OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
February 14, 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:
https://oklahoma.zoom.us/webinar/register/WN_R_AmCBepQpGQggKXT40uxg
After registering, you will receive a confirmation email
containing information about joining the webinar.

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

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – February 14, 2024

DATE: February 7, 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.

Viewing Access Only via Zoom:
Please register for the meeting at:
https://oklahoma.zoom.us/webinar/register/WN_R_AmCBepQpGQggKXT40uxg
After registering, you will receive a confirmation email containing information about joining the webinar.

Enclosed are the following items related to the February 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/ 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) – A8ppendix B

Action Item – Narrow Therapeutic Index (NTI) List – Appendix C

Action Item – 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 – Appendix D

Action Item – Vote to Prior Authorize Exxua™ (Gepirone) and Zurzuvae™ (Zuranolone) and Update the Approval Criteria for the Antidepressants – Appendix E

Action Item – 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 – Appendix F

Action Item – Vote to Prior Authorize Hepzato Kit™ (Mephalan) and Zynyz™ (Retifanlimab-dlwr) and Update the Approval Criteria for the Skin Cancer Medications – Appendix G

Action Item – Vote to Update the Approval Criteria for the Gastrointestinal (GI) Cancer Medications – Appendix H

Action Item – Vote to Prior Authorize Iwilfin™ (Eflornithine), Kepivance® (Palifermin), Loqtorzi™ (Toripalimab-tpzi), and Omisirge® (Omidubicel-onlv) – Appendix I

Action Item – Vote to Prior Authorize Ogsiveo™ (Nirogacestat) – Appendix J

Action Item – Vote to Prior Authorize Xphozah® (Tenapanor) and Update the Approval Criteria for the Hyperphosphatemia Medications – Appendix K

Action Item – Vote to Prior Authorize Atorvaliq® (Atorvastatin Oral Suspension) and Update the Approval Criteria for the Antihyperlipidemics – Appendix L

Action Item – Vote to Prior Authorize Oxybutynin 2.5mg Tablet and Update the Approval Criteria for the Bladder Control Medications – Appendix M

Action Item – Vote to Prior Authorize iDose® TR (Travoprost Intracameral Implant) and Update the Approval Criteria for the Glaucoma Medications – Appendix N

Action Item – Annual Review of Otic Anti-Infective Medications – Appendix O

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

Action Item – Annual Review of Antiviral Medications – Appendix Q

Annual Review of Leukemia Medications and 30-Day Notice to Prior Authorize Vanflyta® (Quizartinib) – Appendix R

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

Annual Review of Anti-Parasitic Medications and 30-Day Notice to Prior Authorize Xdemvy™ (Lotilaner Ophthalmic Solution) – Appendix T

30-Day Notice to Prior Authorize Ycanth™ (Cantharidin) and Zelsuvmi™ (Berdazimer) – Appendix U

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – February 14, 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

Viewing Access Only via Zoom:

Please register for the meeting at:
https://oklahoma.zoom.us/webinar/register/WN_R_AmCBepQpGQggKXT40uxg
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. December 13, 2023 DUR Board Meeting Minutes
   B. December 13, 2023 DUR Board Recommendations Memorandum
   C. January 10, 2024 DUR Board Recommendations Memorandum

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

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 – See Appendix B**
   A. Pharmacy Help Desk Activity for January 2024
   B. Medication Coverage Activity for January 2024
   C. 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

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

5. **Action Item – Narrow Therapeutic Index (NTI) List – See Appendix C**
   A. Introduction
   B. NTI List
   C. College of Pharmacy Recommendations

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

6. **Action Item – 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 – See Appendix D**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Exxua™ (Gepirone) and Zurzuvae™ (Zuranolone) and Update the Approval Criteria for the Antidepressants – See Appendix E**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

8. **Action Item – 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 – See Appendix F**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Hepzato Kit™ (Mephalan) and Zynyz™ (Retifanlimab-dlwr) and Update the Approval Criteria for the Skin Cancer Medications – See Appendix G**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Update the Approval Criteria for the Gastrointestinal (GI) Cancer Medications – See Appendix H**
    A. Market News and Updates
    B. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Iwilfin™ (Eflornithine), Kepivance® (Palifermin), Loqtorzi™ (Toripalimab-tpzi), and Omisirge® (Omidubicel-onlv) – See Appendix I**
    A. Market News and Updates

B. Product Summaries
C. College of Pharmacy Recommendations

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

12. Action Item – Vote to Prior Authorize Ogsiveo™ (Nirogacestat) – See Appendix J

A. Ogsiveo™ (Nirogacestat) Product Summary
B. College of Pharmacy Recommendations

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

13. Action Item – Vote to Prior Authorize Xphozah® (Tenapanor) and Update the Approval Criteria for the Hyperphosphatemia Medications – See Appendix K

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

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

14. Action Item – Vote to Prior Authorize Atorvaliq® (Atorvastatin Oral Suspension) and Update the Approval Criteria for the Antihyperlipidemics – See Appendix L

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

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

15. Action Item – Vote to Prior Authorize Oxybutynin 2.5mg Tablet and Update the Approval Criteria for the Bladder Control Medications – See Appendix M

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

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

16. Action Item – Vote to Prior Authorize iDose® TR (Travoprost Intracameral Implant) and Update the Approval Criteria for the Glaucoma Medications – See Appendix N

A. Market News and Updates
B. iDose® TR (Travoprost Intracameral Implant) Product Summary
C. College of Pharmacy Recommendations

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

17. Action Item – Annual Review of Otic Anti-Infective Medications – See Appendix O

A. Current Prior Authorization Criteria
B. Utilization of Otic Anti-Infective Medications
C. Prior Authorization of Otic Anti-Infective Medications

D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Otic Anti-Infective Medications

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

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

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

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

19. Action Item – Annual Review of Antiviral Medications – See Appendix Q

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

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

20. Annual Review of Leukemia Medications and 30-Day Notice to Prior Authorize Vanflyta® (Quizartinib) – See Appendix R

A. Current Prior Authorization Criteria
B. Utilization of Leukemia Medications
C. Prior Authorization of Leukemia Medications
D. Market News and Updates
E. Vanflyta® (Quizartinib) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Leukemia Medications

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

21. Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize RizaFilm® (Rizatriptan Film) and Zavzpret™ (Zavegepant Nasal Spray) – See Appendix S

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

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

22. Annual Review of Anti-Parasitic Medications and 30-Day Notice to Prior Authorize Xdemvy™ (Lotilaner Ophthalmic Solution) – See Appendix T

A. Current Prior Authorization Criteria
B. Utilization of Anti-Parasitic Medications
C. Prior Authorization of Anti-Parasitic Medications
D. Market News and Updates
E. Xdemvy™ (Lotilaner Ophthalmic Solution) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Anti-Parasitic Medications

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

23. 30-Day Notice to Prior Authorize Ycanth™ (Cantharidin) and Zelsuvmi™ (Berdazimer) – See Appendix U

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

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

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

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

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

A. Hemophilia Medications
B. Growth Hormone Products and Voxzogo® (Vosoritide)
C. Lymphoma Medications
D. Multiple Sclerosis (MS) Medications

*Future product and class reviews subject to change.

26. 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 DECEMBER 13, 2023

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
Emily Borders, Pharm.D., BCOP	X	
Brooke Daugherty, 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	
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:	
Dan O'Donnell, Axsome	Jamie Tobitt, Apellis
Daphne Ni, Biogen	Cheng Yuet, Amgen
Bob Atkins, Biogen	Carmen Hinton, EBSI
Nick Bianchini, Axsome	Bryan Steffan, Boehringer
Janie Huff, Madrigal	Kristen Winters, Centene
Richie Crawford, Otsuka	Mark Kaiser, Otsuka
David Prather, Novo Nordisk	Dave Poskey, UCB
Nima Nabavi, Amgen	Steve George, Boehringer
Irene Chung, Aetna	Brandy Barrett, Aetna
John King, AbbVie	Shellie Keast, Mercer
Rhonda Clark, Indivior	Melissa Abbott, Eisai
Rusty Hailey, Intra-Cellular Therapies	Dana Mennen, Apellis
Peter Lee, OMES	Frank Alvarado, Johnson & Johnson
Phil Lohec, Viatris	Artia Solutions
Jen Tamburo, Astra Zeneca	John Omick, Travere

PRESENT FOR PUBLIC COMMENT:	
Jamie Tobitt, Apellis	Daphne Ni, Biogen
Nick Bianchini, Axsome	

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**

2A: AGENDA ITEM NO. 14 JAMIE TOBITT

2B: AGENDA ITEM NO. 15 DAPHNE NI

2C: AGENDA ITEM NO. 15 NICHOLAS BIANCHINI

ACTION: NONE REQUIRED

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

3A: NOVEMBER 8, 2023 DUR MINUTES

Materials included in agenda packet; presented by Dr. Muchmore

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/ACADEMIC DETAILING PROGRAM UPDATE**

4A: PHARMACY HELPDESK ACTIVITY FOR NOVEMBER 2023

4B: MEDICATION COVERAGE ACTIVITY FOR NOVEMBER 2023

4C: ACADEMIC DETAILING PROGRAM UPDATE

Materials included in agenda packet; presented by Dr. Morgan, Dr. Travers
ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: SOONERCARE MAINTENANCE DRUG LIST
5A: INTRODUCTION
5B: SOONERCARE MAINTENANCE DRUG LIST
5C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. West moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE SYMBICORT AEROSPHERE® (BUDESONIDE/FORMOTEROL) AND UPDATE THE APPROVAL CRITERIA FOR THE ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS
6A: MARKET NEWS AND UPDATES
6B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Haymore
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE SOHONOS™ (PALOVAROTENE)
7A: MARKET NEWS AND UPDATES
7B: SOHONOS™ (PALOVAROTENE) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. West moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE MIEBO™ (PERFLUOROHEXYLOCTANE OPHTHALMIC SOLUTION) AND VEVYE® (CYCLOSPORINE OPHTHALMIC SOLUTION)
8A: MARKET NEWS AND UPDATES
8B: PRODUCT SUMMARIES
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Morgan
Dr. West moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE VEOZAH™ (FEZOLINETANT) AND UPDATE THE APPROVAL CRITERIA FOR VASOMOTOR SYMPTOM (VMS) MEDICATIONS
9A: MARKET NEWS AND UPDATES
9B: VEOZAH™ (FEZOLINETANT) PRODUCT SUMMARY
9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE ELREXFIO™ (ELRANATAMAB-BCMM) AND TALVEY™ (TALQUETAMAB-TGVS) AND UPDATE THE APPROVAL CRITERIA FOR THE MULTIPLE MYELOMA MEDICATIONS
10A: MARKET NEWS AND UPDATES
10B: PRODUCT SUMMARIES

10C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Patatanian moved to approve; seconded by Dr. West
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 11:</u> ANNUAL REVIEW OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
11C: PRIOR AUTHORIZATION OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
11D: MARKET NEWS AND UPDATES
11E: COLLEGE OF PHARMACY RECOMMENDATIONS
11F: UTILIZATION DETAILS OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 12:</u> ANNUAL REVIEW OF CONSTIPATION AND DIARRHEA MEDICATIONS
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF CONSTIPATION AND DIARRHEA MEDICATIONS
12C: PRIOR AUTHORIZATION OF CONSTIPATION AND DIARRHEA MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: COLLEGE OF PHARMACY RECOMMENDATIONS
12F: UTILIZATION DETAILS OF CONSTIPATION AND DIARRHEA MEDICATIONS
Materials included in agenda packet; presented by Dr. Morgan
Dr. Muñoz moved to approve; seconded by Dr. West
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF SKIN CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE HEPZATO KIT™ (MEPHALAN) AND ZYNYZ™ (RETIFANLIMAB-DLWR)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF SKIN CANCER MEDICATIONS
13C: PRIOR AUTHORIZATION OF SKIN CANCER MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: PRODUCT SUMMARIES
13F: COLLEGE OF PHARMACY RECOMMENDATIONS
13G: UTILIZATION DETAILS OF SKIN CANCER MEDICATIONS
Materials included in agenda packet; presented by Dr. Borders
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

<u>AGENDA ITEM NO. 14:</u> ANNUAL REVIEW OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE RYSTIGGO® (ROZANOLIXIZUMAB-NOLI), VYVGART® HYTRULO (EFGARTIGIMOD ALFA/HYALURONIDASE-QVFC), AND ZILBRYSQ® (ZILUCOPLAN)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS
14C: PRIOR AUTHORIZATION OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS

14D: MARKET NEWS AND UPDATES
14E: PRODUCT SUMMARIES
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS

Materials included in agenda packet; presented by Dr. Moss

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

AGENDA ITEM NO. 15: ANNUAL REVIEW OF ANTIDEPRESSANTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE EXXUA™ (GEPIRONE) AND ZURZUVAE™ (ZURANOLONE)

15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ANTIDEPRESSANTS
15C: PRIOR AUTHORIZATION OF ANTIDEPRESSANTS
15D: MARKET NEWS AND UPDATES
15E: PRODUCT SUMMARIES
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF ANTIDEPRESSANTS

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

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

AGENDA ITEM NO. 16: ANNUAL REVIEW OF LYSOSOMAL STORAGE DISEASE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ELFABRIO® (PEGUNIGALSIDASE ALFA-IWXJ), OPFOLDA™ (MIGLUSTAT), AND POMBILITI™ (CIPAGLUCOSIDASE ALFA-ATGA)

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF LYSOSOMAL STORAGE DISEASE MEDICATIONS
16C: PRIOR AUTHORIZATION OF LYSOSOMAL STORAGE DISEASE MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: PRODUCT SUMMARIES
16F: COLLEGE OF PHARMACY RECOMMENDATIONS
16G: UTILIZATION DETAILS OF LYSOSOMAL STORAGE DISEASE MEDICATIONS

Materials included in agenda packet; presented by Dr. Wilson

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

AGENDA ITEM NO. 17: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES

Materials included in agenda packet; presented by Dr. Morgan

ACTION: NONE REQUIRED

AGENDA ITEM NO. 18: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)

18A: ANTIHYPERLIPIDEMICS
18B: BLADDER CONTROL MEDICATIONS
18C: GLAUCOMA MEDICATIONS
18D: NON-MALIGNANT SOLID TUMOR MEDICATIONS

*Future product and class reviews subject to change.

Materials included in agenda packet; presented by Dr. Adams

ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: ADJOURNMENT

The meeting was adjourned at 6:04pm.

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

Memorandum

Date: January 12, 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 Packet Meeting on January 10, 2024

Recommendation 1: Annual Eye Exam in Members with Glaucoma

NO ACTION REQUIRED.

Recommendation 2: Annual Review of Antihyperlipidemics and 30-day Notice to Prior Authorize Atorvaliq® (Atorvastatin Oral Suspension)

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

Recommendation 3: Annual Review of Bladder Control Medications and 30-Day Notice to Prior Authorize Oxybutynin 2.5mg Tablet

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

Recommendation 4: Annual Review of Gastrointestinal (GI) Cancer Medications

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

Recommendation 5: Annual Review of Glaucoma Medications and 30-Day Notice to Prior Authorize iDose® TR (Travoprost Intracameral Implant)

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

Recommendation 6: Annual Review of Hyperphosphatemia Medications and 30-Day Notice to Prior Authorize Xphozah® (Tenapanor)

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

Recommendation 7: Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Iwilfin™ (Eflornithine), Kepivance® (Palifermin), Loqtorzi™ (Toripalimab-tpzi), and Omisirge® (Omidubicel-onlv)

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

Recommendation 8: Annual Review of Non-Malignant Solid Tumor Medications and 30-Day Notice to Prior Authorize Ogsiveo™ (Nirogacestat)

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

Recommendation 9: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

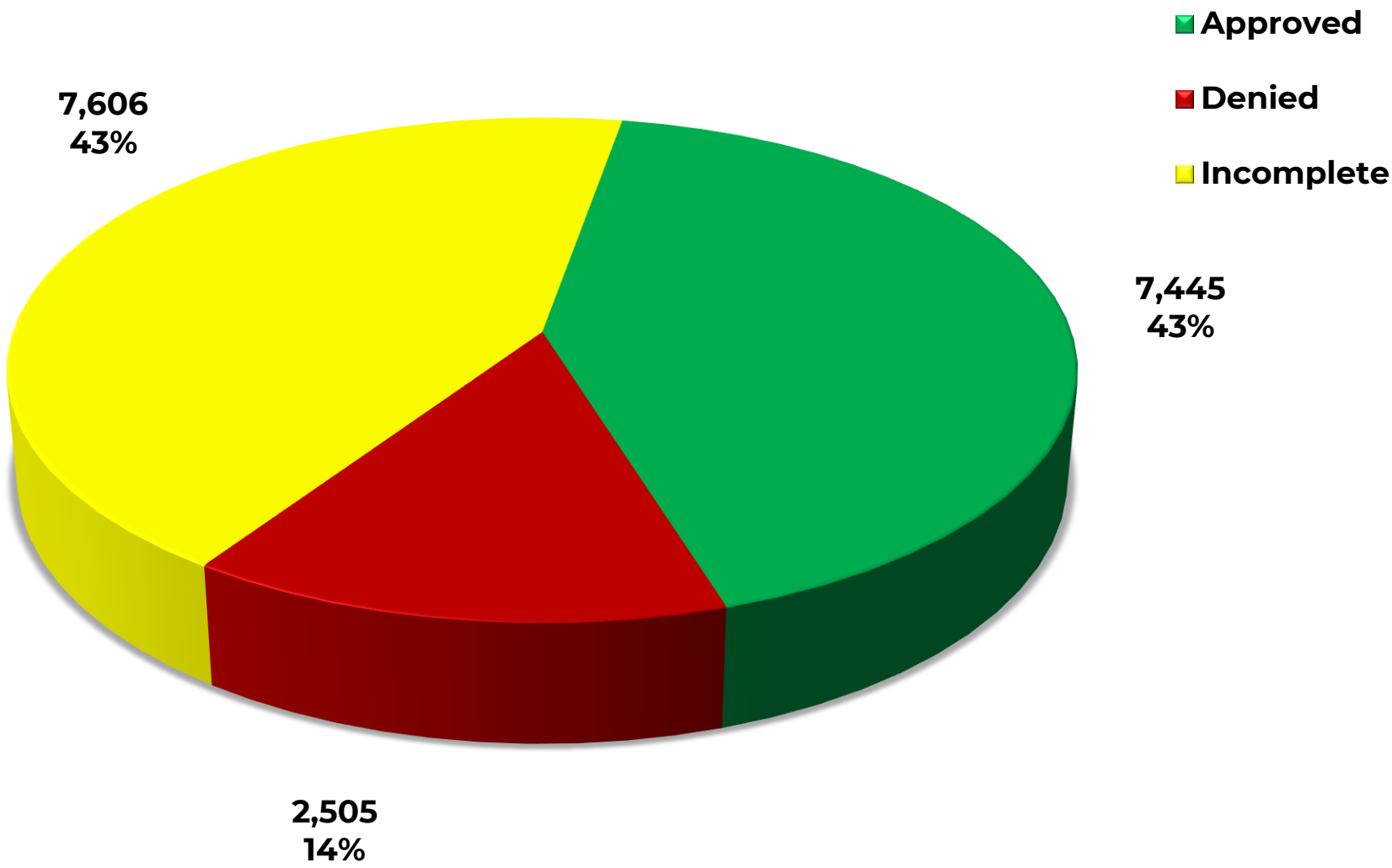
NO ACTION REQUIRED.

Recommendation 10: Future Business

NO ACTION REQUIRED.

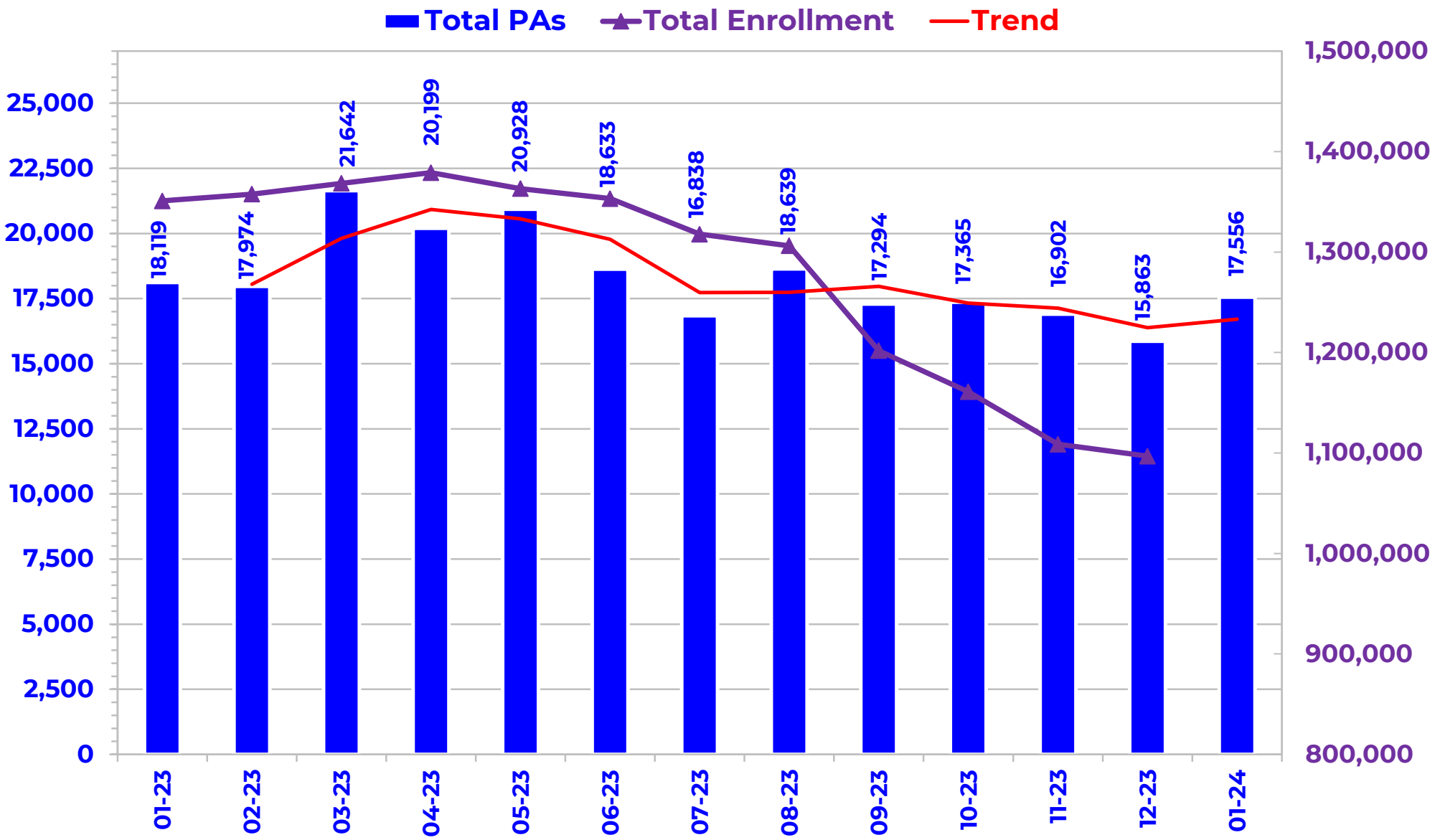
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: JANUARY 2024



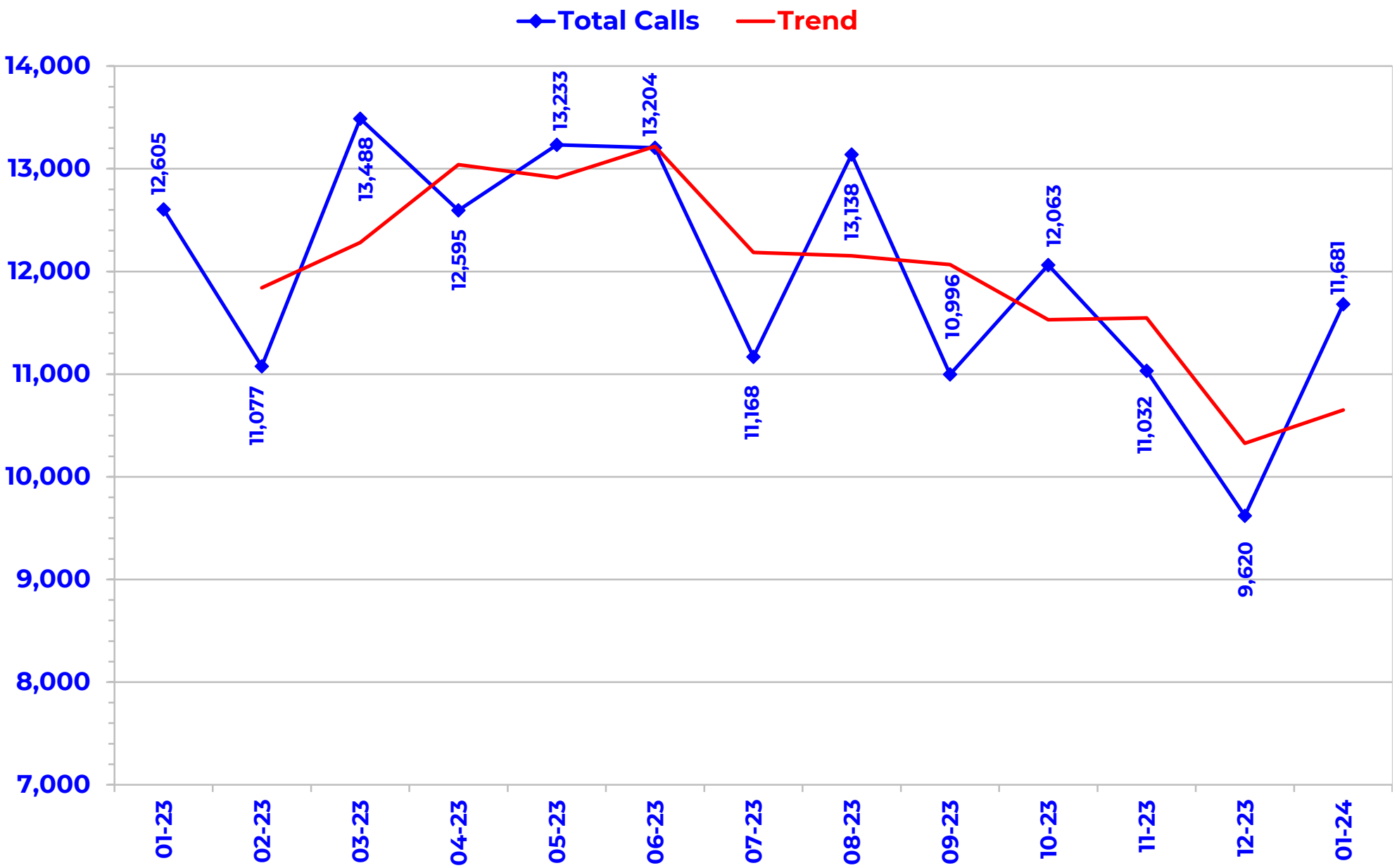
PA totals include approved/denied/incomplete/overrides

