OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
March 13, 2024
4:00pm

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

Viewing Access Only:
Please register for the webinar at:
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The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – March 13, 2024

DATE: March 6, 2024

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/Spring 2024 Pipeline Update – Appendix B

Action Item – Vote to Prior Authorize RizaFilm® (Rizatriptan Film) and Zavzpret™ (Zavegepant Nasal Spray) and Update the Approval Criteria for the Anti-Migraine Medications – Appendix C

Action Item – Vote to Prior Authorize Xdemvy™ (Lotilaner Ophthalmic Solution) and Update the Approval Criteria for the Anti-Parasitic Medications – Appendix D

Action Item – Vote to Prior Authorize Ycanth™ (Cantharidin) and Zelsuvmi™ (Berdazimer) – Appendix E

Action Item – Vote to Prior Authorize Vanflyta® (Quizartinib) and Update the Approval Criteria for the Leukemia Medications – Appendix F

Action Item – Annual Review of Skyclarys™ (Omaveloxolone) – Appendix G

Action Item – Annual Review of Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications – Appendix H

Annual Review of Lymphoma Medications and 30-Day Notice to Prior Authorize Columvi™ (Glofitamab-gxbm) and Epkinly™ (Epcoritamab-bysp) – Appendix I

Annual Review of Hemophilia Medications and 30-Day Notice to Prior Authorize Roctavian™ (Valoctocogene Roxaparvovec-rvox) – Appendix J

Annual Review of Growth Hormone Products and Voxzogo® (Vosoritide) and 30-Day Notice to Prior Authorize Ngenla™ (Somatrogon-ghla) – Appendix K

Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and 30-Day Notice to Prior Authorize Ryzneuta® (Efbemalenograstim Alfa) – Appendix L

Annual Review of Multiple Sclerosis (MS) Medications and 30-Day Notice to Prior Authorize Tyruko® (Natalizumab-sztn) – Appendix M

Annual Review of Stem Cell Mobilizers and 30-Day Notice to Prior Authorize Aphexda™ (Motixafortide) – Appendix N

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – March 13, 2024 @ 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. Muchmore, 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. John Muchmore –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person
Dr. Edna Patatanian –	participating in person
Dr. Vineetha Thomas –	participating in person
Dr. Beth Walton –	participating in person
Dr. Cindy West –	participating in person

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

Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 919 6475 4191
Passcode: 95646190

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. Muchmore, Chairman:

2. **Public Comment Forum**
   A. Acknowledgement of Speakers for Public Comment

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. February 14, 2024 DUR Board Meeting Minutes
   B. February 14, 2024 DUR Board Recommendations Memorandum
   C. Correspondence

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

4. **Update on Medication Coverage Authorization Unit/Spring 2024 Pipeline Update – See Appendix B**
   A. Pharmacy Help Desk Activity for February 2024
   B. Medication Coverage Activity for February 2024
   C. Spring 2024 Pipeline Update

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

5. **Action Item – Vote to Prior Authorize RizaFilm® (Rizatriptan Film) and Zavzpret™ (Zavegepant Nasal Spray) and Update the Approval Criteria for the Anti-Migraine Medications – See Appendix C**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

6. **Action Item – Vote to Prior Authorize Alinia® (Nitazoxanide Tablet) and Xdemvy™ (Lotilaner Ophthalmic Solution) and Update the Approval Criteria for the Anti-Parasitic Medications – See Appendix D**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

Items to be presented by Dr. Morgan, Dr. Muchmore, Chairman:

7. **Action Item – Vote to Prior Authorize Ycanth™ (Cantharidin) and Zelsuvmi™ (Berdazimer) – See Appendix E**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Vanflyta® (Quizartinib) and Update the Approval Criteria for the Leukemia Medications – See Appendix F**
   A. Market News and Updates
   B. Vanflyta® (Quizartinib) Product Summary
   C. College of Pharmacy Recommendations

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

9. **Action Item – Annual Review of Skyclarys™ (Omaveloxolone) – See Appendix G**
   A. Current Prior Authorization Criteria
   B. Utilization of Skyclarys™ (Omaveloxolone)
   C. Prior Authorization of Skyclarys™ (Omaveloxolone)
   D. Market News and Updates
   E. College of Pharmacy Recommendations
   F. Utilization Details of Skyclarys™ (Omaveloxolone)

Items to be presented by Dr. Morgan, Dr. Muchmore, Chairman:

10. **Action Item – Annual Review of Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications – See Appendix H**
    A. Current Prior Authorization Criteria
    B. Utilization of VMAT2 Inhibitor Medications
    C. Prior Authorization of VMAT2 Inhibitor Medications
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of VMAT2 Inhibitor Medications

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

11. **Annual Review of Lymphoma Medications and 30-Day Notice to Prior Authorize Columvi™ (Glofitamab-gxbm) and Epkinly™ (Epcoritamab-bysp) – See Appendix I**

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

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

12. **Annual Review of Hemophilia Medications and 30-Day Notice to Prior Authorize Roctavian™ (Valoctocogene Roxaparvovec-rvox) – See Appendix J**

A. Current Prior Authorization Criteria
B. Utilization of Hemophilia Medications
C. Prior Authorization of Hemophilia Medications
D. Market News and Updates
E. Roctavian™ (Valoctocogene Roxaparvovec-rvox) Product Summary
F. Oklahoma Health Care Authority (OHCA) Recommendations
G. Utilization Details of Hemophilia Medications

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

13. **Annual Review of Growth Hormone Products and Voxzogo® (Vosoritide) and 30-Day Notice to Prior Authorize Ngenla™ (Somatrogon-ghla) – See Appendix K**

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. Ngenla® (Somatrogon-ghla) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Growth Hormone Products and Voxzogo® (Vosoritide)

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

14. **Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and 30-Day Notice to Prior Authorize Ryzneuta® (Efbemalenograstim Alfa) – See Appendix L**

A. Current Prior Authorization Criteria
B. Utilization of G-CSFs
C. Prior Authorization of G-CSFs
D. Market News and Updates
E. Ryzneuta® (Efbemalenograstim Alfa) Product Summary

F. College of Pharmacy Recommendations
G. Utilization Details of G-CSFs

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

15. Annual Review of Multiple Sclerosis (MS) Medications and 30-Day Notice to Prior Authorize Tyruko® (Natalizumab-sztn) – See Appendix M

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

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

16. Annual Review of Stem Cell Mobilizers and 30-Day Notice to Prior Authorize Aphexda™ (Motixafortide) – See Appendix N

A. Current Prior Authorization Criteria
B. Utilization of Stem Cell Mobilizers
C. Prior Authorization of Stem Cell Mobilizers
D. Market News and Updates
E. Aphexda™ (Motixafortide) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Stem Cell Mobilizers

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

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

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

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

A. Age-Related Macular Degeneration (AMD) Medications
B. Anti-Diabetic Medications
C. Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications
D. Phenylketonuria Medications

*Future product and class reviews subject to change.

19. 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.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING FEBRUARY 14, 2024

DUR BOARD MEMBERS:	PRESENT	ABSENT
Kenneth Foster, MHS, PA-C	X	
Megan A. Hanner, D.O.		X
Bret Haymore, M.D.	X	
John Muchmore, M.D.; Ph.D.; Chairman	X	
Lee Muñoz, D.Ph.		X
James Osborne, Pharm.D.	X	
Edna Patatanian, Pharm.D., FASHP; Interim Vice Chairwoman	X	
Vineetha Thomas, Pharm.D., BCOP	X	
Beth Walton, Pharm.D.		X
Cindy West, D.O., FAAP	X	

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	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
Mattie Morgan, Pharm.D.; Pharmacy Resident	X	
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor		X
Peggy Snyder, Pharm.D.; Clinical Pharmacist		X
Ashley Teel, Pharm.D.; Clinical Pharmacist		X
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	X	
Devin Wilcox, D.Ph.; Pharmacy Director	X	
Justin Wilson, Pharm.D.; Clinical Pharmacist	X	
PA Oncology Pharmacists: Tad Autry Pharm.D., BCPS, BCOP		X
Brooke Daugherty, Pharm. D., BCOP	X	
Lauren Sinko, Pharm. D., BCOP	X	
Graduate Students: Rykr Carpenter, Pharm.D.		X
Matthew Dickson, Pharm.D.		X
Michael Nguyen, Pharm.D.		X
Corby Thompson, Pharm.D.		X
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mark Brandenburg, M.D., MSC; Medical Director	X	
Ellen Buettner; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	
Christina Foss; Chief of Staff		X
Josh Holloway, J.D.; Deputy General Counsel	X	

Traylor Rains; State Medicaid Director		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	
Kara Smith, J.D.; General Counsel		X
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
Toney Welborn, M.D., MPH, MS; Medical Director		X

OTHERS PRESENT:	
Gary Parenteau, Dexcom	Rhonda Clark, Indivior
Melissa Abbott, Eisai	Rusty Hailey, Intra-Cellular Therapies
Bob Atkins, Biogen	Brielle Dozier, Artia Solutions
Tom Stephan, Stifel	Alexis Sharabaika, Sage Therapeutics
Richard McCue, Glaukos	Paul Sparks, Amgen
Paul Isikwe, Biogen	Lindsey Baker, Gene
Cathy Paulson, Tarsus	Dave Miley, Teva Pharmaceuticals
Tara McKinley, Madrigal Pharmaceuticals	Gina Heinen, Novo Nordisk
Janie Huff, Madrigal Pharmaceuticals	Aaron Austin
Joanna Janota, Verrica Pharmaceuticals	Deidra Williams, Humana
Charlene Kaiser, Spring Works	Camille Kerr, Regeneron
Brent Young, Karuna	John Stancil, Aria
Irene Chung, Aetna	Kristen Winters, Centene
Frank Alvarado, Johnson & Johnson	David Prather, Novo Nordisk
Audrey Rattan, Alkermes	Ed Clasby, Medtronic
Dan Rattan	

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

1A: ROLL CALL

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

ACTION: NONE REQUIRED

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

ACTION: NONE REQUIRED

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

3A: DECEMBER 13, 2023 DUR MINUTES

Materials included in agenda packet; presented by Dr. Muchmore

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/USE OF GLUCAGON-LIKE PEPTIDE-1 (GLP-1) AGONISTS AND SODIUM-GLUCOSE CO-TRANSPORTER-2 (SGLT-2) INHIBITORS WITH CARDIOVASCULAR (CV) BENEFIT IN MEMBERS WITH TYPE 2 DIABETES (T2D) AND HIGH CV RISK OR ESTABLISHED ATHEROSCLEROTIC CV DISEASE (ASCVD) MAILING UPDATE**

4A: PHARMACY HELPDESK ACTIVITY FOR JANUARY 2024

4B: MEDICATION COVERAGE ACTIVITY FOR JANUARY 2024

4C: USE OF GLP-1 AGONISTS AND SGLT-2 INHIBITORS WITH CV BENEFIT IN MEMBERS WITH T2D AND HIGH CV RISK OR ESTABLISHED ASCVD MAILING UPDATE

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: NARROW THERAPEUTIC INDEX (NTI) LIST

5A: INTRODUCTION

5B: NTI LIST

5C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Morgan

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE RYSTIGGO® (ROZANOLIXIZUMAB-NOLI), VYVGART® HYTRULO (EFGARTIGIMOD ALFA/HYALURONIDASE-QVFC), AND ZILBRYSQ® (ZILUCOPLAN) AND UPDATE THE APPROVAL CRITERIA FOR THE COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS

6A: MARKET NEWS AND UPDATES

6B: PRODUCT SUMMARIES

6C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE EXXUA™ (GEPIRONE) AND ZURZUVAE™ (ZURANOLONE) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTIDEPRESSANTS

7A: MARKET NEWS AND UPDATES

7B: PRODUCT SUMMARIES

7C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE ELFABRIO® (PEGUNIGALSIDASE ALFA-IWXJ), OPFOLDA™ (MIGLUSTAT), AND POMBILITI™ (CIPAGLUCOSIDASE ALFA-ATGA) AND UPDATE THE APPROVAL CRITERIA FOR THE LYSOSOMAL STORAGE DISEASE MEDICATIONS

8A: MARKET NEWS AND UPDATES

8B: PRODUCT SUMMARIES

8C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson

Dr. West moved to approve; seconded by Dr. Haymore

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE HEPZATO KIT™ (MEPHALAN) AND ZYNYZ™ (RETIFANLIMAB-DLWR) AND UPDATE THE APPROVAL CRITERIA FOR THE SKIN CANCER MEDICATIONS

9A: MARKET NEWS AND UPDATES

9B: PRODUCT SUMMARIES

9C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Daugherty

Dr. Patatanian moved to approve; seconded by Dr. Thomas
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 10:</u> VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE GASTROINTESTINAL (GI) CANCER MEDICATIONS
10A: MARKET NEWS AND UPDATES
10B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Daugherty
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 11:</u> VOTE TO PRIOR AUTHORIZE IWILFIN™ (EFLORNITHINE), KEPIVANCE® (PALIFERMIN), LOQTORZI™ (TORIPALIMAB-TPZI), AND OMISIRGE® (OMIDUBICEL-ONLV)
11A: MARKET NEWS AND UPDATES
11B: PRODUCT SUMMARIES
11C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Daugherty
Dr. Haymore moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 12:</u> VOTE TO PRIOR AUTHORIZE OGSIVEO™ (NIROGACESTAT)
12A: OGSIVEO™ (NIROGACESTAT) PRODUCT SUMMARY
12B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Daugherty
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 13:</u> VOTE TO PRIOR AUTHORIZE XPHOZAH® (TENAPANOR) AND UPDATE THE APPROVAL CRITERIA FOR THE HYPERPHOSPHATEMIA MEDICATIONS
13A: MARKET NEWS AND UPDATES
13B: PRODUCT SUMMARIES
13C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Dr. West
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 14:</u> VOTE TO PRIOR AUTHORIZE ATORVALIQ® (ATORVASTATIN ORAL SUSPENSION) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTIHYPERLIPIDEMICS
14A: MARKET NEWS AND UPDATES
14B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 15:</u> VOTE TO PRIOR AUTHORIZE OXYBUTYNIN 2.5MG TABLET AND UPDATE THE APPROVAL CRITERIA FOR THE BLADDER CONTROL MEDICATIONS
15A: MARKET NEWS AND UPDATES
15B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Morgan
Dr. West moved to approve; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 16:</u> VOTE TO PRIOR AUTHORIZE IDOSE® TR (TRAVOPROST INTRACAMERAL IMPLANT) AND UPDATE THE APPROVAL CRITERIA FOR THE GLAUCOMA MEDICATIONS
16A: MARKET NEWS AND UPDATES
16B: IDOSE® TR (TRAVOPROST INTRACAMERAL IMPLANT) PRODUCT SUMMARY
16C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 17:</u> ANNUAL REVIEW OF OTIC ANTI-INFECTIVE MEDICATIONS
17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF OTIC ANTI-INFECTIVE MEDICATIONS
17C: PRIOR AUTHORIZATION OF OTIC ANTI-INFECTIVE MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: COLLEGE OF PHARMACY RECOMMENDATIONS
17F: UTILIZATION DETAILS OF OTIC ANTI-INFECTIVE MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. West moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 18:</u> ANNUAL REVIEW OF TOPICAL ACNE, PSORIASIS, AND ROSACEA PRODUCTS
18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF TOPICAL ACNE, PSORIASIS, AND ROSACEA PRODUCTS
18C: PRIOR AUTHORIZATION OF TOPICAL ACNE, PSORIASIS, AND ROSACEA PRODUCTS
18D: MARKET NEWS AND UPDATES
18E: COLLEGE OF PHARMACY RECOMMENDATIONS
18F: UTILIZATION DETAILS OF TOPICAL ACNE, PSORIASIS, AND ROSACEA PRODUCTS
Materials included in agenda packet; presented by Dr. Morgan
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 19:</u> ANNUAL REVIEW OF ANTIVIRAL MEDICATIONS
19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF ANTIVIRAL MEDICATIONS
19C: PRIOR AUTHORIZATION OF ANTIVIRAL MEDICATIONS
19D: MARKET NEWS AND UPDATES
19E: COLLEGE OF PHARMACY RECOMMENDATIONS
19F: UTILIZATION DETAILS OF ANTIVIRAL MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 20:</u> ANNUAL REVIEW OF LEUKEMIA MEDICATION AND 30-DAY NOTICE TO PRIOR AUTHORIZE VANFLYTA® (QUIZARTINIB)
20A: CURRENT PRIOR AUTHORIZATION CRITERIA
20B: UTILIZATION OF LEUKEMIA MEDICATIONS
20C: PRIOR AUTHORIZATION OF LEUKEMIA MEDICATIONS

20D: MARKET NEWS AND UPDATES
20E: VANFLYTA® (QUIZARTINIB) PRODUCT SUMMARY
20F: COLLEGE OF PHARMACY RECOMMENDATIONS
20G: UTILIZATION DETAILS OF LEUKEMIA MEDICATIONS
Materials included in agenda packet; presented by Dr. Daugherty
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN MARCH

AGENDA ITEM NO. 21: ANNUAL REVIEW OF ANTI-MIGRAINE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE RIZAFILM® (RIZATRIPTAN FILM) AND ZAVZPRET™ (ZAVEGEPANT NASAL SPRAY)
21A: CURRENT PRIOR AUTHORIZATION CRITERIA
21B: UTILIZATION OF ANTI-MIGRAINE MEDICATIONS
21C: PRIOR AUTHORIZATION OF ANTI-MIGRAINE MEDICATIONS
21D: MARKET NEWS AND UPDATES
21E: PRODUCT SUMMARIES
21F: COLLEGE OF PHARMACY RECOMMENDATIONS
21G: UTILIZATION DETAILS OF ANTI-MIGRAINE MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN MARCH

AGENDA ITEM NO. 22: ANNUAL REVIEW OF ANTI-PARASITIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ALINIA® (NITAZOXANIDE TABLET) AND XDEMVY™ (LOTILANER OPHTHALMIC SOLUTION)
22A: CURRENT PRIOR AUTHORIZATION CRITERIA
22B: UTILIZATION OF ANTI-PARASITIC MEDICATIONS
22C: PRIOR AUTHORIZATION OF ANTI-PARASITIC MEDICATIONS
22D: MARKET NEWS AND UPDATES
22E: PRODUCT SUMMARIES
22F: COLLEGE OF PHARMACY RECOMMENDATIONS
22G: UTILIZATION DETAILS OF ANTI-PARASITIC MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN MARCH

AGENDA ITEM NO. 23: 30-DAY NOTICE TO PRIOR AUTHORIZE YCANTH™ (CANTHARIDIN) AND ZELSUVMI™ (BERDAZIMER)
23A: INTRODUCTION
23B: MARKET NEWS AND UPDATES
23C: PRODUCT SUMMARIES
23D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Morgan
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN MARCH

AGENDA ITEM NO. 24: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED

AGENDA ITEM NO. 25: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
25A: HEMOPHILIA MEDICATIONS
25B: GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)
25C: LYMPHOMA MEDICATIONS
25D: MULTIPLE SCLEROSIS (MS) MEDICATIONS
*Future product and class reviews subject to change.

Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 26: ADJOURNMENT
The meeting was adjourned at 6:02pm.

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

Memorandum

Date: February 16, 2024

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

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

Subject: DUR Board Recommendations from Meeting on February 14, 2024

Recommendation 1: Use of Glucagon-Like Peptide-1 (GLP-1) Agonists and Sodium Glucose Co-Transporter-2 (SGLT-2) Inhibitors with Cardiovascular (CV) Benefit in Members with Type 2 Diabetes (T2D) and High CV Risk or Established Atherosclerotic CV Disease (ASCVD) Mailing Update

NO ACTION REQUIRED.

Recommendation 2: Narrow Therapeutic Index (NTI) Drug List

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of Spravato® (esketamine) to the NTI Drug List based on the drug monitoring required per package labeling.

- Carbamazepine
- Clozapine
- Cyclosporine
- Desipramine
- Digoxin
- Esketamine
- Levothyroxine
- Lithium

- Nortriptyline
- Phenytoin
- Sirolimus
- Tacrolimus
- Theophylline
- Warfarin

Recommendation 3: Vote to Prior Authorize Rystiggo® (Rozanolixizumab-noli), Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc), and Zilbrysq® (Zilucoplan) 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 Rystiggo® (rozanolixizumab-noli) and Zilbrysq® (zilucoplan) with the following criteria (shown in red):

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®); 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); 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.

The College of Pharmacy also recommends the prior authorization of Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) with criteria similar to Vyvgart® (efgartigimod alfa-fcab) and recommends updating the Vyvgart® approval criteria to be consistent with clinical practice (new criteria and changes shown in red):

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

1. An FDA approved diagnosis of generalized myasthenia gravis (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®); 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.

Additionally, the College of Pharmacy recommends the following changes to the Ultomiris® (ravulizumab-cwvz) prior authorization criteria based on the FDA approved age expansion, approval of the sub-Q formulation of Ultomiris®, and to be consistent with clinical practice (changes shown in red):

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. 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 verify member is currently vaccinated against *Neisseria meningitidis*, unless the risks of delaying Ultomiris® treatment outweigh the risks of developing a meningococcal infection; and~~
10. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
11. The subcutaneous (sub-Q) formulation of Ultomiris® will not be approved for a diagnosis of gMG; and
12. Member must not be receiving Ultomiris® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo); and
13. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

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

1. An FDA approved diagnosis of PNH; and
2. Member must be:
   a. ~~18 years~~ 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, 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. 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 changes to the Soliris® (eculizumab) prior authorization criteria based on net cost and to be consistent with clinical practice (changes shown in red):

Soliris® (Eculizumab) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS)]:

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. 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 Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. 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.

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. 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 Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
9. Use of Soliris® will require a patient specific, clinically significant reason why the member cannot use Ultomiris® (ravulizumab-cwvz); and
10. Member must not be receiving Soliris® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo); and
11. 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. 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.

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. Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, 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 Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. 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 Empaveli® (pegcetacoplan), Enspryng® (satralizumab-mwge), and Uplizna® (inebilizumab-cdon) 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, 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. 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.

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

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

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

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

Recommendation 4: Vote to Prior Authorize Exxua™ (Gepirone) and Zurzuvae™ (Zuranolone) and Update the Approval Criteria for the Antidepressants

MOTION CARRIED by unanimous approval.

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

1. Prior authorization of Exxua™ (gepirone) and placement into the Special PA Tier with the following additional criteria; and
2. Prior authorization of Zurzuvae™ (zuranolone) and placement into the Special PA Tier with the following additional criteria; and
3. Moving venlafaxine ER (Effexor XR®) 75mg and 150mg tablets to Tier-1 based on net costs; and
4. The removal of Pexeva® (paroxetine) due to product discontinuation.

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram tabs & soln (Celexa®)			citalopram 30mg caps*
escitalopram tabs & soln (Lexapro®)			fluoxetine tabs*
fluoxetine caps & soln (Prozac®)			fluoxetine DR (Prozac® Weekly™)*
fluvoxamine (Luvox®)			fluvoxamine CR (Luvox CR®)
paroxetine (Paxil®)			paroxetine CR (Paxil CR®)
sertraline tabs & soln (Zoloft®)			~~**paroxetine (Pexeva®)**~~
			sertraline 150mg & 200mg caps*
Dual-Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, XL®)	desvenlafaxine (Pristiq®)	desvenlafaxine (Khedezla®)	bupropion ER (Aplenzin®)
duloxetine (Cymbalta®)		levomilnacipran (Fetzima®)	bupropion ER (Forfivo XL®)
mirtazapine (Remeron®, Remeron SolTab®)		nefazodone (Serzone®)	duloxetine (Drizalma Sprinkle™)*
trazodone 50mg, 100mg, & 150mg tabs (Desyrel®)		vilazodone (Viibryd®)	duloxetine 40mg (Irenka™)*
venlafaxine tabs & ER caps (Effexor®, Effexor XR®)			trazodone 300mg tabs (Desyrel®)*
venlafaxine ER 75mg & 150mg tabs (Effexor XR®)			venlafaxine besylate ER 112.5mg tablets*
			venlafaxine ER **225mg** tabs (Effexor XR®)
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	isocarboxazid (Marplan®)*
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
		vortioxetine (Trintellix®)	dextromethorphan/ bupropion (Auvelity™)*

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
			esketamine nasal spray (Spravato®)*
			gepirone (Exxua™)*
			zuranolone (Zurzuvae™)*

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria applies.
caps = capsules; CR = controlled-release; DR = delayed-release; ER = extended-release; PA = prior authorization; soln = solution; tabs = tablets

Exxua™ (Gepirone) Approval Criteria:

1. An FDA approved diagnosis of major depressive disorder (MDD); and
2. Member must be 18 years of age or older; and
3. Member must have a documented, recent (within 6 months) trial with 2 Tier-1 medications (Tier-1 selection must include at least 1 medication from the SSRI category), 1 Tier-2 medication, and 1 Tier-3 medication at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response; and
4. Member must not have any contraindications to Exxua™, including:
   a. Prolonged QTc interval >450msec; and
   b. Congenital long QT syndrome; and
   c. Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, clarithromycin); and
   d. Severe hepatic impairment; and
   e. Concomitant use of a monoamine-oxidase inhibitor (MAOI) or within 14 days of discontinuing an MAOI; and
5. A quantity limit of 30 tablets per 30 days will apply.

Zurzuvae™ (Zuranolone) Approval Criteria:

1. An FDA approved diagnosis of moderate to severe postpartum depression (PPD); and
2. Member must be ≤12 months postpartum and the date of delivery must be provided; and
3. Member must be a female 18 years of age or older; and
4. Prescriber must verify the following:
   a. Member has been counseled on the proper administration of Zurzuvae™ including taking with a fat-containing meal; and
   b. Member has been counseled on the central nervous system (CNS) depression effects of Zurzuvae™ and the member agrees not to drive or engage in other potentially hazardous activities until at least 12 hours after administration; and
   c. Member is not currently pregnant and will use effective contraception while receiving treatment and for 7 days after the last dose of Zurzuvae™; and

d. Member is not breastfeeding or has agreed to temporarily hold breastfeeding during Zurzuvae™ therapy and for 7 days after the last dose; or
e. If the member does not agree to cease breastfeeding, the following must be provided:
    i. Prescriber attests that the benefits of Zurzuvae™ therapy while breastfeeding outweigh the risks to the infant due to studies showing that Zurzuvae™ is present in breastmilk; and
    ii. Member has been counseled on the potential risks of CNS depression effects that may occur in the infant; and

5. Dosing and approval duration will be limited to the following:
    a. 50mg once daily for 14 days; or
    b. For members with severe hepatic impairment, moderate to severe renal impairment, or concomitant use with CYP3A4 inhibitors:
        i. 30mg once daily for 14 days; and
    c. If a dose reduction to 40mg once daily is required due to CNS depression effects, the prescriber should contact the specialty pharmacy that filled the member's initial Zurzuvae™ prescription to obtain the 20mg capsules from the manufacturer for the remainder of the member's treatment course; and
6. Approvals will be for 1 treatment course.

Recommendation 5: Vote to Prior Authorize Elfabrio® (Pegunigalsidase Alfa-iwxj), Opfolda™ (Miglustat), and Pombiliti™ (Cipaglucosidase Alfa-atga) 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 Elfabrio® (pegunigalsidase alfa-iwxj) with criteria similar to Fabrazyme® (agalsidase beta) and recommends updating the Fabrazyme® approval criteria to be consistent with clinical practice (new criteria and changes shown in red):

Elfabrio® (Pegunigalsidase Alfa-iwxj) and Fabrazyme® (Agalsidase Beta) Approval Criteria:

1. An FDA approved diagnosis of Fabry disease confirmed by 1 of the following:
    a. Molecular genetic testing confirming ~~positive~~ a pathogenic variant in the galactosidase alpha (*GLA*) gene ~~mutation~~ (results of genetic testing must be submitted); or
    b. ~~Decreased plasma levels of~~ Enzyme assay demonstrating a deficiency of alpha-galactosidase A enzyme activity (<5% of normal) (results of assay must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Fabry disease; and

3. Requests for Elfabrio® will require a patient-specific, clinically significant reason why the member cannot use Fabrazyme®; and
4. Member will not be approved for concomitant use with Galafold® (migalastat); 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. ~~Fabrazyme® (agalsidase beta) will initially be approved for~~ Initial approvals will be for the duration of 6 months. After that time, compliance will be required for continued authorization and prescriber must verify the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

The College of Pharmacy also recommends the prior authorization of Opfolda™ (miglustat) and Pombiliti™ (cipaglucosidase alfa-atga) with the following criteria (shown in red):

Opfolda™ (Miglustat) and Pombiliti™ (Cipaglucosidase Alfa-atga) Approval Criteria:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency] confirmed by:
   a. Enzyme assay demonstrating a deficiency of GAA enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *GAA* gene (results of genetic testing must be submitted); and
2. Member must be 18 years of age or older and weigh ≥40kg; and
3. Prescriber must document presence of symptoms of Pompe disease; and
4. Member must be receiving a different enzyme replacement therapy (ERT) for Pompe disease and not experiencing improvement on the current ERT product; and
5. Female members of reproductive potential must have a negative pregnancy test prior to initiation and must agree to use effective contraception during treatment and for at least 60 days after the final dose; and
6. Pombiliti™ must be administered in a health care setting by a health care provider with appropriate equipment and personnel to manage anaphylaxis. Approvals will not be granted for self-administration; and
   a. Must be shipped via cold chain supply to the health care setting where the member is scheduled to receive treatment; and
7. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Pompe disease; and
8. Opfolda™ must be used in combination with Pombiliti™; and

   a. A separate, completed prior authorization request must be received for both medications; and
9. Member will not be approved for concomitant use with other ERT products for Pompe disease; and
10. Member's recent weight must be provided in order to authorize the appropriate amount of drug required according to package labeling; and
11. For Opfolda™, the following quantity limits will apply:
   a. Weight ≥50kg: 8 capsules per 28 days; or
   b. Weight 40kg to <50kg: 6 capsules per 28 days; and
12. Initial approvals will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. 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 other lysosomal storage disease medications (Aldurazyme®, Brineura®, Cerdelga®, Cerezyme®, Cystadrops®, Cystaran®, Elaprase®, Elelyso®, Galafold®, Kanuma®, Lamzede®, Lumizyme®, Mepsevii®, Naglazyme®, Nexviazyme®, Procysbi®, Vimizim®, Vpriv®, Xenpozyme®, and Zavesca®) based on clinical practice and net cost (changes shown in red):

Aldurazyme® (Laronidase) Approval Criteria:

1. An FDA approved diagnosis of Hurler, Hurler-Scheie, or Scheie syndrome (mucopolysaccharidosis type I; MPS I) confirmed by:
   a. Enzyme assay demonstrating a deficiency of alpha-L-iduronidase (IDUA) enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing to confirm biallelic pathogenic mutations in the *IDUA* gene (results of genetic testing must be submitted); and
2. For Scheie syndrome, the prescriber must document that the member has moderate-to-severe symptoms; and
3. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS I; and
4. Aldurazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
6. 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 the duration of 1 year if the member is responding well to treatment.

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 have confirmed TPP-1 enzymatic deficiency via enzyme assay, confirmed by molecular analysis; and~~
3. Member must be 3 years of age or older; and
4. 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
5. Brineura® must be administered in a health care facility by a prescriber who is knowledgeable in intraventricular administration; and
6. Member must not have ventriculoperitoneal shunts or acute intraventricular access device-related complications; and
7. Member must not have documented generalized status epilepticus within 4 weeks of initiating treatment; and
8. Prescriber must verify member's blood pressure and heart rate will be monitored prior to each infusion, during infusion, and post-infusion; and
9. 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
10. A baseline assessment must be performed to assess the Motor plus Language CLN2 score; and
11. 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
12. Approval quantity will be based on package labeling and FDA approved dosing regimen.

Cerdelga® (Eliglustat) Approval Criteria:

1. An FDA approved diagnosis of type 1 Gaucher disease (GD1) confirmed by:
    a. Enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity (≤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. Member is classified as 1 of the following as detected by an FDA-cleared test:
   a. CYP2D6 extensive metabolizers (EMs); or
   b. CYP2D6 intermediate metabolizers (IMs); or
   c. CYP2D6 poor metabolizers (PMs); and
3. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of GD1; and
4. Prescriber must verify the member will not take Cerdelga® concurrently with another therapy for GD1; and
5. For CYP2D6 EMs and IMs, a quantity limit of 56 capsules per 28 days will apply. For CYP2D6 PMs, a quantity limit of 28 capsules per 28 days will apply; and
6. 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.

Cerezyme® (Imiglucerase), Elelyso® (Taliglucerase Alfa), and Vpriv® (Velaglucerase Alfa) Approval Criteria:

1. An FDA approved diagnosis of Gaucher disease (GD) confirmed by:
   a. Enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity (≤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. ~~Diagnosis of~~ Prescriber must confirm member has symptomatic (e.g., anemia, thrombocytopenia, bone disease, splenomegaly, hepatomegaly) type 1 or type 3 GD; and
3. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of GD; and
4. Member's weight (kg) must be provided and must have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
5. Prescriber must verify the member will not take the requested therapy concurrently with another therapy for GD; and
6. 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.

Cystadrops® (Cysteamine 0.37% Ophthalmic Solution) and Cystaran® (Cysteamine 0.44% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication for the treatment of corneal cystine crystal accumulation in members with cystinosis confirmed by 1 of the following:
   a. Identification of cystine crystals in the cornea on slit lamp examination; or
   b. Identification of elevated cystine concentration in polymorphonuclear leukocytes; or
   c. Molecular genetic testing confirming biallelic pathogenic variants in the *CTNS* gene (results of genetic testing must be submitted); and
2. The requested medication must be prescribed by, or in consultation with, an ophthalmologist; and
3. Prescriber must verify that the member has been counseled on the proper storage of the requested medication; and
4. For Cystadrops®, a patient-specific, clinically significant reason (beyond convenience) why the member cannot use Cystaran® must be provided; and
5. A quantity limit of 4 bottles per month will apply.

Elaprase® (Idursulfase) Approval Criteria:

1. An FDA approved diagnosis of Hunter syndrome (mucopolysaccharidosis type II; MPS II) confirmed by:
   a. Enzyme assay demonstrating a deficiency of iduronate-2-sulfatase enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing confirming a hemizygous pathogenic variant in the *IDS* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS II; and
3. 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. 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.

