

Drug Utilization Review Board



OKLAHOMA

Health Care Authority

**Wednesday,
April 9, 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:

https://oklahoma.zoom.us/webinar/register/WN_94lCoSe9Ty2msgsLMqg2Ww

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





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 – April 9, 2025

DATE: April 2, 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 March meeting.
Material is arranged in order of the agenda.*

Call to Order

Public Comment Forum

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

Update on the Medication Coverage Authorization Unit – Appendix B

Spring Pipeline Update – Appendix C

Action Item – Vote to Prior Authorize Pantoprazole in 0.9% Sodium Chloride (NaCl) for Intravenous (IV) Injection and Update the Approval Criteria for the Anti-Ulcer Medications – Appendix D

Action Item – Vote to Prior Authorize Entresto® Sprinkle (Sacubitril/Valsartan Oral Pellets) and Update the Approval Criteria for the Heart Failure Medications – Appendix E

Action Item – Vote to Prior Authorize Symbravo® (Meloxicam/Rizatriptan) and Update the Approval Criteria for the Anti-Migraine Medications – Appendix F

Action Item – 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 – Appendix G

Action Item – Vote to Prior Authorize Kebilidi™ (Eladocogene Exuparvovec-tneq) – Appendix H

Action Item – Vote to Prior Authorize Crenessity™ (Crinecerfont) – Appendix I

Action Item – 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 – Appendix J

Action Item – Annual Review of Topical Acne, Psoriasis, and Rosacea Products – Appendix K

Action Item – Annual Review of Molluscum Contagiosum Medications – Appendix L

Action Item – Annual Review of Growth Hormone Products and Voxzogo® (Vosoritide) – Appendix M

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

Annual Review of Muscular Dystrophy Medications and 30-Day Notice to Prior Authorize Agamree® (Vamorolone) and Duvyzat™ (Givinostat) – Appendix O

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

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

30-Day Notice to Prior Authorize Journavx™ (Suzetrigine) – Appendix R

Annual Review of Thrombocytopenia Medications and 30-Day Notice to Prior Authorize Adzynma (ADAMTS13, Recombinant-krhn) and Alvaiz® (Eltrombopag) – Appendix S

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board (DUR Board)

Meeting – April 9, 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:

Mr. Kenneth Foster –	participating in person
Dr. Megan Hanner –	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

Viewing Access Only via Zoom:

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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. March 12, 2025 DUR Board Meeting Minutes
- B. March 12, 2025 DUR Board Recommendations Memorandum
- C. Correspondence

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

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

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

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

5. Spring Pipeline Update – See Appendix C

- A. Spring Pipeline Update

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

6. Action Item – 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 – See Appendix D

- A. Market News and Updates
- B. College of Pharmacy Recommendations

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

7. Action Item – Vote to Prior Authorize Entresto® Sprinkle (Sacubitril/Valsartan Oral Pellets) and Update the Approval Criteria for the Heart Failure Medications – See Appendix E

- A. Market News and Updates
- B. College of Pharmacy Recommendations

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

8. Action Item – Vote to Prior Authorize Symbravo® (Meloxicam/Rizatriptan) and Update the Approval Criteria for the Anti-Migraine Medications – See Appendix F

- A. Market News and Updates
- B. College of Pharmacy Recommendations

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

9. Action Item – Vote to Prior Authorize Ctexli™ (Chenodiol), Iqirvo® (Elafibranor) and Livdelzi® (Seladelpar) and Update the Approval Criteria for the Cholestatic Liver Disease Medications – See Appendix G

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

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

10. Action Item – Vote to Prior Authorize Kebilidi™ (Eladocagene Exuparvovec-tneq) – See Appendix H

- A. Market News and Updates
- B. College of Pharmacy Recommendations

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

11. Action Item – Vote to Prior Authorize Crenessity™ (Crinecerfont) – See Appendix I

- A. Market News and Updates
- B. College of Pharmacy Recommendations

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

12. Action Item – 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– See Appendix J

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

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

13. Action Item – Annual Review of Topical Acne, Psoriasis, and Rosacea Products – See Appendix K

- A. Current Prior Authorization Criteria
- B. Utilization of Topical Acne, Psoriasis, and Rosacea Products
- C. Prior Authorization of Topical Acne, Psoriasis, and Rosacea Products
- D. Market News and Updates
- E. College of Pharmacy Recommendations
- F. Utilization Details of Topical Acne, Psoriasis, and Rosacea Products

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

14. Action Item – Annual Review of Molluscum Contagiosum Medications – See Appendix L

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

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

15. Action Item – Annual Review of Growth Hormone Products and Voxzogo® (Vosoritide) – See Appendix M

- A. Current Prior Authorization Criteria
- B. Utilization of Growth Hormone Products and Voxzogo® (Vosoritide)
- C. Prior Authorization of Growth Hormone Products and Voxzogo® (Vosoritide)
- D. Market News and Updates
- E. College of Pharmacy Recommendations
- F. Utilization Details of Growth Hormone Products and Voxzogo® (Vosoritide)

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

16. Annual Review of Hemophilia Medications Medications and 30-Day Notice to Prior Authorize Alhemo® (Concizumab-mtci), Beqvez™ (Fidanacogene Elaparvovec), Hympavzi™ (Marstacimab-hncq), and Qfitlia™ (Fitusiran) – See Appendix N

- A. Current Prior Authorization Criteria
- B. Utilization of Hemophilia Medications
- C. Prior Authorization of Hemophilia Medications
- D. Market News and Updates
- E. Product Summaries
- F. Oklahoma Health Care Authority Recommendations
- G. Utilization Details of Hemophilia Medications

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

17. Annual Review of Muscular Dystrophy Medications and 30-Day Notice to Prior Authorize Agamree® (Vamorolone) and Duvyzat™ (Givinostat) – See Appendix O

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

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

18. Annual Review of Multiple Sclerosis (MS) Medications and 30-Day Notice to Prior Authorize Ocrevus Zunovo™ (Ocrelizumab/Hyaluronidase-ocsq) – See Appendix P

- A. Current Prior Authorization Criteria
- B. Utilization of MS Medications
- C. Prior Authorization of MS Medications
- D. Market News and Updates
- E. Ocrevus Zunovo™ (Ocrelizumab/Hyaluronidase-ocsq) Product Summary
- F. College of Pharmacy Recommendations
- G. Utilization Details of MS Medications

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

19. Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers and 30-Day Notice to Prior Authorize Xolremdi® (Mavorixafor) – See Appendix Q

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

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

20. 30-Day Notice to Prior Authorize Journavx™ (Suzetrigine) – See Appendix R

- A. Journavx™ (Suzetrigine) Product Summary
- B. College of Pharmacy Recommendations

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

21. Annual Review of Thrombocytopenia Medications and 30-Day Notice to Prior Authorize Adzynma (ADAMTS13, Recombinant-krhn) and Alvaiz® (Eltrombopag) – See Appendix S

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

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

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

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

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

- A. Anti-Diabetic Medications and Kerendia® (Finerenone)
- B. Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications
- C. Botulinum Toxins
- D. Parkinson's Disease Medications
- E. Spinal Muscular Atrophy (SMA) Medications

*Future product and class reviews subject to change.

24. Adjournment

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

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



**OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING MARCH 12, 2025**

DUR BOARD MEMBERS:	PRESENT	ABSENT
Kenneth Foster, MHS, PA-C	X	
Megan A. Hanner, D.O.	X	
Bret Haymore, M.D.; Chair		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 Chair	X	
Vineetha Thomas, Pharm.D., BCOP	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., BCOP, MBA	X	
Lauren Sinko, Pharm.D., BCOP		X
Graduate Students: Matthew Dickson, Pharm.D.	X	
Visiting Pharmacy Student(s): N/A		

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	
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:

John Bullard, Alexion	Lisa Dunn, Amgen
Mike Sullivan, Amgen	Tina Hartmann, Arcutis Biotherapeutics
Brielle Dozier, Artia Solutions	Mandee Bomhoff, AstraZeneca
Crystal Burkhardt, AstraZeneca	Christine Dube, AstraZeneca
Jennifer Tamburo, AstraZeneca	Ronnie DePue, Axsome
Dan O'Donnell, Axsome	Patty Laster, BeiGene
Bryan Steffan, Boehringer	Gary Parenteau, Dexcom
Lindsey Baker, Genentech	Rodney Brown, Genentech
Eardie Curry, Genentech	Ed Eldridge, Gilead
Michael Pazirandeh, Gilead	Justin Springfield, Gilead
Rhonda Clark, Indivior	Jim Gibbs, Intra-Cellular Therapies
Jason Dickerson, Jazz Pharmaceuticals	Michael Faithe, Jazz Pharmaceuticals
Brent Parker, Merck	Brandon Ross, Merck
Jody Legg, Mirum Pharmaceuticals	Albert Mei, Mirum Pharmaceuticals
JJ Roth, Mirum Pharmaceuticals	Kent Douglas, Neurocrine
Ray Kong, Neurocrine	Drew Sligar, Novartis
Logan Poole, Novo Nordisk	David Prather, Novo Nordisk
Kim Corcoran, ODMHSAS	Allie Friesen, ODMHSAS
Curt Rawls, ODMHSAS	Allison Scott, Orchard Therapeutics
Erik Schindler, Sanofi	Dave Miley, Teva Pharmaceuticals
John Omick, Travele Therapeutics	Brent Fushimi, UCB
Roberto Pedraza, Vertex	Phil Lohec, Viartis
Irene Chung, Aetna	Kristen Winters, Centene
Deidra Williams, Humana	Lindsey Walter

PRESENT FOR PUBLIC COMMENT:

Crystal Burkhardt, AstraZeneca	Ronnie DePue, Axsome
Ray Kong, Neurocrine	Michael Pazirandeh, Gilead

AGENDA ITEM NO. 1:

CALL TO ORDER

1A: ROLL CALL

Dr. Patatanian called the meeting to order at 4:00pm. Roll call by Dr. Wilcox did not initially establish the presence of a quorum; however, a quorum was established prior to any action items being voted on.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 2:

PUBLIC COMMENT FORUM

2A: AGENDA ITEM NO. 19

CRYSTAL BURKHARDT

2B: AGENDA ITEM NO. 22

RONNIE DEPUE

2C: AGENDA ITEM NO. 23

RAY KONG

2D: AGENDA ITEM NO. 24

MICHAEL PAZIRANDEH

ACTION: NONE REQUIRED

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

3A: DECEMBER 11, 2024 DUR MINUTES – VOTE

Materials included in agenda packet; presented by Dr. Patatanian
Dr. Walton moved to approve; seconded by Dr. Muñoz

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: UPDATE ON MEDICATION COVERAGE

AUTHORIZATION UNIT

4A: PHARMACY HELP DESK ACTIVITY FOR DECEMBER 2024

4B: MEDICATION COVERAGE ACTIVITY FOR DECEMBER 2024

4C: PHARMACY HELP DESK ACTIVITY FOR JANUARY 2025

4D: MEDICATION COVERAGE ACTIVITY FOR JANUARY 2025

4E: PHARMACY HELP DESK ACTIVITY FOR FEBRUARY 2025

4F: MEDICATION COVERAGE ACTIVITY FOR FEBRUARY 2025

4G: CORRESPONDENCE

Materials included in agenda packet by Dr. Moss; item not presented

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: ACADEMIC DETAILING (AD) UPDATE

5A: AD PROGRAM UPDATE

Materials included in agenda packet; presented by Dr. Travers

ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: NARROW THERAPEUTIC INDEX (NTI) LIST

6A: INTRODUCTION

6B: SOONERCARE NTI LIST

6C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss

ACTION: NONE REQUIRED

**AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE JUBBONTI®
(DENOSUMAB-BBDZ) AND UPDATE THE APPROVAL CRITERIA FOR THE
OSTEOPOROSIS MEDICATIONS**

7A: MARKET NEWS AND UPDATES

7B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. DeRemer

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

ACTION: MOTION CARRIED

**AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE AQNEURSA™
(LEVACETYLLEUCINE), LENMELDY™ (ATIDARSAGENE AUTOTEMCEL), AND
MIPLYFFA™ (ARIMOCLOMOL) AND UPDATE THE APPROVAL CRITERIA FOR THE
LYSOSOMAL STORAGE DISEASE MEDICATIONS**

8A: MARKET NEWS AND UPDATES

8B: PRODUCT SUMMARIES

8C: COST COMPARISON: NIEMANN-PICK DISEASE TYPE C (NPC) PRODUCTS

8D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson

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

ACTION: MOTION CARRIED

**AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE YORVIPATH®
(PALOPEGTERIPARATIDE) AND UPDATE THE APPROVAL CRITERIA FOR THE
PARATHYROID MEDICATIONS**

9A: MARKET NEWS AND UPDATES

9B: YORVIPATH® (PALOPECTERIPARATIDE) PRODUCT SUMMARY

9C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

Dr. Muñoz moved to approve; seconded by Mr. Foster

ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE BKEMV™ (ECULIZUMAB-AEEB), EPYSQLI® (ECULIZUMAB-AAGH), FABHALTA® (IPTACOPAN), PIASKY® (CROVALIMAB-AKKZ), AND VOYDEYA™ (DANICOPAN) AND UPDATE THE APPROVAL CRITERIA FOR THE COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS

10A: MARKET NEWS AND UPDATES

10B: PRODUCT SUMMARIES

10C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: VOTE TO PRIOR AUTHORIZE LABETALOL HYDROCHLORIDE 400MG TABLET, NEXICLON™ XR [CLONIDINE EXTENDED-RELEASE (ER)], AND TRYVIO™ (APROCITENTAN) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTIHYPERTENSIVE MEDICATIONS

11A: MARKET NEWS AND UPDATES

11B: TRYVIO™ (APROCITENTAN) PRODUCT SUMMARY

11C: COST COMPARISONS

11D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. DeRemer

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: VOTE TO PRIOR AUTHORIZE ACTHAR® GEL SELFJECT™ (REPOSITORY CORTICOTROPIN AUTO-INJECTOR) AND PURIFIED CORTROPHIN® GEL (REPOSITORY CORTICOTROPIN INJECTION) AND UPDATE THE APPROVAL CRITERIA FOR THE ADRENOCORTICOTROPIC HORMONE (ACTH) PRODUCTS

12A: MARKET NEWS AND UPDATES

12B: COLLEGE OF PHARMACY RECOMMENDATIONS

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

Mr. Foster moved to approve; seconded by Dr. Thomas

ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: VOTE TO PRIOR AUTHORIZE DIFLUNISAL 500MG TABLET, DOLOBID™ (DIFLUNISAL) 250MG AND 375MG TABLET, AND INDOMETHACIN 50MG SUPPOSITORY AND UPDATE THE APPROVAL CRITERIA FOR THE SYSTEMIC NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)

13A: MARKET NEWS AND UPDATES

13B: DOLOBID™ (DIFLUNISAL) PRODUCT SUMMARY

13C: COST COMPARISON: INDOMETHACIN PRODUCTS

13D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: VOTE TO PRIOR AUTHORIZE TRYNGOLZA™ (OLEZARSEN) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTIHYPERLIPIDEMICS

14A: MARKET NEWS AND UPDATES

14B: TRYNGOLZA™ (OLEZARSEN) PRODUCT SUMMARY

14C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 15: VOTE TO PRIOR AUTHORIZE WYOST® (DENOSUMAB-BBDZ)

15A: MARKET NEWS AND UPDATES

15B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss

Dr. Muñoz moved to approve; seconded by Mr. Foster

ACTION: MOTION CARRIED

AGENDA ITEM NO. 16: VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE OPHTHALMIC ANTIBIOTIC MEDICATIONS

16A: MARKET NEWS AND UPDATES

16B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 17: VOTE TO PRIOR AUTHORIZE TEVEMBRA® (TISLELIZUMAB-JSGR), VYLOY® (ZOLBETUXIMAB-CLZB), AND ZIIHERA® (ZANIDATAMAB-HRII) AND UPDATE THE APPROVAL CRITERIA FOR THE GASTROINTESTINAL (GI) CANCER MEDICATIONS

17A: MARKET NEWS AND UPDATE

17B: PRODUCT SUMMARIES

17C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Hughes

Dr. Thomas moved to approve; seconded by Dr. Walton

ACTION: MOTION CARRIED

AGENDA ITEM NO. 18: VOTE TO PRIOR AUTHORIZE FYARRO® (SIROLIMUS PROTEIN-BOUND PARTICLES FOR INJECTABLE SUSPENSION), NIKTIMVO™ (AXATILIMAB-CSFR), OJEMDA™ (TOVORAFENIB), TECELRA® (AFAMITRESGENE AUTOLEUCEL), AND VORANIGO® (VORASIDENIB) AND UPDATE THE APPROVAL CRITERIA FOR THE MISCELLANEOUS CANCER MEDICATIONS

18A: MARKET NEWS AND UPDATES

18B: PRODUCT SUMMARIES

18C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Hughes

Mr. Foster moved to approve; seconded by Dr. Muñoz

ACTION: MOTION CARRIED

AGENDA ITEM NO. 19: ANNUAL REVIEW OF SHORT-ACTING BETA₂ AGONISTS (SABAS)

19A: CURRENT PRIOR AUTHORIZATION CRITERIA

19B: UTILIZATION OF SABAS

19C: PRIOR AUTHORIZATION OF SABAS

19D: MARKET NEWS AND UPDATES

19E: COLLEGE OF PHARMACY RECOMMENDATIONS

19F: UTILIZATION DETAILS OF SABAS

Materials included in agenda packet; presented by Dr. O'Halloran
Regarding the approval criteria for Airsupra® (albuterol/budesonide), Dr. Kupiec recommended removing criteria 4 (a reason why the member cannot use an ICS/formoterol as recommended by GINA guidelines) based on clinical practice. The DUR Board voted on the amended criteria.

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 20: ANNUAL REVIEW OF LEUKEMIA AND LYMPHOMA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AUCATZYL® (OBECABTAGENE AUTOLEUCEL), DANZITEN™ (NILETINIB), GRAFAPEX™ (TREOSULFAN), REVUFORJ® (REVUMENIB), AND RYTELO™ (IMETELSTAT)

20A: CURRENT PRIOR AUTHORIZATION CRITERIA

20B: UTILIZATION OF LEUKEMIA AND LYMPHOMA MEDICATIONS

20C: PRIOR AUTHORIZATION OF LEUKEMIA AND LYMPHOMA MEDICATIONS

20D: MARKET NEWS AND UPDATES

20E: PRODUCT SUMMARIES

20F: COLLEGE OF PHARMACY RECOMMENDATIONS

20G: UTILIZATION DETAILS OF LEUKEMIA AND LYMPHOMA MEDICATIONS

Materials included in agenda packet; presented by Dr. Hughes

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

AGENDA ITEM NO. 21 30-DAY NOTICE TO PRIOR AUTHORIZE KEBILIDI™ (ELADOCAGENE EXUPARVOVEC-TNEQ)

21A: INTRODUCTION

21B: KEBILIDI™ (ELADOCAGENE EXUPARVOVEC-TNEQ) PRODUCT SUMMARY

21C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. DeRemer

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

AGENDA ITEM NO. 22: ANNUAL REVIEW OF ANTI-MIGRAINE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE SYMBRAVO® (MELOXICAM/RIZATRIPTAN)

22A: CURRENT PRIOR AUTHORIZATION CRITERIA

22B: UTILIZATION OF ANTI-MIGRAINE MEDICATIONS

22C: PRIOR AUTHORIZATION OF ANTI-MIGRAINE MEDICATIONS

22D: MARKET NEWS AND UPDATES

22E: COLLEGE OF PHARMACY RECOMMENDATIONS

22F: UTILIZATION DETAILS OF ANTI-MIGRAINE MEDICATIONS

Materials included in agenda packet; presented by Dr. Moss

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

AGENDA ITEM NO. 23: 30-DAY NOTICE TO PRIOR AUTHORIZE CRENESSITY™ (CRINECERFONT)

23A: INTRODUCTION

23B: CRENESSITY™ (CRINECERFONT) PRODUCT SUMMARY

23C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

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

AGENDA ITEM NO. 24: ANNUAL REVIEW OF CHOLESTATIC LIVER DISEASE AND BILE ACID DISORDER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE CTEXLI™ (CHENODIOL), IQIRVO® (ELAFIBRANOR), AND LIVDELZI® (SELADELPAR)

24A: CURRENT PRIOR AUTHORIZATION CRITERIA

24B: UTILIZATION OF CHOLESTATIC LIVER DISEASE AND BILE ACID DISORDER MEDICATIONS

24C: PRIOR AUTHORIZATION OF CHOLESTATIC LIVER DISEASE AND BILE ACID DISORDER MEDICATIONS

24D: MARKET NEWS AND UPDATES

24E: PRODUCT SUMMARIES

24F: COST COMPARISON: PRIMARY BILIARY CHOLANGITIS (PBC) MEDICATIONS

24G: COLLEGE OF PHARMACY RECOMMENDATIONS

24H: UTILIZATION DETAILS OF CHOLESTATIC LIVER DISEASE MEDICATIONS

Materials included in agenda packet; presented by Dr. Wilson

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

AGENDA ITEM NO. 25: ANNUAL REVIEW OF ANTI-ULCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE PANTOPRAZOLE IN 0.9% SODIUM CHLORIDE (NACL) FOR INTRAVENOUS (IV) INJECTION

25A: CURRENT PRIOR AUTHORIZATION CRITERIA

25B: UTILIZATION OF ANTI-ULCER MEDICATIONS

25C: PRIOR AUTHORIZATION OF ANTI-ULCER MEDICATIONS

25D: MARKET NEWS AND UPDATES

25E: COLLEGE OF PHARMACY RECOMMENDATIONS

25F: UTILIZATION DETAILS OF ANTI-ULCER MEDICATIONS

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

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

AGENDA ITEM NO. 26: ANNUAL REVIEW OF HEART FAILURE (HF) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ENTRESTO® SPRINKLE (SACUBITRIL/VALSARTAN ORAL PELLETS)

26A: CURRENT PRIOR AUTHORIZATION CRITERIA

26B: UTILIZATION OF HF MEDICATIONS

26C: PRIOR AUTHORIZATION OF HF MEDICATIONS

26D: MARKET NEWS AND UPDATES

26E: COLLEGE OF PHARMACY RECOMMENDATIONS

26F: UTILIZATION DETAILS OF HF MEDICATIONS

Materials included in agenda packet; presented by Dr. DeRemer

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

AGENDA ITEM NO. 27: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTRATION (DEA) UPDATES

Materials included in agenda packet by Dr. Moss; item not presented

ACTION: NONE REQUIRED

AGENDA ITEM NO. 28: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)

28A: ANTICONSULTANTS

28B: GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)

28C: MULTIPLE SCLEROSIS MEDICATIONS

28D: MUSCULAR DYSTROPHY MEDICATIONS

*Future product and class reviews subject to change.

Materials included in agenda packet by Dr. Adams; item not presented

ACTION: NONE REQUIRED

AGENDA ITEM NO. 29: ADJOURNMENT

Dr. Walton moved to adjourn; seconded by Dr. Thomas
Dr. Patatanian declared the meeting as adjourned at 6:26pm.

ACTION: MOTION CARRIED



The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: March 14, 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 Packet Meeting on March 12, 2025

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Academic Detailing (AD) Program Update

NO ACTION REQUIRED.

Recommendation 3: Narrow Therapeutic Index (NTI) List

NO ACTION REQUIRED.

Recommendation 4: Vote to Prior Authorize Jubbonti® (Denosumab-bbdz) and Update the Approval Criteria for the Osteoporosis Medications

MOTION CARRIED by unanimous approval.

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

1. Updating the Osteoporosis Medications Tier-2 Approval Criteria to clarify the requirement for hypersensitivity or intolerance to Tier-1 bisphosphonates; and

2. The prior authorization and placement of Jubbonti® (denosumab-bbdz) into the Special PA Tier with unique criteria for use of a biosimilar product; and
3. Adding Bonsity® (teriparatide) to the Forteo® (teriparatide) additional Special PA Approval Criteria for clarity; and
4. Designating Forteo® (teriparatide) as brand preferred and preferring Forteo® (teriparatide) and generic teriparatide over Bonsity® (teriparatide) based on net costs.

Osteoporosis Medications*		
Tier-1	Tier-2	Special PA [‡]
alendronate tabs (Fosamax®)	alendronate + vitamin D tabs (Fosamax® + D)	abaloparatide inj (Tymlos®)
calcium + vitamin D [†]	risedronate tabs (Actonel®)	alendronate effervescent tabs (Binosto®)
ibandronate tabs (Boniva®)		alendronate soln (Fosamax®)
zoledronic acid inj (Reclast®)		alendronate 40mg tabs (Fosamax®)
		denosumab inj (Prolia®)
		denosumab-bbdz inj (Jubbonti®)
		ibandronate inj (Boniva® IV)
		risedronate 30mg tabs (Actonel®)
		risedronate DR tabs (Atelvia®)
		romosozumab-aqqg (Evenity®)
		teriparatide inj (Forteo®) – Brand Preferred
		teriparatide inj (Bonsity®)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

[†]OTC calcium + vitamin D must be used at recommended doses in conjunction with Tier-1 bisphosphonates for trial to be accepted unless member has a recent laboratory result showing adequate vitamin D or member is unable to tolerate calcium. OTC calcium + vitamin D are only covered for members with osteoporosis who are being treated with a bisphosphonate.

[‡]Unique criteria applies to medications in the Special PA Tier.

DR = delayed-release; inj = injection; PA = prior authorization; soln = solution; tabs = tablets

Osteoporosis Medications Tier-2 Approval Criteria:

1. A trial of at least 1 Tier-1 bisphosphonate medication, compliantly used for at least 6 months concomitantly with calcium and vitamin D, that failed to prevent fracture or improve bone mineral density (BMD) scores; or

2. Hypersensitivity to or intolerable adverse effect(s) with all Tier-1 bisphosphonate medications (including oral and intravenous routes of administration); and
3. Quantity limits apply based on FDA approved maximum doses.

Boniva® [Ibandronate Intravenous (IV) Solution], Jubbonti® (Denosumab-bbdz), and Prolia® (Denosumab) Approval Criteria:

1. A minimum of a 12-month trial with a Tier-1 or Tier-2 bisphosphonate medication plus adequate calcium and vitamin D; or
2. Contraindication to or intolerable adverse effects with Tier-1 and Tier-2 bisphosphonate medications (including oral and intravenous routes of administration); and
3. For Jubbonti®, a patient-specific, clinically significant reason why the member cannot use Prolia® (denosumab) 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.

Bonsity® (Teriparatide) and Forteo® (Teriparatide) and Teriparatide Approval Criteria:

1. Diagnosis of 1 of the following:
 - a. Treatment of postmenopausal women with osteoporosis at high risk for fracture; or
 - b. To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture; or
 - c. Treatment of men and women with osteoporosis associated with sustained systemic corticosteroid therapy at high risk for fracture; or
 - d. Treatment of non-healing fracture (this indication only pertains to Forteo®); and
2. A minimum 12-month trial with a bisphosphonate plus adequate calcium and vitamin D or a patient-specific, clinically significant reason why the member cannot use a bisphosphonate must be provided; and
3. Use of generic teriparatide will require a patient-specific, clinically significant reason why the member cannot use the brand formulation, Forteo® (teriparatide); and
4. Use of Bonsity® (teriparatide) will require a patient-specific, clinically significant reason why the member cannot use Forteo® (teriparatide) or generic teriparatide formulations; and
5. The diagnosis of non-healing fracture may be approved for 6 months; and
6. Treatment duration including other parathyroid hormone analogs has not exceeded a total of 24 months during the patient's lifetime; and

7. Approval will be for a maximum of 2 years of parathyroid hormone analog therapy.

Recommendation 5: Vote to Prior Authorize Aqneursa™ (Levacetylleucine), Lenmeldy™ (Atidarsagene Autotemcel), and Miplyffa™ (Arimoclomol) and Update the Approval Criteria for the Lysosomal Storage Disease Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Aqneursa™ (levacetylleucine), Lenmeldy™ (atidarsagene autotemcel), and Miplyffa™ (arimoclomol) with the following criteria (shown in red):

Lenmeldy™ (Atidarsagene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of metachromatic leukodystrophy (MLD) confirmed by:
 - a. Arylsulfatase A (ARSA) enzyme activity below the normal range in peripheral blood mononuclear cells or fibroblasts (results of assay must be submitted); and
 - b. Molecular genetic testing confirming biallelic pathogenic variants in the ARSA gene of known polymorphisms (results of genetic testing must be submitted); or
 - i. If novel ARSA variant(s) are identified, a 24-hour urine collection must demonstrate increased urinary excretion of sulfatides (results must be submitted); and
2. Member must have 1 of the following forms of MLD as determined by the prescriber (clinical documentation must be submitted with the request):
 - a. Pre-symptomatic late infantile (PSLI) MLD with expected disease onset ≤ 30 months of age; or
 - b. Pre-symptomatic early juvenile (PSEJ) MLD with expected disease onset > 30 months and < 7 years of age; or
 - c. Early symptomatic early juvenile (ESEJ) MLD with disease onset > 30 months and < 7 years of age; and
3. Member must be younger than 18 years of age; and
4. Must be prescribed by a geneticist, hematologist/oncologist, neurologist, or other specialist with expertise in the treatment of MLD and the administration of Lenmeldy™; and
5. Member must not have a history of prior hematopoietic stem cell transplantation (HSCT); or
 - a. If member has had a HSCT, there is no evidence of residual cells of donor origin; and
6. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Lenmeldy™); and

7. Member must have a negative serology test for human immunodeficiency virus 1 & 2 (HIV-1/HIV-2), hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2), cytomegalovirus (CMV), and mycoplasma prior to apheresis; and
8. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Lenmeldy™ administration; and
9. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Lenmeldy™; and
10. Prescriber must verify male and female members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member or member's caregiver; and
11. Prescriber must verify the member has been evaluated for and counseled on all warnings and precautions related to Lenmeldy™, including the risk of thrombosis and thromboembolic events, serious infections, and veno-occlusive disease; and
12. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed annually and integration site analysis as warranted for at least 15 years after treatment with Lenmeldy™; and
13. Must be administered at a Lenmeldy™ qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Lenmeldy™ dose from receipt to storage to administration; and
14. Approvals will be for 1 dose per member per lifetime.

Aqneursa™ (Levacetylleucine) Approval Criteria:

1. An FDA approved diagnosis of Niemann-Pick disease type C (NPC) confirmed by molecular genetic testing confirming biallelic pathogenic variants in the *NPC1* or *NPC2* genes (results of genetic testing must be submitted); and
2. Member must have the presence of at least mild disease-related neurological symptoms; and
3. Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPC; and
4. Will not be approved for concomitant use with Miplyffa™ (arimoclomol); and
5. 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
6. 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 7 days after the last dose of Aqneursa™; and

7. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Miplyffa™ (Arimoclomol) Approval Criteria:

1. An FDA approved diagnosis of Niemann-Pick disease type C (NPC) confirmed by molecular genetic testing confirming biallelic pathogenic variants in the *NPC1* or *NPC2* genes (results of genetic testing must be submitted); and
2. Member must have the presence of at least mild disease-related neurological symptoms; and
3. Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPC; and
4. Must be used in combination with Zavesca® (miglustat); and
 - a. Zavesca® is brand preferred. Requests for generic miglustat (including Yargesa®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
5. A patient-specific, clinically significant reason why the member cannot use Aqneursa™ (levacetylleucine) must be provided; and
6. Will not be approved for concomitant use with Aqneursa™; and
7. Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Prescriber must verify that females of reproductive potential have been counseled on the potential risks of embryofetal harm when administered during pregnancy; and
9. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Additionally, the College of Pharmacy recommends updating the approval criteria for Brineura® (cerliponase alfa) based on the recent FDA approved age expansion and label updates (changes shown in red):

Brineura® (Cerliponase Alfa) Approval Criteria:

1. An FDA approved diagnosis of ~~late infantile~~ neuronal ceroid lipofuscinosis type 2 (CLN2) also known as tripeptidyl peptidase-1 (TPP-1) deficiency confirmed by:
 - a. Enzyme assay demonstrating a deficiency of TPP-1 enzyme activity (results of assay must be submitted); or

- b. Molecular genetic testing confirming biallelic pathogenic variants in the *TPP1* gene (results of genetic testing must be submitted); and
2. Member must be ~~3 years of age or older~~ at least 37 weeks post-menstrual age (i.e., gestational age at birth plus post-natal age) and weigh $\geq 2.5\text{kg}$; and
3. Brineura[®] must be prescribed by a specialist with expertise in the treatment of CLN2 (or an advanced care practitioner with a supervising physician who is a specialist with expertise in treating CLN2); and
4. Brineura[®] must be administered in a health care facility by a prescriber who is knowledgeable in intraventricular administration and prepared to manage anaphylaxis; and
5. Member must not have ventriculoperitoneal shunts or acute intraventricular access device-related complications; and
6. Member must not have documented generalized status epilepticus within 4 weeks of initiating treatment; and
7. Prescriber must verify member's blood pressure and heart rate will be monitored prior to each infusion, during infusion, and post-infusion; and
8. Prescriber must be willing to perform regular 12-lead electrocardiogram (ECG) evaluation at baseline and at least every 6 months and verify that they are acceptable to the prescriber; and
9. A baseline assessment must be performed to assess the Motor plus Language CLN2 score; and
10. Initial authorizations will be for the duration of 6 months, at which time compliance will be required for continued approval. After 12 months of utilization, the prescriber must verify the member is responding to the medication as demonstrated by ≤ 2 point decline in Motor plus Language CLN2 score from baseline. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment; and
11. Approval quantity will be based on package labeling and FDA approved dosing regimen.

Lastly, the College of Pharmacy recommends updating the approval criteria for Zavesca[®] (miglustat) based on net cost and to allow use in patients with NPC (changes and new criteria shown in red):

Zavesca[®] (Miglustat) Approval Criteria [Gaucher Disease Diagnosis]:

1. An FDA approved diagnosis of mild/moderate type 1 Gaucher disease (GD1) confirmed by:
 - a. Enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity ($\leq 15\%$ of normal) (results of assay must be submitted); or

- b. Molecular genetic testing confirming biallelic pathogenic variants in the *GBA1* gene (results of genetic testing must be submitted); and
2. A patient-specific, clinically significant reason why the member cannot use 1 of the following enzyme replacement therapies must be provided:
 - a. Cerezyme® (imiglucerase); or
 - b. Elvelo® (taliglucerase alfa); or
 - c. Vpriv® (velaglucerase alfa); and
3. Zavesca® is brand preferred. Requests for generic miglustat (including Yargesa®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
4. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of GD1; and
5. Prescriber must verify the member will not take Zavesca® concurrently with another therapy for GD1; and
6. A quantity limit of 90 capsules per 30 days will apply; and
7. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Zavesca® (Miglustat) Approval Criteria [Niemann-Pick Disease Type C (NPC) Diagnosis]:

1. A diagnosis of NPC confirmed by molecular genetic testing confirming biallelic pathogenic variants in the *NPC1* or *NPC2* genes (results of genetic testing must be submitted); and
2. Member must have the presence of at least mild disease-related neurological symptoms; and
3. Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPC; and
4. Zavesca® is brand preferred. Requests for generic miglustat (including Yargesa®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
5. For members younger than 12 years of age, 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; and
6. A quantity limit of 180 capsules per 30 days will apply; and
7. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Recommendation 6: Vote to Prior Authorize Yorvipath® (Palopegteriparatide) and Update the Approval Criteria for the Parathyroid Medications

MOTION CARRIED by unanimous approval.

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

Yorvipath® (Palopegteriparatide) Approval Criteria

1. An FDA approved diagnosis of hypoparathyroidism; and
2. Member must be 18 years of age or older; and
3. Prescriber must verify the following:
 - a. Member has albumin-corrected serum calcium $\geq 7.8\text{mg/dL}$ and serum 25(OH) vitamin D is within the normal range; and
 - b. Serum calcium will be measured within 7-10 days after the first dose and after any dose change in Yorvipath®, active vitamin D, or calcium supplements; and
 - c. Member or member's caregiver has been trained by a health care professional on proper storage, preparation, and subcutaneous (sub-Q) administration of Yorvipath®; and
 - d. Member must not have acute post-surgical hypoparathyroidism; and
4. Member must be unable to be adequately well-controlled on calcium supplements and active forms of vitamin D alone; and
5. A quantity limit of 2 pre-filled pens [each package contains (2) 14-day pre-filled pens] per 28 days will apply. The maximum covered dose will be 30mcg per day.

Additionally, the College of Pharmacy recommends the removal of SoonerCare coverage and the prior authorization criteria for Natpara® (parathyroid hormone) based on product discontinuation (changes shown in red):

Natpara® (Parathyroid Hormone) Approval Criteria:

- ~~1.—An FDA approved indication for use as an adjunct to calcium and vitamin D to control hypocalcemia in members with hypoparathyroidism; and~~
 - ~~a.—Natpara is not FDA approved for hypoparathyroidism caused by calcium-sensing receptor mutations; and~~
 - ~~b.—Natpara is not FDA approved for hypoparathyroidism due to acute post-surgery; and~~
- ~~2.—Magnesium deficiency must be ruled out; and~~
- ~~3.—Member must have pretreatment serum calcium above 7.5mg/dL before starting Natpara; and~~
- ~~4.—Prescriber must verify the member has sufficient 25-hydroxyvitamin D level per standard of care; and~~

- ~~5. Member must be unable to be adequately well-controlled on calcium supplements and active forms of vitamin D alone; and~~
- ~~6. Health care provider and dispensing pharmacy must be certified through the Natpara REMS Program; and~~
- ~~7. A quantity limit of two cartridges (each package contains two 14-day cartridges) per 28 days will apply. The maximum covered dose will be 100mcg per day.~~

Recommendation 7: Vote to Prior Authorize Bkerv™ (Eculizumab-aeab), Epysli® (Eculizumab-aagh), Fabhalta® (Iptacopan), Piasky® (Crovalimab-akkz), and Voydeya™ (Danicopan) and Update the Approval Criteria for the Complement Inhibitors and Miscellaneous Immunomodulatory Agents

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Fabhalta® (iptacopan), Piasky® (crovalimab-akkz), and Voydeya™ (danicopan) with the following criteria (shown in red):

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

1. An FDA approved indication to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
 - a. Kidney biopsy; 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 $\geq 0.5\text{g/day}$; and
6. Member must be on a stable dose of a maximally tolerated angiotensin convert enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and
7. Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Fabhalta® (Iptacopan) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Fabhalta® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
5. For members switching from Soliris® (eculizumab) to Fabhalta®, the prescriber must verify the member will start Fabhalta® no later than 1 week after the last dose of Soliris®; and
6. For members switching from Ultomiris® (ravulizumab-cwvz) to Fabhalta®, the prescriber must verify the member will start Fabhalta® no later than 6 weeks after the last dose of Ultomiris®; and
7. Member must not be receiving Fabhalta® in combination with another complement inhibitor used to treat PNH (i.e., Empaveli®, Piasky®, Soliris®, Ultomiris®, Voydeya®); 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.

Piasky® (Crovalimab-akkz) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 13 years of age or older and must weigh ≥ 40 kg; and
3. Piasky® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Piasky® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For members switching from another C5 inhibitor (i.e., Soliris® or Ultomiris®), the prescriber must verify the first intravenous (IV) loading dose of Piasky® will be administered no sooner than the time of the next scheduled C5 inhibitor dose and member will be monitored for Type III hypersensitivity reactions; and
7. Member must not be receiving Piasky® in combination with another complement inhibitor used to treat PNH (i.e., Empaveli®, Fabhalta®, Soliris®, Ultomiris®, Voydeya®); and
8. A quantity limit override for the loading dose will be approved upon meeting Piasky® approval criteria. A quantity limit of 6mL per 28 days will apply for the maintenance dose; and

9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Voydeya™ (Danicopan) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Voydeya™ must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Member must have been treated with Soliris® (eculizumab) or Ultomiris® (ravulizumab-cwvz) for at least the previous 6 months; and
5. Prescriber must verify member is experiencing clinically significant extravascular hemolysis (EVH) while on Soliris® or Ultomiris®; and
6. Member must remain on treatment with Soliris® or Ultomiris® while on Voydeya™; and
7. Member must not be receiving Voydeya® in combination with another complement protein C3 inhibitor (i.e., Empaveli®) or complement factor B inhibitor (i.e., Fabhalta®) used to treat PNH; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber must be enrolled in the Voydeya™ Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment through therapy; and
10. Initial approvals will be for the duration of 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Additionally, the College of Pharmacy recommends the addition of prior authorization criteria for Ultomiris® (ravulizumab-cwvz) for a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and for Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) for a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) based on the new FDA approved indications with the following criteria (shown in red):

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have a history of at least 1 relapse in the last 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤7; and

5. Ultomiris® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
7. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. Member must not be receiving Ultomiris® in combination with other immunomodulators to treat NMOSD (i.e., Enspryng®, Soliris®, Uplizna®); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

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

1. An FDA approved diagnosis of CIDP; and
2. Member must be 18 years of age or older; and
3. Vyvgart® Hytrulo must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Member must have previously failed treatment with intravenous immunoglobulin (IVIG) or a patient specific, clinically significant reason why the member cannot use intravenous immunoglobulin (IVIG) must be provided; and
5. Initial approvals will be for 12 weeks. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Additionally, the College of Pharmacy also recommends the prior authorization of Bkernv™ (eculizumab-aeeb) and Epysqli® (eculizumab-aagh) with criteria similar to the Soliris® (eculizumab) approval criteria for atypical hemolytic uremic syndrome (aHUS), generalized myasthenia gravis (gMG), and paroxysmal nocturnal hemoglobinuria (PNH) with the following additional criteria (changes shown in red):

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

1. An FDA approved diagnosis of aHUS; and
2. Prescriber must confirm the member does not have Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HS); and
3. Bkernv™, Epysqli®, or Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS;

4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the **Bkemv™, Epysqli®, or Soliris®** Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For use of **Bkemv™ or Epysqli®**, a patient-specific, clinically significant reason why the member cannot use **Soliris®** must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
7. Member must not be receiving **Bkemv™, Epysqli®, or Soliris®** in combination with another complement inhibitor used to treat aHUS (i.e., **Ultomiris®**); and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

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

1. An FDA approved diagnosis of gMG; and
2. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
3. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
4. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
5. Member must meet 1 of the following:
 - a. Failed treatment over 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; or
 - b. Failed at least 1 IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); and
6. **Bkemv™, Epysqli®, or Soliris®** must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
7. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
8. Prescriber must be enrolled in the **Bkemv™, Epysqli®, or Soliris®** Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
9. For use of **Bkemv™ or Epysqli®**, a patient-specific, clinically significant reason why the member cannot use **Soliris®** 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

10. Use of **Bkembv™, Epysqli®, or Soliris®** will require a patient specific, clinically significant reason why the member cannot use Ultomiris® (ravulizumab-cwvz); and
11. Member must not be receiving **Bkembv™, Epysqli®, or Soliris®** in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo) **or another complement inhibitor used to treat gMG (i.e., Ultomiris®, Zilbrysq®); and**
12. Initial approvals will be for the duration of 6 months at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

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

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. **Bkembv™, Epysqli®, or Soliris®** must be prescribed by, or in consultation with, a ~~gastroenterologist, geneticist,~~ hematologist, **oncologist,** or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the **Bkembv™, Epysqli®, or Soliris®** Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. **For use of Bkembv™ or Epysqli®, a patient-specific, clinically significant reason why the member cannot use Soliris® must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and**
7. **Member must not be receiving Bkembv™, Epysqli®, or Soliris® in combination with another complement protein C5 inhibitor (i.e., Piasky®, Ultomiris®), complement protein C3 inhibitor (i.e., Empaveli®), or complement factor B inhibitor (i.e., Fabhalta®) used to treat PNH; and**
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Additionally, the College of Pharmacy recommends the following change to the Empaveli® (pegcetacoplan) and Ultomiris® (ravulizumab-cwvz) PNH approval criteria based on the new FDA approvals and to be consistent with clinical practice (changes shown in red):

Empaveli® (Pegcetacoplan) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Empaveli® must be prescribed by, or in consultation with, a ~~gastroenterologist~~, hematologist, ~~oncologist~~, ~~geneticist~~, or a specialist with expertise in the treatment of PNH; and
4. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Empaveli®; and
5. Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For members switching from Soliris® to Empaveli®, prescriber must verify the member will continue the current dose of Soliris® for 4 weeks before switching to Empaveli® as monotherapy; and
7. For members switching from Ultomiris® to Empaveli®, prescriber must verify that Empaveli® will be initiated no more than 4 weeks after the last dose of Ultomiris®; and
8. Member must not be receiving Empaveli® in combination with another complement inhibitor used to treat PNH (i.e., Fabhalta®, Piasky®, Soliris®, Ultomiris®, Voydeya®); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be:
 - a. 1 month of age or older for the intravenous (IV) formulation; or
 - b. 18 years of age or older for the subcutaneous (sub-Q) formulation; and
3. Ultomiris® must be prescribed by, or in consultation with, a ~~gastroenterologist~~, ~~geneticist~~, hematologist, ~~oncologist~~, or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For the sub-Q formulation, prescriber must verify the member or caregiver has been trained by a health care provider on the proper administration and storage of Ultomiris®; and

7. Member must not be receiving Ultomiris® in combination with another complement protein C5 inhibitor (i.e., Piasky®, Soliris®), complement protein C3 inhibitor (i.e., Empaveli®), or complement factor B inhibitor (i.e., Fabhalta®) used to treat PNH; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Finally, the College of Pharmacy recommends the following changes to the Enspryng® (satralizumab-mwge), Rystiggo® (rozanolixizumab-noli), Soliris® (eculizumab), Ultomiris® (ravulizumab-cwvz), Uplizna® (inebilizumab-cdon), Veopoz® (pozelimab-bbfg), Vyvgart® (efgartigimod Alfa-fcab), Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc), and Zilbrysq® (zilucoplan) approval criteria to be consistent with clinical practice (changes shown in red):

Enspryng® (Satralizumab-mwge) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤6.5; and
5. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
6. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
7. Enspryng® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
8. Prescriber must verify liver function tests have been assessed prior to initiation of treatment with Enspryng® and levels are acceptable to prescriber; and
9. Prescriber must agree to counsel the member to monitor for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
10. Prescriber must agree to monitor neutrophil counts 4 to 8 weeks after initiation of therapy and thereafter as clinically appropriate; and
11. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
12. Member and/or caregiver must be trained by a health care professional on subcutaneous administration and storage of Enspryng®; and

13. Member must not be receiving Enspryng® in combination with other immunomodulators to treat NMOSD (i.e., Soliris®, Ultomiris®, Uplizna®); and
14. A quantity limit override for the loading dose will be approved upon meeting the Enspryng® approval criteria. A quantity limit of 1 syringe per 28 days will apply for the maintenance dose, according to the package labeling; and
15. 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.

