OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
June 14, 2023
4:00pm

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

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

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – June 14, 2023

DATE: June 7, 2023

NOTE: The DUR Board will meet at 4:00pm at the Oklahoma Health Care Authority (OHCA) at 4345 N. Lincoln Blvd. in Oklahoma City, Oklahoma.

There will be Zoom access to this meeting; however, Zoom access will be set up in view-only mode with no voting, speaking, video, or chat box privileges. Zoom access will allow for viewing of the presentation slides as well as audio of the presentations and discussion during the meeting; however, the DUR Board meeting will not be delayed or rescheduled due to any technical issues that may arise.

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Enclosed are the following items related to the June 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/Opioid Utilization and the SoonerCare Morphine Milligram Equivalent (MME) Limit – Appendix B

Action Item – Vote to Prior Authorize Brenzavvy™ (Bexagliflozin), Mounjaro® (Tirzepatide), and Tzield™ (Teplizumab-mzwv) and Update the Approval Criteria for the Anti-Diabetic Medications and Kerendia® (Finerenone) – Appendix C

Action Item – Vote to Prior Authorize Syfovre™ (Pegcetacoplan) – Appendix D

Action Item – Vote to Prior Authorize Ancobon® (Flucytosine) and Vivjoa® (Oteseconazole) and Update the Approval Criteria for the Systemic Antifungal Medications– Appendix E

Action Item – Vote to Prior Authorize Doral® (Quazepam) – Appendix F

Action Item – Vote to Prior Authorize Konvomep™ (Omeprazole/Sodium Bicarbonate for Oral Suspension) and Update the Approval Criteria for the Anti-Ulcer Medications – Appendix G

Action Item – Vote to Prior Authorize Skyclarys™ (Omaveloxolone) – Appendix H

Action Item – Vote to Prior Authorize Filspari™ (Sparsentan) – Appendix I

Action Item – Vote to Prior Authorize Imjudo® (Tremelimumab-actl) and Krazati® (Adagrasib) and Update the Approval Criteria for the Lung Cancer Medications – Appendix J

Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Adstiladrin® (Nadofaragene Firadenovac-vncg) and Elahere™ (Mirvetuximab Soravtansine-gynx) – Appendix K

Annual Review of the SoonerCare Pharmacy Benefit – Appendix L

Annual Review of Hemophilia Medications and 30-Day Notice to Prior Authorize Altuviiio™ [Antihemophilic Factor (Recombinant), Fc-VMF-XTEN Fusion Protein-ehtl] and Hemgenix® (Etranacogene Dezaparvovec-drlb) – Appendix M

Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Lamryz™ (Sodium Oxybate) and Relexxii® (Methylphenidate Extended-Release Tablet) – Appendix N

Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Abilify Asimtufii® [Aripiprazole Extended-Release (ER) Injection], Quetiapine 150mg Tablet, Rykindo® (Risperidone ER Injection), and Uzedy™ (Risperidone ER Injection) – Appendix O

30-Day Notice to Prior Authorize Daybue™ (Trofinetide) – Appendix P

Annual Review of Muscle Relaxant Medications and 30-Day Notice to Prior Authorize Lyvispah™ (Baclofen Oral Granules), Norgesic®, Norgesic® Forte, and Orphengesic® Forte (Orphenadrine/Aspirin/ Caffeine) – Appendix Q

Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Allopurinol 200mg Tablet, Aponvie™ (Aprepitant Injectable Emulsion), Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules], Austedo® XR (Deutetrabenazine ER Tablet), Entadfi® (Finasteride/Tadalafil Capsule), Ermeza™ (Levothyroxine Oral Solution), Furoscix® (Furosemide On-Body Infusor), Iyuzeh™ (Latanoprost Ophthalmic Solution), Jylamvo® (Methotrexate Oral Solution), Primidone 125mg Tablet, Verkazia® (Cyclosporine Ophthalmic Solution), Xaciato™ (Clindamycin Vaginal Gel), and Zolpidem 7.5mg Capsule – Appendix R

30-Day Notice to Prior Authorize Joenja® (Leniolisib) – Appendix S

Annual Review of Ryplazim® (Plasminogen, Human-tvmh) – Appendix T

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – June 14, 2023 @ 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:

Dr. Jennifer de los Angeles –	participating in person
Mr. Kenneth Foster –	participating in person
Dr. Megan Hanner –	participating in person
Dr. Lynn Mitchell –	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

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

Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 952 7560 1667
Passcode: 69395211

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. April 12, 2023 DUR Board Meeting Minutes
   B. April 12, 2023 DUR Board Recommendations Memorandum

Items to be presented by Dr. Reynolds, Dr. Kottoor, Dr. Muchmore, Chairman:

4. **Update on Medication Coverage Authorization Unit/Opioid Utilization and the SoonerCare Morphine Milligram Equivalent (MME) Limit – See Appendix B**
   A. Pharmacy Help Desk Activity for April 2023
   B. Medication Coverage Activity for April 2023
   C. Pharmacy Help Desk Activity for May 2023
   D. Medication Coverage Activity for May 2023
   E. Opioid Utilization and the SoonerCare Morphine Milligram Equivalent (MME) Limit

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

5. **Action Item – Vote to Prior Authorize Brenzavvy™ (Bexagliflozin), Mounjaro® (Tirzepatide), and Tzield™ (Teplizumab-mzwv) and Update the Approval Criteria for the Anti-Diabetic Medications and Kerendia® (Finerenone) – See Appendix C**
   A. Market News and Updates
   B. Product Summaries

C. College of Pharmacy Recommendations

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

6. **Action Item – Vote to Prior Authorize Syfovre™ (Pegcetacoplan) – See Appendix D**
   A. Introduction
   B. Syfovre™ (Pegcetacoplan) Product Summary
   C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Ancobon® (Flucytosine) and Vivjoa® (Oteseconazole) and Update the Approval Criteria for the Systemic Antifungal Medications – See Appendix E**
   A. Market News and Updates
   B. Vivjoa® (Oteseconazole) Product Summary
   C. Cost Comparison: Recurrent Vulvovaginal Candidiasis (RVVC) Treatments
   D. College of Pharmacy Recommendations

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

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

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

9. **Action Item – Vote to Prior Authorize Konvomep™ (Omeprazole/Sodium Bicarbonate for Oral Suspension) and Update the Approval Criteria for the Anti-Ulcer Medications – See Appendix G**
   A. Market News and Updates
   B. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Skyclarys™ (Omaveloxolone) – See Appendix H**
    A. Skyclarys™ (Omaveloxolone) Product Summary
    B. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Filspari™ (Sparsentan) – See Appendix I**
    A. Introduction
    B. Filspari™ (Sparsentan) Product Summary
    C. College of Pharmacy Recommendations

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

12. **Action Item – Vote to Prior Authorize Imjudo® (Tremelimumab) and Krazati® (Adagrasib) and Update the Approval Criteria for the Lung Cancer Medications – See Appendix J**
    A. Market News and Updates
    B. Product Summaries
    C. College of Pharmacy Recommendations

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

13. **Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Adstiladrin® (Nadofaragene Firadenovac-vncg) and Elahere™ (Mirvetuximab Soravtansine-gynx) – See Appendix K**
    A. Current Prior Authorization Criteria
    B. Utilization of Genitourinary and Gynecologic Cancer Medications
    C. Prior Authorization of Genitourinary and Gynecologic Cancer Medications
    D. Market News and Updates
    E. Product Summaries
    F. College of Pharmacy Recommendations
    G. Utilization Details of Genitourinary and Gynecologic Cancer Medications

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

14. **Annual Review of the SoonerCare Pharmacy Benefit – See Appendix L**
    A. Summary
    B. Medicaid Drug Rebate Program
    C. Alternative Payment Models
    D. Drug Approval Trends
    E. Traditional versus Specialty Pharmacy Products
    F. Top 10 Traditional Therapeutic Classes by Reimbursement
    G. Top 10 Specialty Therapeutic Classes by Reimbursement
    H. Top 10 Medications by Reimbursement
    I. Cost per Claim
    J. Market Projections
    K. Conclusion

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

15. **Annual Review of Hemophilia Medications and 30-Day Notice to Prior Authorize Altuviiio™ [Antihemophilic Factor (Recombinant), Fc-VMF-XTEN Fusion Protein-ehtl] and Hemgenix® (Etranacogene Dezaparvovec-drlb) – See Appendix M**
    A. Current Prior Authorization Criteria
    B. Utilization of Hemophilia Medications
    C. Prior Authorization of Hemophilia Medications
    D. Market News and Updates
    E. Product Summaries
    F. OHCA Recommendations

G. Utilization Details of Hemophilia Medications

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

16. **Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Lamryz™ (Sodium Oxybate) and Relexxii® [Methylphenidate Extended-Release (ER) Tablet] – See Appendix N**
    A. Current Prior Authorization Criteria
    B. Utilization of ADHD and Narcolepsy Medications
    C. Prior Authorization of ADHD and Narcolepsy Medications
    D. Oklahoma Resources
    E. Market News and Updates
    F. Product Summaries
    G. College of Pharmacy Recommendations
    H. Utilization Details of ADHD and Narcolepsy Medications

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

17. **Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Abilify Asimtufii® [Aripiprazole Extended-Release (ER) Injection], Quetiapine 150mg Tablet, Rykindo® (Risperidone ER Injection), and Uzedy™ (Risperidone ER Injection) – See Appendix O**
    A. Current Prior Authorization Criteria
    B. Utilization of Atypical Antipsychotic Medications
    C. Prior Authorization of Atypical Antipsychotic Medications
    D. Oklahoma Resources
    E. Market News and Updates
    F. Cost Comparison: Aripiprazole Long-Acting Injectable (LAI) Products
    G. Cost Comparison: Quetiapine Products
    H. Cost Comparison: Risperidone LAI Products
    I. College of Pharmacy Recommendations
    J. Utilization Details of Atypical Antipsychotic Medications

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

18. **30-Day Notice to Prior Authorize Daybue™ (Trofinetide) – See Appendix P**
    A. Introduction
    B. Daybue™ (Trofinetide) Product Summary
    C. College of Pharmacy Recommendations

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

19. **Annual Review of Muscle Relaxant Medications and 30-Day Notice to Prior Authorize Lyvispah™ (Baclofen Oral Granules), Norgesic®, Norgesic® Forte, and Orphengesic® Forte (Orphenadrine/Aspirin/Caffeine) – See Appendix Q**
    A. Current Prior Authorization Criteria
    B. Utilization of Muscle Relaxant Medications
    C. Prior Authorization of Muscle Relaxant Medications

D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Muscle Relaxant Medications

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

20. Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Allopurinol 200mg Tablet, Aponvie™ (Aprepitant Injectable Emulsion), Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules], Austedo® XR (Deutetrabenazine ER Tablet), Entadfi® (Finasteride/Tadalafil Capsule), Ermeza™ (Levothyroxine Oral Solution), Furoscix® (Furosemide On-Body Infusor), Iyuzeh™ (Latanoprost Ophthalmic Solution), Jylamvo® (Methotrexate Oral Solution), Primidone 125mg Tablet, Verkazia® (Cyclosporine Ophthalmic Solution), Xaciato™ (Clindamycin Vaginal Gel), and Zolpidem 7.5mg Capsule – See Appendix R

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

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

21. 30-Day Notice to Prior Authorize Joenja® (Leniolisib) – See Appendix S

A. Introduction
B. Joenja® (Leniolisib) Product Summary
C. College of Pharmacy Recommendations

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

22. Annual Review of Ryplazim® (Plasminogen, Human-tvmh) – See Appendix T

A. Current Prior Authorization Criteria
B. Utilization of Ryplazim® (Plasminogen, Human-tvmh)
C. Prior Authorization of Ryplazim® (Plasminogen, Human-tvmh)
D. College of Pharmacy Recommendations

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

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

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

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

A. Allergen Immunotherapies
B. Alzheimer's Disease Medications

C. Colorectal Cancer Medications
D. Testosterone Products
*Future product and class reviews subject to change.

25. 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 APRIL 9, 2023

DUR BOARD MEMBERS:	PRESENT	ABSENT
Jennifer de los Angeles, Pharm.D., BCOP	X	
Kenneth Foster, MHS, PA-C	X	
Megan A. Hanner, D.O.		X
Lynn Mitchell, M.D.; Vice Chairwoman		X
John Muchmore, M.D.; Ph.D.; Chairman	X	
Lee Muñoz, D.Ph.	X	
James Osborne, Pharm.D.		X
Edna Patatanian, Pharm.D., FASHP	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
Thara Kottoor, Pharm.D.; Pharmacy Resident	X	
Morgan Masterson, Pharm.D; Clinical Pharmacist		X
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Jo'Nel Reynolds, 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
Allison Baxley, Pharm.D., BCOP		X
Emily Borders, Pharm.D., BCOP	X	
Graduate Students: Rykr Carpenter, Pharm.D.		X
Matthew Dickson, Pharm.D.		X
Victoria Jones, 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 of Staff		X
Kevin Corbett, C.P.A.; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	

Josh Holloway, J.D.; Deputy General Counsel	X	
Brandon Keppner; Chief Operating Officer		X
Traylor Rains; State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Interim 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:	
Jon Buncab, Travere Therapeutics	Lee Hennigan, Kite Pharma
Craig Irwin, Acadia	Vicki Mee, Eversana
Cindy Pennington, Rhythm Pharmaceuticals	Laurie Krekemeyer, Reata Pharmaceuticals
Randall King, Travere Therapeutics	Eric Kimelblatt, Viking Healthcare
Jon Rosenblatt, Horizon Therapeutics	Joe Payne, Horizon Therapeutics
Robert Greely, Biogen	Robin Selsor, Aimmune
Jessica Chardoulias, Novo Nordisk	Burl Beasley, OMES
Todd Dickerson, Jazz Pharmaceuticals	Aaron Austin, Takeda
Phillip Lohec, Viatris	Bob Atkins, Biogen
Marc Bagby, Lilly	Wendi Chandler
Robert Jaramillo, Reata Pharmaceuticals	John Stancil, Artia Solutions
Adrian Quartel, Acer Therapeutics	Brent Young, Karuna Therapeutics
Joseph Auci, Acer Therapeutics	Jamie Tobitt, Apellis Pharmaceuticals
Corey Hicks, Horizon Therapeutics	Rhonda Clark, Indivior
Kenneth Berry, Alermes	Melissa Abbott, Eisai
Waleed Al-Homoud, Provention Bio	Jeff Odell, Provention Bio
Justin Springfield, Gilead	Trebla Grant, Mirati Therapeutics
Lori Howarth, Bayer	Bashir Kalayeh, Bayer
Bobby White, Eisai	Gary Parenteau, Dexcom
Ty Griffin, Ferring Pharmaceuticals	Charlene Kaiser, SpringWorks Therapeutics
Paul Sparks, Horizon Therapeutics	Kimberly Brackett, AbbVie
Todd Ness, AbbVie	Astrid Chatham
Marc Parker, Sunovion	Amanda Nowakowski, ViiV
Doug Pierce, Genentech	Rodney Brown, Genentech

PRESENT FOR PUBLIC COMMENT:	
Corey Hicks, Horizon Therapeutics	Astrid Chatham
Waleed Al-Homoud, Provention Bio	Jamie Tobitt, Apellis Pharmaceuticals
Robert Jaramillo, Reata Pharmaceuticals	Bashir Kalayeh, Bayer

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

1A: ROLL CALL

Dr. Muchmore called the meeting to order at 4:01pm. 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. 9 COREY HICKS
2B: AGENDA ITEM NO. 9 ASTRID CHATHAM
2C: AGENDA ITEM NO. 13 WALEED AL-HOMOUD
2D: AGENDA ITEM NO. 13 BASHIR KALAYEH
2E: AGENDA ITEM NO. 14 JAMIE TOBITT
2F: AGENDA ITEM NO. 15 ROBERT JARAMILLO

ACTION: NONE REQUIRED

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

3A: MARCH 8, 2023 DUR MINUTES

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/SOONERPSYCH AND PEDIATRIC SONNERPSYCH ANTIPSYCHOTIC MONITORING PROGRAM**

4A: PHARMACY HELPDESK ACTIVITY FOR MARCH 2023
4B: MEDICATION COVERAGE ACTIVITY FOR MARCH 2023
4C: SOONERPSYCH AND PEDIATRIC SOONERPSYCH ANTIPSYCHOTIC MONITORING PROGRAM UPDATE

Materials included in agenda packet; presented by Dr. Kottoor, Dr. Travers

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE BRIUMVI™ (UBLITUXIMAB-XIIY) AND TASCENSO ODT® [FINGOLIMOD ORALLY DISINTEGRATING TABLET (ODT)] AND UPDATE THE APPROVAL CRITERIA FOR MULTIPLE SCLEROSIS (MS) MEDICATIONS**

5A: MARKET NEWS AND UPDATES
5B: BRIUMVI™ (UBLITUXIMAB-XIIY) PRODUCT SUMMARY
5C: COST COMPARISON: FINGOLIMOD PRODUCTS
5D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Mr. Foster

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE LAMZEDE® (VELMANASE ALFA)**

6A: LAMZEDE® (VELMANASE ALFA) PRODUCT SUMMARY
6B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Mr. Foster

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE ROLVEDON™ (EFLAPEGRASTIM-XNST) AND STIMUFEND® (PEGFILGRASTIM-FPGK) AND UPDATE THE APPROVAL CRITERIA FOR THE GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS)**

7A: MARKET NEWS AND UPDATES
7B: COST COMPARISON
7C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 8:</u> VOTE TO PRIOR AUTHORIZE AIRSUPRA™ (ALBUTEROL/BUDESONIDE)
8A: MARKET NEWS AND UPDATES
8B: AIRSUPRA™ (ALBUTEROL/BUDESONIDE) INHALATION AEROSOL PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Kottoor
Dr. Muñoz moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 9:</u> VOTE TO PRIOR AUTHORIZE OLPRUVA™ (SODIUM PHENYLBUTYRATE PELLETS FOR ORAL SUSPENSION) AND PHEBURANE® (SODIUM PHENYLBUTYRATE ORAL PELLETS) AND UPDATE THE APPROVAL CRITERIA FOR THE UREA CYCLE DISORDER (UCD) MEDICATIONS
9A: MARKET NEWS AND UPDATES
9B: COST COMPARISON: UCD MEDICATIONS
9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Reynolds
Dr. Muñoz moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 10:</u> VOTE TO PRIOR AUTHORIZE JAYPIRCA™ (PIRTOBRUTINIB) AND LUNSUMIO™ (MOSUNETUZUMAB-AXGB) AND UPDATE THE APPROVAL CRITERIA FOR THE LYMPHOMA MEDICATIONS
10A: MARKET NEWS AND UPDATES
10B: JAYPIRCA™ (PIRTOBRUTINIB) PRODUCT SUMMARY
10C: LUNSUMIO™ (MOSUNETUZUMAB-AXGB) PRODUCT SUMMARY
10D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Muñoz moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 11:</u> ANNUAL REVIEW OF HEREDITARY ANGIOEDEMA (HAE) MEDICATIONS
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF HAE MEDICATIONS
11C: PRIOR AUTHORIZATION OF HAE MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: COLLEGE OF PHARMACY RECOMMENDATIONS
11F: UTILIZATION DETAILS OF HAE MEDICATIONS
Materials included in agenda packet; presented by Dr. Reynolds
Dr. Muñoz moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 12:</u> ANNUAL REVIEW OF LUNG CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE IMJUDO® (TREMELIMUMAB-ACTL) AND KRAZATI® (ADAGRASIB)
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF LUNG CANCER MEDICATIONS
12C: PRIOR AUTHORIZATION OF LUNG CANCER MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: PRODUCT SUMMARIES

12F: COLLEGE OF PHARMACY RECOMMENDATIONS
12G: UTILIZATION DETAILS OF LUNG CANCER MEDICATIONS
Materials included in agenda packet; presented by Dr. Borders
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE) AND 30-DAY NOTICE TO PRIOR AUTHORIZE BRENZAVVY™ (BEXAGLIFLOZIN), MOUNJARO® (TIRZEPATIDE), AND TZIELD™ (TEPLIZUMAB-MZWV)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
13C: PRIOR AUTHORIZATION OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
13D: MARKET NEWS AND UPDATES
13E: PRODUCT SUMMARIES
13F: COLLEGE OF PHARMACY RECOMMENDATIONS
13G: UTILIZATION DETAILS OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 14:</u> 30-DAY NOTICE TO PRIOR AUTHORIZE SYFOVRE™ (PEGCETACOPLAN)
14A: INTRODUCTION
14B: SYFOVRE™ (PEGCETACOPLAN) PRODUCT SUMMARY
14C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 15:</u> 30-DAY NOTICE TO PRIOR AUTHORIZE SKYCLARYS™ (OMAVELOXOLONE)
15A: INTRODUCTION
15B: SKYCLARYS™ (OMAVELOXOLONE) PRODUCT SUMMARY
15C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 16:</u> ANNUAL REVIEW OF SYSTEMIC ANTIFUNGAL MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ANCOBON® (FLUCYTOSINE) AND VIVJOA® (OTESECONAZOLE)
16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF SYSTEMIC ANTIFUNGAL MEDICATIONS
16C: PRIOR AUTHORIZATION OF SYSTEMIC ANTIFUNGAL MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: VIVJOA® (OTESECONAZOLE) PRODUCT SUMMARY
16F: COST COMPARISON: RECURRENT VULVOVAGINAL CANDIDIASIS (RVVC) TREATMENTS
16G: COLLEGE OF PHARMACY RECOMMENDATIONS
16H: UTILIZATION DETAILS OF SYSTEMIC ANTIFUNGAL MEDICATIONS
Materials included in agenda packet; presented by Dr. Reynolds
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

AGENDA ITEM NO. 17: ANNUAL REVIEW OF ANTI-ULCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE KONVOMEP™ (OMEPRAZOLE/SODIUM BICARBONATE)

17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF ANTI-ULCER MEDICATIONS
17C: PRIOR AUTHORIZATION OF ANTI-ULCER MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: COLLEGE OF PHARMACY RECOMMENDATIONS
17F: UTILIZATION DETAILS OF ANTI-ULCER MEDICATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

AGENDA ITEM NO. 18: 30-DAY NOTICE TO PRIOR AUTHORIZE FILSPARI™ (SPARSENTAN)

18A: INTRODUCTION
18B: FILSPARI™ (SPARSENTAN) PRODUCT SUMMARY
18C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 19: ANNUAL REVIEW OF INSOMNIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE DORAL® (QUAZEPAM)

19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF INSOMNIA MEDICATIONS
19C: PRIOR AUTHORIZATION OF INSOMNIA MEDICATIONS
19D: MARKET NEWS AND UPDATES
19E: DORAL® (QUAZEPAM) PRODUCT SUMMARY
19F: COLLEGE OF PHARMACY RECOMMENDATIONS
19G: UTILIZATION DETAILS OF INSOMNIA MEDICATIONS

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

AGENDA ITEM NO. 20: ANNUAL REVIEW OF LUMIZYME® (ALGLUCOSIDASE ALFA) AND NEXVIAZYME® (AVALGLUCOSIDASE ALFA-NGPT)

20A: CURRENT PRIOR AUTHORIZATION CRITERIA
20B: UTILIZATION OF LUMIZYME® (ALGLUCOSIDASE ALFA) AND NEXVIAZYME® (AVALGLUCOSIDASE ALFA-NGPT)
20C: PRIOR AUTHORIZATION OF LUMIZYME® (ALGLUCOSIDASE ALFA) AND NEXVIAZYME® (AVALGLUCOSIDASE ALFA-NGPT)
20D: MARKET NEWS AND UPDATES
20E: COLLEGE OF PHARMACY RECOMMENDATIONS
20F: UTILIZATION DETAILS OF LUMIZYME® (ALGLUCOSIDASE ALFA) AND NEXVIAZYME® (AVALGLUCOSIDASE ALFA-NGPT)

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

AGENDA ITEM NO. 21: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES

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

AGENDA ITEM NO. 22: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)

22A: ANNUAL REVIEW OF THE SOONERCARE PHARMACY BENEFIT

22B: ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS
22C: ATYPICAL ANTIPSYCHOTIC MEDICATIONS
22D: HEMOPHILIA MEDICATIONS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 23: ADJOURNMENT
The meeting was adjourned at 6:07pm.

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

Memorandum

Date: April 14, 2023

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

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

Subject: DUR Board Recommendations from Meeting on April 12, 2023

Recommendation 1: SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Briumvi™ (Ublituximab-xiiy) and Tascenso ODT® [Fingolimod Orally Disintegrating Tablet (ODT)] and Update the Approval Criteria for the Multiple Sclerosis (MS) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Briumvi™ (ublituximab-xiiy) and Tascenso ODT® (fingolimod ODT) with the following criteria (shown in red):

Briumvi™ (Ublituximab-xiiy) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Member must have had at least 1 relapse in the previous 12 months; and
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and

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

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

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Member must have had at least 1 relapse in the previous 12 months; and
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. Prescriber must confirm that member will be observed in the prescriber's office for signs and symptoms of bradycardia for 6 hours after the first dose; and
6. Verification from the prescriber that member has no active infection(s); and
7. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
8. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
9. A patient-specific, clinically significant reason why the member cannot use Gilenya® (fingolimod) capsules must be provided; and

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

Additionally, the College of Pharmacy recommends updating the Ocrevus® (ocrelizumab) approval criteria to address the safe and proper administration of the medication and to be consistent with the approval criteria for Briumvi™ (ublituximab-xiiy) (changes shown in red):

Ocrevus® (Ocrelizumab) Approval Criteria:

1. An FDA approved diagnosis of primary progressive forms of multiple sclerosis (MS) or relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease modifying therapies; and
4. ~~Ocrevus® must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. The prescriber must agree that the member will be monitored for 1 hour after each infusion; and~~
5. Ocrevus® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Ocrevus® will be administered; and
    a. Ocrevus® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Ocrevus® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of Ocrevus®; and
6. Prescriber must confirm that member will be monitored for 1 hour after each infusion; and
7. Prescriber must verify hepatitis B virus (HBV) testing has been performed prior to initiating Ocrevus® therapy and member does not have active HBV; and
8. Verification from the prescriber that member has no active infection(s); and
9. Verification from the prescriber that female members are not currently pregnant and will use contraception while receiving Ocrevus® therapy and for 6 months after the last infusion of Ocrevus®; and
10. Approvals will be for the duration of 1 year, and compliance will be checked for continued approval.

The College of Pharmacy also recommends updating the Mavenclad® (cladribine) approval criteria to be consistent with the package labeling regarding duration of use (changes shown in red):

Mavenclad® (Cladribine) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include relapsing remitting disease and active secondary progressive disease, in adults; and
2. Requests for use in patients with clinically isolated syndrome (CIS) will not generally be approved; and
3. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
4. Member must have had at least 1 relapse in the previous 12 months; and
5. Member must have had an inadequate response to 2 or more medications indicated for the treatment of MS; and
6. Prescriber must confirm that the member does not have any contraindications for use of cladribine; and
7. Prescriber must confirm member does not have an active malignancy; and
8. Prescriber must confirm that female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
9. Prescriber must attest that female and male members of reproductive potential plan to use effective contraception during cladribine dosing and for 6 months after the last dose in each treatment course; and
10. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
11. Verification from the prescriber that member has no active infection(s); and
12. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
13. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
14. Quantity limits according to package labeling will apply; and
15. Approvals will be for 1 year of therapy (1 treatment course/2 cycles) at a time. Lifetime approval duration will be limited to a maximum of 2 treatment courses according to package labeling.

Finally, the College of Pharmacy recommends the following changes to the MS medications approval criteria to be consistent with clinical practice (changes shown in red):

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

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

Multiple Sclerosis (MS) Interferon Medications Approval Criteria:

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

Ampyra® (Dalfampridine) Approval Criteria:

1. An FDA approved indication to improve walking in adult members with multiple sclerosis (MS); and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Kurtzke Expanded Disability Status Scale (EDSS) score between 3 and 7.5; and
4. Initial approvals will be for the duration of 90 days. If the member has responded well to treatment and the prescriber states that the member has shown improvement or the drug was effective, the member may receive authorization for 1 year; and
5. A quantity limit of 60 tablets for 30 days will apply.
6. Ampyra® may be used with other MS therapies.

Aubagio® (Teriflunomide) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Brand name Aubagio® is preferred. Use of generic teriflunomide will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
5. All of the following will be required for initiation of treatment:
    a. Verification that female members are not pregnant and are currently using reliable contraception; and
    b. Verification that the member has no active infection(s); and
    c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and

d. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
e. Blood pressure (BP) measurement and verification that BP is being monitored; and
f. Verification that the member does not have tuberculosis (TB), or completion of standard medical treatment for members with TB; and

6. Initial approvals of Aubagio® will be for 6 months, after which time all of the following will be required for further approval:
   a. Medication compliance; and
   b. Repeat CBC and verification that counts are acceptable to the prescriber; and
   c. Repeat LFTs and verification that levels are acceptable to the prescriber; and
   d. Verification that female members are not pregnant and will continue using reliable contraception; and
   e. Verification that BP and signs of renal failure are being monitored; and
7. Compliance will be checked for continued approval every 6 months; and
8. A quantity limit of 30 tablets per 30 days will apply.

Bafiertam® (Monomethyl Fumarate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Verification from the prescriber that member has no serious active infection(s); and
5. Complete blood counts (CBC), including lymphocyte count, and verification that levels are acceptable to the prescriber; and
6. Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and
7. Intolerable adverse effects associated with a trial of Tecfidera® (dimethyl fumarate) and Vumerity® (diroximel fumarate) that are not expected to occur with Bafiertam® or a patient-specific, clinically significant reason why trials of Tecfidera® and Vumerity® are not appropriate for the member must be provided; and
8. Verification that CBC, including lymphocyte count, levels are acceptable to the prescriber in addition to compliance will be required for continued approval every 6 months; and
9. A quantity limit of 4 capsules per day will apply.

Copaxone® (Glatiramer Acetate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Approvals for the 40mg strength of Copaxone® will require a patient-specific, clinically significant reason why the member cannot use the 20mg strength; and
5. Approvals for the generic formulation of either strength of Copaxone®, including Glatopa®, will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
6. Compliance will be checked for continued approval every 6 months.

Gilenya® (Fingolimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS)*, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; and
   (*The manufacturer of Gilenya® has provided a supplemental rebate to remove the requirement of "at least 1 relapse in the previous 12 months, or transitioning from existing MS therapy"; however, Gilenya® will follow the original criteria if the manufacturer chooses not to participate in supplemental rebates); and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must confirm that member will ~~The first dose should~~ be observed in the prescriber's office for signs and symptoms of bradycardia for 6 hours after the first dose; and
5. Verification from the prescriber that member has no active infection(s); and
6. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
7. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
8. Compliance will be checked for continued approval every 6 months.

Kesimpta® (Ofatumumab) Approval Criteria:

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

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

Lemtrada® (Alemtuzumab) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include relapsing remitting disease and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Member must have had an inadequate response to 2 or more medications indicated for the treatment of MS; and
    a. Lemtrada® must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. The prescriber must agree that the member will be monitored for 2 hours after each infusion; and
4. The prescriber must agree to monitor complete blood counts (CBC) with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of Lemtrada®; and
5. The prescriber must agree that baseline and yearly skin examinations will be performed while the member is utilizing Lemtrada® therapy; and

6. Member, prescriber, pharmacy, and health care facility must all enroll in the Lemtrada® Risk Evaluation and Mitigation Strategy (REMS) Program and maintain enrollment throughout therapy.

Mayzent® (Siponimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Member must have been assessed for CYP2C9 genotype:
    a. Members with a CYP2C9*3/*3 genotype will not generally be approved; or
    b. Members with a CYP2C9*1/*3 or *2/*3 genotype will not be approved for doses exceeding 1mg per day; or
    c. All other genotypes CYP2C9 *1/*1, *1/*2, or *2/*2 will be approved for 2mg per day; and
4. Member must not have any contraindication for use of siponimod including:
    a. CYP2C9*3/*3 genotype; or
    b. Experienced myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or Class III/IV HF in the last 6 months; or
    c. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and
5. Member must not have received prior treatment with alemtuzumab; and
6. Verification from the prescriber that member has no active infection(s); and
7. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
8. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
9. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and
10. Verification from the prescriber that the member has been assessed for medications and conditions that cause reduction in heart rate (HR) or AV conduction delays and that the member will be followed with appropriate monitoring per package labeling; and
11. Verification from the prescriber that the member has been assessed for previous confirmed history of chickenpox or vaccination against varicella. Members without history of chickenpox or varicella vaccination should receive a full course of varicella vaccine prior to commencing treatment with Mayzent®; and

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

Ponvory® (Ponesimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Member must not have any contraindications for use of Ponvory® including:
    a. Myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or
    b. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and
4. Member must not have received prior treatment with alemtuzumab; and
5. Member must not be concurrently using strong CYP3A4 and UGT1A1 inducers (e.g., rifampin, phenytoin, carbamazepine); and
6. Verification from the prescriber that the member has no active infection(s); and
7. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
8. Verification from the prescriber that the member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Ponvory®; and
9. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
10. Verification from the prescriber that the member's blood pressure will be monitored during treatment with Ponvory®; and

11. Verification from the prescriber that the member has undergone an ophthalmic evaluation prior to starting therapy with Ponvory® and the member will be monitored for changes in vision throughout therapy; and
12. Verification from the prescriber that the member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring per package labeling; and
13. Verification from the prescriber that the member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Ponvory®; and
14. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
15. Female members of reproductive potential must be willing to use effective contraception during treatment with Ponvory® and for at least 1 week after discontinuing treatment; and
16. Member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; and
17. Compliance will be checked for continued approval every 6 months; and
18. A quantity limit of 30 tablets per 30 days will apply for the 20mg tablet. A quantity limit of 14 tablets per 14 days will apply for the Ponvory® starter pack.

Tecfidera® (Dimethyl Fumarate) Approval Criteria:

1. An FDA approved diagnosis of clinically isolated syndrome, relapsing forms of multiple sclerosis (MS), or secondary progressive forms of MS in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Verification from the prescriber that member has no active infection(s); and
5. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
6. Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and
7. Compliance will be checked for continued approval every 6 months; and
8. A quantity limit of 60 tablets per 30 days will apply.

Vumerity® (Diroximel Fumarate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Verification from the prescriber that member has no serious active infection(s); and
5. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
6. Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and
7. Verification from the prescriber that member does not have moderate or severe renal impairment; and
8. Verification from the prescriber that the member has been counseled on proper administration of Vumerity® including caloric and fat intake limits at the time of dosing; and
9. Compliance will be checked for continued approval every 6 months; and
10. A quantity limit of 120 capsules per 30 days will apply.

Zeposia® (Ozanimod) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following in adults:
    a. Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; or
    b. Moderately to severely active ulcerative colitis (UC); and
2. For the diagnosis of MS, prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Member must not have any contraindications for use of Zeposia® including:
    a. Experienced myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or
    b. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; or
    c. Have severe untreated sleep apnea; or
    d. Concurrent use of monoamine oxidase inhibitors (MAOIs); and
4. Member must not have received prior treatment with alemtuzumab; and

5. Member must not be concurrently using strong CYP2C8 inhibitors/ inducers or breast cancer resistance protein (BCRP) inhibitors; and
6. Verification from the prescriber that member has no active infection(s); and
7. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
8. Prescriber must conduct an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Zeposia®; and
9. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
10. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and
11. Verification from the prescriber that the member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and that the member will be followed with appropriate monitoring per package labeling; and
12. Verification from the prescriber that the member has been assessed for previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Zeposia®; and
13. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
14. Female members of reproductive potential must be willing to use effective contraception during treatment with Zeposia® and for at least 3 months after discontinuing treatment; and
15. For the diagnosis of MS, member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; or
16. For the diagnosis of UC, member must have had an inadequate response, loss of response, or intolerance to oral aminosalicylates, corticosteroids, immunomodulators (e.g., 6-mercaptopurine, azathioprine), and a biologic [e.g., tumor necrosis factor (TNF) blocker]. Tier structure applies; and
17. Compliance will be checked for continued approval every 6 months; and
18. A quantity limit of 30 capsules per 30 days will apply.

Recommendation 3: Vote to Prior Authorize Lamzede® (Velmanase Alfa-tycv)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Lamzede® (velmanase alfa-tycv) with the following criteria (shown in red):

Lamzede® (Velmanase Alfa-tycv) Approval Criteria:

1. An FDA approved diagnosis of alpha-mannosidosis confirmed by:
   a. Documented lab results verifying alpha-mannosidase activity <11% of normal; or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *MAN2B1* gene; 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.

Recommendation 4: Vote to Prior Authorize Rolvedon™ (Eflapegrastim-xnst) and Stimufend® (Pegfilgrastim-fpgk) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends adding Fylnetra® (pegfilgrastim-pbbk) to the preferred products for the pegfilgrastim products and recommends the prior authorization of Nyvepria™ (pegfilgrastim-apgf), Rolvedon™ (eflapegrastim-xnst), and Stimufend® (pegfilgrastim-fpgk) based on net costs (new criteria and changes shown in red):

Fulphila® (Pegfilgrastim-jmdb), Neulasta® (Pegfilgrastim), Nyvepria™ (Pegfilgrastim-apgf), Stimufend® (Pegfilgrastim-fpgk), and Udenyca® (Pegfilgrastim-cbqv) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fylnetra® (pegfilgrastim-pbbk), Granix® (tbo-filgrastim), Neupogen® (filgrastim), ~~Nyvepria™ (pegfilgrastim-apgf),~~ Zarxio® (filgrastim-sndz), or Ziextenzo® (pegfilgrastim-bmez) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost

product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Rolvedon™ (Eflapegrastim-xnst) Approval Criteria:

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

Recommendation 5: Vote to Prior Authorize Airsupra™ (Albuterol/ Budesonide)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Airsupra™ (albuterol/budesonide) with the following criteria (shown in red):

Airsupra™ (Albuterol/Budesonide) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be 18 years of age or older; and
3. Member must be using maintenance therapy per the Global Initiative for Asthma (GINA) guidelines; and
4. A patient-specific, clinically significant reason why the member cannot use a long-acting beta$_2$ agonist (LABA), inhaled corticosteroid (ICS)/LABA combination, or specific individual ICS and short-acting beta$_2$ agonist (SABA) components must be provided; and
5. Initial approvals will be for the duration of 3 months. For continued consideration, prescriber must verify the member has had a positive clinical response to therapy; and
6. Subsequent approvals will be for the duration of 1 year.

Recommendation 6: Vote to Prior Authorize Olpruva™ (Sodium Phenylbutyrate Pellets for Oral Suspension) and Pheburane® (Sodium Phenylbutyrate Oral Pellets) and Update the Approval Criteria for the Urea Cycle Disorder (UCD) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Olpruva™ (sodium phenylbutyrate pellets for oral suspension) and Pheburane® (sodium phenylbutyrate oral pellets) with the following criteria (shown in red):

Olpruva™ (Sodium Phenylbutyrate Pellets for Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and

2. Member must be actively managing UCD with a protein restricted diet; and
3. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use Pheburane® (sodium phenylbutyrate oral pellets) must be provided; and
5. A maximum daily dose of 20g of sodium phenylbutyrate will apply.

Pheburane® (Sodium Phenylbutyrate Oral Pellets) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
4. A maximum daily dose of 20g of sodium phenylbutyrate will apply; and
5. A quantity limit of 1,218g of pellets (equivalent to 588g of sodium phenylbutyrate) per 29 days will apply.

Additionally, the College of Pharmacy recommends updating the Ravicti® (glycerol phenylbutyrate) approval criteria based on net costs (changes shown in red):

Ravicti® (Glycerol Phenylbutyrate) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use Pheburane® (sodium phenylbutyrate oral pellets) must be provided; and
5. A maximum daily dose of 17.5mL (19g) of glycerol phenylbutyrate will apply; and
6. A quantity limit of 525mL per 30 days will apply.

Recommendation 7: Vote to Prior Authorize Jaypirca™ (Pirtobrutinib) and Lunsumio™ (Mosunetuzumab-axgb) and Update the Approval Criteria for the Lymphoma Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Jaypirca™ (pirtobrutinib) and Lunsumio™ (mosunetuzumab-axgb) with the following criteria (shown in red):

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

1. Diagnosis of MCL; and
2. Relapsed or refractory disease after ≥2 lines of systemic therapy; and
3. Previous treatment must have included a Bruton's tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, zanubrutinib).

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

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

Additionally, the College of Pharmacy recommends updating the Adcetris® (brentuximab vedotin), Breyanzi® (lisocabtagene maraleucel), Brukinsa® (zanubrutinib), Tecartus® (brexucabtagene autoleucel), and Yescarta® (axicabtagene ciloleucel) criteria based on the recent FDA approvals, National Comprehensive Cancer Network (NCCN) guideline recommendations, and to be consistent with the other chimeric antigen receptor (CAR) T-cell therapies (new criteria and changes shown in red):

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

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

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

1. Diagnosis of large B-cell lymphoma; and
    a. One of the following:
        i. Refractory disease to frontline chemoimmunotherapy; or
        ii. Relapse within 12 months of frontline chemoimmunotherapy; or
        iii. Relapse after frontline chemoimmunotherapy and member is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidity or age; or
        iv. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
2. ~~Relapsed or refractory disease; and~~
3. ~~Member must have received at least 2 lines of systemic therapy; and~~
4. Member does not have primary central nervous system (CNS) lymphoma; and
5. 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
6. A patient-specific, clinically significant reason why Kymriah® (tisagenlecleucel) or Yescarta® (axicabtagene ciloleucel) is not appropriate for the member must be provided; and
7. Approvals will be for 1 dose per member per lifetime.

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

1. Diagnosis of CLL/SLL.

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

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

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

1. Diagnosis of mantle cell lymphoma; and
2. Relapsed or refractory disease; and
3. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management

of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements; and
4. Approvals will be for 1 dose per member per lifetime.

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

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

Lastly, the College of Pharmacy recommends the removal of criteria for Copiktra® (duvelisib) for follicular lymphoma (FL) and the removal of criteria for Ukoniq® (umbralisib) for FL and marginal zone lymphoma (MZL) based on the FDA withdrawal of the accelerated approvals for these indications (changes shown in red):

~~**Copiktra® (Duvelisib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:**~~

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

~~**Ukoniq® (Umbralisib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:**~~

~~1. Diagnosis of FL; and~~
~~2. Relapsed or refractory disease; and~~
~~3. Member must have received at least 3 prior lines of systemic therapy.~~

~~**Ukoniq® (Umbralisib) Approval Criteria [Marginal Zone Lymphoma (MZL) Diagnosis]:**~~

~~1. Diagnosis of MZL; and~~
~~2. Relapsed or refractory disease; and~~
~~3. Member must have received at least 1 prior anti-CD20-based regimen.~~

Recommendation 8: Annual Review of Hereditary Angioedema (HAE) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the current HAE prophylactic medications prior authorization criteria based on the FDA approved age expansion for Takhzyro® (lanadelumab-flyo) (changes shown in red):

Cinryze® (C1 Esterase Inhibitor), Haegarda® (C1 Esterase Inhibitor), Orladeyo® (Berotralstat), and Takhzyro® (Lanadelumab-flyo) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for prophylaxis of HAE; and
3. Member must not currently be taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
4. Based on HAE attack frequency, attack severity, comorbid conditions, and member's access to emergent treatment, the prescriber has determined long-term prophylaxis is appropriate for the member; or
5. Approval consideration will be given if the member has a recent hospitalization for a severe episode of angioedema; and
6. Authorization of Cinryze® or Haegarda® will also require a patient-specific, clinically significant reason why the member cannot use Orladeyo®; and
7. Authorization of Takhzyro® (lanadelumab-flyo) will also require a patient-specific, clinically significant reason why the member cannot use Cinryze®, Haegarda®, or Orladeyo®; and
8. Cinryze® Dosing:
    a. The recommended dose of Cinryze® is 1,000 units intravenously (IV) every 3 to 4 days, approximately 2 times per week, to be infused at a rate of 1mL/min; and
    b. Initial doses should be administered in an outpatient setting by a health care provider; members can be taught by their health care provider to self-administer Cinryze® IV; and
    c. A quantity limit of 8,000 units per month will apply (i.e., 2 treatments per week or 8 treatments per 28 days); or
9. Haegarda® Dosing:
    a. The recommended dose of Haegarda® is 60 IU/kg subcutaneously (sub-Q) twice weekly; and

b. 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
c. A quantity limit of 2 treatments per week or 8 treatments per 28 days will apply; or

10. Orladeyo® Dosing:
    a. The recommended dose of Orladeyo® is 150mg by mouth once daily; and
    b. A quantity limit of 28 capsules per 28 days will apply; or
11. Takhzyro® Dosing:
    a. For members 12 years of age and older: The recommended dose of Takhzyro® is 300mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
    b. For members 6 to 11 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
    c. For members 2 to 5 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 4 weeks; and
    d. Prescriber must verify member or caregiver has been trained by a health care professional on proper storage and sub-Q administration of Takhzyro®; and
    e. A quantity limit of (2) ~~300mg/2mL~~ vials per 28 days will apply.

Recommendation 9: Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Imjudo® (Tremelimumab-actl) and Krazati® (Adagrasib)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2023.

Recommendation 10: Annual Review of Anti-Diabetic Medications and Kerendia® (Finerenone) and 30-Day Notice to Prior Authorize Brenzavvy™ (Bexagliflozin), Mounjaro® (Tirzepatide), and Tzield™ (Teplizumab-mzwv)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2023.

Recommendation 11: 30-Day Notice to Prior Authorize Syfovre™ (Pegcetacoplan)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2023.

Recommendation 12: 30-Day Notice to Prior Authorize Skyclarys™ (Omaveloxolone)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2023.

Recommendation 13: Annual Review of Systemic Antifungal Medications and 30-Day Notice to Prior Authorize Ancobon® (Flucytosine) and Vivjoa® (Oteseconazole)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2023.

Recommendation 14: Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize Konvomep™ (Omeprazole/Sodium Bicarbonate for Oral Suspension)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2023.

Recommendation 15: 30-Day Notice to Prior Authorize Filspari™ (Sparsentan)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2023.

Recommendation 16: Annual Review of Insomnia Medications and 30-Day Notice to Prior Authorize Doral® (Quazepam)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2023.

Recommendation 17: Annual Review of Lumizyme® (Alglucosidase Alfa) and Nexviazyme® (Avalglucosidase Alfa-ngpt)

NO ACTION REQUIRED.

Recommendation 18: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

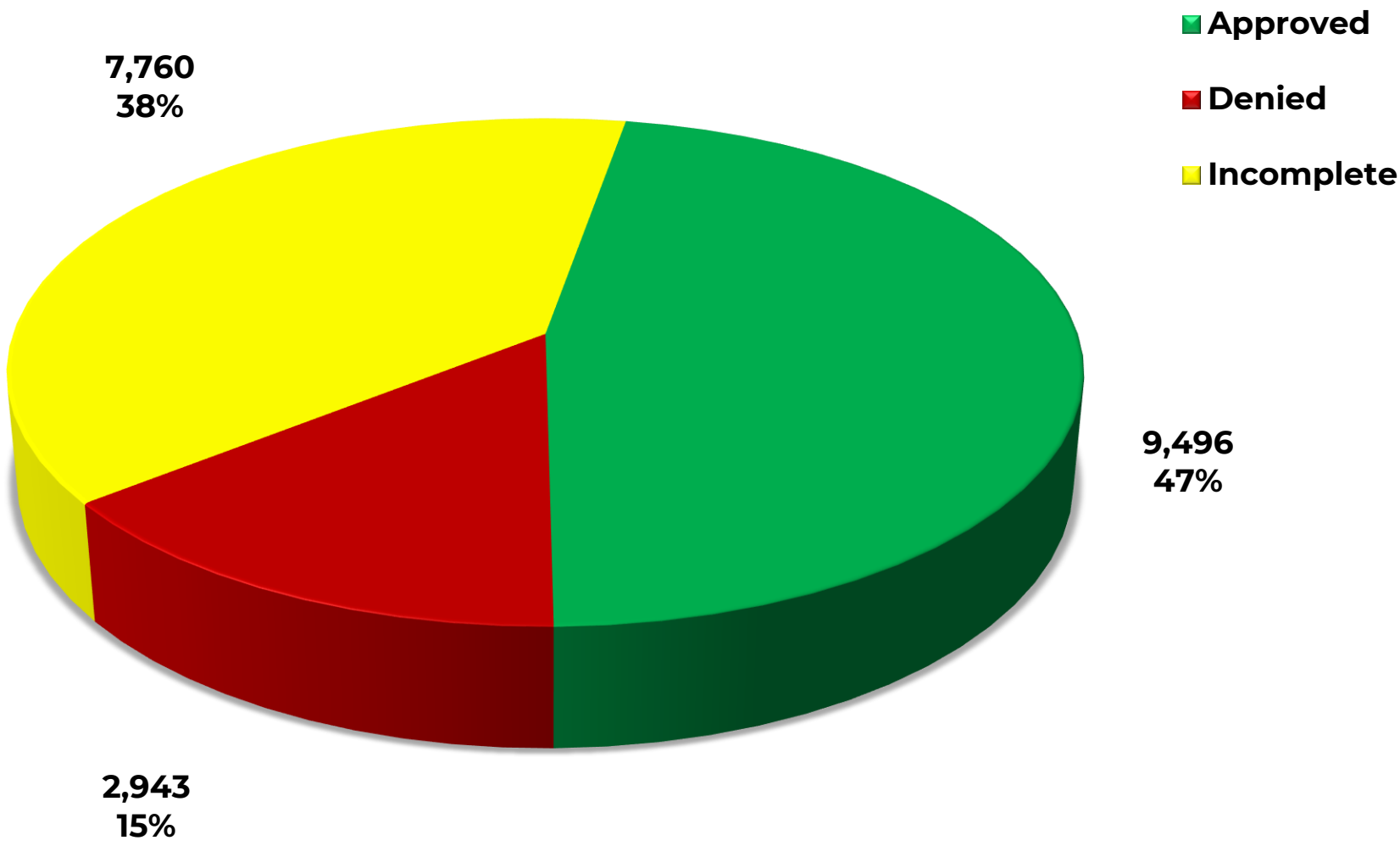
Recommendation 19: Future Business

No DUR Board meeting is scheduled for May 2023.

NO ACTION REQUIRED.

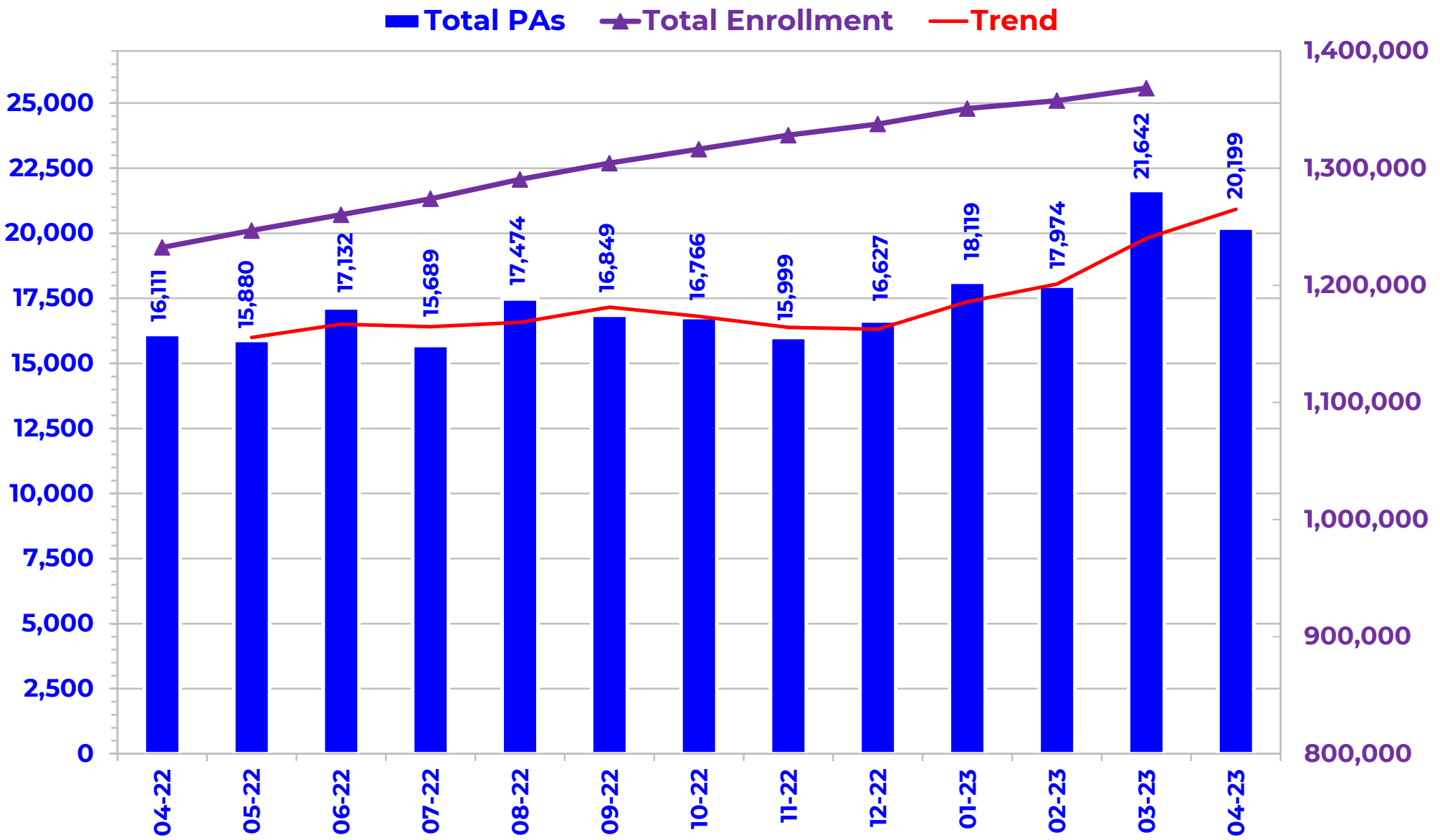
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: APRIL 2023



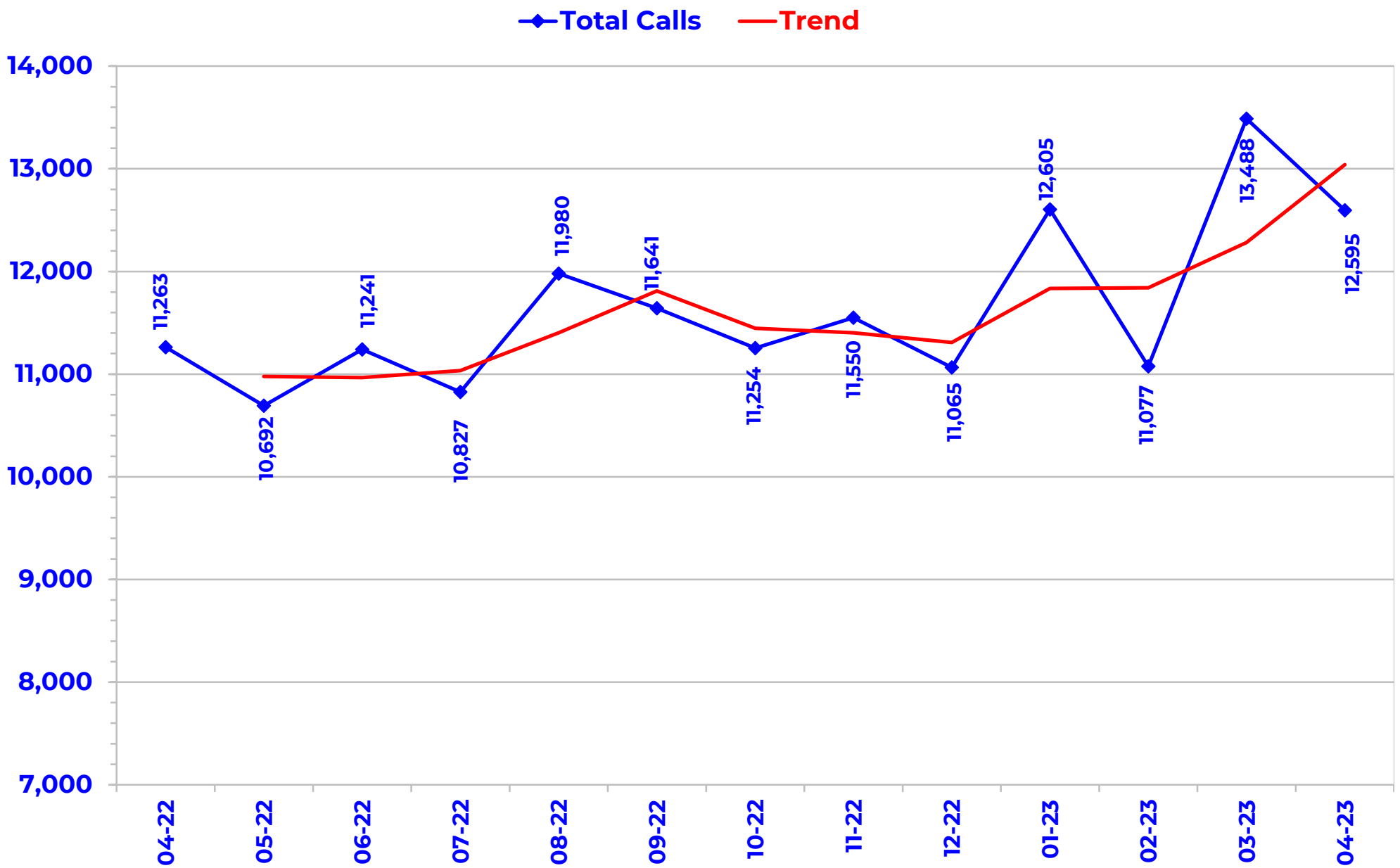
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION (PA) REPORT: APRIL 2022 – APRIL 2023



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
APRIL 2022 – APRIL 2023



Prior Authorization Activity

4/1/2023 Through 4/30/2023

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	114	33	6	75	360
Analgesic - NonNarcotic	21	0	4	17	0
Analgesic, Narcotic	383	171	31	181	135
Angiotensin Receptor Antagonist	20	3	4	13	361
Anti-inflammatory	16	8	0	8	104
Antiasthma	123	45	35	43	229
Antibiotic	47	19	4	24	199
Anticonvulsant	251	117	17	117	336
Antidepressant	516	140	75	301	296
Antidiabetic	3,575	1,377	831	1,367	359
Antifungal	11	3	1	7	17
Antigout	20	7	4	9	336
Antihemophilic Factor	14	9	0	5	320
Antihistamine	71	21	18	32	321
Antimalarial Agent	143	125	1	17	360
Antimigraine	715	121	256	338	252
Antineoplastic	299	207	22	70	175
Antiobesity	83	10	47	26	360
Antiparasitic	41	10	7	24	52
Antiparkinsons	11	1	4	6	361
Antiulcers	61	7	8	46	200
Antiviral	10	3	1	6	48
Anxiolytic	43	6	2	35	284
Atypical Antipsychotics	675	283	56	336	352
Biologics	452	266	38	148	290
Bladder Control	135	23	42	70	360
Blood Thinners	927	553	37	337	348
Botox	76	40	24	12	360
Buprenorphine Medications	116	42	15	59	89
Calcium Channel Blockers	43	8	6	29	360
Cardiovascular	180	93	14	73	328
Chronic Obstructive Pulmonary Disease	377	83	86	208	347
Constipation/Diarrhea Medications	319	67	76	176	245
Contraceptive	78	26	14	38	232
Corticosteroid	20	5	3	12	216
Dermatological	626	226	165	235	207
Diabetic Supplies	1,146	478	201	467	282
Endocrine & Metabolic Drugs	96	29	21	46	271
Erythropoietin Stimulating Agents	32	15	2	15	128

