Issued 04/17/2025. Last accessed 04/17/2025.
[18] Novo Nordisk. Ozempic® (Semaglutide) Injection 1 mg Showed Improved Functional Outcomes and Health-Related Quality of Life in Phase 3 STRIDE Trial in Adults with Type 2 Diabetes and Peripheral Artery Disease (PAD) Presented at ACC 2025. Available online at: https://www.novonordisk-us.com/media/news-archive/news-details.html?id=915964. Issued 03/29/2025. Last accessed 04/17/2025.
[19] Novo Nordisk. Oral Semaglutide 14mg Demonstrated Superior Reduction in Risk of Cardiovascular Events in Late-Breaking SOUL Trial Presented at the American College of Cardiology. Available online at: https://www.novonordisk-us.com/media/news-archive/news-details.html?id=915966. Issued 03/29/2025. Last accessed 04/17/2025.
[20] Vertex. R&D pipeline. Available online at: https://www.vrtx.com/our-science/pipeline/. Last accessed 04/17/2025.
[21] Vertex. Vertex Reports Fourth Quarter and Full Year 2024 Financial Results. Available online at: https://news.vrtx.com/news-releases/news-release-details/vertex-reports-fourth-quarter-and-full-year-2024-financial. Issued 02/10/2025. Last accessed 04/17/2025.
[22] Vertex. Vertex Announces Program Updates for Type 1 Diabetes Portfolio. Available online at: https://news.vrtx.com/news-releases/news-release-details/vertex-announces-program-updates-type-1-diabetes-portfolio. Issued 03/28/2025. Last accessed 04/17/2025.

Appendix N

Fiscal Year 2024 Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Onyda™ XR [Clonidine Extended-Release (ER) Suspension]

Oklahoma Health Care Authority
May 2025

Current Prior Authorization Criteria

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			amphetamine ER susp (Adzenys ER™) amphetamine ER ODT (Adzenys XR-ODT®) amphetamine (Evekeo®) amphetamine ODT (Evekeo ODT™) amphetamine/ dextroamphetamine ER (Mydayis®) dextroamphetamine (Dexedrine®) dextroamphetamine soln (ProCentra®) dextroamphetamine (Xelstrym™) dextroamphetamine (Zenzedi®) methamphetamine (Desoxyn®) methylphenidate ER 72mg
Short-Acting			
amphetamine/ dextroamphetamine (Adderall®)			
Long-Acting			
amphetamine/ dextroamphetamine ER (Adderall XR®) lisdexamfetamine cap and chew tab (Vyvanse®)+ – **Brand Preferred**	amphetamine ER tab (Dyanavel® XR) dextroamphetamine ER (Dexedrine Spansules®)	amphetamine ER susp (Dyanavel® XR)	
Methylphenidate			
Short-Acting			
dexmethylphenidate (Focalin®) methylphenidate tab and soln (Methylin®) methylphenidate (Ritalin®)			
Long-Acting			
dexmethylphenidate ER (Focalin XR®) – **Brand Preferred** methylphenidate ER (Concerta®)	dexmethylphenidate ER (generic Focalin XR®) methylphenidate ER (Aptensio XR®) methylphenidate ER susp (Quillivant XR®)	methylphenidate ER (Adhansia XR®) methylphenidate ER (Jornay PM®) serdexmethylphen-idate/dexmethylphen-idate (Azstarys®)	

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
methylphenidate ER (Daytrana®) – **Brand Preferred** methylphenidate ER (Metadate CD®) methylphenidate ER (Metadate ER®) methylphenidate ER (Methylin ER®) methylphenidate ER (Ritalin SR®)	methylphenidate ER (Ritalin LA®)		methylphenidate ER ODT (Cotempla XR-ODT®) methylphenidate ER (Relexxii®) methylphenidate chew tab (Methylin®) methylphenidate ER chew tab (QuilliChew ER®)
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)Δ		viloxazine (Qelbree®)Δ

*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). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
+Unique criteria applies for the diagnosis of binge eating disorder (BED).
ΔUnique criteria applies in addition to tier trial requirements.
ADHD = attention-deficit/hyperactivity disorder; cap = capsule; chew tab = chewable tablet; ER = extended-release; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tab = tablet

ADHD Medications Tier-2 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response:
   a. Trials should have been within the last 180 days; and
   b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
   c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
3. For Quillivant XR®, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Kapvay® Approval Criteria:

a. An FDA approved diagnosis; and
b. Previously failed trials (within the last 180 days) with a long-acting Tier-1 stimulant, Intuniv®, and Strattera®, unless contraindicated, that did not yield adequate results; and
c. A patient-specific, clinically significant reason why the member cannot use clonidine immediate-release tablets must be provided.

ADHD Medications Tier-3 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response; and
3. A previously failed trial with at least 1 long-acting Tier-2 stimulant that resulted in an inadequate response:
   a. Trials should have been within the last 365 days; and
   b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
   c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
4. For Dyanavel® XR oral suspension, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. Adzenys XR-ODT®, Adzenys ER™, Cotempla XR-ODT®, Evekeo ODT™, QuilliChew ER®, and Xelstrym™ Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use all other available formulations of stimulant medications that can be used for members who cannot swallow capsules or tablets must be provided; and
   c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
2. Desoxyn®, Dexedrine®, Evekeo®, Methylphenidate ER 72mg Tablet, ProCentra®, Relexxii®, and Zenzedi® Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
3. Methylin® Chewable Tablets Approval Criteria:

a. A covered diagnosis; and
b. A patient-specific, clinically significant reason why the member cannot use methylphenidate immediate-release tablets or oral solution must be provided; and
c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

4. Mydayis® Approval Criteria:
   a. A covered diagnosis; and
   b. Member must be 13 years of age or older; and
   c. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
5. Qelbree® Approval Criteria:
   a. An FDA approved diagnosis; and
   b. Member must be 6 years of age or older; and
   c. Previously failed trial (within the last 180 days) with atomoxetine or any ADHD medication, unless contraindicated, that did not yield adequate results; and
      i. Qelbree® will not require a prior authorization and claims will pay at the point of sale if the member has paid claims for atomoxetine or any ADHD medications within the past 180 days of claims history; and
   d. Member must not be taking a monoamine oxidase inhibitor (MAOI) or have taken an MAOI within the last 14 days; and
   e. Member must not be taking sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline) concomitantly with Qelbree®; and
   f. Quantity limits will apply based on FDA-approved dosing.

ADHD Medications Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum dose are not covered.
2. Prior authorization is required for all tiers for members older than 20 years of age and for members younger than 5 years of age. All prior authorization requests for members younger than 5 years of age must be reviewed by an Oklahoma Health Care Authority (OHCA)- or SoonerSelect health plan-contracted psychiatrist.
3. For Daytrana® patches, Methylin® oral solution, and Vyvanse® chewable tablet, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
   a. Daytrana® patches and Vyvanse® chewable tablets are brand preferred. Approval of generic methylphenidate transdermal

patches or lisdexamfetamine chewable tablets will require a patient-specific, clinically significant reason why brand name Daytrana® or Vyvanse® cannot be used.

4. Vyvanse® Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:
    a. An FDA approved diagnosis of moderate-to-severe BED; and
    b. Member must be 18 years of age or older; and
    c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and
    d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and
    e. Vyvanse® is brand preferred. Approval of generic lisdexamfetamine will require a patient-specific, clinically significant reason why brand name Vyvanse® cannot be used; and
    f. A quantity limit of 30 capsules or chewable tablets per 30 days will apply; and
    g. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.

Idiopathic Hypersomnia (IH) Medications Approval Criteria:

1. Diagnosis of IH meeting the following ICSD-3 (International Classification of Sleep Disorders) criteria:
    a. Daily periods of irresistible need to sleep or daytime lapses into sleep for >3 months; and
    b. Absence of cataplexy; and
    c. Multiple sleep latency test (MSLT) results showing 1 of the following:
        i. <2 sleep-onset rapid eye movement (REM) periods (SOREMPs); or
        ii. No SOREMPs if the REM sleep latency on the preceding polysomnogram is ≤15 minutes; and
    d. At least 1 of the following:
        i. MSLT showing mean sleep latency ≤8 minutes; or
        ii. Total 24-hour sleep time ≥660 minutes on 24-hour polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in association with a sleep log (averaged over ≥7 days with unrestricted sleep); and
    e. Insufficient sleep syndrome has been ruled out; and
    f. Hypersomnolence or MSLT findings are not better explained by any other sleep disorder, medical or neurologic disorder, mental disorder, medication use, or substance abuse; and
2. Diagnosis must be confirmed by a sleep specialist; and

3. Use of Xyrem® (sodium oxybate) or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with at least 4 of the following, unless contraindicated, that did not yield adequate results:
    a. Tier-1 stimulant; or
    b. Tier-2 stimulant; or
    c. Nuvigil® (armodafinil); or
    d. Provigil® (modafinil); or
    e. Clarithromycin; and
4. Xyrem® is brand preferred. Requests for generic sodium oxybate will require a patient-specific, clinically significant reason why brand name Xyrem® cannot be used; and
5. Xywav® (calcium/magnesium/potassium/sodium oxybates) additionally requires a patient-specific, clinically significant reason why the member cannot use Xyrem®; and
    a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided.

Narcolepsy Medications Approval Criteria:

1. An FDA approved diagnosis; and
2. Use of Lumryz™ (sodium oxybate), Sunosi® (solriamfetol), Wakix® (pitolisant), Xyrem® (sodium oxybate), or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with Tier-1 and Tier-2 stimulants from different chemical categories, Provigil® (modafinil), and Nuvigil® (armodafinil), unless contraindicated, that did not yield adequate results; and
    a. Xyrem® is brand preferred. Requests for generic sodium oxybate will require a patient-specific, clinically significant reason why brand name Xyrem® cannot be used; and
3. Additionally, use of Lumryz™ (sodium oxybate) or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires a patient-specific, clinically significant reason (beyond convenience) why the member cannot use Xyrem®; and
    a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided; and
4. The diagnosis of obstructive sleep apnea requires concurrent treatment for obstructive sleep apnea; and
5. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the prior authorization request.

Utilization of ADHD and Narcolepsy Medications: Fiscal Year 2024

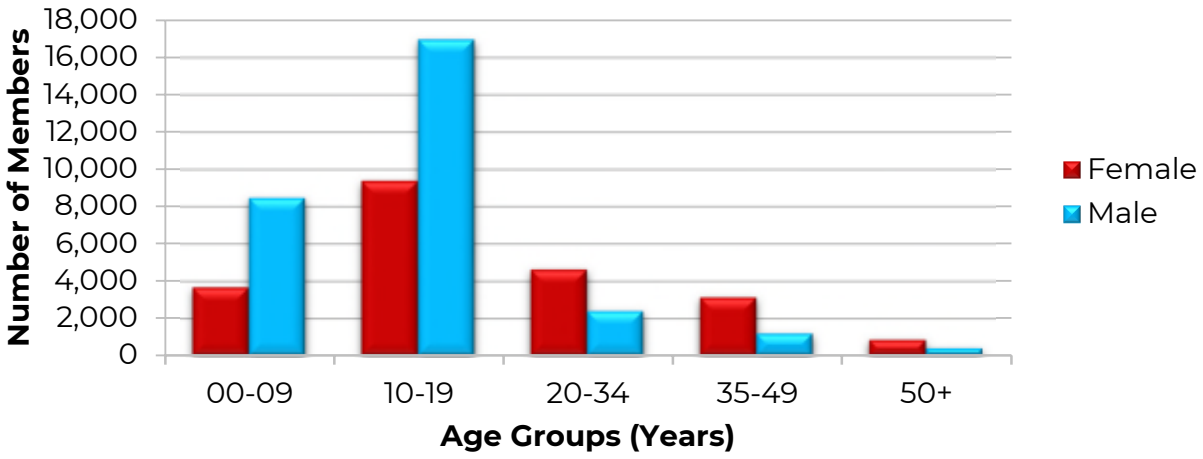
Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	49,131	371,283	$56,676,909.43	$152.65	$5.10	13,034,220	11,113,422
2023 Total	**49,131**	**371,283**	**$56,676,909.43**	**$152.65**	**$5.10**	**13,034,220**	**11,113,422**
Fiscal Year 2024							
FFS	47,776	301,862	$47,272,318.98	$156.60	$5.16	10,774,241	9,160,214
Aetna	6,135	14,588	$2,051,602.52	$140.64	$4.65	531,209	441,650
Humana	6,380	15,170	$2,326,722.28	$153.38	$5.08	547,174	458,385
OCH	10,012	24,790	$2,994,326.59	$120.79	$3.99	868,099	750,997
2024 Total	**50,895**	**356,410**	**$54,644,970.37**	**$153.32**	**$5.05**	**12,720,723**	**10,811,246**
% Change	**3.60%**	**-4.00%**	**-3.60%**	**0.40%**	**-1.00%**	**-2.40%**	**-2.70%**
Change	**1,764**	**-14,873**	**-$2,031,939.06**	**$0.67**	**-$0.05**	**-313,497**	**-302,176**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

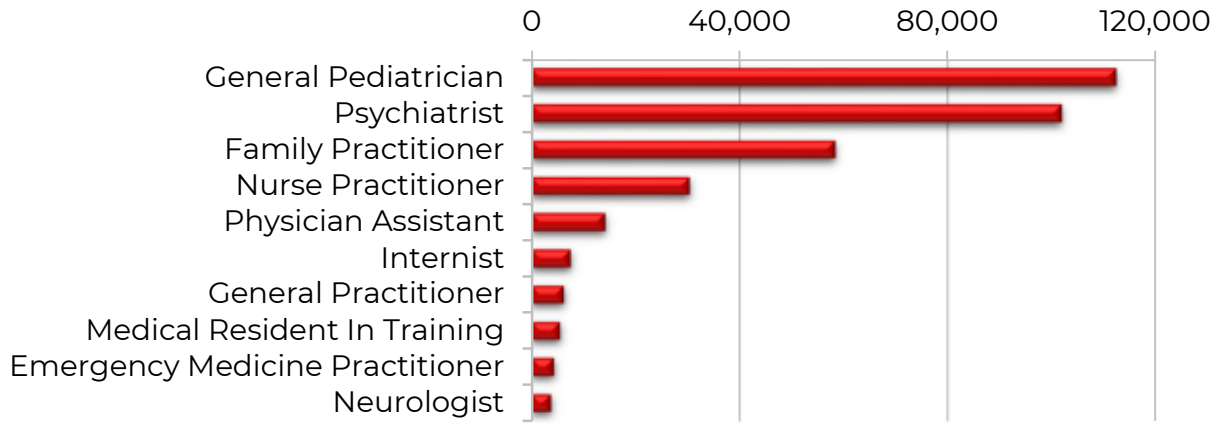
- Aggregate drug rebates collected during fiscal year 2024 for ADHD and narcolepsy medications totaled $43,260,571.79.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing ADHD and Narcolepsy 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.

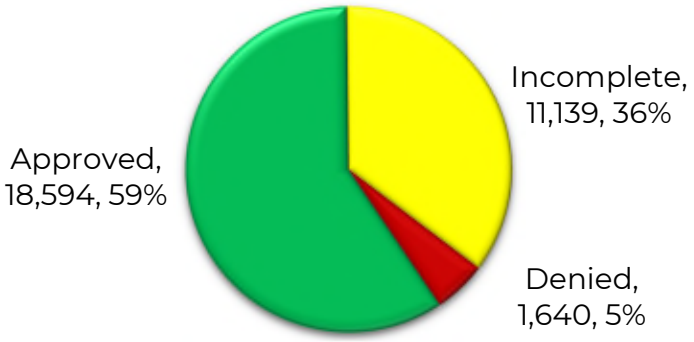
Top Prescriber Specialties of ADHD and Narcolepsy Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of ADHD and Narcolepsy Medications

There were 31,373 prior authorization requests submitted for ADHD and narcolepsy medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	17,475	59%	11,027	37%	1,366	5%	**29,868**
Aetna	823	74%	112	10%	170	15%	**1,105**
Humana	37	55%	0	0%	30	45%	**67**
OCH	259	78%	0	0%	74	22%	**333**
Total	**18,594**	**59%**	**11,139**	**36%**	**1,640**	**5%**	**31,373**

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

Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

Oklahoma Resources

The following list includes local resources available to prescribers, specifically regarding psychotropic medications:

- **Consultation with a Child Psychiatrist:** For children with especially challenging symptoms, a consultation with a child psychiatrist is available for the SoonerCare fee-for-service (FFS) population and can be scheduled by calling 1-405-522-7597.
- **Care Management (Including Behavioral Health):** Additional services are available for SoonerCare members, including Behavioral Health Care Management, through the member's SoonerCare (FFS) or SoonerSelect (managed care) health plan.
- **Project ECHO:** Project ECHO (Extension for Community Health Care Outcomes) is available online for medical education and care management for chronic and complex medical conditions at: https://medicine.okstate.edu/echo/.
- **Oklahoma Pediatric Psychotropic Medication Resource Guide:** The Department of Psychiatry and Behavioral Sciences at Oklahoma State University Center for Health Sciences has provided a psychotropic medication resource guide that can assist in the management of pediatric patients in the state of Oklahoma and can be found at: https://medicine.okstate.edu/academics/psychiatry/.