Rystiggo® (Rozanolixizumab-noli) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies or anti-muscle-specific tyrosine kinase (MuSK) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IVa; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥ 3 (with at least 3 points from non-ocular symptoms); and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Rystiggo® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Member must not be receiving Rystiggo® in combination with a complement inhibitor (i.e., Soliris®, Ultomiris®, Zilbrysq®) or with another neonatal Fc receptor blocker used to treat gMG (i.e., Vyvgart®, Vyvgart® Hytrulo); and
9. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Soliris® (Eculizumab) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have a history of at least 2 NMOSD attacks in last 12 months or 3 attacks in the last 24 months, with at least 1 attack in the past 12 months; and

4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤ 7 ; and
5. Soliris® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
7. Prescriber must be enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. Member must not be receiving Soliris® in combination with other immunomodulators to treat NMOSD (i.e., Enspryng®, Ultomiris®, Uplizna®); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:

1. An FDA approved diagnosis of aHUS; and
2. Member must be:
 - a. 1 month of age or older for the intravenous (IV) formulation; or
 - b. 18 years of age or older for the subcutaneous (sub-Q) formulation; and
3. Prescriber must confirm the member does not have Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HS); and
4. Ultomiris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS; and
5. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
6. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
7. For the sub-Q formulation, prescriber must verify the member or caregiver has been trained by a health care provider on the proper administration and storage of Ultomiris®; and
8. Member must not be receiving Ultomiris® in combination with another complement inhibitor used to treat aHUS (i.e., Soliris®); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and

2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥ 6 ; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Ultomiris[®] must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber must be enrolled in the Ultomiris[®] Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. The subcutaneous (sub-Q) formulation of Ultomiris[®] will not be approved for a diagnosis of gMG; and
11. Member must not be receiving Ultomiris[®] in combination with a neonatal Fc receptor blocker (i.e., Rystiggo[®], Vyvgart[®], Vyvgart[®] Hytrulo) or another complement inhibitor used to treat gMG (i.e., Soliris[®], Zilbrysq[®]); and
12. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

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

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months, or at least 2 attacks in the prior 24 months, requiring rescue therapy; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤ 8 ; and
5. Uplizna[®] must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
7. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and

8. Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
9. Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and
10. Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and
11. The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and
13. Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and
14. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
15. Member must not be receiving Uplizna® in combination with other immunomodulators to treat NMOSD (i.e., Enspryng®, Soliris®, Ultomiris®); and
16. A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and
17. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Veopoz® (Pozelimab-bbfg) Approval Criteria [CD55-Deficient Protein-Losing Enteropathy (PLE) Diagnosis]:

1. An FDA approved diagnosis of CD55-deficient PLE confirmed by all of the following:
 - a. Genetic testing identifying biallelic pathogenic mutations in the CD55 gene (results of genetic testing must be submitted); and
 - b. A history of PLE; and
2. Member has active disease defined by hypoalbuminemia (serum albumin concentration $\leq 3.2\text{g/dL}$) with 1 or more of the following signs or symptoms within the last 6 months: abdominal pain, diarrhea, peripheral edema, or facial edema; and
3. Member must be 1 year of age or older; and
4. Prescriber must verify the member has received the meningococcal vaccine 2 weeks prior to treatment unless urgent treatment is needed; and

5. Veopoz® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or other specialist with expertise in the treatment of CD55-deficient PLE; and
6. The prescriber must verify that Veopoz® will be administered by a health care professional; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a normalization of serum albumin or documentation of a positive clinical response to therapy.
Subsequent approvals will be for 1 year.

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

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

Zilbrysq® (Zilucoplan) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; and

4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥ 6 ; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Zilbrysq[®] must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber and pharmacy must be enrolled in the Zilbrysq[®] Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. Member must not be receiving Zilbrysq[®] in combination with a neonatal Fc receptor blocker (i.e., Rystiggo[®], Vyvgart[®], Vyvgart[®] Hytrulo[®] or another complement inhibitor used to treat gMG (i.e., Soliris[®], Ultomiris[®]); and
11. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Zilbrysq[®]; and
12. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Recommendation 8: Vote to Prior Authorize Labetalol Hydrochloride 400mg Tablet, Nexiclon™ XR [Clonidine Extended-Release (ER)], and Tryvio™ (Aprocitentan) and Update the Approval Criteria for the Antihypertensive Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of labetalol hydrochloride 400mg tablet, Nexiclon™ XR (clonidine ER tablet) and Tryvio™ (aprocitentan) with the following criteria (shown in red):

Labetalol Hydrochloride 400mg Tablet Approval Criteria:

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

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

1. An FDA approved diagnosis of hypertension; and

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

Tryvio™ (Aprocitentan) Approval Criteria:

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

clinically relevant elevation occurs or if elevations occur with an increase in bilirubin that is >2 times the ULN; and

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

Next, the College of Pharmacy recommends moving Atacand® (candesartan) 32mg from Tier 2 to Tier 1 within the Antihypertensive Medications Product Based Prior Authorization (PBPA) category based on net costs (changes noted in red in the following tier chart):

Angiotensin I Converting Enzyme Inhibitors (ACEIs)		
Tier-1	Tier-2	Special PA
benazepril (Lotensin®)	captopril (Capoten®)	enalapril oral solution (Epaned®)
enalapril (Vasotec®)		lisinopril oral solution (Qbrelis®)
enalaprilat (Vasotec® IV)		
fosinopril (Monopril®)		
lisinopril (Prinivil®, Zestril®)		
moexipril (Univasc®)		
perindopril (Aceon®)		
quinapril (Accupril®)		
ramipril (Altace®)		
trandolapril (Mavik®)		
ACEI/Hydrochlorothiazide (HCTZ) Combination Products		
Tier-1	Tier-2	Special PA
benazepril/HCTZ (Lotensin® HCT)	captopril/HCTZ (Capozide®)	fosinopril/HCTZ (Monopril-HCT®)
enalapril/HCTZ (Vaseretic®)		
lisinopril/HCTZ (Prinzide®, Zestoretic®)		
moexipril/HCTZ (Uniretic®)		
quinapril/HCTZ (Accuretic®)		
Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products		
Tier-1	Tier-2	Tier 3
candesartan (Atacand®)*	candesartan 32mg (Atacand®)	azilsartan (Edarbi®)

irbesartan (Avapro®)	olmesartan/amlodipine/HCTZ (Tribenzor®)	azilsartan/chlorthalidone (Edarbyclor®)
irbesartan/HCTZ (Avalide®)	telmisartan/HCTZ (Micardis® HCT)	candesartan/HCTZ (Atacand® HCT)
losartan (Cozaar®)		eprosartan (Teveten®)
losartan/HCTZ (Hyzaar®)		eprosartan/HCTZ (Teveten® HCT)
olmesartan (Benicar®)		telmisartan/amlodipine (Twynsta®)
olmesartan/amlodipine (Azor®)		valsartan 4mg/mL oral solution
olmesartan/HCTZ (Benicar HCT®)		
telmisartan (Micardis®)		
valsartan (Diovan®)		
valsartan/amlodipine (Exforge®)		
valsartan/amlodipine/HCTZ (Exforge® HCT)		
valsartan/HCTZ (Diovan HCT®)		
Calcium Channel Blockers (CCBs)		
Tier-1	Tier-2	Special PA
amlodipine (Norvasc®)	amlodipine/atorvastatin (Caduet®)	amlodipine oral solution (Norliqva®)
diltiazem (Cardizem®)	diltiazem LA (Cardizem® LA, Matzim® LA)	amlodipine oral suspension (Katerzia®)
diltiazem (Tiazac®, Taztia XT®)	diltiazem SR (Cardizem® SR)	amlodipine/celecoxib (Consensi®)
diltiazem CD (Cardizem® CD)*	isradipine (Dynacirc®, Dynacirc CR®)	diltiazem CD 360mg (Cardizem® CD)
diltiazem ER (Cartia XT®, Diltia XT®)	nicardipine (Cardene®)	levamlodipine (Conjupri®)
diltiazem XR (Dilacor® XR)	nicardipine (Cardene® SR)	
felodipine (Plendil®)	nisoldipine (Sular®)	
nifedipine (Adalat®, Procardia®)	verapamil (Covera-HS®)	
nifedipine ER (Adalat® CC)	verapamil ER (Verelan®, Verelan® PM)	
nifedipine XL (Nifedical XL®, Procardia XL®)		
nimodipine (Nimotop®)		
verapamil (Calan®, Isoptin®)		
verapamil SR (Calan® SR, Isoptin® SR)		
ACEI/CCB Combination Products		
Tier-1	Tier-2	Special PA

Tier-1 ACEI + Tier-1 CCB	trandolapril/verapamil (Tarka®)	perindopril/amlodipine (Prestalia®)
benazepril/amlodipine (Lotrel®)		

~~*All strengths other than 32mg.~~

*All strengths other than 360mg.

CD = controlled-delivery; ER, XR, XL = extended-release; LA = long-acting; SR = sustained-release

Lastly, the College of Pharmacy recommends the following additions and changes to the Antihypertensive Medications Special Prior Authorization (PA) Approval Criteria based on clinical practice and to clarify formulation and clinical exceptions for age restrictions in existing criteria (changes shown in red):

Antihypertensive Medications Special Prior Authorization (PA) Approval Criteria:

1. Angiotensin I Converting Enzyme Inhibitors (ACEIs):

a. Epaned® (Enalapril Solution) Approval Criteria:

- i. An age restriction of 7 years or older will apply with the following criteria:
 1. A patient-specific, clinically significant reason why the member cannot use the oral tablet formulation in place of the oral solution formulation, even when the tablets are crushed **or used to prepare an oral suspension**, must be provided **(e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and**
 2. Clinical exceptions for the age restriction (younger than the FDA-approved age) may be considered; and
- ii. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.

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

- i. A patient-specific, clinically significant reason why the member cannot use lisinopril oral tablets in place of the oral solution formulation, even when the tablets are crushed, must be provided **(e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and**
- ii. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.

2. ACEI/Hydrochlorothiazide (HCTZ) Combination Products:

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

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

3. Calcium Channel Blockers (CCBs):

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

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

b. Conjupri® (Levamlodipine Tablets) Approval Criteria:

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

c. Consensi® (Amlodipine/Celecoxib Tablets) Approval Criteria:

- i. A patient-specific, clinically significant reason why the member cannot use the individual components separately, which are available without prior authorization, must be provided; and
- ii. A quantity limit of 30 tablets per 30 days will apply.

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

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

4. ACEI/CCB Combination Products:

a. Prestalia® (Perindopril/Amlodipine) Approval Criteria:

- i. An FDA approved diagnosis; and
- ii. Documented trials of inadequate response to 2 Tier-1 angiotensin I converting enzyme inhibitors (ACEIs) in combination with amlodipine; and
- iii. A patient-specific, clinically significant reason why the member cannot use the individual components separately must be provided; and
- iv. A quantity limit of 30 tablets per 30 days will apply.

CaroSpir® (Spironolactone Oral Suspension) Approval Criteria:

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

Sotylize® (Sotalol Oral Solution) Approval Criteria:

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

Valsartan 4mg/mL Oral Solution Approval Criteria:

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

Recommendation 9: Vote to Prior Authorize Acthar® Gel SelfJect™ (Repository Corticotropin Auto-Injector) and Purified Cortrophin® Gel (Repository Corticotropin Injection) and Update the Approval Criteria for the Adrenocorticotrophic Hormone (ACTH) Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Purified Cortrophin® Gel (repository corticotropin injection) and Acthar® Gel SelfJect™

(repository corticotropin auto-injector) and recommends the following changes to the ACTH products approval criteria based on the new FDA approvals, net costs, and to be consistent with clinical practice (changes shown in red):

~~H.P. Acthar® Gel~~ (Repository Corticotropin Injection) Approval Criteria:

1. An FDA approved diagnosis of infantile spasms; and
 - a. Member must be 2 years of age or younger; and
 - b. Must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); ~~or and~~
 - c. Only the multi-dose vial will be approved. Acthar® Gel SelfJect™ auto-injector will not be approved for this indication; or
2. An FDA approved diagnosis of multiple sclerosis (MS); and
 - a. Member is experiencing an acute exacerbation; and
 - b. Must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist) or a prescriber who specializes in MS; and
 - c. Prescriber must rule out pseudo-exacerbation from precipitating factors (e.g., pain, stress, infection, premenstrual syndrome); and
 - d. Symptoms of acute exacerbation last at least 24 hours; and
 - e. Member must be currently stable within the last 30 days on an immunomodulator agent, unless contraindicated; and
 - f. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy [e.g., intravenous (IV) methylprednisolone, IV dexamethasone, oral prednisone] must be provided; and
 - g. A quantity limit of daily doses of up to 120 units for up to 3 weeks for acute exacerbation will apply; or
3. An FDA approved diagnosis of nephrotic syndrome without uremia of the idiopathic type or that is due to lupus erythematosus to induce diuresis or remission of proteinuria; and
 - a. Must be prescribed by, or in consultation with, a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
 - b. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy (e.g., prednisone) must be provided; or
4. An FDA approved diagnosis of the following disorders or diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; or edematous states; and
 - a. Must be prescribed by or in consultation with a specialist appropriate to the member's disease state (or an advanced care practitioner with a supervising physician who is a specialist appropriate to the member's disease state); and

- b. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy must be provided; and
5. Requests for Purified Cortrophin® Gel (repository corticotropin injection) will require a patient-specific, clinically significant reason why Acthar® Gel (repository corticotropin injection) or Acthar® Gel SelfJect™ (repository corticotropin auto-injector) cannot be used.

Recommendation 10: Vote to Prior Authorize Diflunisal 500mg Tablet, Dolobid™ (Diflunisal) 250mg and 375mg Tablet, and Indomethacin 50mg Suppository and Update the Approval Criteria for the Systemic Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

MOTION CARRIED by unanimous approval.

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

1. Prior authorization and placement of Dolobid™ (diflunisal) 250mg tablet and 375mg tablet into the Special PA Tier with the additional criteria listed below; and
2. Prior authorization and placement of diflunisal 500mg tablet into Tier-2; and
3. Prior authorization and placement of Indocin® (indomethacin) suppository into the Special PA Tier; and
4. Removing the brand preferred status for Flector® (diclofenac epolamine patch) and moving the authorized generics to the Special PA Tier; and
5. Moving Ansaid® (flurbiprofen) and EC-Naprosyn® (naproxen) 500mg tablet from Tier-1 to Tier-2; and
6. Moving Tolectin® (tolmetin) from Tier-2 to the Special PA Tier; and
7. Moving Cataflam® (diclofenac potassium) and Lodine® (etodolac) 200mg capsule and 300mg capsule from Tier-2 to Tier-1; and
8. Moving Indocin® SR (indomethacin extended-release capsule) and Ponstel® (mefenamic acid) from the Special PA Tier to Tier-2; and
9. Moving Celebrex® (celecoxib) 400mg capsule from the Special PA Tier to Tier-1 and removing the unique approval criteria for the 400mg strength based on the FDA's withdrawal of the familial adenomatous polyposis (FAP) indication and net cost; and
10. Removing Anjeso® (meloxicam injection), Dyloject™ (diclofenac sodium injection), Licart® (diclofenac epolamine patch), Qmiiz ODT™ [meloxicam orally disintegrating tablet (ODT)], Tivorbex® (indomethacin), and Zorvolex® (diclofenac) based on product discontinuations or lack of manufacturer rebate participation.

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	Tier-2	Special PA
celecoxib (Celebrex [®]) 50mg, 100mg, & 200mg caps	diclofenac ER (Voltaren [®] XR)	~~celecoxib (Celebrex[®]) 400mg caps~~
~~diclofenac epolamine (Flector[®] Patch) — Brand Preferred~~	~~diclofenac potassium (Cataflam[®])~~	celecoxib (Elyxyb [®]) oral solution
diclofenac potassium (Cataflam[®])	diclofenac sodium/ misoprostol (Arthrotec [®])	~~diclofenac (Zorvolex[®])~~
diclofenac sodium (Voltaren [®]) 50mg & 75mg tabs	diclofenac sodium (Voltaren [®]) 25mg tabs	diclofenac epolamine (generic Flector[®] Patch)
diclofenac sodium 1% (Voltaren [®] Gel)	diflunisal 500mg tabs	~~diclofenac epolamine (Licart[®]) topical system~~
etodolac (Lodine [®]) 400mg & 500mg tabs	~~etodolac (Lodine[®]) 200mg & 300mg caps~~	diclofenac potassium (Cambia [®]) powder pack
~~flurbiprofen (Ansaid[®])~~	etodolac ER (Lodine [®] XL)	diclofenac potassium (Lofena [™]) tabs
ibuprofen (Motrin [®])	flurbiprofen (Ansaid[®])	diclofenac potassium (Zipsor [®]) caps
indomethacin (Indocin [®]) caps	indomethacin (Indocin[®] SR) ER caps	~~diclofenac sodium (Dyloject[™]) inj~~
meloxicam (Mobic [®])	mefenamic acid (Ponstel[®])	diclofenac sodium (Pennsaid [®]) topical drops
nabumetone (Relafen [®])	naproxen DR (EC-Naprosyn[®]) 500mg tab	diflunisal (Dolobid[™]) 250mg and 375mg tabs
naproxen* (Naprosyn [®])	naproxen sodium (Anaprox [®]) 275mg & 550mg tabs	fenoprofen (Nalfon [®])
naproxen DR (EC-Naprosyn [®]) 375mg tab	oxaprozin (Daypro [®])	ibuprofen (Caldolor [®]) inj
sulindac (Clinoril [®])	piroxicam (Feldene [®])	ibuprofen/acetaminophen (Combogesic [®] IV) inj ⁺
	~~tolmetin (Tolectin[®])~~	ibuprofen/famotidine (Duexis [®])
		indomethacin (Indocin [®]) supp & susp & ER caps
		indomethacin (Tivorbex[®])
		ketoprofen (Orudis [®]) caps
		ketoprofen ER (Oruvail [®])
		ketorolac tromethamine (Sprix [®]) nasal spray
		meclofenamate (Meclomen [®])
		~~mefenamic acid (Ponstel[®])~~
		meloxicam (Anjeso[®]) inj⁺
		meloxicam (Vivlodex [®]) caps

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	Tier-2	Special PA
		meloxicam ODT (Qmiiz ODT™)
		nabumetone 1,000mg (Relafen DS®)
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)
		tolmetin (Tolectin®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

*Naproxen oral suspension is available without prior authorization for members 12 years of age and younger. Members older than 12 years of age require a reason why a special formulation product is needed in place of the regular tablet formulation.

*Unique criteria applies.

caps = capsules; DR = delayed-release; ER = extended-release; EC = enteric-coated; inj = injection; ODT = orally disintegrating tablet; PA = prior authorization; **supp = suppository**; susp = suspension; tabs = tablets

NSAIDs Special Prior Authorization (PA) Approval Criteria:

1. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or
2. Previous use of at least 2 Tier-1 NSAID products (from different product lines); and
3. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product; and
4. ~~Additionally, use of Celebrex® (celecoxib) 400mg capsules will require a diagnosis of Familial Adenomatous Polyposis (FAP) and a patient-specific, clinically significant reason why the member cannot use 2 celecoxib 200mg capsules to achieve a 400mg dose; and~~
5. ~~Additionally, use of Dolobid™ (diflunisal) 250mg or 375mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic diflunisal 500mg tablets; and~~
6. Additionally, use of Elyxyb® (celecoxib oral solution) will require a diagnosis of acute migraine treatment in adults 18 years of age and older and a patient-specific, clinically significant reason why the member cannot use Cambia® (diclofenac potassium powder); and
7. Additionally, use of Lofena™ (diclofenac potassium) will require a patient-specific, clinically significant reason why the member cannot use all other available generic diclofenac products. ~~; and~~
8. ~~Additionally, use of Tivorbex® will require a patient-specific, clinically significant reason why the member cannot use all other available generic indomethacin products.~~

Anjeso® (Meloxicam Injection) Approval Criteria:

1. ~~An FDA approved diagnosis of management of moderate to severe pain, alone or in combination with non-NSAID analgesics; and~~
2. ~~Member must be 18 years of age or older; and~~

- ~~3. Member must be well hydrated before Anjeso[®] administration to reduce the risk of renal toxicity; and~~
- ~~4. Anjeso[®] should be used for the shortest duration consistent with individual patient treatment goals; and~~
- ~~5. A patient-specific, clinically significant reason the member cannot use oral meloxicam tablets or other Tier-1 NSAID products must be provided; and~~
- ~~6. A quantity limit of 3 vials per 3 days will apply; and~~
- ~~7. For consideration of a longer duration of use, a patient-specific, clinically significant reason why the member cannot transition to an oral Tier-1 NSAID product must be provided, along with the anticipated duration of treatment.~~

Recommendation 11: Vote Prior Authorize Tryngolza™ (Olezarsen) and Update the Approval Criteria for the Antihyperlipidemics

MOTION CARRIED by unanimous approval.

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

Tryngolza™ (Olezarsen) Approval Criteria:

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

6. Member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tryngolza™; and
7. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment, as indicated by a reduction in fasting triglyceride levels, decreased episodes of acute pancreatitis, and/or other documentation of a positive clinical response to therapy. Subsequent approvals will be for the duration of 1 year.

Additionally, the College of Pharmacy recommends the following changes to the Nexletol® (bempedoic acid) and Nexlizet® (bempedoic acid/ezetimibe) approval criteria based on the new FDA approved label expansion and to be consistent with clinical practice (changes shown in red):

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

1. An FDA approved indication ~~as an adjunct to diet and statin therapy for the treatment~~ of 1 of the following:
 - a. ~~As an adjunct to diet and other low-density lipoprotein cholesterol (LDL-C) lowering therapies or alone when concomitant LDL-C lowering therapies are not possible to reduce LDL-C in those with heterozygous familial hypercholesterolemia (HeFH). HeFH must be as~~ confirmed by 1 of the following:
 - i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
 - ii. Both of the following:
 1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
 2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
 - iii. Dutch Lipid Clinic Network Criteria score of >8; or~~b. Established atherosclerotic cardiovascular disease (ASCVD); and~~
~~i. Supporting diagnoses/conditions and dates of occurrence signifying established ASCVD; or~~
 - c. ~~As an adjunct to diet and other LDL-C lowering therapies or alone when concomitant LDL-C lowering therapies are not possible to reduce LDL-C in those with primary hyperlipidemia; and~~
 - i. Member's untreated LDL-C level must be ≥190mg/dL; and
 - ii. Current LDL-C level is ≥100mg/dL; and
 - d. ~~To reduce the risk of myocardial infarction and coronary revascularization in those unable to take recommended statin therapy with 1 of the following:~~

- i. High risk for a cardiovascular disease (CVD) event without established atherosclerotic CVD (ASCVD); or
 - ii. Established ASCVD; and
 - iii. Supporting diagnoses/conditions/risk factors and dates of occurrences must be submitted; and
- 2. Member must be 18 years of age or older; and
- 3. Member must be on a stable dose of maximally tolerated statin therapy for at least 4 weeks (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
 - a. LDL-C levels should be included following at least 4 weeks of treatment; and
 - b. Member must not be taking simvastatin at doses >20mg or pravastatin at doses >40mg due to drug interactions with Nexletol® and Nexlizet®; and
- 4. Members with statin intolerance must meet 1 of the following:
 - a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
 - b. An FDA labeled contraindication to all statins; or
 - c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
 - d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
- 5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
- 6. A quantity limit of 30 tablets per 30 days will apply; and
- ~~7. Initial approvals will be for the duration of 3 months, after which time compliance and recent LDL-C levels to demonstrate the effectiveness of this medication will be required for continued approval. Subsequent approvals will be for the duration of 1 year.~~
- 8. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Next, the College of Pharmacy recommends the following changes to the proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors approval criteria based on the new FDA approved age expansion, product discontinuation, and to be consistent with clinical practice (changes shown in red):

Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors [Praluent® (Alirocumab) and Repatha® (Evolocumab)] Approval Criteria:

- 1. An FDA approved indication of 1 of the following:

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

- b. LDL-C levels should be included following at least 12 weeks of treatment; and
- 6. Members with statin intolerance must meet 1 of the following:
 - a. Creatinine kinase (CK) labs verifying rhabdomyolysis; or
 - b. An FDA labeled contraindication to all statins; or
 - c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
 - d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
- 7. Member must have a recent trial with a statin with ezetimibe, or a recent trial of ezetimibe without a statin for members with a documented statin intolerance, or a patient-specific, clinically significant reason why ezetimibe is not appropriate must be provided; and
- 8. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
- 9. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
- 10. A quantity limit of 2 syringes or pens per 28 days will apply for Praluent®. A quantity limit of 2 syringes or auto-injectors per 28 days will apply for Repatha® 140mg ~~and a quantity limit of 1 auto-injector per 28 days will apply for Repatha® 420mg. Requests for the Repatha® 420mg dose will not be approved for multiple 140mg syringes or auto-injectors; but instead members need to use (1) 420mg auto-injector;~~ and
- 11. Initial approvals will be for the duration of ~~6~~ 3 months (subsequent approvals for 1 year). Continued authorization ~~at that time~~ will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. ~~and Additionally, compliance will be checked for continued approval. at that time and every 6 months thereafter for continued approval.~~

Next, the College of Pharmacy recommends the following changes to the Evkeeza® (evinacumab-dgnb) and Leqvio® (inclisiran) criteria to be consistent with clinical practice and the other antihyperlipidemic medications (changes shown in red):

Evkeeza® (Evinacumab-dgnb) Approval Criteria:

- 1. An FDA approved diagnosis of homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:
 - a. Documented functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor

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

Leqvio® (Inclisiran) Approval Criteria:

1. An FDA approved indication as an adjunct to diet and statin therapy for the treatment of 1 of the following:
 - a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
 - i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
 - ii. Both of the following:

1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
 2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
 - iii. Dutch Lipid Clinic Network Criteria score of >8; or
 - b. Established atherosclerotic cardiovascular disease (ASCVD); and
 - i. Supporting diagnoses/conditions and dates of occurrence signifying established ASCVD; or
 - c. Primary hyperlipidemia; and
 - i. Member's untreated LDL-C level must be ≥190mg/dL; and
 - ii. Current LDL-C level is ≥100mg/dL; and
2. Member must be 18 years of age or older; and
 3. Documented trial of all of the following for at least 12 weeks in duration each:
 - a. High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy; and
 - b. Ezetimibe; and
 - c. Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®); and
 4. Members with statin intolerance must meet 1 of the following:
 - a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
 - b. An FDA labeled contraindication to all statins; or
 - c. Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
 - d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
 5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C must be provided); and
 6. Leqvio® must be administered by a health care professional. Approvals will not be granted for self-administration; and
 - a. Prior authorization requests must indicate how Leqvio® will be administered (e.g., prescriber, pharmacist, home health care provider); and
 - i. Leqvio® must be shipped to the facility where the member is scheduled to receive treatment; or
 - ii. Prescriber must verify the member has been counseled on the proper storage of Leqvio®; and
 7. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization ~~at that time~~ will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. ~~and Additionally, compliance will be checked for continued approval. at that time and every 6 months thereafter for continued approval.~~

Next, the College of Pharmacy recommends the removal of Epanova® (omega-3-carboxylic acids) from the omega-3 fatty acids approval criteria based on product discontinuation (changes shown in red):

Omega-3 Fatty Acids [~~Epanova® (Omega-3-Carboxylic Acids)~~ and Vascepa® (Icosapent Ethyl)] Approval Criteria:

1. An FDA approved indication of 1 of the following:
 - a. Severe hypertriglyceridemia; and
 - i. Laboratory documentation of severe hypertriglyceridemia (fasting triglycerides $\geq 500\text{mg/dL}$) and controlled diabetes (fasting glucose $< 150\text{mg/dL}$ at the time of triglycerides measurement and HgA1c $< 7.5\%$); and
 - ii. Previous failure with fibric acid medications; and
 - iii. ~~Use of Vascepa® (icosapent ethyl) or Epanova® (omega-3-carboxylic acids) requires a~~ Previous failure of or a patient-specific, clinically significant reason why the member cannot use omega-3-acid ethyl esters (generic Lovaza®), which is available without prior authorization; or
 - b. ~~For the use of Vascepa® (icosapent ethyl)~~ As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult members with elevated triglyceride levels; and
 - i. Member must be on a stable dose of maximally tolerated statin therapy for at least 4 weeks (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
 - ii. Laboratory documentation of fasting triglycerides $\geq 150\text{mg/dL}$; and
 - iii. Member must have 1 of the following:
 1. Established cardiovascular disease; or
 2. Diabetes mellitus and ≥ 2 additional risk factors for cardiovascular disease; and
2. Use of Vascepa® 0.5 gram requires a patient-specific, clinically significant reason why the member cannot use Vascepa® 1 gram.

Finally, the College of Pharmacy recommends moving Lofibra® (fenofibrate micronized) 200mg capsules from Tier-2 to Tier-1 based on net cost (changes shown in red):

Fibric Acid Derivative Medications	
Tier-1	Tier-2
choline fenofibrate DR cap 45mg (Trilipix®)	choline fenofibrate DR cap 135mg (Trilipix®)
fenofibrate micronized cap 67mg, 134mg (Lofibra®)	fenofibrate cap 50mg, 150mg (Lipofen®)

fenofibrate tab 160mg (Triglide®)	~~fenofibrate-micronized cap-200mg (Lofibra®)~~
fenofibrate tab 48mg, 145mg (Tricor®)	fenofibrate micronized cap 30mg, 43mg, 90mg, 130mg (Antara®)
fenofibrate tab 54mg, 160mg (Lofibra®)	fenofibrate tab 40mg, 120mg (Fenoglide®)
~~fenofibrate micronized cap 200mg (Lofibra®)~~	fenofibric acid tab (Fibricor®) 105mg
fenofibric acid tab 35mg (Fibricor®)	
gemfibrozil tab 600mg (Lopid®)	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

cap = capsule; DR = delayed release; tab = tablet

Recommendation 12: Vote to Prior Authorize Wyost® (Denosumab-bbdz)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Wyost® (denosumab-bbdz) with criteria similar to Xgeva® (denosumab) with the following additional criteria (changes shown in red):

Wyost® (Denosumab-bbdz) and Xgeva® (Denosumab) Approval Criteria:

1. An FDA approved indication of 1 of the following:
 - a. Prevention of skeletal-related events in members with multiple myeloma and in members with bone metastases from solid tumors; or
 - b. Treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity; and
 - i. Prescriber must document that tumor is unresectable or that surgical resection is likely to result in severe morbidity; or
 - c. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy; and
 - i. Member must have albumin-corrected calcium of >12.5mg/dL (3.1mmol/L) despite treatment with intravenous bisphosphonate therapy in the last 30 days prior to initiation of Xgeva® therapy; and
2. For Wyost® (denosumab-bbdz), a patient-specific, clinically significant reason why the member cannot use Xgeva® (denosumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Recommendation 13: Vote to Update the Approval Criteria for the Ophthalmic Antibiotic Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Ophthalmic Antibiotic Medications Product Based Prior Authorization (PBPA) category based on net cost and product discontinuations (changes noted in red in the following PBPA Tier chart and approval criteria):

1. Removing the brand preferred status for Tobradex® (tobramycin/dexamethasone) suspension; and
2. Moving Bleph-10® (sulfacetamide sodium) solution and Neosporin® (neomycin/polymyxin B/gramicidin) solution from Tier-1 to Tier-2; and
3. Moving Ciloxan® (ciprofloxacin) ointment, Neo-Polycin® HC (bacitracin/polymyxin B/neomycin/hydrocortisone) ointment, Tobradex® (tobramycin/dexamethasone) ointment, and Zylet® (tobramycin/loteprednol) suspension from Tier-2 to Tier-1; and
4. Moving Azasite® (azithromycin), Besivance® (besifloxacin), and Vigamox® (moxifloxacin) from Tier-3 to Tier-1; and
5. Moving Zymaxid® (gatifloxacin) from Tier-3 to Tier-2; and
6. Removing Blephamide® (sulfacetamide/prednisolone) ointment and suspension, Gentak® (gentamicin) ointment, Moxeza® (moxifloxacin) solution, Pred-G® (gentamicin/prednisolone) ointment and suspension, and Quixin® (levofloxacin) solution based on product discontinuations.

Ophthalmic Antibiotic Medications: Liquids		
Tier-1	Tier-2	Tier-3
azithromycin (Azasite®)	levofloxacin (Quixin®)	azithromycin (Azasite®)
besifloxacin (Besivance®)	gatifloxacin (Zymaxid®)	besifloxacin (Besivance®)
ciprofloxacin (Ciloxan®)	neomycin/polymyxin B/gramicidin (Neosporin®)	gatifloxacin (Zymaxid®)
gentamicin (Gentak®)	sulfacetamide sodium (Bleph-10®)	moxifloxacin (Vigamox®; Moxeza®)
moxifloxacin (Vigamox®)		
neomycin/polymyxin B/gramicidin (Neosporin®)		
ofloxacin (Ocuflox®)		
polymyxin B/trimethoprim (Polytrim®)		
sulfacetamide sodium (Bleph-10®)		
tobramycin (Tobrex®)		
Ophthalmic Antibiotic Medications: Ointments		
Tier-1	Tier-2	
bacitracin/polymyxin B (AK-Poly-Bac®, Polycin®)	bacitracin (AK-Tracin®)	
ciprofloxacin (Ciloxan®)	ciprofloxacin (Ciloxan®)	
erythromycin (Ilotycin™, Romycin®)	sodium sulfacetamide (Bleph-10®)	
gentamicin (Gentak®)		

neomycin/polymyxin B/bacitracin (Neosporin®)	
tobramycin (Tobrex®)	
Ophthalmic Antibiotic/Steroid Combination Products	
Tier-1	Tier-2
bacitracin/polymyxin B/neomycin/hydrocortisone (Neo-Polycin® HC) oint	~~bacitracin/polymyxin B/neomycin/hydrocortisone (Neo-Polycin® HC) oint~~
neomycin/polymyxin B/dexamethasone (Maxitrol®) oint & susp	~~gentamicin/prednisolone (Pred-G®) oint & susp~~
sulfacetamide/prednisolone 10%/0.23% solution	neomycin/polymyxin B/hydrocortisone (Cortisporin®) susp
tobramycin/dexamethasone 0.3%/0.1% (Tobradex®) oint & susp —Brand-Preferred	~~sulfacetamide/prednisolone (Blephamide®) oint & susp~~
tobramycin/dexamethasone 0.3%/0.05% (Tobradex® ST) susp	~~tobramycin/dexamethasone (Tobradex®) oint~~
tobramycin/loteprednol (Zylet®) susp	~~tobramycin/loteprednol (Zylet®) susp~~

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

Recommendation 14: Vote to Prior Authorize Tevimbra® (Tislelizumab-jsgr), Vyloy® (Zolbetuximab-clzb), and Ziihera® (Zanidatamab-hrii) and Update the Approval Criteria for the Gastrointestinal (GI) Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Tevimbra® (tislelizumab-jsgr), Vyloy® (zolbetuximab-clzb), and Ziihera® (zanidatamab-hrii) with the following criteria (shown in red):

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

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

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

1. Diagnosis of unresectable or metastatic gastric or GEJ adenocarcinoma; and
2. Used in the first-line setting in combination with platinum and fluoropyrimidine-based chemotherapy; and

3. Human epidermal receptor 2 (HER2)-negative disease; and
4. Tumor expresses programmed death ligand 1 (PD-L1) $\geq 1\%$.

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

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

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

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

Additionally, the College of Pharmacy recommends updating the Cyramza® (ramucirumab) approval criteria based on National Comprehensive Cancer Network (NCCN) recommendations (changes and new criteria shown in red):

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

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

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

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

Lastly, the College of Pharmacy recommends removal of SoonerCare coverage and of the approval criteria for Truseltiq® (infigratinib) based on the withdrawal of FDA approval for the medication (changes shown in red):

~~Truseltiq® (Infigratinib) Approval Criteria [Cholangiocarcinoma Diagnosis]:~~

- ~~1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma; and~~
- ~~2. Presence of fibroblast growth factor receptor 2 (FGFR2) gene fusion or other rearrangement; and~~
- ~~3. Disease has progressed on at least 1 prior systemic therapy; and~~
- ~~4. As a single agent; and~~
- ~~5. Members who are new to treatment with Truseltiq® will generally not be approved.~~

Recommendation 15: Vote to Prior Authorize Fyarro® (Sirolimus Protein-Bound Particles for Injectable Suspension), Niktimvo™ (Axatilimab-csfr), Ojemda™ (Tovorafenib), Tecelra® (Afamitresgene Autoleucel), and Voranigo® (Vorasidenib) and Update the Approval Criteria for the Miscellaneous Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Fyarro® (sirolimus protein-bound particles for injectable suspension), Niktimvo™ (axatilimab-csfr), Ojemda™ (tovorafenib), Tecelra® (afamitresgene autoleucel), and Voranigo® (vorasidenib) with the following criteria (shown in red):

Fyarro® (Sirolimus Protein-Bound Particles for Injectable Suspension) Approval Criteria [Perivascular Epithelioid Cell Tumor (PEComa) Diagnosis]:

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

Niktimvo™ (Axatilimab-csfr) Approval Criteria [Chronic Graft Versus Host Disease (GVHD) Diagnosis]:

1. Diagnosis of chronic GVHD; and
2. Has failed at least 2 prior lines of systemic therapy for chronic GVHD; and
3. Member's recent weight must be provided and must be ≥40kg.

Ojemda™ (Tovorafenib) Approval Criteria [Low Grade Glioma (LGG) Diagnosis]:

1. Diagnosis of relapsed or refractory pediatric LGG; and
2. Member must be 6 months to 25 years of age; and
3. Presence of BRAF fusion, BRAF rearrangement, or BRAF V600 mutation; and
4. Member's recent body surface area (BSA) must be provided; and

- a. For members with a BSA $\geq 0.90\text{m}^2$, requests for the oral suspension formulation will require a patient-specific, clinically significant reason why the member cannot use the tablet formulation.

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

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

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

1. Diagnosis of grade 2 astrocytoma or oligodendroglioma; and
2. Presence of susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation following surgery including biopsy, sub-total resection, or gross total resection.

Additionally, the College of Pharmacy recommends updating the Lutathera® (lutetium Lu-177 dotatate) approval criteria based on the recent FDA approved age expansion and NCCN recommendations with the following changes (shown in red):

Lutathera® (Lutetium Lu-177 Dotatate) Approval Criteria [Gastroenteropancreatic Neuroendocrine Tumor (GEP-NET) Diagnosis]:

1. Diagnosis of progressive locoregional advanced disease or metastatic disease; and
2. Positive imaging of somatostatin receptor; and
3. Member must be 12 years of age or older; and
4. Used in 1 of the following settings:
 - a. As second-line or subsequent therapy following progression on octreotide or lanreotide; or
 - b. As first-line for treatment of pheochromocytoma/paraganglioma; or
 - c. As alternative front-line therapy if surgical cytoreduction of metastases is not possible and there is clinically significant tumor burden following progression on octreotide or lanreotide.

Lastly, the College of Pharmacy recommends removal of SoonerCare coverage and of the approval criteria for Azedra® (iobenguane I-131) based on product discontinuation (changes shown in red):

Azedra® (iobenguane I-131) Approval Criteria [Pheochromocytoma or Paraganglioma (PPGL) Diagnosis]:

- ~~1. Adult and pediatric members 12 years of age and older; and~~
- ~~2. Iobenguane scan positive; and~~
- ~~3. Unresectable, locally advanced or metastatic pheochromocytoma or PPGL requiring systemic anticancer therapy.~~

Recommendation 16: Annual Review of Short-Acting Beta₂ Agonists (SABAs)

MOTION CARRIED by unanimous approval.

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

1. Removing the brand preferred status from ProAir® HFA, Proventil® HFA, and Ventolin® HFA based on net costs and the discontinuation of brand name ProAir® HFA; and
2. Updating the Airsupra® (albuterol/budesonide) approval criteria for clarity, including removing criteria #4 as recommended by the DUR Board; and
3. Updating the Xopenex® (levalbuterol) nebulizer solution approval criteria to be consistent with the Global Initiative for Asthma (GINA) guidelines; and
4. Removal of ProAir® Digihaler® (albuterol inhalation powder) due to product discontinuation.

Short-Acting Beta ₂ Agonists	
Tier-1	Tier-2
albuterol HFA (ProAir® HFA, Proventil® HFA, Ventolin® HFA) – Brand Preferred	albuterol HFA (generic)
albuterol inhalation powder (ProAir® RespiClick®)	albuterol inhalation powder (ProAir® Digihaler®)*
~~albuterol HFA (Proventil® HFA) – Brand Preferred~~	levalbuterol HFA (generic)
~~albuterol HFA (Ventolin® HFA) – Brand Preferred~~	
levalbuterol HFA (Xopenex® HFA) – Brand Preferred	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

~~*Additional criteria applies.~~

HFA = hydrofluoroalkane

Short-Acting Beta₂ Agonists Tier-2 Approval Criteria:

1. An FDA approved or clinically accepted indication; and
2. A patient-specific, clinically significant reason why the member cannot use all available Tier-1 medications must be provided; and
3. Approval of generic ~~albuterol HFA~~ or levalbuterol HFA requires a patient-specific, clinically significant reason the member cannot use the brand formulation.

