OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
June 8, 2022
4:00pm

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

Viewing Access Only:
Please register for the webinar at:
https://zoom.us/webinar/register/WN_73z8ERX7Sv-KeQGP3GVqPg
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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 8, 2022

DATE: June 1, 2022

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/SoonerPsych Program Update – Appendix B

Action Item – Approval of May 2022 DUR Board Recommendations – Appendix C

Action Item – Vote to Prior Authorize Ryaltris® (Mometasone/ Olopatadine Nasal Spray) and Update the Approval Criteria for the Nasal Allergy Medications – Appendix D

Action Item – Vote to Prior Authorize Nexviazyme® (Avalglucosidase Alfa-ngpt) – Appendix E

Action Item – Vote to Prior Authorize Kerendia® (Finerenone), Rezvoglar™ (Insulin Glargine-aglr), and Semglee® (Insulin Glargine-yfgn) and Update the Approval Criteria for the Anti-Diabetic Medications – Appendix F

Action Item – Vote to Prior Authorize Exkivity® (Mobocertinib), Lumakras™ (Sotorasib), and Rybrevant™ (Amivantamab-vmjw) and Update the Approval Criteria for the Lung Cancer Medications – Appendix G

Annual Review of Genitourinary and Cervical/Endometrial Cancer Medications and 30-Day Notice to Prior Authorize Camcevi™ (Leuprolide), Pluvicto™ (Lutetium Lu 177 Vipivotide Tetraxetan), Tivdak® (Tisotumab Vedotin-tftv), and Welireg™ (Belzutifan) – Appendix H

Annual Review of the SoonerCare Pharmacy Benefit – Appendix I

Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Xelstrym™ (Dextroamphetamine Transdermal System) – Appendix J

Annual Review of Antiviral Medications and 30-Day Notice to Prior Authorize Livtencity™ (Maribavir) – Appendix K

Annual Review of Insomnia Medications and 30-Day Notice to Prior Authorize Quviviq™ (Daridorexant) – Appendix L

Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Invega Hafyera™ (Paliperidone Palmitate) – Appendix M

30-Day Notice to Prior Authorize Ryplazim® (Plasminogen, Human-tvmh) – Appendix N

Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Citalopram Capsule, Dartisla ODT™ (Glycopyrrolate Orally Disintegrating Tablet), Fleqsuvy™ (Baclofen Oral Suspension), Lofena™ (Diclofenac Potassium Tablet), Loreev XR™ (Lorazepam Extended-Release Capsule), Norliqva® (Amlodipine Besylate Oral Solution), Seglentis® (Celecoxib/Tramadol Tablet), Sutab® (Sodium Sulfate/Magnesium Sulfate/Potassium Chloride Tablet), Tarpeyo™ (Budesonide Delayed-Release Capsule), Vuity™ (Pilocarpine 1.25%

Ophthalmic Solution), and Xipere™ (Triamcinolone Acetonide Injection) – Appendix O

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – June 8, 2022 @ 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. Stephen Anderson –	participating in person
Dr. Jennifer de los Angeles –	participating in person
Ms. Jennifer Boyett –	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

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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 13, 2022 DUR Board Meeting Minutes
   B. April 13, 2022 DUR Board Recommendations Memorandum
   C. May 11, 2022 DUR Board Meeting Minutes
   D. May 11, 2022 DUR Board Recommendations Memorandum
   E. Correspondence

Items to be presented by Dr. Chandler, Dr. Travers, Dr. Muchmore, Chairman:

4. **Update on Medication Coverage Authorization Unit/SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update – See Appendix B**
   A. Pharmacy Helpdesk Activity for May 2022
   B. Medication Coverage Activity for May 2022
   C. SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update

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

5. **Action Item – Approval of May 2022 DUR Board Recommendations – See Appendix C**
   A. Vote to Prior Authorize Releuko™ (Filgrastim-ayow) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs)
      i. Market News and Updates

ii. Cost Comparison for Filgrastim Products
iii. College of Pharmacy Recommendations

B. Vote to Prior Authorize Lampit® (Nifurtimox)
i. Market News and Updates
ii. Lampit® (Nifurtimox) Product Summary
iii. College of Pharmacy Recommendations

C. Vote to Prior Authorize Skytrofa® (Lonapegsomatropin-tcgd) and Voxzogo™ (Vosoritide) and Update the Approval Criteria for the Growth Hormone Products
i. Market News and Updates
ii. Product Summaries
iii. College of Pharmacy Recommendations

D. Vote to Prior Authorize Ponvory® (Ponesimod) and Update the Approval Criteria for the Multiple Sclerosis Medications
i. Market News and Updates
ii. Ponvory® (Ponesimod) Product Summary
iii. College of Pharmacy Recommendations

E. Vote to Prior Authorize Brexafemme® (Ibrexafungerp) and Update the Approval Criteria for the Systemic Antifungal Medications
i. Market News and Updates
ii. Brexafemme® (Ibrexafungerp) Product Summary
iii. College of Pharmacy Recommendations

F. Vote to Prior Authorize Zynlonta™ (Loncastuximab Tesirine) and Update the Approval Criteria for the Lymphoma Medications
i. Market News and Updates
ii. Zynlonta™ (Loncastuximab Tesirine) Product Summary
iii. College of Pharmacy Recommendations

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

6. **Action Item – Vote to Prior Authorize Ryaltris™ (Mometasone/Olopatadine Nasal Spray) and Update the Approval Criteria for the Nasal Allergy Medications – See Appendix D**

A. Market News and Updates
B. Ryaltris™ (Mometasone/Olopatadine) Product Summary
C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Nexviazyme® (Avalglucosidase Alfa-ngpt) – See Appendix E**

A. Market News and Updates
B. Nexviazyme® (Avalglucosidase Alfa-ngpt) Product Summary
C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Kerendia® (Finerenone), Rezvoglar™ (Insulin Glargine-aglr), and Semglee® (Insulin Glargine-yfgn) and Update the Approval Criteria for the Anti-Diabetic Medications – See Appendix F**
   A. Market News and Updates
   B. Kerendia® (Finerenone) Product Summary
   C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Exkivity® (Mobocertinib), Lumakras™ (Sotorasib), and Rybrevant™ (Amivantamab-vmjw) and Update the Approval Criteria for the Lung Cancer Medications – See Appendix G**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

10. **Annual Review of Genitourinary and Cervical/Endometrial Cancer Medications and 30-Day Notice to Prior Authorize Camcevi™ (Leuprolide), Pluvicto® (Lutetium Lu 177 Vipivotide Tetraxetan), Tivdak® (Tisotumab Vedotin-tfty) and Welireg™ (Belzutifan) – See Appendix H**
    A. Introduction
    B. Current Prior Authorization Criteria
    C. Utilization of Genitourinary and Cervical/Endometrial Cancer Medications
    D. Prior Authorization of Genitourinary and Cervical/Endometrial Cancer Medications
    E. Market News and Updates
    F. Product Summaries
    G. College of Pharmacy Recommendations
    H. Utilization Details of Genitourinary and Cervical/Endometrial Cancer Medications

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

11. **Annual Review of the SoonerCare Pharmacy Benefit – See Appendix I**
    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: Calendar Year 2021
    G. Top 10 Specialty Therapeutic Classes by Reimbursement: Calendar Year 2021
    H. Top 10 Medications by Reimbursement: Calendar Year 2021
    I. Cost Per Claim
    J. Market Projections
    K. Conclusion

L. Top 50 Reimbursed Drugs by Calendar Year
M. Top 50 Medications by Total Number of Claims: Calendar Year 2021
N. Top 10 Traditional and Specialty Therapeutic Categories by Calendar Year
O. Calendar Year Age Group Comparison

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

12. Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Xelstrym™ (Dextroamphetamine Transdermal System) – See Appendix J

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. College of Pharmacy Recommendations
G. Utilization Details of ADHD and Narcolepsy Medications

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

13. Annual Review of Antiviral Medications and 30-Day Notice to Prior Authorize Livtencity™ (Maribavir) – See Appendix K

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

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

14. Annual Review of Insomnia Medications and 30-Day Notice to Prior Authorize Quviviq™ (Daridorexant) – See Appendix L

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

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

15. Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Invega Hafyera™ (Paliperidone Palmitate Injection) – See Appendix M

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. Invega Hafyera™ (Paliperidone Palmitate Injection) Product Summary
G. College of Pharmacy Recommendations
H. Utilization Details of Atypical Antipsychotic Medications

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

16. 30-Day Notice to Prior Authorize Ryplazim® (Plasminogen, Human-tvmh) – See Appendix N

A. Introduction
B. Ryplazim® (Plasminogen, Human-tvmh) Product Summary
C. College of Pharmacy Recommendations

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

17. Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Citalopram Capsule, Dartisla ODT™ (Glycopyrrolate Orally Disintegrating Tablet), Fleqsuvy™ (Baclofen Oral Suspension), Lofena™ (Diclofenac Potassium Tablet), Loreev XR™ (Lorazepam Extended-Release Capsule), Norliqva® (Amlodipine Besylate Oral Solution), Seglentis® (Celecoxib/Tramadol Tablet), Sutab® (Sodium Sulfate/Magnesium Sulfate/Potassium Chloride Tablet), Tarpeyo™ (Budesonide Delayed-Release Capsule), Vuity™ (Pilocarpine 1.25% Ophthalmic Solution), and Xipere™ (Triamcinolone Acetonide Injections) – See Appendix O

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

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

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

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

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

A. Alzheimer's Disease Medications
B. Colorectal Cancer Medications
C. Testosterone Products
D. Various Systemic Antibiotics

*Future product and class reviews subject to change.

20. 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 13, 2022

DUR BOARD MEMBERS:	PRESENT	ABSENT
Stephen Anderson, Pharm.D.	X	
Jennifer de los Angeles, Pharm.D., BCOP		X
Jennifer Boyett, 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	

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Wendi Chandler, Pharm.D.; Clinical Pharmacist	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Thomas Ha, Pharm.D.; Clinical Pharmacist	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Morgan Masterson, Pharm.D; Clinical Pharmacist		X
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor	X	
Regan Smith, 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: Allison Baxley, Pharm.D., BCOP		X
Emily Borders, Pharm.D., BCOP	X	
Sarah Schmidt, Pharm.D., BCPS, BCOP		X
Graduate Students: Matthew Dickson, Pharm.D.	X	
Michael Nguyen, Pharm.D.	X	
Corby Thompson, Pharm.D.	X	
Laura Tidmore, Pharm.D.	X	
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Melody Anthony; Chief Operating Officer		X
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	

Debra Montgomery, D.O.; Medical Director	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	
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:	
Joe Garcia, AbbVie	Rick Dabner, Alnylam
Gia McLean, Amgen	Nima Nabavi, Amgen
Christopher Dobberpuhl, Ascendis	Tracey Maravilla, Ascendis
Lori Howarth, Bayer	Robert Greely, Biogen
Bryan Steffan, Boehringer-Ingelheim	Emma Selm-Keck, DK Pierce
Vicki Mee, Eversana	Kendal Lopez, Genentech
Rodney Brown, Genentech	Jennifer Davis, Gilead
Heather Higgins, Jazz	Marc Bagby, Lilly
Brandon Ross, Merck	Brent Parker, Merck
Evie Knisely, Novartis	Sarah Sanders, Novartis
Jessica Chardoulias, Novo Nordisk	Gina Heinen, Novo Nordisk
David Prather, Novo Nordisk	John Ford, NS Pharma
Mark Kaiser, Otsuka	Chrystal Mayes, Sanofi
Eric Berthelot, Sobi	Jeff Knappen, Spark Therapeutics
Aaron Austin, Takeda	Annie Huang, Takeda
Raquel Jordan, Takeda	Amy Breen, Teva
Dave Miley, Teva	Julie Kwon, Ultragenyx
J Odell, Ultragenyx	

PRESENT FOR PUBLIC COMMENT:	
Gia McLean, Amgen	

<u>AGENDA ITEM NO. 1:</u> **CALL TO ORDER**

1A: ROLL CALL

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

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 2:</u> **PUBLIC COMMENT FORUM**

2A: AGENDA ITEM NO. 9 GIA MCLEAN

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 3:</u> **APPROVAL OF DUR BOARD MEETING MINUTES**

3A: FEBRUARY 9, 2022 DUR MINUTES – VOTE

Materials included in agenda packet; presented by Dr. Muchmore

Dr. Mitchell moved to approve; seconded by Dr. Hanner

ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 4:</u> **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/SPRING 2022 PIPELINE UPDATE**

4A: PHARMACY HELPDESK ACTIVITY FOR FEBRUARY 2022

4B: MEDICATION COVERAGE ACTIVITY FOR FEBRUARY 2022
4C: PHARMACY HELPDESK ACTIVITY FOR MARCH 2022
4D: MEDICATION COVERAGE ACTIVITY FOR MARCH 2022
4E: SPRING 2022 PIPELINE UPDATE
Materials included in agenda packet; presented by Dr. O'Halloran, Dr. Wilson
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 5:</u> MEDICATION THERAPY MANAGEMENT (MTM) PROGRAM CALENDAR YEAR 2021 REVIEW
5A: BACKGROUND
5B: WORKFLOW
5C: RESULTS
5D: CASE STUDY
5E: SUMMARY
Materials included in agenda packet; presented by Dr. Smith
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 6:</u> VOTE TO PRIOR AUTHORIZE ELEPSIA™ XR [LEVETIRACETAM EXTENDED-RELEASE (ER) TABLET] AND EPRONTIA™ (TOPIRAMATE ORAL SOLUTION)
6A: MARKET NEWS AND UPDATES
6B: ELEPSIA™ (LEVETIRACETAM ER TABLET) PRODUCT SUMMARY
6C: EPRONTIA™ (TOPIRAMATE ORAL SOLUTION) PRODUCT SUMMARY
6D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Ha
Dr. Muñoz moved to approve; seconded by Dr. Mitchell
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 7:</u> VOTE TO PRIOR AUTHORIZE WINLEVI® (CLASCOTERONE 1% CREAM)
7A: MARKET NEWS AND UPDATES
7B: WINLEVI® (CLASCOTERONE 1% CREAM) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Anderson moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 8:</u> VOTE TO PRIOR AUTHROIZE DOJOLVI® (TRIHEPTANOIN)
8A: MARKET NEWS AND UPDATES
8B: DOJOLVI® (TRIHEPTANOIN) PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Mitchell moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 9:</u> VOTE TO PRIOR AUTHORIZE QULIPTA™ (ATOGEPANT) AND TRUDHESA™ (DIHYDROERGOTAMINE NASAL SPRAY) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTI-MIGRAINE MEDICATIONS
9A: MARKET NEWS ANUD UPDATES
9B: QULIPTA™ (ATOGEPANT) PRODUCT SUMMARY
9C: TRUDHESA™ (DIHYDROERGOTAMINE NASAL SPRAY) PRODUCT SUMMARY
9D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Chandler

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

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE ERWINASE® (CRISANTASPASE), ERWINAZE® (ASPARAGINASE *ERWINIA CHRYSANTHEMI*), ONCASPAR® (PEGASPARGASE), RYLAZE™ [ASPARAGINASE *ERWINIA CHRYSANTHEMI* (RECOMBINANT)-RYWN], AND SCEMBLIX® (ASCIMINIB) AND UPDATE THE APPROVAL CRITERIA FOR THE LEUKEMIA MEDICATIONS
10A: MARKET NEWS AND UPDATES
10B: PRODUCT SUMMARIES
10C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Anderson moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF HEMOPHILIA MEDICATIONS
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF HEMOPHILIA MEDICATIONS
11C: PRIOR AUTHORIZATION OF HEMOPHILIA MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: HEMOPHILIA A WITH INHIBITOR TREATMENT
11F: OKLAHOMA HEALTH CARE AUTHORITY RECOMMENDATIONS
11G: UTILIZATION DETAILS OF HEMOPHILIA MEDICATIONS
Materials included in agenda packet; presented by Dr. Ratterman
Dr. Mitchell moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: ANNUAL REVIEW OF LYMPHOMA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ZYNLONTA® (LONCASTUXIMAB TESIRINE-LPLY)
12A: INTRODUCTION
12B: CURRENT PRIOR AUTHORIZATION CRITERIA
12C: UTILIZATION OF LYMPHOMA MEDICATIONS
12D: PRIOR AUTHORIZATION OF LYMPHOMA MEDICATIONS
12E: MARKET NEWS AND UPDATES
12F: ZYNLONTA® (LONCASTUXIMAB TESIRINE-LPLY) PRODUCT SUMMARY
12G: COLLEGE OF PHARMACY RECOMMENDATIONS
12H: UTILIZATION DETAILS OF LYMPHOMA MEDICATIONS
Materials included in agenda packet; presented by Dr. Borders
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN MAY

AGENDA ITEM NO. 13: ANNUAL REVIEW OF LUTATHERA® (LUTETIUM LU-177 DOTATATE) AND VITRAKVI® (LAROTRECTINIB)
13A: INTRODUCTION
13B: CURRENT PRIOR AUTHORIZATION CRITERIA
13C: UTILIZATION OF LUTATHERA® (LUTETIUM LU-177 DOTATATE) AND VITRAKVI® (LAROTRECTINIB)
13D: PRIOR AUTHORIZATION OF LUTATHERA® (LUTETIUM LU-177 DOTATATE) AND VITRAKVI® (LAROTRECTINIB)
13E: MARKET NEWS AND UPDATES
13F: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Borders
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: **ANNUAL REVIEW OF GROWTH HORMONE PRODUCTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE SKYTROFA® (LONAPEGSOMATROPIN-TCGD) AND VOXZOGO™ (VOSORITIDE)**

14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF GROWTH HORMONE PRODUCTS
14C: PRIOR AUTHORIZATION OF GROWTH HORMONE PRODUCTS
14D: MARKET NEWS AND UPDATES
14E: SKYTROFA® (LONAPEGSOMATROPIN-TCGD) PRODUCT SUMMARY
14F: VOXZOGO™ (VOSORITIDE) PRODUCT SUMMARY
14G: COLLEGE OF PHARMACY RECOMMENDATIONS
14H: UTILIZATION DETAILS OF GROWTH HORMONE PRODUCTS

Materials included in agenda packet; presented by Dr. Wilson

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

AGENDA ITEM NO. 15: **ANNUAL REVIEW OF GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS) AND 30-DAY NOTICE TO PRIOR AUTHORIZE RELEUKO™ (FILGRASTIM-AYOW)**

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

Materials included in agenda packet; presented by Dr. Ha

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

AGENDA ITEM NO. 16: **ANNUAL REVIEW OF ANTI-PARASITIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE LAMPIT® (NIFURTIMOX)**

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF ANTI-PARASITIC MEDICATIONS
16C: PRIOR AUTHORIZATION OF ANTI-PARASITIC MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: LAMPIT® (NIFURTIMOX) PRODUCT SUMMARY
16F: COLLEGE OF PHARMACY RECOMMENDATIONS
16G: UTILIZATION DETAILS OF ANTI-PARASITIC MEDICATIONS

Materials included in agenda packet; presented by Dr. Ha

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

AGENDA ITEM NO. 17: **ANNUAL REVIEW OF SYSTEMIC ANTIFUNGAL MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BREXAFEMME® (IBREXAFUNGERP)**

17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF SYSTEMIC ANTIFUNGAL MEDICATIONS
17C: PRIOR AUTHORIZATION OF SYSTEMIC ANTIFUNGAL MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: BREXAFEMME® (IBREXAFUNGERP) PRODUCT SUMMARY
17F: COLLEGE OF PHARMCY RECOMMENDATIONS
17G: UTILIZATION DETAILS OF SYSTEMIC ANTIFUNGAL MEDICATIONS

Materials included in agenda packet; presented by Dr. Chandler

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

AGENDA ITEM NO. 18: **ANNUAL REVIEW OF MULTIPLE SCLEROSIS (MS) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE PONVORY™ (PONESIMOD)**

18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF MS MEDICATIONS
18C: PRIOR AUTHORIZATION OF MS MEDICATIONS
18D: MARKET NEWS AND UPDATES
18E: PONVORY™ (PONESIMOD) PRODUCT SUMMARY
18F: COLLEGE OF PHARMACY RECOMMENDATIONS
18G: UTILIZATION DETAILS OF MS MEDICATIONS

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

AGENDA ITEM NO. 19: **U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES**

Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 20: **FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)**

20A: ANTI-DIABETIC MEDICATIONS
20B: HEART FAILURE MEDICATIONS
20C: LUNG CANCER MEDICATIONS
20D: MUSCULAR DYSTROPHY MEDICATIONS

*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 21: **ADJOURNMENT**

The meeting was adjourned at 5:55pm.

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

Memorandum

Date: April 15, 2022

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 13, 2022

Recommendation 1: Spring 2022 Pipeline Update

NO ACTION REQUIRED.

Recommendation 2: Medication Therapy Management (MTM) Program Calendar Year 2021 Review

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Elepsia™ XR [Levetiracetam Extended-Release (ER) Tablet] and Eprontia™ (Topiramate Oral Solution)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Elepsia™ XR (levetiracetam ER tablet) and Eprontia™ (topiramate oral solution) with the following criteria:

Elepsia™ XR [Levetiracetam Extended-Release (ER) Tablet] Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and

2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use generic formulations of levetiracetam ER must be provided; and
3. A quantity limit of 60 tablets per 30 days will apply.

Eprontia™ (Topiramate Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
   b. Adjunctive therapy in seizures associated with Lennox-Gastaut syndrome (LGS); or
   c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use topiramate tablets and sprinkle capsules must be provided; and
3. An age restriction of 11 years of age and younger will apply. Members older than 11 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
4. A quantity limit of 473mL per 29 days will apply.

Recommendation 4: Vote to Prior Authorize Winlevi® (Clascoterone 1% Cream)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Winlevi® (clascoterone 1% cream) with the following criteria:

Winlevi® (Clascoterone 1% Cream) Approval Criteria:

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

Recommendation 5: Vote to Prior Authorize Dojolvi® (Triheptanoin)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Dojolvi® (triheptanoin) with the following criteria:

Dojolvi® (Triheptanoin) Approval Criteria:

1. An FDA approved diagnosis of molecularly confirmed long-chain fatty acid oxidation disorder (LC-FAOD); and

2. Molecular testing confirms 1 of the following types of LC-FAOD:
    a. Carnitine-acylcarnitine translocase (CACT) deficiency; or
    b. Carnitine palmitoyltransferase I (CPT I) deficiency; or
    c. Carnitine palmitoyltransferase II (CPT II) deficiency; or
    d. Long-chain 3-hydroxyacyl-CoA dehydrogenase (LCHAD) deficiency; or
    e. Trifunctional protein (TFP) deficiency; or
    f. Very long-chain acyl-CoA dehydrogenase (VLCAD) deficiency; and
3. Prescriber must verify member has a history of at least 1 significant or recurrent manifestation of LC-FAOD (e.g., cardiomyopathy, rhabdomyolysis, hypoglycemia); and
4. Member must have tried and failed dietary management with an alternate medium chain triglyceride (MCT) product (e.g., MCT oil) or a patient-specific, clinically significant reason why dietary management with an alternate MCT product is not appropriate for the member must be provided; and
5. Dojolvi® will not be approved for concomitant use with another MCT product (other MCT products must be discontinued prior to the first dose of Dojolvi®); and
6. Member must not be taking a pancreatic lipase inhibitor concomitantly with Dojolvi®; and
7. Prescriber must verify the member does not have pancreatic insufficiency; and
8. Prescriber must verify that member or member's caregiver has been counseled on the proper storage, preparation, and administration of Dojolvi®, including specific considerations for use in a feeding tube, if applicable; and
9. Dojolvi® must be prescribed by a geneticist or other specialist with expertise in the treatment of LC-FAOD; and
10. Prescriber must verify the member is under the care of a clinical specialist knowledgeable in appropriate disease-related dietary management based on member's specific LC-FAOD and current nutritional recommendations; and
11. The member's daily caloric intake (DCI) must be provided (in kcal) on the prior authorization request to verify appropriate dosing based on package labeling; and
12. Initial approvals will be for the duration of 3 months. After 3 months of treatment, compliance will be required, and the prescriber must verify the member has had a positive response to and is tolerating treatment with Dojolvi®. Additionally, for members who switched from another MCT product due to adverse effects, the prescriber must verify the member has experienced fewer adverse effects with Dojolvi®; and
13. Quantity limits according to package labeling will apply, with the maximum approvable dosing regimen based on a target daily dosage of Dojolvi® up to 35% of the member's total DCI.

Recommendation 6: Vote to Prior Authorize Qulipta™ (Atogepant) and Trudhesa™ (Dihydroergotamine Nasal Spray) and Update the Approval Criteria for the Anti-Migraine Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Qulipta™ (atogepant) with criteria similar to Aimovig® (erenumab-aooe) and Vyepti® (eptinezumab-jjmr) and the addition of Nurtec® ODT (rimegepant) to the current criteria for Aimovig® and Vyepti® based on the recent FDA approval for the preventive treatment of episodic migraine (changes noted in red):

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

1. An FDA approved indication for the preventive treatment of migraine in adults; and
2. Member must be 18 years of age or older; and
3. Member has documented chronic migraine or episodic migraine headaches:
    a. Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month; or
    b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months (*Nurtec® ODT and Qulipta™ are only FDA approved for the preventive treatment of episodic migraines); and
        i. For episodic migraine, member must have had a history of migraines for a duration of 12 months or longer; and
4. Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes, but is not limited to:
    a. Increased intracranial pressure (e.g., tumor, pseudotumor cerebri, central venous thrombosis); or
    b. Decreased intracranial pressure (e.g., post-lumbar puncture headache, dural tear after trauma); and
5. Migraine headache exacerbation secondary to other medication therapies or conditions have been ruled out and/or treated. This includes, but is not limited to:
    a. Hormone replacement therapy or hormone-based contraceptives; and
    b. Chronic insomnia; and
    c. Obstructive sleep apnea; and
6. The member has failed medical migraine preventive therapy with at least 3 agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects) within the last 365 days. This includes, but is not limited to:
    a. Select antihypertensive therapy (e.g., beta-blocker therapy); or
    b. Select anticonvulsant therapy; or

c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and

7. Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
   a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and
   b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
   c. Opioids (≥10 days/month for >3 months); and
   d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
   e. Ergotamine-containing medications (≥10 days/month for >3 months); and
   f. Triptans (≥10 days/month for >3 months); and
8. Member is not taking any medications that are likely to be the cause of the headaches; and
9. Member must have been evaluated within the last 6 months by a neurologist for migraine headaches and the requested medication (e.g., Aimovig®, Nurtec® ODT, Qulipta™, Vyepti®) recommended as treatment (not necessarily prescribed by a neurologist); and
10. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
11. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and
12. For Aimovig®, prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
13. For Vyepti®, prescriber must verify the medication will be prepared and administered according the Vyepti® *Prescribing Information*; and
14. A patient-specific, clinically significant reason why member cannot use Ajovy® (fremanezumab-vfrm) or Emgality® (galcanezumab-gnlm) must be provided (members currently taking Nurtec® ODT for acute migraine treatment are not exempt from this criteria requirement); and
15. For consideration of Vyepti® at the maximum recommended dosing (300mg every 3 months), a patient-specific, clinically significant reason why other available CGRP inhibitors for migraine prophylaxis are not appropriate for the member must be provided; and
16. Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly

migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and

17. Quantity limits will apply based on FDA-approved dosing and indication:
    a. For Aimovig®, a quantity limit of 1 syringe or autoinjector per 30 days will apply; and
    b. For Nurtec® ODT, a quantity limit of 15 tablets per 30 days will apply; and
    c. For Qulipta™, a quantity limit of 30 tablets per 30 days will apply; and
    d. For Vyepti®, a quantity limit of 3 vials per 90 days will apply.

Additionally, the College of Pharmacy recommends the placement of Trudhesa™ (dihydroergotamine nasal spray) into the Special Prior Authorization (PA) Tier of the Anti-migraine Product Based Prior Authorization (PBPA) category and updating the D.H.E. 45® (dihydroergotamine injection) and Migranal® (dihydroergotamine nasal spray) criteria based on net cost with the following criteria (changes and new criteria noted in red in the following criteria and Tier chart):

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of brand D.H.E. 45® (dihydroergotamine injection) or brand Migranal® (dihydroergotamine nasal spray) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications. Brand formulation is preferred for D.H.E. 45® and Migranal®; use of the generic formulations will require a patient-specific, clinically significant reason why the member cannot use the brand formulation and lower-tiered triptan medications.
2. ~~Use of dihydroergotamine nasal spray (Migranal®) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications and dihydroergotamine injection (D.H.E. 45®).~~
3. Use of Trudhesa™ (dihydroergotamine nasal spray) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation of D.H.E. 45®, Migranal®, and lower-tiered triptan medications.
4. Use of generic eletriptan will require a patient-specific, clinically significant reason why the member cannot use the brand formulation of Relpax® (brand formulation is preferred).
5. Use of Ergomar® (ergotamine sublingual tablets) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications; and
    a. Member must not have any of the contraindications for use of Ergomar® (e.g., coadministration with a potent CYP3A4 inhibitor, women who are or may become pregnant, peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic or

renal function, sepsis, hypersensitivity to any of the components); and

b. A quantity limit of 20 tablets per 28 days will apply.

6. Use of Reyvow® (lasmiditan) or Ubrelvy® (ubrogepant) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
   a. Reyvow® and Ubrelvy® will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor.
7. Nurtec® ODT (rimegepant) Approval Criteria [Migraine Diagnosis (Acute Treatment)][+]:
   a. Member must have failed therapy with at least 2* triptan medications or a patient-specific, clinically significant reason why a triptan is not appropriate for the member must be provided; and
   b. Nurtec® ODT will not be approved for concurrent use with a prophylactic CGRP inhibitor.

   *The manufacturer of Nurtec® ODT has currently provided a supplemental rebate to require a trial with 2 triptan medications and to be the preferred CGRP product for acute treatment over Reyvow® and Ubrelvy®; however, Nurtec® ODT will follow the same criteria as Reyvow® and Ubrelvy® if the manufacturer chooses not to participate in supplemental rebates.

   [+]Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Aimovig®, Qulipta™, and Vyepti® approval criteria.
8. Use of any non-oral sumatriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.
9. Use of Zembrace® SymTouch® (sumatriptan injection) or Tosymra® (sumatriptan nasal spray) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
eletriptan tablet (Relpax®) – **Brand Preferred**	naratriptan tablet (Amerge®)	almotriptan tablet (Axert®)	dihydroergotamine injection (D.H.E. 45®) – **Brand Preferred**
rizatriptan tablet, ODT (Maxalt®, Maxalt MLT®)	zolmitriptan tablet, ODT, nasal spray (Zomig®, Zomig-ZMT®, Zomig® nasal spray)	frovatriptan tablet (Frova®)	dihydroergotamine nasal spray (Migranal®) – **Brand Preferred**
sumatriptan tablet (Imitrex®)			**dihydroergotamine nasal spray (Trudhesa™)**

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
sumatriptan/ naproxen tablet (Treximet®)			eletriptan tablet (generic Relpax®)
			ergotamine sublingual tablet (Ergomar®)
			lasmiditan tablet (Reyvow®)
			rimegepant ODT (Nurtec™ ODT)
			sumatriptan injection (Imitrex®)
			sumatriptan injection (Zembrace® SymTouch®)
			sumatriptan nasal powder (Onzetra® Xsail®)
			sumatriptan nasal spray (Imitrex®)
			sumatriptan nasal spray (Tosymra®)
			ubrogepant tablet (Ubrelvy®)

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

Recommendation 7: Vote to Prior Authorize Prior Authorize Erwinase® (Crisantaspase), Erwinaze® (Asparaginase *Erwinia Chrysanthemi*), Oncaspar® (Pegaspargase), Rylaze™ [Asparaginase *Erwinia Chrysanthemi* (Recombinant)-rywn], and Scemblix® (Asciminib) and Update the Approval Criteria for the Leukemia Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Erwinase® (crisantaspase), Erwinaze® (asparaginase *Erwinia chrysanthemi*), Rylaze™ [asparaginase *Erwinia chrysanthemi* (recombinant)-rywn], and Scemblix® (asciminib) with the following criteria (shown in red):

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

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

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

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

Additionally, College of Pharmacy recommends the prior authorization of Oncaspar® (pegaspargase) with criteria similar to Asparlas® (calaspargase pegol-mknl) and updating the Asparlas® criteria based on National Comprehensive Cancer Network (NCCN) guideline recommendations and product availability with the following criteria (changes and updates shown in red):

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

1. For Asparlas®, a patient-specific, clinically significant reason why the member cannot use Oncaspar® (pegaspargase) must be provided; and
2. For Asparlas®, member must be 1 month to 21 years of age; and
3. Diagnosis of ALL; and
4. Used as first-line therapy; or
5. May be used to treat members with a hypersensitivity to native forms of L-asparaginase; or
6. Used as systemic central nervous system (CNS)-directed therapy; or
7. Used in relapsed/refractory disease; and
    a. Philadelphia chromosome negative (Ph-); or
    b. Philadelphia chromosome positive (Ph+); and
        i. Refractory to tyrosine kinase inhibitor (TKI) therapy or used in conjunction with a TKI (if not previously used).

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

1. For Asparlas®, a patient-specific, clinically significant reason why the member cannot use Oncaspar® (pegaspargase) must be provided; and
2. For Asparlas®, member must be 1 month to 21 years of age; and
3. Diagnosis of NK/T-Cell lymphoma; and
4. Member has nasal disease; and

a. Used as induction therapy; or
b. Used as additional therapy in members with a positive biopsy following a partial or no response to induction therapy.

Finally, the College of Pharmacy recommends updating the prior authorization criteria for Ayvakit™ (avapritinib), Tecartus® (brexucabtagene autoleucel), and Tibsovo® (ivosidenib) based on recent FDA approvals (changes shown in red):

Ayvakit™ (Avapritinib) Approval Criteria [Systemic Mastocytosis Diagnosis]:

1. Diagnosis of advanced systemic mastocytosis, including members with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematologic neoplasm, and mast cell leukemia; and
2. Platelet count ≥50 x 10^9/L.

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

1. Diagnosis of ALL; and
2. Relapsed or refractory disease; and
3. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements.

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

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

Recommendation 8: Annual Review of Hemophilia Medications

MOTION CARRIED by unanimous approval.

The Oklahoma Health Care Authority recommends the following changes to the current hemophilia A inhibitor treatments approval criteria based on the World Federation of Hemophilia (WFH) and the National Hemophilia Foundation's Medical and Scientific Advisory Council (MASAC) recommendations (changes shown in red):

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

1. Member must be diagnosed with hemophilia A or B with an inhibitor; and
   a. For a diagnosis of hemophilia A with an inhibitor, a patient-specific, clinically significant reason why the member cannot use 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. ~~Member must have failed immune tolerance induction (ITI) or is not a good candidate for ITI; and~~
   b. ~~Member's hemophilia cannot be managed without the use of bypassing agent(s) (e.g., Feiba®, NovoSeven® RT) as prophylaxis for prevention of bleeding episodes, or the member is unable to maintain venous access for daily infusions; and~~
   c. ~~Member's hemophilia is not currently controlled with the use of bypassing agent(s); and~~
   d. 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; and
        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.

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.

Recommendation 9: Annual Review of Lymphoma Medications and 30-Day Notice to Prior Authorize Zynlonta® (Loncastuximab Tesirine-lply)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY 2022.

Recommendation 10: Annual Review of Lutathera® (Lutetium Lu-177 Dotatate) and Vitrakvi® (Larotrectinib)

NO ACTION REQUIRED.

Recommendation 11: Annual Review of Growth Hormone Products and 30-Day Notice to Prior Authorize Skytrofa® (Lonapegsomatropin-tcgd) and Voxzogo™ (Vosoritide)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY 2022.

Recommendation 12: Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and 30-Day Notice to Prior Authorize Releuko™ (Filgrastim-ayow)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY 2022.

Recommendation 13: Annual Review of Anti-Parasitic Medications and 30-day Notice to Prior Authorize Lampit® (Nifurtimox)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY 2022.

Recommendation 14: Annual Review of Systemic Antifungal Medications and 30-Day Notice to Prior Authorize Brexafemme® (Ibrexafungerp)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY 2022.

Recommendation 15: Annual Review of Multiple Sclerosis Medications and 30-Day Notice to Prior Authorize Ponvory™ (Ponesimod)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN MAY 2022.

Recommendation 16: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 17: Future Business

NO ACTION REQUIRED.

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING MAY 11, 2022

DUR BOARD MEMBERS:	PRESENT	ABSENT
Stephen Anderson, Pharm.D.		X
Jennifer de los Angeles, Pharm.D., BCOP		X
Jennifer Boyett, 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

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Wendi Chandler, Pharm.D.; Clinical Pharmacist	X	
Donna Fagans; Administrative Support Specialist	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Thomas Ha, Pharm.D.; Clinical Pharmacist	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Morgan Masterson, Pharm.D; Clinical Pharmacist		X
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor	X	
Regan Smith, 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: Allison Baxley, Pharm.D., BCOP		X
Emily Borders, Pharm.D., BCOP	X	
Sarah Schmidt, Pharm.D., BCPS, BCOP		X
Graduate Students: Matthew Dickson, Pharm.D.		X
Michael Nguyen, Pharm.D.		X
Corby Thompson, Pharm.D.	X	
Laura Tidmore, Pharm.D.	X	
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Melody Anthony; Chief Operating Officer		X
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
Debra Montgomery, D.O.; Medical Director	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	
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:	
Lori Howarth, Bayer	Lindsey Walter, Novartis
Stormy Cameron, Artia Solutions	Brandon Ross, Merck
Brian Maves, Pfizer	Burl Beasley, OMES
Eric Berthelot, Sobi	Kenneth Berry, Alkermes
Aaron Austin, Takeda	Bob Atkins, Biogen
Kathrin Kucharski, Sarepta	Angela Kell, Takeda Oncology
Ann Nelson, Vertex	Mark Kaiser, Otsuka
Chrystal Mayes, Sanofi	Dana Pipkin, Sarepta
Ruthel Goss, BioMarin	Rick Kegler, BioMarin
David Smith, OU Health	Nima Nabavi, Amgen
David Prather, Novo Nordisk	Nader Yamout, Novo Nordisk
Raquel Jordan, Takeda Oncology	Jomy Joseph, Sanofi
Marc Parker, Sunovion	

PRESENT FOR PUBLIC COMMENT:	
David Smith, OU Health Dermatology	Rick Kegler, BioMarin
Angela Kell, Takeda Oncology	Nader Yamout, Novo Nordisk

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

1A: ROLL CALL

Dr. Muchmore called the meeting to order at 4:04pm. Roll call by Dr. Wilcox did not establish the presence of a quorum.

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO. N/A DAVID SMITH
2B: AGENDA ITEM NO. 7 RICK KEGLER
2C: AGENDA ITEM NO. 11 ANGELA KELL
2D: AGENDA ITEM NO. 15 NADER YAMOUT
ACTION: NONE REQUIRED

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

3A: APRIL 13, 2022 DUR MINUTES

Materials included in agenda packet; presented by Dr. Muchmore

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

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/PRENATAL VITAMIN (PNV) UTILIZATION UPDATE**

4A: PHARMACY HELPDESK ACTIVITY FOR APRIL 2022
4B: MEDICATION COVERAGE ACTIVITY FOR APRIL 2022
4C: PNV UTILIZATION UPDATE

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

<u>AGENDA ITEM NO. 5:</u> VOTE TO PRIOR AUTHORIZE RELEUKO™ (FILGRASTIM-AYOW) AND UPDATE THE APPROVAL CRITERIA FOR THE GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS)
5A: MARKET NEWS AND UPDATES
5B: COST COMPARISON FOR FILGRASTIM PRODUCTS
5C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Ha
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 6:</u> VOTE TO PRIOR AUTHORIZE LAMPIT® (NIFURTIMOX)
6A: MARKET NEWS AND UPDATES
6B: LAMPIT® (NIFURTIMOX) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Ha
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 7:</u> VOTE TO PRIOR AUTHORIZE SKYTROFA® (LONAPEGSOMATROPIN-TCGD) AND VOXZOGO™ (VOSORITIDE) AND UPDATE THE APPROVAL CRITERIA FOR THE GROWTH HORMONE PRODUCTS
7A: MARKET NEWS AND UPDATES
7B: SKYTROFA® (LONAPEGSOMATROPIN-TCGD)
7C: VOXZOGO™ (VOSORITIDE) PRODUCT SUMMARY
7D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 8:</u> VOTE TO PRIOR AUTHORIZE PONVORY® (PONESIMOD) AND UPDATE THE APPROVAL CRITERIA FOR THE MULTIPLE SCLEROSIS MEDICATIONS
8A: MARKET NEWS AND UPDATES
8B: PONVORY® (PONESIMOD) PRODUCT SUMMARY
8C: 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. 9:</u> VOTE TO PRIOR AUTHORIZE BREXAFEMME® (IBREXAFUNGERP) AND UPDATE THE APPROVAL CRITERIA FOR THE SYSTEMIC ANTIFUNGAL MEDICATIONS
9A: MARKET NEWS AND UPDATES
9B: BREXAFEMME® (IBREXAFUNGERP) PRODUCT SUMMARY
9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Chandler
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 10:</u> VOTE TO PRIOR AUTHORIZE ZYNLONTA™ (LONCASTUXIMAB TESIRINE) AND UPDATE THE APPROVAL CRITERIA FOR THE LYMPHOMA MEDICATIONS
10A: MARKET NEWS AND UPDATES
10B: ZYNLONTA™ (LONCASTUXIMAB TESIRINE) PRODUCT SUMMARY
10C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

<u>AGENDA ITEM NO. 11:</u> ANNUAL REVIEW OF LUNG CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE EXKIVITY® (MOBOCERTINIB), LUMAKRAS™ (SOTORASIB), AND RYBREVANT™ (AMIVANTAMAB-VMJW)
11A: INTRODUCTION
11B: CURRENT PRIOR AUTHORIZATION CRITERIA
11C: UTILIZATION OF LUNG CANCER MEDICATIONS
11D: PRIOR AUTHORIZATION OF LUNG CANCER MEDICATIONS
11E: MARKET NEWS AND UPDATES
11F: PRODUCT SUMMARIES
11G: COLLEGE OF PHARMACY RECOMMENDATIONS
11H: 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. 12:</u> ANNUAL REVIEW OF AYVAKIT™ (AVAPRITINIB) AND BYNFEZIA PEN™ (OCTREOTIDE)
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF AYVAKIT™ (AVAPRITINIB) AND BYNFEZIA PEN™ (OCTREOTIDE)
12C: PRIOR AUTHORIZATION OF AYVAKIT™ (AVAPRITINIB) AND BYNFEZIA PEN™ (OCTREOTIDE)
12D: MARKET NEWS AND UPDATES
12E: COLLEGE OF PHARMACY RECOMMENDATIONS
12F: UTILIZATION DETAILS OF AYVAKIT™ (AVAPRITINIB) AND BYNFEZIA PEN™ (OCTREOTIDE)
Materials included in agenda packet; presented by Dr. Borders
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF NASAL ALLERGY MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE RYALTRIS™ (MOMETASONE/OLOPATADINE NASAL SPRAY)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF NASAL ALLERGY MEDICATIONS
13C: PRIOR AUTHORIZATION OF NASAL ALLERGY MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: RYALTRIS™ (MOMETASONE/OLOPATADINE) PRODUCT SUMMARY
13F: COLLEGE OF PHARMACY RECOMMENDATIONS
13G: UTILIZATION DETAILS OF NASAL ALLERGY MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 14:</u> ANNUAL REVIEW OF HEART FAILURE (HF) MEDICATIONS
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF HF MEDICATIONS
14C: PRIOR AUTHORIZATION OF HF MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: COLLEGE OF PHARMACY RECOMMENDATIONS
14F: UTILIZATION DETAILS OF HF MEDICATIONS

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

<u>AGENDA ITEM NO. 15:</u> ANNUAL REVIEW OF ANTI-DIABETIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE KERENDIA® (FINERENONE), REZVOGLAR™ (INSULIN GLARGINE-AGLR), AND SEMGLEE® (INSULIN GLARGINE-YFGN)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ANTI-DIABETIC MEDICATIONS
15C: PRIOR AUTHORIZATION OF ANTI-DIABETIC MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: KERENDIA® (FINERENONE) PRODUCT SUMMARY
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF ANTI-DIABETIC MEDICATIONS
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 MUSCULAR DYSTROPHY MEDICATIONS
16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF MUSCULAR DYSTROPHY MEDICATIONS
16C: PRIOR AUTHORIZATION OF MUSCULAR DYSTROPHY MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: COLLEGE OF PHARMACY RECOMMENDATIONS
16F: UTILIZATION DETAILS OF MUSCULAR DYSTROPHY MEDICATIONS
Materials included in agenda packet; presented by Dr. Chandler
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 17:</u> ANNUAL REVIEW OF LUMIZYME® (ALGLUCOSIDASE ALFA) AND 30-DAY NOTICE TO PRIOR AUTHORIZE NEXVIAZYME® (AVALGLUCOSIDASE ALFA-NGPT)
17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF LUMIZYME® (ALGLUCOSIDASE ALFA)
17C: PRIOR AUTHORIZATION OF LUMIZYME® (ALGLUCOSIDSE ALFA)
17D: MARKET NEWS AND UPDATES
17E: NEXVIAZYME® (AVALGLUCOSIDASE ALFA-NGPT) PRODUCT SUMMARY
17F: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Ha
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 18:</u> U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. Ha
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 19:</u> FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
19A: ANTIVIRAL MEDICATIONS
19B: ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS
19C: ATYPICAL ANTIPSYCHOTIC MEDICATIONS
19D: VARIOUS SPECIAL FORMULATIONS
*Future product and class reviews subject to change.