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

Anticipated Patent Expiration(s):

- Wakix® (pitolisant tablet): March 2030
- Quillivant XR® (methylphenidate ER suspension): February 2031
- Jornay PM® (methylphenidate ER capsule): March 2032
- Adzenys XR-ODT® [amphetamine ER orally disintegrating tablet (ODT)]: June 2032
- QuilliChew ER® (methylphenidate ER chewable tablet): August 2033
- Xyrem® (sodium oxybate solution): September 2033
- Qelbree® (viloxazine ER capsule): April 2035
- Dyanavel® XR (amphetamine ER suspension): September 2036
- Evekeo ODT™ (amphetamine ODT): March 2037
- Azstarys® (serdexmethylphenidate/dexmethylphenidate capsule): December 2037
- Cotempla XR-ODT® (methylphenidate ER ODT): January 2038
- Dyanavel® XR (amphetamine ER tablet): September 2038
- Adhansia XR® (methylphenidate ER capsule): November 2038
- Xywav® (calcium/magnesium/potassium/sodium oxybates oral solution): February 2041
- Onyda™ XR (clonidine ER suspension): July 2041
- Xelstrym™ (dextroamphetamine transdermal system): January 2042

- Lumryz™ (sodium oxybate ER): March 2042
- Sunosi® (solriamfetol tablet): December 2042

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

- **May 2024:** The FDA approved Onyda™ XR (clonidine ER suspension) for the treatment of ADHD as monotherapy or as adjunctive therapy to central nervous system (CNS) stimulant medications in pediatric patients 6 years of age and older. Onyda™ XR was approved through the 505(b)(2) pathway based on prior studies utilizing clonidine ER tablets.
- **June 2024:** The FDA approved Wakix® (pitolisant) for a new indication for the treatment of excessive daytime sleepiness (EDS) in pediatric patients 6 years of age or older with narcolepsy. At the same time, the FDA issued a Complete Response Letter (CRL) for Wakix® for the treatment of cataplexy in pediatric patients 6 years of age and older with narcolepsy. Previously, Wakix® was FDA approved for the treatment of EDS or cataplexy only in adult patients with narcolepsy.

News:

- **April 2025:** As of April 2025, the FDA Orange Book lists Adzenys ER™ (amphetamine ER suspension) as a discontinued product. There are currently no generic equivalents for this product.

Onyda™ XR (Clonidine ER Suspension) Product Summary[5]

Therapeutic Class: Centrally acting alpha$_2$-adrenergic agonist

Indication(s): Treatment of ADHD as monotherapy and as adjunctive therapy to CNS stimulant medications in pediatric patients 6 years of age and older

How Supplied: 0.1mg/mL oral suspension in 30mL, 60mL, and 120mL bottles

Dosing and Administration:

- Recommended starting dosage is 0.1mg orally once daily at bedtime with or without food
- Dose may be increased in increments of 0.1mg per day at weekly intervals depending on clinical response up to the maximum recommended dose of 0.4mg once daily at bedtime

Efficacy: The efficacy of Onyda™ XR was based on data from studies utilizing clonidine ER tablets.

Cost Comparison:

Product	Cost Per Unit	Cost Per Month*	Cost Per Year
Onyda™ XR (clonidine ER 0.1mg/mL sus) 60mL bottle	**$7.63**	**$915.60**	**$10,987.20**
clonidine ER 0.1mg tablet (generic Kapvay®)	$0.31	$37.20	$446.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month based on the use of 0.4mg per day for each product.
ER = extended-release; sus = suspension; Unit = each mL or tablet

Recommendations

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

1. Prior authorization of Onyda™ XR (clonidine ER suspension) and placement into Tier-3 of the non-stimulants category based on net costs, with the additional criteria shown below; and
2. Moving Daytrana® (methylphenidate ER patch) from Tier-1 to Tier-2 based on net costs; and
3. Moving Vyvanse® (lisdexamfetamine) chewable tablets from Tier-1 to Tier-3 and removing the brand preferred status based on net costs, with the additional criteria shown below; and
4. Moving Dyanavel® XR (amphetamine ER tablet) from Tier-2 to Tier-3 based on net costs; and
5. Moving Adzenys XR-ODT® (amphetamine ER ODT) from the Special PA Tier to Tier-3 based on net costs; and
6. Updating the approval criteria for Kapvay® (clonidine ER tablet) based on clinical practice and net costs; and
7. Removing Adzenys ER™ (amphetamine ER suspension) based on product discontinuation.

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			~~**amphetamine ER susp (Adzenys ER™)**~~ ~~**amphetamine ER ODT (Adzenys XR-ODT®)**~~
Short-Acting			
amphetamine/ dextroamphetamine (Adderall®)			
Long-Acting			
amphetamine/ dextroamphetamine ER (Adderall XR®)	~~**amphetamine ER tab (Dyanavel® XR)**~~ dextroamphetamine ER (Dexedrine Spansules®)	**amphetamine ER ODT (Adzenys XR-ODT®)**	amphetamine (Evekeo®) amphetamine ODT (Evekeo ODT™)

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
lisdexamfetamine cap ~~**and chew tab**~~ (Vyvanse®)+ – **Brand Preferred**		amphetamine ER susp **and tab** (Dyanavel® XR) **lisdexamfetamine chew tab (Vyvanse®)**	amphetamine/ dextroamphetamine ER (Mydayis®) dextroamphetamine (Dexedrine®) dextroamphetamine soln (ProCentra®) dextroamphetamine (Xelstrym™) dextroamphetamine (Zenzedi®) methamphetamine (Desoxyn®) methylphenidate ER 72mg methylphenidate ER ODT (Cotempla XR-ODT®) methylphenidate ER (Relexxii®) methylphenidate chew tab (Methylin®) methylphenidate ER chew tab (QuilliChew ER®)
Methylphenidate			
Short-Acting			
dexmethylphenidate (Focalin®) methylphenidate tab and soln (Methylin®) methylphenidate (Ritalin®)			
Long-Acting			
dexmethylphenidate ER (Focalin XR®) – **Brand Preferred** methylphenidate ER (Concerta®) ~~**methylphenidate ER (Daytrana®) – Brand Preferred**~~ methylphenidate ER (Metadate CD®) methylphenidate ER (Metadate ER®) methylphenidate ER (Methylin ER®) methylphenidate ER (Ritalin SR®)	dexmethylphenidate ER (generic Focalin XR®) methylphenidate ER (Aptensio XR®) **methylphenidate ER (Daytrana®) – Brand Preferred** methylphenidate ER susp (Quillivant XR®) methylphenidate ER (Ritalin LA®)	methylphenidate ER (Adhansia XR®) methylphenidate ER (Jornay PM®) serdexmethylphen-idate/dexmethylphen-idate (Azstarys®)	
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)Δ	**clonidine ER susp (Onyda™ XR)Δ**	viloxazine (Qelbree®)Δ

*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). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
+Unique criteria applies for the diagnosis of binge eating disorder (BED).
ΔUnique criteria applies in addition to tier trial requirements.
ADHD = attention-deficit/hyperactivity disorder; cap = capsule; chew tab = chewable tablet; ER = extended-release; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tab = tablet

ADHD Medications Tier-2 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response:
    a. Trials should have been within the last 180 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
3. For Daytrana® patches, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
    a. Daytrana® patches are brand preferred. Approval of generic methylphenidate transdermal patches will require a patient-specific, clinically significant reason why brand name Daytrana® cannot be used.
4. For Quillivant XR®, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
5. Kapvay® Approval Criteria:
    a. An FDA approved diagnosis; and
    b. A previously failed trial~~s~~ (within the last 180 days) with a long-acting Tier-1 stimulant~~, Intuniv®, and Strattera®;~~ or non-stimulant unless contraindicated, that did not yield adequate results.~~; and~~
    ~~c. A patient-specific, clinically significant reason why the member cannot use clonidine immediate-release tablets must be provided.~~

ADHD Medications Tier-3 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response; and
3. A previously failed trial with at least 1 long-acting Tier-2 stimulant that resulted in an inadequate response:
    a. Trials should have been within the last 365 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and

doses should be included along with the signature from the physician; and

4. For Adzenys XR-ODT® and Dyanavel® XR oral suspension, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
5. Onyda™ XR Approval Criteria:
    a. An FDA approved diagnosis; and
    b. Member must be 6 years of age or older; and
    c. Previously failed trials (within the last 180 days) with a long-acting Tier-1 stimulant, Intuniv®, and Strattera®, unless contraindicated, that did not yield adequate results; and
    d. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use Kapvay® (clonidine ER tablet) must be provided.
6. For Vyvanse® chewable tablet, a patient-specific, clinically significant reason why the member cannot use brand Vyvanse capsules, even when opened and mixed with yogurt, water, or orange juice must be provided; and
    a. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. ~~Adzenys XR-ODT®, Adzenys ER™,~~ Cotempla XR-ODT®, Evekeo ODT™, QuilliChew ER®, and Xelstrym™ Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use all other available formulations of stimulant medications that can be used for members who cannot swallow capsules or tablets must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
2. Desoxyn®, Dexedrine®, Evekeo®, Methylphenidate ER 72mg Tablet, ProCentra®, Relexxii®, and Zenzedi® Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
3. Methylin® Chewable Tablets Approval Criteria:
    a. A covered diagnosis; and

b. A patient-specific, clinically significant reason why the member cannot use methylphenidate immediate-release tablets or oral solution must be provided; and
c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

4. Mydayis® Approval Criteria:
   a. A covered diagnosis; and
   b. Member must be 13 years of age or older; and
   c. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
5. Qelbree® Approval Criteria:
   a. An FDA approved diagnosis; and
   b. Member must be 6 years of age or older; and
   c. Previously failed trial (within the last 180 days) with atomoxetine or any ADHD medication, unless contraindicated, that did not yield adequate results; and
      i. Qelbree® will not require a prior authorization and claims will pay at the point of sale if the member has paid claims for atomoxetine or any ADHD medications within the past 180 days of claims history; and
   d. Member must not be taking a monoamine oxidase inhibitor (MAOI) or have taken an MAOI within the last 14 days; and
   e. Member must not be taking sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline) concomitantly with Qelbree®; and
   f. Quantity limits will apply based on FDA-approved dosing.

ADHD Medications Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum dose are not covered.
2. Prior authorization is required for all tiers for members older than 20 years of age and for members younger than 5 years of age. All prior authorization requests for members younger than 5 years of age must be reviewed by an Oklahoma Health Care Authority (OHCA)- or SoonerSelect health plan-contracted psychiatrist.
3. For ~~Daytrana® patches,~~ Methylin® oral solution, ~~and Vyvanse® chewable tablet,~~ an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.~~; and~~
   ~~a. Daytrana® patches and Vyvanse® chewable tablets are brand preferred. Approval of generic methylphenidate transdermal patches or lisdexamfetamine chewable tablets will require a~~

~~patient-specific, clinically significant reason why brand name Daytrana® or Vyvanse® cannot be used.~~

4. Vyvanse® Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:
   a. An FDA approved diagnosis of moderate-to-severe BED; and
   b. Member must be 18 years of age or older; and
   c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and
   d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and
   e. Vyvanse® capsules are brand preferred. Approval of generic lisdexamfetamine capsules will require a patient-specific, clinically significant reason why brand name Vyvanse® cannot be used; and
   f. A quantity limit of 30 capsules ~~or chewable tablets~~ per 30 days will apply; and
   g. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.