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Estrogen Derivative	17	1	4	12	361
Fibric Acid Derivatives	16	0	3	13	0
Fibromyalgia	17	1	2	14	19
Fish Oils	25	3	4	18	360
Gastrointestinal Agents	210	51	34	125	207
Genitourinary Agents	20	2	3	15	361
Glaucoma	31	5	5	21	263
Growth Hormones	111	79	4	28	156
Hematopoietic Agents	27	10	3	14	293
Hepatitis C	26	13	3	10	9
HFA Rescue Inhalers	21	1	3	17	361
Insomnia	157	12	40	105	259
Insulin	362	147	33	182	359
Miscellaneous Antibiotics	36	6	6	24	31
Multiple Sclerosis	105	57	14	34	278
Muscle Relaxant	73	12	15	46	252
Nasal Allergy	67	4	17	46	155
Neurological Agents	176	52	34	90	225
Neuromuscular Agents	18	7	5	6	325
NSAIDs	71	1	21	49	361
Ocular Allergy	26	3	2	21	208
Ophthalmic	25	2	7	16	208
Ophthalmic Anti-infectives	44	15	1	28	22
Ophthalmic Corticosteroid	32	9	7	16	255
Osteoporosis	50	19	8	23	350
Other*	386	123	62	201	278
Otic Antibiotic	38	3	9	26	40
Respiratory Agents	44	27	3	14	299
Statins	62	9	18	35	197
Stimulant	2,487	1,753	100	634	349
Testosterone	219	62	53	104	343
Thyroid	40	13	4	23	339
Topical Antifungal	59	7	18	34	99
Topical Corticosteroids	53	1	22	30	23
Vitamin	189	44	108	37	127
Pharmacotherapy	62	56	1	5	288
Emergency PAs	3	3	0	0	
Total	**17,291**	**7,293**	**2,854**	**7,144**	

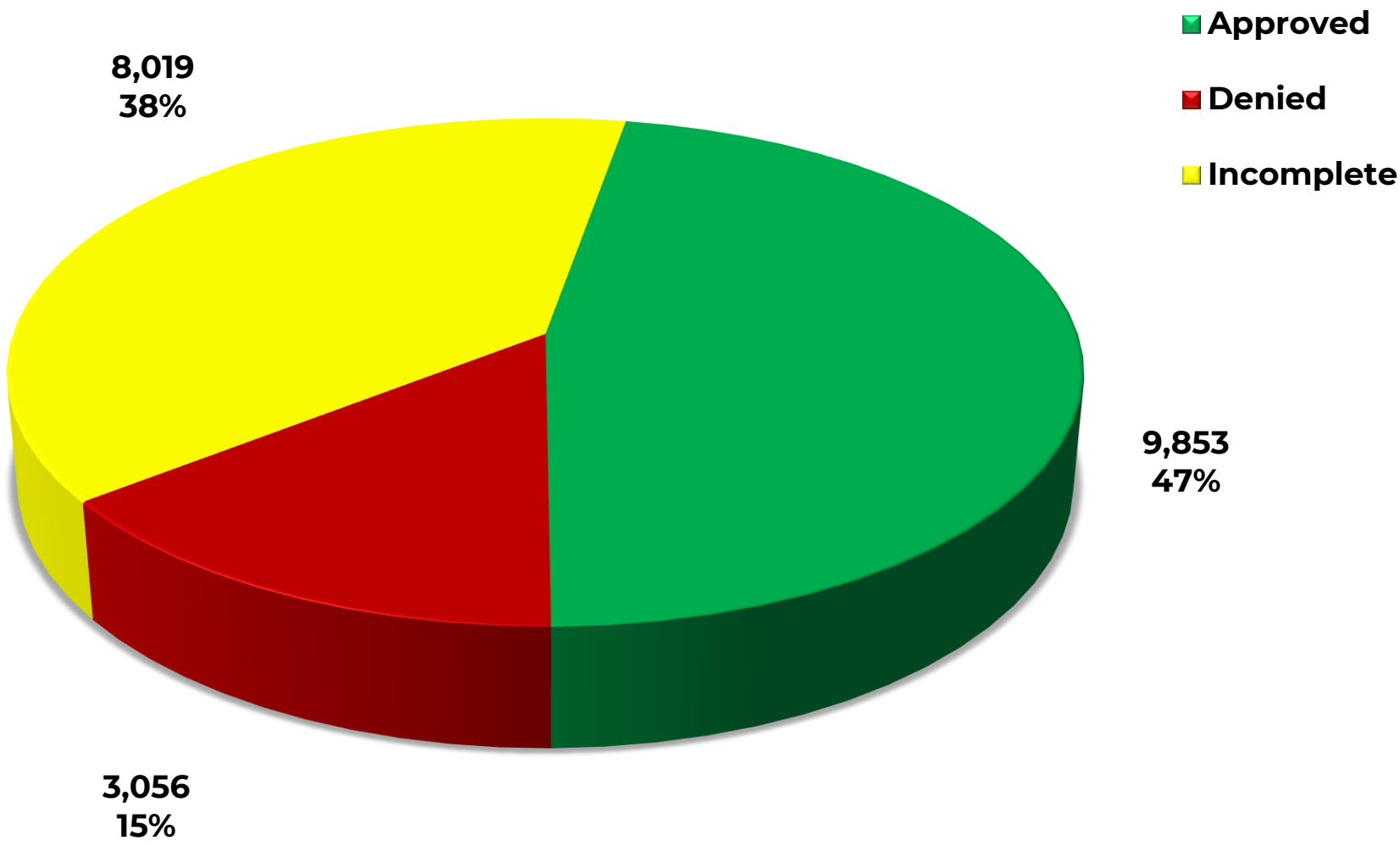
* Includes any therapeutic category with less than 10 prior authorizations for the month.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	99	80	1	18	114
Compound	11	8	1	2	56
Diabetic Supplies	3	3	0	0	132
Dosage Change	557	524	1	32	16
High Dose	2	1	0	1	55
IHS-Brand	4	4	0	0	361
Ingredient Duplication	6	4	0	2	11
Lost/Broken Rx	168	148	4	16	67
MAT Override	299	246	2	51	82
NDC vs Age	311	233	16	62	257
NDC vs Sex	10	9	0	1	126
Nursing Home Issue	74	65	0	9	17
Opioid MME Limit	132	53	3	76	115
Opioid Quantity	34	27	2	5	165
Other	85	67	8	10	29
Quantity vs Days Supply	914	590	45	279	242
STBS/STBSM	23	14	2	7	88
Step Therapy Exception	62	39	4	19	355
Stolen	28	27	0	1	23
Third Brand Request	86	61	0	25	20
Overrides Total	**2,908**	**2,203**	**89**	**616**	
Total Regular PAs + Overrides	**20,199**	**9,496**	**2,943**	**7,760**	

Denial Reasons	
Unable to verify required trials.	6,462
Does not meet established criteria.	2,964
Lack required information to process request.	1,258
Other PA Activity	
Duplicate Requests	2,185
Letters	45,197
No Process	2
Changes to existing PAs	1,709
Helpdesk Initiated Prior Authorizations	1,313
PAs Missing Information	2,783

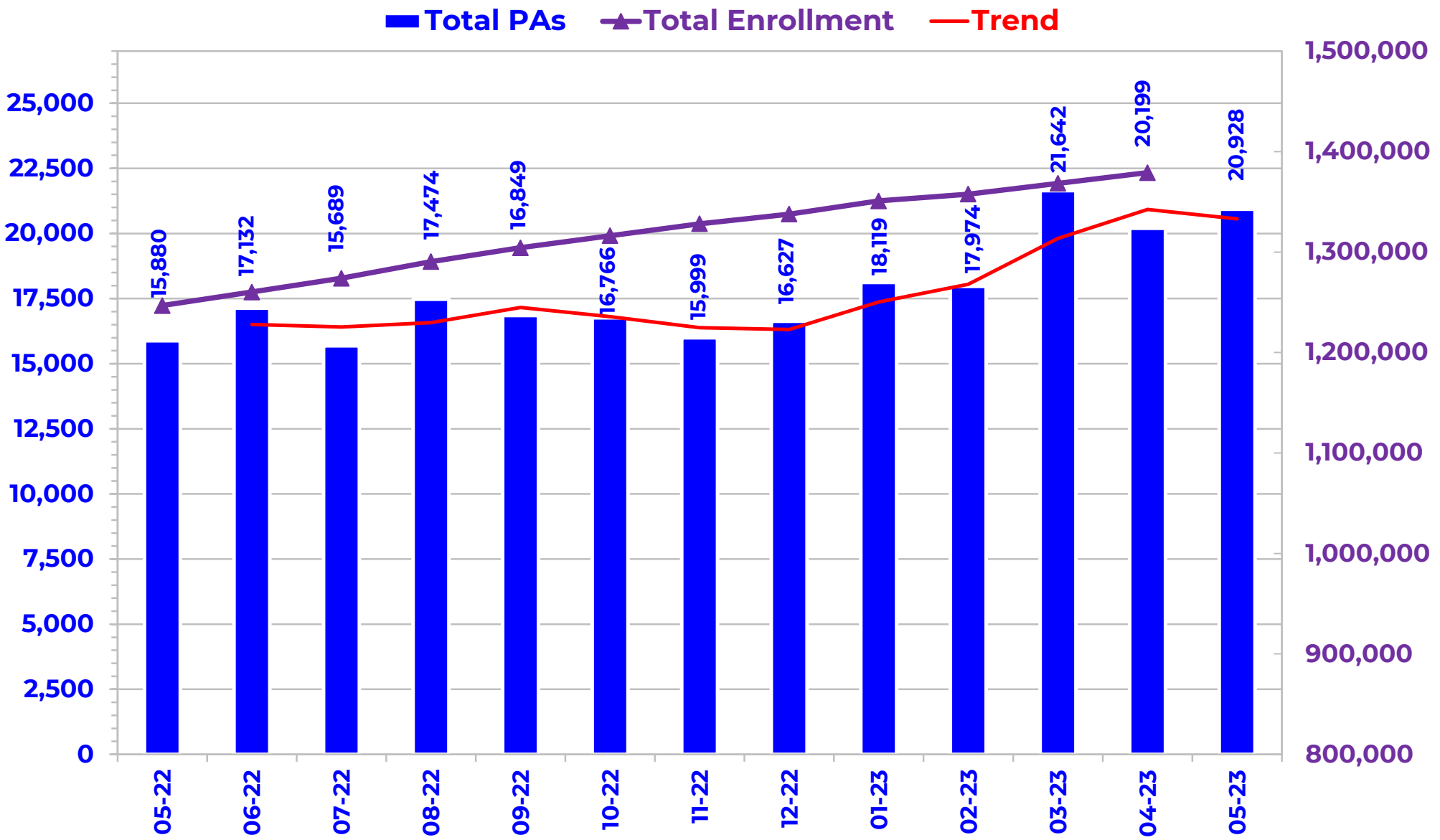
* Includes any therapeutic category with less than 10 prior authorizations for the month.

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: MAY 2023



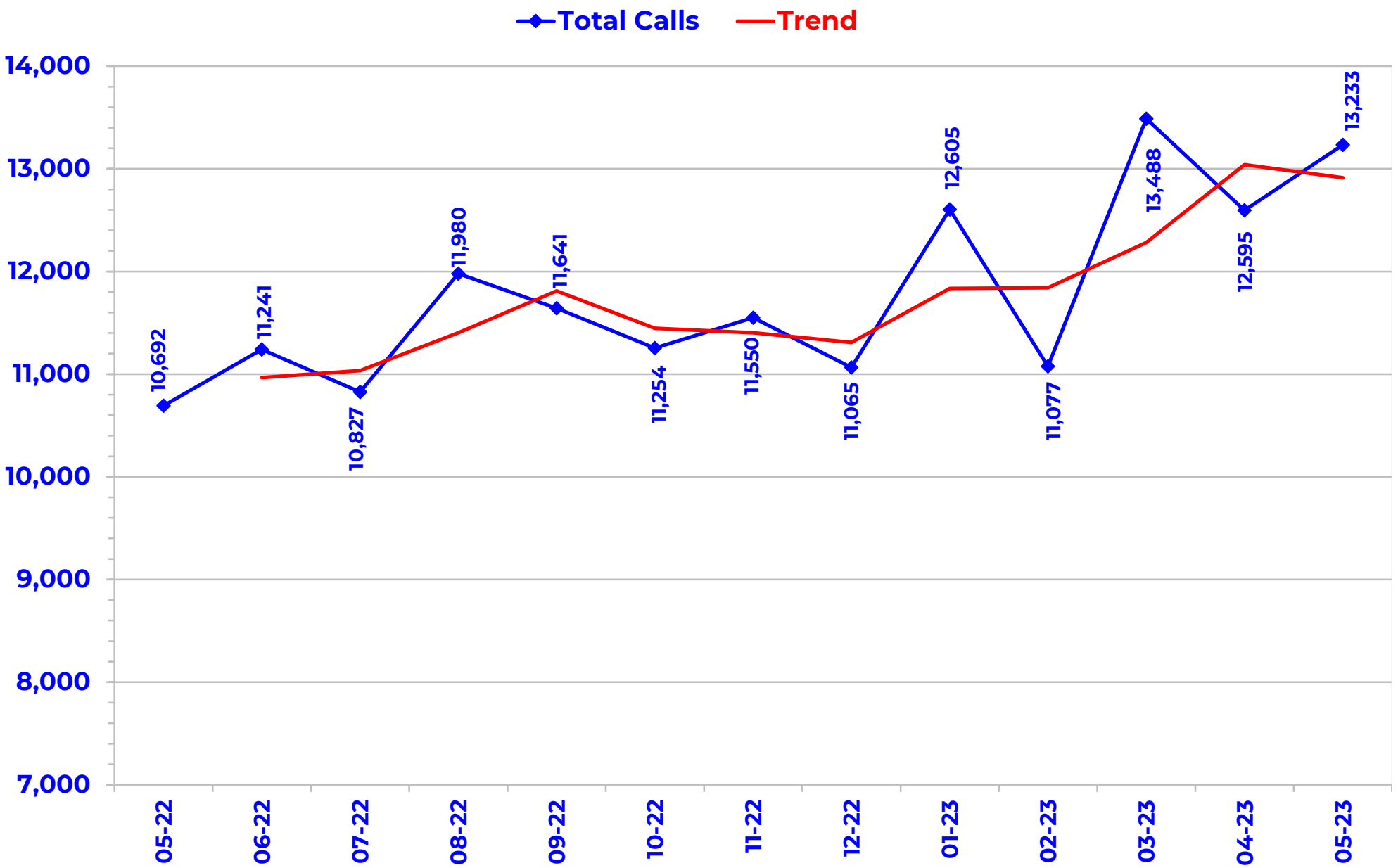
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION (PA) REPORT: MAY 2022 – MAY 2023



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
MAY 2022 – MAY 2023



Prior Authorization Activity

5/1/2023 Through 5/31/2023

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	139	36	6	97	352
Analgesic - NonNarcotic	26	1	6	19	361
Analgesic, Narcotic	424	174	38	212	133
Angiotensin Receptor Antagonist	13	2	2	9	360
Anti-inflammatory	22	14	0	8	110
Antiasthma	118	32	31	55	254
Antibiotic	62	29	4	29	162
Anticonvulsant	343	162	22	159	299
Antidepressant	525	142	64	319	315
Antidiabetic	3,785	1,526	887	1,372	358
Antifungal	14	4	3	7	38
Antigout	19	6	3	10	245
Antihemophilic Factor	12	9	0	3	248
Antihistamine	79	28	16	35	341
Antimalarial Agent	96	76	2	18	352
Antimigraine	660	123	216	321	269
Antineoplastic	288	207	19	62	173
Antiobesity	86	5	74	7	361
Antiparasitic	56	21	4	31	13
Antiparkinsons	10	1	2	7	359
Antiulcers	55	11	8	36	138
Anxiolytic	45	5	4	36	289
Atypical Antipsychotics	744	318	74	352	354
Benign Prostatic Hypertrophy	25	0	15	10	0
Biologics	502	272	59	171	302
Bladder Control	138	23	44	71	338
Blood Thinners	722	456	24	242	344
Botox	77	40	22	15	340
Buprenorphine Medications	135	69	10	56	102
Calcium Channel Blockers	17	2	3	12	361
Cardiovascular	211	111	13	87	337
Chronic Obstructive Pulmonary Disease	427	88	93	246	356
Constipation/Diarrhea Medications	344	62	83	199	189
Contraceptive	63	17	13	33	344
Corticosteroid	29	9	5	15	116
Dermatological	609	219	141	249	231
Diabetic Supplies	1,248	561	201	486	279
Endocrine & Metabolic Drugs	131	55	17	59	269
Erythropoietin Stimulating Agents	28	18	1	9	119
Estrogen Derivative	12	2	3	7	361

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Fibric Acid Derivatives	17	3	3	11	360
Fibromyalgia	16	4	4	8	276
Fish Oils	37	4	9	24	360
Gastrointestinal Agents	261	56	52	153	194
Glaucoma	28	7	4	17	183
Growth Hormones	151	110	18	23	146
Hematopoietic Agents	30	9	5	16	247
Hepatitis C	32	15	8	9	11
HFA Rescue Inhalers	15	0	0	15	0
Insomnia	135	6	34	95	208
Insulin	393	159	31	203	358
Miscellaneous Antibiotics	35	4	6	25	15
Multiple Sclerosis	87	43	7	37	222
Muscle Relaxant	83	11	17	55	137
Nasal Allergy	58	10	13	35	260
Neurological Agents	210	68	36	106	224
Neuromuscular Agents	33	8	7	18	245
Nsaids	59	3	9	47	299
Ocular Allergy	21	2	3	16	224
Ophthalmic	20	5	3	12	298
Ophthalmic Anti-infectives	35	13	1	21	44
Ophthalmic Corticosteroid	35	4	0	31	209
Osteoporosis	38	13	6	19	346
Other*	456	157	57	242	267
Otic Antibiotic	29	3	3	23	26
Pediculicide	19	8	3	8	14
Respiratory Agents	36	21	1	14	251
Statins	76	17	25	34	172
Stimulant	2,660	1,834	117	709	349
Testosterone	255	57	62	136	340
Thyroid	35	10	4	21	354
Topical Antifungal	62	8	19	35	116
Topical Corticosteroids	46	0	19	27	0
Vitamin	202	57	104	41	109
Pharmacotherapy	77	72	1	4	279
Emergency PAs	2	2	0	0	
Total	**18,123**	**7,739**	**2,923**	**7,461**	

* 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	113	90	2	21	126
Compound	5	5	0	0	18
Cumulative Early Refill	1	1	0	0	180
Dosage Change	2	1	0	1	3
Dosage Change	509	476	1	32	17
High Dose	2	2	0	0	74
IHS-Brand	1	1	0	0	361
Ingredient Duplication	4	3	0	1	63
Lost/Broken Rx	129	117	9	3	25
MAT Override	324	269	5	50	87
NDC vs Age	374	268	39	67	277
NDC vs Sex	14	14	0	0	169
Nursing Home Issue	58	54	0	4	16
Opioid MME Limit	119	30	11	78	124
Opioid Quantity	35	29	0	6	157
Other	90	52	19	19	14
Prescriber Temp Unlock	1	1	0	0	361
Quantity vs Days Supply	835	567	35	233	243
Recent Opioid Rx, Concurr	1	1	0	0	30
STBS/STBSM	17	16	0	1	155
Step Therapy Exception	54	36	5	13	359
Stolen	17	16	0	1	26
Third Brand Request	100	65	7	28	17
Overrides Total	**2,805**	**2,114**	**133**	**558**	
Total Regular PAs + Overrides	**20,928**	**9,853**	**3,056**	**8,019**	

Denial Reasons	
Unable to verify required trials.	6,694
Does not meet established criteria.	3,100
Lack required information to process request.	1,340
Other PA Activity	
Duplicate Requests	2,419
Letters	50,181
No Process	2
Changes to existing PAs	1,884
Helpdesk Initiated Prior Authorizations	1,279
PAs Missing Information	2,302

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

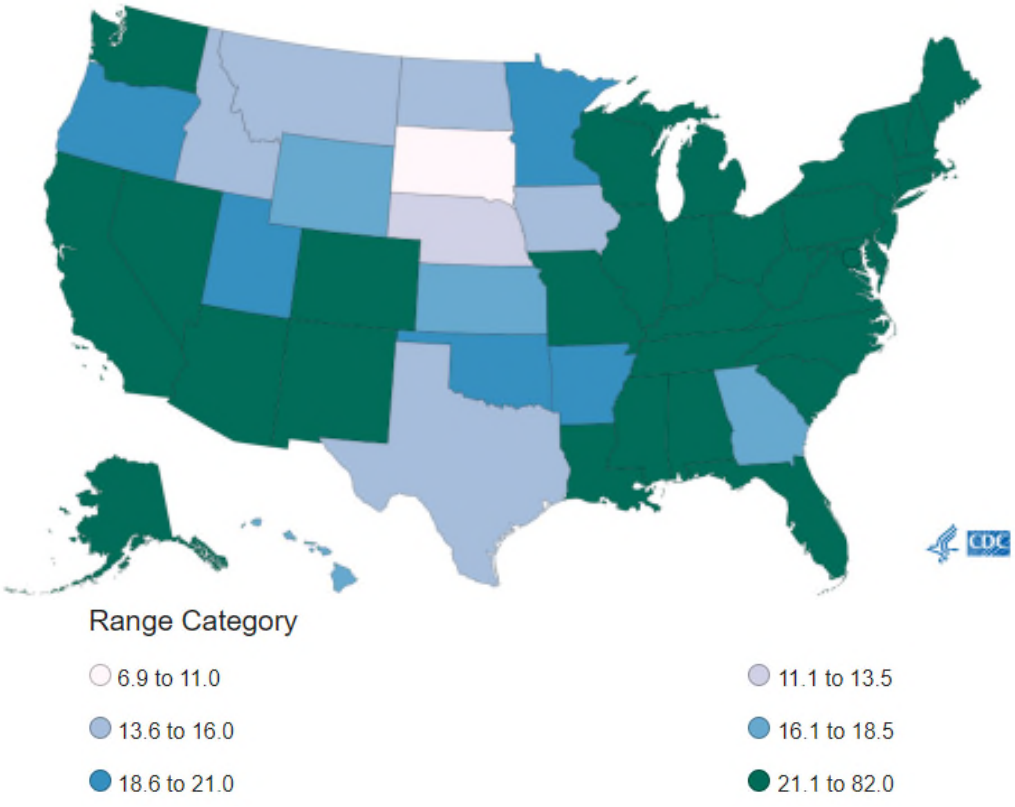
Opioid Utilization and the SoonerCare Morphine Milligram Equivalent (MME) Limit

Oklahoma Health Care Authority
June 2023

Introduction[1,2]

In the United States, there were 91,799 drug overdose deaths in 2020, 762 of which were in Oklahoma. Oklahoma saw a 16.2% increase in the drug overdose death rate from 2019 to 2020. The Centers for Disease Control and Prevention (CDC) recommend clinicians prescribe nonopioid pain medications for acute pain, use the lowest effective opioid dosage when a patient begins opioid therapy for chronic pain, use caution for opioid doses greater than 50 MME per day, and weigh the risks versus benefits when increasing opioid dosages. A reduction in opioid use may result in a decrease in emergency department (ED) visits and inpatient (IP) hospitalizations. The following map from the CDC highlights the age-adjusted rates of drug overdose death by state for 2020.

CDC Number and Age-Adjusted Rates (per 100,000) of Drug Overdose Deaths by State (2020)



Morphine Milligram Equivalent (MME) Summary[3,4,5,6,7,8,9]

Morphine is considered the "gold standard" for the treatment of pain and is used as the basis for comparison via morphine milligram equivalent (MME). The MME provides a conversion factor from opioid to opioid and gives a standard for comparison. The following are MME recommendations or alerts from various government organizations, medical groups, quality measurement programs, and law enforcement:

- CDC: The CDC recommends clinicians prescribe the lowest effective opioid dosage when a patient begins opioid therapy for chronic pain, use caution for doses exceeding 50 MME per day, and weigh the risks versus benefits when increasing opioid dosages.
- Centers for Medicare and Medicaid Services (CMS): In January 2019, CMS finalized new opioid policies for Medicare drug plans. CMS recommended that residents of long-term care facilities, those in hospice care, patients receiving palliative care or end-of-life care, and patients being treated for active cancer-related pain should be excluded from these interventions. It was also recommended that these policies not impact patients' access to medication assisted treatment (MAT), such as buprenorphine. In addition, it was stated that the MME thresholds and day supply limitations are not prescribing limits, and the patient or their prescriber can request an expedited or standard coverage determination from the plan for approval of higher amounts or a longer days' supply. The following CMS safety edits became effective on January 1, 2019 for Medicare drug plans:
    - 7-day supply limit for opioid naïve patients
    - Opioid care coordination edit at 90 MME which alerts pharmacists to review when the patient's cumulative MME per day reaches or exceeds 90 MME across all opioid prescriptions; the 90 MME threshold identifies potentially high-risk patients who may benefit from closer monitoring and care coordination
        - Due to the increased burden on the health care system as a result of the COVID-19 pandemic, it was recommended that plans waive requirements for pharmacist consultation with the prescriber to confirm intent of opioid use in order to lessen the administrative burden on prescribers and pharmacists (all other existing opioid point-of-sale safety edits should be continued during the pandemic)
    - Some plans may implement a hard edit when a patient's cumulative opioid daily dosage reaches 200 MME or greater
    - Concurrent opioid and benzodiazepine use or duplicative long-acting opioid therapy (soft edits)

  CMS also requires all Medicare Part D plans have a drug management program (DMP) that limits access to opioids that may be at risk for

abuse or misuse of prescription drugs. Currently Oklahoma Medicaid has a lock-in program for members who may be at risk of abusing and misusing prescription opioid medications.

- Oklahoma Senate Bill (SB) 1446: In May 2018, SB 1446 was signed into law and placed a 7-day supply limit on initial opioid prescriptions for acute pain. The State Board of Osteopathic Examiners, Oklahoma State Medical Association, Oklahoma Hospital Association, and several medical associations endorsed a best practice document released in October 2018 to clarify some of the details in Oklahoma SB 1446 on opioid prescribing, including instructing prescribers to thoroughly document their rationale for prescribing >100 MME.
- Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) Prescription Monitoring Program (PMP): In February 2018, the OBNDD, via the AWARxE system, initiated 3 clinical alerts featured on the PMP. The clinical alerts were designed to help providers identify at-risk patients. One of the alerts included patients who exceed a daily MME of 100. Current Oklahoma law requires prescribers to check the PMP upon an initial opioid prescription and then at least every 180 days.
- Pharmacy Quality Alliance (PQA) Opioid Measures: PQA is a nationally recognized organization that develops measures to promote appropriate medication use and reporting of performance information related to medications. They have developed the PQA Opioid Measure Set which includes 5 measures to provide important tools to address the opioid epidemic. Included are measures to evaluate the use of opioids at high dosages (≥90 MME/day), opioids from multiple prescribers and pharmacies, and concurrent opioid use with benzodiazepines. Additionally, initial opioid prescribing measures are included to evaluate new prescriptions for long duration (>7 cumulative day supply), or for long-acting or extended-release opioids. Patients with a cancer diagnosis, sickle cell disease, or those receiving hospice care are excluded.

The following table contains MMEs based on strength and quantities for commonly prescribed opioid medications. Daily MMEs in red font exceed the CMS recommendation of ≤90 MME per day.

Drug/Strength	Quantity	Day Supply	Daily MME
Immediate-Release (IR) Products			
codeine 30mg	120	30	18
hydrocodone/APAP 5mg/325mg	120	30	20
hydrocodone/APAP 7.5mg/325mg	120	30	30
hydrocodone/APAP 10mg/325mg	120	30	40
hydromorphone IR 2mg	120	30	32
hydromorphone IR 4mg	120	30	64

Drug/Strength	Quantity	Day Supply	Daily MME
hydromorphone IR 8mg	120	30	128
oxycodone IR 15mg	120	30	90
oxycodone IR 20mg	120	30	120
oxycodone/APAP 7.5mg/325mg	120	30	45
tramadol 50mg	240	30	40
Extended-Release (ER) Products			
Butrans® (buprenorphine) patch 10mcg/hour	4	28	18
Butrans® (buprenorphine) patch 15mcg/hour	4	28	27
Butrans® (buprenorphine) patch 20mcg/hour	4	28	36
fentanyl patch 25mcg/hour	10	30	60
fentanyl patch 50mcg/hour	10	30	120
fentanyl patch 75mcg/hour	10	30	180
Hysingla® ER (hydrocodone ER) 100mg	30	30	100
Hysingla® ER (hydrocodone ER) 120mg	30	30	120
OxyContin® (oxycodone ER) 30mg	60	30	90

APAP = acetaminophen; ER = extended-release; IR = immediate-release; MME = morphine milligram equivalent

Prescriber Mailing: Opioid MME >90

Starting in September 2022, an opioid use retrospective DUR (retroDUR) mailing was sent either monthly or quarterly to prescribers of SoonerCare adult members using opioid medications whose daily MME has been >90 for ≥90 days within the past 180 days. SoonerCare has a daily MME limit of 90; members requiring >90 cumulative MME per day require prior authorization with patient-specific, clinically significant reasoning to support the use of >90 cumulative MME per day. Members with an oncology, hemophilia, or sickle cell diagnosis are excluded from the SoonerCare MME edit; furthermore, medications used for the medication-assisted treatment (MAT) of opioid use disorder (OUD) are excluded from the MME edit. The purpose of this mailing was to decrease chronic opioid use where appropriate in adult members in the Oklahoma Medicaid expansion population [Healthy Adult Program (HAP)] and Title 19 (TXIX) population with a cumulative MME per day >90.

Prescribers were selected to receive letters if their members met the inclusion criteria for the mailing module. If a member had multiple providers who have prescribed opioids, the letter was sent to the prescriber of the most recent paid opioid claim. At the start of the study, prescribers were divided into quarterly and monthly groups. The quarterly group of providers only received letters 4 times a year (September, December, March, and June), and the monthly mailing group was updated each month with members meeting the inclusion criteria and whose prescriber was not in the quarterly mailing group. The intent of the 2 mailing groups was to evaluate the

effectiveness of more frequent versus less frequent mailings and to ensure we are targeting all prescribers with patients on chronic opioids. The mailings were sent at the beginning of the month and included a prescriber summary of their SoonerCare members who are on chronic opioids and have a cumulative daily MME >90. Each month the data was recollected for the previous 180 days, and mailings were sent out to prescribers accordingly. This process was repeated each month through June 2023.

Prescriber Mailing: Trends

The table below includes a summary of the Opioid MME retroDUR mailings sent thus far, which includes the number of prescribers who received a mailing each month, the number of members who met inclusion criteria and were included in the prescriber letters, and the member average MME per day for the members included in each month's mailing(s).

The following table shows the changes observed from the first mailing in September 2022 to the most recent mailing in May 2023. Throughout the mailing period, the number of members included, prescriber letters sent out, and average MME per day was variable. During the first 4 months, the average MME per day began to decrease slightly but then began to increase at the start of 2023. In November 2022, the CDC updated the clinical practice guidelines for prescribing opioids, but did not include a specific recommendation for an MME limit, as in the previous 2016 CDC guidelines where they recommended avoiding opioid doses >90 MME. This may have contributed to an increase in the average MME per day.

Additionally, due to the nature of the study design, the numbers of members varied from month to month to make sure that we were targeting all prescribers of SoonerCare members on chronic opioids. This also may have affected the increase in average MME per day.

Mailing Date	Monthly Mailing		Quarterly Mailing*		Total		
	Members Included	Prescriber Letters	Members Included	Prescriber Letters	Members Included	Prescriber Letters	Average MME/Day
09-2022	42	33	44	33	**86**	**66**	**158.5**
10-2022	57	41	n/a	n/a	**57**	**41**	**157.8**
11-2022	53	41	n/a	n/a	**53**	**41**	**157.3**
12-2022	53	39	35	22	**88**	**61**	**156.8**
01-2023	55	38	n/a	n/a	**55**	**38**	**158.9**
02-2023	56	40	n/a	n/a	**56**	**40**	**161.4**
03-2023	53	37	31	24	**84**	**61**	**163.5**
04-2023	52	37	n/a	n/a	**52**	**37**	**162.5**
05-2023	54	38	n/a	n/a	**54**	**38**	**163.8**

*Prescribers included in the quarterly mailing group only received letters in September, December, March, and June.
MME = morphine milligram equivalent; n/a = not applicable

Prescriber Mailing: Results[10,11]

Table 1: ED Visits

	Amount Paid	Member Months	Number of Members*	PMPM
Overall				
Before Study	$1,719,339.92	84,313	1,470	$20.39
During Study	$49,852.45	1,392	134	$35.80
Monthly Group				
During Study	$36,568.68	932	90	$39.22
Quarterly Group				
During Study	$13,283.77	460	44	$28.86

*Number of unduplicated members
Before Study Time Period: 02/01/2017 to 01/31/2022
During Study Time Period: 02/01/2022 to 03/31/2023
PMPM = cost per member per month

Table 2: IP Visits

	Amount Paid	Member Months	Number of Members*	PMPM
Overall				
Before Study	$37,534,803.23	84,313	934	$445.18
During Study	$1,116,911.92	1,392	134	$802.00
Monthly Group				
During Study	$631,045.16	932	90	$676.77
Quarterly Group				
During Study	$485,866.76	460	44	$1,055.70

*Number of unduplicated members
Before Study Time Period: 02/01/2017 to 01/31/2022
During Study Time Period: 02/01/2022 to 03/31/2023
PMPM = cost per member per month

Table 1 includes data on the total cost of ED visits per member per month (PMPM) and Table 2 includes data on the total cost of IP visits PMPM. The data is compared to 5 years prior (02/01/2017 to 01/31/2022) and included members with daily cumulative MME >90 for ≥90 days. Both the results of the ED visits and IP visits show an increase in PMPM cost. There are multiple factors that could have led to the increase. First, the increase may be due to the increased number of Medicaid expansion members included in our study. On July 1, 2021, the SoonerCare benefit expanded across the state which increased the number of members eligible for Medicaid. The baseline (before study time period) data collected only had 6 months of expansion data, so the majority of the cost was from members on TXIX. Out of the 134 members in our study, 34 (25%) were expansion members. When the expansion population increased, more members had access to physician visits and medication coverage. Additionally, some of the increase may be due to the federal public health emergency (PHE) that was declared at the beginning of the COVID-19 pandemic and ended on May 11, 2023. During the PHE,

Medicaid agencies were required to continue health care coverage for members even if their eligibility changed and they no longer qualified for coverage.

Additionally, the increase in PMPM correlates with the increase in average MME per day that was seen in our data. Patients with a higher MME are at a greater risk for opioid use disorder and overdose, which can result in increased hospitalization and inpatient visits. Finally, the patient population of the study, Medicaid members, generally have more chronic conditions and increased medical expenses.

Prescriber Mailing: Conclusion

Overall, the results of the opioid MME prescriber mailing did not show an improvement in ED or IP costs, possibly due to the recent Medicaid expansion in Oklahoma, the Covid-19 PHE, the new updates to the CDC practice guidelines, and the patient population included in the study. However, at beginning of the study, the results indicated that consistently receiving evidenced based educational mailings may be helpful in reminding prescribers of evidence-based practices and may have reduced some potentially inappropriate prescriptions. The College of Pharmacy will continue to work with the Oklahoma Health Care Authority (OHCA) to identify prescribers who may benefit from opioid prescribing education with the goal of promoting evidence-based use of opioid medications.

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Appendix C

Vote to Prior Authorize Brenzavvy™ (Bexagliflozin), Mounjaro® (Tirzepatide), and Tzield® (Teplizumab-mzwv) and Update the Approval Criteria for the Anti-Diabetic Medications and Kerendia® (Finerenone)

Oklahoma Health Care Authority
June 2023

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

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

- **May 2022:** The FDA approved Mounjaro® (tirzepatide) injection to improve blood sugar control in adults with type 2 diabetes (T2DM), as an addition to diet and exercise. Mounjaro® activates both the glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP) receptors leading to improved blood glucose control. Mounjaro® is administered by subcutaneous (sub-Q) injection once weekly, with the dose adjusted as tolerated.
- **November 2022:** The FDA approved Tzield® (teplizumab-mzwv) injection to delay the onset of stage 3 type 1 diabetes (T1DM) in adults and pediatric patients 8 years of age and older who currently have stage 2 T1DM. Tzield® binds to certain immune system cells and delays progression to stage 3 T1DM. Tzield® is administered by intravenous (IV) infusion once daily for 14 consecutive days.
- **January 2023:** The FDA approved Brenzavvy™ (bexagliflozin), an oral sodium-glucose cotransporter 2 (SGLT-2) inhibitor. Brenzavvy™ is indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.
- **May 2023:** The FDA expanded the indication of Farxiga® (dapagliflozin) from those with heart failure with reduced ejection fraction (HFrEF) to include the full spectrum of left-ventricular ejection fraction (LVEF), including HF with mildly reduced EF (HFmrEF) and preserved EF (HFpEF).

Brenzavvy™ (Bexagliflozin) Product Summary[5]

Therapeutic Class: SGLT-2 inhibitor

Indication(s): Adjunct to diet and exercise to improve glycemic control in adults with T2DM

How Supplied: 20mg oral tablets

Dosing and Administration:

- The recommended dosage is 20mg once daily.
- Renal function should be assessed prior to initiating Brenzavvy™ and as clinically indicated.
- Brenzavvy™ is not recommended if estimated glomerular filtration rate (eGFR) is <30mL/min/1.73m^2.

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

Mounjaro® (Tirzepatide) Product Summary[6]

Therapeutic Class: GLP-1/GIP receptor agonist

Indication(s): Adjunct to diet and exercise to improve glycemic control in adults with T2DM

How Supplied: 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg, or 15mg per 0.5mL in a single-dose pen

Dosing and Administration:

- The recommended starting dosage is 2.5mg injected sub-Q once weekly. After 4 weeks, the dosage should be increased to 5mg sub-Q once weekly. If additional glycemic control is needed, dosage should be increased in 2.5mg increments after at least 4 weeks on the current dose.
- The maximum dosage is 15mg sub-Q once weekly.
- Mounjaro® should be injected sub-Q in the abdomen, thigh, or upper arm and injection sites should be rotated with each dose.

Cost Comparison:

Product	Cost Per mL	Cost Per Month	Cost Per Year
Mounjaro® (tirzepatide inj) 15mg/0.5mL	**$491.00**	**$982.00⁺**	**$12,766.00⁺**
Ozempic® (semaglutide inj) 2mg/0.75mL	$299.85	$899.55*	$11,694.15*
Trulicity® (dulaglutide inj) 4.5mg/0.5mL	$447.40	$894.80±	$11,632.40±

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).
⁺Mounjaro® cost is based on a maximum FDA recommended dose of 15mg once weekly.
*Ozempic® cost is based on the maximum FDA recommended dose of 2mg once weekly.
±Trulicity® cost is based on the maximum FDA recommended dose of 4.5mg once weekly.
inj = injection

Tzield® (Teplizumab-mzwv) Product Summary[7]

Therapeutic Class: CD3-directed antibody

Indication(s): Delay the onset of stage 3 T1DM in adults and pediatric patients 8 years of age and older with stage 2 T1DM

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

Dosing and Administration:

- Tzield® should be administered by IV infusion over a minimum of 30 minutes, using body surface area (BSA)-based dosing, once daily for 14 consecutive days as follows:
  - Day 1: 65mcg/m^2
  - Day 2: 125mcg/m^2
  - Day 3: 250mcg/m^2
  - Day 4: 500mcg/m^2
  - Days 5 through 14: 1,030mcg/m^2
- The diagnosis of stage 2 T1DM should be confirmed by documenting at least 2 positive pancreatic islet autoantibodies in those who have dysglycemia without overt hyperglycemia using an oral glucose tolerance test (OGTT) or alternative method if appropriate and OGTT is not available.
- In patients who meet criteria for a diagnosis of stage 2 T1DM, the patient's clinical history should be reviewed to ensure it does not suggest a diagnosis of T2DM.
- Prior to initiating Tzield®, complete blood count (CBC) and liver function tests (LFTs) should be obtained.
- Patients should be premedicated with: (1) a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, (2) an antihistamine, and/or (3) an antiemetic before each Tzield® dose for at least the first 5 days of the 14-day treatment course.

Cost: The WAC of Tzield® is $6,925 per mL or $13,850 per 2mL SDV, resulting in a total cost of $193,900 for a 14-day treatment course at 1 SDV per dose, which would be adequate dosing for most patients (up to a BSA of 1.9m^2).

Recommendations

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

Tzield® (Teplizumab-mzwv) Approval Criteria:

1. An FDA approved diagnosis of stage 2 Type 1 diabetes mellitus (DM). Diagnosis must be confirmed by the following:

    a. Laboratory testing confirming the presence of ≥2 pancreatic islet autoantibodies; and
        i. Documentation must be submitted with results of autoantibody testing; and
    b. Documented evidence of dysglycemia without overt hyperglycemia as demonstrated by an abnormal oral glucose tolerance test (OGTT) meeting 1 of the following:
        i. Fasting plasma glucose ≥100mg/dL and <126mg/dL; or
        ii. 2-hour plasma glucose ≥140 mg/dL and <200mg/dL; or
        iii. 30-, 60-, or 90-minute value on OGTT ≥200mg/dL; and
2. Member must be 8 years of age or older; and
3. Prescriber must confirm that member's clinical history does not suggest a diagnosis of Type 2 DM; and
4. Tzield® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
5. All of the following will be required for initiation of treatment:
    a. Verification that female members of reproductive potential are not pregnant and are currently using reliable contraception; and
    b. Verification that the member has no active infection(s); and
    c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
    d. Liver function tests and verification that levels are acceptable to the prescriber; and
    e. Verification that all age-appropriate vaccinations have been administered prior to treatment; and
    f. Prescriber must agree to premedicate the member for the first 5 days of dosing and as needed with a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, an antihistamine, and/or an antiemetic; and
6. Tzield® must be administered by a health care professional. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Tzield® will be administered; and
    a. Tzield® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Tzield® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of Tzield®; and
7. The member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. A quantity limit of 28mL per 14 days will apply; and
9. Approvals will be for (1) 14-day cycle per member per lifetime.

The College of Pharmacy also recommends updating the Anti-Diabetic Medications Tier-3 approval criteria to clarify the duration of Tier-2 trials and to be more consistent with clinical practice (changes shown in red):

Anti-Diabetic Medications Tier-3 Approval Criteria:

1. Member must have ~~tried~~ failed a trial at least 3 months in duration and at recommended dosing (and member must be adherent to therapy) with 1 Tier-2 medication in the same category and have a documented clinical reason why ~~the Tier-2 medication is not appropriate~~ the member cannot continue treatment with the Tier-2 medication.
    a. For members who did not complete a 3 month trial (i.e., due to intolerable adverse effects), the member must have a documented clinical reason why they cannot utilize a different Tier-2 medication in the same category, a Tier-2 medication in a different category, or provide detailed information regarding adverse effects occurring with the Tier-2 medication(s) that are not expected to occur with the requested Tier-3 medication that is in the same category.
    b. For Tier-3 medications that do not have a similar category in Tier-2, a medication from any category in Tier-2 may be used.
2. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-1 and Tier-2 medications. Tier structure rules for unique FDA approved indications will apply.

Finally, the College of Pharmacy recommends the following changes to the Anti-Diabetic Medications Product Based Prior Authorization (PBPA) category (changes shown in red in the following Tier chart):

1. Dipeptidyl Peptidase-4 (DPP-4) Inhibitors:
    a. Moving Jentadueto XR® [linagliptin/metformin extended-release (ER)], Onglyza® (saxagliptin), and Kombiglyze XR® (saxagliptin/metformin ER) to Tier-2 based on net costs; and
2. DPP-4/SGLT-2 Inhibitors:
    a. Moving Glyxambi® (empagliflozin/linagliptin) to Tier-1 based on ADA guideline recommendations and net costs after supplemental rebate participation; and
    b. Moving Steglujan® (ertugliflozin/sitagliptin) and Qtern® (dapagliflozin/saxagliptin) to the Special PA Tier based on net costs; and
3. GIP/GLP-1 Agonists:
    a. Prior authorization of Mounjaro® (tirzepatide) and placement into the Special PA Tier based on net costs; and
    b. Moving Rybelsus® (semaglutide) and Bydureon BCise® (exenatide ER autoinjector) to Tier-3 based on net costs; and

4. SGLT-2 Inhibitors:
    a. Prior authorization of Brenzavvy™ (bexagliflozin) and placement into the Special PA Tier; and
    b. Moving Farxiga® (dapagliflozin) and Jardiance® (empagliflozin) to Tier-1 based on ADA guideline recommendations, additional FDA approved indications, and net costs; and
    c. Moving Steglatro® (ertugliflozin) and Segluromet® (ertugliflozin/ metformin) to the Special PA Tier based on net costs; and
5. SGLT-2 Inhibitor/DPP-4 Inhibitor/Biguanides:
    a. Moving Trijardy XR® (empagliflozin/linagliptin/metformin ER) to Tier-1 based on ADA guideline recommendations and net costs after supplemental rebate participation; and
6. Sulfonylureas:
    a. Removing Diabinese® (chlorpropamide) and Orinase® (tolbutamide) due to product discontinuation; and
7. Thiazolidinediones:
    a. Removing Avandaryl® (rosiglitazone/glimepiride) and Avandamet® (rosiglitazone/metformin) due to product discontinuation.

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Alpha-Glucosidase Inhibitors			
acarbose (Precose®)		miglitol (Glyset®)	
Amylinomimetics			
			pramlintide (Symlin®)
Biguanides			
metformin (Glucophage®)			metformin ER (Fortamet®, Glumetza®)
metformin SR (Glucophage XR®)			metformin soln (Riomet®)
metformin/ glipizide (Metaglip®)			metformin ER susp (Riomet ER™)
metformin/ glyburide (Glucovance®)			
DPP-4 Inhibitors			
	linagliptin (Tradjenta®)	alogliptin (Nesina®)	~~**linagliptin/metformin ER (Jentadueto® XR)**~~
	linagliptin/ metformin (Jentadueto®)	alogliptin/ metformin (Kazano®)	
	linagliptin/ metformin ER (Jentadueto® XR)	alogliptin/ pioglitazone (Oseni®)	

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	saxagliptin (Onglyza®)	~~**saxagliptin (Onglyza®)**~~	
	saxagliptin/ metformin (Kombiglyze®, Kombiglyze XR®)	~~**saxagliptin/ metformin (Kombiglyze®, Kombiglyze XR®)**~~	
	sitagliptin (Januvia®)		
	sitagliptin/ metformin (Janumet®)		
	sitagliptin/ metformin ER (Janumet XR®)		
DPP-4 Inhibitors/SGLT-2 Inhibitors			
empagliflozin/ linagliptin (Glyxambi®)	~~**empagliflozin/ linagliptin (Glyxambi®)**~~	~~**dapagliflozin/ saxagliptin (Qtern®)**~~	**dapagliflozin/ saxagliptin (Qtern®)**
		~~**ertugliflozin/ sitagliptin (Steglujan®)**~~	**ertugliflozin/ sitagliptin (Steglujan®)**
Dopamine Agonists			
		bromocriptine (Cycloset®)	
Glinides			
repaglinide (Prandin®)	nateglinide (Starlix®)		
	repaglinide/ metformin (Prandimet®)		
GIP/GLP-1 Agonists			
	dulaglutide (Trulicity®)	**exenatide ER autoinjector (Bydureon BCise®)**	~~**exenatide ER autoinjector (Bydureon BCise®)**~~
	exenatide (Byetta®)	semaglutide (Ozempic®)	lixisenatide (Adlyxin®)
	liraglutide (Victoza®)	**semaglutide (Rybelsus®)**	~~**semaglutide (Rybelsus®)**~~
			tirzepatide (Mounjaro®)
GLP-1 Agonists/Insulin			
		insulin degludec/ liraglutide (Xultophy® 100/3.6)+	
		insulin glargine/ lixisenatide (Soliqua® 100/33)+	

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
SGLT-2 Inhibitors			
dapagliflozin (Farxiga®)	~~**dapagliflozin (Farxiga®)**~~	canagliflozin (Invokana®)	**bexagliflozin (Brenzavvy™)**
empagliflozin (Jardiance®)	dapagliflozin/ metformin ER (Xigduo® XR)	canagliflozin/ metformin (Invokamet®)	canagliflozin/ metformin ER (Invokamet® XR)
	~~**empagliflozin (Jardiance®)**~~	~~**ertugliflozin (Steglatro®)**~~	**ertugliflozin (Steglatro®)**
	empagliflozin/ metformin (Synjardy®)	~~**ertugliflozin/ metformin (Segluromet®)**~~	**ertugliflozin/ metformin (Segluromet®)**
	empagliflozin/ metformin ER (Synjardy® XR)		
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)	~~**empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)**~~		dapagliflozin/ saxagliptin/ metformin ER (Qternmet® XR)
Sulfonylureas			
~~**chlorpropamide (Diabinese®)**~~			
glimepiride (Amaryl®)			
glipizide (Glucotrol®)			
glipizide SR (Glucotrol XL®)			
glyburide (Diabeta®)			
glyburide micronized (Micronase®)			
~~**tolbutamide (Orinase®)**~~			
Thiazolidinediones			
pioglitazone (Actos®)		pioglitazone/ glimepiride (Duetact®)	
		pioglitazone/ metformin (Actoplus Met®, Actoplus Met XR®)	
		rosiglitazone (Avandia®)	

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
		~~**rosiglitazone/ glimepiride (Avandaryl®)**~~	
		~~**rosiglitazone/ metformin (Avandamet®)**~~	

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
†Unique criteria applies.
DPP-4 = dipeptidyl peptidase-4; ER = extended-release; GIP = glucose-dependent insulinotropic polypeptide; GLP-1 = glucagon-like peptide-1; PA = prior authorization; SGLT-2 = sodium-glucose cotransporter-2; soln = solution; SR = sustained-release; susp = suspension

Anti-Diabetic Medications Special Prior Authorization (PA) Approval Criteria:

1. Member must be currently stabilized on the requested product or have attempted at least 3 other categories of Tier-2 or Tier-3 medications, or have a documented clinical reason why the requested product is necessary for the member; and
2. Use of Invokamet® XR [canagliflozin/metformin extended-release (ER)] ~~or Jentaducto® XR (linagliptin/metformin ER)~~ will require a patient-specific, clinically significant reason why the member cannot take the immediate-release formulation(s); and
3. Use of Adlyxin® (lixisenatide)~~, Bydureon BCise® (exenatide ER autoinjector pen), or Rybelsus® (semaglutide)~~ or Mounjaro® (tirzepatide) will require a patient-specific, clinically significant reason (other than convenience) why the member cannot use all available lower-tiered glucagon-like peptide 1 (GLP-1) receptor agonists.

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[1] U.S. Food and Drug Administration (FDA). FDA Approves Novel, Dual-Targeted Treatment for Type 2 Diabetes. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes. Issued 05/13/2022. Last accessed 05/17/2023.
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[6] Mounjaro® (Tirzepatide) Prescribing Information. Lilly USA, LLC. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf. Last revised 05/2022. Last accessed 05/17/2023.
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Appendix D

Vote to Prior Authorize Syfovre™ (Pegcetacoplan)

Oklahoma Health Care Authority
June 2023

Market News and Updates[1,2,3]

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

- **February 2023:** The FDA approved Syfovre™ (pegcetacoplan) for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). Syfovre™ is the first and only FDA approved treatment for GA. The focus of treatment with Syfovre™ is to preserve the retina; thus, it regulates complement activation, the immune process that is thought to lead to retinal cell death and the development of the GA lesions. The approval of Syfovre™ was based on positive results from the Phase 3 OAKS and DERBY studies which showed both monthly and every other month injections of Syfovre™ reduced the rate of GA lesion growth through 24 months compared to sham.

Syfovre™ (Pegcetacoplan) Product Summary[4]

Therapeutic Class: Complement inhibitor

Indication(s): Treatment of GA secondary to AMD

How Supplied: 150mg/mL solution in a 0.1mL single dose vial (SDV) for injection

Dosing and Administration: The recommended dose of Syfovre™ is 15mg (0.1mL of solution) administered by intravitreal injection to each affected eye once every 25 to 60 days.

Cost: The Wholesale Acquisition Cost (WAC) of Syfovre™ is $2,190 per SDV. The annual cost per eye will range from $13,140 to $30,660 per year, depending on injection frequency.

Recommendations

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

Syfovre™ (Pegcetacoplan) Approval Criteria:

1. An FDA approved indication for the treatment of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD); and

2. Member must not have ocular or periocular infections or active intraocular inflammation; and
3. Syfovre™ must be prescribed and administered by an ophthalmologist, or a physician experienced in intravitreal injections; and
4. Prescriber must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, intraocular inflammation, and neovascular (wet) AMD; and
5. A quantity limit of (1) 0.1mL single-dose vial per eye every 25 to 60 days will apply.

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[1] Apellis Pharmaceuticals, Inc. FDA Approves Syfovre™ (Pegcetacoplan Injection) as the First and Only Treatment for Geographic Atrophy (GA), a Leading Cause of Blindness. Available online at: https://www.globenewswire.com/news-release/2023/02/17/2610967/0/en/FDA-Approves-SYFOVRE-pegcetacoplan-injection-as-the-First-and-Only-Treatment-for-Geographic-Atrophy-GA-a-Leading-Cause-of-Blindness.html. Issued 02/17/2023. Last accessed 05/19/2023.
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Appendix E

Vote to Prior Authorize Ancobon® (Flucytosine) and Vivjoa® (Oteseconazole) and Update the Approval Criteria for the Systemic Antifungal Medications

Oklahoma Health Care Authority
June 2023

Market News and Updates[1,2]

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

- **April 2022:** The FDA approved Vivjoa® (oteseconazole) oral capsules to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential.
- **December 2022:** The FDA approved a new indication for Brexafemme® (ibrexafungerp) oral tablets to reduce the incidence of RVVC in adult and post-menarchal females. The reduction in RVVC dosing regimen is 300mg (2 tablets) once and then again 12 hours later on day 1, then repeated monthly for 6 months.

Vivjoa® (Oteseconazole) Product Summary[3]

Therapeutic Class: Azole antifungal

Indication(s): To reduce the incidence of RVVC in females with a history of RVVC who are not of reproductive potential

How Supplied: 150mg oral capsules

Dosing and Administration:

- Vivjoa®-only dosing regimen:
  - 600mg [(4) 150mg capsules] as a single dose on day 1
  - 450mg [(3) 150mg capsules] as a single dose on day 2
  - 150mg once a week (every 7 days) for 11 weeks beginning on day 14 (weeks 2 through 12)
- Fluconazole/Vivjoa® dosing regimen:
  - Fluconazole 150mg on day 1, day 4, and day 7
  - Vivjoa® 150mg once daily on days 14 through 20 for 7 days
  - Vivjoa® 150mg once a week (every 7 days) for 11 weeks beginning on day 28 (weeks 4 through 14)
- Vivjoa® should be taken with food.

Cost Comparison: RVVC Treatments

Medication	Cost Per Unit	Cost Per Treatment†
Brexafemme® (ibrexafungerp) 150mg tablet	$119.82	$2,875.68
Vivjoa® (oteseconazole) 150mg capsule	$156.00	$2,808.00
fluconazole 150mg tablet	$0.64	$19.20

Costs do not reflect rebated prices or net costs. Cost based on National Average Drug Acquisition Cost (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = tablet or capsule
†Cost per treatment based on recommended dosing for RVVC: Brexafemme®: 24 tablets for 6 months; Vivjoa®: 18 capsules for 84 days; fluconazole: 30 tablets for 6 months (fluconazole dosed as 1 tablet every 72 hours for up to 14 days then weekly for 6 months)

Recommendations

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

Vivjoa® (Oteseconazole) Approval Criteria:

1. An FDA approved indication to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC); and
2. Member must be a female who is not pregnant, not lactating, and not of reproductive potential; and
3. Member has a history of RVVC with at least 3 symptomatic episodes of acute vulvovaginal candidiasis (VVC) in the previous 12 months; and
4. Member has experienced a recurrence of VVC during or following 6 months of fluconazole-only maintenance treatment for RVVC or member has a contraindication to fluconazole (e.g., hypersensitivity, drug-drug interactions); and
5. Prescriber must verify member will be monitored if taking breast cancer resistance protein (BCRP) substrates (e.g., rosuvastatin, mitoxantrone, methotrexate, topotecan, imatinib, irinotecan); and
6. A quantity limit of 18 capsules per 84 days will apply.

Additionally, the College of Pharmacy recommends the addition of prior authorization criteria for Brexafemme® (ibrexafungerp) for the diagnosis of RVVC based on the new FDA approved indication (shown in red):

Brexafemme® (Ibrexafungerp) Approval Criteria [Recurrent Vulvovaginal Candidiasis (RVVC) Diagnosis]:

1. An FDA approved indication to reduce the incidence of RVVC; and
2. Member must be an adult female or post-menarchal pediatric female; and
3. Member has a history of RVVC with at least 3 symptomatic episodes of acute vulvovaginal candidiasis (VVC) in the previous 12 months; and

4. Member has experienced a recurrence of VVC during or following 6 months of fluconazole-only maintenance treatment for RVVC or member has a contraindication to fluconazole (e.g., hypersensitivity, drug-drug interactions); and
5. Prescriber must verify member is not pregnant, not lactating, and is currently using reliable contraception and will continue to use throughout the treatment duration and 4 days after last dose; and
6. Member must not be taking concurrent strong CYP3A inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifampin); and
7. A quantity limit of 24 tablets per 180 days will apply.

Lastly, the College of Pharmacy recommends the prior authorization of Ancobon® (flucytosine) to ensure appropriate use:

Ancobon® (Flucytosine) Approval Criteria:

1. An FDA approved indication for treatment of systemic fungal infections (e.g., sepsis, endocarditis, urinary tract infection, meningitis, pulmonary) caused by strains of *Candida* or *Cryptococcus*.

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[1] Cosdon N. FDA Approves Oteseconazole, First and Only Treatment for Chronic Yeast Infection. *Contagion Live*. Available online at: https://www.contagionlive.com/view/fda-approves-oteseconazole-first-and-only-treatment-for-chronic-yeast-infection. Issued 04/28/2022. Last accessed 05/22/2023.
[2] Scynexis, Inc. Scynexis Announces FDA Approval of Second Indication for Brefafemme® (Ibrexafungerp Tablets) for Reduction in Incidence of Recurrent Vulvovaginal Candidiasis. Available online at: https://ir.scynexis.com/news-events/press-releases/detail/314/scynexis-announces-fda-approval-of-second-indication-for. Issued 12/01/2022. Last accessed 05/22/2023.
[3] Vivjoa® (Oteseconazole) Prescribing Information. Mycovia Pharmaceuticals, Inc. Available online at: https://vivjoa.com/pi/VIVJOA-Full-Prescribing-Information.pdf. Last revised 04/2022. Last accessed 05/22/2023.

Appendix F

Vote to Prior Authorize Doral® (Quazepam)

Oklahoma Health Care Authority
June 2023

Market News and Updates

News:

- **April 2023:** Galt Pharmaceuticals, the current manufacturer of Doral® (quazepam), began participating in the federal Medicaid Drug Rebate Program (MDRP) in April 2023. Doral® was approved by the FDA in 1985 for the treatment of insomnia.

Doral® (Quazepam) Product Summary[1]

Therapeutic Class: Benzodiazepine

Indication(s): Treatment of insomnia in adults

How Supplied: 15mg functionally scored oral tablet

Dosing:

- The recommended initial dose is 7.5mg. The 15mg tablet should be split along the score line to achieve 7.5mg dose.
- The dose may be increased to a maximum of 15mg if necessary for efficacy. The lowest effective dose should be used.

Cost: The Wholesale Acquisition Cost (WAC) of Doral® 15mg is $28.33 per tablet, resulting in a monthly cost of $849.90 at the maximum recommended dosage of 15mg per day.

Recommendations

The College of Pharmacy recommends the prior authorization of Doral® (quazepam) and placement into the Special Prior Authorization (PA) Tier of the Insomnia Medications Product Based Prior Authorization (PBPA) category based on net cost (changes noted in red in the following PBPA Tier chart):

Insomnia Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
estazolam (ProSom®)	zolpidem CR (Ambien® CR)	lemborexant (Dayvigo®)	daridorexant (Quviviq™)
eszopiclone (Lunesta®)		suvorexant (Belsomra®)	doxepin (Silenor®)
flurazepam (Dalmane®)			**quazepam (Doral®)**
ramelteon (Rozerem®) – **Brand Preferred**			tasimelteon (Hetlioz®, Hetlioz LQ™)+
temazepam (Restoril®) 15mg and 30mg			temazepam (Restoril®) 7.5mg and 22.5mg
triazolam (Halcion®)			zolpidem SL tablets (Edluar®)
zaleplon (Sonata®)			zolpidem SL tablets (Intermezzo®)
zolpidem (Ambien®)			zolpidem oral spray (Zolpimist®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Medications in the Special PA Tier, including unique dosage formulations, require a special reason for use in place of lower-tiered medications.
+Individual criteria specific to tasimelteon applies.
CR = controlled release; PA = prior authorization; SL = sublingual

[1] Doral® (Quazepam) Prescribing Information. Galt Pharmaceuticals. Available online at: https://doralrx.com/docs/Doral_PI.pdf. Last revised 01/2023. Last accessed 05/22/2023.