Galafold® (Migalastat) Approval Criteria:

1. An FDA approved diagnosis of Fabry disease with a confirmed amenable galactosidase alpha (*GLA*) gene variant based on *in vitro* assay data (results of genetic testing must be submitted); and
2. Galafold® must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Fabry disease (or an advanced care practitioner with a supervising physician who is a

geneticist or other specialist with expertise in the treatment of Fabry disease); and
3. Member must have an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m^2; and
4. Galafold® will not be approved for concomitant use with enzyme replacement therapy (ERT); and
5. Galafold® will initially be approved for 6 months. After that time, compliance will be required for continued approval and prescriber must verify the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment; and
6. A quantity limit of 14 capsules per 28 days will apply.

Kanuma® (Sebelipase Alfa) Approval Criteria:

1. An FDA approved diagnosis of lysosomal acid lipase (LAL) deficiency confirmed by:
   a. Enzyme assay demonstrating a deficiency of LAL enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *LIPA* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of LAL deficiency; and
3. Kanuma® (sebelipase alfa) must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
5. 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.

Lamzede® (Velmanase Alfa-tycv) Approval Criteria:

1. An FDA approved diagnosis of alpha-mannosidosis confirmed by:
   a. ~~Documented lab results~~ Enzyme assay verifying alpha-mannosidase enzyme activity <11% of normal (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *MAN2B1* gene (results of genetic testing must be submitted); and
2. Member's recent weight (kg) taken within the last 3 weeks must be provided to ensure accurate weight-based dosing; and
3. Female members of reproductive potential must have a negative pregnancy test prior to initiation and must agree to use effective

contraception during treatment and for 2 weeks after the final dose of Lamzede®; and
4. Lamzede® must be administered in a health care setting by a health care provider with appropriate equipment and personnel to manage anaphylaxis. Approvals will not be granted for self-administration; and
    a. Lamzede® must be shipped via cold chain supply to the health care setting where the member is scheduled to receive treatment; and
5. Lamzede® must be prescribed by, or in consultation with, a specialist with expertise in the treatment of lysosomal storage disorders; and
6. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Lumizyme® (Alglucosidase Alfa) Approval Criteria [Infantile-Onset Pompe Disease Diagnosis]:

1. An FDA approved diagnosis of infantile-onset Pompe disease [acid alpha-glucosidase (GAA) deficiency] confirmed by:
    a. Enzyme assay demonstrating a deficiency of GAA enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *GAA* gene (results of genetic testing must be submitted); and
~~2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and~~
3. Lumizyme® must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Pompe disease and/or inherited genetic disorders; and
4. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing.

Lumizyme® (Alglucosidase Alfa) Approval Criteria [Late-Onset (Non-Infantile) Pompe Disease Diagnosis]:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency] confirmed by:
    a. Enzyme assay demonstrating a deficiency of GAA enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *GAA* gene (results of genetic testing must be submitted); and
~~2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and~~
3. Provider must document presence of symptoms of Pompe disease; and
4. Lumizyme® must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Pompe disease and/or inherited genetic disorders; and

5. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing; and
6. Initial approval will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent approvals will be for the duration of 1 year.

Mepsevii® (Vestronidase Alfa-vjbk) Approval Criteria:

1. An FDA approved diagnosis of Sly syndrome (mucopolysaccharidosis VII; MPS VII) confirmed by:
   a. Enzyme assay demonstrating a deficiency of beta-glucuronidase enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing to confirm ~~diagnosis of MPS VII~~ biallelic pathogenic variants in the *GUSB* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS VII; and
3. Mepsevii® must be administered by a health care professional prepared to manage anaphylaxis; and
4. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Naglazyme® (Galsulfase) Approval Criteria:

1. An FDA approved diagnosis of Maroteaux-Lamy syndrome (mucopolysaccharidosis type VI; MPS VI) confirmed by:
   a. Enzyme assay demonstrating a deficiency of arylsulfatase B (ASB) enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing to confirm ~~diagnosis of MPS VI~~ biallelic pathogenic variants in the *ARSB* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS VI; and
3. Naglazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
5. 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 the duration of 1 year if the member is responding well to treatment.

Nexviazyme® (Avalglucosidase Alfa-ngpt) Approval Criteria:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency] confirmed by:
   a. Enzyme assay demonstrating a deficiency of GAA enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *GAA* gene (results of genetic testing must be submitted); and
2. ~~Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and~~
3. Prescriber must document presence of symptoms of Pompe disease; and
4. Nexviazyme® must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Pompe disease and/or inherited genetic disorders; and
5. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing; and
6. Initial approval will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent approvals will be for the duration of 1 year.

Procysbi® (Cysteamine Bitartrate) Delayed-Release Capsule and Granule Approval Criteria:

1. An FDA approved diagnosis of nephropathic cystinosis confirmed by 1 of the following:
   a. Identification of elevated cystine concentration in polymorphonuclear leukocytes; or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *CTNS* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a nephrologist or other specialist with expertise in the treatment of cystinosis; and
3. A patient specific, clinically significant reason why the member cannot use the short-acting formulation, Cystagon® (cysteamine bitartrate), must be provided; and
4. Use of Procysbi® granules will also require a patient specific, clinically significant reason why the member cannot use the capsule formulation of Procysbi®.

Vimizim® (Elosulfase Alfa) Approval Criteria:

1. An FDA approved diagnosis of Morquio A syndrome (mucopolysaccharidosis type IVA; MPS IVA) confirmed by:

a. Enzyme assay demonstrating a deficiency of N-acetylgalactosamine-6-sulfatase (GALNS) enzyme activity (results of assay must be submitted); or
b. Molecular genetic testing to confirm biallelic pathogenic variants in the *GALNS* gene (results of genetic testing must be submitted); and

2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS IVA; and
3. Vimizim® must be administered by a health care professional prepared to manage anaphylaxis; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
5. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Xenpozyme® (Olipudase Alfa-rpcp) Approval Criteria:

1. An FDA approved diagnosis of acid sphingomyelinase deficiency (ASMD) type B or A/B confirmed by:
   a. Documented lab results verifying <10% of acid sphingomyelinase (ASM) activity from control (results of assay must be submitted); or
   b. Molecular genetic testing confirming ~~a mutation~~ biallelic pathogenic variants in the *SMPD1* gene (results of genetic testing must be submitted); and
2. Documentation of baseline AST and ALT within 1 month prior to treatment initiation or within 72 hours prior to treatment escalation; and
3. Member's weight (kg) and body mass index (BMI) within the last 3 weeks must be provided to ensure accurate weight-based dosing; and
   a. BMI ≤30: The dosage is based on actual body weight (kg); or
   b. BMI >30: The dosage is based on adjusted body weight; and
4. Female members of reproductive potential must have a negative pregnancy test prior to initiation and must agree to use effective contraception during treatment and for 2 weeks after the final dose of Xenpozyme®; and
5. Prescriber must verify ALT and AST will be assessed to manage the risk of elevated transaminases as directed by package labeling; and
6. Xenpozyme® must be administered by a health care provider prepared to manage anaphylaxis. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Xenpozyme® will be administered; and
   a. Xenpozyme® must be shipped via cold chain supply to the health care facility where the member is scheduled to receive treatment; or

b. Xenpozyme® must be shipped via cold chain supply to the member's home and administered by a home health care provider prepared to manage anaphylaxis, and the member or member's caregiver must be trained on the proper storage of Xenpozyme®; and
    i. For consideration of home administration by a home health care provider, prescriber must verify member is receiving the maintenance dose and is tolerating the Xenpozyme® infusion well; and
7. Xenpozyme® must be prescribed by, or in consultation with, a specialist with expertise in the treatment of lysosomal storage disorders; 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. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Zavesca® (Miglustat) Approval Criteria:

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 (≤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. Elelyso® (taliglucerase alfa); or
    c. Vpriv® (velaglucerase alfa); and
3. Zavesca® is brand preferred. Requests for generic miglustat 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.

Recommendation 6: Vote to Prior Authorize Hepzato Kit™ (Melphalan) and Zynyz™ (Retifanlimab-dlwr) and Update the Approval Criteria for the Skin Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Hepzato Kit™ (melphalan) and Zynyz™ (retifanlimab-dlwr) with the following criteria (shown in red):

Hepzato Kit™ (Melphalan) Approval Criteria [Uveal Melanoma Diagnosis]:

1. Diagnosis of metastatic uveal melanoma; and
2. Presence of hepatic metastases affecting <50% of the liver; and
3. No other extrahepatic metastases; or
4. Presence of extrahepatic metastases limited to the bone, lymph nodes, subcutaneous tissue, and/or lung that is amenable to resection or radiation.

Zynyz™ (Retifanlimab-dlwr) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. Diagnosis of metastatic or recurrent locally advanced MCC; and
2. Member must be 18 years of age or older; and
3. A maximum treatment duration of 24 months will apply.

The College of Pharmacy also recommends updating the approval criteria for Braftovi® (encorafenib), Cotellic® (cobimetinib), Keytruda® (pembrolizumab), Mekinist® (trametinib), Opdivo® (nivolumab), and Tafinlar® (dabrafenib) based on recent FDA approvals (new criteria and changes shown in red):

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

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

Cotellic® (Cobimetinib) Approval Criteria [Histiocytic Neoplasm Diagnosis]:

1. Diagnosis of a histiocytic neoplasm; and
2. Member must be 18 years of age or older; and
3. Used as a single agent.

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

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

Keytruda® (Pembrolizumab) Approval Criteria [Cervical Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic cervical cancer; and
    a. Tumor must express programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1)]; and

b. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
    i. Disease progression on or after chemotherapy; or
    ii. As first-line therapy in combination with chemotherapy, with or without bevacizumab; or
2. Diagnosis of FIGO Stage III-IV cervical cancer; and
    a. Used in combination with concomitant chemotherapy and radiation.

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

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

Keytruda® (Pembrolizumab) Approval Criteria [Nonmetastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

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

Keytruda® (Pembrolizumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:

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

b. As a single agent within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; or
c. As a single agent frontline for members with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy; and
    i. Cisplatin ineligibility is defined as:
        1. Baseline creatinine clearance of <60mL/min; or
        2. ECOG performance status of 2; or
        3. Class III heart failure; or
        4. Grade 2 or greater peripheral neuropathy; or
        5. Grade 2 or greater hearing loss; or
d. In combination with enfortumab vedotin-ejfv for locally advanced or metastatic urothelial carcinoma; and

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

Mekinist® (Trametinib) Approval Criteria [Low-Grade Glioma (LGG) Diagnosis]:

1. Diagnosis of LGG; and
2. Must be a pediatric member 1 year of age or older; and
3. *BRAF* V600E mutation; and
4. Used in combination with dabrafenib.

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

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member must be 1 year of age or older; and
4. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
5. Used in combination with dabrafenib.

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

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

Opdivo® (Nivolumab) Approval Criteria [Adjuvant Treatment of Melanoma Diagnosis]:

1. Member has had complete resection of melanoma; and
2. Diagnosis of stage 2B, 2C, 3, or 4 melanoma following complete resection; and
3. Member is 12 years of age or older; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
5. Used as a single agent; and
6. Dose as follows:

a. Adult and pediatric patients ≥40kg: 240mg every 2 weeks or 480mg every 4 weeks; ~~and~~ or
b. Pediatric patients <40kg: 3mg/kg every 2 weeks or 6mg/kg every 4 weeks; and
c. Maximum duration of 1 year.

Opdivo® (Nivolumab) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. Member is 12 years of age or older; and
3. Used as a single agent or in combination with ipilimumab:
   a. As first-line therapy for untreated melanoma; or
   b. As second-line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy; and
      i. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Dose as follows:
   a. Single agent:
      i. Adult and pediatric patients ≥40kg: 240mg every 2 weeks or 480mg every 4 weeks; or
      ii. Pediatric patients <40kg: 3mg/kg every 2 weeks or 6mg/kg every 4 weeks; or
   b. In combination with ipilimumab:
      i. Adult and pediatric patients ≥40kg: Nivolumab 1mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 240mg every 2 weeks or 480mg every 4 weeks; or
      ii. Pediatric patients <40kg: 1mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 3mg/kg every 2 weeks or 6mg/kg every 4 weeks.

Tafinlar® (Dabrafenib) Approval Criteria [Low-Grade Glioma (LGG) Diagnosis]:

1. Diagnosis of LGG; and
2. Must be a pediatric member 1 year of age or older; and
3. *BRAF* V600E mutation; and
4. Used in combination with trametinib.

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

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member must be 1 year of age or older; and
4. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
5. Used in combination with trametinib.

Lastly, the College of Pharmacy recommends updating the Opdivo® (nivolumab) approval criteria for a diagnosis of classical Hodgkin lymphoma based on National Comprehensive Cancer Network (NCCN) recommendations (changes shown in red):

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

1. Diagnosis of relapsed or refractory classical Hodgkin lymphoma; and
   a. Exception: lymphocyte-predominant HL
2. Nivolumab must be used in 1 of the following settings:
   a. As a single-agent; or
   b. In combination with brentuximab vedotin as second line or subsequent therapy after failure of autologous stem cell transplant (SCT), allogeneic SCT, or those who are transplant-ineligible; and
3. Member has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)].

Recommendation 7: Vote to Update the Approval Criteria for the Gastrointestinal (GI) Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for Ayvakit® (avapritinib) based on the recent FDA approval for indolent systemic mastocytosis (ISM) and updating the approval age for the other Ayvakit® indications to be consistent with FDA approved labeling (changes shown in red):

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

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

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

1. Diagnosis of unresectable or metastatic GIST ~~in adult members~~; and
2. Member must be 18 years of age or older; and
3. Member has a PDGFRA exon 18 mutation (including PDGFRA D842V mutations).

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

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

The College of Pharmacy also recommends updating the approval criteria for Truseltiq® (infigratinib) based on the manufacturer's planned withdrawal of the medication from the market (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 8: Vote to Prior Authorize Iwilfin™ (Eflornithine), Kepivance® (Palifermin), Loqtorzi™ (Toripalimab-tpzi), and Omisirge® (Omidubicel-onlv)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Iwilfin™ (eflornithine), Kepivance® (palifermin), Loqtorzi™ (toripalimab-tpzi), and Omisirge® (omidubicel-onlv) with the following criteria (shown in red):

Iwilfin™ (Eflornithine) Approval Criteria [Neuroblastoma Diagnosis]:

1. Diagnosis of high-risk neuroblastoma (HRNB); and
2. Member has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy; and
3. Used as a single agent to reduce the risk of relapse for a maximum of 2 years; and
4. Member's recent body surface area (BSA) must be provided.

Kepivance® (Palifermin) Approval Criteria [Oral Mucositis Associated with Autologous Stem Cell Transplant Conditioning Diagnosis]:

1. Diagnosis of hematologic malignancy; and
2. Undergoing autologous stem cell transplantation; and
3. Using a preparative regimen predicted to result in ≥Grade 3 mucositis in >50% of patients; and
4. The preparative regimen and a reference for the preparative regimen must be provided; and
    a. Single dose melphalan 200mg/m^2 is not included as an appropriate preparative regimen due to lack of efficacy of palifermin with this regimen.

Loqtorzi™ (Toripalimab-tpzi) Approval Criteria [Nasopharyngeal Carcinoma (NPC) Diagnosis]:

1. Diagnosis of metastatic or recurrent, locally advanced NPC; and
    a. Used in the first-line setting; and

b. Used in combination with cisplatin and gemcitabine; and
c. Dose as follows:
    i. 240mg every 3 weeks; and
    ii. Maximum duration of 2 years; or
2. Diagnosis of previously treated recurrent unresectable or metastatic NPC; and
    a. Disease has progressed on or following a platinum-containing chemotherapy; and
    b. Used as a single agent; and
    c. Dose as follows:
        i. 3mg/kg every 2 weeks.

Omisirge® (Omidubicel-onlv) Approval Criteria:

1. Member is 12 years of age or older; and
2. Diagnosis of hematological malignancy; and
3. Allogeneic stem cell transplant using umbilical cord blood donor source is planned; and
    a. Documentation of the donor source must be provided; and
4. Myeloablative conditioning regimen will be used; and
    a. Documentation of the member's conditioning regimen must be provided; and
5. Will be used to reduce time to neutrophil recovery and incidence of infection.

Recommendation 9: Vote to Prior Authorize Ogsiveo™ (Nirogacestat)

MOTION CARRIED by unanimous approval.

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

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

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

Recommendation 10: Vote to Prior Authorize Renagel® (Sevelamer Hydrochloride) and Xphozah® (Tenapanor) and Update the Approval Criteria for the Hyperphosphatemia Medications

MOTION CARRIED by unanimous approval.

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

Xphozah® (Tenapanor) Approval Criteria:

1. An FDA approved indication to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis; and

2. Member must be 18 years of age or older; and
3. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use all phosphate binders available without prior authorization must be provided; and
4. Documented trial of inadequate response to at least 1 iron-based phosphate binder [e.g., Auryxia® (ferric citrate), Velphoro® (sucroferric oxyhydroxide)] or a patient-specific clinically significant reason why the member cannot use an iron-based phosphate binder must be provided.

The College of Pharmacy also recommends the prior authorization of Renagel® (sevelamer hydrochloride) based on net cost with the following criteria (shown in red):

Renagel® (Sevelamer Hydrochloride) Approval Criteria:

1. An FDA approved indication for the control of serum phosphorus in members with chronic kidney disease (CKD) on dialysis; and
2. A patient-specific, clinically significant reason why the member cannot use Renvela® (sevelamer carbonate) 800mg tablets or other phosphate binders available without prior authorization must be provided.

Additionally, the College of Pharmacy recommends updating the Auryxia® (ferric citrate), Fosrenol® (lanthanum carbonate), and Velphoro® (sucroferric oxyhydroxide) approval criteria based on net cost (changes shown in red):

Auryxia® (Ferric Citrate) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; and
   a. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use ~~a~~ all phosphate binders available without prior authorization must be provided; ~~or~~ and
   b. A patient-specific, clinically significant reason why the member cannot use Velphoro® (sucroferric oxyhydroxide) must be provided; or
2. An FDA approved diagnosis of iron deficiency anemia (IDA) in members with CKD not on dialysis; and
   a. Documented lab results verifying IDA; and
   b. Documented intolerance or inadequate response to prior treatment with oral iron; and
3. A quantity limit of 12 tablets per day will apply based on the maximum recommended dose.

Lanthanum Carbonate (Generic Fosrenol®) ~~(Lanthanum Carbonate) 1,000mg Chewable Tablets, 750mg Oral Powder, and 1,000mg Oral Powder~~ Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with end stage renal disease (ESRD); and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use ~~a~~ all phosphate binders available without prior authorization must be provided; and
3. ~~For the approval of Fosrenol® oral powder, a patient-specific, clinically significant reason why a special formulation is needed over a phosphate binder available without prior authorization, such as brand Fosrenol® 500mg or 750mg chewable tablets which can be crushed, must be provided; and~~
4. ~~For the approval of Fosrenol® 1,000mg chewable tablets, a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without a prior authorization, such as brand Fosrenol® 500mg or 750mg chewable tablets, must be provided; and~~
5. Fosrenol® ~~500mg or 750mg chewable tablets are~~ is brand preferred. Authorization of the generic formulation requires a patient-specific, clinically significant reason why the member cannot use the brand formulation.

Velphoro® (Sucroferric Oxyhydroxide) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use ~~a~~ all phosphate binders available without prior authorization must be provided.

Generic calcium acetate containing products, brand name Fosrenol® (lanthanum carbonate ~~500mg and 750mg~~ chewable tablet and oral powder packet), PhosLo® (calcium acetate gel capsule), Phoslyra® (calcium acetate oral solution), ~~Renagel® (sevelamer hydrochloride tablet),~~ and Renvela® (sevelamer carbonate tablet and packet for suspension) are currently available without prior authorization.

Recommendation 11: Vote to Prior Authorize Atorvaliq® (Atorvastatin Oral Suspension) and Update the Approval Criteria for the Antihyperlipidemics

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Atorvaliq® (atorvastatin oral suspension) and placement into the Special Prior

Authorization (PA) Tier of the Statin Medications and Ezetimibe Product Based Prior Authorization (PBPA) category with the following additional criteria (changes shown in red):

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

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

Statin Medications Special Prior Authorization Approval Criteria:

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

The College of Pharmacy also recommends the following changes to the Evkeeza® (evinacumab-dgnb), Juxtapid® (lomitapide), Leqvio® (inclisiran), Nexletol® (bempedoic acid), Nexlizet® (bempedoic acid/ezetimibe), and the PCSK9 inhibitor approval criteria based on the new FDA approved label expansions and updates and to be consistent with clinical practice (changes shown in red):

Evkeeza® (Evinacumab-dgnb) Approval Criteria:

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

functionality via genetic testing (results of genetic testing must be submitted); or
   b. An untreated LDL >500mg/dL and at least 1 of the following:
      i. Documented evidence of definite HeFH in both parents; or
      ii. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; and
2. Member must be 5 ~~12~~ 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. Continued authorization at that time will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of this medication, and compliance will be checked at that time and every 6 months thereafter for continued approval.

Juxtapid® (Lomitapide) Approval Criteria:

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

ii. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; and

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

Leqvio® (Inclisiran) Approval Criteria:

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

a. High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy; and
b. Ezetimibe; and
c. Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®); and

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

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

1. An FDA approved indication as an adjunct to diet and ~~maximally tolerated~~ 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. 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.

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 know to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
      ii. Both of the following:
         1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and

2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or

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

b. Homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:

i. Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or

ii. An untreated LDL >500mg/dL and at least 1 of the following:

1. Documented evidence of definite HeFH in both parents; or
2. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; or

c. As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease (CVD); and

i. Documentation of established CVD; and

ii. Supporting diagnoses/conditions and date of occurrence signifying established CVD; or

d. Primary hyperlipidemia; and

i. Member's untreated LDL-C level must be ≥190mg/dL; and

ii. Current LDL-C level is ≥100mg/dL; and

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

6. Member must have a recent trial with a statin with ezetimibe, or a recent trial of ezetimibe without a statin for members with a documented statin intolerance, or a patient-specific, clinically significant reason why ezetimibe is not appropriate must be provided; and
7. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
8. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
9. A quantity limit of 2 syringes or pens per 28 days will apply 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
10. Initial approvals will be for the duration of 3 months. Continued authorization at that time will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication, and compliance will be checked at that time and every 6 months thereafter for continued approval.

Finally, the College of Pharmacy recommends the removal of Welchol® (colesevelam) chewable bar due to product discontinuation (changes shown in red):

~~**Welchol (Colesevelam) Chewable Bar and**~~ **Welchol (Colesevelam) Packets for Oral Suspension Approval Criteria:**

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

Recommendation 12: Vote to Prior Authorize Oxybutynin 2.5mg Tablet and Update the Approval Criteria for the Bladder Control Medications

MOTION CARRIED by unanimous approval.

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

1. Adding oxybutynin 2.5mg tablet to the Special Prior Authorization (PA) Tier with the following additional criteria; and
2. Making Toviaz® (fesoterodine) brand preferred; and

3. Moving Gelnique® (oxybutynin gel) from Tier-3 to Tier-1.

Bladder Control Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
fesoterodine (Toviaz®) – **Brand Preferred**	tolterodine (Detrol®)	darifenacin (Enablex®)	desmopressin acetate SL tablets (Nocdurna®)
oxybutynin (Ditropan®)	tolterodine ER (Detrol LA®)	mirabegron (Myrbetriq®)Δ tablets and granulesβ	**oxybutynin 2.5mg tablet**
oxybutynin ER (Ditropan XL®)		~~**oxybutynin gel (Gelnique®)**~~	oxybutynin patch (Oxytrol®)
oxybutynin gel (Gelnique®)		trospium ER (Sanctura XR®)	vibegron (Gemtesa®)
solifenacin (VESIcare®)Δ			
solifenacin oral susp (VESIcare LS™)α			
trospium (Sanctura®)			

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria applies.
ΔUnique criteria specific to use of Myrbetriq® (mirabegron) in combination with VESIcare® (solifenacin) applies.
αAn age restriction of 2 to 10 years of age will apply for VESIcare LS™. Members older than 10 years of age will require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.
βThe Myrbetriq® granule formulation is covered for members 3 years of age or older weighing <35kg. Members weighing ≥35kg will require a patient-specific, clinically significant reason why the granule formulation is needed in place of the regular tablet formulation.
ER = extended-release; PA = prior authorization; SL = sublingual; susp = suspension

Oxybutynin 2.5mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
   A patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including splitting an oxybutynin 5mg tablet to achieve a 2.5mg dose, must be provided.

Recommendation 13: Vote to Prior Authorize iDose® TR (Travoprost Intracameral Implant) and Update the Approval Criteria for the Glaucoma Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of iDose® TR (travoprost intracameral implant) with the following criteria (shown in red):

iDose® TR (Travoprost Intracameral Implant) Approval Criteria:

1. An FDA approved indication to reduce intraocular pressure (IOP) in members with open-angle glaucoma (OAG) or ocular hypertension (OHT); and
2. Member must be 18 years of age or older; and
3. iDose® TR must be prescribed by, or in consultation with, an ophthalmologist; and
4. A patient-specific, clinically significant reason why the member requires iDose® TR and cannot utilize ophthalmic preparations, such as solution or suspension, to treat OAG or OHT must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Durysta® (bimatoprost intracameral implant) must be provided; and
6. The affected eye has not received prior treatment with iDose® TR; and
7. Member has no contraindications to iDose® TR; and
8. A quantity limit of (1) iDose® TR 75mcg implant per eye per lifetime will apply.

Additionally, the College of Pharmacy recommends the following changes to the current Glaucoma Medications Product Based Prior Authorization (PBPA) category based on net costs (changes shown in red):

1. Making Alphagan® P 0.1% (brimonidine) brand preferred; and
2. Moving Betoptic-S® 0.25% (betaxolol) from Tier-2 to Tier-1; and
3. Making Zioptan® 0.0015% (tafluprost) brand preferred; and
4. Moving Xelpros™ 0.005% (latanoprost) from the Special PA Tier to Tier-2.

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
Alpha-2 Adrenergic Agonists		
brimonidine (Alphagan® 0.2%)	apraclonidine (Iopidine® 0.5%, 1%)	brimonidine (Alphagan-P® 0.15%)
brimonidine (Alphagan® P 0.1%) **– Brand Preferred**		
brimonidine/timolol (Combigan® 0.2%/0.5%) **– Brand Preferred**		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		
Beta-Blockers		
betaxolol (Betoptic-S® 0.25%)	betaxolol (Betoptic® 0.5%, ~~**Betoptic-S® 0.25%**~~)	timolol maleate (Istalol® 0.5%)
brimonidine/timolol (Combigan® 0.2%/0.5%) **– Brand Preferred**	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	timolol maleate (Timoptic® in Ocudose® 0.25%, 0.5%)
carteolol (Ocupress® 1%)	timolol (Betimol® 0.25%, 0.5%)	

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
dorzolamide/timolol (Cosopt® 22.3/6.8mg/mL)	timolol maleate (Timoptic-XE® 0.25%, 0.5%)	
levobunolol (Betagan® 0.25%, 0.5%)		
timolol maleate (Timoptic® 0.25%, 0.5%)		
Carbonic Anhydrase Inhibitors		
acetazolamide (Diamox® 500mg caps; 125mg, 250mg tabs)+	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	methazolamide (Neptazane® 25mg, 50mg tabs)+
brinzolamide (Azopt® 1%) – **Brand Preferred**		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		
dorzolamide (Trusopt® 2%)		
dorzolamide/timolol (Cosopt® 22.3/6.8mg/mL)		
Cholinergic Agonists/Cholinesterase Inhibitors		
echothiophate iodide (Phospholine Iodide® 0.125%)		
pilocarpine (Isopto® Carpine 1%, 2%, 4%)		
Prostaglandin Analogs		
bimatoprost (Lumigan® 0.01%)	bimatoprost (Lumigan® 0.03%)	latanoprost (Iyuzeh™ 0.005%)
latanoprost (Xalatan® 0.005%)	**latanoprost (Xelpros™ 0.005%)**	~~**latanoprost (Xelpros™ 0.005%)**~~
netarsudil/latanoprost (Rocklatan®)		latanoprostene bunod (Vyzulta® 0.024%)
tafluprost (Zioptan® 0.0015%) – **Brand Preferred**		omidenepag isopropyl (Omlonti® 0.002%)
travoprost (Travatan-Z® 0.004%) – **Brand Preferred**		
Rho Kinase Inhibitors		
netarsudil (Rhopressa® 0.02%)		
netarsudil/latanoprost (Rocklatan®)		

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
+Indicates available oral medications.
Please note: Combination products are included in both applicable pharmaceutical classes; therefore, combination products are listed twice in the tier chart.
caps = capsules; PA = prior authorization; tabs = tablets

Recommendation 14: Annual Review of Otic Anti-Infective Medications

MOTION CARRIED by unanimous approval.

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

1. Moving ciprofloxacin/dexamethasone (generic Ciprodex®) to Tier-2; and
2. Moving ofloxacin (Floxin® Otic) to Tier-1.

Otic Anti-Infective Medications		
Tier-1	**Tier-2**	**Special PA***
acetic acid (Acetasol®, VoSol®)	ciprofloxacin 0.2% (Cetraxal®)	acetic acid/HC (Acetasol® HC, VoSol® HC)
~~**ciprofloxacin/dexamethasone (Ciprodex®)**~~	**ciprofloxacin/dexamethasone (Ciprodex®)**	ciprofloxacin 6% (Otiprio®)
ciprofloxacin/HC (Cipro® HC)	ciprofloxacin/fluocinolone (Otovel®)	
neomycin/colistin/HC/ thonzonium (Coly-Mycin® S, Cortisporin-TC®)	finafloxacin (Xtoro™)	
ofloxacin (Floxin® Otic)	neomycin/polymyxin B/HC (Cortisporin®, Pediotic®)	
	~~**ofloxacin (Floxin® Otic)**~~	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria applies.
HC = hydrocortisone; PA = prior authorization

Recommendation 15: Annual Review of Topical Acne, Psoriasis, and Rosacea Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Zoryve® (roflumilast 0.3% foam) based on the recent FDA approval with the following criteria (shown in red):

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 ≤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.

Additionally, the College of Pharmacy recommends updating the Zoryve® (roflumilast 0.3% cream) approval criteria based on the new FDA approved age expansion (changes shown in red):

Zoryve® (Roflumilast 0.3% Cream) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis; and
2. Member must be 6 ~~12~~ years of age or older; and
3. Member must have a body surface (BSA) involvement of ≤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.

Recommendation 16: Annual Review of Antiviral Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Prevymis® (letermovir) approval criteria based on the new FDA approved label expansion and indication (changes shown in red):

Prevymis® (Letermovir Tablets and Injection) Approval Criteria
[Hematopoietic Stem Cell Transplant (HSCT) Diagnosis]:

1. An FDA approved indication of prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogenic HSCT; and
2. Member must be CMV R+; and
3. Member must have received a HSCT within the last 28 days; and
4. Members taking concomitant cyclosporine will only be approved for the 240mg dose; and
5. Members must not be taking the following medications:
    a. Pimozide; or
    b. Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or
    c. Rifampin; or
    d. Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and
6. Prevymis® must be prescribed by an oncology, hematology, infectious disease, or transplant specialist or advanced care practitioner with a supervising physician who is an oncology, hematology, infectious disease, or transplant specialist; and
7. Prescriber must verify the member will be monitored for CMV reactivation while on therapy; and
8. Approvals will be for the duration of 100 days post-transplant.
    a. For Prevymis® vials, authorization will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
    b. Approval length for vial formulation will be based on duration of need; and
9. Approvals may be extended to 200 days post-transplant if the member is at risk for developing a late CMV infection (the member's risk factors must be provided); and
10. A quantity limit of 1 tablet or vial per day will apply.

Prevymis® (Letermovir Tablets and Injection) Approval Criteria [Kidney Transplant Diagnosis]:

1. An FDA approved indication of prophylaxis of cytomegalovirus (CMV) disease in adult kidney transplant recipients; and
2. Member must be at high risk [i.e., donor CMV-seropositive/recipient CMV-seronegative (D+/R-)]; and
3. Member must have received a kidney transplant within the last 7 days; and
4. Members taking concomitant cyclosporine will only be approved for the 240mg dose; and
5. Members must not be taking the following medications:
    a. Pimozide; or
    b. Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or
    c. Rifampin; or
    d. Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and
6. Prevymis® must be prescribed by an oncology, hematology, infectious disease, or transplant specialist (or an advanced care practitioner with a supervising physician who is an oncology, hematology, infectious disease, or transplant specialist); and
7. Prescriber must verify the member will be monitored for CMV reactivation while on therapy; and
8. Approvals will be for the duration of 200 days post-transplant; and
    a. For Prevymis® vials, authorization will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
    b. Approval length for vial formulation will be based on duration of need; and
9. A quantity limit of 1 tablet or vial per day will apply.

Recommendation 17: Annual Review of Leukemia Medications and 30-Day Notice to Prior Authorize Vanflyta® (Quizartinib)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MARCH 2024.

Recommendation 18: Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize RizaFilm® (Rizatriptan Film) and Zavzpret™ (Zavegepant Nasal Spray)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MARCH 2024.

Recommendation 19: Annual Review of Anti-Parasitic Medications and 30-Day Notice to Prior Authorize Alinia® (Nitazoxanide Tablet) and Xdemvy™ (Lotilaner Ophthalmic Solution)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MARCH 2024.

Recommendation 20: 30-Day Notice to Prior Authorize Ycanth™ (Cantharidin 0.7% Solution) and Zelsuvmi™ (Berdazimer 10.3% Gel)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MARCH 2024.

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

NO ACTION REQUIRED.

Recommendation 22: Future Business

NO ACTION REQUIRED.

STATEMENT OF:
ANTHONY J. CASTALDO,
CEO AND CHAIRMAN OF THE BOARD
acastaldo@haea.org; (866) 798-5598

ON BEHALF OF:
U.S. HEREDITARY ANGIOEDEMA ASSOCIATION
10560 MAIN STREET, SUITE PS40
FAIRFAX CITY, VA 22030

REGARDING:
March 13, 2024, Oklahoma Medicaid Drug Utilization Review Board Meeting
Education on Hereditary Angioedema Therapies and Patient Needs

SUBMITTED TO:
Michyla Adams, PharmD

SUBMITTED ON:
March 4, 2024

About The U.S. Hereditary Angioedema Association (HAEA)
The U.S. HAEA is an 10,500 member strong non-profit advocacy and research organization dedicated to improving the health and wellbeing of people with Hereditary Angioedema (HAE). We provide a support network and a wide range of personalized services for patients and their families. We are also committed to advancing clinical research designed to improve the lives of HAE patients and ultimately find a cure.