Airsupra® (Albuterol/Budesonide) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be 18 years of age or older; and
- ~~3. Member must be using maintenance therapy per the Global Initiative for Asthma (GINA) guidelines; and~~
- ~~4. A patient-specific, clinically significant reason why the member cannot use a combination inhaled corticosteroid (ICS) and formoterol [e.g., Symbicort® (budesonide/formoterol), Dulera® (mometasone/formoterol)] as recommend by the Global Initiative for Asthma (GINA) guidelines; and~~
5. A patient-specific, clinically significant reason why the member cannot use specific individual ICS and short-acting beta₂ agonist (SABA) components; and
- ~~6. A patient-specific, clinically significant reason why the member cannot use a long-acting beta₂ agonist (LABA), inhaled corticosteroid (ICS)/LABA combination, or specific individual ICS and short-acting beta₂ agonist (SABA) components must be provided; and~~
7. Initial approvals will be for the duration of 3 months. For continued consideration, prescriber must verify the member has had a positive clinical response to therapy; and
8. Subsequent approvals will be for the duration of 1 year.

Xopenex® (Levalbuterol) Nebulizer Solution Approval Criteria:

1. A free-floating 90 days of therapy per 365 days will be in place.
2. Use of this product in excess of 90 days of therapy in a 365-day period will require a patient-specific, clinically significant reason why the member is unable to use ~~a preferred controller and reliever treatment option [e.g., combination inhaled corticosteroid (ICS) and formoterol or ICS and short-acting beta₂ agonist (SABA)] appropriate to the member's age long-acting bronchodilator and/or inhaled corticosteroid (ICS) therapy for long-term control~~ as recommended in the ~~Global Initiative for Asthma (GINA) National Asthma Education and Prevention Program (NAEPP)~~ guidelines; and
3. A patient-specific, clinically significant reason why the member cannot use a metered-dose inhaler (MDI) must be provided; and
4. Clinical exceptions will be made for members with chronic obstructive pulmonary disease (COPD); and
5. A quantity limit of 288mL per 30 days will apply.

ProAir® Digihaler® (Albuterol Inhalation Powder) Approval Criteria:

- ~~1. An FDA approved or clinically accepted indication; and~~
- ~~2. A patient specific, clinically significant reason why the member requires the ProAir® Digihaler® formulation over all available Tier 1 medications must be provided; and~~
- ~~3. The prescriber agrees to closely monitor member adherence; and~~
- ~~4. The member should be capable and willing to use the Companion Mobile App and follow the Instructions for Use and ensure the ProAir® Digihaler® Companion Mobile App is compatible with their specific smartphone; and~~
- ~~5. Member's phone camera must be functional and able to scan the inhaler QR code and register the ProAir® Digihaler® inhaler; and~~
- ~~6. Approvals will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and patient compliance >80% with prescribed therapy must be provided. In addition, a patient-specific, clinically significant reason why the member cannot transition to Tier 1 medications must be provided. Tier structure rules continue to apply.~~

Recommendation 17: Annual Review of Leukemia and Lymphoma Medications and 30-Day Notice to Prior Authorize Aucatzyl® (Obecabtagene Autoleucel), Danziten™ (Nilotinib), Grafapex™ (Treosulfan), Revuforj® (Revumenib), and Rytelo™ (Imetelstat)

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

Recommendation 18: 30-Day Notice to Prior Authorize Kebilidi™ (Eladocogene Exuparvovec-tneq)

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

Recommendation 19: Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize Symbravo® (Meloxicam/Rizatriptan)

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

Recommendation 20: 30-Day Notice to Prior Authorize Crenessity™ (Crinecerfont)

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

Recommendation 21: Annual Review of Cholestatic Liver Disease Medications and 30-Day Notice to Prior Authorize Ctexli™ (Chenodiol), Iqirvo® (Elafibranor), and Livdelzi® (Seladelpar)

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

Recommendation 22: Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize Pantoprazole in 0.9% Sodium Chloride (NaCl) for Intravenous (IV) Injection

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

Recommendation 23: Annual Review of Heart Failure (HF) Medications and 30-Day Notice to Prior Authorize Entresto® Sprinkle (Sacubitril/Valsartan Oral Pellets)

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

Recommendation 24: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 25: Future Business

NO ACTION REQUIRED.



The Headache & Migraine Policy Forum

March 11, 2025

Dear Members of the Oklahoma Drug Utilization Review Board,

On behalf of the Headache & Migraine Policy Forum (HMPF), we appreciate the opportunity to provide comments as the Board considers access to new migraine therapies, including Symbravo.

The Headache & Migraine Policy Forum ([HMPF](#)) is a national [coalition](#) of nearly two dozen stakeholder organizations that seek to advance public policies and practices that promote access to care and treatment for persons living with headache disorders and migraine disease.

Migraine is a serious and disabling neurological disease affecting more than 39 million Americans, including many in Oklahoma. It is the second leading cause of disability worldwide and results in substantial economic burden, [with costs exceeding \\$36 billion annually in the U.S.](#) This is due to lost productivity, emergency room visits, and direct medical expenses.

One of the challenges in managing migraine is its heterogeneity—no single therapy works for all patients. Individual attacks and symptoms vary, meaning patients need a range of treatment options to effectively manage their condition. Unfortunately, restrictive insurance policies, such as excessive step therapy requirements, can delay access to effective treatments, increasing the likelihood of unnecessary healthcare utilization and higher costs for both patients and the healthcare system.

Beyond the broader healthcare impact, excessive step therapy protocols place a significant burden on patients. Delays in accessing effective treatment can lead to more frequent and severe migraine attacks, prolonged pain, and increased reliance on expensive emergency care. These delays not only exacerbate physical suffering but also worsen mental health, disrupt employment, and diminish overall quality of life. Many patients already struggle with managing this disabling disease and requiring them to fail multiple treatments before accessing newer, potentially more effective options only adds to their hardship.

Research shows that greater step therapy restrictions lead to increased emergency room visits and higher overall costs. Recent data shows that patients with a history of being rejected by their health plan for acute and preventative migraine medications are more likely to visit the emergency department for treatment. In addition, patients of color whose health insurance had denied at least two prescription migraine medications use the emergency department at the highest rates. Ensuring timely access to appropriate treatments can improve patient outcomes while reducing long-term healthcare expenditures.

We therefore urge the DUR Board to limit step therapy requirements to no more than two steps when reviewing new therapies like Symbravo.

Thank you for your consideration. We appreciate the Board's commitment to policies that support migraine patients in accessing the treatments they need. Please do not hesitate to reach out at lindsay@headchemigraineforum.org or (202) 299-4310 with any questions or for additional information.

Sincerely,

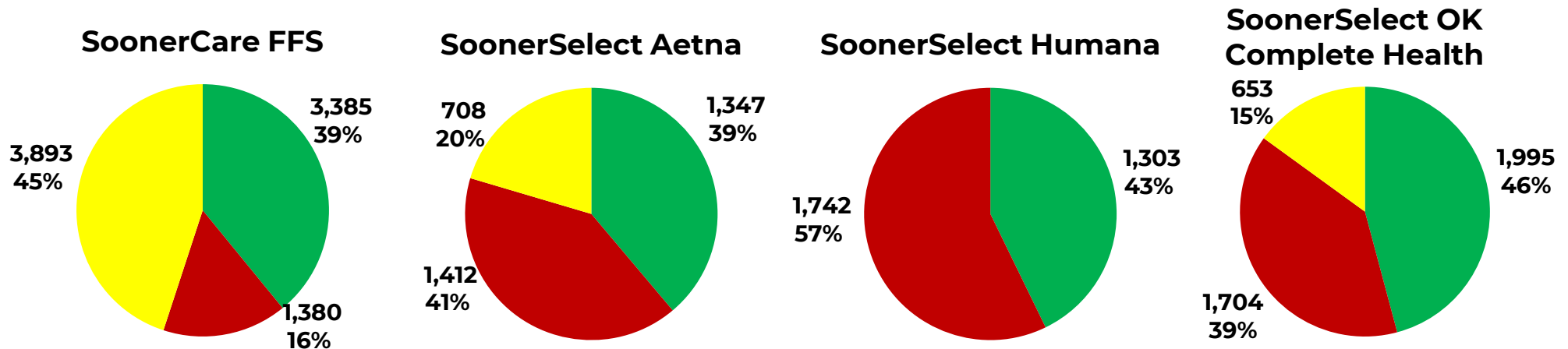
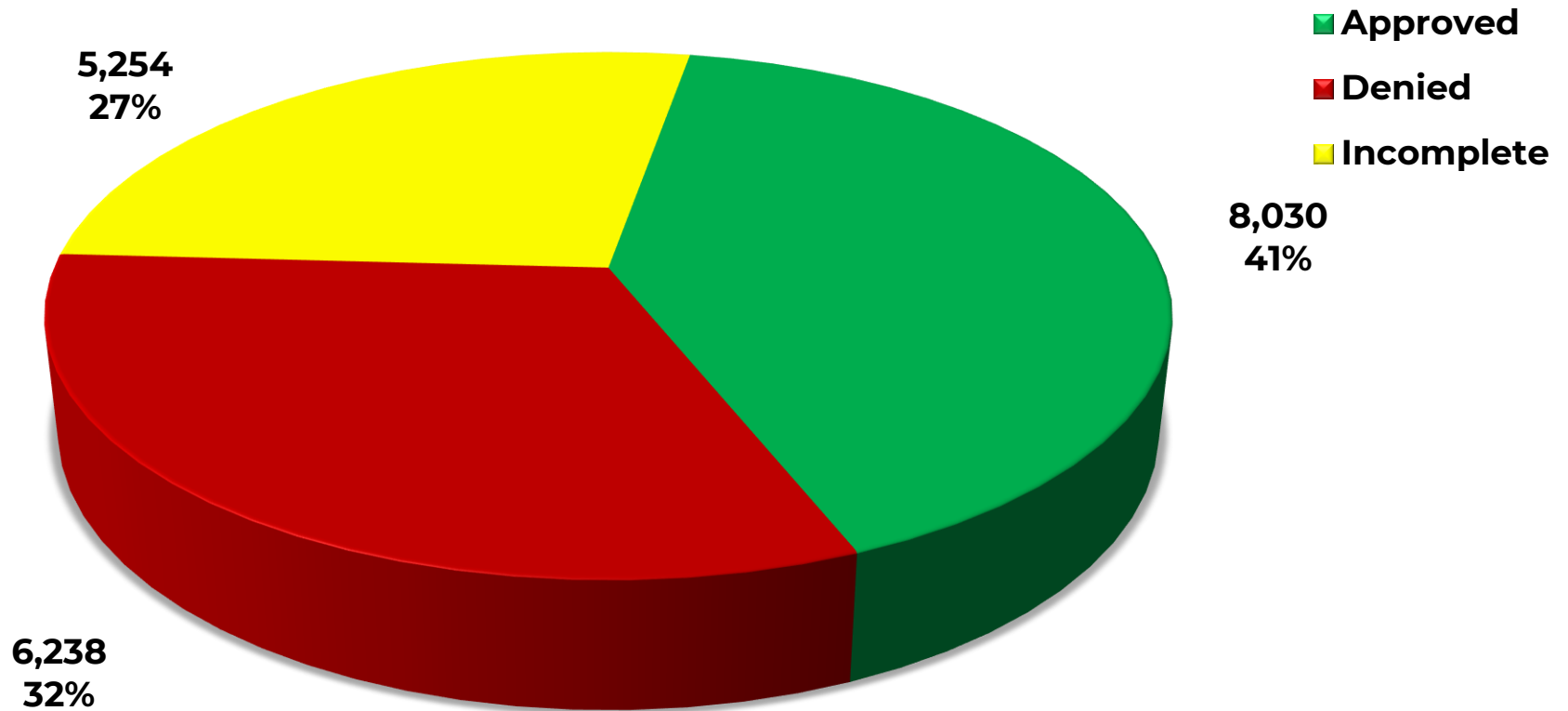
Lindsay Videnieks
Executive Director, HMPF
headchemigraineforum.org

HMPF Stakeholder Members:



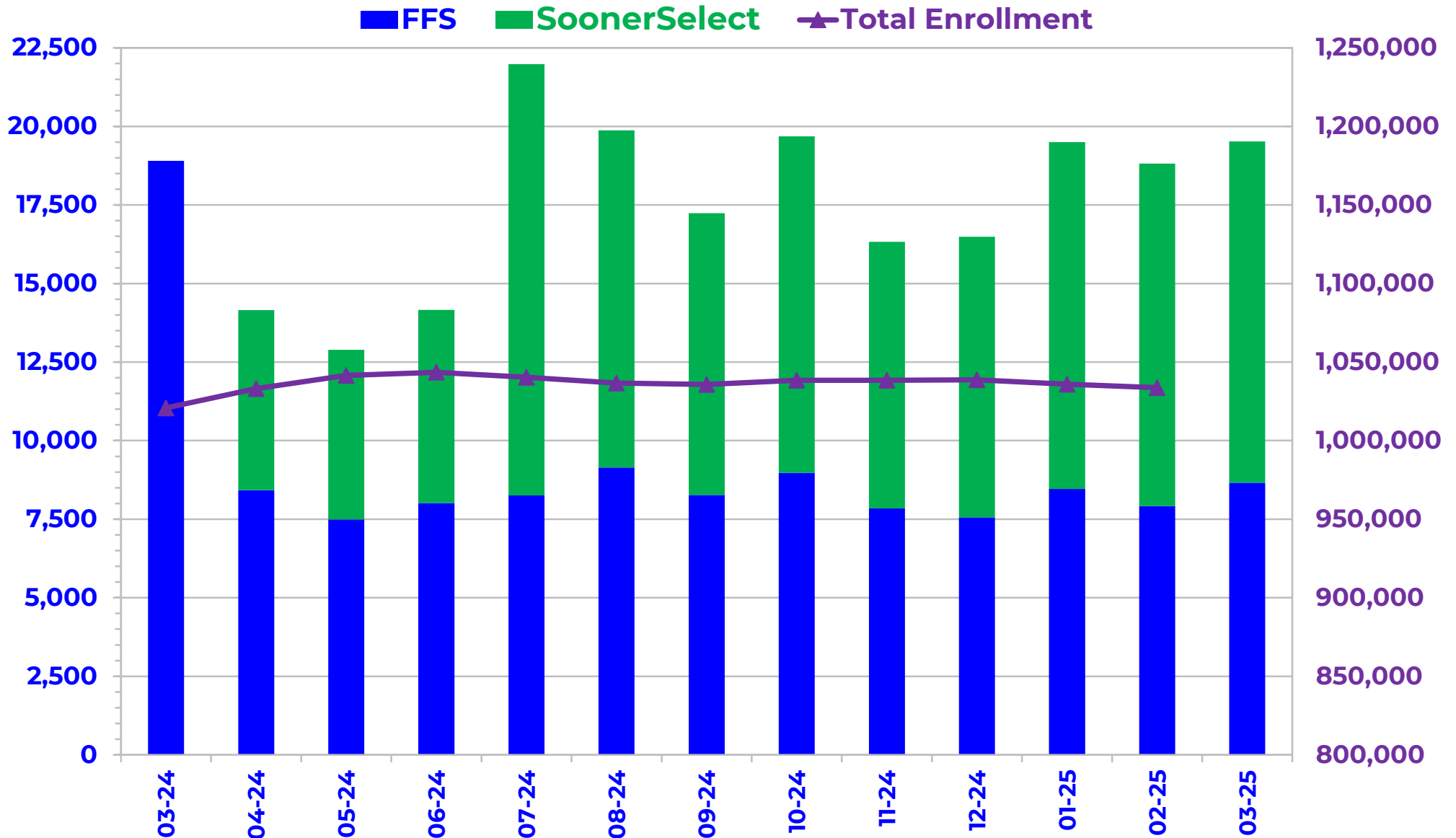


PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: MARCH 2025



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

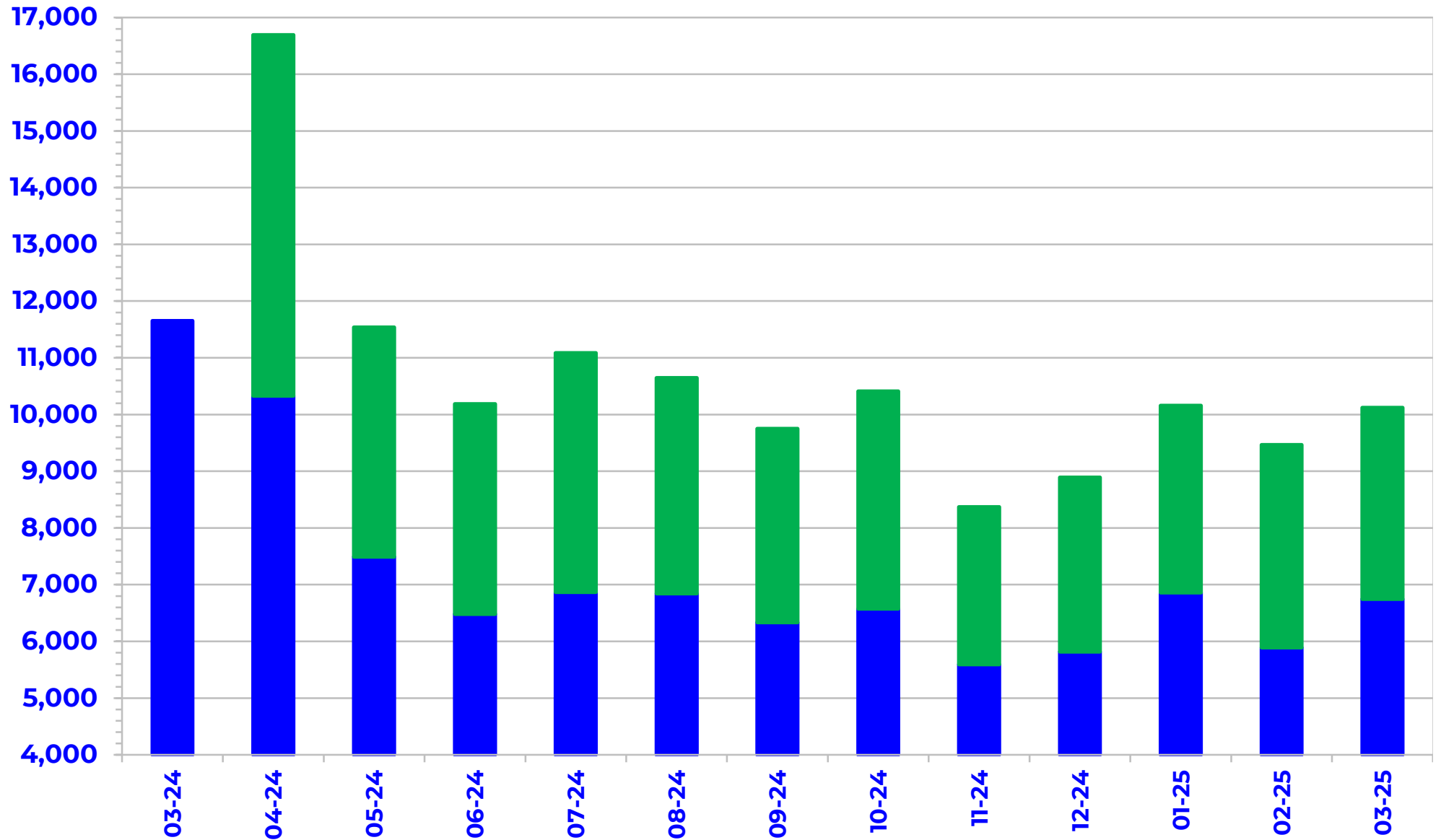
PRIOR AUTHORIZATION (PA) REPORT: MARCH 2024 – MARCH 2025



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: MARCH 2024 – MARCH 2025

■ SoonerSelect ■ FFS



SoonerCare FFS Prior Authorization Activity

3/1/2025 Through 3/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	639	416	5	218	355
Analgesics - Anti-inflammatory	225	94	31	100	311
Analgesics - Nonnarcotic	16	1	7	8	360
Analgesics - Opioid	307	125	32	150	136
Androgens - Anabolic	78	20	15	43	348
Anorectal and Related Products	2	0	2	0	0
Anorexiant Non-amphetamine	1	0	1	0	0
Antacids	2	2	0	0	360
Anthelmintics	16	5	3	8	10
Anti-infective Agents - Misc.	27	10	6	11	222
Anti-obesity Agents	103	10	65	28	192
Antianginal Agents	1	1	0	0	360
Antianxiety Agents	13	1	2	10	179
Antiasthmatic and Bronchodilator Agents	575	106	107	362	332
Antibiotics	29	9	2	18	242
Anticoagulants	12	3	0	9	252
Anticonvulsants	198	83	12	103	334
Antidepressants	190	42	28	120	257
Antidiabetics	1,348	370	311	667	353
Antidiarrheal/Probiotic Agents	1	1	0	0	360
Antidotes and Specific Antagonists	9	5	0	4	310
Antiemetics	14	1	1	12	90
Antifungals	3	1	1	1	56
Antihistamines	23	7	7	9	276
Antihyperlipidemics	63	13	15	35	227
Antihypertensives	19	5	2	12	356
Antimalarials	4	0	0	4	0
Antineoplastics and Adjunctive Therapies	196	132	12	52	182
Antiparkinson and Related Therapy Agents	7	1	3	3	358
Antipsychotics/Antimanic Agents	355	140	37	178	340
Antivirals	19	8	4	7	11
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	243	165	22	56	346
Beta Blockers	7	4	0	3	344
Calcium Channel Blockers	14	3	1	10	354
Cardiovascular Agents - Misc.	105	51	13	41	330
Chemicals	2	0	0	2	0
Contraceptives	40	18	5	17	310
Corticosteroids	8	0	0	8	0
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	410	123	118	169	237
Diagnostic Products	48	19	4	25	201
Dietary Products/Dietary Management Products	2	0	1	1	0
Digestive Aids	4	4	0	0	360
Diuretics	5	3	0	2	357
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	5	2	2	1	360
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	151	69	21	61	222
Estrogens	8	4	0	4	329
Gastrointestinal Agents - Misc.	318	71	76	171	237

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Genitourinary Agents - Misc.	10	3	2	5	356
Gout Agents	3	1	1	1	174
Hematological Agents - Misc.	14	8	0	6	359
Hematopoietic Agents	44	15	10	19	103
Hemostatics	1	0	0	1	0
Hypnotics/Sedatives/Sleep Disorder Agents	51	2	9	40	180
Laxatives	16	9	2	5	284
Medical Devices and Supplies	270	55	67	148	304
Migraine Products	289	58	82	149	308
Minerals and Electrolytes	4	1	0	3	353
Miscellaneous Therapeutic Classes	72	33	7	32	325
Multivitamins	5	3	0	2	299
Musculoskeletal Therapy Agents	43	4	10	29	277
Nasal Agents - Systemic and Topical	13	2	5	6	204
Neuromuscular Agents	85	44	21	20	336
Nutrients	2	1	0	1	117
Ophthalmic Agents	83	20	20	43	260
Other*	43	17	1	25	222
Otic Agents	28	1	6	21	10
Passive Immunizing and Treatment Agents	2	1	1	0	24
Progestins	2	2	0	0	360
Psychotherapeutic and Neurological Agents - Misc.	235	88	40	107	240
Respiratory Agents - Misc.	28	20	1	7	298
Stimulants - Misc.	220	84	15	121	319
Thyroid Agents	8	1	2	5	358
Ulcer Drugs/Antispasmodics/Anticholinergics	45	11	7	27	277
Urinary Antispasmodics	42	3	6	33	360
Vaccines	1	0	1	0	0
Vaginal and Related Products	3	0	0	3	0
Vitamins	32	4	21	7	231
Total	7,560	2,639	1,311	3,610	
Overrides					
Brand	17	11	0	6	323
Compound	16	11	1	4	11
Dosage Change	184	167	3	14	16
Ingredient Duplication	3	2	0	1	101
Lost/Broken Rx	56	55	0	1	16
MAT Override	8	4	0	4	56
NDC vs Age	146	76	23	47	273
NDC vs Sex	39	33	1	5	321
Nursing Home Issue	70	69	1	0	15
Opioid MME Limit	55	20	3	32	121
Opioid Quantity	21	11	5	5	147
Other	36	30	2	4	24
Quantity vs Days Supply	377	221	23	133	279
STBS/STBSM	17	9	4	4	62
Step Therapy Exception	8	1	3	4	115
Stolen	1	1	0	0	3
Third Brand Request	44	25	0	19	34
Overrides Total	1,098	746	69	283	
Total Regular PAs + Overrides	8,658	3,385	1,380	3,893	

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

Denial Reasons	
Unable to verify required trials.	3,420
Does not meet established criteria.	1,420
Lack required information to process request.	527
Other PA Activity	
Duplicate Requests	870
Letters	38,776
No Process	2
Helpdesk Initiated Prior Authorizations	419
PAs Missing Information	296
Pharmacotherapy	60
Changes to Existing PAs	480

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

SoonerSelect Aetna Prior Authorization Activity

3/1/2025 Through 3/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	8	2	5	1	184
Amphetamines	222	169	12	41	363
Analgesics - Anti-inflammatory	131	93	12	26	300
Analgesics - Nonnarcotic	7	4	1	2	128
Analgesics - Opioid	183	114	51	18	222
Androgens - Anabolic	67	11	52	4	339
Anorectal and Related Products	1	0	1	0	0
Anthelmintics	7	2	5	0	5
Antianginal Agents	2	0	0	2	0
Antianxiety Agents	16	5	3	8	292
Antiarrhythmics	2	2	0	0	346
Antiasthmatic and Bronchodilator Agents	238	42	140	56	281
Antibiotics	37	20	7	10	164
Anticoagulants	10	7	0	3	216
Anticonvulsants	53	18	18	17	319
Antidepressants	196	43	80	73	325
Antidiabetics	493	130	276	87	334
Antidotes and Specific Antagonists	2	2	0	0	120
Antiemetics	26	20	3	3	178
Antifungals	4	0	2	2	0
Antihistamines	61	44	16	1	286
Antihyperlipidemics	31	0	12	19	0
Antihypertensives	24	1	3	20	365
Anti-infective Agents - Misc.	14	9	4	1	124
Antineoplastics and Adjunctive Therapies	33	20	1	12	248
Anti-obesity Agents	60	1	53	6	365
Antiparkinson and Related Therapy Agents	8	0	3	5	0
Antipsychotics/Antimanic Agents	154	50	67	37	349
Antivirals	7	2	4	1	126
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	75	57	17	1	381
Beta Blockers	16	2	0	14	365
Calcium Channel Blockers	9	1	2	6	365
Cardiovascular Agents - Misc.	25	9	12	4	365
Contraceptives	21	6	11	4	365
Corticosteroids	36	30	4	2	245
Dermatologicals	236	95	99	42	204
Diagnostic Products	49	29	13	7	322
Dietary Products/Dietary Management Products	1	1	0	0	365
Digestive Aids	1	1	0	0	365
Diuretics	7	1	0	6	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRI's)	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	28	15	11	2	236
Estrogens	4	2	1	1	248
Gastrointestinal Agents - Misc.	103	47	53	3	227
General Anesthetics	5	5	0	0	180
Genitourinary Agents - Misc.	3	0	1	2	0
Gout Agents	11	7	2	2	365
Hematological Agents - Misc.	8	7	0	1	289
Hematopoietic Agents	6	5	0	1	292
Histamine H3-Receptor Antagonist/Inverse Agonists	1	1	0	0	365

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hypnotics/Sedatives/Sleep Disorder Agents	31	3	13	15	152
Laxatives	4	0	3	1	0
Local Anesthetics-Parenteral	3	3	0	0	97
Medical Devices and Supplies	89	33	39	17	338
Migraine Products	179	43	118	18	164
Minerals and Electrolytes	23	12	4	7	157
Miscellaneous Therapeutic Classes	13	10	2	1	237
Multivitamins	4	2	2	0	365
Musculoskeletal Therapy Agents	48	5	12	31	248
Nasal Agents - Systemic and Topical	21	0	14	7	0
Neuromuscular Agents	13	12	1	0	256
Nutrients	2	2	0	0	289
Ophthalmic Agents	22	5	8	9	328
Other	8	4	2	2	346
Otic Agents	25	0	25	0	0
Passive Immunizing and Treatment Agents	8	8	0	0	120
Progestins	4	2	2	0	365
Psychotherapeutic and Neurological Agents - Misc.	33	11	17	5	208
Respiratory Agents - Misc.	4	4	0	0	263
Stimulants - Misc.	76	35	32	9	354
Thyroid Agents	4	0	2	2	0
Ulcer Drugs/Antispasmodics/Anticholinergics	44	7	11	26	282
Urinary Antispasmodics	6	0	6	0	0
Vaccines	2	1	1	0	184
Vaginal and Related Products	10	0	6	4	0
Vasopressors	4	4	0	0	120
Vitamins	44	9	34	1	334
**Total	3,467	1,347	1,412	708	

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

Overrides					
Brand	1	1	0	0	92
Other	699	0	0	699	0
Quantity Level Limit	44	44	0	0	322
Overrides Total	744	45	0	699	

Denial Reason	
Benefit	63
Experimental/Investigational	130
Lack Required Information to Process Request	87
Medical Necessity	1,131
Other	1
Other PA Activity	
Duplicate Requests	17
Letters	3,959
No Process	228
Changes to existing PAs	0
Helpdesk initiated PA	2
PAs missing info	10

*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

3/1/2025 Through 3/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amebicides	2	1	1	0	183
Amphetamines	3	0	3	0	0
Analgesics - Anti-inflammatory	52	39	13	0	361
Analgesics - Nonnarcotic	3	0	3	0	0
Analgesics - Opioid	66	33	33	0	203
Androgens - Anabolic	43	8	35	0	266
Anthelmintics	3	2	1	0	274
Antiasthmatic and Bronchodilator Agents	210	51	159	0	195
Antibiotics	3	0	3	0	0
Anticonvulsants	6	5	1	0	365
Antidepressants	36	15	21	0	704
Antidiabetics	179	66	113	0	247
Antihistamines	4	2	2	0	304
Antihyperlipidemics	15	3	12	0	36
AntiInfective Agents - Misc.	5	5	0	0	365
Antineoplastics and Adjunctive Therapies	17	12	5	0	287
Anti-obesity Agents	51	3	48	0	96
Antiparkinson and Related Therapy Agents	2	0	2	0	0
Antipsychotics/Antimanic Agents	1	0	1	0	0
Antivirals	5	3	2	0	39
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	6	3	3	0	284
Beta Blockers	2	2	0	0	365
Cardiovascular Agents - Misc.	25	9	16	0	407
Chemicals	1	0	1	0	0
Contraceptives	10	8	2	0	278
Corticosteroids	3	1	2	0	92
Dermatologicals	132	61	71	0	255
Diagnostic Products	65	62	3	0	353
Digestive Aids	1	0	1	0	0
Diuretics	1	1	0	0	365
Endocrine and Metabolic Agents - Misc.	44	23	21	0	242
Estrogens	3	0	3	0	0
Gastrointestinal Agents - Misc.	73	30	43	0	142
Gout Agents	2	1	1	0	365
Hematological Agents - Misc.	1	1	0	0	365
Hematopoietic Agents	5	2	3	0	365
Hypnotics/Sedatives/Sleep Disorder Agents	15	3	12	0	210
Laxatives	3	0	3	0	0
Migraine Products	105	50	55	0	173
Miscellaneous Therapeutic Classes	4	4	0	0	334
Multivitamins	2	2	0	0	365
Musculoskeletal Therapy Agents	14	2	12	0	365
Nasal Agents - Systemic and Topical	3	0	3	0	0
Neuromuscular Agents	2	0	2	0	0
Ophthalmic Agents	21	7	14	0	292
Other	0	0	0	0	0
Psychotherapeutic and Neurological Agents - Misc.	31	13	18	0	240
Respiratory Agents - Misc.	2	2	0	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
Stimulants - Misc.	5	1	4	0	365
Thyroid Agents	1	0	1	0	0
Ulcer Drugs/Antispasmodics/Anticholinergics	8	1	7	0	365
Urinary Antispasmodics	9	0	9	0	0
Vitamins	41	2	39	0	189
Total	1,346	539	807	0	

Overrides					
Ingredient Duplication	113	43	70	0	144
NDC vs Age	430	298	132	0	255
Opioid MME Limit	4	4	0	0	347
Opioid Quantity	5	5	0	0	381
Other	297	179	118	0	198
Quantity vs Days Supply	192	112	80	0	224
STBS/STBSM	404	14	390	0	15
Step Therapy Exception	254	109	145	0	156
Overrides Total	1,699	764	935	0	
Total Regular PAs + Overrides	3,045	1,303	1,742	0	

Denial Reasons	
Benefit	790
Medical Necessity	952

*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

3/1/2025 Through 3/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	4	0	3	1	0
Amphetamines	521	397	55	69	263
Analgesics - Anti-inflammatory	111	64	27	20	358
Analgesics - Nonnarcotic	1	0	1	0	0
Analgesics - Opioid	399	138	208	53	257
Androgens - Anabolic	71	10	53	8	334
Anorectal and Related Products	2	0	1	1	0
Anorexiant Non-amphetamine	3	0	3	0	0
Anthelmintics	5	1	4	0	365
Antianxiety Agents	25	8	13	4	314
Antiasthmatic and Bronchodilator Agents	246	63	142	41	336
Antibiotics	13	8	3	2	327
Anticoagulants	5	2	3	0	323
Anticonvulsants	54	26	20	8	348
Antidepressants	121	44	56	21	346
Antidiabetics	626	321	216	89	349
Antiemetics	13	2	5	6	296
Antifungals	6	5	1	0	216
Antihistamines	31	10	15	6	352
Antihyperlipidemics	22	5	11	6	188
Antihypertensives	7	7	0	0	173
Anti-Infective Agents - Misc.	14	5	8	1	281
Antineoplastics and Adjunctive Therapies	65	45	10	10	270
Anti-obesity Agents	68	0	59	9	0
Antiparkinson and Related Therapy Agents	3	0	2	1	0
Antipsychotics/Antimanic Agents	145	63	59	23	355
Antivirals	16	7	7	2	264
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	86	45	35	6	316
Beta Blockers	8	5	2	1	325
Calcium Channel Blockers	2	2	0	0	332
Cardiovascular Agents - Misc.	22	4	15	3	365
Contraceptives	21	9	10	2	328
Corticosteroids	1	0	1	0	0
Cough/Cold/Allergy	1	0	1	0	0
Dermatologicals	390	138	195	57	249
Diagnostic Products	51	20	22	9	363
Dietary Products/Dietary Management Products	1	0	0	1	0
Digestive Aids	2	0	1	1	0
Diuretics	1	0	0	1	0
Endocrine and Metabolic Agents - Misc.	33	12	16	5	298
Estrogens	5	0	4	1	0
Gastrointestinal Agents - Misc.	94	29	53	12	257
Genitourinary Agents - Misc.	4	1	3	0	365
Gout Agents	2	0	2	0	0
Hematological Agents - Misc.	35	21	9	5	274
Hematopoietic Agents	29	17	8	4	158
Histamine H3-Receptor Antagonist/Inverse Agonists	5	1	4	0	365
Hypnotics/Sedatives/Sleep Disorder Agents	34	15	16	3	271

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Laxatives	6	0	6	0	0
Medical Devices and Supplies	133	83	33	17	358
Migraine Products	180	56	106	18	300
Minerals and Electrolytes	3	1	1	1	180
Miscellaneous Therapeutic Classes	17	13	3	1	342
Multivitamins	6	4	2	0	319
Musculoskeletal Therapy Agents	23	6	15	2	173
Nasal Agents - Systemic and Topical	14	1	12	1	365
Neuromuscular Agents	17	6	6	5	275
Ophthalmic Agents	31	5	20	6	280
Other	37	12	1	24	300
Otic Agents	35	5	21	9	222
Passive Immunizing and Treatment Agents	1	1	0	0	300
Progestins	4	0	3	1	0
Psychotherapeutic and Neurological Agents - Misc.	57	25	18	14	285
Respiratory Agents - Misc.	1	0	1	0	0
Stimulants - Misc.	269	175	43	51	277
Thyroid Agents	2	2	0	0	285
Ulcer Drugs/Antispasmodics/Anticholinergics	66	44	17	5	258
Urinary Antispasmodics	18	2	11	5	288
Vaccines	1	1	0	0	180
Vaginal and Related Products	4	1	3	0	365
Vasopressors	3	2	0	1	294
**Total	4,352	1,995	1,704	653	

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

Denial Reasons	
Benefit	112
Medical Necessity	1,592

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



Spring 2025 Pipeline Update

Oklahoma Health Care Authority
April 2025

Introduction

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

Elinzanetant^{1,2,3,4,5,6}

Anticipated Indication(s): Treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause

Clinical Trial(s): In October 2024, the FDA accepted the New Drug Application (NDA) for elinzanetant for the treatment of moderate to severe VMS associated with menopause. The safety and efficacy of elinzanetant were studied in the Phase 3 OASIS clinical trials. OASIS 1 and 2 were randomized, double-blind, placebo-controlled trials that included 796 women 40 to 65 years of age experiencing moderate to severe VMS who were randomized 1:1 to receive elinzanetant 120mg or placebo over 12 weeks. After 12 weeks, all participants received elinzanetant 120mg for an additional 14 weeks. In both trials, reductions in VMS frequency and severity from baseline to weeks 4 and 12 were statistically significantly greater for elinzanetant vs. placebo. OASIS 3 was a double-blind, randomized, placebo-multicenter study that investigated the safety and efficacy of elinzanetant over 52 weeks in 628 postmenopausal women 40 to 65 years of age. OASIS 3 had similar results to OASIS 1 and 2 with no new safety signals. Additionally, improvements were seen in secondary measures of sleep disturbances and menopause-related quality of life over the 52 weeks. OASIS 4 investigated the safety and efficacy of elinzanetant in women with moderate to severe VMS caused by adjuvant endocrine therapy for the treatment or prevention of breast cancer. OASIS 4 met its primary and secondary endpoints and showed a reduction in severity of VMS. Elinzanetant is continuing to be studied in NIRVANA, an exploratory Phase 2 randomized, parallel-group treatment, double blind trial that is

evaluating the efficacy of elinzanetant on sleep disturbances associated with menopause.

Place in Therapy: First-line treatment for women with moderate to severe VMS and no contraindications is menopausal hormone therapy. For women who are not a candidate for hormonal therapy due to contradictions, such as estrogen-dependent cancers or cardiovascular disease, non-hormonal therapies such as selective serotonin reuptake inhibitors (SSRIs)/serotonin-norepinephrine reuptake inhibitors (SNRIs), gabapentin, or Veozah® (fezolinetant) should be considered. In menopausal women, due to decreasing estrogen levels, the hypothalamic kisspeptin/neurokinin B/dynorphin (KNDy) neurons become hypertrophic and hyperactive disrupting thermoregulation. KNDy neurons express neurokinin-1 and 3 (NK-1 and 3) receptors. Elinzanetant is a dual NK-1 and 3 receptor antagonist that reduces VMS and may be another non-hormonal option for VMS. Veozah® was FDA approved in May 2023 and is a NK-3 receptor antagonist. Additionally, elinzanetant showed safety and efficacy in women being treated with adjuvant endocrine therapy (such as tamoxifen or aromatase inhibitors) which commonly cause VMS and affect the treatment compliance with these medications.

Projected FDA Decision: 08/01/2025

SoonerCare Impact: During fiscal year 2024, there were 19,775 paid claims for VMS medications, which includes hormonal therapy, for 5,226 unique members which accounted for a total cost of \$1,467,253.01 and an average cost per claim of \$74.20. These costs do not reflect rebated prices or net costs. Of those, 109 paid claims were for Veozah® with 61 total members utilizing this medication which currently requires prior authorization.

Brensocatib^{7,8,9,10}

Anticipated Indication(s): Non-cystic fibrosis bronchiectasis

Clinical Trial(s): In February 2025, the FDA accepted the NDA for brensocatib for patients with non-cystic fibrosis bronchiectasis. The safety and efficacy of brensocatib were studied in the Phase 3 ASPEN trial in 1,680 adults (ages 18 to 85 years) and 41 adolescents (ages 12 to 17 years) with non-cystic fibrosis bronchiectasis and a history of pulmonary exacerbations in the 12 months prior to screening who were randomly assigned to receive either brensocatib (10mg or 25mg orally) or placebo for 52 weeks. The trial met its primary endpoint and showed a reduction in the annualized rate of pulmonary exacerbations in both treatment groups vs. placebo by 21.1% (P=0.0019) in the 10mg group and 19.4% (P=0.0046) in the 25mg group.

Place in Therapy: Bronchiectasis is chronic lung condition that involves a cycle of airway dilation and damage that leads to impaired mucus clearance, recurrent infection, and dysregulated inflammatory response. There are currently no treatment options approved by the FDA, and management strategies are focused on airway clearance, mucoactive agents, and antibiotics for acute exacerbations. Long-term antibiotics are recommended for patients who have 3 or more exacerbations, which can lead to the development of drug-resistant pathogens. Brensocatib is a small molecule, oral, reversible inhibitor of dipeptidyl peptidase 1 (DPP-1). DPP-1 is an enzyme responsible for activating neutrophil serine proteases (NSPs) which are thought to be overactivated in chronic lung diseases, leading to neutrophilic inflammation. By blocking DPP-1, brensocatib may decrease the damaging effects of this inflammation. If approved, brensocatib would be the first approved treatment for patients with bronchiectasis as well as the first DPP-1 inhibitor, which could treat other neutrophil-mediated diseases.

Projected FDA Decision: 08/12/2025

SoonerCare Impact: There were 642 unique SoonerCare members during fiscal year 2024 with a diagnosis of bronchiectasis.

Deramiocele^{11,12,13,14}

Anticipated Indication(s): Duchenne muscular dystrophy (DMD) cardiomyopathy

Clinical Trial(s): In March 2025, the FDA accepted the Biologics License Application (BLA) for full approval of deramiocele for the treatment of patients with DMD cardiomyopathy. The BLA is supported by the results of the Phase 2 HOPE-2 and HOPE-2-Open Label Extension (OLE) trials. HOPE-2 was a randomized, double-blind, placebo controlled, Phase 2 trial, in late-stage ambulatory or non-ambulatory male patients 10 years of age or older with a genetically confirmed diagnosis of DMD, stable for at least 6 months on a glucocorticoid, and a mid-level elbow Performance of Upper Limb (PUL) version 1.2 score of 2-5. A mid-level elbow PUL 1.2 score of 2-5 meant patients could not fully reach overhead but did retain hand-to-mouth function (a higher score is better). Patients were randomized 1:1 to receive either deramiocele or placebo every 3 months by intravenous (IV) infusion for 4 total doses. The primary efficacy outcome was a change from baseline to the 12-month timepoint in the mid-level elbow PUL 1.2 score. The results, measured in 8 patients in the deramiocele group and 11 patients in the placebo group, showed a change from baseline in the mid-level elbow PUL 1.2 score favoring the treatment group over placebo [36.2% difference, 95% confidence interval (CI): 7.9-64.5; difference: 2.6 points; P=0.014]. A 1-point change in this score was seen as clinically significant as patients are dependent on their upper limbs

for mobility, self-care, and feeding. A 1-point change could represent the loss of the ability to bring the hands to the mouth, for example. Additionally, left ventricular ejection fraction (LVEF) slightly improved in the deramiocele group (0.1%) compared to the placebo group which declined (-3.9%). Also, many of the exploratory cardiac magnetic resonance imaging (MRI) structure endpoints showed improvement in the deramiocele group when compared to the placebo group. The results of the HOPE-2-OLE further supported improvements in the deramiocele treated group with a 4-point mean decline in the PUL version 2.0 compared to an external comparator group which showed a 7.7-point mean decline (difference: 3.7; $P < 0.001$) over 36 months translating to a 47% slowing of disease progression in the deramiocele group. Additionally, the median change in LVEF was 1.9% improvement after 24 months compared to a 5.0% decline in LVEF in the external comparator group.