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

AGENDA ITEM NO. 20: ADJOURNMENT
The meeting was adjourned at 5:41pm.

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

Memorandum

Date: May 13, 2022

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 May 11, 2022

Recommendation 1: Prenatal Vitamin (PNV) Utilization Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Releuko™ (Filgrastim-ayow) and Update the Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs)

VOTE ITEM AT JUNE MEETING

The College of Pharmacy recommends the prior authorization of Releuko™ (filgrastim-ayow) and Neulasta® (pegfilgrastim) and recommends removing the prior authorization requirement for Nyvepria™ (pegfilgrastim-apgf) based on net costs (changes shown in red):

Nivestym® (Filgrastim-aafi) and Releuko™ (Filgrastim-ayow) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Neupogen® (filgrastim), Granix® (tbo-filgrastim), or Zarxio® (filgrastim-sndz) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost

changes in comparison to the reference product and/or other available biosimilar products.

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

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Granix® (tbo-filgrastim), ~~Neulasta® (pegfilgrastim)~~, 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.

Recommendation 3: Vote to Prior Authorize Lampit® (Nifurtimox)

VOTE ITEM AT JUNE MEETING

The College of Pharmacy recommends the prior authorization of Lampit® (nifurtimox) with the following criteria:

Lampit® (Nifurtimox) Approval Criteria:

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

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

Recommendation 4: Vote to Prior Authorize Skytrofa® (Lonapegsomatropin-tcgd) and Voxzogo™ (Vosoritide) and Update the Approval Criteria for the Growth Hormone Products

VOTE ITEM AT JUNE MEETING

The College of Pharmacy recommends the placement of Skytrofa® (lonapegsomatropin-tcgd) into Tier-2 of the growth hormone products Product Based Prior Authorization (PBPA) category with the following additional criteria:

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

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Supplementally rebated product(s)
†Additional approval criteria applies.

Skytrofa® (Lonapegsomatropin-tcgd) Approval Criteria:

1. Member must have a confirmed diagnosis of growth hormone deficiency (GHD) or panhypopituitarism meeting the initial growth hormone approval criteria (listed under "Initial Approval") for the member's specific diagnosis; and
2. Member's weight must be ≥11.5kg; and
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and
4. Prescriber must verify the member has been counseled on proper administration and storage of Skytrofa®; and
5. Initial approvals will be for the 0.24mg/kg weekly dose, using the specific dose recommended in the Skytrofa® *Prescribing Information*; and
6. Initial approvals will be for the duration of 6 months. For additional approval consideration:
    a. Dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Growth velocity should not be <2.5cm/year; and
    e. Prescriber must verify member still has open epiphyses; and
7. Skytrofa® will not be approved following epiphyseal closure. Skytrofa® is contraindicated in children with closed epiphyses.

Additionally, the College of Pharmacy recommends the prior authorization of Voxzogo™ (vosoritide) with the following criteria:

Voxzogo™ (Vosoritide) Approval Criteria:

1. Member must have an FDA approved diagnosis of achondroplasia; and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic mutation in the *FGFR3* gene; and
2. Member must be 5 years of age or older; and
3. Prescriber must verify member has open epiphyses; and
4. The member's baseline height and growth velocity (GV) must be provided; and
5. Voxzogo™ must be prescribed by a geneticist, endocrinologist, or other specialist with expertise in the treatment of achondroplasia (or an advanced care practitioner with a supervising physician who is a geneticist, endocrinologist, or other specialist with expertise in the treatment of achondroplasia); and
6. Member's recent weight (taken within the past 3 weeks) must be provided in order to ensure appropriate dosing in accordance with the Voxzogo™ *Prescribing Information*; and
7. Prescriber must verify the member or member's caregiver has been counseled on proper administration and storage of Voxzogo™,

including the need for adequate food and fluid intake prior to each dose; and
8. A quantity limit of 30 vials per 30 days will apply; and
9. Initial and subsequent approvals will be for the duration of 6 months. For additional approval consideration:
    a. Member's current height must be provided and must demonstrate an improvement in GV from baseline; and
    b. Member's recent weight must be provided and dosing must be appropriate; and
    c. Member should be compliant; and
    d. Prescriber must verify member still has open epiphyses; and
10. Voxzogo™ will not be approved following epiphyseal closure.

Lastly, the College of Pharmacy recommends updating the current growth hormone prior authorization criteria with the following changes to be consistent with current guideline recommendations for growth hormone treatment (changes and additions shown in red):

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

1. Growth hormone deficiency (GHD) of 1 of the following types:
    a. Classic GHD as determined by childhood GH stimulation tests; or
    ~~b. Panhypopituitarism with history of pituitary or hypothalamic injury due to tumor, trauma, surgery, whole brain radiation, irradiation, hemorrhage or infarction, or a congenital anomaly; or~~
    ~~c. Panhypopituitarism in children with height ≥2.25 SD below the mean for age and gender and MRI evidence of pituitary stalk agenesis, empty sella, or ectopic posterior pituitary "bright spot"; or~~
    b. Panhypopituitarism; or
    c. Hypoglycemia with evidence for GHD; or
    d. Neurosecretory dysfunction; or
    e. Other evidence for GHD submitted for panel review and decision; or
2. Short stature associated with Prader-Willi Syndrome; or
3. Short stature associated with Noonan Syndrome; or
4. Short stature associated with chronic renal insufficiency (pre-transplantation); or
5. Growth failure in children born small for gestational age (SGA) who fail to manifest catch-up growth by 2 years of age; or
6. Idiopathic short stature (ISS) in children with height ≥2.25 SD below the mean for age and gender and who are unlikely to catch up in height; or
7. Turner syndrome or 45X, 46XY mosaicism; or
8. Short-stature homeobox-containing gene (SHOX) deficiency with genetic evidence for SHOX deficiency.

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

Growth Hormone Tier-2 Approval Criteria:

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

~~**Requirements for Initiation of Growth Hormone Therapy – All Indications:**~~

~~1. Evaluated and prescribed by an endocrinologist, pediatric nephrologist, or infectious disease specialist; and~~
~~2. Covered indication; and~~
~~3. Member must be 2 years of age or older [*Exceptions*: hypoglycemia related to growth hormone deficiency (GHD): any age; idiopathic short stature (ISS): 8 years of age or older]; and~~
~~4. Height ≥2.25 SD below the mean for age (excludes chronic renal failure); and~~
~~5. Evidence of delayed bone age (undefined delay) (excludes chronic renal failure) and open epiphyses; and~~
~~6. The following information must be provided:~~
~~a. Growth chart; and~~
~~b. Parental heights.~~

Discontinuation of Therapy or Transition to Adult Therapy Criteria:

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

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

1. Children: 22 to 100mcg/kg/day ~~(in 3 to 7 doses per week)~~ according to current pediatric guidelines; or
2. Adults:
   a. Initial Dosing: 0.1 to 0.5mg per day – Doses should be evaluated and titrated at 1 to 2 month intervals targeting an insulin-like growth factor 1 (IGF-1) level within the age-adjusted reference range provided by the laboratory utilized [IGF-1 standard deviation score

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

Growth Hormone Deficiency (GHD) Approval Criteria:

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

vi. Glucagon (not approved for use in children); or

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

2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations ~~Standard dosing applies for members receiving pediatric dosing (0.044mg/kg/day) (Dose may vary based on whether pre-pubertal or pubertal. Is sometimes adjusted based on IGF-1 levels)~~; or
    b. Adult Dosing: Members with this diagnosis may transition to adult dosing (see "Growth Hormone Dosing" section above for recommendations for adult and transition dosing) after 1 or both of the following:
        i. Epiphyseal closure; or
        ~~ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]~~
        iii. GV <2.5cm/year; and
        iv. If either ~~the epiphyses have closed or covered height has been reached~~ of the above have occurred and the member has not yet transitioned to adult dosing, may be approved short term (3 months) to allow time for transition to adult dosing.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. GV should not be <2.5cm/year if not on adult dosing; and
    e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

Panhypopituitarism Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years of age or older (unless hypoglycemia is present); and
    b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    c. Member must meet at least 1 of the following:
        i. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; ~~and~~ or
        ii. Member must have evidence of delayed bone age (undefined delay); and
    d. Member must have open epiphyses; and
    e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
        i. For members with secondary panhypopituitarism due to tumor, trauma, or surgery 12 months post trauma or surgery, approval may be granted if no evidence of tumor recurrence and growth has not restarted. The member must still meet all the other criteria; however, authorization would not require height ≥2.25 SD below the mean in these circumstances; and
    f. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available; and
    g. Member must have a history of pituitary or hypothalamic injury due to tumor, trauma, surgery, documented whole brain radiation, irradiation, hemorrhage or infarction, or a congenital anomaly; and
        i. Deficiency in ≥3 pituitary hormones and insulin-like growth factor 1 (IGF-1) ≥2.5 SD below the mean for member's age; or
        ii. No deficiency, or deficiency in <3 pituitary hormones, and IGF-1 <50th percentile and subnormal response of 10ng/mL or less on at least 2 provocative growth hormone stimulation tests, using the highest level per date of testing. (Stimulation tests are always required for approval unless hypoglycemia is observed, in which case a random low glucose level and low growth hormone level would be acceptable); or
    h. If member has MRI evidence of pituitary stalk agenesis, empty sella, or ectopic posterior pituitary "bright spot", member is exempt from height requirement (*criteria letter e listed above*); and
        i. If they lack the hormones testosterone, luteinizing hormone (LH), or follicle-stimulating hormone (FSH) then an MRI is not required; or
    i. If hypoglycemia is present and member is growth hormone deficient: request may be approved for 6 months (other criteria above is not applicable). If the member has hypoglycemia, a low

glucose level must be submitted along with additional evidence of GHD such as:
    i. Low IGF-1, random growth hormone level, or suboptimal growth hormone stimulation tests; or
    ii. MRI evidence of congenital anomaly which includes pituitary damage or absence; or
    iii. Other pituitary hormones also being replaced (e.g., thyroid, cortisol); and
2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations ~~Standard dosing applies for members receiving pediatric dosing (0.044mg/kg/day) (Dose may vary based on whether pre-pubertal or pubertal. Is sometimes adjusted based on IGF-1 levels)~~; or
    b. Adult Dosing: Members with this diagnosis may transition to adult dosing (see "Growth Hormone Dosing" section above for recommendations for adult and transition dosing) after 1 or both of the following:
        i. Epiphyseal closure; or
        ~~ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]~~
        iii. GV <2.5cm/year; and
        iv. If either ~~the epiphyses have closed or covered height has been reached~~ of the above have occurred and the member has not yet transitioned to adult dosing, may be approved short term (3 months) to allow time for transition to adult dosing.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. GV should not be <2.5cm/year if not on adult dosing; and
    e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

Neurosecretory Dysfunction Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years of age or older; and
    b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and

c. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
d. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
e. Member must have evidence of delayed bone age and open epiphyses; and
f. Member's growth chart and parental heights must be provided; and
    i. If the form is completed, a growth chart is not required; and
    ii. Parental heights are not always available; and
g. Member's serum insulin-like growth factor 1 (IGF-1) must be below the mean for member's age; and
    i. Note: Children with profoundly low GV, who are at risk for growth hormone deficiency due to CNS radiation or other organic causes, termed neurosecretory dysfunction, may demonstrate "normal" responses to provocative tests, often for several years, but often benefit from growth hormone therapy.
h. Growth hormone stimulation testing is required; however, growth hormone levels may be normal; and

2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations ~~Standard dosing applies for members receiving pediatric dosing (0.044mg/kg/day) (Dose may vary based on whether pre-pubertal or pubertal. Is sometimes adjusted based on IGF-1 levels)~~; or
    b. Adult Dosing: Members with this diagnosis may transition to adult dosing (see "Growth Hormone Dosing" section above for recommendations for adult and transition dosing) after 1 ~~or both~~ of the following:
        i. Epiphyseal closure; or
        ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
        iv. If ~~either the epiphyses have closed or covered height has been reached~~ any of the above have occurred and the member has not yet transitioned to adult dosing, may be approved short term (3 months) to allow time for transition to adult dosing.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and

c. Member should be compliant; and
d. GV should not be <2.5cm/year if not on adult dosing; and
e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

Idiopathic Short Stature Approval Criteria:

1. Initial Approval:
   a. Member must be 8 years of age or older; and
   b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
   c. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
   d. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
   e. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
   f. Member's growth chart and parental heights must be provided
      i. If the form is completed, a growth chart is not required; and
      ii. Parental heights are not always available; and
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:
   a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations ~~0.47mg/kg/week~~. Treatment may continue until 1 ~~or both~~ of the following:
      i. Epiphyseal closure; or
      ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
      iii. GV <2.5cm/year; and
   b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
   a. Medications and dosing should be appropriate; and
   b. Member should have had a recent office visit with new information regarding heights provided; and
   c. Member should be compliant; and
   d. Epiphyses are open; and
   e. GV should not be <2.5cm/year.

Short Stature Associated with Chronic Renal Insufficiency (Pre-Transplantation) Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years of age or older; and
    b. Member's estimated creatinine clearance (CrCl) must be <50mL/min; and
    c. Member must not be post-kidney transplant; and
    d. Growth hormone therapy must be prescribed by an endocrinologist or pediatric nephrologist (or an advanced care practitioner with a supervising physician who is an endocrinologist or pediatric nephrologist); and
    e. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available; and
    f. Members meeting the above criteria are exempt from height requirements.
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, growth velocity (GV) is <2.5cm/year, or member has received renal transplant, therapy should be discontinued.
3. Dosing:
    a. Pediatric Dosing: Standard dosing applies for members receiving pediatric dosing (0.05mg/kg/day). Treatment may continue until 1 ~~or both~~ of the following:
        i. Renal transplantation; or
        ii. Epiphyseal closure; or
        iii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
        iv. GV <2.5cm/year; and
    b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
    a. Member is still pre-transplant; and
    b. Medications and dosing should be appropriate; and
    c. Member should have had a recent office visit with new information regarding heights; and
    d. Member should be compliant; and
    e. Epiphyses are open; and
    f. GV should not be <2.5cm/year.

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

1. Initial Approval:
    a. Member must be 2 years of age or older; and

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

2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: 0.24mg/kg/week. Treatment should continue until 1 ~~or both~~ of the following:
        i. Epiphyseal closure; or
        ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
    b. Adult Dosing: After attainment of adult height, adults with PWS may be considered for adult dosing if evidence is submitted documenting adult GH deficiency [e.g., low insulin-like growth factor 1 (IGF-1) level and GH stimulation testing]. ~~No proven benefit to continuing GH treatment in adulthood.~~
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. GV should not be <2.5cm/year; and
    e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

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

1. Initial Approval:
    a. Member must be 2 years of age or older; and
    b. Member must have a chromosome analysis confirming the diagnosis of Turner Syndrome in females or 45X 46XY mosaicism in males; and

c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and

2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or growth velocity (GV) is <2.5cm/year, therapy should be discontinued.
3. Dosing:
   a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations ~~standard dosing applies for members receiving pediatric dosing (0.054mg/kg/day)~~. Treatment should continue until 1 ~~or both~~ of the following:
      i. Epiphyseal closure; or
      ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
      iii. GV <2.5cm/year; and
   b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
   a. Medications and dosing should be appropriate; and
   b. Member should have had a recent office visit with new information regarding heights provided; and
   c. Member should be compliant; and
   d. Epiphyses should be open; and
   e. GV should not be <2.5cm/year.

Short Stature Associated with Noonan Syndrome Approval Criteria:

1. Initial Approval:
   a. Member must be 2 years or older; and
   b. Member must have a chromosome analysis confirming the diagnosis of Noonan Syndrome; and
   c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or growth velocity (GV) is <2.5cm/year, therapy should be discontinued.
3. Dosing:
   a. Pediatric Dosing: Standard dosing applies for members receiving pediatric dosing (up to ~~0.044~~ 0.066mg/kg/day). Treatment should continue until 1 ~~or both~~ of the following:
      i. Epiphyseal closure; or
      ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or

iii. GV <2.5cm/year.

b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.

4. Continuation Approval:
   a. Medications and dosing should be appropriate; and
   b. Member should have had a recent office visit with new information regarding heights provided; and
   c. Member should be compliant; and
   d. Epiphyses should be open; and
   e. GV should not be <2.5cm/year.

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

1. Initial Approval:
   a. Member must be 2 years or older; and
   b. Member must have a chromosome analysis confirming the diagnosis of SHOX deficiency; and
   c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
   d. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
   e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
   f. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
   g. Member's growth chart and parental heights must be provided; and
      i. If the form is completed, a growth chart is not required; and
      ii. Parental heights are not always available; and
   h. Member must have a normal endocrine screen; and
   i. Member must have no evidence of growth hormone deficiency or insensitivity, tumor activity, diabetes mellitus, history of impaired glucose tolerance, or other serious illness known to interfere with growth; and
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:
   a. Pediatric Dosing: Standard dosing applies for members receiving pediatric dosing (up to ~~0.044~~ 0.05mg/kg/day). Treatment should continue until 1 ~~or both~~ of the following:
      i. Epiphyseal closure; or
      ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or

iii. GV <2.5cm/year; and

b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.

4. Continuation Approval:
   a. Medications and dosing should be appropriate; and
   b. Member should have had a recent office visit with new information regarding heights provided; and
   c. Member should be compliant; and
   d. Epiphyses should be open; and
   e. GV should not be <2.5cm/year.

Small for Gestational Age (SGA) Approval Criteria:

1. Initial Approval:
   a. Member must be 2 years or age or older; and
   b. Documentation of birth weight <2,500 grams at gestational age of more than 37 weeks or birth weight or length below the 3rd percentile for gestational age; and
   c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
   d. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
   e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
   f. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
   g. Member's growth chart and parental heights must be provided; and
      i. If the form is completed, a growth chart is not required; and
      ii. Parental heights are not always available; and
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:
   a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations ~~standard dosing applies for members receiving pediatric dosing (0.05-0.068mg/kg/day)~~. Treatment should continue until 1 ~~or both~~ of the following:
      i. Epiphyseal closure; or
      ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
      iii. GV <2.5cm/year; and
   b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.

4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Epiphyses should be open; and
    e. GV should not be <2.5cm/year.

Recommendation 5: Vote to Prior Authorize Ponvory® (Ponesimod) and Update the Approval Criteria for the Multiple Sclerosis Medications

VOTE ITEM AT JUNE MEETING

The College of Pharmacy recommends the prior authorization of Ponvory® (ponesimod) and recommends adding additional prior authorization criteria for Zeposia® (ozanimod), based on the new FDA approved indication for ulcerative colitis (UC), with the following criteria (new criteria and updates noted in red):

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

8. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
9. Verification from the prescriber that the member's blood pressure will be monitored during treatment with Ponvory®; and
10. 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
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 the member will be followed with appropriate monitoring per package labeling; and
12. 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
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 Ponvory® and for at least 1 week 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. 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.

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. 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
3. Member must not have received prior treatment with alemtuzumab; and
4. Member must not be concurrently using strong CYP2C8 inhibitors/inducers or breast cancer resistance protein (BCRP) inhibitors; 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. Prescriber must conduct an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Zeposia®; 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 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 a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Zeposia®; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
13. 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
14. 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
15. 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

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

Recommendation 6: Vote to Prior Authorize Brexafemme® (Ibrexafungerp) and Update the Approval Criteria for the Systemic Antifungal Medications

VOTE ITEM AT JUNE MEETING

The College of Pharmacy recommends the prior authorization of Brexafemme® (ibrexafungerp) with the following criteria:

Brexafemme® (Ibrexafungerp) Approval Criteria:

1. An FDA approved diagnosis of vulvovaginal candidiasis (VVC); and
2. Member must be an adult female or a post-menarchal pediatric female; and
3. Prescriber must verify that female members are not pregnant and are currently using reliable contraception; and
4. 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
5. Authorization consideration requires a patient-specific, clinically significant reason why oral fluconazole and all topical antifungals (prescription and over-the-counter) FDA approved for the treatment of VVC are not appropriate for the member; and
6. A quantity limit of 4 tablets for a 1-day supply will apply.

Additionally, the College of Pharmacy recommends updating the current Noxafil® (posaconazole) criteria based on the recent FDA approvals (changes shown in red):

Noxafil® (Posaconazole) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Prophylaxis of invasive *Aspergillus* and *Candida* infections in high-risk patients due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy with product use as follows:
      i. Delayed-release (DR) tablets: Adults and pediatric members 2 years of age and older who weigh >40kg; or
      ii. Intravenous (IV) injection: Adults and pediatric members 2 years of age and older; or

iii. Oral suspension: Adults and pediatric members 13 years of age and older; or
iv. PowderMix for DR oral suspension: Pediatric members 2 years of age and older who weigh ≤40kg; or

b. Treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adults and pediatric members 13 years of age and older with product use as follows:
   i. For the treatment of OPC, including rOPC to itraconazole and/or fluconazole, only the oral suspension may be used; or
c. Treatment of invasive aspergillosis in adults and pediatric members 13 years of age and older with product use as follows:
   i. For the treatment of invasive aspergillosis, only the IV injection or DR tablets may be used; or

2. Treatment of invasive mucormycosis; or
3. Other appropriate diagnoses for which Noxafil® is not FDA approved may be considered with submission of a manual prior authorization.~~;~~ ~~and~~

~~4. For the diagnosis of OPC, only the oral suspension may be used.~~

Finally, the College of Pharmacy recommends removing the prior authorization criteria for Onmel® (itraconazole oral tablets) based on product discontinuation (changes shown in red):

~~**Onmel® (Itraconazole Oral Tablets) Approval Criteria:**~~

~~1. An FDA approved diagnosis of onychomycosis of the toenail caused by *Trichophyton rubrum* or *T. mentagrophytes;* and~~
~~2. A patient-specific, clinically significant reason why itraconazole 100mg oral capsules cannot be used in place of Onmel® 200mg tablets must be provided.~~

Recommendation 7: Vote to Prior Authorize Zynlonta® (Loncastuximab Tesirine-lply) and Update the Approval Criteria for the Lymphoma Medications

VOTE ITEM AT JUNE MEETING

The College of Pharmacy recommends the prior authorization of Zynlonta® (loncastuximab tesirine-lply) with the following criteria (shown in red):

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

1. Diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified, or DLBCL arising from low grade lymphoma, or high-grade B-cell lymphoma; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy; and

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

Additionally, the College of Pharmacy recommends updating the Brukinsa® (zanubrutinib) and Yescarta® (axicabtagene ciloleucel) criteria based on the recent FDA approvals (shown in red):

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

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

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

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

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 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.

Finally, the College of Pharmacy recommends updating the Keytruda® (pembrolizumab) criteria based on the National Comprehensive Cancer Network (NCCN) guideline update and the manufacturer voluntary market withdrawal (shown in red):

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

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

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

1. Diagnosis of locally advanced, unresectable, or metastatic gastric or GEJ adenocarcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. For first-line therapy:
    a. Human epidermal receptor 2 (HER2)-positive disease; and
    b. In combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy.~~; or~~

~~4. For second-line or greater therapy:~~
    ~~a. As a single agent; and~~
    ~~b. Tumor expresses programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1]; and~~
    ~~c. Following disease progression on or after 2 or more lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2-targeted therapy.~~

Recommendation 8: Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Exkivity® (Mobocertinib), Lumakras™ (Sotorasib), and Rybrevant™ (Amivantamab-vmjw)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2022.

Recommendation 9: Annual Review of Ayvakit™ (Avapritinib) and Bynfezia Pen™ (Octreotide)

NO ACTION REQUIRED.

Recommendation 10: Annual Review of Nasal Allergy Medications and 30-Day Notice to Prior Authorize Ryaltris™ (Olopatadine/Mometasone Nasal Spray)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2022.

Recommendation 11: Annual Review of Heart Failure (HF) Medications

NO ACTION REQUIRED.

Recommendation 12: Annual Review of Anti-Diabetic Medications and 30-Day Notice to Prior Authorize Kerendia® (Finerenone), Rezvoglar™ (Insulin Glargine-aglr), and Semglee® (Insulin Glargine-yfgn)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2022.

Recommendation 13: Annual Review of Muscular Dystrophy Medications

NO ACTION REQUIRED.

Recommendation 14: Annual Review of Lumizyme® (Alglucosidase Alfa) and 30-Day Notice to Prior Authorize Nexviazyme® (Avalglucosidase Alfa-ngpt)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2022.

Recommendation 15: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 16: Future Business

NO ACTION REQUIRED.

OU Health Physicians Dermatology
619 NE 13th St. OKC, OK 73104
Ph: (405) 271-6110
Fax: (405) 271-5992

To Whom It May Concern:

In their 2016 acne guidelines the American Academy of Dermatology refers to topical retinoids as "the core of topical therapy for acne, [they] are ideal for comedonal acne and, when used in combination with other agents, for all acne variants." Indeed topical retinoids appear as a 1st line treatment option for acne of all severities with the highest strength of recommendation supported by the highest levels of evidence.

Their place at the core of acne treatment was reiterated in 2018 by an international consensus statement where, among the many treatment modalities, only topical retinoid treatment was selected to appear in the conclusion which read, "retinoids should form the cornerstone of therapy. The variety of formulations and concentrations of available agents provides great flexibility for clinicians to individualize therapeutic regimens for patients, while achieving good results." However, there is an ongoing issue with pharmacy coverage of topical retinoids that is limiting this touted flexibility, and preventing access to care for Oklahoma Medicaid beneficiaries. Retinoid naive patients will not be able to tolerate higher concentrations of the medication and therefore is not appropriate for all patients. Furthermore, it leads to waste as many providers are forced to prescribe higher concentrations of a medication the patient only uses once and throws away.

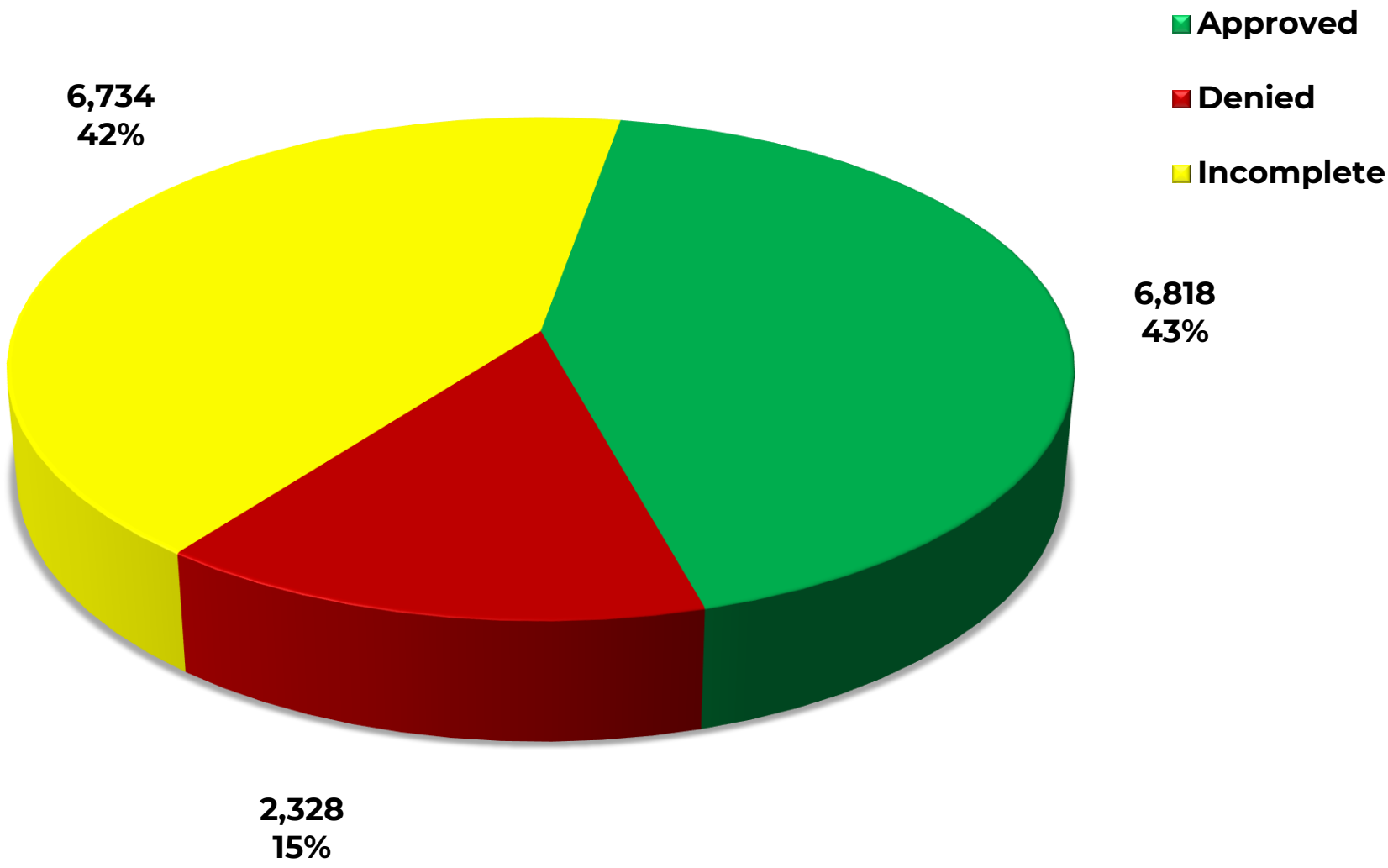
Of the many options currently available on the market, there is in reality only one option available to OK Medicaid patients: Tazorac 0.1%. Supposedly, Tazorac 0.1% and Tazorac 0.05% are both options, however Tazorac 0.05% is, in effect, non-formulary due to current contractual arrangements. At this time, only one NDC for the lower dose option is covered, however this NDC has been discontinued. To be clear, Tazorac 0.05% is on the market, and is available, but of the currently available NDCs, zero are covered. For prescribers wishing to start a retinoid naïve patient with a lower strength retinoid, the reality of the situation is that they have zero options.

This has been an ongoing issue for too long. OU Health's dermatology providers are requesting the DUR Board to take the necessary steps to either approve an NDC(s) of Tazorac 0.05% that is actually available to pharmacies, or approve the much less expensive generic tretinoin. Topical retinoid therapy is the standard of care. Our Oklahoma patients deserve the standard of care. We must do better. Excluding a medication over a loophole rooted in contractual disagreements is hurting our patients.

Thank you for your consideration,
OU Health Dermatology

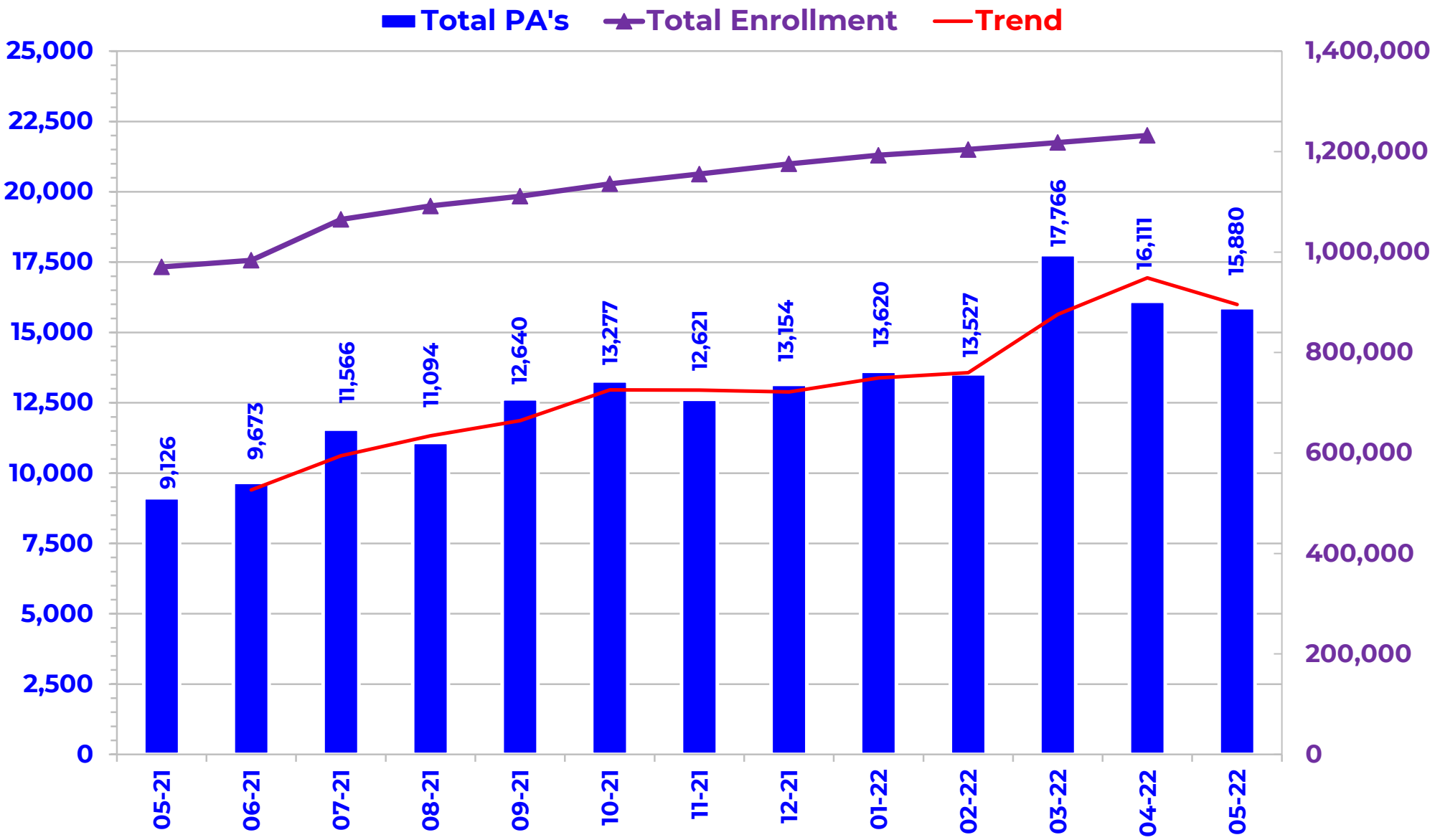
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: MAY 2022



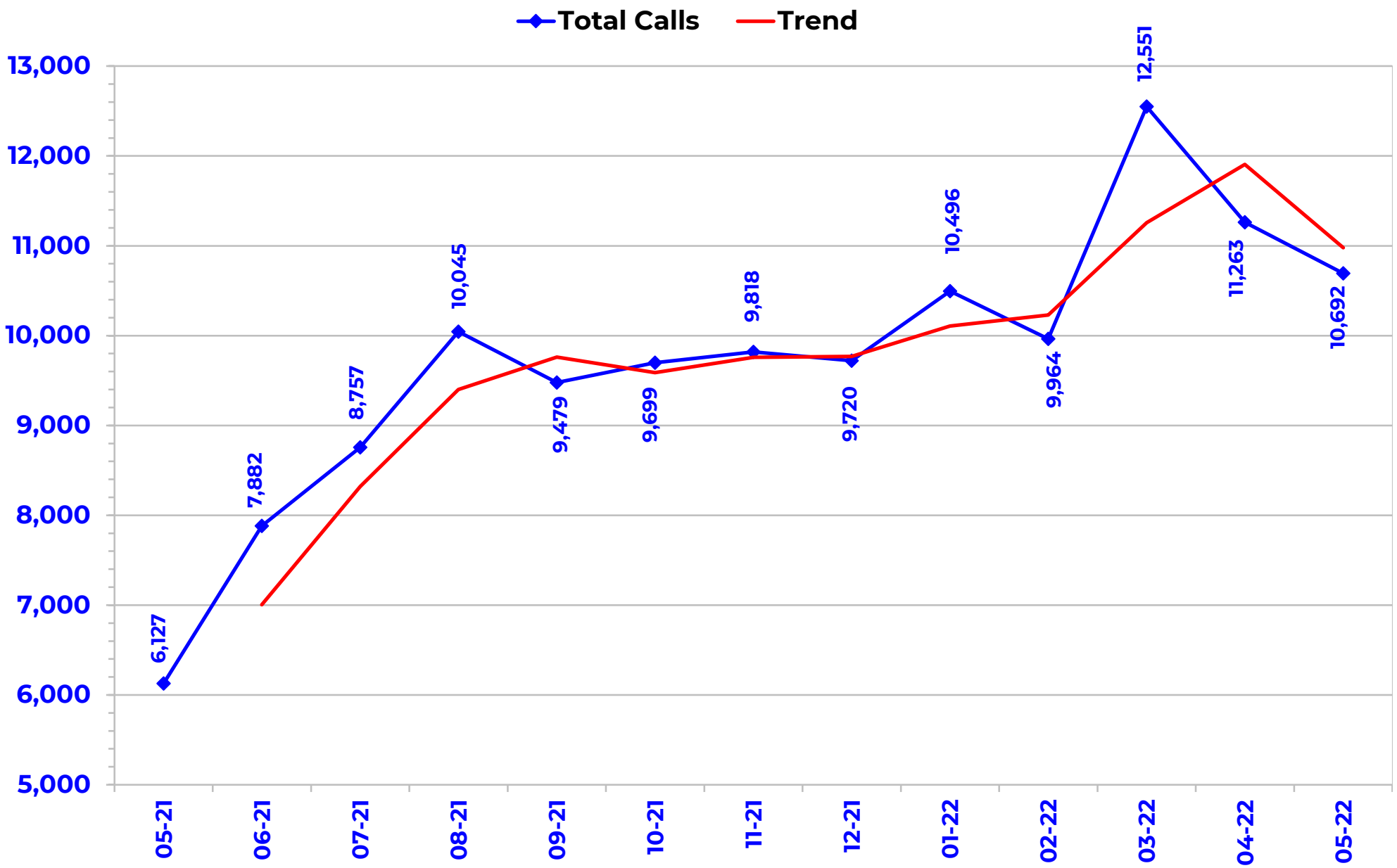
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: MAY 2021 – MAY 2022



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
MAY 2021 – MAY 2022



Prior Authorization Activity

5/1/2022 Through 5/31/2022

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	111	28	8	75	352
Analgesic - NonNarcotic	15	0	2	13	0
Analgesic, Narcotic	369	132	48	189	153
Angiotensin Receptor Antagonist	11	1	1	9	360
Antiasthma	100	32	25	43	242
Antibiotic	46	19	7	20	238
Anticonvulsant	212	109	14	89	301
Antidepressant	465	94	61	310	340
Antidiabetic	1,517	565	272	680	355
Antifungal	10	4	1	5	82
Antigout	13	5	0	8	359
Antihemophilic Factor	13	9	0	4	271
Antihistamine	62	12	16	34	336
Antimalarial Agent	137	97	11	29	346
Antimigraine	577	91	180	306	249
Antineoplastic	272	166	11	95	171
Antiobesity	14	0	14	0	0
Antiparasitic	38	8	5	25	14
Antiulcers	43	7	13	23	102
Anxiolytic	20	1	2	17	179
Atypical Antipsychotics	570	219	66	285	352
Benign Prostatic Hypertrophy	16	0	9	7	0
Biologics	343	168	47	128	289
Bladder Control	114	6	37	71	268
Blood Thinners	749	406	53	290	339
Botox	72	44	19	9	313
Buprenorphine Medications	88	36	11	41	87
Calcium Channel Blockers	30	6	3	21	315
Cardiovascular	116	52	19	45	304
Chronic Obstructive Pulmonary Disease	348	60	96	192	339
Constipation/Diarrhea Medications	335	60	94	181	238
Contraceptive	47	10	12	25	359
Corticosteroid	14	1	4	9	87
Dermatological	491	140	144	207	210
Diabetic Supplies	940	354	151	435	252
Endocrine & Metabolic Drugs	89	44	10	35	229
Erythropoietin Stimulating Agents	34	21	1	12	110
Fibric Acid Derivatives	10	0	2	8	0

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Fibromyalgia	14	2	4	8	194
Fish Oils	42	3	20	19	360
Gastrointestinal Agents	257	49	53	155	204
Genitourinary Agents	17	3	4	10	177
Glaucoma	36	8	5	23	180
Growth Hormones	92	72	6	14	141
Hematopoietic Agents	18	6	3	9	279
Hepatitis C	291	191	13	87	9
HFA Rescue Inhalers	12	0	2	10	0
Insomnia	123	14	29	80	206
Insulin	293	89	42	162	357
Miscellaneous Antibiotics	22	4	1	17	98
Multiple Sclerosis	81	44	8	29	178
Muscle Relaxant	68	3	13	52	136
Nasal Allergy	170	31	41	98	139
Neurological Agents	151	48	34	69	203
Neuromuscular Agents	12	3	0	9	228
NSAIDs	50	2	8	40	268
Ocular Allergy	19	0	4	15	0
Ophthalmic	22	1	4	17	26
Ophthalmic Anti-infectives	18	6	0	12	20
Ophthalmic Corticosteroid	16	4	0	12	291
Osteoporosis	26	10	7	9	358
Other*	389	76	73	240	303
Otic Antibiotic	30	6	4	20	9
Respiratory Agents	56	35	5	16	245
Smoking Cessation	20	1	13	6	148
Statins	95	9	36	50	187
Stimulant	1,787	1,168	109	510	351
Testosterone	182	44	42	96	338
Thyroid	26	7	6	13	279
Topical Antifungal	51	2	11	38	223
Topical Corticosteroids	103	2	58	43	45
Vitamin	175	33	68	74	205
Pharmacotherapy	64	47	1	16	259
Emergency PAs	0	0	0	0	
Total	**13,279**	**5,030**	**2,196**	**6,053**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	38	17	2	19	326
Compound	19	11	0	8	17
Cumulative Early Refill	1	0	0	1	0
Diabetic Supplies	4	4	0	0	266
Dosage Change	482	440	0	42	15
High Dose	5	3	0	2	150
IHS-Brand	2	2	0	0	360
Ingredient Duplication	6	3	0	3	11
Lost/Broken Rx	148	138	2	8	43
MAT Override	270	215	5	50	83
NDC vs. Age	395	231	49	115	253
NDC vs. Sex	12	8	0	4	81
Nursing Home Issue	72	49	3	20	25
Opioid MME Limit	168	38	21	109	120
Opioid Quantity	43	27	4	12	175
Other	45	35	1	9	26
Prescriber Temp Unlock	3	2	0	1	268
Quantity vs. Days Supply	778	494	41	243	256
STBS/STBSM	19	11	1	7	88
Step Therapy Exception	27	13	2	12	337
Stolen	17	14	0	3	13
Third Brand Request	47	33	1	13	17
Overrides Total	**2,601**	**1,788**	**132**	**681**	
Total Regular PAs + Overrides	**15,880**	**6,818**	**2,328**	**6,734**	

Denial Reasons	
Unable to verify required trials.	5,685
Does not meet established criteria.	2,354
Lack required information to process request.	1,014
Other PA Activity	
Duplicate Requests	1,418
Letters	33,454
No Process	17
Changes to existing PAs	1,191
Helpdesk Initiated Prior Authorizations	1,086
PAs Missing Information	1

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

SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update

Oklahoma Health Care Authority
June 2022

SoonerPsych Prescriber Mailing Summary

The SoonerPsych program is an educational quarterly mailing to prescribers treating members utilizing atypical antipsychotic medications. Each mailing includes a gauge showing prescribers how their practice compares to those of other SoonerCare prescribers of atypical antipsychotic medications regarding potential differences from evidence-based prescribing practices. Each mailing also includes an informational page with evidence-based material related to the mailing topics. Mailing topics are comprised of 4 modules: adherence, diagnosis, metabolic monitoring, and polypharmacy as defined below.

The SoonerPsych program has been using a "report card" format since April 2014. Beginning in April 2016, educational letters were sent to the same group of prescribers with all modules included in each mailing. The mailing list is updated approximately every 2 years, and included prescribers receive 4 letters per year to better inform them of their SoonerCare members taking atypical antipsychotic medications and to make it more convenient to track their patients and prescribing over time including any improvements or changes. The mailing list was last updated in January 2022, and inclusion criteria required the prescriber to have at least 4 SoonerCare members taking atypical antipsychotic medications.