Utilization Details of ADHD and Narcolepsy Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LISDEXAMFETAMINE PRODUCTS						
VYVANSE CAP 30MG	20,802	5,644	$7,489,421.41	$360.03	3.69	13.71%
VYVANSE CAP 40MG	16,781	3,869	$6,027,419.17	$359.18	4.34	11.03%
VYVANSE CAP 20MG	16,761	5,036	$5,987,591.84	$357.23	3.33	10.96%
VYVANSE CAP 50MG	11,395	2,471	$4,069,060.79	$357.09	4.61	7.45%
VYVANSE CAP 10MG	7,364	2,812	$2,608,663.08	$354.25	2.62	4.77%
VYVANSE CAP 60MG	5,934	1,341	$2,141,209.09	$360.84	4.43	3.92%
VYVANSE CAP 70MG	3,732	789	$1,341,634.08	$359.49	4.73	2.46%
LISDEXAMFET CAP 30MG	598	445	$93,273.81	$155.98	1.34	0.17%
LISDEXAMFET CAP 40MG	493	365	$73,453.89	$148.99	1.35	0.13%
VYVANSE CHW 10MG	471	237	$168,531.10	$357.82	1.99	0.31%
LISDEXAMFET CAP 50MG	420	281	$61,402.16	$146.20	1.49	0.11%
LISDEXAMFET CAP 20MG	395	299	$59,757.62	$151.29	1.32	0.11%
VYVANSE CHW 20MG	357	161	$126,051.46	$353.09	2.22	0.23%
LISDEXAMFET CAP 60MG	286	205	$47,055.29	$164.53	1.4	0.09%
LISDEXAMFET CAP 70MG	237	166	$47,010.52	$198.36	1.43	0.09%
LISDEXAMFET CAP 10MG	181	138	$27,831.52	$153.77	1.31	0.05%
VYVANSE CHW 30MG	143	67	$51,120.12	$357.48	2.13	0.09%
VYVANSE CHW 40MG	89	32	$30,356.86	$341.09	2.78	0.06%
VYVANSE CHW 50MG	46	11	$14,443.74	$313.99	4.18	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LISDEXAMFET CHW 20MG	21	16	$4,998.11	$238.01	1.31	0.01%
LISDEXAMFET CHW 10MG	21	16	$4,894.74	$233.08	1.31	0.01%
LISDEXAMFET CHW 30MG	17	13	$4,198.43	$246.97	1.31	0.01%
VYVANSE CHW 60MG	12	5	$4,155.37	$346.28	2.4	0.01%
LISDEXAMFET CHW 40MG	1	1	$241.19	$241.19	1	0.00%
SUBTOTAL	**86,557**	**16,391***	**$30,483,775.39**	**$352.18**	**5.28**	**55.79%**
METHYLPHENIDATE PRODUCTS						
METHYLPHENID TAB 10MG	8,738	2,230	$153,828.88	$17.60	3.92	0.28%
METHYLPHENID TAB 5MG	7,808	2,357	$127,166.27	$16.29	3.31	0.23%
METHYLPHENID CAP 20MG	7,035	2,072	$306,503.67	$43.57	3.4	0.56%
METHYLPHENID CAP 30MG	6,111	1,499	$277,870.87	$45.47	4.08	0.51%
METHYLPHENID TAB 20MG	3,935	931	$72,115.26	$18.33	4.23	0.13%
METHYLPHENID CAP 10MG	3,902	1,554	$160,593.10	$41.16	2.51	0.29%
METHYLPHENID CAP 40MG ER	3,871	902	$212,567.55	$54.91	4.29	0.39%
METHYLPHENID TAB 36MG ER	3,188	848	$118,517.12	$37.18	3.76	0.22%
METHYLPHENID TAB 54MG ER	2,221	519	$70,345.23	$31.67	4.28	0.13%
METHYLPHENID TAB 27MG ER	1,975	665	$60,978.88	$30.88	2.97	0.11%
METHYLPHENID CAP 50MG	1,840	371	$112,131.74	$60.94	4.96	0.21%
METHYLPHENID TAB 18MG ER	1,526	702	$45,966.79	$30.12	2.17	0.08%
METHYLPHENID CAP 60MG	1,443	259	$92,819.97	$64.32	5.57	0.17%
METHYLPHENID CAP 20MG ER	1,368	405	$72,968.04	$53.34	3.38	0.13%
METHYLPHENID TAB 20MG ER	1,196	365	$31,085.94	$25.99	3.28	0.06%
METHYLPHENID CAP 30MG ER	992	271	$70,959.68	$71.53	3.66	0.13%
CONCERTA TAB 36MG	984	313	$492,084.42	$500.09	3.14	0.90%
METHYLPHENID SOL 5MG/5ML	862	276	$33,677.68	$39.07	3.12	0.06%
METHYLPHENID CAP 40MG ER	779	207	$49,220.57	$63.18	3.76	0.09%
CONCERTA TAB 54MG	652	195	$278,987.30	$427.89	3.34	0.51%
QUILLIVANT SUS 25MG/5ML	578	118	$244,645.15	$423.26	4.9	0.45%
METHYLPHENID TAB 10MG ER	567	235	$12,215.44	$21.54	2.41	0.02%
METHYLPHENID CAP 10MG ER	539	215	$47,783.74	$88.65	2.51	0.09%
CONCERTA TAB 27MG	512	183	$195,841.47	$382.50	2.8	0.36%
CONCERTA TAB 18MG	463	210	$165,133.09	$356.66	2.2	0.30%
METHYLPHENID SOL 10MG/5ML	444	118	$21,375.98	$48.14	3.76	0.04%
APTENSIO XR CAP 40MG	364	105	$93,126.54	$255.84	3.47	0.17%
METHYLPHENID CAP 40MG ER	342	134	$61,765.74	$180.60	2.55	0.11%
METHYLPHENID CAP 30MG ER	336	142	$54,682.92	$162.75	2.37	0.10%
APTENSIO XR CAP 30MG	326	101	$84,725.44	$259.89	3.23	0.16%
JORNAY PM CAP 60MG ER	295	66	$121,081.93	$410.45	4.47	0.22%
APTENSIO XR CAP 20MG	258	88	$65,756.94	$254.87	2.93	0.12%
METHYLPHENID CAP 60MG ER	257	70	$49,411.75	$192.26	3.67	0.09%
JORNAY PM CAP 40MG ER	244	62	$100,199.73	$410.65	3.94	0.18%
APTENSIO XR CAP 50MG	218	61	$56,410.00	$258.76	3.57	0.10%
METHYLPHENID TAB 18MG ER	196	128	$6,103.12	$31.14	1.53	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
APTENSIO XR CAP 60MG	195	46	$50,117.61	$257.01	4.24	0.09%
METHYLPHENID CAP 50MG ER	193	83	$36,514.60	$189.19	2.33	0.07%
METHYLPHENID CAP 20MG ER	193	107	$35,442.62	$183.64	1.8	0.06%
METHYLIN SOL 5MG/5ML	157	59	$7,404.19	$47.16	2.66	0.01%
METHYLPHENID TAB 72MG ER	142	28	$66,980.87	$471.70	5.07	0.12%
METHYLPHENID DIS 10MG/9HR	130	63	$47,746.97	$367.28	2.06	0.09%
DAYTRANA DIS 30MG/9HR	128	32	$39,310.68	$307.11	4	0.07%
METHYLPHENID DIS 15MG/9HR	123	46	$41,188.28	$334.86	2.67	0.08%
JORNAY PM CAP 80MG ER	121	30	$49,531.52	$409.35	4.03	0.09%
METHYLPHENID CAP 15MG ER	118	56	$20,072.90	$170.11	2.11	0.04%
JORNAY PM CAP 20MG ER	114	45	$49,318.16	$432.62	2.53	0.09%
JORNAY PM CAP 100MG ER	111	21	$47,279.76	$425.94	5.29	0.09%
APTENSIO XR CAP 10MG	108	43	$27,898.92	$258.32	2.51	0.05%
METHYLPHENID DIS 20MG/9HR	105	35	$39,347.29	$374.74	3	0.07%
DAYTRANA DIS 10MG/9HR	94	37	$24,693.02	$262.69	2.54	0.05%
APTENSIO XR CAP 15MG	83	37	$20,998.78	$253.00	2.24	0.04%
DAYTRANA DIS 15MG/9HR	73	28	$19,413.91	$265.94	2.61	0.04%
METHYLPHENID CAP 10MG ER	71	40	$11,051.32	$155.65	1.78	0.02%
METHYLPHENID DIS 30MG/9HR	66	14	$24,359.72	$369.09	4.71	0.04%
QUILLICHEW CHW 20MG ER	51	15	$18,051.64	$353.95	3.4	0.03%
DAYTRANA DIS 20MG/9HR	45	16	$12,409.25	$275.76	2.81	0.02%
METHYLIN SOL 10MG/5ML	41	12	$2,645.66	$64.53	3.42	0.00%
QUILLICHEW CHW 30MG ER	40	10	$15,566.17	$389.15	4	0.03%
RITALIN LA CAP 10MG	34	18	$11,948.32	$351.42	1.89	0.02%
METHYLPHENID TAB 27MG ER	27	19	$835.80	$30.96	1.42	0.00%
METHYLPHENID CAP 60MG LA	27	12	$6,854.42	$253.87	2.25	0.01%
QUILLICHEW CHW 40MG ER	27	5	$9,853.56	$364.95	5.4	0.02%
METHYLPHENID TAB 45MG ER	25	8	$14,428.32	$577.13	3.13	0.03%
METHYLPHENID TAB 54MG ER	15	12	$504.09	$33.61	1.25	0.00%
METHYLPHENID TAB 36MG ER	15	14	$478.41	$31.89	1.07	0.00%
METHYLPHENID CHW 5MG	14	8	$2,064.39	$147.46	1.75	0.00%
METHYLPHENID CHW 2.5MG	11	5	$683.03	$62.09	2.2	0.00%
RITALIN TAB 20MG	10	4	$1,243.48	$124.35	2.5	0.00%
METHYLPHENID TAB 63MG ER	5	2	$3,080.45	$616.09	2.5	0.01%
RITALIN TAB 10MG	4	3	$166.24	$41.56	1.33	0.00%
RITALIN LA CAP 40MG	4	3	$1,494.24	$373.56	1.33	0.00%
METHYLPHENID CHW 10MG	1	1	$91.12	$91.12	1	0.00%
RITALIN TAB 5MG	1	1	$76.81	$76.81	1	0.00%
RITALIN LA CAP 20MG	1	1	$376.03	$376.03	1	0.00%
RELEXXII TAB 27MG ER	1	1	$351.27	$351.27	1	0.00%
SUBTOTAL	**69,089**	**12,120***	**$4,982,521.76**	**$72.12**	**5.7**	**9.12%**
AMPHETAMINE/DEXTROAMPHETAMINE PRODUCTS						
AMPHET/DEXTR TAB 20MG	10,877	2,332	$272,920.27	$25.09	4.66	0.50%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AMPHET/DEXTR TAB 10MG	10,611	2,945	$217,040.58	$20.45	3.6	0.40%
AMPHET/DEXTR TAB 5MG	6,579	1,976	$126,394.73	$19.21	3.33	0.23%
AMPHET/DEXTR TAB 30MG	4,939	1,021	$118,568.30	$24.01	4.84	0.22%
AMPHET/DEXTR CAP 20MG ER	4,715	1,423	$122,052.50	$25.89	3.31	0.22%
AMPHET/DEXTR CAP 30MG ER	4,489	1,017	$111,526.49	$24.84	4.41	0.20%
AMPHET/DEXTR CAP 10MG ER	4,290	1,550	$103,957.35	$24.23	2.77	0.19%
AMPHET/DEXTR TAB 15MG	3,562	907	$76,246.28	$21.41	3.93	0.14%
AMPHET/DEXTR CAP 15MG ER	3,022	950	$79,025.50	$26.15	3.18	0.14%
AMPHET/DEXTR CAP 25MG ER	2,243	557	$54,850.61	$24.45	4.03	0.10%
AMPHET/DEXTR CAP 5MG ER	1,206	547	$29,308.88	$24.30	2.2	0.05%
AMPHET/DEXTR TAB 7.5MG	670	165	$17,254.25	$25.75	4.06	0.03%
AMPHET/DEXTR TAB 12.5MG	359	85	$11,007.09	$30.66	4.22	0.02%
ADDERALL XR CAP 30MG	119	59	$25,366.35	$213.16	2.02	0.05%
ADDERALL XR CAP 20MG	81	40	$17,149.15	$211.72	2.03	0.03%
ADDERALL XR CAP 25MG	53	22	$9,464.62	$178.58	2.41	0.02%
ADDERALL XR CAP 15MG	35	22	$7,869.11	$224.83	1.59	0.01%
ADDERALL XR CAP 10MG	27	19	$5,588.31	$206.97	1.42	0.01%
MYDAYIS CAP 25MG	21	5	$6,084.95	$289.76	4.2	0.01%
ADDERALL TAB 15MG	17	3	$8,334.71	$490.28	5.67	0.02%
AMPHET/DEXTR CAP 37.5 ER	13	5	$2,077.38	$159.80	2.6	0.00%
AMPHET/DEXTR CAP 25MG ER	12	5	$3,101.68	$258.47	2.4	0.01%
MYDAYIS CAP 50MG	12	3	$4,030.29	$335.86	4	0.01%
ADDERALL TAB 20MG	11	4	$5,790.07	$526.37	2.75	0.01%
ADDERALL XR CAP 5MG	8	6	$1,552.44	$194.06	1.33	0.00%
ADDERALL TAB 30MG	6	4	$3,395.97	$566.00	1.5	0.01%
MYDAYIS CAP 37.5MG	6	3	$2,010.67	$335.11	2	0.00%
AMPHET/DEXTR CAP 50MG ER	5	3	$1,359.27	$271.85	1.67	0.00%
MYDAYIS CAP 12.5MG	3	2	$836.34	$278.78	1.5	0.00%
AMPHET/DEXTR CAP 12.5 ER	2	2	$570.68	$285.34	1	0.00%
SUBTOTAL	**57,993**	**11,214***	**$1,444,734.82**	**$24.91**	**5.17**	**2.64%**
GUANFACINE ER PRODUCTS						
GUANFACINE TAB 2MG ER	18,600	4,392	$342,234.03	$18.40	4.23	0.63%
GUANFACINE TAB 1MG ER	15,850	5,198	$284,428.72	$17.95	3.05	0.52%
GUANFACINE TAB 3MG ER	12,126	2,404	$223,236.12	$18.41	5.04	0.41%
GUANFACINE TAB 4MG ER	9,002	1,450	$167,629.88	$18.62	6.21	0.31%
INTUNIV TAB 4MG	27	3	$7,508.40	$278.09	9	0.01%
INTUNIV TAB 2MG	12	2	$4,069.59	$339.13	6	0.01%
INTUNIV TAB 3MG	10	1	$2,946.05	$294.61	10	0.01%
SUBTOTAL	**55,627**	**10,211***	**$1,032,052.79**	**$18.55**	**5.45**	**1.89%**
ATOMOXETINE PRODUCTS						
ATOMOXETINE CAP 40MG	11,752	3,890	$372,903.23	$31.73	3.02	0.68%
ATOMOXETINE CAP 25MG	9,606	3,139	$267,764.61	$27.87	3.06	0.49%
ATOMOXETINE CAP 18MG	5,365	1,911	$168,402.47	$31.39	2.81	0.31%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ATOMOXETINE CAP 60MG	4,959	1,268	$151,127.07	$30.48	3.91	0.28%
ATOMOXETINE CAP 10MG	4,266	1,603	$132,020.43	$30.95	2.66	0.24%
ATOMOXETINE CAP 80MG	2,738	798	$95,678.11	$34.94	3.43	0.18%
ATOMOXETINE CAP 100MG	1,046	268	$37,248.16	$35.61	3.9	0.07%
STRATTERA CAP 40MG	23	2	$9,841.01	$427.87	11.5	0.02%
STRATTERA CAP 100MG	2	1	$944.57	$472.29	2	0.00%
STRATTERA CAP 18MG	1	1	$389.24	$389.24	1	0.00%
SUBTOTAL	**39,758**	**9,389***	**$1,236,318.90**	**$31.10**	**4.23**	**2.26%**
DEXMETHYLPHENIDATE PRODUCTS						
FOCALIN XR CAP 10MG	5,684	1,855	$1,950,555.19	$343.17	3.06	3.57%
FOCALIN XR CAP 20MG	5,454	1,337	$1,983,027.17	$363.59	4.08	3.63%
FOCALIN XR CAP 15MG	5,215	1,381	$1,860,498.94	$356.76	3.78	3.40%
DEXMETHYLPHE TAB 10MG	4,809	1,129	$98,025.12	$20.38	4.26	0.18%
DEXMETHYLPHE TAB 5MG	4,478	1,280	$76,592.55	$17.10	3.5	0.14%
FOCALIN XR CAP 5MG	3,086	1,179	$1,066,851.56	$345.71	2.62	1.95%
FOCALIN XR CAP 30MG	2,981	619	$1,030,391.14	$345.65	4.82	1.89%
FOCALIN XR CAP 25MG	2,768	598	$1,049,049.22	$378.99	4.63	1.92%
DEXMETHYLPHE TAB 2.5MG	1,629	513	$26,599.88	$16.33	3.18	0.05%
FOCALIN XR CAP 40MG	1,336	231	$520,041.70	$389.25	5.78	0.95%
FOCALIN XR CAP 35MG	720	141	$284,418.18	$395.03	5.11	0.52%
DEXMETHYLPHE CAP 10MG ER	312	212	$12,059.95	$38.65	1.47	0.02%
DEXMETHYLPHE CAP 20MG ER	302	166	$14,870.08	$49.24	1.82	0.03%
DEXMETHYLPHE CAP 15MG ER	172	118	$6,447.39	$37.48	1.46	0.01%
DEXMETHYLPHE CAP ER 25MG	133	72	$8,353.66	$62.81	1.85	0.02%
DEXMETHYLPHE CAP 5MG ER	116	87	$4,758.16	$41.02	1.33	0.01%
DEXMETHYLPHE CAP 30MG ER	97	59	$4,182.41	$43.12	1.64	0.01%
FOCALIN TAB 10MG	61	23	$4,330.50	$70.99	2.65	0.01%
DEXMETHYLPHE CAP 40MG ER	55	23	$2,961.87	$53.85	2.39	0.01%
DEXMETHYLPHE CAP ER 35MG	31	16	$2,413.34	$77.85	1.94	0.00%
FOCALIN TAB 5MG	24	17	$1,292.25	$53.84	1.41	0.00%
FOCALIN TAB 2.5MG	9	5	$299.34	$33.26	1.8	0.00%
SUBTOTAL	**39,472**	**6,525***	**$10,008,019.60**	**$253.55**	**6.05**	**18.31%**
VILOXAZINE PRODUCTS						
QELBREE CAP 200MG ER	3,315	902	$1,586,248.73	$478.51	3.68	2.90%
QELBREE CAP 100MG ER	1,397	513	$470,327.52	$336.67	2.72	0.86%
QELBREE CAP 150MG ER	648	195	$314,129.49	$484.77	3.32	0.57%
SUBTOTAL	**5,360**	**1,257***	**$2,370,705.74**	**$442.30**	**4.26**	**4.34%**
CLONIDINE ER PRODUCTS						
CLONIDINE TAB 0.1MG ER	1,026	205	$29,703.35	$28.95	5	0.05%
SUBTOTAL	**1,026**	**205***	**$29,703.35**	**$28.95**	**5**	**0.05%**
MODAFINIL PRODUCTS						
MODAFINIL TAB 200MG	277	91	$7,508.68	$27.11	3.04	0.01%
MODAFINIL TAB 100MG	80	50	$1,438.45	$17.98	1.6	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PROVIGIL TAB 200MG	8	1	$34,319.26	$4,289.91	8	0.06%
SUBTOTAL	**365**	**136***	**$43,266.39**	**$118.54**	**2.68**	**0.08%**
ARMODAFINIL PRODUCTS						
NUVIGIL TAB 250MG	145	31	$146,258.95	$1,008.68	4.68	0.27%
NUVIGIL TAB 150MG	68	23	$81,953.68	$1,205.20	2.96	0.15%
ARMODAFINIL TAB 250MG	43	19	$1,520.87	$35.37	2.26	0.00%
NUVIGIL TAB 200MG	42	9	$44,715.92	$1,064.66	4.67	0.08%
ARMODAFINIL TAB 150MG	20	15	$725.63	$36.28	1.33	0.00%
ARMODAFINIL TAB 200MG	10	7	$292.90	$29.29	1.43	0.00%
ARMODAFINIL TAB 50MG	3	2	$48.77	$16.26	1.5	0.00%
NUVIGIL TAB 50MG	1	1	$374.81	$374.81	1	0.00%
SUBTOTAL	**332**	**84***	**$275,891.53**	**$831.00**	**3.95**	**0.50%**
DEXMETHYLPHENIDATE/SERDEXMETHYLPHENIDATE PRODUCTS						
AZSTARYS CAP 39.2-7.8MG	127	40	$48,370.49	$380.87	3.18	0.09%
AZSTARYS CAP 52.3-10.4MG	68	16	$26,573.79	$390.79	4.25	0.05%
AZSTARYS CAP 26.1-5.2MG	50	21	$20,211.84	$404.24	2.38	0.04%
SUBTOTAL	**245**	**55***	**$95,156.12**	**$388.39**	**4.45**	**0.17%**
AMPHETAMINE PRODUCTS						
DYANAVEL XR SUS 2.5MG/ML	65	15	$22,091.70	$339.87	4.33	0.04%
DYANAVEL XR TAB 10MG	37	11	$15,850.32	$428.39	3.36	0.03%
DYANAVEL XR TAB 15MG	34	9	$14,148.29	$416.13	3.78	0.03%
ADZENYS XR TAB 18.8MG	20	2	$9,492.23	$474.61	10	0.02%
DYANAVEL XR TAB 5MG	13	9	$2,943.36	$226.41	1.44	0.01%
DYANAVEL XR TAB 20MG	12	5	$5,114.10	$426.18	2.4	0.01%
AMPHETAMINE TAB 10MG	12	4	$376.06	$31.34	3	0.00%
ADZENYS XR TAB 6.3MG	8	2	$3,814.19	$476.77	4	0.01%
ADZENYS XR TAB 9.4MG	2	1	$983.28	$491.64	2	0.00%
SUBTOTAL	**203**	**46***	**$74,813.53**	**$368.54**	**4.41**	**0.14%**
DEXTROAMPHETAMINE PRODUCTS						
DEXTROAMPHET CAP 15MG ER	55	14	$4,531.62	$82.39	3.93	0.01%
DEXTROAMPHET CAP 10MG ER	23	6	$748.84	$32.56	3.83	0.00%
DEXTROAMPHET TAB 5MG	20	6	$475.02	$23.75	3.33	0.00%
DEXTROAMPHET TAB 10MG	18	9	$503.89	$27.99	2	0.00%
DEXTROAMPHET TAB 30MG	9	3	$2,136.00	$237.33	3	0.00%
DEXTROAMPHET TAB 20MG	5	3	$940.31	$188.06	1.67	0.00%
DEXTROAMPHET TAB 15MG	3	3	$1,124.83	$374.94	1	0.00%
ZENZEDI TAB 30MG	2	1	$502.23	$251.12	2	0.00%
DEXTROAMPHET CAP 5MG ER	2	2	$74.59	$37.30	1	0.00%
PROCENTRA SOL 5MG/5ML	1	1	$47.30	$47.30	1	0.00%
ZENZEDI TAB 20MG	1	1	$227.96	$227.96	1	0.00%
XELSTRYM DIS 13.5MG/9HR	1	1	$497.57	$497.57	1	0.00%
ZENZEDI TAB 15MG	1	1	$452.51	$452.51	1	0.00%
SUBTOTAL	**141**	**43***	**$12,262.67**	**$86.97**	**3.28**	**0.02%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SODIUM OXYBATE PRODUCTS						
XYREM SOL 500MG/ML	50	10	$831,426.50	$16,628.53	5	1.52%
SOD OXYBATE SOL 500MG/ML	19	3	$237,736.56	$12,512.45	6.33	0.44%
SUBTOTAL	**69**	**12***	**$1,069,163.06**	**$15,495.12**	**5.75**	**1.96%**
PITOLISANT PRODUCTS						
WAKIX TAB 17.8MG	57	10	$672,332.82	$11,795.31	5.7	1.23%
WAKIX TAB 4.45MG	6	6	$10,500.12	$1,750.02	1	0.02%
SUBTOTAL	**63**	**10***	**$682,832.94**	**$10,838.62**	**6.3**	**1.25%**
CALCIUM/MAGNESIUM/POTASSIUM/SODIUM OXYBATES PRODUCTS						
XYWAV SOL 0.5GM/ML	56	9	$759,023.55	$13,553.99	6.22	1.39%
SUBTOTAL	**56**	**9***	**$759,023.55**	**$13,553.99**	**6.22**	**1.39%**
SOLRIAMFETOL PRODUCTS						
SUNOSI TAB 150MG	47	13	$38,808.53	$825.71	3.62	0.07%
SUNOSI TAB 75MG	7	3	$5,919.70	$845.67	2.33	0.01%
SUBTOTAL	**54**	**15***	**$44,728.23**	**$828.30**	**3.6**	**0.08%**
TOTAL	**356,410**	**50,895***	**$54,644,970.37**	**$153.32**	**7**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AMPHET/DEXTR = amphetamine/dextroamphetamine; CAP = capsule; CHW = chewable tablet; DEXMETHYLPHE = dexmethylphenidate; DEXTROAMPHET = dextroamphetamine; DIS = patch; ER = extended-release; HR = hour; LA = long-acting; LISDEXAMFET = lisdexamfetamine; METHYLPHENID = methylphenidate; SOD = sodium; SOL = solution; SUS = suspension; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 04/2025. Last accessed 04/29/2025.
[2] Tris Pharma, Inc. Tris Pharma Receives U.S. FDA Approval for Once-Daily Onyda™ XR (Clonidine Hydrochloride) Extended-Release Oral Suspension, the First-and-Only Liquid Non-Stimulant ADHD Medication. Available online at: https://www.trispharma.com/tris-pharma-receives-u-s-fda-approval-for-once-daily-onyda-xr-clonidine-hydrochloride-extended-release-oral-suspension-the-first-and-only-liquid-non-stimulant-adhd-medication/. Issued 05/29/2024. Last accessed 04/18/2025.
[3] U.S. FDA. Onyda™ XR NDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/217645Orig1s000ltr.pdf. Issued 05/24/2024. Last accessed 04/18/2025.
[4] Harmony Biosciences. Harmony Biosciences Receives U.S. Food and Drug Administration Approval for Wakix® (Pitolisant) in Pediatric Patients with Narcolepsy. Available online at: https://ir.harmonybiosciences.com/news-releases/news-release-details/harmony-biosciences-receives-us-food-and-drug-administration-0. Issued 06/24/2024. Last accessed 04/29/2025.
[5] Onyda™ XR (Clonidine Hydrochloride Extended-Release Oral Suspension) Prescribing Information. Tris Pharma, Inc. Available online at: https://www.trispharma.com/generic/ONYDA%20XR%20Full%20Prescribing%20Information.pdf. Last revised 07/2024. Last accessed 04/15/2025.