About Hereditary Angioedema
Hereditary angioedema (HAE) is a painful, disfiguring, debilitating, and potentially fatal genetic disease that occurs in about 1 in 50,000 people. Symptoms include episodes of swelling in various body parts including the hands, feet, face and airway. Patients often have bouts of excruciating abdominal pain, nausea and vomiting that is caused by swelling in the intestinal wall. Approximately one-third of undiagnosed HAE patients are subject to unnecessary exploratory abdominal surgery. About 50% of patients with HAE at some point in their life will experience dangerous airway swelling, which can lead to death by asphyxiation. The historical mortality rate due to laryngeal swelling is 30 percent.

Due to recent breakthroughs in medical science, HAE is no longer a death sentence and can be managed with appropriate treatments. Modern prophylactic therapies have been proven to eliminate disability and dependency, allowing a relatively full and productive life. People with HAE, however, require constant access to life-saving medication and care. Moreover, care can be highly individualized with patients stable on various therapies and reacting differently to alternatives. Physicians and patients must have access to a full range of HAE treatment options to properly manage and condition.

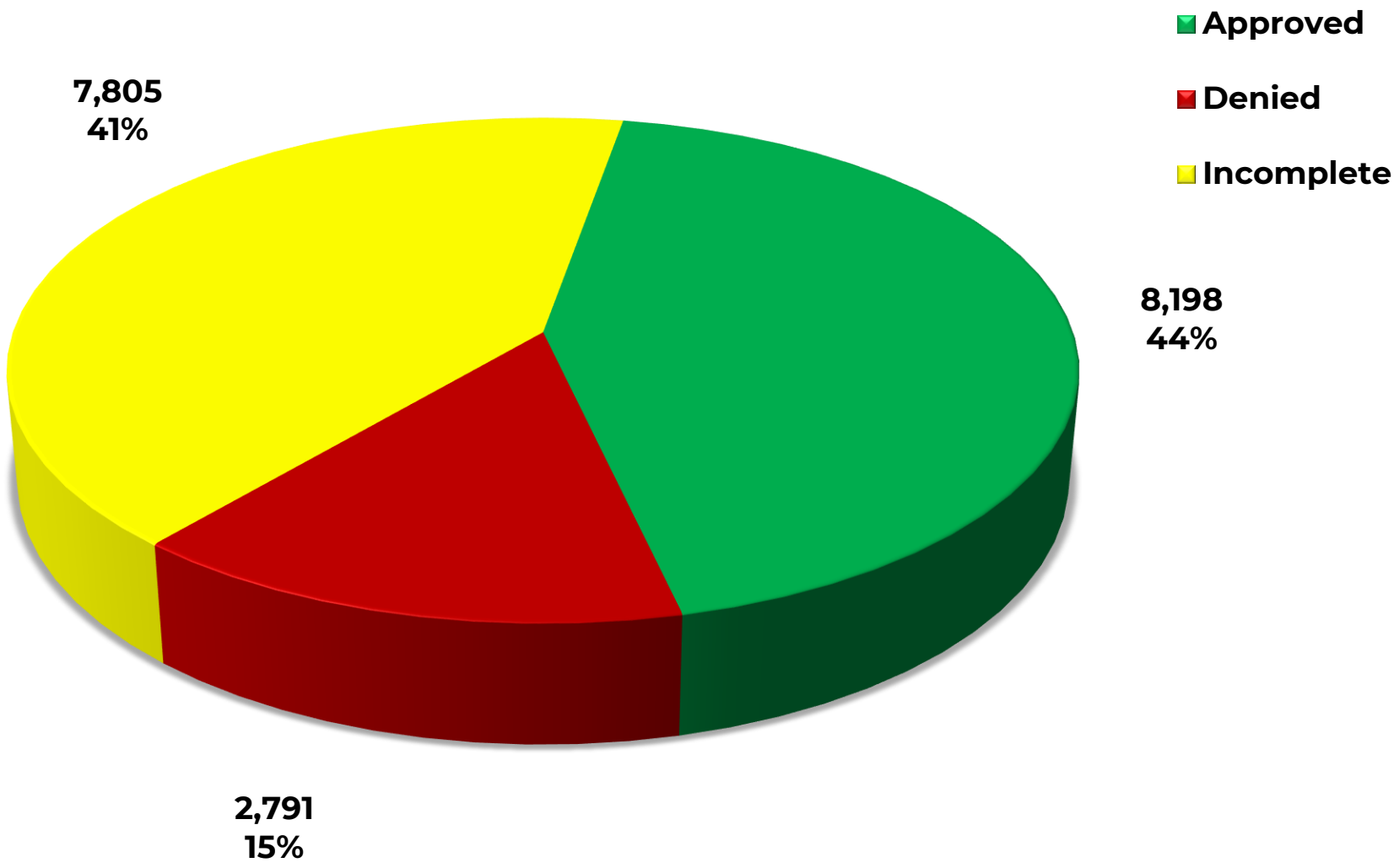
Unfortunately, HAE patients are now facing a variety of arbitrary and life-threatening barriers to access including:

- Baseless prior-authorization requirements,
- Value-frameworks that steer patients away from stable maintenance therapy and into the dangerous situation of treating attacks after they start,
- Restrictions on copay and charitable assistance that jeopardize life-sustaining care, and
- Step-therapy protocols.

Thank you for your time and consideration of these items. Please feel free to call upon the U.S. Hereditary Angioedema Association as a resource.

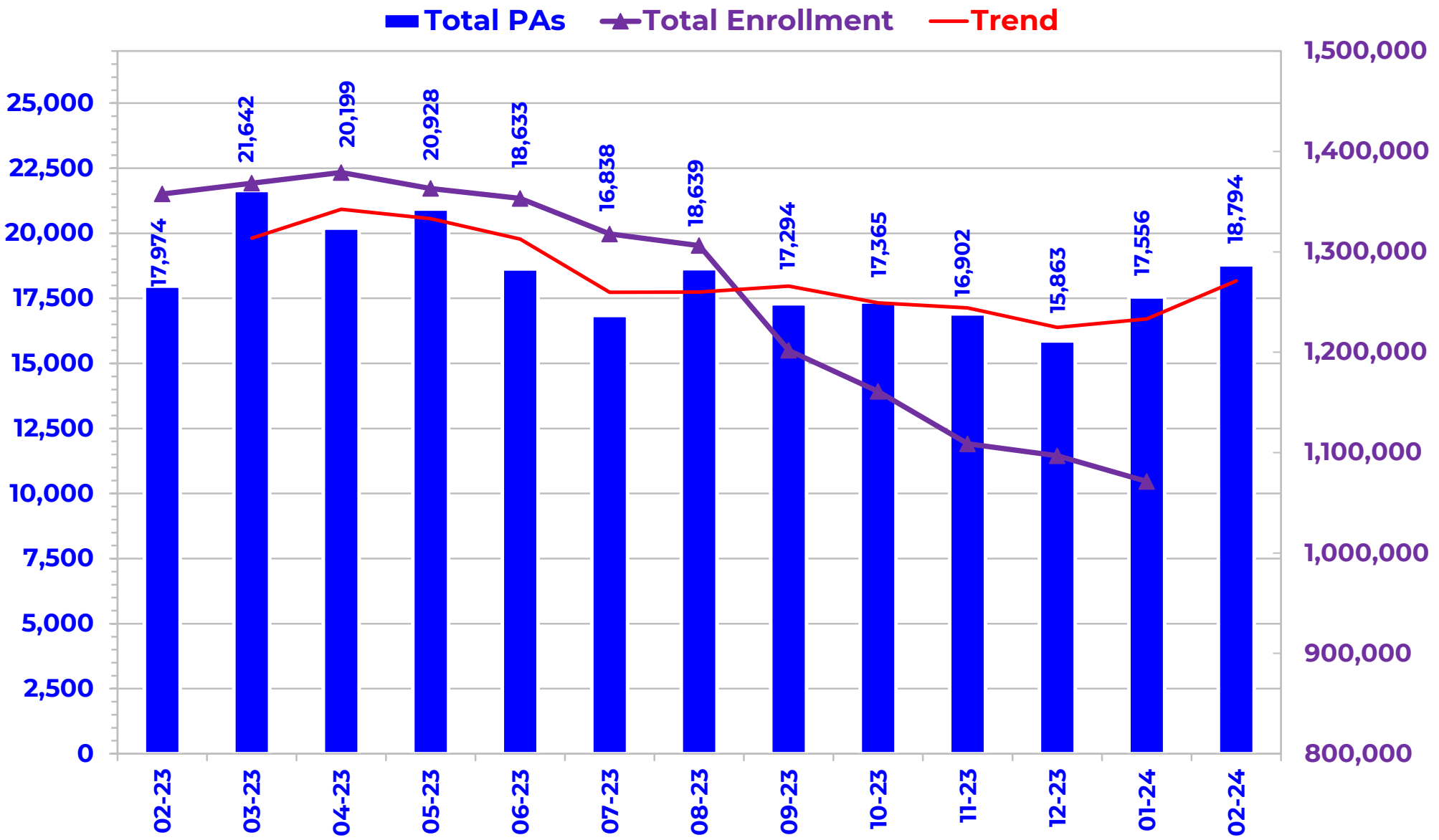
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: FEBRUARY 2024



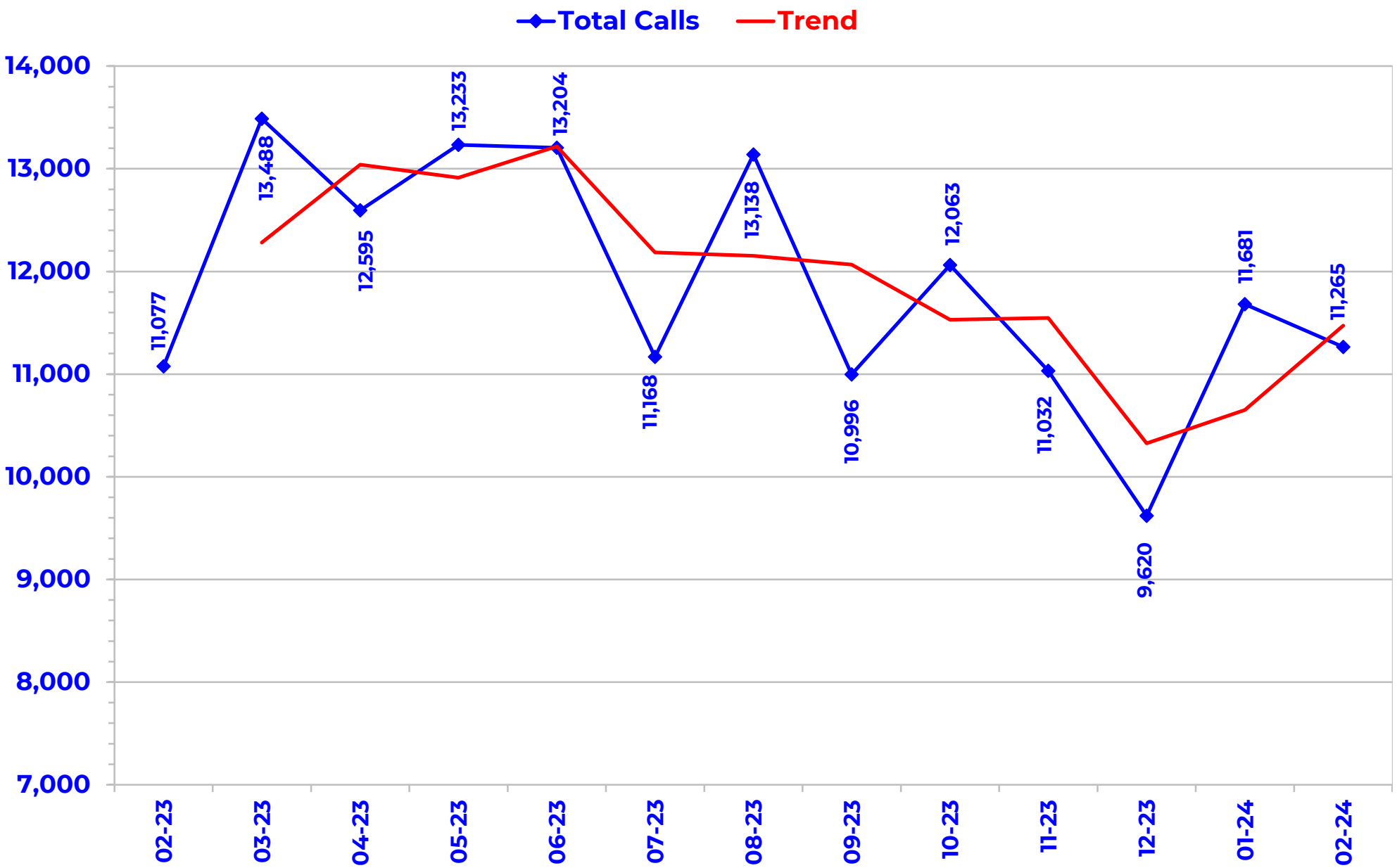
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION (PA) REPORT: FEBRUARY 2023 – FEBRUARY 2024



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: FEBRUARY 2023 – FEBRUARY 2024



Prior Authorization Activity

2/1/2024 Through 2/29/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	228	64	13	151	356
Analgesic - NonNarcotic	14	2	1	11	95
Analgesic, Narcotic	435	199	35	201	126
Angiotensin Receptor Antagonist	10	1	3	6	361
Anti-inflammatory	10	2	2	6	360
Antiasthma	126	24	38	64	264
Antibiotic	48	20	1	27	258
Anticonvulsant	269	122	16	131	327
Antidepressant	497	118	78	301	284
Antidiabetic	2,518	674	722	1,122	356
Antifungal	16	8	1	7	50
Antigout	22	10	3	9	279
Antihemophilic Factor	17	10	0	7	258
Antihistamine	62	23	9	30	344
Antimigraine	733	150	273	310	271
Antineoplastic	299	197	13	89	174
Antiobesity	43	0	40	3	0
Antiparasitic	38	14	2	22	17
Antiparkinsons	21	1	8	12	361
Antiulcers	73	11	8	54	95
Antiviral	21	2	5	14	66
Anxiolytic	36	2	2	32	274
Atypical Antipsychotics	687	255	60	372	355
Benign Prostatic Hypertrophy	20	4	9	7	360
Biologics	486	229	49	208	308
Bladder Control	135	14	33	88	340
Blood Thinners	84	11	1	72	308
Botox	80	52	17	11	360
Buprenorphine Medications	125	42	13	70	123
Calcium Channel Blockers	27	2	4	21	360
Cardiovascular	188	97	18	73	337
Cephalosporins	10	3	1	6	8
Chronic Obstructive Pulmonary Disease	450	69	91	290	355
Constipation/Diarrhea Medications	390	106	95	189	206
Contraceptive	105	55	13	37	279
Corticosteroid	22	6	3	13	167
Dermatological	764	231	226	307	231
Diabetic Supplies	539	216	84	239	185
Endocrine & Metabolic Drugs	388	274	25	89	334

* Includes any therapeutic category with less than 10 prior authorizations for the month.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Erythropoietin Stimulating Agents	37	23	3	11	119
Estrogen Derivative	431	411	4	16	341
Fibric Acid Derivatives	10	0	1	9	0
Fibromyalgia	19	2	0	17	194
Fish Oils	25	3	7	15	360
Gastrointestinal Agents	195	50	33	112	211
Genitourinary Agents	19	1	7	11	361
Glaucoma	26	6	4	16	227
Gonadotropin-releasing Hormone Agonist	82	78	0	4	58
Growth Hormones	129	90	18	21	148
Hematopoietic Agents	26	11	4	11	229
Hepatitis C	23	13	3	7	12
HFA Rescue Inhalers	16	0	0	16	0
Insomnia	167	14	42	111	220
Insulin	440	183	41	216	340
Miscellaneous Antibiotics	26	0	5	21	0
Multiple Sclerosis	103	49	7	47	249
Muscle Relaxant	93	13	18	62	80
Nasal Allergy	46	3	10	33	115
Neurological Agents	252	98	44	110	218
Neuromuscular Agents	16	12	1	3	185
NSAIDs	31	1	6	24	361
Ocular Allergy	16	3	2	11	177
Ophthalmic	23	2	5	16	222
Ophthalmic Anti-infectives	25	8	4	13	65
Ophthalmic Corticosteroid	18	6	2	10	216
Osteoporosis	33	12	7	14	360
Other*	452	136	73	243	282
Otic Antibiotic	30	3	6	21	7
Pediculicide	11	5	0	6	15
Respiratory Agents	63	39	3	21	313
Statins	82	23	22	37	138
Stimulant	2,871	1,623	125	1,123	343
Synagis	14	4	9	1	10
Testosterone	212	47	44	121	332
Thyroid	49	7	9	33	309
Topical Antifungal	55	5	16	34	139
Topical Corticosteroids	42	2	12	28	361
Vitamin	160	27	103	30	233
Pharmacotherapy	59	58	0	1	311
Emergency PAs	0	0	0	0	
Total	**16,463**	**6,391**	**2,715**	**7,357**	

* Includes any therapeutic category with less than 10 prior authorizations for the month.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	38	23	0	15	230
Compound	13	8	0	5	58
Diabetic Supplies	3	3	0	0	128
Dosage Change	419	398	0	21	17
High Dose	5	4	0	1	272
Ingredient Duplication	2	2	0	0	14
Lost/Broken Rx	116	102	4	10	19
MAT Override	302	254	0	48	86
NDC vs Age	342	255	26	61	272
NDC vs Sex	31	26	1	4	259
Nursing Home Issue	87	74	0	13	16
Opioid MME Limit	89	21	4	64	153
Opioid Quantity	38	28	2	8	158
Other	56	48	2	6	20
Quantity vs Days Supply	680	488	30	162	246
STBS/STBSM	16	12	3	1	115
Step Therapy Exception	16	6	4	6	264
Stolen	11	9	0	2	33
Third Brand Request	67	46	0	21	16
Overrides Total	**2,331**	**1,807**	**76**	**448**	
Total Regular PAs + Overrides	**18,794**	**8,198**	**2,791**	**7,805**	

Denial Reasons	
Unable to verify required trials.	6,580
Does not meet established criteria.	2,838
Lack required information to process request.	1,286
Other PA Activity	
Duplicate Requests	1,875
Letters	49,489
No Process	1
Changes to existing PAs	1,277
Helpdesk Initiated Prior Authorizations	1,055
PAs Missing Information	982

* Includes any therapeutic category with less than 10 prior authorizations for the month.

Spring 2024 Pipeline Update

Oklahoma Health Care Authority
March 2024

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.

Invossa™ (TissueGene-C; TG-C)[1,2,3]

Anticipated Indication(s): Treatment of osteoarthritis (OA) of the knee in adults

Clinical Trial(s): Invossa™ is an intra-articular cell and gene therapy containing non-transformed and transduced chondrocytes in a 3:1 ratio that is given on a one-time basis for the treatment of OA in adults. Phase 3 clinical trials for Invossa™ are currently ongoing throughout the United States for the treatment of OA in adults. Invossa™ has been associated with statistically significant improvement in function and pain in patients with OA of the knee.

Place in Therapy: Kolon TissueGene, the maker of Invossa™, is seeking a disease-modifying OA drug designation for Invossa™. The company's goal is for Invossa™ to provide a possible replacement in some patients for traditional treatment and surgeries or to decrease the number of treatments and/or surgeries required by the patient.

SoonerCare Impact: There were approximately 14,500 unique SoonerCare members during calendar year 2023 with a diagnosis of OA of either a single knee or of bilateral knees.

XT-150[4,5]

Anticipated Indication(s): Treatment of OA knee pain in adults is the first indication Xalud Therapeutics is seeking for XT-150. In the future, they plan to

seek indications for diseases such as multiple sclerosis (MS) and neuropathic pain, among others.

Clinical Trial(s): In the initial Phase 2 clinical trial, 56 patients with severe OA of the knee were randomized to 1 intra-articular injection of XT-150 or saline. Dosing of the XT-150 ranged from 15mcg to 600mcg. The Phase 2a trial found only clinically significant improvement in pain after the initial injection for the XT-150 group compared to placebo. The Phase 2b trial included the same patients from the previous trial but did not include a placebo comparator. Preliminary data from this trial found that patients who received 2 injections, the first from Phase 2a and the second from Phase 2b, had greater improvement in their overall knee pain score, with minimal side effects.

Place in Therapy: XT-150 is a novel immune-modulating gene therapy designed to increase the levels of interleukin (IL)-10 and reduce inflammation. IL-10 is rapidly cleared by the body, making it difficult to use in medications for the treatment of inflammation and inflammatory disease states. This novel formulation uses non-integrating DNA plasmids to deliver a long-acting variant of human IL-10 directly to the site of inflammation.

SoonerCare Impact: There were approximately 14,500 unique SoonerCare members during calendar year 2023 with a diagnosis of OA of either a single knee or of bilateral knees.

KarXT (Xanomeline/Trospium)[6,7]

Anticipated Indication(s): Schizophrenia in adults

Clinical Trial(s): The safety and efficacy of KarXT were established in 3 of the clinical trials that were conducted under the EMERGENT program. All 3 evaluated KarXT compared to placebo. In all 3 trials, the primary endpoint was the reduction in the Positive and Negative Syndrome Scale (PANSS) compared to placebo, and KarXT met the primary endpoint in all 3 trials with an 11.6-point reduction in EMERGENT 1, a 9.6-point reduction in EMERGENT 2, and an 8.4-point reduction in EMERGENT 3. Adverse events were said to be mild to moderate in severity and were mostly cholinergic in nature. Complete clinical trial results have not yet been released.

Place in Therapy: KarXT is a dual M1/M4 muscarinic acetylcholine receptor agonist that is thought to decrease the cognitive, positive, and negative symptoms of schizophrenia. The addition of trospium chloride in the combination is thought to decrease the muscarinic side effects caused by xanomeline. Unlike other medications approved to treat schizophrenia, KarXT does not directly block dopamine receptors in order to impact dopamine signaling to the brain.

Projected FDA Decision: 09/26/2024

SoonerCare Impact: During calendar year 2023, diagnosis codes associated with schizophrenia were attributed to approximately 11,600 unique SoonerCare members. There were approximately 51,000 unique members with pharmacy claims for atypical antipsychotic medications (for all diagnoses) during calendar year 2023.

Pipeline Table[8,9]

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
Resmetirom	Madrigal	NASH (liver fibrosis)	Oral	NDA; Brk Thru; Fst Tk	03/14/2024
Atidarsagene Autotemcel	Orchard	Metachromatic leukodystrophy	IV	BLA; OD	03/18/2024
Vadadustat	Akebia	Anemia due to CKD (dialysis-dependent)	Oral	NDA	03/28/2024
RSV Pre-Fusion F Protein Vaccine (mRNA-1345)	Moderna	RSV prevention (ages >60 years)	IM	BLA; Brk Thru; Fst Trk	April 2024
Ceftobiprole Medocaril	Basilea	ABSSSI; CAP; *Staph. aureus* bacteremia	IV	NDA; Fst Trk	April-June 2024
Fidanacogene Elaparvovec	Pfizer/ Genentech	Hemophilia B (adults)	IV	BLA; Brk Thru; OD	April-June 2024
Macitentan/Tadalafil	Janssen	PAH (WHO functional class II-III)	Oral	NDA; OD	05/30/2024
Imetelstat	Geron	MDS (transfusion-dependent, ESA-ineligible)	IV	NDA; Fst Trk; OD	06/20/2024
Ensifentrine	Verona	COPD	Inhaled	NDA	06/26/2024
Marnetegragene Autotemcel	Rocket	Leukocyte adhesion deficiency-I	IV	BLA; Fst Trk; OD	06/30/2024
Crovalimab	Genentech	PNH	IV, SC	BLA; Brk Thru, OD	07/27/2024
Danicopan	AstraZeneca	PNH	Oral	NDA; Brk Thru; OD	07/27/2024
Galantamine Pro-drug (ALPHA-1062)	Alpha Cognition	Alzheimer's disease (mild to moderate)	Oral	505(b)(2) NDA	07/27/2024
Sotatercept	Merck/Bristol-Meyers Squibb	PAH	SC	NDA; Brk Thru; OD	08/01/2024

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
Mavorixafor	X4	WHIM syndrome (ages ≥12 years)	Oral	NDA; Brk Thru; Fst Trk; OD	09/05/2024
Prademagene Zamikeracel (EB-101)	Abeona	Recessive DEB	Surg App	BLA; Brk Thru; OD	09/26/2024
Xanomeline/ Trospium (KarXT)	Karuna	Schizophrenia	Oral	NDA	09/28/2024
Deuruxolitinib	Sun	Alopecia areata (severe)	Oral	NDA; Brk Thru; Fst Trk	10/04/2024

*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. ABSSSI = acute bacterial skin and skin structure infections; BLA = Biologic License Application; Brk Thru = breakthrough; CAP = community acquired pneumonia; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; DEB = dystrophic epidermolysis bullosa; ESA = erythropoietin stimulating agent; Fst Trk = fast track; IM = intramuscular; IV = intravenous; MDS = myelodysplastic syndrome; NASH = non-alcoholic steatohepatitis; NDA = new drug application; OD = orphan drug; PAH = pulmonary arterial hypertension; PNH = paroxysmal nocturnal hemoglobinuria; RSV = respiratory syncytial virus; SC = subcutaneous; SURG APP = surgical application; WHIM = warts, hypogammaglobulinemia, immunodeficiency, and myelokathexis; WHO = World Health Organization

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Appendix C

Vote to Prior Authorize RizaFilm® (Rizatriptan Film) and Zavzpret™ (Zavegepant Nasal Spray) and Update the Approval Criteria for the Anti-Migraine Medications

Oklahoma Health Care Authority
March 2024

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

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

- **March 2023:** The FDA approved Zavzpret™ (zavegepant) migraine nasal spray for the acute treatment of migraine. It is the first nasal spray formulation of a calcitonin gene-related peptide (CGRP) receptor antagonist.
- **April 2023:** The FDA approved RizaFilm® (rizatriptan film) for the treatment of acute migraine.
- **April 2023:** The FDA approved an expanded indication for Qulipta® (atogepant tablet) to include the preventive treatment of both chronic and episodic migraines. Previously, Qulipta® was only indicated for the preventive treatment of episodic migraines.

Guidelines:

- **<u>American Headache Society (AHS):</u>**
  - In April 2020, the AHS created an advisory committee to address the diagnosis and management of migraine in the primary care setting, noting that 36 million people in the United States are affected by migraine and over half (52.8%) of all visits for migraine take place in the primary care setting. However, many primary care providers receive little training in headache medicine during their medical training; therefore, many patients are under-diagnosed and under-treated. Additionally, they estimated a decrease in neurologists and headache specialists in the coming years. The advisory committee met and suggested strategies to help primary care providers which included developing educational materials for primary care providers on the diagnosis and management of headaches.
  - The AHS currently has an online continuing medical education (CME) program called *First Contact–Headache in Primary Care* on their website that includes free resources on topics such as diagnosing migraine, acute and preventive treatment of migraine, lifestyle modification of migraine, and medication overuse headache.

Zavzpret™ (Zavegepant Nasal Spray) Product Summary[7]

Therapeutic Class: CGRP receptor antagonist

Indication(s): Treatment of acute migraines with or without aura in adults

How Supplied: 10mg nasal spray in a single-dose disposable device

Dosing and Administration:

- The recommended dose is 10mg given as a single spray in 1 nostril, as needed.
- The maximum dose in a 24-hour period is 10mg (1 spray).
- The safety of treating more than 8 migraines in a 30-day period has not been established.

Cost Comparison

Product	Cost Per Unit	Cost Per 30 Days*
Zavzpret™ (zavegepant nasal spray) 10mg/1 spray	**$175.94**	**$1,407.52**
Nurtec® ODT (rimegepant ODT) 75mg tablet	$119.63	$2,153.34
Ubrelvy® (ubrogepant) 100mg tablet	$99.24	$1,587.84

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the FDA approved maximum dosing for acute treatment of migraine for each product.
ODT = orally disintegrating tablet; Unit = tablet or nasal spray

Recommendations

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

1. Adding RizaFilm® (rizatriptan film) and Zavzpret™ (zavegepant nasal spray) to the Special PA Tier with the following additional criteria; and
2. Removing the brand preferred status on dihydroergotamine injection (D.H.E. 45®) and dihydroergotamine nasal spray (Migranal®) and making dihydroergotamine nasal spray (Migranal®) the preferred dihydroergotamine product; and
3. Moving Zomig® (zolmitriptan) nasal spray from Tier-1 to the Special PA Tier and removing the brand preferred status; and
4. Moving naratriptan tablet (Amerge®) and zolmitriptan tablet and ODT (Zomig®, Zomig-ZMT®) from Tier-2 to Tier-1; and
5. Moving frovatriptan tablet (Frova®) from Tier-3 to Tier-2; and
6. Moving sumatriptan/naproxen tablet (Treximet®) from Tier-1 to Tier-3.

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
eletriptan tablet (Relpax®)	**frovatriptan tablet (Frova®)**	almotriptan tablet (Axert®)	dihydroergotamine injection (D.H.E. 45®) ~~– Brand Preferred~~
naratriptan tablet (Amerge®)	~~**naratriptan tablet (Amerge®)**~~	~~**frovatriptan tablet (Frova®)**~~	dihydroergotamine nasal spray (Migranal®) – ~~**Brand Preferred**~~
rizatriptan tablet, ODT (Maxalt®, Maxalt MLT®)	~~**zolmitriptan tablet, ODT (Zomig®, Zomig-ZMT®)**~~	**sumatriptan/ naproxen tablet (Treximet®)**	dihydroergotamine nasal spray (Trudhesa®)
sumatriptan tablet (Imitrex®)			ergotamine sublingual tablet (Ergomar®)
~~**sumatriptan/ naproxen tablet (Treximet®)**~~			lasmiditan tablet (Reyvow®)
~~**zolmitriptan nasal spray (Zomig® nasal spray) – Brand Preferred**~~			rimegepant ODT (Nurtec® ODT)
zolmitriptan tablet, ODT (Zomig®, Zomig-ZMT®)			**rizatriptan film (RizaFilm®)**
			sumatriptan injection (Imitrex®)
			sumatriptan injection (Zembrace® SymTouch®)
			sumatriptan nasal powder (Onzetra® Xsail®)
			sumatriptan nasal spray (Imitrex®)
			sumatriptan nasal spray (Tosymra®)
			ubrogepant tablet (Ubrelvy®)
			zolmitriptan nasal spray (~~**generic**~~ Zomig® nasal spray)

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
			zavegepant nasal spray (Zavzpret™)

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

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of ~~brand D.H.E. 45® (dihydroergotamine injection) or brand~~ Migranal® (dihydroergotamine nasal spray) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications. ~~Brand formulation is preferred for D.H.E. 45® and Migranal®; use of the generic formulations will require a patient-specific, clinically significant reason why the member cannot use the brand formulation and lower-tiered triptan medications.~~
2. Use of D.H.E. 45® (dihydroergotamine injection) or Trudhesa® (dihydroergotamine nasal spray) will require a patient-specific, clinically significant reason why the member cannot use ~~the brand formulation of D.H.E. 45®;~~ Migranal® (dihydroergotamine nasal spray)~~,~~ and lower-tiered triptan medications.
3. 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.
4. Use of Reyvow® (lasmiditan), ~~or~~ 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®, ~~and~~ Ubrelvy®, and Zavzpret™ will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor.
5. Nurtec® ODT (rimegepant) Approval Criteria [Migraine Diagnosis (Acute Treatment)]+:
    a. Member must have failed therapy with at least 2* triptan medications or a patient-specific, clinically significant reason why a triptan is not appropriate for the member must be provided; and
    b. Nurtec® ODT will not be approved for concurrent use with a prophylactic CGRP inhibitor; and

c. A quantity limit of 8 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®, ~~and~~ Ubrelvy®, and Zavzpret™ and; however, Nurtec® ODT will follow the same criteria as Reyvow®, ~~and~~ 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.

6. 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.
7. Use of Zembrace® SymTouch® (sumatriptan injection) or Tosymra® (sumatriptan nasal spray) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.
8. Use of ~~generic~~ any non-oral zolmitriptan formulation ~~nasal spray~~ will require a patient-specific, clinically significant reason why the member cannot use the ~~brand formulation of Zomig® nasal spray (brand formulation is preferred) and~~ oral tablet formulation and lower-tiered triptan medications.
9. 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.

Additionally, the College of Pharmacy recommends updating the Nurtec® ODT (rimegepant), Qulipta® (atogepant), and Vyepti® (eptinezumab-jjmr) approval criteria based on the new FDA approved indication for Qulipta® and to be in line with current guideline recommendations (changes shown in red):

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; or
   b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months (*Nurtec® ODT ~~and Qulipta® are~~ 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 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. ~~Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes, but is not limited to:~~
   a. ~~Increased intracranial pressure (e.g., tumor, pseudotumor cerebri, central venous thrombosis); or~~
   b. ~~Decreased intracranial pressure (e.g., post-lumbar puncture headache, dural tear after trauma); and~~
6. 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
7. 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
8. 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
   d. Triptans (≥10 days/month for >3 months); and

9. Member is not taking any medications that are likely to be the cause of the headaches; and
10. ~~Member must have been evaluated within the last 6 months by a neurologist for migraine headaches and the requested medication (e.g., Nurtec® ODT, Qulipta®, Vyepti®) recommended as treatment (not necessarily prescribed by a neurologist); and~~
11. 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
12. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and
13. For Vyepti®, prescriber must verify the medication will be prepared and administered according the Vyepti® package labeling; and
14. A patient-specific, clinically significant reason why member cannot use Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), or Emgality® (galcanezumab-gnlm) must be provided (members currently taking Nurtec® ODT for acute migraine treatment are not exempt from this criteria requirement); and
15. 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
16. 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
17. Quantity limits will apply based on FDA-approved dosing:
    a. For Nurtec® ODT, a quantity limit of 16 orally disintegrating tablets (ODTs) per 30 days will apply; and
    b. For Qulipta®, a quantity limit of 30 tablets per 30 days will apply; and
    c. For Vyepti®, a quantity limit of 3 vials per 90 days will apply.

Finally, the College of Pharmacy recommends updating the Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), and Emgality® (galcanezumab-gnlm) approval criteria 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; 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 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. ~~Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes, but is not limited to:~~
    ~~a. Increased intracranial pressure (e.g., tumor, pseudotumor cerebri, central venous thrombosis); or~~
    ~~b. Decreased intracranial pressure (e.g., post-lumbar puncture headache, dural tear after trauma); and~~
6. 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
7. 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
8. 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
9. Member is not taking any medications that are likely to be the cause of the headaches; and
10. ~~Member must have been evaluated within the last 6 months by a neurologist for migraine headaches and the requested medication (e.g., Aimovig®, Ajovy®, Emgality®) recommended as treatment (not necessarily prescribed by a neurologist); and~~
11. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative CGRP inhibitor; and
12. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and
13. Prescriber must verify member has been counseled on appropriate use, storage of the medication, and administration technique; and
14. 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
15. 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 ≥~~1~~ 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 must have been evaluated within the last 6 months by a neurologist for cluster headaches and the requested medication (e.g., Emgality®) recommended as treatment (not necessarily prescribed by a neurologist); and~~
8. Member will not use Emgality® concurrently with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
9. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and

10. 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
11. A quantity limit of (3) 100mg/mL syringes per 30 days will apply.