Effective January 2017, data collection was expanded from a previous research-based approach to include additional diagnosis fields and monitoring (lipids and glucose) fields in order to provide a more clinically meaningful percentage for prescribers. The following list outlines definitions for each module included in the revised SoonerPsych mailing:

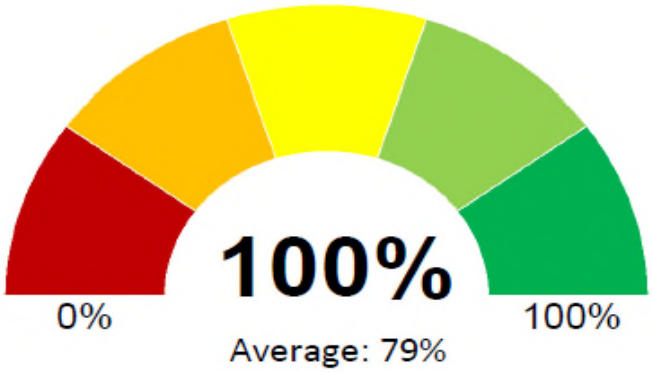
- **Adherence:** Adherence is defined as members whose proportion of days covered (PDC) or adherence calculated from pharmacy claims history for atypical antipsychotic medications was ≥80%.
- **Diagnosis:** Diagnosis is defined as members whose recent 12-month medical claims history included a diagnosis with a strong indication for prescribing an atypical antipsychotic medication. These diagnoses include: schizophrenia, bipolar disorder, delusional disorders, other nonorganic psychoses, autism spectrum disorder, mood disorder,

obsessive-compulsive disorder, and severe depression with or without psychotic features.

- **Metabolic Monitoring:** Metabolic monitoring is defined as members whose recent 12-month medical claims history included glucose testing. Metabolic monitoring also evaluates the recent 12-month medical claims history for lipid testing for members with a diagnosis of hyperlipidemia.
- **Polypharmacy:** Polypharmacy is defined as members whose pharmacy claims history indicated concurrent use of 2 or more atypical antipsychotic medications for >90 days.

SoonerPsych Example Gauge

Each gauge includes the individual prescriber's performance in relation to the specific module as well as the average of other SoonerCare prescribers for comparison. The following is an example gauge included in the mailings.

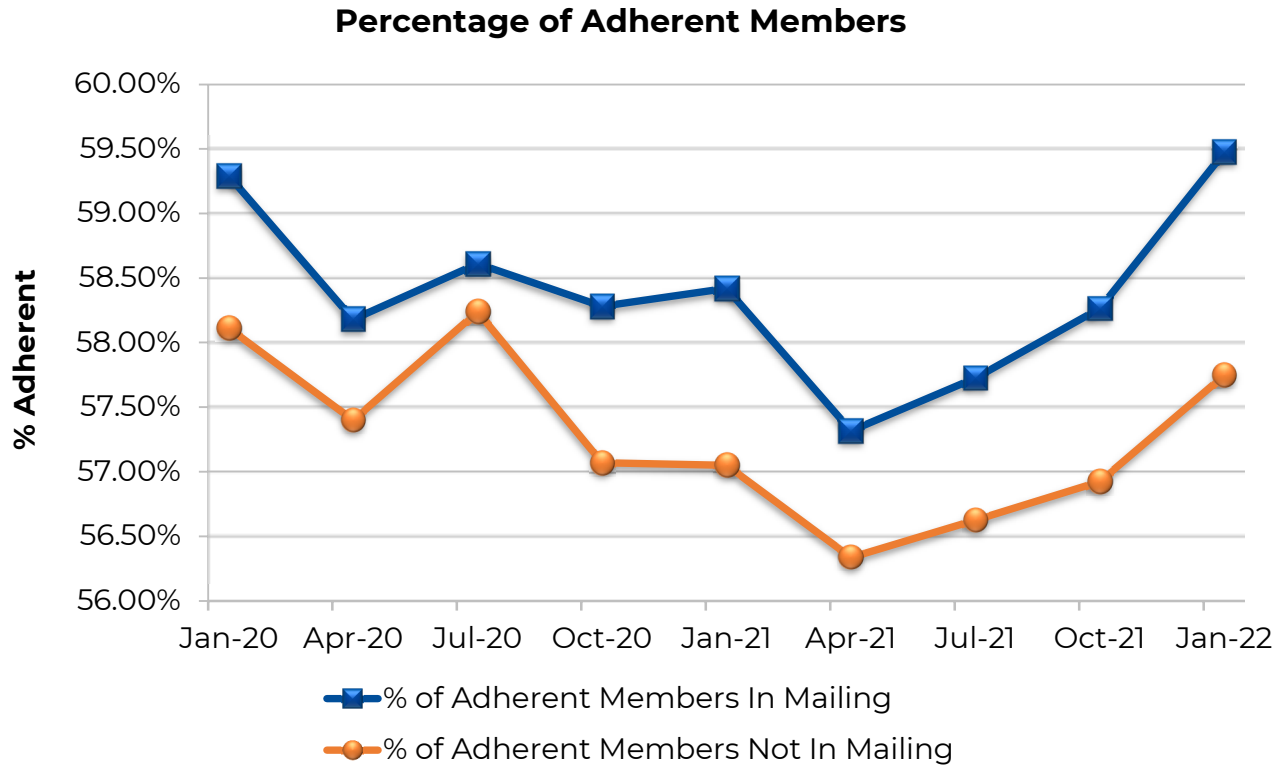


SoonerPsych Trends

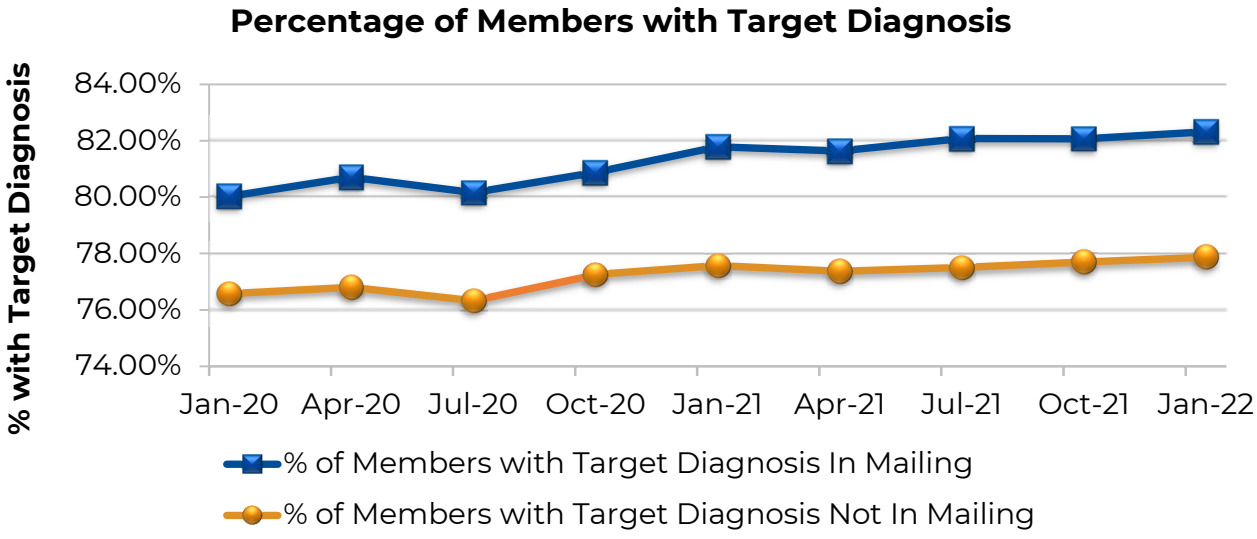
The following graphs show the SoonerPsych trends for member adherence, diagnosis, metabolic monitoring, and polypharmacy from January 2020 to January 2022. Members whose prescribers were included in the SoonerPsych mailings are designated separately from those members whose prescribers were not included in the mailings. It is important to note that starting with the July 2019 mailing, the SoonerPsych data was adjusted for outliers, after input from the Drug Utilization Review (DUR) Board at the July 2019 DUR Board meeting, to show a more meaningful comparison of prescribers included in the mailing and prescribers not included in the mailing. Although SoonerPsych trends are tracked over time, it may be more meaningful to evaluate the mailings starting in January 2020 and going forward as a new data set since the prescriber mailing list was last updated in January 2022 to include a larger number of prescribers and prescribers who were not previously receiving a mailing.

The following graph shows the SoonerPsych trends for the percentage of adherent members. Members are considered adherent if their PDC was

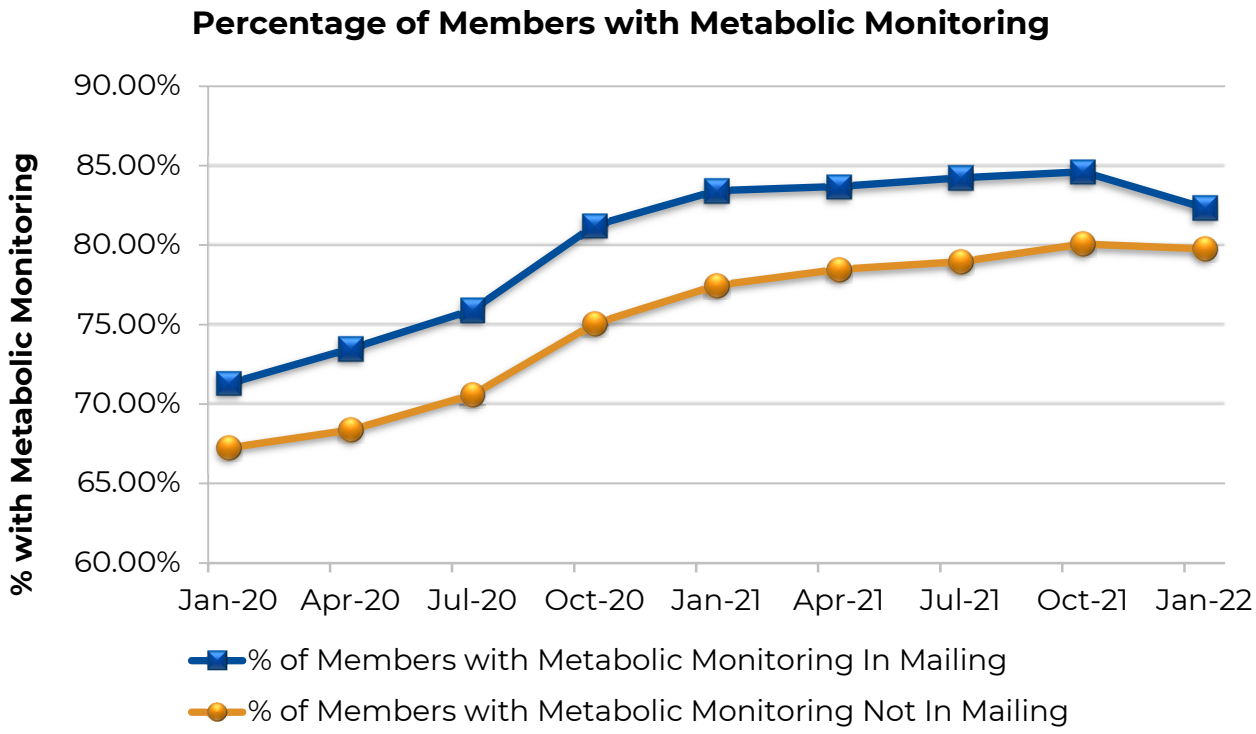
≥80%. Please note, the vertical axis starts at 56% of members in order to reflect small changes.



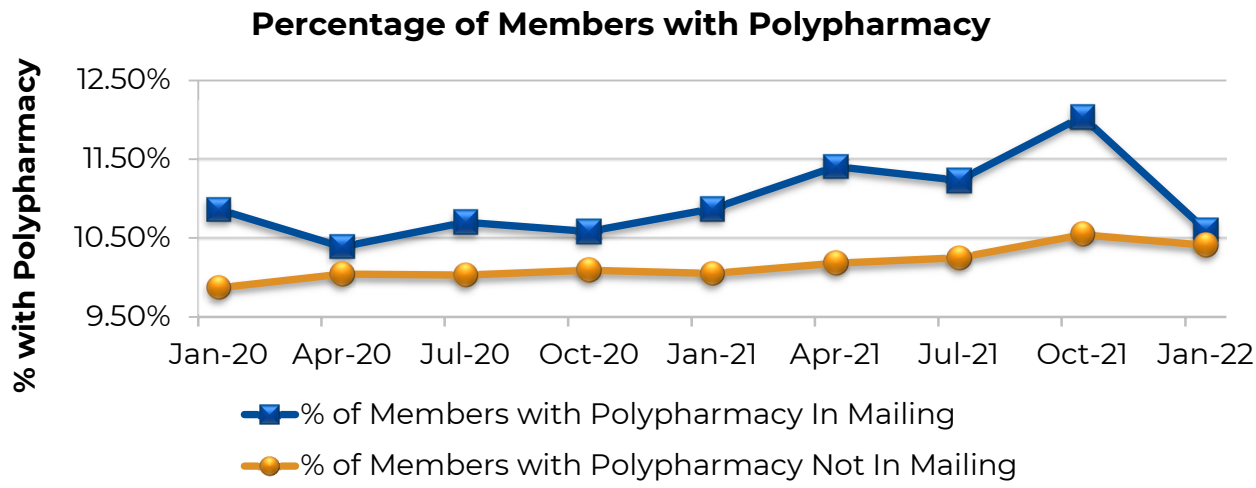
The following graph shows the SoonerPsych trends for the percentage of members whose recent 12-month medical claims history included a diagnosis with a strong indication for prescribing an antipsychotic medication. Please note, the vertical axis starts at 74% of members in order to reflect small changes.



The following graph shows the SoonerPsych trends for the percentage of members with appropriate metabolic monitoring while on an antipsychotic medication. Please note, the vertical axis starts at 60% of members in order to reflect small changes.



The following graph shows the SoonerPsych trends for the percentage of members with polypharmacy (concurrent use of 2 or more atypical antipsychotic medications for >90 days). Please note, the vertical axis starts at 9.5% of members in order to reflect small changes, and a lower percentage is a better outcome (indicates less prescribing of concomitant atypical antipsychotic medications).



Pediatric SoonerPsych Antipsychotic Monitoring Program Prescriber Mailing Summary

The Oklahoma Health Care Authority (OHCA) is also responsible for establishing and maintaining an additional program to monitor and manage appropriate utilization of antipsychotic medications specifically for children, including children in the foster care system, as part of a requirement by the Centers for Medicare and Medicaid Services (CMS). To accomplish these purposes, the College of Pharmacy developed the Pediatric SoonerPsych program in October 2019. Pediatric SoonerPsych is updated twice per year and includes providers caring for pediatric members receiving antipsychotic medications. Specific provider focus alternates on a semi-annual basis between all children and those children in the foster care system. Pediatric SoonerPsych evaluates prescribing patterns and medical claims across 4 topics as previously described: medication adherence, target diagnosis, polypharmacy, and metabolic monitoring.

Pediatric SoonerPsych inclusion criteria was limited to providers whose prescribing of antipsychotic medications for pediatric SoonerCare members varied significantly when compared to other SoonerCare providers in 1 or more of the 4 topics listed above.

Providers received an educational mailing and member list if they were the last prescriber of record for an antipsychotic medication and were in the most concerning cohort of prescribers. Following receipt of the Pediatric SoonerPsych mailings, providers were offered a virtual visit by an academic detailing pharmacist and/or a consultation with an OHCA child psychiatrist. Providers were encouraged to participate in the pediatric psychiatry Project ECHO (Extension for Community Health Care Outcomes) for medical education and care management. Additional services through OHCA Care Management and Behavioral Health Care Management were also encouraged. Providers meeting criteria for pediatric members receive mailings and educational offerings each December. Providers meeting criteria for pediatric members in the foster care system receive mailings and educational offerings each June.

Pediatric SoonerPsych Trends

The following tables show the resultant changes observed from 12/1/2020 through 11/30/21. Provider numbers have been assigned to preserve the privacy of providers and will change as new providers are included in recent cohorts. In all tables, a lower number indicates improvement. Historically, improvement in the area of adherence has proved difficult to measure. For the first time since 2019, medication adherence appeared to improve from 233 total members to 247 members with PDC ≥80%. The Pediatric SoonerPsych educational materials emphasize the appropriate use of

antipsychotic medications for appropriate diagnoses. Lowering the dose and/or frequency (i.e., tapering) of these medications with eventual discontinuation is suggested for members who do not meet diagnostic criteria. With this in mind, some intentional medication tapering may be represented as poor adherence.

Across all topics, at least 1 provider was able to improve to the degree that they no longer met criteria for the next mailing's cohort. Additionally, modest summative improvement was seen across all categories, with the possible exception of adherence.

The following table shows the number of pediatric members having poor adherence (PDC <80%) to antipsychotic medication(s) for each cohort provider.

Pediatric SoonerPsych Trends: Poor Adherence (PDC <80%)		
Provider #	**2020 Number of Members**	**2021 Number of Members**
5	65	65
7	42	*
9	50	43
21	41	48
31	*	33
35	49	*
48	*	38
Total◊	**247**	**227**

*Did not meet cohort criteria
◊ Lower number indicates improvement
PDC = proportion of days covered

The following table shows the number of pediatric members without a diagnosis supporting the use of antipsychotic medications for each cohort provider.

Pediatric SoonerPsych Trends: Lack of Target Diagnosis		
Provider #	**2020 Number of Members**	**2021 Number of Members**
5	79	95
4	44	43
9	65	*
21	45	56
31	*	49
35	80	62
Total◊	**313**	**305**

*Did not meet cohort criteria
◊ Lower number indicates improvement

The following table shows the number of members receiving 2 or more antipsychotic medications for >90 days for each cohort provider.

Pediatric SoonerPsych Trends: Polypharmacy		
Provider #	**2020 Number of Members**	**2021 Number of Members**
21	8	8
28	8	*
35	7	8
36	14	13
44	8	8
45	*	9
48	10	7
Total◊	**55**	**53**

*Did not meet cohort criteria
◊ Lower number indicates improvement

The following table shows the number of pediatric members receiving antipsychotic medication(s) with no metabolic monitoring for each cohort provider.

Pediatric SoonerPsych Trends: Lack of Metabolic Monitoring		
Provider #	**2020 Number of Members**	**2021 Number of Members**
1	*	2
5	4	*
8	*	3
12	3	*
16	4	*
18	*	3
25	4	3
36	4	*
44	*	3
Total◊	**19**	**14**

*Did not meet cohort criteria
◊ Lower number indicates improvement

Conclusions

Recent SoonerPsych trends comparing January 2020 through January 2022 indicate overall improvements in the percentage of adherent members, the percentage of members with a target diagnosis, and metabolic monitoring. The percentage of members with polypharmacy is similar for members whose prescribers received the SoonerPsych mailings compared to those not included in the mailings in 2020 and 2021. Polypharmacy previously did not show positive trends in 2019 for those prescribers included in the mailing;

however, after adjusting the data for outliers starting in July 2019, the percentage of members with polypharmacy was similar for members whose prescribers received the mailings compared to those not included in the mailings. Continuing to adjust the data for outliers and following the results of the new prescriber list over time may provide more opportunities for additional prescriber-specific interventions. Overall, results indicate consistently receiving evidence-based educational mailings reminds prescribers of evidence-based practices and reduces some potentially inappropriate prescribing. Recent changes to the mailing format (including all modules in each mailing, mailing to consistent prescribers, and updating the prescriber mailing list), as well as expanding the data collection process and adjusting the data for outliers, are intended to sustain improvements and reduce waning interventions. The College of Pharmacy will continue to work with OHCA to improve educational mailings with the goal of improving the quality of care for SoonerCare members utilizing atypical antipsychotic medications.

Since the Pediatric SoonerPsych program initiation, trends indicate overall improvements in the areas of diagnosis, metabolic monitoring, and polypharmacy. Improvements in the area of adherence are more difficult to determine, owing to the likely co-occurrences of true poor adherence and intentional tapering. The greatest improvements continue to be seen in the area of metabolic monitoring. In the case of metabolic monitoring, only 1 of the previous year's cohort met the inclusion criteria at the end of the monitoring year. Overall results indicate the Pediatric SoonerPsych focused mailing and educational offerings are likely leading to improvements in antipsychotic medication management resulting in a lower risk of overprescribing and increased rates of recommended metabolic monitoring. The College of Pharmacy will continue to work with OHCA to identify providers who may benefit from Pediatric SoonerPsych activities with the goal of promoting evidence-based use of antipsychotic medications for pediatric members.

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

Appendix C

Vote to Prior Authorize Releuko™ (Filgrastim-ayow) and Update the Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs)

Oklahoma Health Care Authority
June 2022

Market News and Updates[1]

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

- **March 2022:** The FDA approved Releuko™ (filgrastim-ayow) as a biosimilar to Neupogen® (filgrastim) to treat chemotherapy-induced neutropenia (CIN).

Cost Comparison for Filgrastim Products

Product	Cost Per Syringe
Neupogen® (filgrastim) 300mcg/0.5mL PFS	$295.20
Releuko™ (filgrastim-ayow) 300mcg/0.5mL PFS	**$228.00**
Nivestym® (filgrastim-aafi) 300mcg/0.5mL PFS	$219.00
Granix® (tbo-filgrastim) 300mcg/0.5mL PFS	$134.70
Zarxio® (filgrastim-sndz) 300mcg/0.5mL PFS	$91.80

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).
PFS = pre-filled syringe

Recommendations

The College of Pharmacy recommends the prior authorization of Releuko™ (filgrastim-ayow) and Neulasta® (pegfilgrastim) and removing the prior authorization requirement for Nyvepria™ (pegfilgrastim-apgf) based on net costs (changes shown in red):

Nivestym® (Filgrastim-aafi) and Releuko™ (Filgrastim-ayow) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Neupogen® (filgrastim), Granix® (tbo-filgrastim), or Zarxio® (filgrastim-sndz) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost

changes in comparison to the reference product and/or other available biosimilar products.

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

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Granix® (tbo-filgrastim), ~~Neulasta® (pegfilgrastim)~~, 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.

[1] Kashiv Biosciences, LLC. Kashiv Biosciences Receives Approval for Its First Biosimilar Releuko™ (Filgrastim-ayow). *Business Wire*. Available online at: https://www.businesswire.com/news/home/20220302005951/en/Kashiv-Biosciences-Receives-Approval-for-Its-First-Biosimilar-RELEUKOTM-filgrastim-ayow. Issued 03/02/2022. Last accessed 04/27/2022.

Vote to Prior Authorize Lampit® (Nifurtimox)

Oklahoma Health Care Authority
June 2022

Market News and Updates[1]

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

- **August 2020:** The FDA approved Lampit® (nifurtimox) for the treatment of Chagas disease caused by *Trypanosoma cruzi* (*T. cruzi*) in pediatric patients from birth to younger than 18 years of age who weigh ≥2.5kg. Chagas is an infectious tropical disease that affects approximately 300,000 patients in the United States and is commonly found in Latin America. This disease is primarily transmitted to humans via the feces of infected triatomines but may also be transmitted by infected blood transfusions or infected organ transplantation. Chagas disease is curable if detected and treated soon after infection, but if left untreated, individuals become carriers and move to the chronic phase of the disease. Approximately 30% of patients in the chronic phase of the disease may experience life-threatening cardiovascular and gastrointestinal complications. The FDA granted Lampit® accelerated approval based on the number of treated patients who became immunoglobulin G (IgG) antibody negative or who showed at least a 20% decrease in optical density on 2 different IgG antibody tests against antigens of *T. cruzi*. The most common adverse reactions reported in the clinical study were vomiting, abdominal pain, headache, and decreased appetite.

Lampit® (Nifurtimox) Product Summary[2]

Indication(s): Lampit® is a nitrofuran antiprotozoal, indicated in pediatric patients (birth to younger than 18 years of age and weighing ≥2.5kg) for the treatment of Chagas disease (American trypanosomiasis), caused by *T. cruzi*.

How Supplied: 30mg and 120mg oral tablets

Dosing:

- Weight-based dosing to be taken 3 times daily with food for 60 days:
  - ≥41kg: 8-10mg/kg/day
  - <41kg: 10-20mg/kg/day
- Please see the Lampit® *Prescribing Information* for the recommended individual doses based on body weight.

Mechanism of Action: Nifurtimox is an antiprotozoal drug and studies suggest that this medication is metabolized and activated by Type I (oxygen insensitive) and Type II (oxygen sensitive) nitroreductases (NTR) leading to production of toxic intermediate metabolites and/or reactive oxygen species that induce DNA damage and cell death of both intracellular and extracellular forms of *T. cruzi*.

Contraindication(s):

- Known hypersensitivity to nifurtimox
- Alcohol consumption during treatment

Safety

- Potential for Genotoxicity and Carcinogenicity: In a study evaluating the cytogenetic effect of nifurtimox in pediatric patients 7 months to 14 years of age with Chagas disease, a 13-fold increase in chromosomal aberrations were observed. Carcinogenicity has been observed in mice and rats treated chronically with nitrofuran agents, which have a similar structure to nifurtimox. It is unknown if nifurtimox is associated with carcinogenicity in humans.
- Embryo-Fetal Toxicity: Based on animal studies, nifurtimox can cause fetal harm when administered to pregnant women. Pregnancy testing is recommended for females of reproductive potential and prior to treatment. Effective contraception should be used while on therapy and at least 6 months after the first dose. Male patients with female partners of reproductive potential should use condoms during treatment and for 3 months after the last dose.
- Worsening of Neurological and Psychiatric Conditions: Patients with a history of brain injury, seizures, psychiatric disease, or serious behavioral alterations may experience worsening of their condition, and close medical supervision is recommended in these patients and those that develop neurological disturbances or psychiatric drug reactions.
- Decreased Appetite and Weight Loss: This was reported in patients treated with nifurtimox in the clinical studies. Body weight should be checked every 14 days and dose adjustments should be made when clinically appropriate.
- Porphyria: The use of nifurtimox and other nitrofuran derivatives may precipitate acute attacks of porphyria.

Adverse Reactions: The most common adverse reactions reported in clinical studies (incidence ≥5%) were vomiting, abdominal pain, headache, decreased appetite, nausea, pyrexia, and rash.

Cost: The Wholesale Acquisition Cost (WAC) for Lampit® 30mg is $2.50 per tablet, while the WAC for Lampit® 120mg is $3 per tablet. For a member

weighing 30kg, the cost for a full course of treatment would be $540 based on the recommended dose of 360mg/day for 60 days.

Recommendations

The College of Pharmacy recommends the prior authorization of Lampit® (nifurtimox) with the following criteria:

Lampit® (Nifurtimox) Approval Criteria:

1. An FDA approved diagnosis of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi*; and
2. Member must be younger than 18 years of age and weigh ≥2.5kg; and
3. Lampit® must be prescribed by, or in consultation with, an infectious disease specialist; and
4. Prescriber must agree to counsel the member on the contraindication and potential drug interaction that may occur with concomitant use of Lampit® with alcohol, if applicable, based on the Lampit® *Prescribing Information*; and
5. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiating treatment with Lampit®; and
6. Female members of reproductive potential must be willing to use effective contraception during treatment with Lampit® and for 6 months after the last dose; and
7. Male members with female partners of reproductive potential must be willing to use condoms for contraception during treatment with Lampit® and for 3 months after the last dose; and
8. Prescriber must agree to monitor the member's weight every 14 days and adjust the Lampit® dosage accordingly, as recommended in the Lampit® *Prescribing Information*; and
9. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. Initial approvals will be for 30 days. For continuation of therapy after 30 days, an updated weight must be provided in order to authorize the appropriate amount of drug required for the remaining 30 days of treatment. The total approval duration will be for 60 days of treatment; and
11. A quantity limit of 270 tablets per 30 days will apply to the 30mg tablets, and a quantity limit of 225 tablets per 30 days will apply to the 120mg tablets.

[1] Bayer. U.S. Food and Drug Administration Approves Lampit® (Nifurtimox) for the Treatment of Chagas Disease in Children. *Business Wire*. Available online at: https://www.biospace.com/article/releases/u-s-food-and-drug-administration-approves-lampit-nifurtimox-for-the-treatment-of-chagas-disease-in-children/. Issued 08/07/2020. Last accessed 04/18/2022.

[2] Lampit® (Nifurtimox) Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Available online at: https://labeling.bayerhealthcare.com/html/products/pi/Lampit_PI.pdf. Last revised 01/2022. Last accessed 04/17/2022.

Vote to Prior Authorize Skytrofa® (Lonapegsomatropin-tcgd) and Voxzogo™ (Vosoritide) and Update the Approval Criteria for the Growth Hormone Products

Oklahoma Health Care Authority
June 2022

Market News and Updates[1,2]

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

- **August 2021:** The FDA approved Skytrofa® (lonapegsomatropin-tcgd) for the treatment of pediatric patients 1 year of age and older who weigh ≥11.5kg with growth hormone deficiency (GHD). Skytrofa® is the first product for pediatric GHD to be approved for once-weekly subcutaneous (sub-Q) administration.
- **November 2021:** The FDA approved Voxzogo™ (vosoritide), a C-type natriuretic peptide (CNP) analog, to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses. The use of Voxzogo™ for this indication was approved by the FDA under accelerated approval based on improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory studies. With this approval, Voxzogo™ is the first medication to be FDA approved for the treatment of children with achondroplasia.

Skytrofa® (Lonapegsomatropin-tcgd) Product Summary[3,4]

Indication(s): Skytrofa® (lonapegsomatropin-tcgd) is a pegylated prodrug of human growth hormone (hGH) indicated for the treatment of pediatric patients 1 year of age and older weighing ≥11.5kg with GHD.

How Supplied: Lyophilized powder in single-dose, dual-chamber, prefilled cartridges (containing the lyophilized drug in 1 chamber and diluent in the other chamber), available in 9 strengths: 3mg, 3.6mg, 4.3mg, 5.2mg, 6.3mg, 7.6mg, 9.1mg, 11mg, and 13.3mg

- The cartridges are for use only with the Skytrofa™ auto-injector, which is packaged separately and not supplied with the Skytrofa™ cartridges. The Skytrofa™ auto-injector is available for patients with a prescription for Skytrofa™ through Ascendis Pharma Customer Support.

Dosing and Administration:

- Recommended initial dose is 0.24mg/kg once weekly via sub-Q injection into the abdomen, buttock, or thigh for all patients, whether treatment-naïve or switching from daily somatropin injections
- Following initial dosing, the dose should then be individualized and titrated based on response
- Skytrofa™ is contraindicated in patients with closed epiphyses and should be discontinued once epiphyseal fusion has occurred

Contraindication(s):

- Acute critical illness after open-heart surgery, abdominal surgery, or multiple accidental trauma, or those with acute respiratory failure because of the risk of increased mortality with use of pharmacologic doses of somatropin
- Hypersensitivity to somatropin or any of the excipients in Skytrofa®
- Closed epiphyses
- Active malignancy
- Active proliferative or severe non-proliferative diabetic retinopathy
- Children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment due to the risk of sudden death

Adverse Reactions: The most common adverse reactions (occurring in ≥5% of patients receiving Skytrofa® and more frequently than in placebo) in clinical studies were viral infection, pyrexia, cough, nausea and vomiting, hemorrhage (including epistaxis, contusion, petechiae, and eye hemorrhage), diarrhea, abdominal pain, arthralgia, and arthritis.

Cost Comparison:

Product	Cost Per mg	Cost Per 28 Days[+]	Cost Per Year[+]
Skytrofa® (lonapegsomatropin-tcgd) 5.2mg cartridge	**$218.50**	**$4,544.80**	**$59,082.40**
Genotropin® (somatropin) 5mg/mL cartridge	$135.71	$2,714.11	$35,283.43

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
[+]Cost per 28 days and cost per year based on recommended dosing of 0.24mg/kg/week for both products for a member weighing 21kg.

Voxzogo™ (Vosoritide) Product Summary[5,6]

Indication(s): Voxzogo™ (vosoritide) is a human CNP analog indicated to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses.

- This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for

this indication may be contingent upon verification and description of clinical benefit in confirmatory studies.

How Supplied: Voxzogo™ is supplied as a co-pack containing:

- Lyophilized powder in 0.4mg, 0.56mg, or 1.2mg single-dose vials (SDVs)
- Diluent (sterile water for injection) in single-dose prefilled syringes
- Diluent transfer needles
- Single-dose administration syringes

Dosing and Administration:

- Voxzogo™ is administered once daily, at approximately the same time each day, by sub-Q injection into the thighs, abdomen, buttocks, or back of the upper arms. Injection sites should be rotated.
- Recommended dosing is based on actual body weight, with specific dose recommendations depending on the patient's weight range. All patients would require the use of 1 SDV (0.4mg, 0.56mg, or 1.2mg) once daily, regardless of weight (refer to the full dosing recommendations for each weight range in the full Voxzogo™ *Prescribing Information*).
- To reduce the risk of low blood pressure and its signs and symptoms, the patient should have adequate food intake prior to Voxzogo™ administration and should drink approximately 240-300mL of fluid during the hour prior to Voxzogo™ administration.
- Voxzogo™ should be permanently discontinued upon confirmation of no further growth potential, indicated by closure of epiphyses.

Contraindication(s): None

Adverse Reactions: The most common adverse reactions (occurring in ≥5% of patients receiving Voxzogo™ and more frequently than in placebo) in clinical studies were injection site erythema, injection site swelling, vomiting, injection site urticaria, arthralgia, decreased blood pressure, gastroenteritis, diarrhea, dizziness, ear pain, influenza, fatigue, seasonal allergy, and dry skin.

Cost: The Wholesale Acquisition Cost (WAC) of Voxzogo™ is $899 per SDV, regardless of the strength, resulting in an estimated cost of $26,970 per 30 days and $323,640 per year based on the FDA approved dosing requiring the use of 1 SDV per day.

Recommendations

The College of Pharmacy recommends the placement of Skytrofa® (lonapegsomatropin-tcgd) into Tier-2 of the growth hormone products Product Based Prior Authorization (PBPA) category with the following additional criteria:

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

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Supplementally rebated product(s)
ᵗAdditional approval criteria applies.

Skytrofa® (Lonapegsomatropin-tcgd) Approval Criteria:

1. Member must have a confirmed diagnosis of growth hormone deficiency (GHD) or panhypopituitarism meeting the initial growth hormone approval criteria (listed under "Initial Approval") for the member's specific diagnosis; and
2. Member's weight must be ≥11.5kg; and
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and
4. Prescriber must verify the member has been counseled on proper administration and storage of Skytrofa®; and
5. Initial approvals will be for the 0.24mg/kg weekly dose, using the specific dose recommended in the Skytrofa® *Prescribing Information*; and
6. Initial approvals will be for the duration of 6 months. For additional approval consideration:
    a. Dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Growth velocity should not be <2.5cm/year; and
    e. Prescriber must verify member still has open epiphyses; and

7. Skytrofa® will not be approved following epiphyseal closure. Skytrofa® is contraindicated in children with closed epiphyses.

Additionally, the College of Pharmacy recommends the prior authorization of Voxzogo™ (vosoritide) with the following criteria:

Voxzogo™ (Vosoritide) Approval Criteria:

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

Lastly, the College of Pharmacy recommends updating the current growth hormone prior authorization criteria with the following changes to be consistent with current guideline recommendations for growth hormone treatment (changes and additions shown in red):

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

1. Growth hormone deficiency (GHD) of 1 of the following types:
    a. Classic GHD as determined by childhood GH stimulation tests; or

~~b. Panhypopituitarism with history of pituitary or hypothalamic injury due to tumor, trauma, surgery, whole brain radiation, irradiation, hemorrhage or infarction, or a congenital anomaly; or~~
~~c. Panhypopituitarism in children with height ≥2.25 SD below the mean for age and gender and MRI evidence of pituitary stalk agenesis, empty sella, or ectopic posterior pituitary "bright spot"; or~~
b. Panhypopituitarism; or
c. Hypoglycemia with evidence for GHD; or
d. Neurosecretory dysfunction; or
e. Other evidence for GHD submitted for panel review and decision; or

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

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

Growth Hormone Tier-2 Approval Criteria:

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

~~**Requirements for Initiation of Growth Hormone Therapy – All Indications:**~~

~~1. Evaluated and prescribed by an endocrinologist, pediatric nephrologist, or infectious disease specialist; and~~
~~2. Covered indication; and~~
~~3. Member must be 2 years of age or older [*Exceptions*: hypoglycemia related to growth hormone deficiency (GHD): any age; idiopathic short stature (ISS): 8 years of age or older]; and~~
~~4. Height ≥2.25 SD below the mean for age (excludes chronic renal failure); and~~

~~5. Evidence of delayed bone age (undefined delay) (excludes chronic renal failure) and open epiphyses; and~~
~~6. The following information must be provided:~~
~~a. Growth chart; and~~
~~b. Parental heights.~~

Discontinuation of Therapy or Transition to Adult Therapy Criteria:

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

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

1. Children: 22 to 100mcg/kg/day ~~(in 3 to 7 doses per week)~~ according to current pediatric guidelines; or
2. Adults:
    a. Initial Dosing: 0.1 to 0.5mg per day – Doses should be evaluated and titrated at 1 to 2 month intervals targeting an insulin-like growth factor 1 (IGF-1) level within the age-adjusted reference range provided by the laboratory utilized [IGF-1 standard deviation score (SDS) between -2 and +2]. In general, younger patients may require higher doses than older patients. The following **initial** doses are suggested by the current American Association of Clinical Endocrinologists/American College of Endocrinology (AACE/ACE) guidelines, but these doses should be titrated based on IGF-1 levels:
        i. Age <30 years: 0.4 to 0.5mg per day (may be higher for patients transitioning from pediatric treatment); or
        ii. Age 30-60 years: 0.2 to 0.3mg per day; or
        iii. Age >60 years: 0.1 to 0.2mg per day; and
    b. Transition Dosing: In patients transitioning from pediatric to adult dosing, resuming GH doses at 50% of the dose last used in childhood is suggested, as they tend to be more tolerant of higher doses.

Growth Hormone Deficiency (GHD) Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years of age or older (unless hypoglycemia is present); and
    b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    c. Member must meet at least 1 of the following:
        i. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; ~~and~~ or
        ii. Member must have evidence of delayed bone age (undefined delay); and
    d. Member must have open epiphyses; and
    e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
    f. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available; and
    g. There must be no contributing medical conditions (e.g., cystic fibrosis, malnutrition, psychosocial deprivation); and
    h. Member must have suboptimal response of ≤10ng/mL on 2 of the following provocative growth hormone stimulation tests, using the highest level per date of testing. (Stimulation tests are always required for approval unless hypoglycemia is observed, in which case a random low glucose level and low growth hormone level would be acceptable):
        i. Propranolol with exercise; or
        ii. Levodopa; or
        iii. Insulin hypoglycemia test; or
        iv. Arginine HCl infusion; or
        v. Clonidine; or
        vi. Glucagon (not approved for use in children); or
    i. If hypoglycemia is present and member is growth hormone deficient: request may be approved for 6 months (other criteria above is not applicable). If the member has hypoglycemia, a low glucose level must be submitted along with additional evidence of GHD such as:
        i. Low insulin-like growth factor 1 (IGF-1), random growth hormone level, or suboptimal growth hormone stimulation tests; or
        ii. MRI evidence of congenital anomaly which includes pituitary damage or absence; or

iii. Other pituitary hormones also being replaced (e.g., thyroid, cortisol, etc.).

2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
   a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations ~~Standard dosing applies for members receiving pediatric dosing (0.044mg/kg/day) (Dose may vary based on whether pre-pubertal or pubertal. Is sometimes adjusted based on IGF-1 levels)~~; or
   b. Adult Dosing: Members with this diagnosis may transition to adult dosing (see "Growth Hormone Dosing" section above for recommendations for adult and transition dosing) after 1 or both of the following:
      i. Epiphyseal closure; or
      ~~ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]~~
      iii. GV <2.5cm/year; and
      iv. If either ~~the epiphyses have closed or covered height has been reached~~ of the above have occurred and the member has not yet transitioned to adult dosing, may be approved short term (3 months) to allow time for transition to adult dosing.
4. Continuation Approval:
   a. Medications and dosing should be appropriate; and
   b. Member should have had a recent office visit with new information regarding heights provided; and
   c. Member should be compliant; and
   d. GV should not be <2.5cm/year if not on adult dosing; and
   e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

Panhypopituitarism Approval Criteria:

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

    ii. Member must have evidence of delayed bone age (undefined delay); and
d. Member must have open epiphyses; and
e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
    i. For members with secondary panhypopituitarism due to tumor, trauma, or surgery 12 months post trauma or surgery, approval may be granted if no evidence of tumor recurrence and growth has not restarted. The member must still meet all the other criteria; however, authorization would not require height ≥2.25 SD below the mean in these circumstances; and
f. Member's growth chart and parental heights must be provided; and
    i. If the form is completed, a growth chart is not required; and
    ii. Parental heights are not always available; and
g. Member must have a history of pituitary or hypothalamic injury due to tumor, trauma, surgery, documented whole brain radiation, irradiation, hemorrhage or infarction, or a congenital anomaly; and
    i. Deficiency in ≥3 pituitary hormones and insulin-like growth factor 1 (IGF-1) ≥2.5 SD below the mean for member's age; or
    ii. No deficiency, or deficiency in <3 pituitary hormones, and IGF-1 <50th percentile and subnormal response of 10ng/mL or less on at least 2 provocative growth hormone stimulation tests, using the highest level per date of testing. (Stimulation tests are always required for approval unless hypoglycemia is observed, in which case a random low glucose level and low growth hormone level would be acceptable); or
h. If member has MRI evidence of pituitary stalk agenesis, empty sella, or ectopic posterior pituitary "bright spot", member is exempt from height requirement (*criteria letter e listed above*); and
    i. If they lack the hormones testosterone, luteinizing hormone (LH), or follicle-stimulating hormone (FSH) then an MRI is not required; or
i. If hypoglycemia is present and member is growth hormone deficient: request may be approved for 6 months (other criteria above is not applicable). If the member has hypoglycemia, a low glucose level must be submitted along with additional evidence of GHD such as:
    i. Low IGF-1, random growth hormone level, or suboptimal growth hormone stimulation tests; or
    ii. MRI evidence of congenital anomaly which includes pituitary damage or absence; or
    iii. Other pituitary hormones also being replaced (e.g., thyroid, cortisol); and

2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations ~~Standard dosing applies for members receiving pediatric dosing (0.044mg/kg/day) (Dose may vary based on whether pre-pubertal or pubertal. Is sometimes adjusted based on IGF-1 levels)~~; or
    b. Adult Dosing: Members with this diagnosis may transition to adult dosing (see "Growth Hormone Dosing" section above for recommendations for adult and transition dosing) after 1 or both of the following:
        i. Epiphyseal closure; or
        ii. ~~Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]~~
        iii. GV <2.5cm/year; and
        iv. If either ~~the epiphyses have closed or covered height has been reached~~ of the above have occurred and the member has not yet transitioned to adult dosing, may be approved short term (3 months) to allow time for transition to adult dosing.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. GV should not be <2.5cm/year if not on adult dosing; and
    e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

Neurosecretory Dysfunction Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years of age or older; and
    b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    c. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
    d. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
    e. Member must have evidence of delayed bone age and open epiphyses; and

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

2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations ~~Standard dosing applies for members receiving pediatric dosing (0.044mg/kg/day) (Dose may vary based on whether pre-pubertal or pubertal. Is sometimes adjusted based on IGF-1 levels)~~; or
    b. Adult Dosing: Members with this diagnosis may transition to adult dosing (see "Growth Hormone Dosing" section above for recommendations for adult and transition dosing) after 1 ~~or both~~ of the following:
        i. Epiphyseal closure; or
        ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
        iv. If ~~either the epiphyses have closed or covered height has been reached~~ any of the above have occurred and the member has not yet transitioned to adult dosing, may be approved short term (3 months) to allow time for transition to adult dosing.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. GV should not be <2.5cm/year if not on adult dosing; and

e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

Idiopathic Short Stature Approval Criteria:

1. Initial Approval:
   a. Member must be 8 years of age or older; and
   b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
   c. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
   d. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
   e. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
   f. Member's growth chart and parental heights must be provided
      i. If the form is completed, a growth chart is not required; and
      ii. Parental heights are not always available; and
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:
   a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations ~~0.47mg/kg/week~~. Treatment may continue until 1 ~~or both~~ of the following:
      i. Epiphyseal closure; or
      ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
      iii. GV <2.5cm/year; and
   b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
   a. Medications and dosing should be appropriate; and
   b. Member should have had a recent office visit with new information regarding heights provided; and
   c. Member should be compliant; and
   d. Epiphyses are open; and
   e. GV should not be <2.5cm/year.