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: JANUARY 2023 – JANUARY 2024



Prior Authorization Activity

1/1/2024 Through 1/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	209	67	9	133	347
Analgesic - NonNarcotic	15	0	4	11	0
Analgesic, Narcotic	465	182	51	232	136
Anti-inflammatory	13	6	0	7	220
Antiasthma	149	42	36	71	260
Antibiotic	35	21	2	12	249
Anticonvulsant	308	141	18	149	311
Antidepressant	494	128	69	297	282
Antidiabetic	2,565	680	686	1,199	358
Antigout	11	2	1	8	159
Antihemophilic Factor	20	12	0	8	316
Antihistamine	57	16	12	29	360
Antimigraine	652	121	191	340	262
Antineoplastic	353	232	21	100	178
Antiobesity	36	0	34	2	0
Antiparasitic	29	8	2	19	16
Antiparkinsons	13	2	7	4	361
Antiulcers	66	16	5	45	152
Antiviral	18	6	2	10	74
Anxiolytic	47	6	3	38	169
Atypical Antipsychotics	601	227	51	323	350
Benign Prostatic Hypertrophy	12	3	2	7	214
Biologics	370	199	42	129	319
Bladder Control	95	13	32	50	336
Blood Thinners	32	3	0	29	360
Botox	104	45	46	13	352
Buprenorphine Medications	147	64	17	66	125
Calcium Channel Blockers	16	2	2	12	212
Cardiovascular	215	106	18	91	334
Chronic Obstructive Pulmonary Disease	375	76	81	218	355
Constipation/Diarrhea Medications	370	75	100	195	210
Contraceptive	65	19	10	36	309
Corticosteroid	19	2	6	11	315
Dermatological	629	206	158	265	252
Diabetic Supplies	587	241	77	269	179
Endocrine & Metabolic Drugs	97	24	11	62	288
Erythropoietin Stimulating Agents	27	15	2	10	107
Estrogen Derivative	27	4	10	13	315
Fibromyalgia	21	4	5	12	276
Fish Oils	20	5	3	12	361

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Gastrointestinal Agents	191	39	37	115	230
Glaucoma	33	7	2	24	243
Growth Hormones	127	80	12	35	133
Hematopoietic Agents	41	13	5	23	268
Hepatitis C	26	11	4	11	11
HFA Rescue Inhalers	17	0	0	17	0
Insomnia	126	10	25	91	214
Insulin	388	149	33	206	350
Miscellaneous Antibiotics	20	1	4	15	9
Multiple Sclerosis	102	47	9	46	254
Muscle Relaxant	65	8	13	44	135
Nasal Allergy	50	4	12	34	291
Neurological Agents	202	72	37	93	203
Neuromuscular Agents	22	14	3	5	321
NSAIDs	53	4	8	41	361
Ocular Allergy	18	4	2	12	137
Ophthalmic	12	1	4	7	359
Ophthalmic Anti-infectives	30	11	1	18	26
Ophthalmic Corticosteroid	19	7	1	11	225
Osteoporosis	33	11	5	17	358
Other*	399	139	42	218	283
Otic Antibiotic	21	1	3	17	7
Pediculicide	11	4	2	5	16
Prenatal Vitamins	13	1	1	11	363
Respiratory Agents	54	30	2	22	311
Statins	92	23	32	37	187
Stimulant	2,856	1,632	116	1,108	330
Synagis	51	34	5	12	22
Testosterone	241	72	52	117	327
Thyroid	33	7	4	22	360
Topical Antifungal	58	7	14	37	162
Topical Corticosteroids	62	6	17	39	203
Vitamin	124	22	71	31	231
Pharmacotherapy	92	83	1	8	270
Emergency PAs	0	0	0	0	
Total	**15,066**	**5,575**	**2,405**	**7,086**	

* 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	49	27	3	19	222
Compound	7	6	0	1	12
Dosage Change	421	391	1	29	17
High Dose	5	2	0	3	360
Ingredient Duplication	2	2	0	0	193
Lost/Broken Rx	106	98	4	4	18
MAT Override	393	315	8	70	86
NDC vs Age	341	250	28	63	288
NDC vs Sex	11	9	0	2	189
Nursing Home Issue	66	62	0	4	12
Opioid MME Limit	97	36	7	54	133
Opioid Quantity	45	31	5	9	151
Other	82	63	10	9	26
Quantity vs Days Supply	723	485	28	210	259
STBS/STBSM	14	11	2	1	91
Step Therapy Exception	22	12	2	8	337
Stolen	14	13	0	1	30
Third Brand Request	92	57	2	33	17
Overrides Total	**2,490**	**1,870**	**100**	**520**	
Total Regular PAs + Overrides	**17,556**	**7,445**	**2,505**	**7,606**	

Denial Reasons	
Unable to verify required trials.	6,530
Does not meet established criteria.	2,542
Lack required information to process request.	1,089
Other PA Activity	
Duplicate Requests	1,771
Letters	45,057
No Process	0
Changes to existing PAs	1,276
Helpdesk Initiated Prior Authorizations	1,211
PAs Missing Information	884

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

Use of Glucagon-Like Peptide-1 (GLP-1) Agonists or 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

Oklahoma Health Care Authority
February 2024

Introduction[1,2,3,4,5,6,7,8]

ASCVD is the leading cause of morbidity and mortality for individuals with diabetes, and an estimated $37.3 billion is spent annually on CV-related issues associated with diabetes. Co-existing conditions like hypertension (HTN) and hyperlipidemia (HLD) are risk factors for ASCVD, while diabetes itself confers independent risk. The 2024 American Diabetes Association (ADA) *Standards of Medical Care in Diabetes* guidelines include a dedicated decision pathway for individuals with indicators of high CV risk or established ASCVD. For these individuals, either a GLP-1 agonist or an SGLT-2 inhibitor with known CV benefit should be considered independent of baseline hemoglobin A1C target or metformin use. Per the 2024 ADA guidelines, indicators of high CV risk include ≥55 years of age with 2 or more additional risk factors, including obesity, HTN, smoking, dyslipidemia, or albuminuria. The GLP-1 agonists with U.S. Food and Drug Administration (FDA) approved CV benefit include Victoza® (liraglutide), Trulicity® (dulaglutide), and Ozempic® (injectable semaglutide). The SGLT-2 inhibitors with FDA approved CV benefit include Jardiance® (empagliflozin), Farxiga® (dapagliflozin), and Invokana® (canagliflozin).

Mailing Summary

In February 2021, the College of Pharmacy (COP) and the Oklahoma Health Care Authority (OHCA) sent an educational letter to 120 providers regarding 944 unique members with a diagnosis of type 2 diabetes (T2D) with high CV risk or established ASCVD who were not receiving treatment with 1 of the above GLP-1 agonists or SGLT-2 inhibitors based on their SoonerCare pharmacy claims history. The number of members associated with these top 120 providers ranged from 39 members to 3 members per provider. High CV risk was determined using the indicators suggested in the 2021 ADA guidelines (≥55 years of age with left ventricular hypertrophy or with >50% coronary, carotid, or lower-extremity artery stenosis) or a diagnosis of HTN and HLD as evidenced in the member's SoonerCare claims history. The

purpose of the educational mailing was to encourage providers to evaluate evidence-based prescribing practices for SoonerCare members with diabetes and high CV risk or established ASCVD and determine if they may benefit from therapy with a GLP-1 agonist or SGLT-2 inhibitor with FDA approved CV benefit. Providers were selected for this mailing if they were the most recent prescriber for at least 1 SoonerCare member with concurrent diagnoses of T2D and ASCVD or high CV risk factors in the last year who did not have any SoonerCare pharmacy paid claims for a GLP-1 agonist or SGLT-2 inhibitor with CV benefit. Members with a diagnosis of end-stage renal disease (ESRD), heart failure (HF), or pregnancy were excluded.

Mailing Results

Since the mailing in February 2021, a post-mailing claims analysis was performed in May 2021 and then in January each year thereafter for the 944 unique members and 120 providers to assess the impact of the mailing. The most recent post-mailing claims analysis was performed in January 2024 and found 298 members (31.57%) had a paid claim for a GLP-1 agonist or SGLT-2 inhibitor with CV benefit resulting in a 29.13% increase from the first analysis in May 2021. It was also found that of the 120 providers included in the mailing, 101 providers had at least 1 member who was previously included for evaluation of therapy with a GLP-1 agonist or an SGLT-2 inhibitor with FDA approved CV benefit who has now started on therapy with 1 of the indicated medications.

Use of GLP-1 Agonists or SGLT-2 Inhibitors with CV Benefit in SoonerCare Members During Calendar Year 2023 (CY23)

Since the initial mailing, the ADA guidelines have been updated and now have a broader definition of what patients are considered at high CV risk. Per the 2024 guidelines, patients are considered high CV risk if they are ≥55 years of age with 2 or more additional risk factors, including obesity, HTN, smoking, dyslipidemia, or albuminuria.

During CY23, there were a total of 14,450 members with a diagnosis of T2D with high CV risk or established ASCVD per the 2024 ADA guidelines. Currently, 7,396 (51%) of those 14,450 members are not receiving treatment with a GLP-1 agonist or SGLT-2 inhibitor with CV benefit. This is an increase from previous years; however, with the new definition of high CV risk more members appear to fall into this category versus the previous definition of ≥55 years of age with left ventricular hypertrophy or with >50% coronary, carotid, or lower-extremity artery stenosis.

Conclusions

The fourth post-mailing claims analysis in January 2024 showed 31.57% of members with a diagnosis of T2D with high CV risk or established ASCVD who were not previously receiving treatment with a GLP-1 agonist or SGLT-2 inhibitor with CV benefit before the mailing in February 2021 were now receiving guideline recommended treatment.

The May 2021 post-mailing analysis performed had limitations including only 2.5 months had passed between the letter being mailed out and the claims analysis which is shorter than a 90-day medication supply; therefore, some members may not have been due for a prescription refill. A limitation the first 2 analyses have in common is that they occurred during a global pandemic in which members may not have been seen by their primary care provider. The fourth claims analysis now gives a better picture of the results of the mailing now that over 2 years have passed, and it has continued to show a steady increase in the members that have started on the recommended treatment. Additionally, it is important to note that the recommended GLP-1 agonists and some SGLT-2 inhibitors with CV benefit require prior authorization that could delay the time to filling the medication. However, while these medications do require prior authorization, there is a clinical exception that applies for members who require the medication for its CV benefit (Tier structure still applies).

Overall, the purpose of this mailing was not to see all of the members started on therapy with a GLP-1 agonist or SGLT-2 inhibitor with CV benefit, but rather to ensure the providers were evaluating these members for appropriate therapy. In April 2023, Jardiance® and Farxiga® were moved to Tier-1 and no longer require prior authorization due to their lower net costs and in an effort to prevent further delay of treatment caused by the requirement for submission of a manual prior authorization request.

Recommendations

The COP recommends another provider and member educational mailing with the goal of targeting the members with T2D that would meet the new ADA guidelines for ASCVD or other diagnoses conferring high CV risk. This will be in an effort to continue to increase the utilization of GLP-1 agonist or SGLT-2 inhibitor medications with CV benefit in these members where appropriate and to improve the quality of care for SoonerCare members with T2D.

[1] Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes – 2021. *Diabetes Care* 2021; 44(1):S125–S150. doi: 10.2337/dc21-S010.
[2] Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes – 2024. *Diabetes Care* 2024; 47(1):S179–S218. doi: 10.2337/dc24-S010.
[3] Marso SP, Daniels GH, Brown-Frandsen K, et al. LEADER Steering Committee; LEADER Trial Investigators. Liraglutide and Cardiovascular Outcomes in Type 2 Diabetes. *N Engl J Med* 2016; 375:311-322. doi: 10.1056/NEJMoa1603827.
[4] Gerstein HC, Colhoun HM, Dagenais GR, et al. REWIND Investigators. Dulaglutide and Cardiovascular Outcomes in Type 2 Diabetes (REWIND): A Double-blind, Randomized Placebo-controlled Trial. *Lancet* 2019; 394:121-130. doi: 10.1016/S0140-6736(19)31149-3.
[5] Marso SP, Bain SC, Consoli A, et al. SUSTAIN-6 Investigators. Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes. *N Engl J Med* 2016; 375:1834-1844. doi: 10.1056/NEJMoa1607141.
[6] Zinman B, Wanner C, Lachin JM, et al. EMPGA-REG OUTCOME Investigators. Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes. *N Engl J Med* 2015; 373:2117-2128. doi: 10.1056/NEJMoa1504720.
[7] Wiviott SD, Raz I, Bonaca MP, et al. Dapagliflozin and Cardiovascular Outcomes in Type 2 Diabetes. *N Engl J Med* 2019; 380:347-357. doi: 10.1056/NEJMoa1812389.
[8] Neal B, Perkovic V, Mahaffey KW, et al. CANVAS Program Collaborative Group. Canagliflozin and Cardiovascular and Renal Events in Type 2 Diabetes. *N Engl J Med* 2017; 377:644-657. doi: 10.1056/NEJMoa1611925.

Appendix C

Narrow Therapeutic Index (NTI) Drug List

Oklahoma Health Care Authority
February 2024

Introduction[1,2,3]

The U.S. Food and Drug Administration (FDA) defines narrow therapeutic index (NTI) drugs as drugs where small differences in dose or blood concentration may lead to serious therapeutic failures or adverse drug reactions. NTI drugs generally have the following characteristics:

- Little separation between therapeutic and toxic doses
- Sub-therapeutic concentration may lead to serious therapeutic failure
- Drugs that are subject to therapeutic drug monitoring based on pharmacokinetic (PK) or pharmacodynamic (PD) measures
- In clinical practice, doses are often adjusted in very small increments (<20%)

The FDA Office of Generic Drugs assesses brand/generic interchangeability standards for NTI drugs. NTI drugs analyzed for bioequivalence by the FDA include warfarin, lithium, digoxin, theophylline, tacrolimus, phenytoin, levothyroxine, and carbamazepine. Other groups, including Health Canada, also include cyclosporine and sirolimus in their NTI drug classification group.

The Oklahoma Health Care Authority (OHCA) policy and rules state the following regarding brand necessary certification (317:30-5-77):

> "For certain narrow therapeutic index drugs, a prior authorization will not be required. The DUR Board will select and maintain the list of narrow therapeutic index drugs."

The purpose of this report is to provide the Drug Utilization Review (DUR) Board with the current SoonerCare NTI drug list for review, which is to be maintained by the DUR Board. Medications included in the NTI list are set up to bypass brand/generic substitution requirements in the claims processing system. Action by the DUR Board is not required unless the DUR Board recommends changes to the current NTI drug list.

SoonerCare NTI Drug List

- Carbamazepine
- Clozapine
- Cyclosporine
- Desipramine
- Digoxin
- Levothyroxine
- Lithium
- Nortriptyline
- Phenytoin
- Sirolimus
- Tacrolimus
- Theophylline
- Warfarin

Recommendations[4]

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

[1] U.S. Food and Drug Administration (FDA). FY2015 Regulatory Science Research Report: Narrow Therapeutic Index Drugs. Available online at: https://www.fda.gov/industry/generic-drug-user-fee-amendments/fy2015-regulatory-science-research-report-narrow-therapeutic-index-drugs. Last revised 05/09/2017. Last accessed 01/18/2024.
[2] U.S. FDA. Building Confidence in Generic Narrow Therapeutic Index (NTI) Drugs. Available online at: https://www.fda.gov/about-fda/fda-pharmacy-student-experiential-program/building-confidence-generic-narrow-therapeutic-index-nti-drugs. Last revised 04/10/2020. Last accessed 01/18/2024.
[3] Jiang, Wenlei. FDA Drug Topics: Understanding Generic Narrow Therapeutic Index Drugs. *U.S. FDA*. Available online at: https://www.fda.gov/media/162779/download Issued 11/01/2022. Last accessed 01/18/2024.
[4] Spravato® (Esketamine) Prescribing Information. UCB, Inc. Available online at: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SPRAVATO-pi.pdf. Last revised 10/2023. Last accessed 01/18/2024.

Appendix D

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

Oklahoma Health Care Authority
February 2024

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

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

- **June 2021:** The FDA approved Ultomiris® (ravulizumab-cwvz) to treat patients 1 month of age or older with paroxysmal nocturnal hemoglobinuria (PNH). Previously, Ultomiris® was only indicated in adults for PNH.
- **July 2022:** The FDA approved a subcutaneous (sub-Q) formulation of Ultomiris® (ravulizumab-cwvz) for the treatment of adult patients with atypical hemolytic uremic syndrome (aHUS) and PNH. Ultomiris® was previously approved in an intravenous (IV) injection only. The IV product is also indicated for PNH or aHUS in pediatric patients and adults for generalized myasthenia gravis (gMG). The sub-Q formulation is not approved for these indications.
- **June 2023:** The FDA approved Rystiggo® (rozanolixizumab-noli) for the treatment of gMG in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. It is the only treatment approved by the FDA for both anti-AChR and anti-MuSK antibody positive gMG.
- **June 2023:** The FDA approved Vyvgart® Hytrulo (efgartigimod alfa/ hyaluronidase-qvfc) as a sub-Q injection for the treatment of gMG in adult patients who are AChR antibody positive. Previously, Vyvgart® (efgartigimod alfa-fcab) was available as an IV product only. The addition of the recombinant human hyaluronidase PH20 (rHuPH20) helped facilitate the sub-Q delivery of efgartigimod alfa.
- **September 2023:** The FDA approved Empaveli® Injector, a compact, single-use, on-body device designed for self-administration of Empaveli® (pegcetacoplan), which is FDA approved to treat adults with PNH. Previously, Empaveli® was only administered sub-Q through an infusion pump.

- **October 2023:** The FDA approved Zilbrysq® (zilucoplan) for the treatment of gMG in adults who are AChR antibody positive. It is a once-daily, sub-Q, targeted C5 complement inhibitor for gMG that can be self-administered.

Rystiggo® (Rozanolixizumab-noli) Product Summary[7]

Therapeutic Class: Neonatal Fc receptor blocker

Indication(s): Treatment of gMG in adult patients who are anti-AChR or anti-MuSK antibody positive

How Supplied: 280mg/2mL solution in a single-dose vial (SDV)

Dosing and Administration:

- The need to administer age-appropriate vaccines should be evaluated according to immunization guidelines before initiation of a new treatment cycle with Rystiggo®.
- The recommended dosage is administered as a sub-Q infusion using an infusion pump at a rate of up to 20mL/hour once weekly for 6 weeks (see Figure 1 for specific doses).
- Subsequent treatment cycles should be administered based on clinical evaluation; the safety of initiating subsequent cycles sooner than 63 days from the start of the previous treatment cycle has not been established.
- Rystiggo® should only be prepared and infused by a health care provider.

Figure 1: Dose of Rystiggo® by Body Weight

Body Weight	Dose	Volume to be Infused
Less than 50kg	420mg	3mL
50kg to less than 100kg	560mg	4mL
100kg and above	840mg	6mL

Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc) Product Summary[8]

Therapeutic Class: Neonatal Fc receptor blocker/endoglycosidase

Indication(s): Treatment of gMG in adult patients who are anti-AChR antibody positive

How Supplied: 1,008mg efgartigimod alfa and 11,200 units hyaluronidase per 5.6mL (180mg/2,000 units per mL) in a SDV

Dosing and Administration:

- The need to administer age-appropriate vaccines should be evaluated according to immunization guidelines before initiation of a new treatment cycle with Vyvgart® Hytrulo.
- Vyvgart® Hytrulo should only be administered by a health care provider.
- The recommended dose is 1,008mg efgartigimod alfa and 11,200 units hyaluronidase administered as a fixed dose sub-Q injection over approximately 30 to 90 seconds in cycles of once weekly injections for 4 weeks.
- Subsequent treatment cycles should be administered based on clinical evaluation; the safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.

Zilbrysq® (Zilucoplan) Product Summary[9]

Therapeutic Class: Complement inhibitor

Indication(s): Treatment of gMG in adult patients who are anti-AChR antibody positive

How Supplied: 16.6mg/0.416mL, 23mg/0.574mL, or 32.4mg/0.81mL solution in single-dose prefilled syringes

Dosing and Administration:

- Before initiating Zilbrysq®, baseline lipase and amylase levels should be obtained.
- Meningococcal vaccination should be completed or updated at least 2 weeks prior to administering the first dose of Zilbrysq® unless the risk of delaying therapy outweighs the risk of developing a meningococcal infection.
- The recommended dosage is given once daily as a sub-Q injection and is dependent on actual body weight (see Figure 2 below).
- Zilbrysq® should be given under the guidance and supervision of a health care provider; however, patients may self-inject Zilbrysq® after training in sub-Q injection technique.

Figure 2: Dose of Zilbrysq® by Body Weight

Body Weight	Dose
Less than 56kg	16.6mg
56kg to less than 77kg	23mg
77kg and above	32.4mg

Cost Comparison: gMG Therapies

Medication	Cost Per mL	Cost Per Year
Rystiggo® (rozanolixizumab-noli) 280mg/2mL	**$3,025.00**	**$363,000α**
Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) 1,008mg/5.6mL	**$2,816.61**	**$441,644β**
Vyvgart® (efgartigimod alfa-fcab) 400mg/20mL	$303.45	$339,864+
Ultomiris® (ravulizumab-cwvz) 1,100mg/11mL	$2,134.67	$493,109*
Soliris® (eculizumab) 300mg/30mL	$217.43	$678,382±

Costs do not reflect rebated prices or net costs. Cost based on wholesale acquisition cost (WAC).
Cost information for Zilbrysq® is currently not available.
αCosts based on an 80kg patient receiving 560mg weekly for 6 infusions per cycle (5 cycles per year).
βCosts based on a fixed dose of 1,008mg/5.6mL with 4 infusions per cycle (7 cycles per year).
+Costs based on an 80kg patient receiving an 800mg dose with 4 infusions per cycle (7 cycles per year).
*Costs based on an 80kg patient receiving an IV maintenance dose of 3,300mg every 8 weeks.
±Costs based on recommended maintenance dosing of 1,200mg every 2 weeks.

Recommendations

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.