Place in Therapy: Deramiocele is a biologic consisting of allogenic cardiosphere-derived cells (CDCs) which exhibit immunomodulatory, antifibrotic, and regenerative properties. Deramiocele is unique as it is the first treatment to target both skeletal myopathy and cardiomyopathy and was studied in non-ambulatory patients. There currently is no cure for DMD, but there are 2 primary treatment strategies for DMD which include improving muscle function by treating patients with anti-inflammatory agents (i.e., prednisone, Agamree®, Emflaza®, and Duvyzat®) and by restoring dystrophin function through gene therapy (i.e., Elevidys) or exon-skipping therapies (i.e., Amondys 45, Exondys 51, Viltepso®, Vyondys 53). Currently approved therapies for DMD have only been studied in younger ambulatory patients and have not been shown to affect upper limb function and cardiac function in late-stage ambulatory patients. Additionally, deramiocele is not specific to a gene mutation like some of the exon-skipping therapies.

Projected FDA Decision: 08/31/2025

SoonerCare Impact: During fiscal year 2024, there were 110 paid claims for muscular dystrophy medications, for 11 unique members, which accounted for a total cost of \$11,738,195.47 and an average cost per claim of \$106,710.87. These costs do not reflect rebated prices or net costs.

Pipeline Table^{15,16,17}

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
Ataluren	PTC	DMD	PO	NDA; Fst Trk; OD	1/2025- 3/2025
Bentracimab	SFJ Pharmaceuticals	Antiplatelet drug toxicity	IV	BLA; Brk Thru	1/2025- 3/2025
NVX-CoV2373	Novavax	COVID-19 immunization	IM	BLA	04/2025
Reproxalap	Aldeyra	DED	OPH	NDA	04/02/2025
Donidalorsen	Ionis	HAE	SC	BLA; OD	04/18/2025
Prademagene Zamikeracel	Abeona	Recessive DEB	SURG APP	BLA; Brk Thru; OD	04/29/2025
Elamipretide	Stealth	Barth syndrome	SC	NDA; Fst Trk; OD	04/29/2025
Nipocalimab	Janssen	Myasthenia gravis	IV	BLA; Fst Trk; OD	04/29/2025
DHE	Satsuma Pharmaceuticals	Acute migraine	IN	505(b)(2) NDA	04/30/2025
Atrasentan	Novartis	IgA nephropathy	PO	NDA	05/2025-06/2025
Pegzilarginase	Immedica	ARG1-D	IV, SC	BLA; Brk Thru; Fst Trk; OD	05/2025-07/2025
DHE Autoinjector	Amneal Pharmaceuticals	Acute migraine	SC	NDA	05/21/2025
Hydrocortisone Oral Solution	Eton	Adrenocortical insufficiency	PO	NDA	05/28/2025
AR-15512	Aerie	DED	OPH	NDA	05/30/2025
COVID-19 Vaccine (mRNA-1283)	Moderna	COVID-19 immunization	IM	BLA	05/30/2025
Clesrovimab	Merck	RSV prevention (infants, during first RSV season)	IM	NDA	06/10/2025
Sebetralstat	Kalvista	HAE	PO	NDA; Fst Trk; OD	06/17/2025
Oxylanthanum Carbonate	Unicycive	Hyperphos	PO	505(b)(2) NDA	06/28/2025
Copper Histidinate	Zydus	Menkes disease	SC	NDA; Brk Thru; Fst Trk; OD	06/30/2025
Delgocitinib	LEO	Chronic hand eczema	TOP	NDA; Fst Trk	07/2025-12/2025
Rebisufligene Etisparvovec	Ultragenyx	Sanfilippo syndrome type A	IV	BLA; Fst Trk; OD	07/2025-12/2025

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
Zopapogene Imadenovec	Precigen	Recurrent respiratory papillomatosis	SC	BLA; Brk Thru; OD	07/2025-12/2025
Sepiapterin	PTC	PKU	PO	NDA; OD	07/29/2025
Elinzanetant	Bayer	Vasomotor symptoms associated with menopause	PO	NDA	08/01/2025
Telmisartan/ Amlodipine/ Indapamide	George Medicines	HTN	PO	505(b)(2) NDA	08/06/2025
Aceclidine	Lenz	Presbyopia	OPH	NDA	08/08/2025
Brensocatib	Insmmed	Bronchiectasis	PO	NDA; Brk Thru	08/12/2025
Cyclobenzaprine	Tonix	Fibromyalgia	SL	505(b)(2) NDA; Fast Track	08/15/2025
Rilzabrutinib	Sanofi	ITP	PO	NDA; Fst Trk; OD	08/29/2025
Lecanemab-irmb (Leqembi®) SC	Eisai	Alzheimer's disease (mild, weekly maintenance dosing)	SC	BLA	08/31/2025
Deramiocecl	Capricor Therapeutics	DMD cardiomyopathy	IV	NDA; OD	08/31/2025
Sodium Pyruvate	EmphyCorp	IPF	IN	NDA	09/12/2025
Bumetanide	Corstasis Therapeutics	Edema	IN	NDA	09/14/2025
Paltusotine	Crinetics	Acromegaly	PO	NDA; OD	09/25/2025
Aficamten	Cytokinetics	Obstructive hypertrophic cardiomyopathy	PO	NDA; Brk Thru; OD	09/26/2025
Apitegromab	Scholar Rock	SMA	IV	BLA	09/30/2025
Tolebrutinib	Sanofi	Multiple sclerosis	PO	NDA	10/2025-12/2025
Troriluzole	Biohaven	Spinocerebellar ataxia	PO	505(b)(2) NDA; Fst Trk; OD	10/2025-12/2025
Sodium Chlorite	Neuvivo	ALS	IV	NDA; OD	10/07/2025
Plozasiran	Arrowhead	FCS	SC	NDA; Brk Thru; Fst Trk; OD	11/18/2025

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
Sodium Dichloroacetate	Saol Therapeutics	PDCD	PO	NDA; Fst Trk; OD	12/03/2025
Lerodalcibep	LIB Therapeutics	HCH	SC	BLA	12/16/2025
Vatiquinone	PTC	Friedreich's ataxia	PO	NDA; Fst Trk; OD	12/19/2025
Relacorilant	Corcept	Cushing's syndrome	PO	NDA; OD	12/30/2025
Seasonal Influenza/ COVID-19 Vaccine (mRNA-1083)	Moderna	COVID-19 immunization; Seasonal influenza immunization	IM	BLA; Fst Trk	01/13/2026

*Most biosimilars and oncology medications are excluded from the table. Medications known to have received a Complete Response Letter (CRL) from the FDA that have not resubmitted were also excluded. Admin = administration; ALS = amyotrophic lateral sclerosis; ARG1-D = arginase 1 deficiency; BLA = biologic license application; Brk Thru = breakthrough; DEB = dystrophic epidermolysis bullosa; DED = dry eye disease; DHE = dihydroergotamine; DMD = Duchenne muscular dystrophy; FCS = familial chylomicronemia syndrome; Fst Trk = fast track; GSK = GlaxoSmithKline; HAE = hereditary angioedema; HCH = hypercholesteremia; Hyperphos = hyperphosphatemia; HTN = hypertension; IM = intramuscular; IN = intranasal; IPF = idiopathic pulmonary fibrosis; ITP = immune thrombocytopenic purpura; IV = intravenous; NDA = new drug application; OD = orphan drug; OPH = ophthalmic; PDCD = pyruvate dehydrogenase complex deficiency; PKU = phenylketonuria; PO = by mouth; RSV = respiratory syncytial virus; SC = subcutaneous; SL = sublingual; SMA = spinal muscular atrophy; SURG APP = surgical application; TOP = topical

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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

Oklahoma Health Care Authority
April 2025

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

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

- **February 2024:** A New Drug Application (NDA) was approved for pantoprazole sodium chloride (NaCl) 0.9% for intravenous (IV) injection for the short-term treatment of gastroesophageal reflux disease (GERD) associated with erosive esophagitis and pathological hypersecretion conditions, including Zollinger-Ellison Syndrome in adults. Pantoprazole NaCl 0.9% is available as a solution for IV infusion that does not require reconstitution versus Protonix® I.V. (pantoprazole) that is a freeze-dried powder. Pantoprazole NaCl 0.9% is available in 3 different strengths: 40mg/100mL, 40mg/50mL, and 80mg/100mL.
- **August 2024:** The FDA approved Protonix® I.V. (pantoprazole) for an age expansion for patients 3 months of age and older for the treatment of GERD and a history of erosive esophagitis for up to 7 days. The dose for pediatric patients is based on age and actual body weight. Protonix® I.V. was originally approved for this indication for adults only. The age expansion approval was based on evidence from studies of IV and oral pantoprazole in adults and oral pantoprazole in pediatrics with additional pharmacokinetic and safety data in patients 1 year of age and older for IV pantoprazole and oral pantoprazole in patients 3 months of age and older.

News:

- **January 2025:** As of January 2025, the FDA Orange Book lists esomeprazole strontium and Aciphex® sprinkles (rabeprazole) as discontinued products. Additionally, there are no generic equivalents for these products.

Guideline Update(s):

- **American College of Gastroenterology (ACG) Guideline Update(s):** The ACG released an update for the treatment of *Helicobacter pylori* (*H. pylori*) infection that includes changes from the 2017 guideline based on new data from North America including rising rates of resistance to

clarithromycin and levofloxacin and studies that have been conducted with rifabutin and potassium-competitive acid blockers (PCABs) in treatment-naïve individuals. Some notable recommendations include:

- Treatment-naïve patients:
 - Optimized bismuth quadruple therapy (BQT) for 14 days is the preferred option when the antibiotic susceptibility profile is unknown.
 - Rifabutin triple therapy or PCAB dual therapy for 14 days can be suitable alternatives in patients without a penicillin allergy.
 - In patients with unknown antibiotic susceptibility and no history of macrolide exposure or penicillin allergy, PCAB-clarithromycin triple therapy for 14 days is preferable to proton pump inhibitor (PPI)-clarithromycin triple therapy when no other obvious first line treatment option is available.
- Treatment-experienced patients:
 - BQT for 14 days is the preferred option for patients who have not been treated with BQT previously and the *H. pylori* resistance profile is unknown.
 - For patients previously treated with BQT, rifabutin triple therapy is a suitable alternative.
 - For patients with persistent infection after optimized BQT and/or rifabutin triple therapy, or in whom rifabutin therapy cannot be used (e.g., because of true penicillin allergy), antibiotic susceptibility testing is recommended to guide further therapy with salvage regimens containing clarithromycin or levofloxacin.
 - In patients who are known to be infected with clarithromycin-sensitive *H. pylori* and who have not received clarithromycin triple therapy with recommended doses of clarithromycin and amoxicillin, optimized PPI or PCAB-clarithromycin triple therapy for 14 days is a viable option.

Recommendations

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 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 (ESOMEPEZS™)
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.

¹ Pantoprazole Sodium in Sodium Chloride Injection Prescribing Information. Baxter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217512s000lbl.pdf. Last revised 02/2024. Last accessed 03/18/2025.

² U.S. Food and Drug Administration (FDA). National Drug Code Directory Search. Available online at: https://dps.fda.gov/ndc/searchresult?selection=finished_product&content=NONPROPRIETARYNAME&type=Pantoprazole+Sodium+in+0.9%25+Sodium+Chloride. Last revised 03/18/2025. Last accessed 03/18/2025.

³ Protonix® I.V. Prescribing Information. Pfizer. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/020988s070lbl.pdf. Last revised 08/2024. Last accessed 03/18/2025.

⁴ Protonix® I.V. (Pantoprazole) – Expanded Indication. OptumRx®. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/clinical-updates/clinicalupdate_protonixiv_2024-0819.pdf. Issued 08/12/2024. Last accessed 03/18/2025.

⁵ U.S. 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 03/18/2025.

⁶ Chey W, Howden C, Moss S, et al. Olezarsen, ACG Clinical Guideline: Treatment of *Helicobacter pylori* Infection. *Am J Gastroenterol* 2024; 119:1730-1753. doi: 10.14309/ajg.0000000000002968.



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

Oklahoma Health Care Authority
April 2025

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

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

- **April 2024:** The FDA approved Entresto® Sprinkle (sacubitril/valsartan), a new oral formulation available as 6mg/6mg and 15mg/16mg film-coated oral pellets within capsules. This formulation is approved for the same indications as the tablet formulations; however, the dosing recommendations in the package labeling suggest the oral pellets are intended for pediatric use. These oral pellets are to be administered by opening the capsule and sprinkling the full contents onto 1 to 2 teaspoons of soft food. The oral pellets cannot be administered via nasogastric, gastrostomy, or other enteral tubes because they may cause obstruction.
- **August 2024:** The FDA approved an expanded indication for Furoscix® (furosemide on-body infusor) to include treatment of congestion due to fluid overload in adult patients with chronic heart failure (CHF), regardless of New York Heart Association (NYHA) functional class. Previously, the indication limited use to patients with NYHA Class II and III CHF. The revised package labeling also removes ascites from the list of contraindications, removes the limitation of use in emergency situations or in patients with acute pulmonary edema, and adds a warning about the potential of incomplete dosing if patients cannot detect or respond to the device alarms. According to scPharmaceuticals, current literature was utilized to request these changes, and no additional clinical trials were required.
- **March 2025:** The FDA approved an expanded indication for Furoscix® to include the treatment of edema in patients with chronic kidney disease (CKD), including nephrotic syndrome. According to scPharmaceuticals, additional clinical trials were not required to be granted this new indication.

Recommendations⁶

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 $\leq 35\%$; 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 $\leq 45\%$; 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 $\geq$ 95 bpm; or
 - iii. Age 3 to 5 years, HR $\geq$ 75 bpm; or
 - iv. Age 5 to 18 years, HR $\geq$ 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 $\geq$ 90% on exertion; and
 - b. Respiratory rate <24 breaths per minute; and
 - c. Resting heart rate <100 beats per minute; and
 - d. Systolic blood pressure >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/1.73m² 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.

¹ Entresto[®] Sprinkle (Sacubitril/Valsartan) – New Formulation Approval. *OptumRx[®]*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_entresto_2024-0417.pdf. Issued 04/12/2024. Last accessed 03/25/2025.

² Entresto[®] Sprinkle (Sacubitril/Valsartan) Prescribing Information. Novartis. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/207620s025,218591s000lbl.pdf. Last revised 04/12/2024. Last accessed 03/25/2025.

³ Furoscix[®] (Furosemide Injection), for Subcutaneous Use Prescribing Information. scPharmaceuticals, Inc. Available online: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/209988s003lbl.pdf. Last revised 03/06/2025. Last accessed 03/25/2025.

⁴ scPharmaceuticals, Inc. ScPharmaceuticals Announces FDA Approval of Supplemental New Drug Application Expanding the Furoscix[®] Indication in Heart Failure. *GlobeNewswire*. Available online at: https://www.globenewswire.com/en/news-release/2024/08/12/2928205/0/en/scPharmaceuticals-Announces-FDA-Approval-of-Supplemental-New-Drug-Application-Expanding-the-FUROSCIX-Indication-in-Heart-Failure.html#xd_co_f=YzRIMTljYzQtYzlwNy00MDQ1LTllZWEtYTZiNDc5NTdlM2Zm~. Issued 08/12/2024. Last accessed 03/25/2025.

⁵ Ernst D. Wearable furosemide delivery system approved for CKD patients. *Medical Professionals Reference*. Available online at: <https://www.empr.com/news/wearable-furosemide-delivery-system-approved-for-ckd-patients/>. Issued 03/07/2025. Last accessed 03/25/2025.

⁶ Page RL, Joglar JA, Caldwell MA, et al. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients With Supraventricular Tachycardia: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *JACC* 2016; 67(13):e27-e115. doi: 10.1161/CIR.0000000000000311.



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

Oklahoma Health Care Authority
April 2025

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

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

- **January 2025:** The FDA approved Symbravo® (meloxicam/rizatriptan) for the acute treatment of migraine with or without aura in adults. The safety and efficacy of Symbravo® were studied in 2 clinical trials, the Phase 3 MOMENTUM trial and the Phase 3 INTERCEPT trial. The MOMENTUM trial, which studied Symbravo® for the treatment of migraines with moderate to severe pain intensity, showed the percentage of patients achieving headache pain freedom and most bothersome symptom (MBS) freedom 2 hours after a single dose was statistically significantly greater among patients receiving Symbravo® compared to those who received placebo [pain free at hour 2 (19.9% vs. 6.7%; $P < 0.01$) and MBS free at hour 2 (36.9% vs. 24.4%; $P < 0.01$)]. Additionally, the secondary endpoint of sustained pain freedom up to 24 hours was statistically significantly greater among patients who received Symbravo® (16.1 %) compared to those who received meloxicam (9%; $P = 0.001$) or rizatriptan (11%; $P = 0.038$) alone. The results of the INTERCEPT trial, which studied Symbravo® for the treatment of migraines with mild pain intensity, showed the percentage of patients achieving headache pain freedom and MBS freedom at 2 hours after a single dose was statistically significantly greater in the Symbravo® treated group versus placebo [pain free at hour 2 (32.6% vs. 16.3%; $P = 0.002$) and MBS free at hour 2 (43.9% vs. 26.7%; $P = 0.003$)].

News:

- **December 2024:** Teva announced the results from the Phase 3 SPACE trial that looked at the safety and efficacy of Ajovy® (fremanezumab-vfrm) for the prevention of episodic migraine in children and adolescent patients aged 6-17 years over 12 weeks. The results showed Ajovy® significantly reduced monthly migraine days (-2.5 vs. -1.4; $P = 0.0210$) and monthly headache days (-2.6 vs. -1.5; $P = 0.0172$) compared to placebo with a safety profile consistent with that observed in the adult population. Teva is continuing to study Ajovy® in chronic migraines for pediatric patients.

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. Initiation of these therapies should not require a trial and failure of non-specific migraine prevention medication approaches.
 - All therapies previously recommended by the AHS as first-line preventive options are still considered first-line options. 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.

▪ **International Headache Society (IHS):**

- In August 2024, the IHS issued global practice recommendations for the acute pharmacological treatment of migraine. A total of 17 questions addressing different aspects of acute migraine treatment were outlined and for each an optimal recommendation, to be used if possible, and an essential recommendation to be used when an optimal recommendation cannot be used were provided. The key optimal recommendations are listed below:
 - If analgesics (i.e., acetaminophen) or non-steroidal anti-inflammatory drugs (NSAIDs) taken at appropriate doses and early during the attack were not effective, they suggest switching to a triptan for the next attack.
 - If a triptan was only partially effective, the dose should be increased to the maximum effective dose for the next attack. If the triptan is still ineffective, they suggest switching to a different route of administration or to a different triptan for the next attack. If 3 triptans have been tried at appropriate doses without a satisfactory response, they suggest switching to a different class of acute medications.
 - If a triptan was ineffective, when used in adequate doses, route of administration, and taken at proper time in 2 out of

3 attacks, they suggest switching to another triptan up to a maximum of 3 triptans at which time another class of acute medications should be used.

- If triptan was only partially effective, an NSAID should be added after triptan treatment has been optimized (see the previous 2 points), they suggest using sumatriptan in combination with naproxen as first choice. Alternatively, a triptan can be combined with any fast-release oral formulation of a NSAID.
- Gepants and lasmitidan are listed as an option for treating acute migraine attacks in people who have failed triptan monotherapy or combination therapy or in individuals with contraindications to triptans.
- They suggest limiting the use of analgesics, NSAIDs, or lasmiditan to 2-3 days per week and to less than 10 days per month. For combined analgesics (i.e., acetaminophen, aspirin, and caffeine) and triptans, they suggest limiting the intake to 2 days per week and to less than 8 days per month.

Cost Comparison: Acute Migraine Treatment

Product	Cost Per Tablet	Cost Per 7 days*
Symbravo® (meloxicam 20mg/rizatriptan 10mg)	\$127.78	\$894.46[‡]
sumatriptan 85mg/naproxen 500mg tablet (generic)	\$12.29	\$86.03 [‡]
sumatriptan 100mg tablet (generic)	\$0.44	\$6.16 ^β
rizatriptan 10mg tablet (generic)	\$0.30	\$3.60 ^α
naproxen 500mg tablet (generic)	\$0.60	\$0.42 ^γ
ibuprofen 400mg tablet (generic)	\$0.40	\$0.28 ^γ

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 7 days is based on the IHS recommendation that for treatment of acute migraine with combined analgesics and triptans intake should be limited to 2 days per week and to less than 8 days per month.

[‡]Cost per 7 days is based on the FDA approved dose of 1 tablet per day.

^αCost per 7 days is based on the FDA approved maximum dose of 30mg per day.

^βCost per 7 days is based on the FDA approved maximum dose of 200mg per day.

^γCost per 7 days is based on the IHS recommended dose for acute migraine treatment of 1 tablet daily.

Recommendations

The College of Pharmacy recommends the following changes to the current Anti-Migraine Medications Product Based Prior Authorization (PBPA) category based on the new 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)

Anti-Migraine Medications			
Tier-1	Tier-2	Tier-3	Special PA
			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 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:
- For Nurtec[®] ODT, a quantity limit of 16 orally disintegrating tablets (ODTs) per 30 days will apply; and
 - For Qulipta[®], a quantity limit of 30 tablets per 30 days will apply; and
 - For Vyepti[®], a quantity limit of 3 vials per 90 days will apply.

¹ Axsome Therapeutics. Axsome Therapeutics Announces FDA Approval of Symbravo® (Meloxicam and Rizatriptan) for the Acute Treatment of Migraine with or without Aura in Adults. Available online at: <https://axsometherapeuticsinc.qcs-web.com/news-releases/news-release-details/axsome-therapeutics-announces-fda-approval-symbravor-meloxicam>. Issued 01/30/2025. Last access 03/18/2025.

² Symbravo™ (Meloxicam and Rizatriptan) Tablet Prescribing Information. Axsome Therapeutics, Inc. Available online at: <https://www.axsome.com/wp-content/uploads/2025/01/SYM-USPI-001.000-20250130.pdf>. Last revised 01/2025. Last accessed 03/18/2025.

³ Teva Pharmaceutical Industries Ltd. Teva Presents Positive Efficacy and Safety Data of Ajovy® (Fremanezumab) for the Prevention of Episodic Migraine in Children and Adolescents from Phase 3 SPACE Trial. Available online at: <https://www.tevausea.com/news-and-media/press-releases/teva-presents-positive-efficacy-and-safety-data-of-ajovy-fremanezumab-for-the-prevention-of-episodic-m/>. Issued 12/04/2024. Last accessed 03/18/2025.

⁴ 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.

⁵ Puledra F, Sacco S, Tassorelli C, et al. International Headache Society Global Practice Recommendations for the Acute Pharmacological Treatment of Migraine. *Cephalalgia* 2024;44(8). doi:10.1177/03331024241252666.



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

Oklahoma Health Care Authority
April 2025

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

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

- **June 2024:** The FDA granted accelerated approval to Iqirvo® (elafibranor) for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.
- **July 2024:** The FDA approved Livmarli® (maralixibat) for an age expansion for the treatment of cholestatic pruritus in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Livmarli® was previously approved for this indication in patients 5 years of age and older. Additionally, a new 19mg/mL oral solution formulation of Livmarli® was approved, and the Livmarli® label has been updated to specify that the 19mg/mL solution should only be used for patients with PFIC, while the original 9.5mg/mL solution should only be used for patients with Alagille syndrome (ALGS).
- **August 2024:** The FDA granted accelerated approval to Livdelzi® (seladelpar) for the treatment of PBC in combination with UDCA in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.
- **February 2025:** The FDA approved Ctexli™ (chenodiol) for the treatment of cerebrotendinous xanthomatosis (CTX) in adults.

News:

- **November 2024:** The FDA issued a Complete Response Letter (CRL) to Intercept Pharmaceuticals for their supplemental New Drug Application (sNDA) for Ocaliva® (obeticholic acid) seeking full FDA approval of the medication. Ocaliva® was granted accelerated approval in May 2016 for the treatment of PBC in combination with UDCA in adults with inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. In May 2021, due to an identified risk of serious liver injury in patients with advanced cirrhosis taking Ocaliva® to treat PBC, the indication was narrowed and new contraindications were

added to the labeling for patients with decompensated cirrhosis (e.g., Child-Pugh class B or C) or a prior decompensation event, or patients with compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia). In September 2024, the FDA's Gastrointestinal Drugs Advisory Committee voted against recommending full approval of Ocaliva® based on concerns that the medication does not have a favorable benefit-risk profile.

- **December 2024:** The FDA issued a new drug safety communication warning of the risk of serious liver injury that has been observed in patients without cirrhosis who were taking Ocaliva® to treat PBC. Based on this, the FDA states that health care professionals should monitor liver tests frequently to detect and address worsening liver function early but notes that it is unclear if the monitoring will be sufficient to address the risk of serious liver injury. Ocaliva® should be discontinued if there is any sign of liver disease progression or if there is no demonstrated efficacy.

Ctexli™ (Chenodiol) Product Summary^{11,12}

Therapeutic Class: Bile acid

Indication(s): Treatment of CTX in adults

How Supplied: 250mg oral tablets

Dosing and Administration:

- 250mg orally 3 times daily
- Before initiating treatment, baseline alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total bilirubin levels should be obtained in all patients.

Efficacy: The efficacy of Ctexli™ was assessed by the FDA primarily in a Phase 3, randomized, double-blind, placebo-controlled, 2-treatment crossover study that randomized a total of 13 patients with CTX.

- Key Inclusion Criteria:
 - Confirmed diagnosis of CTX (including genetic testing)
 - 16 years of age or older
 - Not treated with cholic acid or any medications which impact bile acid absorption (e.g., cholestyramine, colestipol, aluminum-based antacids)
- Intervention(s): Patients were randomized to receive chenodiol 250mg or placebo 3 times daily for 4 weeks during 2 double-blind treatment periods which were preceded by an 8-week open label treatment period prior to each double-blind period. During the 8-week open label periods, all patients received chenodiol.

- Endpoint(s) Evaluated by the FDA: Change from baseline in plasma cholestanol and urine 23S-pentol levels at day 29
- Results:
 - Plasma Cholestanol: Change from baseline in plasma cholestanol was -2.3mcg/mL in the chenodiol group vs. 6.2mcg/mL in the placebo group [treatment difference: -8.5mcg/mL; 95% confidence interval (CI): -13.2mcg/mL, -3.9mcg/mL].
 - Urine 23S-Pentol: Change from baseline in urine 23S-pentol was 185ng/mL in the chenodiol group vs. 29,506ng/mL in the placebo group (treatment difference: -29,321ng/mL; 95% CI: -45,701ng/mL, -12,941ng/mL).

Cost: The Wholesale Acquisition Cost (WAC) is \$596.67 per tablet which would result in an estimated cost of \$53,700.30 per 30 days or \$644,403.60 per year based on recommended dosing.

Iqirvo® (Elafibranor) Product Summary^{13,14}

Therapeutic Class: Peroxisome proliferator-activated receptor (PPAR) agonist

Indication(s): Treatment of PBC in combination with UDCA in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA

- This indication is approved under accelerated approval based on reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- **Limitation(s) of Use:** Use not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)

How Supplied: 80mg oral tablets

Dosing and Administration:

- 80mg once daily with or without food
- Before treatment, patients should be evaluated for muscle pain or myopathy
- Should verify that females of reproductive potential are not pregnant before treatment

Efficacy: The efficacy of Iqirvo® was assessed primarily in a Phase 3, randomized, double-blind, placebo-controlled study that enrolled a total of 161 adult patients with PBC.

- Key Inclusion Criteria:
 - ALP ≥ 1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤ 2 times the ULN at baseline
 - Use of UDCA for at least 12 months prior to randomization, unless unable to tolerate UDCA treatment
- Intervention(s): Patients were randomized 2:1 to receive elafibranor 80mg or placebo once daily.
- Primary Endpoint(s): Biochemical response (defined as ALP < 1.67 times the ULN with $\geq 15\%$ reduction from baseline plus TB $\leq$ the ULN) assessed at week 52
- Results: Biochemical response was achieved in 51% of patients receiving elafibranor and 4% of patients receiving placebo (treatment difference: 47%; 95% CI: 32%, 57%; $P < 0.0001$).

Livdelzi® (Seladelpar) Product Summary^{15,16}

Therapeutic Class: PPAR-delta agonist

Indication(s): Treatment of PBC in combination with UDCA in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA

- This indication is approved under accelerated approval based on a reduction of ALP. Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- **Limitation(s) of Use:** Use not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)

How Supplied: 10mg oral capsules

Dosing and Administration: 10mg once daily with or without food

Efficacy: The efficacy of Livdelzi® was assessed primarily in a Phase 3, randomized, double-blind, placebo-controlled study that enrolled a total of 193 adult patients with PBC.

- Key Inclusion Criteria:
 - ALP ≥ 1.67 times the ULN and TB ≤ 2 times the ULN at baseline
 - Use of UDCA for at least 12 months prior to randomization, unless unable to tolerate UDCA treatment
- Intervention(s): Patients were randomized 2:1 to receive seladelpar 10mg or placebo once daily.
- Primary Endpoint(s): Biochemical response (defined as ALP < 1.67 times the ULN with $\geq 15\%$ reduction from baseline plus TB $\leq$ the ULN) assessed at month 12

- Results: Biochemical response was achieved in 62% of patients receiving seladelpar and 20% of patients receiving placebo (treatment difference: 42%; 95% CI: 28%, 53%; P<0.0001).

Cost Comparison: PBC Medications

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Iqirvo® (elafibranor) 80mg tablet	\$382.00	\$11,460.00*	\$137,520.00
Livdelzi® (seladelpar) 10mg capsule	\$420.20	\$12,606.00*	\$151,272.00
Ocaliva® (obeticholic acid) 10mg tablet	\$318.47	\$9,554.10 ⁺	\$114,649.20
ursodiol 250mg tablet (generic)	\$0.37	\$55.50 ^Δ	\$666.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

*Cost per month based on 80mg once daily

⁺Cost per month based on 10mg once daily

^ΔCost per month based on a total daily dose of 1,250mg

Unit = each capsule or tablet

Recommendations

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

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 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 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.

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- ¹ Ipsen. Ipsen's Iqirvo® Receives U.S. FDA Accelerated Approval as a First-In-Class PPAR Treatment for Primary Biliary Cholangitis. Available online at: <https://www.ipsen.com/press-releases/ipsens-iqirvo-receives-u-s-fda-accelerated-approval-as-a-first-in-class-ppar-treatment-for-primary-biliary-cholangitis/>. Issued 06/10/2024. Last accessed 03/25/2025.
- ² Mirum Pharmaceuticals, Inc. Mirum's Livmarli® Now Approved for PFIC in Patients 12 Months and Older. Available online at: <https://ir.mirumpharma.com/news-events/News/news-details/2024/Mirums-LIVMARLI-Now-Approved-for-PFIC-in-Patients-12-Months-and-Older/default.aspx>. Issued 07/25/2024. Last accessed 03/25/2025.
- ³ Livmarli® (Maralixibat) Prescribing Information. Mirum Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/214662s011lbl.pdf. Last revised 11/2024. Last accessed 03/25/2025.
- ⁴ Gilead Sciences, Inc. Gilead's Livdelzi® (Seladelpar) Granted Accelerated Approval for Primary Biliary Cholangitis by U.S. FDA. Available online at: <https://www.gilead.com/news-and-press/press-room/press-releases/2024/8/gileads-livdelzi-seladelpar-granted-accelerated-approval-for-primary-biliary-cholangitis-by-us-fda>. Issued 08/14/2024. Last accessed 03/25/2025.
- ⁵ U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for Cerebrotendinous Xanthomatosis, a Rare Lipid Storage Disease. Available online at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-cerebrotendinous-xanthomatosis-rare-lipid-storage-disease>. Issued 02/21/2025. Last accessed 03/25/2025.
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- ⁷ Ingram I. FDA Rejects Full Approval of Liver Disease Drug. *Medpage Today*. Available online at: <https://www.medpagetoday.com/gastroenterology/generalhepatology/112874>. Issued 11/12/2024. Last accessed 03/25/2025.
- ⁸ U.S. FDA. Serious Liver Injury Being Observed in Patients Without Cirrhosis Taking Ocaliva® (Obeticholic Acid) to Treat Primary Biliary Cholangitis. Available online at: <https://www.fda.gov/drugs/drug-safety-and-availability/serious-liver-injury-being-observed-patients-without-cirrhosis-taking-ocaliva-obeticholic-acid-treat>. Issued 12/12/2024. Last accessed 03/25/2025.
- ⁹ U.S. FDA. Due to Risk of Serious Liver Injury, FDA Restricts Use of Ocaliva® (Obeticholic Acid) in Primary Biliary Cholangitis (PBC) Patients with Advanced Cirrhosis. Available online at: <https://www.fda.gov/drugs/drug-safety-and-availability/due-risk-serious-liver-injury-fda-restricts-use-ocaliva-obeticholic-acid-primary-biliary-cholangitis>. Issued 05/26/2021. Last accessed 03/25/2025.
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- ¹¹ Ctexli™ (Chenodiol) Prescribing Information. Mirum Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219488s000lbl.pdf. Last revised 02/2025. Last accessed 03/25/2025.
- ¹² Study to Evaluate Patients with Cerebrotendinous Xanthomatosis (RESTORE). *ClinicalTrials.gov*. Available online at: <https://clinicaltrials.gov/study/NCT04270682>. Last revised 10/28/2024. Last accessed 03/25/2025.
- ¹³ Iqirvo® (Elafibranor) Prescribing Information. Ipsen Biopharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218860s000lbl.pdf. Last revised 06/2024. Last accessed 03/25/2025.
- ¹⁴ Kowdley KV, Bowlus CL, Levy C, et al. Efficacy and Safety of Elafibranor in Primary Biliary Cholangitis. *N Engl J Med* 2024; 390:795-805. doi: 10.1056/NEJMoa2306185.
- ¹⁵ Livdelzi® (Seladelpar) Prescribing Information. Gilead Sciences, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217899s000lbl.pdf. Last revised 08/2024. Last accessed 03/25/2025.
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Vote to Prior Authorize Kebilidi™ (Eladocagene Exuparvovec-tneq)

Oklahoma Health Care Authority
April 2025

Market News and Updates¹

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

- **November 2024:** The FDA granted accelerated approval to Kebilidi™ (eladocagene exuparvovec-tneq), the first gene therapy and targeted treatment for adults and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency. Kebilidi™ is administered intraoperatively directly into the putamen in a single treatment session.

Kebilidi™ (Eladocagene Exuparvovec-tneq) Product Summary²

Therapeutic Class: Adeno-associated viral vector serotype 2 (AAV2) vector-based gene therapy

Indication(s): Treatment of adult and pediatric patients with AADC deficiency

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

How Supplied: 2mL single-dose vial (SDV) containing an extractable suspension volume of 0.5mL with a concentration of 2.8×10^{11} vector genomes (vg)/0.5mL (nominal concentration: 5.6×10^{11} vg/mL) for intraputamenal administration

Dosing and Administration:

- Single-dose intraputamenal infusion
- Recommended total dose is 1.8×10^{11} vg (0.32mL) as (4) 0.08mL (0.45×10^{11} vg) infusions (bilaterally anterior and posterior putamen) at 0.003mL/min for a total of 27 minutes per site
- Administration should occur during a single stereotactic surgery using a cannula that is FDA-authorized for intraparenchymal infusion

Efficacy: The FDA granted accelerated approval to Kebilidi™ based on results from an ongoing, open-label, single-arm, global Phase 2 trial.

- Key Inclusion Criteria:
 - Pediatric patients (1-17 years of age) with genetically confirmed, severe AADC deficiency, defined as having no motor milestone

- achievement at baseline and no clinical response to standard of care therapies
- Presence of clinical symptoms and decreased AADC enzyme activity in plasma
- Skull maturity as assessed by neuroimaging
- Key Exclusion Criteria:
 - Significant brain structure abnormality
- Intervention(s):
 - Intraputaminial administration of Kebilidi™ via the SmartFlow® MR-compatible ventricular cannula in a single operative session compared to an external untreated natural history cohort
- Primary Endpoint(s):
 - Gross motor milestone achievement measured by Peabody Developmental Motor Scale, Second Edition (PDMS-2) from baseline to week 48
- Results:
 - Eight of 12 (67%) patients achieved a new gross motor milestone at week 48 vs. none of the 43 untreated patients in the natural history cohort

Cost: The Wholesale Acquisition Cost (WAC) of Kebilidi™ is \$3.95 million per 1-time treatment.

Recommendations

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 intraputamenal 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.

¹ U.S. Food and Drug Administration (FDA). FDA Approves First Gene Therapy for Treatment of Aromatic L-amino Acid Decarboxylase Deficiency. Available online at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-treatment-aromatic-l-amino-acid-decarboxylase-deficiency>. Issued 11/14/2024. Last accessed 03/25/2025.

² Kebilidi™ (Eladocogene Exuparvovec-tneq) Suspension, For Intraputamenal Infusion Prescribing Information. PTC Therapeutics, Inc. Available online at: <https://www.fda.gov/media/183530/download?attachment>. Last revised 11/13/2024. Last accessed 03/25/2025.



Vote to Prior Authorize Crenessity™ (Crinecerfont)

Oklahoma Health Care Authority
April 2025

Market News and Updates¹

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

- **December 2024:** The FDA approved Crenessity™ (crinecerfont) as an adjunctive treatment to glucocorticoid replacement to control androgens in adult and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH).

Crenessity™ (Crinecerfont) Product Summary²

Therapeutic Class: Corticotropin-releasing factor type 1 receptor antagonist

Indication(s): Adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic CAH

How Supplied:

- Capsules: 25mg, 50mg, and 100mg
- Oral solution: 50mg/mL in a 30mL bottle

Dosing and Administration:

- Adults: The recommended dosing is 100mg orally twice daily with morning and evening meals.
- Pediatrics (4 years of age and older):

Body Weight	Dosage Regimen (Taken with a Meal)
10kg to <20kg	25mg twice daily
20kg to <55kg	50mg twice daily
55kg or more	100mg twice daily

- Patients receiving Crenessity™ should continue glucocorticoid replacement therapy for adrenal insufficiency associated with CAH. The glucocorticoid dose should not be reduced below what is required for replacement therapy.
- See the full *Prescribing Information* for dose modifications for concomitant use with strong and moderate CYP3A4 inducers.

Efficacy: The efficacy of Crenessity™ was evaluated in 2 Phase 3, randomized, double-blind, placebo-controlled trials, CAHtalyst Adult and CAHtalyst Pediatric. CAHtalyst Adult enrolled 182 adults with classic CAH due to

21-hydroxylase deficiency (21-OHD) on supraphysiological glucocorticoid doses and with androgen concentrations in the normal range or with inadequate androgen control. CAHtalyst Pediatric enrolled 103 pediatric patients 4 to 17 years of age with classic CAH due to 21-OHD and with inadequate androgen control on supraphysiological glucocorticoid doses.

▪ **CAHtalyst Adult**

- Key Inclusion Criteria:
 - Medically confirmed diagnosis of classic CAH due to 21-OHD
 - On a stable glucocorticoid treatment regimen for CAH of $>13\text{mg}/\text{m}^2/\text{day}$ in hydrocortisone dose equivalents
- Intervention(s):
 - Patients were randomized 2:1 to received either crinecerfont 100mg or placebo twice daily for 24 weeks.
 - During the first 4 weeks of crinecerfont treatment, a stable glucocorticoid dose was maintained. During weeks 4 to 12, the glucocorticoid dose was reduced as frequently as every 2 weeks without regard to androstenedione (A4) levels, with the goal to achieve a glucocorticoid dose of $8\text{-}10\text{mg}/\text{m}^2/\text{day}$ in hydrocortisone dose equivalents adjusted for body surface area by week 12. From weeks 12 to 20, the glucocorticoid dose was further adjusted, if needed, to achieve A4 control by week 24.
- Primary Endpoint(s):
 - Percent change from baseline in the total glucocorticoid daily dose while A4 was controlled [$\leq 120\%$ of baseline or $\leq$ upper limit of normal (ULN)] after 24 weeks
- Results:
 - Percent change from baseline in the total glucocorticoid daily dose while A4 was controlled was -27% in the crinecerfont group vs. -10% in the placebo group [treatment difference: -17%; 95% confidence interval (CI): -24%, -10%; $P < 0.0001$]

▪ **CAHtalyst Pediatric**

- Key Inclusion Criteria:
 - Medically confirmed diagnosis of classic CAH due to 21-OHD
 - On a stable glucocorticoid treatment regimen for CAH of $>12\text{mg}/\text{m}^2/\text{day}$ in hydrocortisone dose equivalents
 - A4 level greater than the midpoint of the reference range, according to sex and age or pubertal stage
 - 17-OHP level >2 times the ULN, according to sex and age or pubertal stage

- Intervention(s):
 - Patients were randomized 2:1 to receive either crinecerfont 25mg, 50mg, or 100mg based on body weight or placebo twice daily for 28 weeks.
 - During the first 4 weeks of crinecerfont treatment, a stable glucocorticoid dose was maintained and from weeks 4 to 20, the glucocorticoid dose could be reduced as frequently as every 4 weeks provided A4 levels were controlled. The goal was to achieve a glucocorticoid dose of 8-10mg/m²/day by week 28 while maintaining androstenedione control.
- Endpoint(s):
 - Primary Endpoint(s):
 - Change in the androstenedione level from baseline to week 4
 - Key Secondary Endpoint(s):
 - Percent change in the daily dose of glucocorticoid from baseline to week 28 while A4 was controlled
- Results:
 - Primary Endpoint(s):
 - Change from baseline in serum A4 was a reduction of -197ng/dL in the crinecerfont group compared to an increase of 71ng/dL in the placebo group (treatment difference: -268ng/dL; 95% CI: -403ng/dL, -132ng/dL; P=0.0002)
 - Secondary Endpoints:
 - Percent change from baseline in the total glucocorticoid daily dose while A4 was controlled was -18% in the crinecerfont group vs. 6% in the placebo group [treatment difference: -24%; 95% CI: -30%, -17%; P<0.0001]

Cost: The Wholesale Acquisition Cost (WAC) of Crenessity is \$638.88 per capsule (regardless of strength) or per mL. This results in an estimated cost of \$38,332.80 per month or \$459,993.60 per year based on a dose of 50mg using the capsule or oral solution formulation or 100mg twice daily using the capsule formulation.

Recommendations

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 ≥ 10 kg; 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 ≥ 55 kg (or ≥ 20 kg 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.

¹ Neurocrine Biosciences. Neurocrine Biosciences Announces FDA Approval of Crenessity™ (Crinecerfont), a First-in-Class Treatment for Children and Adults with Classic Congenital Adrenal Hyperplasia. *PR Newswire*. Available online at: <https://www.prnewswire.com/news-releases/neurocrine-biosciences-announces-fda-approval-of-crenesity-crinecerfont-a-first-in-class-treatment-for-children-and-adults-with-classic-congenital-adrenal-hyperplasia-302331772.html>. Issued 12/13/2024. Last accessed 03/18/2025.

² Crenessity™ (Crinecerfont) Prescribing Information. Neurocrine Biosciences. Available online at: <https://pi.neurocrine.com/crenesity/CRENESSITY-Full-US-Prescribing-Information.pdf>. Last revised 12/2024. Last accessed 03/18/2025.



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

Oklahoma Health Care Authority
April 2025

Market News and Updates^{1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25}

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

- **March 2024:** The FDA approved Besponsa® (inotuzumab ozogamicin) for an expanded indication for the treatment of relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adult and pediatric patients 1 year of age and older. Previously, Besponsa® was only FDA approved in adults.
- **March 2024:** The FDA granted accelerated approval to Iclusig® (ponatinib) for a new indication for the treatment of adults with newly diagnosed Philadelphia chromosome positive (Ph+) ALL, in combination with chemotherapy.
- **March 2024:** The FDA granted accelerated approval to Breyanzi® (lisocabtagene maraleucel) for a new indication for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.
- **May 2024:** The FDA granted accelerated approval to Breyanzi® for a new indication for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received 2 or more prior lines of systemic therapy.
- **May 2024:** The FDA approved Breyanzi® for a new indication for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least 2 prior lines of systemic therapy, including a BTK inhibitor.
- **June 2024:** The FDA approved Rytelo® (imetelstat) for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell (RBC) units over 8 weeks who have not responded to, have lost response to, or are ineligible for erythropoiesis-stimulating agents (ESAs).