Short Stature Associated with Chronic Renal Insufficiency (Pre-Transplantation) Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years of age or older; and
    b. Member's estimated creatinine clearance (CrCl) must be <50mL/min; and
    c. Member must not be post-kidney transplant; and
    d. Growth hormone therapy must be prescribed by an endocrinologist or pediatric nephrologist (or an advanced care practitioner with a supervising physician who is an endocrinologist or pediatric nephrologist); and
    e. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available; and
    f. Members meeting the above criteria are exempt from height requirements.
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, growth velocity (GV) is <2.5cm/year, or member has received renal transplant, therapy should be discontinued.
3. Dosing:
    a. Pediatric Dosing: Standard dosing applies for members receiving pediatric dosing (0.05mg/kg/day). Treatment may continue until 1 ~~or both~~ of the following:
        i. Renal transplantation; or
        ii. Epiphyseal closure; or
        iii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
        iv. GV <2.5cm/year; and
    b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
    a. Member is still pre-transplant; and
    b. Medications and dosing should be appropriate; and
    c. Member should have had a recent office visit with new information regarding heights; and
    d. Member should be compliant; and
    e. Epiphyses are open; and
    f. GV should not be <2.5cm/year.

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

1. Initial Approval:
    a. Member must be 2 years of age or older; and
    b. Member must have a chromosome analysis confirming the diagnosis of PWS; and
    c. Growth hormone (GH) therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    d. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
    e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
    f. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
    g. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available; and
2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: 0.24mg/kg/week. Treatment should continue until 1 ~~or both~~ of the following:
        i. Epiphyseal closure; or
        ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
    b. Adult Dosing: After attainment of adult height, adults with PWS may be considered for adult dosing if evidence is submitted documenting adult GH deficiency [e.g., low insulin-like growth factor 1 (IGF-1) level and GH stimulation testing]. ~~No proven benefit to continuing GH treatment in adulthood.~~
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. GV should not be <2.5cm/year; and
    e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

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

1. Initial Approval:
    a. Member must be 2 years of age or older; and
    b. Member must have a chromosome analysis confirming the diagnosis of Turner Syndrome in females or 45X 46XY mosaicism in males; and
    c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or growth velocity (GV) is <2.5cm/year, therapy should be discontinued.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations ~~standard dosing applies for members receiving pediatric dosing (0.054mg/kg/day)~~. Treatment should continue until 1 ~~or both~~ of the following:
        i. Epiphyseal closure; or
        ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
    b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Epiphyses should be open; and
    e. GV should not be <2.5cm/year.

Short Stature Associated with Noonan Syndrome Approval Criteria:

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

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

3. Dosing:
    a. Pediatric Dosing: Standard dosing applies for members receiving pediatric dosing (up to ~~0.044~~ 0.066mg/kg/day). Treatment should continue until 1 ~~or both~~ of the following:
        i. Epiphyseal closure; or
        ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year.
    b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Epiphyses should be open; and
    e. GV should not be <2.5cm/year.

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

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

2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:
    a. Pediatric Dosing: Standard dosing applies for members receiving pediatric dosing (up to ~~0.044~~ 0.05mg/kg/day). Treatment should continue until 1 ~~or both~~ of the following:
        i. Epiphyseal closure; or
        ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
    b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Epiphyses should be open; and
    e. GV should not be <2.5cm/year.

Small for Gestational Age (SGA) Approval Criteria:

1. Initial Approval:
    a. Member must be 2 years or age or older; and
    b. Documentation of birth weight <2,500 grams at gestational age of more than 37 weeks or birth weight or length below the 3rd percentile for gestational age; and
    c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    d. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
    e. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
    f. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
    g. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available; and
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed,

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

3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations ~~standard dosing applies for members receiving pediatric dosing (0.05-0.068mg/kg/day)~~. Treatment should continue until 1 ~~or both~~ of the following:
        i. Epiphyseal closure; or
        ii. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
    b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Epiphyses should be open; and
    e. GV should not be <2.5cm/year.

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[6] Savarirayan R, Tofts L, Irving M, et al. Once-Daily, Subcutaneous Vosoritide Therapy in Children with Achondroplasia: A Randomised, Double-Blind, Phase 3, Placebo-Controlled, Multicentre Trial. *Lancet* 2020; 396:684-92.

Vote to Prior Authorize Ponvory® (Ponesimod) and Update the Approval Criteria for the Multiple Sclerosis Medications

Oklahoma Health Care Authority
June 2022

Market News and Updates[1,2]

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

- **March 2021:** The FDA approved Ponvory® (ponesimod), a once-daily oral selective sphingosine-1-phosphate receptor 1 (S1P1) modulator, to treat adults with relapsing forms of multiple sclerosis (RMS) to include clinically isolated syndrome (CIS), relapsing-remitting MS (RRMS), and active secondary progressive MS (SPMS). The FDA approval is based, in part, on a 2-year, head-to-head Phase 3 clinical trial, Oral Ponesimod Versus Teriflunomide in Relapsing Multiple Sclerosis (OPTIMUM), in which Ponvory® 20mg demonstrated superior efficacy in significantly reducing annual relapses by 30.5% compared to teriflunomide (Aubagio®) 14mg in patients with RMS. Over the trial period, 71% of patients treated with Ponvory® had no confirmed relapses, compared to 61% in the teriflunomide group. The most common adverse reactions reported with ponesimod in the clinical trial were upper respiratory tract infection, hepatic transaminase elevation, and hypertension.
- **May 2021:** The FDA approved Zeposia® (ozanimod) oral capsules for the treatment of adults with moderately to severely active ulcerative colitis (UC), a chronic inflammatory bowel disease (IBD). Zeposia® is the first and only S1P1 receptor modulator approved for patients with moderately to severely active UC. The mechanism by which Zeposia® exerts therapeutic effects in UC is unknown but may involve the reduction of lymphocyte migration into the intestines, as it is thought that by targeting S1P1 receptors on lymphocytes, Zeposia® reduces the number of lymphocytes in peripheral blood. The approval for UC is based on data from True North, a pivotal Phase 3 trial evaluating Zeposia® as an induction and maintenance therapy versus placebo in adult patients with moderately to severely active UC. During induction at week 10, the trial met its primary endpoint of clinical remission (18% vs. 6%; P<0.0001). During maintenance at week 52, the trial met its primary endpoint of clinical remission (37% vs. 19%; P<0.0001). Decreases in rectal bleeding and stool frequency sub scores were observed as early as week 2 in patients treated with Zeposia®. Zeposia®

was previously FDA approved in March 2020 for the treatment of adults with RMS. Bristol Myers Squibb is continuing to evaluate Zeposia® in an ongoing open-label extension trial, which is assessing the longer-term profile of Zeposia® for the treatment of UC. The company is also investigating Zeposia® for the treatment of moderately to severely active Crohn's disease in the ongoing Phase 3 YELLOWSTONE clinical trial.

Ponvory® (Ponesimod) Product Summary[3]

Indication(s): Ponvory® (ponesimod) is a S1P1 modulator indicated for the treatment of RMS, to include CIS, RRMS, and active SPMS, in adults.

How Supplied:

- 14-day starter pack containing 2mg, 3mg, 4mg, 5mg, 6mg, 7mg, 8 mg, 9mg, 10mg strength oral tablets
- 20mg oral tablets

Dosing and Administration:

- Assessments should be done prior to the initiation of treatment with Ponvory® which include a complete blood count (CBC) including lymphocyte count, cardiac evaluation, liver function tests (LFTs), ophthalmic evaluation, medication history review for current/prior immunosuppressive/immune-modulating therapy, and varicella zoster virus (VZV) antibody test.
- Ponvory® should be initiated with the 14-day titration starter pack, followed by the recommended maintenance dose of 20mg once daily.
- First-dose monitoring is recommended for patients with sinus bradycardia, first- or second-degree [Mobitz type I] atrioventricular (AV) block, or a history of myocardial infarction (MI) or heart failure (HF).
- Ponvory® tablets should be swallowed whole and intact and can be taken with or without food.

Contraindication(s):

- MI, unstable angina, stroke, transient ischemic attack (TIA), decompensated HF requiring hospitalization, or Class III/IV HF within the last 6 months
- Presence of Mobitz type II second-degree, third-degree AV block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker

Cost Comparison:

Medication	Cost Per Unit	Cost Per Month	Cost Per Year
Ponvory® (ponesimod) 20mg tablet	**$284.00**	**$8,520.00**	**$102,240.00***
Aubagio® (teriflunomide) 14mg tablet	$283.95	$8,518.50	$102,222.00[+]
Gilenya® (fingolimod) 0.5mg capsule	$309.62	$9,288.60	$111,463.20[ß]
Mayzent® (siponimod) 2mg tablet	$282.02	$8,460.60	$101,527.20[¥]
Zeposia® (ozanimod) 0.92mg capsule	$257.30	$7,719.00	$92,628.00[±]

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = capsule or tablet
*Ponvory® cost per year is based on maintenance dose of 20mg once daily.
[+]Aubagio® cost per year based on maintenance dose of 14mg once daily.
[ß]Gilenya® cost per month and cost per year based on the recommended dosage for adults and pediatric patients (10 years of age and older) weighing more than 40kg of 0.5mg once daily.
[¥]Mayzent® cost per month and cost per year based on the recommended maintenance dosage of 2mg once daily.
[±]Zeposia® cost per month and cost per year based on the recommended maintenance dose of 0.92mg once daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Ponvory® (ponesimod) and recommends adding additional prior authorization criteria for Zeposia® (ozanimod), based on the new FDA approved indication for UC, with the following criteria (new criteria and updates noted in red):

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. 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
3. Member must not have received prior treatment with alemtuzumab; and
4. Member must not be concurrently using strong CYP3A4 and UGT1A1 inducers (e.g., rifampin, phenytoin, carbamazepine); and
5. Verification from the prescriber that the member has no active infection(s); and
6. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and

7. Verification from the prescriber that the member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Ponvory®; and
8. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
9. Verification from the prescriber that the member's blood pressure will be monitored during treatment with Ponvory®; and
10. 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
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 the member will be followed with appropriate monitoring per package labeling; and
12. 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
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 Ponvory® and for at least 1 week 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. 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.

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. 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
3. Member must not have received prior treatment with alemtuzumab; and
4. Member must not be concurrently using strong CYP2C8 inhibitors/inducers or breast cancer resistance protein (BCRP) inhibitors; 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. Prescriber must conduct an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Zeposia®; 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 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 a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Zeposia®; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
13. 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
14. 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
15. 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

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

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[1] Janssen Pharmaceutical Companies of Johnson & Johnson. Janssen Announces U.S. FDA Approval of Ponvory™ (Ponesimod), an Oral Treatment for Adults with Relapsing Multiple Sclerosis Proven Superior to Aubagio® (Teriflunomide) in Reducing Annual Relapses and Brain Lesions. Available online at: https://www.janssen.com/janssen-announces-us-fda-approval-ponvory-ponesimod-oral-treatment-adults-relapsing-multiple. Issued 03/19/2021. Last accessed 04/18/2022.

[2] Bristol-Myers Squibb. United States Food and Drug Administration Approves Bristol Myers Squibb's Zeposia® (Ozanimod), a New Oral Treatment for Relapsing Forms of Multiple Sclerosis. *Business Wire*. Available online at: https://news.bms.com/news/corporate-financial/2020/US-Food-and-Drug-Administration-Approves-Bristol-Myers-Squibbs-ZEPOSIA-ozanimod-a-New-Oral-Treatment-for-Relapsing-Forms-of-Multiple-Sclerosis/default.aspx. Issued 03/26/2020. Last accessed 02/17/2022.

[3] Ponvory™ Prescribing Information. Janssen Pharmaceutical Companies. Available online at: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/PONVORY-pi.pdf. Last revised 04/2021. Last accessed 04/18/2022.

Vote to Prior Authorize Brexafemme® (Ibrexafungerp) and Update the Approval Criteria for the Systemic Antifungal Medications

Oklahoma Health Care Authority
June 2022

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

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

- **May 2021:** The FDA approved Noxafil® (posaconazole) PowderMix delayed-release (DR) oral suspension, for the prophylaxis of invasive *Aspergillus* and *Candida* infections in pediatric patients 2 years of age and older (weighing ≤40kg) who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy. Noxafil® oral suspension is not substitutable with Noxafil® DR tablets or Noxafil® PowderMix DR for oral suspension due to the differences in the dosing of each formulation. Therefore, the specific dosage recommendations for each of the formulations should be followed. Merck's launch plans for Noxafil® PowderMix are tentatively set for July 2022. Noxafil® PowderMix will be available as a 300mg DR oral suspension.
- **June 2021:** The FDA approved Brexafemme® (ibrexafungerp tablets) for oral use in patients with vulvovaginal candidiasis (VVC), also known as vaginal yeast infection. Brexafemme® is the first FDA approved drug in a novel antifungal class in more than 20 years. It was approved based on positive results from 2 placebo-controlled Phase 3 studies in which oral ibrexafungerp demonstrated efficacy and a favorable tolerability profile in women with VVC.
- **June 2021:** The FDA approved expanded indications for Noxafil® (posaconazole) intravenous (IV) injection and Noxafil® DR oral tablets to include treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older. Additionally, expanded indications for Noxafil® IV injection and Noxafil® DR tablets have been approved for the prophylactic treatment of invasive *Aspergillus* and *Candida* infections in patients who are at high risk of developing these infections due to being severely immunocompromised. The FDA approved indication now includes patients 2 years of age and older for Noxafil® IV injection and patients who are at least 2 years of age and weigh >40kg for Noxafil® DR oral tablets. Previously, Noxafil® IV injection was only

indicated for use in adults, and Noxafil® DR oral tablets were only indicated for use in patients 13 years of age and older.

Brexafemme® (Ibrexafungerp) Product Summary[5]

Indication(s): Brexafemme® is a triterpenoid antifungal indicated for the treatment of adult and post-menarchal pediatric females with VVC.

How Supplied: 150mg oral tablets

Dosing and Administration:

- The recommended dosing is 300mg [(2) 150mg tablets] twice daily for 1 day for a total treatment dose of 600mg.
- Brexafemme® may be taken with or without food.
- Prior to initiating treatment with Brexafemme®, pregnancy status should be verified in females of reproductive potential due to the potential risk of fetal harm.

Contraindication(s):

- Pregnancy
- Hypersensitivity to ibrexafungerp

Efficacy: Two randomized placebo-controlled clinical trials with a similar design were conducted to evaluate the safety and efficacy of a single day of ibrexafungerp 600mg [(2) 150mg tablets per dose, administered 12 hours apart] for the treatment of VVC. Non-pregnant post-menarchal females with a diagnosis of VVC were eligible. Efficacy was assessed by clinical outcome at the test of cure (TOC) visit. The primary endpoint was a complete clinical response, defined as the complete resolution of signs and symptoms [vulvovaginal signs and symptoms (VSS) score of 0].

- **Trial 1:** In this trial, 95 (50%) ibrexafungerp-treated patients achieved a complete clinical response at TOC compared to 28 (28%) of patients receiving placebo (P=0.001).
- **Trial 2:** In this trial, 120 (63.5%) ibrexafungerp-treated patients achieved a complete clinical response at TOC compared to 40 (44.9%) of patients receiving placebo (P=0.009).

Cost Comparison:

Medication	Cost Per Unit[Δ]	Cost Per Treatment*
Brexafemme® (ibrexafungerp) tablet	**$118.75**	**$475.00**
terconazole 0.8% cream (Rx)	$1.30	$26.00
Monistat® 3 (miconazole 0.4% cream, OTC)[+]	$1.33	$19.99
fluconazole 150mg tablet	$0.68	$0.68

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per treatment based on FDA recommended dosing for VVC (1-day treatment for tablet formulations and 3-day treatment for topical formulations).
[+]Cost for Monistat® 3 (OTC) based on price available as of 03/17/2022 on Walgreens.com.
[Δ]Unit = tablet or gram; OTC = over-the-counter; Rx = prescription

Recommendations

The College of Pharmacy recommends the prior authorization of Brexafemme® (ibrexafungerp) with the following criteria:

Brexafemme® (Ibrexafungerp) Approval Criteria:

1. An FDA approved diagnosis of vulvovaginal candidiasis (VVC); and
2. Member must be an adult female or a post-menarchal pediatric female; and
3. Prescriber must verify that female members are not pregnant and are currently using reliable contraception; and
4. 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
5. Authorization consideration requires a patient-specific, clinically significant reason why oral fluconazole and all topical antifungals (prescription and over-the-counter) FDA approved for the treatment of VVC are not appropriate for the member; and
6. A quantity limit of 4 tablets for a 1-day supply will apply.

Additionally, the College of Pharmacy recommends updating the current Noxafil® (posaconazole) criteria based on the recent FDA approvals (changes shown in red):

Noxafil® (Posaconazole) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Prophylaxis of invasive *Aspergillus* and *Candida* infections in high-risk patients due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy with product use as follows:
        i. Delayed-release (DR) tablets: Adults and pediatric members 2 years of age and older who weigh >40kg; or
        ii. Intravenous (IV) injection: Adults and pediatric members 2 years of age and older; or
        iii. Oral suspension: Adults and pediatric members 13 years of age and older; or
        iv. PowderMix for DR oral suspension: Pediatric members 2 years of age and older who weigh ≤40kg; or
    b. Treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adults and pediatric members 13 years of age and older with product use as follows:

i. For the treatment of OPC, including rOPC to itraconazole and/or fluconazole, only the oral suspension may be used; or

c. Treatment of invasive aspergillosis in adults and pediatric members 13 years of age and older with product use as follows:
   i. For the treatment of invasive aspergillosis, only the IV injection or DR tablets may be used; or

2. Treatment of invasive mucormycosis; or
3. Other appropriate diagnoses for which Noxafil® is not FDA approved may be considered with submission of a manual prior authorization.~~;~~ ~~and~~
~~4. For the diagnosis of OPC, only the oral suspension may be used.~~

Finally, the College of Pharmacy recommends removing the prior authorization criteria for Onmel® (itraconazole oral tablets) based on product discontinuation (changes shown in red):

~~**Onmel® (Itraconazole Oral Tablets) Approval Criteria:**~~
~~1. An FDA approved diagnosis of onychomycosis of the toenail caused by *Trichophyton rubrum* or *T. mentagrophytes;* and~~
~~2. A patient-specific, clinically significant reason why itraconazole 100mg oral capsules cannot be used in place of Onmel® 200mg tablets must be provided.~~

[1] Noxafil® PowderMix, Noxafil® (Posaconazole) – New Formulation Approval, Expanded Indication. OptumRx. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_noxafilpowdermix_noxafil_2021-0607.pdf. Last accessed 04/20/2022.
[2] Scynexis, Inc. Scynexis Announces FDA Approval of Brexafemme® (Ibrexafungerp Tablets) as the First and Only Oral Non-Azole Treatment for Vaginal Yeast Infections. Available online at: https://www.scynexis.com/news-media/press-releases/detail/240/scynexis-announces-fda-approval-of-brexafemme. Issued 06/02/2021. Last accessed 04/20/2022.
[3] Noxafil® Receives Expanded Indication and New Dosage Form. Benecard®. Available online at: https://www.benecard.com/noxafil-receives-expanded-indication-and-new-dosage-form/. Issued 06/04/2021. Last accessed 04/20/2022.
[4] Noxafil® (Posaconazole) Prescribing Information. Merck. Available online at: https://www.merck.com/product/usa/pi_circulars/n/noxafil/noxafil_pi.pdf. Last revised 01/2022. Last accessed 04/20/2022.
[5] Brexafemme® (Ibrexafungerp) Prescribing Information. AbbVie. Available online at: https://d1io3yog0oux5.cloudfront.net/scynexis/files/pages/scynexis/db/pis/Digital+Ibrexafungerp+Prescribing+Information+%28PI%29.pdf. Last revised 06/2021. Last accessed 04/20/2022.

Vote to Prior Authorize Zynlonta® (Loncastuximab Tesirine-lply) and Update the Approval Criteria for the Lymphoma Medications

Oklahoma Health Care Authority
June 2022

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

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

- **April 2021:** The FDA granted accelerated approval to Zynlonta® (loncastuximab tesirine-lpyl), a CD19-directed antibody and alkylating agent conjugate, for the treatment of adult patients with relapsed or refractory large B-cell lymphoma (LBCL) after 2 or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma.
- **August 2021:** The FDA approved Brukinsa® (zanubrutinib) for the treatment of adult patients with Waldenström's macroglobulinemia.
- **September 2021:** The FDA granted accelerated approval to Brukinsa® (zanubrutinib) for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least 1 anti-CD20-based regimen.
- **April 2022:** The FDA approved an expanded indication for Yescarta® (axicabtagene ciloleucel) to include the treatment of adult patients with LBCL that is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy.

News:

- **July 2021:** The accelerated approval indication for Keytruda® (pembrolizumab) in patients with gastric cancer in the third-line setting will be voluntarily withdrawn by Merck, the pharmaceutical company responsible for the agent. This will not affect other indications for pembrolizumab. The accelerated approval was for recurrent locally advanced or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma in patients whose tumors expressed PD-L1 and had disease progression on or after 2 or more prior lines of therapy. The decision was made following consultation with an FDA Oncologic Drugs Advisory Committee evaluation of Keytruda® in the third-line setting. The first Phase 3 trial leading to action was the KEYNOTE-061 trial investigating pembrolizumab monotherapy in the second-line setting for patients with advanced gastric or GEJ adenocarcinoma (N=592). The KEYNOTE-061 trial failed to meet its primary end point of

overall survival (OS; P=0.042). Additionally, the Phase 3 KEYNOTE-062 trial investigated pembrolizumab both as monotherapy and in combination with chemotherapy in the first-line setting in a similar cohort of patients as KEYNOTE-061. While pembrolizumab monotherapy met its primary end point of OS non-inferiority in the intent-to-treat population, the combination therapy was not superior for OS. The safety profile across both studies of pembrolizumab in patients with advanced gastric or GEJ adenocarcinoma was consistent with previously observed data in gastric cancer.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) Guidelines for Hodgkin Lymphoma version 2.2022 includes 2 new updates for the use of pembrolizumab in the refractory/relapsed setting. The first update recommends pembrolizumab monotherapy be considered in this setting based on results of the KEYNOTE-204 trial which showed a significant improvement in progression-free survival compared to brentuximab vedotin. Additionally, a Phase 2 trial of pembrolizumab combined with gemcitabine, vinorelbine, and liposomal doxorubicin demonstrated a 100% objective response rate and a 95% complete response rate in 39 evaluable patients with relapsed/refractory disease.

Zynlonta® (Loncastuximab Tesirine-lply) Product Summary[6]

- **Therapeutic Class:** CD19-directed antibody and alkylating agent conjugate
- **Indication(s):** Treatment of adult patients with relapsed or refractory LBCL after 2 or more lines of systemic therapy, including DLBCL not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma
- **How Supplied:** 10mg of loncastuximab tesirine-lpyl as a lyophilized powder in a single-dose vial for reconstitution
- **Dosing and Administration:**
  - Initial dose: 0.15mg/kg via intravenous (IV) infusion every 3 weeks for 2 cycles
  - Subsequent cycles: 0.075mg/kg every 3 weeks
  - Premedication with dexamethasone 4mg orally or IV twice daily for 3 days beginning the day before treatment with Zynlonta® is recommended
- **Cost:** The Wholesale Acquisition Cost (WAC) is $23,770.25 per vial, resulting in a cost for the initial doses of $47,540.50 and $23,770.25 for subsequent doses for an adult weighing 75kg.

Recommendations

The College of Pharmacy recommends the prior authorization of Zynlonta® (loncastuximab tesirine-lply) with the following criteria (shown in red):

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

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

Additionally, the College of Pharmacy recommends updating the Brukinsa® (zanubrutinib) and Yescarta® (axicabtagene ciloleucel) criteria based on the recent FDA approvals (shown in red):

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

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

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

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

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 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.

Finally, the College of Pharmacy recommends updating the Keytruda® (pembrolizumab) criteria based on the NCCN guideline update and the manufacturer voluntary market withdrawal (shown in red):

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

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

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

1. Diagnosis of locally advanced, unresectable, or metastatic gastric or GEJ adenocarcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. For first-line therapy:
    a. Human epidermal receptor 2 (HER2)-positive disease; and
    b. In combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy.~~; or~~

~~4. For second-line or greater therapy:~~
~~a. As a single agent; and~~
~~b. Tumor expresses programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1]; and~~
~~c. Following disease progression on or after 2 or more lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2-targeted therapy.~~

[1] U.S. Food and Drug Administration (FDA). Hematology/Oncology (Cancer) Approvals & Safety Notifications. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/hematologyoncology-cancer-approvals-safety-notifications. Last revised 04/06/2022. Last accessed 04/15/2022.

[2] Fowler M. Merck to Withdraw Indication for Pembrolizumab in Third Line Gastric Cancer. *Cancer Network*. Available Online at: https://www.cancernetwork.com/view/merck-to-withdraw-indication-for-pembrolizumab-in-third-line-gastric-cancer. Issued 07/07/2021. Last accessed 04/15/2022.

[3] National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (Hodgkin Lymphoma). Version 2.2022. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/hodgkins.pdf. Last accessed 04/15/2022.

[4] Kuruvilla J, Ramchandren R, Santoro A, et al. Pembrolizumab Versus Brentuximab Vedotin in Relapsed or Refractory Classical Hodgkin Lymphoma (KEYNOTE-204): An Interim Analysis of a Multicentre, Randomised, Open-Label, Phase 3 Study. *Lancet Oncol* 2021; 22:512-524.

[5] Moskowitz AJ, Shah G, Schöder H, et al. Phase II Trial of Pembrolizumab Plus Gemcitabine, Vinorelbine, and Liposomal Doxorubicin as Second-Line Therapy for Relapsed or Refractory Classical Hodgkin Lymphoma. *J Clin Oncol* 2021; 39:3109-3117.

[6] Zynlonta® (Loncastuximab Tesirine-lply) Prescribing Information. ADC Therapeutics. Available online at: https://www.adctherapeutics.com/wp-content/uploads/2021/12/ZYNLONTA-PI_8.5-x-11-Format_Download_093021.pdf. Last revised 09/2021. Last accessed 04/15/2022.

Appendix D

Vote to Prior Authorize Ryaltris™ (Olopatadine/ Mometasone Nasal Spray) and Update the Approval Criteria for the Nasal Allergy Medications

Oklahoma Health Care Authority
June 2022

Market News and Updates[1]

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

- **January 2022:** The FDA approved Ryaltris™ (olopatadine/mometasone nasal spray) for the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older. Ryaltris™ contains a fixed-dose combination of olopatadine, a histamine-1 (H1)-receptor inhibitor, and mometasone, a corticosteroid. Ryaltris™ will be marketed and distributed through Hikma Specialty USA, but a launch date for the product has not yet been announced.

Ryaltris™ (Olopatadine/Mometasone Nasal Spray) Product Summary[2]

Indication(s): Ryaltris™ (olopatadine/mometasone nasal spray) is indicated for the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older.

How Supplied: Nasal spray containing 665mcg olopatadine hydrochloride and 25mcg mometasone furoate per spray contained in 29g bottles which deliver 240 metered sprays in addition to 6 initial priming sprays

Dosing and Administration:

- Recommended dose is 2 sprays in each nostril twice daily
- Bottle should be shaken well before each use
- Bottle should be primed with 6 sprays before initial use, and may be re-primed with 2 sprays, or until a fine mist appears, if the bottle has not been used for 14 days or more
- Spraying Ryaltris™ into the eyes or mouth should be avoided

Efficacy: The efficacy of Ryaltris™ for the treatment of seasonal allergic rhinitis was established in 2 Phase 3 randomized, double-blind, placebo- and active-controlled studies which enrolled a total of 2,352 patients 12 years of age and older with seasonal allergic rhinitis. Patients were randomized to 1 of 4 treatment groups: Ryaltris™, olopatadine 665mcg nasal spray, mometasone furoate 25mcg nasal spray, or vehicle nasal spray. Patients were treated with 2 sprays per nostril twice daily for 2 weeks of treatment. The primary endpoint in both studies was the change from baseline in average morning and

evening subject-reported 12-hour reflective total nasal symptom score (rTNSS) over the 14-day treatment period. Treatment with Ryaltris™ resulted in statistically significant improvement in rTNSS relative to placebo in both studies. Treatment with Ryaltris™ also resulted in statistically significant improvements in rTNSS relative to olopatadine monotherapy in both studies, and statistically significant improvement in rTNSS relative to mometasone monotherapy in study 2 (but not in study 1).

Cost: Cost information is not yet available for Ryaltris™.

Recommendations

The College of Pharmacy recommends the placement of Ryaltris™ (olopatadine/mometasone) nasal spray into Tier-3 of the nasal allergy medications Product Based Prior Authorization (PBPA) Tier chart.

Additionally, the College of Pharmacy recommends the following changes to the nasal allergy medications PBPA Tier chart based on net costs:

1. Moving Qnasl® (beclomethasone 80mcg) from Tier-2 to Tier-3; and
2. Moving Astelin® (azelastine 137mcg, 0.1%) from Tier-2 to Tier-1; and
3. Moving Astepro® (azelastine 205.5mcg, 0.15%) and Nasonex® (mometasone 50mcg) from Tier-3 to Tier-2.

Nasal Allergy Medications		
Tier-1	**Tier-2**	**Tier-3**
azelastine (Astelin®)	~~**azelastine (Astelin®)**~~	~~**azelastine (Astepro®)**~~
beclomethasone (Beconase® AQ)	**azelastine (Astepro®)**	azelastine/fluticasone (Dymista®)
fluticasone (Flonase®)	~~**beclomethasone (Qnasl® 80mcg)**~~	beclomethasone (Qnasl® **80mcg,** 40mcg)
	mometasone (Nasonex®)	ciclesonide (Omnaris®, Zetonna®)
		flunisolide (Nasalide®,
		fluticasone (Veramyst®)
		fluticasone (Xhance®)*
		~~**mometasone (Nasonex®)**~~
		olopatadine (Patanase®)
		olopatadine/mometasone (Ryaltris™)

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).
*Xhance®: Unique criteria applies.

[1] Glenmark Pharmaceuticals Limited. Glenmark Specialty S.A. (Switzerland) Receives NDA Approval by the United States Food and Drug Administration (FDA) for Ryaltris™ Nasal Spray for the Treatment of Symptoms of Seasonal Allergic Rhinitis in Adults and Pediatric Patients 12 Years of Age and Older. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/glenmark-specialty-sa-switzerland-receives-nda-approval-by-the-united-states-food-and-drug-administration-fda-for-ryaltris-nasal-spray-for-the-treatment-of-symptoms-of-seasonal-allergic-rhinitis-in-adults-and-pediatric-pati-301461096.html. Issued 01/14/2022. Last accessed 05/16/2022.

[2] Ryaltris™ (Olopatadine/Mometasone) Prescribing Information. Hikma Specialty USA, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/211746s000lbl.pdf. Last revised 01/2022. Last accessed 05/16/2022.

Appendix E

Vote to Prior Authorize Nexviazyme® (Avalglucosidase Alfa-ngpt)

Oklahoma Health Care Authority
June 2022

Market News and Updates[1]

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

- **August 2021:** The FDA approved Nexviazyme® (avalglucosidase alfa-ngpt) for the treatment of patients 1 year of age and older with late-onset Pompe disease (LOPD). Patients with this rare genetic disorder have an enzyme deficiency that leads to an accumulation of glycogen in skeletal and heart muscles that can lead to premature death due to respiratory or heart failure. The approval of Nexviazyme® was based on a Phase 3 study comparing this product with Lumizyme® (alglucosidase alfa), another enzyme replacement therapy used for Pompe disease. In the study, patients treated with Nexviazyme® had improved lung function similar to the improvement seen with patients treated with Lumizyme®. Common adverse reactions reported in the study include headache, fatigue, nausea, arthralgia, and myalgia.

Nexviazyme® (Avalglucosidase Alfa-ngpt) Product Summary[2]

Indication(s): Nexviazyme® is a hydrolytic lysosomal glycogen-specific enzyme indicated for the treatment of LOPD in patients 1 year of age and older.

Boxed Warning: Severe hypersensitivity reactions, infusion-associated reactions (IARs), and risk of acute cardiorespiratory failure in susceptible patients

- If any of these reactions occur, Nexviazyme® should be discontinued immediately and appropriate medical treatment should be initiated.
- Patients susceptible to fluid volume overload, or those with acute underlying respiratory illness or compromised cardiac or respiratory function, may be at risk of serious exacerbation of their cardiac or respiratory status during infusion of the medication.

How Supplied: Single-dose vial (SDV) containing 100mg of avalglucosidase alfa-ngpt as a lyophilized powder

Dosing:

- ≥30kg: The recommended dosage is 20mg/kg (actual body weight) via intravenous (IV) infusion every 2 weeks.
- <30kg: The recommended dosage is 40mg/kg (actual body weight) via IV infusion every 2 weeks.
- Antihistamines, antipyretics, and/or corticosteroids should be administered prior to infusion to reduce the risk of IARs.

Mechanism of Action: Patients with Pompe disease have a deficiency of the lysosomal enzyme acid alpha-glucosidase (GAA), which results in intralysosomal accumulation of glycogen in various tissues. Nexviazyme® provides an exogenous source of GAA to break down glycogen.

Contraindication(s): None

Use in Specific Populations:

- Pregnancy: There is insufficient data to evaluate the drug associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. However, available data from post marketing reports on alglucosidase alfa use in pregnant women have not identified a drug-associated risk of adverse pregnancy outcomes.
- Pediatric Use: The safety and efficacy of Nexviazyme® were established in pediatric patients 1 year of age and older.
- Geriatric Use: Clinical studies of Nexviazyme® included 17 patients 65 years of age and older.

Adverse Reactions: The most common adverse reactions reported in clinical studies (incidence ≥5%) were headache, fatigue, diarrhea, nausea, arthralgia, dizziness, myalgia, pruritus, vomiting, dyspnea, erythema, paresthesia, and urticaria.

Cost Comparison:

Product	Cost Per Vial	Cost Per Month*
Nexviazyme® (avalglucosidase alfa-ngpt) 100mg SDV	**$1,714.90**	**$20,578.80**
Lumizyme® (alglucosidase alfa) 50mg SDV	$840.64	$20,175.36

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month based on the recommended dosage of 20mg/kg every 2 weeks for a 30kg patient.
SDV = single-dose vial

Recommendations

The College of Pharmacy recommends the prior authorization of Nexviazyme® (avalglucosidase alfa-ngpt) with the following criteria:

Nexviazyme® (Avalglucosidase Alfa-ngpt) Approval Criteria:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and
2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Prescriber must document presence of symptoms of Pompe disease; and
4. Nexviazyme® must be prescribed by a geneticist or a physician that specializes in the treatment of Pompe disease and/or inherited genetic disorders; and
5. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing; and
6. Initial approval will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent authorizations will be for the duration of 1 year.

[1] U.S. Food and Drug Administration (FDA). FDA Approves New Treatment for Pompe Disease. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-pompe-disease. Issued 08/06/2021. Last accessed 05/17/2022.

[2] Nexviazyme® (Avalglucosidase Alfa-ngp) Prescribing Information. Genzyme Corporation. Available online at: https://products.sanofi.us/nexviazyme/nexviazyme.pdf. Last revised 08/2021. Last accessed 05/17/2022.

Appendix F

Vote to Prior Authorize Kerendia® (Finerenone), Rezvoglar™ (Insulin Glargine-aglr), and Semglee® (Insulin Glargine-yfgn) and Update the Approval Criteria for the Anti-Diabetic Medications

Oklahoma Health Care Authority
June 2022

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

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

- **July 2021:** The FDA approved Kerendia® (finerenone), a first-in-class non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, kidney failure, cardiovascular (CV) death, non-fatal myocardial infarction (MI), and hospitalization for heart failure (HF) in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes mellitus (T2DM). The approval is based on the results of the Phase 3 FIDELIO-DKD study data that demonstrated positive kidney and CV outcomes in patients with CKD associated with T2DM. The study was a randomized, double-blind, placebo-controlled trial where 5,674 patients were randomly assigned to receive either Kerendia® or placebo. The study compared the 2 groups for the number of patients whose disease progressed to a composite endpoint that included ≥40% reduction in kidney function, progression to kidney failure, or kidney death. Results showed that 504 of the 2,833 patients who received Kerendia® had ≥1 of the events in the composite endpoint compared to 600 of the 2,841 patients who received a placebo [hazard ratio (HR): 0.82; 95% confidence interval (CI): 0.73, 0.93; P=0.001].
- **July 2021:** The first interchangeable biosimilar insulin product was approved by the FDA in the United States. Semglee® (insulin glargine-yfgn) is both biosimilar to, and interchangeable with, its reference product, Lantus® (insulin glargine). This approval is based on evidence that showed the products are highly similar and that there are no clinically meaningful differences between Semglee® and Lantus® in terms of safety, purity, and potency. Semglee® can be expected to produce the same clinical result as Lantus® in any given patient, and the risks in terms of safety or diminished efficacy of switching between Semglee® and Lantus® is not greater than the risk of using Lantus® without such switching.

- **December 2021:** The FDA approved Eli Lilly's biosimilar version of insulin glargine, Rezvoglar™ KwikPen. This is the second long-acting glargine biosimilar after Semglee®. Rezvoglar™ is not approved for interchangeability with Lantus® because Semglee® has 1-year exclusivity from first commercial marketing before another interchangeable biosimilar to Lantus® may be approved.

Guideline Update(s):

- **American Diabetes Association (ADA)** released updated guidelines, the Standards of Medical Care in Diabetes 2022, which provides the latest in comprehensive, evidence-based recommendations for the diagnosis and treatment of children and adults with type 1 diabetes mellitus (T1DM), T2DM, or gestational diabetes; strategies for the prevention or delay of T2DM; and therapeutic approaches that can reduce complications, mitigate CV and renal risk, and improve health outcomes. Some notable updates and additions include: guidance on first-line therapy determined by co-morbidities, screening beginning at age 35 for all people, changes to gestational diabetes recommendations regarding when to test and in whom to test, and updated recommendations on technology selection based on individual and caregiver considerations, ongoing education on use of devices, continued access to devices across payers, support of students using devices in school settings, use of telehealth visits, and early initiation of technology.

Kerendia® (Finerenone) Product Summary[5]

Indication(s): Kerendia® is a non-steroidal MRA indicated to reduce the risk of sustained eGFR decline, end stage kidney disease (ESKD), CV death, non-fatal MI, and hospitalization for HF in adult patients with CKD associated with T2DM.

How Supplied: 10mg and 20mg oral tablets

Dosing:

- Serum potassium and eGFR levels should be measured prior to initiation of Kerendia®
- Recommended starting dose is 10mg or 20mg orally once daily, based on eGFR and serum potassium thresholds
- Doses can be increased after 4 weeks to the target dose of 20mg once daily, based on eGFR and serum potassium thresholds
- Kerendia® can be taken with or without food

Mechanism of Action: Finerenone is a non-steroidal, selective MRA which is activated by aldosterone and cortisol and regulates gene transcription. Finerenone blocks MR mediated sodium reabsorption and MR overactivation

in both epithelial (e.g., kidney) and nonepithelial (e.g., heart, blood vessels) tissues. MR overactivation is thought to contribute to fibrosis and inflammation. Finerenone has a high potency and selectivity for the MR and has no relevant affinity for androgen, progesterone, estrogen, and glucocorticoid receptors.

Contraindication(s):

- Concomitant use with strong CYP3A4 inhibitors
- Patients with adrenal insufficiency

Adverse Reactions: The most common adverse reactions reported in clinical studies (incidence ≥1%) were hyperkalemia, hypotension, and hyponatremia.

Efficacy: The safety and efficacy of finerenone were evaluated in a randomized, double-blind, placebo-controlled, Phase 3 trial in 5,674 patients with CKD associated with T2DM. Patients were randomized 1:1 to receive either finerenone or placebo at doses of 10mg or 20mg based on eGFR. An increase to 20mg was encouraged after 1 month, provided that the patient's serum potassium level was ≤4.8mmol/L and eGFR was stable.

- Primary Endpoint: The primary endpoint was the first occurrence of the composite endpoint of kidney failure, sustained decrease of eGFR ≥40% from baseline for ≥4 weeks, or renal death. This endpoint was assessed in a time-to-event analysis.
- Results: Over a 2.6-year period, the primary composite outcomes were significantly lower in the finerenone group vs the placebo, 17.8% vs. 21.1% respectively (504 of 2,833 patients vs. 600 of 2,841 patients; HR: 0.82; 95% CI: 0.73, 0.93; P=0.001). Based on the absolute risk reduction of 3.4% after 3 years, the number needed to treat to prevent 1 primary outcome event was 29.

Cost Comparison:

Product	Cost Per Unit	Cost Per Month*	Cost Per Year*
Jardiance® (empagliflozin) 25mg tablet	$18.33	$549.90	$6,598.80
Kerendia® (finerenone) 20mg tablet	**$18.17**	**$545.10**	**$6,541.20**
Invokana® (canagliflozin) 300mg tablet	$18.15	$544.50	$6,534.00
Farxiga® (dapagliflozin) 10mg tablet	$17.76	$532.80	$6,393.60

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 month and cost per year are based on 1 tablet daily.

Insulin Glargine Cost Comparison

Product	Cost Per mL
Lantus® (insulin glargine) U-100 syringe	$27.23
Lantus® (insulin glargine) U-100 vial	$27.22
Semglee® (insulin glargine-YFGN) U-100 syringe	**$26.94**
Semglee® (insulin glargine-YFGN) U-100 vial	**$25.83**

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).
Currently there is no cost information available for Rezvoglar™ (insulin glargine-aglr).

Recommendations

The College of Pharmacy recommends the prior authorization of Kerendia® (finerenone) with the following criteria:

Kerendia® (Finerenone) Approval Criteria:

1. An FDA approved indication to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult members with chronic kidney disease (CKD) associated with type 2 diabetes mellitus (T2DM); and
2. Member must be receiving a maximum tolerated dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or have a contraindication to use; and
3. A patient specific, clinically significant reason why the member cannot use a sodium-glucose cotransporter-2 (SGLT-2) inhibitor must be provided; and
4. Member must not be receiving concomitant treatment with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir); and
5. Member must not have adrenal insufficiency; and
6. Member must not have severe hepatic impairment (Child Pugh C); and
7. Prescriber must measure serum potassium and eGFR prior to initiation of Kerendia®; and
8. Prescriber must verify serum potassium is not >5.0mEq/L prior to treatment initiation with Kerendia®; and
9. Prescriber must agree to monitor serum potassium levels 4 weeks after a dose adjustment and throughout treatment and adjust the dose accordingly per package labeling; and
10. Initial authorization will be for 4 weeks, after which time serum potassium levels will be required for continued approval; and
11. A quantity limit of 30 tablets per 30 days will apply. The member's eGFR should be provided for initiation of treatment to ensure the correct recommended dose per package labeling. The following initial dose will be approved based on eGFR:

a. Kerendia® 10mg once daily in members with eGFR 25 to <60mL/min/1.73m^2; or
b. Kerendia® 20mg once daily in members with eGFR ≥60mL/min/1.73m^2.

Additionally, the College of Pharmacy recommends the prior authorization of Rezvoglar™ (insulin glargine-aglr) and Semglee® (insulin glargine-yfgn) with the following criteria:

Rezvoglar™ (Insulin Glargine-aglr) and Semglee® (Insulin Glargine-yfgn) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Levemir® (insulin detemir) 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.

Finally, the College of Pharmacy recommends updating the anti-diabetic medications Tier-2 approval criteria to reflect the current guideline recommendations (changes shown in red):

Anti-Diabetic Medications Tier-2 Approval Criteria:

1. A trial at least 3 months in duration (unless intolerable adverse effects) ~~of 1 Tier-1 medication (must include a trial~~ of metformin titrated up to maximum tolerated dose~~)~~ or a patient-specific, clinically significant reason why a 3-month trial of metformin titrated up to maximum tolerated dose ~~Tier-1 medication~~ is not appropriate must be provided.
2. For initiation with dual or triple therapy, additional Tier-2 medications may be approved based on current American Association of Clinical Endocrinologists (AACE) or American Diabetes Association (ADA) guidelines.
3. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-1 medications. Tier structure rules for unique FDA approved indications will apply.

[1] Bayer HealthCare Pharmaceuticals, Inc. Bayer's Kerendia® (Finerenone) Receives U.S. FDA Approval for Treatment of Patients with Chronic Kidney Disease Associated with Type 2 Diabetes. *BusinessWire*. Available online at: https://www.businesswire.com/news/home/20210709005441/en/Bayer%E2%80%99s-KERENDIA%C2%AE-finerenone-Receives-U.S.-FDA-Approval-for-Treatment-of-Patients-with-Chronic-Kidney-Disease-Associated-with-Type-2-Diabetes. Issued 07/10/2021. Last accessed 05/18/2022.

[2] U.S. Food and Drug Administration (FDA). FDA approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes. Issued 07/28/2021. Last accessed 05/18/2022.

[3] Tucker ME. FDA Approves Lilly's Insulin Glargine Biosimilar, Rezvoglar. *Medscape*. Available online at: https://www.medscape.com/viewarticle/965716. Issued 12/29/2021. Last accessed 05/18/2022.