Appendix G

Vote to Prior Authorize Konvomep™ (Omeprazole/ Sodium Bicarbonate for Oral Suspension) and Update the Approval Criteria for the Anti-Ulcer Medications

Oklahoma Health Care Authority
June 2023

Market News and Updates[1,2]

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

- **September 2022:** The FDA approved Konvomep™ (omeprazole/sodium bicarbonate for oral suspension) for the treatment of active benign gastric ulcer in adults and the reduction of risk of upper gastrointestinal bleeding in critically ill adult patients. It is available as 2mg of omeprazole and 84mg of sodium bicarbonate per mL after reconstitution in 90mL, 150mL, or 300mL bottles. Konvomep™ should be reconstituted by a health care provider and is stable for up to 30 days after reconstitution. The Wholesale Acquisition Cost of Konvomep™ ranges from $1.17 per mL for the 300mL bottle to $1.94 per mL for the 90mL bottle, resulting in a total monthly cost range of $702 to $1,164 respectively, at the recommended dose of 40mg of omeprazole once daily.

Recommendations

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

1. The prior authorization of Konvomep™ (omeprazole/sodium bicarbonate for oral suspension) and placement into the Special PA Tier with criteria similar to Zegerid® (omeprazole/sodium bicarbonate capsules); and
2. Removing the brand preferred status for sucralfate suspension (Carafate®) based on net costs; and
3. Moving Pylera® (bismuth subcitrate potassium/metronidazole/ tetracycline) from the Special PA Tier to Tier-1 based on net costs; and
4. Updating the Talicia® (omeprazole/amoxicillin/rifabutin) approval criteria to require a reason why the member cannot use Pylera® (bismuth subcitrate potassium/metronidazole/tetracycline) based on net costs; and
5. The removal of Helidac® (bismuth subsalicylate/metronidazole/ tetracycline) due to product discontinuation.

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

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

~~**Generic Sucralfate Suspension Approval Criteria:**~~

~~1. Authorization consideration requires a patient specific, clinically significant reason why the member cannot use brand name Carafate® (sucralfate) suspension.~~

~~**Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack) and Pylera® (Bismuth Subcitrate Potassium/Metronidazole/ Tetracycline Capsule) Approval Criteria:**~~

~~1. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and~~

~~2. A patient-specific, clinically significant reason why the member cannot use the individual components [bismuth subsalicylate, metronidazole, and tetracycline plus an histamine type 2 receptor (H_2) antagonist], must be provided; and~~

~~3. A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection (e.g., proton pump inhibitor/H_2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and~~

~~4. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and clarithromycin), which are available without prior authorization, must be provided; and~~

~~5. For Helidac® Therapy, a quantity limit of 224 tablets/capsules per 14 days will apply; and~~

~~6. For Pylera®, a quantity limit of 120 capsules per 10 days will apply.~~

Konvomep™ (Omeprazole/Sodium Bicarbonate for Oral Suspension) and Zegerid® (Omeprazole/Sodium Bicarbonate Capsules) Approval Criteria:

1. Member must be 18 years of age or older; and
2. A patient specific, clinically significant reason why the member cannot use omeprazole and over-the-counter (OTC) sodium bicarbonate must be provided; and
3. For Konvomep™, requests for the 90mL or 150mL package size will require a patient-specific, clinically significant reason why the member cannot use the 300mL package size.

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

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components of other triple-therapy regimens approved for the same diagnosis (e.g., omeprazole, amoxicillin, and clarithromycin) or Pylera® (bismuth subcitrate potassium/

metronidazole/tetracycline capsules), which are available without prior authorization, must be provided; and

3. A quantity limit of 168 capsules per 14 days will apply.

[1] Azurity Pharmaceuticals. Azurity Pharmaceuticals, Inc. Announces FDA Approval of Konvomep™ (Omeprazole/Sodium Bicarbonate for Oral Suspension). *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/azurity-pharmaceuticals-inc-announces-fda-approval-of-konvomep-omeprazole-and-sodium-bicarbonate-for-oral-suspension-301616983.html. Issued 09/02/2022. Last accessed 05/08/2023.

[2] Konvomep™ (Omeprazole/Sodium Bicarbonate for Oral Suspension) Prescribing Information. Azurity Pharmaceuticals, Inc. Available online at: https://konvomep.com/wp-content/uploads/2023/02/Konvomep-PI-LongVersionforWebsite-Dec2022-REV01.pdf. Last revised 12/2022. Last accessed 05/08/2023.

Appendix H

Vote to Prior Authorize Skyclarys™ (Omaveloxolone)

Oklahoma Health Care Authority
June 2023

Market News and Updates[1]

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

- **February 2023:** The FDA approved Skyclarys™ (omaveloxolone) for the treatment of Friedreich's ataxia (FRDA) in adults and adolescents 16 years of age and older. This is the first therapy that has been FDA approved specifically for FRDA.

Skyclarys™ (Omaveloxolone) Product Summary[2]

Therapeutic Class: Nuclear factor-like 2 (Nrf2) activator

Indication(s): Treatment of FRDA in adults and adolescents 16 years of age and older

How Supplied: 50mg oral capsule

Dosing and Administration:

- The recommended dosage is 150mg [(3) 50mg capsules] taken orally once daily.
- Skyclarys™ should be administered on an empty stomach at least 1 hour before eating and should be swallowed whole.
- Alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, B-type natriuretic peptide (BNP), and lipid parameters should be obtained prior to initiating Skyclarys™ and during treatment.
- The dosage of Skyclarys™ should be reduced to 100mg once daily for patients with moderate hepatic impairment. If adverse reactions emerge, the dose should be reduced to 50mg once daily. Use should be avoided in patients with severe hepatic impairment.

Cost: The Wholesale Acquisition Cost of Skyclarys™ is $342.59 per capsule. This results in an estimated cost of $30,833.10 per month and $369,997.20 per year based on the recommended dose of 150mg (3 capsules) once daily.

Recommendations

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

Skyclarys™ (Omaveloxolone) Approval Criteria:

1. An FDA approved diagnosis of Friedreich's ataxia (FRDA); and

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

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[1] Reata Pharmaceuticals. Reata Pharmaceuticals Announces FDA Approval of Skyclarys™ (Omaveloxolone), the First and Only Drug Indicated for Patients with Friedreich's Ataxia. Available online at: https://www.reatapharma.com/investors/news/news-details/2023/Reata-Pharmaceuticals-Announces-FDA-Approval-of-SKYCLARYS-Omaveloxolone-the-First-and-Only-Drug-Indicated-for-Patients-with-Friedreichs-Ataxia/default.aspx. Issued 02/28/2023. Last accessed 05/17/2023.

[2] Skyclarys™ (Omaveloxolone) Prescribing Information. Reata Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216718Orig1s000lbl.pdf. Last revised 02/2023. Last accessed 05/05/2023.

Appendix I

Vote to Prior Authorize Filspari™ (Sparsentan)

Oklahoma Health Care Authority
June 2023

Market News and Updates[1]

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

- **February 2023:** The FDA granted accelerated approval to Filspari™ (sparsentan) to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g. The approval of Filspari™, granted under the FDA's accelerated approval pathway, is based on improvements in proteinuria compared to an active comparator (irbesartan) in the ongoing Phase 3 PROTECT study.

Filspari™ (Sparsentan) Product Summary[2]

Therapeutic Class: Endothelin and angiotensin II receptor antagonist
Indication(s): To reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR ≥1.5 g/g

- This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether Filspari™ slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

How Supplied: 200mg and 400mg oral tablets

Dosing and Administration:

- Prior to initiating treatment with Filspari™, use of renin-angiotensin-aldosterone system (RAAS) inhibitors or endothelin receptor antagonists (ERAs) should be discontinued.
- Filspari™ should be initiated at 200mg orally once daily. After 14 days, the dose should be increased to the recommended dose of 400mg once daily, as tolerated.
- Tablets should be swallowed whole with water prior to the morning or evening meal.

Cost: The Wholesale Acquisition Cost (WAC) of Filspari™ is $330 per tablet for either the 200mg or 400mg tablet, resulting in an estimated cost of $9,900 per 30 days and $118,800 per year based on the recommended once daily dose.

Recommendations

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

Filspari™ (Sparsentan) Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
    a. Kidney biopsy; and
    b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of rapid disease progression as demonstrated by ≥1 of the following, despite 3 months of maximal supportive care:
    a. Urine protein-to-creatinine (UPCR) ratio ≥1.5g/g; or
    b. Proteinuria >0.75g/day; and
6. Member must be on a stable dose of a maximally tolerated angiotensin convert enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and
7. Prescriber must verify the member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin receptor antagonists (ERAs) prior to initiating treatment with Filspari™; and
8. Member must not be taking strong CYP3A4 inhibitors (e.g., itraconazole) or strong CYP3A4 inducers (e.g., rifampin) concomitantly with Filspari™; and
9. Member must not be taking H2 receptor blockers or proton pump inhibitors (PPIs) concomitantly with Filspari™; and
10. If member is using antacids, they must agree to separate antacid and Filspari™ administration by 2 hours; and
11. Prescriber, pharmacy, and member must be enrolled in the Filspari™ Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. A quantity limit of 30 tablets per 30 days will apply.

[1] Travere Therapeutics, Inc. Travere Therapeutics Announces FDA Accelerated Approval of Filspari™ (Sparsentan), the First and Only Non-immunosuppressive Therapy for the Reduction of Proteinuria in IgA Nephropathy. Available online at: https://ir.travere.com/news-releases/news-release-details/travere-therapeutics-announces-fda-accelerated-approval. Issued 02/17/2023. Last accessed 05/09/2023.
[2] Filspari™ (Sparsentan) Prescribing Information. Travere Therapeutics, Inc. Available online at: https://filspari.com/igan/filspari-prescribing-information.pdf. Last revised 02/2023. Last accessed 05/09/2023.

Appendix J

Vote to Prior Authorize Imjudo® (Tremelimumab-actl) and Krazati® (Adagrasib) and Update the Approval Criteria for the Lung Cancer Medications

Oklahoma Health Care Authority
June 2023

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

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

- **July 2022:** The FDA approved a new indication for Xalkori® (crizotinib) for adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory anaplastic lymphoma kinase (ALK)-positive myofibroblastic tumors (IMT).
- **September 2022:** The FDA approved a new indication for Imfinzi® (durvalumab) in combination with gemcitabine and cisplatin for adult patients with locally advanced or metastatic biliary tract cancer (BTC).
- **September 2022:** The FDA granted accelerated approval for a new indication for Retevmo® (selpercatinib) for adult patients with locally advanced or metastatic solid tumors with a rearranged during transfection (RET) gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.
- **October 2022:** The FDA approved Imjudo® (tremelimumab-actl) in combination with Imfinzi® (durvalumab) for adult patients with unresectable hepatocellular carcinoma (HCC).
- **November 2022:** The FDA approved a new indication for Imjudo® (tremelimumab-actl) in combination with Imfinzi® (durvalumab) and platinum-based chemotherapy for adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutation or ALK genomic tumor aberrations.
- **December 2022:** The FDA approved a new indication for Tecentriq® (atezolizumab) for adult and pediatric patients 2 years of age and older with unresectable or metastatic alveolar soft part sarcoma (ASPS).
- **December 2022:** The FDA granted accelerated approval for Krazati® (adagrasib) for adult patients with KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, who have received at least 1 prior systemic therapy.

News:

- **December 2022:** Genentech, the manufacturer of Tecentriq® (atezolizumab), announced the voluntary withdrawal of the previous accelerated approval for the treatment of adults with locally advanced

or metastatic urothelial carcinoma. The withdrawal is based on the results of the required post-marketing study (IMvigor130), which did not meet the co-primary endpoint of overall survival (OS) for Tecentriq® plus chemotherapy compared with chemotherapy alone in patients with previously untreated locally advanced or metastatic urothelial carcinoma.

Imjudo® (Tremelimumab-actl) Product Summary[9]

Therapeutic Class: Cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody

Indication(s):

- Treatment of adult patients with unresectable HCC, in combination with durvalumab
- Treatment of adult patients with metastatic NSCLC with no sensitizing EGFR mutation or ALK genomic tumor aberrations, in combination with durvalumab and platinum-based chemotherapy

How Supplied:

- 25mg/1.25mL (20mg/mL) solution in a single-dose vial (SDV)
- 300mg/15mL (20mg/mL) solution in a SDV

Dose:

- HCC:
  - Weight ≥30kg: 300mg as a single dose in combination with durvalumab 1,500mg at cycle 1/day 1, followed by durvalumab as a single agent every 4 weeks
  - Weight <30kg: 4mg/kg as a single dose in combination with durvalumab 20mg/kg at cycle 1/day 1, followed by durvalumab as a single agent every 4 weeks
- NSCLC:
  - Weight ≥30kg: 75mg every 3 weeks in combination with durvalumab 1,500mg and platinum-based chemotherapy for 4 cycles, then administer durvalumab 1,500mg every 4 weeks as a single agent with histology-based pemetrexed therapy every 4 weeks, and a fifth dose of Imjudo® 75mg in combination with durvalumab dose 6 at week 16
  - Weight <30kg: 1mg/kg every 3 weeks in combination with durvalumab 20mg/kg and platinum-based chemotherapy for 4 cycles, and then administer durvalumab 20mg/kg every 4 weeks as a single agent with histology-based pemetrexed therapy every 4 weeks, and a fifth dose of Imjudo® 1mg/kg in combination with durvalumab dose 6 at week 16

Cost: The Wholesale Acquisition Cost (WAC) is $2,600 per milliliter. For the treatment of HCC, this results in a cost of $39,000 for the single treatment dose of 300mg for a member weighing ≥30kg. For the treatment of NSCLC, this results in a cost of $9,750 per dose or $48,750 for the recommended 5 doses for a member weighing ≥30kg.

Krazati® (Adagrasib) Product Summary[10]

Therapeutic Class: Inhibitor of RAS GTPase

Indication(s): Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA approved test, who have received at least 1 prior systemic therapy

How Supplied: 200mg oral tablets

Dose: 600mg [(3) 200mg tablets] twice daily

Cost: The WAC is $109.72 per tablet, resulting in a cost of $19,749.60 per 30 days and $236,995.20 per year based on the recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Imjudo® (tremelimumab-actl) and Krazati® (adagrasib) based on recent FDA approvals with the following criteria (shown in red):

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

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

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

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

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

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and

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

The College of Pharmacy also recommends updating the Imfinzi® (durvalumab), Retevmo® (selpercatinib), Tecentriq® (atezolizumab), and Xalkori® (crizotinib) approval criteria based on new FDA approvals (changes shown in red):

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

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

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

1. Diagnosis of unresectable HCC; and
2. Used in combination with tremelimumab-actl.

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

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

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

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

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

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

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

1. Diagnosis of soft tissue sarcoma – IMT; and
2. Member must be 1 year of age or older; and

3. Anaplastic lymphoma kinase (ALK) positive; and
4. Used as a single agent only.

Next, the College of Pharmacy recommends updating the Alunbrig® (brigatinib), Gavreto® (pralsetinib), Rozlytrek® (entrectinib), Tagrisso® (osimertinib), Vizimpro® (dacomitinib), and Xalkori® (crizotinib) approval criteria to be more consistent with clinical practice and to clarify appropriate use as a single agent (changes shown in red):

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

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

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

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

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

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

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

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

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

1. Diagnosis of solid tumors; and
2. Member must be 12 years of age or older; and
3. Neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation; and
4. Metastatic or not a surgical candidate; and
5. Progressed following treatment or have no satisfactory alternative therapy; and

6. As a single agent.

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

1. Diagnosis of NSCLC; and
    a. As adjuvant therapy following tumor resection in members with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations; or
2. Diagnosis of metastatic NSCLC; and
    a. EGFR T790M mutation-positive disease; or
    b. EGFR exon 19 deletions or exon 21 L858R mutations; and
3. As a single agent.

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

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

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

1. Members ~~1 to 21 years of age~~ 1 year of age or older:
    a. Diagnosis of systemic ALCL that is anaplastic lymphoma kinase (ALK)-positive; and
    b. Relapsed or refractory disease; ~~or~~ and
~~2. Members older than 21 years of age:~~
    ~~a. Diagnosis of systemic Anaplastic Large Cell Lymphoma (ALCL) that is anaplastic lymphoma kinase (ALK)-positive; and~~
    ~~b. Second-line or initial palliative intent therapy and subsequent therapy.~~
3. As a single agent.

Next, the College of Pharmacy recommends the prior authorization of Sandoz pemetrexed 25mg/mL solution products (billed using J9297), based on net cost, with criteria similar to Pemfexy® (pemetrexed) (changes shown in red):

Pemfexy® (Pemetrexed; J9304) and Pemetrexed 25mg/mL Solution (J9297 - Sandoz) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use Alimta® (pemetrexed; J9305) and other preferred pemetrexed 25mg/mL

solution products (J9294 - Hospira, J9296 - Accord, J9314 - Teva) that do not require prior authorization must be provided.

Lastly, the College of Pharmacy recommends the removal of criteria for Tecentriq® (atezolizumab) for a diagnosis of urothelial carcinoma based on the FDA withdrawal of the accelerated approval for this indication (changes shown in red):

~~**Tecentriq® (Atezolizumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:**~~

~~1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and~~
~~2. Progressed on or following platinum-containing chemotherapy or cisplatin ineligible members.~~

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[9] Imjudo® (Tremelimumab-actl) Prescribing Information. AstraZeneca. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761270s000lbl.pdf. Last revised 11/2022. Last accessed 05/19/2023.
[10] Krazati® (Adagrasib) Prescribing Information. Mirati Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/216340Orig1s000Corrected_lbl.pdf. Last revised 12/2022. Last accessed 05/19/2023.

Appendix K

Calendar Year 2022 Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Adstiladrin® (Nadofaragene Firadenovec-vncg) and Elahere™ (Mirvetuximab Soravtansine-gynx)

Oklahoma Health Care Authority
June 2023

Current Prior Authorization Criteria

Utilization data for Afinitor® (everolimus) and Trodelvy® (sacituzumab govitecan-hziy) and approval criteria for indications other than genitourinary and gynecologic cancers can be found in the September 2022 Drug Utilization Review (DUR) Board packet. These medications and criteria are reviewed annually with the breast cancer medications. Utilization data for Bavencio® (avelumab), Keytruda® (pembrolizumab), Mekinist® (trametinib), Opdivo® (nivolumab), and Yervoy® (ipilimumab) and approval criteria for indications other than genitourinary and gynecologic cancers can be found in the December 2022 DUR Board packet. These medications and criteria are reviewed annually with the skin cancer medications.

Afinitor® (Everolimus) Approval Criteria [Renal Angiomyolipoma (AML) and Tuberous Sclerosis Complex (TSC) Diagnosis]:

1. Diagnosis of AML and TSC; and
2. Not requiring immediate surgery; and
3. Used in pediatric and adult members 1 year of age and older; and
4. Authorizations will be for the duration of 6 months at which time reauthorization may be granted if the member does not show evidence of progressive disease while on everolimus therapy.

Afinitor® (Everolimus) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC; and
2. Failure of treatment with sunitinib or sorafenib; and
3. Everolimus may also be approved to be used in combination with lenvatinib for advanced RCC; and
4. Authorizations will be for the duration of 6 months at which time reauthorization may be granted if the member does not show evidence of progressive disease while on everolimus therapy.

Balversa® (Erdafitinib) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and

2. Tumor positive for *FGFR2* or *FGFR3* genetic mutation; and
3. Used as second-line or greater therapy including:
    a. Following at least 1 line of platinum-containing chemotherapy; and
    b. Within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

Bavencio® (Avelumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC; and
2. Must be used as first-line treatment; and
3. Must be used in combination with axitinib.

Bavencio® (Avelumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and
2. Disease has progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy; and
3. Used as maintenance therapy for members not progressing on first-line platinum-containing regimen.

Cabometyx® (Cabozantinib) Approval Criteria:

1. For cabozantinib monotherapy:
    a. Diagnosis of advanced renal cell carcinoma (RCC); or
    b. Diagnosis of advanced hepatocellular carcinoma (HCC); and
        i. Member has previously received sorafenib; or
    c. Diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC) in adults and pediatric members 12 years of age and older; and
        i. Disease has progressed following prior vascular endothelial growth factor (VEGF)-targeted therapy; and
        ii. Disease is radioactive iodine-refractory or member is ineligible for radioactive iodine; or
2. For cabozantinib in combination with nivolumab:
    a. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with advanced RCC; and
    b. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.

Camcevi® (Leuprolide) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of advanced prostate cancer; and
2. A patient-specific, clinically significant reason why the member cannot use Eligard® (leuprolide acetate), Firmagon® (degarelix), and Lupron Depot® (leuprolide acetate) must be provided [reason(s) must address each medication].

Erleada® (Apalutamide) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of non-metastatic CRPC; or
2. Castration-resistant or disease progression while on androgen deprivation therapy (ADT); and
3. Prostate specific antigen doubling time of ≤10 months; and
4. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Erleada® (Apalutamide) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC; and
2. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Fotivda® (Tivozanib) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of relapsed or refractory advanced RCC; and
2. Member has received at least 2 prior systemic therapies; and
3. As a single agent.

Jelmyto® (Mitomycin) Approval Criteria [Urothelial Cancer Diagnosis]:

1. Diagnosis of non-metastatic upper urinary tract tumor; and
2. Must be a single, residual, low-grade, low-volume (5 to 15mm) tumor; and
3. Member is not a candidate for nephroureterectomy; and
4. Initial approvals will be for the duration of 6 weeks. With documentation from the prescriber of complete response 3 months after initial treatment, subsequent approvals may be authorized for once monthly use for up to 11 additional instillations.

Jemperli (Dostarlimab-gxly) Approval Criteria [Endometrial Cancer Diagnosis]:

1. Diagnosis of advanced, recurrent, or metastatic endometrial cancer; and
2. Mismatch repair deficient (dMMR) disease; and
3. Disease has progressed on or following prior treatment with a platinum-containing regimen.

Jemperli (Dostarlimab-gxly) Approval Criteria [Mismatch Repair Deficient (dMMR) Solid Tumor Diagnosis]:

1. Diagnosis of recurrent or advanced solid tumors that are dMMR; and
2. Disease has progressed on or following prior treatment; and
3. There are no satisfactory treatment alternatives for the member.

Jevtana® (Cabazitaxel) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Previous treatment with a docetaxel-containing regimen; and
3. Used in combination with prednisone.

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

1. Diagnosis of recurrent or metastatic cervical cancer; and
2. Tumor must express programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1]; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
    a. Disease progression on or after chemotherapy; or
    b. As first-line therapy in combination with chemotherapy, with or without bevacizumab.

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

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

Keytruda® (Pembrolizumab) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of high-risk, NMIBC; and
2. Member must have failed therapy with Bacillus Calmette-Guerin (BCG)-therapy; and
3. Member must be ineligible for or has elected not to undergo cystectomy.

Keytruda® (Pembrolizumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

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

2. Diagnosis of RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

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

1. Member must have 1 of the following:
    a. Locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy; or
    b. Within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; or
    c. 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; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)].

Lenvima® (Lenvatinib) Approval Criteria [Differentiated Thyroid Cancer (DTC) Diagnosis]:

1. Locally recurrent or metastatic disease; and
2. Disease progression on prior treatment; and
3. Radioactive iodine-refractory disease.

Lenvima® (Lenvatinib) Approval Criteria [Endometrial Carcinoma Diagnosis]:

1. Advanced disease with progression on prior systemic therapy; and
2. Member is not a candidate for curative surgery or radiation; and
3. Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and
4. Used in combination with pembrolizumab.

Lenvima® (Lenvatinib) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Unresectable disease; and
2. First-line treatment.

Lenvima® (Lenvatinib) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC; and
    a. Used in combination with pembrolizumab; or
    b. Following 1 prior anti-angiogenic therapy; and
        i. Used in combination with everolimus.

Lynparza® (Olaparib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-negative, high-risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy; and
    a. Used in the adjuvant setting; and
    b. Positive test for a germline BRCA-mutation (gBRCAm); and
    c. Maximum treatment duration of 1 year; or
2. Diagnosis of metastatic breast cancer; and
    a. Member must have shown progression on previous chemotherapy; and
    b. Members with hormone receptor positive disease must have failed prior endocrine therapy or are considered to not be a candidate for endocrine therapy.

Lynparza® (Olaparib) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Member must have failed previous first-line therapy; and
3. Used as a single agent except for the following:
    a. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. Disease must be positive for a mutation in a homologous recombination gene.

Lynparza® (Olaparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. **Treatment of Advanced Recurrent/Refractory Disease:**
    a. Diagnosis of deleterious or suspected deleterious germline BRCA-mutated (*gBRCAm*), advanced disease; and
    b. Previous treatment with ≥2 prior lines of chemotherapy (prior chemotherapy regimens should be documented on the prior authorization request); and
    c. A quantity limit based on FDA approved dosing will apply; or
2. **Maintenance Treatment of Advanced Disease:**
    a. Disease must be in a complete or partial response to primary chemotherapy; and

i. Used as a single agent in members with a diagnosis of deleterious or suspected deleterious *gBRCAm* or somatic BRCA-mutated (*sBRCAm*), advanced ovarian cancer; or
ii. Used in combination with bevacizumab following a primary therapy regimen that included bevacizumab; or

b. Complete or partial response to second-line or greater platinum-based chemotherapy (no mutation required); and
c. A quantity limit based on FDA approved dosing will apply.

Lynparza® (Olaparib) Approval Criteria [Pancreatic Cancer Diagnosis]:

1. Diagnosis of metastatic pancreatic adenocarcinoma with known germline BRCA1/BRCA2 mutation; and
2. Maintenance therapy as a single agent; and
3. In members who have not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.

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

1. Diagnosis of persistent disease or recurrent low-grade serous carcinoma; and
2. Meets 1 of the following:
   a. Immediate treatment for serially rising CA-125 in members who previously received chemotherapy; or
   b. Progression on primary, maintenance, or recurrence therapy; or
   c. Stable or persistent disease (if not on maintenance therapy); or
   d. Complete remission and relapse after receiving prior chemotherapy.

Nubeqa® (Darolutamide) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of non-metastatic CRPC; and
2. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Opdivo® (Nivolumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Member has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)]; and
2. Used in 1 of the following settings:
   a. For nivolumab monotherapy:
      i. Diagnosis of relapsed or surgically unresectable stage IV disease; and
      ii. Failed prior therapy with 1 of the following medications:
         1. Sunitinib; or
         2. Sorafenib; or

3. Pazopanib; or
4. Axitinib; or

b. For nivolumab use in combination with ipilimumab:
    i. Diagnosis of relapsed or surgically unresectable stage IV disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; or
c. For nivolumab use in combination with cabozantinib:
    i. Diagnosis of relapsed or surgically unresectable stage IV disease in the initial treatment of members with advanced RCC; and
    ii. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years; and

3. Dose as follows:
    a. Single agent: 240mg every 2 weeks or 480mg every 4 weeks; or
    b. In combination with ipilimumab: nivolumab 3mg/kg followed by ipilimumab 1mg/kg on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240mg every 2 weeks or 480mg every 4 weeks thereafter; or
    c. In combination with cabozantinib: cabozantinib 40mg once daily with nivolumab 240mg every 2 weeks or 480mg every 4 weeks; nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.

Opdivo® (Nivolumab) Approval Criteria [Urothelial Bladder Cancer Diagnosis]:

1. Diagnosis of urothelial carcinoma; and
    a. Member has undergone radical resection; and
    b. Disease is at high risk of recurrence; or
2. Diagnosis of metastatic or unresectable locally advanced disease; and
    a. Used as second-line or greater therapy; and
    b. Previous failure of a platinum-containing regimen; and
    c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)].

Orgovyx® (Relugolix) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of advanced prostate cancer; and
2. A patient-specific, clinically significant reason why the member cannot use Eligard® (leuprolide acetate), Firmagon® (degarelix), and Lupron Depot® (leuprolide acetate) must be provided [reason(s) must address each medication]; and
3. A quantity limit of 30 tablets per 30 days will apply. Upon meeting approval criteria, a quantity limit override will be approved for the day 1 loading dose of 360mg.

Padcev® (Enfortumab Vedotin-ejfv) Approval Criteria [Urothelial Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial cancer; and
2. Previously received a programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced, or metastatic setting.

Pluvicto® (Lutetium Lu 177 Vipivotide Tetraxetan) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC); and
2. Member must have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy.

Provenge® (Sipuleucel-T) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Asymptomatic or minimally symptomatic; and
3. No hepatic metastases; and
4. Life expectancy of >6 months.

Rubraca® (Rucaparib) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Member must have failed previous first-line therapy; and
3. Used as a single agent except for the following:
    a. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. Disease must be positive for a mutation in BRCA1 or BRCA2.

Rubraca® (Rucaparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. **Treatment of Advanced Recurrent/Refractory Disease:**
    a. Diagnosis of recurrent or refractory disease; and
    b. Previous treatment with ≥2 prior lines of chemotherapy (prior chemotherapy regimens should be documented on the prior authorization request); and
    c. Disease is associated with a deleterious or suspected deleterious BRCA mutation; and
    d. Used as a single agent; or
2. **Maintenance Treatment of Advanced Disease:**
    a. Diagnosis of advanced or recurrent disease; and
    b. Disease must be in a complete or partial response to platinum-based chemotherapy; and
    c. Used as a single agent.

Tivdak® (Tisotumab Vedotin-tftv) Approval Criteria [Cervical Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic cervical cancer; and
2. Disease has progressed on or after chemotherapy.

Trodelvy® (Sacituzumab Govitecan-hziy) Approval Criteria [Urothelial Cancer Diagnosis]:

1. Diagnosis of unresectable, locally advanced, or metastatic disease; and
2. Member must have previously received platinum-containing chemotherapy; and
3. Member must have previously received either a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.

Welireg™ (Belzutifan) Approval Criteria [von Hippel-Landau (VHL) Disease Diagnosis]:

1. Diagnosis of VHL disease; and
2. Diagnosis of either renal cell carcinoma, central nervous system hemangioblastomas, or pancreatic neuroendocrine tumor; and
3. Does not require immediate surgery.

Xofigo® (Radium-223 Dichloride) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Symptomatic bone metastases; and
3. No known visceral metastatic disease; and
4. Prescriber must verify radium-223 dichloride will not be used in combination with chemotherapy; and
5. Absolute neutrophil count ≥1.5 x 10^9/L, platelet count ≥100 x 10^9/L, and hemoglobin ≥10g/dL; and
6. Approvals will be for the duration of 6 months at which time additional authorization may be granted if the prescriber documents the following:
    a. The member has not shown evidence of progressive disease while on radium-223 dichloride therapy; and
    b. Member must have an absolute neutrophil count ≥1 x 10^9/L, platelet count ≥100 x 10^9/L (radium-223 dichloride should be delayed 6 to 8 weeks otherwise).

Xtandi® (Enzalutamide) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of CRPC.

Xtandi® (Enzalutamide) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC.

Yervoy® (Ipilimumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of relapsed or surgically unresectable stage IV disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; and
2. Used in combination with nivolumab; and
3. Member has not previously failed programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Dose as follows: nivolumab 3mg/kg followed by ipilimumab 1mg/kg on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240mg every 2 weeks or 480mg every 4 weeks.

Yonsa® (Abiraterone Acetate) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Zejula® (Niraparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. **Treatment of Advanced Recurrent/Refractory Disease as a Single Agent:**
    a. Diagnosis of recurrent or refractory disease; and
    b. Previous treatment with ≥3 prior lines of chemotherapy (prior chemotherapy regimens should be documented on the prior authorization request); and
    c. Diagnosis is associated with homologous recombination deficiency (HRD) positive status defined by either:
        i. Deleterious or suspected deleterious BRCA mutation; or
        ii. Genomic instability and progression >6 months after response to last platinum-based chemotherapy; and
    d. Used as a single agent; or
2. **Treatment of Advanced Recurrent/Refractory Disease in Combination with Bevacizumab:**
    a. Used in combination with bevacizumab for platinum-sensitive persistent disease or recurrence; and
    b. Meets 1 of the following:
        i. As immediate treatment for serially rising CA-125 in members who previously received chemotherapy, or
        ii. Evidence of radiographic and/or clinical relapse in members with previous complete remission and relapse ≥6 months after completing prior chemotherapy; or
3. **Maintenance Treatment of Advanced Disease:**

a. Diagnosis of advanced or recurrent disease; and
b. Disease must be in a complete or partial response to platinum chemotherapy; and
c. Used as a single agent.

Zytiga® (Abiraterone) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Zytiga® (Abiraterone) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic, high-risk, CSPC; and
2. Abiraterone must be used in combination with a corticosteroid.

Utilization of Genitourinary and Gynecologic Cancer Medications: Calendar Year 2022

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

Calendar Year Comparison: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	53	206	$2,834,083.59	$13,757.69	$458.59	17,550	6,180
2022	108	502	$7,510,717.61	$14,961.59	$495.86	40,734	15,147
% Change	**103.80%**	**143.70%**	**165.00%**	**8.80%**	**8.10%**	**132.10%**	**145.10%**
Change	**55**	**296**	**$4,676,634.02**	**$1,203.90**	**$37.27**	**23,184**	**8,967**

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

- Aggregate drug rebates collected during calendar year 2022 for genotourinary and gynecologic cancer medications: $2,150,428.46.[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.

Calendar Year Comparison: Medical Claims

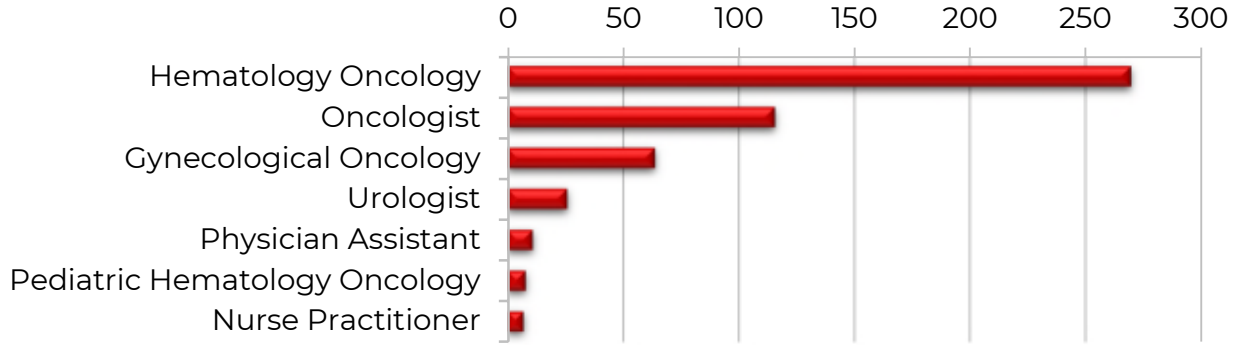
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	4	10	$98,889.57	$9,888.96	2.5
2022	11	35	$430,758.38	$12,307.38	3.18
% Change	**175.00%**	**250.00%**	**335.60%**	**24.46%**	**27.20%**
Change	**7**	**25**	**$331,868.81**	**$2,418.42**	**0.68**

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

Demographics of Members Utilizing Genitourinary and Gynecologic Cancer Medications: Pharmacy Claims

- Due to the limited number of members utilizing genitourinary and gynecologic cancer medications during calendar year 2022, detailed demographic information could not be provided.

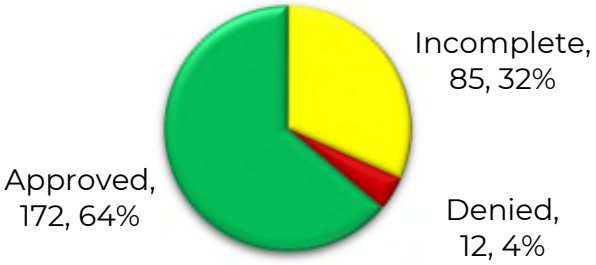
Top Prescriber Specialties of Genitourinary and Gynecologic Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Genitourinary and Gynecologic Cancer Medications

There were 269 prior authorization requests submitted for genitourinary and gynecologic cancer medications during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Camcevi® (leuprolide mesylate): January 2027
- Xtandi® (enzalutamide): August 2027
- Lynparza® (olaparib): December 2029
- Jelmyto® (mitomycin): January 2031
- Jevtana® (cabazitaxel): April 2031
- Cabometyx® (cabozantinib): July 2033
- Yonsa® (abiraterone acetate): May 2034
- Welireg™ (belzutifan): September 2034
- Pluvicto® (lutetium lu-177 vipivotide tetraxetan): October 2034
- Rubraca® (rucaparib): August 2035
- Lenvima® (lenvatinib): February 2036
- Orgovyx® (relugolix): September 2037
- Balversa® (erdafitinib): February 2038
- Nubeqa® (darolutamide): February 2038
- Zejula® (niraparib): March 2038
- Erleada® (apalutamide): April 2038
- Fotivda® (tivozanib): November 2039

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

- **July 2021:** The FDA approved Padcev® (enfortumab vedotin-ejfv) for a new indication for the treatment of adult patients with locally advanced or metastatic urothelial cancer who are ineligible for cisplatin-containing chemotherapy and have previously received 1 or more prior lines of therapy.
- **August 2022:** The FDA approved Nubeqa® (darolutamide) for a new indication, in combination with docetaxel, for adult patients with metastatic hormone-sensitive prostate cancer (mHSPC).
- **November 2022:** The FDA granted accelerated approval to Elahere™ (mirvetuximab soravtansine-gynx) for the treatment of adult patients with folate receptor alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received 1 to 3 prior systemic treatment regimens. Patients should be selected for therapy based on an FDA-approved test.
- **December 2022:** The FDA approved Adstiladrin® (nadofaragene firadenovec-vncg) for adult patients with high-risk Bacillus Calmette-Guérin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
- **February 2023:** The FDA approved a new 240mg strength tablet of Erleada® (apalutamide) for the treatment of metastatic castration-sensitive prostate cancer (CSPC) and non-metastatic castration-resistant prostate cancer (CRPC). Erleada® was previously available as

60mg tablets which required the use of 4 tablets to achieve the recommended daily dose of 240mg.

- **April 2023:** The FDA granted accelerated approval for a new indication for Padcev® (enfortumab vedotin-ejfv), in combination with pembrolizumab, for patients with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy.
- **April 2023:** The FDA approved a new tablet formulation of Zejula® (niraparib) for the same indications as Zejula® capsules. Zejula® tablets will be available in 100mg, 200mg, and 300mg strengths. Previously, Zejula® was only available as a 100mg capsule.
- **May 2023:** The FDA approved Lynparza® (olaparib) for a new indication, in combination with abiraterone and prednisone (or prednisolone), for adult patients with deleterious or suspected deleterious BRCA-mutated metastatic CRPC, as determined by an FDA-approved companion diagnostic test.

News:

- **June 2022:** The indication for Rubraca® (rucaparib) for the treatment of adult patients with deleterious BRCA mutation-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 2 or more chemotherapies has been voluntarily withdrawn by the FDA. The withdrawal was based on potential detrimental impact on overall survival in this patient population.
- **August 2022:** The *Prescribing Information* for Lenvima® (lenvatinib) was updated to specify use for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR), as determined by an FDA-approved test, or not microsatellite instability-high (MSI-H).
- **August 2022:** The indication for Lynparza® (olaparib) for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated ovarian cancer who have been treated with 3 or more prior lines of chemotherapy has been voluntarily withdrawn by the FDA. The withdrawal was based on potential detrimental impact on overall survival in this patient population.
- **September 2022:** The indication for Zejula® (niraparib) for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 3 or more prior chemotherapy regimens has been voluntarily withdrawn by the FDA. The withdrawal was based on potential detrimental impact on overall survival in this patient population.
- **December 2022:** The maintenance treatment indication for Zejula® (niraparib) for patients with recurrent ovarian cancer has been restricted to patients with a germline BRCA mutation only.

- **December 2022:** The maintenance treatment indication for Rubraca® (rucaparib) for patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy has been restricted to patients with a tumor BRCA mutation only.

Adstiladrin® (Nadofaragene Firadenovec-vncg) Product Summary[16]

Therapeutic Class: Non-replicating adenoviral vector-based gene therapy

Indication(s): High-risk BCG-unresponsive NMIBC with CIS with or without papillary tumors

How Supplied: Single-use vials containing suspension for intravesical instillation, with each vial containing a nominal concentration of 3×10^{11} viral particles (vp)/mL and an extractable volume not less than 20mL

Dosing and Administration:
- Recommended dose is 75mL of Adstiladrin® instilled in the bladder once every 3 months
- For intravesical instillation only, not for intravenous, topical, or oral administration
- Should be left in the bladder for 1 hour following each instillation

Cost: Cost information for Adstiladrin® is not yet available.

Elahere™ (Mirvetuximab Soravtansine-gynx) Product Summary[17]

Therapeutic Class: FRα-directed antibody and microtubule inhibitor conjugate

Indication(s): Treatment of patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received 1 to 3 prior systemic treatment regimens

How Supplied: 100mg/20mL (5mg/mL) solution in a single-dose vial (SDV)
Dose: 6mg/kg [based on adjusted ideal body weight (AIBW)] once every 3 weeks by intravenous (IV) infusion until disease progression or unacceptable toxicity

Cost: The Wholesale Acquisition Cost (WAC) of Elahere™ is $311 per milliliter or $6,220 per SDV. This results in an estimated annual cost of $528,700 based on the recommended dosing for a member with an AIBW of 80kg.

Recommendations

The College of Pharmacy recommends the prior authorization of Adstiladrin® (nadofaragene firadenovec-vncg) and Elahere™ (mirvetuximab soravtansine-gynx) with the following criteria (listed in red):

Adstiladrin® (Nadofaragene Firadenovec-vncg) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of NMIBC with carcinoma in situ (CIS) with or without papillary tumors; and
2. High-risk disease that was unresponsive to prior Bacillus Calmette-Guérin (BCG) therapy.

Elahere™ (Mirvetuximab Soravtansine-gynx) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. Diagnosis of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2. Tumor is folate receptor alpha (FRα) positive; and
3. Member has received 1 to 3 prior systemic treatment regimens.

Next, the College of Pharmacy recommends updating the approval criteria for Lenvima® (lenvatinib), Lynparza® (olaparib), Nubeqa® (darolutamide), and Padcev® (enfortumab vedotin-ejfv) prior authorization criteria based on recent FDA approvals and label updates (changes and new criteria noted in red):

Lenvima® (Lenvatinib) Approval Criteria [Endometrial Carcinoma Diagnosis]:

1. Advanced disease with progression on prior systemic therapy; and
2. Member is not a candidate for curative surgery or radiation; and
3. Disease is mismatch repair proficient (pMMR) or is not microsatellite instability-high (MSI-H) ~~or mismatch repair deficient (dMMR)~~; and
4. Used in combination with pembrolizumab.

Lynparza® (Olaparib) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Used in 1 of the following settings:
    a. Member must have failed previous first-line therapy; and
        i. Used as a single agent except for the following:
            1. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
        ii. Disease must be positive for a mutation in a homologous recombination gene; or

b. Used in combination with abiraterone and prednisone (or prednisolone); and
    i. Disease must be positive for a deleterious or suspected deleterious BRCA mutation.

Nubeqa® (Darolutamide) Approval Criteria [Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) Diagnosis]:

1. Diagnosis of mHSPC in combination with docetaxel; and
2. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Padcev® (Enfortumab Vedotin-ejfv) Approval Criteria [Urothelial Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial cancer; and
2. Used in 1 of the following settings:
    a. As a single agent and member has previously received a programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced, or metastatic setting; or
    b. As a single agent and member has received at least 1 prior therapy and is ineligible for cisplatin-containing chemotherapy; or
    c. Used in combination with pembrolizumab and member is ineligible for cisplatin-containing chemotherapy.

Additionally, the College of Pharmacy recommends updating the approval criteria for Lynparza® (olaparib), Rubraca® (rucaparib), and Zejula® (niraparib) for ovarian, fallopian tube, or primary peritoneal cancer based on the FDA withdrawals and restrictions for these indications (changes shown in red):

Lynparza® (Olaparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

~~**1. Treatment of Advanced Recurrent/Refractory Disease:**~~
~~a. Diagnosis of deleterious or suspected deleterious germline BRCA-mutated (*gBRCAm*), advanced disease; and~~
~~b. Previous treatment with ≥2 prior lines of chemotherapy (prior chemotherapy regimens should be documented on the prior authorization request); and~~
~~c. A quantity limit based on FDA approved dosing will apply; or~~

2. Maintenance Treatment of Advanced Disease:
    a. Disease must be in a complete or partial response to primary chemotherapy; and
        i. Used as a single-agent in members with a diagnosis of deleterious or suspected deleterious germline BRCA-mutated (*gBRCAm)* or somatic BRCA-mutated (*sBRCAm*), advanced ovarian cancer; or

ii. Used in combination with bevacizumab following a primary therapy regimen that included bevacizumab; or

b. Complete or partial response to second-line or greater platinum-based chemotherapy (no mutation required); and

c. A quantity limit based on FDA approved dosing will apply.

Rubraca® (Rucaparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

~~**1. Treatment of Advanced Recurrent/Refractory Disease:**~~

~~a. Diagnosis of recurrent or refractory disease; and~~

~~b. Previous treatment with ≥2 prior lines of chemotherapy (prior chemotherapy regimens should be documented on the prior authorization request); and~~

~~c. Disease is associated with a deleterious or suspected deleterious BRCA mutation; and~~

~~d. Used as a single agent; or~~

2. Maintenance Treatment of ~~Advanced~~ Recurrent Disease:

a. Diagnosis of ~~advanced or~~ recurrent disease; and

b. Disease must be in a complete or partial response to platinum-based chemotherapy; and

c. Positive for a BRCA mutation; and

d. Used as a single agent.

Zejula® (Niraparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

~~**1. Treatment of Advanced Recurrent/Refractory Disease as a Single Agent:**~~

~~a. Diagnosis of recurrent or refractory disease; and~~

~~b. Previous treatment with ≥3 prior lines of chemotherapy (prior chemotherapy regimens should be documented on the prior authorization request); and~~

~~c. Diagnosis is associated with homologous recombination deficiency (HRD) positive status defined by either:~~

~~i. Deleterious or suspected deleterious BRCA mutation; or~~

~~ii. Genomic instability and progression >6 months after response to last platinum-based chemotherapy; and~~

~~d. Used as a single agent; or~~

~~**2. Treatment of Advanced Recurrent/Refractory Disease in Combination with Bevacizumab:**~~

~~a. Used in combination with bevacizumab for platinum-sensitive persistent disease or recurrence; and~~

~~b. Meets 1 of the following:~~

~~i. As immediate treatment for serially rising CA-125 in members who previously received chemotherapy, or~~

ii. ~~Evidence of radiographic and/or clinical relapse in members with previous complete remission and relapse ≥6 months after completing prior chemotherapy; or~~

3. **Maintenance Treatment of Advanced Disease:**
   a. Diagnosis of advanced or recurrent disease; and
   b. Disease must be in a complete or partial response to platinum chemotherapy; and
   c. If used for maintenance following recurrence:
      i. Must be positive for a BRCA mutation (this does not apply if used after first-line therapy); and
   d. Used as a single agent.

Lastly, the College of Pharmacy recommends updating the Zytiga® (abiraterone) approval criteria based on net cost (changes shown in red):

Zytiga® (Abiraterone) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Zytiga® (Abiraterone) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic, high-risk, CSPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Utilization Details of Genitourinary and Gynecologic Medications: Calendar Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ENZALUTAMIDE PRODUCTS						
XTANDI CAP 40MG	65	11	$818,135.20	$12,586.70	5.91	10.89%
XTANDI TAB 40MG	25	8	$324,524.23	$12,980.97	3.13	4.32%
XTANDI TAB 80MG	17	4	$221,193.46	$13,011.38	4.25	2.95%
SUBTOTAL	**107**	**23**	**$1,363,852.89**	**$12,746.29**	**4.65**	**18.16%**
CABOZANTINIB PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CABOMETYX TAB 40MG	52	15	$1,206,544.21	$23,202.77	3.47	16.06%
CABOMETYX TAB 60MG	31	9	$720,573.81	$23,244.32	3.44	9.59%
CABOMETYX TAB 20MG	17	4	$396,047.64	$23,296.92	4.25	5.27%
SUBTOTAL	**100**	**28**	**$2,323,165.66**	**$23,231.66**	**3.57**	**30.93%**
ABIRATERONE PRODUCTS						
ABIRATERONE TAB 250MG	41	13	$10,159.46	$247.79	3.15	0.14%
ZYTIGA TAB 500MG	25	3	$272,402.75	$10,896.11	8.33	3.63%
ABIRATERONE TAB 500MG	23	4	$124,203.20	$5,400.14	5.75	1.65%
SUBTOTAL	**89**	**20**	**$406,765.41**	**$4,570.40**	**4.45**	**5.42%**
OLAPARIB PRODUCTS						
LYNPARZA TAB 150MG	65	14	$915,488.82	$14,084.44	4.64	12.19%
LYNPARZA TAB 100MG	23	3	$290,456.45	$12,628.54	7.67	3.87%
SUBTOTAL	**88**	**17**	**$1,205,945.27**	**$13,703.92**	**5.18**	**16.06%**
LENVATINIB PRODUCTS						
LENVIMA CAP 20MG	26	4	$550,851.66	$21,186.60	6.5	7.33%
LENVIMA CAP 12MG	14	7	$297,164.74	$21,226.05	2	3.96%
LENVIMA CAP 14MG	11	4	$232,184.01	$21,107.64	2.75	3.09%
LENVIMA CAP 10MG	8	3	$170,190.28	$21,273.79	2.67	2.27%
LENVIMA CAP 4MG	8	1	$167,267.28	$20,908.41	8	2.23%
LENVIMA CAP 8MG	3	2	$63,578.73	$21,192.91	1.5	0.85%
LENVIMA CAP 18MG	1	1	$20,929.91	$20,929.91	1	0.28%
SUBTOTAL	**71**	**22**	**$1,502,166.61**	**$21,157.28**	**3.23**	**20.00%**
APALUTAMIDE PRODUCTS						
ERLEADA TAB 60MG	27	4	$364,047.09	$13,483.23	6.75	4.85%
SUBTOTAL	**27**	**4**	**$364,047.09**	**$13,483.23**	**6.75**	**4.85%**
NIRAPARIB PRODUCTS						
ZEJULA CAP 100MG	15	6	$236,665.22	$15,777.68	2.5	3.15%
SUBTOTAL	**15**	**6**	**$236,665.22**	**$15,777.68**	**2.5**	**3.15%**
BELZUTIFAN PRODUCTS						
WELIREG TAB 40MG	4	1	$105,645.64	$26,411.41	4	1.41%
SUBTOTAL	**4**	**1**	**$105,645.64**	**$26,411.41**	**4**	**1.41%**
RELUGOLIX PRODUCTS						
ORGOVYX TAB 120MG	1	1	$2,463.82	$2,463.82	1	0.03%
SUBTOTAL	**1**	**1**	**$2,463.82**	**$2,463.82**	**1**	**0.03%**
TOTAL	**502**	**108***	**$7,510,717.61**	**$14,961.59**	**4.65**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ENFORTUMAB VEDOTIN-EJFV J9177	11	2	$73,693.20	$6,699.38	5.5
TISOTUMAB VEDOTIN-TFTV J9273	7	1	$17,492.12	$2,498.87	3.5

PRODUCT UTILIZED	TOTAL CLAIMS[+]	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
MITOMYCIN PYELOCALYCEAL J9281	6	1	$135,979.20	$22,663.20	6
DOSTARLIMAB-GXLY J9272	5	1	$55,155.50	$11,031.10	5
CABAZITAXEL J9043	4	4	$41,427.30	$10,356.83	1
SIPULEUCEL-T Q2043	2	1	$107,011.06	$53,505.53	2
TOTAL	**35**	**11**	**$430,758.38**	**$12,307.38**	**3.18**

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

[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 05/2023. Last accessed 05/08/2023.
[2] U.S. FDA. FDA Grants Regular Approval to Enfortumab Vedotin-ejfv for Locally Advanced or Metastatic Urothelial Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-regular-approval-enfortumab-vedotin-ejfv-locally-advanced-or-metastatic-urothelial-cancer. Issued 07/09/2021. Last accessed 05/08/2023.
[3] U.S. FDA. FDA Approves Darolutamide Tablets for Metastatic Hormone-Sensitive Prostate Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-darolutamide-tablets-metastatic-hormone-sensitive-prostate-cancer. Issued 08/05/2022. Last accessed 05/08/2023.

[4] U.S. FDA. FDA Grants Accelerated Approval to Mirvetuximab Soravtansine-gynx for Frα Positive, Platinum-Resistant Epithelial Ovarian, Fallopian Tube, or Peritoneal Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-mirvetuximab-soravtansine-gynx-fra-positive-platinum-resistant. Issued 11/14/2022. Last accessed 05/08/2023.
[5] Janssen Pharmaceutical Companies. Erleada® (Apalutamide), First-and-Only Next-Generation Androgen Receptor Inhibitor with Once-Daily, Single-Tablet Option Now Available in the U.S. Available online at: https://www.prnewswire.com/news-releases/erleada-apalutamide-first-and-only-next-generation-androgen-receptor-inhibitor-with-once-daily-single-tablet-option-now-available-in-the-us-301787489.html. Issued 04/03/2023. Last accessed 05/08/2023.
[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 05/08/2023.
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Appendix L

Calendar Year 2022 Annual Review of the SoonerCare Pharmacy Benefit

Oklahoma Health Care Authority
June 2023

Summary[1]

During calendar year (CY) 2022, prescription drugs accounted for $1 billion of the approximately $7.65 billion in total SoonerCare spending. On July 1, 2021, the SoonerCare benefit expanded across the state to include the Healthy Adult Program (HAP). The expanded population is included in the CY 2021 and CY 2022 data. The average monthly enrollment increased approximately 20% from CY 2021 to CY 2022, which can be attributed at least partly to the expansion of Oklahoma Medicaid. Additionally, some of the increase may be due to the federal public health emergency (PHE) that was declared at the beginning of the Covid-19 pandemic and ended on May 11, 2023. During the PHE, Medicaid agencies were required to continue health care coverage for members even if their eligibility changed and they no longer qualified for coverage. Comparing SoonerCare pharmacy data from CY 2021, the total reimbursement increased approximately 44% from CY 2021 to CY 2022. The annual pharmacy cost per member increased from $652.12 in CY 2021 to $783.32 in CY 2022, which is a 20.1% increase. Additionally, the specialty pharmaceutical products total pharmacy reimbursement continues to be on the incline as a result of orphan drug approvals for rare diseases, as well as numerous new oncology medications and the high costs associated with these therapies.

Indian Health Service (IHS) reimbursement was updated in 2017 to the Federal Office of Management and Budget encounter rate; therefore, to more accurately compare CY 2022 with previous years, IHS data was excluded from this analysis. Additionally, costs in this report do not reflect the federal and state supplemental rebates that are provided by medication manufacturers. The coverage and prior authorization criteria of many medications, particularly the anti-infective, attention-deficit/hyperactivity disorder (ADHD), antipsychotic, endocrine, and analgesic classes, are significantly influenced by supplemental rebates, and net costs are lower than the total reimbursement to pharmacies included in this analysis.

Total Pharmacy Calendar Year (CY) Comparison

CY	Claims	Members[+]	Utilizers*	Reimbursement	Cost/ Claim	Cost/ Member	Cost/ Day
2020	5,056,083	889,437	469,045	$592,455,468.55	$117.18	$666.10	$4.02
2021	6,000,623	1,067,537	587,745	$696,159,833.49	$116.01	$652.12	$3.91
2022	7,803,717	1,277,220	712,016	$1,000,467,608.03	$128.20	$783.32	$4.18

[+]Average monthly enrollment as obtained from OHCA Fast Facts reports.
*Total number of unduplicated utilizers.
Reimbursement does not reflect rebated costs or net costs.

The per member per year (PMPY) value reflects the total pharmacy cost divided by the unduplicated number of members (total enrollees) for each period. To reflect an accurate PMPY value, average monthly enrollment was used in place of annual enrollment, and dual eligible (members eligible for Medicare and Medicaid) and IHS members were excluded. The PMPY value is used across benefit plans with similar populations to accurately assess health care spending. The following table contains the overall PMPY values for the past few years.

Overall PMPY CY Comparison			
Calendar Year (CY)	**CY 2020***	**CY 2021¥**	**CY 2022**
Overall PMPY Value⁺	$871.47	$835.32	$984.33

PMPY = per member per year
⁺PMPY value calculated using average monthly enrollment, excluding dual eligible and IHS members.
*Pre-expansion data
¥Oklahoma Medicaid expansion became effective 07/01/2021.

Oklahoma currently uses a fee-for-service (FFS) pharmacy benefit for the SoonerCare program. Pharmacy benefit managers (PBMs) are used by some states for their FFS pharmacy programs, contracting out services such as claims processing and payment, prior authorization processing, drug utilization review (DUR), and formulary management. Similarly, Medicaid managed care organizations (MCOs) frequently subcontract the management of the pharmacy benefit to a separate PBM. The Oklahoma Health Care Authority (OHCA) currently contracts with Pharmacy Management Consultants (PMC), a department within the University of Oklahoma College of Pharmacy, for many of these services.

SoonerCare prior authorization policies, coupled with quantity limits and monthly prescription limits, yield better than average results while still providing a comprehensive pharmacy benefit for approximately 1.3 million SoonerCare members.

Medicaid Drug Rebate Program[2,3,4]

Medicaid coverage of a drug requires the manufacturer to have a federal rebate agreement with the Secretary of Health and Human Services (HHS). Participation in the federal drug rebate program requires Medicaid coverage with limited exceptions (e.g., weight loss medications, cosmetic medications, fertility medications). Rebate amounts are based on the “best price” for each drug. Best price refers to the lowest price paid to a manufacturer for a drug by any commercial payer. Best prices are reported to CMS by the manufacturer but are not publicly available.

If a drug’s price increases more quickly than inflation, an additional rebate penalty is included based on the change in price compared with the consumer price index (CPI). The CPI penalty of the federal rebate is designed to keep

Medicaid net cost relatively flat despite increases in drug prices. Until the first quarter of 2017, the CPI penalty only applied to brand medications; however, following a Senate vote in October 2015 in response to increasing generic drug prices, the Medicaid CPI penalty was extended to generic drugs with an effective date of January 1, 2017. The cost increases found in this report do not reflect net cost increases.

Additionally, many states have negotiated supplemental rebate agreements with manufacturers to produce added rebates. In CY 2022, OHCA collected over $577 million in federal and state supplemental rebates, resulting in a total increase from CY 2021 of approximately $182 million ($395 million in federal and state supplemental rebates collected in CY 2021). The rebates are collected after reimbursement for the medication and are not reflected in this report.

Alternative Payment Models[5,6,7,8,9]

The introduction of a greater number of costly specialty medications, finite Medicaid budgets, Medicaid policy, and access requirements has resulted in alternative payment arrangements as particularly compelling opportunities. Medicaid programs must provide comprehensive care to vulnerable individuals while operating under limited budgets and regulatory requirements. An alternative payment model (APM) is an agreement between a payer and manufacturer that is intended to provide improved patient care or increased access to evidence-based therapies while lowering costs or improving health outcomes. In general, there are 2 types of APMs:

- **Financial APM:** Caps or discounts are used to provide predictability or limit spending; these types of contracts are intended to lower costs and expand access. Data collection for financial APMs is minimal, making them easier to administer.
    - Examples: Price volume agreements, market share, patient level utilization caps, manufacturer funded treatment initiation
- **Health Outcome-Based APM:** Payments for medications are tied to clinical outcomes or measurements; these types of contracts are often referred to as “value-based contracts.” Health outcome based APMs require additional planning and data collection but do have the potential to increase the quality and value of treatments.
    - Examples: Outcomes guarantee, conditional coverage, PMPY guarantees, event avoidance (e.g., hospitalizations)

Since October 2016, PMC and OHCA have been engaged in negotiations with pharmaceutical manufacturers regarding pharmacy value-based contracts. Oklahoma was the first Medicaid state to receive approval from CMS to participate in value-based payment arrangements in June 2018. Since that time, PMC and OHCA have initiated talks with numerous pharmaceutical manufacturers regarding APMs and have established multiple APM contracts,

with 7 APM contracts being active in calendar year 2022. Future considerations include the expectation that initial SoonerCare value-based contracts will set the precedent for further collaboration among manufacturers and state Medicaid agencies.