[1] U.S. Food and Drug Administration (FDA). FDA Approves Therapy for Pediatric Patients with Serious Rare Blood Disease. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-therapy-pediatric-patients-serious-rare-blood-disease. Issued on 06/07/2021. Last accessed 01/18/2024.
[2] Ultomiris® (Ravulizumab-cwvz) – New Formulation Approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_ultomiris_2022-0727.pdf. Issued 07/22/2022. Last accessed 01/18/2024.
[3] UCB, Inc. UCB Announces U.S. Food and Drug Administration (FDA) Approval of Rystiggo® (Rozanolixizumab-noli) for the Treatment of Adults with Generalized Myasthenia Gravis. Available online at: https://www.ucb.com/stories-media/Press-Releases/article/UCB-announces-US-FDA-approval-of-RYSTIGGOR-rozanolixizumab-noli-for-the-treatment-of-adults-with-generalized-myasthenia-gravis. Issued 06/27/2023. Last accessed 01/18/2024.
[4] Argenx US, Inc. Argenx Announces U.S. Food and Drug Administration (FDA) Approval of Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc) Injection for Subcutaneous Use in Generalized Myasthenia Gravis. *GlobeNewswire*. Available online at: https://www.globenewswire.com/news-release/2023/06/20/2691658/0/en/argenx-Announces-U-S-Food-and-Drug-Administration-Approval-of-VYVGART-Hytrulo-efgartigimod-alfa-and-hyaluronidase-qvfc-Injection-for-Subcutaneous-Use-in-Generalized-Myasthenia-Grav.html. Issued 06/20/2023. Last accessed 01/18/2024.
[5] Apellis Pharmaceuticals, Inc. Apellis Announces U.S. FDA Approval of the Empaveli® Injector, a Device to Streamline Self-Administration. Available online at: https://investors.apellis.com/news-releases/news-release-details/apellis-announces-us-fda-approval-empavelir-injector-device. Issued 10/02/2023. Last accessed 01/18/2024.
[6] UCB, Inc. UCB Announces U.S. FDA approval of Zilbrysq® (Zilucoplan) for the Treatment of Adults with Generalized Myasthenia Gravis. Available online at: https://www.ucb.com/stories-media/Press-Releases/article/UCB-announces-US-FDA-approval-of-ZILBRYSQR-zilucoplan-for-the-treatment-of-adults-with-generalized-myasthenia-gravis. Issued 10/17/2023. Last accessed 01/18/2024.
[7] Rystiggo® (Rozanolixizumab-noli) Prescribing Information. UCB, Inc. Available online at: https://www.ucb-usa.com/RYSTIGGO-prescribing-information.pdf. Last revised 06/2023. Last accessed 01/18/2024.
[8] Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc) Prescribing Information. Argenx US, Inc. Available online at: https://www.argenx.com/product/vyvgart-hytrulo-prescribing-information.pdf. Last revised 06/2023. Last accessed 01/18/2024.
[9] Zilbrysq® (Zilucoplan) Prescribing Information. UCB, Inc. Available online at: https://www.ucb-usa.com/zilbrysq-prescribing-information.pdf. Last revised 10/2023. Last accessed 01/18/2024.

Appendix E

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

Oklahoma Health Care Authority
February 2024

Market News and Updates[1,2,3]

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

- **August 2023:** The FDA approved Zurzuvae™ (zuranolone) as the first oral medication for the treatment of postpartum depression (PPD) in adults. Previously, the only FDA approved treatment option for PPD was an intravenous (IV) injection given in a health care facility for over 60 hours.
- **September 2023:** Exxua™ (gepirone) was approved by the FDA for the treatment of major depressive disorder (MDD) in adults. Exxua™ is the first antidepressant that selectively targets the serotonin 1A (5-HT_{1A}) receptor.

News:

- **May 2023:** Sebela Pharmaceuticals announced that all strengths of Pexeva® (paroxetine) will be discontinued and no longer available.

Exxua™ (Gepirone) Product Summary[4]

Therapeutic Class: Selective 5-HT_{1A} receptor agonist

Indication(s): MDD in adults

How Supplied: 18.2mg, 36.3mg, 54.5mg, and 72.6mg extended-release (ER) tablets

Dosing and Administration:

- The recommended starting dose is 18.2mg orally once daily with food.
- Depending on tolerability and clinical response, the dose can be increased to 36.3mg daily on day 4, 54.5mg on day 7, and then 72.6mg after an additional week.
- Prior to initiating treatment, electrolyte abnormalities should be corrected, and an electrocardiogram (ECG) should be performed.
- Exxua™ should not be initiated if QTc is >450msec.

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

Zurzuvae™ (Zuranolone) Product Summary[5]

Therapeutic Class: Neuroactive gamma-aminobutyric acid (GABA) A receptor positive modulator

Indication(s): PPD in adults

How Supplied: 20mg, 25mg, and 30mg capsules

Dosing and Administration:

- The recommended dose is 50mg once daily in the evening for 14 days.
- Zurzuvae™ should be administered with a fat-containing food.
- If central nervous system (CNS) depressant effects occur, the dose may be reduced to 40mg once daily.
- The dose should be reduced to 30mg once daily for the following:
  - Severe hepatic impairment
  - Moderate to severe renal impairment
  - Concomitant use with strong CYP3A4 inhibitors

Cost: The Wholesale Acquisition Cost (WAC) of Zurzuvae™ is $567.86 per capsule, regardless of strength. This results in an estimated cost of $15,900 for the recommended dose of 50mg once daily for 14 days.

Recommendations

The College of Pharmacy recommends the following changes to the Antidepressant Medications 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®)

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
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™)*
			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.

---

[1] U.S. FDA. FDA Approves First Oral Treatment for Postpartum Depression. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-treatment-postpartum-depression. Issued 08/04/2023. Last accessed 01/18/2024.
[2] Fabre-Kramer Pharmaceuticals. Fabre-Kramer Pharmaceuticals Announces FDA Approval of Exxua™, the First and Only Oral Selective 5HT1a Receptor Agonist for the Treatment of Major Depressive Disorder in Adults. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/fabre-kramer-pharmaceuticals-announces-fda-approval-of-exxua-the-first-and-only-oral-selective-5ht1a-receptor-agonist-for-the-treatment-of-major-depressive-disorder-in-adults-301941467.html. Issued 09/28/2023. Last accessed 01/18/2024.
[3] Sebela Pharmaceuticals. Our Products. Available online at: https://sebelapharma.com/our-products. Last accessed 01/18/2024.
[4] Exxua™ (Gepirone) Extended-Release Tablets Prescribing Information. Fabre-Kramer Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/021164s000lbl.pdf. Last revised 09/2023. Last accessed 01/18/2024.
[5] Zurzuvae™ (Zuranolone) Prescribing Information. Biogen, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217369Orig2s000Corrected_lbl.pdf. Last revised 08/2023. Last accessed 01/18/2024.

Appendix F

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

Oklahoma Health Care Authority
February 2024

Market News and Updates[1,2]

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

- **May 2023:** The FDA approved Elfabrio® (pegunigalsidase alfa-iwxj) for the treatment of adults with confirmed Fabry disease.
- **September 2023:** The FDA approved Pombiliti™ (cipaglucosidase alfa-atga) in combination with Opfolda™ (miglustat) for the treatment of adult patients with late-onset Pompe disease [lysosomal acid alpha-glucosidase (GAA) deficiency] weighing ≥40kg and who are not improving on their current enzyme replacement therapy (ERT).

Elfabrio® (Pegunigalsidase Alfa-iwxj) Product Summary[3]

Therapeutic Class: Hydrolytic lysosomal neutral glycosphingolipid-specific enzyme

Indication(s): Treatment of adults with confirmed Fabry disease

How Supplied: 20mg/10mL solution in a single-dose vial (SDV)

Dosing and Administration:

- 1mg/kg (based on actual body weight) by intravenous (IV) infusion every 2 weeks
- Initial recommended infusion rates vary for ERT-experienced and ERT-naïve patients. Please refer to the full *Prescribing Information* for the complete infusion rate recommendations, including modifications to the infusion rate for hypersensitivity and/or infusion-associated reactions.

Cost Comparison: Fabry Disease Products

Product	Cost Per Unit	Cost Per 28 Days*	Cost Per Year
Elfabrio® (pegunigalsidase alfa-iwxj) 20mg/10mL vial	**$434.19**	**$34,735.20**	**$451,557.60**
Fabrazyme® (agalsidase beta) 35mg vial	$7,454.73	$34,078.04	$443,014.52
Fabrazyme® (agalsidase beta) 5mg vial	$1,064.78	$34,078.04	$443,014.52
Galafold® (migalastat) 123mg capsule	$2,135.00	$29,890.00	$388,570.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = each mL for Elfabrio®, each vial for Fabrazyme®, or each capsule for Galafold®
*Cost per 28 days based on FDA approved dosing for each product for a member weighing 80kg. Elfabrio® would require 4 vials (40mL) every 2 weeks. Fabrazyme® would require (2) 35mg vials and (2) 5mg vials every 2 weeks.

Opfolda™ (Miglustat) Product Summary[4]

Therapeutic Class: Enzyme stabilizer

Indication(s): Treatment of adult patients with late-onset Pompe disease (lysosomal GAA deficiency) weighing ≥40kg and who are not improving on their current ERT, in combination with Pombiliti™ (cipaglucosidase alfa-atga)

How Supplied: 65mg oral capsule

Dosing and Administration:

- Administered orally in combination with Pombiliti™ (based on actual body weight):
  - Weight ≥50kg: 260mg [(4) 65mg capsules] every other week
  - Weight <50kg: 195mg [(3) 65mg capsules] every other week
- Should be taken with an unsweetened beverage approximately 1 hour before the start of Pombiliti™ infusion
- Other beverages or food should not be consumed for at least 2 hours prior to and 2 hours after taking Opfolda™

Pombiliti™ (Cipaglucosidase Alfa-atga) Product Summary[5]

Therapeutic Class: Hydrolytic lysosomal glycogen-specific enzyme

Indication(s): Treatment of adult patients with late-onset Pompe disease (lysosomal GAA deficiency) weighing ≥40kg and who are not improving on their current ERT, in combination with Opfolda™ (miglustat)

How Supplied: 105mg SDV containing lyophilized powder for reconstitution

Dosing and Administration:

- 20mg/kg (based on actual body weight) by IV infusion over 4 hours every 2 weeks

- Infusion should begin approximately 1 hour after oral administration of Opfolda™

Cost Comparison: Pompe Disease Products

Product	Cost Per Unit	Cost Per 28 Days*	Cost Per Year
Pombiliti™ (cipaglucosidase alfa-atga) 105mg vial	**$1,785.00**	**$57,120.00**	**$742,560.00**
Opfolda™ (miglustat) 65mg capsule	**$32.50**	**$260.00**	**$3,380.00**
Lumizyme® (alglucosidase alfa) 50mg vial	$964.43	$61,723.52	$802,405.76
Nexviazyme® (avalglucosidase alfa-ngpt) 100mg vial	$1,854.67	$59,349.44	$771,542.72

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).
Unit = each vial or capsule
*Cost per 28 days based on FDA approved dosing for each product for a member weighing 80kg. Pombiliti™ would require 16 vials every 2 weeks. Lumizyme® would require 32 vials every 2 weeks. Nexviazyme® would require 16 vials every 2 weeks.

Recommendations

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.

---

[1] Chiesi Global Rare Diseases. Chiesi Global Rare Diseases and Protalix BioTherapeutics Announce FDA Approval of Elfabrio® (Pegunigalsidase Alfa-iwxj) for the Treatment of Fabry Disease. Available online at: https://protalixbiotherapeutics.gcs-web.com/news-releases/news-release-details/chiesi-global-rare-diseases-and-protalix-biotherapeutics-1. Issued 05/10/2023. Last accessed 01/18/2024.
[2] Amicus Therapeutics, Inc. Amicus Therapeutics Announces FDA Approval and Launch of New Treatment for Pompe Disease. Available online at: https://ir.amicusrx.com/news-releases/news-release-details/amicus-therapeutics-announces-fda-approval-and-launch-new. Issued 09/28/2023. Last accessed 01/18/2024.
[3] Elfabrio® (Pegunigalsidase Alfa-iwxj) Prescribing Information. Chiesi USA, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761161s000lbl.pdf. Last revised 05/2023. Last accessed 01/18/2024.
[4] Opfolda™ (Miglustat) Prescribing Information. Amicus Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215211s000lbl.pdf. Last revised 09/2023. Last accessed 01/18/2024.
[5] Pombiliti™ (Cipaglucosidase Alfa-atga) Prescribing Information. Amicus Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761204s000lbl.pdf. Last revised 09/2023. Last accessed 01/18/2024.

Appendix G

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

Oklahoma Health Care Authority
February 2024

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18]

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

- **October 2022:** The FDA approved Cotellic® (cobimetinib) for a new indication for the treatment of adult patients with histiocytic neoplasms.
- **January 2023:** The FDA approved Keytruda® (pembrolizumab) for a new indication for the adjuvant treatment of stage 1B (T2a ≥4cm), stage 2, or stage 3A non-small cell lung cancer (NSCLC) following resection and platinum-based chemotherapy.
- **February 2023:** The FDA approved Opdivo® (nivolumab) for an age expansion for 2 melanoma indications: (1) treatment of adult and pediatric patients 12 years of age and older with unresectable or metastatic melanoma, as a single agent or in combination with ipilimumab and (2) treatment of adult and pediatric patients 12 years of age and older with melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant setting.
- **March 2023:** The FDA approved Mekinist® (trametinib) in combination with Tafinlar® (dabrafenib) for a new indication for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a *BRAF* V600E mutation who require systemic therapy.
- **March 2023:** The FDA granted accelerated approval to Zynyz™ (retifanlimab-dlwr) for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC).
- **April 2023:** The FDA granted accelerated approval for Keytruda® for a new indication in combination with Padcev® (enfortumab vedotin-ejfv) for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.
- **August 2023:** The FDA approved Hepzato Kit™ (melphalan) as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting <50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph

nodes, subcutaneous tissues, or lung that is amenable to resection or radiation.

- **August 2023:** The FDA granted accelerated approval to Mekinist® (trametinib) in combination with Tafinlar® (dabrafenib) for an expanded age range in patients 1 year of age and older with unresectable or metastatic solid tumors with *BRAF* V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. This combination was previously granted accelerated FDA approval for this indication in patients 6 years of age and older in June 2022.
- **October 2023:** The FDA approved Braftovi® (encorafenib) in combination with Mektovi® (binimetinib) for a new indication for the treatment of adult patients with metastatic NSCLC with a *BRAF* V600E mutation, as detected by an FDA-approved test.
- **October 2023:** The FDA approved Opdivo® for an expanded indication for the adjuvant treatment of adult and pediatric patients 12 years of age and older with completely resected stage 2B, 2C, 3, or 4 melanoma.
- **October 2023:** The FDA approved Keytruda® for a new indication for the treatment of patients with resectable (tumors ≥4cm or node positive) NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.
- **October 2023:** The FDA approved Keytruda® for a new indication, in combination with gemcitabine and cisplatin, for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer.
- **November 2023:** The FDA approved a revised indication for Keytruda®, in combination with trastuzumab, fluoropyrimidine, and platinum-containing chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma. The new indication now restricts use to patients whose tumors express programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1] as determined by an FDA-approved test.
- **November 2023:** The FDA approved Keytruda® for a new indication, in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma.
- **December 2023:** The FDA approved Keytruda® for a new indication in combination with Padcev® for the treatment of adult patients with locally advanced or metastatic urothelial cancer. This updates the previous accelerated approval from April 2023 to a regular approval and

removes the limitation to patients who are not eligible for cisplatin-containing chemotherapy.
- **January 2024:** The FDA approved Keytruda® for a new indication, in combination with chemoradiotherapy, for the treatment of patients with FIGO 2014 Stage III-IVA cervical cancer.

Guideline Update(s):
- The National Comprehensive Cancer Network (NCCN) now recommends Opdivo® (nivolumab) in combination with Adcetris® (brentuximab vedotin) as second line or subsequent therapy for relapsed/refractory classical Hodgkin lymphoma after failure of autologous stem cell transplant (SCT), allogeneic SCT, or in those who are transplant-ineligible.

Hepzato Kit™ (Melphalan) Product Summary[19]

Therapeutic Class: Alkylating drug

Indication(s): Liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation

How Supplied: Hepzato Kit™ includes the following components:
- (5) single-dose vials (SDVs) containing 50mg lyophilized melphalan for reconstitution
- (5) SDVs containing 10mL sterile diluent for reconstitution
- (2) plastic containers containing 250mL 0.9% sodium chloride injection
- Hepatic delivery system (HDS) device

Dosing and Administration:
- Administered by infusion into the hepatic artery via the HDS device every 6-8 weeks for up to 6 total infusions
- Recommended dose is 3mg/kg based on ideal body weight (IBW) up to a maximum of 220mg during a single treatment

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

Zynyz™ (Retifanlimab-dlwr) Product Summary[20]

Therapeutic Class: Programmed death receptor-1 (PD-1)–blocking antibody

Indication(s): Treatment of adult patients with metastatic or recurrent locally advanced MCC

How Supplied: 500mg/20mL solution in a SDV

Dose: 500mg by IV infusion over 30 minutes every 4 weeks until disease progression, unacceptable toxicity, or up to 24 months

Cost: The Wholesale Acquisition Cost (WAC) of Zynyz™ is $712 per milliliter, resulting in a cost of $14,240 per dose or $185,120 per year based on the recommended dosing.

Recommendations

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 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)].

---

[1] Virgil H. FDA Approves Cobimetinib for Histiocytic Neoplasms. *Cancer Network*. Available online at: https://www.cancernetwork.com/view/fda-approves-cobimetinib-for-histiocytic-neoplasms. Issued 11/02/2022. Last accessed 01/18/2024.

[2] U.S. Food and Drug Administration (FDA). FDA Approves Pembrolizumab as Adjuvant Treatment for Non-Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-adjuvant-treatment-non-small-cell-lung-cancer. Issued 01/26/2023. Last accessed 01/18/2024.

[3] Opdivo® (Nivolumab) Prescribing Information. Bristol-Myers Squibb Company. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125554s117lbl.pdf. Last revised 02/2023. Last accessed 01/18/2024.

[4] U.S. FDA. FDA Approves Dabrafenib with Trametinib for Pediatric Patients with Low-Grade Glioma with a BRAF V600E Mutation. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-dabrafenib-trametinib-pediatric-patients-low-grade-glioma-braf-v600e-mutation. Issued 03/16/2023. Last accessed 01/18/2024.
[5] U.S. FDA. FDA Grants Accelerated Approval to Retifanlimab-dlwr for Metastatic or Recurrent Locally Advanced Merkel Cell Carcinoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-retifanlimab-dlwr-metastatic-or-recurrent-locally-advanced-merkel. Issued 03/22/2023. Last accessed 01/18/2024.
[6] U.S. FDA. FDA Grants Accelerated Approval to Enfortumab Vedotin-ejfv with Pembrolizumab for Locally Advanced or Metastatic Urothelial Carcinoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-enfortumab-vedotin-ejfv-pembrolizumab-locally-advanced-or-metastatic. Issued 04/03/2023. Last accessed 01/18/2024.
[7] U.S. FDA. FDA Approves Melphalan as a Liver-Directed Treatment for Uveal Melanoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-melphalan-liver-directed-treatment-uveal-melanoma. Issued 08/14/2023. Last accessed 01/18/2024.
[8] Mekinist® (Trametinib) Prescribing Information. Novartis. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/204114s029lbl.pdf. Last revised 08/2023. Last accessed 01/18/2024.
[9] Tafinlar® (Dabrafenib) Prescribing Information. Novartis. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/202806s027lbl.pdf. Last revised 08/2023. Last accessed 01/18/2024.
[10] U.S. FDA. FDA Approves Encorafenib with Binimetinib for Metastatic Non-Small Cell Lung Cancer with a BRAF V600E Mutation. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-encorafenib-binimetinib-metastatic-non-small-cell-lung-cancer-braf-v600e-mutation. Issued 10/11/2023. Last accessed 01/18/2024.
[11] U.S. FDA. FDA Approves Nivolumab for Adjuvant Treatment of Stage IIB/C Melanoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-nivolumab-adjuvant-treatment-stage-iibc-melanoma. Issued 10/13/2023. Last accessed 01/18/2024.
[12] U.S. FDA. FDA Approves Neoadjuvant/Adjuvant Pembrolizumab for Resectable Non-Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-neoadjuvant-adjuvant-pembrolizumab-resectable-non-small-cell-lung-cancer. Issued 10/16/2023. Last accessed 01/18/2024.
[13] U.S. FDA. FDA Approves Pembrolizumab with Chemotherapy for Biliary Tract Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-chemotherapy-biliary-tract-cancer. Issued 10/31/2023. Last accessed 01/18/2024.
[14] U.S. FDA. FDA Amends Pembrolizumab's Gastric Cancer Indication. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-amends-pembrolizumabs-gastric-cancer-indication. Issued 11/07/2023. Last accessed 01/18/2024.
[15] U.S. FDA. FDA Approves Pembrolizumab with Chemotherapy for HER2-Negative Gastric or Gastroesophageal Junction Adenocarcinoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-chemotherapy-her2-negative-gastric-or-gastroesophageal-junction. Issued 11/16/2023. Last accessed 01/18/2024.
[16] U.S. FDA. FDA Approves Enfortumab Vedotin-ejfv with Pembrolizumab for Locally Advanced or Metastatic Urothelial Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-enfortumab-vedotin-ejfv-pembrolizumab-locally-advanced-or-metastatic-urothelial-cancer. Issued 12/15/2023. Last accessed 01/18/2024.
[17] U.S. FDA. FDA Approves Pembrolizumab with Chemoradiotherapy for FIGO 2014 Stage III-IVA Cervical Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-chemoradiotherapy-figo-2014-stage-iii-iva-cervical-cancer. Issued 01/12/2024. Last accessed 01/18/2024.
[18] National Comprehensive Cancer Network (NCCN). Hodgkin Lymphoma Clinical Practice Guidelines in Oncology. Available online at: http://www.nccn.org. Last revised 10/12/2023. Last accessed 01/18/2024.
[19] Hepzato Kit™ (Melphalan) Prescribing Information. Delcath Systems, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/201848s000lbl.pdf. Last revised 08/2023. Last accessed 01/18/2024.
[20] Zynyz™ (Retifanlimab-dlwr) Prescribing Information. Incyte Corporation. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761334Orig1s000correctedlbl.pdf. Last revised 03/2023. Last accessed 01/18/2024.

Appendix H

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

Oklahoma Health Care Authority
February 2024

Market News and Updates[1,2,3]

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

- **May 2023:** The FDA approved Ayvakit® (avapritinib) for a new indication for the treatment of adult patients with indolent systemic mastocytosis (ISM). There is a limitation of use stating that Ayvakit® is not recommended for patients with ISM with platelet counts <50 x 10^9/L.

News:

- **November 2022:** Helsinn Therapeutics announced the planned discontinuation of Truseltiq® (infigratinib) due to difficulty enrolling patients into the required confirmatory trial for the medication. The FDA previously granted accelerated approval for Truseltiq® in May 2021 for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement.

Recommendations

The College of Pharmacy recommends updating the approval criteria for Ayvakit® (avapritinib) based on the recent FDA approval for 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.

---

[1] Blueprint Medicines Corporation. FDA Approves Ayvakit® (Avapritinib) as the First and Only Treatment for Indolent Systemic Mastocytosis. Available online at: https://ir.blueprintmedicines.com/news-releases/news-release-details/fda-approves-ayvakitr-avapritinib-first-and-only-treatment. Issued 05/22/2023. Last accessed 01/18/2024.

[2] Ayvakit® (Avapritinib) Prescribing Information. Blueprint Medicines Corporation. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/212608s013lbl.pdf. Last revised 05/2023. Last accessed 01/18/2024.

[3] Helsinn Therapeutics – Discontinuation of Truseltiq® (Infigratinib). *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-withdrawls/drugwithdrawal_truseltiq_2022-1117.pdf. Issued 11/17/2022. Last accessed 01/18/2024.

Appendix I

Vote to Prior Authorize Iwilfin™ (Eflornithine), Kepivance® (Palifermin), Loqtorzi™ (Toripalimab-tpzi), and Omisirge® (Omidubicel-onlv)

Oklahoma Health Care Authority
February 2024

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

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

- **December 2004:** The FDA initially approved Kepivance® (palifermin) in December 2004. Kepivance® is indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy in the setting of autologous hematopoietic stem cell support. Kepivance® is indicated as supportive care for preparative regimens predicted to result in ≥WHO Grade 3 mucositis in the majority of patients. Following an announcement in February 2023 that Kepivance® was currently unavailable due to FDA regulatory delay, Kepivance® was re-launched in October 2023 with a new 5.16mg vial size.
- **April 2023:** The FDA approved Omisirge® (omidubicel-onlv) for use in adult and pediatric patients 12 years of age and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.
- **October 2023:** The FDA approved Loqtorzi™ (toripalimab-tpzi) for use in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent, locally advanced nasopharyngeal carcinoma (NPC). Additionally, the FDA approved Loqtorzi™ as a single agent for adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.
- **December 2023:** The FDA approved Iwilfin™ (eflornithine) to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy.

Iwilfin™ (Eflornithine) Product Summary[7]

Therapeutic Class: Ornithine decarboxylase inhibitor

Indication(s): To reduce the risk of relapse in adult and pediatric patients with HRNB who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy

How Supplied: 192mg oral tablets

Dosing and Administration: Dosed based on body surface area (BSA) twice daily, with or without food, for 2 years or until recurrence of disease or unacceptable toxicity

- Tablets may be swallowed whole, chewed, or crushed

BSA	Dosage
>1.5m^2	768mg (4 tablets) twice daily
0.75 to 1.5m^2	576mg (3 tablets) twice daily
0.5 to <0.75m^2	384mg (2 tablets) twice daily
0.25 to <0.5m^2	192mg (1 tablet) twice daily

BSA = body surface area

Cost: The Wholesale Acquisition Cost (WAC) of Iwilfin™ is $90 per tablet, resulting in a cost of $21,600 per month or $259,200 per year based on the maximum recommended dose of 768mg twice daily.

Kepivance® (Palifermin) Product Summary[8]

Therapeutic Class: Mucocutaneous epithelial human growth factor

Indication(s): To decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy in the setting of autologous hematopoietic stem cell support; Kepivance® is indicated as supportive care for preparative regimens predicted to result in ≥WHO Grade 3 mucositis in the majority of patients

Limitation(s) of Use:

- The safety and efficacy of Kepivance® have not been established in patients with non-hematologic malignancies.
- Kepivance® was not effective in decreasing the incidence of severe mucositis in patients with hematologic malignancies receiving myelotoxic therapy in the setting of allogeneic hematopoietic stem cell support.
- Kepivance® is not recommended for use with melphalan 200mg/m^2 as a conditioning regimen.