[4] American Diabetes Association. Latest ADA Annual Standards of Care Includes Changes to Diabetes Screening, First-Line Therapy, Pregnancy, and Technology. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/latest-ada-annual-standards-of-care-includes-changes-to-diabetes-screening-first-line-therapy-pregnancy-and-technology-301448533.html. Issued 12/20/2021. Last accessed 05/18/2022.

[5] Kerendia® (Finerenone) Prescribing Information. Available online at: https://labeling.bayerhealthcare.com/html/products/pi/Kerendia_PI.pdf. Last revised 07/2021. Last accessed 05/18/2022.

Appendix G

Vote to Prior Authorize Exkivity® (Mobocertinib), Lumakras™ (Sotorasib), and Rybrevant® (Amivantamab-vmjw) and Update the Approval Criteria for the Lung Cancer Medications

Oklahoma Health Care Authority
June 2022

Market News and Updates[1,2]

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

- **May 2021:** The FDA granted accelerated approval to Rybrevant® (amivantamab-vmjw) for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy.
- **May 2021:** The FDA granted accelerated approval to Lumakras™ (sotorasib), a RAS guanosine triphosphatase (GTPase) family inhibitor, for the treatment of adult patients with *KRAS G12C*-mutated locally advanced or metastatic NSCLC who have received at least 1 prior systemic therapy.
- **September 2021:** The FDA granted accelerated approval to Exkivity® (mobocertinib) for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy.
- **March 2022:** The FDA approved Opdivo® (nivolumab) with platinum-doublet chemotherapy for adult patients with resectable NSCLC in the neoadjuvant setting.
- **March 2022:** The FDA approved Keytruda® (pembrolizumab) as a single agent for patients with advanced endometrial carcinoma that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) who have disease progression following prior systemic therapy in any setting and who are not candidates for curative surgery or radiation.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines were updated to include the use of Imfinzi® (durvalumab) as consolidation immunotherapy in patients with unresectable stage II/III NSCLC and no disease progression after definitive concurrent chemoradiation.

PACIFIC, a Phase 3 randomized trial, compared adjuvant treatment with durvalumab versus placebo in this patient population. After 4 years, 49.6% of patients who received durvalumab were alive versus 36.3% of patients who received placebo. In addition, 35.3% were alive without progression after 4 years if they had received durvalumab compared with 19.5% of patients who received placebo.

- The criteria for Tagrisso® (osimertinib) for the indication of NSCLC found in the *Recommendations* section of this report were updated to better outline specific mutations where osimertinib shows efficacy. These mutations have been defined in the FDA indication and NCCN guidelines for NSCLC.

Product Summaries[3,4,5]

Exkivity® (Mobocertinib):

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):** Locally advanced or metastatic NSCLC with epidermal EGFR exon 20 insertion mutations with disease progression on or after platinum-based chemotherapy
- **How Supplied:** 40mg oral capsule
- **Dose:** 160mg [(4) 40mg capsules] once daily
- **Cost:** The Wholesale Acquisition Cost (WAC) is $208.33 per capsule, resulting in a cost per dose of $833.32 and a cost per 30 days of $24,999.60 based on the recommended dosing.

Lumakras™ (Sotorasib):

- **Therapeutic Class:** Inhibitor of RAS GTPase
- **Indication(s):** *KRAS G12C*-mutated locally advanced or metastatic NSCLC after at least 1 prior systemic therapy
- **How Supplied:** 120mg oral tablets
- **Dose:** 960mg [(8) 120mg tablets] once daily
- **Cost:** The WAC is $76.82 per tablet, resulting in a cost per dose of $614.56 and a cost per 30 days of $18,436.80 based on the recommended dosing.

Rybrevant® (Amivantamab-vmjw):

- **Therapeutic Class:** Bispecific EGFR-directed and mesenchymal epithelial transition (MET) receptor-directed antibody
- **Indication(s):** Locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations with disease progression on or after platinum-based chemotherapy
- **How Supplied:** 350mg/7mL (50mg/mL) solution for intravenous (IV) infusion in a single-dose vial

- **Dose:**
  - The recommended dose is based on baseline body weight:
    - <u><80kg:</u> 1,050mg (3 vials)
    - <u>≥80kg:</u> 1,400mg (4 vials)
  - Dosing schedule:
    - <u>Weeks 1 to 4:</u> Week 1 split infusion on day 1 and day 2; weeks 2 to 4 once weekly on day 1
    - <u>Week 5 and beyond:</u> Once every 2 weeks
- **Cost:** The WAC is $449.67 per mL resulting in a cost per dose of $12,590.76 for an 80kg adult based on the recommended dosing. The cost of initial dosing for an 80kg adult would be $50,363.04 for the first 4 weeks and $25,181.52 per month thereafter.

Recommendations[6]

The College of Pharmacy recommends the prior authorization of Exkivity® (mobocertinib), Lumakras™ (sotorasib), and Rybrevant® (amivantamab-vmjw) based on recent FDA approvals with the following criteria (shown in red):

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

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

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

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

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

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

The College of Pharmacy recommends implementing the prior authorization of Mvasi® (bevacizumab-awwb) with the following updates and recommends

updating the approval criteria for Zirabev® (bevacizumab-bvzr) based on net costs (updates shown in red):

Mvasi® (Bevacizumab-awwb) Approval Criteria~~*~~:

1. A patient-specific, clinically significant reason why the member cannot use Avastin® (bevacizumab) or Zirabev® (bevacizumab-bvzr), which ~~is~~ are available without prior authorization, 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.
   ~~*Based on the net cost in comparison to Avastin®, Mvasi® is currently available without prior authorization.~~

Zirabev® (Bevacizumab-bvzr) Approval Criteria*:

~~1. A patient-specific, clinically significant reason why the member cannot use Avastin® (bevacizumab) 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.
   *Based on the net cost in comparison to available bevacizumab products, Zirabev® is currently available without prior authorization.

Additionally, the College of Pharmacy recommends updating the approval criteria for Keytruda® (pembrolizumab) and Opdivo® (nivolumab) based on recent FDA approvals (changes noted in red):

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

1. Member has not previously failed other 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.

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

1. Diagnosis of NSCLC; and

2. For first-line therapy for recurrent, advanced, or metastatic disease, meeting the following:
    a. Used in combination with Yervoy® (ipilimumab) and 2 cycles of platinum-doublet chemotherapy; and
    b. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
    c. Expresses programmed death ligand 1 (PD-L1) ≥1%; or
3. For first-line therapy for resectable disease (>4cm or node positive), meeting the following:
    a. Used in the neoadjuvant setting in combination with platinum-doublet chemotherapy for up to 3 treatment cycles; or
4. For second-line therapy for metastatic disease, meeting the following:
    a. Tumor histology is 1 of the following:
        i. Adenocarcinoma; or
        ii. Squamous cell; or
        iii. Large cell; and
    b. Disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin); and
    c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
    d. Used as a single agent; and
    e. Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.

The College of Pharmacy also recommends updating the Opdivo® (nivolumab) criteria for the adjuvant treatment of melanoma to more closely reflect the FDA approval granted to nivolumab for this indication. As shown in red, the criteria now includes all stage III melanoma following complete resection. Please note: the data on patients at low risk of recurrence is continuing to develop and will be reviewed as needed.

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

1. Member has complete resection of melanoma; and
2. Diagnosis of stage III~~B/C~~ melanoma following complete resection; and
3. Member has not previously failed other PD-1 inhibitors [e.g., Keytruda (pembrolizumab)]; and
4. Nivolumab must be used as a single agent; and
5. Dose as follows:
    a. Single agent: 240mg every 2 weeks or 480mg every four weeks; and
    b. Maximum duration of 1 year.

The College of Pharmacy recommends updating the Imfinzi® (durvalumab) and Tagrisso® (osimertinib) criteria based on the NCCN guideline updates (changes shown in red):

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

1. Diagnosis of unresectable stage II or III NSCLC; and
2. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

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 ~~and following progression on erlotinib, afatinib, or gefitinib for asymptomatic disease, symptomatic brain lesions, or multiple symptomatic systemic lesions~~; or
    b. ~~First-line treatment of patients with~~ EGFR exon 19 deletions or exon 21 L858R mutations.

Finally, the College of Pharmacy recommends updating the Cosela™ (trilaciclib) criteria to allow prescriber discretion and individualized treatment based on neutropenic fever risk (changes shown in red):

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

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

~~3. Cosela will not be approved for concomitant use with colony-stimulating factors (CSF) [e.g., granulocyte colony-stimulating factors (G-CSF), pegylated G-CSF (peg-G-CSF), granulocyte-macrophage colony-stimulating factors (GM-CSF)] for primary prophylaxis of febrile neutropenia prior to day 1 cycle 1 of chemotherapy.~~

[1] U.S. Food and Drug Administration (FDA). Hematology/Oncology (Cancer) Approvals & Safety Notifications. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/hematologyoncology-cancer-approvals-safety-notifications. Last revised 05/04/2022. Last accessed 05/11/2022.

[2] Faivre-Finn C, Vicente D, Kurata T, et al. Four-year Survival with Durvalumab after Chemoradiotherapy in Stage III NSCLC - An Update from the PACIFIC Trial. *J Thorac Oncol* 2021; 16:860-867.

[3] Exkivity® Prescribing Information. Takeda Pharmaceuticals. Available online at: https://content.takeda.com/?contenttype=pi&product=exkivity&language=eng&country=usa&documentnumber=1. Last revised 09/2021. Last accessed 05/11/2022.

[4] Lumakras™ Prescribing Information. Amgen Inc. Available online at: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Lumakras/lumakras_pi_hcp_english.pdf. Last revised 05/2021. Last accessed 05/11/2022.

[5] Rybrevant™ Prescribing Information. Janssen Biotech. Available online at: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/RYBREVANT-pi.pdf. Last revised 12/2021. Last accessed 05/11/2022.

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Appendix H

Calendar Year 2021 Annual Review of Genitourinary and Cervical/Endometrial Cancer Medications and 30-Day Notice to Prior Authorize Camcevi™ (Leuprolide), Pluvicto™ (Lutetium Lu 177 Vipivotide Tetraxetan), Tivdak® (Tisotumab Vedotin-tftv), and Welireg™ (Belzutifan)

Oklahoma Health Care Authority
June 2022

Introduction[1,2,3]

Genitourinary cancers are a heterogenous group of cancers that impact the urinary tract or male reproductive tract. Examples of malignancies included in this class are prostate, renal, bladder, and urothelial among others. Each cancer is distinctively different in symptoms, staging, and prognosis as well as treatment strategies. In addition to surgery and radiation, treatment of these malignancies often involves pharmacological options including chemotherapy, hormone agents, immune therapies, and targeted therapies.

Endometrial cancer is the most common gynecologic malignancy in the United States. The American Cancer Society estimates in 2022, about 65,950 new cases of cancer of the body of the uterus (uterine body or corpus) will be diagnosed and about 12,550 women will die from cancers of the uterine body. Surgery is the main treatment option for this cancer, but many cases require additive treatment with radiation, chemotherapy, hormone agents, immune therapies, or targeted therapies. Cervical cancer is a less common type of gynecologic malignancy occurring in approximately 14,100 women, of which about 4,280 will die of the disease in 2022. There are a greater number of cervical pre-cancers diagnosed compared to cancers. Treatment largely depends on stage of disease. For the earliest stages, either surgery or radiation combined with chemotherapy is preferred. For later stages, radiation combined with chemotherapy is standard of care. Chemotherapy as a monotherapy is often used to treat advanced cervical cancer.

Current Prior Authorization Criteria

Approval criteria for Afinitor® (everolimus), Lynparza® (olaparib), and Trodelvy® (sacituzumab govitecan-hziy) for indications other than genitourinary and cervical/endometrial cancers can be found in the 2021 Annual Review of Breast Cancer Medications report in the September 2021 Drug Utilization Review (DUR) packet. The complete approval criteria for these medications

are reviewed annually with the breast cancer medications. Additionally, approval criteria for Bavencio® (avelumab), Keytruda® (pembrolizumab), Opdivo® (nivolumab), and Yervoy (ipilimumab) for indications other than genitourinary and cervical/endometrial cancers can be found in the 2021 Annual Review of Skin Cancer Medications report in the December 2021 DUR packet. The complete approval criteria for these medications are reviewed annually with the skin cancer medications. Finally, approval criteria for Tecentriq® (atezolizumab) for indications other than genitourinary and cervical/endometrial cancers can be found in the 2022 Annual Review of Lung Cancer Medications report in the May 2022 DUR packet. The complete approval criteria for this medication is reviewed annually with the lung 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.

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.
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.

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.

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 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.

*The above updated prior authorization criteria for Keytruda® (pembrolizumab) for endometrial cancer is currently pending a vote by the DUR Board at the June 2022 DUR Board meeting; please refer to the vote report [Vote to Prior Authorize Exkivity® (Mobocertinib), Lumakras™ (Sotorasib), and Rybrevant® (Amivantamab-vmjw) and Update the Approval Criteria for the Lung Cancer Medications] in the June 2022 DUR packet for additional information.

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)].

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.

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) 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 a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced, or metastatic setting.

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.

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.

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 a 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.

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 failed previous 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.

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 Cervical/Endometrial Cancer Medications: Calendar Year 2021

The following utilization data includes medications indicated for genitourinary and cervical/endometrial cancers; however, the data does not differentiate between genitourinary cancer, cervical/endometrial cancers, 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
2020	43	267	$4,784,201.95	$17,918.36	$621.32	16,850	7,700
2021	47	258	$4,863,286.46	$18,849.95	$646.97	18,197	7,517
% Change	**9.30%**	**-3.40%**	**1.70%**	**5.20%**	**4.10%**	**8.00%**	**-2.40%**
Change	**4**	**-9**	**$79,084.51**	**$931.59**	**$25.65**	**1,347**	**-183**

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

Calendar Year 2021 Utilization: Medical Claims

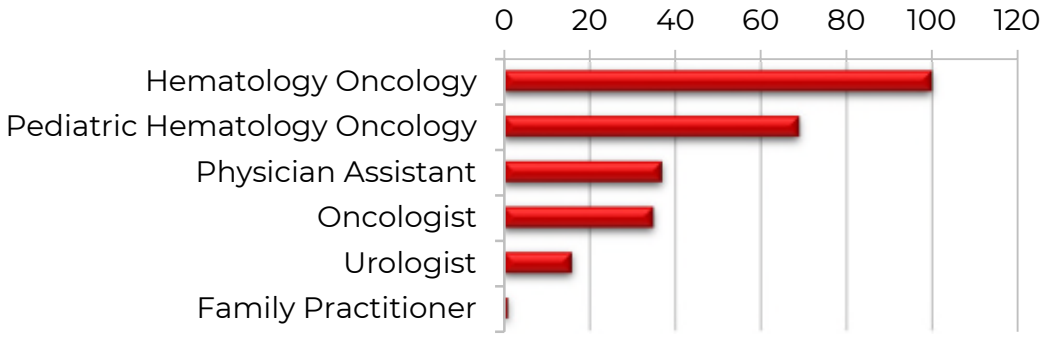
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	266	986	$12,188,336.32	$12,361.40	3.71

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 Cervical/Endometrial Cancer Medications: Pharmacy Claims

- Due to the limited number of members utilizing genitourinary and cervical/endometrial cancer medications during calendar year 2021, detailed demographic information could not be provided.

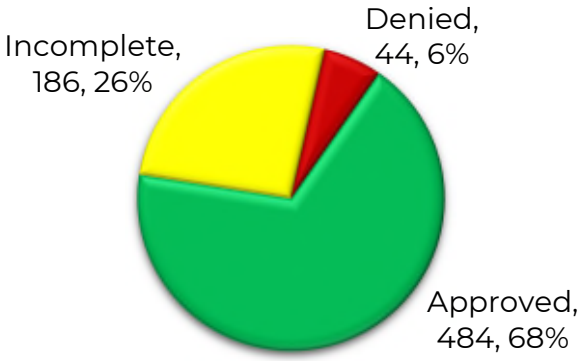
Top Prescriber Specialties of Genitourinary and Cervical/Endometrial Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Genitourinary and Cervical/Endometrial Cancer Medications

There were 714 prior authorization requests submitted for genitourinary and cervical/endometrial cancer medications during calendar year 2021. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions



Market News and Updates[4,5]

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

- **May 2021:** The FDA approved Camcevi™ (leuprolide), a gonadotropin-releasing hormone (GnRH), for the treatment of adult patients with advanced prostate cancer.

- **August 2021:** The FDA approved Welireg™ (belzutifan), a hypoxia-inducible factor inhibitor for the treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery.
- **September 2021:** The FDA granted accelerated approval to Tivdak® (tisotumab vedotin-tftv), a tissue factor-directed antibody and microtubule inhibitor conjugate, for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
- **March 2022:** The FDA approved Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan) for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

Product Summaries[6,7,8,9]

Camcevi™ (Leuprolide):

- **Therapeutic Class:** Gonadotropin-releasing hormone (GnRH) agonist
- **Indication(s):** Advanced prostate cancer
- **How Supplied:** 42mg emulsion for subcutaneous (subQ) administration supplied as a single-dose, pre-filled syringe
- **Dose:** 42mg via subQ injection once every 6 months
- **Cost:** The Wholesale Acquisition Cost (WAC) is $3,900 per single-dose, prefilled syringe resulting in annual cost of $7,800 based on the recommended dosing.

Pluvicto™ (Lutetium Lu 177 Vipivotide Tetraxetan):

- **Therapeutic Class:** Radioligand therapeutic agent
- **Indication(s):** PSMA-positive mCRPC who have been treated with AR pathway inhibition and taxane-based chemotherapy
- **How Supplied:**
  - 1,000MBq/mL (27mCi/mL) solution in a single-dose vial (SDV) for intravenous (IV) administration
  - The solution volume in the vial can range from 7.5mL to 12.5mL for a total of 7.4GBq (200mCi) of radioactivity at the date and time of administration
- **Dose:** 7.4GBq (200mCi) every 6 weeks for up to 6 doses
- **Cost:** The WAC is $42,500 per SDV resulting in a cost of $255,000 for 6 doses based on recommended dosing.

Tivdak® (Tisotumab Vedotin-tftv):

- **Therapeutic Class:** Tissue factor-directed antibody and microtubule inhibitor conjugate
- **Indication(s):** Recurrent or metastatic cervical cancer with disease progression on or after chemotherapy
- **How Supplied:** 40mg as a lyophilized powder for reconstitution in a SDV for IV administration
- **Dose:** 2mg/kg (up to a maximum of 200mg) every 3 weeks
- **Cost:** The WAC is $5,885 per SDV resulting in a cost per dose of $29,425 and an annual cost of $529,650 based on the maximum recommended dosing.

Welireg™ (Belzutifan):

- **Therapeutic Class:** Hypoxia-inducible factor inhibitor
- **Indication(s):** VHL disease requiring therapy for associated RCC, CNS hemangioblastomas, or pNET, not requiring immediate surgery
- **How Supplied:** 40mg oral tablets
- **Dose:** 120mg [(3) 40mg tablets] once daily
- **Cost:** The WAC is $293.33 per tablet resulting in a monthly cost of $26,399.70 and an annual cost of $316,796.40 based on the recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Camcevi™ (leuprolide), Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan), Tivdak® (tisotumab vedotin-tftv), and Welireg™ (belzutifan) with the following criteria listed in red:

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].

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.

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.

Welireg™ (Belzutifan) Approval Criteria:

1. Diagnosis of von Hippel-Landau (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.

Additionally, the College of Pharmacy recommends updating the Cabometyx® (cabozantinib) prior authorization criteria based on the recent FDA approval (changes noted in red):

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.

Utilization Details of Genitourinary and Cervical/Endometrial Cancer Medications: Calendar Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
EVEROLIMUS PRODUCTS					
AFINITOR DIS TAB 3MG	36	4	$1,207,691.56	9	$33,546.99
AFINITOR DIS TAB 5MG	26	4	$1,131,740.73	6.5	$43,528.49
AFINITOR TAB 10MG	14	4	$220,037.68	3.5	$15,716.98
EVEROLIMUS TAB 5MG	14	4	$86,557.51	3.5	$6,182.68
EVEROLIMUS TAB 7.5MG	12	1	$107,609.13	12	$8,967.43
AFINITOR DIS TAB 2MG	7	2	$164,434.61	3.5	$23,490.66
AFINITOR TAB 5MG	2	1	$31,436.24	2	$15,718.12
EVEROLIMUS TAB 10MG	1	1	$3,211.41	1	$3,211.41

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
SUBTOTAL	**112**	**21**	**$2,952,718.87**	**5.33**	**$26,363.56**
ENZALUTAMIDE PRODUCTS					
XTANDI CAP 40MG	38	10	$466,067.10	3.8	$12,264.92
XTANDI TAB 80MG	5	1	$61,435.55	5	$12,287.11
XTANDI TAB 40MG	5	2	$61,423.55	2.5	$12,284.71
SUBTOTAL	**48**	**13**	**$588,926.20**	**3.69**	**$12,269.30**
ABIRATERONE PRODUCTS					
ZYTIGA TAB 500MG	35	3	$381,362.05	11.67	$10,896.06
ABIRATERONE TAB 250MG	11	6	$3,095.91	1.83	$281.45
SUBTOTAL	**46**	**9**	**$384,457.96**	**5.11**	**$8,357.78**
CABOZANTINIB PRODUCTS					
CABOMETYX TAB 40MG	18	7	$390,092.93	2.57	$21,671.83
CABOMETYX TAB 60MG	12	4	$260,054.52	3	$21,671.21
SUBTOTAL	**30**	**11**	**$650,147.45**	**2.72**	**$21,671.58**
APALUTAMIDE PRODUCTS					
ERLEADA TAB 60MG	21	3	$269,658.07	7	$12,840.86
SUBTOTAL	**21**	**3**	**$269,658.07**	**7**	**$12,840.86**
RUCAPARIB PRODUCTS					
RUBRACA TAB 300MG	1	1	$17,377.91	1	$17,377.91
SUBTOTAL	**1**	**1**	**$17,377.91**	**1**	**$17,377.91**
TOTAL	**258**	**47***	**$4,863,286.46**	**5.49**	**$18,849.95**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
PEMBROLIZUMAB J9271	528	138	$6,725,078.00	3.83	$12,736.89
NIVOLUMAB J9299	244	56	$2,882,586.15	4.36	$11,813.88
ATEZOLIZUMAB J9022	150	49	$1,638,211.68	3.06	$10,921.41
IPILIMUMAB J9228	26	12	$494,363.04	2.17	$19,013.96
SACITUZUMAB GOVITECAN-HZIY J9317	23	6	$280,759.08	3.83	$12,206.92
CABAZITAXEL J9043	8	3	$96,349.50	2.67	$12,043.69
AVELUMAB J9023	6	1	$68,448.80	6	$11,408.13
MITOMYCIN PYELOCALYCEAL J9281	1	1	$2,540.07	1	$2,540.07
TOTAL	**986**	**266**	**$12,188,336.32**	**3.71**	**$12,361.40**

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

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Appendix I

Calendar Year 2021 Annual Review of the SoonerCare Pharmacy Benefit

Oklahoma Health Care Authority
June 2022

Summary[1]

During calendar year (CY) 2021, prescription drugs accounted for $696 million of the approximately $5.99 billion in total SoonerCare spending. On July 1, 2021, the SoonerCare benefit expanded across the state to include the Healthy Adult Population (HAP). With this expansion affecting 6 months of this calendar year, it is included in the CY 2021 data. The average monthly enrollment increased 20% from CY 2020 to CY 2021, 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 is still ongoing; during the PHE, Medicaid agencies are required to continue health care coverage for members even if their eligibility changes and they no longer qualify for coverage. Comparing SoonerCare pharmacy data from CY 2020, the total reimbursement increased 17.5% from CY 2020 to CY 2021. The annual pharmacy cost per member decreased from $666.12 in CY 2020 to $652.09 in CY 2021, which is a 2% decrease. Although there was a decrease in reimbursement per member, 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 2021 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 State Fiscal Year (SFY) Comparison							
SFY	**Claims**	**Members⁺**	**Utilizers***	**Reimbursement**	**Cost/ Claim**	**Cost/ Member**	**Cost/ Day**
2020	5,292,337	822,271	495,721	$576,722,981.89	$108.97	$701.38	$3.95
2021	5,069,289	971,781	466,752	$607,507,964.31	$119.84	$625.15	$4.00

⁺Average monthly enrollment as obtained from OHCA Fast Facts reports.
*Total number of unduplicated utilizers.
Reimbursement does not reflect rebated costs or net costs.
State Fiscal Year = July 1 to June 30

Total Pharmacy Calendar Year (CY) Comparison							
CY	**Claims**	**Members**	**Utilizers***	**Reimbursement**	**Cost/ Claim**	**Cost/ Member**	**Cost/ Day**
2019	5,467,453	807,530	518,166	$566,310,541.79	$103.58	$701.29	$3.88
2020	5,056,193	889,437	469,045	$592,469,533.49	$117.18	$666.12	$4.02
2021	6,000,363	1,067,537	587,659	$696,135,194.20	$116.02	$652.09	$3.91

†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 Calendar Year (CY) Comparison				
Calendar Year (CY)	**CY 2019**	**CY 2020**	**CY 2021 with HAP**	**CY 2021 without HAP**
Overall PMPY Value†	$929.22	$871.49	$836.37	$841.14

PMPY = per member per year
†PMPY value calculated using average monthly enrollment, excluding dual eligible and IHS members.

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.

To measure the success of the SoonerCare pharmacy benefit management, Oklahoma's Medicaid statistics were compared to the Medicaid statistics of the largest PBM in the United States, Express Scripts (ESI). ESI 2021 data was not available at the time of this report, so 2020 data was used for calculations. For CY 2020, ESI's Medicaid PMPY was $1,214, making it 45% higher than OHCA's $836 for CY 2021. At the ESI CY 2020 PMPY rate, it would have cost OHCA over $314.3 million more than the $696.1 million spent during CY 2021 for pharmacy reimbursement.

Medicaid PMPY Comparison			
Calendar Year	**ESI**	**OHCA**	**Percent Difference**
2019	$1,102	$929	19%
2020	$1,214	$871	39%
2021	*$1,214	$836	45%

ESI = Express Scripts; OHCA = Oklahoma Health Care Authority; PMPY = per member per year
PMPY costs do not reflect rebated prices or net costs.
*2021 ESI data was not published at time of this report; therefore, 2020 data was used for calculations.

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 1.1 million SoonerCare members. Looking at the cost to manage the pharmacy benefit, the OHCA pharmacy department has a cost of about $1 million, and OHCA's partner, PMC, spent approximately $5 million of their contract in CY 2021. As a return on investment (ROI), using the overage generated by the ESI PMPY rate, for CY 2020 it is $39 to $1, and in CY 2021 it is estimated at $53 to $1.

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., 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 2021, OHCA collected over $395 million in federal and state supplemental rebates, resulting in a total increase from CY 2020 of approximately $9 million ($386 million in federal and state supplemental rebates). These 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 5 APM contracts being active in calendar year 2021. 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 2021	
Manufacturer	**Details**
Amgen	▪ Tumor necrosis factor (TNF) inhibitor – utilization and cost ▪ Focus on population characterizations to inform future value-based contracts
Avexis	▪ Spinal muscular atrophy (SMA) medication – utilization

Overview of Established APM Contracts: Calendar Year 2021	
Manufacturer	**Details**
Janssen	▪ Long-acting injectable (LAI) atypical antipsychotic – adherence; phase 2 will include additional clinical outcomes
Lilly	▪ Anti-migraine medication [calcitonin gene-related peptide (CGRP) antagonist] – utilization and cost
UCB	▪ Anticonvulsant medication – health resource utilization

APM = alternative payment model

Drug Approval Trends[10,11,12]

During CY 2021, 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 2021 included Revlimid® (lenalidomide), Trintellix® (vortioxetine), Tradjenta® (linagliptin), and Chantix® (varenicline tartrate).

A total of 50 novel drugs were approved by the FDA during CY 2021. The active ingredient or ingredients in a novel drug have never before been approved in the United States. Of the novel drugs approved by the FDA in CY 2021, 27 were considered first-in-class, and 26 were designated as orphan drugs and approved to treat rare diseases. Select novel drugs approved during CY 2021 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 2021			
Drug Name	**Date Approved**	**FDA-Approved Indication**	**Estimated Annual Cost Per Member***
Amondys 45 (casimersen)	02/25/2021	Duchenne muscular dystrophy (DMD)	$665,600 for member weighing 25kg
Leqvio® (inclisiran)	12/22/2021	HeFH or ASCVD	$6,500
Rezurock™ (belumosudil)	07/16/2021	chronic GVHD	$186,001
Tezspire™ (tezepelumab-ekko)	12/27/2021	severe asthma as an add-on therapy	$47,229
Verquvo® (vericiguat)	01/19/2021	chronic heart failure	$7,344

*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).
ASCVD = atherosclerotic cardiovascular disease; GVHD = graft-versus-host disease; HeFH = heterozygous familial hypercholesterolemia

Traditional Versus Specialty Pharmacy Products

Traditional pharmaceuticals include products that are typically non-injectable and do not require special transportation, storage, 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 68.4% of the total pharmacy reimbursement and more than 99% of utilizers, in CY 2021.

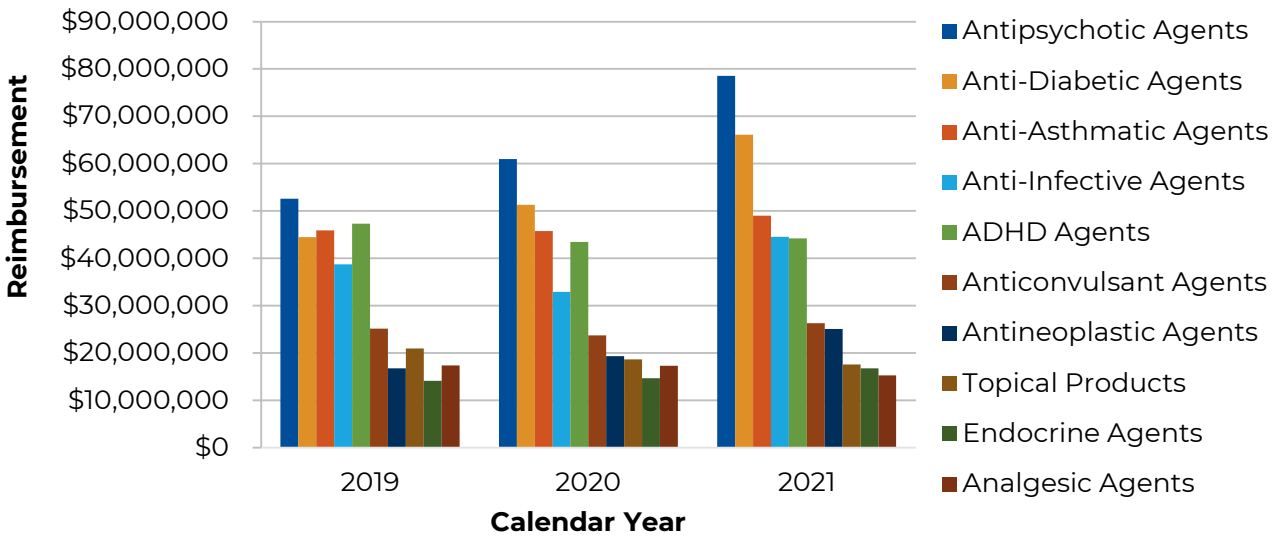
Specialty products, in contrast, are typically injectable and require special handling such as refrigerated transport and special administration techniques or are indicated for rare diseases requiring unique management. These products include treatments for cystic fibrosis (CF), hemophilia, rheumatoid arthritis, and genetic deficiencies. Specialty pharmaceuticals have become a larger part of reimbursement over the last 5 years. Newly FDA approved therapies for Duchenne muscular dystrophy and chronic graft-vs-host disease (GVHD) led to an increase in specialty pharmaceutical expenditures for CY 2021.

Top 10 Traditional Therapeutic Classes by Reimbursement: CY 2021

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.

2019	2020	2021	Therapeutic Class
$52,616,264	$60,984,709	**$78,516,981**	**Antipsychotic Agents**
$44,467,083	$51,313,829	**$66,068,079**	**Anti-Diabetic Agents**
$45,871,216	$45,776,464	**$49,000,455**	**Anti-Asthmatic Agents**
$38,733,735	$32,935,581	**$44,559,630**	**Anti-Infective Agents**
$47,318,536	$43,457,615	**$44,219,854**	**ADHD Agents**
$25,110,544	$23,702,738	**$26,266,543**	**Anticonvulsant Agents**
$16,730,921	$19,294,625	**$25,084,839**	**Antineoplastic Agents**
$20,981,254	$18,663,331	**$17,579,241**	**Topical Products**
$14,138,254	$14,667,793	**$16,783,946**	**Endocrine Agents**
$17,361,647	$17,312,176	**$15,267,071**	**Analgesic Agents**

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



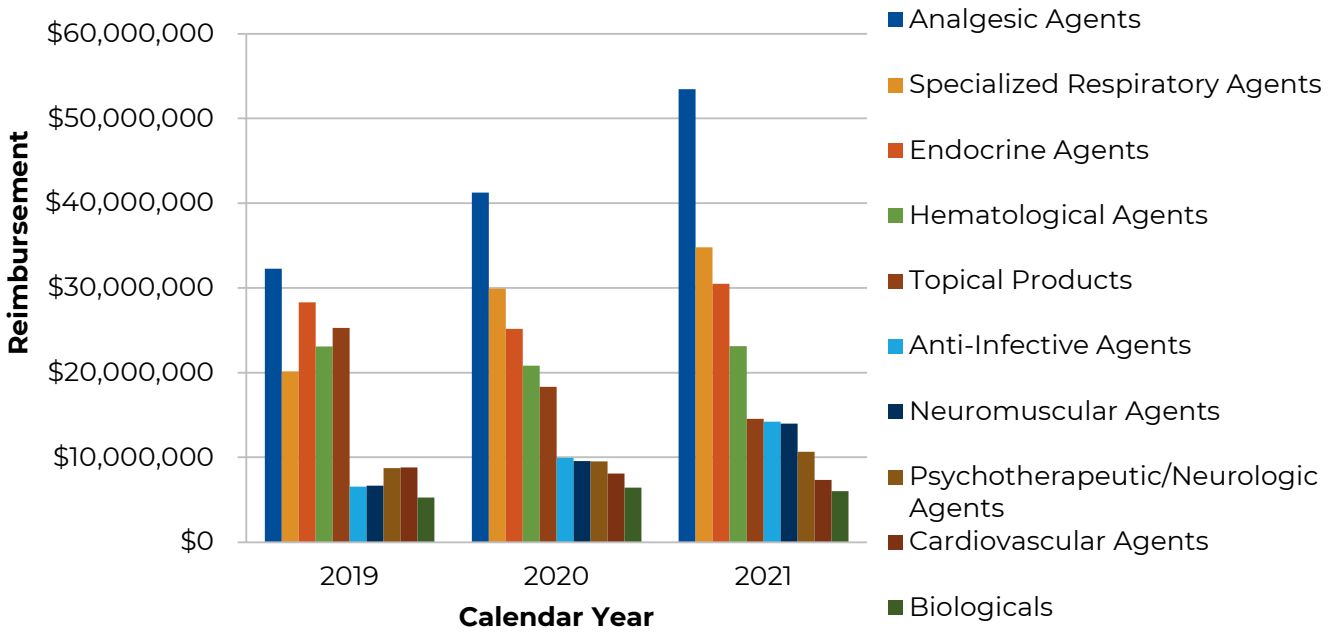
The top 10 traditional pharmaceutical classes that showed the most significant change from CY 2020 to 2021 include the antipsychotic and anti-diabetic agents. Other traditional classes saw minor fluctuations.

- Antipsychotic agents' reimbursement increased by $17.5 million in CY 2021; 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 2021 reimbursement increased by more than $14.8 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 a $11.6 million increase from CY 2020, 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 $5.4 million dollars with 1,419 more claims for 403 more members, compared to CY 2020.

Top 10 Specialty Therapeutic Classes by Reimbursement: CY 2021

2019	2020	2021	Therapeutic Class
$32,260,764	$41,244,853	**$53,429,945**	**Analgesic Agents**
20,128,396	$29,933,715	**$34,808,187**	**Specialized Respiratory Agents**
$28,291,082	$25,153,127	**$30,491,144**	**Endocrine Agents**
$23,088,824	$20,801,563	**$23,118,618**	**Hematological Agents**
$25,285,075	$18,313,938	**$14,546,229**	**Topical Products**
$6,549,815	$9,928,919	**$14,215,018**	**Anti-Infective Agents**
$6,664,209	$9,552,692	**$13,994,766**	**Neuromuscular Agents**
$8,717,200	$9,507,637	**$10,660,814**	**Psychotherapeutic/Neurologic Agents**
$8,799,008	$8,092,050	**$7,345,270**	**Cardiovascular Agents**
$5,262,976	$6,415,482	**$6,017,944**	**Biologicals**

Reimbursement does not reflect rebated prices or net costs.



The cost of specialty therapeutic products is high, largely in part due to biologic therapies 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 declines in reimbursement for topical and cardiovascular agents.

- The cost of specialty analgesic agents increased this year, with a $12 million increase in anti-inflammatory agents. Reimbursement in this class is largely attributed to targeted immunomodulatory agents such as Humira® (adalimumab), Enbrel® (etanercept), Ilaris® (canakinumab), Orencia® (abatacept), Simponi® (golimumab), Xeljanz® (tofacitinib),

Otezla® (apremilast), and Kineret® (anakinra). The majority of utilization was seen in Tier-2 medications (Humira® and Enbrel®), which are supplementally rebated medications. The supplementally rebated prices and net costs are not reflected in this analysis.

- Endocrine agents had a $5.3 million increase in reimbursement from CY 2020 to CY 2021. Somatropin was the main driver of the increase in this class with a $2.5 million increase in reimbursement and a corresponding increase in claims (347 more claims) and members (21 more members) compared to CY 2020. The growth hormone product category is influenced by supplemental rebates, and reimbursement in this report does not reflect rebated prices or net costs.

Top 10 Medications by Reimbursement: CY 2021

Many of the top 10 medications by reimbursement are still branded at this time and not available in a generic formulation. The top 3 medications by reimbursement have been consistent over the past 3 years, with the ranking remaining identical from 2020 to 2021. 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	**2019**	**2020**	**2021**
1	lisdexamfetamine	adalimumab inj	**adalimumab inj**
2	paliperidone inj	paliperidone inj	**paliperidone inj**
3	adalimumab inj	lisdexamfetamine	**lisdexamfetamine**
4	albuterol	elexacaftor/tezacaftor/ ivacaftor	**elexacaftor/tezacaftor/ ivacaftor**
5	sofosbuvir/velpatasvir	lurasidone	**lurasidone**
6	lurasidone	sofosbuvir/velpatasvir	**somatropin inj**
7	somatropin inj	albuterol	**insulin glargine inj**
8	insulin glargine inj	somatropin inj	**albuterol**
9	fluticasone HFA	insulin glargine inj	**etanercept inj**
10	methylphenidate	fluticasone HFA	**dexmethylphenidate**

*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

Claims for generic medications made up 86% of the volume while only accounting for 29% of the reimbursement amount. The SoonerCare cost per claim of traditional medications decreased by 1% in CY 2021 in comparison to CY 2020, and the cost per specialty medication claim increased by 4.8%. As mentioned previously, specialty costs are largely driven by the significant cost associated with medications for rare diseases.