Overview of Established APM Contracts: Calendar Year 2022	
Manufacturer	**Details**
AbbVie	▪ Treatment patterns in Hepatitis C – utilization, treatment duration, and non-responder/re-treatment/ treatment failures (2022-2023)
Amgen	▪ Tumor necrosis factor (TNF) inhibitor – utilization and cost; focus on population characterizations to inform future value-based contracts (2021-2022)
AveXis	▪ Spinal muscular atrophy (SMA) medication – utilization (2021-2023)
Eli Lilly & Co.	▪ Anti-migraine medication [calcitonin gene-related peptide (CGRP) antagonist] – utilization and cost (2021-2022)
Pear Therapeutics	▪ Adherence and persistence with prescription digital therapeutics – resource utilization (2022-2023)
Supernus	▪ Adherence and persistence in ADHD – medication possession ratios (2022-2023)
UCB	▪ Anticonvulsant medication – health resource utilization (2021-2022)

APM = alternative payment model

Drug Approval Trends[10,11,12]

During CY 2022, the U.S. Food and Drug Administration (FDA) approved the first generic product of several key medications that may have a significant impact on SoonerCare reimbursement. Key first-time generics approved by the FDA in CY 2022 included lacosamide (generic Vimpat®), brexpiprazole (generic Rexulti®), and empagliflozin (generic Jardiance®); however, brexpiprazole and empagliflozin have not been launched yet due to patent protections for the brand names products.

A total of 37 novel drugs were approved by the FDA during CY 2022. The active ingredient or ingredients in a novel drug have never before been approved in the United States. Select novel drugs approved during CY 2022 that are expected to be highly utilized or have a particular impact in the SoonerCare population are included in the following table.

Select Novel Drugs FDA Approved During Calendar Year 2022

Drug Name	Date Approved	FDA-Approved Indication	Estimated Annual Cost Per Member*
Relyvrio™ (sodium phenylbutyrate/taurursodiol)	09/29/2022	ALS	$162,555.12¥
Sotyktu™ (deucravacitinib)	09/09/2022	Plaque psoriasis	$73,972.80±
Briumvi™ (ublituximab-xiiy)	12/28/2022	Relapsing forms of MS	$59,000.04≈
Cibinqo™ (abrocitinib)	01/14/2022	Atopic dermatitis	$63,626.40+
Mounjaro® (tirzepatide)	05/13/2022	T2DM	$12,766.00Δ

*Costs do not include rebated or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ALS = amyotrophic lateral sclerosis; MS = multiple sclerosis; T2DM = type 2 diabetes mellitus
¥Relyviro™ cost is based on recommended maintenance dose of 1 packet twice daily.
±Sotyktu™ cost is based on recommended dosing for 6mg once daily.
≈Briumvi™ cost per year based on maintenance dose of 450mg every 24 weeks.
+Cibinqo™ cost is based on the maximum FDA approved dosing of 200mg once daily.
ΔMounjaro® cost is based on the maximum FDA recommended dose of 15mg once weekly.

Traditional Versus Specialty Pharmacy Products

Traditional pharmaceuticals include products that are typically non-injectable, do not require special transportation, storage, or administration, and are not typically indicated for rare diseases requiring unique management. These products treat many common chronic diseases such as diabetes, hypertension, and chronic obstructive pulmonary disease. Traditional pharmaceuticals carried the bulk of the reimbursement costs, accounting for 68.35% of the total pharmacy reimbursement and more than 99% of utilizers, in CY 2022.

Specialty products, in contrast, are typically injectable, require special handling such as refrigerated transport and special administration techniques, or are indicated for rare diseases requiring unique management. These products include treatments for cystic fibrosis (CF), hemophilia, rheumatoid arthritis, and genetic deficiencies. Specialty pharmaceuticals have become a larger part of reimbursement over the last 10 years. Specifically, specialty pharmaceuticals accounted for 31.65% of the total pharmacy reimbursement in CY 2022 and approximately 1% of utilizers.

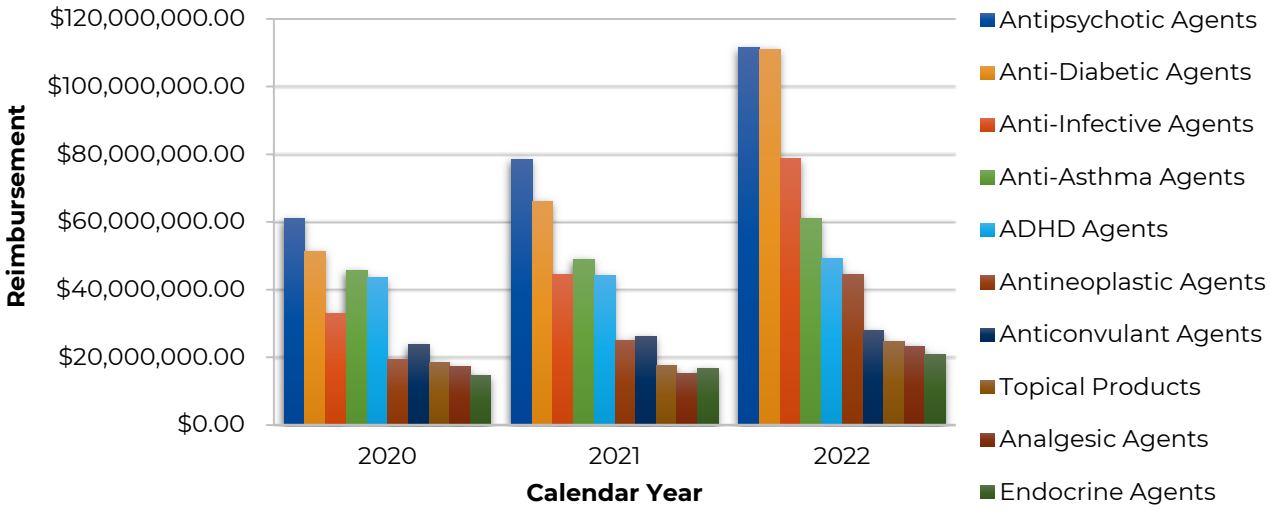
Top 10 Traditional Therapeutic Classes by Reimbursement: CY 2022

Costs in this report do not reflect the federal and state supplemental rebates that are provided by medication manufacturers. Many branded agents, particularly anti-infective, ADHD, antipsychotic, endocrine, and analgesic medications are significantly influenced by supplemental rebates, and net costs are substantially lower than the total reimbursement paid to pharmacies included in this analysis.

2020	2021	2022	Therapeutic Class

$60,984,624.10	$78,516,323.29	**$111,527,671.82**	**Antipsychotic Agents**
$51,313,255.24	$66,068,136.96	**$111,054,477.35**	**Anti-Diabetic Agents**
$32,933,101.16	$44,557,193.08	**$78,664,314.23**	**Anti-Infective Agents**
$45,777,405.32	$49,005,641.90	**$60,892,110.34**	**Anti-Asthma Agents**
$43,460,655.47	$44,221,029.26	**$49,047,287.54**	**ADHD Agents**
$19,294,624.78	$25,084,839.10	**$44,560,656.67**	**Antineoplastic Agents**
$23,702,694.76	$26,266,796.93	**$27,989,301.56**	**Anticonvulsant Agents**
$18,663,325.26	$17,580,087.59	**$24,571,330.81**	**Topical Products**
$17,312,718.91	$15,266,985.57	**$23,391,718.08**	**Analgesic Agents**
$14,667,821.52	$16,783,849.53	**$20,757,838.43**	**Endocrine Agents**

ADHD = attention-deficit/hyperactivity disorder
Reimbursement does not reflect rebated prices or net costs.



The top 10 traditional pharmaceutical classes that showed the most significant change from CY 2021 to 2022 include the antipsychotic and anti-diabetic agents. Other traditional classes saw minor fluctuations.

- Antipsychotic agents' reimbursement increased by $33 million in CY 2022; the antipsychotic agents' reimbursement totals include first-generation (typical) and second-generation (atypical) antipsychotics. The increase in reimbursement in this class can be accounted for by increased utilization of long-acting injectable (LAI) atypical antipsychotics, as well as utilization of brand formulation oral medications. It is important to note that many medications in the atypical antipsychotic class have supplemental rebates in place with Oklahoma Medicaid, and net cost increases are not reflected in this analysis.
- CY 2022 reimbursement increased by approximately $45 million in the anti-diabetic agents, which can be attributed to increased utilization of Tier-2 medications, including glucagon-like peptide 1 (GLP-1) agonists

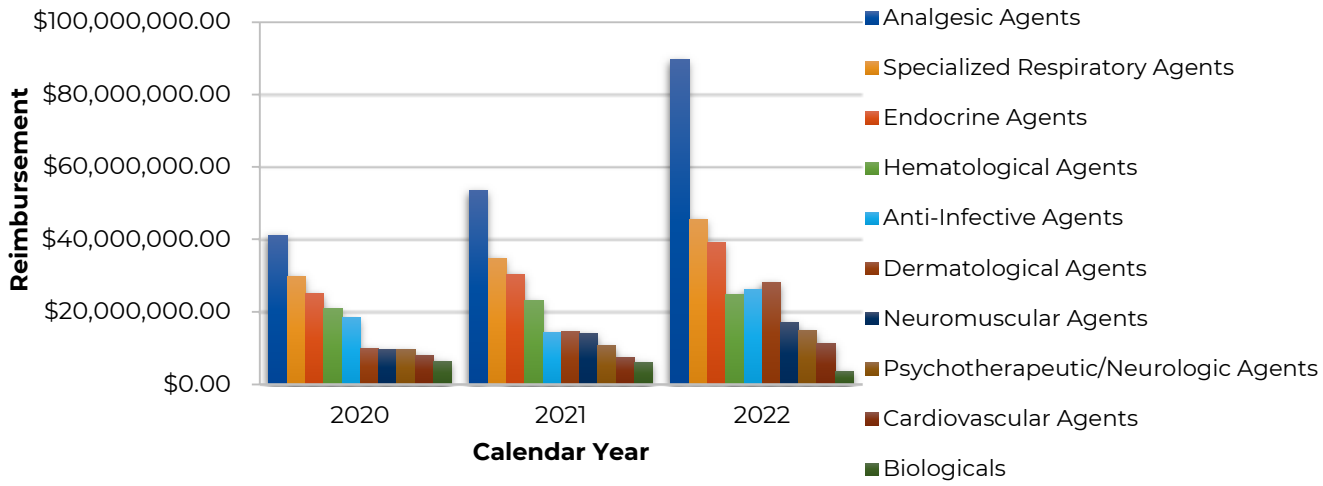
and sodium-glucose cotransporter-2 (SGLT-2) inhibitors, many of which have significant supplemental rebates. Reimbursement in this report does not reflect rebated prices or net costs.

- The anti-infective agents had approximaltely a $34 million increase from CY 2021, which was driven by the antiviral class of medications. Reimbursement and utilization of Biktarvy® (bictegravir/emtricitabine/tenofovir), which is indicated for the treatment of human immunodeficiency virus (HIV), increased by approximately $13.6 million and the number of utilizers increased by 428 members.

Top 10 Specialty Therapeutic Classes by Reimbursement: CY 2022

2020	2021	2022	Therapeutic Class
$41,239,435.84	$53,429,945.30	**$89,631,077.43**	**Analgesic Agents**
$29,933,714.55	$34,804,839.95	**$45,499,309.92**	**Specialized Respiratory Agents**
$25,153,126.89	$30,491,144.37	**$39,101,470.27**	**Endocrine Agents**
$9,928,918.72	$14,546,228.68	**$28,169,889.43**	**Dermatological Agents**
$18,313,937.62	$14,215,017.63	**$26,114,825.89**	**Anti-Infective Agents**
$20,801,562.68	$23,118,617.96	**$24,774,918.32**	**Hematological Agents**
$9,552,692.21	$13,994,765.56	**$17,107,588.45**	**Neuromuscular Agents**
$9,507,637.20	$10,660,813.68	**$14,836,282.79**	**Psychotherapeutic/Neurologic Agents**
$8,092,050.35	$7,364,280.07	**$11,226,948.72**	**Cardiovascular Agents**
$6,415,482.37	$6,030,814.58	**$3,559,204.53**	**Biologicals**

Reimbursement does not reflect rebated prices or net costs.



The cost of specialty therapeutic products is high, largely in part due to the targeted immunomodulator agents and therapies focused on rare diseases, including CF, hemophilia, and spinal muscular atrophy (SMA). Continuous review and management of biological agents and psychotherapeutic/neurologic agents has promoted minimal reimbursement increases, other

than expected yearly price increases by product manufacturers, and has resulted in a decline in reimbursement in biological agents.

- The cost of specialty analgesic agents increased this year, with a $36 million increase in anti-inflammatory agents. Reimbursement in this class is largely attributed to targeted immunomodulator agents such as Humira® (adalimumab), Enbrel® (etanercept), Ilaris® (canakinumab), Orencia® (abatacept), Simponi® (golimumab), Xeljanz® (tofacitinib), Otezla® (apremilast), and Kineret® (anakinra). Most of the utilization was seen in Humira® and Enbrel®, both of which are Tier-2 medications based on supplemental rebate participation. The supplementally rebated prices and net costs are not reflected in this analysis.
- The cost of biologicals decreased by approximately $2.5 million dollars due to the decrease in utilization of passive immunizing agents (i.e., palivizumab, immune globulin).

Top 10 Medications by Reimbursement: CY 2022

Many of the top 10 medications by reimbursement are still branded at this time and not available in a generic formulation. The top products typically come from highly utilized classes such as autoimmune, atypical antipsychotics, ADHD therapies, and respiratory medications (including rescue and maintenance therapies). Top drug reimbursement rankings only slightly change from year to year for several reasons: high use, broad use between age demographics, and high costs of new therapies such as those indicated for CF.

Top 10 Medications by Reimbursement			
Rank	**2020**	**2021**	**2022**
1	adalimumab inj	adalimumab inj	adalimumab inj
2	paliperidone inj	paliperidone inj	paliperidone inj
3	lisdexamfetamine	lisdexamfetamine	elexacaftor/tezacaftor/ivacaftor
4	elexacaftor/tezacaftor/ ivacaftor	elexacaftor/tezacaftor/ ivacaftor	lisdexamfetamine
5	lurasidone	lurasidone	lurasidone
6	sofosbuvir/velpatasvir	somatropin inj	dulaglutide inj
7	albuterol	insulin glargine inj	bictegravir/emtricitabine/tenofovir
8	somatropin inj	albuterol	etanercept inj
9	insulin glargine inj	etanercept inj	insulin glargine inj
10	fluticasone HFA	dexmethylphenidate	somatropin inj

*Includes brand and generic where applicable.
Rank does not reflect rebated prices or net costs.
Medications are listed by generic name but may include both generic and brand formulations.
inj = injection; HFA = hydrofluoroalkane

Cost Per Claim

The SoonerCare cost per claim of traditional medications increased by 10.5% in CY 2022 in comparison to CY 2021, and the cost per specialty medication claim increased by 7.6%. As mentioned previously, specialty costs are largely driven by the significant cost associated with medications for rare diseases.

Cost Per Claim			
Drug Class	**CY 2020**	**CY 2021**	**CY 2022**
Traditional	$80.40	$79.71	$88.09
Specialty	$6,843.12	$7,126.40	$7,672.84

CY = calendar year
Reimbursement does not reflected rebated costs or net costs.

Market Projections[10,11]

Specialty medications made up 1% of the utilizers for CY 2022 but generated approximately 32% of the cost. The top 5 drugs by cost have been identical the past 2 years and are led by specialty products. Briumvi™ (ublituximab-xiiy), a monoclonal antibody treatment for relapsing forms of multiple sclerosis was approved by the FDA in December 2022, and Sotyktu® (deucravacitinib) was approved by the FDA in September 2022 for the treatment of moderate-to-severe plaque psoriasis. These 2 new products have the potential to make a substantial impact on reimbursement in the upcoming year. Oncology medications made up about 35% of drug approvals in 2022 for various indications, as shown in the following table. With new oncology agents continually entering the market, assessment of the oncology medication classes will need frequent reevaluation.

Oncology Medications FDA Approved in Calendar Year 2022			
Brand	**Generic**	**Indication(s)**	**Approval Date**
Lunsumio™	mosunetuzumab-axgb	non-Hodgkin lymphoma	12/22/2022
Adstiladrin®	nadofaragene firadenovec-vncg	bladder cancer	12/16/2022
Krazati™	adagrasib	non-small cell lung cancer	12/12/2022
Rezlidhia™	olutasidenib	acute myeloid lymphoma	12/01/2022
Elahere™	mirvetuximab soravtansine-gynx	ovarian cancer	11/14/2022
Tecvayli™	teclistamab-cqyv	multiple myeloma	10/25/2022
Imjudo®	tremelimumab-actl	hepatocellular carcinoma	10/21/2022
Lytgobi®	futibatinib	intrahepatic cholangiocarcinoma	09/30/2022
Pedmark®	sodium thiosulfate	non-metastatic solid tumors	09/20/2022
Pluvicto™	lutetium Lu 177 vipivotide tetraxetan	prostate cancer	03/23/2022

Opdualag™	nivolumab and relatlimab-rmbw	melanoma	03/18/2022
Carvykti™	ciltacabtagene autoleucel	multiple myeloma	02/28/2022
Kimmtrak®	tebentafusp-tebn	uveal melanoma	01/25/2022

FDA = U.S. Food and Drug Administration

Conclusion

New prior authorization categories and continuous evaluation of categories such as oncology and hemophilia medications, along with new respiratory and anti-diabetic medications that continue to be FDA approved, ensure the most clinically appropriate, cost-effective measures are taken. Modifications to Tier structures and other generic categories reduced elevated spending on high-priced generic products. When new drugs are FDA approved and become available on the market, a cost-effectiveness analysis is performed to minimize spending while ensuring appropriate clinical care. The goal of the SoonerCare program is to provide SoonerCare members with the most appropriate health care in a fiscally responsible manner. For the pharmacy benefit, this is accomplished through DUR services, using prior authorization criteria, quantity limits, monthly total prescription limits and brand name prescription limits for non-institutionalized adult members, continuous product pricing maintenance, and provider outreach and education. Constant market review and response to changes, including evolving gene therapies, growth of the specialty market, and introduction of biosimilars, is necessary. SoonerCare will continue to strive to bring value-based pharmacy services to its members.

Top 50 Reimbursed Drugs by Calendar Year

Generic	Brand	CY 2022		CY 2021	
		Rank	Amount Paid	Rank	Amount Paid
Adalimumab	HUMIRA	**1**	**$61,254,156**	1	$37,199,373
Paliperidone inj	MULTIPLE	**2**	**$46,040,500**	2	$32,047,730
Elexacaftor/Tezacaftor/ Ivacaftor	TRIKAFTA	**3**	**$33,439,856**	4	$22,347,222
Lisdexamfetamine	VYVANSE	**4**	**$27,822,986**	3	$24,545,143
Lurasidone	LATUDA	**5**	**$24,286,117**	5	$17,903,097
Dulaglutide	TRULICITY	**6**	**$23,814,678**	18	$7,080,514
Bictegravir/ Emtricitabine/Tenofovir	BIKTARVY	**7**	**$22,021,118**	16	$8,399,611
Etanercept	ENBREL	**8**	**$18,174,839**	9	$10,551,375
Insulin Glargine	MULTIPLE	**9**	**$17,523,869**	7	$12,654,276
Somatropin	MULTIPLE	**10**	**$16,190,582**	6	$13,546,167

Generic	Brand	CY 2022		CY 2021	
		Rank	Amount Paid	Rank	Amount Paid
Glecaprevir/Pibrentasvir	MAVYRET	**11**	**$15,847,031**	44	$3,355,778
Aripiprazole tab	ABILIFY	**12**	**$14,148,498**	11	$9,078,466
Dupilumab	DUPIXENT	**13**	**$12,939,368**	20	$6,533,528
Albuterol	VENTOLIN HFA	**14**	**$12,632,365**	8	$10,678,566
Dexmethylphenidate	FOCALIN XR	**15**	**$11,250,068**	10	$9,306,255
Emicizumab-kxwh	HEMLIBRA	**16**	**$11,208,545**	15	$8,643,774
Ustekinumab	STELARA	**17**	**$11,139,960**	26	$5,446,971
Fluticasone-Salmeterol	ADVAIR HFA	**18**	**$11,060,215**	14	$8,692,143
Empagliflozin	JARDIANCE	**19**	**$10,299,283**	32	$4,438,466
Insulin Lispro	HUMALOG	**20**	**$9,645,801**	19	$6,977,780
Insulin Aspart	NOVOLOG	**21**	**$9,520,065**	17	$7,746,795
Fluticasone	MULTIPLE	**22**	**$9,332,132**	12	$9,070,937
Budesonide/Formoterol	SYMBICORT	**23**	**$8,858,238**	22	$5,965,524
Tiotropium	MULTIPLE	**24**	**$8,507,913**	23	$5,855,939
Apixaban	ELIQUIS	**25**	**$8,451,164**	28	$4,775,290
Sofosbuvir/Velpatasvir	EPCLUSA	**26**	**$8,093,921**	13	$8,758,613
Cariprazine	VRAYLAR	**27**	**$8,003,511**	29	$4,628,948
Aripiprazole inj	MULTIPLE	**28**	**$7,212,214**	27	$5,080,960
Pancrelipase	ZENPEP	**29**	**$7,106,872**	31	$4,506,647
Insulin Detemir	LEVEMIR	**30**	**$7,098,604**	24	$5,798,997
Abacavir/Dolutegravir/ Lamivudine	TRIUMEQ	**31**	**$5,505,774**	43	$3,397,530
Darunavir/Cobicistat/ Emtricitabine/Tenofovir	SYMTUZA	**32**	**$5,399,178**	37	$3,936,034
Dornase Alfa	PULMOZYME	**33**	**$5,372,403**	36	$4,015,380
Casimersen	AMONDYS 45	**34**	**$5,230,777**	65	$2,208,166
Liraglutide	VICTOZA	**35**	**$5,214,319**	30	$4,527,371
Vigabatrin	MULTIPLE	**36**	**$5,159,027**	33	$4,246,490
Asfotase Alfa	STRENSIQ	**37**	**$4,956,433**	55	$2,694,668
Palbociclib	IBRANCE	**38**	**$4,838,231**	38	$3,725,619
Cannabidiol	EPIDIOLEX	**39**	**$4,816,082**	40	$3,623,030
Sitagliptin	JANUVIA	**40**	**$4,739,666**	42	$3,450,280
Sacubitril/Valsartan	ENTRESTO	**41**	**$4,697,528**	68	$2,085,533
Ciprofloxacin/ Dexamethasone	CIPRODEX	**42**	**$4,675,125**	35	$4,080,090
Rifaximin	XIFAXAN	**43**	**$4,536,677**	57	$2,579,334
Methylphenidate	MULTIPLE	**44**	**$4,439,267**	25	$5,490,585
Valbenazine	INGREZZA	**45**	**$4,402,312**	49	$3,063,645
Lacosamide	VIMPAT	**46**	**$4,378,093**	21	$6,458,548
Dasatinib	SPRYCEL	**47**	**$4,362,182**	59	$2,436,169

Generic	Brand	CY 2022		CY 2021	
		Rank	Amount Paid	Rank	Amount Paid
Dapagliflozin	FARXIGA	**48**	**$4,292,458**	84	$1,637,049
Secukinumab	COSENTYX	**49**	**$4,218,732**	66	$2,143,239
Buprenorphine	MULTIPLE	**50**	**$4,171,161**	71	$1,976,808

Includes brand and generic where applicable.
Reimbursement does not reflect rebated costs or net costs.
CY = calendar year; HFA = hydrofluoroalkane, INJ = injection; TAB = tablet

Top 50 Medications by Total Number of Claims: Calendar Year 2022

Top 50 Medications by Total Number of Claims								
Rank	Generic Name	Claims	Members	Cost	Units/ Day	Claims/ Member	Cost/ Claim	% Cost
1	Albuterol	275,731	122,220	$12,632,364.78	1.95	2.26	$45.81	10.87%
2	Amoxicillin	231,557	175,854	$2,920,058.55	10.84	1.32	$12.61	2.51%
3	Cetirizine	184,630	83,112	$2,239,175.88	2.88	2.22	$12.13	1.93%
4	Hydrocodone/APAP	153,107	66,413	$2,460,251.28	3.78	2.31	$16.07	2.12%
5	Gabapentin	147,844	36,943	$2,541,391.52	2.97	4	$17.19	2.19%
6	Sertraline	120,974	33,112	$1,527,471.51	1.16	3.65	$12.63	1.31%
7	Ondansetron	120,481	89,269	$1,673,797.55	2.36	1.35	$13.89	1.44%
8	Azithromycin	115,581	90,447	$1,782,600.32	2.59	1.28	$15.42	1.53%
9	Fluticasone	108,177	60,966	$1,639,309.74	0.41	1.77	$15.15	1.41%
10	Trazodone	103,921	27,216	$1,197,592.89	1.23	3.82	$11.52	1.03%
11	Ibuprofen	103,038	70,073	$1,202,602.18	3.02	1.47	$11.67	1.04%
12	Montelukast	102,875	34,734	$1,483,724.85	1	2.96	$14.42	1.28%
13	Prednisone	99,954	72,659	$1,017,039.17	1.8	1.38	$10.18	0.88%
14	Fluoxetine	94,318	24,450	$1,169,583.76	1.21	3.86	$12.40	1.01%
15	Omeprazole	91,666	33,905	$1,121,538.06	1.19	2.7	$12.24	0.97%
16	Lisinopril	89,639	29,577	$961,256.07	1.08	3.03	$10.72	0.83%
17	Clonidine	88,874	17,891	$989,425.44	1.51	4.97	$11.13	0.85%
18	Lisdexamfetamine	85,666	15,259	$27,822,986.49	1	5.61	$324.78	23.95%
19	Amoxicillin & K Clavulanate	85,309	72,525	$1,723,714.96	7.03	1.18	$20.21	1.48%
20	Escitalopram	84,149	24,516	$1,094,583.32	1.05	3.43	$13.01	0.94%
21	Atorvastatin	82,684	27,969	$1,046,047.42	1	2.96	$12.65	0.90%
22	Levothyroxine	76,876	18,891	$1,480,099.63	1	4.07	$19.25	1.27%
23	Cefdinir	74,268	59,804	$1,555,617.05	6.37	1.24	$20.95	1.34%
24	Methylphenidate	73,375	11,721	$4,439,267.10	1.37	6.26	$60.50	3.82%
25	Bupropion	72,605	20,389	$1,247,680.65	1.19	3.56	$17.18	1.07%
26	Aripiprazole	71,558	16,794	$14,148,497.68	0.94	4.26	$197.72	12.18%
27	Metformin	71,051	24,194	$733,540.60	2.03	2.94	$10.32	0.63%
28	Buspirone	70,983	20,089	$962,233.48	2.22	3.53	$13.56	0.83%

Top 50 Medications by Total Number of Claims								
Rank	**Generic Name**	**Claims**	**Members**	**Cost**	**Units/ Day**	**Claims/ Member**	**Cost/ Claim**	**% Cost**
29	Hydroxyzine	70,947	28,015	$932,467.08	3.04	2.53	$13.14	0.80%
30	Cephalexin	69,536	60,390	$1,099,643.71	8.18	1.15	$15.81	0.95%
31	Quetiapine	66,084	14,341	$968,226.26	1.39	4.61	$14.65	0.83%
32	Cyclobenzaprine	62,277	29,728	$649,131.02	2.26	2.09	$10.42	0.56%
33	Amlodipine	59,997	19,964	$602,415.68	1.04	3.01	$10.04	0.52%
34	Amphetamine/ Dextroamphetamine	59,776	10,204	$1,443,403.43	1.42	5.86	$24.15	1.24%
35	Guanfacine	58,304	9,335	$1,072,910.70	1	6.25	$18.40	0.92%
36	Pantoprazole	57,316	21,862	$755,641.18	1.14	2.62	$13.18	0.65%
37	Duloxetine	56,365	15,073	$894,928.93	1.27	3.74	$15.88	0.77%
38	Alprazolam	51,533	8,799	$565,029.56	2.21	5.86	$10.96	0.49%
39	Oxycodone/APAP	51,531	19,953	$946,847.17	3.72	2.58	$18.37	0.82%
40	Triamcinolone	50,791	36,865	$751,222.78	4.75	1.38	$14.79	0.65%
41	Meloxicam	49,771	24,770	$475,765.06	1.06	2.01	$9.56	0.41%
42	Hydroxyzine Pamoate	49,059	18,922	$779,347.43	2.6	2.59	$15.89	0.67%
43	Methylprednisolone	48,863	41,885	$650,422.88	3.42	1.17	$13.31	0.56%
44	Lamotrigine	48,249	10,031	$1,094,795.27	1.77	4.81	$22.69	0.94%
45	Oseltamivir	47,170	45,346	$2,084,727.67	10.2	1.04	$44.20	1.79%
46	Sulfamethoxazole-Trimethoprim	46,121	37,681	$616,390.74	5.22	1.22	$13.36	0.53%
47	Mupirocin	45,280	38,876	$702,088.68	2.34	1.16	$15.51	0.60%
48	Risperidone	43,964	8,388	$2,341,354.56	1.49	5.24	$53.26	2.02%
49	Prednisolone	43,096	32,031	$776,876.05	6.59	1.35	$18.03	0.67%
50	Tizanidine	42,693	14,777	$527,625.93	2.68	2.89	$12.36	0.46%

APAP = acetaminophen; K = potassium
Includes brand and generic where applicable.
Reimbursement does not reflect rebated costs or net costs.

Top 10 Traditional and Specialty Therapeutic Categories by Calendar Year

Traditional Therapeutic Category	2022 Total Claims	2022 Total Cost	2022 Cost/ Member	2021 Total Claims	2021 Total Cost	2021 Cost/ Member
	CALENDAR YEAR 2022			CALENDAR YEAR 2021		
ANTIPSYCHOTICS & ANTIMANIC AGENTS						
Antipsychotics	309,708	$111,527,671.82	$2,236.32	248,825	$78,516,323.29	$2,017.12
Total	**309,708**	**$111,527,671.82**	**$2,236.32**	**248,825**	**$78,516,323.29**	**$2,017.12**
ANTI-DIABETIC AGENTS						
Anti-Diabetics	239,894	$111,054,477.35	$2,954.36	158,324	$66,068,136.96	$2,490.98
Total	**239,894**	**$111,054,477.35**	**$2,954.36**	**158,324**	**$66,068,136.96**	**$2,490.98**
ANTI-INFECTIVE AGENTS						
Antivirals	98,539	$54,776,802.03	$803.71	32,581	$26,956,606.04	$1,641.89

Traditional Therapeutic Category	2022 Total Claims	2022 Total Cost	2022 Cost/ Member	2021 Total Claims	2021 Total Cost	2021 Cost/ Member
Misc. Anti-Infectives	140,929	$8,466,525.14	$88.26	106,654	$5,543,172.26	$74.94
Penicillins	326,452	$5,110,274.25	$22.23	251,089	$3,977,047.47	$22.27
Cephalosporins	150,883	$3,240,170.67	$27.46	116,383	$2,413,895.79	$26.53
Macrolide Antibiotics	118,881	$2,712,422.75	$29.36	96,651	$2,305,351.04	$30.67
Antifungals	44,969	$2,135,581.20	$71.47	32,410	$1,828,217.76	$82.13
Tetracyclines	47,940	$1,025,273.35	$29.37	32,655	$686,607.29	$29.62
Aminoglycosides	594	$378,683.21	$1,387.12	456	$76,271.32	$401.43
Antimalarial	12,675	$335,193.50	$103.07	8,112	$197,656.51	$85.97
Fluoroquinolones	24,042	$335,090.09	$17.27	16,833	$242,033.47	$17.83
Anthelmintic	1,657	$109,629.63	$74.78	3,448	$287,997.01	$93.75
Antimycobacterial Agents	598	$35,801.54	$140.95	491	$38,241.85	$208.97
Sulfonamides	2	$2,583.51	$1,291.76	6	$2,959.76	$986.59
Amebicides	1	$283.36	$283.36	4	$1,135.51	$378.50
Total	**968,162**	**$78,664,314.23**	**$113.39**	**697,773**	**$44,557,193.08**	**$89.14**
ANTI-ASTHMATIC AGENTS						
Antiasthmatic & Bronchodilatory Agents	530,781	$60,892,110.34	$419.62	457,248	$49,005,641.90	$398.63
Total	**530,781**	**$60,892,110.34**	**$419.62**	**457,248**	**$49,005,641.90**	**$398.63**
ADHD AGENTS						
ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants	356,428	$49,047,287.54	$1,065.60	319,976	$44,221,029.26	$1,095.34
Total	**356,428**	**$49,047,287.54**	**$1,065.60**	**319,976**	**$44,221,029.26**	**$1,095.34**
ANTINEOPLASTICS						
Antineoplastics	17,384	$44,560,656.67	$10,088.44	12,072	$25,084,839.10	$8,211.08
Total	**17,384**	**$44,560,656.67**	**$10,088.44**	**12,072**	**$25,084,839.10**	**$8,211.08**
ANTICONVULSANT PRODUCTS						
Anticonvulsants	443,224	$27,989,301.56	$369.96	348,941	$26,266,796.93	$459.05
Total	**443,224**	**$27,989,301.56**	**$369.96**	**348,941**	**$26,266,796.93**	**$459.05**
TOPICAL PRODUCTS						
Dermatological	223,563	$15,447,327.63	$123.44	187,681	$10,303,323.20	$97.69
Otic	32,104	$4,809,368.32	$180.55	26,622	$4,224,987.24	$192.71
Ophthalmic	79,361	$3,646,475.83	$67.62	55,136	$2,533,777.97	$67.49
Mouth/Throat/Dental Agents	33,452	$496,357.67	$18.07	24,279	$388,546.24	$19.66
Anorectal	2,314	$171,801.36	$88.97	1,779	$129,452.94	$88.24
Total	**295,479**	**$17,579,241.32**	**$94.43**	**266,567**	**$18,663,331.10**	**$113.46**
ANALGESIC AGENTS						
Analgesics - Narcotic	353,763	$13,233,125.14	$121.03	262,641	$10,473,654.35	$127.48

Traditional Therapeutic Category	2022 Total Claims	2022 Total Cost	2022 Cost/ Member	2021 Total Claims	2021 Total Cost	2021 Cost/ Member
Analgesics - Anti-Inflammatory	241,147	$8,290,355.60	$66.47	163,170	$3,783,804.53	$42.50
Migraine Products	21,923	$1,607,013.74	$162.54	14,553	$783,702.47	$114.49
Gout	9,190	$134,970.47	$50.59	6,409	$109,757.62	$59.10
Analgesics - NonNarcotic	6,191	$124,001.82	$52.30	5,348	$113,643.00	$55.95
Local Anesthetics - Parenteral	135	$2,251.31	$19.75	134	$2,423.60	$24.00
Total	**632,349**	**$23,391,718.08**	**$93.91**	**452,255**	**$15,266,985.57**	**$83.88**
ENDOCRINE AGENTS						
Contraceptives	134,560	$8,935,437.50	$224.69	114,549	$7,501,191.48	$216.90
Misc. Endocrine	16,783	$4,586,900.76	$1,140.74	15,220	$3,649,251.98	$1,046.83
Corticosteroids	244,243	$3,552,767.60	$21.43	191,883	$2,872,544.20	$21.70
Thyroid	86,314	$1,883,422.34	$91.19	63,115	$1,577,808.11	$103.35
Estrogens	16,885	$1,260,490.45	$295.06	10,193	$839,903.37	$288.03
Progestin	12,446	$294,826.33	$56.51	8,030	$217,686.64	$60.81
Androgen-Anabolic	1,985	$233,002.82	$506.53	1,079	$108,465.04	$444.53
Oxytocics	104	$10,990.63	$106.71	113	$16,998.71	$155.95
Total	**513,320**	**$20,757,838.43**	**$86.40**	**404,182**	**$16,783,849.53**	**$87.16**

Table is not an all-inclusive list.
Reimbursement does not reflect rebated costs or net costs.

Specialty Therapeutic Category	2022 Total Claims	2022 Total Cost	2022 Cost/ Member	2021 Total Claims	2021 Total Cost	2021 Cost/ Member
	CALENDAR YEAR 2022			**CALENDAR YEAR 2021**		
ANALGESIC AGENTS						
Analgesic - Anti-Inflammatory	12,601	$86,931,982.47	$43,078.29	1,298	$52,376,167.84	$40,351.44
Migraine Products	2,154	$1,395,441.62	$3,370.63	249	$807,053.00	$3,241.18
Analgesic - Narcotics	715	$1,299,747.25	$6,840.78	46	$244,515.48	$5,315.55
Local Anesthetics - Parenteral	161	$3,906.09	$36.51	72	$2,208.98	$30.68
Total	**15,631**	**$89,631,077.43**	**$32,843.93**	**9,591**	**$53,429,945.30**	**$32,090.06**
SPECIALIZED RESPIRATORY AGENTS						
Misc. Respiratory	3,193	$45,499,309.92	$183,464.96	2,514	$34,804,839.95	$171,452.41
Total	**3,193**	**$45,499,309.92**	**$183,464.96**	**2,514**	**$34,804,839.95**	**$171,452.41**
ENDOCRINE AGENTS						
Misc. Endocrine	4,503	$36,487,384.94	$69,499.78	4,112	$27,463,722.27	$55,707.35
Progestins	1,050	$2,614,085.33	$7,780.02	1,144	$3,027,422.10	$8,073.13
Total	**5,553**	**$39,101,470.27**	**$45,414.02**	**5,256**	**$30,491,144.37**	**$35,128.05**
HEMATOLOGICAL AGENTS						

Specialty Therapeutic Category	2022 Total Claims	2022 Total Cost	2022 Cost/ Member	2021 Total Claims	2021 Total Cost	2021 Cost/ Member
Misc. Hematological	958	$21,820,175.49	$180,332.03	934	$20,613,681.03	$173,224.21
Hematopoietic Agents	408	$2,954,742.83	$26,381.63	493	$2,504,936.93	$24,319.78
Total	**1,366**	**$24,774,918.32**	**$106,330.12**	**1,427**	**$23,118,617.96**	**$104,137.92**
DERMATOLOGICAL AGENTS						
Dermatological	3,909	$28,169,889.43	$41,609.88	2,431	$14,546,228.68	$37,782.41
Total	**3,909**	**$28,169,889.43**	**$41,609.88**	**2,431**	**$14,546,228.68**	**$37,782.41**
ANTI-INFECTIVE AGENTS						
Antiviral	2,252	$24,363,182.87	$23,745.79	1,002	$12,656,903.77	$28,570.89
Aminoglycosides	479	$1,043,423.40	$6,864.63	439	$848,501.94	$5,892.37
Misc. Anti-Infectives	59	$598,289.05	$35,193.47	66	$630,095.67	$30,004.56
Antifungals	19	$109,930.57	$27,482.64	15	$79,516.25	$19,879.06
Total	**2,809**	**$26,114,825.89**	**$21,780.51**	**1,522**	**$14,215,017.63**	**$23,227.15**
NEUROMUSCULAR AGENTS						
Neuromuscular Agents	302	$16,596,625.52	$488,136.04	228	$13,674,795.73	$427,337.37
Antimyasthenic Agents	16	$510,962.93	$255,481.47	14	$319,969.83	$319,969.83
Total	**318**	**$17,107,588.45**	**$475,210.79**	**242**	**$13,994,765.56**	**$424,083.80**
PSYCHOTHERAPEUTIC/NEUROLOGIC AGENTS						
Misc. Psychotherapeutic and Neurologic Agents	2,014	$14,836,282.79	$47,400.26	1,504	$10,660,813.68	$45,754.57
Total	**2,014**	**$14,836,282.79**	**$47,400.26**	**1,504**	**$10,660,813.68**	**$45,754.57**
CARDIOVASCULAR AGENTS						
Misc. Cardiovascular	2,152	$11,116,468.23	$40,131.65	1,808	$7,321,013.22	$28,049.86
Vasopressors	0	$0.00	$0.00	0	$0.00	$0.00
Antihyperlipidemic	219	$110,480.49	$2,350.65	92	$43,087.43	$2,393.75
Antihypertensive	0	$0.00	$0.00	3	$179.42	$179.42
Total	**2,371**	**$11,226,948.72**	**$34,651.08**	**1,903**	**$7,364,280.07**	**$26,301.00**
BIOLOGICALS						
Passive Immunizing Agents	1,375	$3,559,204.53	$10,656.30	2,530	$6,030,814.58	$8,284.09
Total	**1,375**	**$3,559,204.53**	**$10,656.30**	**2,530**	**$6,030,814.58**	**$8,284.09**

Table is not an all-inclusive list.
Reimbursement does not reflect rebated costs or net costs.

Calendar Year Age Group Comparison

Traditional Pharmacy Reimbursement by Age Group			
Age Group (Years)	**CY 2020**	**CY 2021**	**CY 2022**
Age 0 to 2	$8,771,155	$9,531,232	$13,487,419
Age 3 to 5	$14,485,626	$13,526,650	$14,863,305
Age 6 to 9	$35,425,195	$35,431,331	$40,022,685
Age 10 to 14	$56,046,502	$56,046,502	$61,423,013
Age 15 to 18	$39,515,768	$43,040,906	$51,510,252
Age 19 to 25	$27,557,475	$37,526,061	$54,618,990
Age 26 to 34	$40,696,613	$51,994,394	$83,520,961
Age 35 to 54	$102,568,288	$135,047,408	$214,791,181
Age 55 to 64	$68,129,315	$81,811,926	$132,654,365
Age 65+	$11,112,224	$12,058,550	$16,901,809
Total (All Ages)	**$404,308,160**	**$476,014,960**	**$683,793,979**

Reimbursement does not reflect rebated costs or net costs.

Specialty Pharmacy Reimbursement by Age Group			
Age Group (Years)	**CY 2020**	**CY 2021**	**CY 2022**
Age 0 to 2	$11,097,551	$10,367,580	$6,637,360
Age 3 to 5	$8,514,078	$7,926,890	$10,173,566
Age 6 to 9	$16,987,283	$24,703,074	$25,884,252
Age 10 to 14	$32,560,771	$35,510,944	$44,959,720
Age 15 to 18	$30,128,625	$32,000,859	$38,240,636
Age 19 to 25	$13,872,096	$20,906,112	$35,312,897
Age 26 to 34	$17,028,858	$22,181,231	$36,705,619
Age 35 to 54	$37,614,717	$44,500,346	$79,071,179
Age 55 to 64	$18,745,943	$20,232,692	$36,469,688
Age 65+	$1,586,502	$1,961,427	$3,216,228
Total (All Ages)	**$188,136,425**	**$220,291,156**	**$316,671,145**

Reimbursement does not reflect rebated costs or net costs.

Total Enrollment by Age Group Comparison by Calendar Year				
Age Group (Years)	**2020**	**2021**	**2022**	**% Change (2021 vs. 2022)**
Age 0 to 2	94,533	100,587	101,858	1.3%
Age 3 to 5	92,513	99,914	104,301	4.4%
Age 6 to 9	118,793	130,688	138,788	6.2%
Age 10 to 14	146,397	159,970	167,227	4.5%

Age 15 to 18	97,109	111,921	124,031	10.8%
Age 19 to 25	49,258	85,544	130,046	52.0%
Age 26 to 34	63,963	93,505	133,136	42.4%
Age 35 to 54	87,749	132,007	204,810	55.2%
Age 55 to 64	46,254	59,272	85,377	44.0%
Age 65+	65,652	69,298	77,569	11.9%
Total (All Ages)	**863,073**	**1,042,706**	**1,267,142**	**21.5%**

The sum of each age group does not add up to the total average per year from enrollment.
Average monthly enrollment as obtained from OHCA Fast Facts reports.

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Appendix M

Calendar Year 2022 Annual Review of Hemophilia Medications and 30-Day Notice to Prior Authorize Altuviiio™ [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl] and Hemgenix® (Etranacogene Dezaparvovec-drlb)

Oklahoma Health Care Authority
June 2023

Current Prior Authorization Criteria

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

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

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

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

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

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

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

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

Hemlibra® (Emicizumab-kxwh) Approval Criteria:

1. Member must have a diagnosis of hemophilia A; and
2. Hemlibra® must be prescribed by a hematologist specializing in rare bleeding disorders or a mid-level practitioner with a supervising physician that is a hematologist specializing in rare bleeding disorders; and
3. Prescriber must be able to monitor appropriate blood clotting tests and levels utilizing testing which accounts for the interaction of Hemlibra® and blood factors by following the Medical and Scientific Advisory Council (MASAC) guidance; and
4. For members with hemophilia A with an inhibitor to factor VIII:
    a. A treatment plan must be developed to address breakthrough bleeds and procedures. Prescriber must counsel member and/or caregiver on the risks of utilizing Feiba® for breakthrough bleeding while on Hemlibra®, and member should be monitored closely if any bypassing agent is given; or
5. For members with hemophilia A without an inhibitor:
    a. Member's current prophylaxis therapy is not adequate to prevent spontaneous bleeding episodes, or the member is unable to maintain venous access for prophylactic infusions; and

b. Treatment plan must be made to address breakthrough bleeds and procedures; and
c. Routine lab screenings must occur for factor VIII inhibitor while using Hemlibra® since this would change the treatment plan for bleeds and procedures; and

6. First dose must be given in a health care facility; and
7. In order to calculate appropriate dosing, the member's recent weight must be provided and been taken within the last 3 months; and
8. Initial approvals will be for 3 months of therapy. Subsequent approvals will be for the duration of 1 year, if there has been a decrease in the member's spontaneous bleeding episodes since initiating Hemlibra® treatment.

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

1. An FDA approved diagnosis of 1 of the following:
   a. Hemophilia A or B with inhibitors; or
      i. For a diagnosis of hemophilia A with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Hemlibra® (emicizumab-kxwh) for prophylaxis therapy must be provided; or
   b. Congenital factor VII deficiency; or
   c. Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets; or
   d. Acquired hemophilia; and
2. NovoSeven® RT must be prescribed by a hematologist specializing in rare bleeding disorders or a mid-level practitioner with a supervising physician that is a hematologist specializing in rare bleeding disorders.

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

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

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

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

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

Utilization of Hemophilia Medications: Calendar Year 2022

Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost Per Utilizer Per Year
2021	114	875	$19,283,451.85	$22,038.23	$169,153.09
2022	119	968	$23,264,624.46	$24,033.70	$195,501.05
% Change	**4.4%**	**10.6%**	**20.6%**	**9.1%**	**15.58%**
Change	**5**	**93**	**$3,981,175.61**	**$1,995.47**	**$26,347.96**

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

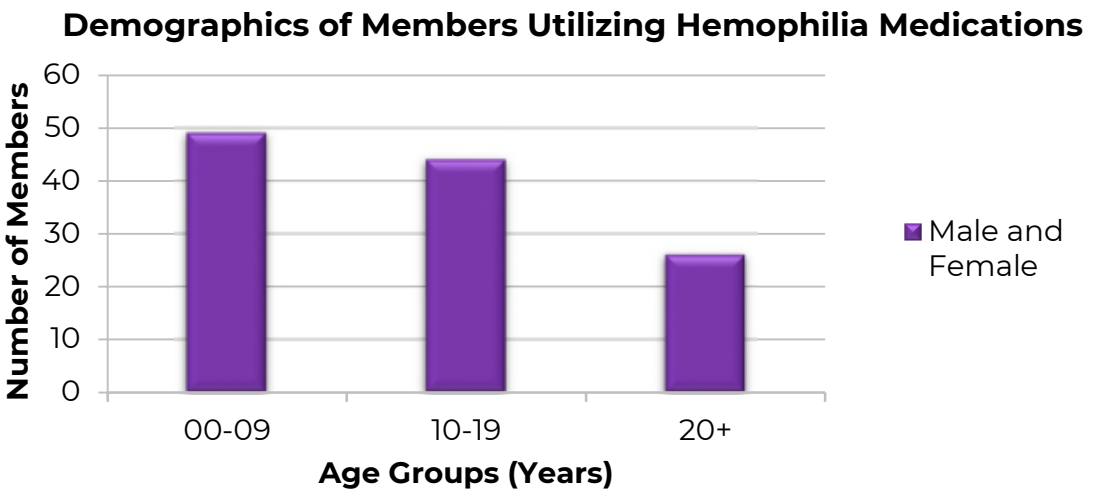
- Aggregate drug rebates collected during calendar year 2022 for hemophilia medications: $2,321,353.26.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

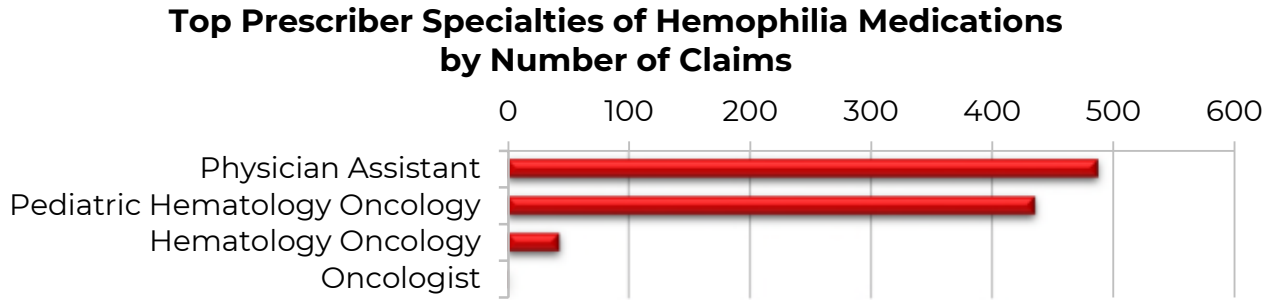
Comparison of Calendar Years: Medical Claims

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Cost Per Utilizer Per Year
2021	8	63	$3,131,167.14	$97,848.97	$391,395.89
2022	16	39	$695,835.15	$17,841.93	$43,489.70
% Change	**100%**	**-38.1%**	**-77.78%**	**-81.77%**	**-88.89%**
Change	**8**	**-24**	**-$2,435,331.99**	**-$80,007.04**	**-$347,906.19**

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

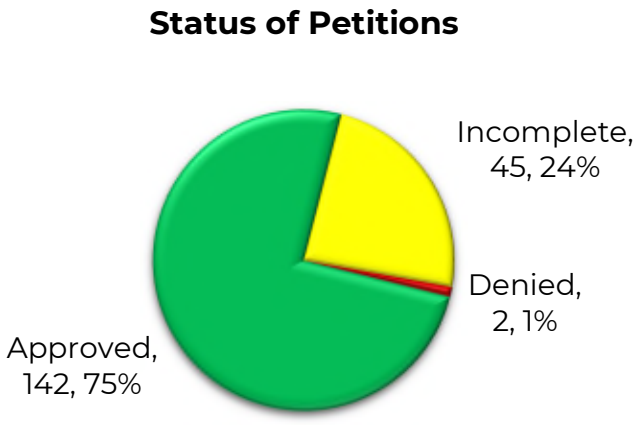
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.





Prior Authorization of Hemophilia Medications

There were 189 prior authorization requests submitted for hemophilia medications during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.



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

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

- **November 2022:** The FDA approved Hemgenix® (etranacogene dezaparvovec-drlb), an adeno-associated virus (AAV) vector-based gene therapy for the treatment of hemophilia B in adults who currently use factor IX (FIX) prophylactic therapy, have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.
- **February 2023:** The FDA approved Altuviiio™ [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl] for use as prophylaxis and on-demand treatment for bleeding episodes in adults and children with hemophilia A. Altuviiio™, formerly known as efanesoctocog alfa, is also indicated for perioperative management of bleeding in patients with hemophilia A.

News:

- **May 2022:** The FDA lifted the clinical hold on the Phase 3 AFFINE study for giroctocogene fitelparvovec, an AAV-mediated gene therapy being studied for the treatment of hemophilia A. The clinical hold had been placed due to some treated patients having factor VIII (FVIII) levels over 150%, increasing the risk of blood clots. One patient experienced blood clots; however, this patient had a history of blood clots prior to the clinical trial. After the clinical hold was lifted, recruitment was re-opened and a pivotal readout of the Phase 3 data is expected the first half of 2024.
- **June 2022:** Bayer announced the discontinuation of Kogenate® FS due to the changing marketplace. The remaining stock is expected to be depleted in 2023.
- **May 2023:** Novo Nordisk received a Complete Response Letter (CRL) from the FDA requesting more information relating to monitoring, dosing, and the manufacturing process. Concizumab is a monoclonal antibody being studied for subcutaneous use in patients with hemophilia A or B without regard to inhibitor status.

Pipeline:

- **Fidanacogene Elaparvovec:** Fidanacogene elaparvovec is an investigational AAV-mediated gene therapy for the treatment of hemophilia B. Pfizer released top-line results from the Phase 3 open-label, single arm BENEGENE-2 study indicating that the annualized bleed rate (ABR) decreased from 4.43 during the lead-in pre-treatment period (of at least 6 months) to a mean ABR of 1.3 during the 12 months (week 12 to month 15) after the gene therapy was given. The company is expected to release additional data from the trial in 2023 and is in continued discussions with the FDA.

- **Fitusiran:** Fitusiran is an investigational small interfering RNA (siRNA) therapy that targets antithrombin and is being studied for the prophylactic treatment of hemophilia A or B regardless of inhibitor status. In the Phase 3 randomized, open-label ATLAS-INH study, patients with hemophilia A or B with inhibitors were randomized to receive on-demand treatment with bypassing agents or fitusiran 80mg monthly. At the end of the 9 months, the mean ABR was 18.1 in the on-demand group and 1.7 in the fitusiran group. In the Phase 3 randomized, open-label ATLAS-A/B study, patients with severe hemophilia A or B without inhibitors were randomized to receive on-demand factor treatment or fitusiran 80mg monthly and were followed for 9 months. The estimated mean ABR was 31.0 in the group receiving on-demand treatment and 3.1 in the fitusiran group. Sanofi is continuing to investigate fitusiran at lower and less frequent dosing to maintain more appropriate antithrombin levels and is planning to file a Biologics License Application (BLA) in 2024.
- **Roctavian™ (Valoctocogene Roxaparvovec):** Roctavian™ (valoctocogene roxaparvovec) is an AAV vector-mediated FVIII gene transfer intended for patients with hemophilia A. BioMarin submitted additional data in September 2022 after receiving a CRL from the FDA in August 2020 required additional safety and efficacy data. The anticipated Prescription Drug User Fee Act (PDUFA) date was March 31, 2023; however, due to the substantial amount of additional data submitted, the FDA extended the PDUFA date to June 30, 2023. The FVIII expression, post valoctocogene roxaparvovec infusion, has declined over time in participants in both the Phase 1/2 and Phase 3 clinical studies.

Altuviiio™ [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl] Product Summary[14]

Therapeutic Class: Von Willebrand factor (VWF)-independent recombinant DNA-derived, FVIII concentrate

Indication(s): Use in adults and children with hemophilia A (congenital FVIII deficiency) for:

- Routine prophylaxis to reduce the frequency of bleeding episodes; or
- On-demand treatment and control of bleeding episodes; or
- Perioperative management of bleeding

How Supplied: Kits comprising a single-dose vial (SDV) for reconstitution [containing nominally 250, 500, 750, 1,000, 2,000, 3,000, or 4,000 international units (IU) of FVIII potency], a prefilled syringe with 3mL sterile water for injection, and a sterile vial adapter

Dosing and Administration: Administered intravenously (IV) as follows:

- Routine Prophylaxis:
  - The recommended dosing for routine prophylaxis for adults and children is 50 IU/kg once weekly.
- On-Demand Treatment and Control of Bleeding Episodes:
  - Minor and moderate bleeding episode:
    - Single dose 50 IU/kg:
      - For minor and moderate bleeding episodes occurring within 2 to 3 days after a prophylactic dose, a lower dose of 30 IU/kg dose may be used
      - Additional doses of 30 or 50 IU/kg every 2 to 3 days may be considered
  - Major bleeding episode:
    - Single dose of 50 IU/kg:
      - Additional doses of 30 or 50 IU/kg every 2 to 3 days can be considered
- Perioperative Management:
  - Minor surgery:
    - Single dose of 50 IU/kg:
      - An additional dose of 30 or 50 IU/kg after 2 to 3 days may be considered
  - Major surgery:
    - Single dose of 50 IU/kg:
      - Additional doses of 30 or 50 IU/kg every 2 to 3 days may be administered as clinically needed for perioperative management

Cost Comparison:

Product	Cost Per Unit	FDA Approved Prophylactic Dosing	Cost Per 4 Weeks₮
Altuviiio™	**$5.11**	**50 IU/kg once weekly**	**$51,100**
Advate® (standard half-life product)	$1.45	20-40 IU/kg every other day	$20,300-$40,600
Eloctate® (extended half-life product)	$2.18	25-65 IU/kg every 3-5 days	$13,625-$63,765

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC), or Specialty Pharmaceutical Acquisition Cost (SPAC).
₮ Cost per 4 weeks based on a member weighing 50kg using routine prophylaxis therapy.

Hemgenix® (Etranacogene Dezaparvovec-drlb) Product Summary[15,16,17]

Therapeutic Class: AAV vector-based gene therapy

Indication(s): Treatment of adults with hemophilia B (congenital FIX deficiency) who:

- Currently use FIX prophylaxis therapy, or
- Have current or historical life-threatening hemorrhage, or
- Have repeated, serious spontaneous bleeding episodes

How Supplied: Customized kits to meet dosing requirements for each patient with each kit containing 10 to 48 single-use vials to make the appropriate dose based on weight

Dosing and Administration: The recommended dose is 2×10^{13} genome copies per kilogram of body weight administered as an IV infusion after dilution with normal saline.

Efficacy: The open-label Phase 3 HOPE-B study evaluated the use of etranacogene dezaparvovec in adult males with hemophilia B with FIX activity ≤2% of normal levels regardless of preexisting AAV5 neutralizing antibodies. The primary endpoint was the ABR. The patients used FIX prophylaxis for a ≥6-month lead in period to determine the ABR while using standard of care. The ABR during the lead in period was 4.19, while the ABR post gene therapy treatment was 1.51 ($P<0.001$) between 7 and 18 months. The FIX activity level at 18 months post infusion was 39.0% and 31.1% in the patients without and with preexisting AAV5 neutralizing antibodies, respectively. Two patients did not show an increase in FIX levels: one who discontinued treatment after receiving approximately 10% of the gene therapy dose due to a hypersensitivity reaction and one who had a high AAV5 titer of 3,212 on the day of the etranacogene dezaparvovec infusion. For those patients who had an increase in FIX levels and had pretreatment AAV5 neutralizing antibodies, the titer levels were ≤678. An analysis and statistical modeling for long-term durability of FIX production were performed using the data from the Phase 2b and 3 clinical studies (N=55). The 2 patients who did not respond to the gene therapy were excluded from the analysis. The model-based extrapolation predicted approximately 11% of the 55 participants would have a FIX activity level of below 2% at 25.5 years post gene therapy.