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[7] Zavzpret™ (Zavegepant) Nasal Spray Prescribing Information. Pfizer, Inc. Available online: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216386s000lbl.pdf. Last revised 03/2023. Last accessed 02/20/2024.

Appendix D

Vote to Prior Authorize Alinia® (Nitazoxanide Tablet) and Xdemvy™ (Lotilaner Ophthalmic Solution) and Update the Approval Criteria for the Anti-Parasitic Medications

Oklahoma Health Care Authority
March 2024

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

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

- **July 2004:** The FDA approved Alinia® (nitazoxanide) tablets. Nitazoxanide tablets are available generically and are indicated for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum* in patients 12 years of age or older.
- **July 2023:** The FDA approved Xdemvy™ (lotilaner ophthalmic solution) for the treatment of *Demodex* blepharitis. Xdemvy™ targets the underlying cause of *Demodex* blepharitis, *Demodex* mites, and is the first FDA approved treatment for the condition.

Guideline Update(s):

- The National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Human Immunodeficiency Virus (HIV) Medicine Association of the Infectious Disease Society of America (HIVMA/IDSA) guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV recommend trimethoprim/sulfamethoxazole (TMP/SMX) as the preferred regimen for the primary prophylaxis of *Toxoplasma gondii* encephalitis in patients with HIV who are immunoglobulin G (IgG) seropositive for anti-toxoplasma antibodies and who have a CD4 count <100 cells/mm^3. In patients who cannot tolerate TMP/SMX, pyrimethamine (in combination with other agents) is recommended as an alternative regimen for *Toxoplasma* primary prophylaxis, which should be continued until the CD4 count is >200 cells/mm^3 for >3 months in response to antiretroviral therapy (ART). Pyrimethamine is also recommended as the preferred regimen (in combination with other agents) for the treatment of *Toxoplasma* encephalitis in patients with HIV. Acute treatment should be continued for at least 6 weeks, followed by chronic maintenance therapy which should last until the member is asymptomatic and the CD4 count is >200 cells/mm^3 for >6 months in response to ART. Secondary prophylaxis or chronic

maintenance should be restarted if the CD4 count falls below 200 cells/mm^3 following acute treatment.

Alinia® (Nitazoxanide Tablet) Product Summary[5]

Therapeutic Class: Antiprotozoal

Indication(s): Treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum* in patients 12 years of age or older

- **Limitation(s) of Use:** Alinia® tablets have not been shown to be effective for the treatment of diarrhea caused by *Cryptosporidium parvum* in HIV-infected or immunodeficient patients.

How Supplied: 500mg oral tablet

Dosing and Administration: 500mg orally every 12 hours with food for 3 days

Cost: The Wholesale Acquisition Cost (WAC) of generic nitazoxanide tablets varies, with a cost of up to $130.09 per tablet. This results in an estimated cost of up to $780.54 per 3-day treatment course based on recommended dosing.

Xdemvy™ (Lotilaner Ophthalmic Solution) Product Summary[6]

Therapeutic Class: Ectoparasiticide (anti-parasitic agent)

Indication(s): Treatment of *Demodex* blepharitis

How Supplied: 0.25% (2.5mg/mL) ophthalmic solution in a 10mL bottle

Dosing and Administration: 1 drop in each eye twice daily (approximately 12 hours apart) for 6 weeks

- If more than 1 topical ophthalmic drug is being used, the drugs should be administered at least 5 minutes apart.
- If 1 dose is missed, treatment should continue with the next scheduled dose.
- Contact lenses should be removed prior to instillation of Xdemvy™ and may be reinserted 15 minutes following administration.

Cost: The WAC of Xdemvy™ is $1,850 per 10mL bottle. Based on recommended dosing, the cost of the 6-week treatment course would be $1,850, requiring the use of 1 bottle.

Recommendations

The College of Pharmacy recommends the prior authorization of Alinia® (nitazoxanide tablet) and Xdemvy™ (lotilaner ophthalmic solution) with the following criteria (shown in red):

Alinia® (Nitazoxanide Tablet) Approval Criteria:

1. An FDA approved indication for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum; and*
2. Member must be 12 years of age or older; and
3. For *Giardia*, member must have a recent trial of metronidazole or tinidazole or a patient-specific, clinically significant reason why the member cannot use metronidazole and tinidazole must be provided; and
4. A quantity limit of 6 tablets per 3 days will apply.

Xdemvy™ (Lotilaner Ophthalmic Solution) Approval Criteria:

1. An FDA approved diagnosis of *Demodex* blepharitis; and
2. Member must be 18 years or older; and
3. Must be prescribed by an ophthalmologist or optometrist; and
4. Member must meet all of the following in at least 1 eye:
    a. >10 lashes with collarettes present on the upper lid; and
    b. Presence of at least mild erythema of the upper eyelid margin; and
5. Member must agree to remove artificial eyelashes (if present) and forego their use during treatment with Xdemvy™; and
6. A quantity limit of 10mL per 42 days will apply. Approvals will be limited to 1 treatment course per year.

Additionally, the College of Pharmacy recommends updating the Daraprim® (pyrimethamine) approval criteria based the current FDA approved indications and to be in line with guideline-recommended use in patients with HIV (changes shown in red):

Daraprim® (Pyrimethamine) Approval Criteria:

1. An ~~FDA approved~~ indication ~~for the treatment~~ of 1 of the following:
    a. Treatment of toxoplasmosis; or
    ~~b. Susceptible strains of acute malaria; and~~
    c. Prophylaxis of *Toxoplasma gondii* encephalitis in members with human immunodeficiency virus (HIV); and
        i. Member is *Toxoplasma* IgG seropositive; and
        ii. CD4 count is <100 cells/mm^3 (or <200 cells/mm^3 for secondary prophylaxis); and
        iii. A patient-specific, clinically significant reason why trimethoprim/sulfamethoxazole cannot be used must be provided; and
2. Member must take Daraprim® concomitantly with a sulfonamide (for treatment of toxoplasmosis) or with a guideline-recommended regimen (for *Toxoplasma* prophylaxis); and
3. Approval length will be based on recommended dosing regimen specific to the member's diagnosis.

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[2] Tarsus Pharmaceuticals, Inc. FDA Approves Xdemvy™ (Lotilaner Ophthalmic Solution) 0.25% for the Treatment of Demodex Blepharitis. Available online at: https://ir.tarsusrx.com/news-releases/news-release-details/fda-approves-xdemvytm-lotilaner-ophthalmic-solution-025. Issued 07/25/2023. Last accessed 02/26/2024.
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Appendix E

Vote to Prior Authorize Ycanth™ (Cantharidin 0.7% Solution) and Zelsuvmi™ (Berdazimer 10.3% Gel)

Oklahoma Health Care Authority
March 2024

Market News and Updates[1,2]

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

- **July 2023:** Verrica Pharmaceuticals announced the FDA approval of Ycanth™ (cantharidin 0.7% solution) for the treatment of molluscum contagiosum in patients 2 years of age and older. The approval of Ycanth™ is based on 2 Phase 3 randomized controlled trials, CAMP-1 and CAMP-2, that evaluated the safety and efficacy of Ycanth™ compared to placebo in 582 patients. Between the 2 trials, around 50% of patients treated with Ycanth™ saw a complete clearance of molluscum contagiosum lesions after 12 weeks of therapy with minimal side effects compared to about 15% of patients in the placebo group.
- **January 2024:** The FDA approved Zelsuvmi™ (berdazimer 10.3% gel) for the treatment of molluscum contagiosum in patients 1 year of age and older. Its approval is based on the Phase 3 B-Simple trial that enrolled 891 patients who were randomized to either Zelsuvmi™ or placebo. Of the patients randomized to Zelsuvmi™, 43% of patients had 0 to 1 lesion at the 12-week mark compared to only 24.6% of the placebo population. The product is expected to be available in the second half of 2024.

Ycanth™ (Cantharidin 0.7% Solution) Product Summary[3]

Therapeutic Class: Keratolytic agent

Indication(s): Topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older

How Supplied: Carton of 6 or 12 single-use 0.45mL ampules

Dosing and Administration: A small droplet of solution should be applied to each lesion every 3 weeks as needed.

- Ycanth™ should be administered by a health care provider
- More than 2 applicators should not be used in a single treatment session

Cost: The Wholesale Acquisition Cost for Ycanth™ is $685 per ampule, resulting in $5,480 for a 12-week course of treatment, based on the maximum of 2 applicators used per visit.

Zelsuvmi™ (Berdazimer 10.3% Gel) Product Summary[4]

Therapeutic Class: Nitric oxide releasing agent

Indication(s): Topical treatment of molluscum contagiosum in adult and pediatric patients 1 year of age and older

How Supplied: 14 gram tube containing berdazimer 10.3% gel and 17 gram tube containing hydrogel vehicle

Dosing and Administration: Zelsuvmi™ should be applied once daily to each lesion for up to 12 weeks.

- Prior to administration, Zelsuvmi™ and the hydrogel vehicle should be mixed together in equal amounts using the dosing guide provided in each carton.
- An even, thin layer of the mixture should be applied to each lesion immediately after mixing and should be allowed to dry for 10 minutes.
- Swimming, bathing, or washing should be avoided for at least 1 hour.

Cost: Cost information for Zelsuvmi™ is not available at this time.

Recommendations

The College of Pharmacy recommends the prior authorization of Ycanth™ (cantharidin 0.7% solution) and Zelsuvmi™ (berdazimer 10.3% gel) with the following criteria (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. 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

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[1] Verrica Pharmaceuticals. Verrica Pharmaceuticals Announces FDA Approval of Ycanth™ (Cantharidin) Topical Solution 0.7%. Available online at: https://verrica.com/press_release/verrica-pharmaceuticals-announces-fda-approval-of-ycanth-cantharidin-topical-solution-0-7/. Issued 07/21/2023. Last accessed 02/15/2024.

[2] Ligand Pharmaceuticals. U.S. Food and Drug Administration Approves Zelsuvmi™ as a First-in-Class Medication for the Treatment of Molluscum Contagiosum. Available online at: https://investor.ligand.com/news-and-events/press-releases/news-details/2024/U.S.-Food-and-Drug-Administration-Approves-ZELSUVMI-as-a-First-in-Class-Medication-for-the-Treatment-of-Molluscum-Contagiosum/default.aspx. Issued 01/05/2024. Last accessed 02/15/2024.

[3] Ycanth™ (Cantharidin 0.7% Solution) Prescribing Information. Verrica Pharmaceuticals. Available online at: https://verrica.com/wp-content/uploads/2023/07/USPI_FPI-0003_YCANTH.pdf. Last revised 07/2023. Last accessed 02/26/2024.

[4] Zelsuvmi™ (Berdazimer 10.3% Gel) Prescribing Information. Ligand Pharmaceuticals Inc. Available online at: https://zelsuvmi.com/wp-content/uploads/2024/01/ZELSUVMI-Berdazimer-Topical-Gel-10.3.-Prescribing-Information-and-Instructions-for-Use.pdf. Last revised 01/2024. Last accessed 02/26/2024.

Appendix F

Vote to Prior Authorize Vanflyta® (Quizartinib) and Update the Approval Criteria for the Leukemia Medications

Oklahoma Health Care Authority
March 2024

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

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

- **November 2019:** The FDA approved dosing for Calquence® (acalabrutinib) for the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) indicates that it may be used in combination with obinutuzumab in patients with previously untreated CLL or SLL.
- **June 2023:** The FDA approved dosing for Columvi™ (glofitamab-gxbm) for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including large B-cell lymphoma (LBCL) arising from follicular lymphoma indicates that it should be used following a single dose of obinutuzumab 1,000mg administered intravenously (IV) 7 days before initiation of Columvi™.
- **July 2023:** The FDA approved Vanflyta® (quizartinib), in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, as maintenance monotherapy following consolidation chemotherapy, for the treatment of adults with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive, as detected by an FDA-approved test.
- **October 2023:** The FDA approved Tibsovo® (ivosidenib) for a new indication for the treatment of adults with relapsed or refractory myelodysplastic syndromes (MDS) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test.

News:

- **April 2023:** Janssen, the manufacturer of Imbruvica® (ibrutinib), announced the voluntary withdrawal of 2 accelerated approvals for Imbruvica®. Based on discussion with the FDA and the results from the Phase 3 confirmatory studies, the accelerated approvals for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least 1 prior therapy and the treatment of patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least 1 prior anti-CD20-based therapy have been withdrawn. Additionally, the 560mg strength tablet has been

discontinued, as this strength was only FDA approved for the treatment of MCL or MZL.
- **October 2023:** Erwinaze® (asparaginase *Erwinia chrysanthemi*) is currently not being supplied due to ongoing manufacturing issues and capacity constraints. It is currently unknown if the product will be available again. Additionally, Erwinase® (crisantaspase) is no longer being provided for importation into the United States. In 2021, the FDA had previously allowed temporary importation of Erwinase®, which is approved for use in the United Kingdom, to address drug shortages in the United States.

Guideline Update(s):
- The National Comprehensive Cancer Network (NCCN) guidelines for B-cell lymphoma were updated and released on January 18, 2024. The NCCN guidelines continue to make recommendations for ibrutinib for MCL or MZL in certain situations despite the FDA withdrawal of these indications. NCCN guidelines also make recommendations for the use of ibrutinib in hairy cell leukemia and primary central nervous system (CNS) lymphoma. Additionally, the NCCN guidelines make recommendations for the use of zanubrutinib in combination with obinutuzumab for third line or subsequent therapy in follicular lymphoma in patients with no response, relapsed, or progressive disease.

Vanflyta® (Quizartinib) Product Summary[10]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment, in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for adult patients with newly diagnosed AML that is FLT3 ITD-positive
- **Limitation(s) of Use:** Vanflyta® is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with Vanflyta® in this setting has not been demonstrated.

How Supplied: 17.7mg and 26.5mg oral tablets

Dosing and Administration: A treatment course consists of up to 2 cycles of Vanflyta® in combination with induction cytarabine and anthracycline, up to 4 cycles of Vanflyta® in combination with high-dose cytarabine consolidation, and up to 36 cycles of Vanflyta® as maintenance therapy or until disease progression or unacceptable toxicity. Vanflyta® maintenance therapy should be initiated following consolidation chemotherapy upon blood count

recovery of absolute neutrophil count >500/mm^3 and platelet count >50,000/mm^3.

- Induction Cycles: 35.4mg [(2) 17.7mg tablets] once daily on days 8-21 of each 28-day cycle (up to 2 cycles)
- Consolidation Cycles: 35.4mg [(2) 17.7mg tablets] once daily on days 6-19 of each 28-day cycle (up to 4 cycles)
- Maintenance Cycles: 26.5mg or 53mg [(2) 26.5mg tablets] once daily (depending on QTcF) (up to 36 cycles)
- Refer to the full *Prescribing Information* for the complete dosing recommendations.

Cost: The Wholesale Acquisition Cost (WAC) is $546 per tablet, regardless of strength. For induction or consolidation dosing, this would result in a cost of $15,288 per 28-day cycle. For maintenance dosing, this would result in a maximum cost of $30,576 per 28 days or $397,488 per year for a member using the 53mg once daily dose.

Recommendations

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

Vanflyta® (Quizartinib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly diagnosed AML; and
2. Disease is positive for FLT3 internal tandem duplication (FLT3-ITD) as detected by an FDA-approved test; and
3. Will be used in 1 of the following settings:
    a. In combination with standard anthracycline and cytarabine-based induction; or
    b. In combination with standard cytarabine-based consolidation; or
    c. As maintenance therapy following standard anthracycline and cytarabine-based induction and cytarabine-based consolidation.

Additionally, the College of Pharmacy recommends updating the prior authorization criteria for Gazyva® (obinutuzumab) and Tibsovo® (ivosidenib) based on recent FDA approval, to be consistent with the FDA approved dosing for Calquence® (acalabrutinib) and Columvi™ (glofitamab-gxbm), and based on NCCN recommendations (changes shown in red):

Gazyva® (Obinutuzumab) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

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

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

Gazyva® (Obinutuzumab) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. Diagnosis of relapsed or refractory DLBCL not otherwise specified, including large B-cell lymphoma (LBCL) arising from follicular lymphoma; and
2. Used as lymphoid depletion pretreatment prior to glofitamab; and
3. Member must meet criteria for glofitamab; and
4. Dosing will be 1,000mg as a single dose 7 days prior to start of glofitamab.

Gazyva® (Obinutuzumab) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Grade 1 or 2 members with Stage I (≥7cm), contiguous Stage II (≥7cm), noncontiguous Stage II, Stage III, or Stage IV members (first, second, or subsequent therapy); and
   a. In combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP), cyclophosphamide, vincristine, and prednisone (CVP), or bendamustine; and
   b. When used for maintenance therapy, a total of 12 doses will be approved; or
2. Third line or subsequent therapy for FL in members with no response, relapsed, or progressive disease; and
   a. Used in combination with zanubrutinib.

Tibsovo® (Ivosidenib) Approval Criteria [Myelodysplastic Syndromes (MDS) Diagnosis]:

1. Diagnosis of relapsed or refractory MDS; and
2. Presence of isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test.

Next, the College of Pharmacy recommends updating the prior authorization criteria for Asparlas® (calaspargase pegol-mknl) and Oncaspar® (pegaspargase) for a diagnosis of ALL to be more consistent with the FDA-approved labeling for these medications (changes shown in red):

Asparlas® (Calaspargase Pegol-mknl) and Oncaspar® (Pegaspargase) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of ALL; and
2. Used as a component of multi-agent chemotherapy; and
~~3. Used as first line therapy; or~~

~~4. May be used to treat members with a hypersensitivity to native forms of L-asparaginase; or~~
~~5. Used as systemic central nervous system (CNS)-directed therapy; or~~
~~6. Used in relapsed/refractory disease; and~~
~~a. Philadelphia chromosome negative (Ph-); or~~
~~b. Philadelphia chromosome positive (Ph+); and~~
~~i. Refractory to tyrosine kinase inhibitor (TKI) therapy or used in conjunction with a TKI (if not previously used); and~~

7. For Asparlas®, a patient-specific, clinically significant reason why the member cannot use Oncaspar® (pegaspargase) must be provided; and
8. For Asparlas®, member must be 1 month to 21 years of age.

The College of Pharmacy also recommends updating the prior authorization criteria for Erwinase® (crisantaspase), Erwinaze® (asparaginase *Erwinia chrysanthemi*), and Rylaze® [asparaginase *Erwinia chrysanthemi* (recombinant)-rywn] based on current product availability in the United States (changes shown in red):

~~Erwinase® (Crisantaspase), Erwinaze® (Asparaginase *Erwinia Chrysanthemi*), and~~ Rylaze® [Asparaginase *Erwinia Chrysanthemi* (Recombinant)-rywn] Approval Criteria [Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma Diagnosis]:

1. Diagnosis of ALL or lymphoblastic lymphoma; and
2. Used as a component of multi-agent chemotherapy; and
3. Member has a documented hypersensitivity to *Escherichia coli*-derived ~~asparaginase~~ asparagine-deprivation product.

The College of Pharmacy also recommends updating the approval criteria for Imbruvica® (ibrutinib) based on NCCN recommendations (changes shown in red)

Imbruvica® (Ibrutinib) Approval Criteria [~~Histologic Transformation of Marginal Zone Lymphoma (MZL) to Diffuse Large B-Cell Lymphoma (DLBCL)~~ B-Cell Lymphomas Diagnosis]:

1. As ~~third~~ second-line or ~~greater~~ subsequent therapy for members ~~who have transformed to non-germinal center DLBCL~~ with a diagnosis of B-cell lymphoma [including diffuse large B-cell lymphomas, human immunodeficiency virus (HIV)-related B-cell lymphomas, post-transplant lymphoproliferative disorders, and high-grade B-cell lymphoma].

Imbruvica® (Ibrutinib) Approval Criteria [Hairy Cell Leukemia Diagnosis]:

1. Diagnosis of hairy cell leukemia; and
2. As third-line or subsequent therapy for refractory or progressive disease.

Imbruvica® (Ibrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. As second-line or subsequent therapy; ~~and~~ or
2. ~~As a single agent or in combination with rituximab or lenalidomide/rituximab~~
3. Used in combination with rituximab prior to induction therapy; or
4. Used as a component of aggressive induction therapy; or
5. Used as maintenance therapy following aggressive induction therapy or hematopoietic stem cell transplant (HSCT).

Imbruvica® (Ibrutinib) Approval Criteria [Primary Central Nervous System (CNS) Lymphoma Diagnosis]:

1. Diagnosis of primary CNS lymphoma; and
2. Member is not a candidate for or is intolerant to high-dose methotrexate according to the prescriber; or
3. As second-line or subsequent therapy for refractory or progressive disease.

Lastly, the College of Pharmacy recommends adding additional approval criteria for all oncology medication categories to clarify the typical approval duration and the requirement for oncology specialist review (new criteria shown in red):

Oncology Medications Additional Criteria:

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

[1] Calquence® (Acalabrutinib) Prescribing Information. AstraZeneca. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/216387Orig2s000Correctedlbl.pdf. Last revised 08/2022. Last accessed 02/26/2024.
[2] Columvi™ (Glofitamab-gxbm) Prescribing Information. Genentech, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761309s000lbl.pdf. Last revised 06/2023. Last accessed 02/26/2024.
[3] U.S. FDA. FDA Approves Quizartinib for Newly Diagnosed Acute Myeloid Leukemia. Available online at: https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-quizartinib-newly-diagnosed-acute-myeloid-leukemia. Issued 07/20/2023. Last accessed 02/26/2024.
[4] U.S. FDA. FDA Approves Ivosidenib for Myelodysplastic Syndromes. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-ivosidenib-myelodysplastic-syndromes. Issued 10/24/2023. Last accessed 02/26/2024.
[5] Janssen Pharmaceutical Companies. Update on Imbruvica® (ibrutinib) U.S. Accelerated Approvals for Mantle Cell Lymphoma and Marginal Zone Lymphoma Indications. Available online at: https://www.jnj.com/update-on-imbruvica-ibrutinib-u-s-accelerated-approvals-for-mantle-cell-lymphoma-and-marginal-zone-lymphoma-indications. Issued 04/06/2023. Last accessed 02/26/2024.
[6] Current Drug Shortages – Asparaginase Erwinia Chrysanthemi. *ASHP*. Available online at: https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=482. Issued 10/21/2023. Last accessed 02/26/2024.
[7] U.S. FDA. Temporary Importation of Erwinase® (Crisantaspase) Injection, Powder, Lyophilized, for Solution to Address a Drug Shortage in the United States (U.S.). Available online at: https://www.fda.gov/media/149614/download. Issued 05/25/2021. Last accessed 02/26/2024.
[8] National Comprehensive Cancer Network (NCCN). B-Cell Lymphomas Clinical Practice Guidelines in Oncology. Available online at: http://www.nccn.org. Last revised 01/18/2024. Last accessed 02/26/2024.
[9] Dreyling M, Doorduijn JK, Gine E, et al. Efficacy and Safety of Ibrutinib Combined with Standard First-Line Treatment or As Substitute for Autologous Stem Cell Transplantation in Younger Patients with Mantle Cell Lymphoma: Results from the Randomized Triangle Trial by the European MCL Network. *Blood* 2022; 140 (Supplement 1): 1–3. doi: 10.1182/blood-2022-163018.
[10] Vanflyta® (Quizartinib) Prescribing Information. Daiichi Sankyo, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216993s000lbl.pdf. Last revised 07/2023. Last accessed 02/26/2024.

Appendix G

Calendar Year 2023 Annual Review of Skyclarys® (Omaveloxolone)

Oklahoma Health Care Authority
March 2024

Current Prior Authorization Criteria

Skyclarys® (Omaveloxolone) Approval Criteria:

1. An FDA approved diagnosis of Friedrich's ataxia (FRDA); and
    a. Diagnosis must be confirmed by genetic testing identifying a mutation in the *FXN* gene (results of genetic testing must be submitted); and
2. Member must be 16 years of age or older; and
3. Skyclarys® 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 a left ventricular ejection fraction of ≥40%; and
5. Member must not be taking concomitant strong or moderate CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin) or the prescriber must verify the dose of Skyclarys® will be adjusted during concomitant use according to package labeling; and
6. Member must not be taking concurrent strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, long-acting barbiturates, bosentan, efavirenz, etravirine); and
7. Member must not have severe hepatic impairment (Child-Pugh class C); and
8. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Skyclarys® treatment, every month for the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
9. Prescriber must verify that B-type natriuretic peptide (BNP) will be assessed prior to initiation of Skyclarys® and cardiac function will be monitored as clinically indicated; and
10. Prescriber must verify lipid parameters will be monitored prior to initiation of Skyclarys® treatment and periodically thereafter or as clinically indicated; and
11. Female members must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective non-hormonal contraception during therapy and for 28 days after discontinuation of therapy; and
12. Approvals will be for the duration of 1 year. For each subsequent approval, the prescriber must document that the member is

responding to the medication, as indicated by slower disease progression and/or other documentation of a positive clinical response to therapy; and

13. A quantity limit of 90 capsules per 30 days will apply.

Utilization of Skyclarys® (Omaveloxolone): Calendar Year 2023

Calendar Year 2023 Utilization

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2023	2	8	$246,729.92	$30,841.24	$1,028.04	720	240

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Please note: There were no paid pharmacy claims for Skyclarys® during calendar year 2022 to allow for a calendar year comparison. Skyclarys® was FDA approved in February 2023.

Demographics of Members Utilizing Skyclarys® (Omaveloxolone)

- There were 2 unique members utilizing Skyclarys® (omaveloxolone) during calendar year 2023. Due to the limited number of utilizing members, detailed demographic information could not be provided.

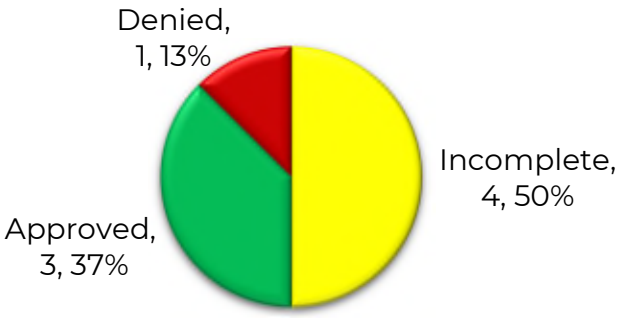
Top Prescriber Specialties of Skyclarys® (Omaveloxolone) by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for Skyclarys® (omaveloxolone) during calendar year 2023 was neurologist.

Prior Authorization of Skyclarys® (Omaveloxolone)

There were 8 prior authorization requests submitted for Skyclarys® (omaveloxolone) during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Skyclarys® (omaveloxolone): April 2033

Recommendations

The College of Pharmacy recommends the following changes to the current Skyclarys® (omaveloxolone) approval criteria to be consistent with clinical practice (changes shown in red):

Skyclarys® (Omaveloxolone) Approval Criteria:

1. An FDA approved diagnosis of Friedrich's ataxia (FRDA); and
   a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants ~~a mutation~~ in the *FXN* gene (results of genetic testing must be submitted); and
2. Member must be 16 years of age or older; and
3. Skyclarys® 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 a left ventricular ejection fraction of ≥40%; and
5. Member must not be taking concomitant strong or moderate CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin) or the prescriber must verify the dose of Skyclarys® will be adjusted during concomitant use according to package labeling; and
6. Member must not be taking concurrent strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, long-acting barbiturates, bosentan, efavirenz, etravirine); and
7. Member must not have severe hepatic impairment (Child-Pugh class C); and
8. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Skyclarys® treatment, every month for the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
9. Prescriber must verify that B-type natriuretic peptide (BNP) will be assessed prior to initiation of Skyclarys® and cardiac function will be monitored as clinically indicated; and
10. Prescriber must verify lipid parameters will be monitored prior to initiation of Skyclarys® treatment and periodically thereafter or as clinically indicated; and
11. Female members must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective non-hormonal contraception during therapy and for 28 days after discontinuation of therapy; and
12. Approvals will be for the duration of 1 year. For each subsequent approval, the prescriber must document that the member is responding to the medication, as indicated by slower disease progression and/or other documentation of a positive clinical response to therapy; and
13. A quantity limit of 90 capsules per 30 days will apply.

Utilization Details of Skyclarys® (Omaveloxolone): Calendar Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SKYCLARYS CAP 50MG	8	2	$246,729.92	$30,841.24	4	100%
TOTAL	**8**	**2***	**$246,729.92**	**$30,841.24**	**4**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule

[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 02/2024. Last accessed 02/28/2024.

Appendix H

Calendar Year 2023 Annual Review of Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications

Oklahoma Health Care Authority
March 2024

Current Prior Authorization Criteria

Austedo® (Deutetrabenazine) and Austedo® XR [Deutetrabenazine Extended-Release (ER) Tablet] Approval Criteria [Huntington's Disease Diagnosis]:

1. An FDA approved diagnosis of chorea associated with Huntington's disease; and
2. Deutetrabenazine must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. A previous trial of Xenazine® (tetrabenazine) or a patient-specific, clinically significant reason why the member cannot use Xenazine® (tetrabenazine) must be provided; and
4. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting deutetrabenazine therapy and throughout treatment; and
5. Member must not have hepatic impairment; and
6. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
7. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
8. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with deutetrabenazine; and
9. For members who are using deutetrabenazine concomitantly with other medications that are known to 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
10. Member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and

11. The daily dose of deutetrabenazine must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion) or if they are a known poor CYP2D6 metabolizer; and
12. Female members must not be pregnant or breastfeeding; and
13. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea have decreased, and the member is not showing worsening signs of depression.

Austedo® (Deutetrabenazine) and Austedo® XR [Deutetrabenazine Extended-Release (ER) Tablet] Approval Criteria [Tardive Dyskinesia Diagnosis]:

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
    a. Involuntary athetoid or choreiform movements; and
    b. History of treatment with a dopamine receptor blocking agent (DRBA); and
    c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Deutetrabenazine must be prescribed by a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
4. Member must not have hepatic impairment; and
5. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
6. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
7. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with deutetrabenazine; and
8. For members who are using deutetrabenazine concomitantly with other medications that are known to 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
9. Member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and
10. The daily dose of deutetrabenazine must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine,

fluoxetine, quinidine, bupropion) or if they are a known poor CYP2D6 metabolizer; and
11. Female members must not be pregnant or breastfeeding; and
12. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
13. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Ingrezza® (Valbenazine) Approval Criteria:

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
    a. Involuntary athetoid or choreiform movements; and
    b. History of treatment with a dopamine receptor blocking agent (DRBA); and
    c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Ingrezza® must be prescribed by a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
4. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine); and
5. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); and
6. Member must not be taking strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and
7. Member must not be taking monoamine oxidase inhibitors (MAOIs); and
8. Member must not be taking other vesicular monoamine transporter 2 (VMAT2) inhibitors (e.g., tetrabenazine, deutetrabenazine); and
9. The daily dose of Ingrezza® must not exceed 40mg per day for members with moderate or severe hepatic impairment (Child-Pugh score 7 to 15); and
10. Member must not have congenital long QT syndrome or a history of arrhythmias associated with a prolonged QT interval; and
11. Female members must not be pregnant or breastfeeding; and
12. Prescriber must agree to monitor digoxin concentration when co-administering Ingrezza® with digoxin; and
13. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and

14. A quantity limit of 1 capsule per day will apply; and
15. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Xenazine® (Tetrabenazine) Approval Criteria:

1. Diagnosis of 1 of the following:
    a. Chorea associated with Huntington's disease; or
    b. Tardive dyskinesia; or
    c. Tourette syndrome; and
2. Xenazine® must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Xenazine® therapy and throughout treatment; and
4. Member must not have hepatic impairment; and
5. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
6. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
7. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., deutetrabenazine, valbenazine) concurrently with Xenazine®; and
8. Member must not be taking medications that are known to prolong the QTc interval concomitantly with Xenazine® [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]; and
9. Members who require doses of tetrabenazine greater than 50mg per day must be tested and genotyped to determine if they are poor metabolizers (PMs), intermediate metabolizers (IMs), or extensive metabolizers (EMs) by their ability to express the drug metabolizing enzyme, CYP2D6. The following dose limits will apply based on the member's metabolizer status:
    a. Extensive and Intermediate CYP2D6 Metabolizers: 100mg divided daily; or
    b. Poor CYP2D6 Metabolizers: 50mg divided daily; and
10. The daily dose of Xenazine® must not exceed 50mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion); and

11. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea, tardive dyskinesia, or Tourette syndrome have decreased, and the member is not showing worsening signs of depression.