Appendix O

30-Day Notice to Prior Authorize Sofdra™ (Sofpironium 12.45% Topical Gel)

Oklahoma Health Care Authority
May 2025

Introduction[1,2,3,4]

Primary axillary hyperhidrosis is a chronic skin disorder characterized by idiopathic sweating in the underarms (axillae) beyond what is needed to maintain normal body temperature. The etiology of primary hyperhidrosis is thought to be over-activity of the sympathetic nervous system in localized regions. Sweating can range in severity from mild dampness to dripping. These symptoms can have detrimental effects for patients on social interactions, confidence, physical comfort, and mental health. A 2016 epidemiological survey estimated the prevalence of primary hyperhidrosis in the United States at 15.3 million people (4.8%), including 1.5 million people (2.1%) younger than 18 years of age. Furthermore, 65% of the 8,160 survey respondents specifically reported axillary hyperhidrosis.

The International Hyperhidrosis Society, an independent, non-profit organization, and the American Academy of Dermatology (AAD) recommend utilizing conservative topical therapies to treat primary axillary hyperhidrosis before escalating to more invasive options (e.g., onabotulinumtoxinA injections, microwave thermolysis, local sweat gland ablation). Initial therapeutic agents include over-the-counter (OTC) or prescription strength topical products containing aluminum salts, such as aluminum chloride hexahydrate in varying strengths. If these treatments fail to provide adequate relief, topical or systemic anticholinergic medications are additional non-invasive therapy options. In June 2024, the U.S. Food and Drug Administration (FDA) approved the topical anticholinergic medication Sofdra™ (sofpironium 12.45% topical gel) for the treatment of primary axillary hyperhidrosis in patients 9 years of age and older.

Sofdra™ (Sofpironium 12.45% Topical Gel) Product Summary[5,6]

Therapeutic Class: Topical anticholinergic

Indication(s): Treatment of primary axillary hyperhidrosis in adult and pediatric patients 9 years of age and older

How Supplied: Topical gel in a multi-dose metered pump bottle containing 60 pump actuations (0.67mL per actuation) with an applicator

Dosing and Administration:

- 1 pump actuation topically per underarm once daily at bedtime
- Underarms should not be washed for at least 30 minutes before and 8 hours after application
- Underarms should not be shaved at least 8 hours before application
- Use of occlusive dressings should be avoided

Efficacy: The safety and efficacy of Sofdra™ were evaluated in a pooled analysis of 2 randomized, vehicle-controlled multicenter trials, CARDIGAN 1 and CARDIGAN 2, that included a total of 701 patients.

- Key Inclusion Criteria:
  - 9 years of age and older with primary axillary hyperhidrosis
  - Symptoms of axillary hyperhidrosis for ≥6 months
  - Produce ≥50mg of sweat in each underarm with a combined total of ≥150mg over a 5-minute period
  - Hyperhidrosis Disease Severity Measure-Axillary 7-item (HDSM-Ax-7) score ≥3
- Intervention(s):
  - Patients were randomized to receive Sofdra™ or inert vehicle applied once daily a bedtime to each underarm
- Primary Endpoint(s):
  - Proportion of patients having ≥2-point improvement in the HDSM-Ax-7 score from baseline to day 43
  - Change in median gravimetric sweat production (GSP) from baseline to day 43
- Results:
  - 56.3% (N=353) in the Sofdra™ group vs. 37.3% (N=348) in the vehicle group achieved the HDSM-Ax-7 score endpoint (difference: 19%; P<0.0001).
  - The median change in GSP from baseline to day 43 was -138.1mg/5 minutes in the Sofdra™ group vs. -114.5mg/5 minutes in the vehicle group (difference: -23.6mg/5 minutes; P=0.0002).

Cost: The Wholesale Acquisition Cost (WAC) of Sofdra™ is $967.50 per bottle, resulting in a cost of $967.50 per month or $11,640 per year based on recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Sofdra™ (sofpironium 12.45% topical gel) with the following criteria (shown in red):

Sofdra™ (Sofpironium 12.45% Topical Gel) Approval Criteria:

1. An FDA approved diagnosis of primary axillary hyperhidrosis; and
2. Member must be 9 to 20 years of age; and
3. Documentation of assessment by a licensed behavior specialist or the prescribing physician indicating the member's hyperhidrosis is causing social anxiety, depression, or similar mental health-related issues that impact the member's ability to function in day-to-day living must be provided; and
4. Member must have failed a trial, at least 3 weeks in duration, with the following:
    a. Xerac® AC (aluminum chloride hexahydrate 6.25% topical solution) or at least 1 over-the-counter Certain Dri® product; and
    b. Drysol® (aluminum chloride 20% topical solution); and
5. Prescriber must verify that the member has received counseling on the safe and proper use of Sofdra™; and
6. A quantity limit of 40.2mL per 30 days will apply; and
7. Initial approvals will be for the duration of 3 months. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

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[1] Doolittle J, Walker P, Mills T, Thurston J. Hyperhidrosis: An Update on Prevalence and Severity in the United States. *Arch Dermatol Res* 2016; 308:743-749. doi: 10.1007/s00403-016-1697-9.
[2] International Hyperhidrosis Society. Primary Focal Axillary Hyperhidrosis. Available online at: https://www.sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-axillary.html. Last revised 2025. Last accessed 04/17/2025.
[3] American Academy of Dermatology Association. Hyperhidrosis: Diagnosis and Treatment. Available online at: https://www.aad.org/public/diseases/a-z/hyperhidrosis-treatment. Last revised 07/16/2024. Last accessed 04/17/2025.
[4] Botanix Pharmaceuticals. FDA Approval of Sofdra™ - The First New Drug for Primary Axillary Hyperhidrosis. Available online at: https://cdn-api.markitdigital.com/apiman-gateway/ASX/asx-research/1.0/file/2924-02819259-6A1212299. Issued 06/20/2024. Last accessed 04/17/2025.
[5] Sofdra™ (Sofpironium) Topical Gel, 12.45% Prescribing Information. Botanix SB Inc. Available online: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217347s000lbl.pdf. Last revised 06/18/2024. Last accessed 04/17/2025.
[6] Pariser D, Glaser DA, Rosso JD, et al. Sofpironium Topical Gel, 12.45%, for the Treatment of Axillary Hyperhidrosis: Pooled Efficacy and Safety Results from 2 Phase 3 Randomized, Controlled, Double-Blind Studies. *J Am Acad Dermatol.* 2025; S0190-9622(25):393-397. doi: 10.1016/j.jaad.2025.02.086.

Appendix P

Fiscal Year 2024 Annual Review of Age-Related Macular Degeneration (AMD) Medications and 30-Day Notice to Prior Authorize Enzeevu™ (aflibercept-abzv), Opuviz™ (aflibercept-yszy), and Yesafili™ (aflibercept-jbvf)

Oklahoma Health Care Authority
May 2025

Current Prior Authorization Criteria

Izervay™ (Avacincaptad Pegol) Approval Criteria:

1. An FDA approved indication for the treatment of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD); and
2. Member must not have ocular or periocular infections or active intraocular inflammation; and
3. Izervay™ must be prescribed and administered by an ophthalmologist, or a physician experienced in intravitreal injections; and
4. Prescribers must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, and neovascular (wet) AMD; and
5. A patient specific, clinically significant reason why the member cannot use Syfovre® (pegcetacoplan) must be provided; and
6. A quantity limit of (1) 0.1mL single-dose vial per eye once monthly for up to 12 months will apply.

Susvimo™ (Ranibizumab Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of neovascular (wet) age-related macular degeneration (AMD) in adults; and
2. Member must have previously responded to ≥2 intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor; and
3. Member must not have ocular or periocular infections or active intraocular inflammation; and
4. Susvimo™ must be prescribed and administered by an ophthalmologist or a physician experienced in vitreoretinal surgery; and
5. Prescriber must verify the member will be monitored for endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, and conjunctival blebs; and
6. A patient-specific, clinically significant reason why the member cannot use ranibizumab intravitreal injection or other VEGF inhibitor injection products (appropriate to disease state) available without prior

authorization [i.e., Beovu® (brolucizumab-dbll), Byooviz™ (ranibizumab-nuna), Cimerli® (ranibizumab-eqrn), Eylea®/Eylea® HD (aflibercept), Lucentis® (ranibizumab)] must be provided; and
7. A quantity limit of one 100mg/0.1mL single-dose vial per 180 days will apply.

Syfovre® (Pegcetacoplan) Approval Criteria:
1. An FDA approved indication for the treatment of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD); and
2. Member must not have ocular or periocular infections or active intraocular inflammation; and
3. Syfovre® must be prescribed and administered by an ophthalmologist, or a physician experienced in intravitreal injections; and
4. Prescriber must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, intraocular inflammation, and neovascular (wet) AMD; and
5. A quantity limit of (1) 0.1mL single-dose vial per eye every 25 to 60 days will apply.

Vabysmo® (Faricimab-svoa Intravitreal Injection) Approval Criteria:
1. An FDA approved diagnosis of 1 of the following:
   a. Neovascular (wet) age-related macular degeneration (AMD); or
   b. Diabetic macular edema (DME); or
   c. Macular edema following retinal vein occlusion (RVO); and
2. Member must be 18 years of age or older; and
3. Member must not have ocular or periocular infections or active intraocular inflammation; and
4. Vabysmo® must be prescribed and administered by an ophthalmologist or a physician experienced in vitreoretinal injections; and
5. Prescriber must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, and arterial thromboembolic events, and
6. Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 3 months after the final dose of Vabysmo®; and
7. A patient-specific, clinically significant reason why the member cannot use VEGF inhibitor injection products (appropriate to the disease state) available without prior authorization [i.e., Beovu® (brolucizumab-dbll), Byooviz™ (ranibizumab-nuna), Cimerli® (ranibizumab-eqrn), Eylea®/Eylea® HD (aflibercept), Lucentis® (ranibizumab)] must be provided; and
8. A quantity limit of 0.05mL per 28 days will apply.

Utilization of AMD Medications: Fiscal Year 2024

Comparison of Fiscal Years: Medical Claims (All Plans)

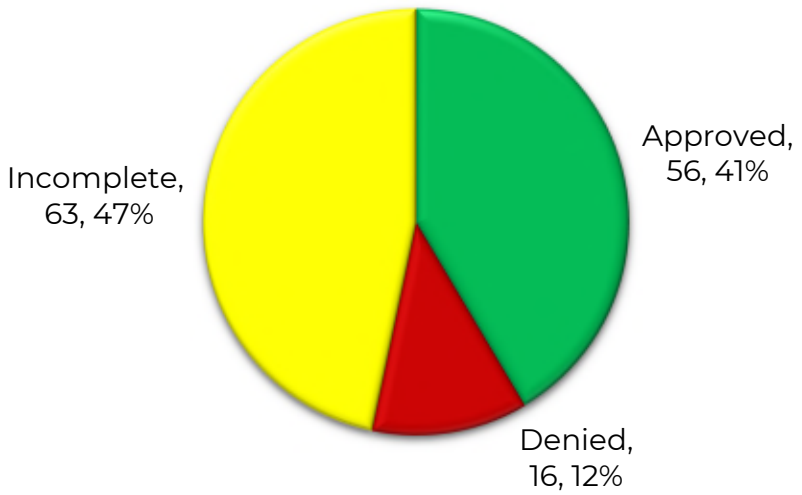
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	219	765	$1,629,155.82	$2,129.62	3.49
2023 Total	**219**	**765**	**$1,629,155.82**	**$2,129.62**	**3.49**
Fiscal Year 2024					
FFS	322	846	$1,680,346.72	$1,986.23	2.63
Aetna	8	8	$16,352.99	$2,044.12	1
Humana	28	34	$63,552.74	$1,869.20	1.21
OCH	17	19	$43,406.18	$2,284.54	1.12
2024 Total	**333**	**907**	**$1,803,658.63**	**$1,988.60**	**2.72**
% Change	**52.05%**	**18.56%**	**10.71%**	**-6.62%**	**-22.06%**
Change	**114**	**142**	**$174,502.81**	**-$141.02**	**-0.77**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Prior Authorization of AMD Medications

There were 135 prior authorization requests submitted for AMD medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	52	42%	61	50%	10	8%	**123**
Aetna	0	0%	2	100%	0	0%	**2**
Humana	4	40%	0	0%	6	60%	**10**
OCH	0	N/A	0	N/A	0	N/A	**0**
Total	**56**	**41%**	**63**	**47%**	**16**	**12%**	**135**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

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

Anticipated Patent Expiration(s):

- Izervay™ (avacincaptad pegol): July 2034
- Syfovre® (pegcetacoplan injection): February 2037

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

- **May 2024:** The FDA approved Opuviz™ (aflibercept-yszy) and Yesafili™ (aflibercept-jbvf) as interchangeable biosimilars to Eylea® (aflibercept).
- **August 2024:** The FDA approved Enzeevu™ (aflibercept-abzv) and Pavblu™ (aflibercept-ayyh) as biosimilars to Eylea® (aflibercept). The Wholesale Acquisition Cost (WAC) of Pavblu™ is $1,665.00 per vial. The cost for the other biosimilars are not available at this time.
- **February 2025:** The FDA approved Susvimo™ (ranibizumab injection), a refillable eye implant that is surgically inserted, for the treatment of diabetic macular edema (DME). Susvimo™ was previously FDA approved for neovascular age-related macular degeneration (nAMD) only. Susvimo™ for a diagnosis of DME was approved based on the results of the Phase 3 Pagoda trial, a randomized, active treatment-controlled, non-inferiority trial comparing Susvimo™ refilled every 6 months to monthly ranibizumab 0.5mg intravitreal injections. The results showed similar improvements in vision for each group.
- **February 2025:** The FDA approved a label expansion for Izervay™ (avacincaptad pegol intravitreal solution) to allow use beyond 12 months. The decision was based on the results of the Phase 3 GATHER2 clinical trial which evaluated the safety and efficacy of Izervay™ through 2 years. The results showed Izervay continued to reduce the rate of geographic atrophy (GA) lesion growth in patients through year 2 versus placebo.

Pipeline:

- **Lytenava™:** Lytenava™ is an ophthalmic formulation of bevacizumab for intravitreal injection. Currently, there are no FDA approved ophthalmic formulations of bevacizumab available; however, Avastin®

(bevacizumab) is often used off-label and repackaged via a compounding pharmacy for use in the eye. In February 2025, Outlook Therapeutics® announced the resubmission of its Biologics License Application (BLA) to the FDA for Lytenava™ with additional chemistry, manufacturing, and controls (CMC) information requested by the FDA. The resubmission was based on the efficacy and safety data from the NORSE EIGHT clinical trial. An FDA decision is expected within 6 months.

- **Xlucane®:** Xlucane® (ranibizumab) is a biosimilar candidate for the vascular endothelial growth factor (VEGF) inhibitor, Lucentis® (ranibizumab). In April 2024, the FDA issued a Complete Response Letter (CRL) to Xbrane Biopharma regarding Xlucane®. In the CRL, the FDA requested additional information related to the reference standard and follow-up actions with its manufacturing partners' sites. In December 2024, Xbrane Biopharma announced it resubmitted its BLA to the FDA for Xlucane® after resolving the issues noted in the CRL. An FDA decision is expected within 6 months.

Recommendations

The College of Pharmacy recommends the prior authorization of Enzeevu™ (aflibercept-abzv), Opuviz™ (aflibercept-yszy), and Yesafili™ (aflibercept-jbvf) with the following criteria (shown in red):

Enzeevu™ (aflibercept-abzv), Opuviz™ (Aflibercept-yszy), and Yesafili™ (Aflibercept-jbvf) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Eylea®/Eylea® HD (aflibercept) or Pavblu™ (aflibercept-ayyh) 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 Izervay™ (avacincaptad pegol) and Susvimo™ (ranibizumab intravitreal implant) based on the FDA label expansions and net costs (changes shown in red):

Izervay™ (Avacincaptad Pegol) Approval Criteria:

1. An FDA approved indication for the treatment of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD); and
2. Member must not have ocular or periocular infections or active intraocular inflammation; and

3. Izervay™ must be prescribed and administered by an ophthalmologist, or a physician experienced in intravitreal injections; and
4. Prescribers must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, and neovascular (wet) AMD; and
5. ~~A patient specific, clinically significant reason why the member cannot use Syfovre® (pegcetacoplan) must be provided; and~~
6. A quantity limit of (1) 0.1mL single-dose vial per eye once monthly ~~for up to 12 months~~ will apply.