Cost: $3,500,000 per 1 time treatment

Recommendations

The Oklahoma Health Care Authority recommends the prior authorization of Altuviiio™ [antihemophilic factor (recombinant), Fc-VMF-XTEN fusion protein-ehtl] and Hemgenix® (etranacogene dezaparvovec-drlb) as follows (changes and new criteria shown in red):

Adynovate®, Afstyla®, Alprolix®, Altuviiio™, Eloctate®, Esperoct®, Idelvion®, Jivi®, and Rebinyn® Approval Criteria:

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

Hemgenix® (Etranacogene Dezaparvovec-drlb) Approval Criteria:

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

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

Utilization Details of Hemophilia Medications: Calendar Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HEMLIBRA PRODUCTS						
HEMLIBRA INJ 60MG/0.4ML	256	38	$5,218,312.66	$20,384.03	6.74	22.43%
HEMLIBRA INJ 105MG/0.7ML	103	18	$2,856,677.73	$27,734.74	5.72	12.28%
HEMLIBRA INJ 30MG/ML	71	15	$556,131.59	$7,832.84	4.73	2.39%
HEMLIBRA INJ 150MG/ML	53	12	$2,577,423.23	$48,630.63	4.42	11.08%
SUBTOTAL	**483**	**83**	**$11,208,545.21**	**$23,206.10**	**5.82**	**48.18%**
KOGENATE PRODUCTS						
KOGENATE FS INJ 2,000U	41	12	$1,420,554.30	$34,647.67	3.42	6.11%
KOGENATE FS INJ 3,000U	20	3	$1,027,846.38	$51,392.32	6.67	4.42%
KOGENATE FS INJ 250U	16	2	$82,622.12	$5,163.88	8	0.36%
KOGENATE FS INJ 1,000U	7	7	$82,506.81	$11,786.69	1	0.35%
KOGENATE FS INJ 500U	6	3	$56,754.22	$9,459.04	2	0.24%
SUBTOTAL	**90**	**27**	**$2,670,283.83**	**$29,669.82**	**3.33**	**11.48%**
ALPROLIX PRODUCTS						
ALPROLIX INJ 2,000U	19	3	$482,690.55	$25,404.77	6.33	2.07%
ALPROLIX INJ 4,000U	13	3	$664,600.85	$51,123.14	4.33	2.86%
ALPROLIX INJ 250U	12	2	$22,349.36	$1,862.45	6	0.10%
ALPROLIX INJ 3,000U	11	2	$253,211.75	$23,019.25	5.5	1.09%
ALPROLIX INJ 1,000U	8	2	$162,000.66	$20,250.08	4	0.70%
ALPROLIX INJ 500U	5	2	$29,358.44	$5,871.69	2.5	0.13%
SUBTOTAL	**68**	**14**	**$1,614,211.61**	**$23,738.41**	**4.86**	**6.95%**
ADVATE PRODUCTS						
ADVATE INJ 3,000U	24	4	$1,034,587.57	$43,107.82	6	4.45%
ADVATE INJ 2,000U	23	10	$291,650.83	$12,680.47	2.3	1.25%
ADVATE INJ 1,500U	7	6	$55,001.99	$7,857.43	1.17	0.24%
ADVATE INJ 500U	5	5	$10,728.41	$2,145.68	1	0.05%
ADVATE INJ 250U	4	1	$17,647.46	$4,411.87	4	0.08%
ADVATE INJ 1,000U	4	4	$19,191.86	$4,797.97	1	0.08%
SUBTOTAL	**67**	**30**	**$1,428,808.12**	**$21,325.49**	**2.23**	**6.15%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
KOATE PRODUCTS						
KOATE INJ 1,000U	29	1	$39,457.06	$1,360.59	29	0.17%
KOATE INJ 500U	24	1	$14,241.56	$593.40	24	0.06%
SUBTOTAL	**53**	**2**	**$53,698.62**	**$1,013.18**	**26.50**	**0.23%**
NUWIQ PRODUCTS						
NUWIQ KIT 500	15	8	$23,442.96	$1,562.86	1.88	0.10%
NUWIQ KIT 1,000U	11	10	$30,631.18	$2,784.65	1.1	0.13%
NUWIQ KIT 2,000U	4	1	$14,207.08	$3,551.77	4	0.06%
NUWIQ KIT 250U	4	4	$2,525.33	$631.33	1	0.01%
SUBTOTAL	**34**	**23**	**$70,806.55**	**$2,082.55**	**1.48**	**0.30%**
NOVOSEVEN PRODUCTS						
NOVOSEVEN RT INJ 1MG	18	6	$372,553.38	$20,697.41	3	1.60%
NOVOSEVEN RT INJ 2MG	6	2	$173,002.46	$28,833.74	3	0.74%
NOVOSEVEN RT INJ 5MG	3	2	$386,321.23	$128,773.74	1.5	1.66%
NOVOSEVEN RT INJ 8MG	1	1	$56,435.41	$56,435.41	1	0.24%
SUBTOTAL	**28**	**11**	**$988,312.48**	**$35,296.87**	**2.55**	**4.24%**
HUMATE PRODUCTS						
HUMATE-P SOL 500-1,200U	13	10	$28,588.22	$2,199.09	1.3	0.12%
HUMATE-P SOL 2,400U	7	5	$75,575.96	$10,796.57	1.4	0.32%
HUMATE-P SOL 250-600U	4	4	$6,058.04	$1,514.51	1	0.03%
SUBTOTAL	**24**	**19**	**$110,222.22**	**$4,592.59**	**1.26**	**0.47%**
KOVALTRY PRODUCTS						
KOVALTRY INJ 2,000U	16	7	$282,496.34	$17,656.02	2.29	1.21%
KOVALTRY INJ 3,000U	3	1	$70,780.47	$23,593.49	3	0.30%
KOVALTRY INJ 1,000U	1	1	$1,275.42	$1,275.42	1	0.01%
KOVALTRY INJ 500U	1	1	$8.00	$8.00	1	0.00%
SUBTOTAL	**21**	**10**	**$354,560.23**	**$16,883.82**	**2.10**	**1.52%**
WILATE PRODUCTS						
WILATE INJ 1,000U	19	4	$545,496.21	$28,710.33	4.75	2.34%
WILATE INJ 500U	1	1	$593.88	$593.88	1	0.00%
SUBTOTAL	**20**	**5**	**$546,090.09**	**$27,304.50**	**4**	**2.34%**
ELOCTATE PRODUCTS						
ELOCTATE INJ 2,000U	6	2	$166,665.48	$27,777.58	3	0.72%
ELOCTATE INJ 4,000U	4	1	$145,552.64	$36,388.16	4	0.63%
ELOCTATE INJ 1,500U	2	2	$57,500.76	$28,750.38	1	0.25%
ELOCTATE INJ 3,000U	2	1	$207,897.74	$103,948.87	2	0.89%
ELOCTATE INJ 750U	1	1	$9,019.45	$9,019.45	1	0.04%
ELOCTATE INJ 250U	1	1	$2,651.29	$2,651.29	1	0.01%
SUBTOTAL	**16**	**8**	**$589,287.36**	**$36,830.46**	**2**	**2.54%**
SEVENFACT PRODUCTS						
SEVENFACT INJ 1MG	16	1	$2,633,108.15	$164,569.26	16	11.32%
SUBTOTAL	**16**	**1**	**$2,633,108.15**	**$164,569.26**	**16**	**11.32%**
ESPEROCT PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ESPEROCT INJ 3,000U	9	1	$572,121.15	$63,569.02	9	2.46%
ESPEROCT INJ 1,000U	2	1	$39,437.62	$19,718.81	2	0.17%
ESPEROCT INJ 1,500U	2	1	$58,117.62	$29,058.81	2	0.25%
SUBTOTAL	**13**	**3**	**$669,676.39**	**$51,513.57**	**4.33**	**2.88%**
RIXUBIS PRODUCTS						
RIXUBIS INJ 2,000U	6	4	$24,388.77	$4,064.80	1.5	0.10%
RIXUBIS INJ 500U	5	4	$5,128.14	$1,025.63	1.25	0.02%
RIXUBIS INJ 3,000U	1	1	$4,394.25	$4,394.25	1	0.02%
RIXUBIS INJ 1,000U	1	1	$1,632.05	$1,632.05	1	0.01%
SUBTOTAL	**13**	**10**	**$35,543.21**	**$2,734.09**	**1.30**	**0.15%**
ADYNOVATE PRODUCTS						
ADYNOVATE INJ 2,000U	4	2	$55,152.38	$13,788.10	2	0.24%
ADYNOVATE INJ 3,000U	3	1	$29,045.58	$9,681.86	3	0.12%
ADYNOVATE INJ 1,000U	2	1	$54,149.32	$27,074.66	2	0.23%
SUBTOTAL	**9**	**4**	**$138,347.28**	**$15,371.92**	**2.25**	**0.59%**
IDELVION PRODUCTS						
IDELVION SOL 2,000U	5	1	$124,505.76	$24,901.15	5	0.54%
SUBTOTAL	**5**	**1**	**$124,505.76**	**$24,901.15**	**5**	**0.54%**
BENEFIX PRODUCTS						
BENEFIX INJ 500U	2	1	$2,990.90	$1,495.45	2	0.01%
BENEFIX INJ 1,000U	1	1	$4,271.32	$4,271.32	1	0.02%
BENEFIX INJ 2,000U	1	1	$9,443.11	$9,443.11	1	0.04%
SUBTOTAL	**4**	**3**	**$16,705.33**	**$4,176.33**	**1.33**	**0.07%**
ALPHANATE PRODUCTS						
ALPHANATE INJ 1,000U	1	1	$2,520.59	$2,520.59	1	0.01%
ALPHANATE INJ 500U	1	1	$2,353.33	$2,353.33	1	0.01%
SUBTOTAL	**2**	**2**	**$4,873.92**	**$2,436.96**	**1**	**0.02%**
NOVOEIGHT PRODUCTS						
NOVOEIGHT INJ 500U	1	1	$5,545.72	$5,545.72	1	0.02%
SUBTOTAL	**1**	**1**	**$5,545.72**	**$5,545.72**	**1**	**0.02%**
RIASTAP PRODUCTS						
RIASTAP SOL 1GM	1	1	$1,492.38	$1,492.38	1	0.01%
SUBTOTAL	**1**	**1**	**$1,492.38**	**$1,492.38**	**1**	**0.01%**
TOTAL	**968**	**119***	**$23,264,624.46**	**$24,033.70**	**8.13**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FS = formulated with sucrose; INJ = injection; RT = recombinant; SOL = solution; U = units

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS[+]	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM
J7189 FACTOR VIIA RT	18	1	$599,315.38	$32,253.85
J7192 FACTOR VIII RT	10	8	$43,766.25	$4,376.63
J7187 VWF COMPLEX	6	5	$25,011.72	$4168.62
J7195 FACTOR IX RT	4	1	$22,769.80	$5,692.45
J7186 ANTIHEMOPHILIC FACTOR VIII/VWF COMPLEX	1	1	$4,972.00	$4,972.00
TOTAL	**39**	**16**	**$695, 835.15**	**$18,273.82**

Costs do not reflect rebated prices or net costs.
[+]Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
RT = recombinant; VWF = von Willebrand factor

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Appendix N

Calendar Year 2022 Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Lumryz™ (Sodium Oxybate) and Relexxii® [Methylphenidate Extended-Release (ER) Tablet]

Oklahoma Health Care Authority
June 2023

Current Prior Authorization Criteria

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			amphetamine ER susp (Adzenys ER™) amphetamine ER ODT (Adenyls XR-ODT®) amphetamine (Evekeo®) amphetamine ODT (Evekeo ODT™) amphetamine/ dextroamphetamine ER (Mydayis®) dextroamphetamine (Dexedrine®) dextroamphetamine ER (Dexedrine Spansules®) dextroamphetamine soln (ProCentra®) dextroamphetamine (Xelstrym™) dextroamphetamine (Zenzedi®) lisdexamfetamine chew tab (Vyvanse®)+
Short-Acting			
amphetamine/ dextroamphetamine (Adderall®)			
Long-Acting			
amphetamine/ dextroamphetamine ER (Adderall XR®) lisdexamfetamine cap (Vyvanse®)+	amphetamine ER susp and tab (Dyanavel® XR)		
Methylphenidate			
Short-Acting			
dexmethylphenidate (Focalin®) methylphenidate tab and soln (Methylin®) methylphenidate (Ritalin®)			
Long-Acting			
dexmethylphenidate ER (Focalin XR®) – **Brand Preferred** methylphenidate ER (Concerta®) methylphenidate ER (Daytrana®) methylphenidate ER (Metadate CD®)	dexmethylphenidate ER (generic Focalin XR®) methylphenidate ER (Aptensio XR®) methylphenidate ER susp (Quillivant XR®)	methylphenidate ER 72mg methylphenidate ER (Adhansia XR®) methylphenidate ER (Jornay PM®) serdexmethylphen-idate/dexmethylphen-idate (Azstarys®)	

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
methylphenidate ER (Metadate ER®) methylphenidate ER (Methylin ER®) methylphenidate ER (Ritalin LA®) methylphenidate ER (Ritalin SR®)			methamphetamine (Desoxyn®) methylphenidate ER ODT (Cotempla XR-ODT®) methylphenidate chew tab (Methylin®) methylphenidate ER chew tab (QuilliChew ER®) viloxazine (Qelbree®)Δ
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)Δ		

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
+Unique criteria applies for the diagnosis of binge eating disorder (BED).
ΔUnique criteria applies in addition to tier trial requirements.
ADHD = attention-deficit/hyperactivity disorder; cap = capsule; chew tab = chewable tablet; ER = extended-release; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tab = tablet

ADHD Medications Tier-2 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response:
   a. Trials should have been within the last 180 days; and
   b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
   c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
3. For Dyanavel® XR oral suspension and Quillivant XR®, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Kapvay® [Clonidine Extended-Release (ER) Tablet] Approval Criteria:
   a. An FDA approved diagnosis; and

b. Previously failed trials (within the last 180 days) with a long-acting Tier-1 stimulant, Intuniv®, and Strattera®, unless contraindicated, that did not yield adequate results; and
c. A patient-specific, clinically significant reason why the member cannot use clonidine immediate-release tablets must be provided.

ADHD Medications Tier-3 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response; and
3. A previously failed trial with at least 1 long-acting Tier-2 stimulant that resulted in an inadequate response:
   a. Trials should have been within the last 365 days; and
   b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
   c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician.

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. Adzenys XR-ODT®, Adzenys ER™, Cotempla XR-ODT®, Evekeo ODT™, QuilliChew ER®, Vyvanse® Chewable Tablets, and Xelstrym™ Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use all other available formulations of stimulant medications that can be used for members who cannot swallow capsules or tablets must be provided; and
   c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
2. Desoxyn®, Dexedrine®, Dexedrine Spansules®, Evekeo®, ProCentra®, and Zenzedi® Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
3. Methylin® Chewable Tablets Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use methylphenidate immediate-release tablets or oral solution must be provided; and

c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

4. Mydayis® Approval Criteria:
   a. A covered diagnosis; and
   b. Member must be 13 years of age or older; and
   c. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
5. Qelbree® [Viloxazine Extended-Release (ER) Capsule] Approval Criteria:
   a. An FDA approved diagnosis; and
   b. Member must be 6 years of age or older; and
   c. Previously failed trial(s) (within the last 180 days) with atomoxetine or any 2 Tier-1 or Tier-2 ADHD medications, unless contraindicated, that did not yield adequate results; and
      i. Qelbree® will not require a prior authorization and claims will pay at the point of sale if the member has paid claims for atomoxetine or 2 Tier-1 or Tier-2 ADHD medications within the past 180 days of claims history; and
   d. Member must not be taking a monoamine oxidase inhibitor (MAOI) or have taken an MAOI within the last 14 days; and
   e. Member must not be taking sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline) concomitantly with Qelbree®; and
   f. A quantity limit of 30 capsules per 30 days will apply for the 100mg strengths and 60 capsules per 30 days will apply for the 150mg and 200mg strength.

ADHD Medications Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum dose are not covered.
2. Prior authorization is required for all tiers for members older than 20 years of age and for members younger than 5 years of age. All prior authorization requests for members younger than 5 years of age must be reviewed by an Oklahoma Health Care Authority (OHCA)-contracted psychiatrist.
3. For Daytrana® patches and Methylin® oral solution, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Vyvanse® (Lisdexamfetamine) Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:
   a. An FDA approved diagnosis of moderate-to-severe BED; and
   b. Member must be 18 years of age or older; and

c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and
d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and
e. A quantity limit of 30 capsules or chewable tablets per 30 days will apply; and
f. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.

Idiopathic Hypersomnia (IH) Medications Approval Criteria:

1. Diagnosis of IH meeting the following ICSD-3 (International Classification of Sleep Disorders) criteria:
   a. Daily periods of irresistible need to sleep or daytime lapses into sleep for >3 months; and
   b. Absence of cataplexy; and
   c. Multiple sleep latency test (MSLT) results showing 1 of the following:
      i. <2 sleep-onset rapid eye movement (REM) periods (SOREMPs); or
      ii. No SOREMPs if the REM sleep latency on the preceding polysomnogram is ≤15 minutes; and
   d. At least 1 of the following:
      i. MSLT showing mean sleep latency ≤8 minutes; or
      ii. Total 24-hour sleep time ≥660 minutes on 24-hour polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in association with a sleep log (averaged over ≥7 days with unrestricted sleep); and
   e. Insufficient sleep syndrome has been ruled out; and
   f. Hypersomnolence or MSLT findings are not better explained by any other sleep disorder, medical or neurologic disorder, mental disorder, medication use, or substance abuse; and
2. Diagnosis must be confirmed by a sleep specialist; and
3. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
   a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; and
4. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant

reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and

5. Use of Xyrem® (sodium oxybate) or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with at least 4 of the following, unless contraindicated, that did not yield adequate results:
    a. Tier-1 stimulant; or
    b. Tier-2 stimulant; or
    c. Nuvigil®; or
    d. Provigil®; or
    e. Clarithromycin; and
6. Xywav® (calcium/magnesium/potassium/sodium oxybates) additionally requires a patient-specific, clinically significant reason why the member cannot use Xyrem®; and
    a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided.

Narcolepsy Medications Approval Criteria:

1. An FDA approved diagnosis; and
2. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
    a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; or
3. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; or
4. Use of Sunosi® (solriamfetol), Wakix® (pitolisant), Xyrem® (sodium oxybate), or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with Tier-1 and Tier-2 stimulants from different chemical categories, Provigil®, and Nuvigil®, unless contraindicated, that did not yield adequate results; and
5. Additionally, use of Xywav® (calcium/magnesium/potassium/sodium oxybates) requires a patient-specific, clinically significant reason why the member cannot use Xyrem®; and
    a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided; and

6. The diagnosis of obstructive sleep apnea requires concurrent treatment for obstructive sleep apnea; and
7. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the prior authorization request.

Utilization of ADHD and Narcolepsy Medications: Calendar Year 2022

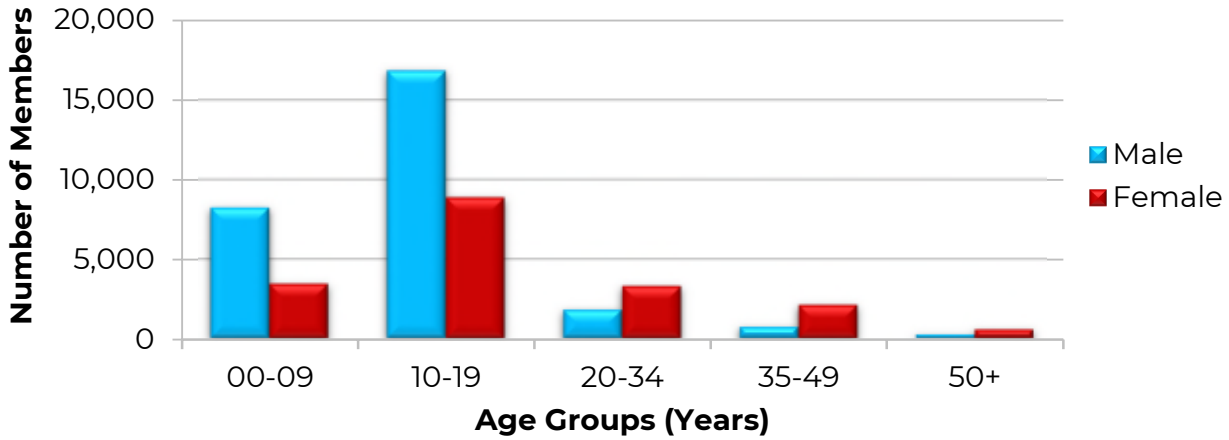
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	40,368	320,035	$45,212,391.22	$141.27	$4.75	11,131,812	9,512,000
2022	46,024	356,505	$50,458,756.01	$141.54	$4.77	12,494,502	10,582,336
% Change	**14.00%**	**11.40%**	**11.60%**	**0.20%**	**0.40%**	**12.20%**	**11.30%**
Change	**5,656**	**36,470**	**$5,246,364.79**	**$0.27**	**$0.02**	**1,362,690**	**1,070,336**

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

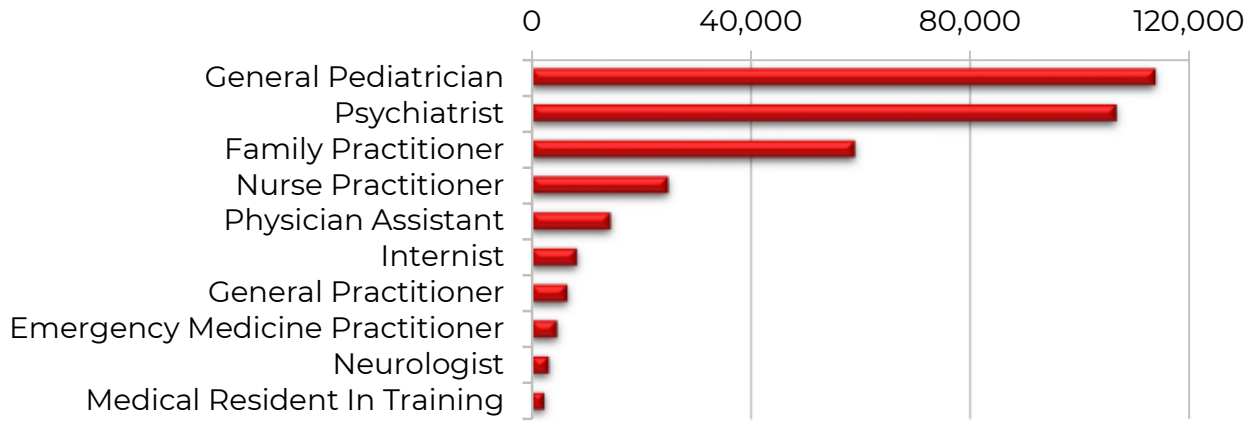
- The ADHD and Narcolepsy Medications Product Based Prior Authorization (PBPA) category is heavily influenced by supplemental rebates. Some brand name ADHD and narcolepsy products are preferred over available generic products due to a lower net cost compared to generics, after taking into account federal and/or supplemental rebate participation. These 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.
  - Aggregate drug rebates collected during calendar year 2022 for ADHD and narcolepsy medications: $40,154,189.23 [Δ]

Demographics of Members Utilizing ADHD and Narcolepsy 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.

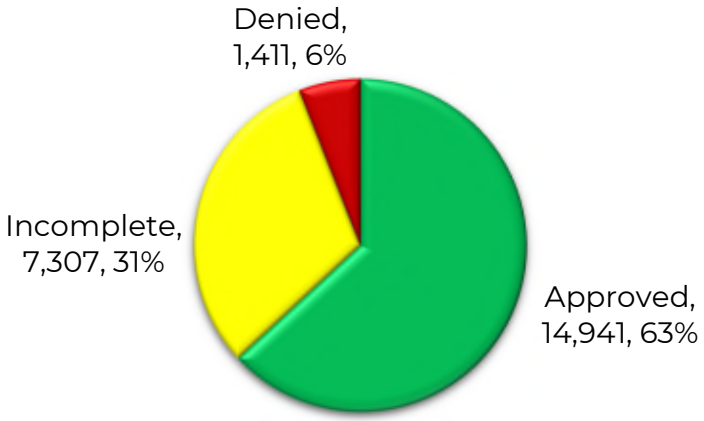
Top Prescriber Specialties of ADHD and Narcolepsy Medications by Number of Claims



Prior Authorization of ADHD and Narcolepsy Medications

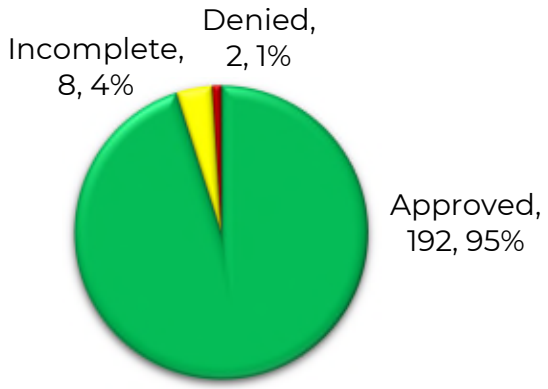
There were 23,659 prior authorization requests submitted for ADHD and narcolepsy medications during calendar year 2022. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



There were 202 prior authorization requests submitted for a total of 151 unique members for ADHD and narcolepsy medications during calendar year 2022 that were referred for a psychiatric consultation. Most requests were for children 3 or 4 years of age. The following chart shows the status of the submitted petitions referred for psychiatric consultation for calendar year 2022.

Status of Psychiatric Consultations



Oklahoma Resources

The following list includes local resources available to prescribers, specifically regarding psychotropic medications:

- **Consultation with a Child Psychiatrist:** For children with especially challenging symptoms, a consultation with a child psychiatrist is available. A psychiatrist can be reached by calling 1-405-522-7597 to schedule a consultation.
- **Care Management (Including Behavioral Health):** Additional services are available for SoonerCare members, by contacting *Care Management* at 1-877-252-6002 or *Behavioral Health Care Management* at 1-800-652-2010.
- **Project ECHO:** Project ECHO (Extension for Community Health Care Outcomes) is available online for medical education and care management for chronic and complex medical conditions at: https://health.okstate.edu/echo/index.html.
- **Oklahoma Pediatric Psychotropic Medication Resource Guide:** The Department of Psychiatry and Behavioral Sciences at Oklahoma State University Center for Health Sciences has provided a psychotropic medication resource guide that can assist in the management of pediatric patients in the state of Oklahoma and can be found at: https://medicine.okstate.edu/academics/psychiatry/index.html.

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

Anticipated Patent Expiration(s):

- Vyvanse® (lisdexamfetamine capsule and chewable tablet): August 2023
- Daytrana® [methylphenidate extended-release (ER) transdermal patch]: October 2025
- Mydayis® (amphetamine/dextroamphetamine ER capsule): August 2029
- Wakix® (pitolisant tablet): March 2030

- Quillivant XR® (methylphenidate ER suspension): February 2031
- Jornay PM® (methylphenidate ER capsule): March 2032
- Adzenys ER™ (amphetamine ER suspension): June 2032
- Adzenys XR-ODT® [amphetamine extended-release (ER) orally disintegrating tablet (ODT)]: June 2032
- Qelbree® (viloxazine ER capsule): February 2033
- QuilliChew ER® (methylphenidate ER chewable tablet): August 2033
- Xyrem® (sodium oxybate solution): September 2033
- Dyanavel® XR (amphetamine ER suspension): September 2036
- Evekeo ODT™ (amphetamine ODT): March 2037
- Xywav® (calcium/magnesium/potassium/sodium oxybates oral solution): September 2037
- Azstarys® (serdexmethylphenidate/dexmethylphenidate capsule): December 2037
- Cotempla XR-ODT® (methylphenidate ER ODT): January 2038
- Dyanavel® XR (amphetamine ER tablet): September 2038
- Adhansia XR® (methylphenidate ER capsule): November 2038
- Sunosi® (solriamfetol tablet): March 2040
- Xelstrym™ (dextroamphetamine transdermal system): January 2042

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

- **June 2022:** The FDA approved Relexxii® (methylphenidate ER) tablets for the treatment of ADHD in adults and pediatric patients 6 years of age and older. Relexxii® will be available in 18mg, 27mg, 36mg, 45mg, 54mg, 63mg, and 72mg strengths.
- **May 2023:** The FDA granted final approval to Lumryz™ (sodium oxybate), an ER formulation of sodium oxybate, for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy. Lumryz™ is the first once nightly oxybate formulation for the treatment of narcolepsy.

News:

- **June 2022:** Viatris launched the first generic formulation of Daytrana® (methylphenidate transdermal patch) for the treatment of ADHD. The generic formulation is available in 10mg/9hr, 15mg/9hr, 20mg/9hr, and 30mg/9hr strength patches.
- **January 2023:** Hikma Pharmaceuticals launched an authorized generic formulation of Xyrem® (sodium oxybate) for the treatment of cataplexy or EDS in patients 7 years of age and older with narcolepsy. The generic formulation is available as an oral solution containing 0.5g of sodium oxybate per milliliter in a 180mL bottle. This is the first generic formulation of Xyrem®.
- **May 2023:** The FDA issued a Drug Safety Communication regarding prescription stimulants and the risks involved with misuse, abuse,

addiction, and sharing of these medications. The FDA is requiring updates to the *Prescribing Information* of all prescription stimulants, including updates to the *Boxed Warning*, to ensure the information provided is consistent across the entire class of the medications. New information will be added stating patients should never share their prescription stimulants with anyone and advises health care professionals to monitor patients closely who are prescribed stimulants for signs of misuse, abuse, and addiction. In addition, the FDA is requiring updates to existing Medication Guides to help educate patients and caregivers regarding these risks.

Lumryz™ (Sodium Oxybate) Product Summary[9]

Therapeutic Class: Central nervous system (CNS) depressant

Indication(s): Treatment of cataplexy or EDS in adults with narcolepsy

How Supplied: Packets for oral suspension in 4.5g, 6g, 7.5g, and 9g strengths

Dosing and Administration:

- Should be initiated at 4.5g orally once nightly
- May be titrated to effect in increments of 1.5g per night at weekly intervals
- Recommended dosage range: 6g to 9g orally once nightly
- Dose should be prepared before bedtime by suspending the dose in 1/3 cup of water in the provided mixing cup
- Should be administered while in bed 2 hours after eating, and the patient should lie down after dosing

Cost: The Wholesale Acquisition Cost (WAC) for Lumryz™ is $582 per packet for the 9g strength, resulting in a cost of $17,460 per month or $209,520 per year for a patient using the maximum recommended dose of 9g per night.

Relexxii® (Methylphenidate ER) Product Summary[10]

Therapeutic Class: CNS stimulant

Indication(s): Treatment of ADHD in adults (up to 65 years of age) and pediatric patients 6 years of age and older

How Supplied: 18mg, 27mg, 36mg, 45mg, 54mg, 63mg, and 72mg ER tablets

Dosing and Administration: Initial recommended dose of 18mg once daily for pediatric patients or 18mg or 36mg once daily for adult patients

- May increase in 18mg increments weekly up to maximum of 72mg once daily

Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days[+]
Relexxii® (methylphenidate ER) 72mg tablet	**$23.02**	**$690.60**
methylphenidate ER 72mg tablet (generic)	$15.38	$461.40
methylphenidate ER 36mg tablet (generic)	$1.10	$66.00

ER = extended-release
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 maximum FDA approved dose of 72mg per day for each product.

Recommendations

The College of Pharmacy recommends the following changes to the ADHD and Narcolepsy Medications PBPA category (changes noted in red in the following PBPA Tier chart and approval criteria):

1. The prior authorization of Relexxii® (methylphenidate ER tablet) and placement into the Special PA Tier of the ADHD Medications PBPA Tier chart; and
2. The prior authorization of Lumryz™ (sodium oxybate) with criteria similar to Xywav® (calcium/magnesium/potassium/sodium oxybates); and
3. Moving Dexedrine Spansules® (dextroamphetamine ER capsule) from the Special PA Tier to Tier-2, moving methylphenidate ER 72mg tablet from Tier-3 to the Special PA Tier, moving Vyvanse® (lisdexamfetamine chewable tablet) from the Special PA Tier to Tier-1, and moving Ritalin LA® (methylphenidate ER capsule) from Tier-1 to Tier-2 based on net costs; and
4. Making Aptensio XR® (methylphenidate ER capsule), Daytrana® (methylphenidate ER patch), and Xyrem® (sodium oxybate solution) brand preferred based on net costs; and
5. Updating the approval criteria for Qelbree® (viloxazine) based on the higher FDA approved maximum dosing in adults.

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			amphetamine ER susp (Adzenys ER™) amphetamine ER ODT (Adenyls XR-ODT®) amphetamine (Evekeo®) amphetamine ODT (Evekeo ODT™) amphetamine/ dextroamphetamine ER (Mydayis®) dextroamphetamine (Dexedrine®) ~~**dextroamphetamine ER (Dexedrine Spansules®)**~~ dextroamphetamine soln (ProCentra®) dextroamphetamine (Xelstrym™) dextroamphetamine (Zenzedi®) ~~**lisdexamfetamine chew tab (Vyvanse®)+**~~ methamphetamine (Desoxyn®) **methylphenidate ER 72mg** methylphenidate ER ODT (Cotempla XR-ODT®) **methylphenidate ER (Relexxii®)** methylphenidate chew tab (Methylin®)
Short-Acting			
amphetamine/ dextroamphetamine (Adderall®)			
Long-Acting			
amphetamine/ dextroamphetamine ER (Adderall XR®) lisdexamfetamine cap **and chew tab** (Vyvanse®)+	amphetamine ER susp and tab (Dyanavel® XR) **dextroamphetamine ER (Dexedrine Spansules®)**		
Methylphenidate			
Short-Acting			
dexmethylphenidate (Focalin®) methylphenidate tab and soln (Methylin®) methylphenidate (Ritalin®)			
Long-Acting			
dexmethylphenidate ER (Focalin XR®) – **Brand Preferred** methylphenidate ER (Concerta®) methylphenidate ER (Daytrana®) **– Brand Preferred** methylphenidate ER (Metadate CD®) methylphenidate ER (Metadate ER®) methylphenidate ER (Methylin ER®) ~~**methylphenidate ER (Ritalin LA®)**~~ methylphenidate ER (Ritalin SR®)	dexmethylphenidate ER (generic Focalin XR®) methylphenidate ER (Aptensio XR®) **– Brand Preferred** methylphenidate ER susp (Quillivant XR®) **methylphenidate ER (Ritalin LA®)**	~~**methylphenidate ER 72mg**~~ methylphenidate ER (Adhansia XR®) methylphenidate ER (Jornay PM®) serdexmethylphen-idate/dexmethylphen-idate (Azstarys®)	

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Non-Stimulants			methylphenidate ER chew tab (QuilliChew ER®) viloxazine (Qelbree®)Δ
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)Δ		

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
+Unique criteria applies for the diagnosis of binge eating disorder (BED).
ΔUnique criteria applies in addition to tier trial requirements.
ADHD = attention-deficit/hyperactivity disorder; cap = capsule; chew tab = chewable tablet; ER = extended-release; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tab = tablet

ADHD Medications Tier-2 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response:
   a. Trials should have been within the last 180 days; and
   b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
   c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
3. For Dyanavel® XR oral suspension and Quillivant XR®, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Kapvay® [Clonidine Extended-Release (ER) Tablet] Approval Criteria:
   a. An FDA approved diagnosis; and
   b. Previously failed trials (within the last 180 days) with a long-acting Tier-1 stimulant, Intuniv®, and Strattera®, unless contraindicated, that did not yield adequate results; and
   c. A patient-specific, clinically significant reason why the member cannot use clonidine immediate-release tablets must be provided.

ADHD Medications Tier-3 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response; and

3. A previously failed trial with at least 1 long-acting Tier-2 stimulant that resulted in an inadequate response:
    a. Trials should have been within the last 365 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician.

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. Adzenys XR-ODT®, Adzenys ER™, Cotempla XR-ODT®, Evekeo ODT™, QuilliChew ER®, ~~Vyvanse® Chewable Tablets,~~ and Xelstrym™ Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use all other available formulations of stimulant medications that can be used for members who cannot swallow capsules or tablets must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
2. Desoxyn®, Dexedrine®, ~~Dexedrine Spansules®,~~ Evekeo®, Methylphenidate ER 72mg Tablet, ProCentra®, Relexxii®, and Zenzedi® Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
3. Methylin® Chewable Tablets Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use methylphenidate immediate-release tablets or oral solution must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Mydayis® Approval Criteria:
    a. A covered diagnosis; and
    b. Member must be 13 years of age or older; and
    c. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.

5. Qelbree® [Viloxazine Extended-Release (ER) Capsule] Approval Criteria:
    a. An FDA approved diagnosis; and
    b. Member must be 6 years of age or older; and
    c. Previously failed trial(s) (within the last 180 days) with atomoxetine or any 2 Tier-1 or Tier-2 ADHD medications, unless contraindicated, that did not yield adequate results; and
        i. Qelbree® will not require a prior authorization and claims will pay at the point of sale if the member has paid claims for atomoxetine or 2 Tier-1 or Tier-2 ADHD medications within the past 180 days of claims history; and
    d. Member must not be taking a monoamine oxidase inhibitor (MAOI) or have taken an MAOI within the last 14 days; and
    e. Member must not be taking sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline) concomitantly with Qelbree®; and
    ~~f. A quantity limit of 30 capsules per 30 days will apply for the 100mg strengths and 60 capsules per 30 days will apply for the 150mg and 200mg strength.~~
    g. Quantity limits will apply based on FDA-approved dosing.

ADHD Medications Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum dose are not covered.
2. Prior authorization is required for all tiers for members older than 20 years of age and for members younger than 5 years of age. All prior authorization requests for members younger than 5 years of age must be reviewed by an Oklahoma Health Care Authority (OHCA)-contracted psychiatrist.
3. For Daytrana® patches, Methylin® oral solution, and Vyvanse® chewable tablet, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
    a. Daytrana® patches are brand preferred. Approval of generic methylphenidate transdermal patches will require a patient-specific, clinically significant reason why brand name Daytrana® cannot be used.
4. Vyvanse® (Lisdexamfetamine) Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:
    a. An FDA approved diagnosis of moderate-to-severe BED; and
    b. Member must be 18 years of age or older; and
    c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and
    d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone.

The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and

e. A quantity limit of 30 capsules or chewable tablets per 30 days will apply; and
f. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.

Idiopathic Hypersomnia (IH) Medications Approval Criteria:

1. Diagnosis of IH meeting the following ICSD-3 (International Classification of Sleep Disorders) criteria:
    a. Daily periods of irresistible need to sleep or daytime lapses into sleep for >3 months; and
    b. Absence of cataplexy; and
    c. Multiple sleep latency test (MSLT) results showing 1 of the following:
        i. <2 sleep-onset rapid eye movement (REM) periods (SOREMPs); or
        ii. No SOREMPs if the REM sleep latency on the preceding polysomnogram is ≤15 minutes; and
    d. At least 1 of the following:
        i. MSLT showing mean sleep latency ≤8 minutes; or
        ii. Total 24-hour sleep time ≥660 minutes on 24-hour polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in association with a sleep log (averaged over ≥7 days with unrestricted sleep); and
    e. Insufficient sleep syndrome has been ruled out; and
    f. Hypersomnolence or MSLT findings are not better explained by any other sleep disorder, medical or neurologic disorder, mental disorder, medication use, or substance abuse; and
2. Diagnosis must be confirmed by a sleep specialist; and
3. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
    a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; and
4. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
5. Use of Xyrem® (sodium oxybate) or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the

last 180 days) with at least 4 of the following, unless contraindicated, that did not yield adequate results:
   a. Tier-1 stimulant; or
   b. Tier-2 stimulant; or
   c. Nuvigil®; or
   d. Provigil®; or
   e. Clarithromycin; and
6. Xyrem® is brand preferred. Requests for generic sodium oxybate will require a patient-specific, clinically significant reason why brand name Xyrem® cannot be used; and
7. Xywav® (calcium/magnesium/potassium/sodium oxybates) additionally requires a patient-specific, clinically significant reason why the member cannot use Xyrem®; and
   b. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided.

Narcolepsy Medications Approval Criteria:

1. An FDA approved diagnosis; and
2. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
   a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; or
3. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; or
4. Use of Lumryz™ (sodium oxybate), Sunosi® (solriamfetol), Wakix® (pitolisant), Xyrem® (sodium oxybate), or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with Tier-1 and Tier-2 stimulants from different chemical categories, Provigil®, and Nuvigil®, unless contraindicated, that did not yield adequate results; and
   a. Xyrem® is brand preferred. Requests for generic sodium oxybate will require a patient-specific, clinically significant reason why brand name Xyrem® cannot be used; and
5. Additionally, use of Lumryz™ (sodium oxybate) or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires a patient-specific, clinically significant reason (beyond convenience) why the member cannot use Xyrem®; and

a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided; and

6. The diagnosis of obstructive sleep apnea requires concurrent treatment for obstructive sleep apnea; and
7. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the prior authorization request.

Utilization Details of ADHD and Narcolepsy Medications: Calendar Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LISDEXAMFETAMINE PRODUCTS						
VYVANSE CAP 30MG	20,887	5,284	$6,790,969.18	$325.13	3.95	13.46%
VYVANSE CAP 20MG	17,064	4,946	$5,551,408.05	$325.33	3.45	11.00%
VYVANSE CAP 40MG	16,469	3,641	$5,342,127.48	$324.37	4.52	10.59%
VYVANSE CAP 50MG	11,275	2,238	$3,673,557.02	$325.81	5.04	7.28%
VYVANSE CAP 10MG	7,359	2,839	$2,379,687.69	$323.37	2.59	4.72%
VYVANSE CAP 60MG	6,395	1,113	$2,062,960.26	$322.59	5.75	4.09%
VYVANSE CAP 70MG	5,540	852	$1,805,654.34	$325.93	6.5	3.58%
VYVANSE CHW 20MG	253	183	$81,988.47	$324.07	1.38	0.16%
VYVANSE CHW 10MG	198	155	$65,159.84	$329.09	1.28	0.13%
VYVANSE CHW 30MG	124	85	$37,183.18	$299.86	1.46	0.07%
VYVANSE CHW 40MG	56	43	$18,115.40	$323.49	1.3	0.04%
VYVANSE CHW 50MG	39	17	$11,889.03	$304.85	2.29	0.02%
VYVANSE CHW 60MG	7	5	$2,286.55	$326.65	1.4	0.00%
SUBTOTAL	**85,666**	**15,259***	**$27,822,986.49**	**$324.78**	**5.61**	**55.14%**
METHYLPHENIDATE PRODUCTS						
METHYLPHENID TAB 10MG	9,274	2,193	$160,697.13	$17.33	4.23	0.32%
METHYLPHENID TAB 5MG	7,492	2,175	$115,904.40	$15.47	3.44	0.23%
METHYLPHENID CAP 20MG	7,483	2,096	$343,305.38	$45.88	3.57	0.68%
METHYLPHENID CAP 30MG	7,026	1,618	$319,200.64	$45.43	4.34	0.63%
METHYLPHENID CAP 40MG ER	4,519	979	$264,743.72	$58.58	4.62	0.52%
METHYLPHENID TAB 20MG	4,204	803	$80,168.75	$19.07	5.24	0.16%
METHYLPHENID TAB 36MG ER	3,886	892	$151,315.64	$38.94	4.36	0.30%
METHYLPHENID CAP 10MG	3,603	1,426	$180,824.65	$50.19	2.53	0.36%
METHYLPHENID TAB 54MG ER	2,979	593	$97,161.77	$32.62	5.02	0.19%
METHYLPHENID CAP 50MG	2,105	424	$156,122.75	$74.17	4.96	0.31%
METHYLPHENID TAB 27MG ER	2,049	660	$59,644.04	$29.11	3.1	0.12%
METHYLPHENID TAB 18MG ER	1,847	728	$49,491.35	$26.80	2.54	0.10%
METHYLPHENID CAP 60MG	1,756	285	$111,143.17	$63.29	6.16	0.22%
METHYLPHENID CAP 20MG ER	1,719	485	$86,572.61	$50.36	3.54	0.17%
METHYLPHENID CAP 30MG ER	1,138	302	$58,034.25	$51.00	3.77	0.12%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
METHYLPHENID CAP 40MG ER	886	201	$41,162.16	$46.46	4.41	0.08%
METHYLPHENID CAP 30MG ER	866	207	$188,745.20	$217.95	4.18	0.37%
METHYLPHENID SOL 5MG/5ML	852	280	$34,990.46	$41.07	3.04	0.07%
METHYLPHENID CAP 10MG ER	792	309	$80,865.35	$102.10	2.56	0.16%
METHYLPHENID CAP 40MG ER	783	174	$169,935.97	$217.03	4.5	0.34%
METHYLPHENID TAB 20MG ER	775	260	$19,190.56	$24.76	2.98	0.04%
METHYLPHENID CAP 60MG ER	659	112	$138,446.13	$210.09	5.88	0.27%
QUILLIVANT SUS 25MG/5ML	562	132	$232,684.91	$414.03	4.26	0.46%
METHYLPHENID CAP 20MG ER	528	143	$113,636.17	$215.22	3.69	0.23%
METHYLPHENID CAP 50MG ER	459	91	$102,039.81	$222.31	5.04	0.20%
CONCERTA TAB 36MG	424	175	$160,485.30	$378.50	2.42	0.32%
METHYLPHENID SOL 10MG/5ML	410	116	$19,736.53	$48.14	3.53	0.04%
METHYLPHENID TAB 10MG ER	340	154	$6,617.48	$19.46	2.21	0.01%
METHYLPHENID TAB 36MG ER	298	150	$10,848.14	$36.40	1.99	0.02%
CONCERTA TAB 54MG	284	110	$79,052.41	$278.35	2.58	0.16%
METHYLPHENID TAB 54MG ER	252	132	$8,374.38	$33.23	1.91	0.02%
METHYLPHENID TAB 27MG ER	240	151	$7,051.49	$29.38	1.59	0.01%
METHYLPHENID CAP 15MG ER	230	60	$51,396.13	$223.46	3.83	0.10%
QUILLICHEW CHW 20MG ER	227	135	$76,635.28	$337.60	1.68	0.15%
METHYLPHENID TAB 72MG ER	212	36	$93,076.83	$439.04	5.89	0.18%
METHYLPHENID CAP 10MG ER	192	66	$40,698.51	$211.97	2.91	0.08%
APTENSIO XR CAP 40MG	173	39	$44,980.46	$260.00	4.44	0.09%
CONCERTA TAB 27MG	169	88	$46,232.69	$273.57	1.92	0.09%
QUILLICHEW CHW 30MG ER	168	82	$60,675.04	$361.16	2.05	0.12%
DAYTRANA DIS 10MG/9HR	165	75	$68,864.15	$417.36	2.2	0.14%
CONCERTA TAB 18MG	143	80	$38,870.27	$271.82	1.79	0.08%
DAYTRANA DIS 30MG/9HR	131	29	$53,942.86	$411.78	4.52	0.11%
JORNAY PM CAP 40MG ER	130	29	$50,538.66	$388.76	4.48	0.10%
DAYTRANA DIS 20MG/9HR	129	43	$55,499.34	$430.23	3	0.11%
METHYLPHENID TAB 18MG ER	117	77	$3,071.63	$26.25	1.52	0.01%
JORNAY PM CAP 60MG ER	99	30	$31,236.02	$315.52	3.3	0.06%
APTENSIO XR CAP 60MG	99	26	$25,461.21	$257.18	3.81	0.05%
APTENSIO XR CAP 20MG	97	29	$25,200.69	$259.80	3.34	0.05%
DAYTRANA DIS 15MG/9HR	96	37	$40,038.73	$417.07	2.59	0.08%
METHYLIN SOL 5MG/5ML	93	41	$4,355.80	$46.84	2.27	0.01%
APTENSIO XR CAP 30MG	90	36	$23,328.37	$259.20	2.5	0.05%
METHYLPHENID CAP 60MG LA	70	18	$15,392.58	$219.89	3.89	0.03%
APTENSIO XR CAP 50MG	57	18	$14,789.92	$259.47	3.17	0.03%
RITALIN LA CAP 10MG	55	18	$17,286.68	$314.30	3.06	0.03%
JORNAY PM CAP 100MG ER	52	9	$20,283.30	$390.06	5.78	0.04%
JORNAY PM CAP 80MG ER	52	12	$19,820.03	$381.15	4.33	0.04%
METHYLPHENID DIS 10MG/9HR	51	31	$20,354.93	$399.12	1.65	0.04%
QUILLICHEW CHW 40MG ER	50	25	$18,461.40	$369.23	2	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
JORNAY PM CAP 20MG ER	47	26	$18,175.80	$386.72	1.81	0.04%
APTENSIO XR CAP 10MG	47	9	$11,999.61	$255.31	5.22	0.02%
METHYLPHENID CHW 5MG	38	11	$5,621.96	$147.95	3.45	0.01%
METHYLPHENID CHW 10MG	37	8	$4,693.61	$126.85	4.63	0.01%
METHYLPHENID CHW 2.5MG	37	6	$3,283.34	$88.74	6.17	0.01%
APTENSIO XR CAP 15MG	36	8	$9,414.72	$261.52	4.5	0.02%
METHYLPHENID DIS 15MG/9HR	34	17	$14,353.76	$422.17	2	0.03%
METHYLPHENID DIS 20MG/9HR	23	15	$10,404.74	$452.38	1.53	0.02%
METHYLPHENID DIS 30MG/9HR	17	7	$6,374.46	$374.97	2.43	0.01%
ADHANSIA XR CAP 55MG	15	4	$3,538.64	$235.91	3.75	0.01%
ADHANSIA XR CAP 70MG	13	3	$4,431.21	$340.86	4.33	0.01%
METHYLIN SOL 10MG/5ML	13	4	$841.02	$64.69	3.25	0.00%
RITALIN TAB 20MG	10	1	$1,659.08	$165.91	10	0.00%
ADHANSIA XR CAP 85MG	8	1	$2,732.32	$341.54	8	0.01%
ADHANSIA XR CAP 25MG	7	2	$2,415.28	$345.04	3.5	0.00%
COTEMPLA TAB 25.9MG	5	1	$2,196.80	$439.36	5	0.00%
ADHANSIA XR CAP 45MG	2	2	$476.31	$238.16	1	0.00%
SUBTOTAL	**74,026**	**11,830***	**$4,711,296.87**	**$63.64**	**6.26**	**9.34%**
AMPHETAMINE/DEXTROAMPHETAMINE PRODUCTS						
AMPHET/DEXTR TAB 10MG	12,170	2,964	$252,569.26	$20.75	4.11	0.50%
AMPHET/DEXTR TAB 20MG	11,078	2,086	$280,111.63	$25.29	5.31	0.56%
AMPHET/DEXTR TAB 5MG	7,451	2,143	$143,633.17	$19.28	3.48	0.28%
AMPHET/DEXTR TAB 30MG	5,337	919	$129,662.29	$24.29	5.81	0.26%
AMPHET/DEXTR CAP 20MG ER	5,066	1,326	$134,967.97	$26.64	3.82	0.27%
AMPHET/DEXTR CAP 30MG ER	4,446	855	$119,751.99	$26.93	5.2	0.24%
AMPHET/DEXTR TAB 15MG	3,836	826	$82,313.79	$21.46	4.64	0.16%
AMPHET/DEXTR CAP 10MG ER	3,494	1,220	$87,179.69	$24.95	2.86	0.17%
AMPHET/DEXTR CAP 15MG ER	2,715	816	$69,623.44	$25.64	3.33	0.14%
AMPHET/DEXTR CAP 25MG ER	1,909	448	$47,310.43	$24.78	4.26	0.09%
AMPHET/DEXTR TAB 7.5MG	993	223	$25,345.57	$25.52	4.45	0.05%
AMPHET/DEXTR CAP 5MG ER	821	396	$21,887.26	$26.66	2.07	0.04%
AMPHET/DEXTR TAB 12.5MG	281	74	$8,658.96	$30.81	3.8	0.02%
ADDERALL XR CAP 20MG	43	18	$6,460.78	$150.25	2.39	0.01%
ADDERALL XR CAP 30MG	30	14	$5,839.37	$194.65	2.14	0.01%
MYDAYIS CAP 25MG	20	4	$3,142.21	$157.11	5	0.01%
ADDERALL XR CAP 25MG	16	4	$957.56	$59.85	4	0.00%
ADDERALL TAB 15MG	15	3	$8,022.77	$534.85	5	0.02%
MYDAYIS CAP 50MG	15	2	$4,743.13	$316.21	7.5	0.01%
MYDAYIS CAP 37.5MG	13	3	$4,195.87	$322.76	4.33	0.01%
ADDERALL XR CAP 15MG	11	7	$1,708.97	$155.36	1.57	0.00%
ADDERALL XR CAP 10MG	9	5	$1,769.43	$196.60	1.8	0.00%
ADDERALL TAB 20MG	5	4	$2,505.32	$501.06	1.25	0.00%
ADDERALL TAB 30MG	1	1	$525.06	$525.06	1	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ADDERALL TAB 10MG	1	1	$517.51	$517.51	1	0.00%
SUBTOTAL	**59,776**	**10,204***	**$1,443,403.43**	**$24.15**	**5.86**	**2.86%**
GUANFACINE ER PRODUCTS						
GUANFACINE TAB 2MG ER	19,612	4,058	$353,855.86	$18.04	4.83	0.70%
GUANFACINE TAB 1MG ER	15,568	4,588	$273,680.41	$17.58	3.39	0.54%
GUANFACINE TAB 3MG ER	12,326	2,137	$226,388.15	$18.37	5.77	0.45%
GUANFACINE TAB 4MG ER	10,703	1,477	$190,952.01	$17.84	7.25	0.38%
INTUNIV TAB 4MG	47	5	$14,146.15	$300.98	9.4	0.03%
INTUNIV TAB 3MG	28	4	$8,130.24	$290.37	7	0.02%
INTUNIV TAB 2MG	20	3	$5,757.88	$287.89	6.67	0.01%
SUBTOTAL	**58,304**	**9,335***	**$1,072,910.70**	**$18.40**	**6.25**	**2.13%**
DEXMETHYLPHENIDATE PRODUCTS						
FOCALIN XR CAP 10MG	6,160	1,863	$2,349,778.91	$381.46	3.31	4.66%
DEXMETHYLPHE TAB 10MG	6,106	1,151	$125,621.05	$20.57	5.3	0.25%
DEXMETHYLPHE TAB 5MG	5,822	1,332	$101,311.46	$17.40	4.37	0.20%
FOCALIN XR CAP 20MG	5,689	1,273	$2,254,648.78	$396.32	4.47	4.47%
FOCALIN XR CAP 15MG	5,120	1,267	$2,016,622.56	$393.87	4.04	4.00%
FOCALIN XR CAP 30MG	3,168	599	$1,206,512.31	$380.84	5.29	2.39%
FOCALIN XR CAP 5MG	2,848	1,147	$1,057,781.40	$371.41	2.48	2.10%
FOCALIN XR CAP 25MG	2,733	514	$1,141,782.18	$417.78	5.32	2.26%
DEXMETHYLPHE TAB 2.5MG	1,897	518	$29,673.13	$15.64	3.66	0.06%
FOCALIN XR CAP 40MG	1,370	224	$596,703.24	$435.55	6.12	1.18%
FOCALIN XR CAP 35MG	828	154	$361,902.97	$437.08	5.38	0.72%
FOCALIN TAB 10MG	35	6	$2,318.20	$66.23	5.83	0.00%
FOCALIN TAB 5MG	28	3	$2,317.26	$82.76	9.33	0.00%
DEXMETHYLPHE CAP 30MG ER	22	10	$818.17	$37.19	2.2	0.00%
DEXMETHYLPHE CAP 5MG ER	20	8	$249.55	$12.48	2.5	0.00%
DEXMETHYLPHE CAP 10MG ER	18	4	$542.41	$30.13	4.5	0.00%
DEXMETHYLPHE CAP 25MG ER	15	3	$771.59	$51.44	5	0.00%
DEXMETHYLPHE CAP 15MG ER	15	6	$214.55	$14.30	2.5	0.00%
DEXMETHYLPHE CAP 20MG ER	11	5	$304.36	$27.67	2.2	0.00%
DEXMETHYLPHE CAP 40MG ER	7	2	$194.00	$27.71	3.5	0.00%
DEXMETHYLPHE CAP 35MG ER	3	1	$0.00	$0.00	3	0.00%
SUBTOTAL	**41,915**	**6,191***	**$11,250,068.08**	**$268.40**	**6.77**	**22.30%**
ATOMOXETINE PRODUCTS						
ATOMOXETINE CAP 40MG	9,934	3,107	$392,222.11	$39.48	3.2	0.78%
ATOMOXETINE CAP 25MG	8,083	2,531	$326,796.97	$40.43	3.19	0.65%
ATOMOXETINE CAP 60MG	4,613	1,077	$185,424.13	$40.20	4.28	0.37%
ATOMOXETINE CAP 18MG	4,558	1,571	$175,708.65	$38.55	2.9	0.35%
ATOMOXETINE CAP 10MG	3,598	1,353	$149,386.64	$41.52	2.66	0.30%
ATOMOXETINE CAP 80MG	2,456	654	$113,040.75	$46.03	3.76	0.22%
ATOMOXETINE CAP 100MG	1,055	242	$58,182.97	$55.15	4.36	0.12%
STRATTERA CAP 40MG	25	2	$10,824.25	$432.97	12.5	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**34,322**	**7,567***	**$1,411,586.47**	**$41.13**	**4.54**	**2.80%**
CLONIDINE ER PRODUCTS						
CLONIDINE TAB 0.1MG ER	849	154	$29,152.13	$34.34	5.51	0.06%
SUBTOTAL	**849**	**154***	**$29,152.13**	**$34.34**	**5.51**	**0.06%**
VILOXAZINE PRODUCTS						
QELBREE CAP 200MG ER	469	161	$170,664.30	$363.89	2.91	0.34%
QELBREE CAP 100MG ER	264	130	$75,301.32	$285.23	2.03	0.15%
QELBREE CAP 150MG ER	65	21	$21,311.35	$327.87	3.1	0.04%
SUBTOTAL	**798**	**246***	**$267,276.97**	**$334.93**	**3.24**	**0.53%**
ARMODAFINIL PRODUCTS						
NUVIGIL TAB 150MG	125	25	$128,360.17	$1,026.88	5	0.25%
NUVIGIL TAB 250MG	118	24	$115,694.76	$980.46	4.92	0.23%
NUVIGIL TAB 200MG	24	11	$24,423.91	$1,017.66	2.18	0.05%
ARMODAFINIL TAB 250MG	12	3	$469.29	$39.11	4	0.00%
ARMODAFINIL TAB 200MG	8	4	$281.11	$35.14	2	0.00%
ARMODAFINIL TAB 150MG	2	2	$79.95	$39.98	1	0.00%
ARMODAFINIL TAB 50MG	1	1	$14.50	$14.50	1	0.00%
SUBTOTAL	**290**	**57***	**$269,323.69**	**$928.70**	**5.09**	**0.53%**
MODAFINIL PRODUCTS						
MODAFINIL TAB 200MG	161	24	$5,041.61	$31.31	6.71	0.01%
MODAFINIL TAB 100MG	11	4	$202.80	$18.44	2.75	0.00%
PROVIGIL TAB 200MG	8	1	$32,916.16	$4,114.52	8	0.07%
SUBTOTAL	**180**	**29***	**$38,160.57**	**$212.00**	**6.21**	**0.08%**
DEXTROAMPHETAMINE PRODUCTS						
DEXTROAMPHET CAP 15MG ER	48	5	$6,820.49	$142.09	9.6	0.01%
DEXTROAMPHET CAP 10MG ER	10	1	$782.98	$78.30	10	0.00%
DEXTROAMPHET TAB 10MG	13	2	$401.29	$30.87	6.5	0.00%
DEXTROAMPHET TAB 20MG	6	2	$2,294.10	$382.35	3	0.00%
DEXTROAMPHET CAP 5MG ER	6	1	$245.42	$40.90	6	0.00%
DEXTROAMPHET SOL 5MG/5ML	5	1	$2,539.66	$507.93	5	0.01%
DEXTROAMPHET TAB 5MG	3	1	$85.02	$28.34	3	0.00%
DEXTROAMPHET TAB 15MG	1	1	$173.88	$173.88	1	0.00%
SUBTOTAL	**92**	**14***	**$13,342.84**	**$145.03**	**6.57**	**0.03%**
AMPHETAMINE PRODUCTS						
DYANAVEL XR SUS 2.5MG/ML	33	6	$12,864.11	$389.82	5.5	0.03%
ADZENYS XR TAB 18.8MG	19	2	$8,244.91	$433.94	9.5	0.02%
DYANAVEL XR CHW 10MG	14	6	$5,897.24	$421.23	2.33	0.01%
ADZENYS XR TAB 6.3MG	10	1	$4,329.38	$432.94	10	0.01%
DYANAVEL XR CHW 15MG	5	3	$2,182.05	$436.41	1.67	0.00%
ADZENYS XR TAB 15.7MG	4	1	$1,705.20	$426.30	4	0.00%
DYANAVEL XR CHW 5MG	1	1	$236.41	$236.41	1	0.00%
SUBTOTAL	**86**	**17***	**$35,459.30**	**$412.32**	**5.06**	**0.07%**
PITOLISANT PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
WAKIX TAB 17.8MG	50	8	$646,732.25	$12,934.65	6.25	1.28%
WAKIX TAB 4.45MG	5	5	$7,988.15	$1,597.63	1	0.02%
SUBTOTAL	**55**	**8***	**$654,720.40**	**$11,904.01**	**6.88**	**1.30%**
CALCIUM/MAGNESIUM/POTASSIUM/SODIUM OXYBATES PRODUCTS						
XYWAV SOL 0.5GM/ML	50	5	$738,710.86	$14,774.22	10	1.46%
SUBTOTAL	**50**	**5***	**$738,710.86**	**$14,774.22**	**10**	**1.46%**
SODIUM OXYBATE PRODUCTS						
XYREM SOL 500MG/ML	44	10	$677,452.32	$15,396.64	4.4	1.34%
SUBTOTAL	**44**	**10***	**$677,452.32**	**$15,396.64**	**4.4**	**1.34%**
DEXMETHYLPHENIDATE/SERDEXMETHYLPHENIDATE PRODUCTS						
AZSTARYS CAP 39.2/7.8MG	19	6	$6,804.75	$358.14	3.17	0.01%
AZSTARYS CAP 52.3/10.4MG	11	4	$2,159.52	$196.32	2.75	0.00%
AZSTARYS CAP 26.1/5.2MG	4	3	$1,060.30	$265.08	1.33	0.00%
SUBTOTAL	**34**	**9***	**$10,024.57**	**$294.84**	**3.78**	**0.02%**
SOLRIAMFETOL PRODUCTS						
SUNOSI TAB 150MG	18	5	$12,880.32	$715.57	3.6	0.03%
SUBTOTAL	**18**	**5***	**$12,880.32**	**$715.57**	**3.6**	**0.03%**
TOTAL	**356,505**	**46,024***	**$50,458,756.01**	**$141.54**	**7.75**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AMPHET/DEXTR = amphetamine/dextroamphetamine; CAP = capsule; CHW = chewable tablet; DEXMETHYLPHE = dexmethylphenidate; DEXTROAMPHET = dextroamphetamine; DIS = patch; ER = extended-release; HR = hour; LA = long-acting; METHYLPHENID = methylphenidate; SOL = solution; SUS = suspension; TAB = tablet

[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 05/2023. Last accessed 05/04/2023.
[2] Relexxii® (Methylphenidate Hydrochloride Extended-Release) – New Drug Approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_relexxii_2022-0627.pdf. Issued 06/23/2022. Last accessed 05/08/2023.
[3] Avadel Pharmaceuticals. Avadel Pharmaceuticals Announces Final FDA Approval of Lumryz™ (Sodium Oxybate) for Extended-Release Oral Suspension as the First and Only Once-at-Bedtime Oxybate for Cataplexy or Excessive Daytime Sleepiness in Adults with Narcolepsy. *BioSpace*. Available online at: https://www.biospace.com/article/releases/avadel-pharmaceuticals-announces-final-fda-approval-of-lumryz-sodium-oxybate-for-extended-release-oral-suspension-as-the-first-and-only-once-at-bedtime-oxybate-for-cataplexy-or-excessive-daytime-sleepiness-in-adults-with-narcolepsy/. Issued 05/01/2023. Last accessed 05/08/2023.
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Appendix O

Calendar Year 2022 Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Abilify Asimtufii® [Aripiprazole Extended-Release (ER) Injection], Quetiapine 150mg Tablet, Rykindo® (Risperidone ER Injection), and Uzedy™ (Risperidone ER Injection)

Oklahoma Health Care Authority
June 2023

Current Prior Authorization Criteria

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole (Abilify®)¥	asenapine (Saphris®)	aripiprazole tablets with sensor (Abilify MyCite®)~
aripiprazole IM inj (Abilify Maintena®)^	lurasidone (Latuda®)	asenapine transdermal system (Secuado®)+
aripiprazole lauroxil IM inj (Aristada®)^		brexpiprazole (Rexulti®)
aripiprazole lauroxil IM inj (Aristada Initio®)^		cariprazine (Vraylar®)
clozapine (Clozaril®)◊		clozapine (Fazaclo®)+
olanzapine (Zyprexa®)		clozapine oral susp (Versacloz®)+
paliperidone palmitate IM inj (Invega Hafyera™)^		iloperidone (Fanapt®)
paliperidone palmitate IM inj (Invega Sustenna®)^		lumateperone (Caplyta®)
paliperidone palmitate IM inj (Invega Trinza®)^		olanzapine/fluoxetine (Symbyax®)
quetiapine (Seroquel®)		olanzapine/samidorphan (Lybalvi®)β
quetiapine ER (Seroquel XR®)		paliperidone (Invega®)
risperidone (Risperdal®)		
risperidone IM inj (Risperdal Consta®)^		
risperidone ER sub-Q inj (Perseris®)^		
ziprasidone (Geodon®)		

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
ER = extended-release; IM = intramuscular; inj = injection; sub-Q = subcutaneous; susp = suspension
¥Aripiprazole (Abilify®) orally disintegrating tablet (ODT) is considered a special formulation and requires a patient-specific, clinically significant reason why a special formulation product is needed in place of the regular tablet formulation.
◊Clozapine does not count towards a Tier-1 trial.
^Use of a long-acting injectable product may require the member to have been adequately treated with another oral or injectable product prior to use and/or during initiation. The package labeling should be referenced for each individual product.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.
βUnique criteria applies to Lybalvi® (olanzapine/samidorphan).