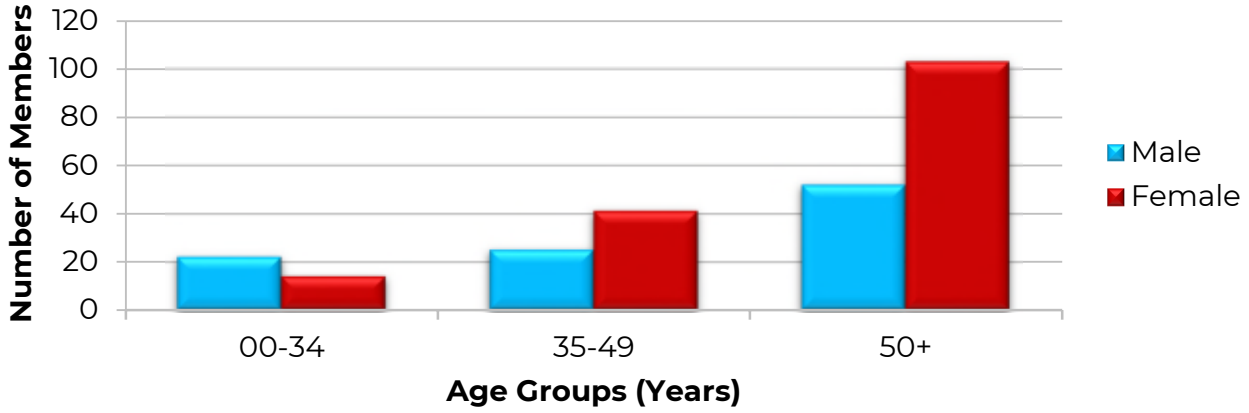
Utilization of VMAT2 Inhibitor Medications: Calendar Year 2023

Comparison of Calendar Years

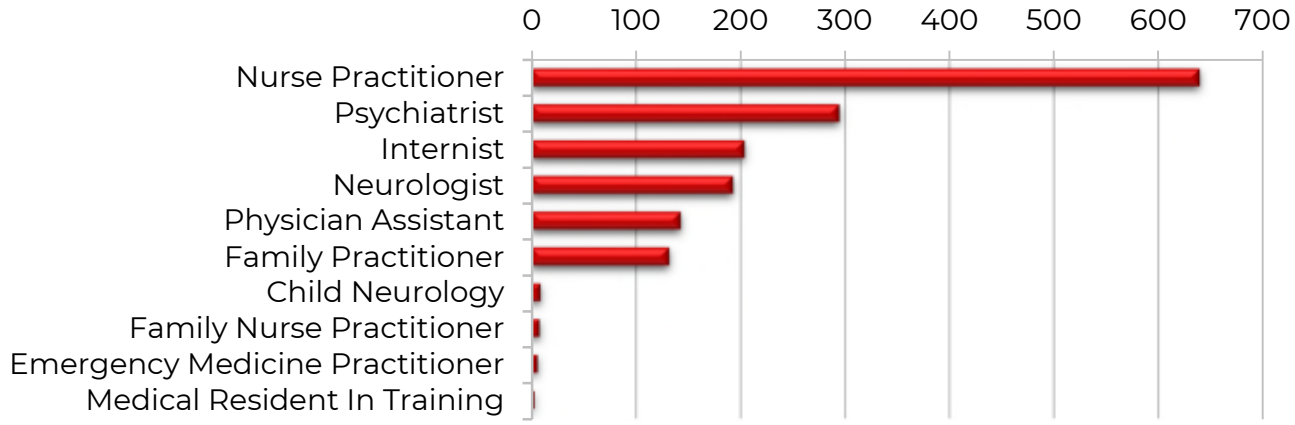
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	209	1,208	$8,837,028.78	$7,315.42	$245.12	63,807	36,052
2023	260	1,633	$12,078,688.45	$7,396.62	$251.76	80,501	47,977
% Change	**24.40%**	**35.20%**	**36.70%**	**1.10%**	**2.70%**	**26.20%**	**33.10%**
Change	**51**	**425**	**$3,241,659.67**	**$81.20**	**$6.64**	**16,694**	**11,925**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

Demographics of Members Utilizing VMAT2 Inhibitor Medications

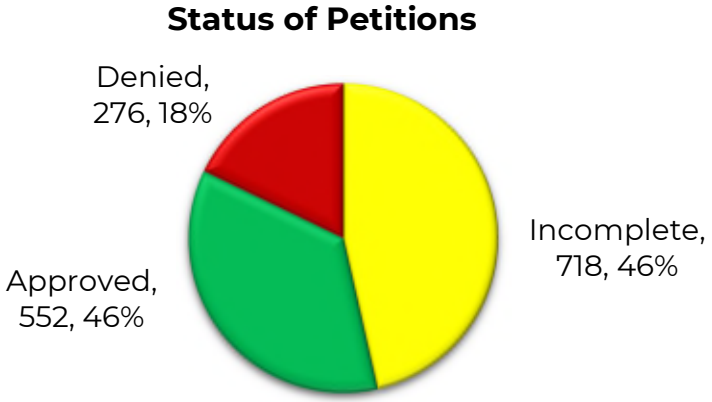


Top Prescriber Specialties of VMAT2 Inhibitor Medications by Number of Claims



Prior Authorization of VMAT2 Inhibitor Medications

There were 1,546 prior authorization requests submitted for VMAT2 inhibitor medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Austedo® (deutetrabenazine): September 2038
- Ingrezza® (valbenazine): August 2040
- Austedo XR® (deutetrabenazine extended-release): June 2041

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

- **August 2023:** The FDA approved Ingrezza® (valbenazine) for use in the treatment of chorea associated with Huntington's disease (HD) based on the results of the KINECT-HD and KINECT-HD2 trials. Ingrezza® was shown to improve the change in chorea severity after an average of 10-12 weeks, with improvement seen as early as 2 weeks. KINECT-HD found a statistically significant improvement in the Total Maximal Chorea score with a reduction of 3.2 units compared to placebo.

Pipeline:

- **September 2023:** The FDA accepted a New Drug Application (NDA) for Ingrezza® oral granules formulation. The new formulation will be supplied in a capsule that is intended to be opened and sprinkled on soft foods. The new formulation is expected to be available in 40mg, 60mg, and 80mg dosages. The Prescription Drug User Fee Act (PDUFA) target action date has been set for April 30, 2024.

Recommendations

The College of Pharmacy recommends the following changes to the Ingrezza® (valbenazine) approval criteria based on the new FDA approved indication (changes shown in red):

Ingrezza® (Valbenazine) Approval Criteria [Huntington's Disease Diagnosis]

1. An FDA approved diagnosis of chorea associated with Huntington's disease; and
2. Member must be 18 years of age or older; and
3. Ingrezza® must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. A previous trial of Xenazine® (tetrabenazine) or a patient-specific, clinically significant reason why the member cannot use Xenazine® (tetrabenazine) must be provided; and
5. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting valbenazine therapy and throughout treatment; and
6. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine); and
7. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); and
8. Member must not be taking strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and
9. Member must not be taking monoamine oxidase inhibitors (MAOIs); and
10. Member must not be taking other vesicular monoamine transporter 2 (VMAT2) inhibitors (e.g., tetrabenazine, deutetrabenazine); and
11. The daily dose of Ingrezza® must not exceed 40mg per day for members with moderate or severe hepatic impairment (Child-Pugh score 7 to 15); and
12. Member must not have congenital long QT syndrome or a history of arrhythmias associated with a prolonged QT interval; and
13. Female members must not be pregnant or breastfeeding; and
14. Prescriber must agree to monitor digoxin concentration when co-administering Ingrezza® with digoxin; and
15. A quantity limit of 1 capsule per day will apply; and
16. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea have decreased, and the member is not showing worsening signs of depression.

Ingrezza® (Valbenazine) Approval Criteria [Tardive Dyskinesia Diagnosis]:

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
    a. Involuntary athetoid or choreiform movements; and

   b. History of treatment with dopamine receptor blocking agent (DRBA); and
   c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Ingrezza® must be prescribed by a neurologist or psychiatrist, or a mid-level practitioner with a supervising physician that is a neurologist or psychiatrist; and
4. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine); and
5. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); and
6. Member must not be taking strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and
7. Member must not be taking monoamine oxidase inhibitors (MAOIs); and
8. Member must not be taking other vesicular monoamine transporter 2 (VMAT2) inhibitors (e.g., tetrabenazine, deutetrabenazine); and
9. The daily dose of Ingrezza® must not exceed 40mg per day for members with moderate or severe hepatic impairment (Child-Pugh score 7 to 15); and
10. The member must not have congenital long QT syndrome or a history of arrhythmias associated with a prolonged QT interval; and
11. Female members must not be pregnant or breastfeeding; and
12. Prescriber must agree to monitor digoxin concentration when co-administering Ingrezza® with digoxin; and
13. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
14. A quantity limit of 1 capsule per day will apply; and
15. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

The College of Pharmacy also recommends the following changes to the approval criteria for Xenazine® (tetrabenazine) to be consistent with the other VMAT2 inhibitor medications (changes shown in red):

Xenazine® (Tetrabenazine) Approval Criteria:

1. Diagnosis of 1 of the following:
   a. Chorea associated with Huntington's disease; or
   b. Tardive dyskinesia; or

   c. Tourette syndrome; and
2. Xenazine® must be prescribed by a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
3. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Xenazine® therapy and throughout treatment; and
4. Member must not have hepatic impairment; and
5. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
6. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
7. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., deutetrabenazine, valbenazine) concurrently with Xenazine®; and
8. Member must not be taking medications that are known to prolong the QTc interval concomitantly with Xenazine® [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]; and
9. Members who require doses of tetrabenazine greater than 50mg per day must be tested and genotyped to determine if they are poor metabolizers (PMs), intermediate metabolizers (IMs), or extensive metabolizers (EMs) by their ability to express the drug metabolizing enzyme, CYP2D6. The following dose limits will apply based on the member's metabolizer status:
   a. Extensive and Intermediate CYP2D6 Metabolizers: 100mg divided daily; or
   b. Poor CYP2D6 Metabolizers: 50mg divided daily; and
10. The daily dose of Xenazine® must not exceed 50mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion); and
11. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea, tardive dyskinesia, or Tourette syndrome have decreased, and the member is not showing worsening signs of depression.

Utilization Details of VMAT2 Inhibitor Medications: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIM/ MEMBER	% COST
VALBENAZINE PRODUCTS						
INGREZZA 80MG CAP	445	79	$3,469,562.57	$7,796.77	5.63	28.72%
INGREZZA 40MG CAP	291	75	$2,088,815.61	$7,178.06	3.88	17.29%
INGREZZA 60MG CAP	77	19	$612,518.57	$7,954.79	4.05	5.07%
INGREZZA 40-80MG CAP	10	10	$80,326.10	$8,032.61	1	0.67%
SUBTOTAL	**823**	**183**	**$6,251,222.85**	**$7,595.65**	**4.5**	**51.75%**
DEUTETRABENAZINE PRODUCTS						
AUSTEDO 12MG TAB	326	55	$3,011,313.23	$9,237.16	5.93	24.93%
AUSTEDO 9MG TAB	217	39	$1,248,047.97	$5,751.37	5.56	10.33%
AUSTEDO 6MG TAB	155	37	$674,681.14	$4,352.78	4.19	5.59%
AUSTEDO XR 24MG TAB	35	12	$375,601.45	$10,731.47	2.92	3.11%
AUSTEDO XR 12 MG TAB	22	9	$151,275.02	$6,876.14	2.44	1.25%
AUSTEDO XR 6MG TAB	6	3	$14,219.46	$2,369.91	2	0.12%
AUSTEDO XR TITR 6-12-24MG TAB	2	2	$13,236.18	$6,618.09	1	0.11%
SUBTOTAL	**763**	**157**	**$5,488,374.45**	**$7,193.15**	**4.86**	**45.44%**
TETRABENAZINE PRODUCTS						
TETRABENAZINE 12.5MG TAB	15	6	$4,950.16	$330.01	2.5	0.04%
TETRABENAZINE 25MG TAB	15	5	$15,960.64	$1,064.04	3	0.13%
XENAZINE 12.5MG TAB	6	1	$63,507.56	$10,584.59	6	0.53%
XENAZINE 25MG TAB	11	2	$254,672.79	$23,152.07	5.5	2.11%
SUBTOTAL	**47**	**14**	**$339,091.15**	**$7,214.71**	**3.36**	**2.81%**
TOTAL	**1,633**	**260***	**$12,078,688.45**	**$7,396.62**	**6.28**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet, TITR = titration kit; XR = extended release

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 02/2024. Last accessed 02/28/2024.
[2] Neurocrine Biosciences, Inc. Neurocrine Biosciences Announces FDA Approval of Ingrezza® (Valbenazine) Capsules for the Treatment of Chorea Associated with Huntington's Disease. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/neurocrine-biosciences-announces-fda-approval-of-ingrezza-valbenazine-capsules-for-the-treatment-of-chorea-associated-with-huntingtons-disease-301904823.html. Issued 08/18/2023. Last accessed 02/28/2024.
[3] Neurocrine Biosciences, Inc. Neurocrine Biosciences Announces U.S. FDA Accepts New Drug Application for Ingrezza® (Valbenazine) Oral Granules Sprinkle Formulation. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/neurocrine-biosciences-announces-us-fda-accepts-new-drug-application-for-ingrezza-valbenazine-oral-granules-sprinkle-formulation-301926943.html. Issued 09/14/2023. Last accessed 02/28/2024.

Appendix I

Calendar Year 2023 Annual Review of Lymphoma Medications and 30-Day Notice to Prior Authorize Columvi™ (Glofitamab-gxbm) and Epkinly™ (Epcoritamab-bysp)

Oklahoma Health Care Authority
March 2024

Current Prior Authorization Criteria

Utilization data for Arzerra® (ofatumumab), Asparlas® (calaspargase pegol-mknl), Gazyva® (obinutuzumab), Imbruvica® (ibrutinib), Kymriah® (tisagenlecleucel), Oncaspar® (pegaspargase), Rylaze® [asparaginase *Erwinia chrysanthemi* (recombinant)-rywn], Venclexta® (venetoclax), and Zydelig® (idelalisib) and approval criteria for indications other than lymphoma can be found in the February 2024 Drug Utilization Review (DUR) Board packet. These medications are reviewed annually with the leukemia medications. Utilization data for Keytruda® (pembrolizumab) and Opdivo® (nivolumab) and approval criteria for indications other than lymphoma can be found in the December 2023 DUR Board packet. These medications are reviewed annually with the skin cancer medications. Utilization data for Xalkori® (crizotinib) and approval criteria for indications other than lymphoma can be found in the April 2023 DUR Board packet. Xalkori® (crizotinib) is reviewed annually with the lung cancer medications. Utilization data for Xpovio® (selinexor) and approval criteria for indications other than lymphoma can be found in the November 2023 DUR Board packet. Xpovio® (selinexor) is reviewed annually with the multiple myeloma medications.

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

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

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

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

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

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

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

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

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

1. As a single agent; and
2. CD30+ disease; and
3. DLBCL relapsed/refractory disease in non-autologous stem cell transplant (SCT) candidates; or
4. 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.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Peripheral T-Cell Lymphoma (PTCL) Diagnosis]:

1. Treatment of previously untreated CD30+ disease in combination with cyclophosphamide, doxorubicin, and prednisone (CHP); or
2. In members who have received ≥1 line of therapy as a single agent.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. As a single agent as primary treatment or in relapsed/refractory disease.

Adcetris® (Brentuximab Vedotin) Approval Criteria [T-Cell Lymphoma, Extranodal NK/T-Cell Lymphoma, Nasal Type Diagnosis]:

1. CD30+ disease; and
2. As a single agent; and
3. Relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen not previously used.

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.

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

1. 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.

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; and
    a. Used as induction therapy; 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 [Adult T-Cell Leukemia/ Lymphoma Diagnosis]:

1. As a single agent in relapsed/refractory disease.

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

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

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

1. As a single agent in relapsed/refractory disease.

Beleodaq® (Belinostat) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. Primary treatment in stage IV non Sézary or visceral disease (solid organ) with or without radiation therapy for local control; or
2. Primary treatment for large cell transformation with generalized cutaneous or extracutaneous lesions with or without skin-directed therapy; or
3. As a single agent (with or without skin-directed therapy) in relapsed/refractory disease.

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

1. As a single agent; and
2. Relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen not previously used.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma; and
    a. One of the following:
        i. Refractory disease to frontline chemoimmunotherapy; or
        ii. Relapse within 12 months of frontline chemoimmunotherapy; or
        iii. Relapse after frontline chemoimmunotherapy and member is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidity or age; or
        iv. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
2. Member does not have primary central nervous system (CNS) lymphoma; and
3. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and

4. A patient-specific, clinically significant reason why Kymriah® (tisagenlecleucel) or Yescarta® (axicabtagene ciloleucel) are not appropriate for the member must be provided; and
5. Approvals will be for 1 dose per member per lifetime.

Brukinsa® (Zanubrutinib) Approval Criteria [Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) Diagnosis]:

1. Diagnosis of CLL/SLL.

Brukinsa® (Zanubrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. Diagnosis of MCL in adult members; and
2. Member must have received at least 1 prior therapy.

Brukinsa® (Zanubrutinib) Approval Criteria [Marginal Zone Lymphoma (MZL) Diagnosis]:

1. Diagnosis of MZL in adult members; and
2. Member must have received at least 1 prior anti-CD20 monoclonal antibody-based therapy.

Brukinsa® (Zanubrutinib) Approval Criteria [Waldenström's Macroglobulinemia Diagnosis]:

1. Diagnosis of Waldenström's macroglobulinemia in adult members; and
2. Used as primary or subsequent therapy.

Calquence® (Acalabrutinib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. As a single agent.

Calquence® (Acalabrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. As a single agent.

Copiktra® (Duvelisib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Relapsed/refractory CLL or SLL; and
2. Progression of disease following 2 or more lines of systemic therapy; and
3. As a single agent.

Folotyn® (Pralatrexate) Approval Criteria [Adult T-Cell Leukemia/ Lymphoma Diagnosis]:

1. As a single agent in relapsed/refractory disease.

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

1. As a single agent in members with multifocal lesions or regional nodes either as primary treatment or in relapsed/refractory disease.

Folotyn® (Pralatrexate) Approval Criteria [Peripheral T-Cell Lymphoma (PTCL) Diagnosis]:

1. As a single agent in relapsed/refractory disease.

Folotyn® (Pralatrexate) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. As a single agent as primary treatment or in relapsed/refractory disease.

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

1. As a single agent; and
2. Relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen not previously used.

Gazyva® (Obinutuzumab) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Grade 1 or 2 members with Stage I (≥7cm), contiguous Stage II (≥7cm), noncontiguous Stage II, Stage III, or Stage IV members (first, second, or subsequent therapy); and
    a. In combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP), cyclophosphamide, vincristine, and prednisone (CVP), or bendamustine; and
    b. When used for maintenance therapy, a total of 12 doses will be approved; or
2. 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. As second-line or subsequent therapy in combination with bendamustine; or
2. Maintenance therapy as second-line consolidation or extended dosing in rituximab-refractory members treated with obinutuzumab and bendamustine for a total of 12 doses.

Gazyva® (Obinutuzumab) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. Diagnosis of relapsed or refractory DLBCL not otherwise specified, including large B-cell lymphoma (LBCL) arising from follicular lymphoma; and
2. Used as lymphoid depletion pretreatment prior to glofitamab; and
3. Member must meet criteria for glofitamab; and
4. Dosing will be 1,000mg as a single dose 7 days prior to start of glofitamab.

Imbruvica® (Ibrutinib) Approval Criteria [B-Cell Lymphomas Diagnosis]:

1. As second-line or subsequent therapy for members with a diagnosis of B-cell lymphoma [including diffuse large B-cell lymphomas, human immunodeficiency virus (HIV)-related B-cell lymphomas, post-transplant lymphoproliferative disorders, and high-grade B-cell lymphoma].

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.

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).

Imbruvica® (Ibrutinib) Approval Criteria [Gastric or Nongastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma, Nodal or Splenic Marginal Zone Lymphoma (MZL) Diagnosis]:

1. As second-line or subsequent therapy for refractory or progressive disease.

Imbruvica® (Ibrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. As second-line or subsequent therapy; or
2. Used in combination with rituximab prior to induction therapy; or
3. Used as a component of aggressive induction therapy; or
4. Used as maintenance therapy following aggressive induction therapy or hematopoietic stem cell transplant (HSCT).

Imbruvica® (Ibrutinib) Approval Criteria [Post-Transplant Lymphoproliferative Disorders Diagnosis]:

1. As second-line or subsequent therapy in members with partial response, persistent, or progressive disease; and
2. Non-germinal center B-cell type.

Imbruvica® (Ibrutinib) Approval Criteria [Primary Central Nervous System (CNS) Lymphoma Diagnosis]:

1. Diagnosis of primary CNS lymphoma; and
2. Member is not a candidate for or is intolerant to high-dose methotrexate according to the prescriber; or
3. As second-line or subsequent therapy for refractory or progressive disease.

Imbruvica® (Ibrutinib) Approval Criteria [Waldenström's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma Diagnosis]:

1. As first-line or subsequent therapy; and
2. As a single agent or in combination with rituximab.

Istodax® (Romidepsin) and Romidepsin 27.5mg/5.5mL Vial Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL), Primary Cutaneous Diagnosis]:

1. As a single agent in members with multifocal lesions or regional nodes either as primary treatment or in relapsed/refractory disease.

Istodax® (Romidepsin) and Romidepsin 27.5mg/5.5mL Vial Approval Criteria [Peripheral T-Cell Lymphoma (PTCL) Diagnosis]:

1. As a single agent in relapsed/refractory disease.

Istodax® (Romidepsin) and Romidepsin 27.5mg/5.5mL Vial Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. As a single agent as primary treatment or in relapsed/refractory disease.

Istodax® (Romidepsin) and Romidepsin 27.5mg/5.5mL Vial Approval Criteria [T-Cell Lymphoma, Extranodal NK/T-Cell Lymphoma, Nasal Type Diagnosis]:

1. As a single agent; and
2. Relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen not previously used.

Jaypirca® (Pirtobrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. Diagnosis of MCL; and
2. Relapsed or refractory disease after ≥2 lines of systemic therapy; and

3. Previous treatment must have included a Bruton's tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, zanubrutinib).

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

1. Member has not previously failed other PD-1 inhibitors [i.e., Opdivo® (nivolumab)]; and
2. For adult members:
    a. Diagnosis of relapsed or refractory cHL; and
        i. As a single agent; or
        ii. Exception: lymphocyte-predominant Hodgkin lymphoma; or
        iii. Second-line or subsequent systemic therapy in combination with gemcitabine, vinorelbine, and liposomal doxorubicin; or
3. For pediatric members:
    a. As a single agent; and
    b. Diagnosis of refractory cHL; or
    c. Relapsed disease after ≥2 therapies.

Keytruda® (Pembrolizumab) Approval Criteria [Primary Mediastinal Large B-cell Lymphoma (PMBCL) Diagnosis]:

1. Diagnosis of PMBCL in adult or pediatric members; and
2. Member must have refractory disease or pembrolizumab must be used in members who have relapsed after 2 or more prior lines of therapy; and
3. Authorizations will not be granted for members who require urgent cytoreduction; and
4. Member has not previously failed other PD-1 inhibitors [e.g., Opdivo® (nivolumab)].

Kymriah® (Tisagenlecleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma [including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and
2. Relapsed/refractory disease; and
3. Member must be 18 years of age or older; and
4. Member must not have primary central nervous system lymphoma; and
5. Member must have had ≥2 lines of therapy; and
6. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells, must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities, and must comply with the Kymriah® Risk Evaluation and Mitigation Strategy (REMS) requirements; and
7. Approvals will be for 1 dose per member per lifetime.

Lunsumio™ (Mosunetuzumab-axgb) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of FL; and
2. Relapsed or refractory disease after ≥2 lines of systemic therapy.

Monjuvi® (Tafasitamab-cxix) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. Diagnosis of DLBCL in adults; and
2. Relapsed or refractory disease; and
3. Used in combination with lenalidomide.

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

1. Diagnosis of relapsed or refractory classical HL; and
    a. Exception: lymphocyte-predominant HL
2. Nivolumab must be used in 1 of the following settings:
    a. As a single-agent; or
    b. In combination with brentuximab vedotin as second line or subsequent therapy after failure of autologous stem cell transplant (SCT), allogeneic SCT, or those who are transplant-ineligible; and
3. Member has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)].

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

1. Relapsed/refractory DLBCL or high grade B-cell lymphoma after at least 2 prior therapies; and
2. Used in combination with bendamustine and rituximab; and
3. Member is not a candidate for transplant.

Poteligeo® (Mogamulizumab-kpkc) Approval Criteria [Adult T-Cell Leukemia/Lymphoma Diagnosis]:

1. As a single-agent in relapsed/refractory disease.

Poteligeo® (Mogamulizumab-kpkc) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. As a single-agent as primary treatment or in relapsed/refractory disease.

Rylaze® [Asparaginase *Erwinia Chrysanthemi* (Recombinant)-rywn] Approval Criteria [Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma Diagnosis]:

1. Diagnosis of ALL or lymphoblastic lymphoma; and
2. Used as a component of multi-agent chemotherapy; and
3. Member has a documented hypersensitivity to *Escherichia coli*-derived asparagine-deprivation product.

Tazverik® (Tazemetostat) Approval Criteria [Epitheloid Sarcoma Diagnosis]:

1. Diagnosis of metastatic or locally advanced epithelioid sarcoma; and
2. Member is not eligible for complete resection; and
3. Member must be 16 years of age or older.

Tazverik® (Tazemetostat) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Treatment of adult members with relapsed/refractory disease; and
2. *EZH2* mutation detected; and
3. Member must have received 2 lines of therapy or as subsequent therapy with no satisfactory alternative treatment options.

Tecartus® (Brexucabtagene Autoleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of ALL; and
2. Relapsed or refractory disease; and
3. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
4. Approvals will be for 1 dose per member per lifetime.

Tecartus® (Brexucabtagene Autoleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of mantle cell lymphoma; and
2. Relapsed or refractory disease; and
3. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
4. Approvals will be for 1 dose per member per lifetime.

Venclexta® (Venetoclax) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. As second-line or subsequent therapy; and
2. As a single agent.

Xalkori® (Crizotinib) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL) Diagnosis]:

1. Members 1 year of age or older:
    a. Diagnosis of systemic ALCL that is anaplastic lymphoma kinase (ALK)-positive; and

b. Relapsed or refractory disease; and
2. As a single agent.

Xpovio® (Selinexor) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. Diagnosis of relapsed/refractory DLBCL, not otherwise specified, including DLBCL arising from follicular lymphoma; and
2. Member has received ≥2 prior lines of systemic therapy.

Yescarta® (Axicabtagene Ciloleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma [including diffuse large B cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and
2. Member must be 18 years of age or older; and
3. Relapsed or refractory disease used in 1 of the following settings:
   a. After 2 or more lines of therapy; or
   b. After 1 line of therapy, if member is refractory to first-line chemotherapy or relapses within 12 months of first-line chemotherapy; and
4. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
5. For large B-cell lymphoma (including DLBCL, high grade B-cell lymphoma, and DLBCL arising from FL), member must not have primary central nervous system lymphoma; and
6. Approvals will be for 1 dose per member per lifetime.

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

1. As a single agent; and
2. Relapsed/refractory disease.

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

1. As a single agent; and
2. 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.

Zolinza® (Vorinostat) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. As a single agent as primary treatment or in relapsed/refractory disease.

Zydelig® (Idelalisib) Approval Criteria [Gastric or Nongastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma, Nodal or Splenic Marginal Zone Lymphoma (MZL) Diagnosis]:

1. As second-line or subsequent therapy for refractory or progressive disease; and
2. Refractory to both alkylator and rituximab therapy.

Zynlonta® (Loncastuximab Tesirine-lpyl) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified, or DLBCL arising from low grade lymphoma, or high-grade B-cell lymphoma; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
3. If previous CD19-directed therapy was used, patient must have a biopsy that shows CD19 protein expression after completion of the CD19-directed therapy; and
4. A patient-specific, clinically significant reason why tafasitamab in combination with lenalidomide is not appropriate for the member must be provided.

Oncology Medications Additional Criteria:

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

d. Any peer-to-peer request for an oncology medication.

Utilization of Lymphoma Medications: Calendar Year 2023

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

Calendar Year Comparison: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	8	41	$578,568.09	$14,111.42	$479.74	2,412	1,206
2023	18	90	$1,246,924.94	$13,854.72	$466.14	6,282	2,675
% Change	**125.0%**	**119.5%**	**115.5%**	**-1.8%**	**-2.8%**	**160.4%**	**121.8%**
Change	**10**	**49**	**$668,356.85**	**-$256.70**	**-$13.60**	**3,870**	**1,469**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

Calendar Year Comparison: Medical Claims

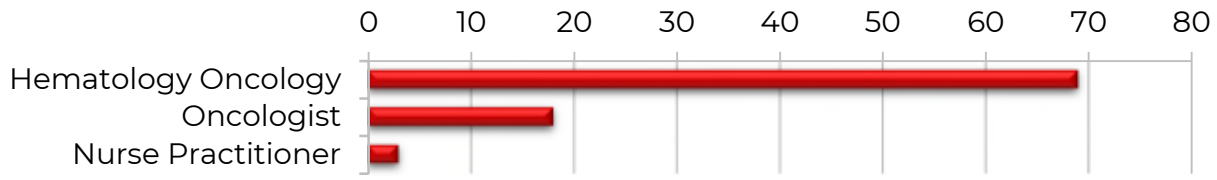
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	30	159	$3,772,486.99	$23,726.33	5.3
2023	38	180	$5,284,599.66	$29,358.89	4.74
% Change	**26.67%**	**13.21%**	**40.08%**	**23.74%**	**-10.57%**
Change	**8**	**21**	**$1,512,112.67**	**$5,632.56**	**-0.56**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.

Demographics of Members Utilizing Lymphoma Medications: Pharmacy Claims

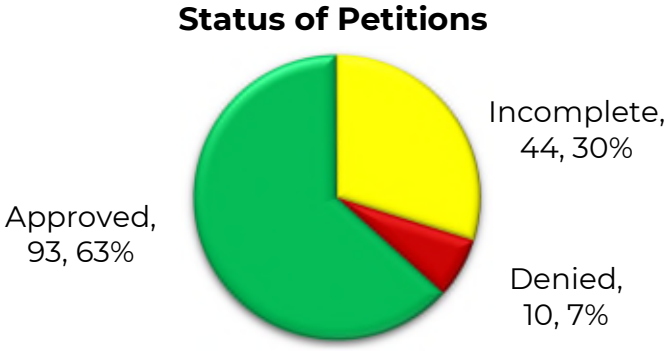
- Due to the limited number of members utilizing lymphoma medications during calendar year 2023, detailed demographic information could not be provided.

Top Prescriber Specialties of Lymphoma Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Lymphoma Medications

There were 147 prior authorization requests submitted for lymphoma medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.



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

Anticipated Patent Expiration(s):

- Folotyn® (pralatrexate): May 2025
- Beleodaq® (belinostat): October 2027
- Zolinza® (vorinostat): March 2028
- Aliqopa® (copanlisib): March 2032
- Copiktra® (duvelisib): May 2032
- Tazverik® (tazemetostat): December 2035
- Calquence® (acalabrutinib): July 2036
- Jaypirca® (pirtobrutinib): December 2036
- Brukinsa® (zanubrutinib): January 2043

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

- **November 2019:** The FDA approved dosing for Calquence® (acalabrutinib) for the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) indicates that it may be used in combination with obinutuzumab in patients with previously untreated CLL or SLL.
- **April 2023:** The FDA approved Polivy® (polatuzumab vedotin-piiq) for a new indication, in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP), for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified, or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index score of 2 or greater.
- **May 2023:** The FDA granted accelerated approval to Epkinly™ (epcoritamab-bysp) for the treatment of adult patients with relapsed or refractory DLBCL, not otherwise specified, including DLBCL arising

from indolent lymphoma, and HGBL after 2 or more lines of systemic therapy.

- **June 2023:** The FDA granted accelerated approval to Columvi™ (glofitamab-gxbm) for the treatment of adult patients with relapsed or refractory DLBCL, not otherwise specified, or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after 2 or more lines of systemic therapy.
- **December 2023:** The FDA granted accelerated approval to Jaypirca® (pirtobrutinib) for a new indication for the treatment of adult patients with CLL or SLL who have received at least 2 prior lines of therapy, including a Bruton's tyrosine kinase (BTK) inhibitor and a BCL-2 inhibitor.

News:

- **November 2023:** Bayer, the manufacturer of Aliqopa® (copanlisib) announced the planned withdrawal of Aliqopa® based on the results of the required confirmatory study. Aliqopa® was granted accelerated approval for the treatment of adult patients with relapsed follicular lymphoma who have received at least 2 prior systemic therapies.
- **January 2024:** The FDA is requiring new *Boxed Warnings* for all chimeric antigen receptor (CAR) T-cell (CAR-T) therapies regarding the risk of secondary T-cell malignancies. The updating warnings will apply to all FDA-approved CAR-T therapies, including Abecma® (idecabtagene vicleucel), Breyanzi® (lisocabtagene maraleucel), Carvykti® (ciltacabtagene autoleucel), Kymriah® (tisagenlecleucel), Tecartus® (brexucabtagene autoleucel), and Yescarta® (axicabtagene ciloleucel).

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for relapsed/refractory DLBCL allow the use of Polivy® without bendamustine as a bridge to CAR-T therapy (if the intent is to proceed to CAR-T therapy after Polivy®). The use of bendamustine in this setting would make it very difficult to collect T cells for CAR-T therapy.
- The NCCN guidelines for follicular lymphoma allow the use of Brukinsa® (zanubrutinib) as a third-line or subsequent line therapy in combination with obinutuzumab.
- The NCCN guidelines for peripheral T-cell lymphomas (PTCL) recommend Copiktra® (duvelisib) as a preferred regimen for initial palliative therapy or second-line/subsequent therapy in patients with PTCL.
- The NCCN guidelines for primary cutaneous lymphomas no longer recommend the use of Beleodaq® (belinostat) for mycosis fungoides (MF)/Sézary syndrome (SS).

Columvi™ (Glofitamab-gxbm) Product Summary[15]

Therapeutic Class: Bispecific CD20-directed CD3 T-cell engager

Indication(s): Treatment of adult patients with relapsed or refractory DLBCL, not otherwise specified or LBCL arising from follicular lymphoma, after 2 or more lines of systemic therapy

- 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:

- 2.5mg/2.5mL single-dose vial (SDV)
- 10mg/10mL SDV

Dosing and Administration: Administered as an intravenous (IV) infusion in 21-day cycles (for a maximum of 12 cycles) according to the following schedule:

- Cycle 1:
  - Day 1: Pretreat with a single dose of obinutuzumab 1,000mg by IV infusion
  - Day 8: Columvi™ 2.5mg
  - Day 15: Columvi™ 10mg
- Cycles 2 through 12:
  - Day 1: Columvi™ 30mg

Cost: The Wholesale Acquisition Cost (WAC) is $2,554.74 for the 2.5mg vial and $10,218.98 for the 10mg vial. This results in a cost of $12,773.72 for cycle 1 and $30,656.94 for each subsequent cycle. This would result in an estimated cost of approximately $350,000 for the recommended 12 cycles.

Epkinly™ (Epcoritamab-bysp) Product Summary[16]

Therapeutic Class: Bispecific CD20-directed CD3 T-cell engager

Indication(s): Treatment of adult patients with relapsed or refractory DLBCL, not otherwise specified, including DLBCL arising from indolent lymphoma, and HGBL after 2 or more lines of systemic therapy

- 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:

- 4mg/0.8mL SDV which must be diluted prior to use
- 48mg/0.8mL SDV

Dosing and Administration:

- Administered by subcutaneous (sub-Q) injection in 28-day cycles according to the following schedule:
  - Cycle 1: 0.16mg on day 1, 0.8mg on day 8, 48mg on day 15, and 48mg on day 22
  - Cycles 2 and 3: 48mg on days 1, 8, 15, and 22
  - Cycles 4 through 9: 48mg on days 1 and 15
  - Cycles 10 and beyond: 48mg on day 1

Cost: The WAC is $1,287.83 for the 4mg vial and $15,453.96 for the 48mg vial. This results in a cost of $33,483.58 for cycle 1, a cost of $61,815.84 for cycles 2-3, a cost of $30,907.92 for cycles 4-9, and a cost of $15,453.96 for each subsequent cycle.