Cost Per Claim			
Drug Class	**CY 2019**	**CY 2020**	**CY 2021**
Traditional	$72.03	$80.66	$79.74
Specialty	$7,043.67	$6,798.35	$7,124.43

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

Market Projections[11,12,13]

Specialty medications made up 1% of the utilizers for CY 2021 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. Tezspire™ (tezepelumab-ekko), a monoclonal antibody and the first asthma treatment targeting thymic stromal lymphopoietin (TSLP), was approved by the FDA in December 2021 to treat severe asthma as an add-on therapy. Leqvio® (inclisiran), an antilipemic small interfering ribonucleic acid (siRNA) agent, was also approved in December 2021 as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or with clinical atherosclerotic cardiovascular disease. These 2 new products have the potential to make a substantial impact on reimbursement in the upcoming year. Oncology medications made up about 30% of drug approvals in 2021 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 2021			
Brand	**Generic**	**Indication(s)**	**Approval Date**
Besremi®	ropeginterferon alfa-2b-njft	polycythemia vera	Nov-21
Cosela™	trilaciclib	chemotherapy-induced myelosuppression	Feb-21
Cytalux™	pafolacianine	ovarian cancer imaging	Nov-21
Exkivity®	mobocertinib	non-small cell lung cancer	Sep-21
Fotivda®	tivozanib	renal cell carcinoma	Mar-21
Jemperli	dostarlimab-gxly	endometrial cancer	Apr-21
Lumakras™	sotorasib	non-small cell lung cancer	May-21

Pepaxto®	melphalan flufenamide	multiple myeloma	Feb-21
Pylarify®	piflufolastat F 18	prostate cancer imaging	May-21
Rybrevant®	amivantamab-vmjw	non-small cell lung cancer	May-21
Rylaze™	asparaginase *Erwinia chrysanthemi* (recombinant)-rywn	acute lymphoblastic leukemia/lymphoma	Jun-21
Scemblix®	asciminib	chronic myeloid leukemia	Oct-21
Tepmetko®	tepotinib	non-small cell lung cancer	Feb-21
Tivdak™	tisotumab vedotin-tftv	cervical cancer	Sep-21
Truseltiq®	infigratinib	cholangiocarcinoma	May-21
Ukoniq®	umbralisib	follicular & marginal zone lymphoma	Feb-21
Welireg™	belzutifan	von Hippel-Lindau disease	Aug-21
Zynlonta®	loncastuximab tesirine-lpyl	cervical cancer	Sep-21

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 2021		CY 2020	
		Rank	Amount Paid	Rank	Amount Paid
Adalimumab	HUMIRA	**1**	**$37,199,373**	1	$26,820,571
Paliperidone inj	MULTIPLE	**2**	**$32,047,730**	2	$24,433,216
Lisdexamfetamine	VYVANSE	**3**	**$24,545,143**	3	$23,475,202
Elexacaftor-Tezacaftor-Ivacaftor	TRIKAFTA	**4**	**$22,347,222**	4	$16,766,241
Lurasidone	LATUDA	**5**	**$17,903,097**	5	$14,472,541
Somatropin	MULTIPLE	**6**	**$13,546,167**	8	$11,055,496
Insulin Glargine	MULTIPLE	**7**	**$12,654,559**	9	$10,799,671
Albuterol	MULTIPLE	**8**	**$10,678,829**	7	$11,343,618
Etanercept	ENBREL	**9**	**$10,551,375**	12	$8,092,955
Dexmethylphenidate	MULTIPLE	**10**	**$9,306,255**	11	$8,297,993
Aripiprazole tab	ABILIFY	**11**	**$9,078,441**	17	$6,806,322
Fluticasone HFA	FLOVENT	**12**	**$9,072,182**	10	$9,394,049
Sofosbuvir-Velpatasvir	EPCLUSA	**13**	**$8,758,613**	6	$11,848,522
Fluticasone-Salmeterol	MULTIPLE	**14**	**$8,693,058**	13	$8,010,461
Emicizumab-kxwh	HEMLIBRA	**15**	**$8,643,774**	16	$6,865,928
Bictegravir-Emtricitabine-Tenofovir	BIKTARVY	**16**	**$8,399,611**	46	$2,928,801
Insulin Aspart	NOVOLOG	**17**	**$7,745,952**	14	$7,794,606
Dulaglutide	TRULICITY	**18**	**$7,080,514**	72	$1,753,394
Insulin Lispro	HUMALOG	**19**	**$6,977,780**	20	$5,484,888
Dupilumab	DUPIXENT	**20**	**$6,533,528**	32	$3,707,435
Lacosamide	VIMPAT	**21**	**$6,458,548**	19	$5,529,466
Budesonide-Formoterol	SYMBICORT	**22**	**$5,965,892**	24	$4,104,585
Tiotropium	SPIRIVA	**23**	**$5,855,472**	23	$4,682,525
Insulin Detemir	LEVEMIR	**24**	**$5,798,997**	22	$5,128,327
Methylphenidate	MULTIPLE	**25**	**$5,490,585**	15	$6,930,474
Ustekinumab	STELARA	**26**	**$5,446,971**	39	$3,402,711
Aripiprazole inj	MULTIPLE	**27**	**$5,080,960**	41	$3,182,597
Apixaban	ELIQUIS	**28**	**$4,775,290**	31	$3,712,834
Cariprazine	VRAYLAR	**29**	**$4,630,171**	42	$3,116,474
Liraglutide	VICTOZA	**30**	**$4,527,692**	25	$4,022,335
Pancrelipase	MULTIPLE	**31**	**$4,506,647**	37	$3,517,255
Empagliflozin	JARDIANCE	**32**	**$4,438,466**	53	$2,328,800
Vigabatrin	MULTIPLE	**33**	**$4,246,490**	36	$3,524,038
Golodirsen	VYONDYS 53	**34**	**$4,141,519**	62	$1,966,777
Ciprofloxacin-Dexamethasone	CIPRODEX	**35**	**$4,080,090**	21	$5,217,241
Dornase Alfa	PULMOZYME	**36**	**$4,018,728**	34	$3,687,134

Generic	Brand	CY 2021		CY 2020	
		Rank	Amount Paid	Rank	Amount Paid
Darunavir-Cobicistat-Emtricitabine-Tenofovir	SYMTUZA	**37**	**$3,936,034**	50	$2,723,582
Palbociclib	IBRANCE	**38**	**$3,725,619**	33	$3,702,275
Blood Glucose Test Strips	MULTIPLE	**39**	**$3,657,153**	28	$3,835,296
Cannabidiol	EPIDIOLEX	**40**	**$3,623,030**	44	$3,063,397
Palivizumab	SYNAGIS	**41**	**$3,489,180**	30	$3,713,086
Sitagliptin	JANUVIA	**42**	**$3,450,268**	43	$3,088,429
Abacavir-Dolutegravir-Lamivudine	TRIUMEQ	**43**	**$3,397,530**	76	$1,586,762
Glecaprevir-Pibrentasvir	MAVYRET	**44**	**$3,355,778**	49	$2,756,997
CGM and Supplies	MULTIPLE	**45**	**$3,312,199**	66	$1,817,222
Lumacaftor-Ivacaftor	ORKAMBI	**46**	**$3,228,819**	47	$2,867,498
Covid-19 mRNA Vaccine	MULTIPLE	**47**	**$3,111,910**	1296	$678
Nusinersen	SPINRAZA	**48**	**$3,073,148**	35	$3,574,524
Valbenazine	INGREZZA	**49**	**$3,063,645**	45	$2,966,909
Hydroxyprogesterone	MAKENA	**50**	**$3,027,422**	27	$3,892,441

Includes brand and generic where applicable.
Reimbursement does not reflect rebated costs or net costs.
CGM = continuous glucose monitor; CY = calendar year; HFA = hydrofluoroalkane, inj = injection; tab = tablet

Top 50 Medications by Total Number of Claims: Calendar Year 2021

Top 50 Medications by Total Number of Claims								
Rank	**Generic Name**	**Claims**	**Members**	**Cost**	**Units/ Day**	**Claims/ Member**	**Cost/ Claim**	**% Cost**
1	Albuterol	**229,319**	102,118	$10,678,828.90	1.9	2.25	$46.57	9.37%
2	Cetirizine	**202,815**	89,379	$2,421,656.29	2.99	2.27	$11.94	2.13%
3	Amoxicillin	**184,534**	140,062	$2,347,681.50	11.27	1.32	$12.72	2.06%
4	Hydrocodone-APAP	**115,338**	49,779	$1,886,623.36	3.81	2.32	$16.36	1.66%
5	Gabapentin	**105,978**	26,658	$1,864,692.57	3.06	3.98	$17.60	1.64%
6	Montelukast	**105,820**	32,576	$1,551,274.91	1	3.25	$14.66	1.36%
7	Fluticasone Nasal	**96,312**	53,166	$1,461,781.56	0.41	1.81	$15.18	1.28%
8	Sertraline	**95,305**	26,158	$1,215,893.66	1.16	3.64	$12.76	1.07%
9	Azithromycin	**94,095**	73,728	$1,568,281.06	2.6	1.28	$16.67	1.38%
10	Clonidine	**82,797**	15,852	$947,519.84	1.48	5.22	$11.44	0.83%
11	Trazodone	**80,327**	20,598	$947,092.34	1.23	3.9	$11.79	0.83%
12	Ondansetron	**79,602**	59,712	$1,158,009.02	2.36	1.33	$14.55	1.02%
13	Lisdexamfetamine	**78,965**	14,177	$24,545,142.70	1	5.57	$310.84	21.54%
14	COVID-19 mRNA Vaccine	**78,221**	50,014	$3,098,981.55	0.01	1.56	$39.62	2.72%
15	Ibuprofen	**74,079**	51,419	$901,275.94	3.03	1.44	$12.17	0.79%
16	Fluoxetine	**73,059**	18,885	$950,921.87	1.23	3.87	$13.02	0.83%
17	Prednisone	**71,872**	53,200	$764,357.66	1.81	1.35	$10.63	0.67%

Top 50 Medications by Total Number of Claims								
Rank	**Generic Name**	**Claims**	**Members**	**Cost**	**Units/ Day**	**Claims/ Member**	**Cost/ Claim**	**% Cost**
18	Omeprazole	**71,032**	26,208	$880,486.97	1.2	2.71	$12.40	0.77%
19	Methylphenidate	**69,342**	10,765	$5,490,585.10	1.32	6.44	$79.18	4.82%
20	Lisinopril	**58,972**	20,824	$637,905.36	1.08	2.83	$10.82	0.56%
21	Cefdinir	**58,735**	46,544	$1,249,994.96	6.3	1.26	$21.28	1.10%
22	Amoxicillin & K Clavulanate	**58,709**	50,278	$1,289,517.28	7.07	1.17	$21.96	1.13%
23	Escitalopram	**58,445**	17,053	$788,655.08	1.06	3.43	$13.49	0.69%
24	Levothyroxine	**56,809**	14,027	$1,299,130.15	1	4.05	$22.87	1.14%
25	Guanfacine	**55,999**	8,730	$1,123,563.93	1	6.41	$20.06	0.99%
26	Aripiprazole tab	**54,382**	12,599	$9,078,440.80	0.96	4.32	$166.94	7.97%
27	Atorvastatin	**53,666**	18,739	$705,307.05	1	2.86	$13.14	0.62%
28	Cephalexin	**52,078**	45,275	$829,029.15	8.31	1.15	$15.92	0.73%
29	Hydroxyzine	**51,869**	20,626	$693,948.58	3.17	2.51	$13.38	0.61%
30	Quetiapine	**51,620**	10,942	$803,039.79	1.43	4.72	$15.56	0.70%
31	Buspirone	**49,186**	14,153	$693,801.47	2.24	3.48	$14.11	0.61%
32	Metformin	**47,137**	16,646	$510,548.93	2.02	2.83	$10.83	0.45%
33	Bupropion	**46,714**	13,646	$852,211.87	1.19	3.42	$18.24	0.75%
34	Amphetamine-Dextroamphetamine	**46,272**	7,918	$1,245,682.17	1.46	5.84	$26.92	1.09%
35	Triamcinolone	**43,710**	31,481	$668,661.16	4.69	1.39	$15.30	0.59%
36	Cyclobenzaprine	**42,528**	20,473	$433,759.90	2.29	2.08	$10.20	0.38%
37	Loratadine	**40,639**	17,972	$458,009.17	2.82	2.26	$11.27	0.40%
38	Alprazolam	**39,851**	6,997	$438,973.18	2.25	5.7	$11.02	0.39%
39	Risperidone	**39,715**	7,188	$1,590,377.84	1.51	5.53	$40.04	1.40%
40	Oxycodone-APAP	**39,389**	15,387	$755,616.58	3.73	2.56	$19.18	0.66%
41	Duloxetine	**38,886**	10,947	$619,693.68	1.27	3.55	$15.94	0.54%
42	Pantoprazole	**38,593**	14,595	$514,978.97	1.15	2.64	$13.34	0.45%
43	Sulfamethoxazole-Trimethoprim	**38,380**	31,303	$575,045.89	5.86	1.23	$14.98	0.50%
44	Amlodipine	**38,100**	13,402	$377,053.23	1.04	2.84	$9.90	0.33%
45	Fluticasone HFA	**36,789**	15,224	$9,072,182.13	0.33	2.42	$246.60	7.96%
46	Dexmethylphenidate	**36,778**	5,413	$9,306,255.14	1.14	6.79	$253.04	8.17%
47	Mupirocin	**36,597**	31,318	$573,775.11	2.45	1.17	$15.68	0.50%
48	Lamotrigine	**36,265**	7,458	$1,035,512.15	1.84	4.86	$28.55	0.91%
49	Prednisolone	**35,956**	28,610	$494,842.64	6.52	1.26	$13.76	0.43%
50	Hydroxyzine Pamoate	**35,823**	14,344	$547,082.76	2.68	2.5	$15.27	0.48%

APAP = acetaminophen; HFA = hydrofluoroalkane; tab = tablet
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	2021 Total Claims	2021 Total Cost	2021 Cost/ Member	2020 Total Claims	2020 Total Cost	2020 Cost/ Member
	CALENDAR YEAR 2021			CALENDAR YEAR 2020		
ANTIPSYCHOTICS & ANTIMANIC AGENTS						
Antipsychotics	248,801	$78,516,980.92	$2,017.50	219,376	$60,984,709.15	$2,084.88
Total	**248,801**	**$78,516,980.92**	**$2,017.50**	**219,376**	**$60,984,709.15**	**$2,084.88**
ANTI-DIABETIC AGENTS						
Anti-diabetics	158,318	$66,068,079.08	$2,491.16	129,360	$51,313,828.78	$2,912.08
Total	**158,318**	**$66,068,079.08**	**$2,491.16**	**129,360**	**$51,313,828.78**	**$2,912.08**
ANTI-ASTHMATIC AGENTS						
Anti-asthmatic & Bronchodilatory Agents	457,202	$49,000,455.49	$398.62	428,591	$45,776,464.03	$481.23
Total	**457,202**	**$49,000,455.49**	**$398.62**	**428,591**	**$45,776,464.03**	**$481.23**
ADHD AGENTS						
ADHD/Anti-Narcolepsy/ Anti-Obesity/ Anorexiants	319,970	$44,219,854.05	$1,095.39	313,037	$43,457,614.79	$1,136.68
Total	**319,970**	**$44,219,854.05**	**$1,095.39**	**313,037**	**$43,457,614.79**	**$1,136.68**
ANTI-INFECTIVE AGENTS						
Antiviral	32,579	$26,951,482.72	$1,641.78	69,967	$18,732,880.40	$339.62
Misc. Anti-Infectives	106,656	$5,551,112.15	$75.05	87,607	$4,995,638.75	$83.74
Penicillins	251,078	$3,976,903.07	$22.27	179,903	$2,932,581.63	$21.58
Cephalosporins	116,379	$2,413,797.65	$26.53	91,214	$1,980,461.57	$27.17
Macrolide Antibiotics	96,648	$2,305,294.87	$30.67	66,797	$1,651,484.62	$31.26
Antifungals	32,408	$1,828,161.45	$82.14	25,470	$1,258,400.63	$73.29
Tetracyclines	32,653	$686,582.58	$29.62	22,646	$653,185.01	$45.20
Anthelmintic	3,448	$287,997.01	$93.75	2,172	$303,712.88	$164.88
Fluoroquinolones	16,833	$242,033.47	$17.83	12,930	$190,617.75	$18.77
Antimalarial	8,112	$197,656.51	$85.97	5,552	$165,404.26	$113.21
Aminoglycosides	456	$76,271.32	$401.43	389	$20,664.21	$141.54
Antimycobacterial Agents	491	$38,241.85	$208.97	410	$45,352.86	$298.37
Sulfonamides	6	$2,959.76	$986.59	24	$4,630.84	$1,157.71
Amebicides	4	$1,135.51	$378.50	2	$565.90	$282.95
Total	**697,751**	**$44,559,629.92**	**$89.15**	**565,083**	**$32,935,581.31**	**$78.08**
ANTICONVULSANT AGENTS						
Anticonvulsants	348,929	$26,266,543.46	$459.11	314,115	$23,702,737.54	$557.40
Total	**348,929**	**$26,266,543.46**	**$459.11**	**314,115**	**$23,702,737.54**	**$557.40**
ANTINEOPLASTICS						
Antineoplastics	12,072	$25,084,839.10	$8,211.08	10,361	$19,294,624.78	$8,141.19
Total	**12,072**	**$25,084,839.10**	**$8,211.08**	**10,361**	**$19,294,624.78**	**$8,141.19**
TOPICAL PRODUCTS						
Dermatological	187,672	$10,303,300.57	$97.69	176,106	$10,208,675.04	$105.11

Traditional Therapeutic Category	2021 Total Claims	2021 Total Cost	2021 Cost/ Member	2020 Total Claims	2020 Total Cost	2020 Cost/ Member
Otic	26,618	$4,224,268.10	$192.70	23,408	$5,370,118.03	$273.02
Ophthalmic	55,133	$2,533,711.63	$67.49	45,788	$2,670,570.80	$86.24
Mouth/Throat/Dental Agents	24,277	$388,508.08	$19.66	19,954	$331,196.25	$21.15
Anorectal	1,779	$129,452.94	$88.24	1,311	$82,770.98	$77.65
Total	**295,479**	**$17,579,241.32**	**$94.43**	**266,567**	**$18,663,331.10**	**$113.46**
ANALGESIC AGENTS						
Analgesics - Narcotic	262,630	$10,473,795.08	$127.49	233,880	$14,718,042.77	$227.06
Analgesics - Anti-Inflammatory	163,170	$3,783,799.68	$42.51	127,746	$1,964,406.89	$29.69
Migraine Products	14,550	$783,652.42	$114.50	11,360	$405,316.33	$81.05
Analgesics - Non-Narcotic	5,348	$113,643.00	$55.95	5,072	$108,356.77	$56.09
Gout	6,409	$109,757.62	$59.10	5,617	$113,845.26	$87.17
Local Anesthetics - Parenteral	134	$2,423.60	$24.00	164	$2,208.05	$17.25
Total	**452,241**	**$15,267,071.40**	**$83.88**	**383,839**	**$17,312,176.07**	**$124.23**
ENDOCRINE AGENTS						
Contraceptives	114,549	$7,501,191.48	$216.90	96,108	$6,083,975.10	$216.02
Misc. Endocrine	15,221	$3,649,277.80	$1,046.84	15,766	$4,305,462.65	$1,268.93
Corticosteroids	191,881	$2,872,562.27	$21.70	119,504	$1,865,576.46	$22.05
Thyroid	63,117	$1,577,860.75	$103.35	54,077	$1,408,436.37	$125.04
Estrogens	10,193	$839,903.37	$288.03	7,739	$709,890.45	$356.37
Progestin	8,030	$217,686.64	$60.81	5,823	$177,091.37	$71.96
Androgen-Anabolic	1,079	$108,465.04	$444.53	735	$80,906.82	$496.36
Oxytocics	113	$16,998.71	$155.95	118	$36,453.84	$319.77
Total	**404,183**	**$16,783,946.06**	**$87.16**	**299,870**	**$14,667,793.06**	**$110.99**

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

Specialty Therapeutic Category	2021 Total Claims	2021 Total Cost	2021 Cost/ Member	2020 Total Claims	2020 Total Cost	2020 Cost/ Member
	CALENDAR YEAR 2021			**CALENDAR YEAR 2020**		
ANALGESIC AGENTS						
Analgesic - Anti-Inflammatory	8,049	$52,376,167.84	$40,351.44	6,633	$40,523,255.00	$42,432.73
Migraine Products	1,295	$807,053.00	$3,241.18	942	$567,908.02	$3,036.94
Analgesic - Narcotics	156	$244,515.48	$5,315.55	113	$151,679.47	$6,067.18
Local Anesthetics - Parenteral	91	$2,208.98	$30.68	71	$2,010.77	$41.04
Total	**9,591**	**$53,429,945.30**	**$32,090.06**	**7,759**	**$41,244,853.26**	**$33,918.46**
SPECIALIZED RESPIRATORY AGENTS						
Misc. Respiratory	2,515	$34,808,187.47	$171,468.90	2,244	$29,933,714.55	$163,572.21
Total	**2,515**	**$34,808,187.47**	**$171,468.90**	**2,244**	**$29,933,714.55**	**$163,572.21**
ENDOCRINE AGENTS						

Specialty Therapeutic Category	2021 Total Claims	2021 Total Cost	2021 Cost/ Member	2020 Total Claims	2020 Total Cost	2020 Cost/ Member
Misc. Endocrine	4,112	$27,463,722.27	$55,707.35	3,773	$21,260,685.61	$46,319.58
Progestins	1,144	$3,027,422.10	$8,073.13	1,405	$3,892,441.28	$8,669.13
Total	**5,256**	**$30,491,144.37**	**$35,128.05**	**5,178**	**$25,153,126.89**	**$27,701.68**
HEMATOLOGICAL AGENTS						
Misc. Hematological	934	$20,613,681.03	$173,224.21	880	$19,149,424.37	$189,598.26
Hematopoietic Agents	493	$2,504,936.93	$24,319.78	558	$1,652,138.31	$19,436.92
Total	**1,427**	**$23,118,617.96**	**$104,137.92**	**1,438**	**$20,801,562.68**	**$111,836.36**
TOPICAL PRODUCTS						
Dermatological	2,431	$14,546,228.68	$37,782.41	1,792	$9,928,918.72	$37,048.20
Total	**2,431**	**$14,546,228.68**	**$37,782.41**	**1,792**	**$9,928,918.72**	**$37,048.20**
ANTI-INFECTIVE AGENTS						
Antiviral	1,002	$12,656,903.77	$28,570.89	752	$16,324,829.05	$48,441.63
Aminoglycosides	439	$848,501.94	$5,892.37	429	$1,128,160.48	$8,116.26
Misc. Anti-Infectives	66	$630,095.67	$30,004.56	86	$781,975.21	$37,236.91
Antifungals	15	$79,516.25	$19,879.06	16	$78,972.88	$19,743.22
Total	**1,522**	**$14,215,017.63**	**$23,227.15**	**1,283**	**$18,313,937.62**	**$36,554.77**
NEUROMUSCULAR AGENTS						
Neuromuscular Agents	228	$13,674,795.73	$427,337.37	79	$9,552,692.21	$382,107.69
Antimyasthenic Agents	14	$319,969.83	$319,969.83	0	$0.00	$0.00
Total	**242**	**$13,994,765.56**	**$424,083.80**	**79**	**$9,552,692.21**	**$367,411.24**
PSYCHOTHERAPEUTIC/NEUROLOGIC AGENTS						
Misc. Psychotherapeutic and Neurologic Agents	1,504	$10,660,813.68	$45,754.57	1,458	$9,507,637.20	$48,018.37
Total	**1,504**	**$10,660,813.68**	**$45,754.57**	**1,458**	**$9,507,637.20**	**$48,018.37**
CARDIOVASCULAR AGENTS						
Misc. Cardiovascular	1,807	$7,302,003.14	$28,084.63	1,831	$7,987,904.64	$33,847.05
Vasopressors	0	$0.00	$0.00	4	$67,223.23	$67,223.23
Antihyperlipidemic	92	$43,087.43	$2,393.75	80	$36,448.12	$2,144.01
Antihypertensive	3	$179.42	$179.42	9	$474.36	$118.59
Total	**1,902**	**$7,345,269.99**	**$26,327.13**	**1,924**	**$8,092,050.35**	**$31,364.54**
BIOLOGICS						
Passive Immunizing Agents	2,524	$6,017,944.11	$8,266.41	2,733	$6,415,482.37	$8,463.70
Total	**2,524**	**$6,017,944.11**	**$8,266.41**	**2,733**	**$6,415,482.37**	**$8,463.70**

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 2019**	**CY 2020**	**CY 2021 with HAP**	**CY 2021 without HAP**
Age 0 to 2	$11,396,330	$8,767,241	$9,533,373	$9,532,820
Age 3 to 5	$17,342,393	$14,488,726	$13,522,016	$13,521,994
Age 6 to 9	$41,141,161	$35,425,204	$35,433,842	$35,433,842
Age 10 to 14	$57,252,786	$56,047,328	$55,897,757	$55,897,757
Age 15 to 18	$39,014,685	$39,521,861	$43,041,159	$43,041,159
Age 19 to 25	$23,202,715	$27,560,594	$37,524,130	$30,389,290
Age 26 to 34	$36,312,397	$40,697,915	$51,991,928	$40,968,731
Age 35 to 54	$91,012,254	$102,572,115	$135,043,923	$106,389,092
Age 55 to 64	$65,152,948	$68,131,055	$81,817,754	$68,600,889
Age 65+	$10,139,410	$11,112,912	$12,064,223	$11,884,280
Total (All Ages)	**$391,967,079**	**$404,324,951**	**$475,870,106**	**$415,659,852**

Reimbursement does not reflect rebated costs or net costs.

Specialty Pharmacy Reimbursement by Age Group				
Age Group (Years)	**CY 2019**	**CY 2020**	**CY 2021 with HAP**	**CY 2021 without HAP**
Age 0 to 2	$11,612,210	$11,097,551	$10,367,580	$10,367,580
Age 3 to 5	$10,110,091	$8,514,078	$7,926,890	$7,926,890
Age 6 to 9	$10,034,039	$16,987,283	$24,703,074	$24,703,074
Age 10 to 14	$27,702,938	$32,560,771	$35,510,944	$35,510,944
Age 15 to 18	$22,866,403	$30,128,625	$32,000,859	$32,000,859
Age 19 to 25	$14,583,198	$13,872,096	$20,911,318	$18,565,147
Age 26 to 34	$17,867,758	$17,030,227	$22,181,231	$19,238,907
Age 35 to 54	$35,898,991	$37,614,717	$44,500,346	$37,209,931
Age 55 to 64	$21,647,289	$18,751,360	$20,232,692	$17,884,756
Age 65+	$2,017,339	$1,586,502	$1,961,427	$1,961,427
Total (All Ages)	**$174,340,256**	**$188,143,211**	**$220,296,362**	**$205,369,517**

Reimbursement does not reflect rebated costs or net costs.

Total Enrollment by Age Group Comparison by Calendar Year			
Age Group (Years)	**2019**	**2020**	**2021**
Age 0 to 2	90,859	94,533	100,587
Age 3 to 5	87,317	92,513	99,914
Age 6 to 9	111,656	118,793	130,688
Age 10 to 14	137,051	146,397	159,970
Age 15 to 18	88,283	97,109	111,921
Age 19 to 25	37,208	49,258	85,544
Age 26 to 34	51,992	63,963	93,505
Age 35 to 54	76,076	87,749	132,007
Age 55 to 64	44,619	46,254	59,272
Age 65+	63,889	65,652	69,298
Total (All Ages)	**788,958**	**863,073**	**1,042,707**

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 J

Calendar Year 2021 Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Xelstrym™ (Dextroamphetamine Transdermal System)

Oklahoma Health Care Authority
June 2022

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 (Zenzedi®) lisdexamfetamine chew tab (Vyvanse®)+ methamphetamine (Desoxyn®)
Short-Acting			
amphetamine/ dextroamphetamine (Adderall®)			
Long-Acting			
amphetamine/ dextroamphetamine ER (Adderall XR®) lisdexamfetamine cap (Vyvanse®)+	amphetamine ER susp (Dyanavel® XR)		
Methylphenidate			
Short-Acting			
dexmethylphenidate (Focalin®) methylphenidate tab and soln (Methylin®) methylphenidate (Ritalin®)			
Long-Acting			
dexmethylphenidate ER (Focalin XR®) – **Brand Preferred** methylphenidate ER (Concerta®) 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®)			methylphenidate ER ODT (Cotempla XR-ODT®) methylphenidate chew tab (Methylin®) methylphenidate ER chew tab (QuilliChew ER®) viloxazine (Qelbree®)
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 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®, and Vyvanse® Chewable Tablets 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 to 17 years of age; and
   c. Previously failed trials (within the last 180 days) with 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 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®.

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 2021

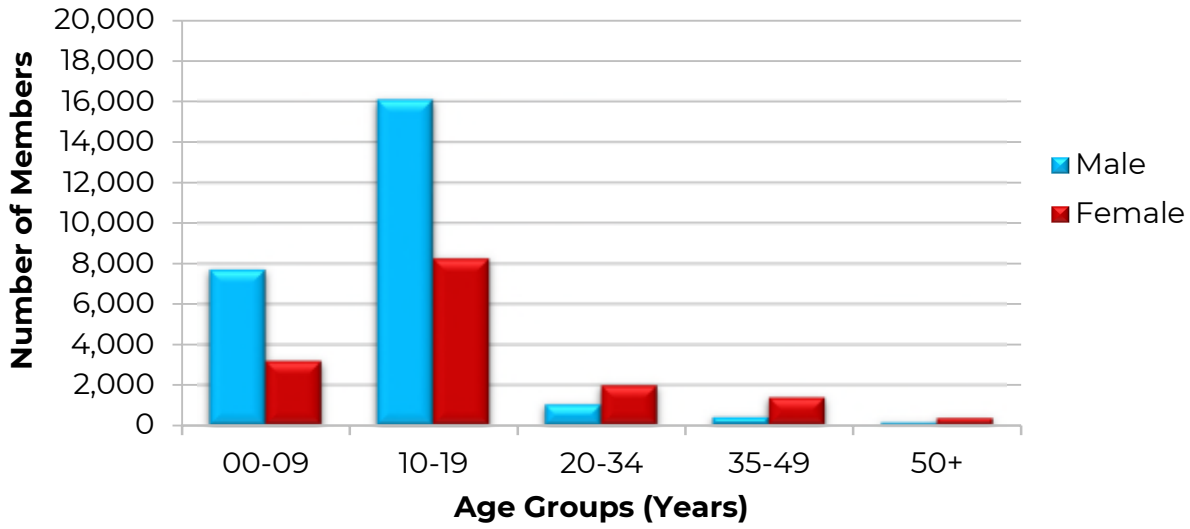
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	38,217	313,061	$44,254,590.86	$141.36	$4.75	10,853,525	9,309,202
2021	40,362	319,996	$45,211,155.37	$141.29	$4.75	11,127,693	9,510,988
% Change	**5.60%**	**2.20%**	**2.20%**	**0.00%**	**0.00%**	**2.50%**	**2.20%**
Change	**2,145**	**6,935**	**$956,564.51**	**-$0.07**	**$0.00**	**274,168**	**201,786**

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

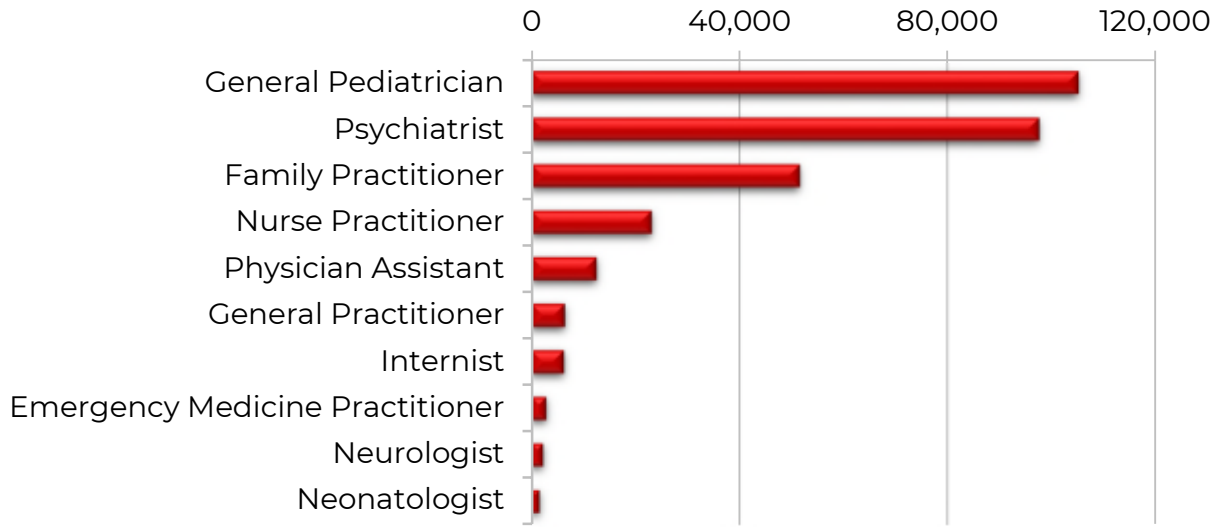
- The ADHD and Narcolepsy Medications Product Based Prior Authorization (PBPA) category is heavily influenced by supplemental rebates. Some brand name ADHD and narcolepsy products are preferred over available generic products due to a lower net cost compared to generics, after taking into account federal 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 2021 for ADHD and narcolepsy medications: $35,317,578.49 [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.

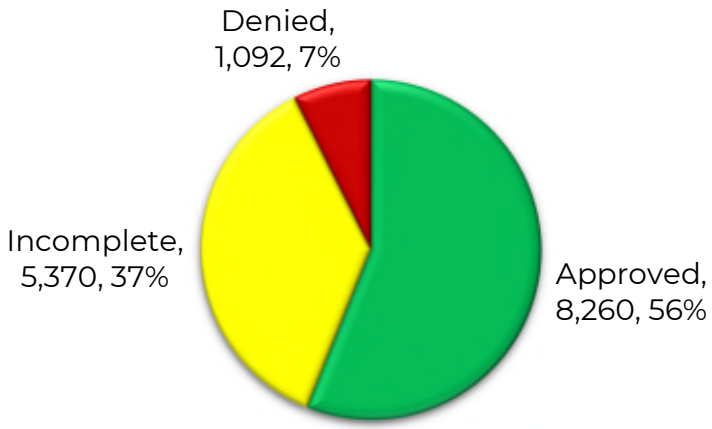
Top Prescriber Specialties of ADHD and Narcolepsy Medications by Number of Claims



Prior Authorization of ADHD and Narcolepsy Medications

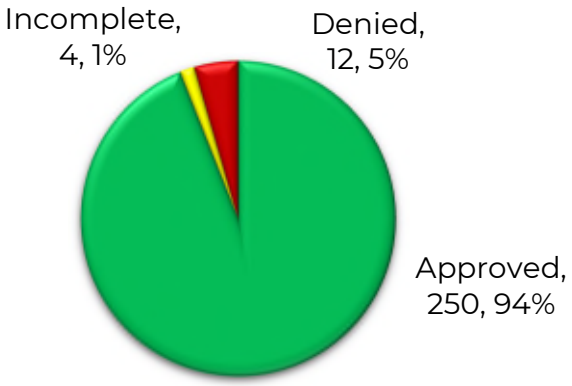
There were 14,722 prior authorization requests submitted for ADHD and narcolepsy medications during calendar year 2021. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions



There were 266 prior authorization requests submitted for a total of 196 unique members for ADHD and narcolepsy medications during calendar year 2021 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 2021.

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[1-12]

Anticipated Patent Expiration(s):

- Vyvanse® (lisdexamfetamine capsule and chewable tablet): August 2023
- Adzenys XR-ODT® [amphetamine extended-release (ER) orally disintegrating tablet (ODT)]: June 2025
- Mydayis® (amphetamine/dextroamphetamine ER capsule): August 2025
- Daytrana® [methylphenidate ER transdermal patch]: October 2025

- Cotempla XR-ODT® (methylphenidate ER ODT): July 2026
- Dyanavel® XR (amphetamine ER suspension): March 2027
- Wakix® (pitolisant tablet): September 2027
- Quillivant XR® (methylphenidate ER suspension): February 2031
- Jornay PM® (methylphenidate ER capsule): March 2032
- Adzenys ER™ (amphetamine ER suspension): June 2032
- Qelbree® (viloxazine ER capsule): February 2033
- Xywav® (calcium/magnesium/potassium/sodium oxybates oral solution): March 2033
- QuilliChew ER® (methylphenidate ER chewable tablet): August 2033
- Xyrem® (sodium oxybate solution): September 2033
- Adhansia XR® (methylphenidate ER capsule): November 2035
- Evekeo ODT™ (amphetamine ODT): March 2037
- Azstarys® (serdexmethylphenidate/dexmethylphenidate capsule): December 2037
- Sunosi® (solriamfetol tablet): March 2040

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

- **August 2021:** The FDA approved Xywav® (calcium/magnesium/potassium/sodium oxybates oral solution) for the treatment of idiopathic hypersomnia (IH) in adults. IH is a rare chronic sleep disorder causing excessive sleepiness during the day even after a good night's sleep. This is an expanded indication for Xywav®, it was initially FDA approved in 2020 for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy. Xywav® is a central nervous system (CNS) depressant similar to Xyrem® (sodium oxybate oral solution), but is formulated as a combination of oxybate salts, resulting in 92% less sodium content relative to Xyrem®. Accordingly, the *Prescribing Information* for Xywav® does not contain any warnings about high sodium content. Xywav® is a Schedule III controlled dangerous substance (CDS) and is the first medication to receive FDA approval for the treatment of IH.
- **November 2021:** The FDA approved Dyanavel XR® (amphetamine ER tablets) for the treatment of ADHD in patients 6 years of age and older. This is a new formulation of Dyanavel XR®, initially FDA approved as an ER oral suspension in 2015. Dyanavel XR® is a Schedule II CDS amphetamine product and should not be substituted for other amphetamine products on a milligram-per-milligram basis, because of different amphetamine salt compositions and differing pharmacokinetic profiles.
- **March 2022:** The FDA approved Xelstrym™ (dextroamphetamine transdermal system) for the treatment of ADHD in patients 6 years of age and older. This is the first and only amphetamine-based

transdermal product for once daily use. Xelstrym™ is available as 4.5mg, 9mg, 13.5mg, and 18mg patches to be worn during a 9-hour period. Xelstrym™ is a Schedule II CDS dextroamphetamine product and should not be substituted for other amphetamine products on a milligram-per-milligram basis, because of different amphetamine salt compositions and differing pharmacokinetic profiles.

- **May 2022:** The FDA approved Qelbree® (viloxazine ER capsules) for the treatment of ADHD in patients 18 years of age and older. This is an expanded age indication for viloxazine, a selective norepinephrine reuptake inhibitor, which was initially FDA approved in April 2021 for the treatment of ADHD in pediatric patients 6 to 17 years of age as the first novel, non-stimulant medication for ADHD approved by the FDA since 2002.

News:

- **September 2021:** The American Academy of Sleep Medicine (AASM) published a clinical practice guideline for the treatment of central disorders of hypersomnolence in which they addressed the treatment of IH in adult patients. They encourage use of modafinil with a strong recommendation. Agents recommended with a conditional recommendation include methylphenidate, clarithromycin, pitolisant, and sodium oxybate. Recommendations build on recent publications assessing diagnostic criteria including biologic and electrophysiological markers as well as a systematic review of treatment options.
- **October 2021:** The American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, and Children's Hospital Association in a joint statement declared a national state of emergency in children's mental health. They called on national leaders to advocate for increased federal funding to increase access to screening, diagnosis and treatment of mental health needs. The statement addressed regulatory challenges, school-based health care, and primary care. Additional focus was given to suicide prevention, acute inpatient and emergency care, community-based care, and trauma-informed care.

Pipeline:

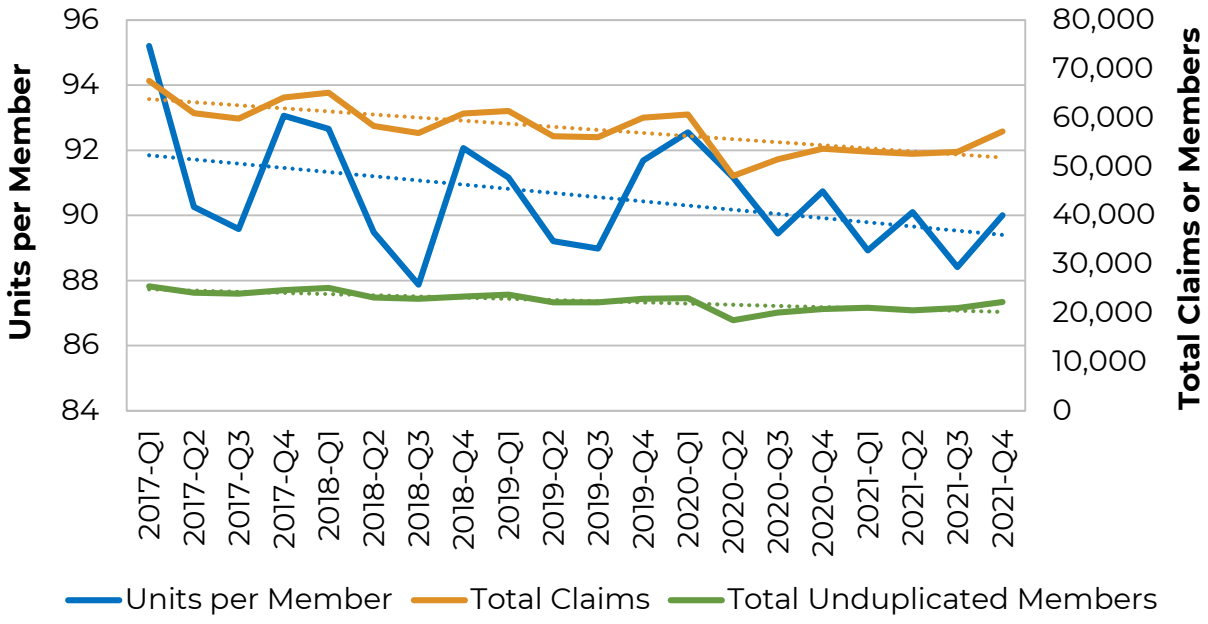
- **Centanafadine:** Otsuka is conducting both Phase 3 studies evaluating the use of centanafadine in adult patients and Phase 1 studies evaluating the use of centanafadine in pediatric patients with ADHD. Centanafadine is a serotonin-norepinephrine-dopamine triple-reuptake inhibitor. In June 2020, Otsuka announced positive topline results from 2 Phase 3 studies of centanafadine in approximately 900 adult patients with ADHD, ranging from 18 to 55 years of age. Patients were randomized 1:1:1 to receive centanafadine 100mg, centanafadine 200mg, or placebo twice daily for 6 weeks. The primary endpoint,

change from baseline to day 42 on the adult ADHD investigator symptom rating scale (AISRS) total score, was met in both studies demonstrating statistically significant improvement relative to placebo for both doses of centanafadine (P<0.05 in study 1; P<0.01 in study 2). A long-term safety and tolerability study of centanafadine is currently ongoing.

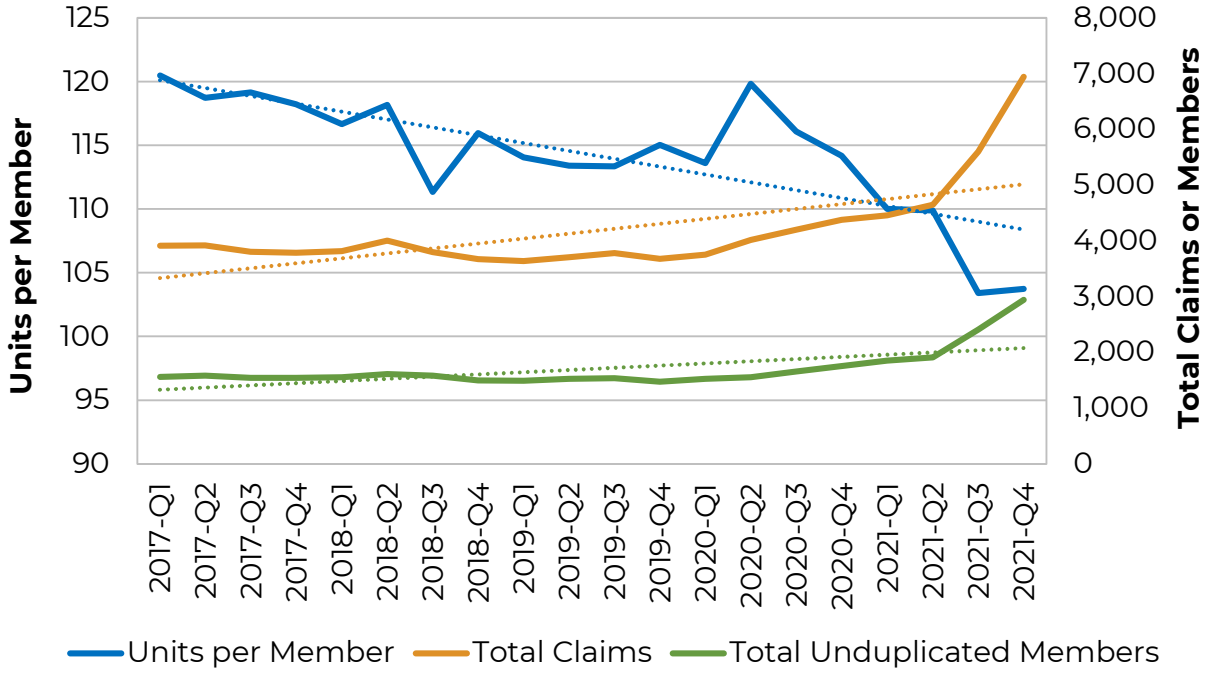
ADHD Trends:

- According to recent national reports, stimulant use in on the rise in the United States. National trends suggest the growing potential for a public health crisis similar to the opioid epidemic. Much like the opioid epidemic, both prescription and illicit medications in the drug class are likely contributing to misuse and abuse. In order to determine the impact on SoonerCare members, the following analysis was completed for the previous 5 years. The following graphs show SoonerCare data for the number of unduplicated pediatric and adult members with paid claims for stimulant medications from January 1, 2017, to December 31, 2021. Please note, the vertical axis starts at 84 units per pediatric member and 90 units per adult member in order to reflect small changes.

Pediatric Member Stimulant Trends: January 2017 to December 2021



Adult Member Stimulant Trends: January 2017 to December 2021



Across all ages, units per member have followed a linear decline since 2017. Linear trends are noted in the graph by a color-matched dotted line for each parameter. While there are periods in which stimulant use increased from one quarter to the next, current trends suggest prescription stimulant use per member is decreasing overall and additional action is not currently recommended by the College of Pharmacy.

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. Updating the approval criteria for Qelbree® (viloxazine) based on the recent FDA approved age expansion
2. Updating the approval criteria for Xywav® (calcium/magnesium/ potassium/sodium oxybates) based on the recent FDA approval for idiopathic hypersomnia
3. The prior authorization of Dyanavel XR® ER tablets and placement into Tier-2 of the Long-Acting Stimulants category of the ADHD Medications PBPA Tier chart

4. The prior authorization of Xelstrym™ and placement into the Special PA Tier of the ADHD Medications PBPA Tier chart with the following additional 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®)+ methamphetamine (Desoxyn®) methylphenidate ER ODT (Cotempla XR-ODT®) methylphenidate chew tab (Methylin®)
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®) methylphenidate ER (Metadate ER®) methylphenidate ER (Methylin ER®) methylphenidate ER (Ritalin LA®)	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 (Ritalin SR®)			methylphenidate ER chew tab (QuilliChew ER®) viloxazine (Qelbree®)
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 ~~to 17~~ years of age or older; and
   c. Previously failed trials (within the last 180 days) with 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 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®.

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.