Tier-1 products are available without prior authorization for members 5 years of age and older. Prior authorization requests for members younger than 5 years of age are reviewed by an Oklahoma Health Care Authority (OHCA)-contracted child psychiatrist.

Atypical Antipsychotic Medications Tier-2 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
    a. Clozapine does not count towards a Tier-1 trial.

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
    a. Clozapine does not count towards a Tier-1 trial; and
2. Trials of all oral Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or
3. A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and
4. Use of Versacloz® (clozapine oral suspension) or Fazaclo® (clozapine orally disintegrating tablet) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
5. Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the oral sublingual tablet formulation. Tier structure rules continue to apply; and

6. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

Approval Criteria for Atypical Antipsychotic Medications as Adjunctive Treatment of Major Depressive Disorder (MDD):

1. Authorization of Symbyax® (olanzapine/fluoxetine) or Rexulti® (brexpiprazole) for a diagnosis of MDD requires current use of an antidepressant and previous trials with at least 2 other antidepressants from both categories (an SSRI and a dual-acting medication) and aripiprazole tablets that did not yield adequate response; and
2. Tier structure rules still apply.

Abilify MyCite® (Aripiprazole Tablet with Sensor) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must not have dementia-related psychosis; and
3. A patient-specific, clinically significant reason why the member cannot use all oral or injectable Tier-1 or Tier-2 medications must be provided. Tier structure rules continue to apply. Please note, the ability of Abilify MyCite® to improve patient compliance or modify aripiprazole dosage has not been established; and
4. Previous use of aripiprazole tablets and a reason why the Tier-1 aripiprazole tablets are no longer appropriate for the member must be provided; and
5. Prescriber agrees to closely monitor patient adherence; and
6. Patients should be capable and willing to use the MyCite® App and follow the *Instructions for Use* and ensure the MyCite® App is compatible with their specific smartphone; and
7. Initial approval will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and patient compliance greater than 80% with prescribed therapy must be provided. In addition, a patient-specific, clinically significant reason why the member cannot transition to oral aripiprazole tablets or to any of the oral or injectable Tier-1 or Tier-2 medications must be provided. Tier structure rules continue to apply.

Lybalvi® (Olanzapine/Samidorphan) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. Member must be stable on olanzapine for at least 14 days and be experiencing significant weight gain (baseline and current weight must be provided); or
4. A patient specific, clinically significant reason why the member cannot use a lower-tiered product with a lower weight gain profile must be provided; and

5. Member must not be taking opioids or undergoing acute opioid withdrawal; and
6. Initial approvals will be for 3 months. For continuation consideration, documentation that the member is responding well to treatment and has had no excessive weight gain while on therapy must be provided.

Utilization of Atypical Antipsychotic Medications: Calendar Year 2022

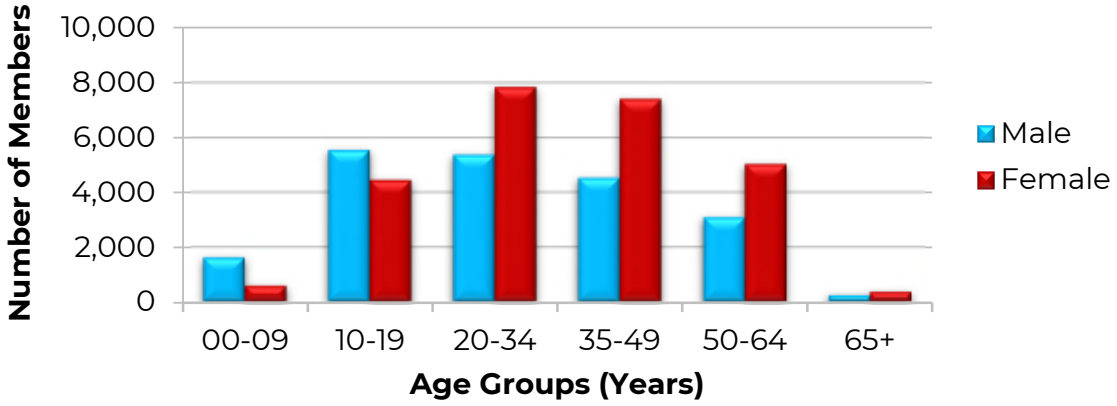
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	36,022	224,340	$76,887,748.68	$342.73	$10.24	9,044,518	7,510,166
2022	45,841	279,860	$110,468,985.54	$394.73	$11.36	11,335,718	9,726,188
% Change	**27.3%**	**24.7%**	**43.7%**	**15.2%**	**10.9%**	**25.3%**	**29.5%**
Change	**9,819**	**55,520**	**$33,581,236.86**	**$52.00**	**$1.12**	**2,291,200**	**2,216,022**

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

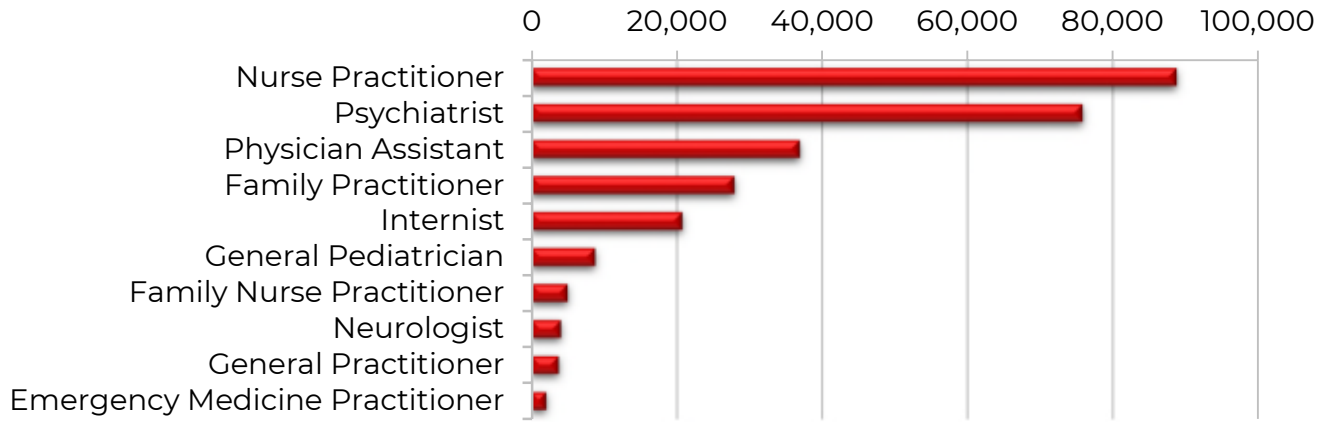
- The Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) category is heavily influenced by supplemental rebates. These rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.
  - Aggregate drug rebates collected during calendar year 2022 for atypical antipsychotic medications: $77,156,506.00[Δ]

Demographics of Members Utilizing Atypical Antipsychotic 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.

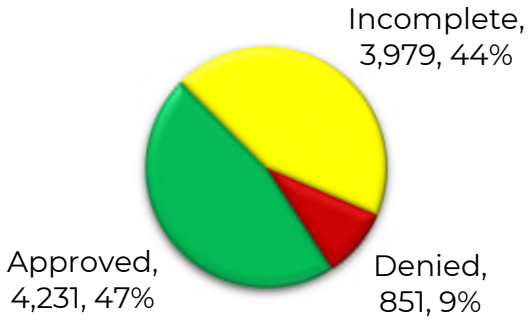
Top Prescriber Specialties of Atypical Antipsychotic Medications by Number of Claims



Prior Authorization of Atypical Antipsychotic Medications

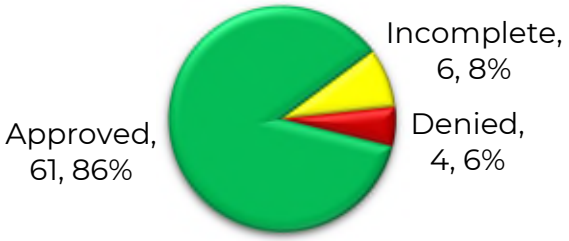
There were 9,061 prior authorization requests submitted for atypical antipsychotic medications during calendar year 2022. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



There were 71 prior authorization requests submitted for a total of 50 unique members for atypical antipsychotic medications during calendar year 2022 that were referred for a psychiatric consultation. Most requests were for children 3 or 4 years of age. The following chart shows the status of the submitted petitions that were referred for a psychiatric consultation for calendar year 2022.

Status of Psychiatric Consultations



Oklahoma Resources

The following list includes local resources available to prescribers, specifically regarding psychotropic medications:

- **Consultation with a Child Psychiatrist:** For children with especially challenging symptoms, a consultation with a child psychiatrist is available. A psychiatrist can be reached by calling 1-405-522-7597 to schedule a consultation.
- **Care Management (Including Behavioral Health):** Additional services are available for SoonerCare members by contacting *Care Management* at 1-877-252-6002 or *Behavioral Health Care Management* at 1-800-652-2010.
- **Project ECHO:** Project ECHO (Extension for Community Health Care Outcomes) is available online for medical education and care management for chronic and complex medical conditions at: https://health.okstate.edu/echo/index.html.
- **Oklahoma Pediatric Psychotropic Medication Resource Guide:** The Department of Psychiatry and Behavioral Sciences at Oklahoma State University Center for Health Sciences has provided a psychotropic medication resource guide that can assist in the management of pediatric patients in the state of Oklahoma and can be found at: https://medicine.okstate.edu/academics/psychiatry/index.html.

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

Anticipated Patent Expiration(s):

- Saphris® [asenapine sublingual (SL) tablet]: October 2026
- Perseris® [risperidone extended-release (ER) subcutaneous (sub-Q) injection]: February 2028
- Versacloz® (clozapine oral suspension): May 2028
- Vraylar® (cariprazine capsule): September 2029
- Invega Sustenna® [paliperidone intramuscular (IM) injection]: January 2031
- Latuda® (lurasidone tablet): November 2031

- Fanapt® (iloperidone tablet): December 2031
- Lybalvi® (olanzapine/samidorphan tablet): February 2032
- Rykindo® (risperidone ER IM injection): April 2032
- Rexulti® (brexpiprazole tablet): October 2032
- Abilify Asimtufii® (aripiprazole IM injection): April 2033
- Uzedy™ (risperidone ER sub-Q injection): April 2033
- Secuado® (asenapine transdermal system): July 2033
- Abilify MyCite® (aripiprazole tablet with sensor): October 2033
- Abilify Maintena® (aripiprazole IM injection): March 2034
- Aristada® (aripiprazole lauroxil IM injection): March 2035
- Invega Trinza® (paliperidone IM injection): April 2036
- Caplyta® (lumateperone capsule): August 2039
- Invega Hafyera™ (paliperidone palmitate IM injection): May 2041

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

- **April 2022:** The FDA approved 2 new strengths of Caplyta® (lumateperone), 10.5mg and 21mg, to provide dosing recommendations for patients who are taking concomitant strong or moderate CY3A4 inhibitors. The 21mg strength can also be utilized for patients with moderate or severe hepatic impairment (Child-Pugh class B or C).
- **December 2022:** The FDA approved Vraylar® (cariprazine) as an adjunctive therapy to antidepressants for major depressive disorder (MDD) in adults. The efficacy of cariprazine for this indication was established in 2 trials in patients with MDD who had an inadequate response to 1-3 prior antidepressant therapies. Vraylar® was previously FDA approved for bipolar I disorder and schizophrenia in adults.
- **January 2023:** The FDA approved Rykindo® (risperidone ER injection) for the treatment of schizophrenia in adults or as monotherapy or adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults. Rykindo® is administered via IM injection once every 2 weeks. Doses should not exceed 50mg every 2 weeks and, prior to initiation, tolerability with oral risperidone should be established.
- **April 2023:** The FDA approved Uzedy™ (risperidone ER injection) for the treatment of schizophrenia in adults. Uzedy™ is the first sub-Q, long-acting formulation of risperidone to utilize MedinCell's SteadyTeq™ technology. This new technology helps control the steady release of risperidone allowing therapeutic blood concentrations to be reached within 6-24 hours. Uzedy™ is administered once every month or once every 2 months, with the dose being dependent on the patient's prior oral risperidone therapy.
- **April 2023:** The FDA approved Abilify Asimtufii® (aripiprazole ER injection) for the treatment of schizophrenia or maintenance

monotherapy treatment of bipolar I disorder, both in adults. Abilify Asimtufii® is given once every 2 months via IM injection by a health care professional. Tolerability with oral aripiprazole should be established in patients who are naïve to aripiprazole.

- **May 2023:** The FDA approved a new indication for Rexulti® (brexpiprazole) for the treatment of agitation associated with dementia due to Alzheimer's disease. This is the first FDA approved treatment for this indication. Rexulti® was previously FDA approved for schizophrenia in patients 13 years of age or older and as adjunctive therapy to antidepressants for MDD in adults.

News:

- **February 2023:** Generic Latuda® (lurasidone) was launched in the United States by several different manufacturers including Accord, Amneal, Dr. Reddy's, Lupin, and various others. The generics have been rated as therapeutically equivalent to Sunovion's brand name Latuda®. Lurasidone will be available in 20mg, 40mg, 60mg, 80mg, and 120mg tablets.

Pipeline:

- **KarXT (Xanomeline/Trospium):** KarXT is an M1/M4-preferring muscarinic agonist that is currently in Phase 3 trials for the treatment of schizophrenia. A New Drug Application (NDA) is expected to be submitted to the FDA in mid-2023.

Cost Comparison: Aripiprazole Long-Acting Injectable (LAI) Products

Medication	Cost Per Syringe	Cost Per Year
Abilify Asimtufii® (aripiprazole) 960mg/3.2mL PFS	**$5,438.46**	**$32,630.76ß**
Abilify Maintena® (aripiprazole) 400mg PFS	$2,603.06	$31,236.72*
Aristada® (aripiprazole lauroxil) 1,064mg/3.9mL PFS	$3,454.70	$20,728.20⁺

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC), or Specialty Pharmaceutical Acquisition Cost (SPAC).
PFS = pre-filled syringe
ßAbilify Asimtufii® cost per year is based on maximum dose of 960mg once every 2 months.
*Abilify Maintena® cost per year is based on maximum dose of 400mg once monthly.
⁺Aristada® cost per year is based on maximum dose of 1,064mg once every 2 months.

Cost Comparison: Quetiapine Products

Medication	Cost Per Tablet	Cost Per Month*
quetiapine 150mg tablets	**$1.49**	**$44.70**
quetiapine 50mg tablets	$0.04	$3.60
quetiapine 300mg tablets	$0.14	$2.10
quetiapine 100mg tablets	$0.04	$1.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month is based on a dose of 150mg daily.

Cost Comparison: Risperidone LAI Products

Medication	Cost Per Unit	Cost Per Year
Uzedy™ (risperidone) 125mg/0.35mL	**$3,080.00**	**$36,960.00***
Uzedy™ (risperidone) 250mg/0.7mL	**$6,160.00**	**$36,960.00***
Perseris® (risperidone sub-Q inj) 120mg	$2,760.80	$33,129.60[β]
Risperdal Consta® (risperidone IM inj) 50mg/2mL	$1,124.80	$29,244.80[+]

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC), or Specialty Pharmaceutical Acquisition Cost (SPAC).
IM = intramuscular; inj = injection; sub-Q = subcutaneous
Unit = each syringe for Uzedy™, each vial for Risperdal Consta®, and each kit for Perseris®
*Uzedy™ cost per year is based on maximum dose of 125mg once monthly or 250mg once every 2 months.
[β]Perseris® cost per year is based on maximum dose of 120mg once monthly.
[+]Risperdal Consta® cost per year is based on maximum dose of 50mg every 2 weeks.
Please note: There is no cost information for Rykindo® available at this time to allow for comparison.

Recommendations

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

1. The prior authorization of Abilify Asimtufii® (aripiprazole ER injection), quetiapine 150mg tablet, Rykindo® (risperidone ER injection), and Uzedy™ (risperidone ER injection) and placement into Tier-3; and
2. Moving Fanapt® (iloperidone) and Invega ER® (paliperidone) tablet to Tier-2 based on net costs; and
3. Moving Risperdal Consta® (risperidone ER injection) to Tier-3 based on net costs; and
4. Updating the Tier-3 approval criteria to clarify the number of Tier-2 trials needed; and
5. Adding Vraylar® (cariprazine) to the approval criteria for atypical antipsychotics as adjunctive treatment for MDD; and

6. Updating the Lybalvi® (olanzapine/samidorphan) approval criteria to be more consistent with clinical practice; and
7. Updating the Rexulti® (brexpiprazole) approval criteria based on the new FDA approved indication for the treatment of agitation associated with dementia due to Alzheimer's disease.

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole (Abilify®)¥	asenapine (Saphris®)	**aripiprazole IM inj (Abilify Asimtufii®)^+**
aripiprazole IM inj (Abilify Maintena®)^	**iloperidone (Fanapt®)**	aripiprazole tablets with sensor (Abilify MyCite®)~
aripiprazole lauroxil IM inj (Aristada®)^	lurasidone (Latuda®)	asenapine transdermal system (Secuado®)+
aripiprazole lauroxil IM inj (Aristada Initio®)^	**paliperidone (Invega®)**	brexpiprazole (Rexulti®)
clozapine (Clozaril®)◊		cariprazine (Vraylar®)
olanzapine (Zyprexa®)		clozapine (Fazaclo®)+
paliperidone palmitate IM inj (Invega Hafyera)^		clozapine oral susp (Versacloz®)+
paliperidone palmitate IM inj (Invega Sustenna®)^		~~**iloperidone (Fanapt®)**~~
paliperidone palmitate IM inj (Invega Trinza®)^		lumateperone (Caplyta®)
quetiapine (Seroquel®)		olanzapine/fluoxetine (Symbyax®)+
quetiapine ER (Seroquel XR®)		olanzapine/samidorphan (Lybalvi®)β
risperidone (Risperdal®)		~~**paliperidone (Invega®)**~~
~~**risperidone IM inj (Risperdal Consta®)^**~~		**quetiapine 150mg tablets+**
risperidone ER sub-Q inj (Perseris®)^		**risperidone IM inj (Risperdal Consta®)^+**
ziprasidone (Geodon®)		**risperidone IM inj (Rykindo®)^+**
		risperidone sub-Q inj (Uzedy™)^+

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
ER = extended-release; IM = intramuscular; inj = injection; sub-Q = subcutaneous; susp = suspension

¥Aripiprazole (Abilify®) orally disintegrating tablet (ODT) is considered a special formulation and requires a patient-specific, clinically significant reason why a special formulation product is needed in place of the regular tablet formulation.
◊Clozapine does not count towards a Tier-1 trial.
^Use of a long-acting injectable product may require the member to have been adequately treated with another oral or injectable product prior to use and/or during initiation. The package labeling should be referenced for each individual product.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.
βUnique criteria applies to Lybalvi® (olanzapine/samidorphan).

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
    a. Clozapine does not count towards a Tier-1 trial; and
2. Trials of 2 ~~all~~ oral Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or
3. A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and
4. Use of Abilify Asimtufii® [aripiprazole extended-release (ER) injection] will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the Tier-1 aripiprazole long-acting injectable products, which are available without a prior authorization; and
5. Use of quetiapine 150mg tablet will require a patient-specific, clinically significant reason why the member cannot use the lower tiered quetiapine products, which are available without a prior authorization; and
6. Use of Fazaclo® (clozapine orally disintegrating tablet) or Versacloz® (clozapine oral suspension) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
7. Use of Risperdal Consta® (risperidone ER injection), Rykindo® (risperidone ER injection), or Uzedy™ (risperidone ER injection) will require a patient-specific, clinically significant reason why the member cannot use the Tier-1 risperidone long-acting injectable products, which are available without a prior authorization; and
8. Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the oral sublingual tablet formulation. Tier structure rules continue to apply; and

9. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

Approval Criteria for Atypical Antipsychotics as Adjunctive Treatment for Major Depressive Disorder (MDD):

1. Authorization of Rexulti® (brexpiprazole), Symbyax® (olanzapine/fluoxetine), or Vraylar® (cariprazine) for a diagnosis of MDD requires current use of an antidepressant and previous trials with at least 2 other antidepressants from both categories (an SSRI and a dual-acting medication) and aripiprazole tablets that did not yield adequate response; and
2. Tier structure rules still apply.

Lybalvi® (Olanzapine/Samidorphan) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. Member must have a positive clinical response to ~~be stable on~~ olanzapine ~~for at least 14 days~~ and ~~be experiencing significant weight gain~~ gained ≥10% from baseline body weight after starting olanzapine (baseline and current weight must be provided); or
4. A patient specific, clinically significant reason why the member cannot use a lower-tiered product with a lower weight gain profile must be provided; and
5. Member must not be taking opioids or undergoing acute opioid withdrawal; and
6. Initial approvals will be for 3 months. For continuation consideration, documentation that the member is responding well to treatment and any increase in body weight is <10% of baseline body weight (current weight must be provided) ~~has had no excessive weight gain~~ while on therapy must be provided.

Rexulti® (Brexpiprazole) Approval Criteria [Agitation Associated with Dementia Due to Alzheimer's Disease Diagnosis]:

1. An FDA approved indication of the treatment of agitation associated with dementia due to Alzheimer's disease; and
2. Diagnosis must be confirmed by the following:
    a. Mini-Mental State Exam (MMSE) score between 5 and 22; and
    b. Documentation of the member's dementia due to Alzheimer's disease diagnosis [i.e., chart notes consistent with findings of a diagnosis of dementia due to Alzheimer's disease as per the National Institute on Aging and the Alzheimer's Association (NIA-AA)]; and

    c. Neuropsychiatric Inventory (NPI)/NPI-Nursing Home (NH) agitation/aggression score ≥4; and
    d. Exhibiting sufficient agitation behaviors warranting the use of pharmacotherapy; and
3. Prescriber must document a baseline evaluation using the Cohen-Mansfield Agitation Inventory total (CMAI) score; and
4. Prescriber must verify member will be closely monitored due to the risk of dementia-related psychosis; and
5. Initial approvals will be for 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the CMAI total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Utilization Details of Atypical Antipsychotic Medications: Calendar Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TIER-1 UTILIZATION					
QUETIAPINE ORAL PRODUCTS					
QUETIAPINE TAB 100MG	15,885	4,919	$196,392.73	$12.36	3.23
QUETIAPINE TAB 50MG	13,453	4,608	$164,489.47	$12.23	2.92
QUETIAPINE TAB 200MG	9,399	2,533	$133,404.98	$14.19	3.71
QUETIAPINE TAB 25MG	9,295	3,438	$108,528.65	$11.68	2.7
QUETIAPINE TAB 300MG	7,459	1,777	$123,118.69	$16.51	4.2
QUETIAPINE TAB 400MG	6,466	1,315	$122,468.85	$18.94	4.92
QUETIAPINE TAB 150MG ER	982	307	$18,278.16	$18.61	3.2
QUETIAPINE TAB 50MG ER	898	335	$15,261.97	$17.00	2.68
QUETIAPINE TAB 400MG ER	847	165	$24,456.57	$28.87	5.13
QUETIAPINE TAB 300MG ER	810	213	$20,850.70	$25.74	3.8
QUETIAPINE TAB 200MG ER	568	169	$12,327.51	$21.70	3.36
SEROQUEL TAB 400MG	12	1	$13,563.48	$1,130.29	12
SEROQUEL XR TAB 400MG	10	1	$15,084.50	$1,508.45	10
SUBTOTAL	**66,084**	**19,781**	**$968,226.26**	**$14.65**	**3.34**
ARIPIPRAZOLE ORAL PRODUCTS					
ARIPIPRAZOLE TAB 5MG	21,643	7,523	$322,843.40	$14.92	2.88
ARIPIPRAZOLE TAB 10MG	17,473	5,883	$262,743.16	$15.04	2.97
ARIPIPRAZOLE TAB 15MG	9,228	2,735	$140,135.77	$15.19	3.37
ARIPIPRAZOLE TAB 2MG	8,249	3,069	$122,832.63	$14.89	2.69
ARIPIPRAZOLE TAB 20MG	5,647	1,508	$100,439.58	$17.79	3.74
ARIPIPRAZOLE TAB 30MG	3,319	736	$60,155.78	$18.12	4.51
ARIPIPRAZOLE SOL 1MG/ML	383	78	$71,512.81	$186.72	4.91
ABILIFY TAB 30MG	12	2	$21,553.22	$1,796.10	6
ABILIFY TAB 15MG	6	1	$1,750.44	$291.74	6
ABILIFY TAB 10MG	6	2	$6,850.03	$1,141.67	3
ABILIFY TAB 5MG	5	2	$2,855.25	$571.05	2.5
ARIPIPRAZOLE TAB 15MG ODT	3	1	$6,054.75	$2,018.25	3
ABILIFY TAB 20MG	1	1	$833.46	$833.46	1
SUBTOTAL	**65,975**	**21,541**	**$1,120,560.28**	**$16.98**	**3.06**
RISPERIDONE ORAL PRODUCTS					
RISPERIDONE TAB 1MG	12,738	3,395	$152,480.79	$11.97	3.75
RISPERIDONE TAB 0.5MG	10,212	2,589	$122,272.03	$11.97	3.94
RISPERIDONE TAB 2MG	8,573	2,217	$105,867.00	$12.35	3.87
RISPERIDONE TAB 0.25MG	4,032	1,054	$48,393.67	$12.00	3.83
RISPERIDONE TAB 3MG	3,763	813	$47,194.43	$12.54	4.63
RISPERIDONE TAB 4MG	1,843	397	$24,568.16	$13.33	4.64
RISPERIDONE SOL 1MG/ML	1,240	249	$37,779.20	$30.47	4.98

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
RISPERIDONE TAB 1MG ODT	266	88	$13,858.92	$52.10	3.02
RISPERIDONE TAB 0.5MG ODT	258	66	$11,773.15	$45.63	3.91
RISPERIDONE TAB 2MG ODT	136	45	$7,312.39	$53.77	3.02
RISPERIDONE TAB 0.25 ODT	101	32	$11,797.20	$116.80	3.16
RISPERIDONE TAB 3MG ODT	43	11	$3,317.37	$77.15	3.91
RISPERIDONE TAB 4MG ODT	28	5	$2,253.96	$80.50	5.6
RISPERDAL TAB 2MG	5	1	$2,493.95	$498.79	5
RISPERDAL SOL 1MG/ML	4	1	$9,079.94	$2,269.99	4
RISPERDAL TAB 0.5MG	3	1	$795.09	$265.03	3
SUBTOTAL	**43,245**	**10,964**	**$601,237.25**	**$13.90**	**3.94**
OLANZAPINE ORAL PRODUCTS					
OLANZAPINE TAB 10MG	10,774	3,368	$146,744.53	$13.62	3.2
OLANZAPINE TAB 20MG	8,254	1,805	$127,192.66	$15.41	4.57
OLANZAPINE TAB 5MG	7,011	2,560	$89,596.37	$12.78	2.74
OLANZAPINE TAB 15MG	3,983	1,117	$57,063.68	$14.33	3.57
OLANZAPINE TAB 2.5MG	1,964	746	$24,767.74	$12.61	2.63
OLANZAPINE TAB 7.5MG	1,046	326	$14,024.38	$13.41	3.21
OLANZAPINE TAB 10MG ODT	782	321	$22,011.99	$28.15	2.44
OLANZAPINE TAB 5MG ODT	777	356	$18,064.06	$23.25	2.18
OLANZAPINE TAB 20MG ODT	385	146	$14,680.45	$38.13	2.64
OLANZAPINE TAB 15MG ODT	242	76	$9,254.69	$38.24	3.18
ZYPREXA TAB 15MG	13	1	$13,053.36	$1,004.10	13
ZYPREXA TAB 10MG	4	1	$7,968.80	$1,992.20	4
SUBTOTAL	**35,235**	**10,823**	**$544,422.71**	**$15.45**	**3.26**
PALIPERIDONE INJECTABLE PRODUCTS					
INVEGA SUST INJ 234MG/1.5ML	8,213	1,690	$24,425,999.74	$2,974.07	4.86
INVEGA SUST INJ 156MG/ML	3,470	1,158	$6,893,909.31	$1,986.72	3
INVEGA TRINZ INJ 819MG/2.63ML	1,092	391	$9,729,116.20	$8,909.45	2.79
INVEGA SUST INJ 117MG/0.75ML	558	162	$831,610.92	$1,490.34	3.44
INVEGA TRINZ INJ 546MG/1.75ML	428	167	$2,517,041.67	$5,880.94	2.56
INVEGA TRINZ INJ 410MG/1.32ML	134	54	$590,498.06	$4,406.70	2.48
INVEGA SUST INJ 78MG/0.5ML	91	22	$87,776.38	$964.58	4.14
INVEGA TRINZ INJ 273MG/0.88ML	42	14	$121,734.87	$2,898.45	3
INVEGA HAFYE INJ 1560MG/5ML	34	25	$628,839.40	$18,495.28	1.36
INVEGA SUST INJ 39MG/0.25ML	25	7	$12,910.08	$516.40	3.57
INVEGA HAFYE INJ 1092MG/3.5ML	16	14	$201,063.52	$12,566.47	1.14
SUBTOTAL	**14,103**	**3,704**	**$46,040,500.15**	**$3,264.59**	**3.81**
CLOZAPINE PRODUCTS					
CLOZAPINE TAB 100MG	5,124	462	$248,280.74	$48.45	11.09
CLOZAPINE TAB 50MG	2,318	230	$77,725.16	$33.53	10.08
CLOZAPINE TAB 200MG	1,876	191	$118,115.59	$62.96	9.82
CLOZAPINE TAB 25MG	1,180	148	$28,431.47	$24.09	7.97
CLOZARIL TAB 100MG	26	2	$32,947.19	$1,267.20	13

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SUBTOTAL	**10,524**	**1033**	**$505,500.15**	**$48.03**	**10.19**
ZIPRASIDONE PRODUCTS					
ZIPRASIDONE CAP 40MG	2,536	767	$62,827.35	$24.77	3.31
ZIPRASIDONE CAP 20MG	2,346	811	$56,579.01	$24.12	2.89
ZIPRASIDONE CAP 80MG	1,794	353	$58,346.49	$32.52	5.08
ZIPRASIDONE CAP 60MG	1,597	348	$45,327.68	$28.38	4.59
SUBTOTAL	**8,273**	**2279**	**$223,080.53**	**$26.96**	**3.63**
ARIPIPRAZOLE INJECTABLE PRODUCTS					
ABILIFY MAIN INJ 400MG	4,351	814	$10,523,488.94	$2,418.64	5.35
ABILIFY MAIN INJ 300MG	567	152	$1,004,725.20	$1,772.00	3.73
ABILIFY MAIN INJ 400MG	525	201	$1,247,358.47	$2,375.92	2.61
ABILIFY MAIN INJ 300MG	140	54	$252,364.79	$1,802.61	2.59
SUBTOTAL	**5,583**	**1221**	**$13,027,937.40**	**$2,333.50**	**4.57**
ARIPIPRAZOLE LAUROXIL INJECTABLE PRODUCTS					
ARISTADA INJ 882MG/3.2ML	1,553	288	$4,279,438.73	$2,755.59	5.39
ARISTADA INJ 1,064MG/3.9ML	539	210	$1,757,542.73	$3,260.75	2.57
ARISTADA INJ 662MG/2.4ML	304	78	$632,377.15	$2,080.19	3.9
ARISTADA INJ INITIO 675MG/2.4ML	165	147	$328,291.26	$1,989.64	1.12
ARISTADA INJ 441MG/1.6ML	154	41	$214,564.61	$1,393.28	3.76
SUBTOTAL	**2,715**	**764**	**$7,212,214.48**	**$2,656.43**	**3.55**
RISPERIDONE INJECTABLE PRODUCTS					
PERSERIS INJ 120MG	507	130	$1,332,517.34	$2,628.24	3.9
PERSERIS INJ 90MG	212	55	$407,599.97	$1,922.64	3.85
RISPERDAL INJ 50MG	172	17	$271,945.36	$1,581.08	10.12
RISPERDAL INJ 25MG	88	20	$75,815.92	$861.54	4.4
RISPERDAL INJ 37.5MG	18	2	$26,566.10	$1,475.89	9
RISPERDAL INJ 12.5MG	4	1	$1,348.75	$337.19	4
SUBTOTAL	**1,001**	**225**	**$2,115,793.44**	**$2,113.68**	**4.45**
OLANZAPINE INJECTABLE PRODUCTS					
ZYPREXA RELP INJ 405MG	10	1	$11,451.95	$1,145.20	10
OLANZAPINE INJ 10MG	2	2	$518.98	$259.49	1
ZYPREXA INJ 10MG	1	1	$60.21	$60.21	1
SUBTOTAL	**13**	**4**	**$12,031.14**	**$925.47**	**3.25**
ZIPRASIDONE INJECTABLE PRODUCTS					
GEODON INJ 20MG	3	2	$206.28	$68.76	1.5
SUBTOTAL	**3**	**2**	**$206.28**	**$68.76**	**1.5**
TIER-1 SUBTOTAL	**252,754**	**72,341**	**$72,371,710.07**	**$286.33**	**3.49**
TIER-2 UTILIZATION					
LURASIDONE PRODUCTS					
LATUDA TAB 40MG	4,804	1,476	$7,250,298.41	$1,509.22	3.25
LATUDA TAB 20MG	3,696	1,365	$5,449,324.82	$1,474.38	2.71
LATUDA TAB 60MG	2,811	759	$4,356,240.06	$1,549.71	3.7
LATUDA TAB 80MG	2,755	624	$4,586,334.88	$1,664.73	4.42

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LATUDA TAB 120MG	1,132	247	$2,643,918.52	$2,335.62	4.58
SUBTOTAL	**15,198**	**4,471**	**$24,286,116.69**	**$1,597.98**	**3.4**
ASENAPINE PRODUCTS					
ASENAPINE SUB 10MG	523	129	$102,095.35	$195.21	4.05
ASENAPINE SUB 5MG	425	162	$78,811.79	$185.44	2.62
SAPHRIS SUB 10MG	119	27	$122,077.91	$1,025.86	4.41
ASENAPINE SUB 2.5MG	90	50	$32,332.29	$359.25	1.8
SAPHRIS SUB 5MG	56	25	$54,686.32	$976.54	2.24
SAPHRIS SUB 2.5MG	1	1	$1,208.22	$1,208.22	1
SUBTOTAL	**1,214**	**394**	**$391,211.88**	**$322.25**	**3.08**
TIER-2 TOTAL	**16,412**	**4,865**	**$24,677,328.57**	**$1,503.61**	**3.49**
TIER-3 UTILIZATION					
CARIPRAZINE PRODUCTS					
VRAYLAR CAP 3MG	2,203	585	$3,239,757.04	$1,470.61	3.77
VRAYLAR CAP 1.5MG	1,395	497	$2,029,533.64	$1,454.86	2.81
VRAYLAR CAP 6MG	954	191	$1,401,119.66	$1,468.68	4.99
VRAYLAR CAP 4.5MG	891	232	$1,331,842.10	$1,494.77	3.84
VRAYLAR CAP 1.5-3MG	4	4	$1,258.20	$314.55	1
SUBTOTAL	**5,447**	**1509**	**$8,003,510.64**	**$1,469.34**	**3.61**
BREXIPRAZOLE PRODUCTS					
REXULTI TAB 2MG	606	186	$945,059.08	$1,559.50	3.26
REXULTI TAB 1MG	585	188	$861,489.57	$1,472.63	3.11
REXULTI TAB 3MG	292	87	$473,419.71	$1,621.30	3.36
REXULTI TAB 4MG	240	52	$333,661.17	$1,390.25	4.62
REXULTI TAB 0.5MG	130	54	$187,485.60	$1,442.20	2.41
REXULTI TAB 0.25MG	10	6	$14,601.51	$1,460.15	1.67
SUBTOTAL	**1,863**	**573**	**$2,815,716.64**	**$1,511.39**	**3.25**
PALIPERIDONE ORAL PRODUCTS					
PALIPERIDONE TAB ER 6MG	862	187	$170,309.33	$197.57	4.61
PALIPERIDONE TAB ER 9MG	435	87	$94,085.26	$216.29	5
PALIPERIDONE TAB ER 3MG	372	101	$62,005.11	$166.68	3.68
PALIPERIDONE TAB ER 1.5MG	83	29	$13,678.29	$164.80	2.86
INVEGA TAB 9MG	9	1	$4,897.05	$544.12	9
INVEGA TAB 3MG	8	2	$5,714.20	$714.28	4
INVEGA TAB 6MG	1	1	$366.61	$366.61	1
SUBTOTAL	**1,770**	**408**	**$351,055.85**	**$198.34**	**4.34**
LUMATEPERONE PRODUCTS					
CAPLYTA CAP 42MG	757	210	$1,068,313.46	$1,411.25	3.6
CAPLYTA CAP 21MG	12	8	$16,761.53	$1,396.79	1.5
CAPLYTA CAP 10.5MG	2	1	$2,978.32	$1,489.16	2
SUBTOTAL	**771**	**219**	**$1,088,053.31**	**$1,411.22**	**3.52**
ILOPERIDONE PRODUCTS					
FANAPT TAB 6MG	99	20	$158,026.73	$1,596.23	4.95

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
FANAPT TAB 12MG	90	12	$259,586.82	$2,884.30	7.5
FANAPT TAB 8MG	78	20	$122,655.84	$1,572.51	3.9
FANAPT TAB 4MG	75	13	$96,343.34	$1,284.58	5.77
FANAPT TAB 10MG	38	8	$94,427.25	$2,484.93	4.75
FANAPT TAB 2MG	29	8	$38,168.02	$1,316.14	3.63
FANAPT TAB 1/2/4/6MG PACK	7	6	$1,650.29	$235.76	1.17
FANAPT TAB 1MG	6	1	$4,676.52	$779.42	6
SUBTOTAL	**422**	**88**	**$775,534.81**	**$1,837.76**	**4.8**
CLOZAPINE ORALLY DISINTEGRATING PRODUCTS					
CLOZAPINE ODT 100MG	117	13	$47,271.03	$404.03	9
CLOZAPINE ODT 150MG	41	6	$49,688.50	$1,211.91	6.83
CLOZAPINE ODT 200MG	20	3	$40,550.73	$2,027.54	6.67
CLOZAPINE ODT 25MG	19	3	$3,681.34	$193.75	6.33
SUBTOTAL	**197**	**25**	**$141,191.60**	**$716.71**	**7.88**
OLANZAPINE/SAMIDORPHAN COMBINATION PRODUCTS					
LYBALVI TAB 20/10MG	50	13	$60,902.37	$1,218.05	3.85
LYBALVI TAB 5/10MG	44	15	$59,698.50	$1,356.78	2.93
LYBALVI TAB 15/10MG	41	13	$51,629.95	$1,259.27	3.15
LYBALVI TAB 10/10MG	34	12	$45,868.90	$1,349.09	2.83
SUBTOTAL	**169**	**53**	**$218,099.72**	**$1,290.53**	**3.19**
OLANZAPINE/FLUOXETINE COMBINATION PRODUCTS					
OLANZ/FLUOX CAP 12-50MG	20	2	$10,364.52	$518.23	10
OLANZ/FLUOX CAP 6-50MG	11	1	$2,056.14	$186.92	11
OLANZ/FLUOX CAP 6-25MG	11	1	$2,020.07	$183.64	11
OLANZ/FLUOX CAP 12-25MG	5	1	$2,076.32	$415.26	5
SUBTOTAL	**47**	**5**	**$16,517.05**	**$351.43**	**9.4**
ASENAPINE TRANSDERMAL SYSTEM PRODUCTS					
SECUADO PATCH 3.8MG	6	2	$7,700.46	$1,283.41	3
SECUADO PATCH 5.7MG	2	1	$2,566.82	$1,283.41	2
SUBTOTAL	**8**	**3**	**$10,267.28**	**$1,283.41**	**2.67**
TIER-3 SUBTOTAL	**10,694**	**2,883**	**$13,419,946.90**	**$1,254.90**	**3.71**
TOTAL	**279,860**	**45,841***	**$110,468,985.54**	**$394.73**	**3.49**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; ER/XR = extended release; HAFYE = Hafyera; INJ = injection; MAIN = Maintena; ODT = orally disintegrating tablet; OLANZ/FLUOX = olanzapine/fluoxetine; PS = prefilled syringe; RELP = Relprevv; SOL = solution; SUST = Sustenna; SUB = sublingual; TAB = tablet; TRINZ = Trinza

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Appendix P

30-Day Notice to Prior Authorize Daybue™ (Trofinetide)

Oklahoma Health Care Authority
June 2023

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

Rett syndrome is a rare neurodevelopmental disorder that occurs primarily in females, although there are rare reports of the disorder in males. Rett syndrome is characterized by a period of normal early development during the first 7-18 months of life, followed by a period of developmental regression during which previously acquired skills are lost, such as spoken language and purposeful hand skills. Patients often experience symptoms such as slowed development, loss of mobility in the hands, loss of speech, distinctive repetitive hand movements (e.g., hand wringing), slowed brain and head growth, difficulty with gait and walking, seizures, cognitive difficulties, digestive problems, and certain breathing difficulties (e.g., breath holding, hyperventilation, swallowing air). Patients may also experience screaming fits, inconsolable crying, autistic features, panic attacks, and teeth grinding. Some patients may lose, or never obtain, the ability to walk. After Down syndrome, Rett syndrome is the second most common cause of severe intellectual disability.

Rett syndrome is believed to occur in 1 in 10,000 female births, although the true incidence is difficult to determine because it is often undiagnosed or misdiagnosed. The disorder is much rarer in males, but when it occurs, it is sometimes associated with more severe brain dysfunction and early death.

Rett syndrome can be diagnosed clinically by observation of the patient's signs and symptoms during development. The clinical diagnostic criteria for Rett syndrome classify patients into 2 categories, typical Rett syndrome or atypical Rett syndrome, based on the individual patient's history and presentation. Nearly all cases of Rett syndrome are caused by mutations in the *MECP2* gene, the majority of which are *de novo* mutations that are not inherited from a parent. The gene encodes a protein called methyl-CpG-binding protein 2 (MeCP2) which is believed to regulate the activity of other genes which are necessary for normal brain development. Genetic testing is available to identify mutations in the *MECP2* gene, and more than 200 different mutations have been identified. It is possible that the severity of the disease may be related to the type of mutation a patient possesses.

Management of patients with Rett syndrome is primarily supportive and focused on the individual patient's symptoms and behaviors, but may include medications to help with breathing difficulties, seizures, anxiety, muscle

spasticity, or other complications of the disorder. In March 2023, the U.S. Food and Drug Administration (FDA) approved Daybue™ (trofinetide) for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older. Daybue™ is the first and only FDA approved medication for this indication.

Daybue™ (Trofinetide) Product Summary[7]

Therapeutic Class: Glycine-proline-glutamate analog

Indication(s): Treatment of Rett syndrome in adults and pediatric patients 2 years of age and older

How Supplied: 200mg/mL oral solution in a 450mL bottle

Dosing and Administration: Recommended dosing regimen is twice daily, with or without food, administered orally or via gastrostomy (G) tube, according to patient weight:

Patient Weight	Dosage	Volume
9kg to <12kg	5,000mg twice daily	25mL twice daily
12kg to <20kg	6,000mg twice daily	30mL twice daily
20kg to <35kg	8,000mg twice daily	40mL twice daily
35kg to <50kg	10,000mg twice daily	50mL twice daily
≥50kg	12,000mg twice daily	60mL twice daily

Cost: The Wholesale Acquisition Cost (WAC) of Daybue™ is $21.10 per milliliter or $9,495 per bottle. This results in an estimated cost of $75,960 per 30 days or $911,520 per year based on the recommended dose for a member weighing ≥50kg.

Recommendations

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

Daybue™ (Trofinetide) Approval Criteria:

1. Diagnosis of typical Rett syndrome confirmed by all of the following:
    a. Prescriber must verify all clinical diagnostic criteria are met supporting a diagnosis of typical Rett syndrome including:
        i. A period of regression followed by recovery or stabilization; and
        ii. Partial or complete loss of acquired purposeful hand skills; and
        iii. Partial or complete loss of acquired spoken language; and
        iv. Gait abnormalities (impaired/dyspraxic or absence of ability); and

v. Stereotypic hand movements (e.g., hand wringing/squeezing, clapping/tapping, mouthing, washing/rubbing automatisms); and
vi. Lack of brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection causing neurological problems; and
vii. Lack of grossly abnormal psychomotor development in the first 6 months of life; and

b. Genetic testing documenting a disease-causing mutation in the *MECP2* gene (results of genetic testing must be submitted); and

2. Member must be 2 years of age or older; and
3. Daybue™ must be prescribed by a geneticist, neurologist, or other specialist with expertise in the treatment of Rett syndrome; and
4. Prescriber must agree to counsel members and caregivers on the risks of diarrhea and weight loss associated with Daybue™ and agree to monitor appropriately for these adverse effects; and
5. Prescriber must agree to counsel members and caregivers on proper storage and administration of Daybue™, including the use of a calibrated device for measuring each dose; and
6. Prescriber must verify the member does not have moderate or severe renal impairment; and
7. Member's current weight (kg) taken within the past 3 weeks must be provided on initial and subsequent prior authorization requests to ensure accurate weight-based dosing according to package labeling; and
8. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for a duration of 1 year; and
9. A quantity limit of 3,600mL per 30 days will apply.

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Appendix Q

Annual Review of Muscle Relaxant Medications and 30-Day Notice to Prior Authorize Lyvispah™ (Baclofen Oral Granules) and Norgesic®, Norgesic® Forte, and Orphengesic® Forte (Orphenadrine/Aspirin/Caffeine)

Oklahoma Health Care Authority
June 2023

Current Prior Authorization Criteria

Muscle Relaxant Medications*		
Tier-1	**Tier-2**	**Special PA**
baclofen 10mg, 20mg (Lioresal®)	metaxalone (Skelaxin®)	baclofen 5mg (Lioresal®)
Chlorzoxazone 500mg (Parafon Forte®)		baclofen 5mg/5mL oral soln (Ozobax®)
cyclobenzaprine (Flexeril®)		baclofen 25mg/5mL oral susp (Fleqsuvy®)
methocarbamol (Robaxin®)		carisoprodol 250mg (Soma®)
orphenadrine (Norflex®)		carisoprodol 350mg (Soma®)
tizanidine tabs (Zanaflex®)		carisoprodol/ASA
		carisoprodol/ASA/codeine
		chlorzoxazone 375mg, 750mg (Lorzone®)
		cyclobenzaprine 7.5mg tabs (Fexmid®)
		cyclobenzaprine ER caps (Amrix®)
		tizanidine caps (Zanaflex®)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ASA = aspirin; caps = capsules; ER = extended-release; PA = prior authorization; soln = solution; susp = suspension; tabs = tablets

Muscle Relaxant Medications Tier-2 Approval Criteria:

1. Member must have failure with at least 2 Tier-1 medications within the past 90 days defined as no beneficial response after at least 2 weeks of use during which time the drug has been titrated to the recommended dose; and
2. Approvals will be for the duration of 3 months, except for members with chronic diseases such as multiple sclerosis, cerebral palsy, muscular dystrophy, paralysis, or other chronic musculoskeletal diagnosis confirmed with diagnostic results, in which case authorizations will be for the duration of 1 year; and

3. For repeat authorizations, there must be documentation of a failed withdrawal attempt within the past 3 months defined as increase in pain and debilitating symptoms when medication was discontinued.

Amrix® [Cyclobenzaprine Extended-Release (ER) Capsule] and Fexmid® (Cyclobenzaprine 7.5mg Tablet) Approval Criteria:

1. Authorization requires clinical documentation of inability to take other generically available forms of cyclobenzaprine tablets; and
2. The following quantity limits apply:
   a. Amrix® 15mg and 30mg ER capsules: 30 capsules per 30 days; or
   b. Fexmid® 7.5mg tablets: 90 tablets per 30 days.

Baclofen 5mg Tablets Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including splitting a baclofen 10mg tablet to achieve a 5mg dose, must be provided.

Fleqsuvy® 25mg/5mL (Baclofen Oral Suspension) and Ozobax® 5mg/5mL (Baclofen Oral Solution) Approval Criteria:

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

Lorzone® (Chlorzoxazone) Approval Criteria:

1. Generic chlorzoxazone 500mg tablets must be tried prior to consideration of Lorzone®; and
2. A patient-specific, clinically significant reason why the member cannot use generic chlorzoxazone 500mg tablets must be provided; and
3. The following quantity limits apply:
   a. Lorzone® 375mg tablets: 120 tablets per 30 days; or
   b. Lorzone® 750mg tablets: 120 tablets per 30 days.

Soma® (Carisoprodol 250mg) Approval Criteria:

1. Authorization requires detailed documentation regarding member's inability to use other skeletal muscle relaxants including carisoprodol 350mg, and patient-specific reason(s) why member cannot be drowsy for even a short time period must be provided. Member must not have other sedating medications in current claims history; and
2. For a diagnosis of acute musculoskeletal pain, the approval will be for the duration of 14 days per 365-day period. Conditions requiring chronic use will not be approved.

Soma® (Carisoprodol 350mg) or Soma® (Carisoprodol 350mg) Combination Product(s) Approval Criteria:

1. Members may receive 3 months of carisoprodol 350mg per rolling 365 days without prior authorization; and
2. After the member has received the 3 months, an additional approval for 1 month may be granted to allow titration or change to a Tier-1 muscle relaxant. This additional 1-month approval will be granted 1 time only. Further authorizations will not be granted; or
3. Clinical exceptions may be made for members with the following diagnoses and approvals will be granted for the duration of 1 year: multiple sclerosis, cerebral palsy, muscular dystrophy, paralysis, or cancer pain; and
4. A quantity limit of 120 tablets per 30 days will apply for carisoprodol and carisoprodol combination products.

Zanaflex® (Tizanidine Capsule) Approval Criteria:

1. Tizanidine tablets must be tried prior to consideration of tizanidine capsules; and
2. The capsule formulation may be considered for approval only if there is supporting information as to why the member cannot take the tablets.

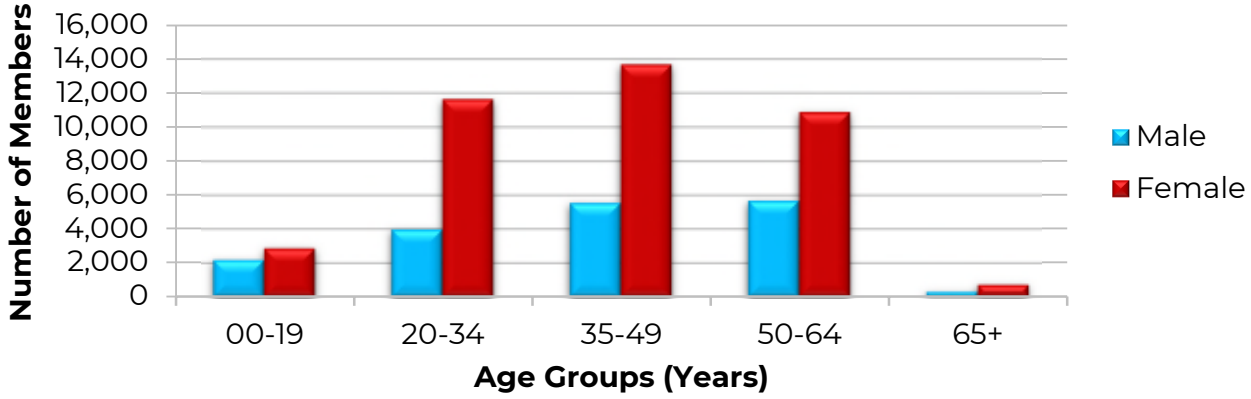
Utilization of Muscle Relaxant Medications: Calendar Year 2022

Comparison of Calendar Years

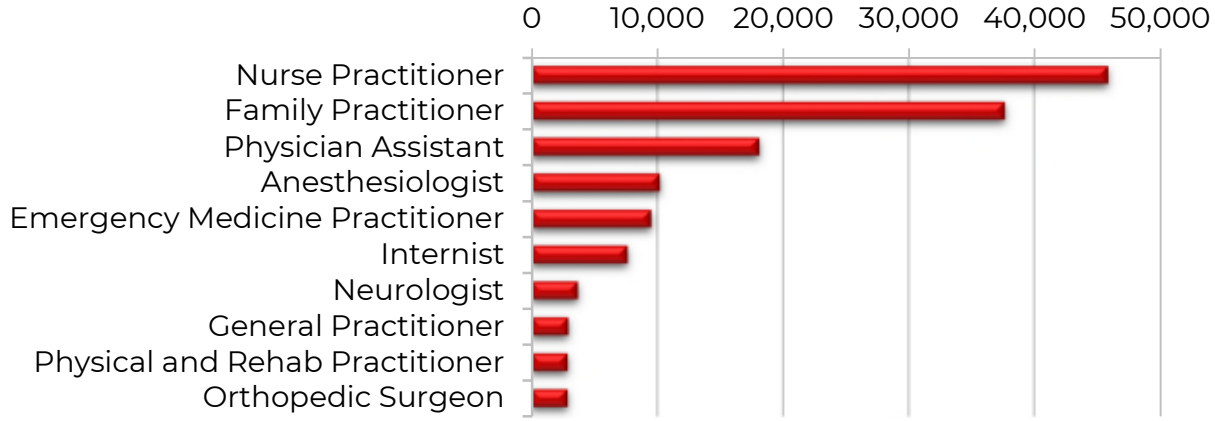
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	39,291	108,888	$1,444,149.31	$13.26	$0.54	7,142,750	2,665,663
2022	57,336	156,051	$1,988,022.01	$12.74	$0.53	9,866,395	3,761,088
% Change	**45.90%**	**43.30%**	**37.70%**	**-3.90%**	**-1.90%**	**38.10%**	**41.10%**
Change	**18,045**	**47,163**	**$543,872.70**	**-$0.52**	**-$0.01**	**2,723,645**	**1,095,425**

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

Demographics of Members Utilizing Muscle Relaxant Medications



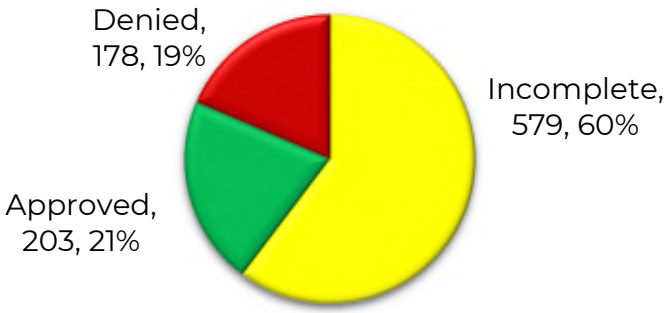
Top Prescriber Specialties of Muscle Relaxant Medications by Number of Claims



Prior Authorization of Muscle Relaxant Medications

There were 960 prior authorization requests submitted for muscle relaxant medications during calendar year 2022. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Amrix® [cyclobenzaprine extended-release (ER) capsule]: February 2025
- Skelaxin® (metaxalone tablet): February 2026
- Fleqsuvy® (baclofen oral suspension 25mg/5mL): September 2037
- Ozobax® (baclofen oral suspension 5mg/5mL): August 2039
- Lyvispah™ (baclofen oral granules): September 2041

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

- **December 2021:** Saol Therapeutics announced the FDA approval of Lyvispah™ (baclofen oral granules). Lyvispah™ was commercially launched in June 2022 by Amneal Pharmaceuticals.

News:

- **April 2023:** Galt Pharmaceuticals, the current manufacturer of Norgesic®, Norgesic Forte®, and Orphengesic Forte® (orphenadrine/aspirin/caffeine), began participating in the federal Medicaid Drug Rebate Program (MDRP) in April 2023. Orphengesic Forte® was approved by the FDA in 1998 for the treatment of mild to moderate pain associated with musculoskeletal disorders.