How Supplied: 5.16mg lyophilized powder in a single-dose vial (SDV)

Dosing and Administration: 60mcg/kg as an intravenous (IV) bolus injection given for 3 consecutive days before and 3 consecutive days after myelotoxic therapy, for a total of 6 doses

Cost: The WAC of Kepivance® is $3,313.61 per SDV. For a member weighing 80kg, it would require the use of 1 SDV per dose, resulting in a cost of $19,881.66 for the recommended 6 doses.

Loqtorzi™ (Toripalimab-tpzi) Product Summary[9]

Therapeutic Class: Programmed death receptor-1 (PD-1)- blocking antibody

Indication(s):

- In combination with cisplatin and gemcitabine, for first-line treatment of adults with metastatic or recurrent locally advanced NPC
- As a single agent for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy

How Supplied: 240mg/6mL solution in a SDV

Dosing and Administration:

- In combination with cisplatin and gemcitabine: 240mg every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months
- As a single agent: 3mg/kg every 2 weeks until disease progression or unacceptable toxicity
- Administered as an IV infusion over 60 minutes for the first infusion or over 30 minutes for subsequent infusions if no infusion-related reactions occurred during the first infusion

Cost: The WAC of Loqtorzi™ is $1,482.01 per milliliter, resulting in a cost of $8,892.06 per SDV. For a member weighing 80kg and using Loqtorzi™ every 2 weeks as a single agent, it would result in an estimated cost of $17,784.12 per 28 days or $231,193.56 per year.

Omisirge® (Omidubicel-onlv) Product Summary[10]

Therapeutic Class: Nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood

Indication(s): For use in adults and pediatric patients 12 years of age and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection

How Supplied: Omisirge® is a cell suspension for IV infusion that consists of a cultured fraction (CF) and a non-cultured fraction (NF) supplied cryopreserved in 2 separate bags containing the following:

- CF: Contains a minimum of 8.0 x 10^8 total viable cells of which a minimum of 8.7% is CD34+ and a minimum of 9.2 x 10^7 CD34+ cells
- NF: Contains a minimum of 4.0 x 10^8 total viable cells with a minimum of 2.4 x 10^7 CD3+ cells

Dosing and Administration:

- Should be administered by gravity infusion, preferably through central venous access
- The CF bag should be thawed, diluted, and infused first; infusion time should not exceed 2 hours from the end of dilution to the end of the CF infusion
- The NF bag should be thawed, diluted, and infused within 1 hour of safely administering the CF infusion; infusion time should not exceed 1 hour from the end of dilution to the end of infusion

Cost: The WAC of Omisirge® is $338,000 per dose.

Recommendations

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.

[1] Amgen Inc. FDA Approves Kepivance® for Severe Oral Mucositis in Cancer Patients Undergoing Bone Marrow Transplant; Pivotal Phase 3 Study Published in This Week's New England Journal of Medicine. Available online at: https://investors.amgen.com/news-releases/news-release-details/fda-approves-kepivance-severe-oral-mucositis-cancer-patients. Issued 12/15/2004. Last accessed 01/18/2024.
[2] Ernst D. Oral Mucositis Therapy Kepivance® Currently Unavailable. *Medical Professionals Reference*. Available online at: https://www.empr.com/home/news/oral-mucositis-therapy-kepivance-currently-unavailable/. Issued 02/13/2023. Last accessed 01/18/2024.
[3] Sobi. Kepivance® (Palifermin) for Injection, for Intravenous Use Clarification Regarding the Labeled Quantity and Change in Vial Size. Available online at: https://www.sobi.com/sites/default/files/2023-10/Kepivance%20DHCP_October%202023.pdf. Issued 10/2023. Last accessed 01/18/2024.
[4] U.S. FDA. FDA Approves Omidubicel to Reduce Time to Neutrophil Recovery and Infection in Patients with Hematologic Malignancies. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-omidubicel-reduce-time-neutrophil-recovery-and-infection-patients-hematologic. Issued 04/17/2023. Last accessed 01/18/2024.
[5] U.S. FDA. FDA Approves Toripalimab-Tpzi for Nasopharyngeal Carcinoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-toripalimab-tpzi-nasopharyngeal-carcinoma. Issued 10/27/2023. Last accessed 01/18/2024.
[6] U.S. FDA. FDA Approves Eflornithine for Adult and Pediatric Patients with High-Risk Neuroblastoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-eflornithine-adult-and-pediatric-patients-high-risk-neuroblastoma. Issued 12/13/2023. Last accessed 01/18/2024.
[7] Iwilfin™ (Eflornithine) Prescribing Information. US WorldMeds, LLC. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215500s000lbl.pdf. Last revised 12/2023. Last accessed 01/18/2024.
[8] Kepivance® (Palifermin) Prescribing Information. Swedish Orphan Biovitrum. Available online at: https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=426f6e64-2c20-4a61-6d65-7320426f6e64&type=pdf. Last revised 07/2023. Last accessed 01/18/2024.
[9] Loqtorzi™ (Toripalimab-tpzi) Prescribing Information. Coherus BioSciences, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761240s000lbl.pdf. Last revised 10/2023. Last accessed 01/18/2024.
[10] Omisirge® (Omidubicel-onlv) Prescribing Information. Gamida Cell, Inc. Available online at: https://www.fda.gov/media/167202/download?attachment. Last revised 04/2023. Last accessed 01/18/2024.

Appendix J

Vote to Prior Authorize Ogsiveo™ (Nirogacestat)

Oklahoma Health Care Authority
February 2024

Market News and Updates[1]

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

- **November 2023:** The FDA approved Ogsiveo™ (nirogacestat) for adult patients with progressing desmoid tumors who require systemic treatment. This is the first FDA approved treatment for desmoid tumors.

Ogsiveo™ (Nirogacestat) Product Summary[2]

Therapeutic Class: Gamma secretase inhibitor

Indication(s): Treatment of adult patients with progressing desmoid tumors who require systemic treatment

How Supplied: 50mg oral tablets

Dose: 150mg [(3) 50mg tablets] twice daily until disease progression or unacceptable toxicity

Cost: The Wholesale Acquisition Cost (WAC) of Ogsiveo™ is $161.11 per tablet, resulting in a cost of $28,999.80 per 30 days or $347,997.60 per year based on the recommended dosing.

Recommendations

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.

---

[1] U.S. FDA. FDA Approves Nirogacestat for Desmoid Tumors. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-nirogacestat-desmoid-tumors. Issued 11/27/2023. Last accessed 01/18/2024.
[2] Ogsiveo™ (Nirogacestat) Prescribing Information. SpringWorks Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217677Orig1s000_Corrected_lbl.pdf. Last revised 11/2023. Last accessed 01/18/2024.

Appendix K

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

Oklahoma Health Care Authority
February 2024

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

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

- **October 2023:** The FDA approved Xphozah® (tenapanor) to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. The FDA previously issued a Complete Response Letter (CRL) for Xphozah® in 2021, stating that the magnitude of the treatment effect was small and of unclear clinical significance. Ardelyx appealed the decision and, following a positive advisory committee vote in November 2022, the New Drug Application (NDA) for Xphozah® was resubmitted to the FDA in April 2023 and approved in October 2023. Xphozah® was launched to the market in the United States in November 2023.

Xphozah® (Tenapanor) Product Summary[5]

Therapeutic Class: Sodium hydrogen exchanger 3 (NHE3) inhibitor

Indication(s): To reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy

How Supplied: 10mg, 20mg, and 30mg oral tablets

Dosing and Administration:

- Recommended dose is 30mg twice daily before the morning and evening meals
- Serum phosphorus should be monitored, and dosage should be adjusted as needed to manage gastrointestinal tolerability
- Xphozah® should not be taken right before a hemodialysis session; the dose should be taken right before the next meal following dialysis, as patients may experience diarrhea after taking Xphozah®

Cost Comparison: Hyperphosphatemia Medications

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Xphozah® (tenapanor) 30mg tab	**$49.33**	**$2,959.80**	**$35,517.60**
Velphoro® (sucroferric oxyhydroxide) 500mg tab	$17.05	$1,534.50	$18,414.00
Auryxia® (ferric citrate) 210mg tab	$7.17	$1,290.60	$15,487.20
Fosrenol® (lanthanum carbonate) 500mg tab	$12.01	$1,080.90	$12,970.80
sevelamer hydrochloride 800mg tab (generic)	**$1.88**	**$338.40**	**$4,060.80**
calcium acetate 667mg cap (generic)	$0.27	$48.60	$583.20
sevelamer carbonate 800mg tab (generic)	$0.24	$43.20	$518.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the initial FDA recommended dosing for each product
cap = capsule; tab = tablet; unit = each tablet or capsule

Recommendations

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.

---

[1] Ardelyx, Inc. FDA Approves Xphozah® (Tenapanor), a First-In-Class Phosphate Absorption Inhibitor. Available online at: https://ir.ardelyx.com/news-releases/news-release-details/fda-approves-xphozahr-tenapanor-first-class-phosphate-absorption. Issued 10/17/2023. Last accessed 01/18/2024.

[2] Ardelyx, Inc. Ardelyx Receives Complete Response Letter from U.S. FDA for New Drug Application for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis. Available online at: https://ir.ardelyx.com/news-releases/news-release-details/ardelyx-receives-complete-response-letter-us-fda-new-drug. Issued 07/29/2021. Last accessed 01/18/2024.

[3] Ardelyx, Inc. Ardelyx Announces FDA Advisory Committee Votes that the Benefits of Xphozah® (Tenapanor) Outweigh its Risks for the Control of Serum Phosphorus in Adult Patients with Chronic Kidney Disease on Dialysis. Available online at: https://ir.ardelyx.com/news-releases/news-release-details/ardelyx-announces-fda-advisory-committee-votes-benefits-xphozahr. Issued 11/16/2022. Last accessed 01/18/2024.

[4] Ardelyx, Inc. Ardelyx Resubmits New Drug Application to U.S. Food and Drug Administration for Xphozah® (Tenapanor). Available online at: https://ir.ardelyx.com/news-releases/news-release-details/ardelyx-resubmits-new-drug-application-us-food-and-drug. Issued 04/18/2023. Last accessed 01/18/2024.

[5] Xphozah® (Tenapanor) Prescribing Information. Ardelyx, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213931s000lbl.pdf. Last revised 10/2023. Last accessed 01/18/2024.

Appendix L

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

Oklahoma Health Care Authority
February 2024

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

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

- **February 2023:** The FDA approved Atorvaliq® (atorvastatin oral suspension) the first oral suspension formulation of atorvastatin. Atovaliq® has the same indications as the oral tablet and is approved for adults and pediatric patients 10 years of age and older. Atorvaliq® will be available in a 20mg/5mL suspension.
- **March 2023:** The FDA approved an age expansion for Evkeeza® (evinacumab-dgnb) down to 5 years of age as an adjunct to other lipid-lowering therapies for homozygous familial hypercholesterolemia (HoFH). This makes Evkeeza® the first angiopoietin-like 3 (ANGPTL3) inhibitor treatment indicated for children as young as 5 years of age to control dangerously high levels of low-density lipoprotein cholesterol (LDL-C) caused by HoFH. Evkeeza® was initially approved by the FDA in February 2021 as an adjunct to other lipid-lowering therapies in those 12 years of age and older with HoFH.
- **July 2023:** The FDA approved a label update for Leqvio® (inclisiran) for the indication of primary hyperlipidemia as an adjunct to diet and statin therapy. Previously Leqvio® was approved only for patients with atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH). The update also included the removal of the previous limitations of use stating, “the effect of Leqvio® on cardiovascular (CV) morbidity and mortality has not been determined.” Additionally, 4 adverse reactions (urinary tract infections, diarrhea, pain in extremities, and dyspnea) were removed due to the frequency of these events being equal to those in the placebo arm.
- **December 2023:** The FDA approved label updates for Nexletol® (bempedoic acid) and Nexlizet® (bempedoic acid/ezetimibe) to include the diagnosis of primary hyperlipidemia. Similar to Leqvio®, the prior limitations of use stating “the effect of Nexlizet® or Nexletol® on CV morbidity and mortality has not been determined” has also been removed. Additionally, the labels have been updated and now state that Nexletol® and Nexlizet® are indicated for use as an adjunct to diet

and statin therapy. The prior indication stated they must be used as an adjunct to diet and maximally tolerated statin therapy.

Recommendations

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

---

[1] Atorvaliq® (Atorvastatin) – New Drug Approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_atorvaliq_20230-0202.pdf. Issued 02/01/2023. Last accessed 01/30/2024.

[2] Regeneron Pharmaceuticals. FDA Approves First-in-class Evkeeza® (Evinacumab-dgnb) for Young Children with Ultra-rare Form of High Cholesterol. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2023/03/22/2632063/0/en/FDA-Approves-First-in-class-Evkeeza-evinacumab-dgnb-for-Young-Children-with-Ultra-rare-Form-of-High-Cholesterol.html. Issued 03/22/2023. Last accessed 01/18/2024.

[3] Novartis Pharmaceuticals. U.S. FDA Approves Expanded Indication for Novartis Leqvio® (Inclisiran) to Include Treatment of Adults with High LDL-C and Who Are at Increased Risk of Heart Disease. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/us-fda-approves-expanded-indication-for-novartis-leqvio-inclisiran-to-include-treatment-of-adults-with-high-ldl-c-and-who-are-at-increased-risk-of-heart-disease-301872495.html. Issued 07/10/2023. Last accessed 01/18/2024.

[4] Esperion Therapeutics. U.S. FDA Updates LDL-C Lowering Indication for Esperion's Nexletol® (Bempedoic Acid) Tablet and Nexlizet® (Bempedoic Acid and Ezetimibe) Tablet. *Globe Newswire*. Available online at: https://www.globenewswire.com/en/news-release/2023/12/13/2795859/0/en/U-S-FDA-Updates-LDL-C-Lowering-Indication-for-Esperion-s-NEXLETOL-bempedoic-acid-Tablet-and-NEXLIZET-bempedoic-acid-and-ezetimibe-Tablet.html. Issued 12/13/2023. Last accessed 01/18/2024.

Appendix M

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

Oklahoma Health Care Authority
February 2024

Market News and Updates[1]

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

- **February 2023:** The FDA approved an Abbreviated New Drug Application (ANDA) for oxybutynin chloride 2.5mg tablets. Manufactured by Rising Pharmaceuticals, this new strength is indicated for the management of symptoms of bladder instability associated with voiding, similar to other available oxybutynin products.

Cost Comparison

Product	Cost Per Tablet	Cost Per Month	Cost Per Year
oxybutynin IR 2.5mg tablet (generic)	**$2.33**	**$559.20***	**$6,710.40***
oxybutynin IR 5mg tablet (generic)	$0.06	$7.20*	$86.40*
oxybutynin ER 15mg tablet (generic)	$0.16	$9.60[α]	$115.00[α]

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost based on maximum daily dose of 20mg
[α]Cost based on maximum daily dose of 30mg
ER = extended-release; IR = immediate-release

Recommendations

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 additional criteria listed below; 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®)

Bladder Control Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
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
2. 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.

[1] Oxybutynin Chloride Prescribing Information. Rising Pharmaceuticals, Inc. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f8ed80f2-6c3d-4d7f-b761-c2447973c1f9. Last revised 03/2023. Last accessed 01/31/2024.

Appendix N

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

Oklahoma Health Care Authority
February 2024

Market News and Updates[1]

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

- **December 2023:** The FDA approved iDose® TR (travoprost intracameral implant) 75mcg, a prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with ocular hypertension (OHT) or open-angle glaucoma (OAG).

iDose® TR (Travoprost Intracameral Implant) Product Summary[2]

Therapeutic Class: Prostaglandin analog

Indication(s): The reduction of IOP in patients with OAG or OHT

How Supplied: Intracameral implant containing 75mcg travoprost, pre-loaded in a single-dose inserter

Dosing and Administration:

- For ophthalmic intracameral administration under aseptic conditions only
- iDose® TR should not be readministered to an eye that received a prior iDose® TR implant

Cost Comparison:

Product	Cost Per Implant
iDose® TR (travoprost intracameral implant) 75mcg	**$13,950.00**
Durysta® (bimatoprost intracameral implant) 10mcg	$1,987.05

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).

Recommendations

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%) –	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	timolol maleate

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
Brand Preferred		(Timoptic® in Ocudose® 0.25%, 0.5%)
carteolol (Ocupress® 1%)	timolol (Betimol® 0.25%, 0.5%)	
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		

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
(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

[1] Glaukos Corporation. Glaukos Announces FDA Approval of iDose® TR (Travoprost Intracameral Implant). Available online at: https://investors.glaukos.com/investors/news/news-details/2023/Glaukos-Announces-FDA-Approval-of-iDoseTR-travoprost-intracameral-implant/default.aspx. Issued 12/14/2023. Last accessed 01/18/2024.
[2] iDose® TR (Travoprost Intracameral Implant) Prescribing Information. Glaukos Corporation. Available online at: https://www.idosetrhcp.com/wp-content/uploads/2023/12/iDose-TR-Prescribing-Information.pdf. Last revised 12/2023. Last accessed 01/18/2024.

Appendix O

Fiscal Year 2023 Annual Review of Otic Anti-Infective Medications

Oklahoma Health Care Authority
February 2024

Current Prior Authorization Criteria

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/fluocinolone (Otovel®)	ciprofloxacin 6% (Otiprio®)
ciprofloxacin/HC (Cipro® HC)	finafloxacin (Xtoro™)	
neomycin/colistin/HC/ thonzonium (Coly-Mycin® S, Cortisporin-TC®)	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

Otic Anti-Infective Medications Tier-2 Approval Criteria:

1. Member must have an adequate 14-day trial of at least 2 Tier-1 medications; or
2. Approval may be granted if there is a unique FDA approved indication not covered by Tier-1 medications or infection by an organism not known to be covered by any of the Tier-1 medications.

Acetasol® HC and VoSol® HC (Acetic Acid/Hydrocortisone Otic Solution) Approval Criteria:

1. Diagnosis of acute otitis externa; and
2. Member must have recent trials (within the last 6 months) with all other commonly used topical otic anti-infective medications that have failed to resolve infection; or
3. Allergy to all available products and failure of acetic acid alone.

Otiprio® (Ciprofloxacin 6% Otic Suspension) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Bilateral otitis media with effusion in members undergoing tympanostomy tube placement; or
   b. Acute otitis externa due to *Pseudomonas aeruginosa (P. aeruginosa)* or *Staphylococcus aureus (S. aureus)*; and

2. Member must be 6 months of age or older; and
3. Otiprio® must be administered by a health care professional; and
4. A patient-specific, clinically significant reason why appropriate lower tiered otic anti-infective medications cannot be used must be provided; and
5. A quantity limit of 1 vial per treatment course will apply.

Utilization of Otic Anti-Infective Medications: Fiscal Year 2023

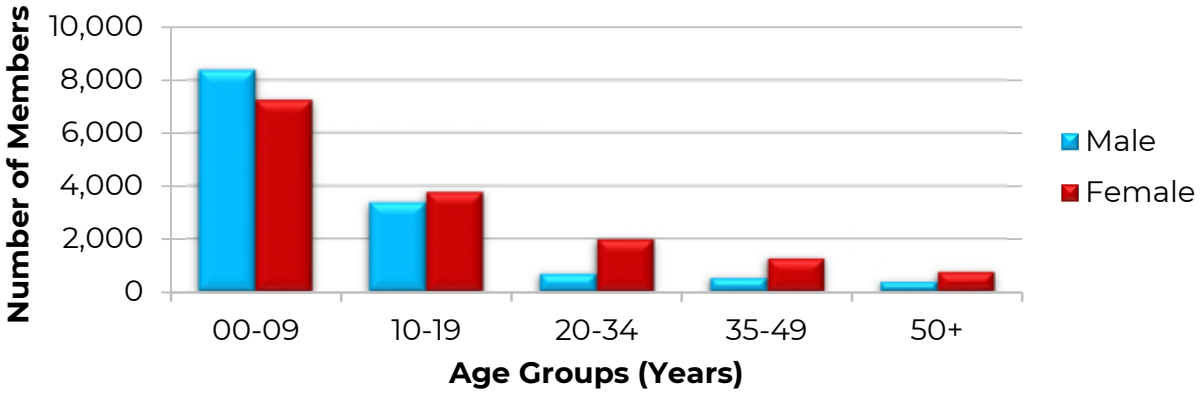
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	24,985	30,517	$4,705,166.44	$154.18	$14.92	232,140	315,292
2023	28,232	34,245	$5,098,031.59	$148.87	$14.06	259,984	362,679
% Change	**13.0%**	**12.2%**	**8.3%**	**-3.4%**	**-5.8%**	**12.0%**	**15.0%**
Change	**3,247**	**3,728**	**$392,865.15**	**-$5.31**	**-$0.86**	**27,844**	**47,387**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

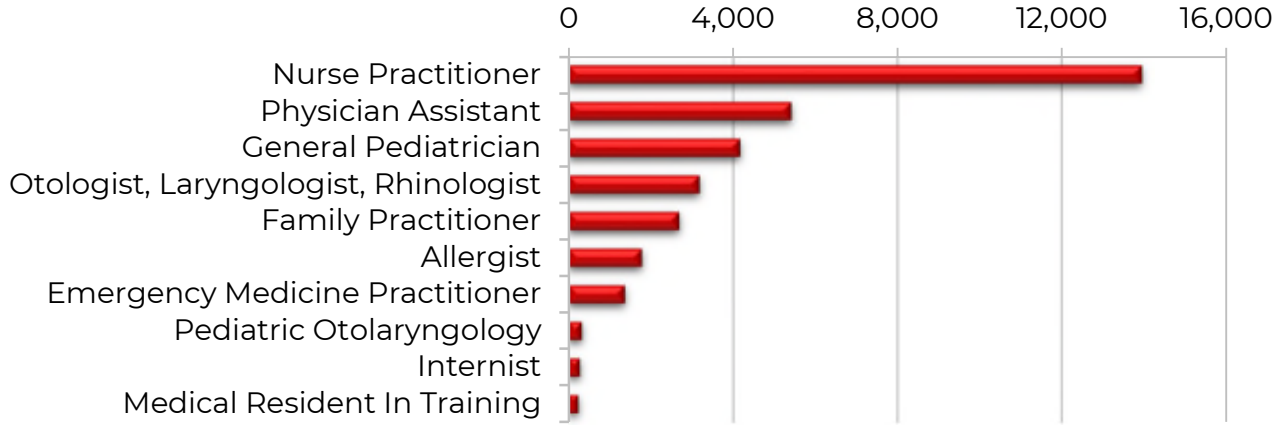
- Aggregate drug rebates collected during fiscal year 2023 for otic anti-infectivemedications totaled $756,789.67.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Otic Anti-Infective 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 Otic Anti-Infective Medications by Number of Claims



Prior Authorization of Otic Anti-Infective Medications

There were 315 prior authorization requests submitted for otic anti-infective medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Ciprodex® (ciprofloxacin/dexamethasone): June 2025
- Otovel® (ciprofloxacin/fluocinolone): March 2030
- Xtoro™ (finafloxacin): November 2033
- Otiprio® (ciprofloxacin): November 2038

News:

- **June 2023:** Novartis Pharmaceuticals announced the permanent discontinuation of brand name Ciprodex® (ciprofloxacin/ dexamethasone) otic suspension. The discontinuation is not due to any

safety or efficacy concerns and the authorized generic will continue to be available.

Recommendations

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

Utilization Details of Otic Anti-Infective Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
CIPRO/DEXA SUS 0.3-0.1%	32,281	26,776	$4,663,401.58	$144.46	1.21	91.47%
CIPRODEX SUS 0.3-0.1%	1,271	1,215	$309,161.36	$243.24	1.05	6.06%
ACETIC ACID SOL OTIC 2%	284	271	$8,195.30	$28.86	1.05	0.16%
CIPRO HC SUS OTIC 0.2-1%	255	251	$86,580.04	$339.53	1.02	1.70%
CORTISPORIN-TC SUS 0.33-0.3-1-0.05%	130	117	$29,527.95	$227.14	1.11	0.58%
SUBTOTAL	**34,221**	**28,630**	**$5,096,866.23**	**$148.94**	**1.2**	**99.97%**
TIER-2 PRODUCTS						
OFLOXACIN DRO 0.3% OTIC	10	10	$266.23	$26.62	1	0.01%
NEO/POLY/HC SUS 1% OTIC	8	8	$527.48	$65.94	1	0.01%
NEO/POLY/HC SOL 1% OTIC	5	5	$302.15	$60.43	1	0.01%
SUBTOTAL	**23**	**23**	**$1,095.86**	**$47.65**	**1**	**0.03%**
SPECIAL PA PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HC/ACETIC ACID SOL OTIC 1-2%	1	1	$69.50	$69.50	1	0.00%
SUBTOTAL	**1**	**1**	**$69.50**	**$69.50**	**1**	**0.00%**
TOTAL	**34,245**	**28,232***	**$5,098,031.59**	**$148.87**	**1.21**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CIPRO/DEXA = ciprofloxacin/dexamethasone; DRO = drops; HC = hydrocortisone; NEO = neomycin; PA = prior authorization; POLY = polymyxin; SOL = solution; SUS = suspension
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[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 01/2024. Last accessed 01/16/2024.
[2] U.S. FDA. FDA Drug Shortages: Discontinuations. Available online at: https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Ciprofloxacin+Hydrochloride%2C+Dexamethasone+Suspension%2F+Drops&st=d&tab=tabs-2. Issued 06/26/2023. Last accessed 01/16/2024.