Idiopathic Hypersomnia (IH) Medications Approval Criteria:

1. A 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.

Utilization Details of ADHD and Narcolepsy Medications: Calendar Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LISDEXAMFETAMINE PRODUCTS						
VYVANSE CAP 30MG	18,119	4,506	$5,653,945.55	$312.05	4.02	12.51%
VYVANSE CAP 40MG	14,478	3,158	$4,499,337.32	$310.77	4.58	9.95%
VYVANSE CAP 20MG	13,574	4,033	$4,214,007.47	$310.45	3.37	9.32%
VYVANSE CAP 50MG	10,044	1,938	$3,107,095.17	$309.35	5.18	6.87%
VYVANSE CAP 60MG	5,960	1,067	$1,850,626.49	$310.51	5.59	4.09%
VYVANSE CAP 10MG	5,093	1,967	$1,586,345.12	$311.48	2.59	3.51%
VYVANSE CAP 70MG	5,012	792	$1,562,334.34	$311.72	6.33	3.46%
VYVANSE CHW 20MG	2,331	718	$717,657.04	$307.88	3.25	1.59%
VYVANSE CHW 10MG	1,912	798	$597,296.35	$312.39	2.4	1.32%
VYVANSE CHW 30MG	1,391	394	$427,095.84	$307.04	3.53	0.94%
VYVANSE CHW 40MG	689	181	$217,801.14	$316.11	3.81	0.48%
VYVANSE CHW 50MG	242	62	$70,233.46	$290.22	3.9	0.16%
VYVANSE CHW 60MG	120	28	$41,367.41	$344.73	4.29	0.09%
SUBTOTAL	**78,965**	**19,642***	**$24,545,142.70**	**$311.90**	**4.06**	**54.29%**
METHYLPHENIDATE PRODUCTS						
METHYLPHENID TAB 10MG	8,764	1,981	$156,809.69	$17.89	4.42	0.35%
METHYLPHENID TAB 5MG	6,858	1,931	$109,861.64	$16.02	3.55	0.24%
METHYLPHENID CAP 20MG	6,553	1,988	$325,644.86	$49.69	3.3	0.72%
METHYLPHENID CAP 30MG	6,359	1,488	$334,408.35	$52.59	4.27	0.74%
METHYLPHENID CAP 40MG ER	4,394	925	$297,162.25	$67.63	4.75	0.66%
METHYLPHENID TAB 20MG	3,836	730	$78,662.73	$20.51	5.25	0.17%
METHYLPHENID CAP 10MG	3,433	1,351	$177,923.16	$51.83	2.54	0.39%
METHYLPHENID TAB 36MG ER	3,402	643	$178,162.18	$52.37	5.29	0.39%
METHYLPHENID TAB 54MG ER	2,825	482	$123,363.61	$43.67	5.86	0.27%
METHYLPHENID CAP 50MG	2,071	403	$147,957.44	$71.44	5.14	0.33%
QUILLICHEW CHW 20MG ER	2,016	577	$654,662.07	$324.73	3.49	1.45%
METHYLPHENID CAP 60MG	1,737	283	$118,146.08	$68.02	6.14	0.26%
METHYLPHENID TAB 27MG ER	1,400	366	$51,517.18	$36.80	3.83	0.11%
METHYLPHENID CAP 20MG ER	1,377	413	$71,123.69	$51.65	3.33	0.16%
METHYLPHENID CAP 30MG ER	1,127	245	$245,467.06	$217.81	4.6	0.54%
QUILLICHEW CHW 30MG ER	1,115	252	$397,281.23	$356.31	4.42	0.88%
METHYLPHENID TAB 18MG ER	1,033	307	$36,979.32	$35.80	3.36	0.08%
METHYLPHENID CAP 30MG ER	955	250	$46,112.14	$48.28	3.82	0.10%
METHYLPHENID CAP 40MG ER	788	186	$170,695.00	$216.62	4.24	0.38%
METHYLPHENID CAP 40MG ER	768	157	$43,115.42	$56.14	4.89	0.10%
METHYLPHENID CAP 20MG ER	743	179	$158,351.28	$213.12	4.15	0.35%
METHYLPHENID SOL 5MG/5ML	717	216	$27,394.77	$38.21	3.32	0.06%
METHYLPHENID CAP 60MG ER	648	121	$136,597.08	$210.80	5.36	0.30%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
METHYLPHENID CAP 50MG ER	597	113	$131,090.52	$219.58	5.28	0.29%
METHYLPHENID CAP 10MG ER	576	242	$55,939.02	$97.12	2.38	0.12%
QUILLICHEW CHW 40MG ER	391	83	$142,511.46	$364.48	4.71	0.32%
QUILLIVANT SUS 25MG/5ML	376	79	$156,350.60	$415.83	4.76	0.35%
APTENSIO XR CAP 30MG	357	108	$88,794.25	$248.72	3.31	0.20%
APTENSIO XR CAP 40MG	355	111	$89,237.53	$251.37	3.2	0.20%
METHYLPHENID CAP 15MG ER	337	83	$74,363.04	$220.66	4.06	0.16%
APTENSIO XR CAP 60MG	317	72	$78,751.39	$248.43	4.4	0.17%
METHYLPHENID CAP 10MG ER	309	76	$66,313.94	$214.61	4.07	0.15%
METHYLPHENID SOL 10MG/5ML	293	85	$15,812.13	$53.97	3.45	0.03%
APTENSIO XR CAP 20MG	280	86	$72,671.23	$259.54	3.26	0.16%
METHYLPHENID TAB 20MG ER	267	107	$8,732.40	$32.71	2.5	0.02%
DAYTRANA DIS 10MG/9HR	171	71	$66,013.66	$386.04	2.41	0.15%
METHYLPHENID TAB 54MG ER	168	57	$8,902.41	$52.99	2.95	0.02%
METHYLPHENID TAB 72MG ER	164	30	$82,252.96	$501.54	5.47	0.18%
METHYLPHENID TAB 36MG ER	161	77	$8,608.61	$53.47	2.09	0.02%
APTENSIO XR CAP 50MG	158	44	$39,043.53	$247.11	3.59	0.09%
DAYTRANA DIS 20MG/9HR	136	44	$54,819.80	$403.09	3.09	0.12%
DAYTRANA DIS 30MG/9HR	122	29	$45,726.03	$374.80	4.21	0.10%
JORNAY PM CAP 40MG ER	115	21	$41,256.07	$358.75	5.48	0.09%
CONCERTA TAB 36MG	113	17	$48,499.85	$429.20	6.65	0.11%
APTENSIO XR CAP 10MG	105	43	$25,872.27	$246.40	2.44	0.06%
DAYTRANA DIS 15MG/9HR	94	47	$38,513.34	$409.72	2	0.09%
METHYLPHENID CAP 60MG LA	94	15	$25,871.29	$275.23	6.27	0.06%
METHYLPHENID TAB 27MG ER	89	39	$3,926.70	$44.12	2.28	0.01%
METHYLPHENID TAB 10MG ER	79	49	$1,967.35	$24.90	1.61	0.00%
APTENSIO XR CAP 15MG	78	22	$20,087.18	$257.53	3.55	0.04%
JORNAY PM CAP 60MG ER	75	20	$18,473.90	$246.32	3.75	0.04%
METHYLPHENID CHW 10MG	74	15	$11,411.45	$154.21	4.93	0.03%
METHYLPHENID TAB 18MG ER	73	28	$2,891.28	$39.61	2.61	0.01%
METHYLPHENID CHW 5MG	65	22	$8,564.63	$131.76	2.95	0.02%
METHYLPHENID CHW 2.5MG	57	10	$4,816.66	$84.50	5.7	0.01%
METHYLIN SOL 5MG/5ML	51	25	$2,550.20	$50.00	2.04	0.01%
RITALIN LA CAP 10MG	51	16	$15,807.96	$309.96	3.19	0.03%
JORNAY PM CAP 80MG ER	33	11	$9,562.18	$289.76	3	0.02%
JORNAY PM CAP 20MG ER	28	11	$9,076.00	$324.14	2.55	0.02%
JORNAY PM CAP 100MG ER	24	7	$8,500.54	$354.19	3.43	0.02%
ADHANSIA XR CAP 70MG	19	3	$6,153.02	$323.84	6.33	0.01%
CONCERTA TAB 54MG	19	2	$4,184.52	$220.24	9.5	0.01%
CONCERTA TAB 18MG	16	5	$934.61	$58.41	3.2	0.00%
ADHANSIA XR CAP 25MG	13	3	$4,068.90	$312.99	4.33	0.01%
ADHANSIA XR CAP 45MG	13	3	$2,744.20	$211.09	4.33	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RITALIN TAB 20MG	9	1	$1,460.22	$162.25	9	0.00%
ADHANSIA XR CAP 55MG	7	3	$2,053.58	$293.37	2.33	0.00%
COTEMPLA TAB 17.3MG	6	1	$2,638.08	$439.68	6	0.01%
ADHANSIA XR CAP 35MG	5	3	$1,328.63	$265.73	1.67	0.00%
METHYLIN SOL 10MG/5ML	5	5	$203.31	$40.66	1	0.00%
ADHANSIA XR CAP 85MG	3	2	$979.71	$326.57	1.5	0.00%
CONCERTA TAB 27MG	3	2	$255.68	$85.23	1.5	0.00%
COTEMPLA TAB 25.9MG	3	1	$1,310.64	$436.88	3	0.00%
RITALIN LA CAP 20MG	1	1	$309.96	$309.96	1	0.00%
SUBTOTAL	**69,874**	**17,524***	**$5,699,606.65**	**$195.69**	**3.89**	**12.60%**
GUANFACINE ER PRODUCTS						
GUANFACINE TAB 2MG ER	18,585	3,818	$369,285.20	$19.87	4.87	0.82%
GUANFACINE TAB 1MG ER	14,085	4,022	$272,391.05	$19.34	3.5	0.60%
GUANFACINE TAB 3MG ER	12,665	2,116	$253,493.73	$20.02	5.99	0.56%
GUANFACINE TAB 4MG ER	10,537	1,485	$192,977.59	$18.31	7.1	0.43%
INTUNIV TAB 4MG	59	6	$15,636.42	$265.02	9.83	0.03%
INTUNIV TAB 3MG	45	4	$13,050.60	$290.01	11.25	0.03%
INTUNIV TAB 2MG	23	2	$6,729.34	$292.58	11.5	0.01%
SUBTOTAL	**55,999**	**11,453***	**$1,123,563.93**	**$132.17**	**7.72**	**2.48%**
AMPHETAMINE/DEXTROAMPHETAMINE PRODUCTS						
AMPHET/DEXTR TAB 10MG	10,843	2,504	$248,436.31	$22.91	4.33	0.55%
AMPHET/DEXTR TAB 20MG	8,926	1,612	$253,555.88	$28.41	5.54	0.56%
AMPHET/DEXTR TAB 5MG	6,900	1,935	$158,754.89	$23.01	3.57	0.35%
AMPHET/DEXTR TAB 30MG	4,333	708	$121,541.45	$28.05	6.12	0.27%
AMPHET/DEXTR TAB 15MG	3,330	690	$82,555.85	$24.79	4.83	0.18%
AMPHET/DEXTR CAP 30MG ER	2,911	522	$90,695.41	$31.16	5.58	0.20%
AMPHET/DEXTR CAP 20MG ER	2,822	708	$87,894.72	$31.15	3.99	0.19%
AMPHET/DEXTR CAP 15MG ER	1,651	446	$50,247.81	$30.43	3.7	0.11%
AMPHET/DEXTR CAP 10MG ER	1,626	576	$47,555.49	$29.25	2.82	0.11%
AMPHET/DEXTR CAP 25MG ER	1,172	266	$34,374.44	$29.33	4.41	0.08%
AMPHET/DEXTR TAB 7.5MG	1,009	229	$29,501.16	$29.24	4.41	0.07%
AMPHET/DEXTR CAP 5MG ER	391	175	$11,900.38	$30.44	2.23	0.03%
AMPHET/DEXTR TAB 12.5MG	231	60	$7,768.61	$33.63	3.85	0.02%
ADDERALL XR CAP 20MG	31	5	$2,668.82	$86.09	6.2	0.01%
ADDERALL XR CAP 30MG	25	4	$4,913.06	$196.52	6.25	0.01%
ADDERALL XR CAP 10MG	16	4	$1,453.87	$90.87	4	0.00%
ADDERALL XR CAP 25MG	16	5	$2,352.00	$147.00	3.2	0.01%
MYDAYIS CAP 50MG	12	1	$3,610.28	$300.86	12	0.01%
MYDAYIS CAP 25MG	8	3	$1,759.97	$220.00	2.67	0.00%
ADDERALL TAB 15MG	4	1	$2,003.16	$500.79	4	0.00%
ADDERALL TAB 20MG	3	1	$1,220.69	$406.90	3	0.00%
ADDERALL XR CAP 15MG	3	2	$174.15	$58.05	1.5	0.00%
MYDAYIS CAP 37.5MG	2	1	$610.22	$305.11	2	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**46,265**	**10,458***	**$1,245,548.62**	**$116.69**	**4.36**	**2.76%**
DEXMETHYLPHENIDATE PRODUCTS						
DEXMETHYLPH TAB 10MG	5,879	1,095	$126,579.65	$21.53	5.37	0.28%
DEXMETHYLPH TAB 5MG	5,491	1,291	$95,822.88	$17.45	4.25	0.21%
FOCALIN XR CAP 20MG	5,061	1,142	$1,953,542.18	$386.00	4.43	4.32%
FOCALIN XR CAP 10MG	4,794	1,477	$1,789,822.42	$373.35	3.25	3.96%
FOCALIN XR CAP 15MG	4,140	1,023	$1,596,910.22	$385.73	4.05	3.53%
FOCALIN XR CAP 30MG	2,850	574	$1,063,974.95	$373.32	4.97	2.35%
FOCALIN XR CAP 25MG	2,481	483	$1,007,229.92	$405.98	5.14	2.23%
FOCALIN XR CAP 5MG	2,109	863	$769,183.75	$364.71	2.44	1.70%
DEXMETHYLPH TAB 2.5MG	1,796	488	$29,356.71	$16.35	3.68	0.06%
FOCALIN XR CAP 40MG	1,321	211	$561,929.58	$425.38	6.26	1.24%
FOCALIN XR CAP 35MG	720	126	$303,981.24	$422.20	5.71	0.67%
FOCALIN TAB 10MG	55	6	$3,461.84	$62.94	9.17	0.01%
FOCALIN TAB 5MG	35	3	$2,644.13	$75.55	11.67	0.01%
DEXMETHYLPHE CAP 10MG ER	11	4	$440.25	$40.02	2.75	0.00%
DEXMETHYLPHE CAP 20MG ER	11	5	$557.51	$50.68	2.2	0.00%
DEXMETHYLPH CAP 15MG ER	9	4	$351.92	$39.10	2.25	0.00%
AZSTARYS CAP 39.2-7.8	6	4	$2,071.58	$345.26	1.5	0.00%
DEXMETHYLPHE CAP ER 35MG	5	1	$25.40	$5.08	5	0.00%
DEXMETHYLPH CAP 30MG ER	4	2	$102.12	$25.53	2	0.00%
AZSTARYS CAP 52.3-10.	2	1	$160.37	$80.19	2	0.00%
DEXMETHYLPH CAP 40MG ER	2	1	$70.62	$35.31	2	0.00%
DEXMETHYLPHE CAP 5MG ER	2	2	$99.04	$49.52	1	0.00%
DEXMETHYLPHE CAP ER 25MG	2	2	$168.81	$84.41	1	0.00%
SUBTOTAL	**36,786**	**8,808***	**$9,308,487.09**	**$177.63**	**4.00**	**20.57%**
ATOMOXETINE PRODUCTS						
ATOMOXETINE CAP 40MG	8,740	2,496	$416,653.89	$47.67	3.5	0.92%
ATOMOXETINE CAP 25MG	7,494	2,249	$428,451.54	$57.17	3.33	0.95%
ATOMOXETINE CAP 60MG	4,272	916	$230,813.71	$54.03	4.66	0.51%
ATOMOXETINE CAP 18MG	3,833	1,353	$196,879.28	$51.36	2.83	0.44%
ATOMOXETINE CAP 10MG	3,106	1,136	$177,820.32	$57.25	2.73	0.39%
ATOMOXETINE CAP 80MG	2,281	544	$141,652.04	$62.10	4.19	0.31%
ATOMOXETINE CAP 100MG	860	192	$60,710.42	$70.59	4.48	0.13%
STRATTERA CAP 40MG	24	2	$10,126.84	$421.95	12	0.02%
STRATTERA CAP 80MG	8	1	$4,726.28	$590.79	8	0.01%
STRATTERA CAP 100MG	1	1	$474.91	$474.91	1	0.00%
SUBTOTAL	**30,619**	**8,890***	**$1,668,309.23**	**$188.78**	**4.672**	**3.68%**
CLONIDINE ER PRODUCTS						
CLONIDINE TAB 0.1MG ER	865	143	$46,689.11	$53.98	6.05	0.10%
SUBTOTAL	**865**	**143***	**$46,689.11**	**$53.98**	**6.05**	**0.10%**
ARMODAFINIL PRODUCTS						
NUVIGIL TAB 250MG	92	21	$81,408.13	$884.87	4.38	0.18%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NUVIGIL TAB 150MG	61	12	$54,858.02	$899.31	5.08	0.12%
NUVIGIL TAB 200MG	29	5	$26,916.25	$928.15	5.8	0.06%
ARMODAFINIL TAB 250MG	5	3	$213.40	$42.68	1.67	0.00%
SUBTOTAL	**187**	**41***	**$163,395.80**	**$688.75**	**4.23**	**0.36%**
MODAFINIL PRODUCTS						
MODAFINIL TAB 200MG	127	21	$4,134.93	$32.56	6.05	0.01%
PROVIGIL TAB 200MG	10	1	$37,294.02	$3,729.40	10	0.08%
MODAFINIL TAB 100MG	5	2	$98.93	$19.79	2.5	0.00%
SUBTOTAL	**142**	**24***	**$41,527.88**	**$1,260.58**	**6.18**	**0.09%**
DEXTROAMPHETAMINE PRODUCTS						
DEXTROAMPHET CAP 15MG ER	56	7	$9,370.37	$167.33	8	0.02%
DEXTROAMPHET TAB 10MG	22	3	$717.86	$32.63	7.33	0.00%
DEXTROAMPHET CAP 10MG ER	15	2	$1,061.30	$70.75	7.5	0.00%
DEXTROAMPHET SOL 5MG/5ML	4	2	$1,446.37	$361.59	2	0.00%
DEXTROAMPHET CAP 5MG ER	2	1	$82.22	$41.11	2	0.00%
DEXTROAMPHET TAB 20MG	2	1	$764.70	$382.35	2	0.00%
SUBTOTAL	**101**	**16***	**$13,442.82**	**$175.96**	**4.81**	**0.02%**
PITOLISANT PRODUCTS						
WAKIX TAB 4.45MG	56	8	$809,599.58	$14,457.14	7	1.79%
WAKIX TAB 17.8MG	26	3	$319,135.29	$12,274.43	8.67	0.71%
SUBTOTAL	**82**	**11***	**$1,128,734.87**	**$13,365.78**	**7.84**	**2.50%**
AMPHETAMINE PRODUCTS						
ADZENYS XR TAB 6.3MG	18	2	$7,687.21	$427.07	9	0.02%
ADZENYS XR TAB 15.7MG	15	3	$6,144.79	$409.65	5	0.01%
ADZENYS XR TAB 18.8MG	8	2	$3,427.68	$428.46	4	0.01%
DYANAVEL XR SUS 2.5MG/ML	5	1	$1,912.92	$382.58	5	0.00%
ADZENYS XR TAB 12.5MG	4	1	$1,718.32	$429.58	4	0.00%
ADZENYS XR TAB 9.4MG	4	1	$1,716.92	$429.23	4	0.00%
SUBTOTAL	**54**	**10***	**$22,607.84**	**$417.76**	**5.17**	**0.04%**
VILOXAZINE PRODUCTS						
QELBREE CAP 200MG ER	17	8	$6,277.52	$369.27	2.13	0.01%
QELBREE CAP 100MG ER	13	4	$3,975.78	$305.83	3.25	0.01%
SUBTOTAL	**30**	**12***	**$10,253.30**	**$337.55**	**2.69**	**0.02%**
CALCIUM/MAGNESIUM/POTASSIUM/SODIUM OXYBATES PRODUCTS						
XYWAV SOL 0.5GM/ML	16	2	$184,082.88	$11,505.18	8	0.41%
SUBTOTAL	**16**	**2***	**$184,082.88**	**$11,505.18**	**8**	**0.41%**
SOLRIAMFETOL PRODUCTS						
SUNOSI TAB 150MG	8	3	$5,195.79	$649.47	2.67	0.01%
SUBTOTAL	**8**	**3***	**$5,195.79**	**$649.47**	**2.67**	**0.01%**
SODIUM OXYBATE PRODUCTS						
XYREM SOL 500MG/ML	3	3	$4,566.86	$1,522.29	1	0.01%
SUBTOTAL	**3**	**3***	**$4,566.86**	**$1,522.29**	**1**	**0.01%**
TOTAL	**319,996**	**40,362***	**$45,211,155.37**	**$141.29**	**7.93**	**100.00%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AMPHET/DEXTR = amphetamine/dextroamphetamine; CAP = capsule; CHW = chewable; DEXMETHYLPHE = dexmethylphenidate; DEXTROAMPHET = dextroamphetamine; DIS = patch;
ER/XR = extended-release; HR = hour; LA = long-acting; METHYLPHENID = methylphenidate;
SOL = solution; SUS = suspension; TAB = tablet

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Appendix K

Calendar Year 2021 Annual Review of Antiviral Medications and 30-Day Notice to Prior Authorize Livtencity™ (Maribavir)

Oklahoma Health Care Authority
June 2022

Current Prior Authorization Criteria

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

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

Avaclyr™ (Acyclovir 3% Ophthalmic Ointment) Approval Criteria:

1. An FDA approved diagnosis of acute herpetic keratitis (dendritic ulcers) in members with herpes simplex virus (HSV); and
2. A patient-specific, clinically significant reason why the member cannot use trifluridine 1% ophthalmic solution must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use oral acyclovir, famciclovir, or valacyclovir must be provided.

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

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

Prevymis™ (Letermovir Tablet and Injection) Approval Criteria:

1. An FDA approved indication of prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogenic hematopoietic stem cell transplant (HSCT); and
2. Member must be CMV R+; and
3. Member must have received a HSCT within the last 28 days; and
4. Members taking concomitant cyclosporine will only be approved for the 240mg dose; and
5. Members must not be taking the following medications:
    a. Pimozide; or
    b. Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or
    c. Rifampin; or

    d. Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and
6. Prevymis™ must be prescribed by an oncology, hematology, infectious disease, or transplant specialist (or an advanced care practitioner with a supervising physician who is an oncology, hematology, infectious disease, or transplant specialist); and
7. Prescriber must verify the member will be monitored for CMV reactivation while on therapy; and
8. Approvals will be for the duration of 100 days post-transplant; and
    a. For Prevymis™ vials, authorization will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
    b. Approval length for the vial formulation will be based on duration of need; and
9. A quantity limit of 1 tablet or vial per day will apply.

Rebetol® (Ribavirin Solution), RibaPak® (Ribavirin Dose Pack), and Ribasphere® (Ribavirin 400mg and 600mg Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the 200mg tablets or 200mg capsules in place of the unique dosage formulations must be provided.

Zovirax® (Acyclovir Ointment) Approval Criteria:

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

Zovirax® (Acyclovir Suspension) Approval Criteria:

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

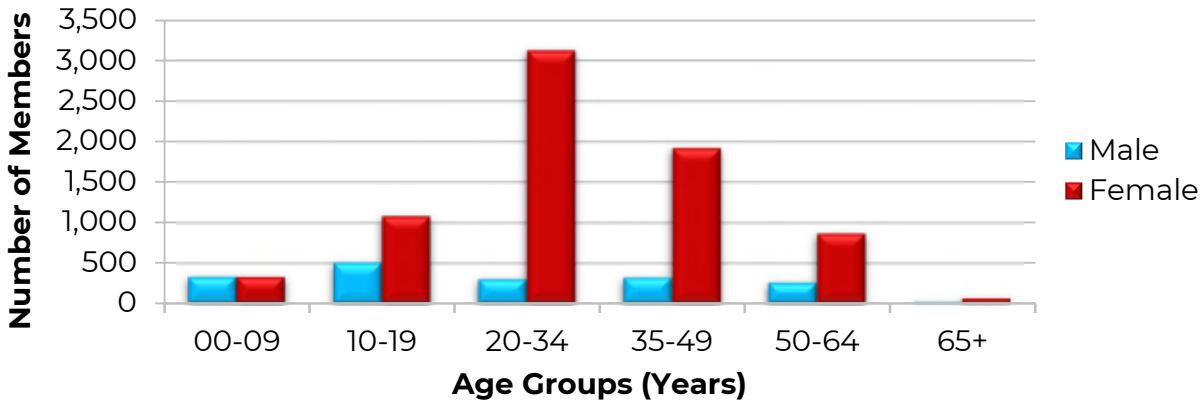
Utilization of Antiviral Medications: Calendar Year 2021

Comparison of Calendar Years

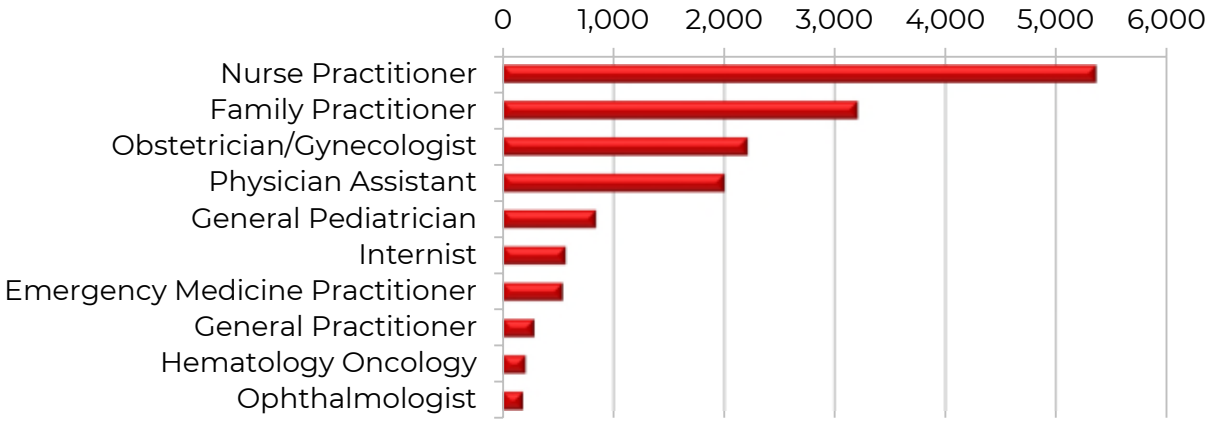
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	6,891	13,282	$495,175.15	$37.28	$1.78	597,341	278,580
2021	9,078	16,766	$678,488.54	$40.47	$1.84	743,415	368,562
% Change	**31.7%**	**26.2%**	**37.0%**	**8.6%**	**3.4%**	**24.5%**	**32.3%**
Change	**2,187**	**3,484**	**$183,313.39**	**$3.19**	**$0.06**	**146,074**	**89,982**

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

Demographics of Members Utilizing Antiviral Medications



Top Prescriber Specialties of Antiviral Medications by Number of Claims



Prior Authorization of Antiviral Medications

There were 319 prior authorization requests submitted for antiviral medications during calendar year 2021. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Xerese® (acyclovir/hydrocortisone 5%/1% cream): November 2022
- Rebetol® (ribavirin oral solution): October 2023
- Prevymis™ (letermovir oral tablet): May 2024
- Avaclyr™ (acyclovir 3% ophthalmic ointment): March 2026
- Livtencity™ (maribavir tablet): November 2026
- Sitavig® (acyclovir buccal tablet): June 2030
- Prevymis™ (letermovir injection): February 2033

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

- **November 2021:** The FDA approved Livtencity™ (maribavir) for the treatment of post-transplant cytomegalovirus (CMV) infection/disease that does not respond to other available CMV treatments, which include ganciclovir, valganciclovir, cidofovir, or foscarnet. CMV is a type of herpes virus that commonly causes infection in patients who undergo a hematopoietic stem cell transplant (HSCT) or a solid organ transplant (SOT). If left untreated, this could cause loss of the transplanted organ and death. The approval of Livtencity™ was based on a Phase 3 study comparing this product to the other available CMV treatments that were previously mentioned. At 8 weeks, 56% of the patients treated with Livtencity™ had an undetectable level of CMV DNA compared to 24% in patients who received the other available CMV treatments. Common adverse reactions from the clinical study included taste disturbance, nausea, diarrhea, vomiting, and fatigue.

Livtencity™ (Maribavir) Product Summary[3]

Indication(s): For the treatment of adults and pediatric patients (12 years of age and older and weighing ≥35kg) with post-transplant CMV infection/ disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet.

How Supplied: 200mg oral tablet

Dosing: The recommended dosage is 400mg [(2) 200mg tablets] orally twice daily with or without food.

Warnings/Precautions

- Maribavir may antagonize the antiviral activity of ganciclovir and valganciclovir, so coadministration is not recommended.
- Due to virologic failure during and after treatment, CMV DNA levels should be monitored, and resistance checking should occur if the patient does not respond to treatment.

- Strong inducers of CYP3A4 are expected to decrease maribavir plasma concentrations and are not recommended to be taken with maribavir, except for selected anticonvulsants which include carbamazepine, phenytoin, and phenobarbital.
- Maribavir has the potential to increase the drug concentrations of immunosuppressant drugs that are CYP3A4 and/or P-gp substrates (e.g., tacrolimus, cyclosporine, sirolimus). Frequent monitoring of immunosuppressant drug levels throughout treatment is recommended.

Mechanism of Action: The antiviral activity of maribavir is mediated by competitive inhibition of the protein kinase activity of human CMV enzyme pUL97, which results in inhibition of the phosphorylation of proteins.

Contraindication(s): None

Use in Specific Populations:
- Pregnancy: There is insufficient data to evaluate the drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. In animal studies, embryo-fetal survival was decreased in rats, but not rabbits.
- Pediatric Use: The safety and efficacy of maribavir were established in pediatric patients 12 years of age and older and weighing ≥35kg.
- Geriatric Use: Clinical studies of maribavir included 54 patients 65 years of age and older. The safety, effectiveness, and pharmacokinetics were consistent between elderly patients and younger patients.

Adverse Reactions: The most common adverse reactions reported in clinical studies (incidence >10%) were taste disturbance, nausea, diarrhea, vomiting, and fatigue.

Efficacy: The safety and efficacy of maribavir were assessed in a Phase 3, multicenter, randomized, open-label, active-controlled superiority study comparing maribavir to an investigator-assigned treatment (IAT) which included ganciclovir, valganciclovir, foscarnet, or cidofovir in 352 HSCT and SOT recipients with CMV infections. These patients were refractory to treatment with ganciclovir, valganciclovir, foscarnet, or cidofovir, including CMV infections with or without confirmed resistance to 1 or more of the IATs. Patients were randomized in a 2:1 allocation ration to receive either maribavir 400mg twice daily or IAT as dosed by the investigator for up to 8 weeks. After completion of the treatment period, subjects entered in a 12-week follow-up phase.
- Primary Endpoint: The primary efficacy endpoint was the number of patients achieving an undetectable CMV DNA level at the end of 8 weeks as assessed by COBAS® AmpliPrep/COBAS® TaqMan® CMV test.

- Results: At week 8, maribavir was shown to be statistically superior to IAT in the number of patients who achieved an undetectable CMV DNA level [adjusted difference: 33%; 95% confidence interval (CI): 23, 43; P <0.001].

Cost: The Wholesale Acquisition Cost (WAC) of Livtencity™ is $222.32 per tablet, resulting in a cost of $49,799.68 for an 8-week treatment course at the recommended dosage of 400mg twice daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Livtencity™ (maribavir) with the following criteria:

Livtencity™ (Maribavir) Approval Criteria:

1. An FDA approved indication of the treatment of post-transplant cytomegalovirus (CMV) infection and disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet in adults and pediatric members (12 years of age and older weighing ≥35kg); and
2. A previously failed trial at least 14 days in duration with intravenous (IV) ganciclovir and/or oral valganciclovir and IV cidofovir or IV foscarnet; and
3. Prescriber must verify the member does not have CMV disease involving the central nervous system including the retina (CMV retinitis); and
4. Prescriber must verify member will not receive concurrent treatment with ganciclovir and/or valganciclovir while taking Livtencity™; and
5. Prescriber must verify the member will be monitored for virologic failure during and after treatment with Livtencity™; and
6. Livtencity™ must be prescribed by an oncology, hematology, infectious disease, or transplant specialist (or advanced care practitioner with a supervising physician who is an oncology, hematology, infectious disease, or transplant specialist); and
7. Prescriber must verify Livtencity™ will not be used concomitantly with strong inducers of CYP3A4 (e.g., rifampin, rifabutin, St. John's wort) except carbamazepine, phenobarbital, or phenytoin. Use of carbamazepine, phenobarbital, or phenytoin concomitantly with Livtencity™ will require dose adjustment according to package labeling; and
8. Prescriber must agree to monitor drug concentrations of immunosuppressant drugs that are CYP3A4 and/or P-glycoprotein (P-gp) substrates (e.g., tacrolimus, cyclosporine, sirolimus, everolimus) throughout treatment with Livtencity™ and adjust the dose of immunosuppressant drug(s) as needed; and

9. A quantity limit of 112 tablets per 28 days will apply.

Utilization Details of Antiviral Medications: Calendar Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VALACYCLOVIR PRODUCTS						
VALACYCLOVIR TAB 1GM	4,866	3,153	$121,960.92	$25.06	1.54	17.98%
VALACYCLOVIR TAB 500MG	3,920	1,975	$87,405.60	$22.30	1.98	12.88%
SUBTOTAL	**8,786**	**5,128**	**$209,366.52**	**$23.83**	**1.71**	**30.86%**
ACYCLOVIR PRODUCTS						
ACYCLOVIR TAB 400MG	4,409	2,336	$62,822.02	$14.25	1.89	9.26%
ACYCLOVIR TAB 800MG	1,601	1,085	$25,064.96	$15.66	1.48	3.69%
ACYCLOVIR SUS 200/5ML	722	554	$49,456.82	$68.50	1.3	7.29%
ACYCLOVIR CAP 200MG	653	395	$9,663.42	$14.80	1.65	1.42%
ZOVIRAX CRE 5%	224	153	$131,331.21	$586.30	1.46	19.36%
ACYCLOVIR CRE 5%	4	4	$1,251.92	$312.98	1	0.18%
ACYCLOVIR OIN 5%	3	3	$118.73	$39.58	1	0.02%
SUBTOTAL	**7,616**	**4,530**	**$279,709.08**	**$36.73**	**1.68**	**41.22%**
FAMCICLOVIR PRODUCTS						
FAMCICLOVIR TAB 500MG	210	145	$7,175.44	$34.17	1.45	1.06%
FAMCICLOVIR TAB 250MG	103	44	$3,508.85	$34.07	2.34	0.52%
FAMCICLOVIR TAB 125MG	12	3	$182.36	$15.20	4	0.03%
SUBTOTAL	**325**	**192**	**$10,866.65**	**$33.44**	**1.69**	**1.61%**
LETERMOVIR PRODUCTS						
PREVYMIS TAB 480MG	28	10	$177,150.81	$6,326.81	2.8	26.11%
SUBTOTAL	**28**	**10**	**$177,150.81**	**$6,326.81**	**2.8**	**26.11%**
RIBAVIRIN PRODUCTS						
RIBAVIRIN CAP 200MG	6	4	$890.23	$148.37	1.5	0.13%
RIBAVIRIN TAB 200MG	5	3	$505.25	$101.05	1.67	0.07%
SUBTOTAL	**11**	**7**	**$1,395.48**	**$126.86**	**1.57**	**0.20%**
TOTAL	**16,766**	**9,078***	**$678,488.54**	**$40.47**	**1.85**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CRE = cream; OIN = ointment; 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 05/2022. Last accessed 05/16/2022.
[2] U.S. FDA. FDA Approves First Treatment for Common Type of Post-Transplant Infection that is Resistant to Other Drugs. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-common-type-post-transplant-infection-resistant-other-drugs. Issued 11/23/2021. Last accessed 05/18/2022.
[3] Livtencity™ (Maribavir) Prescribing Information. Takeda Pharmaceuticals. Available online at: https://content.takeda.com/?contenttype=pi&product=liv&language=eng&country=usa&documentnumber=1. Last revised 11/2021. Last accessed 05/17/2022.

Appendix L

Calendar Year 2021 Annual Review of Insomnia Medications and 30-Day Notice to Prior Authorize Quviviq™ (Daridorexant)

Oklahoma Health Care Authority
June 2022

Current Prior Authorization Criteria

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

CR = controlled release; PA = prior authorization; SL = sublingual
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 dosage formulations require a special reason for use in place of Tier-1 formulations.
⁺Individual criteria specific to tasimelteon applies.

- Tier-1 medications are available without a prior authorization for members 19 years of age and older.
- Members 18 years of age or younger will be required to submit a prior authorization for consideration of all insomnia medications.
- All medications have a quantity limit of 30 units per 30 days.

Insomnia Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have a minimum of a 30-day trial with at least 2 Tier-1 medications and clinical documentation of attempts to correct any primary cause for insomnia; and
3. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and
4. Approvals will be granted for the duration of 6 months.

Insomnia Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have a minimum of a 30-day trial with at least 2 Tier-1 medications and clinical documentation of attempts to correct any primary cause for insomnia; and
3. Member must have a minimum of a 30-day trial with at least 2 Tier-2 medications; and
    a. If only 1 Tier-2 medication is available, a minimum of a 30-day trial with 1 Tier-2 medication will be required; and
4. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and
5. Approvals will be granted for the duration of 6 months.

Hetlioz® (Tasimelteon) Approval Criteria:

1. An FDA approved diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24) confirmed by a sleep specialist; and
2. Member must be 18 years of age or older; and
3. Member must have a failed trial of appropriately timed doses of melatonin; and
4. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication; and
5. A quantity limit of 30 capsules for 30 days will apply.

Ramelteon (Generic Rozerem®) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the brand formulation (Rozerem®) of ramelteon must be provided.

Seconal Sodium™ (Secobarbital Sodium Capsule) Approval Criteria:

1. An FDA approved indication for 1 of the following:
    a. The short-term treatment of insomnia; or
    b. A preanesthetic; and
2. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives must be provided; and
3. For the short-term treatment of insomnia, a quantity limit of 1 capsule per day not to exceed 14 capsules per 30 days will apply.

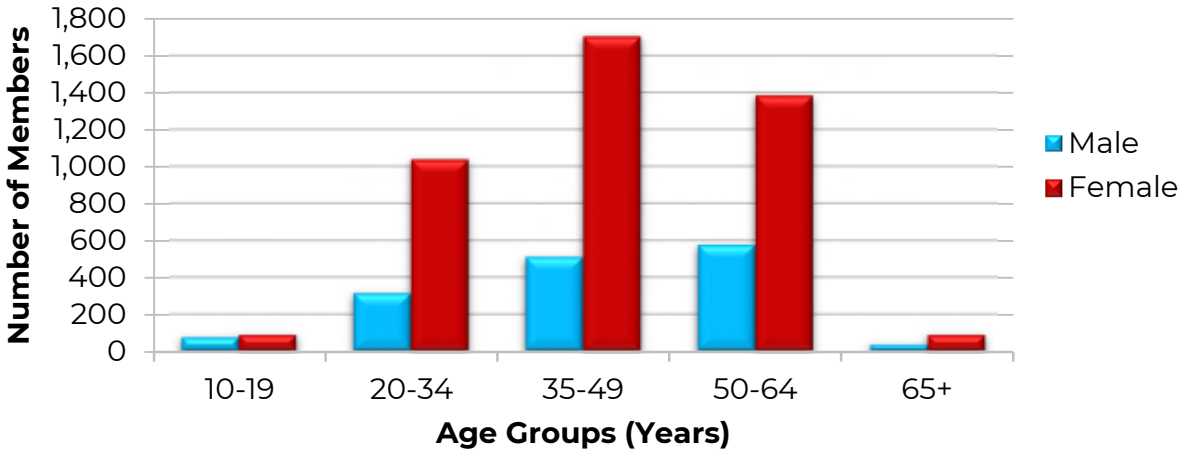
Utilization of Insomnia Medications: Calendar Year 2021

Comparison of Calendar Years

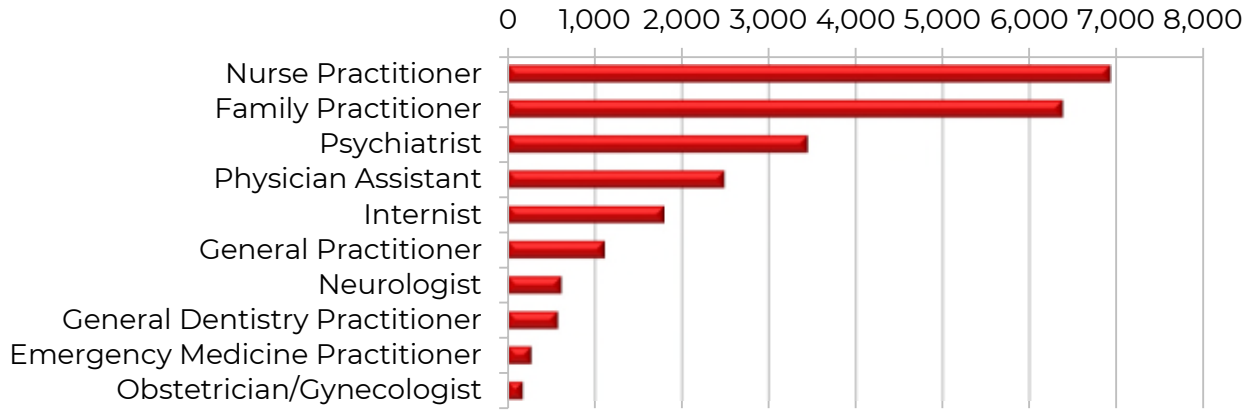
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	4,207	22,007	$918,373.02	$41.73	$1.44	637,500	637,839
2021	5,780	24,987	$1,127,434.67	$45.12	$1.60	706,289	706,433
% Change	**37.4%**	**13.5%**	**22.8%**	**8.1%**	**11.1%**	**10.8%**	**10.8%**
Change	**1,573**	**2,980**	**$209,061.65**	**$3.39**	**$0.16**	**68,789**	**68,594**

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

Demographics of Members Utilizing Insomnia Medications



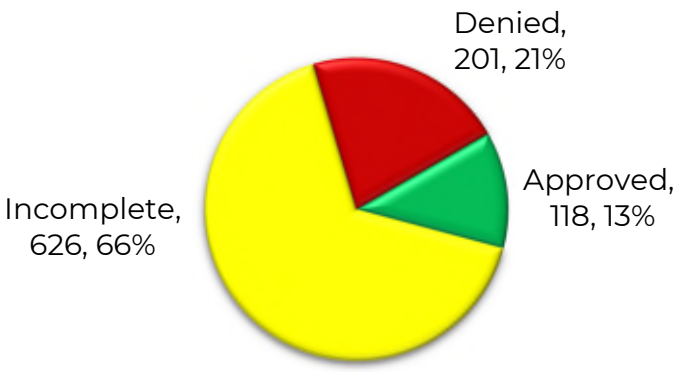
Top Prescriber Specialties of Insomnia Medications by Number of Claims



Prior Authorization of Insomnia Medications

There were 945 prior authorization requests submitted for insomnia medications during calendar year 2021. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Silenor® (doxepin tablets): September 2030
- Edluar® (zolpidem sublingual tablets): February 2031
- Zolpimist® (zolpidem oral spray): August 2032
- Belsomra® (suvorexant tablets): May 2033
- Quviviq™ (daridorexant tablets): December 2034
- Hetlioz® (tasimelteon capsules): August 2035
- Dayvigo® (lemborexant tablets): October 2035
- Hetlioz LQ™ (tasimelteon oral suspension): December 2040

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

- **December 2020:** The FDA approved an expanded indication for Hetlioz® (tasimelteon capsules) for the treatment of patients 16 years of age and older with nighttime sleep disturbances associated with Smith-Magenis Syndrome (SMS) and also approved a new formulation, Hetlioz LQ™ (tasimelteon oral suspension), for use in pediatric patients 3 to 15 years of age with nighttime sleep disturbances associated with SMS. SMS is a rare neurodevelopmental disorder with a defining feature of an inverted circadian rhythm, making it difficult for these patients to sleep during the night. The approval of this new indication was based on a single placebo-controlled efficacy study that included adults taking Hetlioz® capsule and children taking the liquid formulation. The safety profile of Hetlioz® in this study was similar to that seen in the previous studies for Hetlioz® conducted for Non-24-Hour-Sleep-Wake Disorder. Hetlioz® capsules were immediately available for patients with SMS, while Hetlioz LQ™ oral suspension became available for SMS patients in the first quarter of 2021.

- **January 2022:** The FDA approved Quviviq™ (daridorexant) for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. Quviviq™ is a dual orexin receptor antagonist that blocks the binding of the wake-promoting neuropeptides (orexin A and orexin B) and is thought to decrease overactive wakefulness, as opposed to treatments that generally sedate the brain (e.g., zolpidem, temazepam). The approval of Quviviq™ was based on 2 pivotal, multicenter, randomized, double-blind, placebo-controlled studies that included a total of 1,854 patients diagnosed with insomnia. Both studies showed a statistically significant improvement versus placebo on objective measures of sleep onset and sleep maintenance and patient-reported total sleep time. Common adverse reactions from these studies included headache, somnolence, and fatigue.

Quviviq™ (Daridorexant) Product Summary[4]

Indication(s): For the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

How Supplied: 25mg and 50mg oral tablet

Dosing: The recommended dosage is 25 to 50mg once per night, taken orally within 30 minutes before bed, with at least 7 hours remaining prior to planned awakening.

Safety:

- Hepatic Impairment: Patients with moderate hepatic impairment should not exceed 25mg per dose.
- Central Nervous System (CNS)-Depressant Effects and Daytime Impairment: Daridorexant is a CNS depressant that can impair daytime wakefulness; co-administration with other CNS depressants can increase CNS depression. The risk of daytime impairment is increased when daridorexant is taken with ≤7 hours of sleep remaining or if a higher than recommended dose is taken.
- Worsening of Depression/Suicidal Ideation: Patients with psychiatric disorders, including insomnia, are at an increased risk of suicide. Worsening of depression and suicidal ideation may occur. As with other hypnotics, daridorexant should be administered with caution in patients exhibiting symptoms of depression. Monitoring of suicide risk and protective manners may be required.
- Sleep Paralysis, Hypnagogic/Hypnopompic Hallucinations, and Cataplexy-Like Symptoms: Sleep paralysis and hypnagogic/hypnopompic hallucinations can occur with the use of daridorexant. Prescribers should explain the nature of these events to

patients when prescribing daridorexant. Symptoms similar to mild cataplexy have been reported with orexin receptor antagonists.