Lyvispah™ (Baclofen Oral Granules) Product Summary[4]

Therapeutic Class: Gamma-aminobutyric acid agonist

Indication(s): Treatment of spasticity resulting from multiple sclerosis or spinal cord injuries or diseases, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity

How Supplied: 5mg, 10mg, and 20mg packets of oral granules

Dosing:

- Should be initiated with a low dose, taken orally, preferably in divided doses, increasing gradually based on clinical response and tolerability
- The maximum dose is 80mg daily (20mg 4 times daily).
- The dose may be taken with or without water.
- The oral granules can be mixed with soft food for administration within 2 hours.
- The oral granules can be administered via enteral feeding tube.
- When discontinuing, the dose should be reduced slowly.

Cost Comparison:

Product	Cost Per Unit†	Cost Per Month*
Lyvispah™ (baclofen oral granules) 20mg packet	**$3.28**	**$393.60**
Fleqsuvy™ (baclofen oral suspension) 25mg/5mL	$6.05	$2,904.00
baclofen oral solution 5mg/5mL (generic)	$1.09	$2,616.00
baclofen 20mg oral tablet (generic)	$0.09	$10.80

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 = mL, packet, or tablet
*Cost per month is based on a maximum FDA approved dose of 80mg daily for 30 days.

Norgesic®, Norgesic® Forte, and Orphengesic® Forte (Orphenadrine/Aspirin/Caffeine) Product Summary[5,6]

Therapeutic Class: Centrally acting musculoskeletal relaxant

Indication(s): Treatment of mild to moderate pain of acute musculoskeletal disorders as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with painful musculoskeletal conditions

How Supplied:

- Norgesic®: 25/385/30mg orphenadrine/aspirin/caffeine oral tablets
- Norgesic® Forte/Orphengesic® Forte: 50/770/60mg caffeine orphenadrine/aspirin/caffeine oral tablets

Dosing:

- Norgesic®: 1 to 2 tablets 3 to 4 times daily
- Norgesic® Forte/Orphengesic® Forte: 0.5 to 1 tablet 3 to 4 times daily

Cost Comparison: Orphenadrine Products

Product	Cost Per Tablet	Cost Per Day*
orphenadrine/ASA/caffeine 25/385/30mg tab (generic)	**$16.25**	**$130.00**
orphenadrine/ASA/caffeine 50/770/60mg tab (generic)	**$10.65**	**$42.60**
orphenadrine citrate ER 100mg tab (generic)	$0.35	$0.70

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 day is based on the maximum FDA approved dose for each product: 2 tablets 4 times daily for Norgesic®; 1 tablet 4 times daily for Norgesic® Forte and Orphengesic® Forte; 1 tablet twice daily for generic orphenadrine citrate.
ASA = aspirin; ER = extended-release; tab = tablet

Recommendations

The College of Pharmacy recommends the prior authorization of Lyvispah™ (baclofen oral granules) and Norgesic®, Norgesic® Forte, and Orphengesic® Forte (orphenadrine/aspirin/caffeine) and placement into the Special PA Tier of the Muscle Relaxant Medications Product Based Prior Authorization (PBPA) category with the following additional criteria (changes and new criteria shown in red):

Fleqsuvy® 25mg/5mL (Baclofen Oral Suspension), Lyvispah™ (Baclofen Oral Granules), and Ozobax® 5mg/5mL (Baclofen Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and

2. Requests for Fleqsuvy® and Ozobax® will require a patient-specific, clinically significant reason why the member cannot use Lyvispah™; and
3. Members older than 10 years of age require a patient-specific, clinically significant reason why the member cannot use baclofen oral tablets, even when tablets are crushed.

Norgesic®, Norgesic® Forte, and Orphengesic® Forte (Orphenadrine/ Aspirin/Caffeine) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all lower-tiered products must be provided.

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

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ASA = aspirin; caps = capsules; ER = extended-release; PA = prior authorization; soln = solution; susp = suspension; tabs = tablets.

Utilization Details of Muscle Relaxant Medications: Calendar Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
CYCLOBENZAPRINE PRODUCTS						
CYCLOBENZAPRINE TAB 10MG	48,790	22,454	$506,298.99	$10.38	2.17	25.47%
CYCLOBENZAPRINE TAB 5MG	13,486	8,257	$142,795.08	$10.59	1.63	7.18%
SUBTOTAL	**62,276**	**30,711**	**$649,094.07**	**$10.42**	**2.03**	**32.65%**
TIZANIDINE PRODUCTS						
TIZANIDINE TAB 4MG	36,456	12,255	$449,309.14	$12.32	2.97	22.60%
TIZANIDINE TAB 2MG	6,230	2,877	$78,192.58	$12.55	2.17	3.93%
SUBTOTAL	**42,686**	**15,132**	**$527,501.72**	**$12.36**	**2.82**	**26.53%**
BACLOFEN PRODUCTS						
BACLOFEN TAB 10MG	17,738	5,533	$250,821.21	$14.14	3.21	12.62%
BACLOFEN TAB 20MG	7,098	1,504	$129,039.49	$18.18	4.72	6.49%
BACLOFEN POWDER	261	49	$3,582.04	$13.72	5.33	0.18%
LIORESAL INT INJ 40MG/20ML	17	6	$18,141.13	$1,067.13	2.83	0.91%
BACLOFEN INJ 40MG/20ML	11	1	$9,905.50	$900.50	11	0.50%
GABLOFEN INJ 40000MCG/20ML	3	1	$2,495.91	$831.97	3	0.13%
SUBTOTAL	**25,128**	**7,094**	**$413,985.28**	**$16.38**	**3.54**	**20.70%**
METHOCARBAMOL PRODUCTS						
METHOCARBAMOL TAB 750MG	9,564	4,620	$127,188.96	$13.30	2.07	6.40%
METHOCARBAMOL TAB 500MG	9,252	5,517	$114,259.24	$12.35	1.68	5.75%
METHOCARBAMOL INJ 1,000MG	3	1	$2,722.23	$907.41	3	0.14%
SUBTOTAL	**18,819**	**10,138**	**$244,170.43**	**$12.97**	**1.86**	**12.29%**
ORPHENADRINE PRODUCTS						
ORPHENADRINE TAB 100MG ER	5,014	3,594	$95,624.63	$19.07	1.4	4.81%
ORPHENADRINE INJ 30MG/ML	2	1	$152.06	$76.03	2	0.01%
SUBTOTAL	**5,016**	**3,595**	**$95,776.69**	**$19.09**	**1.4**	**4.82%**
CHLORZOXAZONE PRODUCTS						
CHLORZOXAZONE TAB 500MG	918	331	$23,422.94	$25.52	2.77	1.18%
SUBTOTAL	**918**	**331**	**$23,422.94**	**$25.52**	**2.77**	**1.18%**
TIER-1 SUBTOTAL	**154,843**	**67,001**	**$1,953,951.13**	**$12.62**	**2.31**	**98.30%**
TIER-2 UTILIZATION						
METAXALONE PRODUCTS						
METAXALONE TAB 800MG	206	61	$8,944.03	$43.42	3.38	0.45%
METAXALONE TAB 400MG	8	4	$4,686.08	$585.76	2	0.24%
SUBTOTAL	**214**	**65**	**$13,630.11**	**$63.69**	**3.29**	**0.69%**
TIER-2 SUBTOTAL	**214**	**65**	**$13,630.11**	**$63.69**	**3.29**	**0.69%**
SPECIAL PA UTILIZATION						
CARISOPRODOL PRODUCTS						
CARISOPRODOL TAB 350MG	908	412	$11,226.37	$12.36	2.2	0.56%
SUBTOTAL	**908**	**412**	**$11,226.37**	**$12.36**	**2.2**	**0.56%**
BACLOFEN PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BACLOFEN TAB 5MG	57	13	$2,609.43	$45.78	4.38	0.13%
BACLOFEN SOL 5MG/5ML	18	7	$4,649.58	$258.31	2.57	0.23%
FLEQSUVY SUS 5MG	2	1	$1,342.82	$671.41	2	0.07%
LYVISPAH GRA TAB 5MG	1	1	$451.41	$451.41	1	0.02%
SUBTOTAL	**78**	**22**	**$9,053.24**	**$116.07**	**3.55**	**0.45%**
TIZANIDINE PRODUCTS						
TIZANIDINE CAP 4MG	7	5	$124.21	$17.74	1.4	0.01%
SUBTOTAL	**7**	**5**	**$124.21**	**$17.74**	**1.4**	**0.01%**
CYCLOBENZAPRINE PRODUCTS						
CYCLOBENZAPRINE TAB 7.5MG	1	1	$36.95	$36.95	1	0.00%
SUBTOTAL	**1**	**1**	**$36.95**	**$36.95**	**1**	**0.00%**
SPECIAL PA SUBTOTAL	**994**	**440**	**$20,440.77**	**$20.56**	**2.26**	**1.02%**
TOTAL	**156,051**	**57,336***	**$1,988,022.01**	**$12.74**	**2.72**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; ER = extended-release; GRA = granules; INJ = injection; INT = intrathecal; PA = prior authorization; SOL = solution; SUS = suspension; TAB = tablet

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 05/2023. Last accessed 05/02/2023.
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[3] Amneal Pharmaceuticals, Inc. Amneal Launches Lyvispah® (Baclofen) for Spasticity Related to Multiple Sclerosis and Other Spinal Cord Disorders. Available online at: https://investors.amneal.com/news/press-releases/press-release-details/2022/Amneal-Launches-LYVISPAH-baclofen-for-Spasticity-Related-to-Multiple-Sclerosis-and-Other-Spinal-Cord-Disorders/default.aspx. Issued 06/01/2022. Last accessed 05/25/2023.
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Appendix R

Calendar Year 2022 Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Allopurinol 200mg Tablet, Aponvie™ (Aprepitant Injectable Emulsion), Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules], Austedo® XR (Deutetrabenazine ER Tablet), Entadfi® (Finasteride/ Tadalafil Capsule), Ermeza™ (Levothyroxine Oral Solution), Furoscix® (Furosemide On-Body Infusor), Iyuzeh™ (Latanoprost Ophthalmic Solution), Jylamvo® (Methotrexate Oral Solution), Primidone 125mg Tablet, Verkazia® (Cyclosporine Ophthalmic Solution), Xaciato™ (Clindamycin Vaginal Gel), and Zolpidem Tartrate 7.5mg Capsule

Oklahoma Health Care Authority
June 2023

Introduction

Multiple formulations of medications are made for ease of administration, to increase bioavailability, or as new technologies are created to provide a more efficient treatment response. Some of the new formulations incur greater costs for production, resulting in greater costs for the payer and consumer. A clinical review of each product and its comparative cost to other formulations is provided in the following report for reference.

Current Prior Authorization Criteria

Absorica LD™ (Isotretinoin Capsule) Approval Criteria:

1. An FDA approved diagnosis of severe recalcitrant nodular acne in non-pregnant members 12 years of age and older with multiple inflammatory nodules with a diameter of 5mm or greater; and
2. Absorica LD™ is not covered for members older than 20 years of age; and
3. Prescriber must verify member is enrolled in the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) program; and
4. Prescriber must verify lipid profile and liver function tests will be monitored prior to initiation of Absorica LD™ and at regular intervals during treatment in accordance with the package labeling; and

5. A patient-specific, clinically significant reason why the member cannot use other isotretinoin capsules available without prior authorization must be provided; and
6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of medication according to package labeling.

Gimoti® (Metoclopramide Nasal Spray) Approval Criteria:

1. An FDA approved indication of acute or recurrent diabetic gastroparesis in adult members; and
2. A patient-specific, clinically significant reason why the member cannot use metoclopramide oral tablets and metoclopramide oral solution must be provided; and
3. For members 65 years of age or older, approvals will not be granted for initiation of metoclopramide therapy; and
4. For members 65 years of age or older requesting to switch from an alternative metoclopramide product to Gimoti®:
    a. Member must be taking a stable dose of metoclopramide 10mg 4 times daily for at least 10 days; and
    b. Duration of current metoclopramide treatment must be provided; and
5. A maximum approval duration of 8 weeks total from all sources will apply; and
6. A quantity limit of 9.8mL per 28 days will apply.

GoNitro® (Nitroglycerin Sublingual Powder) Approval Criteria:

1. An FDA approved indication of acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease; and
2. A patient-specific, clinically significant reason why the member cannot use nitroglycerin sublingual tablets or nitroglycerin lingual spray must be provided.

Gralise® [Gabapentin Extended-Release (ER) Tablet] Approval Criteria:

1. An FDA approved indication of postherpetic neuralgia (PHN); and
2. Documented treatment attempts, at recommended dosing, with at least 1 agent from 2 of the following drug classes that did not yield adequate relief:
    a. Tricyclic antidepressants; or
    b. Anticonvulsants; or
    c. Topical or oral analgesics; and
3. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.

Horizant® [Gabapentin Enacarbil Extended-Release (ER) Tablet] Approval Criteria:

1. For the FDA approved indication of restless leg syndrome:
    a. Member must be 18 years of age or older; and
    b. Documented treatment attempts at recommended dosing with at least 2 of the following medications that did not yield adequate relief:
        i. Carbidopa/levodopa; or
        ii. Pramipexole; or
        iii. Ropinirole; and
    c. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.
2. For the FDA approved indication of postherpetic neuralgia (PHN):
    a. Member must be 18 years of age or older; and
    b. Documented treatment attempts, at recommended dosing, with at least 1 agent from 2 of the following drug classes that did not yield adequate relief:
        i. Tricyclic antidepressants; or
        ii. Anticonvulsants; or
        iii. Topical or oral analgesics; and
    c. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.

Khapzory™ (Levoleucovorin Injection) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Rescue after high-dose methotrexate (MTX) therapy in members with osteosarcoma; or
    b. Diminishing the toxicity associated with overdosage of folic acid antagonists or impaired MTX elimination; or
    c. Treatment of members with metastatic colorectal cancer in combination with fluorouracil; and
2. A patient-specific, clinically significant reason why the member cannot use generic leucovorin injection or generic levoleucovorin calcium injection must be provided.

Klor-Con® 20mEq Packet (Potassium Chloride) Approval Criteria:

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

Kristalose® (Lactulose Packet for Oral Solution) Approval Criteria:

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

Lyrica® CR [Pregabalin Extended-Release (ER) Capsule] Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Neuropathic pain associated with diabetic peripheral neuropathy (DPN); or
    b. Neuropathic pain associated with postherpetic neuralgia (PHN); and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation of pregabalin must be provided; and
3. Requests exceeding once daily dosing will not be approved.

Metozolv® ODT [Metoclopramide Orally Disintegrating Tablet (ODT)] Approval Criteria:

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

Nextstellis® (Drospirenone/Estetrol Tablet) and Slynd® (Drospirenone Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all alternative formulations of hormonal contraceptives available without a prior authorization must be provided.

Nuvessa® (Metronidazole 1.3% Vaginal Gel) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis in non-pregnant women; and
2. A patient-specific, clinically significant reason why the member cannot use MetroGel-Vaginal® 0.75% (metronidazole 0.75% vaginal gel) or generic metronidazole oral tablets must be provided.

Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use an over-the-counter (OTC) spermicide and all other forms of contraception (e.g., condoms, oral contraceptives) must be provided. Various OTC spermicides containing nonoxynol 9 are covered by SoonerCare without prior authorization.

Purixan® (Mercaptopurine Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of acute lymphoblastic leukemia (ALL); and
2. An age restriction for members older than 10 years of age applies. Purixan® does not require prior authorization for members 10 years of age and younger; and
3. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

Pyridostigmine 30mg Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use pyridostigmine 60mg tablets, which are available without prior authorization, must be provided.

Rasuvo®, RediTrex®, and Otrexup® (Methotrexate Injection Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Severe, active rheumatoid arthritis (RA) in adult members; or
    b. Active polyarticular juvenile idiopathic arthritis (pJIA) in pediatric members; or
    c. Severe, recalcitrant, disabling psoriasis confirmed by biopsy or dermatologic consultation; and
2. A patient-specific, clinically significant reason why the oral tablets and the generic injectable formulation cannot be used must be provided; and
3. Authorization of Otrexup® will also require a patient-specific, clinically significant reason why the member cannot use Rasuvo® or RediTrex®.

Reltone® (Ursodiol Capsule) Approval Criteria:

1. An FDA approved indication for the dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter or the prevention of gallstone formation in obese members experiencing rapid weight loss; and
2. For the indication of dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter:
    a. Prescriber must confirm member is not a candidate for elective cholecystectomy due to 1 or more of the following:
        i. Increased surgical risk due to systemic disease; or
        ii. Advanced age; or
        iii. Idiosyncratic reaction to general anesthesia; or
        iv. Member refuses surgery; and
    b. Prescriber must confirm the member does not have compelling reasons for cholecystectomy including unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary-gastrointestinal fistula; and
3. For the indication of prevention of gallstone formation in obese members experiencing rapid weight loss:
    a. Member's baseline body mass index (BMI) and weight must be provided; and
    b. Member's current weight must be provided supporting rapid weight loss compared to baseline; and

4. For both FDA approved indications, a patient-specific, clinically significant reason why the member cannot use other generic formulations of ursodiol must be provided; and
5. Initial approvals for the indication of dissolution of gallstones will be for the duration of 6 months, after which time the prescriber must confirm (via ultrasound imaging) partial or complete dissolution of gallstone(s). Subsequent approvals will be for the duration of 12 months; and
6. Approvals for prevention of gallstone formation in obese members experiencing rapid weight loss will be for 6 months, after which time the member's current weight must be provided to justify continued rapid weight loss and need for preventative treatment; and
7. Treatment duration will be limited to a maximum of 24 months for all diagnoses.

Soltamox® (Tamoxifen Citrate 10mg/5mL Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of metastatic breast cancer in women and men; or
    b. Adjuvant treatment of node-positive breast cancer in postmenopausal women and for the adjuvant treatment of axillary node-negative breast cancer in women following total mastectomy or segmental mastectomy, axillary dissection, and breast irradiation; or
    c. To reduce the risk of invasive breast cancer in women with ductal carcinoma in situ (DCIS), following breast surgery and radiation; or
    d. To reduce the incidence of breast cancer in women at high risk for breast cancer; and
2. A patient-specific, clinically significant reason why the member cannot use tamoxifen oral tablets must be provided.

Taytulla® (Norethindrone Acetate/Ethinyl Estradiol Capsule and Ferrous Fumarate Capsule) Approval Criteria:

1. An FDA approved indication to prevent pregnancy in women; and
2. A patient-specific, clinically significant reason why the member cannot use all other generic formulations of norethindrone acetate/ethinyl estradiol tablets with ferrous fumarate tablets must be provided.

Thyquidity™ (Levothyroxine Oral Solution), Tirosint® (Levothyroxine Capsule), and Tirosint®-SOL (Levothyroxine Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism; or
    b. Pituitary Thyrotropin (thyroid-stimulating hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in

the management of thyrotropin-dependent well-differentiated thyroid cancer; and
2. A patient-specific, clinically significant reason why the member cannot use all other formulations of levothyroxine must be provided. For the oral solutions, a reason why the member cannot use the levothyroxine tablet formulation, even when the tablets are crushed, must be provided; and
3. Prescriber must verify member has been compliant with levothyroxine tablets at a greatly increased dose for at least 8 weeks; and
4. Prescriber must verify that member has not been able to achieve normal thyroid lab levels despite a greatly increased dose and compliance with levothyroxine tablets.

Vuity® (Pilocarpine Hydrochloride 1.25% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication of the treatment of presbyopia in adults; and
2. Must be prescribed by an ophthalmologist or optometrist; and
3. Prescriber must verify the member does not have iritis; and
4. Prescriber must verify the member has been counseled on the risk of retinal detachment with use of Vuity® and when to seek immediate medical care; and
5. Prescriber must verify the member has been advised to use caution with night driving and hazardous occupations in poor illumination as vision may not be clear in these conditions while using Vuity®; and
6. A patient-specific, clinically significant reason why the member cannot use corrective lenses must be provided; and
7. A patient-specific, clinically significant reason why the member cannot use generic pilocarpine ophthalmic solution (Isopto® Carpine) must be provided.

Xatmep® (Methotrexate 2.5mg/mL Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of pediatric members with acute lymphoblastic leukemia (ALL) as a component of a combination chemotherapy maintenance regimen; or
    b. Management of pediatric members with active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant of or had an inadequate response to first-line therapy; and
2. A patient-specific, clinically significant reason why the oral tablets or generic injectable formulation cannot be used must be provided.

Utilization of Various Special Formulations: Calendar Year 2022

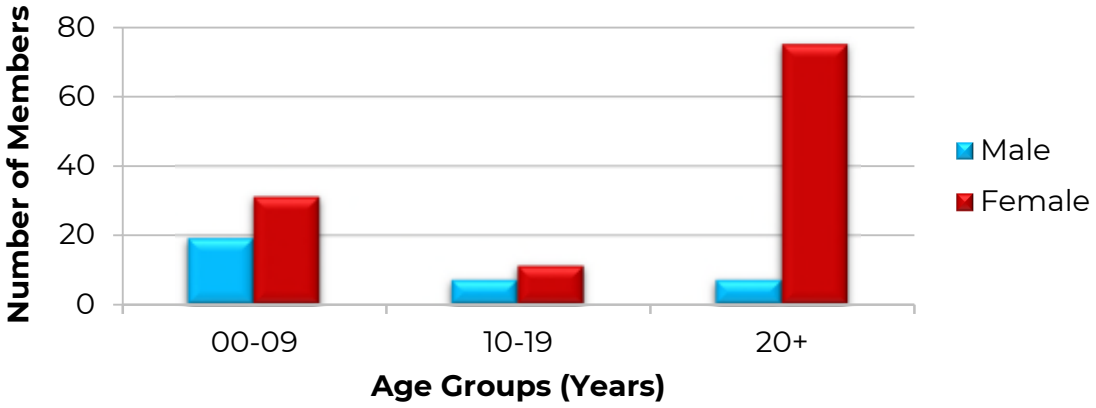
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	151	764	$376,494.56	$492.79	$13.40	40,293	28,089
2022	150	754	$281,146.38	$372.87	$9.95	35,130	28,270
% Change	**-0.70%**	**-1.30%**	**-25.30%**	**-24.30%**	**-25.70%**	**-12.80%**	**0.60%**
Change	**-1**	**-10**	**-$95,348.18**	**-$119.92**	**-$3.45**	**-5,163**	**181**

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

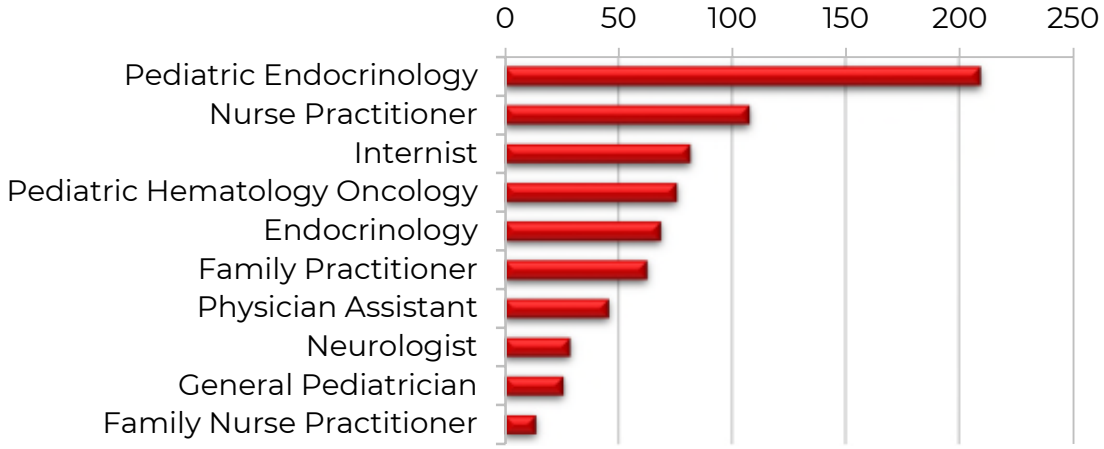
- Due to the evolving nature of this category, calendar year comparisons may not reflect the same product utilization from year to year.
- There were no paid medical claims for various special formulations during calendar year 2022.
- Aggregate drug rebates collected during calendar year 2022 for the various special formulations: $105,595.98.[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 Various Special Formulations



[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.

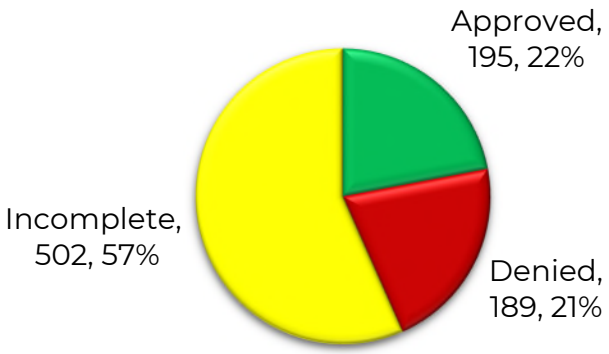
Top Prescriber Specialties of Various Special Formulations by Number of Claims



Prior Authorization of Various Special Formulations

There were 886 prior authorization requests submitted for various special formulations during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



Allopurinol 200mg Tablet Product Summary[1]

Therapeutic Class: Xanthine oxidase inhibitor

Indication(s): Treatment of gout, recurrent calcium renal calculus, and increased uric acid levels in cancer patients receiving chemotherapy

Dosing and Administration:

- The recommended dosing is based on diagnosis:
  - Gout:
    - The dose of allopurinol varies based on disease severity. It should be dosed to accomplish full control of gout and lower serum uric acid to normal or near normal levels.

- The minimal effective dose is 100mg to 200mg daily and the maximal recommended dose is 800mg/day.
- Dosages higher than 300mg should be administered in divided doses.
- The dose should be titrated by 100mg daily at weekly intervals until serum uric acid level of 6mg/dL or less is attained.

- Recurrent Calcium Renal Calculus:
  - Initially, 200mg to 300mg orally daily in divided doses or as a single dose
  - The dose may be titrated based on 24 hours urinary urate determination with a maximum dose of 800mg/day.
- Increased Uric Acid Levels in Cancer Patients:
  - Initially, 600mg to 800mg orally daily for 2 or 3 days together with high fluid intake based on severity of disease with a maximum dose of 800mg/day

Other Formulation(s) Available:

- Allopurinol 100mg and 300mg tablets

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*
allopurinol 200mg tablet (generic)	**$6.61**	**$793.20**
allopurinol 100mg tablet (generic)	$0.04	$9.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the FDA approved maximum daily dose of 800mg.

Calendar Year 2022 Utilization: There was no SoonerCare utilization of allopurinol 200mg tablets during calendar year 2022.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
ALLOPURINOL TAB 100MG	4,417	1,414	$51,887.49	$0.23	3.12	$11.75
ALLOPURINOL TAB 300MG	3,198	1,014	$43,391.78	$0.24	3.15	$13.57
TOTAL	**7,615**	**2,312***	**$95,279.27**	**$0.23**	**3.29**	**$12.51**

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

Aponvie™ (Aprepitant Injectable Emulsion) Product Summary[2,3,4,5]

Therapeutic Class: Substance P/neurokinin-1 (NK_1) receptor antagonist

Indication(s): Prevention of postoperative nausea and vomiting (PONV) in adults

How Supplied: 32mg/4.4mL (7.2mg/mL) injectable emulsion in single-dose vial (SDV)

Dosing and Administration: The recommended dose is 32mg administered as a 30 second intravenous (IV) injection prior to induction of anesthesia.

Other Formulation(s) Available:

- Aprepitant 40mg Capsule:
  - Aprepitant 40mg capsule has the same indication as Aponvie™; the recommended dosing is 40mg within 3 hours prior to induction of anesthesia.
  - Aprepitant capsules may also be used for the prevention of chemotherapy induced nausea and vomiting in 40mg, 80mg, and 125mg strengths; however, only the aprepitant 40mg capsule is indicated for PONV.
- Ondansetron Orally Disintegrating Tablets (ODTs) and Ondansetron Injection:
  - Both ondansetron ODTs and ondansetron hydrocholoride injection have the same indication as Aponvie™.
  - The recommended dose for ondansetron ODTs is 16mg dissolved orally on the tongue 1 hour prior to the induction of anesthesia.
  - The recommended dose for ondansetron injection is 4mg IV or intramuscularly (IM) undiluted immediately prior to anesthesia induction or postoperatively.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Dose*
Aponvie™ (aprepitant 32mg/4.4mL injectable emulsion)	**$12.23**	**$53.81**
aprepitant 40mg capsule (generic)	$52.16	$52.16
ondansetron 8mg orally disintegrating tablet (generic)	$0.21	$0.42
ondansetron 4mg/2mL injection (generic)	$0.17	$0.34

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= capsule, mL, or tablet
*Cost per dose is based on FDA approved dosing for the prevention of PONV for each product.

Calendar Year 2022 Utilization: There was no SoonerCare utilization of Aponvie™ during calendar year 2022.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
ONDANSETRON TAB 4MG ODT	99,989	77,908	$1,378,749.04	$2.04	1.28	$13.78
ONDANSETRON TAB 4MG	22,436	16,234	$260,842.24	$1.25	1.38	$11.63
ONDANSETRON TAB 8MG ODT	20,492	14,005	$295,048.51	$1.74	1.46	$14.40
ONDANSETRON TAB 8MG	6,667	4,207	$80,869.18	$1.27	1.58	$12.13

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
ONDANSETRON SOL 4MG/5ML	6,523	5,865	$124,579.24	$2.22	1.11	$19.10
ONDANSETRON INJ 4MG/2ML	35	18	$503.50	$1.46	1.94	$14.39
ONDANSETRON INJ 40/20ML	16	6	$470.73	$1.57	2.67	$29.42
ONDANSETRON INJ 4MG/2ML	11	1	$423.18	$5.57	11	$38.47
APREPITANT CAP 40MG	2	2	$1,787.24	$55.85	1	$893.62
TOTAL	**156,171**	**109,365***	**$2,143,272.86**	**$1.83**	**1.43**	**$13.72**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP= capsule; INJ= injection; ODT = orally disintegrating tablet; TAB = tablet; SOL= solution

Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules] Product Summary[6,7]

Therapeutic Class: Antianginal

Indication(s): Treatment of chronic angina

How Supplied: 500mg and 1,000mg unit-dose sachets containing ranolazine ER granules

Dosing and Administration:

- Initial dose is 500mg orally twice daily; the dose may be increased to 1,000mg orally twice daily, as needed, based on clinical symptoms.
- The maximum recommended daily dose is 1,000mg twice daily.
- Directions for use with soft food (e.g., applesauce, yogurt):
  - Granules should be sprinkled on 1 tablespoonful of soft food and consumed immediately.
  - Granules should not be crushed or chewed.
- Aspruzyo Sprinkle™ may be administered via nasogastric (NG) tube or gastrostomy/gastric (G) tube. Please refer to the package labeling for administration instructions.

Other Formulation(s) Available:

- Ranolazine ER Tablets:
  - Ranolazine ER tablets and Aspruzyo Sprinkle™ have the same indication and recommended dosing.
  - Ranolazine ER tablets should be swallowed whole and should not be crushed, chewed, or broken.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Aspruzyo Sprinkle™ (ranolazine ER 1,000mg granules)	**$8.30**	**$498.00**
ranolazine ER 1,000mg tablets (generic)	$0.33	$19.80

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 daily dose of 1000mg twice daily.
Unit = tablet or sachet
ER = extended-release

Calendar Year 2022 Utilization: There was 1 claim for 1 member utilizing Aspruzyo Sprinkle™ with a total cost of $314.74 during calendar year 2022. This cost does not reflect rebated prices or net costs.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
RANOLAZINE TAB 500MG ER	1,471	449	$45,803.90	$0.69	3.16	$32.32
RANEXA TAB 500MG	1	1	$1,190.75	$13.23	1.00	$1,190.75
TOTAL	**1,418**	**450***	**$46,994.65**	**$0.70**	**3.15**	**$33.14**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ER = extended-release; TAB = tablet

Austedo® XR (Deutetrabenazine ER Tablet) Product Summary[8]

Therapeutic Class: Vesicular monoamine transporter 2 (VMAT2) inhibitor

Indication(s): Treatment of chorea associated with Huntington's disease and tardive dyskinesia (TD) in adults

How Supplied: 6mg, 12mg, and 24mg ER tablets

Dosing and Administration:

- The recommended starting dose is 12mg with or without food once daily.
- The dose may be titrated at weekly intervals by 6mg per day based on tolerability and the reduction of chorea or TD, up to a maximum recommended daily dose of 48mg.

Other Formulation(s) Available:

- Austedo® (Deutetrabenazine Tablet):
  - Austedo® has the same indications and *Boxed Warning* as Austedo® XR.
  - Austedo® tablets are available in 6mg, 9mg, and 12mg tablets.
  - The recommended starting dose for Austedo® tablets is 6mg twice daily (12mg per day), and, like Austedo® XR, the dose should be titrated based on response and tolerability in weekly intervals.
  - Austedo® tablets should be administered with food, and total daily doses of 12mg or above should be given in 2 divided doses.
  - The maximum recommended daily dose is 48mg.

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*
Austedo® XR (deutetrabenazine 24mg ER) tablet	**$236.02**	**$14,161.20**
Austedo® (deutetrabenazine 12mg) tablet	$113.24	$13,588.80

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 daily dose of 48mg/day.
ER = extended-release

Calendar Year 2022 Utilization: There was no SoonerCare utilization of Austedo® XR during calendar year 2022.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
AUSTEDO TAB 12MG	277	62	$2,236,230.30	$272.01	4.47	$8,073.03
AUSTEDO TAB 9MG	171	41	$1,114,286.83	$219.18	4.17	$6,516.30
AUSTEDO TAB 6MG	79	26	$367,678.44	$155.40	3.04	$4,654.16
TOTAL	**527**	**93***	**$3,718,195.57**	**$237.27**	**5.67**	**$7,055.40**

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

Entadfi® (Finasteride/Tadalafil Capsule) Product Summary[9]

Therapeutic Class: Combination of a 5α-reductase inhibitor (finasteride) and a phosphodiesterase 5 (PDE5) inhibitor (tadalafil)

Indication(s): To initiate treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks

- Limitations of Use: Entadfi® is not recommended for more than 26 weeks because the incremental benefit of tadalafil decreased from 4 weeks until 26 weeks, and the incremental benefit beyond 26 weeks is unknown.

How Supplied: Fixed-dose combination of 5/5mg finasteride/tadalafil oral capsules

Dosing and Administration: One capsule orally once daily taken without food at approximately the same time every day for up to 26 weeks

Other Formulation(s) Available:

- Finasteride 5mg Tablet and Tadalafil 5mg Tablet:
  - The safety and efficacy of Entadfi® is based on an adequate and well controlled study of tadalafil co-administered with finasteride.
  - Tadalafil and finasteride administered together demonstrated statistically significant improvement in the signs and symptoms of BPH compared to placebo with finasteride.
  - Entadfi®, being composed of finasteride and tadalafil, has a similar indication, *Limitations of Use*, warnings, and precautions to the individual products.

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*
Entadfi® (finasteride/tadalafil 5/5mg capsule)	**$3.17**	**$95.10**
tadalafil 5mg tablet (generic)	$0.15	$4.50
finasteride 5mg tablet (generic)	$0.06	$1.80

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 once daily dosing.

Calendar Year 2022 Utilization: There was no SoonerCare utilization of Entadfi® during calendar year 2022.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
FINASTERIDE TAB 5MG	1,795	558	$23,398.13	$0.24	3.22	$13.04
TADALAFIL TAB 5MG	37	5	$717.24	$0.82	7.4	$19.38
TOTAL	**1,832**	**563***	**$24,115.37**	**$0.25**	**3.25**	**$13.16**

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

Ermeza™ (Levothyroxine Oral Solution) Product Summary[10,11,12,13]

Therapeutic Class: Levothyroxine sodium (T4)

Indication(s): Hypothyroidism and pituitary thyrotropin suppression

- Limitations of Use: Ermeza™ is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients nor is it indicated for the treatment of hypothyroidism during the recovery phase of subacute thyroiditis.

How Supplied: 150mcg/5mL (30mcg/mL) oral solution in 75mL or 150mL bottles; the bottle must be used within 90 days of opening

Dosing and Administration: The starting dose will depend on a variety of factors (e.g., age, body weight, cardiovascular status, concomitant medication).

- Administer once daily on an empty stomach, 30 minutes to 1 hour before breakfast.
- Administer at least 4 hours before or after medications that are known to interfere with absorption.
- Administer using the appropriate syringe provided in the original carton. The 5mL syringe should be used for doses up to 5mL. The 10mL syringe should be used for doses >5mL.

Other Formulation(s) Available:

- Levothyroxine Tablets, Thyquidity™ (Levothyroxine Oral Solution), and Tirosint®-SOL (Levothyroxine Oral Solution):
  - Levothyroxine tablets, Thyquidity™, and Tirosint®-SOL have the same indications and dosing as Ermeza™.
  - Levothyroxine tablets, Thyquidity™, and Tirosint®-SOL also include the same *Boxed Warning* and *Limitations of Use* as Thyquidity™.
  - Levothyroxine tablets are available in 12 strengths: 25mcg, 50mcg, 75mcg, 88mcg, 100mcg, 112mcg, 125mcg, 137mcg, 150mcg, 175mcg, 200mcg, or 300mcg.
  - Levothyroxine tablets can be crushed and mixed in a small amount (5mL to 10mL) of water for those unable to swallow tablets.
  - Tirosint®-SOL is supplied as an oral solution in 1mL unit-dose ampules and is available in 15 strengths which are similar to the levothyroxine tablet strengths with the exclusion of 300mcg and the addition of 13mcg, 37.5mcg, 44mcg, and 62.5mcg.
  - The contents of the Tirosint®-SOL ampule can be mixed with a glass of water prior to administration, emptied onto a spoon and consumed, or administered directly into the mouth.
  - Thyquidity™ is supplied as 100mcg/5mL (20mcg/mL) oral solution in 100mL bottles. The bottle must be used within 8 weeks of opening.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Tirosint®-SOL 50mcg/mL (levothyroxine oral solution)	$4.44+	$133.20
Ermeza™ 150mcg/5mL (levothyroxine oral solution)	**$1.72**	**$86.17**
Thyquidity™ 100mcg/5mL (levothyroxine oral solution)	$1.20	$90.00
levothyroxine 50mcg tablet (generic)	$0.08	$2.40

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).
Unit = mL or tablet
*Cost per 30 days based on a dose of 50mcg daily. Cost for Ermeza™, Thyquidity™, and levothyroxine tablets will vary based on dose required.
+Cost per mL is the same for all strengths of Tirosint®-SOL.

Calendar Year 2022 Utilization: There was no SoonerCare utilization of Ermeza™ during calendar year 2022. For Thyquidity™ (levothyroxine oral solution) and Tirosint®-SOL (levothyroxine oral solution), there were 241 claims for 39 unduplicated utilizing members with a total cost of $35,645.74 during calendar year 2022, resulting in a cost per claim of $147.91. These costs do not reflect rebated prices or net costs.

Furoscix® (Furosemide On-Body Infusor) Product Summary[14,15,16,17]

Therapeutic Class: Loop diuretic

Indication(s): Treatment of congestion due to fluid overload in adults with New York Heart Association (NYHA) Class II/III chronic heart failure

- Limitations of Use: Furoscix® is not indicated for emergency situations or in patients with acute pulmonary edema. The on-body infusor will only deliver an 80mg dose of furosemide.

How Supplied: 80mg/10mL injection in a single-dose prefilled cartridge co-packaged with a single-use, on-body infusor

Dosing and Administration: The single-use, on-body infusor is pre-programmed to deliver 30mg of furosemide over the first hour then 12.5mg per hour for the subsequent 4 hours.

- Furoscix® is not for chronic use and should be replaced with oral diuretics as soon as practical.
- Furoscix® is intended for use in a setting where the patient can limit their activity for the duration of administration.

Other Formulation(s) Available:

- Furosemide Tablets and Furosemide Injection:
  - Both the tablets and the injection are indicated for the treatment of edema associated with congestive heart failure with similar warnings and precautions as Furoscix®.
  - For all products, therapy should be individualized according to patient response to gain maximal therapeutic response and to determine the minimal dose needed to maintain that response.
  - The usual initial dose of furosemide tablets is 20mg to 80mg given as a single dose. Based on response, the dose may be titrated up. The individually determined daily dose should then be given once or twice daily.
  - Furosemide injections should only be used in patients unable to take oral medication or in emergency situations and should be replaced with oral furosemide as soon as practical.
  - Unlike Furoscix®, furosemide injection is indicated as adjunctive therapy in acute pulmonary edema or in emergency situations.
  - The initial recommended dose of furosemide injection is 20mg to 40mg given as a single dose, injected IM or IV. The dose may be adjusted based on response. The individually determined single dose should then be given once or twice daily. Close medical supervision is needed for furosemide injection.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Incident*
Furoscix® (furosemide 80mg on-body infusor)	**$822.00**	**$6,576.00**
furosemide 10mg/mL injection (generic)	$0.34	$21.76
furosemide 80mg tablet (generic)	$0.05	$0.40

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).
Unit = package or mL
*Cost per incident is based on 80mg twice daily for 4 days; however, please note that therapy is individualized according to the patient response.

Calendar Year 2022 Utilization: There was no SoonerCare utilization of Furoscix® during calendar year 2022.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
FUROSEMIDE TAB 40MG	16,624	5,882	$172,242.11	$0.21	2.83	$10.36
FUROSEMIDE TAB 20MG	13,635	5,396	$132,445.02	$0.21	2.53	$9.71
FUROSEMIDE TAB 80MG	1,548	622	$18,977.22	$0.24	2.49	$12.26
FUROSEMIDE INJ 20MG/2ML	19	1	$323.59	$2.43	19	$17.03
FUROSEMIDE INJ 40MG/4ML	5	2	$173.29	$5.98	2.5	$34.66
FUROSEMIDE INJ 10MG/ML	2	2	$41.60	$5.20	1	$20.80
TOTAL	**31,833**	**10,844***	**$324,202.83**	**$0.22**	**2.94**	**$10.18**

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

Iyuzeh™ (Latanoprost Ophthalmic Solution) Product Summary[18,19,20]

Therapeutic Class: Prostaglandin F2α analogue

Indication(s): Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension

How Supplied: Latanoprost 0.005% (50mcg/mL) ophthalmic solution

Dosing and Administration: One drop in the affected eye(s) once daily in the evening

Other Formulation(s) Available:

- Xalatan® 0.005% (Latanoprost Ophthalmic Solution) and Xelpros® 0.005% (Latanoprost Ophthalmic Emulsion):
  - Xalatan® and Xelpros® have the same indication, warnings, and precautions as Iyuzeh™.
  - Xalatan® 0.005% (latanoprost ophthalmic solution) is available in a generic formulation and contains benzalkonium chloride as a preservative.

- Xelpros® contains potassium sorbate as a preservative.
- Iyuzeh™ is a preservative-free formulation.

Formulation Cost Comparison:

Product	Cost Per mL	Cost Per 25 Days*
Xelpros® 0.005% (latanoprost ophthalmic emulsion)	$24.00	$60.00
latanoprost 0.005% ophthalmic solution (generic)	$1.81	$4.53

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 information for Iyuzeh™ is currently not available.
*Cost per 25 days based on the FDA approved dose of 1 drop in affected eye(s) once daily, assuming both eyes are affected.

Calendar Year 2022 Utilization: There was no SoonerCare utilization of Iyuzeh™ or Xelpros® during calendar year 2022.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
LATANOPROST SOL 0.005%	3,218	946	$51,124.40	$0.41	3.40	$15.89
TOTAL	**3,218**	**946***	**$51,124.40**	**$0.41**	**3.40**	**$15.89**

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

Jylamvo® (Methotrexate Oral Solution) Product Summary[21,22,23,24,25]

Therapeutic Class: Folate analog metabolic inhibitor

Indication(s): Treatment of adults with:
- Acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen
- Mycosis fungoides
- Relapsed or refractory non-Hodgkin lymphoma as part of a metronomic combination regimen
- Rheumatoid arthritis
- Severe psoriasis

How Supplied: 2mg/mL oral solution

Dosing and Administration:
- The recommended dosing is based on diagnosis:
  - ALL: 20mg/m^2 orally once weekly as a part of a combination chemotherapy maintenance regimen
  - Mycosis Fungoides: 25mg to 75mg orally once weekly as monotherapy; 10mg/m^2 orally twice weekly as part of combination chemotherapy

- Relapsed or Refractory Non-Hodgkin Lymphoma: 2.5mg orally 2 to 4 times per week as part of metronomic combination chemotherapy
- Rheumatoid Arthritis: 7.5mg orally once weekly; adjust dose to achieve an optimal response
- Psoriasis: 10mg to 25mg orally once weekly until adequate response is achieved

Other Formulation(s) Available:

- Methotrexate Tablet, Methotrexate Injection, Trexall® Tablet, and Xatmep® (Methotrexate Oral Solution):
  - Methotrexate tablets, generic methotrexate injections, and Trexall® tablets have the same indications and *Boxed Warning* as Jylamvo®.
  - Xatmep® (methotrexate oral solution) is indicated for pediatric patients with ALL or active polyarticular juvenile idiopathic arthritis (pJIA) with similar warnings and precautions to Jylamvo®. Xatmep® does not require a prior authorization for members younger than 10 years of age.
  - Dosing varies based on the diagnosis being treated. Methotrexate tablets are generically available in a 2.5mg strength. Methotrexate injection solution is available generically in 2mL, 10mL, and 40mL vials containing 25mg of methotrexate sodium per milliliter. Trexall® film-coated tablets are available as 5mg, 7.5mg, 10mg, and 15mg strengths. Xatmep® is available in 2.5mg/mL oral solution.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days*
Xatmep® 2.5mg/mL (methotrexate oral solution)	$17.38	$208.56
Trexall® (methotrexate tablet) 7.5mg	$28.91	$115.64
methotrexate injection solution 25mg/mL (generic)	$1.93	$15.44⁺
methotrexate tablet 2.5mg (generic)	$0.22	$2.64

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 = tablet or mL
Cost information for Jylamvo® is currently not available.
*Cost per 28 days based on weekly dosing of 7.5mg for each product.
⁺Cost per 28 days of methotrexate injection solution based on use of a 2mL single-use vial for each weekly dose.

Calendar Year 2022 Utilization: There was no SoonerCare utilization of Jylamvo® during calendar year 2022.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
METHOTREXATE TAB 2.5MG	4,684	1,398	$80,589.08	$0.41	3.35	$17.21
METHOTREXATE INJ 25MG/ML	841	296	$19,078.03	$0.54	2.84	$22.68

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
METHOTREXATE INJ 50MG/2ML	772	269	$14,843.01	$0.55	2.87	$19.23
TREXALL TAB 10MG	35	13	$17,231.55	$12.88	2.69	$492.33
XATMEP 2.5MG/ML SOL	31	7	$17,068.18	$15.52	4.43	$550.59
METHOTREXATE 25MG/ML	29	17	$1,083.89	$0.64	1.71	$37.38
TREXALL TAB 15MG	28	8	$7,929.52	$6.44	3.5	$283.20
METHOTREXATE INJ 250MG/10ML	20	12	$259.66	$0.19	1.67	$12.98
TREXALL TAB 7.5MG	15	10	$4,724.60	$6.54	1.5	$314.97
TREXALL TAB 5MG	10	4	$4,899.76	$7.42	2.5	$489.98
TOTAL	**6,465**	**1,872***	**$167,707.28**	**$0.62**	**3.45**	**$25.94**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; SOL = solution; TAB = tablet

Primidone 125mg Tablet Product Summary[26]

Therapeutic Class: Anticonvulsant

Indication(s): As monotherapy or concomitantly with other anticonvulsants, in the control of grand mal, psychomotor, and focal epileptic seizures; primidone may control grand mal seizures refractory to other anticonvulsant therapy

Dosing and Administration:

- Usual Dosage:
  - Patients 8 years of age and older who have received no previous treatment may be started on primidone tablets according to the following regimen using either 50mg or scored 250mg primidone tablets:
    - Days 1 to 3: 100mg to 125mg at bedtime
    - Days 4 to 6: 100mg to 125mg twice a day
    - Days 7 to 9: 100mg to 125mg 3 times a day
    - Day 10 to maintenance: 250mg 3 times a day
  - For most adults and children 8 years of age and over, the usual maintenance dose is 250mg 3 or 4 times a day. The dose may be increased if required, but the maximum daily dose should not exceed 2,000mg/day.
  - Dosage should be individualized to provide maximum benefit.
- Patients Already Receiving Other Anticonvulsants:
  - Primidone tablets should be started at 100mg to 125mg at bedtime and gradually increased to maintenance level as the other drug is gradually decreased.
  - This regimen should be continued until satisfactory dosage level is achieved for the combination, or the other medication is completely withdrawn.

- When monotherapy with primidone tablets is the objective, the transition from concomitant therapy should not be completed in less than 2 weeks.

- Pediatric Dosage:
  - For children younger than 8 years of age, the following regimen may be used:
    - Days 1 to 3: 50mg at bedtime
    - Days 4 to 6: 50mg twice a day
    - Days 7 to 9: 100mg twice a day
    - Day 10 to maintenance: 125mg to 250mg 3 times a day
  - For children younger than 8 years of age, the usual maintenance dosage is 125mg to 250mg 3 times daily or 10 to 25mg/kg/day in divided doses.

Other Formulation(s) Available:

- Primidone 50mg tablet and 250mg tablet

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*
primidone 125mg tablet (generic)	**$1.49**	**$134.10**
primidone 250mg tablet (generic)	$0.27	$12.15

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 dosing regimen of 125mg 3 times per day.

Calendar Year 2022 Utilization: There was no SoonerCare utilization of primidone 125mg tablet during calendar year 2022.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
PRIMIDONE TAB 50MG	1,060	246	$20,463.00	$0.55	4.31	$11.75
PRIMIDONE TAB 250MG	251	43	$5,906.23	$0.69	5.84	$23.23
MYSOLINE TAB 250MG	18	2	$99,704.36	$151.07	9	$5,539.13
TOTAL	**1,329**	**281***	**$126,073.59**	**$2.71**	**4.73**	**$94.86**

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

Verkazia® (Cyclosporine Ophthalmic Emulsion) Product Summary[27,28,29,30]

Therapeutic Class: Calcineurin inhibitor immunosuppressant

Indication(s): Treatment of vernal keratoconjunctivitis (VKC) in children and adults

How Supplied: cyclosporine 0.1% (1mg/mL) ophthalmic emulsion in single-use vials

Dosing and Administration: Instill 1 drop of Verkazia®, 4 times daily (QID; morning, noon, afternoon, and evening) in each affected eye.

Other Formulation(s) Available:

- Cyclosporine 0.05% Ophthalmic Emulsion:
  - Cyclosporine 0.05% ophthalmic emulsion is FDA approved to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Although not FDA approved for VKC, the American Academy of Ophthalmology Conjunctivitis Preferred Practice Pattern recommends the use of 0.05% topical cyclosporine for the treatment of VKC as it has been shown to be effective in more frequent dosing for the treatment of severe VKC.
  - Additionally, in a pooled analysis of the NOVATIVE and VEKTIS studies which were used to approve Verkazia®, the data indicated that both cyclosporine 0.05% emulsion QID and cyclosporine 0.1% emulsion QID were significantly more effective than the vehicle control in improving keratitis as measured by the corneal fluorescein staining (CFS) scores in patients with VKC. The pooled analysis also showed that both regimens were safe and well tolerated.

Formulation Cost Comparison:

Product	Cost Per Vial	Cost Per 30 Days
Verkazia® (cyclosporine 0.1% ophthalmic emulsion)	**$12.21**	**$1,465.20**
cyclosporine 0.05% ophthalmic emulsion (generic)	$3.27	$392.40

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 is based on the use of 1 single-use vial 4 times daily.

Calendar Year 2022 Utilization: There was no SoonerCare utilization of Verkazia® during calendar year 2022.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
CYCLOSPORINE EMU 0.05% OP	810	360	$302,990.61	$12.37	2.25	$374.06
RESTASIS EMU 0.05% OP	720	316	$414,660.87	$19.61	2.28	$575.92
TOTAL	**1,530**	**589***	**$717,651.48**	**$15.72**	**2.6**	**$469.05**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
EMU = emulsion; OP = ophthalmic

Xaciato™ (Clindamycin Vaginal Gel) Product Summary[31,32,33,34]

Therapeutic Class: Lincosamide antibacterial

Indication(s): Treatment of bacterial vaginosis in female patients 12 years of age and older

How Supplied: Clindamycin 2% vaginal gel in an 8g tube. One single-dose, user-filled disposable applicator delivers 5g of gel containing 100mg of clindamycin.

Dosing and Administration:

- Administer 1 applicatorful (5g of gel containing 100mg of clindamycin) once intravaginally as a single dose at any time of the day.
- Not for ophthalmic, dermal, or oral use.

Other Formulation(s) Available:

- Clindamycin 2% Vaginal Cream, Clindesse® (Clindamycin Phosphate 2% Vaginal Cream), and Cleocin® Vaginal Ovules (Clindamycin Phosphate 2.5g Vaginal Suppositories):
  - Clindamycin 2% vaginal cream, Clindesse®, and Cleocin® all have the same indication as Xaciato™.
  - Clindamycin 2% vaginal cream is supplied in a 40g tube with 7 disposable applicators and is dosed as 1 applicatorful (5g containing approximately 100mg of clindamycin) intravaginally, preferably at bedtime, for 3 or 7 consecutive days in non-pregnant patients and for 7 consecutive days in pregnant patients.
  - Clindesse® is supplied as 1 single-dose prefilled disposable applicator. Each applicator delivers approximately 5g of vaginal cream containing approximately 100mg of clindamycin. The recommended dose is a single prefilled applicator administered once intravaginally any time of day.
  - Cleocin® vaginal ovule is supplied as a vaginal suppository. The recommended dose is 1 Cleocin® vaginal ovule (containing clindamycin phosphate equivalent to 100mg clindamycin per 2.5g suppository) intravaginally per day, preferably at bedtime, for 3 consecutive days.
  - Clindesse® and Cleocin® are indicated for use in non-pregnant women. Xaciato™ and clindamycin 2% vaginal cream may be used in non-pregnant women and pregnant women during the second and third trimester.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment*
Xaciato™ (clindamycin 2% vaginal gel)	**$18.75**	**$150.00**
Cleocin® (clindamycin phosphate 2.5g vaginal suppositories)	$58.94	$176.82
Clindesse® (clindamycin phosphate 2% vaginal cream)	$26.96	$134.80

clindamycin 2% vaginal cream (generic)	$1.62	$64.80

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 = gram or suppository
*Cost per treatment is based on the total package size for each product as 1 package will be dispensed for each treatment course: 8g tube for Xaciato™, 3 suppositories for Cleocin®, 5g tube for Clindesse®, and 40g tube for clindamycin 2% vaginal cream.

Calendar Year 2022 Utilization: There was no SoonerCare utilization of Xaciato™ during calendar year 2022.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
CLINDAMYCIN CRE 2% VAG	814	711	$59,317.50	$6.99	1.14	$74.05
CLINDESSE CRE 2%	242	217	$31,496.16	$40.54	1.12	$130.15
CLEOCIN SUP 100MG	45	43	$11,685.04	$59.31	1.05	$259.67
TOTAL	**1,101**	**953***	**$102,498.70**	**$10.84**	**1.16**	**$93.10**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CRE = cream; SUP = suppositories; VAG = vaginal

Zolpidem Tartrate 7.5mg Capsule Product Summary[35,36]

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

Indication(s): Short-term treatment of transient insomnia characterized by difficulties with sleep initiation in adults younger than 65 years of age

How Supplied: 7.5mg capsule

Dosing and Administration:

- The lowest effective zolpidem tartrate dosage should be used.
  - The recommended starting dose of zolpidem tartrate immediate-release (IR) in females is 5mg once nightly. Another zolpidem tartrate IR product should be used for dosage initiation in females.
  - The recommended starting dose of zolpidem tartrate IR in males is either 5mg, 7.5mg, or 10mg once nightly.
  - In both males and females, if a 5mg once nightly dose is not effective, the dosage may be increased to 7.5mg once nightly or 10mg once nightly.
  - The maximum recommended dose of zolpidem tartrate IR is 10mg once nightly.
  - Zolpidem tartrate 7.5mg capsules are not indicated in geriatric patients (patients older than 65 years of age). Use of zolpidem tartrate 7.5mg capsules should be avoided in geriatric patients because the recommended dose (5mg once nightly) in these patients cannot be achieved with the 7.5mg strength. Another

zolpidem tartrate product should be used to achieve the dose for geriatric patients.
- Zolpidem tartrate 7.5mg capsules should be avoided in patients with mild or moderate hepatic impairment because the recommended dosage (5mg once nightly) in such patients cannot be achieved with the 7.5mg strength.
- Any zolpidem tartrate use should be avoided in patients with severe hepatic impairment because its use may contribute to encephalopathy.

Other Formulation(s) Available:

- Zolpidem Tartrate 5mg and 10mg Tablet:
  - Zolpidem tartrate 5mg and 10mg tablets have the same indication as zolpidem tartrate 7.5mg capsules except the 5mg tablet may be used in patients older than 65 years of age.
  - All 3 strengths have the same warnings and precautions.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
zolpidem tartrate 7.5mg capsule (generic)	**$8.33**	**$249.90**
zolpidem tartrate 5mg tablet (generic)	$0.03	$0.90
zolpidem tartrate 10mg tablet (generic)	$0.03	$0.90

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 = capsule or tablet
*Cost per 30 days is based on the FDA approved once nightly dose.

Calendar Year 2022 Utilization: There was no SoonerCare utilization of zolpidem 7.5mg capsules during calendar year 2022.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
ZOLPIDEM TAB 10MG	15,824	2,919	$160,929.36	$0.34	5.42	$10.17
ZOLPIDEM TAB 5MG	3,971	1,394	$39,798.11	$0.36	2.85	$10.02
TOTAL	**19,795**	**4,048***	**$200,727.47**	**$0.35**	**4.89**	**$10.14**

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

Recommendations

The College of Pharmacy recommends the prior authorization of allopurinol 200mg tablets, Aponvie™ (aprepitant injectable emulsion), and Aspruzyo Sprinkle™ (ranolazine ER granules) with the following criteria (shown in red):

Allopurinol 200mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use 2 allopurinol 100mg tablets in place of allopurinol 200mg must be provided.

Aponvie™ (Aprepitant 32mg/4.4mL Vial) Approval Criteria:

1. An FDA approved diagnosis of the prevention of postoperative nausea and vomiting (PONV); and
2. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives for the prevention of PONV (e.g., ondansetron) must be provided.

Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules] Approval Criteria:

1. An FDA approved diagnosis of chronic angina; and
2. A patient-specific, clinically significant reason why the member cannot use ranolazine ER tablets must be provided.

The College of Pharmacy recommends the prior authorization of Austedo® XR (deutetrabenazine ER tablet) with criteria similar to Austedo® (deutetrabenazine). The College of Pharmacy also recommends updating the approval criteria for Huntington's disease diagnosis for safety and consistency with the approval criteria for tardive dyskinesia as follows (changes shown in red):

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

1. An FDA approved diagnosis of chorea associated with Huntington's disease; and
2. Deutetrabenazine ~~Austedo®~~ must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. A previous trial of Xenazine® (tetrabenazine) or a patient-specific, clinically significant reason why the member cannot use Xenazine® (tetrabenazine) must be provided; and
4. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting deutetrabenazine therapy and throughout treatment; and
5. Member must not have hepatic impairment; and
6. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and

7. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
8. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with deutetrabenazine; and
9. For members who are using deutetrabenazine ~~Austedo®~~ concomitantly with other medications that are known to prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval] the prescriber must agree to monitor the member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures); and
10. Member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and
11. The daily dose of deutetrabenazine ~~Austedo®~~ must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion) or if they are a known poor CYP2D6 metabolizer; and
12. Female members must not be pregnant or breastfeeding; and
13. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea have decreased, and the member is not showing worsening signs of depression.