Appendix P

Fiscal Year 2023 Annual Review of Topical Acne, Psoriasis, and Rosacea Products

Oklahoma Health Care Authority
February 2024

Current Prior Authorization Criteria

Aczone® (Dapsone Gel) Approval Criteria:

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

Amzeeq® (Minocycline 4% Topical Foam) Approval Criteria:

1. An FDA approved indication of inflammatory lesions of non-nodular, moderate-to-severe acne vulgaris; and
2. Member must be 9 years of age or older; and
3. Amzeeq® will not be covered for members older than 20 years of age; and
4. A patient-specific, clinically significant reason why the member cannot use erythromycin 2% topical solution, clindamycin 1% topical solution, benzoyl peroxide, preferred tazarotene formulations, oral isotretinoin medications, and other generically available preferred oral or topical antibiotic products must be provided; and
5. A quantity limit of 30 grams per 30 days will apply.

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

1. An FDA approved diagnosis of persistent (non-transient) facial erythema of rosacea; and
2. Member must be 18 to 20 years of age; and
3. A patient-specific, clinically significant reason why the member cannot utilize clindamycin topical solution (generic), metronidazole topical gel and cream 0.75%, erythromycin topical 2% solution, oral isotretinoin medications, or other generically available preferred oral or topical antibiotic products; and

4. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
5. Brand name Mirvaso® is not a covered product; and
6. A quantity limit of 30 grams per 30 days will apply.

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

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

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

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

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

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

MetroGel® (Metronidazole 1% Gel) Approval Criteria:

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

Noritate® (Metronidazole 1% Cream) Approval Criteria:

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

Sorilux® (Calcipotriene 0.005% Foam) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis of the scalp and body in members 12 years of age and older; and

2. A patient-specific, clinically significant reason why the member cannot use the generic formulations of topical calcipotriene, which are available without a prior authorization, must be provided; and
3. A quantity limit of 120 grams per 30 days will apply.

Tazorac® (Tazarotene Cream and Gel) Approval Criteria:

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

Vtama® (Tapinarof 1% Cream) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis; and
2. Member must be 18 years of age or older; and
3. Member must have a body surface area (BSA) involvement of ≤20%; and
4. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
5. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance):
    a. An ultra-high to high potency topical corticosteroid (TCS); or
    b. A generic topical calcipotriene product; or
    c. A topical tazarotene product; and
6. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 60 grams per 30 days will apply.

Winlevi® (Clascoterone 1% Cream) Approval Criteria:

1. An FDA approved diagnosis of acne vulgaris; and
2. Member must be 12 to 20 years of age; and
3. A patient-specific, clinically significant reason why the member cannot use erythromycin 2% topical solution, clindamycin 1% solution, benzoyl peroxide, preferred tazarotene formulations, oral isotretinoin

medications, and other generically available preferred oral or topical antibiotic products must be provided; and
4. A quantity limit of 60 grams per 30 days will apply.

Zilxi® (Minocycline 1.5% Topical Foam) Approval Criteria:
1. An FDA approved diagnosis of inflammatory lesions of rosacea in adults; and
2. Member must be 18 to 20 years of age; and
3. A patient-specific, clinically significant reason why the member cannot utilize clindamycin topical solution (generic), metronidazole topical gel and cream 0.75%, erythromycin topical 2% solution, oral isotretinoin medications, and other generically available preferred oral or topical antibiotic products must be provided; and
4. A quantity limit of 30 grams per 30 days will apply.

Zoryve® (Roflumilast 0.3% Cream) Approval Criteria:
1. An FDA approved diagnosis of plaque psoriasis; and
2. Member must be 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.

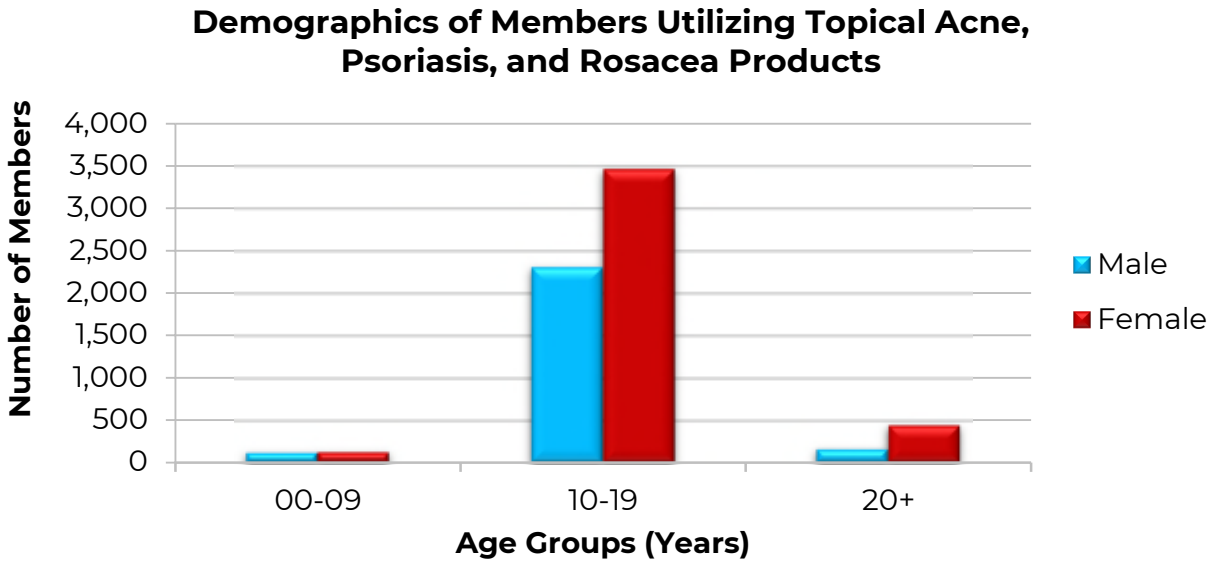
Utilization of Topical Acne, Psoriasis, and Rosacea Products: Fiscal Year 2023

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	6,252	12,501	$814,561.18	$65.16	$2.48	654,807	328,747
2023	6,589	13,350	$758,130.81	$56.79	$2.11	698,289	358,899
% Change	**5.5%**	**7%**	**-5.6%**	**-11.8%**	**-14.2%**	**6.9%**	**9.9%**
Change	**346**	**874**	**-$45,230.84**	**-$7.60**	**-$0.35**	**45,282**	**32,332**

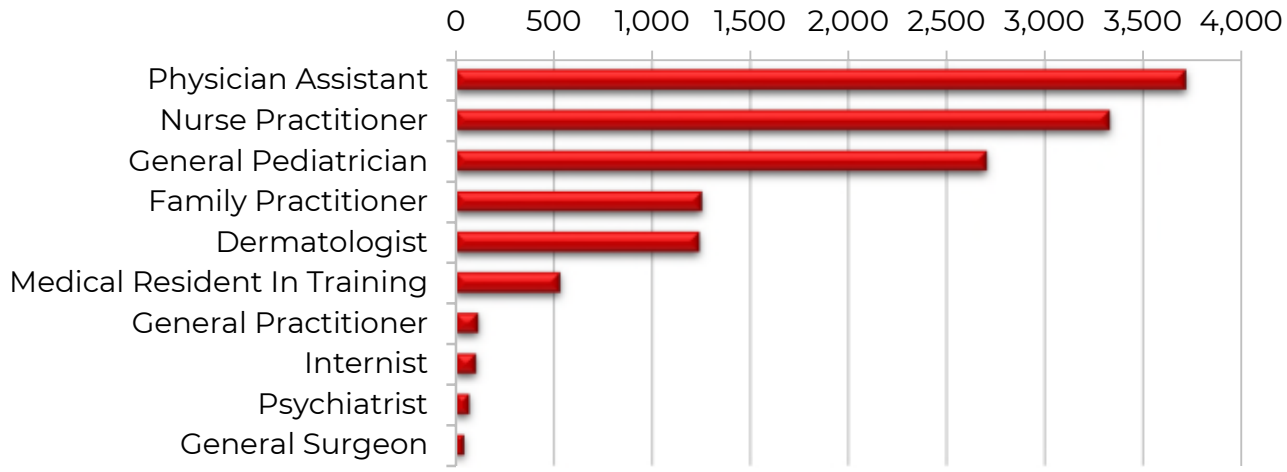
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 6/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

- Aggregate drug rebates collected during fiscal year 2023 for topical acne, psoriasis, and rosacea products: $48,908.33.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.



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

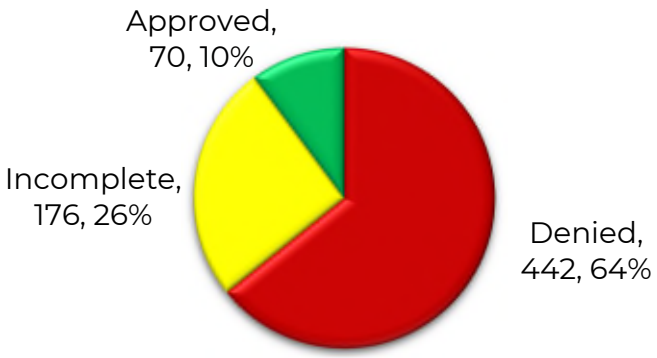
Top Prescriber Specialties of Topical Acne, Psoriasis, and Rosacea Products by Number of Claims



Prior Authorization of Topical Acne, Psoriasis, and Rosacea Products

There were 688 prior authorization requests submitted for topical acne, psoriasis, and rosacea products during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Sorilux® (calcipotriene 0.005% foam): May 2028
- Winlevi® (clascoterone 1% cream): July 2030
- Zilxi® (minocycline 1.5% foam): October 2030
- Mirvaso® (brimonidine 0.33% gel): June 2031
- Aczone® (dapsone 7.5% gel): November 2033
- Duobrii® (halobetasol propionate/tazarotene 0.01%/0.045% lotion): June 2036
- Zoryve® (roflumilast 0.3% cream): June 2037
- Amzeeq® (minocycline 4% foam): September 2037

- Vtama® (tapinarof 1% cream): November 2039
- Zoryve® (roflumilast 0.3% foam): December 2041

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

- **October 2023:** The FDA approved a label expansion for Zoryve® (roflumilast) 0.3% cream for the treatment of psoriasis in children 6 to 11 years of age. Zoryve® was originally FDA approved in 2022 for use in patients 12 years of age and older with psoriasis. The new approval is based on the Maximal Usage Systemic Exposure (MUSE) trial that specifically evaluated use in children 6 to 11 years of age. There are also plans to study this product in patients as young as 2 years of age in the coming years.
- **December 2023:** The FDA approved a new formulation for Zoryve® (roflumilast) 0.3% foam that is indicated to treat seborrheic dermatitis in patients 9 years of age and older and can be used on the scalp or on the body. The approval was based on the STRATUM trial that found clinically significant improvement in the presence of seborrheic dermatitis. The clinical trial is ongoing for a psoriasis indication as well as an age expansion for seborrheic dermatitis. Zoryve® foam is supplied in a 60 gram pressurized aluminum can, and the Wholesale Acquisition Cost (WAC) is $14.30 per gram or $858 per 60 gram can.

Pipeline:

- **Zoryve® (Roflumilast 0.3% Foam):** A Phase 3 trial studying roflumilast foam in patients 12 years of age and older with scalp and body psoriasis has been completed. The ARRECTOR trial found that patients who used the foam experienced a significant improvement in their psoriasis by week 8. The foam was studied with once daily administration and reported positive safety data. The company has not yet submitted a supplemental New Drug Application (sNDA) to the FDA.
- **Zoryve® (Roflumilast 0.15% cream):** The FDA accepted an sNDA in November 2023 for Zoryve® (roflumilast) 0.15% cream for use in patients ages 6 years and older with atopic dermatitis. Three clinical trials titled the INTEGUMENT trials were conducted, demonstrating improvement in itching and atopic dermatitis severity by week 4 of the trials. As early as 1 week into treatment with Zoryve®, 40% of patients with atopic dermatitis saw a 75% reduction in their Eczema Area and Severity Index (EASI-75). The Prescription Drug User Fee Act (PDUFA) date has been set as July 7, 2024. There is also a 0.05% strength of roflumilast cream that is still in clinical trials for use in patients ages 2 to 5 years with atopic dermatitis.

Recommendations

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.

Utilization Details of Topical Acne, Psoriasis, and Rosacea Products: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CLINDAMYCIN PRODUCTS						
CLINDAMYCIN 1% GEL	4,928	2,740	$153,828.57	$31.22	1.78	20.29%
CLINDAMYCIN 1% SOL	2,520	1,421	$54,859.55	$21.77	1.77	7.24%
CLINDAMYCIN 1% LOT	1,989	1,122	$86,322.66	$43.40	1.77	11.39%
CLINDAMYCIN 1% SWAB	976	376	$27,360.35	$28.03	2.59	3.61%
CLINDAMYCIN 10MG/ML LOT	94	69	$3,920.83	$41.71	1.36	0.52%
CLINDACIN-P 1% PAD	6	4	$182.67	$30.45	1.5	0.02%
SUBTOTAL	**10,513**	**5,732**	**$326,474.63**	**$31.05**	**1.83**	**43.06%**
TAZAROTENE PRODUCTS						
TAZAROTENE 0.1% CRE	2,143	1,312	$268,151.21	$125.13	1.63	35.37%
TAZAROTENE 0.05% GEL	189	155	$97,016.68	$513.32	1.22	12.80%
TAZAROTENE 0.1% GEL	66	43	$36,477.76	$552.69	1.53	4.81%
TAZORAC 0.05% CRE	3	2	$2,544.83	$848.28	1.5	0.34%
TAZORAC 0.05% GEL	3	3	$1,289.61	$429.87	1	0.17%
TAZORAC 0.1% CRE	1	1	$900.39	$900.39	1	0.12%
TAZORAC 0.1% GEL	1	1	$455.97	$455.97	1	0.06%
SUBTOTAL	**2,406**	**1,517**	**$406,836.45**	**$169.09**	**1.59**	**53.66%**
METRONIDAZOLE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
METRONIDAZOLE 0.75% CRE	128	97	$4,568.79	$35.69	1.32	0.60%
METRONIDAZOLE 0.75% GEL	93	72	$2,956.24	$31.79	1.29	0.39%
METRONIDAZOLE 0.75% LOT	8	7	$935.90	$116.99	1.14	0.12%
SUBTOTAL	**229**	**176**	**$8,460.93**	**$36.95**	**1.3**	**1.12%**
ERYTHROMYCIN PRODUCTS						
ERYTHROMYCIN 2% SOL	185	122	$7,736.47	$41.82	1.52	1.02%
SUBTOTAL	**185**	**122**	**$7,736.47**	**$41.82**	**1.52**	**1.02%**
ROFLUMILAST PRODUCTS						
ZORYVE 0.3% CRE	7	2	$5,763.34	$823.33	3.5	0.76%
SUBTOTAL	**7**	**2**	**$5,763.34**	**$823.33**	**3.5**	**0.76%**
MINOCYCLINE PRODUCTS						
AMZEEQ 4% AER	5	2	$2,425.77	$485.15	2.5	0.32%
SUBTOTAL	**5**	**2**	**$2,425.77**	**$485.15**	**2.5**	**0.32%**
SULFACETAMIDE PRODUCTS						
SULFACETAMIDE 10% LOT	5	4	$433.22	$86.64	1.25	0.06%
SUBTOTAL	**5**	**4**	**$433.22**	**$86.64**	**1.25**	**0.06%**
TOTAL	**13,350**	**6,589***	**$758,130.81**	**$56.79**	**2.03**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AER = aerosol foam; CRE = cream; LOT = lotion; SOL = solution
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

---

[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 01/2024. Last accessed 01/18/2024.

[2] Arcutis Biotherapeutics Inc. FDA Approves Arcutis' Zoryve® (Roflumilast) Cream 0.3% for Treatment of Psoriasis in Children Ages 6 to 11. Available online at: https://www.arcutis.com/fda-approves-arcutis-zoryve-roflumilast-cream-0-3-for-treatment-of-psoriasis-in-children-ages-6-to-11/. Issued 10/06/2023. Last accessed 01/18/2024.

[3] Arcutis Biotherapeutics Inc. FDA Approves Arcutis' Zoryve® (Roflumilast) Topical Foam, 0.3% for Treatment of Seborrheic Dermatitis in Individuals Aged 9 Years and Older. Available online at: https://www.arcutis.com/fda-approves-arcutis-zoryve-roflumilast-topical-foam-0-3-for-the-treatment-of-seborrheic-dermatitis-in-individuals-aged-9-years-and-older/. Issued 12/15/2023. Last accessed 01/18/2024.

[4] Desai S, McCormick E, Friedman A. An Up-to-Date Approach to the Management of Seborrheic Dermatitis. *J Drugs Dermatol* 2022; 21:1373. doi: 10.36849/JDD.1022.

[5] Seborrheic Dermatitis: Diagnosis and Treatment. *American Academy of Dermatology Association*. Available online at: https://www.aad.org/public/diseases/a-z/seborrheic-dermatitis-treatment. Last revised 12/26/2022. Last accessed 02/07/2023.

[6] Clark G. Pope S, Jaboori K. Diagnosis and Treatment of Seborrheic Dermatitis. *Amer Fam Phys* 2015; 91:185-190.

[7] Topical Roflumilast Foam (ARQ-154): Clinical Development. *Arcutis Biotherapeutics Inc*. Available online at: https://www.arcutis.com/pipeline/topical-roflumilast-foam/. Issued . Last accessed 01/31/2024.

[8] Arcutis Biotherapeutics Inc. FDA Sets Review Date for Zoryve® in Atopic Dermatitis. *Formulary Watch*. Available online at: https://www.formularywatch.com/view/fda-sets-review-date-for-zoryve-in-atopic-dermatitis. Issued 11/29/2023. Last accessed 01/31/2024.

Appendix Q

Fiscal Year 2023 Annual Review of Antiviral Medications

Oklahoma Health Care Authority
February 2024

Current Prior Authorization Criteria

Acyclovir 5% cream (Generic Zovirax®) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the brand formulation must be provided.

Denavir® (Penciclovir Cream), Sitavig® (Acyclovir Buccal Tablets), and Xerese® (Acyclovir/Hydrocortisone Cream) Approval Criteria:

1. An FDA approved diagnosis of recurrent herpes labialis (cold sores); and
2. A patient-specific, clinically significant reason why the member cannot use oral acyclovir, famciclovir, or valacyclovir tablets must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use acyclovir cream must be provided.

Livtencity® (Maribavir) Approval Criteria:

1. An FDA approved diagnosis of post-transplant cytomegalovirus (CMV) infection and disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet in adults and pediatric members (12 years of age and older weighing ≥35kg); and
2. A previously failed trial at least 14 days in duration with ganciclovir, valganciclovir, cidofovir, or foscarnet; and
3. Prescriber must verify the member does not have CMV disease involving the central nervous system including the retina (CMV retinitis); and
4. Prescriber must verify member will not receive concurrent treatment with ganciclovir and/or valganciclovir while taking Livtencity®; and
5. Prescriber must verify the member will be monitored for virologic failure during and after treatment with Livtencity®; and
6. Livtencity® 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 Livtencity® will not be used concomitantly with strong inducers of CYP3A4 (e.g., rifampin, rifabutin, St. John's wort) except carbamazepine, phenobarbital, or phenytoin. Use of carbamazepine, phenobarbital, or phenytoin concomitantly with

Livtencity® will require dose adjustment according to package labeling; and
8. Prescriber must agree to monitor drug concentrations of immunosuppressant drugs that are CYP3A4 and/or P-glycoprotein (P-gp) substrates (e.g., tacrolimus, cyclosporine, sirolimus, everolimus) throughout treatment with Livtencity® and adjust the dose of immunosuppressant drug(s) as needed; and
9. Approvals will be for a maximum duration of 8 weeks, and a quantity limit of 112 tablets per 28 days will apply.

Prevymis® (Letermovir Tablets and Injection) Approval Criteria:

1. An FDA approved indication of prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogenic hematopoietic stem cell transplant (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. A quantity limit of 1 tablet or vial per day will apply.

Zovirax® (Acyclovir Ointment) Approval Criteria:

1. An FDA approved indication of management of initial genital herpes or in limited non-life-threatening mucocutaneous herpes simplex virus (HSV) infections in immunocompromised patients; and
2. A patient-specific clinically significant reason why the member cannot use oral acyclovir, famciclovir, or valacyclovir tablets.

Zovirax® (Acyclovir Suspension) Approval Criteria:

1. An age restriction of 7 years and younger will apply. Members older than 7 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

Utilization of Antiviral Medications: Fiscal Year 2023

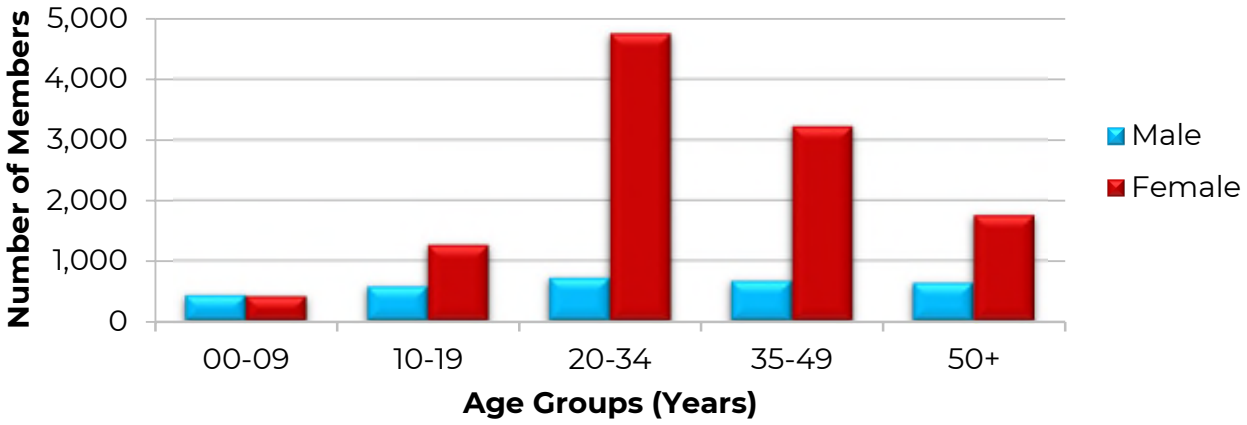
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	11,421	21,610	$864,990.35	$40.03	$1.79	953,840	482,436
2023	14,352	28,289	$1,062,311.29	$37.55	$1.62	1,219,493	656,504
% Change	**25.7%**	**30.9%**	**22.8%**	**-6.2%**	**-9.5%**	**27.9%**	**36.1%**
Change	**2,931**	**6,679**	**$197,320.94**	**-$2.48**	**-$0.17**	**265,653**	**174,068**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

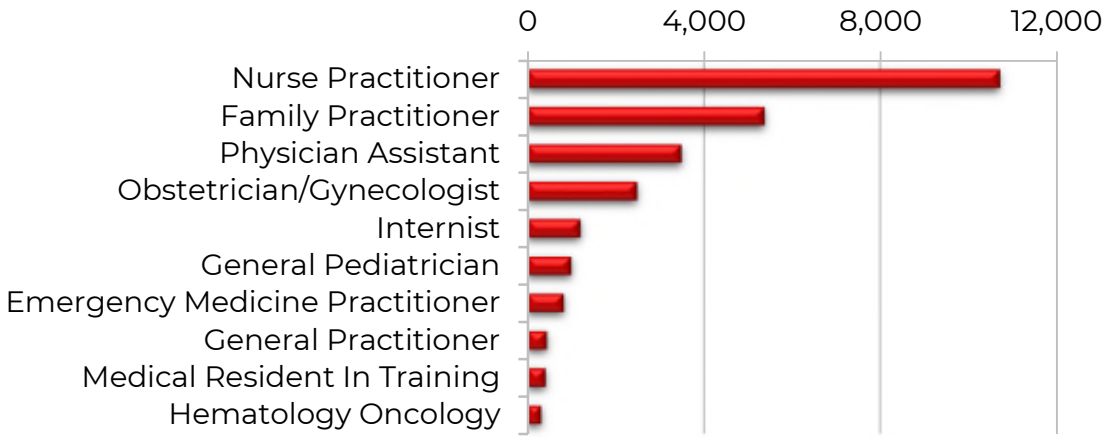
- Aggregate drug rebates collected during fiscal year 2023 for antiviral medications totaled $118,696.75.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Antiviral 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.