Recommendations

The College of Pharmacy recommends the prior authorization of Columvi™ (glofitamab-gxbm) and Epkinly™ (epcoritamab-bysp) with the following criteria (shown in red):

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
2. Has received ≥2 lines of systemic therapy; and
3. Will receive a single dose of obinutuzumab for pre-treatment purposes.

Epkinly™ (Epcoritamab-bysp) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory 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.

The College of Pharmacy also recommends updating the approval criteria for Calquence® (acalabrutinib) and Jaypirca® (pirtobrutinib) for CLL/SLL based on recent FDA approval and to be consistent with the FDA approved dosing for Calquence® (changes shown in red):

Calquence® (Acalabrutinib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. ~~Must be~~ Used as a single agent; or
2. In combination with obinutuzumab.

Jaypirca® (Pirtobrutinib) Approval Criteria [Chronic Lymphocytic/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.

Next, the College of Pharmacy recommends updating the approval criteria for Polivy® (polatuzumab vedotin-piiq) based on recent FDA approval and NCCN recommendations (changes shown in red):

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

1. Previously untreated DLBCL not otherwise specified or high-grade B-cell lymphoma; and
    a. Has an International Prognostic Index score of ≥2; and
    b. Used in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP); or
2. Relapsed/refractory DLBCL not otherwise specified or high-grade B-cell lymphoma; and
    a. Has received at least 2 prior therapies; and
    b. May be used in combination with bendamustine and rituximab; or
        i. May be used without bendamustine if the member will proceed to CAR-T therapy; and
    c. Member is not a candidate or has no intention to proceed to transplant.

Additionally, the College of Pharmacy recommends updating the approval criteria for Beleodaq® (belinostat), Brukinsa® (zanubrutinib) and Copiktra® (duvelisib) based on NCCN recommendations (changes shown in red):

~~**Beleodaq® (Belinostat) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:**~~

~~1. Primary treatment in stage IV non Sézary or visceral disease (solid organ) with or without radiation therapy for local control; or~~
~~2. Primary treatment for large cell transformation with generalized cutaneous or extracutaneous lesions with or without skin-directed therapy; or~~
~~3. As a single agent (with or without skin-directed therapy) in relapsed/refractory disease.~~

Brukinsa® (Zanubrutinib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of FL; and
2. Third line or subsequent therapy for no response, relapsed, or progressive disease; and
3. Used in combination with obinutuzumab.

Copiktra® (Duvelisib) Approval Criteria [Peripheral T-Cell Lymphomas (PTCL) Diagnosis]:

1. Diagnosis of PTCL; and
2. As a single agent.

Lastly, the College of Pharmacy recommends updating the approval criteria for Aliqopa® (copanlisib) based on the planned withdrawal of its accelerated approval (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.

Utilization Details of Lymphoma Medications: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ACALABRUTINIB PRODUCTS						
CALQUENCE TAB 100MG	66	13	$955,285.45	$14,474.02	5.08	76.61%
ZANUBRUTINIB PRODUCTS						
BRUKINSA CAP 80MG	24	6	$291,639.49	$12,151.65	4	23.39%
TOTAL	**90**	**18***	**$1,246,924.94**	**$13,854.72**	**5**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BRENTUXIMAB VEDOTIN J9042	150	30	$3,966,211.79	$26,441.41	5
POLATUZUMAB VEDOTIN-PIIQ J9309	27	5	$361,408.46	$13,385.50	5.4
AXICABTAGENE CILOLEUCEL Q2041	3	3	$956,979.41	$318,993.14	1
TOTAL	**180**	**38**	**$5,284,599.66**	**$29,358.89**	**4.74**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
+Total number of unduplicated claims.

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[3] U.S. FDA. FDA Approves Polatuzumab Vedotin-piiq for Previously Untreated Diffuse Large B-Cell Lymphoma, Not Otherwise Specified, and High-Grade B-Cell Lymphoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-polatuzumab-vedotin-piiq-previously-untreated-diffuse-large-b-cell-lymphoma-not. Issued 04/19/2023. Last accessed 02/16/2024.
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Appendix J

Calendar Year 2023 Annual Review of Hemophilia Medications and 30-Day Notice to Prior Authorize Roctavian™ (Valoctocogene Roxaparvovec-rvox)

Oklahoma Health Care Authority
March 2024

Current Prior Authorization Criteria

Adynovate®, Afstyla®, Alprolix®, Altuviiio®, 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. Member must have a 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.

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: Calendar Year 2023

Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost Per Utilizer Per Year
2022	119	966	$23,250,780.47	$24,069.13	$195,384.71
2023	126	1,053	$27,152,571.78	$25,785.92	$215,496.60
% Change	**5.9%**	**9.0%**	**16.8%**	**7.1%**	**1.1%**
Change	**7**	**87**	**$3,901,791.31**	**$1,716.79**	**$20,111.89**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

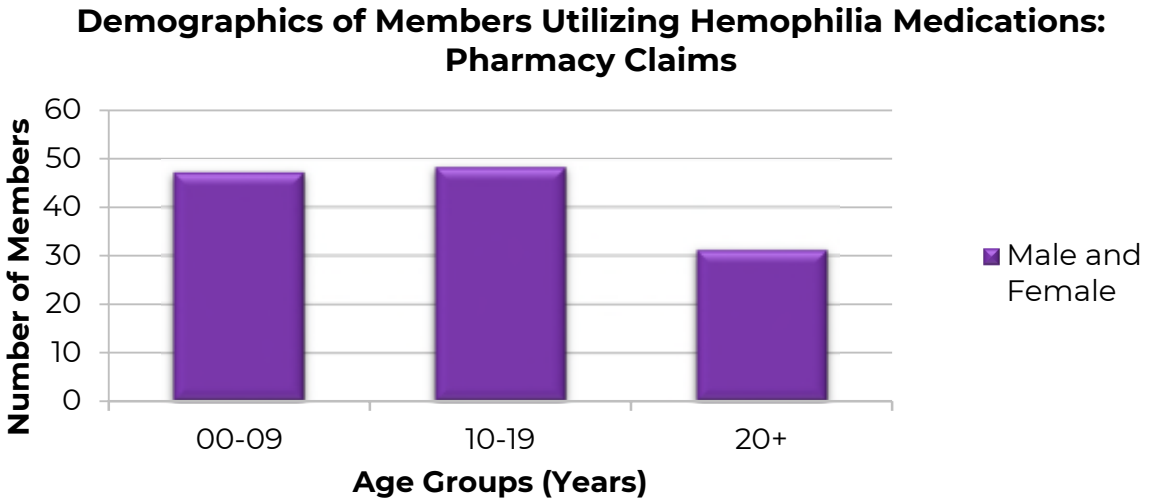
Comparison of Calendar Years: Medical Claims

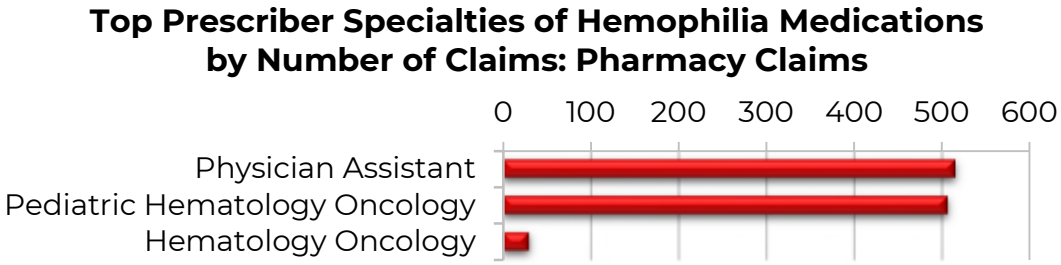
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Cost Per Utilizer Per Year
2022	16	39	$695,835.15	$17,841.93	$43,489.70
2023	11	24	$660,347.45	$27,514.48	$60,031.59
% Change	**-31.25%**	**-38.46**	**-5.10%**	**54.51%**	**38.04%**
Change	**-5**	**-15**	**-$35,487.18**	**$9,672.55**	**$16,541.89**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.

- Aggregate drug rebates collected during fiscal year 2023 (07/01/2022 to 06/30/2023) for hemophilia medications totaled $5,591,205.25.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2023 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for calendar year 2023 are still being collected at this time. The costs included in this report do not reflect net costs.

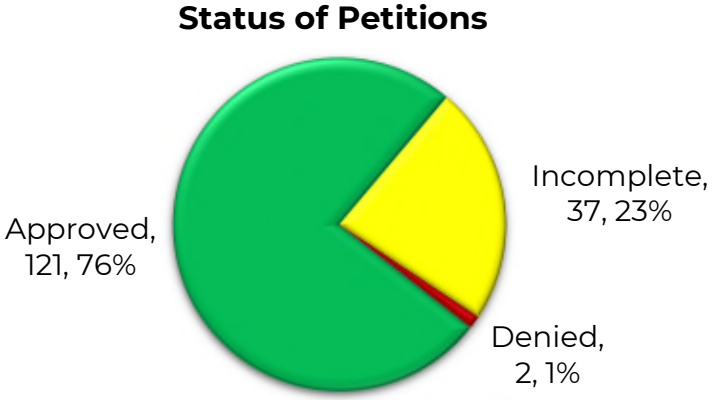
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.





Prior Authorization of Hemophilia Medications

There were 160 prior authorization requests submitted for hemophilia medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.



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

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

- **June 2023:** The FDA approved Roctavian™ (valoctocogene roxaparvovec-rvox), an adeno-associated virus (AAV) vector-based gene therapy for the treatment of adults with severe hemophilia A.

News:

- **September 2023:** The FDA granted Orphan Drug designation (ODD) to TI-168, a factor VIII (FVIII) specific T cell receptor therapy utilizing human regulatory T cells that is being developed for the treatment of patients with hemophilia A with an inhibitor.
- **November 2023:** The FDA granted ODD and Rare Pediatric Disease designation (RPDD) for a cell therapy for hemophilia A treatment. The manufacturer, Sernova, has developed a proprietary Cell Pouch™ technology targeting a patient's blood outgrowth endothelial cells (BOECs). These cells are removed from the patient and modified to affect the release of FVIII into the bloodstream.
- **November 2023:** A 3 year follow up study post treatment of etranacogene dezaparvovec (Hemgenix®), a viral vector-based gene therapy for hemophilia B, was published in *Blood* and later presented at the annual meeting of the American Society of Hematology (ASH). Of the 54 HOPE-B trial participants, 52 participants completed the 36 months of follow up. The mean annualized bleed rate (ABR) was decreased by 64% (1.52 in months 7-36) when compared to the 6-month lead-in period (4.19 in months 0-6) prior to receiving the gene therapy. The mean endogenous factor IX activity level has remained in the mild hemophilia range (6-49%) at 41.5 in year 1, 36.7 in year 2, and 38.6 in year 3. In the follow up period, 51 of the 52 participants continued off of prophylaxis therapy, with 70% in year 2 and 75% in year 3 remaining bleed-free.

Pipeline:

- **Concizumab:** Concizumab is a monoclonal antibody against tissue factor pathway inhibitor (TFPI), a natural anticoagulant protein that functions to prevent the formation of blood clots, which binds the Kunitz-2 domain of TFPI, preventing it from binding to activated factor X. It was evaluated in a Phase 3 clinical trial, explorer7, in patients with hemophilia A or B with inhibitors. In explorer7, patients were either randomized to receive no prophylaxis treatment (group 1, n=19) or concizumab prophylaxis (group 2, n=33) for 24 weeks or were nonrandomly assigned to receive concizumab prophylaxis (groups 3 and 4, n=81) for 24 weeks. Explorer7 was halted by the FDA due to 3 nonfatal thrombotic events; however, once the hold was lifted, patients were restarted on a loading dose of 1mg/kg followed by 0.2mg/kg subcutaneously daily with adjustments to be made based on plasma

concentrations at week 4. The mean ABR was 11.8 and 1.7 in groups 1 and 2, respectively. After the study was restarted there were no thrombotic events reported. In March 2023, concizumab was approved in Canada for patients with hemophilia B with inhibitors while still being reviewed for patients with hemophilia A with inhibitors. In May 2023, Novo Nordisk announced the FDA issued a complete response letter (CRL) which stated the Biological License Application (BLA) was not ready for approval based on the August 2022 submission. Novo Nordisk is working with the FDA to answer the questions around monitoring and dosing presented in the CRL and is looking to resubmit a BLA in the future.

- **Fidanacogene Elaparvovec:** Fidanacogene elaparvovec is an investigational AAV vector mediated gene therapy being studies for the treatment of adults with moderately severe or severe hemophilia B. In the Phase 3 BENEGENE-2 trial there was a 71% decrease in the ABR from 4.4 in the prophylaxis lead in period to 1.3 in the post infusion period, which was the primary endpoint. As a secondary endpoint, the factor IX activity level was between 25%-30% for 24 months post infusion which is considered mild hemophilia B. In June 2023, Pfizer announced the FDA had accepted the BLA and is expected to make a decision in the second quarter of 2024.
- **Giroctocogene Fitelparvovec:** Giroctocogene fitelparvovec is a recombinant AAV vector mediated B-domain deleted gene therapy for hemophilia A. In a Phase ½ clinical trial, the mean circulating FVIII in the high dose cohort was 42.6 % and 25.4% at week 52 and 104, respectively. AFFINE is an ongoing Phase 3 trial in adult males 18 to 64 years of age with moderately severe to severe hemophilia A. Dosing for the AFFINE trial has been completed and a read out is expected mid-2024 with a submission to the FDA in the second half of the year.
- **Marstacimab:** Marstacimab is a monoclonal immunoglobulin G that targets the Kunitz-2 domain of TFPI. It has been studied in an open label Phase 3 clinical trial, BASIS, which enrolled patients 12 to 74 years of age with severe hemophilia A and moderately severe to severe hemophilia B with or without inhibitors. Patients were treated with either marstacimab as a 300mg subcutaneous loading dose followed by 150mg weekly or with routine prophylaxis and on demand regimens of FVIII or IX. In the cohort of patients without inhibitors, over the course of the 12 months there was a 35.2% decrease in the mean ABR when compared to routine prophylaxis and 91.6% when compared to on demand treatment. The inhibitor cohort of the trial has also completed enrollment with a readout expected sometime in 2024. Pfizer is also conducting a clinical trial in children 1 to 17 years of age with severe hemophilia A and moderately severe to severe hemophilia B without inhibitors, BASIS KIDS. In December 2023, Pfizer announced the FDA

had accepted the BLA for marstacimab and is expected to make a decision sometime in the fourth quarter of 2024.

Roctavian™ (Valoctocogene Roxaparvovec-rvox) Product Summary[13,14,15]

Therapeutic Class: AAV vector-based gene therapy

Indication(s): Adults with severe hemophilia A [congenital factor VIII deficiency with factor VIII activity <1 international units per deciliter (IU/dL)] without pre-existing antibodies to AAV serotype 5 detected by an FDA-approved test

How Supplied: Single-dose vial (SDV) containing 2×10^{13} vector genomes (vg) per mL with not less than 8mL of extractable volume per vial

Dosing and Administration: The recommended dose is 6×10^{13}vg/kg of body weight administered as a single intravenous (IV) infusion.

Efficacy: Valoctocogene roxaparvovec was evaluated in an open label Phase 3 clinical trial, GENEr8-1, which enrolled adult men with severe hemophilia A without inhibitors and no anti-AAV antibodies. The participants were on prophylactic FVIII therapy for at least 1 year prior to enrolling. The modified intent-to-treat population included 132 patients. The primary endpoint was the FVIII activity level at weeks 49 through 52 post infusion. There was an increase in FVIII activity levels by a mean of 41.9 IU/dL at weeks 49-52 with 7 patients having a FVIII level of greater than 150 IU/dL, 12 patients having a FVIII level of less than 3 IU/dL, and 2 with levels less than 1 IU/dL. In a 2 year follow up report on GENEr8-1, the mean FVIII level had increased by 22 IU/dL from baseline to week 104 post infusion with 31 participants having a FVIII level of less than 5 IU/dL and 5 of those 31 had resumed prophylaxis treatments. In an extrapolation model the FVIII level is predicted to be a mean of 16.9 IU/dL at week 156, 13.6 IU/dL at week 208, and 11.8 IU/dL at week 260. In the Phase 1/2 clinical trial of valoctocogene roxaparvovec, the median FVIII levels in participants decreased over time from 60.3, 26.2, 19.9, 14.5, and 8.2 IU/dL at weeks 52, 104, 156, 208, and 260, respectively. In the GENEr8-1 trial, there were 7 patients with a systemic hypersensitivity reaction during the infusion with 1 being reported as anaphylaxis. The most common adverse event was an increase in alanine aminotransferase (ALT) levels in 85.8% of the treated participants followed by headache (38.1%), nausea (37.3%), and increase in aspartate aminotransferase (AST) levels (35.1%). The elevated liver enzymes were managed with the use of corticosteroids.

Cost: The Wholesale Acquisition Cost (WAC) of valoctocogene roxaparvovec is $90,625 per SDV. For a member weighing 70kg, a total of 27 SDVs would be required, resulting in an estimated cost of $2,446,875 for the one-time treatment.

Recommendations

The Oklahoma Health Care Authority recommends the prior authorization of Roctavian™ (valoctocogene roxaparvovec-rvox) with the following criteria (shown in red):

Roctavian™ (Valoctogene Roxaparvovec-rvox) Approval Criteria:

1. An FDA approved diagnosis of severe congenital (or X-linked) hemophilia A; and
2. Member must be a male 18 years of age or older; and
3. Member must not have a history of or a recent positive screening of an inhibitor defined as ≥0.6 Bethesda units; and
4. Member must be on prophylactic therapy with continued frequent breakthrough bleeding episodes or has experienced a life-threatening bleeding episode; and
5. Member must not have acute infections; and
6. Member must not have chronic active infections such as hepatitis B or C; and
7. Member must not have uncontrolled human immunodeficiency virus (HIV) as shown by CD4+ counts ≤200u/L; and
8. Member must not be taking efavirenz; and
9. Member must not have antibodies to AAV5; and
10. Member must not have 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. Alanine aminotransferase (ALT) >1.25x upper limit of normal (ULN); or
        ii. Aspartate aminotransferase (AST) >1.25x ULN; or
        iii. Gamma-glutamyl transferase (GGT) >1.25x ULN; or
        iv. Total bilirubin >1.25x ULN; or
        v. Alkaline phosphatase >1.25x ULN; or
        vi. International normalized ratio (INR) ≥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.

Utilization Details of Hemophilia Medications: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HEMLIBRA PRODUCTS						
HEMLIBRA INJ 60MG/0.4ML	299	36	$5,916,115.89	$19,786.34	8.31	21.79%
HEMLIBRA INJ 105MG/0.7ML	104	16	$4,338,285.03	$41,714.28	6.5	15.98%
HEMLIBRA INJ 150MG/ML	97	15	$4,486,244.96	$46,249.95	6.47	16.52%
HEMLIBRA INJ 30MG/ML	70	13	$651,248.49	$9,303.55	5.38	2.40%
SUBTOTAL	**570**	**80**	**$15,391,894.37**	**$27,003.32**	**7.13**	**56.69%**
ADVATE PRODUCTS						
ADVATE INJ 2,000U	31	16	$686,258.24	$22,137.36	1.94	2.53%
ADVATE INJ 3,000U	29	9	$1,043,045.88	$35,967.10	3.22	3.84%
ADVATE INJ 1,500U	16	12	$197,062.52	$12,316.41	1.33	0.73%
ADVATE INJ 500U	5	3	$47,519.66	$9,503.93	1.67	0.18%
ADVATE INJ 1,000U	5	4	$44,932.17	$8,986.43	1.25	0.17%
ADVATE INJ 250U	5	2	$17,892.81	$3,578.56	2.5	0.07%
ADVATE INJ 4,000U	1	1	$72,509.95	$72,509.95	1	0.27%
SUBTOTAL	**92**	**47**	**$2,109,221.23**	**$22,926.32**	**1.96**	**7.79%**
ALPROLIX PRODUCTS						
ALPROLIX INJ 1,000U	14	2	$178,942.25	$12,781.59	7	0.66%
ALPROLIX INJ 4,000U	12	2	$328,081.16	$27,340.10	6	1.21%
ALPROLIX INJ 2,000U	12	2	$336,454.28	$28,037.86	6	1.24%
ALPROLIX INJ 3,000U	11	2	$397,665.73	$36,151.43	5.5	1.46%
ALPROLIX INJ 250U	7	3	$27,763.36	$3,966.19	2.33	0.10%
ALPROLIX INJ 500U	6	2	$54,076.50	$9,012.75	3	0.20%
SUBTOTAL	**62**	**13**	**$1,322,983.28**	**$21,338.44**	**4.77**	**4.87%**
KOATE PRODUCTS						
KOATE INJ 1,000U	39	2	$417,489.19	$10,704.85	19.5	1.54%
KOATE INJ 500 U	16	2	$43,034.96	$2,689.69	8	0.16%
KOATE INJ 250U	2	1	$1,305.86	$652.93	2	0.00%
SUBTOTAL	**57**	**5**	**$461,830.01**	**$8,102.28**	**11.40**	**1.70%**
KOVALTRY PRODUCTS						
KOVALTRY INJ 2,000U	25	13	$341,863.07	$13,674.52	1.92	1.26%
KOVALTRY INJ 3,000U	10	6	$170,363.64	$17,036.36	1.67	0.63%
KOVALTRY INJ 1,000U	9	7	$50,126.20	$5,569.58	1.29	0.18%
KOVALTRY INJ 500U	1	1	$3,853.73	$3,853.73	1	0.01%
SUBTOTAL	**45**	**27**	**$566,206.64**	**$12,582.37**	**1.67**	**2.08%**
NUWIQ PRODUCTS						
NUWIQ KIT 1,000U	15	9	$102,587.89	$6,839.19	1.67	0.38%
NUWIQ KIT 500U	10	8	$44,640.65	$4,464.07	1.25	0.16%
NUWIQ KIT 1,500U	6	1	$158,436.75	$26,406.13	6	0.58%
NUWIQ KIT 2,000U	5	2	$13,973.89	$2,794.78	2.5	0.05%
NUWIQ KIT 250U	3	2	$1,728.35	$576.12	1.5	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**39**	**22**	**$321,367.53**	**$8,240.19**	**1.77**	**1.18%**
HUMATE PRODUCTS						
HUMATE-P SOL 250-600U	15	9	$62,543.56	$4,169.57	1.67	0.23%
HUMATE-P SOL 2,400U	11	5	$203,580.92	$18,507.36	2.2	0.75%
HUMATE-P SOL 500-1,200U	8	7	$58,802.56	$7,350.32	1.14	0.22%
SUBTOTAL	**34**	**21**	**$324,927.04**	**$9,556.68**	**1.62**	**1.20%**
KOGENATE PRODUCTS						
KOGENATE FS INJ 2,000U	19	7	$835,411.50	$43,969.03	2.71	3.08%
KOGENATE FS INJ 1,000U	4	3	$27,195.42	$6,798.86	1.33	0.10%
KOGENATE FS INJ 500U	2	2	$8,745.61	$4,372.81	1	0.03%
KOGENATE FS INJ 3,000U	1	1	$13,654.51	$13,654.51	1	0.05%
KOGENATE FS INJ 250U	1	1	$1,896.51	$1,896.51	1	0.01%
SUBTOTAL	**27**	**14**	**$886,903.55**	**$32,848.28**	**1.93**	**3.27%**
NOVOSEVEN PRODUCTS						
NOVOSEVEN RT INJ 1MG	16	6	$254,480.06	$15,905.00	2.67	0.94%
NOVOSEVEN RT INJ 5MG	6	3	$226,174.46	$37,695.74	2	0.83%
NOVOSEVEN RT INJ 2MG	4	3	$66,416.14	$16,604.04	1.33	0.24%
NOVOSEVEN RT INJ 8MG	1	1	$56,435.41	$56,435.41	1	0.21%
SUBTOTAL	**27**	**13**	**$603,506.07**	**$22,352.08**	**2.08**	**2.22%**
WILATE PRODUCTS						
WILATE INJ 1,000-1,000U	20	5	$445,727.23	$22,286.36	4	1.64%
WILATE INJ 500-500U	5	3	$4,748.07	$949.61	1.67	0.02%
SUBTOTAL	**25**	**8**	**$450,475.30**	**$18,019.01**	**3.13**	**1.66%**
ADYNOVATE PRODUCTS						
ADYNOVATE INJ 3,000U	10	2	$361,440.44	$36,144.04	5	1.33%
ADYNOVATE INJ 2,000U	3	2	$20,120.51	$6,706.84	1.5	0.07%
SUBTOTAL	**13**	**4**	**$381,560.95**	**$29,350.84**	**3.25**	**1.40%**
FEIBA PRODUCTS						
FEIBA INJ 2,500U	7	1	$914,011.55	$130,573.08	7	3.37%
FEIBA INJ 500U	5	1	$1,142,140.63	$228,428.13	5	4.21%
SUBTOTAL	**12**	**2**	**$2,056,152.18**	**$171,346.02**	**6**	**7.58%**
ALTUVIIIO PRODUCTS						
ALTUVIIIO INJ 500U	4	1	$30,389.52	$7,597.38	4	0.11%
ALTUVIIIO INJ 2,000U	4	1	$131,521.16	$32,880.29	4	0.48%
ALTUVIIIO INJ 3,000U	3	2	$181,592.12	$60,530.71	1.5	0.67%
SUBTOTAL	**11**	**4**	**$343,502.80**	**$31,227.53**	**2.75**	**1.26%**
RIXUBIS PRODUCTS						
RIXUBIS INJ 2,000U	7	3	$65,040.14	$9,291.45	2.33	0.24%
RIXUBIS INJ 1,000U	3	2	$8,120.77	$2,706.92	1.5	0.03%
SUBTOTAL	**10**	**5**	**$73,160.91**	**$7,316.09**	**2**	**0.27%**
SEVENFACT PRODUCTS						
SEVENFACT INJ 1MG	6	2	$904,584.46	$150,764.08	3	3.33%
SEVENFACT INJ 5MG	2	2	$494,218.82	$247,109.41	1	1.82%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**8**	**4**	**$1,398,803.28**	**$174,850.41**	**2**	**5.15%**
JIVI PRODUCTS						
JIVI INJ 3,000U	3	1	$166,055.97	$55,351.99	3	0.61%
JIVI INJ 500U	2	1	$17,665.56	$8,832.78	2	0.07%
SUBTOTAL	**5**	**2**	**$183,721.53**	**$36,744.31**	**2.5**	**0.68%**
ESPEROCT PRODUCTS						
ESPEROCT INJ 500U	2	1	$43,338.82	$21,669.41	2	0.16%
ESPEROCT INJ 2,000U	2	1	$83,322.82	$41,661.41	2	0.31%
SUBTOTAL	**4**	**2**	**$126,661.64**	**$31,665.41**	**2**	**0.47%**
IDELVION PRODUCTS						
IDELVION SOL 2,000U	3	1	$85,595.25	$28,531.75	3	0.32%
SUBTOTAL	**3**	**1**	**$85,595.25**	**$28,531.75**	**3**	**0.32%**
BENEFIX PRODUCTS						
BENEFIX INJ 2,000U	2	1	$19,584.32	$9,792.16	2	0.07%
BENEFIX INJ 1,000U	1	1	$4,834.97	$4,834.97	1	0.02%
SUBTOTAL	**3**	**2**	**$24,419.29**	**$8,139.76**	**1.5**	**0.09%**
ALPHANATE PRODUCTS						
ALPHANATE INJ 2,000U	1	1	$7,687.21	$7,687.21	1	0.03%
ALPHANATE INJ 1,000U	1	1	$2,565.01	$2,565.01	1	0.01%
ALPHANATE INJ 500U	1	1	$1,197.67	$1,197.67	1	0.00%
SUBTOTAL	**3**	**3**	**$11,449.89**	**$3,816.63**	**1**	**0.04%**
REBINYN PRODUCTS						
REBINYN SOL 1,000U	2	1	$24,056.33	$12,028.17	2	0.09%
SUBTOTAL	**2**	**1**	**$24,056.33**	**$12,028.17**	**2**	**0.09%**
NOVOEIGHT PRODUCTS						
NOVOEIGHT INJ 3,000U	1	1	$4,172.71	$4,172.71	1	0.02%
SUBTOTAL	**1**	**1**	**$4,172.71**	**$4,172.71**	**1**	**0.02%**
TOTAL	**1,053**	**126***	**$27,152,571.78**	**$25,785.92**	**8.36**	**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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM
J7187 VON WILLEBRAND FACTOR COMPLEX	6	5	$14,412.59	$2,402.10
J7189 FACTOR VIIA RT	13	2	$630,560.00	$90,080.00
J7192 FACTOR VIII RT	3	3	$5,473.51	$1,824.50
J7195 FACTOR IX RT	1	1	$9,900.00	$9,900.00
J7209 FACTOR VIII RT (NUWIQ)	1	1	$1.35	$1.35
TOTAL	**24⁺**	**11***	**$660,347.45**	**$27,514.48**

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

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Appendix K

Calendar Year 2023 Annual Review of Growth Hormone Products and Voxzogo® (Vosoritide) and 30-Day Notice to Prior Authorize Ngenla® (Somatrogon-ghla)

Oklahoma Health Care Authority
March 2024

Current Prior Authorization Criteria

Growth Hormone Products	
Tier-1*	**Tier-2**
Genotropin® (somatropin) (Pfizer) - Cartridge, MiniQuick	**Humatrope®** (somatropin) (Eli Lilly) - Vial, Cartridge Kit
	Norditropin® (somatropin) (Novo Nordisk) - FlexPro® Pen
	Nutropin® and Nutropin AQ® (somatropin) (Genentech) - Vial, Pen Cartridge, NuSpin®
	Omnitrope® (somatropin) (Sandoz) - Vial, Cartridge
	Saizen® (somatropin) (EMD Serono) - Vial, click.easy®
	ᵗSerostim® (somatropin) (EMD Serono) - Vial
	ᵗSkytrofa® (lonapegsomatropin-tcgd) (Ascendis) - Cartridge
	ᵗSogroya® (somapacitan-beco) (Novo Nordisk) - Pen
	Zomacton® and Zoma-Jet® (somatropin) (Ferring) - Vial, Injection Device
	ᵗZorbtive® (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)
ᵗAdditional approval criteria applies.

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

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

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

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

Growth Hormone Tier-2 Approval Criteria:

1. Documented allergic reaction to non-active components of all available Tier-1 products; or
2. A clinical exception applies to members with a diagnosis of acquired immunodeficiency syndrome (AIDS) wasting syndrome, in which case Serostim® can be used, regardless of its current Tier status; 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 <2.5cm/year unless associated with another growth-limiting and treatable medical condition (i.e., hypothyroidism); or
3. Epiphyseal closure; or
4. Covered height has been reached:
    a. 152.4cm (60 inches) for girls; or
    b. 165.1cm (65 inches) for boys; or
    c. The covered height does not apply for members with a diagnosis of growth hormone deficiency (GHD) or panhypopituitarism; or
5. Inadequate compliance; or
6. Significant adverse effects.

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

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

(SDS) between -2 and +2]. In general, younger patients may require higher doses than older patients. The following **initial** doses are suggested by the current American Association of Clinical Endocrinologists/American College of Endocrinology (AACE/ACE) guidelines, but these doses should be titrated based on IGF-1 levels:
    i. Age <30 years: 0.4 to 0.5mg per day (may be higher for patients transitioning from pediatric treatment); or
    ii. Age 30-60 years: 0.2 to 0.3mg per day; or
    iii. Age >60 years: 0.1 to 0.2mg per day; and
b. Transition Dosing: In patients transitioning from pediatric to adult dosing, resuming GH doses at 50% of the dose last used in childhood is suggested, as they tend to be more tolerant of higher doses.

Growth Hormone Deficiency (GHD) Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years of age or older (unless hypoglycemia is present); and
    b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    c. Member must meet at least 1 of the following:
        i. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; or
        ii. Member must have evidence of delayed bone age (undefined delay); and
    d. Member must have open epiphyses; and
    e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
    f. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available; and
    g. There must be no contributing medical conditions (e.g., cystic fibrosis, malnutrition, psychosocial deprivation); and
    h. Member must have suboptimal response of ≤10ng/mL on 2 of the following provocative growth hormone stimulation tests, using the highest level per date of testing. (Stimulation tests are always required for approval unless hypoglycemia is observed, in which case a random low glucose level and low growth hormone level would be acceptable):
        i. Propranolol with exercise; or
        ii. Levodopa; or
        iii. Insulin hypoglycemia test; or

iv. Arginine HCl infusion; or
v. Clonidine; or
vi. Glucagon (not approved for use in children); or

i. If hypoglycemia is present and member is growth hormone deficient, request may be approved for 6 months (other criteria above is not applicable). If the member has hypoglycemia, a low glucose level must be submitted along with additional evidence of GHD such as:
    i. Low insulin-like growth factor 1 (IGF-1), random growth hormone level, or suboptimal growth hormone stimulation tests; or
    ii. MRI evidence of congenital anomaly which includes pituitary damage or absence; or
    iii. Other pituitary hormones also being replaced (e.g., thyroid, cortisol).

2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations; or
    b. Adult Dosing: Members with this diagnosis may transition to adult dosing (see "Growth Hormone Dosing" section above for recommendations for adult and transition dosing) after 1 or both of the following:
        i. Epiphyseal closure; or
        ii. GV <2.5cm/year; and
        iii. If either of the above have occurred and the member has not yet transitioned to adult dosing, may be approved short term (3 months) to allow time for transition to adult dosing.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. GV should not be <2.5cm/year if not on adult dosing; and
    e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

Idiopathic Short Stature Approval Criteria:

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

b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
c. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
d. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
e. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
f. Member's growth chart and parental heights must be provided; and
    i. If the form is completed, a growth chart is not required; and
    ii. Parental heights are not always available.

2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations. Treatment may continue until 1 of the following:
        i. Epiphyseal closure; or
        ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
    b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Epiphyses are open; and
    e. GV should not be <2.5cm/year.