Susvimo™ (Ranibizumab Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Neovascular (wet) age-related macular degeneration (AMD) in adults; or
   b. Diabetic macular edema (DME); and
2. Member must have previously responded to ≥2 intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor; and
3. Member must not have ocular or periocular infections or active intraocular inflammation; and
4. Susvimo™ must be prescribed and administered by an ophthalmologist or a physician experienced in vitreoretinal surgery; and
5. Prescriber must verify the member will be monitored for endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, and conjunctival blebs; and
6. A patient-specific, clinically significant reason why the member cannot use ranibizumab intravitreal injection or other VEGF inhibitor injection products (appropriate to disease state) available without prior authorization [i.e., Beovu® (brolucizumab-dbll), Byooviz™ (ranibizumab-nuna), Cimerli® (ranibizumab-eqrn), Eylea®/Eylea® HD (aflibercept), Lucentis® (ranibizumab)] must be provided; and
7. A quantity limit of one 100mg/0.1mL single-dose vial per 180 days will apply.

Utilization Details of AMD Medications: Fiscal Year 2024

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J0178 AFLIBERCEPT (EYLEA)	443	187	$970,290.63	$2,190.27	2.37
Q5128 RANIBIZUMAB-EQRN (CIMERLI)	289	113	$368,993.37	$1,276.79	2.56
J2777 FARICIMAB-SVOA (VABYSMO)	166	52	$453,009.90	$2,728.98	3.19
Q5124 RANIBIZUMAB-NUNA (BYOOVIZ)	5	4	$4,868.35	$973.67	1.25
J0179 BROLUCIZUMAB-DBLL (BEOVU)	3	1	$5,786.64	$1,928.88	3
J2778 RANIBIZUMAB (LUCENTIS)	1	1	$709.74	$709.74	1
TOTAL	**907**	**333**	**$1,803,658.63**	**$1,988.60**	**2.72**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 04/2025. Last accessed 04/02/2025.
[2] U.S. FDA. FDA Approves First Interchangeable Biosimilars to Eylea® to Treat Macular Degeneration and Other Eye Conditions. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-interchangeable-biosimilars-eylea-treat-macular-degeneration-and-other-eye. Issued 05/20/2024. Last accessed 04/14/2025.
[3] Sandoz. Sandoz Receives FDA Approval for Enzeevu™ (Aflibercept-abzv), Further Strengthening U.S. Biosimilar Position. *GlobeNewswire.* Available online at: https://www.globenewswire.com/news-release/2024/08/12/2928076/0/en/Sandoz-receives-FDA-approval-for-Enzeevu-aflibercept-abzv-further-strengthening-US-biosimilar-position.html. Issued 08/12/2024. Last accessed 04/14/2025.
[4] Pavblu™ (aflibercept-ayyh) – New biosimilar approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_pavblu_2024-0829.pdf. Issued 08/23/2024. Last accessed 04/14/2025.
[5] Roche. FDA Approves Roche's Susvimo™ as the First and Only Continuous Delivery Treatment for the Leading Cause of Diabetes-Related Blindness. Available online at: https://www.roche.com/media/releases/med-cor-2025-02-04. Issued 02/03/2025. Last accessed 04/14/2025.
[6] Astellas. U.S. FDA Approves Expanded Label for Astellas Izervay™ (Avacincaptad Pegol Intravitreal Solution) for Geographic Atrophy. Available online at: https://newsroom.astellas.us/2025-02-12-U-S-FDA-Approves-Expanded-Label-for-Astellas-IZERVAY-TM-avacincaptad-pegol-intravitreal-solution-for-Geographic-Atrophy. Issued 02/12/2025. Last accessed 04/14/2025.
[7] Outlook Therapeutics®. Outlook Therapeutics® Doses First Subject in NORSE EIGHT. Available online at: https://ir.outlooktherapeutics.com/news-releases/news-release-details/outlook-therapeuticsr-doses-first-subject-norse-eight. Issued 01/31/2024. Last accessed 04/14/2025.
[8] Outlook Therapeutics®. Outlook Therapeutics® Re-Submits Biologics License Application for ONS-5010 as a Treatment for Wet AMD to the U.S. Food and Drug Administration. Available online at: https://ir.outlooktherapeutics.com/news-releases/news-release-details/outlook-therapeuticsr-re-submits-biologics-license-application-0. Issued 02/28/2025. Last accessed 04/14/2025.
[9] Xbrane BioPharma. Xbrane Provides Regulatory Update on FDA Review of its Ranibizumab Biosimilar Candidate. Available online at: https://xbrane.com/en/mfn_news/xbrane-provides-regulatory-update-on-fda-review-of-its-ranibizumab-biosimilar-candidate/. Issued 04/21/2024. Last accessed 04/14/2025.
[10] Xbrane BioPharma. Xbrane Re-Submits BLA for Ranibizumab Biosimilar Candidate to the FDA. Available online at: https://storage.mfn.se/c597aab8-f93b-409b-9a38-24d0fceac0f3/xbrane-re-submits-bla-for-ranibizumab-biosimilar-candidate-to-fda.pdf. Issued 12/31/2024. Last Accessed 04/14/2025.

Appendix Q

Fiscal Year 2024 Annual Review of Parkinson's Disease (PD) Medications and 30-Day Notice to Prior Authorize Crexont® [Carbidopa/Levodopa Extended-Release (ER) Capsule], Onapgo™ (Apomorphine Injection for Continuous Infusion), and Vyalev™ (Foscarbidopa/ Foslevodopa Injection for Continuous Infusion)

Oklahoma Health Care Authority
May 2025

Current Prior Authorization Criteria

Duopa® (Carbidopa/Levodopa Enteral Suspension) Approval Criteria:

1. An FDA approved diagnosis of advanced Parkinson's disease (PD); and
2. For long-term administration, member or caregivers must be willing and able to administer Duopa® through a percutaneous endoscopic gastrostomy; and
3. Member must be experiencing 3 hours or more of "off" time on current PD drug treatment and must have demonstrated a clear responsiveness to treatment with levodopa; and
4. Approvals will be for a quantity of 1 cassette per day.

Gocovri® [Amantadine Extended-Release (ER)] Approval Criteria:

1. An FDA approved indication for the treatment of dyskinesia in members with Parkinson's disease (PD) receiving levodopa-based therapy; and
2. Member must use Gocovri® concomitantly with levodopa therapy; and
3. Member must not have end-stage renal disease [ESRD; creatinine clearance (CrCl) <15mL/min/1.73m^2]; and
4. A minimum of a 6-month trial of amantadine immediate-release (IR) that resulted in inadequate effects or intolerable adverse effects that are not expected to occur with amantadine ER; and
5. A patient-specific, clinically significant reason why amantadine IR products cannot be used must be provided; and
6. A patient-specific, clinically significant reason why Osmolex® ER (amantadine ER) cannot be used must be provided; and
7. A quantity limit of (1) 68.5mg capsule or (2) 137mg capsules per day will apply.

Inbrija® (Levodopa Inhalation Powder) Approval Criteria:

1. An FDA approved indication for the treatment of "off" episodes in members with Parkinson's disease (PD) treated with carbidopa/levodopa; and
2. Member must be taking carbidopa/levodopa in combination with Inbrija®. Inbrija® has been shown to be effective only in combination with carbidopa/levodopa; and
3. Member must be experiencing motor fluctuations with a minimum of 2 hours of "off" time and demonstrate levodopa responsiveness; and
4. Member must not be taking nonselective monoamine oxidase inhibitors (MAOIs) concomitantly with Inbrija® or within 2 weeks prior to initiating Inbrija® and
5. A previous failed trial of immediate-release (IR) carbidopa/levodopa formulations alone or in combination with long-acting carbidopa/levodopa formulations or a reason why supplementation with IR carbidopa/levodopa formulations is not appropriate for the member must be provided; and
6. A quantity limit of 10 capsules for inhalation per day will apply.

Kynmobi® [Apomorphine Sublingual (SL) Film] Approval Criteria:

1. An FDA approved diagnosis of acute, intermittent treatment of "off" episodes in patients with Parkinson's disease (PD); and
2. Member must be taking carbidopa/levodopa in combination with Kynmobi®; and
3. Member should be experiencing at least 1 well defined "off" episode per day with a total daily "off" time duration of ≥2 hours during the waking day; and
4. Initial dose titration should occur in an "off" state and in a setting supervised by a health care provider to monitor blood pressure and heart rate; and
5. Member should not use apomorphine concomitantly with 5-HT_3 antagonists (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron); and
6. Prescriber must verify the member has been counseled on separating doses by at least 2 hours; and
7. The maximum single dose approvable is 30mg; and
8. A quantity limit of 5 doses per day will apply.

Mirapex ER® (Pramipexole ER) and Requip XL® [Ropinirole Extended-Release (ER)] Approval Criteria:

1. An FDA approved diagnosis of Parkinson's disease (PD); and
2. A patient-specific, clinically significant reason why the immediate-release products cannot be used must be provided.

Neupro® (Rotigotine Transdermal System) Approval Criteria:

1. For the diagnosis of Parkinson's disease (PD), the following criteria apply:
    a. An FDA approved indication for the treatment of signs and symptoms of PD; and
    b. Member must be 18 years of age or older; and
    c. Failed treatment, intolerance, or a patient-specific, clinically significant reason why the member cannot use oral dopamine agonists must be provided.
2. For the diagnosis of restless leg syndrome (RLS), the following criteria apply:
    a. An FDA approved diagnosis of RLS; and
    b. Member must be 18 years of age or older; and
    c. Documented treatment attempts at the recommended dose with at least 2 of the following that did not yield adequate relief:
        i. Carbidopa/levodopa; or
        ii. Pramipexole; or
        iii. Ropinirole.

Nourianz® (Istradefylline) Approval Criteria:

1. An FDA approved diagnosis of Parkinson's disease (PD); and
2. Member must be taking carbidopa/levodopa in combination with istradefylline (istradefylline has not been shown to be effective as monotherapy for the treatment of PD); and
3. Prescriber must verify the dose is appropriate for the member based on degree of hepatic impairment, concomitant strong CYP3A4 inhibitors, and smoking status of the member; and
4. Member must be experiencing at least 2 hours of "off" time per day; and
5. A quantity limit of 1 tablet per day will apply.

Nuplazid® (Pimavanserin) Approval Criteria:

1. An FDA approved diagnosis of hallucinations and delusions associated with Parkinson's disease (PD) psychosis; and
2. Member must have a concomitant diagnosis of PD; and
3. Member must not be taking concomitant medications known to prolong the QT interval including Class 1A antiarrhythmics (e.g., quinidine, procainamide) or Class 3 antiarrhythmics (e.g., amiodarone, sotalol), certain antipsychotic medications (e.g., ziprasidone, chlorpromazine, thioridazine), and certain antibiotics (e.g., gatifloxacin, moxifloxacin); and
4. Member must not have a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic

bradycardia, hypokalemia, hypomagnesemia, and the presence of congenital prolongation of the QT interval; and
5. Nuplazid® will not be approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with PD psychosis; and
6. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/ effectiveness of this medication; and
7. A quantity limit of 1 tablet per day will apply.

Ongentys® (Opicapone) Approval Criteria:

1. An FDA approved indication of adjunctive treatment to levodopa/carbidopa in members with Parkinson's disease (PD) experiencing "off" episodes; and
2. Member must be taking levodopa/carbidopa in combination with Ongentys®; and
3. Member must not use non-selective monoamine-oxidase inhibitors (MAOIs) concomitantly with Ongentys®; and
4. Member must not have a history of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms; and
5. Prescriber must verify member has been counseled to avoid eating food 1 hour before and at least 1 hour after taking Ongentys®; and
6. For members with moderate hepatic impairment, the prescriber must verify the dose of Ongentys® will be reduced in accordance with package labeling; and
7. Prescriber must agree to monitor member for changes in heart rate, heart rhythm, and blood pressure in members concurrently taking medications known to be metabolized by catechol-O-methyltransferase (COMT); and
8. A patient-specific, clinically significant reason why the member cannot use entacapone must be provided; and
9. A quantity limit of 30 capsules per 30 days will apply.

Osmolex® ER [Amantadine Extended-Release (ER)] Approval Criteria:

1. An FDA approved indication for the treatment of Parkinson's disease (PD) or drug-induced extrapyramidal reactions in adult members; and
2. Member must not have end-stage renal disease [ESRD; creatinine clearance (CrCl) <15mL/min/1.73m^2]; and
3. A minimum of a 6-month trial of amantadine immediate-release (IR) that resulted in inadequate effects or intolerable adverse effects that are not expected to occur with amantadine ER; and
4. A patient-specific, clinically significant reason why amantadine IR products cannot be used must be provided; and
5. A quantity limit will apply based on FDA approved dosing regimen(s).

Rytary® [Carbidopa/Levodopa Extended-Release (ER) Capsule] Approval Criteria:

1. An FDA approved diagnosis of Parkinson's disease (PD), post-encephalitic parkinsonism, or parkinsonism that may follow carbon monoxide intoxication or manganese intoxication; and
2. A patient-specific, clinically significant reason why the member cannot use other generic carbidopa/levodopa combinations including Sinemet® CR (carbidopa/levodopa ER tablet) must be provided.

Xadago® (Safinamide) Approval Criteria:

1. An FDA approved indication as adjunctive treatment to carbidopa/levodopa in members with Parkinson's disease (PD) experiencing "off" episodes; and
2. Member must be taking carbidopa/levodopa in combination with safinamide (safinamide has not been shown to be effective as monotherapy for the treatment of PD); and
3. A patient-specific, clinically significant reason why the member cannot use rasagiline or other cost-effective monoamine oxidase type B (MAO-B) inhibitors must be provided; and
4. Member must not have severe hepatic impairment; and
5. Member must not be taking any of the following medications concomitantly with safinamide:
    a. Monoamine oxidase inhibitors (MAOIs); or
    b. Linezolid; or
    c. Opioid analgesics (including tramadol); or
    d. Selective norepinephrine reuptake inhibitors (SNRIs); or
    e. Tri- or tetra-cyclic or triazolopyridine antidepressants; or
    f. St. John's wort; or
    g. Cyclobenzaprine; or
    h. Methylphenidate and its derivatives; or
    i. Amphetamine and its derivatives; or
    j. Dextromethorphan; and
6. Prescriber must verify member has been counseled on avoiding foods that contain a large amount of tyramine while taking safinamide; and
7. A quantity limit of 1 tablet per day will apply.

Utilization of PD Medications: Fiscal Year 2024

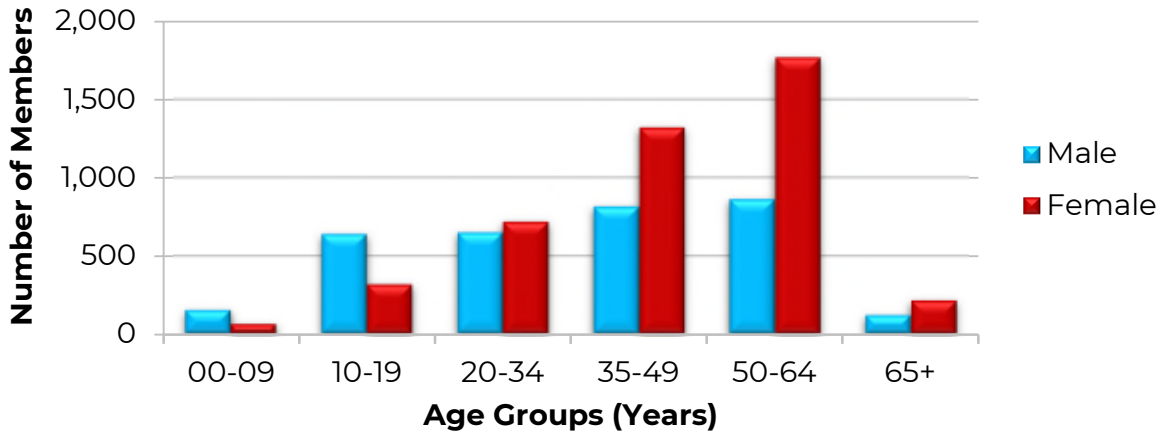
Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	7,693	36,608	$910,100.38	$24.86	$0.69	2,532,453	1,312,575
2023 Total	**7,693**	**36,608**	**$910,100.38**	**$24.86**	**$0.69**	**2,532,453**	**1,312,575**
Fiscal Year 2024							
FFS	7,158	31,595	$833,373.01	$26.38	$0.73	2,285,920	1,143,852
Aetna	526	954	$18,693.60	$19.59	$0.57	61,621	33,085
Humana	682	1,331	$33,247.53	$24.98	$0.70	84,693	47,450
OCH	686	1,237	$32,327.39	$26.13	$0.78	81,158	41,457
2024 Total	**7,612**	**35,117**	**$917,641.53**	**$26.13**	**$0.72**	**2,513,392**	**1,265,844**
% Change	**-1.10%**	**-4.10%**	**0.80%**	**5.10%**	**4.30%**	**-0.80%**	**-3.60%**
Change	**-81**	**-1,491**	**$7,541.15**	**$1.27**	**$0.03**	**-19,061**	**-46,731**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

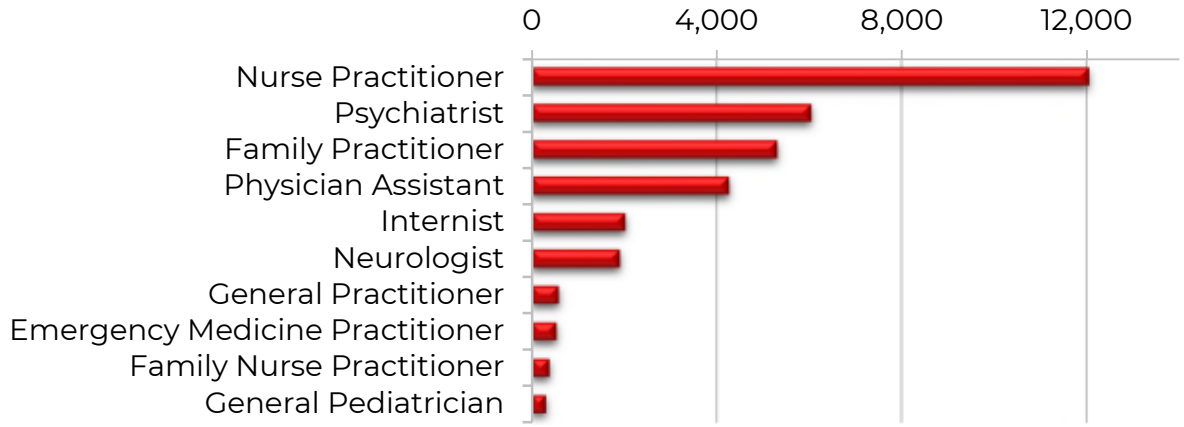
- Aggregate drug rebates collected during fiscal year 2024 for PD medications totaled $172,280.27.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing PD 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.