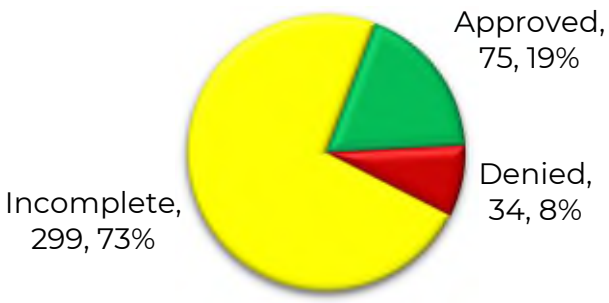
Top Prescriber Specialties of Antiviral Medications by Number of Claims



Prior Authorization of Antiviral Medications

There were 408 prior authorization requests submitted for antiviral medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Prevymis® (letermovir oral tablet): May 2024
- Sitavig® (acyclovir buccal tablet): June 2030
- Livtencity® (maribavir tablet): January 2032
- Prevymis® (letermovir injection): February 2033

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

- **June 2023:** The FDA approved Prevymis® (letermovir) for the expanded indication of prophylaxis of cytomegalovirus (CMV) disease in adults who have received a kidney transplant and are at high risk (donor CMV-

seropositive/recipient CMV-seronegative). Prevymis® is administered once daily as oral tablets or an intravenous (IV) infusion, initiated on day 0 up to day 7 post-kidney transplant, and continued through day 200 post-transplant. Prevymis® was originally approved in 2017 for prophylaxis of CMV in adults who have received an allogeneic hematopoietic stem cell transplant (HSCT) who are CMV-seropositive.

- **August 2023:** The FDA approved a supplemental New Drug Application (sNDA) for Prevymis® to allow for the extension of treatment to 200 days post-transplant in adults who are CMV-seropositive recipients of an allogeneic HSCT and are at risk of developing a late CMV infection. The original FDA approval only allowed for treatment up to 100 days post-transplant.

Pipeline:

- **Posoleucel (Viralym-M):** Posoleucel is a multi-virus specific T cell therapy that targets 6 viral pathogens including adenovirus, BK virus (BKV), CMV, Epstein-Barr virus (EBV), herpesvirus 6, and JC virus (JCV). By providing this immunologic bridge, posoleucel may substantially reduce or prevent virus-associated morbidity and mortality in transplant patients. Posoleucel has been studied in a Phase 2 multi-virus prevention trial and a Phase 2 trial for the treatment of BKV infection in adult kidney transplant patients. Posoleucel has been granted Orphan Drug designation and 3 Regenerative Medicine Advanced Therapy (RMAT) designations from the FDA.

Recommendations

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.

Utilization Details of Antiviral Medications: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VALACYCLOVIR PRODUCTS						
VALACYCLOVIR TAB 1GM	9,262	5,774	$207,226.91	$22.37	1.6	19.51%
VALACYCLOVIR TAB 500MG	6,814	3,250	$138,581.95	$20.34	2.1	13.05%
SUBTOTAL	**16,076**	**9,024**	**$345,808.86**	**$21.51**	**1.78**	**32.56%**
ACYCLOVIR PRODUCTS						
ACYCLOVIR TAB 400MG	6,482	3,136	$87,258.45	$13.46	2.07	8.21%
ACYCLOVIR TAB 800MG	2,561	1,685	$37,410.82	$14.61	1.52	3.52%
ACYCLOVIR CAP 200MG	934	528	$13,271.57	$14.21	1.77	1.25%
ACYCLOVIR SUS 200MG/5ML	817	652	$30,169.77	$36.93	1.25	2.84%
ZOVIRAX 5% CREAM	348	207	$69,511.09	$199.74	1.68	6.54%
ACYCLOVIR INJ 50MG/ML	14	4	$2,944.15	$210.30	3.5	0.28%
SUBTOTAL	**11,156**	**6,212**	**$240,565.85**	**$21.56**	**1.8**	**22.64%**
FAMCICLOVIR PRODUCTS						
FAMCICLOVIR TAB 500MG	353	220	$10,349.00	$29.32	1.6	0.97%
FAMCICLOVIR TAB 250MG	139	59	$4,103.20	$29.52	2.36	0.39%
FAMCICLOVIR TAB 125MG	10	7	$204.46	$20.45	1.43	0.02%
SUBTOTAL	**502**	**286**	**$14,656.66**	**$29.20**	**1.76**	**1.38%**
VALGANCICLOVIR PRODUCTS						
VALGANCICLOVIR TAB 450MG	365	112	$59,666.74	$163.47	3.26	5.62%
VALGANCICLOVIR SOL 50MG/ML	107	31	$94,883.77	$886.76	3.45	8.93%
VALCYTE SOL 50MG/ML	11	2	$44,002.48	$4,000.23	5.5	4.14%
SUBTOTAL	**483**	**145**	**$198,552.99**	**$411.08**	**3.33**	**18.69%**
LETERMOVIR PRODUCTS						
PREVYMIS TAB 480MG	37	12	$248,963.96	$6,728.76	3.08	23.44%
SUBTOTAL	**37**	**12**	**$248,963.96**	**$6,728.76**	**3.08**	**23.44%**
RIBAVIRIN PRODUCTS						
RIBAVIRIN TAB 200MG	24	10	$2,175.52	$90.65	2.4	0.20%
RIBAVIRIN CAP 200MG	8	5	$742.77	$92.85	1.6	0.07%
SUBTOTAL	**32**	**15**	**$2,918.29**	**$91.20**	**2.13**	**0.27%**
FOSCARNET PRODUCTS						
FOSCARNET INJ 6,000MG/250ML	2	2	$10,785.87	$5,392.94	1	1.02%
SUBTOTAL	**2**	**2**	**$10,785.87**	**$5,392.94**	**1**	**1.02%**
GANCICLOVIR PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GANCICLOVIR INJ 500MG	1	1	$58.81	$58.81	1	0.01%
SUBTOTAL	**1**	**1**	**$58.81**	**$58.81**	**1**	**0.01%**
TOTAL	**28,289**	**14,352***	**$1,062,311.29**	**$37.55**	**1.97**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; INJ = injection; SOL = solution; SUS = suspension; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[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 01/2024. Last accessed 01/18/2024.
[2] Merck. U.S. FDA Approves New Indication for Merck's Prevymis® (Letermovir) for Prevention of Cytomegalovirus (CMV) Disease in High-Risk Adult Kidney Transplant Recipients. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20230606005563/en/U.S.-FDA-Approves-New-Indication-for-Merck%E2%80%99s-PREVYMIS%C2%AE-letermovir-for-Prevention-of-Cytomegalovirus-CMV-Disease-in-High-Risk-Adult-Kidney-Transplant-Recipients/. Issued 06/06/2023. Last accessed 01/18/2024.
[3] Prevymis® (Letermovir) Prescribing Information. Merck. Available online at: https://www.merck.com/product/usa/pi_circulars/p/prevymis/prevymis_pi.pdf. Last revised 08/2023. Last accessed 01/18/2024.
[4] Allovir. Posoleucel (Viralym-M, ALVR105): A Multi-Virus Specific T Cell Therapy (VST) Targeting Six Devastating Viruses. Available online at: https://www.allovir.com/products/alvr105. Last accessed 01/18/2024.

Appendix R

Fiscal Year 2023 Annual Review of Leukemia Medications and 30-Day Notice to Prior Authorize Vanflyta® (Quizartinib)

Oklahoma Health Care Authority
February 2024

Current Prior Authorization Criteria

Utilization data for Adcetris® (brentuximab vedotin), Beleodaq® (belinostat), Calquence® (acalabrutinib), Copiktra® (duvelisib), Folotyn® (pralatrexate), Poteligeo® (mogamulizumab-kpkc), and Tecartus® (brexucabtagene autoleucel) and approval criteria for indications other than leukemia diagnoses can be found in the March 2023 Drug Utilization Review (DUR) Board packet. These medications are reviewed annually with the lymphoma medications. Utilization data for Ayvakit™ (avapritinib) and approval criteria for indications other than leukemia diagnoses can be found in the January 2024 DUR Board packet. Ayvakit™ is reviewed annually with the gastrointestinal cancer medications. Utilization data for Zelboraf® (vemurafenib) and approval criteria for indications other than leukemia diagnoses can be found in the December 2023 DUR Board packet. Zelboraf® is reviewed annually with the skin cancer 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. As a single agent in members who have received ≥1 line of therapy.

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

1. For first-line treatment of CLL/SLL in combination with chlorambucil or bendamustine; or
2. Relapsed/refractory disease as a single agent or in combination with fludarabine and cyclophosphamide; or

3. Maintenance therapy as second-line extended dosing following complete or partial response to relapsed/refractory therapy (maximum 2 years).

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

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

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

1. Diagnosis of ALL; and
2. Used as first line therapy; or
3. May be used to treat members with a hypersensitivity to native forms of L-asparaginase; or
4. Used as systemic central nervous system (CNS)-directed therapy; or
5. 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
6. For Asparlas®, a patient-specific, clinically significant reason why the member cannot use Oncaspar® (pegaspargase) must be provided; and
7. For Asparlas®, member must be 1 month to 21 years of age.

Asparlas® (Calaspargase Pegol-mknl) and Oncaspar® (Pegaspargase) Approval Criteria [Extranodal NK/T-Cell Lymphoma Diagnosis]:

1. Diagnosis of NK/T-Cell lymphoma; and
2. Member has 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.

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

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

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

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

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

1. Member must have 1 of the following:
    a. Relapsed/refractory Philadelphia chromosome negative (Ph-) ALL; or
    b. Relapsed/refractory Philadelphia chromosome positive (Ph+) ALL who are intolerant/refractory to ≥2 tyrosine kinase inhibitors (TKIs); and
2. As a single agent only.

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

1. Member must have 1 of the following:
    a. Relapsed/refractory Philadelphia chromosome negative (Ph-) ALL; or
    b. Relapsed/refractory Philadelphia chromosome positive (Ph+) ALL after failure of ≥2 tyrosine kinase inhibitors (TKIs); or
    c. Ph- ALL as consolidation in adolescent/young adults or members younger than 65 years of age without substantial comorbidity with persistent or late clearance minimal residual disease positive (MRD+) following a complete response to induction; and
2. As a single agent.

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

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

Bosulif® (Bosutinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Chronic, accelerated, or blast phase CML; and
2. Newly diagnosed or resistant/intolerant to other tyrosine kinase inhibitors (TKIs).

Calquence® (Acalabrutinib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) 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 lines of systemic therapy; and
3. As a single agent.

Daurismo® (Glasdegib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly-diagnosed AML; and
2. Member meets 1 of the following:
   a. Member is 75 years of age or older; or
   b. If the member is younger than 75 years of age, must be unable to tolerate intensive induction chemotherapy; and
3. In combination with low-dose cytarabine (LDAC).

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.

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

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

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 chlorambucil, bendamustine, 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 [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
2. In combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP), cyclophosphamide, vincristine, and prednisone (CVP), or bendamustine; and

3. When used for maintenance therapy, a total of 12 doses will be approved.

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.

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

1. Used in 1 of the following settings:
    a. Induction/consolidation with hyperfractionated cyclophosphamide, vincristine sulfate, doxorubicin hydrochloride (Adriamycin®), and dexamethasone (HyperCVAD); or
    b. Maintenance therapy in combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
    c. Maintenance therapy post-hematopoietic stem cell transplantation; or
    d. Relapsed/refractory disease either as a single agent, in combination with chemotherapy not previously given, or in patients with T315I mutations.

Iclusig® (Ponatinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Member must have 1 of the following:
    a. T315I mutation; or
    b. Intolerant or resistant to ≥2 tyrosine kinase inhibitors (TKIs); or
    c. Post-hematopoietic stem cell transplantation in patients with prior accelerated or blast phase prior to transplant or who have relapsed.

Idhifa® (Enasidenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly diagnosed AML; and
    a. Member meets 1 of the following:
        i. Member is 75 years of age or older; or
        ii. If the member is younger than 75 years of age, must be unable to tolerate intensive induction chemotherapy; and
    b. As a single agent; and
    c. Isocitrate dehydrogenase-2 (IDH2) mutation; or
2. Relapsed/refractory AML; and
    a. IDH2 mutation; and

b. As a single agent.

Imbruvica® (Ibrutinib) Approval Criteria [Chronic Graft-Versus-Host Disease (cGVHD) Diagnosis]:

1. Failure of 1 or more lines of therapy; and
2. Member must be 1 year of age or older; and
3. For members younger than 12 years of age:
   a. The member's current body surface area (BSA) must be provided; and
   b. Requests for use of the 70mg capsule formulation will require a patient-specific, clinically significant reason why the member cannot use the 70mg/mL oral suspension formulation.

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

1. As first-line or subsequent therapy for CLL/SLL; and
2. As a single agent or in combination with bendamustine, rituximab, or obinutuzumab.

Imbruvica® (Ibrutinib) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis or Acquired Immunodeficiency Syndrome (AIDS)-Related B-Cell Lymphoma Diagnosis]:

1. 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. 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 [Hairy Cell Leukemia (HCL) Diagnosis]:

1. As a single agent in members with indication(s) for treatment for progression.

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

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

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

1. As third-line or greater therapy for members who have transformed to non-germinal center 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 [Post-Transplantation 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 [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.

Inqovi® (Decitabine/Cedazuridine) Approval Criteria [Myelodysplastic Syndromes (MDS) Diagnosis]:

1. Diagnosis of MDS (intermediate-1, intermediate-2, or high risk) in adults including previously treated and untreated, de novo, and secondary MDS with the 1 of the following subtypes:
    a. Refractory anemia; or
    b. Refractory anemia with ring sideroblasts; or
    c. Refractory anemia with excess blasts; or
    d. Chronic myelomonocytic leukemia (CMML).

Kymriah® (Tisagenlecleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Members must meet all of the following:
    a. B-cell precursor ALL; and
    b. Member must be 25 years of age or younger; and
    c. Refractory or in second or later relapse:
        i. Philadelphia chromosome negative (Ph-) ALL: Must be refractory or with ≥2 relapses; or
        ii. Philadelphia chromosome positive (Ph+) ALL: Must have failed ≥2 tyrosine kinase inhibitors (TKIs); and
    d. Therapies to consider prior to tisagenlecleucel if appropriate: Clinical trial, multi-agent chemotherapy with or without

hematopoietic cell transplantation (HCT), blinatumomab (category 1 recommendation), and inotuzumab (category 1 recommendation); and
2. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells, must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities, and must comply with the Kymriah® Risk Evaluation and Mitigation Strategy (REMS) requirements; and
3. Approvals will be for 1 dose per member per lifetime.

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

1. 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.

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

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

Onureg® (Azacitidine) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Diagnosis of AML; and
2. Used as maintenance therapy in members who have achieved first complete remission (CR) or complete remission with incomplete blood count recover (CRi) following intensive induction chemotherapy; and
3. Member is unable to complete intensive curative therapy.

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

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

Rezlidhia™ (Olutasidenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Relapsed/refractory AML; and
    a. As a single agent; and
    b. Isocitrate dehydrogenase-1 (IDH1) mutation.

Scemblix® (Asciminib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Diagnosis of Philadelphia chromosome-positive (Ph+) CML in chronic phase; and
    a. Previously treated with ≥2 tyrosine kinase inhibitors (TKIs); or
    b. Frontline or subsequent therapy in members with the T315I mutation.

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

1. Member must have 1 of the following:
    a. Upfront therapy (including induction and consolidation) in combination with multi-agent chemotherapy or as a single agent; or
    b. Maintenance therapy including:
        i. In combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
        ii. Post-hematopoietic stem cell transplantation; or
    c. Relapsed/refractory disease as a single agent or in combination with multi-agent chemotherapy.

Sprycel® (Dasatinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Member must have 1 of the following:
    a. Chronic, accelerated, or blast phase CML; or
    b. Post-hematopoietic stem cell transplantation.

Sprycel® (Dasatinib) Approval Criteria [Soft Tissue Sarcoma – Gastrointestinal Stromal Tumors (GIST) Diagnosis]:

1. Member must have all of the following:
    a. Progressive disease and failed imatinib, sunitinib, or regorafenib; and
    b. PDGFRA D842V mutation.

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

1. Member must have 1 of the following:
    a. Primary treatment of advanced phase CML with disease progression to accelerated phase; or

b. Post-hematopoietic stem cell transplant in members who have relapsed; or
c. T315I mutation; or
d. Members who are intolerant or resistant to ≥2 tyrosine kinase inhibitors (TKIs); and

2. As a single agent.

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

1. Member must have 1 of the following:
   a. Upfront therapy (including induction and consolidation) in combination with multi-agent chemotherapy or as a single agent; or
   b. Maintenance therapy including:
      i. In combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
      ii. Post-hematopoietic stem cell transplant; or
   c. Relapsed/refractory disease as a single agent or in combination with multi-agent chemotherapy.

Tasigna® (Nilotinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Member must have 1 of the following:
   a. Newly diagnosed chronic, accelerated, or blast phase CML; or
   b. Philadelphia Chromosome Positive (Ph+) CML chronic phase (CP) resistant or intolerant to prior tyrosine kinase inhibitor (TKI) therapy; or
   c. Post-hematopoietic stem cell transplantation.

Tasigna® (Nilotinib) Approval Criteria [Soft Tissue Sarcoma – Gastrointestinal Stromal Tumors (GIST) Diagnosis]:

1. Member must have progressive disease and failed imatinib, sunitinib, or regorafenib.

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.

Tibsovo® (Ivosidenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly diagnosed AML; and
    a. Member meets 1 of the following:
        i. Member is 75 years of age or older; or
        ii. If the member is younger than 75 years of age, must be unable to tolerate intensive induction chemotherapy; and
    b. As a single agent or in combination with azacitidine; and
    c. Isocitrate dehydrogenase-1 (IDH1) mutation; or
2. Relapsed/refractory AML; and
    a. As a single agent; and
    b. IDH1 mutation.

Tibsovo® (Ivosidenib) Approval Criteria [Cholangiocarcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic cholangiocarcinoma; and
2. An isocitrate dehydrogenase-1 (IDH1) mutation; and
3. Member has received prior treatment for this diagnosis.

Venclexta® (Venetoclax) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Member meets 1 of the following:
    a. Member is 75 years of age or older; or
    b. If the member is younger than 75 years of age, must be unable to tolerate intensive induction chemotherapy; and
2. As first-line therapy or in relapsed/refractory disease; and
3. In combination with azacitidine, decitabine, or low-dose cytarabine (LDAC).

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

1. As first-line therapy in combination with obinutuzumab for a maximum duration of 12 months; or
2. Relapsed/refractory disease in combination with rituximab or as a single agent.

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

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

Xospata® (Gilteritinib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

2. Relapsed/refractory AML; and
3. FMS-related tyrosine kinase 3 (FLT3) mutation; and
4. As a single agent.

Zelboraf® (Vemurafenib) Approval Criteria [Hairy Cell Leukemia (HCL) Diagnosis]:

1. Disease progression following failure of purine analog therapy (i.e., pentostatin, cladribine); and
2. As a single agent.

Zydelig® (Idelalisib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL) Diagnosis]:

1. Relapsed/refractory disease; and
2. In combination with rituximab; or
3. As a single agent.

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

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

Utilization of Leukemia Medications: Fiscal Year 2023

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

Fiscal Year Comparison: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	84	563	$8,551,735.27	$15,189.58	$515.91	30,673	16,576
2023	111	739	$12,003,808.14	$16,243.31	$555.60	37,865	21,605
% Change	**32.10%**	**31.30%**	**40.40%**	**6.90%**	**7.70%**	**23.40%**	**30.30%**
Change	**27**	**176**	**$3,452,072.87**	**$1,053.73**	**$39.69**	**7,192**	**5,029**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

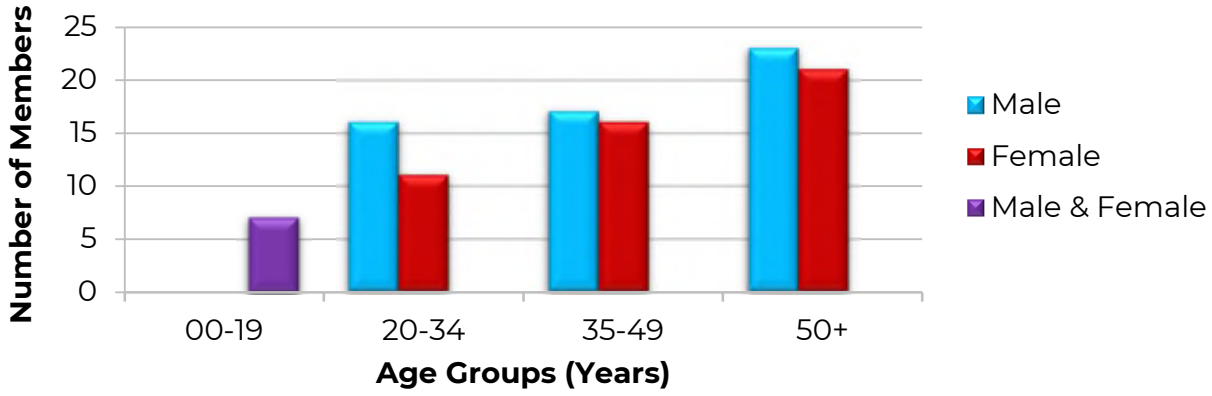
Fiscal Year Comparison: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	39	119	$2,089,506.59	$17,558.88	3.05
2023	42	180	$2,766,213.65	$15,367.85	4.29
% Change	**7.69%**	**51.26%**	**32.39%**	**-12.48%**	**40.66%**
Change	**3**	**61**	**$676,707.06**	**-$2,191.03**	**1.24**

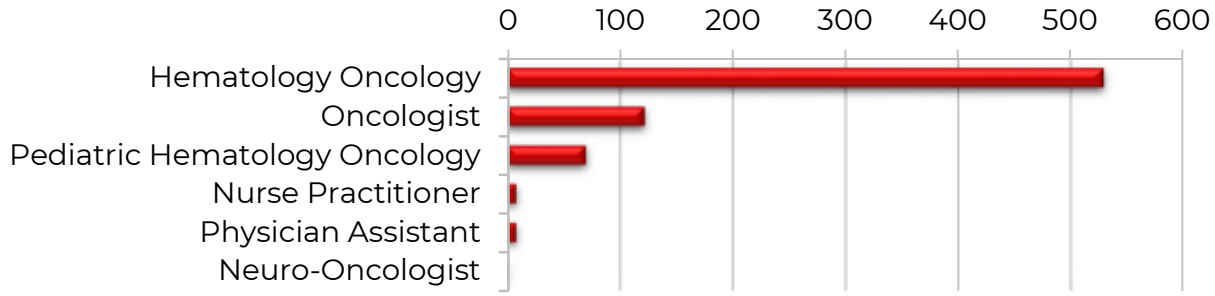
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

- Aggregate drug rebates collected during fiscal year 2023 for leukemia medications: $5,276,408.03.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Leukemia Medications: Pharmacy Claims



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

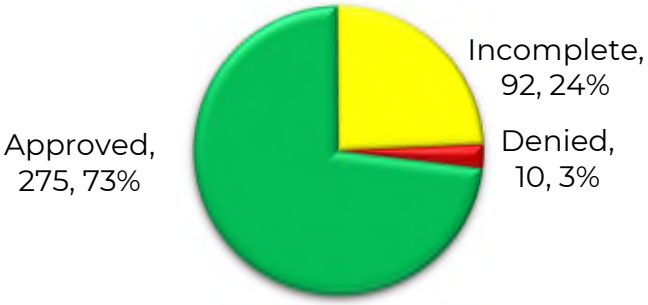


Prior Authorization of Leukemia Medications

There were 377 prior authorization requests submitted for leukemia medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

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

Status of Petitions



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

Anticipated Patent Expiration(s):

- Sprycel® (dasatinib): September 2026
- Onureg® (azacitidine): June 2030
- Inqovi® (decitabine): August 2030
- Tasigna® (nilotinib): October 2032
- Vanflyta® (quizartinib): September 2033
- Venclexta® (venetoclax): September 2033
- Zydelig® (idelalisib): September 2033
- Iclusig® (ponatinib): December 2033
- Bosulif® (bosutinib): August 2034
- Idhifa® (enasidenib): September 2034
- Daurismo® (glasdegib): April 2036
- Xospata® (gilteritinib): July 2036
- Imbruvica® (ibrutinib): September 2036
- Tibsovo® (ivosidenib): June 2039
- Rezlidhia™ (olutasidenib): November 2039
- Scemblix® (asciminib): May 2040

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 granted full approval for Blincyto® (blinatumomab) for the treatment of adult and pediatric patients with CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%. Blincyto® was previously granted accelerated approval for this indication by the FDA in March 2018.
- **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.
- **September 2023:** The FDA approved Bosulif® (bosutinib) for a new pediatric indication in patients 1 year of age and older with chronic phase (CP) Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) that is newly-diagnosed or resistant or intolerant to prior therapy. The FDA also approved a new capsule formulation of Bosulif® in 50mg and 100mg strengths. The capsules can be opened and the contents may be mixed with applesauce or yogurt for patients who are unable to swallow whole capsules.
- **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.

Vanflyta® (Quizartinib) Product Summary[13]

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 and to be consistent with the FDA approved dosing for Calquence® (acalabrutinib) and Columvi™ (glofitamab-gxbm) (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 [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. 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.

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.