Neurosecretory Dysfunction Approval Criteria:

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

d. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
e. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
f. Member's growth chart and parental heights must be provided; and
    i. If the form is completed, a growth chart is not required; and
    ii. Parental heights are not always available; and
g. Member's serum insulin-like growth factor 1 (IGF-1) must be below the mean for member's age; and
    i. Note: Children with profoundly low GV, who are at risk for growth hormone deficiency due to CNS radiation or other organic causes, termed neurosecretory dysfunction, may demonstrate "normal" responses to provocative tests, often for several years, but often benefit from growth hormone therapy.
h. Growth hormone stimulation testing is required; however, growth hormone levels may be normal.

2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations; or
    b. Adult Dosing: Members with this diagnosis may transition to adult dosing (see "Growth Hormone Dosing" section above for recommendations for adult and transition dosing) after 1 of the following:
        i. Epiphyseal closure; or
        ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
        iv. If any of the above have occurred and the member has not yet transitioned to adult dosing, may be approved short term (3 months) to allow time for transition to adult dosing.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. GV should not be <2.5cm/year if not on adult dosing; and
    e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

Panhypopituitarism Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years of age or older (unless hypoglycemia is present); and
    b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    c. Member must meet at least 1 of the following:
        i. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; or
        ii. Member must have evidence of delayed bone age (undefined delay); and
    d. Member must have open epiphyses; and
    e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
        i. For members with secondary panhypopituitarism due to tumor, trauma, or surgery 12 months post trauma or surgery, approval may be granted if no evidence of tumor recurrence and growth has not restarted. The member must still meet all the other criteria; however, authorization would not require height ≥2.25 SD below the mean in these circumstances; and
    f. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available; and
    g. Member must have a history of pituitary or hypothalamic injury due to tumor, trauma, surgery, documented whole brain radiation, irradiation, hemorrhage or infarction, or a congenital anomaly; and
        i. Deficiency in ≥3 pituitary hormones and insulin-like growth factor 1 (IGF-1) ≥2.5 SD below the mean for member's age; or
        ii. No deficiency, or deficiency in <3 pituitary hormones, and IGF-1 <50th percentile and subnormal response of 10ng/mL or less on at least 2 provocative growth hormone stimulation tests, using the highest level per date of testing. (Stimulation tests are always required for approval unless hypoglycemia is observed, in which case a random low glucose level and low growth hormone level would be acceptable); or
    h. If member has MRI evidence of pituitary stalk agenesis, empty sella, or ectopic posterior pituitary "bright spot", member is exempt from height requirement (*criteria letter e listed above*); and
        i. If they lack the hormones testosterone, luteinizing hormone (LH), or follicle-stimulating hormone (FSH) then an MRI is not required; or

i. If hypoglycemia is present and member is growth hormone deficient: request may be approved for 6 months (other criteria above is not applicable). If the member has hypoglycemia, a low glucose level must be submitted along with additional evidence of GHD such as:
    i. Low IGF-1, random growth hormone level, or suboptimal growth hormone stimulation tests; or
    ii. MRI evidence of congenital anomaly which includes pituitary damage or absence; or
    iii. Other pituitary hormones also being replaced (e.g., thyroid, cortisol).

2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations; or
    b. Adult Dosing: Members with this diagnosis may transition to adult dosing (see "Growth Hormone Dosing" section above for recommendations for adult and transition dosing) after 1 or both of the following:
        i. Epiphyseal closure; or
        ii. GV <2.5cm/year; and
        iii. If either of the above have occurred and the member has not yet transitioned to adult dosing, may be approved short term (3 months) to allow time for transition to adult dosing.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. GV should not be <2.5cm/year if not on adult dosing; and
    e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

Short Stature Associated with 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 be 2 years of age or older; and
    b. Member must have a chromosome analysis confirming the diagnosis of PWS; 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.
2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: 0.24mg/kg/week. Treatment should continue until 1 of the following:

i. Epiphyseal closure; or
ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
iii. GV <2.5cm/year; and

b. Adult Dosing: After attainment of adult height, adults with PWS may be considered for adult dosing if evidence is submitted documenting adult growth hormone deficiency [e.g., low insulin-like growth factor 1 (IGF-1) level and GH stimulation testing].

4. Continuation Approval:
   a. Medications and dosing should be appropriate; and
   b. Member should have had a recent office visit with new information regarding heights provided; and
   c. Member should be compliant; and
   d. GV should not be <2.5cm/year; and
   e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

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

1. Initial Approval:
   a. Member must be 2 years or older; and
   b. Member must have a chromosome analysis confirming the diagnosis of SHOX deficiency; and
   c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
   d. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
   e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
   f. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
   g. Member's growth chart and parental heights must be provided; and
      i. If the form is completed, a growth chart is not required; and
      ii. Parental heights are not always available; and
   h. Member must have a normal endocrine screen; and
   i. Member must have no evidence of growth hormone deficiency or insensitivity, tumor activity, diabetes mellitus, history of impaired glucose tolerance, or other serious illness known to interfere with growth.
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed,

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

3. Dosing:
    a. 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 45X, 46XY 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 45X 46XY 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.

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® (Somatropin) Approval Criteria:

1. Member must have a confirmed diagnosis of adult growth hormone deficiency (GHD) confirmed by 1 of the following:
    a. Insulin tolerance test (ITT) or glucagon test with a peak growth hormone (GH) response <3ng/mL; or
    b. ≥3 pituitary hormone deficiencies and insulin like growth factor-1 (IGF-1) standard deviation score (SDS) <-2.0; and
2. Member must be 18 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, compliance will be evaluated and 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.

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. Member must be 5 years of age or older; and
3. Prescriber must verify member has open epiphyses; and
4. The member's baseline height and growth velocity (GV) must be provided; and
5. Voxzogo® must be prescribed by a geneticist, endocrinologist, or other specialist with expertise in the treatment of achondroplasia; and
6. Member's recent weight (taken within the past 3 weeks) must be provided in order to ensure appropriate dosing in accordance with the package labeling; and
7. 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
8. A quantity limit of 30 vials per 30 days will apply; and

9. 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
10. 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.

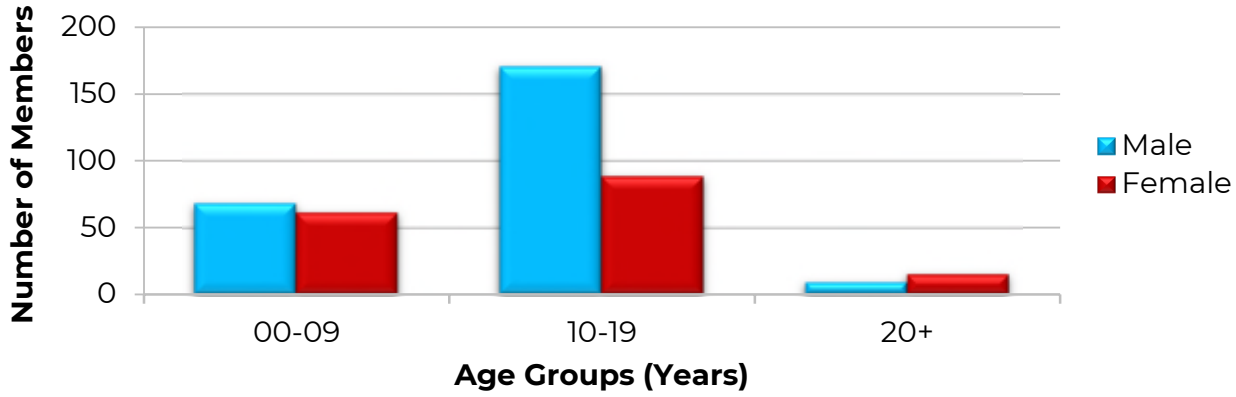
Utilization of Growth Hormone Products and Voxzogo® (Vosoritide): Calendar Year 2023

Comparison of Calendar Years

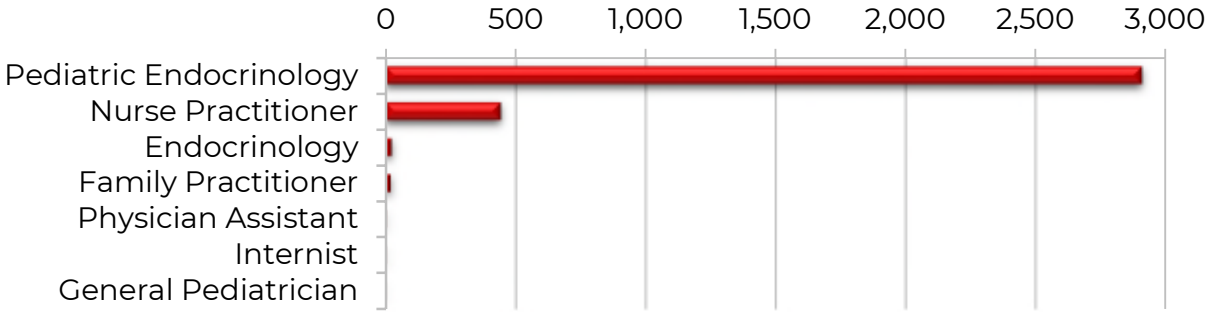
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	369	3,571	$16,421,304.86	$4,598.52	$159.70	50,064	102,827
2023	411	3,404	$16,263,885.02	$4,777.87	$163.03	40,364	99,762
% Change	**11.40%**	**-4.70%**	**-1.00%**	**3.90%**	**2.10%**	**-19.40%**	**-3.00%**
Change	**42**	**-167**	**-$157,419.84**	**$179.35**	**$3.33**	**-9,700**	**-3,065**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

Demographics of Members Utilizing Growth Hormone Products and Voxzogo® (Vosoritide)



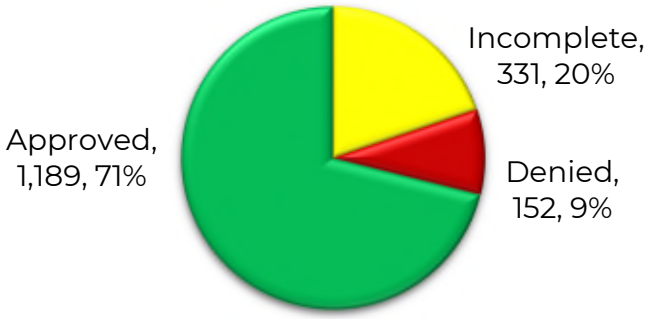
Top Prescriber Specialties of Growth Hormone Products and Voxzogo® (Vosoritide) by Number of Claims



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

There were 1,672 prior authorization requests submitted for 471 unique members for growth hormone products and Voxzogo® (vosoritide) during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Voxzogo® (vosoritide): August 2036

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

- **April 2023:** The FDA approved Sogroya® (somapacitan-beco) for a new indication for the treatment of pediatric patients 2.5 years of age and older who have growth failure due to inadequate secretion of endogenous growth hormone. Sogroya® was previously FDA approved in August 2020 for the replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD). Sogroya® is a long-acting human growth hormone analog that is administered once weekly.
- **June 2023:** The FDA approved Ngenla® (somatrogon-ghla) for the treatment of pediatric patients 3 years of age and older who have growth failure due to inadequate secretion of endogenous growth hormone. Ngenla® is a long-acting human growth hormone analog that is administered once weekly.
- **October 2023:** The FDA approved an age expansion for Voxzogo® (vosoritide) for use in pediatric patients younger than 5 years of age with achondroplasia and open epiphyses. Voxzogo® was previously only FDA approved in patients 5 years of age and older. With this new approval, Voxzogo® is now indicated to increase linear growth in pediatric patients of all ages with open epiphyses. This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Guideline Update(s):

- **May 2023:** New international consensus guidelines were published regarding the management of children born small for gestational age (SGA). The guidelines were developed by experts in the field of SGA, including representatives from the Pediatric Endocrine Society (PES) in the United States. The guidelines continue to recommend the use of growth hormone in children born SGA with persistent short stature at an age after which catch-up growth is unlikely to occur provided other common causes for short stature have been ruled out. Additionally, the guidelines discuss and provide recommendations on the use of genetic testing to identify genetic causes of short stature after being born SGA. Gonadotropin-releasing hormone (GnRH) agonist treatment is also recommended as a treatment consideration for a maximum duration of 2 years to delay puberty in children born SGA if the expected adult

height standard deviation score (SDS) is below -2.5 at the onset of puberty.

Ngenla® (Somatrogon-ghla) Product Summary[6]

Therapeutic Class: Human growth hormone analog

Indication(s): Treatment of pediatric patients 3 years of age and older who have growth failure due to inadequate secretion of endogenous growth hormone

How Supplied: Single-patient-use, prefilled pens available in 2 formulations:
- 24mg/1.2mL (20mg/mL) Pen: Delivers a dose in 0.2mg increments
- 60mg/1.2mL (50mg/mL) Pen: Delivers a dose in 0.5mg increments

Dosing and Administration: The recommended initial dose for all patients is 0.66mg/kg once weekly via subcutaneous (sub-Q) injection into the abdomen, thighs, buttock, or upper arms.
- The dose should then be individualized and titrated based on growth response.
- Ngenla® is contraindicated in children with closed epiphyses.

Cost Comparison:

Product	Cost Per Dose	Cost Per 28 Days[+]	Cost Per Year[+]
Ngenla® (somatrogon-ghla) 60mg/1.2mL pen	**$2,199.50**	**$8,798.00**	**$114,374.00**
Skytrofa® (lonapegsomatropin-tcgd) 9.1mg cartridge	$2,181.72	$8,726.88	$113,449.44
Sogroya® (somapacitan-beco) 15mg/1.5mL cartridge	$1,786.43	$7,145.72	$92,894.36
Genotropin® (somatropin) 1.4mg MiniQuick	$212.52	$5,950.56	$77,357.28

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
[+]Cost per 28 days and cost per year based on recommended initial dosing for each product for a pediatric member weighing 40kg.

Recommendations

The College of Pharmacy recommends the placement of Ngenla® (somatrogon-ghla) into Tier-2 of the Growth Hormone Products Product Based Prior Authorization (PBPA) category with the following additional criteria (shown in red):

Growth Hormone Products	
Tier-1*	**Tier-2**
Genotropin® (somatropin) (Pfizer) - Cartridge, MiniQuick	**Humatrope®** (somatropin) (Eli Lilly) - Vial, Cartridge Kit

Growth Hormone Products	
Tier-1*	**Tier-2**
	⁺**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.

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.

The College of Pharmacy also recommends updating the approval criteria for Sogroya® (somapacitan-beco) and Voxzogo® (vosoritide) based on recent FDA approvals (changes shown in red):

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 ~~18~~ 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. ~~Member must be 5 years of age or older; and~~
3. Prescriber must verify member has open epiphyses; and
4. The member's baseline height and growth velocity (GV) must be provided; and
5. Voxzogo® must be prescribed by a geneticist, endocrinologist, or other specialist with expertise in the treatment of achondroplasia; and
6. Member's recent weight (taken within the past 3 weeks) must be provided in order to ensure appropriate dosing in accordance with the package labeling; and
7. 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
8. A quantity limit of 30 vials per 30 days will apply; and
9. 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
10. Voxzogo® will not be approved following epiphyseal closure.

Utilization Details of Growth Hormone Products and Voxzogo® (Vosoritide): Calendar Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 GROWTH HORMONE (GH) PRODUCTS						
GENOTROPIN INJ 5MG	1,135	143	$4,239,559.10	$3,735.29	7.94	26.07%
GENOTROPIN INJ 12MG	995	139	$6,790,146.07	$6,824.27	7.16	41.75%
GENOTROPIN INJ 0.4MG	238	45	$420,491.38	$1,766.77	5.29	2.59%
GENOTROPIN INJ 0.6MG	148	41	$362,679.82	$2,450.54	3.61	2.23%
GENOTROPIN INJ 1MG	132	33	$554,078.92	$4,197.57	4	3.41%
GENOTROPIN INJ 1.4MG	112	32	$642,443.07	$5,736.10	3.5	3.95%
GENOTROPIN INJ 0.8MG	106	30	$361,886.50	$3,414.02	3.53	2.23%
GENOTROPIN INJ 0.2MG	89	18	$74,736.99	$839.74	4.94	0.46%
GENOTROPIN INJ 1.2MG	63	25	$290,180.15	$4,606.03	2.52	1.78%
GENOTROPIN INJ 2MG	54	18	$450,949.95	$8,350.93	3	2.77%
GENOTROPIN INJ 1.6MG	51	21	$347,412.51	$6,812.01	2.43	2.14%
GENOTROPIN INJ 1.8MG	28	9	$220,283.43	$7,867.27	3.11	1.35%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 GH SUBTOTAL	**3,151**	**554**	**$14,754,847.89**	**$4,682.59**	**5.69**	**90.72%**
TIER-2 GH PRODUCTS⁺						
DAILY GH PRODUCTS						
NORDITROPIN INJ 30MG/3ML	53	24	$296,480.66	$5,593.97	2.21	1.82%
NORDITROPIN INJ 10MG/1.5ML	49	23	$161,645.63	$3,298.89	2.13	0.99%
OMNITROPE INJ 5MG/1.5ML	33	18	$141,678.51	$4,293.29	1.83	0.87%
NORDITROPIN INJ 15MG/1.5ML	25	14	$113,743.68	$4,549.75	1.79	0.70%
NORDITROPIN INJ 5MG/1.5ML	23	14	$69,895.61	$3,038.94	1.64	0.43%
OMNITROPE INJ 10MG/1.5ML	18	3	$45,111.96	$2,506.22	6	0.28%
NUTROPIN AQ INJ 20MG/2ML	6	3	$30,244.62	$5,040.77	2	0.19%
NUTROPIN AQ INJ NUSPIN 5MG/2ML	3	1	$4,571.97	$1,523.99	3	0.03%
NUTROPIN AQ INJ 10MG/2ML	2	2	$7,562.92	$3,781.46	1	0.05%
SEROSTIM INJ 5MG	2	1	$64,596.42	$32,298.21	2	0.40%
HUMATROPE INJ 6MG	1	1	$3,733.81	$3,733.81	1	0.02%
DAILY GH SUBTOTAL	**215**	**104**	**$939,265.79**	**$4,368.68**	**2.07**	**5.78%**
WEEKLY GH PRODUCTS						
SKYTROFA INJ 3MG	5	1	$2,418.98	$483.80	5	0.01%
SKYTROFA INJ 11MG	4	1	$40,232.16	$10,058.04	4	0.25%
SOGROYA INJ 15MG/1.5ML	4	1	$15,860.44	$3,965.11	4	0.10%
SOGROYA INJ 10MG/1.5ML	4	1	$10,588.84	$2,647.21	4	0.07%
SKYTROFA INJ 5.2MG	2	1	$9,316.93	$4,658.47	2	0.06%
SKYTROFA INJ 7.6MG	2	1	$13,905.42	$6,952.71	2	0.09%
SKYTROFA INJ 9.1MG	1	1	$16,634.01	$16,634.01	1	0.10%
WEEKLY GH SUBTOTAL	**22**	**7**	**$108,956.78**	**$4,952.58**	**3.14**	**0.67%**
TIER-2 GH SUBTOTAL	**237**	**111**	**$1,048,222.57**	**$4,422.88**	**2.14**	**6.45%**
GH SUBTOTAL	**3,388**	**409***	**$15,803,070.46**	**$4,664.42**	**8.28**	**97.17%**
VOSORITIDE PRODUCTS						
VOXZOGO INJ 0.56MG	16	2	$460,814.56	$28,800.91	8	2.83%
VOSORITIDE SUBTOTAL	**16**	**2**	**$460,814.56**	**$28,800.91**	**8**	**2.83%**
TOTAL	**3,404**	**411***	**$16,263,885.02**	**$4,777.87**	**8.28**	**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

[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 02/2024. Last accessed 02/19/2024.
[2] Novo Nordisk. FDA Approves Once-Weekly Sogroya® for the Treatment of Children Living with Growth Hormone Deficiency. Available online at: https://www.novonordisk-us.com/media/news-archive/news-details.html?id=166098. Issued 04/28/2023. Last accessed 02/19/2024.
[3] Pfizer, Inc. and OPKO Health, Inc. FDA Approves Pfizer's Ngenla®, a Long-Acting Once-Weekly Treatment for Pediatric Growth Hormone Deficiency. Available online at: https://www.pfizer.com/news/press-release/press-release-detail/fda-approves-pfizers-ngenlatm-long-acting-once-weekly. Issued 06/28/2023. Last accessed 02/19/2024.
[4] BioMarin Pharmaceutical, Inc. U.S. Food and Drug Administration Approves BioMarin's Voxzogo® (Vosoritide) for Children Under 5 Years with Achondroplasia. Available online at: https://investors.biomarin.com/news/news-details/2023/U.S.-Food-and-Drug-Administration-Approves-BioMarins-VOXZOGO-vosoritide-for-Children-Under-5-Years-with-Achondroplasia-10-20-2023/default.aspx. Issued 10/20/2023. Last accessed 02/19/2024.
[5] Hokken-Koelega ACS, van der Steen M, Boguszewski MCS, et al. International Consensus Guideline on Small for Gestational Age: Etiology and Management from Infancy to Early Adulthood. *Endocr Rev* 2023; 44(3):539-565. doi: 10.1210/endrev/bnad002.
[6] Ngenla® (Somatrogon-ghla) Prescribing Information. Pfizer, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761184Orig1s000Corrected_lbl.pdf. Last revised 06/2023. Last accessed 02/19/2024.

Appendix L

Calendar Year 2023 Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and 30-Day Notice to Prior Authorize Ryzneuta® (Efbemalenograstim Alfa-vuxw)

Oklahoma Health Care Authority
March 2024

Current Prior Authorization Criteria

Fulphila® (Pegfilgrastim-jmdb), 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 Fylnetra® (pegfilgrastim-pbbk), Granix® (tbo-filgrastim), Neupogen® (filgrastim), Zarxio® (filgrastim-sndz), 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.

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) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fylnetra® (pegfilgrastim-pbbk), Granix® (tbo-filgrastim), Neupogen® (filgrastim), Zarxio® (filgrastim-sndz), or Ziextenzo® (pegfilgrastim-bmez) must be provided.

Utilization of G-CSFs: Calendar Year 2023

Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	88	277	$745,804.90	$2,692.44	$205.29	1,270	3,633
2023	125	355	$855,160.81	$2,408.90	$132.01	2,038	6,478
% Change	**42.00%**	**28.20%**	**14.70%**	**-10.50%**	**-35.70%**	**60.50%**	**78.30%**
Change	**37**	**78**	**$109,355.91**	**-$283.54**	**-$73.28**	**768**	**2,845**

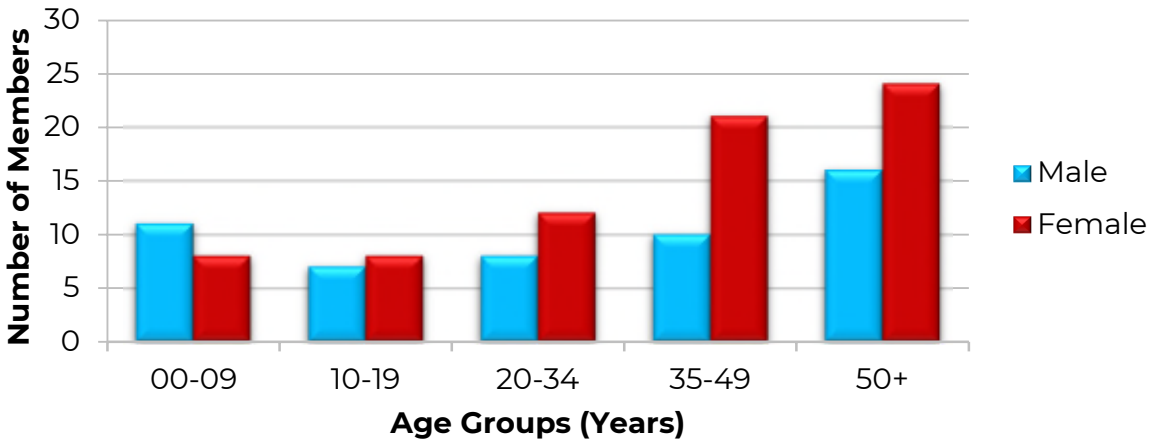
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

Comparison of Calendar Years: Medical Claims

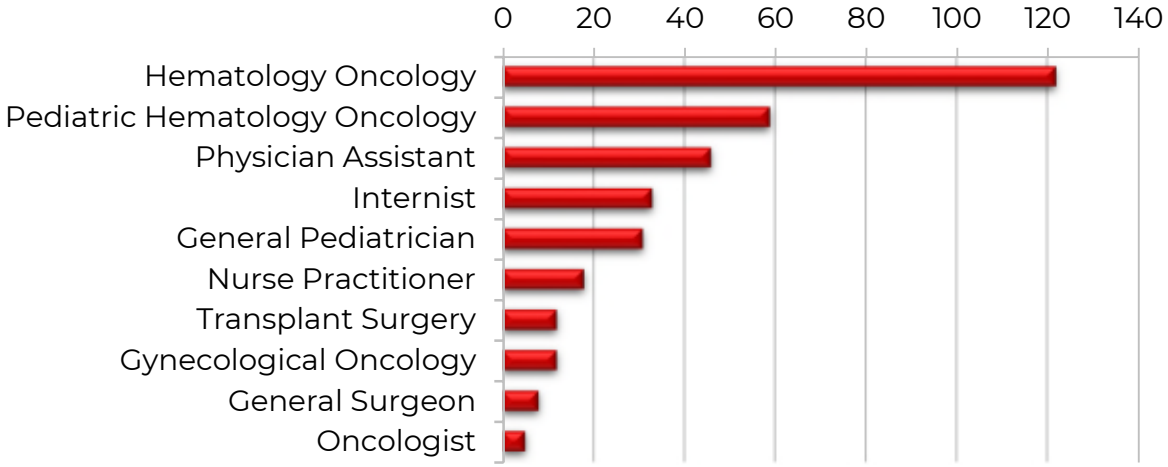
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	458	1,668	$3,141,517.47	$1,883.40	3.64
2023	406	1,422	$1,766,107.34	$1,241.99	3.5
% Change	**-11.35%**	**-14.75%**	**-43.78%**	**-34.01%**	**-3.85%**
Change	**-52**	**-246**	**-$1,375,410.12**	**-$641.41**	**-0.14**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.

Demographics of Members Utilizing G-CSFs: Pharmacy Claims



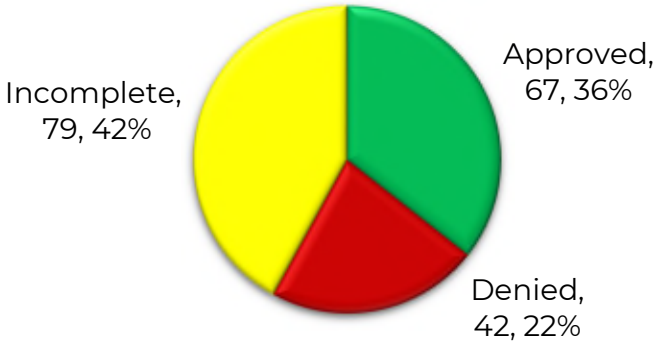
Top Prescriber Specialties of G-CSFs by Number of Claims: Pharmacy Claims



Prior Authorization of G-CSFs

There were 188 prior authorization requests submitted for G-CSFs during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



Market News and Updates[1,2]

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

- **November 2023:** The FDA approved Ryzneuta® (efbemalenograstim alfa-vuxw) to treat chemotherapy-induced neutropenia (CIN), the first long-acting, non-pegylated G-CSF approved by the FDA.
- **December 2023:** The FDA approved an on-body injector formulation of Udenyca® (pegfilgrastim-cbqv), a biosimilar to Neulasta® (pegfilgrastim).

Ryzneuta® (Efbemalenograstim Alfa-vuxw) Product Summary[3]

Therapeutic class: Leukocyte growth factor

Indication(s): To decrease the incidence of infections, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

- **Limitation(s) of Use:** Ryzneuta® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

How Supplied: 20mg/mL solution in a single-dose prefilled syringe

Dosing and Administration:

- 20mg administered subcutaneously once per chemotherapy cycle
- Administer approximately 24 hours after cytotoxic chemotherapy
- Do not administer between 14 days before and 24 hours after administration of cytotoxic chemotherapy

Cost: The Wholesale Acquisition Cost (WAC) of Ryzneuta® is not available at this time to allow for a cost analysis.

Recommendations

The College of Pharmacy recommends adding Ryzneuta® (efbemalenograstim alfa-vuxw) to the current prior authorization criteria for Rolvedon® (eflapegrastim-xnst) and updating the current criteria based on net costs and to be consistent with clinical practice (changes shown in red):

Rolvedon® (Eflapegrastim-xnst) and Ryzneuta® (Efbemalenograstim Alfa-vuxw) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fulphila® (pegfilgrastim-jmdb), Fylnetra® (pegfilgrastim-pbbk), ~~Granix® (tbo-filgrastim), Neupogen® (filgrastim), Zarxio® (filgrastim-sndz)~~, Neulasta® Onpro® (pegfilgrastim), or Ziextenzo® (pegfilgrastim-bmez) must be provided; and
3. Neulasta® Onpro® (pegfilgrastim) will be covered as a medical only benefit without prior authorization.

Additionally, the College of Pharmacy recommends updating the current prior authorization criteria for the G-CSF medications based on net costs and to be consistent with clinical practice (changes shown in red):

~~**Fulphila® (Pegfilgrastim-jmdb),**~~ **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), ~~Granix® (tbo-filgrastim), Neupogen® (filgrastim), Zarxio® (filgrastim-sndz)~~), 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.

Utilization Details of G-CSFs: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FILGRASTIM PRODUCTS						
NEUPOGEN INJ 300MCG/1ML	53	14	$188,298.88	$3,552.81	3.79	22.02%
ZARXIO INJ 300MCG/0.5ML PFS	39	15	$22,310.99	$572.08	2.6	2.61%
NEUPOGEN INJ 480MCG/0.8ML	26	17	$64,180.35	$2,465.71	1.53	7.50%
ZARXIO INJ 480MCG/0.8ML PFS	23	14	$17,604.35	$765.41	1.64	2.06%
NEUPOGEN INJ 300MCG/0.5ML	16	14	$29,293.46	$1,830.84	1.14	3.43%
NEUPOGEN INJ 480MCG/1.6ML	14	2	$185,582.78	$13,255.91	7	21.70%
GRANIX INJ 480MCG/0.8ML PFS	8	3	$7,232.40	$904.05	2.67	0.85%
GRANIX INJ 300MCG/0.5ML PFS	7	3	$4,684.37	$669.20	2.33	0.55%
GRANIX INJ 480MCG/1.6ML	1	1	$5,857.81	$5,857.81	1	0.68%
SUBTOTAL	**187**	**83**	**$524,973.39**	**$2,807.34**	**2.25**	**61.39%**
PEGFILGRASTIM PRODUCTS						
ZIEXTENZO INJ 6MG/0.6ML PFS	93	37	$103,604.33	$1,114.03	2.51	12.12%
FULPHILA INJ 6MG/0.6ML PFS	50	19	$157,101.00	$3,142.02	2.63	18.37%
FYLNETRA INJ 6MG/0.6ML PFS	23	13	$57,722.43	$2,509.67	1.77	6.75%
NEULASTA INJ 6MG/0.6ML PFS	2	2	$11,759.66	$5,879.83	1	1.38%
SUBTOTAL	**168**	**71**	**$330,187.42**	**$1,965.40**	**2.37**	**38.61%**
TOTAL	**355**	**125***	**$855,160.81**	**$2,408.90**	**2.84**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; PFS = prefilled syringe

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PEGFILGRASTIM PRODUCTS					
PEGFILGRASTIM-BMEZ INJ (Q5120)	448	157	$428,665.08	$956.84	2.85
PEGFILGRASTIM-APGF INJ (Q5122)	352	107	$520,409.46	$1,478.44	3.29
PEGFILGRASTIM-JMDB INJ (Q5108)	256	110	$310,265.88	$1,211.98	2.33
PEGFILGRASTIM-PBBK INJ (Q5130)	169	64	$420,973.94	$2,490.97	2.64
PEGFILGRASTIM INJ (J2506)	47	16	$59,370.78	$1,263.21	2.94
SUBTOTAL	**1,272**	**454**	**$1,739,685.14**	**$1,367.68**	**2.8**
FILGRASTIM PRODUCTS					
TBO-FILGRASTIM INJ (J1447)	74	17	$12,724.20	$171.95	4.35
FILGRASTIM-SNDZ INJ (Q5101)	55	15	$4,839.60	$87.99	3.67
FILGRASTIM INJ (J1442)	21	9	$8,858.40	$421.83	2.33
SUBTOTAL	**150**	**41**	**$26,422.20**	**$176.15**	**3.66**
TOTAL	**1,422†**	**406***	**$1,766,107.34**	**$1,241.99**	**3.5**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection

[1] Evive Biotech. Evive Biotech and Acrotech Biopharma Announce FDA Approval of Ryzneuta® (Efbemalenograstim Alfa Injection) for Chemotherapy-Induced Neutropenia. Available online at: https://www.evivebiotech.com/en/newsd/index?id=56. Issued 11/22/2023. Last accessed 02/07/2024.
[2] Park, B. FDA Approves On-Body Injector Presentation of Udenyca. *Cancer Therapy Advisor*. Available online at: https://www.cancertherapyadvisor.com/home/cancer-topics/general-oncology/fda-approves-on-body-injector-presentation-udenyca/. Issued 12/28/2023. Last accessed 02/07/2024.
[3] Ryzneuta® (Efbemalenograstim Alfa-vuxw) Prescribing Information. BioLineRx. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761134s000lbl.pdf. Last revised 09/2023. Last accessed 02/09/2024.

Appendix M

Calendar Year 2023 Annual Review of Multiple Sclerosis (MS) Medications and 30-Day Notice to Prior Authorize Tyruko® (Natalizumab-sztn)

Oklahoma Health Care Authority
March 2024

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 The first dose should 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.