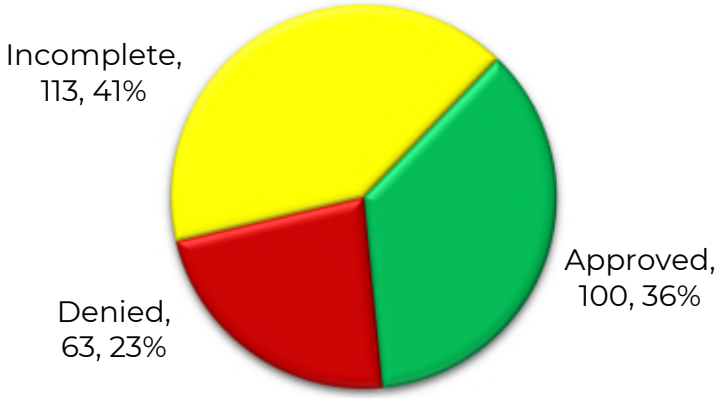
Top Prescriber Specialties of PD Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of PD Medications

There were 276 prior authorization requests submitted for PD medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	97	39%	97	39%	57	23%	**251**
Aetna	0	0%	16	76%	5	24%	**21**
Humana	1	100%	0	0%	0	0%	**1**
OCH	2	67%	0	0%	1	33%	**3**
Total	**100**	**36%**	**113**	**41%**	**63**	**23%**	**276**

FFS = fee-for-service; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans

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

Anticipated Patent Expiration(s):

- Azilect® (rasagiline tablet): August 2027
- Nourianz® (istradefylline tablet): January 2028
- Rytary® [carbidopa/levodopa extended-release (ER) capsule]: December 2028
- Xadago® (safinamide tablet): March 2031
- Neupro® (rotigotine transdermal patch): March 2032
- Inbrija® (levodopa inhalation powder): November 2032
- Ongentys® (opicapone capsule): December 2032
- Kynmobi® [apomorphine sublingual (SL) film]: April 2036
- Osmolex® ER (amantadine ER tablet): February 2038
- Gocovri® (amantadine ER capsule): August 2038
- Nuplazid® (pimavanserin tablet): August 2038
- Vyalev™ (foscarbidopa/foslevodopa injection): June 2040
- Crexont® (carbidopa/levodopa ER capsule): December 2041

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

- **August 2024:** The FDA approved Crexont® (carbidopa/levodopa ER) for the treatment of Parkinson's disease (PD), post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication in adults. Crexont® is an oral formulation of carbidopa/levodopa that combines both immediate-release (IR) granules and ER pellets. Rytary® (carbidopa/levodopa ER) was FDA approved in 2015 and is another ER formulation of carbidopa/levodopa. Both Crexont® and Rytary® are formulated with IR and ER components that are designed to lengthen the effective time of carbidopa/levodopa; however, Crexont® is formulated with a new mucoadhesive polymer technology that allows longer plasma levels of carbidopa/levodopa in the body. They are available in slightly different strengths and a typical daily dose of Rytary® is 3 capsules, 3 to 4 times per day versus Crexont® which has a typical daily dose of 1 to 2 capsules, 2 to 4 times per day.
- **October 2024:** The FDA approved Vyalev™ (foscarbidopa/foslevodopa injection for continuous infusion) as the first and only subcutaneous (sub-Q) 24-hour infusion of levodopa-based therapy for the treatment of motor fluctuations in adults with advanced PD.
- **February 2025:** The FDA approved Onapgo™ (apomorphine injection for continuous infusion) as the first and only sub-Q apomorphine infusion device for the treatment of motor fluctuations in adults with advanced PD.

News:

- **June 2023:** Sunovion announced that Kynmobi® (apomorphine SL film) will be discontinued in the United States due to limited utilization.

Pipeline:

- **ND0612:** ND0612 is an investigational 24-hour, continuous sub-Q infusion of carbidopa/levodopa being studied for the treatment of motor fluctuations in patients with PD. Results from the Phase 3 BouNDless trial showed a statistically significant improvement of 1.72 hours of "on" time without troublesome dyskinesias when compared to oral carbidopa/levodopa IR. Additionally, the key secondary endpoint showed a 1.4 hour reduction in daily "off" time for patients treated with ND0612 vs. carbidopa/levodopa IR. A New Drug Application (NDA) was submitted to the FDA in 2023 and ND0612 received a Complete Response Letter (CRL) in June 2024. The manufacturer stated that a Type A meeting was held with the FDA to discuss the contents of the CRL, including the need for additional safety information on the carbidopa ingredient of ND0612, product quality, device, and manufacturing site inspections, and next steps, and it was stated the FDA did not identify any issues related to the efficacy of ND0612. The resubmission of a new NDA for ND0612 is being targeted for mid-2025.
- **Solengepras:** Solengepras is an investigational oral, non-dopaminergic therapy being studied in patients with early PD who have not been treated with dopaminergic or anti-Parkinson's therapies. Solengepras is designed to inhibit G protein-coupled receptor 6 (GPR6) and to selectively target and modulate the specific brain circuits responsible for controlling motor and non-motor functions without directly affecting dopaminergic pathways. In the Phase 2 ASCEND trial, solengepras showed a small, non-statistically significant improvement in PD motor symptoms from baseline to week 12 compared to placebo as assessed by the combined Movement Disorder Society – Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Parts II and III. The Phase 3 ARISE trial is currently ongoing and studying solengepras as an adjunctive therapy to levodopa and other PD medications with results expected in the first half of 2026.
- **Tavapadon:** Tavapadon is an investigational selective dopamine 1/dopamine 5 (D1/D5) receptor partial agonist under investigation for PD and is currently being studied as a once-daily treatment for use as monotherapy and as an adjunctive therapy to levodopa in the TEMPO clinical trials. TEMPO-1 and TEMPO-2 are evaluating tavapadon as monotherapy and TEMPO-3 as adjunctive therapy. All 3 trials have met their primary endpoint showing statistically significant improvements in MDS-UPDRS Parts II and III combined score in TEMPO-1 and TEMPO-

2 and total “on” time without troublesome dyskinesia in TEMPO-3. AbbVie is planning to submit an NDA for tavapadon to the FDA in 2025.

Onapgo™ (Apomorphine Injection for Continuous Infusion) Product Summary[13,14]

Therapeutic Class: Dopaminergic agonist

Indication(s): Treatment of motor fluctuations in adults with advanced PD

How Supplied: One carton containing 5 single-dose, prefilled cartridges with each cartridge containing 98mg/20mL of apomorphine hydrochloride

Dosing and Administration:

- Onapgo™ should be administered by sub-Q infusion via the Onapgo™ pump.
  - Patients selected for treatment with Onapgo™ should be capable of understanding and trained on using the delivery system, either themselves or with the assistance of a caregiver.
- The daily dosage is determined by individualized patient titration and is composed of a continuous dosage and as needed extra dose(s). Initiation and dose titrations should be done under medical supervision.
- The recommended initial continuous dosage is 1mg/hour with a maximum of 6mg/hour for up to 16 hours per day. The maximum recommended total daily dosage, including the continuous dosage and any extra dose(s), is 98mg generally administered over the waking day.
- Onapgo™ is not substitutable for apomorphine products intended for intermittent use.
- See the full *Prescribing Information* for dose calculations, titration recommendations, premedication and concomitant medications, preparation and administration instructions, and recommended dose adjustments.

Efficacy: The safety and efficacy of Onapgo™ were evaluated in a Phase 3 multicenter, parallel-group, double-blind, randomized, placebo-controlled trial in patients with PD who experienced motor fluctuations while receiving carbidopa/levodopa and other concomitant medications to treat PD for 12 weeks, including 1-4 weeks of dose titration and then continued treatment at an individualized, stable dosage. Patients then had the option to receive Onapgo™ in a 52-week, open-label treatment period.

- <u>Key Inclusion Criteria:</u>
  - Diagnosis of PD >3 years without any other known or suspected cause of parkinsonism
  - Levodopa-related motor fluctuations that had not been adequately controlled by optimized medical treatment

        - Mean “off” time >3 hours/day for 2 days (based on diaries at screening and baseline), with no day with <2 hours of “off” time recorded
    - Intervention(s): Patients were randomized 1:1 to receive Onapgo™ 5mg/mL solution or placebo for 12 weeks.
    - Endpoint(s):
        - Primary Endpoint
            - Change in total daily “off” time assessed from baseline to the end of the 12-week treatment period based on patient diaries
        - Key Secondary Endpoint:
            - Change in daily “on” time without troublesome dyskinesia from baseline to the end of the 12-week treatment period
    - Results:
        - Primary Endpoint:
            - Change from baseline in mean total daily “off” time was -2.55 hours in the Onapgo™ group vs. -0.90 hours in the placebo group [treatment difference: -1.65 hours; 95% confidence interval (CI): -2.91, -0.38; P=0.0114]
        - Key Secondary Endpoint:
            - Change from baseline in mean total daily “on” time without troublesome dyskinesia was 2.76 hours in the Onapgo™ group vs. 1.12 hours in the placebo group (treatment difference: 1.64 hours; 95% CI: 0.28, 3.00; P=0.0188).

Cost: The Wholesale Acquisition Cost (WAC) of Onapgo™ is $14.38 per mL or $1,438 per carton. This results in an estimated cost of $8,628 per month or $103,536 per year based on the maximum recommended dose of 98mg (20mL) per day.

Vyalev™ (Foscarbidopa/Foslevodopa Injection for Continuous Infusion) Product Summary[15,16]

Therapeutic Class: Aromatic amino acid decarboxylation inhibitor and an aromatic amino acid

Indication(s): Treatment of motor fluctuations in adults with advanced PD

How Supplied: One carton containing 7 single-dose vials with each vial containing 120mg foscarbidopa and 2,400mg foslevodopa per 10mL

Dosing and Administration:

- Vyalev™ should be administered as a sub-Q infusion via the Vyafuser™ pump
    - Patients selected for treatment with Vyalev™ should be capable of understanding and using the delivery system themselves or with

assistance from a caregiver. Patients should be trained on the proper use of Vyalev™ and the delivery system prior to initiating.
- The maximum recommended daily dosage of Vyalev™ is 3,525mg of foslevodopa (approximately 2,500mg of levodopa).
- Prescribing a backup oral carbidopa/levodopa product should be recommended in the event that delivery of Vyalev™ is interrupted, which may result in underdosing. Sudden discontinuation or rapid dose reduction of Vyalev™, without administration of alternative dopaminergic therapy, should be generally avoided.
- See the full *Prescribing Information* for calculation of the base continuous dosage, hourly infusion rate, optional loading dose, extra dose, and preparation and administration instructions.

Efficacy: The efficacy of Vyalev™ was studied in a 12-week, randomized, double-blind, double-dummy, active-controlled, multicenter trial in patients with advanced PD. The study included a screening period, an oral carbidopa/levodopa stabilization period, and a double-blind treatment period.

- Key Inclusion Criteria:
  - Diagnosis of idiopathic PD responsive to levodopa
  - On a minimum of 400mg/day of levodopa equivalents and having inadequately controlled motor fluctuations
  - Average "off" time of ≥2.5 hours/day over 3 consecutive diary days with ≥2 hours each day
- Intervention(s): Patients were randomized 1:1 to receive continuous sub-Q infusion of Vyalev™ plus oral placebo capsules or placebo continuous sub-Q infusion plus oral carbidopa/levodopa IR tablets for 12 weeks.
- Endpoint(s):
  - Primary Endpoint:
    - Mean change from baseline to week 12 in the total daily mean "on" time without troublesome dyskinesia based on PD diary
  - Key Secondary Endpoint:
    - Mean change from baseline to week 12 in the total daily mean "off" time
- Results:
  - Primary Endpoint:
    - The change from baseline in total daily mean "on" time without troublesome dyskinesia was 2.72 hours in the Vyalev™ group vs. 0.97 hours in the oral carbidopa/levodopa group (treatment difference: 1.75 hours; 95% CI: 0.46, 3.05; P=0.0083).
  - Key Secondary Endpoint:
    - The change from baseline in mean total daily "off" time was -2.75 hours in the Vyalev™ group vs. -0.96 hours in the oral

carbidopa/levodopa group (treatment difference: -1.79 hours; 95% CI: -3.03, -0.54; P=0.0054).

Cost: The WAC of Vyalev™ is $32.75 per mL or $2,292.50 per carton. This results in an estimated cost of $19,650 per month or $235,800 per year based on the use of 2 vials (20mL) per day.

Cost Comparison: Oral Carbidopa/Levodopa Products

Product	Cost Per Unit	Cost Per Month*	Cost Per Year*
Crexont® (carbidopa/levodopa ER) 87.5-350mg cap	**$4.35**	**$783.00***	**$9,396.00**
Rytary® (carbidopa/levodopa ER) 48.75-195mg cap	$3.99	$1,077.30⁺	$12,927.60
carbidopa/levodopa CR 50-200mg tab (generic)	$0.21	$31.50ᵝ	$378.00
carbidopa/levodopa IR 25-250mg tab (generic)	$0.14	$16.80ᵅ	$201.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Cap = capsule; tab = tablet; Unit = capsule or tablet
*Cost per month based on FDA recommended dosing of 700mg of levodopa 3 times daily for a patient converting from 1,000mg of IR levodopa per day.
⁺Cost per month based on FDA recommended dosing of 1,755mg of levodopa per day for a patient converting from 1,000mg of IR levodopa per day.
ᵝCost per month based on FDA recommended dosing of 1,000mg of levodopa per day for a patient converting from 1,000mg of IR levodopa per day.
ᵅCost per month based on an average dose of 1,000mg of levodopa per day using four 25-250mg tablets.

Recommendations

The College of Pharmacy recommends the prior authorization of Crexont® (carbidopa/levodopa ER capsules) with criteria similar to the Rytary® (carbidopa/levodopa ER capsules) approval criteria (changes shown in red):

Crexont® [Carbidopa/Levodopa Extended-Release (ER) Capsules] and Rytary® (Carbidopa/Levodopa ER Capsules) Approval Criteria

1. An FDA approved diagnosis of Parkinson's disease, post-encephalitic parkinsonism, or parkinsonism that may follow carbon monoxide intoxication or manganese intoxication; and
2. A patient-specific, clinically significant reason why the member cannot use other generic carbidopa/levodopa combinations including Sinemet® CR (carbidopa/levodopa ER tablets); and
3. For Crexont® (carbidopa/levodopa ER capsules), a patient-specific, clinically significant reason why the member cannot use Rytary® (carbidopa/levodopa ER capsules) must be provided.

Additionally, the College of Pharmacy recommends the prior authorization of Onapgo™ (apomorphine injection for continuous infusion) and Vyalev™

(foscarbidopa/foslevodopa injection for continuous infusion) with the following criteria (shown in red):

Onapgo™ (Apomorphine Injection for Continuous Infusion) Approval Criteria:

1. An FDA approved indication for the treatment of motor fluctuations in patients with advanced Parkinson's disease; and
2. Member must be 18 years of age or older; and
3. Onapgo™ must be prescribed by, or in consultation with, a neurologist; and
4. Prescriber must verify that member has demonstrated a clear responsiveness to treatment with levodopa and is experiencing persistent motor fluctuations with 3 hours or more of "off" time per day despite optimized carbidopa/levodopa therapy; and
5. Member has documented trials that resulted in an inadequate response despite optimized treatment (or documented intolerance or contraindication) with oral carbidopa/levodopa and 1 of the following:
    a. Dopamine agonist (e.g., pramipexole, ropinirole); or
    b. Monoamine oxidase-B (MAO-B) inhibitor (e.g., selegiline, rasagiline); or
    c. Catechol-O-methyltransferase (COMT) inhibitor (e.g., entacapone, tolcapone); or
    d. Amantadine; and
6. Member must not be taking 5-HT_3 antagonists (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron) concomitantly with Onapgo™; and
7. Onapgo™ must be used with the Onapgo™ pump and prescriber must verify that the patient or caregiver has been trained on the proper administration of Onapgo™ with the Onapgo™ pump prior to starting treatment; and
8. Onapgo™ will not be approved for concomitant use with Vyalev™ (foscarbidopa/foslevodopa injection for continuous infusion) or Apokyn® (apomorphine injection); and
9. Initial approvals will be for 6 months. For continued authorization, prescriber must verify member demonstrated a positive clinical response to Onapgo™. Subsequent approvals will be for 1 year.