Utilization Details of Leukemia Medications: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DASATINIB PRODUCTS						
SPRYCEL TAB 100MG	225	29	$3,549,290.82	$15,774.63	7.76	29.57%
SPRYCEL TAB 70MG	47	7	$423,642.76	$9,013.68	6.71	3.53%
SPRYCEL TAB 20MG	38	4	$368,045.95	$9,685.42	9.5	3.07%
SPRYCEL TAB 140MG	27	6	$441,371.89	$16,347.11	4.5	3.68%
SPRYCEL TAB 50MG	2	2	$18,654.32	$9,327.16	1	0.16%
SPRYCEL TAB 80MG	2	1	$32,659.60	$16,329.80	2	0.27%
SUBTOTAL	**341**	**49**	**$4,833,665.34**	**$14,174.97**	**6.96**	**40.27%**
IBRUTINIB PRODUCTS						
IMBRUVICA TAB 420MG	88	12	$1,360,526.68	$15,460.53	7.33	11.33%
IMBRUVICA TAB 280MG	26	3	$433,803.38	$16,684.75	8.67	3.61%
IMBRUVICA CAP 140MG	22	4	$362,648.76	$16,484.03	5.5	3.02%
IMBRUVICA TAB 560MG	18	4	$273,995.22	$15,221.96	4.5	2.28%
SUBTOTAL	**154**	**23**	**$2,430,974.04**	**$15,785.55**	**6.7**	**20.25%**
VENETOCLAX PRODUCTS						
VENCLEXTA TAB 100MG	64	20	$725,366.39	$11,333.85	3.2	6.04%
VENCLEXTA TAB START PK	6	6	$18,792.98	$3,132.16	1	0.16%
VENCLEXTA TAB 50MG	3	2	$4,102.63	$1,367.54	1.5	0.03%
VENCLEXTA TAB 10MG	3	1	$1,760.13	$586.71	3	0.01%
SUBTOTAL	**76**	**29**	**$750,022.13**	**$9,868.71**	**2.62**	**6.25%**
NILOTINIB PRODUCTS						
TASIGNA CAP 150MG	58	9	$1,037,160.43	$17,882.08	6.44	8.64%
TASIGNA CAP 200MG	13	2	$231,813.61	$17,831.82	6.5	1.93%
SUBTOTAL	**71**	**11**	**$1,268,974.04**	**$17,872.87**	**6.45**	**10.57%**
BOSUTINIB PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BOSULIF TAB 100MG	16	2	$218,749.68	$13,671.86	8	1.82%
BOSULIF TAB 500MG	5	3	$92,335.83	$18,467.17	1.67	0.77%
BOSULIF TAB 400MG	2	2	$36,111.39	$18,055.70	1	0.30%
SUBTOTAL	**23**	**7**	**$347,196.90**	**$15,095.52**	**3.29**	**2.89%**
AZACITIDINE PRODUCTS						
ONUREG TAB 300MG	19	9	$432,228.75	$22,748.88	2.11	3.60%
ONUREG TAB 200MG	2	1	$45,561.90	$22,780.95	2	0.38%
SUBTOTAL	**21**	**10**	**$477,790.65**	**$22,751.94**	**2.1**	**3.98%**
PONATINIB PRODUCTS						
ICLUSIG TAB 45MG	8	3	$154,510.28	$19,313.79	2.67	1.29%
ICLUSIG TAB 15MG	5	1	$136,970.55	$27,394.11	5	1.14%
ICLUSIG TAB 10MG	2	1	$37,633.82	$18,816.91	2	0.31%
ICLUSIG TAB 30MG	1	1	$18,816.91	$18,816.91	1	0.16%
SUBTOTAL	**16**	**6**	**$347,931.56**	**$21,745.72**	**2.67**	**2.90%**
ENASIDENIB PRODUCTS						
IDHIFA TAB 100MG	15	3	$451,742.05	$30,116.14	5	3.76%
SUBTOTAL	**15**	**3**	**$451,742.05**	**$30,116.14**	**5**	**3.76%**
ASCIMINIB PRODUCTS						
SCEMBLIX TAB 40MG	11	2	$840,959.91	$76,450.90	5.5	7.01%
SUBTOTAL	**11**	**2**	**$840,959.91**	**$76,450.90**	**5.5**	**7.01%**
IVOSIDENIB PRODUCTS						
TIBSOVO TAB 250MG	6	2	$176,042.36	$29,340.39	3	1.47%
SUBTOTAL	**6**	**2**	**$176,042.36**	**$29,340.39**	**3**	**1.47%**
GILTERITINIB PRODUCTS						
XOSPATA TAB 40MG	3	2	$53,634.68	$17,878.23	1.5	0.45%
SUBTOTAL	**3**	**2**	**$53,634.68**	**$17,878.23**	**1.5**	**0.45%**
IDELALISIB PRODUCTS						
ZYDELIG TAB 150MG	2	1	$24,874.48	$12,437.24	2	0.21%
SUBTOTAL	**2**	**1**	**$24,874.48**	**$12,437.24**	**2**	**0.21%**
TOTAL	**739**	**111***	**$12,003,808.14**	**$16,243.31**	**6.66**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; START PK = starter pack; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PEGASPARGASE J9266	59	21	$1,649,940.10	$27,965.09	2.81
OBINUTUZUMAB J9301	55	12	$321,242.55	$5,840.77	4.58
BLINATUMOMAB J9039	31	4	$122,298.26	$3,945.11	7.75
ASPARAGINASE, RECOMB J9021	23	3	$332,052.00	$14,437.04	7.67
CALASPARGASE PEGOL J9118	9	6	$208,742.00	$23,193.56	1.5
INOTUZUMAB OZOGAMICIN J9229	3	1	$131,938.74	$43,979.58	3

PRODUCT UTILIZED	TOTAL CLAIMS[+]	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TOTAL	180	42	$2,766,213.65	$15,367.85	4.29

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
[+]Total number of unduplicated claims.
RECOMB = recombinant
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

---

[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 01/2024. Last accessed 01/05/2024.
[2] 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 01/09/2024.
[3] Amgen. FDA Grants Full Approval for Blincyto® (Blinatumomab) to Treat Minimal Residual Disease-Positive B-Cell Precursor Acute Lymphoblastic Leukemia. Available online at: https://www.amgen.com/newsroom/press-releases/2023/06/fda-grants-full-approval-for-blincyto-blinatumomab-to-treat-minimal-residual-diseasepositive-bcell-precursor-acute-lymphoblastic-leukemia. Issued 06/21/2023. Last accessed 01/09/2024.
[4] 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 01/09/2024.
[5] 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 01/09/2024.
[6] U.S. FDA. FDA Approves Bosutinib for Pediatric Patients with Chronic Myelogenous Leukemia. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-bosutinib-pediatric-patients-chronic-myelogenous-leukemia. Issued 09/26/2023. Last accessed 01/09/2024.
[7] 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 01/09/2024.
[8] 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 01/09/2024.
[9] 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 01/09/2024.
[10] 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 01/09/2024.
[11] 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 01/24/2024.
[12] 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.
[13] 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 01/18/2024.

Appendix S

Fiscal Year 2023 Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize RizaFilm® (Rizatriptan Film) and Zavzpret™ (Zavegepant Nasal Spray)

Oklahoma Health Care Authority
February 2024

Current Prior Authorization Criteria

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

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
			ubrogepant tablet (Ubrelvy®)
			zolmitriptan nasal spray (generic Zomig® nasal spray)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ODT = orally disintegrating tablet; PA = prior authorization

Anti-Migraine Medications Tier-2 Approval Criteria:

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

Anti-Migraine Medications Tier-3 Approval Criteria:

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

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of 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 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®, 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) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
   a. Reyvow® and Ubrelvy® 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®; however, Nurtec® ODT will follow the same criteria as Reyvow® and Ubrelvy® 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 zolmitriptan 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 lower-tiered triptan medications.

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. 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
5. Migraine headache exacerbation secondary to other medication therapies or conditions have been ruled out and/or treated. This includes, but is not limited to:
    a. Hormone replacement therapy or hormone-based contraceptives; and
    b. Chronic insomnia; and
    c. Obstructive sleep apnea; and
6. The member has failed medical migraine preventive therapy with at least 2¥ agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects) within the last 365 days. [¥The manufacturers of Ajovy® and Emgality® have currently provided a supplemental rebate to be the preferred calcitonin gene-related peptide (CGRP) inhibitor(s) and require a trial with 2 other migraine preventative therapies; however, Ajovy® and Emgality® will follow the original criteria and require trials with 3 other migraine preventative therapies if the manufacturers choose not to participate in supplemental rebates.] This includes, but is not limited to:
    a. Select antihypertensive therapy (e.g., beta-blocker therapy); or
    b. Select anticonvulsant therapy; or
    c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and
7. Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
    a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and

   b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
   c. Opioids (≥10 days/month for >3 months); and
   d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
   e. Ergotamine-containing medications (≥10 days/month for >3 months); and
   f. Triptans (≥10 days/month for >3 months); and
8. Member is not taking any medications that are likely to be the cause of the headaches; and
9. Member 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
10. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative CGRP inhibitor; and
11. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and
12. Prescriber must verify member has been counseled on appropriate use, storage of the medication, and administration technique; and
13. 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
14. 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 month; and
4. 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
5. Member has failed prophylactic therapy with at least 1 other medication (e.g., verapamil, select anticonvulsants, corticosteroids); and
6. 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
7. Member will not use Emgality® concurrently with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
8. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
9. Initial approvals will be for the duration of 3 months. Continuation approvals will be granted until the end of the cluster period if the prescriber documents that the member is responding well to treatment as indicated by a reduction in cluster headache attack frequency; and
10. A quantity limit of (3) 100mg/mL syringes per 30 days will apply.

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

1. An FDA approved indication for the preventive treatment of migraine in adults; and
2. Member must be 18 years of age or older; and
3. Member has documented chronic migraine or episodic migraine headaches:
    a. Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month; or
    b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months (*Nurtec® ODT and Qulipta® are 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. 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
5. Migraine headache exacerbation secondary to other medication therapies or conditions have been ruled out and/or treated. This includes, but is not limited to:
    a. Hormone replacement therapy or hormone-based contraceptives; and
    b. Chronic insomnia; and
    c. Obstructive sleep apnea; and
6. The member has failed medical migraine preventive therapy with at least 3 agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects) within the last 365 days. This includes, but is not limited to:
    a. Select antihypertensive therapy (e.g., beta-blocker therapy); or
    b. Select anticonvulsant therapy; or
    c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and
7. Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
    a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and

   b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
   c. Opioids (≥10 days/month for >3 months); and
   d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
   e. Ergotamine-containing medications (≥10 days/month for >3 months); and
   d. Triptans (≥10 days/month for >3 months); and
8. Member is not taking any medications that are likely to be the cause of the headaches; and
9. Member must have been evaluated within the last 6 months by a neurologist for migraine headaches and the requested medication (e.g., Nurtec® ODT, Qulipta®, Vyepti®) recommended as treatment (not necessarily prescribed by a neurologist); and
10. 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
11. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and
12. For Vyepti®, prescriber must verify the medication will be prepared and administered according the Vyepti® package labeling; and
13. 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
14. For consideration of Vyepti® at the maximum recommended dosing (300mg every 3 months), a patient-specific, clinically significant reason why other available CGRP inhibitors for migraine prophylaxis are not appropriate for the member must be provided; and
15. Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and
16. Quantity limits will apply based on FDA-approved dosing:
   a. For Nurtec® ODT, a quantity limit of 16 orally disintegrating tablets (ODTs) per 30 days will apply; and
   b. For Qulipta®, a quantity limit of 30 tablets per 30 days will apply; and
   c. For Vyepti®, a quantity limit of 3 vials per 90 days will apply.

Utilization of Anti-Migraine Medications: Fiscal Year 2023

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	8,763	20,192	$2,256,656.92	$111.76	$5.67	206,076	397,996
2023	11,454	27,638	$3,591,427.48	$129.95	$6.38	282,955	562,983
% Change	**30.70%**	**36.90%**	**59.10%**	**16.30%**	**12.50%**	**37.30%**	**41.50%**
Change	**2,691**	**7,446**	**$1,334,770.56**	**$18.19**	**$0.71**	**76,879**	**164,987**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Comparison of Fiscal Years: Medical Claims

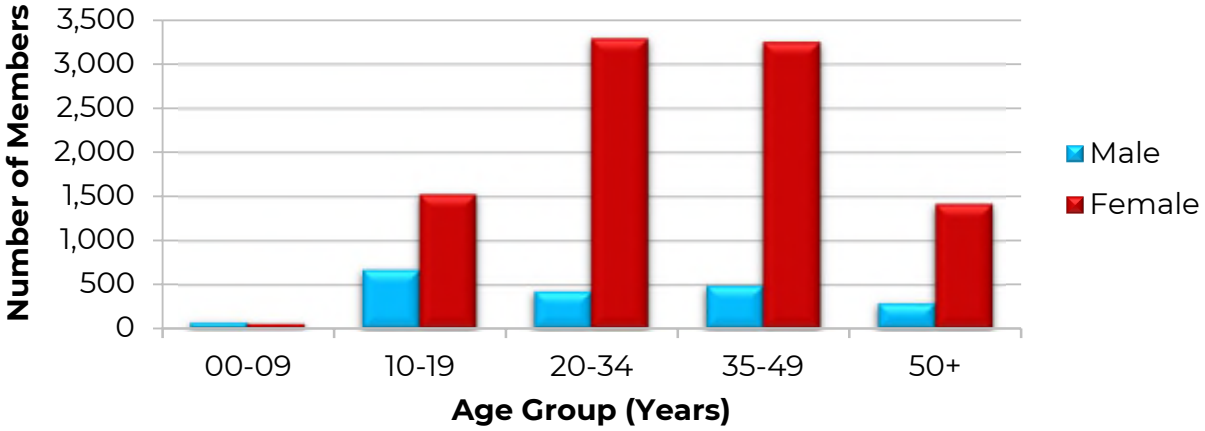
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	1	1	$1,601.00	$1,601.00	1
2023	8	13	$31,513.80	$2,424.14	1.63
% Change	**7**	**12**	**$29,912.80**	**$823.14**	**0.625**
Change	**700.00%**	**1,200.00%**	**1,868.38%**	**51.41%**	**62.50%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

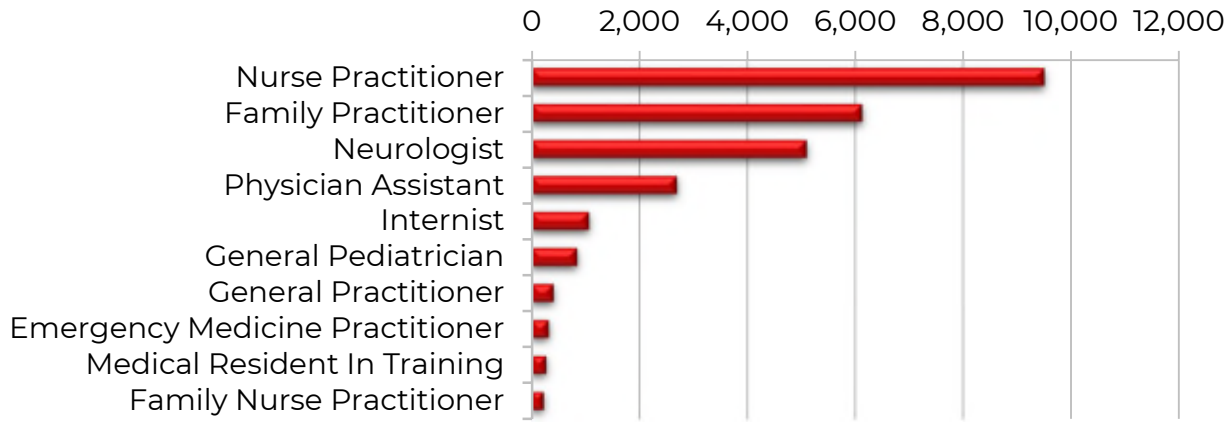
- Aggregate drug rebates collected during fiscal year 2023 for the anti-migraine medications totaled $2,487,454.04.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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

Demographics of Members Utilizing Anti-Migraine Medications



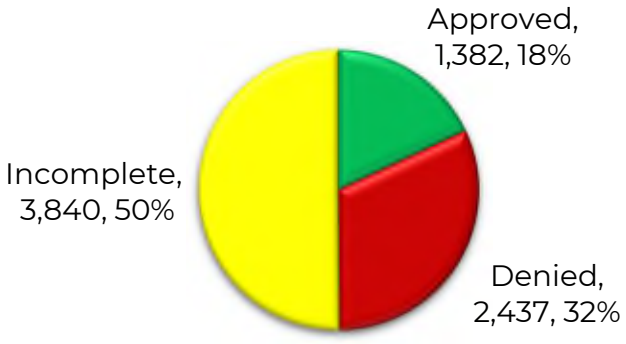
Top Prescriber Specialties of Anti-Migraine Medications by Number of Claims



Prior Authorization of Anti-Migraine Medications

There were 7,659 prior authorization requests submitted for anti-migraine medications during fiscal year 2023. Computer edits are in place to detect lower tiered medications in the member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Tosymra® (sumatriptan nasal spray): July 2031
- Zavzpret™ (zavegepant nasal spray): October 2031
- Rizafilm® (rizatriptan film): July 2034
- Onzetra® Xsail® (sumatriptan nasal powder): October 2034
- Qulipta® (atogepant tablet): January 2035
- Zembrace® SymTouch® [sumatriptan subcutaneous (sub-Q) injection]: January 2036
- Reyvow® (lasmiditan tablet): December 2037
- Trudhesa® [dihydroergotamine (DHE) nasal spray]: January 2039
- Nurtec® ODT [rimegepant orally disintegrating tablet (ODT)]: March 2039
- Ubrelvy® (ubrogepant tablet): December 2041

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 both the preventive treatment of 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 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.

Pipeline:

- **AXS-07 (Rizatriptan/Meloxicam):** AXS-07 is a combination product containing rizatriptan and meloxicam that uses Axsome Therapeutics' Molecular Solubility Enhanced Inclusion Complex (MoSEIC) technology that is designed to improve drug absorption. Axsome Therapeutics announced that it intends to resubmit its New Drug Application (NDA) for AXS-07 for acute treatment of migraine in the first half of 2024. Previously, the FDA issued a complete response letter (CRL) for AXS-07 citing issues related to chemistry, manufacturing, and controls (CMC).
- **STS101 (DHE Nasal Powder):** STS101 is a dry powder nasal formulation of dihydroergotamine mesylate (DHE) used for the treatment of acute migraine. In January 2024, the FDA issued a CRL to Satsuma Pharmaceuticals for STS101 citing problems related to CMC. Satsuma announced they will work with the FDA to resubmit the NDA. The CRL did not identify any safety issues with STS101.

Zavzpret™ (Zavegepant Nasal Spray) Product Summary[11]

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®)

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
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)
			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
    h. 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
    d. 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.

Utilization Details of Anti-Migraine Medications: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 MEDICATIONS						
SUMATRIPTAN PRODUCTS						
SUMATRIPTAN TAB 50MG	6,623	3,631	$96,129.49	$14.51	1.82	2.68%
SUMATRIPTAN TAB 100MG	5,374	2,208	$79,764.74	$14.84	2.43	2.22%
SUMATRIPTAN TAB 25MG	3,653	2,161	$52,760.64	$14.44	1.69	1.47%
SUBTOTAL	**15,650**	**8,000**	**$228,654.87**	**$14.61**	**1.96**	**6.37%**
RIZATRIPTAN PRODUCTS						
RIZATRIPTAN TAB 10MG	3,563	1,669	$53,654.62	$15.06	2.13	1.49%
RIZATRIPTAN ODT 10MG	2,040	1,012	$34,196.29	$16.76	2.02	0.95%
RIZATRIPTAN TAB 5MG	893	491	$14,367.71	$16.09	1.82	0.40%
RIZATRIPTAN ODT 5MG	656	357	$12,163.69	$18.54	1.84	0.34%
SUBTOTAL	**7,152**	**3,529**	**$114,382.31**	**$15.99**	**2.03**	**3.18%**
ELETRIPTAN PRODUCTS						
ELETRIPTAN TAB 40MG	253	159	$9,156.12	$36.19	1.59	0.25%
RELPAX TAB 40MG	252	114	$168,691.05	$669.41	2.21	4.70%
RELPAX TAB 20MG	89	44	$60,459.11	$679.32	2.02	1.68%
ELETRIPTAN TAB 20MG	76	56	$2,825.02	$37.17	1.36	0.08%
SUBTOTAL	**670**	**373**	**$241,131.30**	**$359.90**	**1.8**	**6.71%**
SUMATRIPTAN/NAPROXEN COMBINATION PRODUCTS						
SUMAT-NAPROX TAB 85-500MG	100	46	$18,522.12	$185.22	2.17	0.52%
SUBTOTAL	**100**	**46**	**$18,522.12**	**$185.22**	**2.17**	**0.52%**
ZOLMITRIPTAN PRODUCTS						
ZOMIG SPR 5MG	21	13	$12,080.90	$575.28	1.62	0.34%
ZOMIG SPR 2.5MG	20	14	$11,931.60	$596.58	1.43	0.33%
SUBTOTAL	**41**	**27**	**$24,012.50**	**$585.67**	**1.52**	**0.67%**
TIER-1 SUBTOTAL	**23,613**	**11,975**	**$626,703.10**	**$26.54**	**1.97**	**17.45%**
TIER-2 MEDICATIONS						
NARATRIPTAN PRODUCTS						
NARATRIPTAN TAB 2.5MG	33	9	$730.60	$22.14	3.67	0.02%
SUBTOTAL	**33**	**9**	**$730.60**	**$22.14**	**3.67**	**0.02%**
ZOLMITRIPTAN PRODUCTS						
ZOLMITRIPTAN TAB 5MG	28	11	$517.54	$18.48	2.55	0.01%
ZOLMITRIPTAN ODT 2.5MG	7	4	$192.35	$27.48	1.75	0.01%
ZOLMITRIPTAN ODT 5MG	5	2	$133.65	$26.73	2.5	0.00%
ZOLMITRIPTAN TAB 2.5MG	4	3	$64.87	$16.22	1.33	0.00%
SUBTOTAL	**44**	**20**	**$908.41**	**$20.65**	**2.2**	**0.03%**
TIER-2 SUBTOTAL	**77**	**29**	**$1,639.01**	**$21.29**	**2.66**	**0.05%**
TIER-3 MEDICATIONS						
FROVATRIPTAN PRODUCTS						
FROVATRIPTAN TAB 2.5MG	6	2	$309.67	$51.61	3	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**6**	**2**	**$309.67**	**$51.61**	**3**	**0.01%**
ALMOTRIPTAN PRODUCTS						
ALMOTRIPTAN TAB 12.5MG	3	1	$656.64	$218.88	3	0.02%
SUBTOTAL	**3**	**1**	**$656.64**	**$218.88**	**3**	**0.02%**
TIER-3 SUBTOTAL	**9**	**3**	**$966.31**	**$107.37**	**3**	**0.03%**
SPECIAL PRIOR AUTHORIZATION (PA) MEDICATIONS						
ZOLMITRIPTAN PRODUCTS						
ZOLMITRIPTAN SPR 5MG	47	18	$21,936.15	$466.73	2.61	0.61%
ZOLMITRIPTAN SPR 2.5MG	6	2	$3,177.84	$529.64	3	0.09%
SUBTOTAL	**53**	**20**	**$25,113.99**	**$473.85**	**2.65**	**0.70%**
SUMATRIPTAN PRODUCTS						
SUMATRIPTAN INJ 6MG/0.5ML	38	8	$8,022.39	$211.12	4.75	0.22%
SUMATRIPTAN SPR 20MG/ACT	5	2	$880.50	$176.10	2.5	0.02%
SUMATRIPTAN INJ 4MG/0.5ML	5	3	$1,036.75	$207.35	1.67	0.03%
SUMATRIPTAN SPR 5MG/ACT	1	1	$128.31	$128.31	1	0.00%
SUBTOTAL	**49**	**14**	**$10,067.95**	**$205.47**	**3.5**	**0.28%**
LASMIDITAN PRODUCTS						
REYVOW TAB 100MG	13	5	$9,157.65	$704.43	2.6	0.25%
REYVOW TAB 50MG	3	3	$2,092.33	$697.44	1	0.06%
SUBTOTAL	**16**	**8**	**$11,249.98**	**$703.12**	**2**	**0.31%**
DIHYDROERGOTAMINE PRODUCTS						
MIGRANAL SPR 4MG/ML	**1**	**1**	**$3,830.34**	**$3,830.34**	**1**	**0.11%**
SUBTOTAL	**1**	**1**	**$3,830.34**	**$3,830.34**	**1**	**0.11%**
SPECIAL PA SUBTOTAL	**119**	**43**	**$50,262.26**	**$422.37**	**2.77**	**1.40%**
CALCITONIN GENE-RELATED PEPTIDE (CGRP) PRODUCTS⁺						
GALCANEZUMAB PRODUCTS						
EMGALITY INJ 120MG/ML	1,687	323	$1,083,302.13	$642.15	5.22	30.16%
EMGALITY SYR 120MG/ML	183	44	$117,207.94	$640.48	4.16	3.26%
EMGALITY SYR 100MG/ML	10	3	$16,229.73	$1,622.97	3.33	0.45%
SUBTOTAL	**1,880**	**370**	**$1,216,740.00**	**$647.20**	**5.08**	**33.88%**
RIMEGEPANT PRODUCTS						
NURTEC ODT 75MG	737	262	$749,379.36	$1,016.80	2.81	20.87%
SUBTOTAL	**737**	**262**	**$749,379.36**	**$1,016.80**	**2.81**	**20.87%**
FREMANEZUMAB PRODUCTS						
AJOVY INJ 225MG/1.5ML	375	97	$250,664.22	$668.44	3.87	6.98%
AJOVY SYR 225MG/1.5ML	186	37	$124,611.02	$669.95	5.03	3.47%
SUBTOTAL	**561**	**134**	**$375,275.24**	**$668.94**	**4.19**	**10.45%**
ERENUMAB PRODUCTS						
AIMOVIG INJ 140MG/ML	206	40	$155,459.68	$754.66	5.15	4.33%
AIMOVIG INJ 70MG/ML	105	21	$78,946.80	$751.87	5	2.20%
SUBTOTAL	**311**	**61**	**$234,406.48**	**$753.72**	**5.1**	**6.53%**
UBROGEPANT PRODUCTS						
UBRELVY TAB 100 MG	180	50	$187,375.71	$1,040.98	3.6	5.22%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
UBRELVY TAB 50 MG	52	14	$50,707.34	$975.14	3.71	1.41%
SUBTOTAL	**232**	**64**	**$238,083.05**	**$1,026.22**	**3.63**	**6.63%**
ATOGEPANT PRODUCTS						
QULIPTA TAB 60MG	87	23	$86,255.15	$991.44	3.78	2.40%
QULIPTA TAB 30MG	8	4	$7,678.64	$959.83	2	0.21%
QULIPTA TAB 10MG	4	2	$4,039.08	$1,009.77	2	0.11%
SUBTOTAL	**99**	**29**	**$97,972.87**	**$989.62**	**3.41**	**2.73%**
CGRP SUBTOTAL	**3,820**	**920**	**$2,911,856.80**	**$762.27**	**4.15**	**81.08%**
TOTAL	**27,638**	**11,454***	**$3,591,427.48**	**$129.95**	**2.41**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Please note: Nurtec® ODT and Ubrelvy® are CGRP products but are included in the Anti-Migraine Medications Special PA Tier for acute migraine treatment. Nurtec® ODT is also FDA approved for the preventive treatment of episodic migraine and has separate criteria for preventive treatment.
ACT = actuation; DIHYDROERGOT = dihydroergotamine; INJ = injection; NAPROX = naproxen; ODT = orally disintegrating tablet; SPR = nasal spray; SUMAT = sumatriptan; SYR = prefilled syringe; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
EPTINEZUMAB-JJMR INJ 1MG (J3032)	13⁺	8*	$31,513.80	$2,424.14	1.63
TOTAL	**13⁺**	**8***	**$31,513.80**	**$2,424.14**	**1.63**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[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 01/2024. Last accessed 01/11/2024.
[2] IntelGenx Corp. IntelGenx Announces FDA Approval of RizaFilm® for the Treatment of Acute Migraine. *GlobeNewswire*. Available online at: https://www.globenewswire.com/en/news-release/2023/04/17/2647913/0/en/IntelGenx-Announces-FDA-Approval-of-RIZAFILM-for-the-Treatment-of-Acute-Migraine.html. Issued 04/17/2023. Last accessed 01/15/2024.
[3] RizaFilm® (Rizatriptan) Oral Film Prescribing Information. IntelGenx Corp. Available online: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/205394s002lbl.pdf. Last revised 12/2023. Last accessed 01/15/2024.
[4] Pfizer Inc. Pfizer's Zavzpret™ (Zavegepant) Migraine Nasal Spray Receives FDA Approval. Available online: https://www.pfizer.com/news/press-release/press-release-detail/pfizers-zavzprettm-zavegepant-migraine-nasal-spray. Issued 03/10/2023. Last accessed 01/15/2024.
[5] AbbVie. U.S. FDA Approves Qulipta® (Atogepant) for Adults with Chronic Migraine. *PR Newswire*. Available online: https://www.prnewswire.com/news-releases/us-fda-approves-qulipta-atogepant-for-adults-with-chronic-migraine-301799554.html. Issued 04/17/2023. Last accessed 01/15/2024.
[6] Minen M, Robbins M, Loder E, et al. Addressing the Crisis of Diagnosis and Management of Migraine in Primary Care: A Summary of the American Headache Society Frontline Primary Care Advisory Board. Headache 2020; 60:1000-1004. doi: 10.1111/head.13797.
[7] American Headache Society. First Contact—Headache in Primary Care. Available online: https://americanheadachesociety.org/primarycare/. Last Revised 2022. Last accessed 01/25/2024.
[8] Axsome Therapeutics, Inc. Axsome Therapeutics Announces Plans to Resubmit AXS-07 NDA Based on Successful FDA Type A Meeting. *GlobeNewswire*. Available online: https://www.globenewswire.com/news-release/2022/09/29/2525054/33090/en/Axsome-Therapeutics-Announces-Plans-to-Resubmit-AXS-07-NDA-Based-on-Successful-FDA-Type-A-Meeting.html. Issued 09/29/2022. Last accessed 01/16/2024.
[9] Axsome Therapeutics, Inc. Axsome Therapeutics Provides Preliminary Fourth Quarter and Full Year 2023 Net Revenue and 2024 Anticipated Milestones. *GlobeNewswire*. Available online: https://www.globenewswire.com/news-release/2024/01/04/2803829/33090/en/Axsome-Therapeutics-Provides-Preliminary-Fourth-Quarter-and-Full-Year-2023-Net-Revenue-and-2024-Anticipated-Milestones.html. Issued 01/04/2024. Last accessed 01/16/2024.
[10] Manalac T. Satsuma Fails to Secure FDA Approval of Nasal Powder Migraine Drug. *BioSpace*. Available online: https://www.biospace.com/article/satsuma-fails-to-secure-fda-approval-for-nasal-powder-migraine-drug-/. Issued 01/18/2024. Last accessed 01/18/2024.
[11] 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 01/15/2024.