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

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
   a. Involuntary athetoid or choreiform movements; and
   b. History of treatment with dopamine receptor blocking agent (DRBA); and
   c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Deutetrabenazine ~~Austedo®~~ must be prescribed by a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
4. Member must not have hepatic impairment; and
5. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
6. Member must not be taking reserpine or have taken reserpine within the last 20 days; and

7. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with deutetrabenazine; and
8. For members who are using deutetrabenazine ~~Austedo®~~ concomitantly with other medications that are known to prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval] the prescriber must agree to monitor the member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures); and
9. Member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and
10. The daily dose of deutetrabenazine ~~Austedo®~~ must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion) or if they are a known poor CYP2D6 metabolizer; and
11. Female members must not be pregnant or breastfeeding; and
12. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
13. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Additionally, the College of Pharmacy recommends the prior authorization of Entadfi™ (finasteride/tadalafil capsule) with placement into Tier 3 of the Benign Prostatic Hypertrophy (BPH) Product Based Prior Authorization (PBPA) category with the following additional criteria (shown in red):

Entadfi™ (Finasteride 5mg/Tadalafil 5mg) Approval Criteria:

1. An FDA approved diagnosis of benign prostatic hyperplasia (BPH); and
2. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components (finasteride and tadalafil) must be provided; and
4. A quantity limit of 30 capsules per 30 days will apply; and
5. Maximum treatment duration of 26 weeks will apply.

The College of Pharmacy also recommends making Tirosint® (levothyroxine capsule) brand preferred based on net costs and recommends the prior

authorization of Ermeza™ (levothyroxine oral solution) with criteria similar to Thyquidity™, Tirosint®, and Tirosint®-SOL as follows (changes shown in red):

Ermeza™ (Levothyroxine Oral Solution), Thyquidity™ (Levothyroxine Oral Solution), Tirosint® (Levothyroxine Capsule), and Tirosint®-SOL (Levothyroxine Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism; or
    b. Pituitary Thyrotropin (thyroid-stimulating hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer; and
2. A patient-specific, clinically significant reason why the member cannot use all other formulations of levothyroxine must be provided. For the oral solutions, a reason why the member cannot use the levothyroxine tablet formulation, even when the tablets are crushed, must be provided; and
3. Tirosint® (levothyroxine capsule) is brand preferred. Use of generic levothyroxine capsules will require a patient specific, clinically significant reason why the member cannot use the brand formulation; and
4. Prescriber must verify member has been compliant with levothyroxine tablets at a greatly increased dose for at least 8 weeks; and
5. Prescriber must verify that member has not been able to achieve normal thyroid lab levels despite a greatly increased dose and compliance with levothyroxine tablets.

The College of Pharmacy also recommends the prior authorization of Furoscix® (furosemide on-body infusor) with the following criteria (shown in red):

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

1. An FDA approved indication for the treatment of congestion due to fluid overload in members with NYHA Class II-III heart failure; and
2. Member must be 18 years of age or older; and
3. Furoscix® must be prescribed by, or in consultation with, a cardiologist or a provider trained in managing acute decompensated heart failure (ADHF); and
4. Member is currently showing signs of fluid overload; and
5. Member has been stable and refractory to at least 1 of the following loop diuretics, at maximally indicated doses:
    a. Bumetanide oral tablets; or
    b. Furosemide oral tablets; or

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

The College of Pharmacy also recommends the placement of Iyuzeh™ into the Special PA Tier of the Glaucoma PBPA category with the following criteria:

Glaucoma Medications Special Prior Authorization (PA) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 or Tier-2 medication; or
3. Approvals may be granted if there is a documented adverse effect, drug interaction, or contraindication to all Tier-1 and Tier-2 medications; or
4. Approvals may be granted if there is a unique FDA approved indication not covered by all Tier-1 and Tier-2 medications; and
5. The member must have had a comprehensive, dilated eye exam within the last 365-day period as recommended by the National Institutes of Health; and
6. Approvals will be for the duration of 1 year.

Additionally, the College of Pharmacy recommends the prior authorization of Jylamvo® (methotrexate oral solution), primidone 125mg tablet, Verkazia®

(cyclosporine 0.1% ophthalmic emulsion), and Xaciato™ (clindamycin vaginal gel) with the following criteria (shown in red):

Jylamvo® (Methotrexate Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen; or
    b. Mycosis fungoides (cutaneous T-cell lymphoma) as a single agent or as part of a combination chemotherapy regimen; or
    c. Relapsed or refractory non-Hodgkin lymphomas as part of a metronomic combination chemotherapy regimen; or
    d. Rheumatoid arthritis; or
    e. Severe psoriasis; and
2. Member must be 18 years of age or older; and
3. A patient-specific clinically significant reason why the oral tablets and the generic injectable formulation cannot be used must be provided.

Primidone 125mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific clinically significant reason why the member cannot split the 250mg tablet to achieve the 125mg dose must be provided.

Verkazia® (Cyclosporine 0.1% Ophthalmic Emulsion) Approval Criteria:

1. An FDA approved indication of vernal keratoconjunctivitis (VKC); and
2. Member has had 1 recurrence of VKC in the last year; and
3. Verkazia® must be prescribed by, or in consultation with, an allergist, optometrist, or ophthalmologist (or an advanced care practitioner with a supervising physician who is an allergist, optometrist, or ophthalmologist); and
4. Prescriber must verify that environmental factors (e.g., sun, wind, salt water) have been addressed; and
5. Member must have a trial of a topical mast cell stabilizer, antihistamine, or combination product or a patient-specific, clinically significant reason why those products are not appropriate must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use cyclosporine 0.05% ophthalmic emulsion single-use vials, which are available without a prior authorization, must be provided; and
7. A quantity limit of 120 single-use vials per 30 days will apply.

Xaciato™ (Clindamycin Vaginal Gel) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis; and
2. A patient specific, clinically significant reason why the member cannot use clindamycin 2% vaginal cream, Clindesse® (clindamycin phosphate 2% vaginal cream), and Cleocin® vaginal ovules (clindamycin phosphate

2.5g vaginal suppositories), which are available without a prior authorization, must be provided.

Finally, the College of Pharmacy recommends the prior authorization of zolpidem 7.5mg capsules with placement into the Special PA tier of the Insomnia Medications PBPA category based on net cost (changes noted in red in the following PBPA Tier chart):

Insomnia Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
estazolam (ProSom®)	zolpidem CR (Ambien® CR)	lemborexant (Dayvigo®)	daridorexant (Quviviq™)
eszopiclone (Lunesta®)		suvorexant (Belsomra®)	doxepin (Silenor®)
flurazepam (Dalmane®)			quazepam (Doral®)
ramelteon (Rozerem®) – **Brand Preferred**			tasimelteon (Hetlioz®, Hetlioz LQ™)†
temazepam (Restoril®) 15mg and 30mg			temazepam (Restoril®) 7.5mg and 22.5mg
triazolam (Halcion®)			zolpidem 7.5mg capsule
zaleplon (Sonata®)			zolpidem SL tablets (Edluar®)
zolpidem (Ambien®)			zolpidem SL tablets (Intermezzo®)
			zolpidem oral spray (Zolpimist®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Medications in the Special PA Tier, including unique dosage formulations, require a special reason for use in place of lower-tiered medications.
†Individual criteria specific to tasimelteon applies.
CR = controlled release; PA = prior authorization; SL = sublingual

Utilization Details of Various Special Formulations: Calendar Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LEVOTHYROXINE PRODUCTS					
TIROSINT-SOL SOL 25MCG/ML	52	8	$6,908.16	$132.85	6.5
TIROSINT-SOL SOL 50MCG/ML	33	10	$4,624.01	$140.12	3.3
TIROSINT-SOL SOL 37.5MCG/ML	31	8	$4,140.66	$133.57	3.88
TIROSINT CAP 100MCG	29	7	$7,656.23	$264.01	4.14
TIROSINT-SOL SOL 62.5MCG/ML	28	8	$4,049.08	$144.61	3.5
TIROSINT CAP 25MCG	27	4	$4,908.16	$181.78	6.75
TIROSINT CAP 112MCG	25	6	$5,235.95	$209.44	4.17
TIROSINT CAP 75MCG	25	8	$5,988.13	$239.53	3.13

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TIROSINT CAP 150MCG	23	5	$3,298.67	$143.42	4.6
TIROSINT CAP 200MCG	22	5	$3,291.69	$149.62	4.4
TIROSINT-SOL SOL 13MCG/ML	22	4	$2,559.82	$116.36	5.5
TIROSINT-SOL SOL 88MCG/ML	20	3	$2,892.20	$144.61	6.67
TIROSINT CAP 50MCG	20	5	$3,513.97	$175.70	4
TIROSINT CAP 137MCG	18	4	$3,269.11	$181.62	4.5
TIROSINT CAP 125MCG	12	5	$3,974.03	$331.17	2.4
TIROSINT-SOL SOL 100MCG/ML	12	2	$1,703.32	$141.94	6
TIROSINT-SOL SOL 150MCG/ML	11	1	$3,956.31	$359.66	11
TIROSINT CAP 13MCG	10	2	$2,460.82	$246.08	5
TIROSINT CAP 175MCG	10	5	$2,163.67	$216.37	2
TIROSINT-SOL SOL 75MCG/ML	10	3	$1,446.10	$144.61	3.33
TIROSINT CAP 88MCG	9	3	$1,749.66	$194.41	3
LEVOTHYROXINE CAP 75MCG	8	2	$1,728.46	$216.06	4
LEVOTHYROXINE CAP 13MCG	8	2	$982.16	$122.77	4
LEVOTHYROXINE CAP 88MCG	8	3	$1,094.16	$136.77	2.67
TIROSINT-SOL SOL 112MCG	8	2	$1,156.88	$144.61	4
TIROSINT-SOL SOL 44MCG/ML	6	3	$867.66	$144.61	2
LEVOTHYROXINE CAP 200MCG	6	3	$1,392.98	$232.16	2
LEVOTHYROXINE CAP 100MCG	4	1	$1,271.16	$317.79	4
LEVOTHYROXINE CAP 150MCG	3	1	$1,167.97	$389.32	3
TIROSINT-SOL SOL 200MCG	3	2	$546.69	$182.23	1.5
TIROSINT-SOL SOL 125MCG	3	2	$427.33	$142.44	1.5
LEVOTHYROXINE CAP 112MCG	1	1	$387.99	$387.99	1
TIROSINT-SOL SOL 137MCG	1	1	$140.61	$140.61	1
THYQUIDITY SOL 100MCG	1	1	$226.91	$226.91	1
SUBTOTAL	**509**	**130**	**$91,180.71**	**$179.14**	**5.53**
MERCAPTOPURINE PRODUCTS					
PURIXAN SUS 20MG/ML	88	21	$128,271.37	$1,457.63	4.19
SUBTOTAL	**88**	**21**	**$128,271.37**	**$1,457.63**	**4.19**
METHOTREXATE PRODUCTS					
XATMEP SOL 2.5MG/ML	31	7	$17,068.18	$550.59	4.43
RASUVO INJ 25MG	9	3	$4,629.01	$514.33	3
RASUVO INJ 17.5MG	2	1	$1,056.82	$528.41	2
RASUVO INJ 15MG	2	1	$1,001.38	$500.69	2
SUBTOTAL	**44**	**12**	**$23,755.39**	**$539.90**	**4**
GABAPENTIN PRODUCTS					
HORIZANT TAB 600MG ER	31	5	$15,404.15	$496.91	6.2
GRALISE TAB 600MG	11	**1**	$3,259.84	$296.35	11
SUBTOTAL	**42**	**6**	**$18,663.99**	**$444.38**	**7**
DROSPIRENONE PRODUCTS					
SLYND TAB 4MG	25	8	$11,439.35	$457.57	3.13
SUBTOTAL	**25**	**8**	**$11,439.35**	**$457.57**	**3.13**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
POTASSIUM PRODUCTS					
POT CHLORIDE POW 20MEQ	23	5	$1,358.92	$59.08	4.6
SUBTOTAL	**23**	**5**	**$1,358.92**	**$59.08**	**4.6**
NORETHINDRONE ACE/ETHINYL ESTRADIOL/FE PRODUCTS					
GEMMILY CAP 1/20	7	1	$387.16	$55.31	7
SUBTOTAL	**7**	**1**	**$387.16**	**$55.31**	**7**
PREGABALIN PRODUCTS					
PREGABALIN ER TAB 165MG	6	2	$613.88	$102.31	3
SUBTOTAL	**6**	**2**	**$613.88**	**$102.31**	**3**
LACTULOSE PRODUCTS					
KRISTALOSE PAK 10GM	2	1	$506.02	$253.01	2
KRISTALOSE PAK 20GM	2	2	$1,026.08	$513.04	1
SUBTOTAL	**4**	**3**	**$1,532.10**	**$383.03**	**1.33**
DROSPIRENONE/ESTETROL PRODUCTS					
NEXTSTELLIS TAB 3/14.2MG	2	2	$386.18	$193.09	1
SUBTOTAL	**2**	**2**	**$386.18**	**$193.09**	**1**
ISOTRETINOIN PRODUCTS					
ABSORICA LD CAP 24MG	1	1	$2,413.63	$2,413.63	1
SUBTOTAL	**1**	**1**	**$2,413.63**	**$2,413.63**	**1**
METOCLOPRAMIDE PRODUCTS					
METOCLOPRAM TAB 5MG ODT	1	1	$535.01	$535.01	1
SUBTOTAL	**1**	**1**	**$535.01**	**$535.01**	**1**
LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE PRODUCTS					
PHEXXI GEL	1	1	$293.95	$293.95	1
SUBTOTAL	**1**	**1**	**$293.95**	**$293.95**	**1**
RANOLAZINE PRODUCTS					
ASPRUZYO SPR GRA 500MG	1	1	$314.74	$314.74	1
SUBTOTAL	**1**	**1**	**$314.74**	**$314.74**	**1**
TOTAL	**754**	**150***	**$281,146.38**	**$372.87**	**5.03**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACE = acetate; CAP = capsule; ER = extended release; FE = iron; GRA = granules; INJ = injection; METOCLOPRAM = metoclopramide; ODT = orally disintegrating tablet; PAK = packet; POT = potassium; POW = powder; SOL = solution; SPR = sprinkles; SUS = suspension; TAB = tablet

- There were no SoonerCare paid pharmacy claims for calendar year 2022 for the following various special formulation products: Gimoti® (metoclopramide nasal spray), GoNitro™ (nitroglycerin sublingual powder), Khapzory™ (levoleucovorin injection), Nuvessa® (metronidazole vaginal gel 1.3%), Otrexup® (methotrexate injection solution), pyridostigmine 30mg tablet, RediTrex® (methotrexate injection solution), Reltone® (ursodiol capsule), Soltamox® (tamoxifen citrate 10mg/5mL oral solution), and Vuity™ (pilocarpine hydrochloride ophthalmic solution 1.25%).

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Appendix S

30-Day Notice to Prior Authorize Joenja® (Leniolisib)

Oklahoma Health Care Authority
June 2023

Introduction[1,2,3]

Activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS) is an ultra-rare, genetic autosomal dominant primary immunodeficiency (PID). There are 2 types of APDS: APDS1 which is caused by pathogenic variants in the *PIK3CD* gene and APDS2 caused by variants in the *PIK3R1* gene. Both forms have similar symptoms and are inherited in the same autosomal dominant pattern. These genes encode the protein phosphoinositide-3 kinase delta (PI3Kd) which is needed for normal development and function of certain T cells and B cells. The variants in these genes cause the T cells and B cells not to function normally, leading to infections, inflammation, as well as autoimmune disease.

APDS affects each person differently and most will suffer from at least 2 or more symptoms. The first and most frequent signs are typically bacterial or viral infections that are difficult to treat and may never completely resolve. The most common are infections of the ear, sinuses, or respiratory tract. Patients may also develop enlarged lymph nodes, hepatomegaly or splenomegaly, inflammation of the intestine, and developmental delays. Development of autoimmune conditions is also possible and can affect many different organs. APDS patients are also at an increased risk of developing lymphoma and other blood cancers.

The exact prevalence of patients with APDS is unknown but it is thought to affect approximately 1-2 people per million, is not found to be more common in any one ethnic group, and affects males and females equally. The first signs usually begin in infancy or early childhood; however, symptoms can begin at any age with some patients not developing symptoms until adulthood.

A diagnosis of APDS is made based on the patient's symptoms, clinical examination, family history, and laboratory testing to identify abnormalities in the immune cells; however, genetic testing is necessary to confirm the diagnosis. APDS symptoms may be associated with a variety of different disorders, including other PIDs, and patients can often be misdiagnosed with common variable immune deficiency (CVID) or hyper-IgM (HIGM) syndrome.

Historically, treatment of APDS has been symptom-based and supportive including long-term immunoglobulin replacement, immunosuppressants, and daily antibiotics for infection prevention, with some patients progressing to hematopoietic stem cell transplantation (HSCT). In March 2023, the U.S.

Food and Drug Administration (FDA) approved Joenja® (leniolisib) for the treatment of APDS in adults and pediatric patients 12 years of age and older, making it the first therapy to be approved specifically for APDS.

Joenja® (Leniolisib) Product Summary[4]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of APDS in adult and pediatric patients 12 years of age and older weighing ≥45kg

How Supplied: 70mg oral tablets

Dosing and Administration:

- The recommended dosage is 70mg orally twice daily.
- Pregnancy status should be verified prior to initiating treatment in females of reproductive potential, as leniolisib may cause fetal harm.

Cost: The Wholesale Acquisition Cost (WAC) of Joenja® is $750 per tablet. This results in an estimated cost of $45,000 per month and $540,000 per year based on the recommended dose of 70mg twice daily.

Recommendations

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

Joenja® (Leniolisib) Approval Criteria:

1. An FDA approved diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS). Diagnosis must be confirmed by all of the following:
    a. Genetic testing identifying a documented pathogenic variant in either the *PIK3CD* or *PIK3R1* gene; and
    b. Nodal and/or extranodal lymphoproliferation; and
    c. Clinical findings compatible with APDS (i.e., history of repeated oto-sino-pulmonary infections and/or organ dysfunction); and
2. Member must be 12 years of age or older and weigh ≥45kg; and
3. Joenja® must be prescribed by, or in consultation with, an immunologist, geneticist, or a specialist with expertise in treatment of APDS; and
4. Female members of reproductive potential must not be breastfeeding, must have a negative pregnancy test prior to initiation, and must agree to use effective contraception during treatment and for 1 week after the final dose of Joenja®; and
5. Member must not have moderate to severe hepatic impairment (Child-Pugh class B or C); and

6. Member must not be taking any of the following medications concomitantly with Joenja®:
    a. Strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); and
    b. Strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone); and
    c. CYP1A2 metabolized drugs with a narrow therapeutic range (e.g., tizanidine, theophylline); and
    d. OATP1B1/3 substrates (e.g., statins, bosentan, glyburide, nateglinide, repaglinide, methotrexate, furosemide); and
    e. BCRP transporter substrates (e.g., sulfasalazine, ubrogepant, tenofovir); and
7. Initial approvals will be for the duration of 3 months. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
8. A quantity limit of 60 tablets per 30 days will apply.

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Appendix T

Calendar Year 2022 Annual Review of Ryplazim® (Plasminogen, Human-tvmh)

Oklahoma Health Care Authority
June 2023

Current Prior Authorization Criteria

Ryplazim® (Plasminogen, Human-tvmh) Approval Criteria:

1. An FDA approved diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia) as confirmed by at least 2 of the following:
   a. Genetic testing confirming biallelic mutations in the plasminogen (PLG) gene; or
   b. Plasminogen activity level ≤45%; or
   c. Documentation of clinical symptoms and lesions consistent with plasminogen deficiency type 1 (e.g., ligneous conjunctivitis, ligneous gingivitis or gingival overgrowth, vision abnormalities, respiratory distress and/or obstruction, abnormal wound healing); and
2. Ryplazim® must be prescribed by, or in consultation with, a hematologist, pulmonologist, ophthalmologist, geneticist, or other specialist with expertise in the treatment of plasminogen deficiency (or an advanced care practitioner with a supervising physician who is a hematologist, pulmonologist, ophthalmologist, geneticist, or other specialist with expertise in the treatment of plasminogen deficiency); and
3. Prescriber must verify that members at high risk for bleeding and/or confirmed or suspected airway disease will be monitored by a health care provider for 4 hours after receiving the first dose; and
4. Documented vaccination history to hepatitis A and B must be provided or provider must verify member has received the first vaccine dose and is scheduled to receive the second vaccine dose; 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 6 months, after which time the prescriber must document improvement in clinical symptoms, partial or complete lesion resolution, and increased plasminogen activity level; and
7. Subsequent approvals will be for the duration of 1 year and will require documentation from the prescriber that member has not developed new or recurrent lesions while on Ryplazim® and that adequate plasminogen activity trough levels are being maintained.

Utilization of Ryplazim® (Plasminogen, Human-tvmh): Calendar Year 2022

There was no SoonerCare utilization of Ryplazim® (plasminogen, human-tvmh) during calendar year 2021 or calendar year 2022.

Prior Authorization of Ryplazim® (Plasminogen, Human-tvmh)

There were no prior authorization requests submitted for Ryplazim® (plasminogen, human-tvmh) during calendar year 2022.

Recommendations

The College of Pharmacy does not recommend any changes to the current Ryplazim® (plasminogen, human-tvmh) prior authorization criteria at this time.

Appendix U

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: May 30, 2023

FDA Proposes New, Easy-to-Read Medication Guide for Patients, Patient Medication Information

Providing people with accurate and timely information to help them take their prescription medications safely and effectively is an important priority for the U.S. Food and Drug Administration. Evidence suggests that more easy-to-read information can help patients reduce preventable adverse drug reactions and improve health outcomes.

Currently, patients may receive one or more types of written information for prescription drugs and certain biological products, depending on the medication they are prescribed. Studies have found that the current system for written information for prescription drugs and certain biological products can be confusing, conflicting, incomplete, or repetitive.

When such critical information is difficult to understand, patients can become frustrated, stop taking their medications, or not take their medications as directed, which can be harmful to their health. Research suggests that medication nonadherence can contribute to nearly 25% of hospital admissions, 50% of treatment failures, and approximately 125,000 deaths in our country each year. While medication nonadherence is complex, inconsistency with the existing types of written information for prescription drugs and certain biological products can negatively impact public health, and the FDA is eager to fix it.

To address this problem, the FDA is proposing to require a new type of Medication Guide called Patient Medication Information for prescription drugs and certain biological products (both brand name and generic) used, dispensed, or administered on an outpatient basis, as well as for blood and blood components transfused in an outpatient setting.

Patient Medication Information would provide patients with clear, concise, accessible, and useful written information for prescription drugs and certain biological products and would be delivered in a consistent and easy-to-understand format to help patients use their prescription drug and certain biological products safely and effectively. Patient Medication Information's consistent formatting may help facilitate translations to other languages and make it easier for artificial intelligence or other technologies to convert the information, where feasible, to formats that assist the visually impaired.

These FDA-approved, 1-page documents would highlight the essential information patients need to know in a standardized format, including: drug/biological product name, concise summary of the indications and uses, important safety information, common side effects, directions for use.

Patient Medication Information would be given to patients with their prescription drugs and certain biological products when provided in an outpatient setting and also be available online for the public to access. In addition to the primary goal of more easily helping patients use medications safely and effectively, Patient Medication Information would also replace 2 types of FDA-approved written prescription drug patient information and certain biological product information that are currently required, which

would reduce duplicative information and be more cost-efficient for drug and certain biological product manufacturers.

The FDA also view this proposal as one way to fight our nation's crisis with health care misinformation and disinformation, which is a top priority for the agency. Having ready access to direct and easy to understand information in a consistent format for prescription drugs and certain biological products may reduce instances of both accidental and purposeful misinterpretations.

This proposed rule is a practical step towards improving the nation's health. Our public health mission is to ensure drugs and certain biological products are used safely and effectively, help people feel empowered and confident in their ability to manage their care, and prevent negative health outcomes.

The FDA encourage public comments for the Medication Guide: Patient Medication Information proposed rule during the public comment period. As always, the FDA will review and consider feedback as they develop the final rule.

FDA NEWS RELEASE

For Immediate Release: May 25, 2023

FDA Approves First Oral Antiviral for Treatment of COVID-19 in Adults

The FDA approved the oral antiviral Paxlovid™ (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. Paxlovid is the fourth drug—and first oral antiviral pill—approved by the FDA to treat COVID-19 in adults.

Paxlovid™ manufactured and packaged under the emergency use authorization (EUA) and distributed by the U.S. Department of Health and Human Services will continue to be available to ensure continued access for adults, as well as treatment of eligible children ages 12 to 18 years who are not covered by today's approval. Paxlovid™ is not approved or authorized for use as a pre-exposure or post-exposure prophylaxis for prevention of COVID-19.

Under the Federal Food, Drug, and Cosmetic Act, approval of a new drug requires, among other things, substantial evidence of effectiveness and a demonstration of safety for the drug's intended use(s). In considering approval of a drug, the FDA conducts a benefit-risk assessment based on rigorous scientific standards to ensure that the product's benefits outweigh its risks for the intended population.

The efficacy of Paxlovid™ was primarily supported by the final results of the EPIC-HR clinical trial. EPIC-HR was a randomized, double-blind, placebo-controlled clinical trial studying Paxlovid™ for the treatment of non-hospitalized symptomatic adults with a laboratory confirmed diagnosis of SARS-CoV-2 infection. Patients were adults 18 years of age and older with a prespecified risk factor for progression to severe disease or were 60 years and older regardless of prespecified chronic medical conditions. All patients had not received a COVID-19 vaccine and had not been previously infected with COVID-19. Paxlovid™ significantly reduced the proportion of people with COVID-19 related hospitalization or death from any cause through 28 days of follow-up by 86% compared to placebo among patients treated within five days of symptom onset and who did not receive COVID-19 therapeutic monoclonal antibody treatment. In this analysis, 977 patients received Paxlovid™, and 989 patients received placebo, and among these patients, 0.9% who received Paxlovid™ were hospitalized due to COVID-19 or died from any cause during 28 days of follow-up compared to 6.5% of the patients who received the placebo.

Benefit of Paxlovid™ was observed in patients with prior immunity to the virus that causes COVID-19. Among patients in EPIC-HR who were antibody positive at trial enrollment, the risk of COVID-19-related hospitalization or death from any cause during 28 days of follow-up was 0.2% among the 490 patients treated with Paxlovid™ compared with 1.7% of the 479 patients receiving placebo. EPIC-SR was another clinical trial that enrolled vaccinated patients with at least one risk factor for progression to severe COVID-19. Although not statistically significant, among these vaccinated patients, there was a reduction in the risk of COVID-19 related hospitalization or death from any cause.

EPIC-HR and EPIC-SR were randomized controlled trials and provide information about COVID-19 rebound. Data from these two trials showed that rebound in SARS-CoV-2 (RNA or virus) shedding or COVID-19 symptoms occurred in a subset of patients and happened in both the patients receiving Paxlovid™ and the placebo. Based on the data currently available to the FDA, there is not a clear association between Paxlovid™ treatment and COVID-19 rebound.

Because of the importance of reducing the risk of significant drug-drug interactions with Paxlovid™, the approved label and authorized Fact Sheet for Health Care Providers for the Paxlovid™ EUA come with a boxed warning with instructions for prescribers. Prescribers should review all medications taken by the patient to assess for potential drug-drug interactions and determine if other medicines that a patient may be taking require a dose adjustment, interruption and/or additional monitoring. Prescribers should consider the benefit of Paxlovid™ treatment in reducing hospitalization and death, and whether the risk of potential drug-drug interactions for an individual patient can be appropriately managed.

In conjunction with this approval, the FDA is providing all prescribers with important information for prescribing Paxlovid™ properly and safely, such as dosing instructions, potential side effects and information regarding drugs that may cause drug-drug interactions with Paxlovid™. The most common side effects of taking Paxlovid™ include impaired sense of taste and diarrhea. Patients should discuss with their health care provider whether Paxlovid™ is right for them.

FDA NEWS RELEASE

For Immediate Release: May 23, 2023

FDA Approves New Buprenorphine Treatment Option for Opioid Use Disorder

The FDA approved Brixadi™ (buprenorphine) extended-release injection for subcutaneous use to treat moderate to severe opioid use disorder (OUD). Brixadi™ is available in 2 formulations, a weekly injection that can be used in patients who have started treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine, and a monthly version for patients already being treated with buprenorphine.

Buprenorphine is a safe and effective medication for the treatment of OUD. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), patients receiving medication for their OUD cut their risk of death from all causes in half.

The FDA continues to implement a comprehensive approach to increase options to treat OUD. Earlier this month, the agency issued a joint letter with SAMHSA to clarify the importance of counseling and other services as part of a comprehensive treatment plan for OUD, and to also reiterate that supplying buprenorphine should not be made contingent upon participation in such services. The agency also held a virtual public workshop that highlighted the need for additional strengths and dosing regimens for extended-release formulations.

Brixadi™ is approved in both weekly and monthly subcutaneous injectable formulations at varying doses, including lower doses that may be appropriate for those who do not tolerate higher doses of extended-release buprenorphine that are currently available. The weekly doses are 8mg, 16mg, 24mg, and 32mg; and the monthly doses are 64mg, 96mg, and 128mg. The approved weekly formulation in various lower strengths offers a new option for people in recovery who may benefit from a weekly injection to maintain treatment adherence. Brixadi™ will be available through a Risk Evaluation and Mitigation Strategy (REMS) program and administered only by health care providers in a health care setting.

The most common adverse reactions (occurring in ≥5% of patients) with Brixadi™ include injection-site pain, headache, constipation, nausea, injection-site erythema, itchy skin at the injection site (injection-site pruritus), insomnia and urinary tract infections.

The safety and efficacy of Brixadi™ were evaluated in a behavioral pharmacology study assessing the ability of two weekly doses of Brixadi™ to block the subjective effects of opioids, and one randomized, double-blind, active-controlled clinical trial in 428 adults with a diagnosis of moderate-to-severe OUD. After an initial test dose of transmucosal buprenorphine, patients were randomized to treatment with Brixadi™ plus a sublingual placebo, or active sublingual buprenorphine plus placebo injections. After titration over the first week, patients were treated with weekly injections over 12 weeks and then transitioned to monthly injections for an additional 12 weeks. A response to treatment was measured by urine drug screening and self-reporting of illicit opioid use during the treatment period. Patients were considered responders if they had negative opioid assessments at the end of each of the two treatment phases. The proportion of patients meeting the responder definition was 16.9% in the Brixadi™ group and 14.0% in the sublingual buprenorphine group. The FDA granted approval of Brixadi™ to Braeburn Inc.

The agency remains focused on responding to all facets of substance use, misuse, substance use disorders, overdose and death in the U.S. through its FDA Overdose Prevention Framework. The framework's priorities include: supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing; encouraging harm reduction through innovation and education; advancing development of evidence-based treatments for substance use disorders; and protecting the public from unapproved, diverted or counterfeit drugs presenting overdose risks.

FDA NEWS RELEASE

For Immediate Release: May 23, 2023

FDA Approves New Treatment for Pneumonia Caused by Certain Difficult-to-Treat Bacteria

The FDA approved Xacduro® (sulbactam for injection; durlobactam for injection), a new treatment for hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) caused by susceptible strains of bacteria called *Acinetobacter baumannii-calcoaceticus* complex, for patients 18 years of age and older.

According to the World Health Organization, *Acinetobacter* species top the list of critical bacterial pathogens that pose the greatest threat to human health, highlighting the high level of need for additional treatment options amid growing global resistance to antimicrobial medicines.

Acinetobacter baumannii-calcoaceticus complex (henceforth referred to as *A. baumannii*) includes 4 species of bacteria in the *Acinetobacter* family. These bacteria can cause infections in various parts of the body, occurring most frequently in health care

settings and predominantly causing pneumonia. *A. baumannii* can become highly resistant to multiple antibacterial drugs and current treatment options for drug-resistant *A. baumannii* are limited.

Xacduro® consists of sulbactam, a drug structurally related to penicillin, and durlobactam. Sulbactam kills *A. baumannii* whereas durlobactam protects sulbactam from being degraded by enzymes that may be produced by *A. baumannii*. Xacduro® is administered by intravenous infusion.

Xacduro®'s efficacy was established in a multicenter, active-controlled, open-label, non-inferiority clinical trial in 177 hospitalized adults with pneumonia caused by carbapenem-resistant *A. baumannii*. Patients received either Xacduro® or colistin (a comparator antibiotic) for up to 14 days. Both treatment arms also received an additional antibiotic, imipenem/cilastatin, as background therapy for potential HABP/VABP pathogens other than *Acinetobacter baumannii-calcoaceticus* complex. The primary measure of efficacy was mortality from all causes within 28 days of treatment in patients with a confirmed infection with carbapenem-resistant *A. baumannii*. Of those who received Xacduro®, 19% (12 of 63 patients) died, compared to 32% (20 of 62 patients) who received colistin; this demonstrated that Xacduro® was noninferior to colistin. The most common adverse reaction with Xacduro® was liver function test abnormalities. Xacduro® comes with certain warnings and precautions, such as hypersensitivity reactions and *Clostridioides difficile*-associated diarrhea.

Patients should not receive Xacduro® if they have a history of known severe hypersensitivity to components of Xacduro®, sulbactam, or other beta-lactam antibacterial drugs. The FDA granted Xacduro® Fast Track, Qualified Infectious Disease Product, and Priority Review designations for this application. The FDA granted the approval of Xacduro® to Entasis Therapeutics.

FDA NEWS RELEASE

For Immediate Release: May 22, 2023

FDA Approves Prescription Nasal Spray to Reverse Opioid Overdose

The FDA approved Opvee®, the first nalmefene hydrochloride nasal spray for the emergency treatment of known or suspected opioid overdose in adults and pediatric patients 12 years of age and older. This is the first FDA approval of nalmefene hydrochloride nasal spray for health care and community use.

Drug overdose persists as a major public health issue in the United States, with more than 103,000 reported fatal overdoses occurring in the 12-month period ending in November 2022, primarily driven by synthetic opioids like illicit fentanyl.

Nalmefene is an opioid receptor antagonist which is used to treat acute opioid overdose. If nalmefene is administered quickly, it can reverse the effects of opioid overdose, including respiratory depression, sedation, and low blood pressure. The newly approved product, which delivers 2.7mg of nalmefene into the nasal cavity, is available by prescription and is intended for use in health care and community settings.

The approval of Opvee® was supported by safety and pharmacokinetic studies, as well as a study in people who use opioids recreationally to assess how quickly the drug works. The most common adverse reactions include nasal discomfort, headache, nausea, dizziness, hot flush, vomiting, anxiety, fatigue, nasal congestion and throat irritation, pain in the nose, decreased appetite, skin redness, and excessive sweating.

The use of nalmefene hydrochloride in patients who are opioid-dependent may result in opioid withdrawal characterized by the following signs and symptoms: body aches, diarrhea, fast heart rate, fever, runny nose, sneezing, goosebumps, sweating,

yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure.

The FDA granted this application Priority Review designation which expedites the development and review of drugs that have the potential to provide a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. The FDA granted approval of Opvee® to Opiant Pharmaceuticals Inc.

The FDA's Overdose Prevention Framework is the agency's vision to undertake impactful, creative actions to prevent drug overdoses and reduce deaths. The framework consists of 4 priorities, including encouraging harm reduction through efforts to increase availability and expand access of overdose reversal products.

FDA NEWS RELEASE

For Immediate Release: May 19, 2023

FDA Approves First Topical Gene Therapy for Treatment of Wounds in Patients with Dystrophic Epidermolysis Bullosa (DEB)

The FDA approved Vyjuvek™, a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy, for the treatment of wounds in patients 6 months of age and older with DEB with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene.

DEB is a genetic disorder that affects the connective tissue in the skin and nails and results from mutation(s) in the COL7A1 gene. This gene encodes type VII collagen (COL7), which is an essential protein that helps strengthen and stabilize the outer and middle layers of the skin. When COL7A1 is deficient, skin layers can separate, causing painful and debilitating blisters and wounds. DEB usually presents itself at birth and is divided into 2 major types depending on the inheritance pattern: recessive dystrophic epidermolysis bullosa (RDEB) and dominant dystrophic epidermolysis bullosa (DDEB).

Symptoms can vary widely among affected people. Individuals with DDEB typically have mild cases with blistering primarily affecting the hands, feet, knees, and elbows. RDEB cases can be painful and debilitating, often involving widespread blistering that can lead to vision loss, disfigurement, and other serious medical complications, which could be fatal.

Vyjuvek™ is a genetically modified HSV used to deliver normal copies of the COL7A1 gene to the wounds. COL7 molecules arrange themselves into long, thin bundles that form anchoring fibrils that hold the epidermis and dermis together, which is essential for maintaining the integrity of the skin. Vyjuvek™ has also been modified to eliminate its ability to replicate in normal cells. Vyjuvek™ is mixed into an excipient gel prior to topical application. A health care professional evenly applies Vyjuvek™ gel in droplets to a patient's wounds once a week.

The safety and effectiveness of Vyjuvek™ was established primarily in a randomized, double-blinded, placebo-controlled study involving a total of 31 subjects with DEB, including 30 subjects with RDEB and 1 subject with DDEB. In the study, 2 DEB wounds of comparable size on each patient were identified and randomized to receive either topical administration of Vyjuvek™ or the placebo on a weekly basis. The age of the subjects ranged from 1 year to 44 years (mean age 17 years). Efficacy was established by improved wound healing, defined as the difference in the proportion of confirmed complete (100%) wound closure between the Vyjuvek™-treated and the placebo-treated wounds at 24 weeks. Sixty-five percent of the Vyjuvek™-treated wounds completely closed while only 26% of the placebo-treated wound completely closed.

In addition, in a different clinical study, 2 young patients with RDEB (6 and 7 months of age, respectively) received topical Vyjuvek™ weekly without any new safety findings.

The most common adverse reactions associated with Vyjuvek™ included itching, chills, redness, rash, cough, and runny nose. Patients and caregivers should take the following precautions during treatment with Vyjuvek™: avoid direct contact with treated wounds and dressings of treated wounds for approximately 24 hours following Vyjuvek™ application. In the event of accidental exposure, patients and exposed individuals should clean the affected area, wash hands and wear protective gloves when changing wound dressings, disinfect bandages from the first dressing change following Vyjuvek™ treatment with a virucidal agent, such as 70% isopropyl alcohol, 6% hydrogen peroxide, or <0.4% ammonium chloride, and dispose of the disinfected bandages in a separate sealed plastic bag in household waste. Dispose of the subsequent used dressings and cleaning materials into a sealed plastic bag and dispose in household waste.

This application received Orphan Drug and Fast Track designations. Vyjuvek™ also received Regenerative Medicine Advanced Therapy and Priority Review designations and a Rare Pediatric Disease Priority Review Voucher. The FDA's rare pediatric disease priority review voucher program is intended to encourage development of new drugs and biologics to prevent and/or treat rare diseases in children. The approval of Vyjuvek™ was granted to Krystal Biotech, Inc.

FDA NEWS RELEASE

For Immediate Release: May 19, 2023

FDA Clears New Insulin Pump and Algorithm-Based Software to Support Enhanced Automatic Insulin Delivery

The FDA cleared the Beta Bionics iLet® ACE Pump and the iLet® Dosing Decision Software for people 6 years of age and older with type 1 diabetes mellitus (T1DM). These 2 devices, along with a compatible FDA-cleared integrated continuous glucose monitor (iCGM), will form a new system called the iLet® Bionic Pancreas. This new automated insulin dosing (AID) system uses an algorithm to determine and command insulin delivery.

More than 11% of Americans are diagnosed with diabetes, which impairs the body's ability to make or properly use the blood glucose-regulating hormone insulin. Because the pancreas does not make insulin in people with T1DM, they have to consistently monitor their glucose levels throughout the day and have insulin therapy through injection with a syringe, an insulin pen, or insulin pump to avoid becoming hyperglycemic. In addition, management of T1DM includes following a healthy eating plan and physical activity.

The iLet® Bionic Pancreas uses an adaptive closed-loop algorithm that is initialized only with a user's body weight and requires no additional insulin dosing parameters. This adaptive algorithm removes the need to manually adjust insulin pump therapy settings and variables as is needed with conventional pump therapy and is easier to initiate than other available AID systems. The iLet® device also simplifies use at mealtime by replacing conventional carb counting with a new meal announcement feature. With the new feature, users can estimate the amount of carbs in their meal as small, medium, or large and the algorithm learns over time to respond to users' individual insulin needs.

The human pancreas naturally supplies a low, continuous rate of insulin, known as basal or background insulin. In patients with T1DM, the body's ability to produce insulin is impaired. The iLet® Dosing Decision Software independently determines and commands

an increase, decrease, maintenance, or suspension of all basal insulin doses and determines and commands correction doses of insulin based on input from an iCGM. It also independently determines and commands meal doses of insulin based on meal announcements.

The FDA reviewed the iLet® ACE Pump and iLet® Dosing Decision Software through the 510(k) premarket clearance pathway. A 510(k) is a premarket submission made to the FDA to demonstrate that a new device is substantially equivalent to a legally marketed predicate device. The FDA granted clearance of the iLet® ACE Pump and iLet® Dosing Decision Software to Beta Bionics Inc.

FDA NEWS RELEASE

For Immediate Release: May 12, 2023

FDA Approves Novel Drug to Treat Moderate to Severe Hot Flashes Caused by Menopause

The FDA approved Veozah™ (fezolinetant), an oral medication for the treatment of moderate to severe vasomotor symptoms, or hot flashes, caused by menopause. Veozah™ is the first neurokinin 3 (NK3) receptor antagonist approved by the FDA to treat moderate to severe hot flashes from menopause. It works by binding to and blocking the activities of the NK3 receptor, which plays a role in the brain's regulation of body temperature.

Some women who experience hot flashes and have a history of vaginal bleeding, stroke, heart attack, blood clots or liver disease, cannot take hormone therapies. Veozah™ is not a hormone. It targets the neural activity which causes hot flashes during menopause.

Patients taking Veozah™ should take one 45mg pill orally, once a day, with or without food. The pill should be taken at the same time each day. If a dose is missed, or not taken at the regular time, patients should take it as soon as possible and return to their regular schedule the following day.

The effectiveness of Veozah™ to treat moderate to severe hot flashes was demonstrated in each of the first 12-week, randomized, placebo-controlled, double-blind portions of 2 Phase 3 clinical trials. In both trials, after the first 12 weeks, the women on placebo were then re-randomized to Veozah™ for a 40-week extension study to evaluate safety. Each trial ran a total of 52 weeks. The average age of the trial participants was 54 years old.

The *Prescribing Information* for Veozah™ includes a warning for elevated hepatic transaminase, or liver injury. Before using Veozah™, patients should have blood work done to test for liver damage. While on Veozah™, routine bloodwork should be performed every 3 months for the first 9 months of using the medication. Patients experiencing symptoms related to liver damage, such as nausea, vomiting, or yellowing of the skin and eyes, should contact a physician. Veozah™ cannot be used with CYP1A2 inhibitors. Patients with known cirrhosis, severe renal damage, or end-stage renal disease should not take Veozah™. The most common side effects of Veozah™ include abdominal pain, diarrhea, insomnia, back pain, hot flush, and elevated hepatic transaminases.

The FDA granted the Veozah™ application Priority Review designation. The approval of Veozah™ was granted to Astellas Pharma US, Inc.

FDA NEWS RELEASE

For Immediate Release: May 3, 2023

FDA Approves First Respiratory Syncytial Virus (RSV) Vaccine

The FDA approved Arexvy, the first RSV vaccine approved for use in the United States. Arexvy is approved for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 60 years of age and older.

RSV is a highly contagious virus that causes infections of the lungs and breathing passages in individuals of all age groups. RSV circulation is seasonal, typically starting during the fall and peaking in the winter. In older adults, RSV is a common cause of LRTD, which affects the lungs and can cause life-threatening pneumonia and bronchiolitis.

According to the U.S. Centers for Disease Control and Prevention (CDC), each year in the United States, RSV leads to approximately 60,000-120,000 hospitalizations and 6,000-10,000 deaths among adults 65 years of age and older.

The safety and effectiveness of Arexvy is based on the FDA's analysis of data from an ongoing, randomized, placebo-controlled clinical study conducted in the United States and internationally in individuals 60 years of age and older. The main clinical study of Arexvy was designed to assess the safety and effectiveness of a single dose administered to individuals 60 years of age and older. Participants will remain in the study through 3 RSV seasons to assess the duration of effectiveness and the safety and effectiveness of repeat vaccination. Data for a single dose of Arexvy from the first RSV season of the study were available for the FDA's analysis.

In this study, approximately 12,500 participants have received Arexvy and 12,500 participants have received a placebo. Among the participants who have received Arexvy and the participants who have received a placebo, the vaccine significantly reduced the risk of developing RSV-associated LRTD by 82.6% and reduced the risk of developing severe RSV-associated LRTD by 94.1%.

Among a subset of these clinical trial participants, the most commonly reported side effects by individuals who received Arexvy were injection site pain, fatigue, muscle pain, headache, and joint stiffness/pain. Among all clinical trial participants, atrial fibrillation within 30 days of vaccination was reported in 10 participants who received Arexvy and 4 participants who received placebo.

In 2 other studies, approximately 2,500 participants 60 years of age and older received Arexvy. In 1 of these studies, in which some participants received Arexvy concomitantly with an FDA-approved influenza vaccine, 2 participants developed acute disseminated encephalomyelitis (ADEM), a rare type of inflammation that affects the brain and spinal cord, 7 and 22 days, respectively, after receiving Arexvy and the influenza vaccine. One of the participants who developed ADEM died. In the other study, 1 participant developed Guillain-Barré syndrome 9 days after receiving Arexvy.

The FDA is requiring the company to conduct a post marketing study to assess the signals of serious risks for Guillain-Barré syndrome and ADEM. In addition, although not an FDA requirement, the company has committed to assess atrial fibrillation in the postmarketing study.

FDA NEWS RELEASE

For Immediate Release: April 26, 2023

FDA Approves First Orally Administered Fecal Microbiota Product for the Prevention of Recurrence of *Clostridioides difficile* Infection

The FDA approved Vowst™, the first fecal microbiota product that is taken orally. Vowst™ is approved for the prevention of recurrence of *Clostridioides difficile* (*C. difficile*)

infection (CDI) in individuals 18 years of age and older, following antibacterial treatment for recurrent CDI. The risk of additional recurrences increases with each infection and treatment options for recurrent CDI are limited. The administration of fecal microbiota is thought to facilitate restoration of the gut flora to prevent further episodes of CDI.

The dosing regimen of Vowst™ is 4 capsules taken once a day, orally, for 3 consecutive days. Vowst™ contains live bacteria and is manufactured from human fecal matter that has been donated by qualified individuals. Although the donors and donated stool are tested for a panel of transmissible pathogens, Vowst™ may carry a risk of transmitting infectious agents. It is also possible for Vowst™ to contain food allergens; the potential for Vowst™ to cause adverse reactions due to food allergens is unknown.

The safety of Vowst™ was evaluated in a randomized, double-blind, placebo-controlled, clinical study and an open-label clinical study conducted in the United States and Canada. The participants had recurrent CDI, were 48 to 96 hours post-antibacterial treatment and their symptoms were controlled. Across both studies, 346 individuals 18 years of age and older with recurrent CDI received all scheduled doses of Vowst™. In an analysis among 90 Vowst™ recipients, when compared to 92 placebo recipients, the most commonly reported side effects by Vowst™ recipients, which occurred at a greater frequency than reported by placebo recipients, were abdominal bloating, fatigue, constipation, chills, and diarrhea.

The effectiveness of Vowst™ was evaluated in the randomized, placebo-controlled clinical study in which 89 participants received Vowst™ and 93 participants received placebo. Through 8 weeks after treatment, CDI recurrence in Vowst™-treated participants was lower compared to placebo-treated participants (12.4% compared to 39.8%).

The application was granted Priority Review, Breakthrough Therapy, and Orphan Drug designations. The FDA granted approval of Vowst™ to Seres Therapeutics Inc.

FDA NEWS RELEASE

For Immediate Release: April 18, 2023

FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines

The FDA amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent mRNA vaccines to simplify the vaccination schedule for most individuals. This action includes authorizing the current bivalent vaccines (original and omicron BA.4/BA.5 strains) to be used for all doses administered to individuals 6 months of age and older, including for an additional dose or doses for certain populations. The monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.

Available data show that almost all of the United States population 5 years of age and older now have antibodies as a result of either vaccination or infection against SARS-CoV-2. The use of bivalent COVID-19 vaccines for all doses administered to individuals 6 months of age and older is supported by the data described below, as well as post-marketing data, including real-world data, with the monovalent and bivalent mRNA COVID-19 vaccines, which have been administered to millions of people, including young children. A second bivalent dose for individuals 65 years of age and older is supported by data showing the waning of immunity in this population over time and its restoration by an additional dose. Additionally, based on evidence from studies conducted previously, immunocompromised individuals may require additional doses.

Moderna COVID-19 Vaccine, Bivalent

The safety and effectiveness of Moderna COVID-19 Vaccine, Bivalent is based on FDA's previous analyses of clinical trials data of monovalent Moderna COVID-19 Vaccine in individuals 6 months of age and older and an investigational bivalent Moderna COVID-19 vaccine (original and omicron BA.1) in individuals 18 years of age and older.

In addition, effectiveness of a single dose is supported by the FDA's analysis of immune response data from clinical studies in which 145 individuals 6 years of age and older who had evidence of prior SARS-CoV-2 infection and 1,376 individuals 6 years of age and older without evidence of prior SARS-CoV-2 infection had received 2 doses of monovalent Moderna COVID-19 Vaccine. The immune response after 1 dose of vaccine among participants with evidence of prior infection was comparable to the immune response after 2 doses among participants without evidence of prior infection.

The data accrued with the investigational bivalent Moderna COVID-19 vaccine (original and omicron BA.1) and with the monovalent Moderna COVID-19 Vaccine are relevant to the Moderna COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent

The safety and effectiveness of Pfizer-BioNTech COVID-19 Vaccine, Bivalent is based on the FDA's previous analyses of clinical trials data of monovalent Pfizer-BioNTech COVID-19 Vaccine for use in individuals 6 months of age and older, an investigational bivalent Pfizer-BioNTech COVID-19 vaccine (original and omicron BA.1) in individuals older than 55 years of age, as well as safety data with Pfizer-BioNTech COVID-19 Vaccine, Bivalent (original and omicron BA.4/BA.5) in individuals 6 months of age and older and immune response data in individuals 6 months through 4 years of age.

In addition, effectiveness of a single dose is supported by observational data from England on the effectiveness of 1 dose of monovalent Pfizer-BioNTech COVID-19 Vaccine. Among individuals 12 to 17 years of age who had received only 1 dose of Pfizer-BioNTech COVID-19 Vaccine, those who had evidence of previous infection with alpha, delta, or omicron variants had increased protection against symptomatic omicron infection compared with those with no evidence of previous infection.

The data accrued with the investigational Pfizer-BioNTech bivalent COVID-19 vaccine (original and omicron BA.1) and with the monovalent Pfizer-BioNTech COVID-19 Vaccine are relevant to the Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

The fact sheets have been updated and consolidated for the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Each vaccine now has 1 fact sheet for health care providers and 1 fact sheet for recipients and caregivers, rather than different fact sheets for the various authorized age groups.

Vaccines and Related Biological Products Advisory Committee

The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommended harmonizing the strain composition of COVID-19 vaccines used in the United States. There was also support for simplifying the vaccine dosing schedule.

In June, the FDA will hold a meeting of its VRBPAC to discuss the strain composition of the COVID-19 vaccines for fall of 2023. Much like the FDA does yearly with the influenza vaccines, the FDA will seek input from the committee on which SARS-CoV-2 variants and lineages are most likely to circulate in the upcoming year. Once the specific strains are selected for the COVID-19 vaccines, the FDA expects manufacturers to make updated formulations of the vaccines for availability this fall.

The amendments to the EUAs were issued to ModernaTX Inc. and Pfizer Inc.

FDA NEWS RELEASE

For Immediate Release: April 17, 2023

FDA Approves Cell Therapy for Patients with Blood Cancers to Reduce Risk of Infection Following Stem Cell Transplantation

The FDA approved Omisirge® (omidubicel-onlv), a substantially modified allogeneic cord blood-based cell therapy to quicken the recovery of neutrophils in the body and reduce the risk of infection. The product is intended for use in adults and pediatric patients 12 years of age and older with blood cancers planned for umbilical cord blood transplantation following a myeloablative conditioning regimen.

Stem cell transplantation is a common treatment for blood cancers. It involves putting healthy stem cells into the body to help restore the normal production and function of blood cells. One source of healthy stem cells is umbilical cord blood. Generally, before receiving this kind of transplant, the patient will undergo a course of treatments to remove their own stem cells and prepare the body for the new stem cells. This process may include undergoing therapies such as radiation or chemotherapy, both of which may weaken an individual's immune system. As a result, a frequent and serious risk of this treatment is the occurrence of severe and sometimes deadly infections.

Omisirge®, administered as a single intravenous (IV) dose, is composed of human allogeneic stem cells from umbilical cord blood that are processed and cultured with nicotinamide. Each dose is patient-specific, containing healthy stem cells from an allogeneic pre-screened donor.

The safety and effectiveness of Omisirge® was supported by a randomized, multicenter study comparing transplantation of Omisirge® to transplantation of umbilical cord blood, in subjects between 12 and 65 years of age. The study enrolled a total of 125 subjects. All subjects in the study had confirmed blood cancers. The efficacy of Omisirge® was based on the amount of time needed for recovery of the subject's neutrophils and the incidence of infections following transplantation.

Eighty-seven percent of subjects who were randomized to receive Omisirge® achieved neutrophil recovery with a median of 12 days following treatment with the product, compared to 83% of subjects who were randomized to receive umbilical cord blood transplantation and who achieved neutrophil recovery with a median of 22 days. Bacterial or fungal infections by 100 days following transplantation were seen in 39% of subjects receiving Omisirge® versus 60% of subjects in the control group who received umbilical cord blood.

Treatment with Omisirge® has the potential to cause severe side effects, which must be considered in assessing the risks and benefits of using this product. Similar to all approved umbilical cord products, the label carries a *Boxed Warning* for infusion reactions, graft versus host disease (GvHD), engraftment syndrome, and graft failure.

The most common adverse reactions associated with Omisirge® included infections, GvHD, and infusion reactions. Patients who receive Omisirge® should be monitored for signs and symptoms of infusion reactions, GvHD, engraftment syndrome, graft failure, transmission of serious infections or rare genetic diseases from the donor cells, as well as life-long for secondary malignancies.

This application received Priority Review, Breakthrough Therapy, and Orphan Drug designations. The FDA granted regular approval of Omisirge® to Gamida Cell Ltd.

FDA NEWS RELEASE

For Immediate Release: April 6, 2023

FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena®

The FDA announced the final decision to withdraw approval of Makena® – a drug that had been approved under the accelerated approval pathway. This drug was approved to reduce the risk of preterm birth in women pregnant with 1 baby who have a history of spontaneous preterm birth. The decision was issued jointly by the FDA Commissioner and Chief Scientist. As of April 6th 2023, Makena® and its generics are no longer approved and cannot lawfully be distributed in interstate commerce.

The FDA approved Makena® under the accelerated approval pathway in 2011 based on a determination that the sponsor had demonstrated a drug effect on an intermediate clinical endpoint that was reasonably likely to predict clinical benefit. The agency's approval included a requirement that the sponsor conduct a post marketing confirmatory study. The ensuing confirmatory study did not verify clinical benefit and the FDA's Center for Drug Evaluation and Research (CDER) proposed withdrawing the drug's approval in 2020. The sponsor requested a hearing, which was held in October 2022.

Following the hearing, the FDA Commissioner and Chief Scientist reviewed the record for this matter, including the submissions by CDER and sponsor Covis Pharma, public comments to the docket, the transcript of the hearing, and the Presiding Officer's report. Based on that review, they have decided to withdraw approval of Makena® and generic versions of Makena®.

The decision issued by the FDA Commissioner and Chief Scientist outlines their rationale and also recognizes the crucial need to develop treatments to reduce the serious risks associated with preterm birth.

While the approvals of Makena® and its generics have been withdrawn, the FDA recognizes that there is a supply of product that has already been distributed. Patients who have questions should talk to their health care provider. Approvals of these drugs have been withdrawn because the drugs are no longer shown to be effective, and the benefits do not outweigh the risks for the indication for which they were approved.

Current Drug Shortages Index (as of May 31, 2023):

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.

0.9% Sodium Chloride Irrigation	***Currently in Shortage***
Albuterol Sulfate Inhalation Solution, 0.5%	***Currently in Shortage***
Alprostadil (Muse) Suppository	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acids	***Currently in Shortage***
Amoxapine Tablets	***Currently in Shortage***
Amoxicillin Oral Powder for Suspension	***Currently in Shortage***
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine for Injection	***Currently in Shortage***
Azithromycin (Azasite) Ophthalmic Solution 1%	***Currently in Shortage***
Bacteriostatic 0.9% Sodium Chloride Injection	***Currently in Shortage***
Bacteriostatic Water for Injection	***Currently in Shortage***
Belatacept (Nulojix) Lyophilized Powder for Injection	***Currently in Shortage***
Belladonna and Opium Suppositories	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride and Epinephrine Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Capecitabine Tablets	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefixime Oral Capsules	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloramphenicol Sodium Succinate Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Chlorothiazide Oral Suspension	***Currently in Shortage***
Cisplatin Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablets	***Currently in Shortage***
Collagenase Ointment	***Currently in Shortage***
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container	***Currently in Shortage***
Conjugated Estrogens/Bazedoxifene (Duavee) Tablet, Film Coated	***Currently in Shortage***
Cyclopentolate Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***
Desmopressin Acetate Nasal Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Injection	***Currently in Shortage***
Dextrose 10% Injection	***Currently in Shortage***
Dextrose 25% Injection	***Currently in Shortage***

Dextrose 5% Injection	***Currently in Shortage***
Dextrose 50% Injection	***Currently in Shortage***
Diazepam Rectal Gel	***Currently in Shortage***
Diflunisal Tablets	***Currently in Shortage***
Difluprednate Ophthalmic Emulsion	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Dimercaprol (Bal in Oil) Injection	***Currently in Shortage***
Disopyramide Phosphate (Norpace) Capsules	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide (Trulicity) Injection	***Currently in Shortage***
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution	***Currently in Shortage***
Edetate Calcium Disodium Injection	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Injection, 0.1 mg/mL	***Currently in Shortage***
Erythromycin Ophthalmic Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Fluorescein Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsules	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Guanfacine Hydrochloride Tablets	***Currently in Shortage***
Heparin Sodium and Sodium Chloride 0.9% Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert	***Currently in Shortage***
Ibutilide Fumarate Injection	***Currently in Shortage***
Indigotindisulfonate Sodium Injection	***Currently in Shortage***
Isoniazid Injection	***Currently in Shortage***
Isoniazid Tablets	***Currently in Shortage***
IV Fat Emulsion	***Currently in Shortage***
Ketamine Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Viscous) Oral Topical Solution	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto) Injection	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***
Mepivacaine Hydrochloride Injection	***Currently in Shortage***
Methamphetamine Hydrochloride Tablets	***Currently in Shortage***
Methotrexate Injection	***Currently in Shortage***
Methyldopa Tablets	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***

Midazolam Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Neomycin Sulfate Tablets	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Oxybutynin Chloride Syrup	***Currently in Shortage***
Oxytocin Injection	***Currently in Shortage***
Palifermin (Kepivance) Lyophilized Powder for Injection	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Parathyroid Hormone (Natpara) Injection	***Currently in Shortage***
Penicillin G Benzathine Injectable Suspension	***Currently in Shortage***
Physostigmine Salicylate Injection	***Currently in Shortage***
Potassium Acetate Injection	***Currently in Shortage***
Potassium Chloride Concentrate Injection	***Currently in Shortage***
Quinapril and Hydrochlorothiazide Tablets	***Currently in Shortage***
Quinapril Hydrochloride Tablets	***Currently in Shortage***
Remifentanil Injection	***Currently in Shortage***
Rifampin Capsules	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablets	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Semaglutide (Ozempic) Injection	***Currently in Shortage***
Semaglutide (Wegovy) Injection	***Currently in Shortage***
Sincalide (Kinevac) Lyophilized Powder for Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection Bags	***Currently in Shortage***
Sodium Chloride 14.6% Injection	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection, 0.9% Vials and Syringes	***Currently in Shortage***
Sodium Phosphates Injection	***Currently in Shortage***
Somatropin Injection	***Currently in Shortage***
Sterile Water for Injection	***Currently in Shortage***
Sterile Water for Irrigation	***Currently in Shortage***
Streptozocin (Zanosar) Sterile Powder	***Currently in Shortage***
Sucralfate Tablets	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Sulfasalazine Tablets	***Currently in Shortage***
Technetium TC-99M Mebrofenin Injection	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injectable Suspension	***Currently in Shortage***
Triamcinolone Hexacetonide Injectable suspension	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsules	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***