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. Prescriber, infusion center, and member must enroll in the TOUCH Prescribing Program; and
5. 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: Calendar Year 2023

Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	210	1,439	$10,443,802.79	$7,257.68	$241.02	51,904	43,332
2023	227	1,620	$11,637,746.68	$7,183.79	$240.94	56,219	48,301
% Change	**8.1%**	**12.6%**	**11.4%**	**-1.0%**	**-0.0%**	**8.3%**	**11.5%**
Change	**17**	**181**	**$1,193,943.89**	**-$73.89**	**-$0.08**	**4,315**	**4,969**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

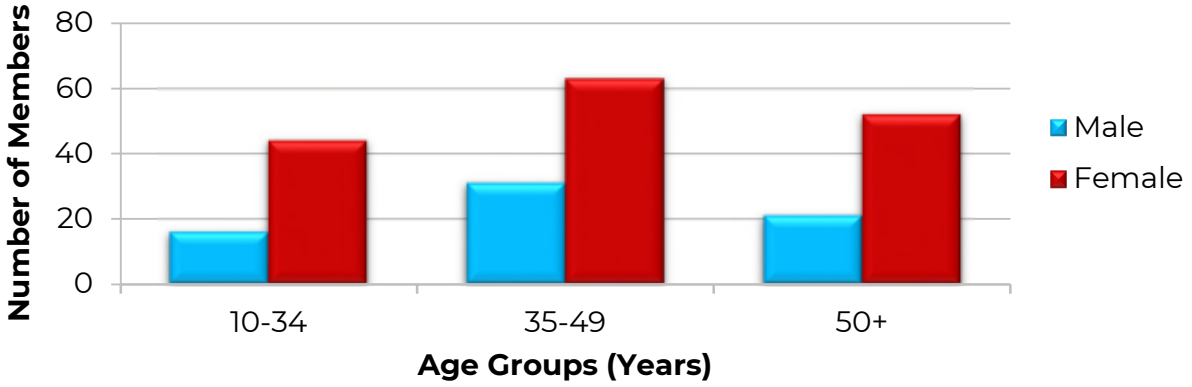
Comparison of Calendar Years: Medical Claims

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	100	313	$5,183,944.50	$16,562.12	3.13
2023	140	360	$6,636,435.73	$18,434.54	2.57
% Change	**40%**	**15.02%**	**28.02%**	**11.31%**	**-17.89%**
Change	**40**	**47**	**$1,452,491.23**	**$1,872.42**	**-0.56**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.

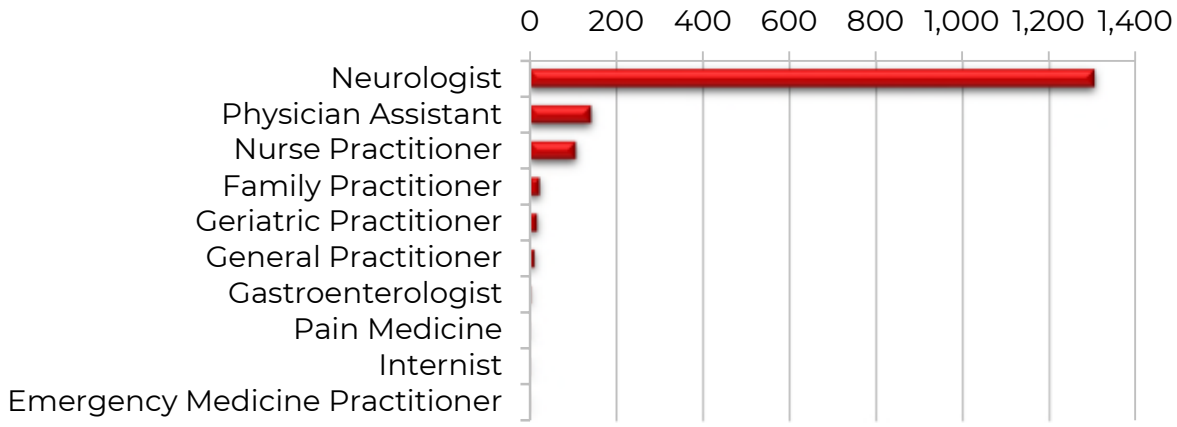
- Aggregate drug rebates collected during fiscal year 2023 (07/01/2022 to 06/30/2023) for MS medications totaled $10,564,479.70.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2023 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for calendar year 2023 are still being collected at this time. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing MS Medications



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

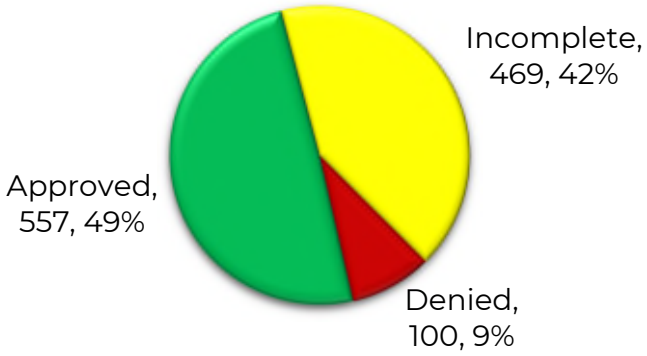
Top Prescriber Specialties of MS Medications by Number of Claims



Prior Authorization of MS Medications

There were 1,126 prior authorization requests submitted for MS medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Mayzent® (siponimod tablets): November 2030
- Zeposia® (ozanimod capsules): November 2030
- Gilenya® (fingolimod capsules): September 2032
- Vumerity® (diroximel fumarate capsules): September 2033
- Aubagio® (teriflunomide tablets): August 2034
- Bafiertam® (monomethyl fumarate capsules): August 2035
- Tecfidera® (dimethyl fumarate capsules): November 2035
- Ponvory® (ponesimod tablets): December 2035
- Tascenso ODT® [fingolimod orally disintegrating tablets (ODT)]: January 2036

- Mavenclad® (cladribine tablets): November 2038

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

- **August 2023:** The FDA approved Tyruko® (natalizumab-sztn), a biosimilar to Tysabri® (natalizumab). Tyruko® is approved to treat all the same indications as Tysabri®, which include Crohn's disease and relapsing forms of multiple sclerosis (RMS), making Tyruko® the first and only biosimilar medication approved for RMS. Tyruko® will be available in the same intravenous (IV) dosage form and follow the same dosing and administration. Similar to Tysabri®, Tyruko® will only be available through a Risk Evaluation and Mitigation Strategy (REMS) program due to the increased risk of progressive multifocal leukoencephalopathy (PML).

Pipeline:

- **Bruton's Tyrosine Kinase (BTK) Inhibitors:** BTK inhibitors are small molecules that block the BTK enzyme, which controls how immune B-cells and microglia grow, survive, and become activated to help provide an immune response. BTK inhibition is being studied to reduce inflammation and nerve cell damage in MS patients and there are currently 4 BTK inhibitors in Phase 3 trials: evobrutinib, fenebrutinib, remibrutinib, and tolebrutinib. Three of these BTK inhibitors have been placed on a partial clinical hold due to suspected drug-induced liver injury which could be a class-wide effect. Evobrutinib was also shown to not meet its primary endpoint of reducing the annualized relapse rate versus Aubagio® (teriflunomide) as of December 2023.
- **Frexalimab:** Frexalimab is a novel second-generation anti-CD40L antibody that works by blocking the CD40/CD40L pathway. The unique mechanism of action is thought to have the potential to address both acute and chronic neuroinflammation in MS patients without lymphocyte reduction. Phase 2 trials studied frexalimab at 2 different dosing regimens, a high dose of 120mg every 4 weeks and a low dose of 300mg every 2 weeks, with both regimens requiring a loading dose. After 12 weeks, both dosing regimens showed significant reduction in the number of T2 lesions versus placebo with the high dose frexalimab showing a greater reduction being sustained over time. Phase 3 trials are currently ongoing.
- **GA Depot:** The FDA has accepted a New Drug Application (NDA) for GA Depot, a long-acting glatiramer acetate that is being investigated as a 40mg injection administered every 4 weeks for the treatment of RMS. Glatiramer acetate is currently available as a 20mg injection given once daily and a 40mg injection given three times weekly. A Prescription Drug User Fee Act (PDUFA) action date of March 8, 2024 has been set.

- **KYV-101:** KYV-101 is an autologous, fully human CD19 chimeric antigen receptor (CAR) T-cell product that has been granted Fast Track designation by the FDA for the treatment of progressive forms of MS in treatment-resistant patients. The CAR receptor recognizes the CD19 protein on B-cells and provides the patient's immune system with the ability to target the antibody producing B-cells. A Phase 2 trial is currently ongoing and expected to last through 2027.
- **Masitinib:** Masitinib is a tyrosine kinase (TK) inhibitor that targets mast cells and microglia which are associated with progressive MS. The mechanism of action is different than other TK inhibitors currently being developed (i.e., BTK inhibitors) and masitinib could be complementary to other TK inhibitors. Masitinib has been granted FDA approval to start the Phase 3 trial in progressive forms of MS. The Phase 3 trial is currently recruiting patients and will include those with primary progressive MS (PPMS) or non-active secondary progressive MS (nSPMS). Currently there is only 1 FDA approved treatment for PPMS and none for nSPMS.
- **Ocrevus® (Ocrelizumab) Subcutaneous (Sub-Q) Formulation:** Ocrelizumab is being studied in a new sub-Q formulation that can be given over 10 minutes versus the currently available IV formulation that is given over 2 hours every 6 months. The Phase 3 trial showed the sub-Q formulation was non-inferior to the IV formulation with a similar efficacy and safety profile. The sub-Q formulation is combined with Halozyme Therapeutics' Enhanze® drug delivery technology which increases the permeability of the tissue under the skin, allowing space for large molecules to enter, and enables the sub-Q formulation to be rapidly dispersed and absorbed into the bloodstream. Ocrelizumab remains the first and only therapy approved for both RMS and PPMS.

Recommendations

The College of Pharmacy recommends the prior authorization of Tyruko® (natalizumab-sztn) with criteria similar to Tysabri® (natalizumab) (changes shown in red):

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 Tyruko® 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.

Additionally, the College of Pharmacy recommends the following changes to the MS Interferon Medications Product Based Prior Authorization (PBPA) category based on net costs (changes shown in red):

1. Moving interferon β - 1a (Avonex®) to Tier-2; and
2. Moving interferon β - 1a (Rebif®) to Tier-1.

Multiple Sclerosis Interferon Medications	
Tier-1	**Tier-2**
~~**interferon β - 1a (Avonex®)**~~	~~**interferon β - 1a (Rebif®)**~~
interferon β - 1a (Rebif®)	**interferon β - 1a (Avonex®)**
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.

Utilization Details of MS Medications: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OFATUMUMAB PRODUCTS						
KESIMPTA INJ 20MG/0.4ML	371	53	$3,190,948.05	$8,600.94	7	27.42%
SUBTOTAL	**371**	**53**	**$3,190,948.05**	**$8,600.94**	**7**	**27.42%**
DALFAMPRIDINE PRODUCTS						
DALFAMPRIDINE TAB 10MG ER	212	29	$8,763.77	$41.34	7.31	0.08%
AMPYRA TAB 10MG	22	3	$85,304.76	$3,877.49	7.33	0.73%
SUBTOTAL	**234**	**32**	**$94,068.53**	**$402.00**	**7.31**	**0.81%**
GLATIRAMER ACETATE PRODUCTS						
COPAXONE INJ 40MG/ML	110	16	$622,518.97	$5,659.26	6.88	5.35%
COPAXONE INJ 20MG/ML	86	16	$612,523.76	$7,122.37	5.38	5.26%
GLATIRAMER INJ 40MG/ML	13	1	$20,552.67	$1,580.97	13	0.18%
GLATIRAMER INJ 20MG/ML	3	1	$5,884.23	$1,961.41	3	0.05%
SUBTOTAL	**212**	**34**	**$1,261,479.63**	**$5,950.38**	**6.24**	**10.84%**
TERIFLUNOMODE PRODUCTS						
AUBAGIO TAB 14MG	115	20	$1,052,522.28	$9,152.37	5.75	9.04%
TERIFLUNOMIDE TAB 14MG	49	10	$4,538.21	$92.62	4.9	0.04%
AUBAGIO TAB 7MG	2	1	$18,082.26	$9,041.13	2	0.16%
SUBTOTAL	**166**	**31**	**$1,075,142.75**	**$6,476.76**	**5.35**	**9.24%**
FINGOLIMOD PRODUCTS						
GILENYA CAP 0.5MG	103	12	$1,043,170.66	$10,127.87	8.58	8.96%
FINGOLIMOD CAP 0.5MG	60	7	$31,529.13	$525.49	8.57	0.27%
SUBTOTAL	**163**	**19**	**$1,074,699.79**	**$6,593.25**	**8.58**	**9.23%**
DIROXIMEL FUMARATE PRODUCTS						
VUMERITY CAP 231MG	151	28	$1,199,660.93	$7,944.77	5.39	10.31%
SUBTOTAL	**151**	**28**	**$1,199,660.93**	**$7,944.77**	**5.39**	**10.31%**
DIMETHYL FUMARATE PRODUCTS						
DIMETHYL FUM CAP 240MG DR	96	20	$7,219.83	$75.21	4.8	0.06%
TECFIDERA CAP 240MG	25	3	$223,847.85	$8,953.91	8.33	1.92%
DIMETHYL FUM CAP STARTER PAK	7	7	$1,646.87	$235.27	1	0.01%
DIMETHYL FUM CAP 120MG DR	2	2	$168.82	$84.41	1	0%
SUBTOTAL	**130**	**32**	**$232,883.37**	**$1,791.41**	**4.06**	**1.99%**
INTERFERON BETA-1A PRODUCTS						
AVONEX PEN KIT 30MCG	48	5	$367,176.36	$7,649.51	9.6	3.16%
REBIF REBIDOSE INJ 22MCG/0.5ML	12	1	$118,494.85	$9,874.57	12	1.02%
REBIF REBIDOSE INJ 44MCG/0.5ML	11	1	$108,518.60	$9,865.33	11	0.93%
REBIF INJ 22MCG/0.5ML	4	2	$38,336.70	$9,584.18	2	0.33%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
REBIF INJ 44MCG/0.5ML	4	1	$39,020.85	$9,755.21	4	0.34%
SUBTOTAL	**79**	**10**	**$671,547.36**	**$8,500.60**	**7.9**	**5.78%**
CLADRIBINE PRODUCTS						
MAVENCLAD 7-PAK 10MG	10	7	$670,058.18	$67,005.82	1.43	5.76%
MAVENCLAD 8-PAK 10MG	5	5	$373,750.41	$74,750.08	1	3.21%
MAVENCLAD 10-PAK 10MG	5	3	$473,138.05	$94,627.61	1.67	4.07%
MAVENCLAD 4-PAK 10MG	4	2	$157,247.88	$39,311.97	2	1.35%
MAVENCLAD 5-PAK 10MG	2	1	$94,634.42	$47,317.21	2	0.81%
SUBTOTAL	**26**	**18**	**$1,768,828.94**	**$68,031.88**	**1.44**	**15.20%**
SIPONIMOD PRODUCTS						
MAYZENT TAB 2MG	22	3	$203,313.48	$9,241.52	7.33	1.75%
MAYZENT STARTER PAK	1	1	$930.80	$930.80	1	0.01%
SUBTOTAL	**23**	**4**	**$204,244.28**	**$8,880.19**	**5.75**	**1.76%**
OZANIMOD PRODUCTS						
ZEPOSIA CAP 0.92MG	20	6	$165,454.80	$8,272.74	3.33	1.42%
SUBTOTAL	**20**	**6**	**$165,454.80**	**$8,272.74**	**3.33**	**1.42%**
NATALIZUMAB PRODUCTS						
TYSABRI INJ 300MG/15ML	19	3	$138,351.09	$7,281.64	6.33	1.19%
SUBTOTAL	**19**	**3**	**$138,351.09**	**$7,281.64**	**6.33**	**1.19%**
INTERFERON BETA-1B PRODUCTS						
BETASERON INJ 0.3MG	13	2	$115,963.52	$8,920.27	6.5	1%
SUBTOTAL	**13**	**2**	**$115,963.52**	**$8,920.27**	**6.50**	**1%**
OCRELIZUMAB PRODUCTS						
OCREVUS INJ 300MG/10ML	10	6	$375,606.10	$37,560.61	1.67	3.23%
SUBTOTAL	**10**	**6**	**$375,606.10**	**$37,560.61**	**1.67**	**3.23%**
UBLITUXIMAB-XIIY PRODUCTS						
BRIUMVI INJ 150MG/6ML	3	1	$68,867.54	$22,955.85	3	0.59%
SUBTOTAL	**3**	**1**	**$68,867.54**	**$22,955.85**	**3**	**0.59%**
TOTAL	**1,620**	**227***	**$11,637,746.68**	**$7,183.79**	**7.14**	**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; PAK = pack; PREFL = prefilled; TAB = tablet

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
OCREVUS INJ 300MG/10ML (J2350)	178	110	$5,271,222.73	1.62	$29,613.61
TYSABRI INJ 300MG/15ML (J2323)	177	27	$1,275,567	6.56	$7,206.59
BRIUMVI INJ 150MG/6ML (J2329)	5	3	$89,646	1.67	$17,929.20
TOTAL	**360†**	**140***	**$6,636,435.73**	**2.57**	**$18,434.54**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims

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Appendix N

Calendar Year 2023 Annual Review of Stem Cell Mobilizers and 30-Day Notice to Prior Authorize Aphexda® (Motixafortide)

Oklahoma Health Care Authority
March 2024

Current Prior Authorization Criteria

Mozobil® (Plerixafor) Approval Criteria:

1. An FDA approved indication for use in combination with a granulocyte-colony stimulating factor (G-CSF) 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 G-CSF filgrastim; 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 the duration of 2 months.

Utilization of Stem Cell Mobilizers: Calendar Year 2023

Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	1	1	$74,539.01	$74,539.01	$18,634.75	10	4
2023	0	0	$0.00	$0.00	$0.00	0	0
% Change	**-100%**	**-100%**	**-100%**	**-100%**	**-100%**	**-100%**	**-100%**
Change	**-1**	**-1**	**-$74,539.01**	**-$74,539.01**	**-$18,634.75**	**-10**	**-4**

Costs do not reflect rebated prices or net costs.
Please note: Utilization only includes Mozobil® (plerixafor).
*Total number of unduplicated utilizing members.

Comparison of Calendar Years: Medical Claims

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	2	3	$21,737.16	$7,245.72	1.5
2023	4	4	$25,815.57	$6,453.89	1
% Change	**100.00%**	**33.33%**	**18.76%**	**-10.93%**	**-33.3%**
Change	**2**	**1**	**$4,078.41**	**-$791.83**	**-0.5**

Costs do not reflect rebated prices or net costs.
Please note: Utilization only includes Mozobil® (plerixafor).
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.

Demographics of Members Utilizing Stem Cell Mobilizers: Pharmacy Claims

- Due to the limited number of members utilizing stem cell mobilizers, detailed demographic information could not be provided.

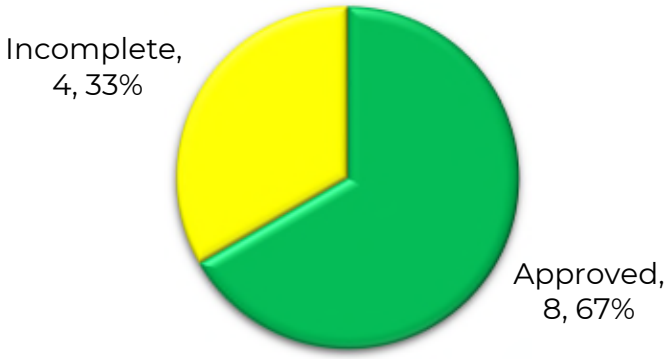
Top Prescriber Specialties of Stem Cell Mobilizers by Number of Claims: Pharmacy Claims

- The only prescriber specialty listed on approved prior authorization requests for stem cell mobilizers during calendar year 2023 was hematologist/oncologist.

Prior Authorization of Stem Cell Mobilizers

There were 12 prior authorization requests submitted for 8 unique members for stem cell mobilizers during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Aphexda® (motixafortide): September 2030

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

- **July 2023:** The FDA approved plerixafor injection, a generic equivalent to Mozobil® (plerixafor).
- **September 2023:** The FDA approved Aphexda® (motixafortide) in combination with filgrastim, a granulocyte colony-stimulating factor (G-CSF), to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma.
- **September 2023:** The FDA updated the indication for Mozobil® (plerixafor) to specify filgrastim as the G-CSF to be used in combination with Mozobil®.

Aphexda® (Motixafortide) Product Summary[5]

Therapeutic class: Stem cell mobilizer

Indication(s): In combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma

How Supplied: 62mg as a lyophilized powder in a single-dose vial for reconstitution

Dosing and Administration:

- Aphexda® treatment should be initiated after filgrastim has been administered daily for 4 days.
- The recommended dosage is 1.25mg/kg actual body weight by subcutaneous injection 10 to 14 hours prior to initiation of apheresis.
- A second dose of Aphexda® can be administered 10 to 14 days hours to a third apheresis if necessary.
- See full *Prescribing Information* for instructions on preparation and administration.

Cost Comparison

Product	Cost Per Vial	Cost Per Treatment*
Aphexda® (motixafortide) 62mg SDV	**$5,900.00**	**$23,600.00**
Mozobil® (plerixafor) 24mg/1.2mL SDV	$9,968.07	$39,872.28
plerixafor 24mg/1.2mL SDV (generic)	$3,987.23[α]	$15,948.92

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 treatment is based on the maximum FDA approved dosing of each product for an 80kg patient, resulting in 2 doses of Aphexda® and 4 doses of plerixafor per treatment.
[α]Cost per vial varies per NDC.
SDV = single-dose vial

Recommendations

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

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.

Additionally, the College of Pharmacy recommends updating the current approval criteria for Mozobil® (plerixafor) to be consistent with the FDA approved indication and to be consistent with clinical practice (changes shown in red):

Mozobil® (Plerixafor) Approval Criteria:

1. An FDA approved indication for use in combination with ~~a granulocyte-colony stimulating factor (G-CSF)~~ 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.

Utilization Details of Stem Cell Mobilizers: Calendar Year 2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PLERIXAFOR INJ (J2562)	4	4	$25,815.57	$6,453.89	1
TOTAL	**4⁺**	**4***	**$25,815.57**	**$6,453.89**	**1**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 02/2024. Last accessed 02/09/2024.
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Appendix O

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 5, 2024

FDA Clears First Over-the-Counter Continuous Glucose Monitor

The FDA cleared for marketing the first over-the-counter (OTC) continuous glucose monitor (CGM). The Dexcom Stelo Glucose Biosensor System is an integrated CGM (iCGM) intended for anyone 18 years of age and older who does not use insulin, such as individuals with diabetes treating their condition with oral medications, or those without diabetes who want to better understand how diet and exercise may impact blood sugar levels. Importantly, this system is not for individuals with problematic hypoglycemia as the system is not designed to alert the user to this potentially dangerous condition.

The Stelo Glucose Biosensor System uses a wearable sensor, paired with an application installed on a user's smartphone or other smart device, to continuously measure, record, analyze, and display glucose values in people 18 years of age and older that are not on insulin and who do not have problematic hypoglycemia. Users can wear each sensor for up to 15 days before replacing it with a new sensor. The device presents blood glucose measurements and trends every 15 minutes in the accompanying app. Users should not make medical decisions based on the device's output without talking to their healthcare provider.

Data from a clinical study provided to the FDA showed that the device performed similarly to other iCGMs. Adverse events reported in the study included local infection, skin irritation and pain or discomfort.

As part of the Center for Devices and Radiological Health's (CDRH) strategic priority to advance health equity, CDRH will continue to support innovation that addresses health equity by moving care and wellness into the home setting.

FDA NEWS RELEASE

For Immediate Release: February 16, 2024

FDA Approves First Cellular Therapy to Treat Patients with Unresectable or Metastatic Melanoma

The FDA approved Amtagvi™ (lifileucel), the first cellular therapy indicated for the treatment of adult patients with melanoma that is unresectable or metastatic that previously has been treated with other therapies (a PD-1 blocking antibody, and if *BRAF* V600 mutation positive, a *BRAF* inhibitor with or without a MEK inhibitor).

Melanoma is a form of skin cancer that is often caused by exposure to ultraviolet light, which can come from sunlight or indoor tanning. Although melanomas only represent approximately 1% of all skin cancers, they account for a significant number of cancer-related deaths. Melanoma can spread to other parts of the body if not detected and treated early, resulting in metastatic disease. Treatment for unresectable or metastatic melanoma may include immunotherapy using PD-1 inhibitors. In addition, drugs targeting the *BRAF* gene may be used for treating melanoma associated with *BRAF* gene mutations. Those patients whose melanoma has progressed with these therapies have a high unmet medical need.

Amtagvi™ is a tumor-derived autologous T cell immunotherapy composed of a patient's own T cells. A portion of the patient's tumor tissue is removed during a surgical procedure prior to treatment. The patients' T cells are separated from the tumor tissue, further manufactured, and then returned to the same patient as a single dose for infusion. This is the first FDA-approved tumor-derived T cell immunotherapy.

Amtagvi™ was approved through the Accelerated Approval pathway, under which the FDA may approve drugs for serious or life-threatening illnesses or conditions where there is an unmet medical need, and the drug is shown to have an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients. This pathway generally gives patients the opportunity for earlier access to a promising therapy while the company conducts further trials to verify the predicted clinical benefit. A confirmatory trial is ongoing to verify the clinical benefit of Amtagvi™.

The safety and effectiveness of Amtagvi™ were evaluated in a global, multicenter, multicohort clinical study including adult patients with unresectable or metastatic melanoma who had previously been treated with at least 1 systemic therapy, including a PD-1 blocking antibody, and if positive for the *BRAF* V600 mutation, a *BRAF* inhibitor or *BRAF* inhibitor with an MEK inhibitor. Effectiveness was established based on objective response rate to treatment and duration of response (measured from the date of confirmed initial objective response to the date of progression, death from any cause, starting a new anti-cancer treatment or discontinuation from follow-up, whichever came first). Among the 73 patients treated with Amtagvi™ at the recommended dose, the objective response rate was 31.5%, including 3 (4.1%) patients with a complete response and 20 (27.4%) patients with a partial response. Among patients who were responsive to the treatment, 56.5%, 47.8% and 43.5% continued to maintain responses without tumor progression or death at 6, 9, and 12 months, respectively.

Patients treated with Amtagvi™ may exhibit prolonged severe low blood count, severe infection, cardiac disorder, or develop worsened respiratory or renal function or have fatal treatment-related complications. A *Boxed Warning* is included in the label containing information about these risks. Patients receiving this product should be closely monitored before and after infusion for signs and symptoms of adverse reactions. Treatment should be withheld or discontinued in the presence of these symptoms, as indicated. The most common adverse reactions associated with Amtagvi™ included chills, fever, fatigue, tachycardia, diarrhea, febrile neutropenia, edema, rash, hypotension, hair loss, infection, and feeling short of breath.

Amtagvi™ also received Orphan Drug, Regenerative Medicine Advanced Therapy, Fast Track, and Priority Review designations. The FDA granted the approval of Amtagvi™ to Iovance Biotherapeutics Inc.

FDA NEWS RELEASE

For Immediate Release: February 16, 2024

FDA Approves First Medication to Help Reduce Allergic Reactions to Multiple Foods After Accidental Exposure

The FDA approved Xolair® (omalizumab) for immunoglobulin E (IgE)-mediated food allergy in certain adults and children 1 year of age or older for the reduction of allergic reactions (Type I), including reducing the risk of anaphylaxis, that may occur with accidental exposure to 1 or more foods. Patients who take Xolair® must continue to avoid foods they are allergic to. Xolair® is intended for repeated use to reduce the risk of allergic reactions and is not approved for the immediate emergency treatment of allergic reactions, including anaphylaxis. Xolair® was originally approved in 2003 for the treatment

of moderate to severe persistent allergic asthma in certain patients. Xolair® is also approved to treat chronic spontaneous urticaria and chronic rhinosinusitis with nasal polyps in certain patients.

According to the Centers for Disease Control and Prevention, almost 6% of people in the United States in 2021 had a food allergy and exposure to the particular food(s) to which they are allergic can lead to potentially life-threatening allergic reactions (i.e., anaphylaxis). There is currently no cure for food allergy. Current treatment requires strict avoidance of the food(s) the patient is allergic to, and prompt administration of epinephrine to treat anaphylaxis should accidental exposures occur. Palforzia® (peanut allergen powder) is an oral immunotherapy product approved in patients 4-17 years of age for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut, but its benefits are restricted to peanut allergy. Xolair® is the first FDA-approved medication to reduce allergic reactions to more than 1 type of food after accidental exposure.

Xolair® is a drug that binds to IgE, the antibody type that triggers allergic reactions, and blocks IgE from binding to its receptors. Safety and efficacy of Xolair® in reducing allergic reactions in subjects with food allergies was established in 1 multi-center, double-blind, placebo-controlled study of 168 pediatric and adult patients at least 1 year of age or older who were allergic to peanut and at least 2 other foods, including milk, egg, wheat, cashew, hazelnut, or walnut. Researchers randomly gave subjects either Xolair® or placebo treatment for 16 to 20 weeks. The primary measure of efficacy was the percentage of subjects who were able to eat a single dose (600mg or greater) of peanut protein (equivalent to 2.5 peanuts) without moderate to severe allergic symptoms, such as moderate to severe skin, respiratory, or gastrointestinal symptoms, at the end of the 16-to-20-week treatment course. Of those who received Xolair®, 68% were able to eat the single dose of peanut protein without moderate to severe allergic symptoms compared to 6% who received placebo; these results are statistically significant and clinically meaningful for subjects with food allergy. Of note, however, 17% of subjects receiving Xolair® had no significant change in the amount of peanut protein tolerated. As a result, continuation of strict allergen avoidance is still necessary, despite treatment with Xolair®.

The key secondary measures of efficacy were the percentage of subjects who were able to consume a single dose (1,000mg or greater) of cashew, milk, or egg protein without moderate to severe allergic symptoms at the end of the 16-to-20-week treatment course. For cashew, 42% who received Xolair® achieved this endpoint compared to 3% who received placebo. For milk, 66% who received Xolair® achieved this endpoint, compared to 11% who received placebo. For egg, 67% who received Xolair® achieved this endpoint, compared to 0% of the 19 who received placebo. As a result, Xolair® treatment is approved for certain patients with 1 or more IgE-mediated food allergies.

The most common side effects of Xolair® observed included injection site reactions and fever. Xolair® comes with certain warnings and precautions, such as anaphylaxis, malignancy, fever, joint pain, rash, parasitic infection, and abnormal laboratory tests. In addition, Xolair® comes with a *Boxed Warning* for anaphylaxis, which can be life threatening, based on pre-marketing and post-marketing reports of anaphylaxis that occurred after Xolair® administration. Anaphylaxis has occurred after the first dose of Xolair®, but also has occurred beyond 1 year after beginning treatment. Xolair® should only be started in a health care setting equipped to manage anaphylaxis. For selected patients who tolerate initial Xolair® treatments in a health care setting without anaphylaxis, self-administration or administration by a caregiver may be appropriate and should be discussed with a health care provider. Patients should not receive Xolair® if they have a

history of known severe hypersensitivity to Xolair® or any of its components. Xolair® is not approved for the immediate emergency treatment of allergic reactions, including anaphylaxis.

Xolair® received Priority Review and Breakthrough Therapy designations for this indication. The FDA granted the approval of Xolair® to Genentech.

FDA NEWS RELEASE

For Immediate Release: February 14, 2024

FDA Approves First Medication to Treat Severe Frostbite

The FDA approved Aurlumyn™ (iloprost) injection to treat severe frostbite in adults to reduce the risk of finger or toe amputation. Iloprost was originally approved in 2004 for the treatment of pulmonary arterial hypertension.

Frostbite can occur in several stages, ranging from mild frostbite that does not require medical intervention and does not cause permanent skin damage, to severe frostbite when both the skin and underlying tissue are frozen and blood flow is stopped, sometimes requiring amputation. Iloprost, the active ingredient in Aurlumyn™, is a vasodilator and prevents blood from clotting.

Iloprost's efficacy in treating severe frostbite was primarily established in an open-label, controlled trial that randomized 47 adults with severe frostbite, who all received aspirin intravenously (IV) and standard of care, into 1 of 3 treatment groups. One of these groups (Group 1) received iloprost IV for 6 hours daily for up to 8 days. The 2 other groups received other medications that are unapproved for frostbite, given with iloprost (Group 2) or without iloprost (Group 3). The primary measure of efficacy was a bone scan obtained 7 days after initial frostbite that was used to predict the need for amputation of at least 1 finger or toe. On day 7, the bone scan finding predictive of needing amputation was observed in 0% of patients receiving iloprost alone (Group 1) compared to 19% of patients in Group 2 and 60% of patients in Group 3. The presence of the bone scan abnormality was significantly lower in the 2 groups receiving iloprost. Most patients had follow-up information on whether they subsequently underwent at least 1 finger or toe amputation. The need for amputation was consistent with the bone scan findings.

The most common side effects of Aurlumyn™ include headache, flushing, heart palpitations, fast heart rate, nausea, vomiting, dizziness, and hypotension. Aurlumyn™ also has a warning and precaution noting that it may cause symptomatic hypotension.

Aurlumyn™ received Priority Review and Orphan Drug designations for this indication. The FDA granted the approval of Aurlumyn™ to Eicos Sciences Inc.

Current Drug Shortages Index (as of February 28th, 2024):

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***
Alprostadil Suppository	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amoxapine Tablet	***Currently in Shortage***
Amoxicillin Powder, For Suspension	***Currently in Shortage***

Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropa Belladonna, Opium Suppository	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bazedoxifene Acetate, Estrogens, Conjugated Tablet	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Capecitabine Tablet	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefixime Capsule	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Cisplatin Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Collagenase Clostridium Histolyticum Ointment	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Cyclopentolate Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Cyclopentolate Hydrochloride, Phenylephrine Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate Injection	***Currently in Shortage***
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection	***Currently in Shortage***
Diazepam Gel	***Currently in Shortage***
Difluprednate Emulsion	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Disopyramide Phosphate Capsule	***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***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Epinephrine Injection	***Currently in Shortage***
Erythromycin Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***

Fentanyl Citrate Injection	***Currently in Shortage***
Fluconazole Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
Indigotindisulfonate Sodium Injection	***Currently in Shortage***
Isoniazid Tablet	***Currently in Shortage***
Ketamine Hydrochloride Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Lidocaine Hydrochloride Solution	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***
Mepivacaine Hydrochloride Injection	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methotrexate Sodium Tablet	***Currently in Shortage***
Methyldopa Tablet, Film Coated	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Neomycin Sulfate Tablet	***Currently in Shortage***
Nitroglycerin Injection	***Currently in Shortage***
Nizatidine Capsule	***Currently in Shortage***
Oxybutynin Chloride Syrup	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Potassium Acetate Injection	***Currently in Shortage***
Potassium Chloride Injection	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***

Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Semaglutide Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection	***Currently in Shortage***
Sodium Chloride 0.9% Irrigation	***Currently in Shortage***
Sodium Chloride 14.6% Injection	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection	***Currently in Shortage***
Sodium Pyrophosphate Injection	***Currently in Shortage***
Somatropin Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sucralfate Tablet	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Sulfasalazine Tablet	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsule	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide Injection	***Currently in Shortage***
Vinblastine Sulfate Injection	***Currently in Shortage***