Appendix T

Fiscal Year 2023 Annual Review of Anti-Parasitic Medications and 30-Day Notice to Prior Authorize Alinia® (Nitazoxanide Tablet) and Xdemvy™ (Lotilaner Ophthalmic Solution)

Oklahoma Health Care Authority
February 2024

Current Prior Authorization Criteria

Albenza® (Albendazole) Approval Criteria:

1. A quantity of 6 tablets will process without prior authorization.
2. For infections requiring additional doses, a prior authorization will need to be submitted and the following criteria will apply:
    a. An FDA approved indication for treatment of 1 of the following:
        i. Parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, *Taenia solium*; or
        ii. Cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, *Echinococcus granulosus*.

Benznidazole Tablets Approval Criteria:

1. An FDA approved diagnosis of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi*; and
2. Benznidazole must be prescribed by, or in consultation with, an infectious disease specialist; and
3. Female members of reproductive potential must have a negative pregnancy test prior to treatment with benznidazole; and
4. Female members of reproductive potential must be willing to use effective contraception during treatment with benznidazole tablets and for 5 days after the last dose; and
5. Member must not have taken disulfiram within the last 2 weeks; and
6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug according to package labeling. The approval duration will be for 60 days of therapy.

Daraprim® (Pyrimethamine) Approval Criteria:

1. An FDA approved indication for the treatment of 1 of the following:
    a. Toxoplasmosis; or
    b. Susceptible strains of acute malaria; and
2. Member must take Daraprim® concomitantly with a sulfonamide; and

3. Approval length will be based on recommended dosing regimen specific to the member's diagnosis.

Emverm® (Mebendazole) Approval Criteria:

1. An FDA approved indication for treatment of 1 of the following:
   a. *Enterobius vermicularis* (pinworm); or
   b. *Trichuris trichiura* (whipworm); or
   c. *Ascaris lumbricoides* (roundworm); or
   d. *Ancylostoma duodenale* (hookworm); or
   e. *Necator americanus* (hookworm); and
2. For the treatment of *Enterobius vermicularis* (pinworm), *Ascaris lumbricoides* (roundworm), *Ancylostoma duodenale* (hookworm), or *Necator americanus* (hookworm), a patient-specific, clinically significant reason why a more cost-effective anthelmintic therapy, such as albendazole or pyrantel pamoate, cannot be used must be provided; and
3. The following quantity limits will apply:
   a. *Enterobius vermicularis* (pinworm): 2 tablets per approval.
   b. *Trichuris trichiura* (whipworm): 6 tablets per approval.
   c. *Ascaris lumbricoides* (roundworm): 6 tablets per approval.
   d. *Ancylostoma duodenale* (hookworm): 6 tablets per approval.
   e. *Necator americanus* (hookworm): 6 tablets per approval.

Lampit® (Nifurtimox) Approval Criteria:

1. An FDA approved diagnosis of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi*; and
2. Member must be younger than 18 years of age and weigh ≥2.5kg; and
3. Lampit® must be prescribed by, or in consultation with, an infectious disease specialist; and
4. Prescriber must agree to counsel the member on the contraindication and potential drug interaction that may occur with concomitant use of Lampit® with alcohol, if applicable, based on package labeling; and
5. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiating treatment with Lampit®; and
6. Female members of reproductive potential must be willing to use effective contraception during treatment with Lampit® and for 6 months after the last dose; and
7. Male members with female partners of reproductive potential must be willing to use condoms for contraception during treatment with Lampit® and for 3 months after the last dose; and
8. Prescriber must agree to monitor the member's weight every 14 days and adjust the Lampit® dosage accordingly, as recommended in the package labeling; and

9. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. Initial approvals will be for 30 days. For continuation of therapy after 30 days, an updated weight must be provided in order to authorize the appropriate amount of drug required for the remaining 30 days of treatment. The total approval duration will be for 60 days of treatment; and
11. A quantity limit of 270 tablets per 30 days will apply to the 30mg tablet, and a quantity limit of 225 tablets per 30 days will apply to the 120mg tablet.

Utilization of Anti-Parasitic Medications: Fiscal Year 2023

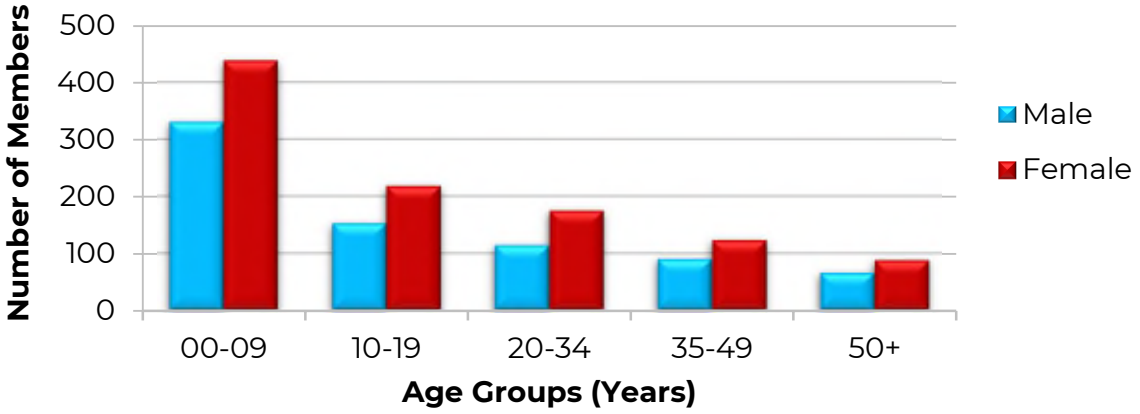
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	2,484	2,733	$226,083.88	$82.72	$10.55	31,970	21,439
2023	1,786	2,062	$177,641.06	$86.15	$10.84	7,735	16,391
% Change	**-28.10%**	**-24.60%**	**-21.40%**	**4.10%**	**2.70%**	**-75.80%**	**-23.50%**
Change	**-698**	**-671**	**-$48,442.82**	**$3.43**	**$0.29**	**-24,235**	**-5,048**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

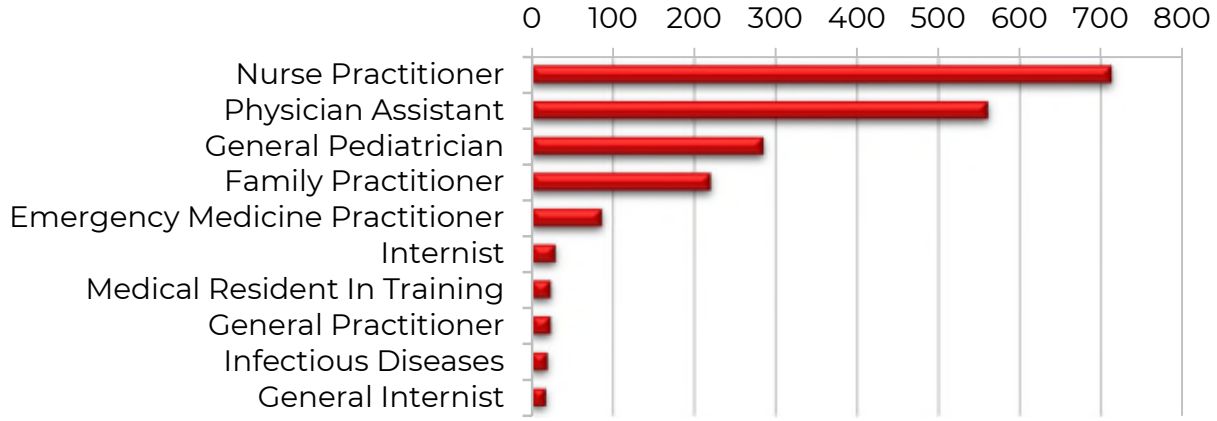
- Aggregate drug rebates collected during fiscal year 2023 for anti-parasitic medications totaled $15,680.28.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Anti-Parasitic 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.

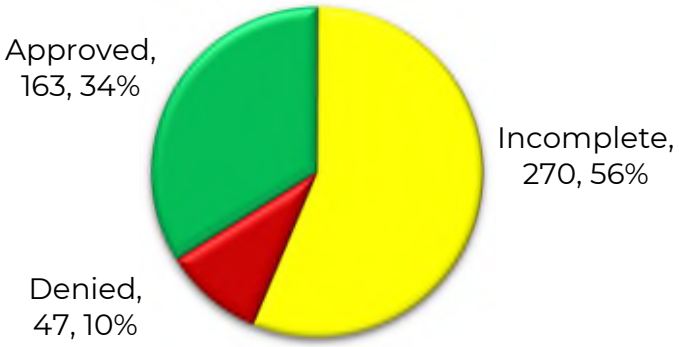
Top Prescriber Specialties of Anti-Parasitic Medications by Number of Claims



Prior Authorization of Anti-Parasitic Medications

There were 480 prior authorization requests submitted for anti-parasitic medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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

Anticipated Patent and/or Exclusivity Expiration(s):

- Lampit® (nifurtimox tablets): August 2027
- Xdemvy™ (lotilaner ophthalmic solution): December 2038

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[6]

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 human immunodeficiency virus (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 based on recommended dosing.

Xdemvy™ (Lotilaner Ophthalmic Solution) Product Summary[7]

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. 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.

Utilization Details of Anti-Parasitic Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALBENDAZOLE TAB 200MG	1,904	1,691	$86,232.08	$45.29	1.13	48.54%
IVERMECTIN TAB 3MG	96	92	$5,202.73	$54.20	1.04	2.93%
NITAZOXANIDE TAB 500MG	22	17	$11,301.76	$513.72	1.29	6.36%
PRAZIQUANTEL TAB 600MG	21	17	$4,801.90	$228.66	1.24	2.70%
PYRIMETHAMINE TAB 25MG	17	4	$65,472.41	$3,851.32	4.25	36.86%
EMVERM CHW 100MG	2	2	$4,630.18	$2,315.09	1	2.61%
TOTAL	**2,062**	**1,786***	**$177,641.06**	**$86.15**	**1.15**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CHW = chewable tablet; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[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 01/2024. Last accessed 01/09/2024.
[2] U.S. FDA. Alinia® (Nitazoxanide Tablet) New Drug Application (NDA) Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/21497,21498s001ltr.pdf. Issued 07/21/2004. Last accessed 01/26/2024.
[3] 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 01/09/2024.
[4] Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. National Institutes of Health, Centers for Disease Control and Prevention, HIV Medicine Association, and Infectious Diseases Society of America. 2023. Available online at: https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections. Last revised 09/25/2023. Last accessed 01/26/2024.
[5] Daraprim® (Pyrimethamine) Prescribing Information. Turing Pharmaceuticals, LLC. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/008578s020lbl.pdf. Last revised 06/2017. Last accessed 02/07/2024.
[6] Alinia® (Nitazoxanide) Prescribing Information. Romark, L.C. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/021497s018,021498s019lbl.pdf. Last revised 01/2022. Last accessed 01/26/2024.
[7] Xdemvy™ (Lotilaner Ophthalmic Solution) Prescribing Information. Tarsus Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217603s000lbl.pdf. Last revised 07/2023. Last accessed 01/09/2024.

Appendix U

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

Oklahoma Health Care Authority
February 2024

Introduction[1,2,3,4,5,6]

Molluscum contagiosum is a common childhood virus, affecting around 5% of the United States population each year and accounting for 1% of diagnosed skin diseases worldwide. It originates from the Poxvirus family, causing a rash of small, raised benign bumps on the patient's skin. Molluscum contagiosum typically impacts small children and adolescents but can also infect adults. It is spread through skin-to-skin contact, including sexual contact, or through indirect contact with items that have come into contact with lesions. Lesions will typically present on the arms, chest, trunk, legs, and face and will rarely present on mucous membranes of the lip and tongue. Some patients may be at risk of developing more lesions than others due to other underlying conditions such as atopic dermatitis, human immunodeficiency virus (HIV), or other immunocompromising diseases.

The virus is self-limiting and usually resolves within 18 months, but some lesions have been reported to last as long as 5 years in patients who are immunocompromised. Scarring is rare after lesions resolve. Complications of this virus include irritation, inflammation, and secondary infections if lesions become open wounds.

Treatments for molluscum contagiosum lesions were limited to surgical methods and cryotherapy, prior to the recent U.S. Food and Drug Administration (FDA) approvals of Ycanth™ (cantharidin 0.7% solution) and Zelsuvmi™ (berdazimer 10.3% gel) in July 2023 and January 2024, respectively. Over the counter medications treated symptoms such as itching or irritation but are not approved by the FDA and do not treat the lesions themselves. Both Ycanth™ (cantharidin 0.7% solution) and Zelsuvmi™ (berdazimer 10.3% gel) demonstrated a reduction in lesions after 12 weeks of therapy, with minimal side effects.

Ycanth™ (Cantharidin 0.7% Solution) Product Summary[7]

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 healthcare 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[8]

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 is experiencing itching or pain, has concomitant bacterial infection, has concomitant atopic dermatitis, or there is concern for contagion (e.g., siblings, daycare) and lesions cannot be reasonably covered using a bandage; and
4. Member must not have lesions exclusively on genitals or around eyes; and
5. 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
6. 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
7. 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
8. Approvals will be for a maximum of 12 weeks of therapy; and
9. A quantity limit of 2 applicators every 3 weeks for a maximum of 4 applications will apply.

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 is experiencing itching or pain, has concomitant bacterial infection, has concomitant atopic dermatitis, or there is concern for contagion (e.g., siblings, daycare) and lesions cannot be reasonably covered using a bandage; and
4. Member must not have lesions exclusively on genitals or around eyes; and
5. Prescriber must attest that the member or caregiver has been counseled on and demonstrates understanding of the proper storage and preparation of Zelsuvmi™; and
6. 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
7. A patient-specific, clinically significant reason why the member cannot use Ycanth™ (cantharidin) must be provided; and
8. Approvals will be for a maximum of 12 weeks of therapy; and

9. 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.

[1] Bhatia AC. Molluscum Contagiosum. *Medscape*. Available online at: https://emedicine.medscape.com/article/910570-overview#a4. Issued 01/09/2024. Last accessed 01/26/2024.
[2] Molluscum Contagiosum. *American Academy of Dermatology Association*. Available online at: https://www.aad.org/public/diseases/a-z/molluscum-contagiosum-overview. Last updated 11/06/2023. Last accessed 01/26/2024.
[3] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for Molluscum Contagiosum. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-treatment-molluscum-contagiosum. Last revised 07/24/2023. Last accessed 01/26/2024.
[4] Gallagher A. FDA Approves Berdazimer Topical Gel as First Treatment for Molluscum Contagiosum. *Pharmacy Times*. Available online at: https://www.pharmacytimes.com/view/fda-approves-berdazimer-topical-gel-as-first-treatment-for-molluscum-contagiosum. Issued 01/09/2024. Last accessed 01/26/2024.
[5] Sugarman J, Hebert A, Browning J, et al. Berdazimer Gel for Molluscum Contagiosum: An Integrated Analysis of 3 Randomized Controlled Trials. *J Am Acad Dermatol* 2023; 90:299-308. doi: 10.1016/j.jaad.2023.09.066.
[6] Eichenfield L, Kwong P, Gonzalez M, et al. Safety and Efficacy of VP-102 (Cantharidin 0.7% w/v) in Molluscum Contagiosum by Body Region: Post Hoc Pooled Analysis from Two Phase III Randomized Trials. *J Clin Aesthet Dermatol* 2021; 14:42-47.
[7] Ycanth™ (Cantharidin) 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 01/26/2024.
[8] 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 01/26/2024.

Appendix V

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: January 5, 2024

FDA Authorizes Florida's Drug Importation Program

The FDA authorized Florida's Agency for Health Care Administration's drug importation program under section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This is the first step on this pathway toward Florida facilitating importation of certain prescription drugs from Canada.

Through this pathway, the FDA may authorize section 804 importation program (SIP) proposals from states or Indian tribes to import certain prescription drugs from Canada if the SIP will significantly reduce the cost to the American consumer without imposing additional risk to public health and safety. President Biden's *Executive Order on Promoting Competition in the American Economy* directed the FDA to work with states and Indian tribes on these plans to reduce costs to American consumers while supporting public health and safety.

Florida's SIP is authorized for 2 years from the date the FDA is notified of the first shipment of drugs to be imported. Among other obligations related to this SIP, before drugs can be imported, Florida's Agency for Health Care Administration must:

- Submit additional drug-specific information for the FDA's review and approval.
- Ensure that the drugs Florida seeks to import have been tested for, among other things, authenticity and compliance with the FDA-approved drugs' specifications and standards.
- Re-label the drugs to be consistent with the FDA-approved labeling.

In addition, Florida's Agency for Health Care Administration must submit a quarterly report to the FDA that includes information about the imported drugs, cost savings, and any potential safety and quality issues.

The FDA will exercise oversight to help ensure the authorized proposal is followed and that Florida's program continues to meet the requirements in section 804 of the FD&C Act and the FDA's regulations. Florida's obligations under the FDA's regulations will include, among other things: ensuring supply chain integrity, monitoring, and submitting adverse event reports, complying with drug recall procedures, and reporting quarterly to the FDA. The sponsor of any program the FDA authorizes is responsible for implementing all aspects of their program such as importation and distribution.

States and Indian tribes may submit SIP proposals to the FDA for review and authorization under section 804 of the FD&C Act. Prior to authorization, a SIP proposal must provide all the information required by the FD&C Act and the FDA's regulations.

The FDA previously posted a small entity compliance question-and-answer guide and developed *Tips for SIPs* to assist sponsors in developing their proposals as a part of the FDA's ongoing commitment to working with interested states and tribes.

FDA NEWS RELEASE

For Immediate Release: December 14, 2023

Federal Court Enters Consent Decree Against Pharmasol for Distributing Adulterated Drugs

The U.S. District Court for the District of Massachusetts has entered a consent decree of permanent injunction ordering Pharmasol Corporation, a Massachusetts-based company, and President Marc L. Badia to stop distributing drugs until the company complies with the FD&C Act and other requirements listed in the consent decree. According to the complaint, which was filed along with the consent decree by the U.S. Department of Justice, Pharmasol and Badia unlawfully distributed adulterated drugs, meaning they do not comply with manufacturing quality requirements within the United States marketplace.

Pharmasol manufactures and distributes over-the-counter drugs, as well as human and animal prescription drugs such as topical corticosteroids and inhalant anesthetics. Pharmasol is under contract with multiple pharmaceutical companies.

According to the complaint, the defendants violated federal law under the FD&C Act by introducing drugs into interstate commerce that fail to comply with current good manufacturing practice requirements; therefore, these drugs are adulterated.

The most recent inspection of the company's facilities in 2022 found the majority of the inspectional observations repeated those found in past FDA inspections and detailed in a 2019 warning letter. Violations mentioned in the complaint include failure to:

- Fully investigate errors and ensure that the responsibilities and procedures applicable to the quality control unit are in writing and fully followed, including reporting drug defects to customers; and
- Follow written procedures that describe the handling of written and oral complaints regarding a drug product; and
- Adequately clean and maintain equipment.

In the 2019 warning letter, the FDA cited customer complaints of product leakage out of the container and the company's failure to investigate. Despite repeated warnings, the company and Badia continued to violate the law.

The consent decree prohibits Pharmasol and Badia from directly or indirectly manufacturing, preparing, processing, packing, repacking, receiving, labeling, holding, and/or distributing any drug, at or from their facilities, unless and until defendants meet certain requirements to ensure that Pharmasol operates in compliance with the FD&C Act, the FDA's regulations, and the decree, and defendants receive written notice from the FDA that they appear to be in compliance with these requirements.

Current Drug Shortages Index (as of January 26th, 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***