Vyalev™ (Foscarbidopa/Foslevodopa Injection for Continuous Infusion) Approval Criteria:

1. An FDA approved indication for the treatment of motor fluctuations with advanced Parkinson's disease; and
2. Member must be 18 years of age or older; and
3. Must be prescribed by, or in consultation with, a neurologist; and

4. Prescriber must verify that member has demonstrated a clear responsiveness to treatment with levodopa and is experiencing persistent motor fluctuations with 2 and one-half hours or more of "off" time per day despite optimized carbidopa/levodopa therapy; and
5. Member has documented trials that resulted in an inadequate response despite optimized treatment (or documented intolerance or contraindication) with oral carbidopa/levodopa and 1 of the following:
    a. Dopamine agonist (e.g., pramipexole, ropinirole); or
    b. Monoamine oxidase-B (MAO-B) inhibitor (e.g., selegiline, rasagiline); or
    c. Catechol-O-methyltransferase (COMT) inhibitor (e.g., entacapone, tolcapone); or
    d. Amantadine; and
6. Member must not be taking nonselective monoamine oxidase inhibitors (MAOIs) concomitantly with Vyalev™ or within 2 weeks prior to initiating treatment with Vyalev™; and
7. Vyalev™ must be used with the Vyafuser™ pump and prescriber must verify that the patient or caregiver has been trained on the proper administration of Vyalev™ with the Vyafuser™ pump prior to starting treatment; and
8. Vyalev™ will not be approved for concomitant use with Onapgo™ (apomorphine subcutaneous injection); and
9. Initial approvals will be for 6 months. For continued authorization, prescriber must verify member demonstrated a positive clinical response to Vyalev™. Subsequent approvals will be for 1 year.

Finally, the College of Pharmacy recommends removal of SoonerCare coverage and of the approval criteria for Kynmobi® (apomorphine SL film) based on product discontinuation (changes shown in red):

~~**Kynmobi® [Apomorphine Sublingual (SL) Film] Approval Criteria:**~~

~~1. An FDA approved diagnosis of acute, intermittent treatment of "off" episodes in patients with Parkinson's disease (PD); and~~
~~2. Member must be taking carbidopa/levodopa in combination with Kynmobi®; and~~
~~3. Member should be experiencing at least 1 well defined "off" episode per day with a total daily "off" time duration of ≥2 hours during the waking day; and~~
~~4. Initial dose titration should occur in an "off" state and in a setting supervised by a health care provider to monitor blood pressure and heart rate; and~~
~~5. Member should not use apomorphine concomitantly with 5-HT_3 antagonists (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron); and~~

~~6. Prescriber must verify the member has been counseled on separating doses by at least 2 hours; and~~
~~7. The maximum single dose approvable is 30mg; and~~
~~8. A quantity limit of 5 doses per day will apply.~~

Utilization Details of PD Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BENZTROPINE PRODUCTS						
BENZTROPINE TAB 1MG	6,149	1,470	$84,634.11	$13.76	4.18	17.16%
BENZTROPINE TAB 2MG	2,614	534	$40,077.37	$15.33	4.9	0.00%
BENZTROPINE TAB 0.5MG	2,281	524	$32,295.37	$14.16	4.35	13.16%
BENZTROPINE INJ 1MG/ML	1	1	$481.41	$481.41	1	6.22%
SUBTOTAL	**11,045**	**2,529**	**$157,488.26**	**$14.26**	**4.37**	**17.16%**
ROPINIROLE PRODUCTS						
ROPINIROLE TAB 1MG	2,581	807	$31,861.40	$12.34	3.2	3.47%
ROPINIROLE TAB 0.5MG	2,360	848	$29,692.49	$12.58	2.78	3.24%
ROPINIROLE TAB 0.25MG	1,664	620	$20,307.11	$12.20	2.68	2.21%
ROPINIROLE TAB 2MG	1,394	420	$18,419.53	$13.21	3.32	2.01%
ROPINIROLE TAB 3MG	436	121	$6,714.56	$15.40	3.6	0.73%
ROPINIROLE TAB 4MG	402	120	$5,947.17	$14.79	3.35	0.65%
ROPINIROLE TAB 5MG	165	43	$2,684.62	$16.27	3.84	0.29%
ROPINIROLE TAB 2MG ER	8	3	$179.85	$22.48	2.67	0.02%
ROPINIROLE TAB 12MG ER	5	1	$314.62	$62.92	5	0.03%
ROPINIROLE TAB 8MG ER	2	1	$100.60	$50.30	2	0.01%
ROPINIROLE TAB 4MG ER	2	1	$65.94	$32.97	2	0.01%
ROPINIROLE TAB 6MG ER	1	1	$42.53	$42.53	1	0.00%
SUBTOTAL	**9,020**	**2,986**	**$116,330.42**	**$12.90**	**3.02**	**12.68%**
AMANTADINE PRODUCTS						
AMANTADINE TAB 100MG	3,434	804	$120,787.56	$35.17	4.27	13.16%
AMANTADINE CAP 100MG	2,981	554	$57,078.25	$19.15	5.38	6.22%
AMANTADINE SOL 50MG/5ML	372	74	$8,176.21	$21.98	5.03	0.89%
AMANTADINE SOL 100/10ML	6	4	$243.82	$40.64	1.5	0.03%
SUBTOTAL	**6,793**	**1,436**	**$186,285.84**	**$27.42**	**4.73**	**20.30%**
TRIHEXYPHENIDYL PRODUCTS						
TRIHEXYPHENIDYL TAB 2MG	1,526	362	$18,028.37	$11.81	4.22	1.96%
TRIHEXYPHENIDYL TAB 5MG	1,369	258	$20,918.68	$15.28	5.31	2.28%
TRIHEXYPHENIDYL SOL 0.4MG/ML	205	33	$7,687.12	$37.50	6.21	0.84%
SUBTOTAL	**3,100**	**653**	**$46,634.17**	**$15.04**	**4.75**	**5.08%**
PRAMIPEXOLE PRODUCTS						
PRAMIPEXOLE TAB 0.5MG	632	201	$11,808.38	$18.68	3.14	1.29%
PRAMIPEXOLE TAB 0.125MG	572	217	$7,934.76	$13.87	2.64	0.86%
PRAMIPEXOLE TAB 0.25MG	546	202	$7,403.36	$13.56	2.7	0.81%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PRAMIPEXOLE TAB 1MG	425	133	$6,200.06	$14.59	3.2	0.68%
PRAMIPEXOLE TAB 1.5MG	226	60	$3,215.77	$14.23	3.77	0.35%
PRAMIPEXOLE TAB 0.75MG	128	35	$1,895.11	$14.81	3.66	0.21%
PRAMIPEXOLE TAB 3MG ER	1	1	$173.64	$173.64	1	0.02%
PRAMIPEXOLE TAB 1.5MG ER	1	1	$159.16	$159.16	1	0.02%
PRAMIPEXOLE TAB 4.5MG ER	1	1	$150.90	$150.90	1	0.02%
PRAMIPEXOLE TAB 0.375 ER	1	1	$111.13	$111.13	1	0.01%
SUBTOTAL	**2,533**	**852**	**$39,052.27**	**$15.42**	**2.97**	**4.26%**
CARBIDOPA/LEVODOPA PRODUCTS						
CARB/LEVO TAB 25-100MG	1,054	270	$20,483.16	$19.43	3.9	2.23%
CARB/LEVO ER TAB 50-200MG	172	33	$5,158.39	$29.99	5.21	0.56%
CARB/LEVO TAB 10-100MG	170	52	$2,610.81	$15.36	3.27	0.28%
CARB/LEVO TAB 25-250MG	161	42	$4,389.43	$27.26	3.83	0.48%
CARB/LEVO ER TAB 25-100MG	73	25	$2,326.43	$31.87	2.92	0.25%
RYTARY CAP 195MG	21	2	$21,308.79	$1,014.70	10.5	2.32%
RYTARY CAP 145MG	11	1	$5,388.49	$489.86	11	0.59%
RYTARY CAP 245MG	9	1	$4,112.57	$456.95	9	0.45%
RYTARY CAP 95MG	6	1	$2,939.13	$489.86	6	0.32%
SUBTOTAL	**1,677**	**427**	**$68,717.20**	**$40.98**	**3.93**	**7.49%**
BROMOCRIPTINE PRODUCTS						
BROMOCRIPTINE TAB 2.5MG	502	106	$40,812.97	$81.30	4.74	4.45%
BROMOCRIPTINE CAP 5MG	219	41	$48,170.80	$219.96	5.34	5.25%
SUBTOTAL	**721**	**147**	**$88,983.77**	**$123.42**	**4.9**	**9.70%**
CARBIDOPA/LEVODOPA/ENTACAPONE PRODUCTS						
CARB/LEVO/EN TAB 50-200-200MG	22	3	$1,259.67	$57.26	7.33	0.14%
CARB/LEVO/EN TAB 12.5-50-200MG	15	2	$1,774.96	$118.33	7.5	0.19%
CARB/LEVO/EN TAB 31.25-125-200MG	13	2	$1,955.84	$150.45	6.5	0.21%
CARB/LEVO/EN TAB 25-100-200MG	12	1	$698.59	$58.22	12	0.08%
CARB/LEVO/EN TAB 37.5-150-200MG	8	1	$704.72	$88.09	8	0.08%
SUBTOTAL	**70**	**9**	**$6,393.78**	**$91.34**	**7.78**	**0.70%**
ENTACAPONE PRODUCTS						
ENTACAPONE TAB 200MG	44	9	$2,144.66	$48.74	4.89	0.23%
SUBTOTAL	**44**	**9**	**$2,144.66**	**$48.74**	**4.89**	**0.23%**
PIMAVANSERIN PRODUCTS						
NUPLAZID CAP 34MG	36	4	$175,841.26	$4,884.48	9	19.16%
NUPLAZID TAB 10MG	1	1	$5,006.41	$5,006.41	1	0.55%
SUBTOTAL	**37**	**5**	**$180,847.67**	**$4,887.77**	**7.4**	**19.71%**
RASAGILINE PRODUCTS						
RASAGILINE TAB 1MG	18	2	$720.68	$40.04	9	0.08%
RASAGILINE TAB 0.5MG	11	2	$639.27	$58.12	5.5	0.07%
SUBTOTAL	**29**	**4**	**$1,359.95**	**$46.89**	**7.25**	**0.15%**
SELEGILINE PRODUCTS						
SELEGILINE CAP 5MG	19	5	$678.95	$35.73	3.80	0.07%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SELEGILINE TAB 5MG	1	1	$60.14	$60.14	1	0.01%
SUBTOTAL	**20**	**6**	**$739.09**	**$36.95**	**3.33**	**0.08%**
ROTIGOTINE PRODUCTS						
NEUPRO 3MG/24HR PATCH	8	1	$6,426.35	$803.29	8	0.70%
NEUPRO 1MG/24HR PATCH	7	2	$5,634.12	$804.87	3.5	0.61%
NEUPRO 4MG/24HR PATCH	3	2	$2,351.56	$783.85	1.5	0.26%
SUBTOTAL	**18**	**5**	**$14,412.03**	**$800.67**	**3.6**	**1.57%**
CARBIDOPA PRODUCTS						
CARBIDOPA TAB 25MG	6	2	$639.90	$106.65	3	0.07%
SUBTOTAL	**6**	**2**	**$639.90**	**$106.65**	**3**	**0.07%**
ISTRADEFYLLINE PRODUCTS						
NOURIANZ TAB 20MG	4	1	$7,612.52	$1,903.13	4	0.83%
SUBTOTAL	**4**	**1**	**$7,612.52**	**$1,903.13**	**4**	**0.83%**
TOTAL	**35,117**	**7,612***	**$917,641.53**	**$26.13**	**4.61**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CARB = carbidopa; EN = entacapone; ER = extended release; HR = hour; INJ = injection; LEVO = levodopa; SOL = solution; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

[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 04/2025. Last accessed 04/17/2025.
[2] Amneal Pharmaceuticals. Amneal Receives U.S. FDA Approval for IPX203 for Treatment of Parkinson's Disease to Be Launched as Crexont® (Carbidopa and Levodopa) Extended-Release Capsules. Available online at: https://investors.amneal.com/news/press-releases/press-release-details/2024/Amneal-Receives-U.S.-FDA-Approval-for-IPX203-for-Treatment-of-Parkinsons-Disease-to-Be-Launched-as-CREXONT-Carbidopa-and-Levodopa-Extended-Release-Capsules/default.aspx. Issued 08/07/2024. Last accessed 04/16/2025.

[3] American Parkinson Disease Association. Exploring the Variations of Carbidopa/Levodopa: The Mainstay of Parkinson's Disease Treatment. Available online at: https://www.apdaparkinson.org/article/carbidopa-levodopa-formulations-and-parkinsons-disease/. Issued 10/08/2024. Last accessed 04/16/2025.
[4] AbbVie. U.S. FDA Approves Vyalev™ (Foscarbidopa and Foslevodopa) for Adults Living with Advanced Parkinson's Disease. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/us-fda-approves-vyalev-foscarbidopa-and-foslevodopa-for-adults-living-with-advanced-parkinsons-disease-302278666.html. Issued 10/17/2024. Last accessed 04/16/2025.
[5] Supernus Pharmaceuticals. Supernus Announces FDA Approval of Onapgo™ (Apomorphine Hydrochloride) for Parkinson's Disease. *GlobeNewswire*. Available online at: https://www.globenewswire.com/news-release/2025/02/04/3020423/19871/en/Supernus-Announces-FDA-Approval-of-ONAPGO-apomorphine-hydrochloride-for-Parkinson-s-Disease.html. Issued 02/04/2025. Last accessed 04/16/2025.
[6] Wexler M. Kynmobi to be Discontinued in US and Canada Due to Limited Use. *Parkinson's News Today*. Available online at: https://parkinsonsnewstoday.com/news/kynmobi-discontinued-us-canada-limited-use-sunovion/. Issued 06/12/2023. Last accessed 04/16/2025.
[7] NeuroDerm. Positive Results from Phase 3 BouNDless Trial Evaluating ND0612 in Parkinson's Disease Patients with Motor Fluctuations. Available online at: https://neuroderm.com/our-company/news-and-events/boundless-phase-3/. Issued 03/18/2024. Last accessed 04/16/2025.
[8] Mitsubishi Tanabe Pharma. Update on U.S. Development Plan of Investigational ND0612 for the Treatment of Motor Fluctuations in People with Parkinson's Disease. Available online at: https://www.mt-pharma.co.jp/e/news/assets/pdf/e_MTPC241101.pdf. Issued 11/01/2024. Last accessed 04/16/2025.
[9] Cerevance. Cerevance Presents Topline Results from Phase 2 ASCEND Trial of Solengepras as Monotherapy Treatment for Early-Stage Parkinson's Disease at AD/PD 2025. Available online at: https://www.cerevance.com/media/cerevance-presents-topline-results-from-phase-2-ascend-trial-of-solengepras-as-monotherapy-treatment-for-early-stage-parkinsons-disease-at-ad-pd-2025. Issued 04/01/2025. Last accessed 04/16/2025.
[10] Cerevel Therapeutics. Cerevel Therapeutics Announces Positive Topline Results for Tavapadon in Phase 3 Adjunctive Trial for People Living with Parkinson's Disease. *GlobeNewswire*. Available online at: https://www.globenewswire.com/news-release/2024/04/18/2865216/0/en/Cerevel-Therapeutics-Announces-Positive-Topline-Results-for-Tavapadon-in-Phase-3-Adjunctive-Trial-for-People-Living-with-Parkinson-s-Disease.html. Issued 04/18/2024. Last accessed 04/16/2025.
[11] AbbVie. AbbVie Announces Positive Topline Results from Phase 3 TEMPO-1 Trial Evaluating Tavapadon as a Monotherapy for Parkinson's Disease. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/abbvie-announces-positive-topline-results-from-phase-3-tempo-1-trial-evaluating-tavapadon-as-a-monotherapy-for-parkinsons-disease-302259265.html. Issued 09/26/2024. Last accessed 04/16/2025.
[12] AbbVie. AbbVie Announces Positive Topline Results for the Phase 3 TEMPO-2 Trial Evaluating Tavapadon as a Monotherapy for Parkinson's Disease. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/abbvie-announces-positive-topline-results-for-the-phase-3-tempo-2-trial-evaluating-tavapadon-as-a-monotherapy-for-parkinsons-disease-302325607.html. Issued 12/09/2024. Last accessed 04/16/2025.
[13] Onapgo™ (Apomorphine) Prescribing Information. Supernus Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/214056s000lbl.pdf. Last revised 02/2025. Last accessed 04/16/2025.
[14] Katzenschlager R, Poewe W, et al. Apomorphine Subcutaneous Infusion in Patients with Parkinson's Disease with Persistent Motor Fluctuations (TOLEDO): A Multicentre, Double-Blind, Randomised, Placebo-Controlled Trial. *Lancet Neurol* 2018; 17: 749–759. doi: 10.1016/S1474-4422(18)30239-4.
[15] Vyalev™ (Foscarbidopa/Foslevodopa) Prescribing Information. AbbVie. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216962s000lbl.pdf. Last revised 10/2024. Last accessed 04/16/2025.
[16] Soileau M, Aldred J, et al. Safety and efficacy of Continuous Subcutaneous Foslevodopa-Foscarbidopa in Patients with Advanced Parkinson's Disease: A Randomised, Double-Blind, Active-Controlled, Phase 3 Trial. *Lancet Neurol* 2022; 21: 1099–1109. doi: 10.1016/S1474-4422(22)00400-8.

Appendix R

Fiscal Year 2024 Annual Review of Primary Immunoglobulin A Nephropathy (IgAN) Medications and 30-Day Notice to Prior Authorize Vanrafia™ (Atrasentan)

Oklahoma Health Care Authority
May 2025

Current Prior Authorization Criteria

Utilization data for Fabhalta® (iptacopan) and approval criteria for indications other than primary IgAN can be found in the December 2024 Drug Utilization Review (DUR) Board packet. This medication and criteria are reviewed annually with the Complement Inhibitors and Miscellaneous Immunomodulatory Agents.

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; 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-converting 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.