- **June 2024:** The FDA approved Blincyto® (blinatumomab) for a new indication for the treatment of adults and pediatric patients 1 month of age and older with CD19-positive Philadelphia chromosome negative (Ph-) B-cell precursor ALL in the consolidation phase of multiphase chemotherapy.
- **June 2024:** The FDA granted accelerated approval to Epkinly™ (epcoritamab-bysp) for a new indication for the treatment of adult patients with relapsed or refractory FL after 2 or more lines of systemic therapy.
- **October 2024:** The FDA granted accelerated approval to Scemblix® (asciminib) for a new indication for the treatment of adults with newly diagnosed Ph+ chronic myeloid leukemia (CML) in chronic phase.
- **November 2024:** The FDA approved Danziten™ (nilotinib) for the treatment of adults with newly diagnosed Ph+ CML in chronic phase and for the treatment of adults with chronic phase and accelerated phase Ph+ CML that is resistant to or intolerant to prior therapy that included imatinib.
- **November 2024:** The FDA approved Aucatzyl® (obecabtagene autoleucel) for the treatment of adults with relapsed or refractory B-cell precursor ALL.
- **November 2024:** The FDA approved Revuforj® (revumenib) for the treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year of age and older.
- **January 2025:** The FDA approved Calquence® (acalabrutinib) for a new indication, in combination with bendamustine and rituximab, for the treatment of adult patients with previously untreated MCL who are ineligible for autologous hematopoietic stem cell transplantation (HSCT).
- **January 2025:** The FDA approved Grafapex™ (treosulfan), in combination with fludarabine, as a preparative regimen for allogeneic HSCT in adult and pediatric patients 1 year of age and older with acute myeloid leukemia (AML) or MDS.
- **February 2025:** The FDA approved Adcetris® (brentuximab vedotin) for a new indication, in combination with lenalidomide and a rituximab product, for adult patients with relapsed or refractory large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma, after 2 or more lines of systemic therapy who are ineligible for autologous HSCT or chimeric antigen receptor (CAR) T-cell therapy.

News:

- **August 2020:** Arzerra® (ofatumumab) has been discontinued from the United States market. In 2020, Genmab announced plans to transition Arzerra® to an oncology access program to allow patients with CLL who were benefitting from the medication to remain on treatment through a Novartis patient access program.
- **July 2023:** AstraZeneca permanently discontinued Lumoxiti® (moxetumomab pasudotox-tdfk) from the United States market. The decision to withdraw the product was not based on the safety or efficacy of Lumoxiti®.
- **March 2024:** The FDA has withdrawn its previous accelerated approval for Aliqopa® (copanlisib) for the treatment of adults with relapsed FL who have received at least 2 prior systemic therapies. Bayer, the manufacturer of Aliqopa®, had previously announced the planned withdrawal of the medication based on results of the required confirmatory study which did not verify the clinical benefit of copanlisib for FL.
- **April 2024:** Synribo® (omacetaxine) has been discontinued by the manufacturer.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for B-cell lymphomas allow for the use of Adcetris® (brentuximab vedotin) for DLBCL or high-grade lymphoma as a single agent in CD30+ relapsed/refractory disease in patients who are not candidates for autologous stem cell transplant (SCT) or CAR T-cell therapy. Additionally, Adcetris® may be used in combination with nivolumab for CD30+ relapsed or refractory primary mediastinal large B-cell lymphoma.
- The NCCN guidelines for T-cell lymphomas allow for the use of Asparlas® (calaspargase pegol-mknl) and Oncaspar® (pegaspargase) for induction therapy for nasal or extranasal disease.
- The NCCN guidelines for T-cell lymphomas allow for the use of Beleodaq® (belinostat) for peripheral T-cell lymphoma (PTCL) as a single agent for initial palliative intent or in relapsed/refractory disease. Additionally, for T-cell lymphoma, extranodal NK/T-cell lymphoma, nasal type, Beleodaq® should be used for relapsed/refractory disease following additional therapy with an alternative asparaginase-based chemotherapy regimen.
- The NCCN guidelines for ALL allow for the use of Blincyto® (blinatumomab) for Ph- ALL as consolidation therapy as a component of multiphase chemotherapy, as consolidation, as maintenance in combination with mercaptopurine, vincristine, methotrexate, and prednisone (POMP), or for management of relapsed/refractory Ph- ALL.

Additionally, the guidelines allow use for Ph+ ALL in combination with a tyrosine kinase inhibitor (TKI) as frontline consolidation, with or without a TKI as consolidation, as maintenance in combination with POMP, or management of relapsed/refractory Ph+ ALL after failure of 2 TKIs.

- The NCCN guidelines for ALL allow for the use of Bosulif® (bosutinib) for frontline and relapsed/refractory therapy as a single agent or in combination with multiagent chemotherapy, or as maintenance therapy. Additionally, the guidelines specify that use is contraindicated for the following mutations of BCR-ABL1: T315I, V299L, G250E, or F317L.
- The NCCN guidelines for B-cell lymphomas allow for the use of Columvi™ (glofitamab-gxbm) for DLBCL as second-line and subsequent therapy in combination with GemOx (gemcitabine and oxaliplatin) in patients who are not candidates for CAR T-cell therapy or have no intention to proceed to transplant.
- The NCCN guidelines for T-cell lymphomas allow for the use of Copiktra® (duvelisib) for PTCL as a single agent or in combination with romidepsin.
- The NCCN guidelines for T-cell lymphomas specify that for T-cell lymphoma, extranodal NK/T-cell lymphoma, nasal type, Folutyn® (pralatrexate) should be used for relapsed/refractory disease following additional therapy with an alternative asparaginase-based chemotherapy regimen.
- The NCCN guidelines for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) recommendations for the use of Gazyva® (obinutuzumab) vary depending on the presence or absence of the del(17p)/TP53 mutation. Gazyva® may be used as a single agent or in combination with other medications depending on the mutation status.
- The NCCN guidelines for B-cell lymphomas allow for the use of Gazyva® (obinutuzumab) in combination with lenalidomide as second-line or subsequent therapy for gastric or nongastric mucosa-associated lymphoid tissue (MALT) lymphoma and nodal or splenic marginal zone lymphoma (MZL). Additionally, for FL, Gazyva® may be used in combination with lenalidomide for grade 1 or 2 FL or as second line as a single agent therapy.
- The NCCN guidelines for ALL allow for the use of Iclusig® (ponatinib) for newly diagnosed Ph+ ALL in combination with chemotherapy, corticosteroids, or as single agent. Additionally, the guidelines allow use for maintenance therapy as single agent.
- The NCCN guidelines for AML allow for the use of Idhifa® (enasidenib) as a single agent in patients with isocitrate dehydrogenase-2 (IDH2)-mutated AML for lower-intensity treatment induction when not a candidate for intensive induction therapy.

- The NCCN guidelines for CLL/SLL allow for the use of Imbruvica® (ibrutinib) in combination with venetoclax as first-line therapy. Additionally, the guidelines do not recommend use in combination with bendamustine.
- The NCCN guidelines for B-cell lymphomas no longer recommend Imbruvica® (ibrutinib) for follicular lymphoma. Additionally, for non-germinal center DLBCL, NCCN guidelines specify that Imbruvica® should be used in patients who are not a candidate for CAR T-cell therapy or who have no intention to proceed to transplant.
- The NCCN guidelines for T-cell lymphomas allow for the use of Istodax® (romidepsin) for PTCL as a single agent in initial palliative intent or relapsed/refractory disease. Additionally, Istodax® may be used in combination with duvelisib as second-line and subsequent therapy. For T-cell lymphoma, extranodal NK/T-cell lymphoma, nasal type, Istodax® should be used for relapsed/refractory disease following additional therapy with an alternative asparaginase-based chemotherapy regimen
- The NCCN guidelines for CLL/SLL allow for the use of Jaypirca® (pirtobrutinib) as second-line or subsequent therapy following resistance or intolerance to prior covalent Bruton's kinase (BTK) inhibitor and a BCL-2 inhibitor or if the patient demonstrates histologic (Richter) transformation to DLBCL.
- The NCCN guidelines for B-cell lymphomas recommends Monjuvi® (tafasitamab-cxix) in patients who are not eligible for autologous stem cell transplant or who are not candidates for CAR T-cell therapy.
- The NCCN guidelines for primary cutaneous lymphomas do not recommend Poteligeo® (mogamulizumab-kpkc) as primary treatment for Stage IA disease.
- The NCCN guidelines for ALL allow for the use of Sprycel® (dasatinib) as maintenance therapy as a single agent for patients who are unfit for additional therapies or if the patient previously received blinatumomab plus a TKI. Additionally, the guidelines specify that use is contraindicated for the following mutations of BCR-ABL1: T315I/A, F317L/V/I/C, or V299L.
- The NCCN guidelines for gastrointestinal stromal tumors (GIST) allow for the use of Sprycel® (dasatinib) for second-line therapy as a single agent after treatment with avapritinib for gross residual disease (R2 resection), unresectable primary disease, tumor rupture, or recurrent/metastatic disease with generalized (widespread, systemic) progression in patients with performance status 0-2 and PDGFRA exon 18 mutations that are insensitive to imatinib (including PDGFRA D842V).
- The NCCN guidelines for ALL allow for the use of Tassigna® (nilotinib) as maintenance therapy as a single agent for patients who are unfit for additional therapies or if the patient previously received blinatumomab

plus a TKI. Additionally, the guidelines specify that use is contraindicated for the following mutations of BCR-ABL1: T315I, Y253H, E255K/V, F359V/C/I or G250E.

- The NCCN guidelines for GIST allow for the use of Tassigna® (nilotinib) as a single agent for gross residual disease (R2 resection), unresectable primary disease, tumor rupture, or recurrent/metastatic disease after progression on approved therapies (imatinib, sunitinib, regorafenib, and standard dose ripretinib).
- The NCCN guidelines for B-cell lymphomas allow for the use of Tazverik® (tazemetostat) for relapsed/refractory FL irrespective of EZH2 mutation status in certain settings.
- The NCCN guidelines for CLL/SLL allow for the use of Venclexta® (venetoclax) in combination with ibrutinib as first-line therapy and in combination with obinutuzumab for relapsed/refractory disease.
- The NCCN guidelines for B-cell lymphomas no longer recommend the use of Zevalin® (ibritumomab tiuxetan) for any indication.
- The NCCN guidelines for B-cell lymphomas no longer recommend Zydelig® (idelalisib) for the treatment of gastric or nongastric MALT lymphoma, nodal or splenic MZL.
- The NCCN guidelines for CLL/SLL specify that Zydelig® (idelalisib) treatment should be used after prior therapy with Bruton tyrosine kinase inhibitor- and venetoclax-based regimens.
- The NCCN guidelines for B-cell lymphomas, regarding use of Zynlonta® (loncastuximab tesirine-lpyl), do not require the patient to have a biopsy that shows CD19 protein expression if a previous CD19-directed therapy was used.

Aucatzyl® (Obecabtagene Autoleucel) Product Summary²⁶

Therapeutic Class: CD19-directed genetically modified autologous T cell immunotherapy

Indication(s): Treatment of adults with relapsed or refractory B-cell precursor ALL

How Supplied: Cell suspension for intravenous (IV) infusion containing a total of 410×10^6 CD19 CAR-positive viable T-cells supplied in 3 to 5 infusion bags for split dose administration

Dosing and Administration:

- Recommended total dose is 410×10^6 CD19 CAR-positive viable T cells
- Treatment regimen consists of a split dose infusion to be administered on day 1 and day 10 (± 2 days)

- Dosage regimen will be determined by the tumor burden assessed by bone marrow blast percentage from a sample obtained within 7 days prior to the start of lymphodepletion
- For bone marrow blast >20%:

Day 1	Day 10 (±2 Days)
10 x 10 ⁶ dose administered via syringe	100 x 10 ⁶ dose administered via bag infusion; and 300 x 10 ⁶ dose administered via bag infusion

- For bone marrow blast ≤20%:

Day 1	Day 10 (±2 Days)
100 x 10 ⁶ dose administered via bag infusion	10 x 10 ⁶ dose administered via syringe; and 300 x 10 ⁶ dose administered via bag infusion

Cost: The Wholesale Acquisition Cost (WAC) is \$525,000, which includes both days of the split dose administration.

Danziten™ (Nilotinib) Product Summary²⁷

Therapeutic Class: Kinase inhibitor

Indication(s):

- Treatment of adult patients with newly diagnosed Ph+ CML in chronic phase
- Treatment of adult patients with chronic phase and accelerated phase Ph+ CML resistant to or intolerant to prior therapy that included imatinib

How Supplied: 71mg and 95mg oral tablets

Dosing and Administration:

- Newly diagnosed Ph+ CML in chronic phase: 142mg twice daily at approximately 12-hour intervals with or without food
- Resistant or intolerant Ph+ CML in chronic phase and accelerated phase: 190mg twice daily at approximately 12-hour intervals with or without food

Cost: The WAC is \$160.94 per tablet, regardless of strength. This would result in an estimated cost of \$18,025.28 per 28 days or \$234,328.64 per year based on recommended dosing.

Grafapex™ (Treosulfan) Product Summary²⁸

Therapeutic Class: Alkylating drug

Indication(s):

- Use in combination with fludarabine as a preparative regimen for allogeneic HSCT in adult and pediatric patients 1 year of age and older with AML
- Use in combination with fludarabine as a preparative regimen for allogeneic HSCT in adult and pediatric patients 1 year of age and older with MDS

How Supplied: Lyophilized powder in 1g and 5g single-dose vials (SDV)

Dosing and Administration:

- Recommended dose is 10g/m² administered as an IV infusion over 2 hours daily for 3 days, beginning on day -4 prior to transplantation
- Should be given in combination with fludarabine as a preparative regimen for allogeneic HSCT, with fludarabine administered for 5 days beginning on day -6 prior to transplantation

Cost: The WAC is \$610 per 1g SDV and \$3,050 per 5g SDV. For an adult member with a body surface area (BSA) of 1.73m², this would result in an estimated cost of \$32,940 for the recommended 3 doses.

Revuforj® (Revumenib) Product Summary²⁹

Therapeutic Class: Menin inhibitor

Indication(s): Treatment of relapsed or refractory acute leukemia with a KMT2A translocation in adult and pediatric patients 1 year of age and older

How Supplied: 25mg, 110mg, and 160mg oral tablets

Dosing and Administration: Recommended dosage is based on patient weight and concomitant use of strong CYP3A4 inhibitors

- Weight ≥40kg: 270mg twice daily (or 160mg twice daily if used with strong CYP3A4 inhibitors)
- Weight <40kg: 160mg/m² twice daily (or 95mg/m² twice daily if used with strong CYP3A4 inhibitors)
- See full *Prescribing Information* for the recommended body surface area (BSA)-based tablet doses
- If patients are unable to swallow tablets whole, tablets may be crushed and dispersed in water and taken within 2 hours of preparation
- For patients without disease progression or unacceptable toxicity, treatment should continue for a minimum of 6 months to allow time for clinical response

Cost: The WAC is \$658.33 per tablet for both the 110mg and 160mg strengths. For a member weighing ≥40kg using a dose of 270mg twice daily, this would result in an estimated cost of \$78,999.60 per 30 days or \$947,995.20 per year.

Rytelo® (Imetelstat) Product Summary³⁰

Therapeutic Class: Oligonucleotide telomerase inhibitor

Indication(s): Treatment of adult patients with low- to intermediate-1 risk MDS with transfusion-dependent anemia requiring 4 or more RBC units over 8 weeks who have not responded to, have lost response to, or are ineligible for ESAs

How Supplied: Lyophilized powder in a 47mg or 188mg SDV

Dosing and Administration:

- Recommended dose is 7.1mg/kg administered as an IV infusion over 2 hours every 4 weeks
- Should be discontinued if patient does not experience a decrease in RBC transfusion burden after 24 weeks of treatment (administration of 6 doses) or if unacceptable toxicity occurs at any time

Cost: The WAC is \$2,545.13 per 47mg vial or \$10,180.52 per 188mg vial. For a member weighing 80kg, this would result in an estimated cost of \$30,541.56 per 28 days or \$397,040.28 per year based on the use of (3) 188mg SDVs per dose.

Recommendations

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 allogeneic 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 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), Folutyn® (pralatrexate), Gazyva® (obinutuzumab), Idhifa® (enasidenib), Imbruvica® (ibrutinib), Istodax® (romidepsin), Jaypirca® (pirtobrutinib), Monjuvi® (tafasitamab-cxix), Poteligeo® (mogamulizumab-kpkc), Sprycel® (dasatinib), Tassigna® (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/V/I/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.

Foloty® (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 (≥ 7 cm), contiguous Stage II (≥ 7 cm), 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-Ipyl) 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) ≥30 mL/min/1.73m²; 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.~~

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- ¹ U.S. FDA. FDA Approves Inotuzumab Ozogamicin for Pediatric Patients with Acute Lymphoblastic Leukemia. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-inotuzumab-ozogamicin-pediatric-patients-acute-lymphoblastic-leukemia>. Issued 03/06/2024. Last accessed 03/25/2025.
- ² U.S. FDA. FDA Grants Accelerated Approval to Ponatinib with Chemotherapy for Newly Diagnosed Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-ponatinib-chemotherapy-newly-diagnosed-philadelphia-chromosome>. Issued 03/19/2024. Last accessed 03/25/2025.
- ³ Bristol Myers Squibb. U.S. FDA Approves Bristol Myers Squibb's Breyanzi® as the First and Only CAR T Cell Therapy for Adults with Relapsed or Refractory Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL). Available online at: <https://news.bms.com/news/details/2024/U.S.-FDA-Approves-Bristol-Myers-Squibbs-Breyanzi--as-the-First-and-Only-CAR-T-Cell-Therapy-for-Adults-with-Relapsed-or-Refractory-Chronic-Lymphocytic-Leukemia-CLL-or-Small-Lymphocytic-Lymphoma-SLL/default.aspx>. Issued 03/14/2024. Last accessed 03/25/2025.
- ⁴ U.S. FDA. FDA Grants Accelerated Approval to Lisocabtagene Maraleucel for Follicular Lymphoma. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-lisocabtagene-maraleucel-follicular-lymphoma>. Issued 05/15/2024. Last accessed 03/25/2025.
- ⁵ U.S. FDA. FDA Approves Lisocabtagene Maraleucel for Relapsed or Refractory Mantle Cell Lymphoma. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-lisocabtagene-maraleucel-relapsed-or-refractory-mantle-cell-lymphoma>. Issued 05/30/2024. Last accessed 03/25/2025.
- ⁶ U.S. FDA. FDA Approves Imetelstat for Low- to Intermediate-1 Risk Myelodysplastic Syndromes with Transfusion-Dependent Anemia. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-imetelstat-low-intermediate-1-risk-myelodysplastic-syndromes-transfusion-dependent>. Issued 06/06/2024. Last accessed 03/25/2025.
- ⁷ U.S. FDA. FDA Approves Blinatumomab as Consolidation for CD19-Positive Philadelphia Chromosome-Negative B-Cell Precursor Acute Lymphoblastic Leukemia. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-blinatumomab-consolidation-cd19-positive-philadelphia-chromosome-negative-b-cell>. Issued 06/14/2024. Last accessed 03/25/2025.
- ⁸ U.S. FDA. FDA Grants Accelerated Approval to Epcoritamab-bysp for Relapsed or Refractory Follicular Lymphoma. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-epcoritamab-bysp-relapsed-or-refractory-follicular-lymphoma>. Issued 06/26/2024. Last accessed 03/25/2025.
- ⁹ U.S. FDA. FDA Grants Accelerated Approval to Asciminib for Newly Diagnosed Chronic Myeloid Leukemia. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-asciminib-newly-diagnosed-chronic-myeloid-leukemia>. Issued 10/29/2024. Last accessed 03/25/2025.
- ¹⁰ Azurity Pharmaceuticals. Azurity Pharmaceuticals, Inc. Announces FDA Approval of Danziten™ (Nilotinib) Tablets, the First and Only Nilotinib with No Mealtime Restrictions. Available online at: <https://azurity.com/azurity-pharmaceuticals-inc-announces-fda-approval-of-danziten-nilotinib-tablets-the-first-and-only-nilotinib-with-no-mealtime-restrictions/>. Issued 11/14/2024. Last accessed 03/25/2025.
- ¹¹ U.S. FDA. FDA Approves Obecabtagene Autoleucel for Adults with Relapsed or Refractory B-Cell Precursor Acute Lymphoblastic Leukemia. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-obecabtagene-autoleucel-adults-relapsed-or-refractory-b-cell-precursor-acute>. Issued 11/08/2024. Last accessed 03/25/2025.
- ¹² U.S. FDA. FDA Approves Revumenib for Relapsed or Refractory Acute Leukemia with a KMT2A Translocation. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-revumenib-relapsed-or-refractory-acute-leukemia-kmt2a-translocation>. Issued 11/15/2024. Last accessed 03/25/2025.
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Fiscal Year 2024 Annual Review of Topical Acne, Psoriasis, and Rosacea Products

Oklahoma Health Care Authority
April 2025

Current Prior Authorization Criteria

Aczone® (Dapsone Gel) Approval Criteria:

1. An FDA approved diagnosis of acne vulgaris; and
2. For Aczone® 7.5% gel, the member must be 9 years of age or older; and
3. Aczone® will not be covered for members older than 20 years of age; and
4. A previous trial of benzoyl peroxide or a patient-specific, clinically significant reason why benzoyl peroxide is not appropriate for the member must be provided; and
5. A previous trial of a topical antibiotic, such as clindamycin or erythromycin, or a patient-specific, clinically significant reason why a topical antibiotic is not appropriate for the member must be provided.

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% 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.

Clindacin® ETZ Kit (Clindamycin 1% Swabs and Cleanser) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient specific, clinically significant reason the member cannot use the preferred topical clindamycin products including lotion, solution, swabs, or the preferred generic clindamycin gel (generic Cleocin T®) must be provided; and
3. Clindacin® ETZ kit will not be covered for members older than 20 years of age.

Clindagel® (Clindamycin 1% Topical Gel) and Evoclin® (Clindamycin 1% Topical Foam) Approval Criteria:

1. Member must have failed a trial of a different formulation of topical clindamycin such as lotion, solution, swabs, or the preferred generic clindamycin gel (generic for Cleocin T®; this generic medication is not interchangeable with Clindagel®); and
2. Member must be 20 years of age or younger.

Duobrii® (Halobetasol Propionate/Tazarotene 0.01%/0.045% Lotion) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis in adults; and
2. Female members must not be pregnant and must be willing to use an effective method of contraception during treatment; and
3. A patient-specific, clinically significant reason why the member cannot use individual components of tazarotene and a topical corticosteroid separately must be provided; and
4. A quantity limit of 100 grams per 30 days will apply.

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

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

MetroGel® (Metronidazole 1% Gel) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use metronidazole 0.75% gel, which is available without prior authorization for members 20 years of age and younger, must be provided; and
2. MetroGel® will not be covered for members older than 20 years of age.

Noritate® (Metronidazole 1% Cream) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use metronidazole 0.75% cream, which is available without prior authorization for members 20 years of age or younger, must be provided; and
2. Noritate® will not be covered for members older than 20 years of age.

Sorilux® (Calcipotriene 0.005% Foam) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis of the scalp and body in members 12 years of age and older; and
2. A patient-specific, clinically significant reason why the member cannot use the generic formulations of topical calcipotriene, which are available without a prior authorization, must be provided; and
3. A quantity limit of 120 grams per 30 days will apply.

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% 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.

Vtama® (Tapinarof 1% Cream) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis; and
2. Member must be 18 years of age or older; and
3. Member must have a body surface area (BSA) involvement of $\leq 20\%$; 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. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance):
 - a. An ultra-high to high potency topical corticosteroid (TCS); or
 - b. A generic topical calcipotriene product; or
 - c. A topical tazarotene product; and
6. 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
7. A quantity limit of 60 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 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.

Zoryve® (Roflumilast 0.3% Cream) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis; and

2. Member must be 6 years of age or older; and
3. Member must have a body surface (BSA) involvement of $\leq 20\%$; and
4. Member must not have moderate or severe hepatic impairment (Child-Pugh B or C); and
5. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
6. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance):
 - a. An ultra-high to high potency topical corticosteroid (TCS); or
 - b. A generic topical calcipotriene product; or
 - c. A topical tazarotene product; and
7. 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
8. A quantity limit of 60 grams per 30 days will apply.

Zoryve® (Roflumilast 0.3% Foam) Approval Criteria:

1. An FDA approved diagnosis of seborrheic dermatitis; and
2. Prescriber must confirm member's condition is moderate or severe; and
3. Member must be 9 years of age or older; and
4. Member must have a body surface area (BSA) involvement of $\leq 20\%$; and
5. Member must not have moderate or severe hepatic impairment (Child-Pugh B or C); and
6. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
7. If the affected area is limited to the scalp, member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 1 product from all of the following categories (or have a contraindication or documented intolerance):
 - a. Over-the-counter (OTC) antifungal shampoo (e.g., selenium sulfide, zinc pyrithione); and
 - b. OTC coal tar shampoo; and
 - c. Tier-1 prescription antifungal shampoo (e.g., ketoconazole 2% shampoo); and
 - d. Tier-1 topical corticosteroid; and
8. If the affected area includes the face or body, member must have documented trials within the last 6 months for a minimum of at least 2 weeks that resulted in failure with at least 1 product from all of the

following categories (or have a contraindication or documented intolerance):

- a. Tier-1 topical antifungal (e.g., ketoconazole, ciclopirox); and
 - b. Tier-1 topical corticosteroid; and
 - c. Topical calcineurin inhibitor (e.g., pimecrolimus 1% cream, tacrolimus 0.1% ointment); and
9. Initial approvals will be for a duration of 8 weeks. After 8 weeks, the prescriber will need to provide clinical documentation that the member is improving on the medication and provide justification for continuation of therapy; and
10. A quantity limit of 60 grams per 30 days will apply.

Utilization of Topical Acne, Psoriasis, and Rosacea Products: 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	6,837	13,793	\$827,764.59	\$60.01	\$2.21	736,119	374,179
2023 Total	6,837	13,793	\$827,764.59	\$60.01	\$2.21	736,119	374,179
Fiscal Year 2024							
FFS	5,938	11,266	\$595,351.97	\$52.85	\$1.93	609,372	308,256
Aetna	594	798	\$50,804.30	\$63.66	\$2.40	42,741	21,180
Humana	584	800	\$59,699.15	\$74.62	\$2.81	42,883	21,263
OCH	636	872	\$66,615.30	\$76.39	\$2.81	47,433	23,739
2024 Total	6,903	13,736	\$772,470.72	\$56.24	\$2.06	742,429	374,438
% Change	1.00%	-0.40%	-6.70%	-6.30%	-6.80%	0.90%	0.10%
Change	66	-57	-\$55,293.87	-\$3.77	-\$0.15	6,310	259

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

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

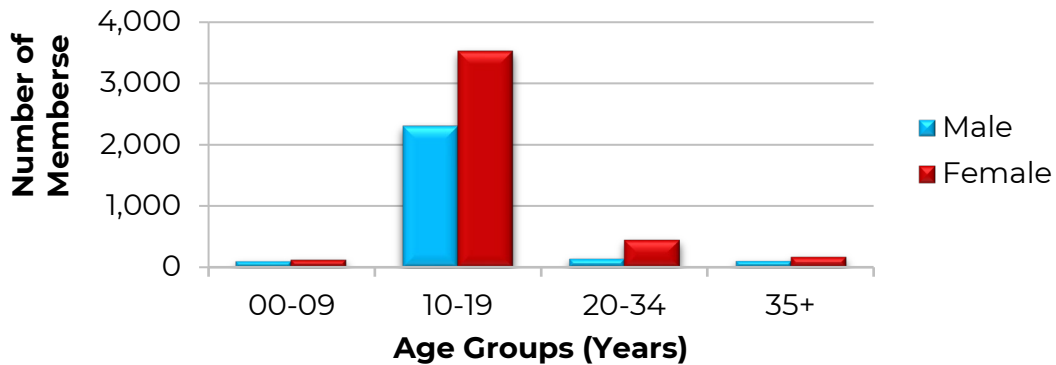
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024

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 topical acne, psoriasis, and rosacea products totaled \$72,797.87.^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 Topical Acne, Psoriasis, and Rosacea Products: Pharmacy Claims (All Plans)



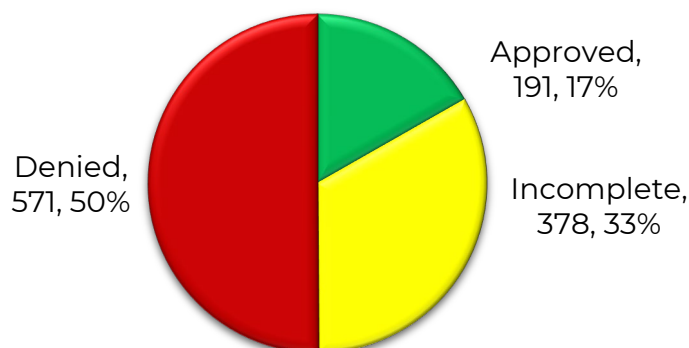
Top Prescriber Specialties of Topical Acne, Psoriasis, and Rosacea Products by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Topical Acne, Psoriasis, and Rosacea Products

There were 1,140 prior authorization requests submitted for topical acne, psoriasis, and rosacea products 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	145	15%	374	38%	471	48%	990
Aetna	33	35%	4	4%	58	61%	95
Humana	7	29%	0	0%	17	71%	24
OCH	6	19%	0	0%	25	81%	31
Total	191	17%	378	33%	571	50%	1,140

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}

Anticipated Patent Expiration(s):

- Sorilux® (calcipotriene 0.005% foam): May 2028
- Winlevi® (clascoterone 1% cream): July 2030
- Mirvaso® (brimonidine 0.33% gel): June 2031
- Aczone® (dapsone 7.5% gel): November 2033
- Duobrii® (halobetasol propionate/tazarotene 0.01%/0.045% lotion): June 2036
- Zoryve® (roflumilast cream): June 2037
- Vtama® (tapinarof 1% cream): November 2039
- Zoryve® (roflumilast 0.3% foam): December 2041

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

- **July 2024:** The FDA approved Zoryve® (roflumilast 0.15% cream) for the topical treatment of mild-to-moderate atopic dermatitis (AD) in adult and pediatric patients 6 years of age and older. This is a new indication and new formulation for Zoryve®, which is also available as a 0.3% cream for the treatment of plaque psoriasis and as a 0.3% foam for the treatment of seborrheic dermatitis.
- **July 2024:** The FDA approved an Abbreviated New Drug Application (ANDA) for the first generic formulation of tazarotene 0.05% cream. The approval was granted to Padagis Isreal Pharmaceuticals.
- **December 2024:** The FDA approved Vtama® (tapinarof 1% cream) for a new indication for the topical treatment of AD in adults and pediatric patients 2 years of age and older. Vtama® is also FDA approved for the topical treatment of plaque psoriasis in adults.

Pipeline:

- **Zoryve® (Roflumilast 0.05% Cream):** The FDA accepted a supplemental New Drug Application (sNDA) for Zoryve® 0.05% cream for the treatment of children 2 to 5 years of age with mild-to-moderate AD. The sNDA is supported by data from the Phase 3 INTEGUMENT-PED and INTEGUMENT-OLE studies. The FDA has assigned a

Prescription Drug User Fee Act (PDUFA) action data of October 13, 2025 for reviewing the sNDA.

- **Zoryve® (Roflumilast 0.3% Foam):** The FDA accepted an sNDA for Zoryve® 0.3% foam for the treatment of scalp and body psoriasis in adults and adolescents 12 years of age or older. The sNDA is supported by data from a Phase 2b study and the Phase 3 ARRECTOR study. The FDA has assigned a PDUFA action date of May 22, 2025 for reviewing the sNDA.

Recommendations

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 (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, 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 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 mild-to-moderate 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.

Utilization Details of Topical Acne, Psoriasis, and Rosacea Products: Fiscal Year 2024

Pharmacy Claims (All Plans)						
PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CLINDAMYCIN PRODUCTS						
CLINDAMYCIN GEL 1%	4,685	2,712	\$132,205.12	\$28.22	1.73	17.11%
CLINDAMYCIN LOT 1%	2,364	1,352	\$75,110.79	\$31.77	1.75	9.72%
CLINDAMYCIN SOL 1%	2,248	1,241	\$49,322.20	\$21.94	1.81	6.38%
CLINDAMYCIN SWAB 1%	1,079	418	\$30,562.14	\$28.32	2.58	3.96%
CLINDAMYCIN LOT 10MG/ML	53	34	\$1,815.29	\$34.25	1.56	0.23%
CLINDACIN-P PAD 1%	4	3	\$127.08	\$31.77	1.33	0.02%
CLINDAMYCIN AER 1%	1	1	\$199.22	\$199.22	1	0.03%
SUBTOTAL	10,434	5,761	\$289,341.84	\$27.73	1.81	37.46%
TAZAROTENE PRODUCTS						
TAZAROTENE CRE 0.1%	2,213	1,379	\$271,733.44	\$122.79	1.6	35.18%
TAZAROTENE GEL 0.05%	34	28	\$11,103.64	\$326.58	1.21	1.44%
TAZAROTENE GEL 0.1%	18	12	\$6,244.73	\$346.93	1.5	0.81%
SUBTOTAL	2,265	1,419	\$289,081.81	\$127.63	1.6	37.42%
CALCIPOTRIENE PRODUCTS						
CALCIPOTRIENE CRE 0.005%	315	216	\$29,564.60	\$93.86	1.46	3.83%
CALCIPOTRIENE OIN 0.005%	107	66	\$22,873.21	\$213.77	1.62	2.96%
CALCIPOTRIENE SOL 0.005%	86	51	\$5,206.28	\$60.54	1.69	0.67%
SORILUX AER 0.005%	1	1	\$1,706.26	\$1,706.26	1	0.22%
SUBTOTAL	509	334	\$59,350.35	\$116.60	1.52	7.68%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
METRONIDAZOLE PRODUCTS						
METRONIDAZOLE CRE 0.75%	121	102	\$3,869.37	\$31.98	1.19	0.50%
METRONIDAZOLE GEL 0.75%	66	56	\$1,776.80	\$26.92	1.18	0.23%
METRONIDAZOLE LOT 0.75%	11	10	\$1,218.34	\$110.76	1.1	0.16%
METRONIDAZOLE GEL 1%	6	6	\$321.22	\$53.54	1	0.04%
SUBTOTAL	204	174	\$7,185.73	\$35.22	1.17	0.93%
ERYTHROMYCIN PRODUCTS						
ERYTHROMYCIN SOL 2%	138	97	\$5,245.34	\$38.01	1.42	0.68%
ERYTHROMYCIN GEL 2%	5	5	\$167.71	\$33.54	1	0.02%
SUBTOTAL	143	102	\$5,413.05	\$37.85	1.4	0.70%
ROFLUMILAST PRODUCTS						
ZORYVE FOAM 0.3%	39	30	\$32,788.52	\$840.73	1.3	4.24%
ZORYVE CRE 0.3%	35	20	\$29,108.83	\$831.68	1.75	3.77%
SUBTOTAL	74	50	\$61,897.35	\$836.45	1.48	8.01%
DAPSONE PRODUCTS						
DAPSONE GEL 7.5%	26	15	\$3,978.33	\$153.01	1.73	0.52%
DAPSONE GEL 5%	16	10	\$2,951.92	\$184.50	1.6	0.38%
SUBTOTAL	42	25	\$6,930.25	\$165.01	1.68	0.90%
TAPINAROF PRODUCTS						
VTAMA CRE 1%	29	20	\$39,412.48	\$1,359.05	1.45	5.10%
SUBTOTAL	29	20	\$39,412.48	\$1,359.05	1.45	5.10%
CLASCOTERONE PRODUCTS						
WINLEVI CRE 1%	22	11	\$12,761.87	\$580.09	2	1.65%
SUBTOTAL	22	11	\$12,761.87	\$580.09	2	1.65%
SULFACETAMIDE PRODUCTS						
SULFACETAMIDE LOT 10%	14	9	\$1,095.99	\$78.29	1.56	0.14%
SUBTOTAL	14	9	\$1,095.99	\$78.29	1.56	0.14%
TOTAL	13,736	6,903*	\$772,470.72	\$56.24	1.99	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

AER = aerosol foam; CRE = cream; LOT = lotion; OIN = ointment; SOL = solution

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 02/2025. Last accessed 02/07/2025.

² Arcutis Biotherapeutics, Inc. FDA Approves Arcutis' Zoryve® (Roflumilast) Cream 0.15% for the Treatment of Atopic Dermatitis in Adults and Children Down to 6 Years of Age. Available online at: <https://www.arcutis.com/fda-approves-arcutis-zoryve-roflumilast-cream-0-15-for-the-treatment-of-atopic-dermatitis-in-adults-and-children-down-to-6-years-of-age/>. Issued 07/09/2024. Last accessed 02/07/2025.

³ U.S. FDA. First Generic Drug Approvals. Available online at: <https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals>. Last revised 11/25/2024.

⁴ Organon. FDA Approves Vtama® (Tapinarof) Cream, 1% for the Treatment of Atopic Dermatitis in Adults and Children 2 Years of Age and Older. Available online at: <https://www.organon.com/news/fda-approves-vtama-tapinarof-cream-1-for-the-treatment-of-atopic-dermatitis-in-adults-and-children-2-years-of-age-and-older/>. Issued 12/16/2024. Last accessed 02/07/2025.

⁵ Arcutis Biotherapeutics, Inc. Pipeline. Available online at: <https://www.arcutis.com/pipeline/>. Last accessed 03/25/2025.

⁶ Arcutis Biotherapeutics, Inc. U.S. FDA Accepts Supplemental New Drug Application for Arcutis' Zoryve® (Roflumilast) Cream 0.05% for the Treatment of Children Aged 2 to 5 with Mild to Moderate Atopic Dermatitis. Available online at: <https://www.arcutis.com/u-s-fda-accepts-supplemental-new-drug-application-for-arcutis-zoryve-roflumilast-cream-0-05-for-the-treatment-of-children-aged-2-to-5-with-mild-to-moderate-atopic-dermatitis/>. Issued 02/26/2025. Last accessed 03/25/2025.

⁷ Arcutis Biotherapeutics, Inc. FDA Accepts Arcutis' Supplemental New Drug Application for Zoryve® (Roflumilast) Foam for the Treatment of Scalp and Body Psoriasis in Adults and Adolescents Ages 12 and Over. Available online at: <https://www.arcutis.com/fda-accepts-arcutis-supplemental-new-drug-application-for-zoryve-roflumilast-foam-for-the-treatment-of-scalp-and-body-psoriasis-in-adults-and-adolescents-ages-12-and-over/>. Issued 09/24/2024. Last accessed 03/25/2025.



Fiscal Year 2024 Annual Review of Molluscum Contagiosum Medications

Oklahoma Health Care Authority
April 2025

Current Prior Authorization Criteria

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. 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. Cryotherapy; or
 - b. Curettage; or
 - c. Laser therapy; or
 - d. Cimetidine; or
 - e. Potassium hydroxide; or
 - f. Salicylic acid; and
6. Member must not have lesions exclusively on genitals or around eyes; and
7. Ycanth™ must be 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. 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. Cryotherapy; or
 - b. Curettage; or
 - c. Laser therapy; or
 - d. Cimetidine; or
 - e. Potassium hydroxide; or
 - f. Salicylic acid; 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.

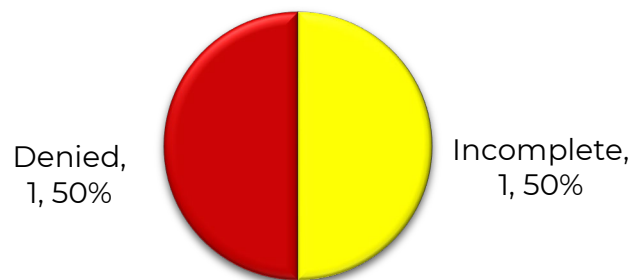
Utilization of Molluscum Contagiosum Medications: Fiscal Year 2024

There was no SoonerCare utilization of molluscum contagiosum medications during fiscal year 2024.

Prior Authorization of Molluscum Contagiosum Medications

There were 2 prior authorization requests submitted for 2 unique members for molluscum contagiosum 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	%	Number	%	Number	%	
FFS	0	0%	1	50%	1	50%	2
Aetna	0	N/A	0	N/A	0	N/A	0
Humana	0	N/A	0	N/A	0	N/A	0
OCH	0	N/A	0	N/A	0	N/A	0
Total	0	0%	1	50%	1	50%	2

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 Updates¹

Anticipated Patent Expiration(s):

- Ycanth™ (cantharidin 0.7% solution): July 2028
- Zelsuvmi™ (berdazimer 10.3% gel): January 2029

Recommendations

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 (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.

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 03/2025. Last accessed 03/25/2025.



Fiscal Year 2024 Annual Review of Growth Hormone Products and Voxzogo® (Vosoritide)

Oklahoma Health Care Authority
April 2025

Current Prior Authorization Criteria

Growth Hormone Products	
Tier-1*	Tier-2
Genotropin® (somatropin) (Pfizer) - Cartridge, MiniQuick	Humatrope® (somatropin) (Eli Lilly) - Vial, Cartridge Kit
	* Ngenla® (somatrogon-ghla) (Pfizer) - Pen
	Norditropin® (somatropin) (Novo Nordisk) - FlexPro® Pen
	Nutropin® and Nutropin AQ® (somatropin) (Genentech) - Vial, Pen Cartridge, NuSpin®
	Omnitrope® (somatropin) (Sandoz) - Vial, Cartridge
	Saizen® (somatropin) (EMD Serono) - Vial, click.easy®
	* Serostim® (somatropin) (EMD Serono) - Vial
	* Skytrofa® (lonapegsomatropin-tcgd) (Ascendis) - Cartridge
	* Sogroya® (somapacitan-beco) (Novo Nordisk) - Pen
	Zomacton® and Zoma-Jet® (somatropin) (Ferring) - Vial, Injection Device
	* Zorbtive® (somatropin) (EMD Serono) - Vial

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

*Supplementally rebated product(s)

*Additional approval criteria applies.

Growth Hormone Covered Indications (prior to epiphyseal closure)*:

- Growth hormone deficiency (GHD) of 1 of the following types:
 - Classic GHD as determined by childhood GH stimulation tests; or
 - Panhypopituitarism; or
 - Hypoglycemia with evidence for GHD; or
 - Neurosecretory dysfunction; or
 - Other evidence for GHD submitted for panel review and decision; or
- Short stature associated with Prader-Willi syndrome; or
- Short stature associated with Noonan syndrome; or

4. Short stature associated with chronic renal insufficiency (pre-transplantation); or
5. Growth failure in children born small for gestational age (SGA) who fail to manifest catch-up growth by 2 years of age; or
6. Idiopathic short stature (ISS) in children with height ≥ 2.25 SD below the mean for age and gender and who are unlikely to catch up in height; or
7. Turner syndrome or 45X, 46XY mosaicism; or
8. Short-stature homeobox-containing gene (SHOX) deficiency with genetic evidence for SHOX deficiency.

*Please refer to the complete prior authorization criteria for each indication, listed below.

Growth Hormone Tier-2 Approval Criteria:

1. Documented allergic reaction to non-active components of all available Tier-1 products; or
2. A clinical exception applies to members with a diagnosis of acquired immunodeficiency syndrome (AIDS) wasting syndrome, in which case Serostim® can be used, regardless of its current Tier status; or
3. A clinical exception applies to members with a diagnosis of short bowel syndrome (SBS), in which case Zorbtive® can be used, regardless of its current Tier status.

Discontinuation of Therapy or Transition to Adult Therapy Criteria:

1. Failure to show improvement in height percentile on growth chart after 1 year of treatment; or
2. Growth velocity < 2.5 cm/year unless associated with another growth-limiting and treatable medical condition (i.e., hypothyroidism); or
3. Epiphyseal closure; or
4. Covered height has been reached:
 - a. 152.4cm (60 inches) for girls; or
 - b. 165.1cm (65 inches) for boys; or
 - c. The covered height does not apply for members with a diagnosis of growth hormone deficiency (GHD) or panhypopituitarism; or
5. Inadequate compliance; or
6. Significant adverse effects.