Filspari® (Sparsentan) Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
    a. Kidney 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 advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of rapid disease progression as demonstrated by ≥1 of the following, despite 3 months of maximal supportive care:
    a. Urine protein-to-creatinine (UPCR) ratio ≥1.5g/g; or
    b. Proteinuria >0.75g/day; and
6. Member must be on a stable dose of a maximally tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and
7. Prescriber must verify the member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin receptor antagonists (ERAs) prior to initiating treatment with Filspari®; and
8. Member must not be taking strong CYP3A4 inhibitors (e.g., itraconazole) or strong CYP3A4 inducers (e.g., rifampin) concomitantly with Filspari®; and
9. Member must not be taking H2 receptor blockers or proton pump inhibitors (PPIs); and
10. If member is using antacids, they must agree to separate antacid and Filspari® administration by 2 hours; and
11. Prescriber, pharmacy, and member must be enrolled in the Filspari® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. A quantity limit of 30 tablets per 30 days will apply.

Tarpeyo® [Budesonide Delayed Release (DR) Capsule] Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
    a. Kidney 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 advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of rapid disease progression as demonstrated by ≥1 of the following, despite maximal supportive care:
   a. Urine protein-to-creatinine ratio (UPCR) ≥1.5g/g; or
   b. Proteinuria >0.75g/day; and
6. Member must be on a stable dose of a maximally-tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and
7. A patient-specific, clinically significant reason why a 6-month trial of an alternative formulation of budesonide DR oral capsules (e.g., Entocort® EC) or alternative oral corticosteroids is not appropriate for the member must be provided; and
8. Approval duration will be for 9 months; and
9. A quantity limit of 120 capsules per 30 days will apply.

Utilization of Primary IgAN Medications: Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	2	7	$104,011.92	$14,858.85	$495.29	840	210
2023 Total	**2**	**7**	**$104,011.92**	**$14,858.85**	**$495.29**	**840**	**210**
Fiscal Year 2024							
FFS	3	12	$188,314.92	$15,692.91	$523.10	1,440	360
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	2	4	$42,636.82	$10,659.20	$409.97	194	104
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**5**	**16**	**$230,951.74**	**$14,434.48**	**$497.74**	**1,634**	**464**
% Change	**150.00%**	**128.60%**	**122.00%**	**-2.90%**	**0.50%**	**94.50%**	**121.00%**
Change	**3**	**9**	**$126,939.82**	**-$424.37**	**$2.45**	**794**	**254**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Demographics of Members Utilizing Primary IgAN Medications (All Plans)

- Due to the limited number of members utilizing primary IgAN medications during fiscal year 2024, detailed demographic information could not be provided.

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

- The only prescriber specialty listed on paid claims for primary IgAN medications during fiscal year 2024 was nephrologist.

Prior Authorization of Primary IgAN Medications

There were 29 prior authorization requests submitted for primary IgAN medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	4	15%	15	58%	7	27%	**26**
Aetna	0	0%	1	50%	1	50%	**2**
Humana	1	100%	0	0%	0	0%	**1**
OCH	0	N/A	0	N/A	0	N/A	**0**
Total	**5**	**17%**	**16**	**55%**	**8**	**28%**	**29**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

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

Anticipated Patent Expiration(s):

- Filspari® (sparsentan): March 2030
- Fabhalta® (iptacopan): July 2041
- Tarpeyo® (budesonide DR capsule): January 2043

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

- **December 2023:** The FDA granted full approval to Tarpeyo® (budesonide DR capsule) to reduce the loss of kidney function in adults with primary IgAN at risk for disease progression. It was previously approved under accelerated approval, based on the surrogate marker of proteinuria. The confirmatory trial showed a statistically significant benefit over placebo in estimated glomerular filtration rate (eGFR) over the 2-year trial period. At 2 years, there was a 6.11mL/min/1.73m^2 decline in eGFR in the Tarpeyo® group compared with a 12.0mL/min/1.73m^2 decline in the placebo group (P<0.0001).
- **September 2024:** The FDA granted full approval to Filspari® (sparsentan) to slow kidney function decline in adults with primary IgAN who are at risk of disease progression. Filspari® was previously approved under accelerated approval based on the surrogate marker of proteinuria. The full FDA approval was based on the results of the PROTECT confirmatory trial which showed the mean eGFR slope from baseline to week 110 was -3.0mL/min/1.73m^2/year for Filspari® and -4.2mL/min/1.73m^2/year for irbesartan, corresponding to a statistically significant treatment effect of 1.2mL/min/1.73m^2/year (P=0.0168).
- **April 2025:** The FDA approved Vanrafia™ (atrasentan) for the reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression.

Guideline Update(s):

- **August 2024:** Updated draft guidelines for the management of IgAN and immunoglobulin A vasculitis (IgAV) were published by Kidney Disease Improving Global Outcomes (KDIGO) for public draft review. Some of the key updates included:
    - The definition of a patient at risk of progressive loss of kidney function was changed from the prior definition of proteinuria >0.75-1g/day despite ≥90 days of optimized supportive care. The update defines at risk patients as having proteinuria ≥0.5g/day (or equivalent), while on or off treatment for IgAN, and recommends treatment/additional treatment should be started in all cases.
    - The treatment goal is to reduce the rate of loss of kidney function <1mL/min per year for the rest of a patient's life. Urine protein excretion is the only validated biomarker to help guide clinical decision making and should be maintained <0.5g/day and multiple therapies may be needed to achieve this goal.
    - The focus of management for most patients should be simultaneous to prevent or reduce IgA immune complex formation and immune complex-mediated glomerular injury [i.e., treatment with Tarpeyo® (budesonide DR capsule)] as well as to manage the consequences of existing IgAN induced nephron loss [i.e.,

treatment with lifestyle modifications, renin-angiotensin system inhibitors (RASi), and sodium-glucose cotransporter-2 (SGLT-2) inhibitors].
- Tarpeyo® is the only treatment to date proven to reduce the levels of pathogenic forms of IgA and IgA immune complexes. These effects have not been shown with other oral formulations of budesonide. Healthcare providers should also advise that it is possible that repeated 9-month cycles of Tarpeyo® or a reduced-dose maintenance regimen may be required to maintain disease remission, as an increase in proteinuria and decline in eGFR was observed on stopping Tarpeyo® treatment.

Pipeline:

- **Sibeprenlimab:** Sibeprenlimab is a monoclonal antibody that binds to and selectively inhibits the activity of APRIL (A Proliferation-Inducing Ligand). By blocking APRIL, IgA and pathogenic galactose-deficient IgA1 (Gd-IgA1) levels are reduced leading to less immune complex formation and may help slow kidney damage and progression toward end-stage renal disease (ESRD). The results of a Phase 2 ENVISION trial and Phase 3 VISIONARY trial found that intravenous sibeprenlimab led to significantly greater decrease in 24-hour urinary protein-to-creatinine ratio (UPCR) compared to placebo. In March 2025, Otsuka announced the filing of the Biologics License Application (BLA) with the FDA for sibeprenlimab for the treatment of IgAN.

Vanrafia™ (Atrasentan) Product Summary[7]

Therapeutic Class: Endothelin receptor antagonist (ERA)

Indication(s): To reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR ≥1.5g/g

- This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether Vanrafia™ slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

How Supplied: 0.75mg tablet

Dosing and Administration:

- The recommended dose of Vanrafia™ is 0.75mg orally once daily with or without food.
- Tablets should be swallowed whole and should not be cut, crushed, or chewed.

Efficacy: The safety and efficacy of Vanrafia™ were studied in a randomized, double-blind, placebo-controlled, multicenter Phase 3 ALIGN clinical trial.

- Key Inclusion Criteria:
  - 18 years of age or older
  - Biopsy proven primary IgAN
  - eGFR ≥30mL/min/1.73m^2
  - Urine protein ≥1g/day
  - Stable dose of maximally tolerated RASi which was continued throughout the trial
  - 64 patients were also on an SGLT-2 inhibitor
- Intervention: Randomized 1:1 to receive either Vanrafia™ 0.75mg or placebo once daily
- Primary Outcome: The primary endpoint was the percent reduction in UPCR at week 36 relative to baseline.
- Results: Vanrafia™ showed a 36% reduction in UPCR compared to placebo [95% confidence interval (CI): 26%, 45%; P<0.0001] at week 36. The treatment effect on UPCR at week 36 was also consistent in the 64 patients who were also on an SGLT-2 inhibitor.

Cost Comparison:

Product	Cost Per Tablet	Cost Per Month	Cost Per Year
Vanrafia™ (atrasentan) 0.75mg tablet	**$445.21**	**$13,356.30**	**$160,275.60***
Filspari® (sparsentan) 400mg tablet	$414.41	$12,432.30	$ 149,187.60*

Costs do not reflect rebated prices or net costs.
Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost is based on the FDA approved dosing of 1 tablet daily.

Recommendations

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

Vanrafia™ (Atrasentan) Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney 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, despite 3 months of maximal supportive care; and
6. Member must be on a stable dose of a maximally tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and
7. Females of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 2 weeks after the last dose of Vanrafia™; 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 updating the Filspari® (sparsentan) and Tarpeyo® (budesonide DR capsule) approval criteria based on the FDA full approvals and the KDIGO guidelines (changes shown in red):

Filspari® (Sparsentan) Approval Criteria:

1. An FDA approved indication to ~~reduce proteinuria~~ slow kidney decline in adults with primary immunoglobulin A nephropathy (IgAN) at risk of ~~rapid~~ disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney 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 rapid disease progression as demonstrated by ≥1 of the following, despite 3 months of maximal supportive care:~~
   ~~a. Urine protein-to-creatinine (UPCR) ratio ≥1.5g/g; or~~
   ~~b. Proteinuria >0.75g/day; and~~
6. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day, despite 3 months of maximal supportive care; and
7. Member must be on a stable dose of a maximally tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II

receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and
8. Prescriber must verify the member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin receptor antagonists (ERAs) prior to initiating treatment with Filspari®; and
9. Member must not be taking strong CYP3A4 inhibitors (e.g., itraconazole) or strong CYP3A4 inducers (e.g., rifampin) concomitantly with Filspari®; and
10. Member must not be taking H2 receptor blockers or proton pump inhibitors (PPIs) concomitantly with Filspari®; and
11. If member is using antacids, they must agree to separate antacid and Filspari® administration by 2 hours; and
12. Prescriber, pharmacy, and member must be enrolled in the Filspari® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
13. A quantity limit of 30 tablets per 30 days will apply.

Tarpeyo® [Budesonide Delayed Release (DR) Capsule] Approval Criteria:

1. An FDA approved indication to reduce ~~proteinuria~~ the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) at risk of ~~rapid~~ disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney 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 advanced care practitioner with a supervising physician who is a nephrologist); and
~~5. Member must be at risk of rapid disease progression as demonstrated by ≥1 of the following, despite maximal supportive care:~~
   ~~a. Urine protein-to-creatinine ratio (UPCR) ≥1.5g/g; or~~
   ~~b. Proteinuria >0.75g/day; and~~
6. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day; and
7. Member must be on a stable dose of a maximally-tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and
~~8. A patient-specific, clinically significant reason why a 6-month trial of an alternative formulation of budesonide DR oral capsules (e.g., Entocort® EC) or alternative oral corticosteroids is not appropriate for the member must be provided; and~~

9. Approval duration will be for 9 months. The safety and efficacy of Tarpeyo® have not been established beyond 9 months of treatment. For continued authorization consideration after 9 months of treatment, a patient-specific, clinically significant reason why a longer treatment duration is medically necessary for the member must be provided; and
10. A quantity limit of 120 capsules per 30 days will apply.

Utilization Details of Primary IgAN Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TARPEYO CAP 4MG	13	4	$204,568.33	$15,736.03	3.25	88.58%
FILSPARI TAB 400MG	2	1	$21,387.02	$10,693.51	2	9.26%
FILSAPRI TAB 200MG	1	1	$4,996.39	$4,996.39	1	2.16%
TOTAL	**16**	**5***	**$230,951.74**	**$14,434.48**	**3.2**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 04/2025. Last accessed 04/08/2025.
[2] Calliditas Therapeutics. Calliditas Therapeutics Announces Full FDA Approval of Tarpeyo®, the Only FDA-Approved Treatment for IgA Nephropathy to Significantly Reduce the Loss of Kidney Function. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/calliditas-therapeutics-announces-full-fda-approval-of-tarpeyo-the-only-fda-approved-treatment-for-iga-nephropathy-to-significantly-reduce-the-loss-of-kidney-function-302020478.html. Issued 12/20/2023. Last accessed 04/14/2025.
[3] Travere® Therapeutics. Travere® Therapeutics Announces Full FDA Approval of Filspari® (Sparsentan), the Only Non-Immunosuppressive Treatment that Significantly Slows Kidney Function Decline in IgA Nephropathy. Available online at: https://ir.travere.com/press-releases/news-details/2024/Travere-Therapeutics-Announces-Full-FDA-Approval-of-FILSPARI-sparsentan-the-Only-Non-Immunosuppressive-Treatment-that-Significantly-Slows-Kidney-Function-Decline-in-IgA-Nephropathy-09-05-2024/default.aspx. Issued 09/05/2024. Last accessed 04/14/2025.
[4] Novartis. Novartis Receives FDA Accelerated Approval for Vanrafia™ (Atrasentan), the First and Only Selective Endothelin A Receptor Antagonist for Proteinuria Reduction in Primary IgA nephropathy (IgAN). *GlobeNewswire*. Available online at: https://www.globenewswire.com/news-release/2025/04/03/3054782/0/en/Novartis-receives-FDA-accelerated-approval-for-Vanrafia-atrasentan-the-first-and-only-selective-endothelin-A-receptor-antagonist-for-proteinuria-reduction-in-primary-IgA-nephropath.html. Issued 04/02/2025. Last accessed 04/14/2025.
[5] Kidney Diseases: Improving Global Outcomes (KDIGO). KDIGO 2024 Clinical Practice Guidelines for the Management of Immunoglobin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). Available at: https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2024-IgAN-IgAV-Guideline-Public-Review-Draft.pdf. Issued 08/2024. Last accessed 04/14/2025.
[6] Otsuka Pharmaceutical, Co. Ltd. Otsuka Files Biologics License Application (BLA) for Sibeprenlimab in the Treatment of Immunoglobin A Nephropathy. Available online at: https://www.otsuka.co.jp/en/company/newsreleases/2025/20250331_1.html. Issued 03/31/2025. Last accessed 04/15/2025.
[7] Vanrafia™ (Atrasentan) Prescribing Information. Novartis Pharmaceuticals Corporation. Available online at: https://www.novartis.com/us-en/sites/novartis_us/files/vanrafia.pdf. Issued 04/2025. Last accessed 04/15/2025.

Appendix S

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: April 10, 2025

FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs

The FDA is taking a groundbreaking step to advance public health by replacing animal testing in the development of monoclonal antibody therapies and other drugs with more effective, human-relevant methods. The new approach is designed to improve drug safety and accelerate the evaluation process, while reducing animal experimentation, lowering research and development (R&D) costs, and ultimately, drug prices.

The FDA's animal testing requirement will be reduced, refined, or potentially replaced using a range of approaches, including artificial intelligence (AI)-based computational models of toxicity and cell lines and organoid toxicity testing in a laboratory setting (so-called New Approach Methodologies or NAMs data). Implementation of the regimen will begin immediately for investigational new drug (IND) applications, where inclusion of NAMs data is encouraged, and is outlined in a roadmap also being released today. To make determinations of efficacy, the FDA will also begin using pre-existing, real-world safety data from other countries, with comparable regulatory standards, where the drug has already been studied in humans.

Key benefits of replacing animal testing in monoclonal antibody safety evaluation include:

- Advanced Computer Simulations: The roadmap encourages developers to leverage computer modeling and artificial intelligence to predict a drug's behavior. For example, software models could simulate how a monoclonal antibody distributes through the human body and reliably predict side effects based on this distribution as well as the drug's molecular composition. The FDA believes this will drastically reduce the need for animal trials.
- Human-Based Lab Models: The FDA will promote the use of lab-grown human "organoids" and organ-on-a-chip systems that mimic human organs – such as liver, heart, and immune organs – to test drug safety. These experiments can reveal toxic effects that could easily go undetected in animals, providing a more direct window into human responses.
- Regulatory Incentives: The FDA will work to update its guidelines to allow consideration of data from these new methods. Companies that

submit strong safety data from non-animal tests may receive streamlined review, as the need for certain animal studies is eliminated, which would incentivize investment in modernized testing platforms.

- Faster Drug Development: The use of these modern techniques should help speed up the drug development process, enabling monoclonal antibody therapies to reach patients more quickly without compromising safety.
- Global Leadership in Regulatory Science: With this move, the FDA reaffirms its role as a global leader in modern regulatory science, setting new standards for the industry and encouraging the adoption of innovative, humane testing methods. In recent years, Congress and the scientific community have pressed for more human-relevant testing methods. Today's announcement is a step by the FDA towards its commitment to modernize regulatory science as technology advances.

Working in close partnership with federal agencies such as the National Institutes of Health, the National Toxicology Program, and the Department of Veterans Affairs, the FDA aims to accelerate the validation and adoption of these innovative methods through the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The FDA and federal partners will host a public workshop later this year to discuss the roadmap and gather stakeholder input on its implementation. Over the coming year, the FDA aims to launch a pilot program allowing select monoclonal antibody developers to use a primarily non-animal-based testing strategy, under close FDA consultation. Findings from an accompanying pilot study will inform broader policy changes and guidance updates expected to roll out in phases.

Current Drug Shortages Index (as of April 30, 2025):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma. Additional information regarding drug shortages can be found on the FDA website at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

Albuterol Sulfate Solution	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amoxicillin Powder, For Suspension	***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***
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide 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***
Indocyanine Green Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lactated Ringers Injection	***Currently in Shortage***
Leucovorin Calcium Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Lidocaine Hydrochloride Solution	***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***
Mefloquine Hydrochloride Tablet	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methylphenidate Film, Extended Release	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Naltrexone Hydrochloride Tablet	***Currently in Shortage***
Nitroglycerin Injection	***Currently in Shortage***
Oxazepam Capsule	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Peginterferon alfa-2a Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Peritoneal Dialysis Solution	***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***
Sodium Chloride 0.9% Injection	***Currently in Shortage***
Sodium Chloride 0.9% Irrigation	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Somatropin 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***