Growth Hormone Dosing (*doses must be individualized and titrated*):

1. Children: 22 to 100mcg/kg/day according to current pediatric guidelines; or
2. Adults:
 - a. Initial Dosing: 0.1 to 0.5mg per day – Doses should be evaluated and titrated at 1- to 2-month intervals targeting an insulin-like growth factor 1 (IGF-1) level within the age-adjusted reference range provided by the laboratory utilized [IGF-1 standard deviation score

(SDS) 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 (AAACE/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 $\leq 10\text{ng/mL}$ 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.

Idiopathic Short Stature Approval Criteria:

- 1. Initial Approval:
 - a. Member must be 8 years of age or older; and

- b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
 - c. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
 - d. Member's height must be ≥ 2.25 standard deviations (SD) below the mean for age and gender; and
 - e. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
 - f. Member's growth chart and parental heights must be provided; and
 - i. If the form is completed, a growth chart is not required; and
 - ii. Parental heights are not always available.
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:
- a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations. Treatment may continue until 1 of the following:
 - i. Epiphyseal closure; or
 - ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
 - iii. GV <2.5cm/year; and
 - b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
- a. Medications and dosing should be appropriate; and
 - b. Member should have had a recent office visit with new information regarding heights provided; and
 - c. Member should be compliant; and
 - d. Epiphyses are open; and
 - e. GV should not be <2.5cm/year.

Neurosecretory Dysfunction Approval Criteria:

1. Initial Approval:
- a. Member must be 2 years of age or older; and
 - b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
 - c. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and

- d. Member's height must be ≥ 2.25 standard deviations (SD) below the mean for age and gender; and
 - e. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
 - f. Member's growth chart and parental heights must be provided; and
 - i. If the form is completed, a growth chart is not required; and
 - ii. Parental heights are not always available; and
 - g. Member's serum insulin-like growth factor 1 (IGF-1) must be below the mean for member's age; and
 - i. Note: Children with profoundly low GV, who are at risk for growth hormone deficiency due to CNS radiation or other organic causes, termed neurosecretory dysfunction, may demonstrate "normal" responses to provocative tests, often for several years, but often benefit from growth hormone therapy.
 - h. Growth hormone stimulation testing is required; however, growth hormone levels may be normal.
2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
- a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations; or
 - b. Adult Dosing: Members with this diagnosis may transition to adult dosing (see "Growth Hormone Dosing" section above for recommendations for adult and transition dosing) after 1 of the following:
 - i. Epiphyseal closure; or
 - ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
 - iii. GV < 2.5 cm/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 < 2.5 cm/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 < 50 th 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 Chronic Renal Insufficiency (Pre-Transplantation) Approval Criteria:

1. Initial Approval:
 - a. Member must be 2 years of age or older; and
 - b. Member's estimated creatinine clearance (CrCl) must be <50mL/min; and
 - c. Member must not be post-kidney transplant; and

- d. Growth hormone therapy must be prescribed by an endocrinologist or pediatric nephrologist (or an advanced care practitioner with a supervising physician who is an endocrinologist or pediatric nephrologist); and
 - e. Member's growth chart and parental heights must be provided; and
 - i. If the form is completed, a growth chart is not required; and
 - ii. Parental heights are not always available; and
 - f. Members meeting the above criteria are exempt from height requirements.
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or growth velocity (GV) is <2.5cm/year, therapy should be discontinued.
 3. Dosing:
 - a. Pediatric Dosing: Standard dosing applies for members receiving pediatric dosing (0.05mg/kg/day). Treatment may continue until 1 of the following:
 - i. Renal transplantation; or
 - ii. Epiphyseal closure; or
 - iii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
 - iv. GV <2.5cm/year; and
 - b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
 4. Continuation Approval:
 - a. Member is still pre-transplant; and
 - b. Medications and dosing should be appropriate; and
 - c. Member should have had a recent office visit with new information regarding heights; and
 - d. Member should be compliant; and
 - e. Epiphyses are open; and
 - f. GV should not be <2.5cm/year.

Short Stature Associated with Noonan Syndrome Approval Criteria:

1. Initial Approval:
 - a. Member must be 2 years or older; and
 - b. Member must have a chromosome analysis confirming the diagnosis of Noonan syndrome; and
 - c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist).
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed,

covered height has been met, or growth velocity (GV) is <2.5cm/year, therapy should be discontinued.

3. Dosing:
 - a. Pediatric Dosing: Standard dosing applies for members receiving pediatric dosing (up to 0.066mg/kg/day). Treatment should continue until 1 of the following:
 - i. Epiphyseal closure; or
 - ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
 - iii. GV <2.5cm/year.
 - b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
 - a. Medications and dosing should be appropriate; and
 - b. Member should have had a recent office visit with new information regarding heights provided; and
 - c. Member should be compliant; and
 - d. Epiphyses should be open; and
 - e. GV should not be <2.5cm/year.

Short Stature Associated with Prader-Willi Syndrome (PWS) Approval Criteria:

1. Initial Approval:
 - a. Member must have a chromosome analysis confirming the diagnosis of PWS; and
 - b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
 - c. Member's growth chart and parental heights must be provided; and
 - i. If the form is completed, a growth chart is not required; and
 - ii. Parental heights are not always available.
2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
 - a. Pediatric Dosing: 0.5-1mg/m²/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 $<2.5\text{cm/year}$; 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.

Short Stature Associated with Short Stature Homeobox-Containing Gene (SHOX) Deficiency Approval Criteria:

1. Initial Approval:

- a. Member must be 2 years or older; and
- b. Member must have a chromosome analysis confirming the diagnosis of SHOX deficiency; and
- c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
- d. Member's growth velocity (GV) must be $<10\%$ on a GV curve for gender and age; and
- e. Member's height must be ≥ 2.25 standard deviations (SD) below the mean for age and gender; and
- f. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
- g. Member's growth chart and parental heights must be provided; and
 - i. If the form is completed, a growth chart is not required; and
 - ii. Parental heights are not always available; and
- h. Member must have a normal endocrine screen; and
- i. Member must have no evidence of growth hormone deficiency or insensitivity, tumor activity, diabetes mellitus, history of impaired glucose tolerance, or other serious illness known to interfere with growth.

2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is $<2.5\text{cm/year}$, therapy should be discontinued.

3. Dosing:

- a. Pediatric Dosing: Standard dosing applies for members receiving pediatric dosing (up to 0.05mg/kg/day). Treatment should continue until 1 of the following:

- i. Epiphyseal closure; or
 - ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
 - iii. GV <2.5cm/year; and
 - b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
- a. Medications and dosing should be appropriate; and
 - b. Member should have had a recent office visit with new information regarding heights provided; and
 - c. Member should be compliant; and
 - d. Epiphyses should be open; and
 - e. GV should not be <2.5cm/year.

Short Stature Associated with Turner Syndrome or 45,X/46,XY Mosaicism Approval Criteria:

- 1. Initial Approval:
 - a. Member must be 2 years of age or older; and
 - b. Member must have a chromosome analysis confirming the diagnosis of Turner syndrome in females or 45,X/46,XY mosaicism in males; and
 - c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist).
- 2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or growth velocity (GV) is <2.5cm/year, therapy should be discontinued.
- 3. Dosing:
 - a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations. Treatment should continue until 1 of the following:
 - i. Epiphyseal closure; or
 - ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
 - iii. GV <2.5cm/year; and
 - b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
- 4. Continuation Approval:
 - a. Medications and dosing should be appropriate; and
 - b. Member should have had a recent office visit with new information regarding heights provided; and
 - c. Member should be compliant; and

- d. Epiphyses should be open; and
- e. GV should not be <2.5cm/year.

Small for Gestational Age (SGA) Approval Criteria:

1. Initial Approval:
 - a. Member must be 2 years or age or older; and
 - b. Documentation of birth weight <2,500 grams at gestational age of more than 37 weeks or birth weight or length below the 3rd percentile for gestational age; and
 - c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
 - d. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
 - e. Member's height must be ≥ 2.25 standard deviations (SD) below the mean for age and gender; and
 - f. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
 - g. Member's growth chart and parental heights must be provided; and
 - i. If the form is completed, a growth chart is not required
 - ii. Parental heights are not always available.
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:
 - a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations. Treatment should continue until 1 of the following:
 - i. Epiphyseal closure; or
 - ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
 - iii. GV <2.5cm/year; and
 - b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
 - a. Medications and dosing should be appropriate; and
 - b. Member should have had a recent office visit with new information regarding heights provided; and
 - c. Member should be compliant; and
 - d. Epiphyses should be open; and
 - e. GV should not be <2.5cm/year.

Insulin-Like Growth Factor-1 (IGF-1) Analog Medications: Increlex® and Iplex™ [Mecasermin (rDNA Origin) Injection] Approval Criteria:

1. Therapy initiated by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
2. Diagnosis of primary IGF-1 deficiency with all of the following:
 - a. Height >3 standard deviations (SD) below the mean; and
 - b. Basal IGF-1 >3 SD below the mean; and
 - c. Normal or elevated growth hormone (GH); and
3. Documentation of mutation in GH receptor (GHR) or mutation in post-GHR signaling pathway or IGF-1 gene defects (Laron Syndrome); and
4. IGF-1 analog medications will not be approved for use in secondary IGF-1 deficiencies related to GH deficiency, malnutrition, hypothyroidism, or chronic steroid therapy.

Ngenla® (Somatrogon-ghla) Approval Criteria:

1. Member must have a confirmed diagnosis of growth hormone deficiency (GHD) or panhypopituitarism meeting the initial growth hormone approval criteria (listed under “Initial Approval”) for the member’s specific diagnosis; and
2. Member must be 3 years of age or older; and
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and
4. Prescriber must verify the member has been counseled on proper administration and storage of Ngenla®; and
5. Initial approvals will be for the 0.66mg/kg dose recommended in package labeling; and
6. Initial approvals will be for the duration of 6 months. For additional approval consideration:
 - a. Dosing should be appropriate; and
 - b. Member should have had a recent office visit with new information regarding heights provided; and
 - c. Member should be compliant; and
 - d. Growth velocity should not be <2.5cm/year; and
 - e. Prescriber must verify member still has open epiphyses; and
7. Ngenla® will not be approved following epiphyseal closure. Ngenla® is contraindicated in children with closed epiphyses.

Serostim® (Somatropin) Approval Criteria:

1. Initial Approval:
 - a. An FDA approved diagnosis of human immunodeficiency virus (HIV)-associated wasting; and
 - b. Member must be receiving optimal antiretroviral treatment; and

- c. Member must have an unintentional weight loss of >10% if baseline pre-morbid weight was <120% of ideal body weight (IBW) or unintentional weight loss of >20% if baseline pre-morbid weight was >120% of IBW; and
 - d. Member must not have a reversible cause of weight loss such as infection, gastrointestinal (GI) bleed/obstruction, or malnutrition; and
 - e. Member is receiving aggressive nutritional intake or supplementation; and
 - f. Member must not have an active malignancy (except localized Kaposi's sarcoma); and
 - g. Member has failed a trial of megestrol acetate and/or dronabinol; and
 - h. Male members must have been evaluated for testosterone deficiency and treated as needed; and
 - i. Approvals will be for 4 weeks initially and a quantity limit of 28 vials per 28 days will apply.
2. Continuation Approval:
- a. At 4 weeks, member must be evaluated for response to therapy (weight gain), side effects, and compliance. If member's response and compliance are appropriate, another 4 weeks of therapy will be approved; and
 - b. Subsequent follow up evaluations will be required every 4 weeks to assess response and compliance. The member may receive another 4 weeks of therapy for a maximum of 12 weeks continuous therapy.
3. Discontinuation Criteria:
- a. Completion of the FDA approved 12 week 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.

Skytrofa® (Lonapegsomatropin-tcgd) Approval Criteria:

- 1. Member must have a confirmed diagnosis of growth hormone deficiency (GHD) or panhypopituitarism meeting the initial growth hormone approval criteria (listed under "Initial Approval") for the member's specific diagnosis; and
- 2. Member's weight must be ≥11.5kg; and
- 3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and

4. Prescriber must verify the member has been counseled on proper administration and storage of Skytrofa®; and
5. Initial approvals will be for the 0.24mg/kg weekly dose, using the specific dose recommended in the package labeling; and
6. Initial approvals will be for the duration of 6 months. For additional approval consideration:
 - a. Dosing should be appropriate; and
 - b. Member should have had a recent office visit with new information regarding heights provided; and
 - c. Member should be compliant; and
 - d. Growth velocity should not be <2.5cm/year; and
 - e. Prescriber must verify member still has open epiphyses; and
7. Skytrofa® will not be approved following epiphyseal closure. Skytrofa® is contraindicated in children with closed epiphyses.

Sogroya® (Somapacitan-beco) Approval Criteria:

1. Member must have a confirmed diagnosis of 1 of the following:
 - a. Pediatric growth hormone deficiency (GHD) or panhypopituitarism meeting all the “Initial Approval” criteria for the member’s specific diagnosis; or
 - b. Adult GHD confirmed by 1 of the following:
 - i. Insulin tolerance test (ITT) or glucagon test with a peak growth hormone (GH) response <3ng/mL; or
 - ii. ≥3 pituitary hormone deficiencies and insulin like growth factor-1 (IGF-1) standard deviation score (SDS) <-2.0; and
2. Member must be 2.5 years of age or older; and
3. Sogroya® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
4. Member’s baseline IGF-1 level and SDS must be provided; and
5. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and
6. Prescriber must verify the member does not have active malignancy or active proliferative or severe non-proliferative diabetic retinopathy; and
7. Prescriber must verify the member has been counseled on proper administration and storage of Sogroya®; and
8. Approval quantity will be based on the FDA approved dosing in accordance with the package labeling; and
9. Initial approvals will be for the duration of 6 months. For additional approval consideration:
 - a. Dosing should be appropriate; and
 - b. Member should have had a recent office visit with new information regarding heights provided; and
 - c. Member should be compliant; and

- d. Growth velocity should not be <2.5cm/year if not on adult dosing; and
 - e. For members on adult dosing, recent IGF-1 level and SDS should be submitted and SDS should be 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.

Voxzogo® (Vosoritide) Approval Criteria:

- 1. Member must have an FDA approved indication of achondroplasia; and
 - a. Diagnosis must be confirmed by genetic testing identifying a pathogenic mutation in the *FGFR3* gene; and
- 2. Prescriber must verify member has open epiphyses; and
- 3. The member's baseline height and growth velocity (GV) must be provided; and
- 4. Voxzogo® must be prescribed by a geneticist, endocrinologist, or other specialist with expertise in the treatment of achondroplasia; and
- 5. Member's recent weight (taken within the past 3 weeks) must be provided in order to ensure appropriate dosing in accordance with the package labeling; and
- 6. Prescriber must verify the member or member's caregiver has been counseled on proper administration and storage of Voxzogo®, including the need for adequate food and fluid intake prior to each dose; and
- 7. A quantity limit of 30 vials per 30 days will apply; and
- 8. Initial and subsequent approvals will be for the duration of 6 months.
For additional approval consideration:
 - a. Member's current height must be provided and must demonstrate an improvement in GV from baseline; and
 - b. Member's recent weight must be provided and dosing must be appropriate; and
 - c. Member should be compliant; and
 - d. Prescriber must verify member still has open epiphyses; and
- 9. Voxzogo® will not be approved following epiphyseal closure.

Zorbtive® (Somatropin) Approval Criteria:

- 1. An FDA approved diagnosis of short bowel syndrome (SBS); and
- 2. Documentation of specialized nutritional support (may consist of a high carbohydrate, low-fat diet, adjusted for individual patient requirements and preferences; nutritional supplements may be added according to the discretion of the treating physician); and

3. Must be used in conjunction with optimal management of SBS (may include dietary adjustments, enteral feedings, parenteral nutrition, fluids, and micronutrient supplements as needed); and
4. Member must be under the care of a gastroenterologist (or an advanced care practitioner with a supervising physician who is a gastroenterologist); and
5. Dose does not exceed 8mg/day; and
6. Approvals will be for 4 weeks of treatment.

Utilization of Growth Hormone Products and Voxzogo® (Vosoritide): 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	390	3,508	\$16,586,438.81	\$4,728.18	\$162.97	49,849	101,774
2023 Total	390	3,508	\$16,586,438.81	\$4,728.18	\$162.97	49,849	101,774
Fiscal Year 2024							
FFS	424	2,929	\$13,997,211.48	\$4,778.84	\$162.01	26,488	86,395
Aetna	57	169	\$1,103,534.03	\$6,529.79	\$226.18	1,535	4,879
Humana	54	128	\$652,411.57	\$5,096.97	\$179.14	1,079	3,642
OCH	91	225	\$1,161,418.71	\$5,161.86	\$172.14	1,749	6,747
2024 Total	463	3,451	\$16,914,575.79	\$4,901.35	\$166.38	30,850	101,663
% Change	18.70%	-1.60%	2.00%	3.70%	2.10%	-38.10%	-0.10%
Change	73	-57	\$328,136.98	\$173.17	\$3.41	-18,999	-111

Costs do not reflect rebated prices or net costs.

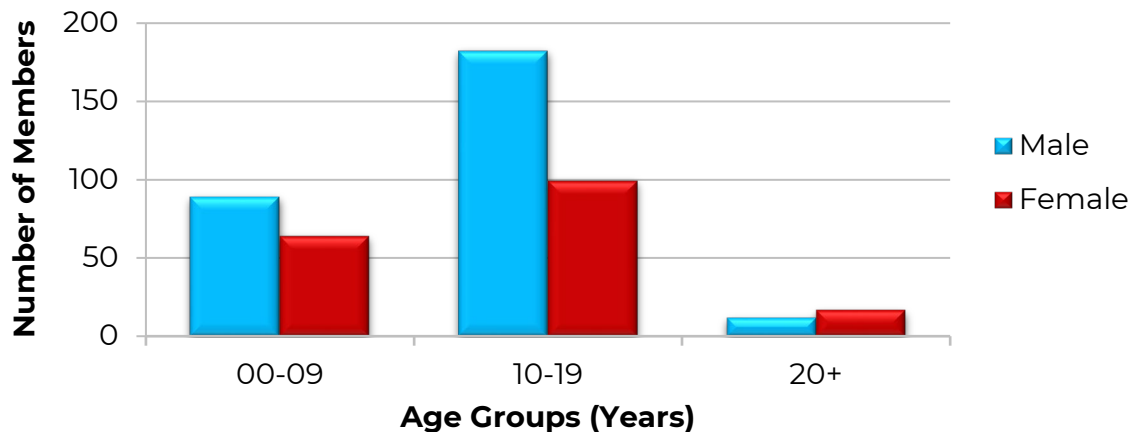
*Total number of unduplicated utilizing members.

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

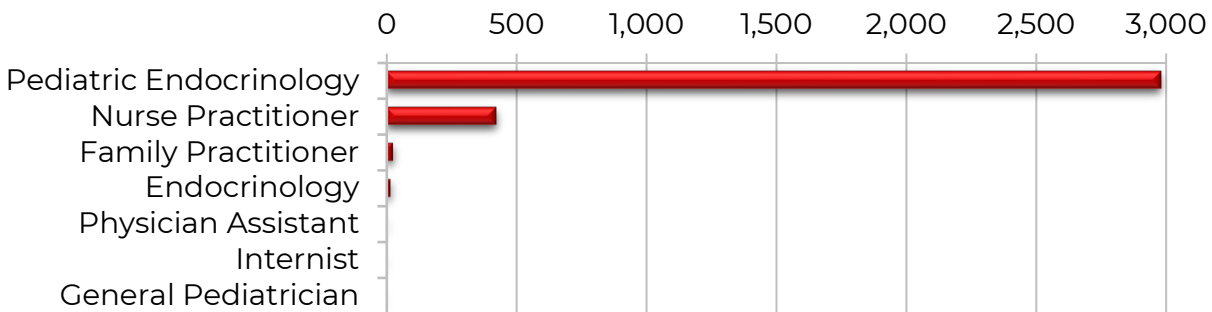
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Demographics of Members Utilizing Growth Hormone Products and Voxzogo® (Vosoritide): Pharmacy Claims (All Plans)



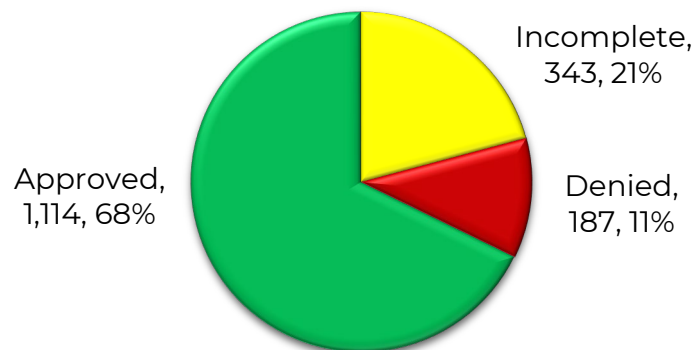
Top Prescriber Specialties of Growth Hormone Products and Voxzogo® (Vosoritide) by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Growth Hormone Products and Voxzogo® (Vosoritide)

There were 1,644 prior authorization requests submitted for growth hormone products and Voxzogo® (vosoritide) 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	1,047	69%	340	22%	140	9%	1,527
Aetna	27	53%	3	6%	21	41%	51
Humana	10	53%	0	0%	9	47%	19
OCH	30	64%	0	0%	17	36%	47
Total	1,114	68%	343	21%	187	11%	1,644

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}

Anticipated Patent Expiration(s):

- Voxzogo® (vosoritide): August 2036

Pipeline:

- **Infigratinib:** Infigratinib is an oral fibroblast growth factor receptor (FGFR) inhibitor. Low-dose infigratinib is being evaluated for the treatment of achondroplasia and hypochondroplasia. BridgeBio is currently conducting the Phase 3 PROPEL 3 study in patients with achondroplasia and the Phase 2 ACCEL study in patients with hypochondroplasia. Infigratinib was previously granted accelerated approval by the FDA in May 2021 for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement and was marketed under the brand name Truseltiq®, but was voluntarily withdrawn in May 2024 due to difficulties recruiting and enrolling study participants into clinical trials for that indication.
- **Lonapegsomatropin (TransCon hGH):** Lonapegsomatropin is being evaluated for new potential indications, including the treatment of adult growth hormone deficiency (GHD) (Phase 3) and Turner syndrome (Phase 2). A supplemental Biologics License Application (sBLA) has been submitted to the FDA for the treatment of adults with GHD and a Prescription Drug User Fee Act (PDUFA) date has been set for July 27, 2025. Lonapegsomatropin was previously FDA approved in August 2021 for the treatment of pediatric patients 1 year of age and older weighing ≥11.5kg who have growth failure due to inadequate secretion of endogenous growth hormone and is marketed under the brand name Skytrofa®.
- **Navepegritide (TransCon CNP):** Navepegritide is a prodrug formulation of C-type natriuretic peptide (CNP) intended for once-weekly administration that is being evaluated for the treatment of children with achondroplasia. In March 2025, Ascendis announced that they have submitted a New Drug Application (NDA) for navepegritide to the FDA. A PDUFA date has not yet been announced.
- **Vosoritide:** Vosoritide is being evaluated for the treatment of multiple new indications, including hypochondroplasia (Phase 3) as well as idiopathic short stature, Noonan syndrome, Turner syndrome, and SHOX deficiency (Phase 2). In February 2025, BioMarin announced that they expect to complete enrollment into the pivotal study in patients with hypochondroplasia in the first half of 2025, with a potential launch for that indication in 2027. Vosoritide was previously granted accelerated approval by the FDA in November 2021 to increase linear growth in pediatric patients with achondroplasia with open epiphyses and is marketed under the brand name Voxzogo®.

Recommendations

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~~ $\leq +2$]. 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 $\leq 10\text{ng/mL}$ 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 $< 2.5\text{cm/year}$; 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 $<2.5\text{cm/year}$ 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~~ $\leq +2$.

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~~ $\leq +2$.

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 < 50 th 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 < 2.5 cm/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 $<2.5\text{cm/year}$ 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~~ $\leq +2$.

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: $0.5\text{-}1\text{mg/m}^2/\text{day}$ 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. $\text{GV} < 2.5\text{cm/year}$; 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 $<2.5\text{cm/year}$; 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~~ $\leq +2$.

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 $<3\text{ng/mL}$; 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 $<2.5\text{cm/year}$ 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~~ $\leq +2$; 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.

Utilization Details of Growth Hormone Products and Voxzogo® (Vosoritide): Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 GROWTH HORMONE (GH) PRODUCTS						
GENOTROPIN INJ 5MG	1,326	181	\$5,154,386.80	\$3,887.17	7.33	30.47%
GENOTROPIN INJ 12MG	1,113	164	\$7,556,487.97	\$6,789.30	6.79	44.67%
GENOTROPIN INJ 0.4MG	175	43	\$326,422.35	\$1,865.27	4.07	1.93%
GENOTROPIN INJ 0.6MG	84	35	\$229,536.39	\$2,732.58	2.4	1.36%
GENOTROPIN INJ 0.2MG	79	18	\$65,160.63	\$824.82	4.39	0.39%
GENOTROPIN INJ 1MG	71	33	\$291,973.47	\$4,112.30	2.15	1.73%
GENOTROPIN INJ 0.8MG	46	25	\$156,284.96	\$3,397.50	1.84	0.92%
GENOTROPIN INJ 1.2MG	37	18	\$173,843.93	\$4,698.48	2.06	1.03%
GENOTROPIN INJ 2MG	32	11	\$264,597.68	\$8,268.68	2.91	1.56%
GENOTROPIN INJ 1.6MG	28	10	\$173,734.78	\$6,204.81	2.8	1.03%
GENOTROPIN INJ 1.4MG	27	10	\$149,443.82	\$5,534.96	2.7	0.88%
GENOTROPIN INJ 1.8MG	12	6	\$72,820.66	\$6,068.39	2	0.43%
TIER-1 SUBTOTAL	3,030	418*	\$14,614,693.44	\$4,823.33	7.25	86.40%
TIER-2 GH PRODUCTS*						
DAILY GH PRODUCTS						
NORDITROPIN INJ 10MG/1.5ML	111	32	\$365,772.47	\$3,295.25	3.47	2.16%
NORDITROPIN INJ 15MG/1.5ML	68	23	\$294,795.56	\$4,335.23	2.96	1.74%
NORDITROPIN INJ 30MG/3ML	67	24	\$387,084.35	\$5,777.38	2.79	2.29%
OMNITROPE INJ 5MG/1.5ML	51	21	\$202,531.20	\$3,971.20	2.43	1.20%
NORDITROPIN INJ 5MG/1.5ML	22	11	\$69,475.25	\$3,157.97	2	0.41%
OMNITROPE INJ 10MG/1.5ML	11	4	\$34,287.92	\$3,117.08	2.75	0.20%
NUTROPIN AQ INJ 10MG/2ML	8	2	\$25,214.28	\$3,151.79	4	0.15%
NUTROPIN AQ INJ 20MG/2ML	5	2	\$22,689.17	\$4,537.83	2.5	0.13%
HUMATROPE INJ 6MG	3	1	\$11,201.43	\$3,733.81	3	0.07%
SEROSTIM INJ 5MG	2	1	\$64,596.42	\$32,298.21	2	0.38%
DAILY GH SUBTOTAL	348	94*	\$1,477,648.05	\$4,246.12	3.7	8.74%
WEEKLY GH PRODUCTS						
SOGROYA INJ 10MG/1.5ML	15	4	\$44,718.58	\$2,981.24	3.75	0.26%
SKYTROFA INJ 7.6MG	11	3	\$79,603.44	\$7,236.68	3.67	0.47%
SKYTROFA INJ 6.3MG	9	4	\$54,477.72	\$6,053.08	2.25	0.32%
SKYTROFA INJ 11MG	8	2	\$82,473.64	\$10,309.21	4	0.49%
SOGROYA INJ 15MG/1.5ML	6	1	\$32,631.06	\$5,438.51	6	0.19%
SKYTROFA INJ 5.2MG	3	1	\$14,994.57	\$4,998.19	3	0.09%
SKYTROFA INJ 9.1MG	3	1	\$51,564.31	\$17,188.10	3	0.30%
SKYTROFA INJ 13.3MG	3	1	\$38,298.15	\$12,766.05	3	0.23%
SKYTROFA INJ 4.3MG	1	1	\$4,135.09	\$4,135.09	1	0.02%
WEEKLY GH SUBTOTAL	59	17*	\$402,896.56	\$6,828.76	3.47	2.38%
TIER-2 GH SUBTOTAL	407	109*	\$1,880,544.61	\$4,620.50	3.73	11.12%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GH SUBTOTAL	3,437	461*	\$16,495,238.05	\$4,799.31	7.46	97.52%
VOSORITIDE PRODUCTS						
VOXZOGO INJ 0.56MG	11	1	\$326,756.51	\$29,705.14	11	1.93%
VOXZOGO INJ 0.4MG	3	1	\$92,581.23	\$30,860.41	3	0.55%
VOSORITIDE SUBTOTAL	14	2*	\$419,337.74	\$29,952.70	7	2.48%
TOTAL	3,451	463*	\$16,914,575.79	\$4,901.35	7.45	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

*Claims for Tier-2 products largely consist of claims for which SoonerCare is not the primary payer; therefore, the reimbursed amount included in the above data is not a true reflection of the cost of the medication for SoonerCare.

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/index.cfm>. Last revised 02/2025. Last accessed 02/04/2025.

² BridgeBio Pharma, Inc. Science & Pipeline: Pipeline. Available online at: <https://bridgebio.com/pipeline/#pipeline>. Last accessed 04/01/2025.

³ BridgeBio Pharma, Inc. BridgeBio Pharma Reports Fourth Quarter and Full Year 2024 Financial Results and Commercial Update. Available online at: <https://investor.bridgebio.com/news-releases/news-release-details/bridgebio-pharma-reports-fourth-quarter-and-full-year-2024>. Issued 02/20/2025. Last accessed 04/01/2025.

⁴ U.S. FDA. WITHDRAWN: FDA Grants Accelerated Approval to Infigratinib for Metastatic Cholangiocarcinoma. Available online at: <https://www.fda.gov/drugs/resources-information-approved-drugs/withdrawn-fda-grants-accelerated-approval-infigratinib-metastatic-cholangiocarcinoma>. Issued 05/16/2024. Last accessed 04/01/2025.

⁵ Ascendis Pharma. Pipeline Overview. Available online at: <https://ascendispharma.us/pipeline/>. Last accessed 04/01/2025.

⁶ Ascendis Pharma. Ascendis Pharma Reports Fourth Quarter and Full Year 2024 Financial Results. Available online at: <https://investors.ascendispharma.com/news-releases/news-release-details/ascendis-pharma-reports-fourth-quarter-and-full-year-2024>. Issued 02/12/2025. Last accessed 04/01/2025.

⁷ Ascendis Pharma. Ascendis Submits U.S. NDA for TransCon CNP (Navepegritide) for the Treatment of Children with Achondroplasia. Available online at: <https://investors.ascendispharma.com/news-releases/news-release-details/ascendis-submits-us-nda-transcon-cnp-navepegritide-treatment>. Issued 03/31/2025. Last accessed 04/01/2025.

⁸ BioMarin Pharmaceutical, Inc. Products & Pipeline: Pipeline. Available online at: <https://www.biopharm.com/products-and-pipeline/research-pipeline/>. Last accessed 04/01/2025.

⁹ BioMarin Pharmaceutical, Inc. BioMarin Reports Fourth Quarter and Full Year 2024 Results; Sets Full Year 2025 Guidance. Available online at: <https://www.biopharm.com/news/press-releases/biopharm-reports-fourth-quarter-and-full-year-2024-results-sets-full-year-2025-guidance/>. Issued 02/19/2025. Last accessed 04/01/2025.



Fiscal Year 2024 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)

**Oklahoma Health Care Authority
April 2025**

Current Prior Authorization Criteria

Adynovate®, Afstylia®, Alprolix®, Altuviio® Eloctate®, Esperoct®, Idelvion®, Jivi®, and Rebinyn® Approval Criteria:

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

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

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

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

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

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

1. Member must be diagnosed with hemophilia A or B with an inhibitor; and
 - a. For a diagnosis of hemophilia A with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Hemlibra® (emicizumab-kxwh) for prophylaxis therapy must be provided; and
2. Feiba® must be prescribed by a hematologist specializing in rare bleeding disorders or a mid-level practitioner with a supervising physician that is a hematologist specializing in rare bleeding disorders.

Hemgenix® (Etranacogene Dezaparvovec-drlb) Approval Criteria:

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

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

Hemlibra® (Emicizumab-kxwh) Approval Criteria:

- 1. An FDA approved diagnosis of hemophilia A; and
- 2. Hemlibra® must be prescribed by a hematologist specializing in rare bleeding disorders or a mid-level practitioner with a supervising physician that is a hematologist specializing in rare bleeding disorders; and
- 3. 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 with hemophilia A without an inhibitor:
 - 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. First dose must be given in a health care facility; and
- 7. In order to calculate appropriate dosing, the member's recent weight must be provided and been taken within the last 3 months; and
- 8. 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.

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 Hemlibra® (emicizumab-kxwh) 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 or a mid-level practitioner with a supervising physician that is a hematologist specializing in rare bleeding disorders.

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

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

Roctavian™ (Valoctocogene Roxaparvovec-rvox) Approval Criteria:

1. An FDA approved diagnosis of severe congenital (or X-linked) hemophilia A; and
2. Member must be a male 18 years of age or older; and
3. Member must not have a history of or a recent positive screening of an inhibitor defined as ≥ 0.6 Bethesda units; and
4. Member must be on prophylactic therapy with continued frequent breakthrough bleeding episodes or has experienced a life-threatening bleeding episode; and
5. Member must not have acute infections; and

6. Member must not have chronic active infections such as Hepatitis B or C; and
7. Member must not have uncontrolled human immunodeficiency virus (HIV) as shown by CD4+ counts ≤ 200 u/L; and
8. Member must not be taking efavirenz; and
9. Member must not have antibodies to AAV5; and
10. Member must not have any of the following:
 - a. Significant liver fibrosis:
 - i. Defined as ≥ 3 as rated on a scale of 0-4 on the METAVIR scoring system or equivalent grade on an alternative scale; and
 - ii. Measured by ultrasound and elastography or laboratory assessments; or
 - b. Liver cirrhosis; or
 - c. Significant liver dysfunction with any of the following abnormal lab results:
 - i. ALT (alanine aminotransferase) > 1.25 x upper limit of normal (ULN); or
 - ii. AST (aspartate aminotransferase) > 1.25 x ULN; or
 - iii. GGT (gamma-glutamyltransferase) > 1.25 x ULN; or
 - iv. Total bilirubin > 1.25 x ULN; or
 - v. Alkaline phosphatase > 1.25 x ULN; or
 - vi. INR (international normalized ratio) ≥ 1.4 ; and
11. Must be prescribed by a hematologist practicing in a federally recognized hemophilia treatment center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
12. Prescriber must counsel member to not donate semen, and if member is of reproductive potential then their female partners must agree to prevent or postpone pregnancy for 6 months after treatment with valoctocogene roxaparvovec-rvox; and
13. Valoctocogene roxaparvovec-rvox must be administered in an appropriate clinical setting and member must be monitored for at least 3 hours post infusion; and
14. Prescriber must follow liver enzymes weekly for 26 weeks, every 1 to 2 weeks for weeks 26 through 52, every 3 months in the second year and every 6 months thereafter; and
15. Prescriber agrees to start corticosteroids (or other immunosuppressives if corticosteroids are contraindicated) as outlined in the package labeling; and
16. Prescriber agrees to monitor factor VIII levels weekly for 26 weeks, every 1 to 2 weeks for weeks 26 through 52, every 3 months in the second year and every 6 months thereafter; and
17. Approvals will be for 1 treatment per member per lifetime.

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

1. An FDA approved diagnosis; and
 - a. For a diagnosis of hemophilia A with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Hemlibra® (emicizumab-kxwh) for prophylaxis therapy must be provided; and
2. Sevenfact® must be prescribed by a hematologist specializing in rare bleeding disorders or a mid-level practitioner with a supervising physician that is a hematologist specializing in rare bleeding disorders.

Standards-of-Care for Pharmacies Providing Factor Replacement

Products can be found on the Oklahoma Health Care Authority (OHCA) website on the Pharmacy Prior Authorization (PA) page in the Hemophilia Therapeutic Category at <https://oklahoma.gov/ohca/pa>.

Utilization of Hemophilia Medications: Fiscal Year 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	125	1,004	\$25,535,819.54	\$25,434.08	\$1,161.99	6,648,749	21,976
2023 Total	125	1,004	\$25,535,819.54	\$25,434.08	\$1,161.99	6,648,749	21,976
Fiscal Year 2024							
FFS	122	916	\$24,905,402.95	\$27,189.30	\$1,209.53	5,665,569	20,591
Aetna	19	49	\$1,168,343.24	\$23,843.74	\$992.65	316,440	1,177
Humana	10	33	\$1,415,925.66	\$42,906.84	\$1,824.65	476,756	776
OCH	9	23	\$506,391.77	\$22,017.03	\$855.39	49,659	592
2024 Total	128	1,021	\$27,996,063.62	\$27,420.24	\$1,210.06	6,508,424	23,136
% Change	2.40%	1.70%	9.60%	7.80%	4.10%	-2.10%	5.30%
Change	3	17	\$2,460,244.08	\$1,986.16	\$48.07	-140,325	1,160

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	12	65	\$893,917.14	\$13,752.57	5.42
2023 Total	12	65	\$893,917.14	\$13,752.57	5.42
Fiscal Year 2024					
FFS	11	22	\$50,700.01	\$2,304.55	2
Aetna	0	0	\$0.00	\$0.00	0
Humana	1	2	\$9,720.00	\$4,860.00	2
OCH	0	0	\$0.00	\$0.00	0
2024 Total	12	24	\$60,420.01	\$2,517.50	2
% Change	0.00%	-63.08%	-93.24%	-81.69%	-63.08%
Change	0	-41	-\$833,497.13	-\$11,235.07	-3.42

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

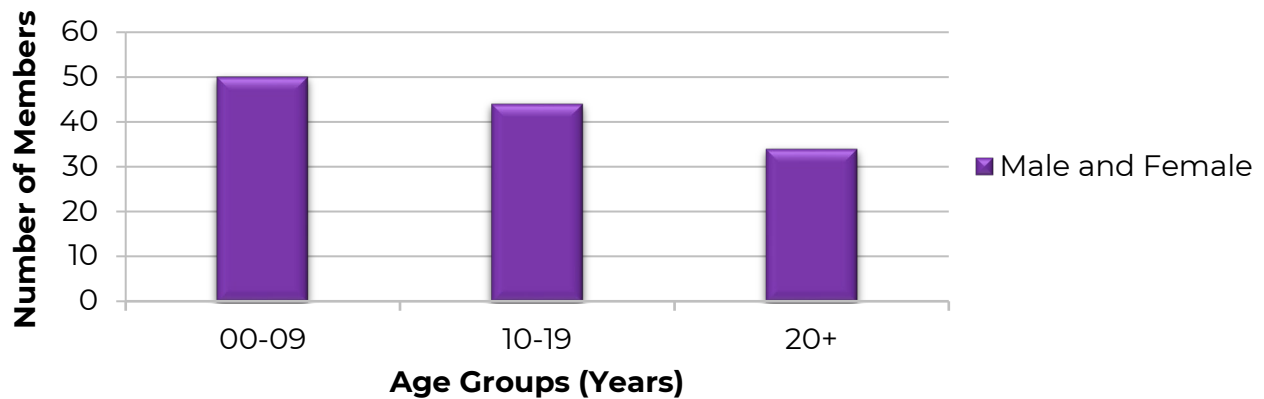
FFS = fee-for-service; OCH = Oklahoma Complete Health

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.

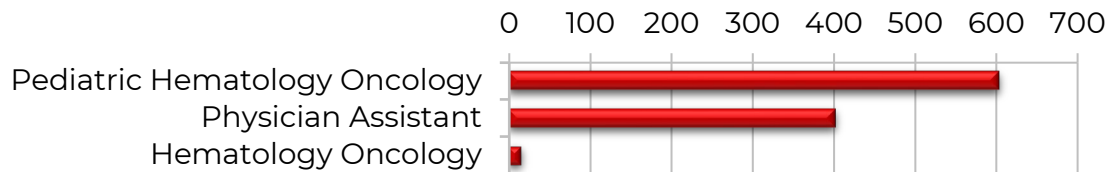
- Aggregate drug rebates collected during fiscal year 2024 for hemophilia medications totaled \$5,311,144.38.[^] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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



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

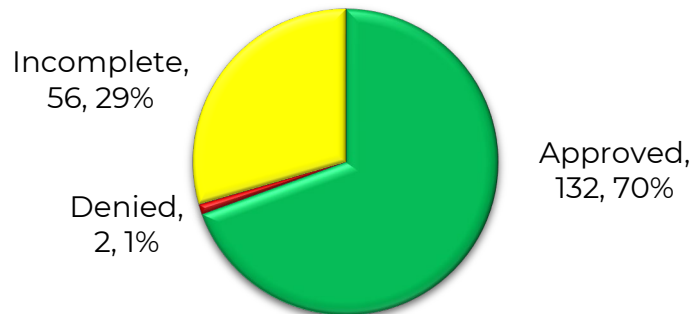
Top Prescriber Specialties of Hemophilia Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Hemophilia Medications

There were 190 prior authorization requests submitted for hemophilia 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	123	68%	56	31%	2	1%	181
Aetna	6	100%	0	0%	0	0%	6
Humana	1	100%	0	0%	0	0%	1
OCH	2	100%	0	0%	0	0%	2
Total	132	70%	56	29%	2	1%	190

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}

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

- **April 2024:** The FDA approved Beqvez™ (fidanacogene elaparovectdzt), an adeno-associated virus vector-based gene therapy for the treatment of adults with hemophilia B.
- **October 2024:** The FDA approved Hymavzi™ (marstacimab-hncq), a tissue factor pathway inhibitor (TFPI) antagonist, for the 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 the 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:

- **August 2024:** Pfizer announced topline results from the Phase 3 AFFINE trial for giroctocogene fitelparvovec in patients with hemophilia A. The primary endpoint, annualized bleed rate (ABR) through 15 months following treatment, showed a statistically significant reduction to 1.24 after treatment with giroctocogene fitelparvovec compared to 4.73 during the pre-treatment phase.
- **August 2024:** The Children's Hospital of Philadelphia and the University of Pennsylvania School of Medicine conducted a pre-clinical study looking at the durability of factor VIII gene therapy. They found an enhanced function factor VIII variant seemingly resistant to inactivation, which in the long term could lead to the development of a more durable factor VIII gene therapy.
- **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.

Alhemo® (Concizumab-mtci) Product Summary^{10,11}

Therapeutic Class: Tissue factor pathway inhibitor (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 received 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.

Cost Comparison:

Product	Cost Per Month	Cost Per Year
Alhemo® (concizumab-mtci)	\$103,200.00	\$1,238,400.00[∞]
Feiba® (anti-inhibitor coagulant complex)	\$301,282.50	\$3,615,390.00 [‡]
Hemlibra® (emicizumab-kxwh)	\$62,422.80	\$811,496.40 ^α

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).

[∞]Cost 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 85U/kg every other day for a 100kg patient.

^αCost is based on the FDA approved dosing of 1.5mg/kg every week for a 100kg patient.

Beqvez™ (Fidanacogene Elaparvovec-dzkt) Product Summary^{12,13}

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 1×10^{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 5×10^{11} vg/kg of body weight based on the patient's body mass index (BMI) in kg/m².
 - For patients with a BMI >30kg/m² 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 ($\leq 2\%$ factor IX levels). There were 45 participants who were dosed with the gene therapy. The primary endpoint was met, which was noninferiority of 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.

Hypavzi™ (Marstacimab-hncq) Product Summary^{14,15}

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.

Cost Comparison:

Product	Cost Per Month	Cost Per Year
Hypavzi™ (marstacimab-hncq)	\$61,200.00	\$795,600.00[∞]
Advate® [antihemophilic factor (recombinant)]	\$86,352.00	\$1,122,576.00 [±]
Hemlibra® (emicizumab-kxwh)	\$62,422.80	\$811,496.40 ^α
Alprolix® [coagulation factor IX (recombinant), Fc fusion protein]	\$71,500.00	\$929,500.00 ^β

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).

[∞]Cost is based on the FDA approved dosing of 150 mg every week 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.

Qfitlia™ (Fitusiran) Product Summary^{16,17}

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: The Wholesale Acquisition Cost (WAC) of Qfitlia™ is not available at this time.

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 $\leq 2\%$); 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 be controlled with antiviral therapy as shown by CD4+ counts ≤ 200 cells/mm³ 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 ≤ 200 cells/mm³; and

6. Prescriber must agree the member will not be continuing other prophylactic therapies; and
7. Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
8. Prescriber must verify that the member or caregiver has been trained on the subcutaneous administration and counseled on the storage of Hympavzi™; and
9. Prescriber must verify that the member has been counseled on the use of factor replacement therapy at the lowest possible dose for breakthrough bleeding episodes; and
10. Initial approvals will be for 3 months of therapy. Subsequent approvals will be the duration of 1 year if there is documentation of clinical effectiveness; and
11. Approvals will be for 300mg loading dose followed by 150mg weekly doses. Approvals may be granted for dose escalation to 300mg weekly when the following are met:
 - a. Member weighs $\geq 50\text{kg}$; 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 be controlled with antiviral therapy as shown by CD4+ counts $\leq 200\text{cells/mm}^3$ 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) or Hemlibra® (emicizumab-kxwh) 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) 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) or Hemlibra® (emicizumab-kxwh) 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) 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) or Hemlibra® (emicizumab-kxwh) 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) 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.

Utilization Details of Hemophilia Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HEMLIBRA PRODUCTS						
HEMLIBRA INJ 60MG/0.4ML	309	42	\$7,060,845.05	\$22,850.63	7.36	25.22%
HEMLIBRA INJ 30MG/ML	91	16	\$822,977.58	\$9,043.71	5.69	2.94%
HEMLIBRA INJ 150MG/ML	86	15	\$4,126,846.25	\$47,986.58	5.73	14.74%
HEMLIBRA INJ 105MG/0.7ML	77	16	\$3,574,872.47	\$46,426.92	4.81	12.77%
HEMLIBRA INJ 300MG/2ML	1	1	\$122,032.21	\$122,032.21	1	0.44%
SUBTOTAL	564	90	\$15,707,573.56	\$27,850.31	6.27	56.11%
ADVATE PRODUCTS						
ADVATE INJ 2,000U	34	11	\$967,866.26	\$28,466.65	3.09	3.46%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ADVATE INJ 1,500U	21	11	\$610,531.67	\$29,072.94	1.91	2.18%
ADVATE INJ 3,000U	17	7	\$700,344.46	\$41,196.73	2.43	2.50%
ADVATE INJ 1,000U	7	6	\$106,664.22	\$15,237.75	1.17	0.38%
ADVATE INJ 500U	6	2	\$66,823.57	\$11,137.26	3	0.24%
ADVATE INJ 250U	4	1	\$10,588.02	\$2,647.01	4	0.04%
ADVATE INJ 4,000U	3	3	\$195,027.37	\$65,009.12	1	0.70%
SUBTOTAL	92	41	\$2,657,845.57	\$28,889.63	2.24	9.49%
ALPROLIX PRODUCTS						
ALPROLIX INJ 3,000U	18	3	\$584,514.85	\$32,473.05	6	2.09%
ALPROLIX INJ 2,000U	16	2	\$494,691.34	\$30,918.21	8	1.77%
ALPROLIX INJ 1,000U	16	2	\$125,500.24	\$7,843.77	8	0.45%
ALPROLIX INJ 4,000U	11	2	\$373,988.54	\$33,998.96	5.5	1.34%
ALPROLIX INJ 500U	8	3	\$67,502.91	\$8,437.86	2.67	0.24%
ALPROLIX INJ 250U	7	2	\$32,844.67	\$4,692.10	3.5	0.12%
SUBTOTAL	76	14	\$1,679,042.55	\$22,092.67	5.43	6.00%
KOATE PRODUCTS						
KOATE INJ 1,000U	25	2	\$390,388.31	\$15,615.53	12.5	1.39%
KOATE INJ 500U	14	2	\$35,397.10	\$2,528.36	7	0.13%
KOATE INJ 250U	6	1	\$8,006.46	\$1,334.41	6	0.03%
SUBTOTAL	45	5	\$433,791.87	\$9,639.82	9	1.55%
NUWIQ PRODUCTS						
NUWIQ KIT 1,000U	16	12	\$68,298.17	\$4,268.64	1.33	0.24%
NUWIQ KIT 500U	15	14	\$20,947.28	\$1,396.49	1.07	0.07%
NUWIQ KIT 1,500U	6	2	\$149,434.32	\$24,905.72	3	0.53%
NUWIQ KIT 2,000U	3	3	\$19,369.98	\$6,456.66	1	0.07%
NUWIQ KIT 250U	2	2	\$411.62	\$205.81	1	0.00%
NUWIQ KIT 3,000U	1	1	\$3,779.68	\$3,779.68	1	0.01%
SUBTOTAL	43	34	\$262,241.05	\$6,098.63	1.26	0.94%
KOVALTRY PRODUCTS						
KOVALTRY INJ 2,000U	15	12	\$160,879.03	\$10,725.27	1.25	0.57%
KOVALTRY INJ 1,000U	12	9	\$50,816.97	\$4,234.75	1.33	0.18%
KOVALTRY INJ 3,000U	9	7	\$94,413.80	\$10,490.42	1.29	0.34%
KOVALTRY INJ 250U	2	2	\$861.30	\$430.65	1	0.00%
KOVALTRY INJ 500U	1	1	\$1,110.86	\$1,110.86	1	0.00%
SUBTOTAL	39	31	\$308,081.96	\$7,899.54	1.26	1.10%
WILATE PRODUCTS						
WILATE INJ 1,000-1,000U	21	7	\$446,481.64	\$21,261.03	3	1.59%
WILATE INJ 500-500U	9	3	\$56,710.54	\$6,301.17	3	0.20%
SUBTOTAL	30	10	\$503,192.18	\$16,773.07	3	1.80%
NOVOSEVEN PRODUCTS						
NOVOSEVEN RT INJ 1MG	16	5	\$240,260.56	\$15,016.29	3.2	0.86%
NOVOSEVEN RT INJ 2MG	5	4	\$97,385.05	\$19,477.01	1.25	0.35%
NOVOSEVEN RT INJ 5MG	5	2	\$242,503.05	\$48,500.61	2.5	0.87%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	26	11	\$580,148.66	\$22,313.41	2.36	2.07%
ALTUVIIIIO PRODUCTS						
ALTUVIIIIO INJ 3,000U	16	2	\$844,068.87	\$52,754.30	8	3.01%
ALTUVIIIIO INJ 500U	4	1	\$30,389.52	\$7,597.38	4	0.11%
ALTUVIIIIO INJ 2,000U	4	1	\$131,521.16	\$32,880.29	4	0.47%
ALTUVIIIIO INJ 1,000U	1	1	\$16,686.64	\$16,686.64	1	0.06%
SUBTOTAL	25	5	\$1,022,666.19	\$40,906.65	5	3.65%
HUMATE PRODUCTS						
HUMATE-P SOL 2,400U	12	8	\$172,237.83	\$14,353.15	1.5	0.62%
HUMATE-P SOL 250-600U	7	5	\$35,611.36	\$5,087.34	1.4	0.13%
HUMATE-P SOL 500-1,200U	5	5	\$13,934.03	\$2,786.81	1	0.05%
SUBTOTAL	24	18	\$221,783.22	\$9,240.97	1.33	0.79%
ADYNOVATE PRODUCTS						
ADYNOVATE INJ 3,000U	6	2	\$103,819.36	\$17,303.23	3	0.37%
ADYNOVATE INJ 2,000U	5	1	\$37,430.09	\$7,486.02	5	0.13%
SUBTOTAL	11	3	\$141,249.45	\$12,840.86	3.67	0.50%
RIXUBIS PRODUCTS						
RIXUBIS INJ 2,000U	6	3	\$57,817.07	\$9,636.18	2	0.21%
RIXUBIS INJ 1,000U	3	2	\$9,669.89	\$3,223.30	1.5	0.03%
RIXUBIS INJ 3,000U	2	2	\$28,015.82	\$14,007.91	1	0.10%
SUBTOTAL	11	7	\$95,502.78	\$8,682.07	1.57	0.34%
ESPEROCT PRODUCTS						
ESPEROCT INJ 1,500U	4	1	\$221,066.54	\$55,266.64	4	0.79%
ESPEROCT INJ 500U	2	1	\$43,338.82	\$21,669.41	2	0.15%
ESPEROCT INJ 3,000U	2	1	\$143,424.62	\$71,712.31	2	0.51%
ESPEROCT INJ 2,000U	2	1	\$83,322.82	\$41,661.41	2	0.30%
SUBTOTAL	10	4	\$491,152.80	\$49,115.28	2.5	1.75%
SEVENFACT PRODUCTS						
SEVENFACT INJ 5MG	8	1	\$2,459,734.87	\$307,466.86	8	8.79%
SUBTOTAL	8	1	\$2,459,734.87	\$307,466.86	8	8.79%
FEIBA PRODUCTS						
FEIBA INJ 2,500U	3	1	\$555,635.48	\$185,211.83	3	1.98%
FEIBA INJ 500U	3	1	\$699,747.85	\$233,249.28	3	2.50%
FEIBA INJ 1,000U	1	1	\$23,118.49	\$23,118.49	1	0.08%
SUBTOTAL	7	3	\$1,278,501.82	\$182,643.12	2.33	4.57%
VONVENDI PRODUCTS						
VONVENDI INJ 650U	3	1	\$45,969.94	\$15,323.31	3	0.16%
SUBTOTAL	3	1	\$45,969.94	\$15,323.31	3	0.16%
KOGENATE PRODUCTS						
KOGENATE FS INJ 1,000U	1	1	\$6,389.93	\$6,389.93	1	0.02%
KOGENATE FS INJ 2,000U	1	1	\$9,684.81	\$9,684.81	1	0.03%
SUBTOTAL	2	2	\$16,074.74	\$8,037.37	1	0.06%
ALPHANATE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALPHANATE INJ 1,000U	2	1	\$3,964.04	\$1,982.02	2	0.01%
SUBTOTAL	2	1	\$3,964.04	\$1,982.02	2	0.01%
JIVI PRODUCTS						
JIVI INJ 3,000U	1	1	\$61,083.59	\$61,083.59	1	0.22%
SUBTOTAL	1	1	\$61,083.59	\$61,083.59	1	0.22%
IDELVION PRODUCTS						
IDELVION SOL 2,000U	1	1	\$21,096.37	\$21,096.37	1	0.08%
SUBTOTAL	1	1	\$21,096.37	\$21,096.37	1	0.08%
BENEFIX PRODUCTS						
BENEFIX INJ 1,000U	1	1	\$5,366.41	\$5,366.41	1	0.02%
SUBTOTAL	1	1	\$5,366.41	\$5,366.41	1	0.02%
TOTAL	1,021	121	\$27,996,063.62	\$27,420.24	8.44	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

FS = formulated with sucrose; INJ = injection; RT = recombinant; SOL = solution; U = units

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.

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS*	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM
J7186 FACTOR	6	2	\$4,264.15	\$710.69
J7187 VWF	8	5	\$22,427.55	\$2,803.44
J7189 FACTOR	3	2	\$14,580.00	\$4,860.00
J7192 FACTOR	4	3	\$6,041.51	\$1,510.38
J7200 FACTOR	3	1	\$13,106.80	\$4,368.93
TOTAL	24	12	\$60,420.01	\$2,517.50

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated claims.

*Total number of unduplicated utilizing members.

RT = recombinant; VWF = von Willebrand factor

Fiscal Year 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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- 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 03/18/2025.
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Fiscal Year 2024 Annual Review of Muscular Dystrophy Medications and 30-Day Notice to Prior Authorize Agamree® (Vamorolone) and Duvyzat™ (Givinostat)

Oklahoma Health Care Authority
April 2025

Current Prior Authorization Criteria

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

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

medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and

11. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Elevidys (Deltandistrogene 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 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 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.

Emflaza® (Deflazacort) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD); 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®; 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 the tablets, a quantity limit of 30 tablets per 30 days will apply, and for the suspension, a quantity limit of 39mL (3 bottles) per 30 days will

apply. Quantity limit override requests will be approved as appropriate based on the member's recent weight taken within the last 30 days.

Utilization of Muscular Dystrophy Medications: Fiscal Year 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	10	115	\$9,220,663.34	\$80,179.68	\$2,834.51	11,826	3,253
2023 Total	10	115	\$9,220,663.34	\$80,179.68	\$2,834.51	11,826	3,253
Fiscal Year 2024							
FFS	11	105	\$11,640,891.00	\$110,865.63	\$3,908.96	13,585	2,978
Aetna	1	3	\$46,081.65	\$15,360.55	\$512.02	90	90
Humana	0	0	\$0.00	\$0.00	\$0.00	0	0
OCH	1	2	\$51,222.82	\$25,611.41	\$914.69	64	56
2024 Total	11	110	\$11,738,195.47	\$106,710.87	\$3,757.42	13,739	3,124
% Change	10.00%	-4.35%	27.30%	33.09%	32.56%	16.18%	-3.97%
Change	1	-5	\$2,517,532.13	\$26,531.19	\$922.91	1,913	-129

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

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

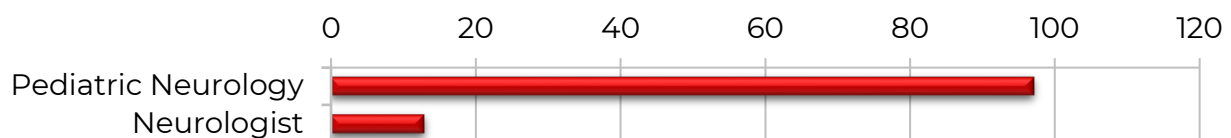
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

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

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

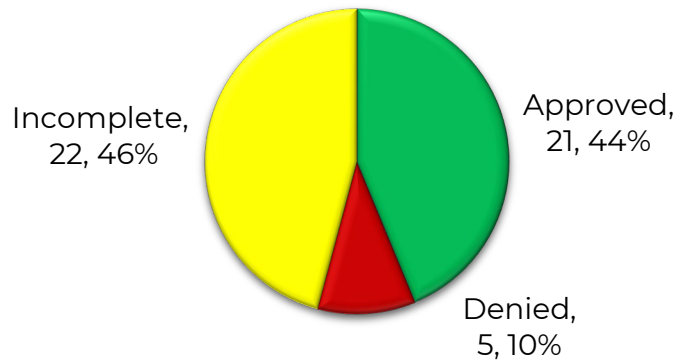
Top Prescriber Specialties of Muscular Dystrophy Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Muscular Dystrophy Medications

There were 48 prior authorization requests submitted for muscular dystrophy medications for 15 unique members 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	21	44%	22	46%	5	10%	48
Aetna	0	N/A	0	N/A	0	N/A	0
Humana	0	N/A	0	N/A	0	N/A	0
OCH	0	N/A	0	N/A	0	N/A	0
Total	21	44%	22	46%	5	10%	48

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^{1,2,3,4,5,6,7,8,9,10,11}

Anticipated Patent Expiration(s):

- Vyondys 53 (golodirsén injection): June 2025
- Amondys 45 (casimersén injection): November 2030
- Viltepso® (viltolarsén injection): August 2031
- Exondys 51 (eteplirsén injection): March 2034
- Duvyzat™ (givinostat suspension): October 2036
- Agamree® (vamorolone suspension): July 2040

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.

News:

- **March 2024:** In March 2024, a study conducted by Sarepta Therapeutics was published in the journal of *Muscle and Nerve*, that showed that patients who received Exondys 51 survived longer (median age of 32.8 years) than those in the natural history group (median age of 27.4 years). Additionally, Exondys 51-treated patients had significantly longer survival from treatment initiation versus age-matched controls [age-adjusted hazard ratio (HR): 0.65; 95% confidence interval (CI): 0.44, 0.98; $P < 0.05$] and longer treatment exposure to Exondys 51 was associated with improved survival (HR: 0.15; 95% CI: 0.05, 0.41; $P < 0.001$).
- **May 2024:** NS Pharma announced the results of the Phase 3 confirmatory clinical trial, RACER53, that studied the safety and efficacy of Viltepso®, which was approved in August 2020 under accelerated approval. The results of the trial showed an increase in velocity (rise/sec) in the Time to Stand from Supine for both the Viltepso® group and the placebo group, and there was no statistically significant difference between the groups. NS Pharma stated they are conducting further data analysis and will work closely with the FDA to determine the next steps which will be announced later.
- **January 2025:** Roche announced the results from year 2 of the EMBARK trial, a global, randomized, double-blind Phase 3 clinical trial of Elevidys. The results showed functional improvements in patients treated with Elevidys after 2 years compared to an external control group including improvements in the NSAA, TTR from the floor, and 10MWR. Additionally, muscle biopsies from a subset of patients taken at 64 weeks after dosing with Elevidys showed expression of micro-dystrophin as measured by a western blot.

Pipeline:

- **Ataluren:** In October 2024, PTC Therapeutics announced that the FDA accepted the resubmission of the New Drug Application (NDA) for Translarna™ (ataluren) for the treatment of nonsense mutation DMD. Ataluren is a protein restoration therapy designed to enable the formation of a functioning protein in patients with genetic disorders caused by a nonsense mutation. The NDA is supported by the results of the placebo-controlled trial, Study 041, which did not meet its primary endpoint of 6-minute walk distance (6MWD), but significant benefit was found in the intent to treat population (N=359) for 6MWD and other key study endpoints. Additionally, data recorded in the STRIDE registry of the patients treated with ataluren showed a 3.5-year delay in loss of ambulation ($P < 0.001$) and a 1.8-year delay in reaching a predicted forced vital capacity of less than 60% ($P = 0.0028$). Since the NDA resubmission is following a Complete Response Letter (CRL), the FDA is not required to follow Prescription Drug User Fee Act (PDUFA) timelines; therefore, an action date has not been provided.
- **Deramiocele:** In March 2025, Capricor Therapeutics announced that the FDA accepted their application and granted priority review for deramiocele, an investigational cell therapy used to treat patients with DMD cardiomyopathy. The application was supported by data from the Phase 2 HOPE-2 trial and the open-label extension trial, HOPE-2-OLE, which studied deramiocele in both non-ambulatory and ambulatory male patients 10 years of age and older with DMD. Patients were randomly assigned to receive deramiocele or placebo by intravenous infusion every 3 months for a total of 4 doses. The results showed treatment with deramiocele reduced upper limb function deterioration and improved cardiac function and structure when compared to placebo. A PDUFA date of August 31, 2025 has been set.
- **Fordadistrogene Movaparvovec:** In June 2024, Pfizer announced the results of the Phase 3 ClFFREO trial, which evaluated the use of fordadistrogene movaparvovec, an investigational mini-dystrophin gene therapy, in ambulatory patients with DMD. The trial did not meet its primary endpoint of improvement in motor function among boys 4 to 7 years of age treated with fordadistrogene movaparvovec versus placebo. Additionally, key secondary endpoints did not show a significant difference. Following that announcement, in July 2024, Pfizer announced the discontinued development of fordadistrogene movaparvovec.

Agamree® (Vamorolone) Product Summary^{12,13,14}

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% 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 adrenocorticotrophic 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	\$213,220.80 ^α
deflazacort 36 mg tablet (generic)	\$473.82	\$14,214.60	\$170,575.20 ^α
prednisone 10mg tablet (generic)	\$0.05	\$4.50	\$54.00 ^β

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.

^αCost 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^{15,16}

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 $<150 \times 10^9/L$ 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 \$264.29 per mL which results in a cost of \$95,144.40 for a 30-day supply or \$1,141,732.80 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. A quantity limit of 200mL per 26 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.

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

Utilization Details of Muscular Dystrophy Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
VYONDYS 53 INJ 100MG/2ML	38	3	\$3,458,049.18	\$91,001.29	12.67
AMONDYS 45 INJ 50MG/ML	30	3	\$4,313,900.30	\$143,796.68	10
EMFLAZA TAB 30MG	14	2	\$202,377.90	\$14,455.56	7
EXONDYS 51 SOL 500MG/10ML	11	1	\$352,125.51	\$32,011.41	11
EXONDYS 51 SOL 100MG/2ML	11	1	\$211,325.51	\$19,211.41	11
AGAMREE SUS 40MG/ML	5	1	\$405.66 [†]	\$81.13	5
ELEVIDYS KIT	1	1	\$3,200,011.41	\$3,200,011.41	1
TOTAL	110	11	\$11,738,195.47	\$106,710.87	10

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

[†]This claim is for a member for which SoonerCare was not the primary payer; therefore, the reimbursed amount is not a true reflection of the cost of the medication for SoonerCare.

INJ = injection; SOL = solution; SUS = suspension; TAB = tablet

Fiscal Year 2024 = 07/01/2023 to 06/30/2024

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 02/2025. Last accessed 02/06/2025.

² 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 02/06/2025.

³ U.S. 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 02/06/2025.

⁴ 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 02/06/2025.

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- ⁵ Iff J, Done N, Tuttle E, et al. Survival Among Patients Receiving Eteplirsen for Up to 8 Years for the Treatment of Duchenne Muscular Dystrophy and Contextualization with Natural History Controls. *Muscle & Nerve*. 2024; 70(1): 60-70. doi:10.1002/mus.28075.
- ⁶ NS Pharma, Inc. NS Pharma Shares Preliminary Results of Viltolarsen (NS-065/NCNP-01) Phase 3 Clinical Trial (RACER53 Study). *PR Newswire*. Available online at: <https://www.prnewswire.com/news-releases/ns-pharma-shares-preliminary-results-of-viltolarsen-ns-065--ncnp-01-phase-3-clinical-trial-racer53-study-302155379.html>. Issued 05/27/2024. Last accessed 03/10/2025.
- ⁷ PTC Therapeutics. PTC Therapeutics Announces FDA Acceptance of Translarna™ NDA Resubmission. Available online at: <https://ir.ptcbio.com/news-releases/news-release-details/ptc-therapeutics-announces-fda-acceptance-translarnatm-nda>. Issued 10/30/2024. Last accessed 03/11/2025.
- ⁸ Ernst D. Deramiocecel Granted Priority Review for DMD Cardiomyopathy. *Cardiology Advisor*. Available online at: <https://www.thecardiologyspecialtyadvisor.com/news/deramiocecel-priority-review-for-duchenne-muscular-dystrophy-dmd-cardiomyopathy/>. Issued 03/10/2025. Last accessed 03/11/2025.
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Fiscal Year 2024 Annual Review of Multiple Sclerosis (MS) Medications and 30-Day Notice to Prior Authorize Ocrevus Zunovo™ (Ocrelizumab/Hyaluronidase-ocsq)

Oklahoma Health Care Authority
April 2025

Current Prior Authorization Criteria

Multiple Sclerosis Interferon Medications	
Tier-1	Tier-2
interferon β - 1a (Avonex®)	interferon β - 1a (Rebif®)
interferon β - 1b (Betaseron®)	interferon β - 1b (Extavia®)
peginterferon β - 1a (Plegridy®)	

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).

Multiple Sclerosis (MS) Interferon Medications Approval Criteria:

1. An FDA approved diagnosis of clinically isolated syndrome, relapsing forms of MS, or secondary progressive forms of MS; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Authorization of Tier-2 medications requires previous failure of preferred Tier-1 medication(s) defined as:
 - a. Occurrence of an exacerbation after 6 months; or
 - b. Significant increase in magnetic resonance imaging (MRI) lesion after 6 months; or
 - c. Adverse reactions or intolerable side effects; and
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. Compliance will be checked for continued approval every 6 months.

Ampyra® (Dalfampridine) Approval Criteria:

1. An FDA approved indication to improve walking in adult members with multiple sclerosis (MS); and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Kurtzke Expanded Disability Status Scale (EDSS) score between 3 and 7.5; and
4. Initial approvals will be for the duration of 90 days. If the member has responded well to treatment and the prescriber states that the member has shown improvement or the drug was effective, the member may receive authorization for 1 year; and

5. A quantity limit of 60 tablets for 30 days will apply.
6. Ampyra® may be used with other MS therapies.

Aubagio® (Teriflunomide) 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. All of the following will be required for initiation of treatment:
 - a. Verification that female members 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 (LFTs) and verification that levels are acceptable to the prescriber; and
 - e. Blood pressure (BP) measurement and verification that BP is being monitored; and
 - f. Verification that the member does not have tuberculosis (TB), or completion of standard medical treatment for members with TB; and
5. Initial approvals of Aubagio® will be for 6 months, after which time all of the following will be required for further approval:
 - a. Medication compliance; and
 - b. Repeat CBC and verification that counts are acceptable to the prescriber; and
 - c. Repeat LFTs and verification that levels are acceptable to the prescriber; and
 - d. Verification that female members are not pregnant and will continue using reliable contraception; and
 - e. Verification that BP and signs of renal failure are being monitored; and
6. Compliance will be checked for continued approval every 6 months; and
7. A quantity limit of 30 tablets per 30 days will apply.

Bafiertam® (Monomethyl Fumarate) 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. Verification from the prescriber that member has no serious active infection(s); and
5. Complete blood counts (CBC), including lymphocyte count, and verification that levels are acceptable to the prescriber; and
6. Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and
7. Intolerable adverse effects associated with a trial of Tecfidera® (dimethyl fumarate) and Vumerity® (diroximel fumarate) that are not expected to occur with Bafiertam® or a patient-specific, clinically significant reason why trials of Tecfidera® and Vumerity® are not appropriate for the member must be provided; and
8. Verification that CBC, including lymphocyte count, levels are acceptable to the prescriber in addition to compliance will be required for continued approval every 6 months; and
9. A quantity limit of 4 capsules per day will apply.

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.

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. Approvals for the 40mg strength of Copaxone® will require a patient-specific, clinically significant reason why the member cannot use the 20mg strength; and
5. 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
6. 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. Verification from the prescriber that member has no active infection(s); and

6. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
7. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
8. Compliance will be checked for continued approval every 6 months.

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. 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
5. Prescriber must agree to monitor quantitative serum immunoglobulin level before, during, and after discontinuation of treatment with Kesimpta® until B-cell repletion; and
6. Prescriber must verify the member has no active infection(s); and
7. Prescriber must verify the first injection of Kesimpta® will be administered by a health care professional prepared to manage injection-related adverse reactions; and
8. 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
9. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of treatment with Kesimpta®; and
10. Female members of reproductive potential must use an effective method of contraception during treatment and for 6 months after stopping Kesimpta®; and
11. 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
12. Compliance will be checked for continued approval every 6 months.

Lemtrada® (Alemtuzumab) 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. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Member must have had an inadequate response to 2 or more medications indicated for the treatment of MS; and

- a. Lemtrada® must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. The prescriber must agree that the member will be monitored for 2 hours after each infusion; and
4. The prescriber must agree to monitor complete blood counts (CBC) with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of Lemtrada®; and
5. The prescriber must agree that baseline and yearly skin examinations will be performed while the member is utilizing Lemtrada® therapy; and
6. Member, prescriber, pharmacy, and health care facility must all enroll in the Lemtrada® Risk Evaluation and Mitigation Strategy (REMS) Program and maintain enrollment throughout therapy.

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. Member must have had an inadequate response to 2 or more medications indicated for the treatment of MS; and
6. Prescriber must confirm that the member does not have any contraindications for use of cladribine; and
7. Prescriber must confirm member does not have an active malignancy; and
8. 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
9. 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
10. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
11. Verification from the prescriber that member has no active infection(s); and
12. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and

13. 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
14. Quantity limits according to package labeling will apply; and
15. 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.

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. 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
4. 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
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. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
8. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
9. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and
10. 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

11. 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
12. 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
13. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
14. 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
15. 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
16. Compliance will be checked for continued approval every 6 months; and
17. Quantity limits according to package labeling will apply.

Ocrevus® (Ocrelizumab) 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 who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease modifying therapies; and
4. Ocrevus® 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 Ocrevus® will be administered; and
 - a. Ocrevus® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
 - b. Ocrevus® 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 Ocrevus®; and
5. Prescriber must confirm that member will be monitored for 1 hour after each infusion; and

6. Prescriber must verify hepatitis B virus (HBV) testing has been performed prior to initiating 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 Ocrevus® therapy and for 6 months after the last infusion of Ocrevus®; and
9. Approvals will be for the duration of 1 year, and compliance will be checked for continued approval.

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. 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
4. Member must not have received prior treatment with alemtuzumab; and
5. Member must not be concurrently using strong CYP3A4 and UGT1A1 inducers (e.g., rifampin, phenytoin, carbamazepine); and
6. Verification from the prescriber that the member has no active infection(s); and
7. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
8. Verification from the prescriber that the member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Ponvory®; and
9. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
10. Verification from the prescriber that the member's blood pressure will be monitored during treatment with Ponvory®; and
11. 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

12. 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
13. 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
14. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
15. 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
16. 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
17. Compliance will be checked for continued approval every 6 months; and
18. 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. Verification from the prescriber that member has no active infection(s); and
7. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
8. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
9. A patient-specific, clinically significant reason why the member cannot use Gilenya® (fingolimod) capsules must be provided; and

10. Compliance will be checked for continued approval every 6 months.

Tecfidera® (Dimethyl Fumarate) Approval Criteria:

1. An FDA approved diagnosis of clinically isolated syndrome, relapsing forms of multiple sclerosis (MS), or secondary progressive forms of MS 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. Verification from the prescriber that member has no active infection(s); and
5. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
6. Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and
7. Compliance will be checked for continued approval every 6 months; and
8. A quantity limit of 60 tablets per 30 days will apply.

Tyruko® (Natalizumab-sztn) and Tysabri® (Natalizumab) 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, or Crohn's disease in adults; and
2. For a diagnosis of MS, the following criteria will apply:
 - 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; or
3. For a diagnosis of Crohn's disease, the following criteria will apply:
 - a. Treatment with at least 2 different first-line therapeutic categories for Crohn's disease that have failed to yield an adequate clinical response, or a patient-specific, clinically significant reason why the member cannot use all available first- and second-line alternatives must be provided; and
4. For Tyruko®, a patient-specific, clinically significant reason why the member cannot use Tysabri® 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
5. For Tyruko®, prescriber, infusion center, and member must enroll in the Risk Evaluation and Mitigation Strategy (REMS) program; and

6. For Tysabri®, prescriber, infusion center, and member must enroll in the TOUCH Prescribing Program; and
7. Compliance will be checked for continued approval every 6 months.

Vumerity® (Diroximel Fumarate) 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. Verification from the prescriber that member has no serious active infection(s); and
5. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
6. Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and
7. Verification from the prescriber that member does not have moderate or severe renal impairment; and
8. Verification from the prescriber that the member has been counseled on proper administration of Vumerity® including caloric and fat intake limits at the time of dosing; and
9. Compliance will be checked for continued approval every 6 months; and
10. A quantity limit of 120 capsules per 30 days will apply.

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, prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); 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. Member must not have received prior treatment with alemtuzumab; and
- 5. Member must not be concurrently using strong CYP2C8 inhibitors/inducers or breast cancer resistance protein (BCRP) inhibitors; and
- 6. Verification from the prescriber that member has no active infection(s); and
- 7. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
- 8. Prescriber must conduct an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Zeposia®; and
- 9. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
- 10. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and
- 11. 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
- 12. 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
- 13. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
- 14. 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
- 15. 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
- 16. 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

17. Compliance will be checked for continued approval every 6 months;
and
18. A quantity limit of 30 capsules per 30 days will apply.

Utilization of MS 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	220	1,573	\$11,566,467.47	\$7,353.13	\$247.73	56,983	46,690
2023 Total	220	1,573	\$11,566,467.47	\$7,353.13	\$247.73	56,983	46,690
Fiscal Year 2024							
FFS	220	1,497	\$9,913,759.35	\$6,622.42	\$220.78	49,971	44,904
Aetna	26	53	\$413,581.96	\$7,803.43	\$269.79	1,816	1,533
Humana	45	111	\$951,639.39	\$8,573.33	\$291.82	4,454	3,261
OCH	26	65	\$334,747.87	\$5,149.97	\$178.34	1,351	1,877
2024 Total	240	1,726	\$11,613,728.57	\$6,728.70	\$225.18	57,592	51,575
% Change	9.10%	9.70%	0.40%	-8.50%	-9.10%	1.10%	10.50%
Change	20	153	\$47,261.10	-\$624.43	-\$22.55	609	4,885

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	112	354	\$6,005,418.59	\$16,964.46	3.16
2023 Total	112	354	\$6,005,418.59	\$16,964.46	3.16
Fiscal Year 2024					
FFS	118	302	\$5,819,547.49	\$19,270.02	2.56
Aetna	1	1	\$35,256.00	\$35,256.00	1
Humana	0	0	\$0.00	\$0.00	0
OCH	2	2	\$42,525.00	\$21,262.50	1
2024 Total	118	305	\$5,975,109.49	\$19,590.52	2.58
% Change	5.36%	-13.84%	-0.50%	15.48%	-18.22%
Change	6	-49	-\$30,309.10	\$2,626.06	-0.58

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

*Total number of unduplicated claims.

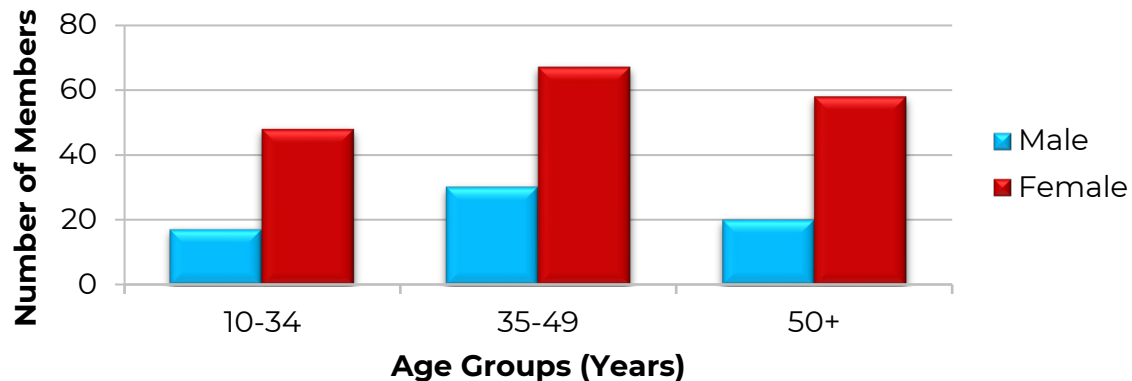
FFS = fee-for-service; OCH = OK Complete Health

Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024

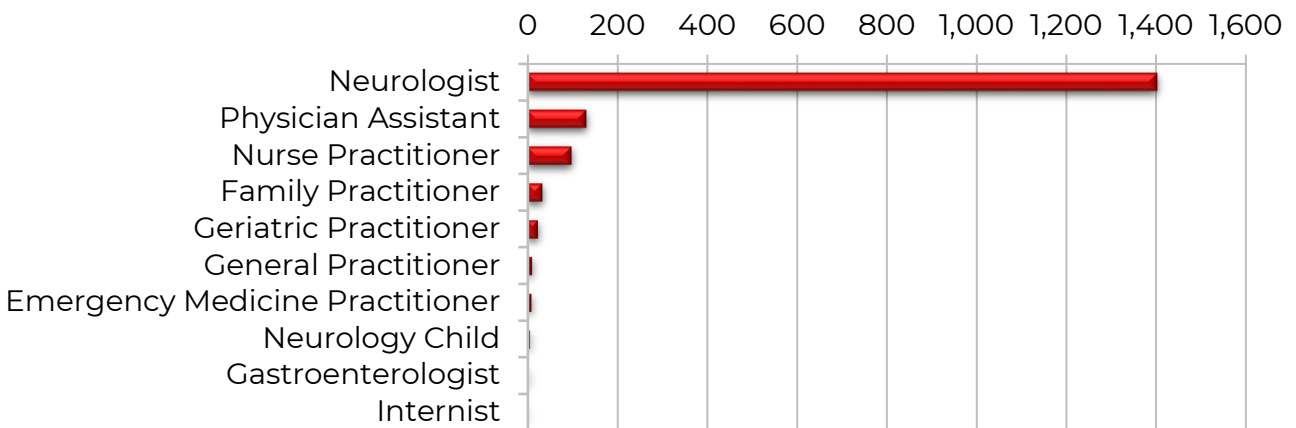
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

- Aggregate drug rebates collected during fiscal year 2024 for MS medications totaled \$10,093,769.60.[^] 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 MS Medications: Pharmacy Claims (All Plans)



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

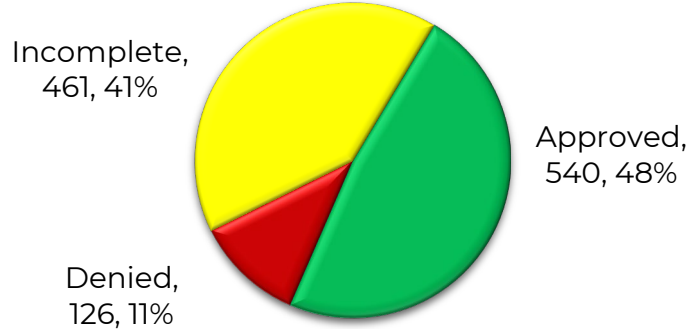


Prior Authorization of MS Medications

There were 1,127 prior authorization requests submitted for MS medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

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

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	520	48%	454	42%	99	9%	1,073
Aetna	8	38%	7	33%	6	29%	21
Humana	9	36%	0	0%	16	64%	25
OCH	3	38%	0	0%	5	63%	8
Total	540	48%	461	41%	126	11%	1,127

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}

Anticipated Patent Expiration(s):

- Gilenya® (fingolimod capsules): September 2032
- Vumerity® (diroximel fumarate capsules): September 2033
- Aubagio® (teriflunomide tablets): August 2034
- Tecfidera® (dimethyl fumarate capsules): November 2035
- Tascenso ODT® [fingolimod orally disintegrating tablets (ODT)]: January 2036
- Bafiertam® (monomethyl fumarate capsules): March 2036
- Mayzent® (siponimod tablets): April 2036
- Zeposia® (ozanimod capsules): September 2038
- Mavenclad® (cladribine tablets): November 2038
- Ponvory® (ponesimod tablets): November 2042

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.

Pipeline:

- **Fenebrutinib:** Fenebrutinib is an investigational oral Bruton's tyrosine kinase (BTK) inhibitor being studied for RMS and PPMS. Results from the FENopta open-label extension (OLE) trial evaluating fenebrutinib in patients with RMS showed that 96% of patients were free of relapses at 1 year with an annualized relapse rate (ARR) of 0.04, and no change in disability over 48 weeks. Fenebrutinib treatment suppressed disease activity in the brain as measured by MRI scans and at 48 weeks, 99% of patients were free of T1 gadolinium-enhancing (T1-Gd+) lesions. Additionally, fenebrutinib is being studied in 3 Phase 3 trials, the FENhance 1 and 2 trials in RMS compared to teriflunomide and the FENTrepid trial in PPMS compared to ocrelizumab with results expected at the end of 2025.
- **Tolebrutinib:** Tolebrutinib is an investigational oral BTK inhibitor that is being studied in 3 Phase 3 trials, HERCULES for non-relapsing secondary progressive multiple sclerosis (nrSPMS) and GEMINI 1 and 2 for RMS. Results from the HERCULES trial showed tolebrutinib had delayed time to onset of 6-month confirmed disability progression (CDP) by 31% compared to placebo [hazard ratio (HR): 0.69; 95% confidence interval (CI): 0.55, 0.88; P=0.0026]. The GEMINI 1 and 2 Phase 3 trial results of tolebrutinib compared to teriflunomide in participants with RMS did not meet their primary endpoints of statistically significant improvement in ARR compared to teriflunomide. However, in the key secondary endpoint, from a pooled analysis of data from GEMINI 1 and 2, tolebrutinib delayed the time to onset of 6-month confirmed disability worsening (CDW) by 29% (HR 0.71; 95% CI: 0.53, 0.95; nominal P=0.023]. The FDA has granted tolebrutinib Priority Review designation for nrSPMS and to slow disability accumulation independent of relapse activity in adult patients, and a Prescription Drug User Fee Act (PDUFA) target date has been set for September 28, 2025.

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; 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
 - c. Baseline QTc interval ≥ 500 msec; 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
 - 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 6 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; 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
 - c. Baseline QTc interval ≥ 500 msec; 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.

Utilization Details of MS Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OFATUMUMAB PRODUCTS						
KESIMPTA INJ 20MG/0.4ML	496	69	\$4,331,394.81	\$8,732.65	7.19	37.30%
SUBTOTAL	496	69	\$4,331,394.81	\$8,732.65	7.19	37.30%
DALFAMPRIDINE PRODUCTS						
DALFAMPRIDINE TAB 10MG ER	246	31	\$9,642.67	\$39.20	7.94	0.08%
AMPYRA TAB 10MG	13	2	\$52,728.23	\$4,056.02	6.5	0.45%
SUBTOTAL	259	33	\$62,370.90	\$240.81	7.85	0.54%
GLATIRAMER ACETATE PRODUCTS						
COPAXONE INJ 40MG/ML	99	16	\$560,502.88	\$5,661.65	6.19	4.83%
COPAXONE INJ 20MG/ML	73	13	\$513,025.73	\$7,027.75	5.62	4.42%
GLATIRAMER INJ 40MG/ML	15	2	\$22,689.80	\$1,512.65	7.5	0.20%
GLATIRAMER INJ 20MG/ML	4	2	\$7,350.63	\$1,837.66	2	0.06%
GLATOPA INJ 40MG/ML	1	1	\$1,353.31	\$1,353.31	1	0.01%
SUBTOTAL	192	34	\$1,104,922.35	\$5,754.80	5.65	9.51%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FINGOLIMOD PRODUCTS						
GILENYA CAP 0.5MG	97	14	\$992,608.49	\$10,233.08	6.93	8.55%
FINGOLIMOD CAP 0.5MG	82	13	\$32,397.82	\$395.10	6.31	0.28%
TASCENSO ODT TAB 0.25MG	4	1	\$41,733.60	\$10,433.40	4	0.36%
SUBTOTAL	183	28	\$1,066,739.91	\$5,829.18	6.54	9.19%
TERIFLUNOMIDE PRODUCTS						
AUBAGIO TAB 14MG	92	12	\$860,380.51	\$9,351.96	7.67	7.41%
TERIFLUNOMIDE TAB 14MG	66	15	\$3,542.46	\$53.67	4.4	0.03%
TERIFLUNOMIDE TAB 7MG	1	1	\$29.55	\$29.55	1	0.00%
SUBTOTAL	159	28	\$863,952.52	\$5,433.66	5.68	7.44%
DIROXIMEL FUMARATE PRODUCTS						
VUMERITY CAP 231MG	157	31	\$1,290,657.80	\$8,220.75	5.06	11.11%
SUBTOTAL	157	31	\$1,290,657.80	\$8,220.75	5.06	11.11%
DIMETHYL FUMARATE PRODUCTS						
DIMETHYL FUM CAP 240MG DR	100	19	\$6,806.98	\$68.07	5.26	0.06%
TECFIDERA CAP 240MG	15	3	\$137,756.30	\$9,183.75	5	1.19%
DIMETHYL FUM CAP STARTER PAK	3	3	\$709.23	\$236.41	1	0.01%
DIMETHYL FUM CAP 120MG DR	3	3	\$423.63	\$141.21	1	0.00%
SUBTOTAL	121	28	\$145,696.14	\$1,204.10	4.32	1.25%
INTERFERON BETA-1A PRODUCTS						
AVONEX PEN KIT 30MCG	33	5	\$259,609.62	\$7,866.96	6.6	2.24%
REBIF REBIDOSE INJ 4MCG/0.5ML	11	1	\$112,447.00	\$10,222.45	11	0.97%
REBIF REBIDOSE INJ 2MCG/0.5ML	11	1	\$111,834.15	\$10,166.74	11	0.96%
AVONEX PREFL KIT 30MCG	1	1	\$8,066.64	\$8,066.64	1	0.07%
SUBTOTAL	56	8	\$491,957.41	\$8,784.95	7	4.24%
SIPONIMOD PRODUCTS						
MAYZENT TAB 2MG	21	3	\$197,784.24	\$9,418.30	7	1.70%
SUBTOTAL	21	3	\$197,784.24	\$9,418.30	7	1.70%
CLADRIBINE PRODUCTS						
MAVENCLAD 6-PAK 10MG	5	3	\$298,311.69	\$59,662.34	1.67	2.57%
MAVENCLAD 7-PAK 10MG	4	4	\$275,166.06	\$68,791.52	1	2.37%
MAVENCLAD 8-PAK 10MG	4	4	\$316,198.30	\$79,049.58	1	2.72%
MAVENCLAD 4-PAK 10MG	4	2	\$157,247.88	\$39,311.97	2	1.35%
MAVENCLAD 5-PAK 10MG	2	1	\$101,175.92	\$50,587.96	2	0.87%
MAVENCLAD 9-PAK 10MG	1	1	\$93,664.33	\$93,664.33	1	0.81%
SUBTOTAL	20	15	\$1,241,764.18	\$62,088.21	1.33	10.69%
OZANIMOD PRODUCTS						
ZEPOSIA CAP 0.92MG	19	7	\$164,571.33	\$8,661.65	2.71	1.42%
ZEPOSIA CAP STR KIT	1	1	\$8,308.62	\$8,308.62	1	0.07%
SUBTOTAL	20	8	\$172,879.95	\$8,644.00	2.5	1.49%
NATALIZUMAB PRODUCTS						
TYSABRI INJ 300/15ML	20	2	\$147,139.60	\$7,356.98	10	1.27%
SUBTOTAL	20	2	\$147,139.60	\$7,356.98	10	1.27%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INTERFERON BETA-1B PRODUCTS						
BETASERON INJ 0.3MG	11	1	\$101,777.05	\$9,252.46	11	0.88%
SUBTOTAL	11	1	\$101,777.05	\$9,252.46	11	0.88%
OCRELIZUMAB PRODUCTS						
OCREVUS INJ 300MG/10ML	8	6	\$304,240.00	\$38,030.00	1.33	2.62%
SUBTOTAL	8	6	\$304,240.00	\$38,030.00	1.33	2.62%
UBLITUXIMAB PRODUCTS						
BRIUMVI INJ 150MG/6ML	3	1	\$90,451.71	\$30,150.57	3	0.78%
SUBTOTAL	3	1	\$90,451.71	\$30,150.57	3	0.78%
Total	1,726	240*	\$11,613,728.57	\$6,728.70	7.19	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CAP = capsule; DR = delayed-release; ER = extended-release; FUM = fumarate; INJ = injection; ODT = orally disintegrating tablet; PAK = pack; PREFL = prefilled; STR = starter; 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
OCREVUS INJ 300MG/10ML (J2350)	147	97	\$4,727,166.49	\$32,157.60	1.52
TYSABRI INJ 300MG/15ML (J2323)	152	19	\$1,127,850.00	\$7,420.07	8
BRIUMVI INJ 150MG/6ML (J2329)	6	3	\$120,093.00	\$20,015.50	2
TOTAL	305	118	\$5,975,109.49	\$19,590.52	2.58

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

*Total number of unduplicated claims

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 03/18/2025.

² U.S. FDA. Zeposia® Supplement Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/209899Orig1s013s014ltr.pdf. Issued 06/05/2024. Last accessed 03/27/2025.

³ U.S. FDA. Ponvory® Supplement Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/213498Orig1s005s006ltr.pdf. Issued 06/05/2024. Last accessed 03/27/2025.

⁴ 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 03/27/2025.

⁵ 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 03/18/2025.

⁶ 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 03/18/2025.

⁷ 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 03/18/2025.

⁸ 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 03/18/2025.

⁹ Roche. Roche's Fenebrutinib Demonstrated Near-Complete Suppression of Disease Activity and Disability Progression For Up to 48 Weeks in Patients with Relapsing Multiple Sclerosis. Available online at: <https://www.roche.com/media/releases/med-cor-2024-09-04>. Issued 09/03/2024. Last accessed 03/27/2025.

¹⁰ Sanofi. Tolebrutinib Demonstrated a 31% Delay in Time to Onset of Confirmed Disability Progression in Non-Relapsing Secondary Progressive Multiple Sclerosis Phase 3 Study. Available online at: <https://www.sanofi.com/en/media-room/press-releases/2024/2024-09-20-09-30-00-2949552>. Issued 09/20/2024. Last accessed 03/27/2025.

¹¹ Sanofi. Tolebrutinib Regulatory Submission Accepted for Priority Review in the US for Patients with Multiple Sclerosis. Available online at: <https://www.news.sanofi.us/2025-03-25-Tolebrutinib-regulatory-submission-accepted-for-priority-review-in-the-US-for-patients-with-multiple-sclerosis>. Issued 03/25/2025. Last accessed 03/27/2025.



Fiscal Year 2024 Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers and 30-Day Notice to Prior Authorize Xolremdi® (Mavorixafor)

Oklahoma Health Care Authority
April 2025

Current Prior Authorization Criteria

Aphexda® (Motixafortide) Approval Criteria:

1. An FDA approved indication for use in combination with filgrastim to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in members with multiple myeloma (MM); and
2. Member must have an oncology diagnosis of MM. This medication is not covered for the diagnosis of leukemia; and
3. Aphexda® must be prescribed by an oncologist; and
4. Member must be 18 years of age or older; and
5. Aphexda® must be given in combination with the granulocyte-colony stimulating factor (G-CSF) filgrastim per package labeling; and
6. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use generic plerixafor must be provided; and
7. The following dosing restrictions will apply (current body weight in kilograms is required):
 - a. Recommended dose is 1.25mg/kg actual body weight by subcutaneous injection 10 to 14 hours prior to initiation of apheresis; and
 - b. A second dose of Aphexda® can be administered 10 to 14 hours prior to a third apheresis if necessary; and
8. Approvals will be for 2 cycles for the duration of 2 months.

Mozobil® (Plerixafor) Approval Criteria:

1. An FDA approved indication for use in combination with filgrastim to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in members with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM); and
2. Member must have an oncology diagnosis of NHL or MM. This medication is not covered for the diagnosis of leukemia; and
3. Mozobil® must be prescribed by an oncologist; and
4. Member must be 18 years of age or older; and

5. Mozobil® must be used in combination with the granulocyte-colony stimulating factor (G-CSF) filgrastim per package labeling; and
6. The following dosing restrictions will apply (current body weight in kilograms is required):
 - a. Recommended dose is 0.24mg/kg (maximum dose is 40mg/day) administered 11 hours prior to apheresis for up to 4 consecutive days; or
 - b. For members with renal impairment (creatinine clearance ≤50mL/min), the recommended dose is 0.16mg/kg (maximum dose is 27mg/day); and
7. Approvals will be for 2 cycles for the duration of 2 months.

Neulasta® (Pegfilgrastim), 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), 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) will be covered as a medical only benefit without prior authorization.

Nivestym® (Filgrastim-aafi) and Releuko® (Filgrastim-ayow) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Granix® (tbo-filgrastim), Neupogen® (filgrastim), or Zarxio® (filgrastim-sndz) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Rolvedon® (Eflapegrastim-xnst) and Ryzneuta® (Efbemalenograstim Alfa-vuxw) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fulphila® (pegfilgrastim-jmdb), Fylnetra® (pegfilgrastim-pbbk), Neulasta® Onpro® (pegfilgrastim), or Ziextenzo® (pegfilgrastim-bmez) must be provided; and

- Neulasta® Onpro® (pegfilgrastim) will be covered as a medical only benefit without prior authorization.

Utilization of G-CSFs and Stem Cell Mobilizers: 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	109	303	\$695,516.50	\$2,295.43	\$139.10	1,605	5,000
2023 Total	109	303	\$695,516.50	\$2,295.43	\$139.10	1,605	5,000
Fiscal Year 2024							
FFS	107	294	\$786,711.60	\$2,675.89	\$148.83	1,803	5,286
Aetna	8	14	\$48,374.47	\$3,455.32	\$270.25	100	179
Humana	7	11	\$24,380.21	\$2,216.38	\$123.13	32	198
OCH	9	13	\$43,184.77	\$3,321.91	\$167.38	96	258
2024 Total	121	332	\$902,651.05	\$2,718.83	\$152.45	2,031	5,921
% Change	11.00%	9.60%	29.80%	18.40%	9.60%	26.50%	18.40%
Change	12	29	\$207,134.55	\$423.40	\$13.35	426	921

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	246	801	\$1,185,014.59	\$1,479.42	3.26
2023 Total	246	801	\$1,185,014.59	\$1,479.42	3.26
Fiscal Year 2024					
FFS	312	1,107	\$1,675,178.67	\$1,513.26	3.55
Aetna	5	19	\$21,666.56	\$1,140.35	3.8
Humana	11	20	\$39,578.16	\$1,978.91	1.82
OCH	10	19	\$28,237.08	\$1,486.16	1.9
2024 Total	325	1,165	\$1,764,660.47	\$1,514.73	3.58
% Change	32.11%	45.44%	48.91%	2.39%	9.96%
Change	79	364	\$579,645.88	\$35.31	0.32

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

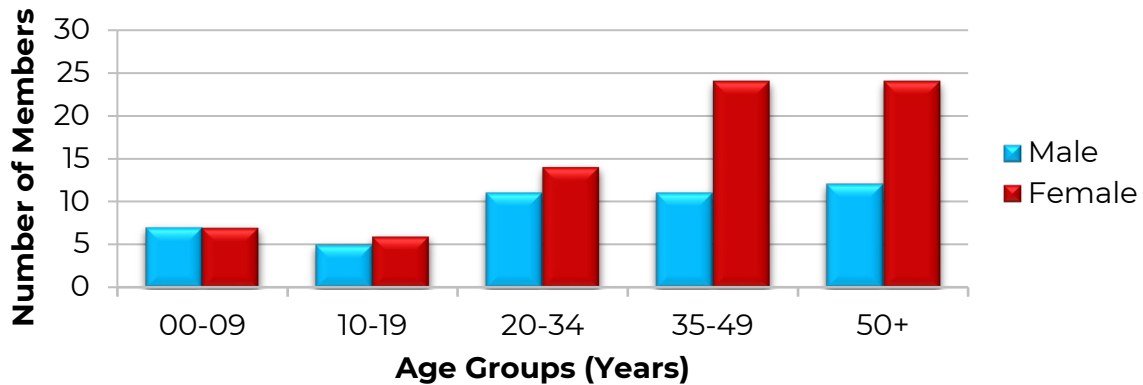
*Total number of unduplicated claims.

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

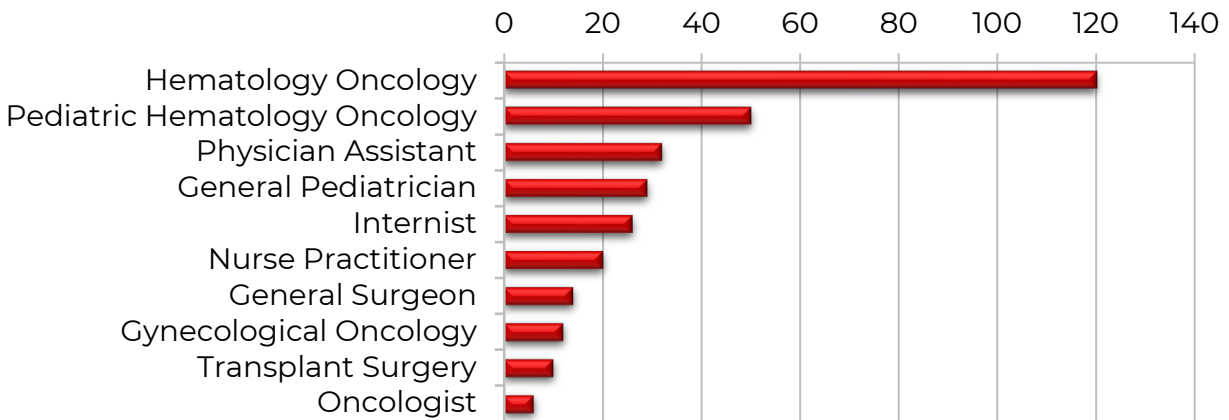
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Demographics of Members Utilizing G-CSFs and Stem Cell Mobilizers: Pharmacy Claims (All Plans)



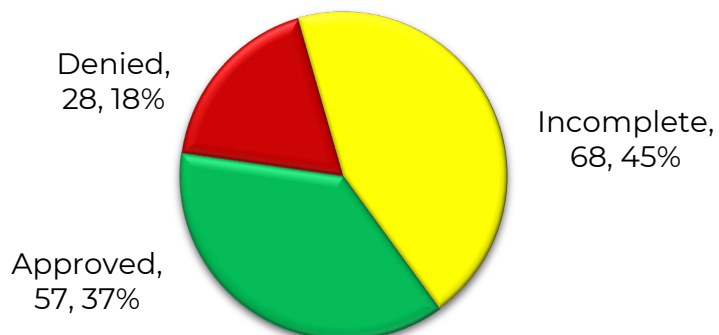
Top Prescriber Specialties of G-CSFs and Stem Cell Mobilizers by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of G-CSFs and Stem Cell Mobilizers

There were 153 prior authorization requests submitted for the G-CSFs and stem cell mobilizers 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	55	39%	66	47%	19	14%	140
Aetna	0	0%	2	67%	1	33%	3
Humana	2	20%	0	0%	8	80%	10
OCH	0	N/A	0	N/A	0	N/A	0
Total	57	37%	68	45%	28	18%	153

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}

Anticipated Patent Expiration(s):

- Aphexda® (motixafortide): September 2030
- Xolremdi® (mavorixafor): December 2038

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

- **July 2023:** The FDA approved the first generics of Mozobil® (plerixafor) injection. Mozobil® and the new generic formulations are FDA approved in combination with filgrastim, a G-CSF, to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma or multiple myeloma.
- **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.

Pipeline:

- **Plerixafor:** A Phase 3 randomized, blinded crossover trial, published in October 2023, evaluated plerixafor for the treatment of WHIM syndrome. The primary endpoint was the total infection severity score (TISS) in patients with WHIM syndrome who received 12 months of plerixafor versus 12 months of a G-CSF. While the results demonstrated that plerixafor was not superior to a G-CSF (P=0.54), exploratory endpoints suggested that plerixafor is noninferior to a G-CSF for maintaining neutrophil counts >500cells/mcL and was superior to a G-CSF for maintaining lymphocyte counts >1,000 cells/mcL. The results of this study supported the continued study of plerixafor as a possible treatment of WHIM syndrome.

Xolremdi® (Mavorixafor) Product Summary^{6,7}

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 Neutrophil 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:
 - Patients were randomized 1:1 to placebo or Xolremdi® once daily 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, 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® vs. 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 consultation with, a hematologist, immunologist, or other specialist with expertise in treatment of WHIM syndrome (or an advanced care practitioner with a supervising physician who is a hematologist, immunologist, or other specialist with expertise in treatment of WHIM syndrome); and
4. The member's recent weight (within the last 3 months) must be provided with the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
5. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must be willing to use an effective method of contraception during treatment and for at least 3 weeks after discontinuing treatment; and
6. Female members must not be breastfeeding during treatment and for at least 3 weeks after discontinuation of treatment; and
7. Prescriber must agree to counsel the member on proper administration, including taking Xolremdi® on an empty stomach after an overnight fast and at least 30 minutes before food; and
8. Prescriber must verify the member does not have severe renal impairment [creatinine clearance (CrCl) 15-30mL/min] or end-stage renal disease (CrCl <15mL/min); and
9. Provider must verify the member does not have moderate or severe hepatic impairment (Child-Pugh B or C); and
10. Prescriber must evaluate the potential for drug interactions, including the need for dose adjustments or increased monitoring of Xolremdi® or the concomitant medication(s), according to package labeling, before initiating and throughout treatment with Xolremdi®; and

11. Prescriber must verify that any modifiable risk factors for QTc prolongation (e.g., hypokalemia, hypomagnesemia) are corrected prior to initiation of therapy; and
12. Prescriber must agree to perform and monitor electrocardiogram (ECG) at baseline and as clinically indicated, thereafter, for patients with risk factors for QTc prolongation (e.g., receiving concomitant medications with known potential to prolong the QTc interval or concomitant medications that increase Xolremdi® exposure); and
13. For members who are using Xolremdi® concomitantly with other medications that are known to increase Xolremdi® exposure and/or prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval] the prescriber must agree to monitor the member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures) and evaluate the need for a dose reduction based on clinical response; and
14. A quantity limit of 120 capsules per 30 days will apply; and
15. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment as indicated by 1 of the following:
 - a. Documentation of sustained improvement in absolute neutrophil count (ANC) and/or absolute lymphocyte count (ALC) is provided; or
 - b. If the member does not show a sustained improvement in ANC and/or ALC, a clinical rationale for continuation of treatment must be provided for reauthorization.

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.

Utilization Details of G-CSFs and Stem Cell Mobilizers: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FILGRASTIM PRODUCTS						
NEUPOGEN INJ 300MCG/ML	62	12	\$266,092.88	\$4,291.82	5.17	29.48%
ZARXIO INJ 300MCG/0.5ML	31	11	\$11,560.85	\$372.93	2.82	1.28%
NEUPOGEN INJ 480MCG/ML	28	19	\$76,599.64	\$2,735.70	1.47	8.49%
ZARXIO INJ 480MCG/0.8ML	23	13	\$18,142.45	\$788.80	1.77	2.01%
NEUPOGEN INJ 480MCG/ML	12	4	\$119,327.16	\$9,943.93	3	13.22%
NEUPOGEN INJ 300MCG/0.5ML	12	10	\$11,093.82	\$924.49	1.2	1.23%
GRANIX INJ 480MCG/0.8ML	10	6	\$12,674.70	\$1,267.47	1.67	1.40%
GRANIX INJ 300MCG/0.5ML	6	5	\$4,113.76	\$685.63	1.2	0.46%
NIVESTYM INJ 300MCG/0.5ML	1	1	\$230.41	\$230.41	1	0.03%
NIVESTYM INJ 480MCG/0.8ML	1	1	\$4,917.01	\$4,917.01	1	0.54%
SUBTOTAL	186	86	\$524,752.68	\$2,821.25	2.16	58.13%
PEGFILGRASTIM PRODUCTS						
FULPHILA INJ 6MG/0.6ML	90	33	\$243,094.90	\$2,701.05	2.73	26.93%
FYLNETRA INJ 6MG/0.6ML	47	19	\$110,992.32	\$2,361.54	2.47	12.30%
ZIEXTENZO INJ 6MG/0.6ML	5	5	\$1,860.00	\$372.00	1	0.21%
NEULASTA INJ 6MG/0.6ML	3	3	\$17,639.49	\$5,879.83	1	1.95%
STIMUFEND INJ 6MG/0.6ML	1	1	\$4,311.66	\$4,311.66	1	0.48%
SUBTOTAL	146	61	\$377,898.37	\$2,588.35	2.39	41.87%
TOTAL	332	121*	\$902,651.05	\$2,718.83	2.74	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
PEGFILGRASTIM PRODUCTS					
PEGFILGRASTIM-JMDB INJ (Q5108)	518	171	\$706,566.52	\$1,364.04	3.03
PEGFILGRASTIM-PBBK INJ (Q5130)	345	101	\$809,170.22	\$2,353.65	3.45
PEGFILGRASTIM-APGF INJ (Q5122)	124	51	\$150,527.88	\$1,213.93	2.43
PEGFILGRASTIM INJ (J2506)	37	10	\$35,681.52	\$964.37	3.7
PEGFILGRASTIM-FPGK INJ (Q5127)	1	1	\$3,943.68	\$3,943.68	1
SUBTOTAL	1,025	334	\$1,705,889.82	\$1,664.28	3.07
FILGRASTIM PRODUCTS					
FILGRASTIM-SNDZ INJ (Q5101)	58	9	\$5,780.40	\$100.46	6.33
FILGRASTIM INJ (J1442)	38	11	\$17,657.20	\$464.66	3.45
FILGRASTIM-TBO INJ (J1447)	33	8	\$5,443.80	\$164.96	4.13
FILGRASTIM-AAFI INJ (Q5110)	2	1	\$174.00	\$87.00	2
SUBTOTAL	131	29	\$29,055.40	\$221.80	4.52
PLERIXAFOR PRODUCTS					
PLERIXAFOR INJ (J2562)	9	5	\$29,715.25	\$5,943.05	1.8
SUBTOTAL	9	5	\$29,715.25	\$5,943.05	1.8
TOTAL	1,165*	325*	\$1,764,660.47	\$1,514.73	3.58

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 03/25/2025.

² U.S. FDA. 2023 First Generic Drug Approvals. Available online at: <https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/2023-first-generic-drug-approvals>. Last revised 03/08/2024. Last accessed 03/25/2025.

³ Mozobil® (Plerixafor) Prescribing Information. Genzyme Corporation. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022311s023lbl.pdf. Last revised 09/21/2023. Last accessed 03/25/2025.

⁴ U.S. 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 03/25/2025.

⁵ McDermott DH, Velez D, Cho E, et al. A Phase III Randomized Crossover Trial of Plerixafor Versus G-CSF for Treatment of WHIM Syndrome. *J Clin Invest* 2023; 133(19): e164918. doi: 10.1172/JCI164918.

⁶ 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.

⁷ 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: 03/25/2025.



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

Oklahoma Health Care Authority
April 2025

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

Anticipated Patent Expiration(s):

- Journavx™ (suzetrigine): December 2040

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 Nav1.8 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 Summary⁴

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	\$4.48 ^α

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 baseline 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. For members with moderate pain (NPRS score 4-7), 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.

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 02/2025. Last accessed 02/25/2025.

² U.S. 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 02/04/2025.

³ 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 02/04/2025.

⁴ 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 02/04/2025.



Fiscal Year 2024 Annual Review of Thrombocytopenia Medications and 30-Day Notice to Prior Authorize Adzynma (ADAMTS13, Recombinant-krhn) and Alvaiz® (Eltrombopag)

**Oklahoma Health Care Authority
April 2025**

Current Prior Authorization Criteria

Cablivi® (Caplacizumab-yhdp) Approval Criteria:

1. An FDA approved indication for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP) in combination with plasma exchange and immunosuppressive therapy; and
2. Member must be undergoing plasma exchange therapy; and
 - a. Dates of initiation of plasma exchange therapy must be listed on the prior authorization request; and
 - b. Authorizations will be for the duration of plasma exchange and for 30 days after discontinuation of plasma exchange; and
3. Member must be utilizing immunosuppressant therapy; and
4. Cablivi® must be prescribed by, or in consultation with, a hematologist; and
5. A quantity limit of 11mg per day will apply. Initial approvals will be for the duration of plasma exchange plus 30 days. Reauthorization, after completing 30 days post-plasma exchange, may be considered if the prescriber documents sign(s) of persistent underlying disease remain. Reauthorization will be for a maximum of 28 days.

Doptelet® (Avatrombopag) Approval Criteria [Chronic Immune Thrombocytopenia (ITP) Diagnosis]:

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with chronic ITP who have had an insufficient response to a previous treatment; and
2. Member must be 18 years of age or older; and
3. Previous insufficient response with at least 1 of the following treatments:
 - a. Corticosteroids; or
 - b. Immunoglobulins; or
 - c. Splenectomy; and
4. A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and

5. Prescriber must verify the degree of thrombocytopenia and clinical condition increase the risk for bleeding; and
6. Prescriber must verify platelet counts will be assessed weekly until a stable platelet count $>50 \times 10^9/L$ has been achieved, and then obtained monthly thereafter; and
7. Must be prescribed by, or in consultation with, a hematologist or oncologist; and
8. Doptelet® must not be used in an attempt to normalize platelet counts; and
9. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
10. Prescriber must verify female member is not breastfeeding; and
11. A quantity limit of 60 tablets per 30 days will apply.

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

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with CLD who are scheduled to undergo a procedure; and
2. Date of procedure must be listed on the prior authorization request; and
3. Prescriber must verify the member will have the procedure within 5 to 8 days after the member receives the last dose of Doptelet®; and
4. Member must have a baseline platelet count $<50 \times 10^9/L$ (recent baseline platelet count must be provided); and
5. Must be prescribed by, or in consultation with, a hematologist, gastroenterologist, or hepatologist; and
6. Doptelet® must not be used in an attempt to normalize platelet counts; and
7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
8. Prescriber must verify female member is not breastfeeding; and
9. A quantity limit of 15 tablets per scheduled procedure will apply.

Mulpleta® (Lusutrombopag) Approval Criteria:

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

5. Must be prescribed by, or in consultation with, a hematologist, gastroenterologist, or hepatologist; and
6. Mulpleta® must not be used in an attempt to normalize platelet counts; and
7. A quantity limit of 7 tablets per scheduled procedure will apply.

Tavalisse® (Fostamatinib) Approval Criteria:

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment; and
2. Member must be 18 years of age or older (Tavalisse® is not recommended for use in patients younger than 18 years of age because adverse effects on actively growing bones were observed in nonclinical studies); and
3. Member must have a clinical diagnosis of persistent/chronic ITP for at least 3 months; and
4. Previous insufficient response with at least 2 of the following treatments:
 - a. Corticosteroids; or
 - b. Immunoglobulins; or
 - c. Splenectomy; or
 - d. Thrombopoietin (TPO) receptor agonists; and
5. Prescriber must verify degree of thrombocytopenia and clinical condition increase the risk for bleeding; and
6. Must be prescribed by, or in consultation with, a hematologist or oncologist; and
7. Prescriber must verify the member's complete blood count (CBC), including platelet counts, will be monitored monthly until a stable platelet count (at least $50 \times 10^9/L$) is achieved and will be monitored regularly thereafter; and
8. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored monthly; and
9. Prescriber must verify member's blood pressure will be monitored every 2 weeks until establishment of a stable dose, then monthly thereafter; and
10. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy and for at least 1 month after therapy completion; and
11. Prescriber must verify female member is not breastfeeding; and
12. Member must not be taking strong CYP3A4 inducers (e.g., rifampicin) concurrently with Tavalisse®; and
13. Initial approvals will be for the duration of 12 weeks; and

14. Discontinuation criteria:

- a. Platelet count does not increase to a level sufficient to avoid clinically important bleeding after 12 weeks of therapy; and

15. A quantity limit of 2 tablets per day will apply.

Utilization of Thrombocytopenia 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	44	201	\$2,320,854.41	\$11,546.54	\$396.39	6,665	5,855
2023 Total	44	201	\$2,320,854.41	\$11,546.54	\$396.39	6,665	5,855
Fiscal Year 2024							
FFS	39	180	\$2,387,523.31	\$13,264.02	\$453.56	6,179	5,264
Aetna	5	11	\$223,755.34	\$20,341.39	\$678.05	390	330
Humana	4	5	\$89,415.01	\$17,883.00	\$715.32	160	125
OCH	7	13	\$151,104.30	\$11,623.41	\$444.42	350	340
2024 Total	44	209	\$2,851,797.96	\$13,644.97	\$470.67	7,079	6,059
% Change	0.00%	4.00%	22.90%	18.20%	18.70%	6.20%	3.50%
Change	0	8	\$530,943.55	\$2,098.43	\$74.28	414	204

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)

Fiscal Year	*Total Members	*Total Claims	Total Cost	Cost/Claim	Claims/Member
Fiscal Year 2023					
FFS	18	289	\$822,457.90	\$2,845.88	16.06
2023 Total	18	289	\$822,457.90	\$2,845.88	16.06
Fiscal Year 2024					
FFS	23	491	\$1,396,708.46	\$2,844.62	21.35
Aetna	0	0	\$0.00	\$0.00	0
Humana	2	11	\$23,728.16	\$2,157.11	5.50
OCH	1	7	\$14,042.43	\$2,006.06	7
2024 Total	23	508	\$1,434,585.80	\$2,823.99	22.09
% Change	27.78%	75.78%	74.43%	-0.77%	37.57%
Change	5	219	\$612,127.90	-\$21.89	6.03

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

*Total number of unduplicated claims.

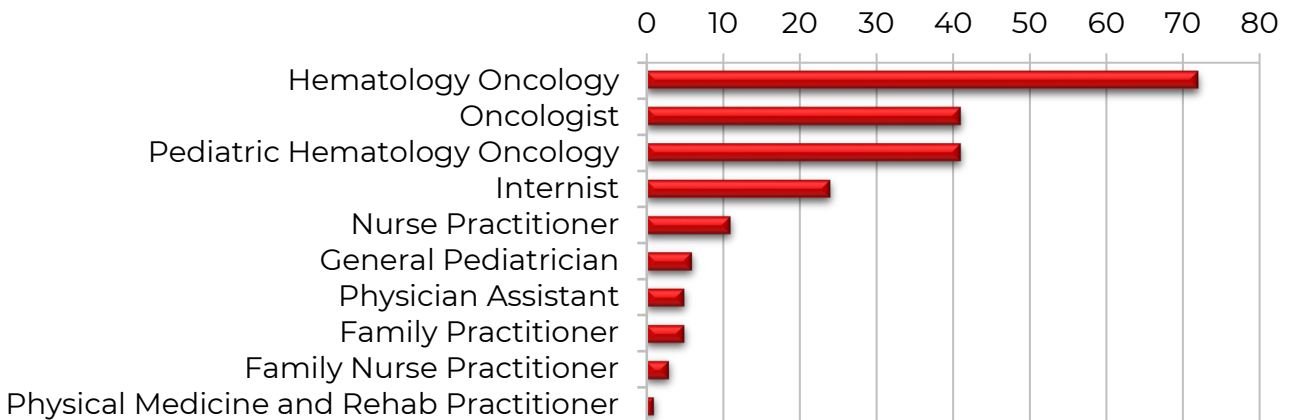
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

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

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

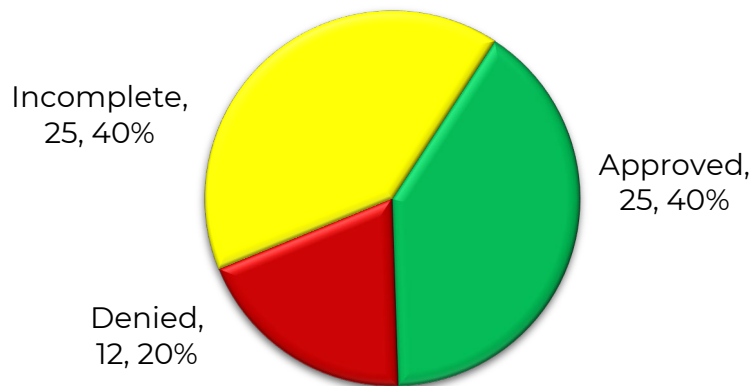
Top Prescriber Specialties of Thrombocytopenia Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Thrombocytopenia Medications

There were 62 prior authorization requests submitted for thrombocytopenia 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	20	35%	25	44%	12	21%	57
Aetna	3	100%	0	0%	0	0%	3
Humana	0	N/A	0	N/A	0	N/A	0
OCH	2	100%	0	0%	0	0%	2
Total	25	40%	25	40%	12	20%	62

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}

Anticipated Patent Expiration(s):

- Promacta® (eltrombopag oral suspension): January 2026
- Promacta® (eltrombopag tablets): February 2028
- Doptelet® (avatrombopag): July 2027
- Mulpleta® (lusutrombopag): September 2031
- Tavalisse® (fostamatinib): July 2032
- Alvaiz™ (eltrombopag): November 2038

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

- **November 2023:** The FDA approved Adzyna (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 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.

Pipeline:

- **Rilzabrutinib:** Rilzabrutinib is an investigational oral, reversible, covalent, Bruton's tyrosine kinase (BTK) inhibitor being studied for the treatment of ITP. BTK, expressed in B cells, macrophages, and other immune cells, plays a critical role in inflammatory pathways and multiple immune-mediated disease processes. Rilzabrutinib selectively inhibits the BTK target while potentially reducing the risk of off-target side effects. In the Phase 3 LUNA trial, rilzabrutinib showed a rapid and durable platelet response in 65% of patients compared to 33% of patients on placebo. The primary endpoint was met with rilzabrutinib demonstrating durable platelet response in 23% of ITP adult patients compared to 0% in the placebo arm ($P < 0.0001$), as well as key secondary endpoints including reduced bleeding, number of weeks with platelet response, the need for rescue therapy use, and improved physical fatigue and quality of life measures. The FDA has issued a Prescription Drug User Fee Act (PDUFA) date of August 29, 2025.

Adzynma (ADAMTS13, Recombinant-krhn) Product Summary⁵

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^{6,7}

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 ($\leq 50\text{mg}$) 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 $\geq 50 \times 10^9/\text{L}$.
 - 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 $\geq 50 \times 10^9/\text{L}$.
- 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 is based on the FDA approved maximum dose for refractory severe aplastic anemia of 108mg per day.

⁺Cost is based on the FDA approved maximum dose for refractory severe aplastic anemia of 150mg per 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 $<30 \times 10^9/L$; 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. Member must have eye exam prior to initiation of Alvaiz® to assess for cataracts; 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 $\leq 30 \times 10^9/L$; 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. Member must have eye exam prior to initiation of Alvaiz® to assess for cataracts; 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.

Utilization Details of Thrombocytopenia Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ELTROMBOPAG PRODUCTS						
PROMACTA TAB 50MG	105	20	\$1,354,423.50	\$12,899.27	5.25	47.49%
PROMACTA TAB 75MG	28	12	\$654,568.98	\$23,377.46	2.33	22.95%
PROMACTA TAB 12.5MG	20	2	\$138,680.97	\$6,934.05	10	4.86%
PROMACTA TAB 25MG	19	6	\$130,351.89	\$6,860.63	3.17	4.57%
SUBTOTAL	172	40	\$2,278,025.34	\$13,244.33	4.30	79.88%
FOSTAMATINIB PRODUCTS						
TAVALISSE TAB 150MG	21	2	\$296,526.11	\$14,120.29	10.5	10.4%
SUBTOTAL	21	2	\$296,526.11	\$14,120.29	10.5	10.4%
AVATROMBOPAG PRODUCTS						
DOPTELET TAB 20MG	14	9	\$118,730.69	\$8,480.76	1.56	4.16%
SUBTOTAL	14	9	\$118,730.69	\$8,480.76	1.56	4.16%
CAPLACIZUMAB PRODUCTS						
CABLIVI KIT 11MG	2	1	\$158,515.82	\$79,257.91	2	5.56%
SUBTOTAL	2	1	\$158,515.82	\$79,257.91	2	5.56%
TOTAL	209	44*	\$2,851,797.96	\$13,644.97	4.75	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

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 SoonerSelect plans.

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ROMIPLOSTIM INJ (J2796)	508	23	\$1,434,585.80	\$2,823.99	22.09
TOTAL	508	23	\$1,434,585.80	\$2,823.99	22.09

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 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 03/19/2025.

² U.S. 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 03/19/2025.

³ 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 03/19/2025.

⁴ Sanofi. Rilzabrutinib Demonstrated Significant Patient Benefit in the First Positive Phase 3 Study of a BTK inhibitor in ITP. Available online at: <https://www.sanofi.com/en/media-room/press-releases/2024/2024-12-07-16-30-00-2993342>. Issued 12/07/2024. Last accessed 03/19/2025.

⁵ Adzynma (ADAMTS13, Recombinant-krhn) Prescribing Information. Takeda Pharmaceuticals. Available online at: <https://www.fda.gov/media/173756/download>. Last revised 11/2023. Last accessed 03/19/2025.

⁶ 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 03/19/2025.

⁷ 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 03/19/2025.



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: March 28, 2025

FDA Approves Novel Treatment for Hemophilia A or B, with or without Factor Inhibitors

The FDA approved Qfitlia™ (fitusiran) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A or hemophilia B, with or without factor VIII (FVIII) or factor IX (FIX) inhibitors.

Hemophilia A and hemophilia B are genetic bleeding disorders caused by a dysfunction or deficiency of coagulation FVIII or FIX, respectively. Patients with these hemophilias are unable to clot properly and may bleed for a longer time than normal after injury or surgery. They may also have spontaneous bleeding in muscles, joints, and organs, which can be life-threatening. These bleeding episodes are typically managed by either on-demand, episodic treatment, or prophylaxis using products containing FVIII or FIX, or a product that mimics a factor.

Qfitlia™ does not replace the missing clotting factor. Rather, it reduces the amount of a protein called antithrombin, leading to an increase in thrombin, an enzyme critical for blood clotting.

Qfitlia™ is administered subcutaneously starting once every 2 months. The dose and frequency of injections are adjusted using the FDA-cleared INNOVANCE Antithrombin companion diagnostic test. This companion diagnostic is intended to monitor and—by informing dosing and frequency of injections—achieve antithrombin activity in the target range to reduce the risk of bleeding and to reduce the risk of excessive blood clotting. The FDA granted clearance of the INNOVANCE Antithrombin test to Siemens Healthcare Diagnostics GmbH.

Qfitlia™'s efficacy and safety were assessed in 2 multicenter, randomized clinical trials which enrolled a total of 177 adult and pediatric male patients with either hemophilia A or hemophilia B. In 1 study, participants had inhibitory antibodies to FVIII or FIX and previously received on-demand treatment with medicines known as “bypassing agents” for bleeding. In the second study, participants did not have inhibitory antibodies to FVIII or FIX and previously received on-demand treatment with clotting factor concentrates. In the 2 randomized trials, participants received either a fixed dose of Qfitlia™ monthly or their usual on-demand treatment (bypassing agents or clotting factor concentrates) as needed for 9 months.

The fixed dose of Qfitlia™ is not approved because it led to excessive clotting in some patients.

Participants subsequently entered a long-term extension study in which they received an adjustable dose of Qfitlia™ based on periodic measurements of antithrombin activity. This antithrombin-based dosing regimen is the approved dosage regimen. Efficacy of Qfitlia™ using the antithrombin-based dosing regimen was established by comparing patients on this dosing regimen of Qfitlia™ during the long-term extension study to the on-demand control data from the 2 randomized clinical trials.

The primary measure of efficacy of Qfitlia™ was the estimated annualized bleeding rate of treated bleeds. In the participants with inhibitors who received the antithrombin-based dosing regimen of Qfitlia™, there was a 73% reduction in estimated annualized bleeding rate compared to those who received on-demand treatment with bypassing agents. In participants without inhibitors who received the antithrombin-based dosing regimen of Qfitlia™, there was a 71% reduction in estimated annualized bleeding rate compared to those who received on-demand treatment with clotting factor concentrates.

Qfitlia™ has a *Boxed Warning* for thrombotic events and gallbladder disease (with some patients requiring gallbladder removal). Qfitlia™ also has a warning about liver toxicity and the need to monitor liver blood tests at baseline and then monthly for at least 6 months after initiating treatment with Qfitlia™ or after a dose increase of Qfitlia™. The most common side effects of Qfitlia are viral infection, nasopharyngitis, and bacterial infection. The FDA granted Qfitlia™ Orphan Drug and Fast Track designations for this application. The FDA granted the approval of Qfitlia™ to Sanofi.

FDA NEWS RELEASE

For Immediate Release: March 28, 2025

FDA Grants Marketing Authorization of First Home Test for Chlamydia, Gonorrhea and Trichomoniasis

The FDA granted marketing authorization to Visby Medical for the Visby Medical Women's Sexual Health Test. This is the first diagnostic test for chlamydia, gonorrhea, and trichomoniasis that can be purchased without a prescription and performed entirely at home. The test is intended for females with or without symptoms and delivers results in approximately 30 minutes.

According to the Centers for Disease Control and Prevention (CDC)'s Sexually Transmitted Infections (STI) Surveillance Report, more than 2.2 million cases of chlamydia and gonorrhea were diagnosed and reported in the United States in 2023. Additionally, it is estimated that trichomoniasis is the most prevalent nonviral STI worldwide, affecting approximately 2.6 million people in the United States, according to the CDC's treatment guidelines. Typically, all 3 infections can be treated with antibiotics, but if left untreated, can cause serious health complications for patients, including infertility.

The Visby Medical Women's Sexual Health Test is a single use, at home test, that includes a collection kit (self-collected vaginal swab) and a powered testing device, which communicates securely to the Visby Medical App, which displays results when the test is complete.

In individuals with and without symptoms, the Visby Medical Women's Sexual Health Test correctly identified 98.8% of negative and 97.2% of positive *Chlamydia trachomatis* samples, 99.1% of negative and 100% of positive *Neisseria gonorrhoeae* samples and 98.5% of negative and 97.8% of positive *Trichomonas vaginalis* samples.

Individuals with positive results for any of the 3 infections should seek medical care. Individuals with symptoms, recent exposure to an STI, or other concerns despite a negative result should contact their health care provider for additional testing.

As with many other tests, the risks associated with this test are mainly the possibility of false positive and false negative test results. False negative test results can result in delays to effective treatment and spread of infection to other persons. False positive results could lead to unnecessary treatment and/or a delay in receiving a correct diagnosis and appropriate treatment.

The FDA reviewed this test under the FDA's De Novo premarket review pathway, a regulatory pathway for low- to moderate-risk devices of a new type. Along with this De Novo authorization, the FDA is establishing special controls that define the requirements related to labeling and performance testing. When met, the special controls, in combination with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through FDA's 510(k) premarket notification process, whereby devices can obtain marketing authorization by demonstrating substantial equivalence to a predicate device, which may save a developer time and expense compared to other review pathways.

This announcement follows last year's authorization of the first at-home syphilis test, as well as the authorization of the first diagnostic test for chlamydia and gonorrhea with at-home sample collection in 2023, which was the first FDA-authorized test with at-home sample collection for any sexually transmitted infection other than HIV.

Current Drug Shortages Index (as of March 27, 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](#)
[Furosemide Injection](#)
[Heparin Sodium Injection](#)
[Hydrocortisone Sodium Succinate Injection](#)
[Hydromorphone Hydrochloride Injection](#)
[Hydroxocobalamin Injection](#)
[Hydroxypropyl Cellulose \(1600000 Wamw\) Insert](#)
[Indocyanine Green Injection](#)
[Ketamine Hydrochloride Injection](#)
[Ketorolac Tromethamine Injection](#)
[Lactated Ringers Injection](#)
[Leucovorin Calcium Injection](#)
[Lidocaine Hydrochloride Injection](#)
[Lidocaine Hydrochloride Solution](#)
[Liraglutide Injection](#)
[Lisdexamfetamine Dimesylate Capsule](#)
[Lisdexamfetamine Dimesylate Tablet, Chewable](#)
[Lorazepam Injection](#)
[Mefloquine Hydrochloride Tablet](#)
[Methamphetamine Hydrochloride Tablet](#)
[Methotrexate Sodium Injection](#)
[Methylphenidate Film, Extended Release](#)
[Methylphenidate Hydrochloride Tablet, Extended Release](#)
[Methylprednisolone Acetate Injection](#)
[Metronidazole Injection](#)
[Midazolam Hydrochloride Injection](#)
[Morphine Sulfate Injection](#)
[Naltrexone Hydrochloride Tablet](#)
[Nitroglycerin Injection](#)
[Oxazepam Capsule](#)
[Parathyroid Hormone Injection](#)
[Peginterferon alfa-2a Injection](#)
[Penicillin G Benzathine Injection](#)
[Peritoneal Dialysis Solution](#)
[Promethazine Hydrochloride Injection](#)
[Propranolol Hydrochloride Injection](#)
[Quinapril Hydrochloride Tablet](#)
[Quinapril/Hydrochlorothiazide Tablet](#)
[Remifentanyl Hydrochloride Injection](#)

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