- Complex Sleep Behaviors: Complex sleep behaviors such as sleepwalking, sleep-driving, and engaging in other activities while not fully awake have been reported to occur with the use of hypnotics, including orexin receptor antagonists such as daridorexant. Therapy with daridorexant should be discontinued immediately if this occurs.
- Patients with Compromised Respiratory Function: The effects of daridorexant on respiratory function should be considered if prescribed to patients with compromised respiratory function. Daridorexant has not been studied in patients with moderate obstructive sleep apnea (OSA) requiring continuous positive airway pressure (CPAP) or severe OSA and has not been studied in patients with severe chronic obstructive pulmonary disease (COPD).
- Need to Evaluate for Comorbid Diagnoses: Because sleep disturbances may be the presenting manifestation of a medical and/or psychiatric disorder, treatment of insomnia should only be initiated after careful evaluation of the patient. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated.

Mechanism of Action: Daridorexant is a dual orexin receptor antagonist that blocks the binding of the wake-promoting neuropeptides, orexin A and orexin B, to receptors OX1R and OX2R.

Contraindication(s): Patients with narcolepsy

Use in Specific Populations:

- Pregnancy: There is insufficient data to evaluate the drug associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. In animal reproduction studies, oral daridorexant at doses up to 8 and 10 times the maximum recommended human dose did not cause fetal toxicity or malformation.
- Pediatric Use: The safety and efficacy of daridorexant have not been established in pediatric patients.
- Geriatric Use: Clinical studies of daridorexant included 727 patients 65 years of age and older, and 110 of these patients were 75 years of age and older. No dose adjustment is required for patients 65 years of age and older, but the likelihood of somnolence and fatigue increased with patient age in the clinical study.

Adverse Reactions: The most common adverse reactions reported in clinical studies (incidence ≥5%) were headache, somnolence, and fatigue.

Efficacy: The safety and efficacy of daridorexant were assessed in 2 multicenter, randomized, double-blind, placebo-controlled, parallel-group studies. A total of 1,854 patients with Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5®) insomnia were randomized to receive daridorexant or placebo once daily in the evening for 3 months. In study 1, patients were randomized to either the 50mg, 25mg, or placebo. Patients in study 2 were randomized to either 25mg, 10mg, or placebo.

- Primary Endpoint: The primary efficacy endpoints for both studies were the change from baseline to month 1 and month 3 in Latency to Persistent Sleep (LPS) and Wake After Sleep Onset (WASO), measured objectively by polysomnography in a sleep laboratory. LPS is a measure of sleep induction, while WASO is a measure of sleep maintenance.
- Results: For study 1, daridorexant 25mg and 50mg showed a statistically significant improvement versus placebo in LPS and WASO at month 1 and month 3. Patients in this study also showed a statistically significant improvement in self-reported sleep time (sTST) in both treatment groups when compared to placebo. For study 2, daridorexant 25mg showed a statistically significant improvement versus placebo on WASO at month 1 and 3 but did not show a significant improvement in LPS when compared to placebo. Patients on daridorexant 25mg also reported a statistically significant improvement in sTST. The 10mg dose did not show a statistically significant improvement on the primary efficacy endpoints, and this dose was not approved by the FDA.

Cost: The Wholesale Acquisition Cost (WAC) of Quviviq™ 50mg is $15.23 per tablet, resulting in a monthly cost of $456.90 at the maximum recommended dosage of 50mg per day.

Recommendations

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

1. Updating the approval criteria for Hetlioz® (tasimelteon capsules) based on the new FDA approved indication
2. The prior authorization of Hetlioz LQ™ (tasimelteon oral suspension) and placement into the Special Prior Authorization (PA) Tier of the Insomnia Medications PBPA Tier chart with the following additional criteria
3. The prior authorization of Quviviq™ (daridorexant) and placement into the Special PA category of the Insomnia Medications PBPA category

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®)			tasimelteon (Hetlioz®, **Hetlioz LQ™**)+
ramelteon (Rozerem®) – **Brand Preferred**			temazepam (Restoril®) 7.5mg and 22.5mg
temazepam (Restoril®) 15mg and 30mg			zolpidem SL tablets (Edluar®)
triazolam (Halcion®)			zolpidem SL tablets (Intermezzo®)
zaleplon (Sonata®)			zolpidem oral spray (Zolpimist®)
zolpidem (Ambien®)			

CR = controlled release; PA = prior authorization; SL = sublingual
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 ~~Tier 1 formulations~~ lower-tiered medications.
+Individual criteria specific to tasimelteon applies.

Hetlioz® (Tasimelteon Capsule) Approval Criteria:

1. An FDA approved diagnosis of one of the following:
   a. ~~An FDA approved diagnosis of~~ Non-24-Hour Sleep-Wake Disorder (Non-24) confirmed by a sleep specialist; ~~and~~ or
   b. Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) confirmed by a sleep specialist; and
2. Member must be 18 years of age or older for a diagnosis of Non-24 or 16 years of age or older for a diagnosis of SMS; and
3. Member must have a failed trial of appropriately timed doses of melatonin; and
4. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication; and
5. A quantity limit of 30 capsules for 30 days will apply.

Hetlioz LQ™ (Tasimelteon Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) confirmed by a sleep specialist; and
2. Member must be 3 to 15 years of age; and
3. Member must have a failed trial of appropriately timed doses of melatonin; and

4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the Hetlioz LQ™ *Prescribing Information*; and
5. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication.

Utilization Details of Insomnia Medications: Calendar Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
ZOLPIDEM TAB 10MG	11,794	2,339	$118,662.69	$10.06	5.04	10.53%
ZOLPIDEM TAB 5MG	2,932	1,095	$29,345.52	$10.01	2.68	2.60%
TEMAZEPAM CAP 30MG	2,226	460	$25,924.09	$11.65	4.84	2.30%
ESZOPICLONE TAB 3MG	1,897	476	$26,839.20	$14.15	3.99	2.38%
TEMAZEPAM CAP 15MG	1,336	461	$14,706.37	$11.01	2.9	1.30%
ROZEREM TAB 8MG	831	189	$289,568.50	$348.46	4.4	25.68%
TRIAZOLAM TAB 0.25MG	811	641	$14,013.58	$17.28	1.27	1.24%
ESZOPICLONE TAB 2MG	788	301	$11,999.44	$15.23	2.62	1.06%
ZALEPLON CAP 10MG	397	158	$5,677.74	$14.30	2.51	0.50%
ESZOPICLONE TAB 1MG	338	176	$4,988.50	$14.76	1.92	0.44%
ZALEPLON CAP 5MG	102	75	$1,163.54	$11.41	1.36	0.10%
TRIAZOLAM TAB 0.125MG	34	34	$427.71	$12.58	1	0.04%
ESTAZOLAM TAB 2MG	33	4	$1,571.57	$47.62	8.25	0.14%
FLURAZEPAM CAP 30MG	9	1	$198.18	$22.02	9	0.02%
TIER-1 SUBTOTAL	**23,528**	**6,410**	**$545,086.63**	**$23.17**	**3.67**	**48.33%**
TIER-2 PRODUCTS						
ZOLPIDEM ER TAB 12.5MG	1,066	172	$20,363.84	$19.10	6.2	1.81%
ZOLPIDEM ER TAB 6.25MG	94	34	$1,773.30	$18.86	2.76	0.16%
AMBIEN CR TAB 12.5MG	12	1	$6,819.20	$568.27	12	0.60%
TIER-2 SUBTOTAL	**1,172**	**207**	**$28,956.34**	**$24.71**	**5.66**	**2.57%**
TIER-3 PRODUCTS						
BELSOMRA TAB 20MG	78	20	$29,153.64	$373.76	3.9	2.59%
DAYVIGO TAB 10MG	67	20	$19,119.30	$285.36	3.35	1.70%
DAYVIGO TAB 5MG	44	12	$12,541.39	$285.03	3.67	1.11%
BELSOMRA TAB 10MG	37	10	$13,863.32	$374.68	3.7	1.23%
BELSOMRA TAB 15MG	5	2	$1,682.76	$336.55	2.5	0.15%
BELSOMRA TAB 5MG	1	1	$376.13	$376.13	1	0.03%
TIER-3 SUBTOTAL	**232**	**65**	**$76,736.54**	**$330.76**	**3.57**	**6.81%**
SPECIAL PRIOR AUTHORIZATION (PA) PRODUCTS						
TEMAZEPAM CAP 7.5MG	30	4	$1,649.06	$54.97	7.5	0.15%
HETLIOZ CAP 20MG	23	2	$474,716.86	$20,639.86	11.5	42.11%
DOXEPIN TAB 6MG	1	1	$236.47	$236.47	1	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RAMELTEON TAB 8MG	1	1	$52.77	$52.77	1	0.00%
SPECIAL PA SUBTOTAL	**55**	**8**	**$476,655.16**	**$8,666.46**	**6.88**	**42.28%**
TOTAL	**24,987**	**5,780***	**$1,127,434.67**	**$45.12**	**4.32**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CR = controlled-release; ER = extended-release; 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 05/2022. Last accessed 05/18/2022.
[2] FDA Approves Hetlioz® (tasimelteon) for the Treatment of Nighttime Sleep Disturbances in Smith-Magenis Syndrome. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/fda-approves-hetlioz-tasimelteon-for-the-treatment-of-nighttime-sleep-disturbances-in-smith-magenis-syndrome-301183162.html. Issued 12/01/2021. Last accessed 05/18/2022.
[3] Idorsia Receives U.S. FDA Approval of Quviviq™ (Daridorexant) 25 and 50mg for the Treatment of Adults with Insomnia. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/idorsia-receives-us-fda-approval-of-quviviq-daridorexant-25-and-50-mg-for-the-treatment-of-adults-with-insomnia-301456774.html. Issued 01/10/2022. Last accessed 05/18/2022.
[4] Quviviq™ (Daridorexant) Prescribing Information. Idorsia Pharmaceuticals. Available online at: https://www.idorsia.us/documents/us/label/Quviviq_PI.pdf. Last revised 04/2022. Last accessed 05/17/2022.

Appendix M

Calendar Year 2021 Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Invega Hafyera™ (Paliperidone Palmitate Injection)

Oklahoma Health Care Authority
June 2022

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 Sustenna®)		iloperidone (Fanapt®)
paliperidone palmitate IM inj (Invega Trinza®)**		lumateperone (Caplyta®)
quetiapine (Seroquel®)		olanzapine/fluoxetine (Symbyax®)
quetiapine ER (Seroquel XR®)		olanzapine/samidorphan (Lybalvi®)
risperidone (Risperdal®)		paliperidone (Invega®)
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 Invega Trinza® requires members to have been adequately treated with the 1-month paliperidone palmitate injection (Invega Sustenna®) for at least 4 months.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.

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.
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:

1. Authorization of Symbyax® (olanzapine/fluoxetine) or Rexulti® (brexpiprazole) for a diagnosis of major depressive disorder requires current use of an antidepressant, previous trials with at least 2 other antidepressants from both categories (an SSRI and a dual-acting medication) and a trial of 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. The 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.

Utilization of Atypical Antipsychotic Medications: Calendar Year 2021

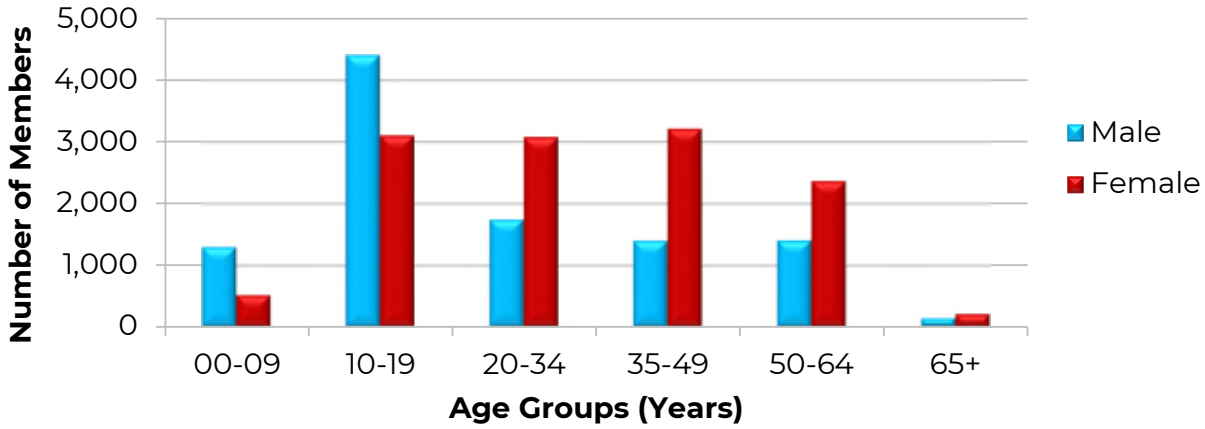
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	27,191	198,017	$59,274,316.79	$299.34	$9.15	7,999,635	6,476,630
2021	36,020	224,333	$76,887,732.02	$342.74	$10.25	9,044,330	7,509.997
% Change	**32.5%**	**13.3%**	**29.7%**	**14.50%**	**11.90%**	**13.1%**	**16.0%**
Change	**8,829**	**26,316**	**$17,613,415.23**	**$43.40**	**$1.09**	**1,044,695**	**1,033,367**

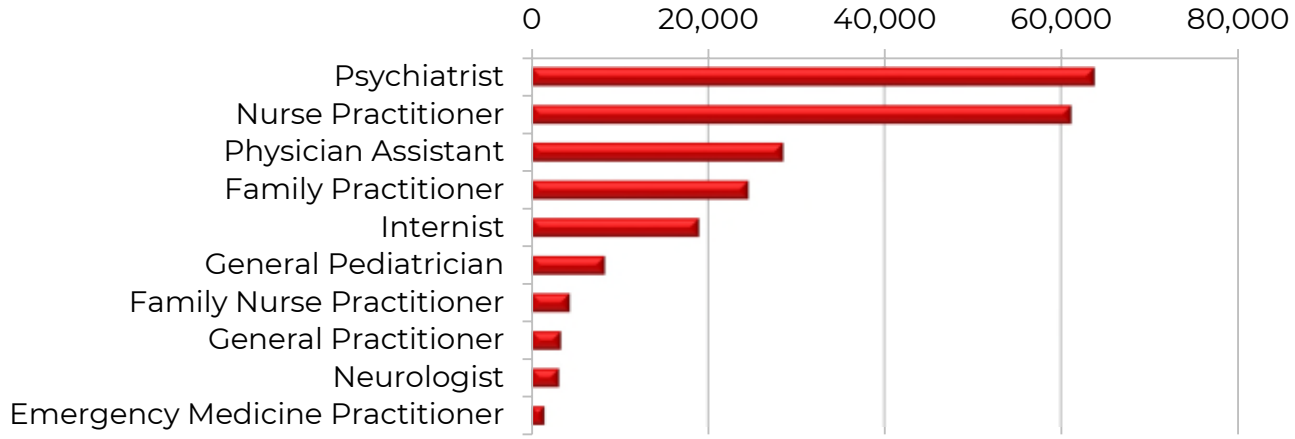
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

- 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 2021 for atypical antipsychotic medications: $50,127,366.72[Δ]

Demographics of Members Utilizing Atypical Antipsychotic Medications



Top Prescriber Specialties of Atypical Antipsychotic Medications by Number of Claims



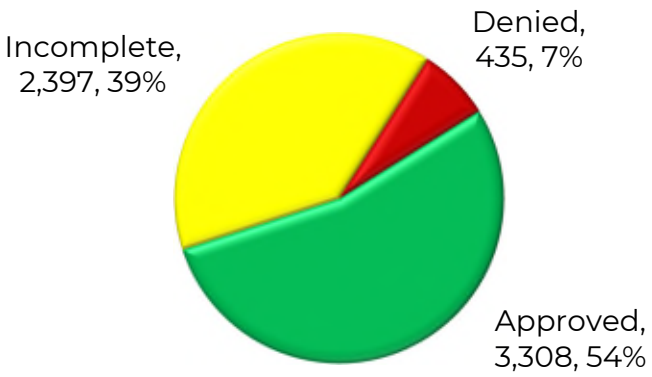
Prior Authorization of Atypical Antipsychotic Medications

There were 6,140 prior authorization requests submitted for atypical antipsychotic medications during calendar year 2021. Computer edits are in place to detect lower tiered medications in a member's recent claims history

[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.

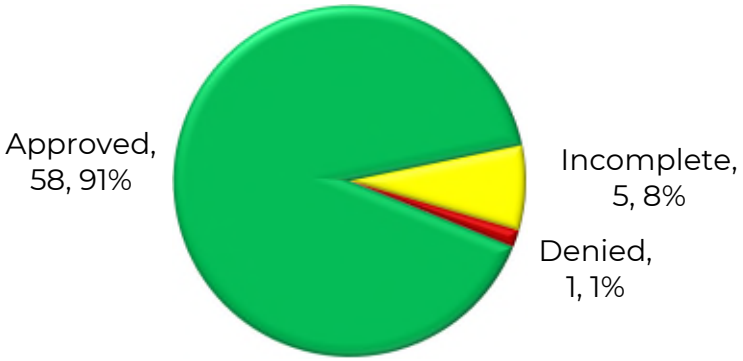
and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions



There were 64 prior authorization requests submitted for a total of 53 unique members for atypical antipsychotic medications during calendar year 2021 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 2021.

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]

Anticipated Patent Expiration(s):

- Saphris® [asenapine sublingual (SL) tablet]: October 2026
- Perseris® [risperidone extended-release (ER) subcutaneous (sub-Q) injection]: February 2028
- Vraylar® (cariprazine capsule): September 2029
- Latuda® (lurasidone tablet): November 2031
- Invega Sustenna® [paliperidone palmitate intramuscular (IM) injection]: January 2031
- Fanapt® (iloperidone tablet): December 2031
- Lybalvi® (olanzapine/samidorphan tablet): February 2032
- Rexulti® (brexpiprazole tablet): October 2032
- 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 palmitate IM injection): April 2036
- Caplyta® (lumateperone capsule): August 2039
- Invega Hafyera™ (paliperidone palmitate IM injection): May 2041

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

- **September 2021:** The FDA approved Invega Hafyera™ (paliperidone palmitate) a 6-month IM injectable for the treatment of schizophrenia in adults. The approval was based on a randomized, double blind Phase 3 global study that was designed to demonstrate that Invega Hafyera™ was not less effective than Invega Trinza® in delaying time to first relapse in patients who were previously stabilized on doses of Invega Sustenna® or Invega Trinza®. The results showed that Invega Hafyera™

at 92.5% was non-inferior to Invega Trinza® at 95% for time to first relapse at the end of the 12-month period. Relapse was defined as psychiatric hospitalization, increase in Positive and Negative Syndrome Scale (PANNS) total score, increase in individual PANSS item scores, self-injury, violent behavior, or suicidal/homicidal ideation. The most common adverse reactions reported in the clinical study (incidence of ≥5%) were upper respiratory infection, injection site reaction, weight gain, headache, and parkinsonism.

- **December 2021:** Intra-Cellular Therapies announced that the FDA approved Caplyta® for the treatment of depressive episodes associated with bipolar I or II disorder in adults, as monotherapy and as adjunctive therapy with lithium or valproate. The approval was based on 2 Phase 3 placebo-controlled studies, which evaluated the effects of Caplyta® on depression in adult patients with bipolar I or bipolar II disorder both as monotherapy and as adjunctive therapy with lithium or valproate. In these studies, the efficacy of Caplyta® 42 mg was established by demonstrating statistically significant improvements over placebo for the change from baseline in the Montgomery-Asberg Depression Rating Scale (MADRS) total score at week 6. In addition, Caplyta® demonstrated a favorable tolerability and safety profile consistent with findings in prior clinical studies in schizophrenia. The most common reported adverse reactions in the clinical study (occurring at a rate of 5% or more and at least twice the rate of placebo) were somnolence/sedation, dizziness, nausea, and dry mouth. Mean changes from baseline in weight, fasting glucose, total cholesterol, triglycerides, and LDL cholesterol were similar between Caplyta® and placebo.
- **January 2022:** The FDA approved a supplemental New Drug Application (sNDA) for Rexulti® for the treatment of schizophrenia in pediatric patients 13 to 17 years of age. The submission was based on an extrapolation analysis that used data from prior studies among adult patients, pharmacokinetic results from adult and pediatric trials, and 6-month data from an ongoing open-label, long-term trial among adolescent patients with schizophrenia. The interim data from the long-term trial, comprising data from 194 adolescent patients, of whom 140 received Rexulti® for at least 6 months, were recently presented at the Psych Congress, and a manuscript is planned for submission to a peer-reviewed scientific journal in 2022. Adverse events reported for this age group were generally similar to those observed in adult patients. The effectiveness and safety of Rexulti® in pediatric patients with major depressive disorder have not been established.

News:

- **April 2022:** Teva Pharmaceuticals and MedinCell previously announced the acceptance of the New Drug Application (NDA) for TV-46000/mdc-

IRM (risperidone ER subcutaneous injection) for the treatment of schizophrenia. It was then announced that the FDA has issued a Complete Response Letter (CRL) in response to the NDA. The companies did not provide further information regarding the details of the CRL, but they remain committed to the development of the ER risperidone SQ injection and to providing patients with access to the product in the United States as quickly as possible. Teva is reviewing its next steps based on the letter and will work closely with the FDA to address their recommendations.

Pipeline:

- **NRX-101 (Cyclurad):** NeuroRx was granted Fast Track and Breakthrough Therapy designations by the FDA for NRX-101. NRX-101 is a fixed dose combination oral capsule composed of D-cycloserine (DCS) and lurasidone for the maintenance of remission from severe bipolar depression with acute suicidal ideation or behavior in adults with bipolar depression following initial stabilization with ketamine. NRX-101 was developed with the objective of seeking a safe, non-hallucinogen, non-addictive, oral medication that might maintain the effects of ketamine in patients with severe depression and acute suicidal ideation. Phase 3 study patients are currently being recruited.
- **MIN-101 (Roluperidone):** Minerva Neurosciences announced results from a 40-week open-label extension of its Phase 3 study of roluperidone for the treatment of negative symptoms (NS) of schizophrenia. The extension followed the 12-week double-blind, placebo-controlled portion of this study. During the extension study, both investigators and patients were blinded to the roluperidone dose received. Over the 40-week extension period, 333 patients participated, of whom 166 patients received the 32mg dose and 167 patients received the 64mg dose. The mean improvement in NS (measured by PANSS) was 6.8 points in the 32mg arm and 7.5 points in the 64mg arm. Personal and Social Performance (PSP) total score improved by a mean of 12.3 points in the 32mg arm and 14.5 points in the 64mg arm, suggesting functional improvement. Minerva intends to submit the NDA for roluperidone to the FDA in the first half of 2022.

Invega Hafyera™ (Paliperidone Palmitate) Product Summary[10]

Indication(s): Invega Hafyera™, an injection given every 6 months, is an atypical antipsychotic indicated for the treatment of schizophrenia in adults after they have been adequately treated with:

- A once-a-month paliperidone palmitate ER injectable suspension (e.g., Invega Sustenna®) for at least 4 months; or
- An every 3-month paliperidone palmitate ER injectable suspension (e.g., Invega Trinza®) for at least one 3-month cycle

Boxed Warning: Increased Mortality in Elderly Patients with Dementia-Related Psychosis

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
- Invega Hafyera™ is not approved for use in patients with dementia-related psychosis.

How Supplied: 1,092mg/3.5mL and 1,560mg/5mL single-dose prefilled syringes

Dosing:

- Invega Hafyera™ should be administered by gluteal IM injection once every 6 months by a health care professional.
- Invega Hafyera™ should be initiated when the next dose of Invega Sustenna® or Trinza® is scheduled.
- Please refer to the Invega Hafyera™ *Prescribing Information* for proper dosing based on the previous paliperidone palmitate ER injectable suspension used.

Mechanism of Action: Paliperidone palmitate is hydrolyzed to paliperidone. Paliperidone is the major active metabolite of risperidone. The mechanism of action of paliperidone is unclear. However, its efficacy in the treatment of schizophrenia could be mediated through a combination of central dopamine D2 and serotonin 5-HT2A receptor antagonism.

Contraindication(s): Known hypersensitivity to paliperidone, risperidone, or to any excipients in Invega Hafyera™.

Warnings and Precautions:

- Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis: Elderly patients taking Invega Hafyera™ have an increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack, including fatalities).
- Neuroleptic Malignant Syndrome (NMS): If NMS occurs, it should be managed with immediate discontinuation of Invega Hafyera™ and close monitoring.
- QT Prolongation: Invega Hafyera™ should be avoided with drugs that increase QT interval and in patients with risk factors for prolonged QT interval.
- Tardive Dyskinesia: If tardive dyskinesia occurs, treatment with Invega Hafyera™ should be discontinued if clinically appropriate.
- Metabolic Changes: Patients should be monitored for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain.

- Orthostatic Hypotension and Syncope: Caution should be taken in patients with known cardiovascular or cerebrovascular disease and patients predisposed to hypotension.
- Leukopenia, Neutropenia, and Agranulocytosis: Complete blood counts (CBC) should be performed in patients with pre-existing low white blood cell count (WBC) or a history of leukopenia or neutropenia. Discontinuing Invega Hafyera™ should be considered if a clinically significant decline in WBC occurs in the absence of other causative factors.
- Hyperprolactinemia: Prolactin elevations occur and persist during chronic administration of Invega Hafyera™.
- Potential for Cognitive and Motor Impairment: Caution should be taken when operating machinery.
- Seizures: Caution should be taken in patients with a history of seizures or with conditions that lower the seizure threshold.

Adverse Reactions: The most common adverse reactions reported in clinical studies (incidence ≥5%) were upper respiratory tract infection, injection site reaction, weight gain, headache, and parkinsonism.

Efficacy: The safety and efficacy of Invega Hafyera™ were based on a randomized, double-blind, non-inferiority Phase 3 global study that enrolled 702 adults who were previously stabilized with either paliperidone palmitate 1-month injection for at least 4 months or paliperidone 3-month injection for at least one 3-month injection cycle and who had a PANSS score of <70 points. Patients were randomized 2:1 to receive either Invega Hafyera™ or paliperidone palmitate 3-month injection.

- Primary Endpoint: The primary efficacy endpoint was time to first relapse at the end of the 12-month period. Relapse was pre-defined as emergence of 1 or more of the following: psychiatric hospitalization; ≥25% increase (if the baseline score was >40) or a 10-point increase (if the baseline score was ≤40) in total PANSS score on 2 consecutive assessments; or deliberate self-injury, violent behavior, or suicidal/homicidal ideation [a score of ≥5 (if the maximum baseline score was ≤3) or ≥6 (if the maximum baseline score was 4) on 2 consecutive assessments of the specific PANSS items].
- Results: A relapse event was experienced by 7.5% and 4.9% of patients in the Invega Hafyera™ and paliperidone palmitate 3-month injection treatment groups, respectively. The study demonstrated non-inferiority of Invega Hafyera™ to the paliperidone palmitate 3-month injection. An evaluation of population subgroups did not reveal any clinically significant differences in responsiveness based on gender, age, or race.

Cost Comparison:

Medication	Cost Per Unit	Cost Per Year
Invega Sustenna® (paliperidone palmitate) 234mg/1.5mL PFS	$1,987.04	$25,831.52*
Invega Trinza® (paliperidone palmitate) 819mg/2.63mL PFS	$3,392.88	$13,571.52+
Invega Hafyera™ (paliperidone palmitate) 1,560mg/5mL PFS	**$3,718.52**	**$7,437.04ß**

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).
PFS = pre-filled syringe; Unit = pre-filled syringe
*Invega Sustenna® cost per year is based on maintenance dose of 234mg once monthly.
+Invega Trinza® cost per year is based on maintenance dose of 819mg once every 3 months.
ß Invega Hafyera™ cost per year is based on maintenance dose of 1,560mg once every 6 months.

Recommendations

The College of Pharmacy recommends the placement of Invega Hafyera™ (paliperidone palmitate IM injection) into Tier-3 of the Atypical Antipsychotic Medications PBPA category with the following additional criteria (changes noted in red):

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.
6. Use of Symbyax (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

7. Use of Invega Hafyera™ (paliperidone palmitate) will require a patient specific, clinically significant reason (beyond convenience) why the member cannot use Invega Sustenna® (paliperidone palmitate) or (Invega Trinza® (paliperidone palmitate).

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 Sustenna®)		iloperidone (Fanapt®)
paliperidone palmitate IM inj (Invega Trinza®)**		lumateperone (Caplyta®)
quetiapine (Seroquel®)		olanzapine/fluoxetine (Symbyax®)^
quetiapine ER (Seroquel XR®)		olanzapine/samidorphan (Lybalvi™)
risperidone (Risperdal®)		paliperidone (Invega®)
risperidone IM inj (Risperdal Consta®)		**paliperidone palmitate IM inj (Invega Hafyera™)+^**
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; susp = suspension; sub-Q = subcutaneous
¥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 Invega Trinza® requires members to have been adequately treated with the 1-month paliperidone palmitate injection (Invega Sustenna®) for at least 4 months.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.
^Use of Invega Hafyera™ requires members to have been adequately treated with the 1-month paliperidone palmitate injection (Invega Sustenna®) for at least 4 months or the 3-month paliperidone palmitate injection (Invega Trinza®) for at least one 3-month cycle.

Utilization Details of Atypical Antipsychotic Medications: Calendar Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIM/ MEMBER	COST/ CLAIM	% COST
TIER-1 PRODUCTS						
QUETIAPINE PRODUCTS						
QUETIAPINE TAB 100MG	12,393	3,749	$158,866.64	3.31	$12.82	0.21%
QUETIAPINE TAB 50MG	10,079	3,315	$125,718.00	3.04	$12.47	0.16%
QUETIAPINE TAB 200MG	7,642	2,012	$115,782.56	3.8	$15.15	0.15%
QUETIAPINE TAB 25MG	6,848	2,463	$81,712.90	2.78	$11.93	0.11%
QUETIAPINE TAB 300MG	6,114	1,436	$103,900.33	4.26	$16.99	0.14%
QUETIAPINE TAB 400MG	5,348	1,148	$104,446.12	4.66	$19.53	0.14%
QUETIAPINE TAB 400MG ER	810	164	$26,600.83	4.94	$32.84	0.03%
QUETIAPINE TAB 300MG ER	699	173	$20,783.17	4.04	$29.73	0.03%
QUETIAPINE TAB 150MG ER	659	200	$13,664.24	3.3	$20.73	0.02%
QUETIAPINE TAB 50MG ER	571	235	$11,312.67	2.43	$19.81	0.01%
QUETIAPINE TAB 200MG ER	437	139	$10,143.15	3.14	$23.21	0.01%
SEROQUEL XR TAB 400MG	12	1	$16,594.51	12	$1,382.88	0.02%
SEROQUEL TAB 400MG	12	1	$13,563.48	12	$1,130.29	0.02%
SUBTOTAL	**51,624**	**15,036**	**$803,088.60**	**3.43**	**$15.56**	**1.05%**
ARIPIPRAZOLE ORAL PRODUCTS						
ARIPIPRAZOLE TAB 5MG	15,977	5,380	$251,066.93	2.97	$15.71	0.33%
ARIPIPRAZOLE TAB 10MG	12,885	4,330	$206,315.19	2.98	$16.01	0.27%
ARIPIPRAZOLE TAB 15MG	7,325	2,174	$115,289.64	3.37	$15.74	0.15%
ARIPIPRAZOLE TAB 2MG	6,151	2,226	$96,208.32	2.76	$15.64	0.13%
ARIPIPRAZOLE TAB 20MG	5,120	1,280	$93,465.01	4	$18.25	0.12%
ARIPIPRAZOLE TAB 30MG	2,813	592	$54,468.06	4.75	$19.36	0.07%
ARIPIPRAZOLE SOL 1MG/ML	386	75	$103,946.03	5.15	$269.29	0.14%
ABILIFY TAB 20MG	14	2	$17,187.92	7	$1,227.71	0.02%
ABILIFY TAB 5MG	12	1	$9,556.23	12	$796.35	0.01%
ABILIFY TAB 30MG	11	2	$22,160.81	5.5	$2,014.62	0.03%
ABILIFY TAB 10MG	5	1	$7,457.33	5	$1,491.47	0.01%
ARIPIPRAZOLE 15MG ODT	3	1	$6,054.75	3	$2,018.25	0.01%
ARIPIPRAZOLE 10MG ODT	1	1	$2,018.25	1	$2,018.25	0.00%
SUBTOTAL	**50,703**	**16,065**	**$985,194.47**	**3.16**	**$19.43**	**1.29%**
RISPERIDONE ORAL PRODUCTS						
RISPERIDONE TAB 1MG	11,294	2,752	$137,322.29	4.1	$12.16	0.18%
RISPERIDONE TAB 0.5MG	9,614	2,283	$115,784.75	4.21	$12.04	0.15%
RISPERIDONE TAB 2MG	7,095	1,754	$88,848.48	4.05	$12.52	0.12%
RISPERIDONE TAB 0.25MG	4,112	1,057	$47,959.26	3.89	$11.66	0.06%
RISPERIDONE TAB 3MG	3,433	739	$42,810.19	4.65	$12.47	0.06%
RISPERIDONE TAB 4MG	1,806	362	$23,601.44	4.99	$13.07	0.03%
RISPERIDONE SOL 1MG/ML	1,151	220	$34,527.00	5.23	$30.00	0.04%
RISPERIDONE 1MG ODT	222	58	$12,875.84	3.83	$58.00	0.02%
RISPERIDONE 0.5MG ODT	193	58	$9,005.69	3.33	$46.66	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIM/ MEMBER	COST/ CLAIM	% COST
RISPERIDONE 0.25MG ODT	124	38	$13,627.69	3.26	$109.90	0.02%
RISPERIDONE 2MG ODT	115	40	$6,615.34	2.88	$57.52	0.01%
RISPERIDONE 3MG ODT	54	12	$6,241.08	4.5	$115.58	0.01%
RISPERIDONE 4MG ODT	41	8	$5,182.22	5.13	$126.40	0.01%
RISPERDAL TAB 2MG	11	1	$8,538.45	11	$776.22	0.01%
RISPERDAL SOL 1MG/ML	5	1	$15,285.03	5	$3,057.01	0.02%
RISPERDAL TAB 0.5MG	5	1	$930.13	5	$186.03	0.00%
SUBTOTAL	**39,275**	**9,384**	**$569,154.88**	**4.19**	**$14.49**	**0.75%**
OLANZAPINE ORAL PRODUCTS						
OLANZAPINE TAB 10MG	8,373	2,523	$111,153.00	3.32	$13.28	0.14%
OLANZAPINE TAB 20MG	7,042	1,519	$105,960.69	4.64	$15.05	0.14%
OLANZAPINE TAB 5MG	5,131	1,827	$65,078.16	2.81	$12.68	0.08%
OLANZAPINE TAB 15MG	3,035	835	$43,949.99	3.63	$14.48	0.06%
OLANZAPINE TAB 2.5MG	1,680	588	$21,471.49	2.86	$12.78	0.03%
OLANZAPINE TAB 7.5MG	702	232	$9,724.45	3.03	$13.85	0.01%
OLANZAPINE 10MG ODT	555	173	$16,594.61	3.21	$29.90	0.02%
OLANZAPINE 5MG ODT	457	168	$11,853.39	2.72	$25.94	0.02%
OLANZAPINE 20MG ODT	352	82	$12,470.58	4.29	$35.43	0.02%
OLANZAPINE 15MG ODT	181	49	$7,269.06	3.69	$40.16	0.01%
ZYPREXA TAB 5MG	9	2	$4,952.76	4.5	$550.31	0.01%
ZYPREXA TAB 15MG	8	1	$7,819.20	8	$977.40	0.01%
ZYPREXA TAB 10MG	4	1	$7,737.96	4	$1,934.49	0.01%
SUBTOTAL	**27,529**	**8,000**	**$426,035.34**	**3.44**	**$15.48**	**0.56%**
PALIPERIDONE INJECTABLE PRODUCTS						
INVEGA SUST INJ 234MG/1.5ML	6,017	1,204	$16,956,954.50	5	$2,818.17	22.05%
INVEGA SUST INJ 156MG/ML	2,454	778	$4,628,830.92	3.15	$1,886.24	6.02%
INVEGA TRINZ INJ 819MG/2.63ML	875	320	$7,326,389.28	2.73	$8,373.02	9.53%
INVEGA SUST INJ 117MG/0.75ML	471	133	$678,157.28	3.54	$1,439.82	0.88%
INVEGA TRINZ INJ 546MG/1.75ML	340	127	$1,921,596.52	2.68	$5,651.75	2.50%
INVEGA TRINZ INJ 410MG/1.32ML	83	38	$351,098.00	2.18	$4,230.10	0.46%
INVEGA SUST INJ 78MG/0.5ML	73	22	$69,367.72	3.32	$950.24	0.09%
INVEGA TRINZ INJ 273MG/0.88ML	32	13	$87,933.57	2.46	$2,747.92	0.11%
INVEGA SUST INJ 39MG/0.25ML	20	4	$9,751.08	5	$487.55	0.01%
SUBTOTAL	**10,365**	**2,639**	**$32,030,078.87**	**3.93**	**$3,090.22**	**41.65%**
CLOZAPINE PRODUCTS						
CLOZAPINE TAB 100MG	5,177	427	$254,548.92	12.12	$49.17	0.33%
CLOZAPINE TAB 200MG	2,091	180	$134,206.19	11.62	$64.18	0.17%
CLOZAPINE TAB 50MG	1,921	180	$65,423.09	10.67	$34.06	0.09%
CLOZAPINE TAB 25MG	1,109	124	$24,628.86	8.94	$22.21	0.03%
CLOZARIL TAB 100MG	21	2	$27,272.49	10.5	$1,298.69	0.04%
SUBTOTAL	**10,319**	**913**	**$506,079.55**	**11.30**	**$49.04**	**0.66%**
ZIPRASIDONE PRODUCTS						
ZIPRASIDONE CAP 40MG	2,137	616	$50,539.65	3.47	$23.65	0.07%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIM/ MEMBER	COST/ CLAIM	% COST
ZIPRASIDONE CAP 20MG	1,801	653	$44,065.75	2.76	$24.47	0.06%
ZIPRASIDONE CAP 80MG	1,650	309	$47,920.50	5.34	$29.04	0.06%
ZIPRASIDONE CAP 60MG	1,471	337	$39,041.38	4.36	$26.54	0.05%
SUBTOTAL	**7,059**	**1,915**	**$181,567.28**	**3.69**	**$25.72**	**0.24%**
ARIPIPRAZOLE INJECTABLE PRODUCTS						
ABILIFY MAIN INJ 400MG	2,787	559	$6,358,544.77	4.99	$1,033.74	8.27%
ABILIFY MAIN INJ 400MG	382	90	$861,167.47	4.24	$168.20	1.12%
ABILIFY MAIN INJ 300MG	287	68	$491,476.84	4.22	$174.72	0.64%
ABILIFY MAIN INJ 300MG	223	64	$382,057.25	3.48	$989.79	0.50%
SUBTOTAL	**3,679**	**781**	**$8,093,246.33**	**4.71**	**$2,199.85**	**10.53%**
ARIPIPRAZOLE LAUROXIL INJECTABLE PRODUCTS						
ARISTADA INJ 882MG/3.2ML	1,159	236	$3,097,732.92	4.91	$2,672.76	4.03%
ARISTADA INJ 1064MG/3.9ML	357	132	$1,159,902.18	2.7	$3,249.03	1.51%
ARISTADA INJ 662MG/2.4ML	246	59	$497,873.22	4.17	$2,023.87	0.65%
ARISTADA INJ 441MG/1.6ML	99	26	$134,261.52	3.81	$1,356.18	0.17%
ARISTADA INJ INITIO 675MG/2.4ML	96	93	$191,190.08	1.03	$1,991.56	0.25%
SUBTOTAL	**1,957**	**546**	**$5,080,959.92**	**3.58**	**$2,596.30**	**6.61%**
RISPERIDONE INJECTABLE PRODUCTS						
PERSERIS INJ 120MG	304	72	$765,307.50	4.22	$2,517.46	1.00%
RISPERDAL INJ 50MG	159	17	$253,856.41	9.35	$1,596.58	0.33%
PERSERIS INJ 90MG	135	32	$255,902.55	4.22	$1,895.57	0.33%
RISPERDAL INJ 25MG	38	7	$37,625.21	5.43	$990.14	0.05%
RISPERDAL INJ 12.5MG	26	3	$6,942.21	8.67	$267.01	0.01%
RISPERDAL INJ 37.5MG	25	3	$32,329.58	8.33	$1,293.18	0.04%
SUBTOTAL	**687**	**134**	**$1,351,963.46**	**5.13**	**$1,967.92**	**1.76%**
OLANZAPINE INJECTABLE PRODUCTS						
ZYPREXA RELP INJ 405MG	9	1	$10,289.85	9	$1,143.32	0.01%
OLANZAPINE INJ 10MG	4	4	$1,395.88	1	$348.97	0.00%
ZYPREXA RELP INJ 210MG	2	1	$2,365.54	2	$1,182.77	0.00%
SUBTOTAL	**15**	**6**	**$14,051.27**	**2.50**	**$936.75**	**0.01%**
TIER-1 SUBTOTAL	**203,212**	**55,419**	**$50,041,419.97**	**3.67**	**$246.25**	**65.11%**
TIER-2 PRODUCTS						
LURASIDONE PRODUCTS						
LATUDA TAB 40MG	3,864	1,175	$5,237,937.23	3.29	$1,355.57	6.81%
LATUDA TAB 20MG	2,962	1,064	$3,987,090.75	2.78	$1,346.08	5.19%
LATUDA TAB 80MG	2,228	525	$3,412,059.17	4.24	$1,531.44	4.44%
LATUDA TAB 60MG	2,190	614	$3,143,712.95	3.57	$1,435.49	4.09%
LATUDA TAB 120MG	1,007	211	$2,122,297.13	4.77	$2,107.54	2.76%
SUBTOTAL	**12,251**	**3,589**	**$17,903,097.23**	**3.41**	**$1,461.36**	**23.29%**
ASENAPINE PRODUCTS						
ASENAPINE SUB 10MG	376	113	$99,210.30	3.33	$263.86	0.13%
ASENAPINE SUB 5MG	294	123	$69,356.35	2.39	$235.91	0.09%
SAPHRIS SUB 10MG	266	58	$258,795.59	4.59	$972.92	0.34%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIM/ MEMBER	COST/ CLAIM	% COST
ASENAPINE SUB 2.5MG	132	57	$56,538.29	2.32	$428.32	0.07%
SAPHRIS SUB 5MG	117	50	$124,659.69	2.34	$1,065.47	0.16%
SAPHRIS SUB 2.5MG	13	8	$14,139.28	1.63	$1,087.64	0.02%
SUBTOTAL	**1,198**	**409**	**$622,699.50**	**2.93**	**$519.78**	**0.81%**
TIER-2 SUBTOTAL	**13,449**	**3,998**	**$18,525,796.73**	**3.36**	**$1,377.49**	**24.10%**
TIER-3 PRODUCTS						
CARIPRAZINE PRODUCTS						
VRAYLAR CAP 3MG	1,377	404	$1,858,064.93	3.41	$1,349.36	2.42%
VRAYLAR CAP 1.5MG	802	290	$1,073,978.94	2.77	$1,339.13	1.40%
VRAYLAR CAP 6MG	756	130	$988,416.76	5.82	$1,307.43	1.29%
VRAYLAR CAP 4.5MG	543	137	$707,266.85	3.96	$1,302.52	0.92%
VRAYLAR CAP 1.5-3MG PACK	4	4	$1,220.80	1	$305.20	0.00%
SUBTOTAL	**3,482**	**965**	**$4,628,948.28**	**3.61**	**$1,329.39**	**6.03%**
PALIPERIDONE ORAL PRODUCTS						
PALIPERIDONE TAB ER 6MG	904	170	$256,336.06	5.32	$283.56	0.33%
PALIPERIDONE TAB ER 9MG	450	80	$137,228.44	5.63	$304.95	0.18%
PALIPERIDONE TAB ER 3MG	349	98	$80,862.70	3.56	$231.70	0.11%
PALIPERIDONE TAB ER 1.5MG	76	24	$18,028.68	3.17	$237.22	0.02%
INVEGA TAB 3MG	16	2	$23,479.04	8	$1,467.44	0.03%
INVEGA TAB 9MG	12	1	$17,743.39	12	$1,478.62	0.02%
SUBTOTAL	**1,807**	**375**	**$533,678.31**	**4.82**	**$295.34**	**0.69%**
BREXIPRAZOLE PRODUCTS						
REXULTI TAB 2MG	447	133	$580,349.46	3.36	$1,298.32	0.75%
REXULTI TAB 1MG	286	111	$394,000.59	2.58	$1,377.62	0.51%
REXULTI TAB 3MG	238	64	$349,107.52	3.72	$1,466.84	0.45%
REXULTI TAB 4MG	145	36	$218,165.76	4.03	$1,504.59	0.28%
REXULTI TAB 0.5MG	81	27	$103,134.74	3	$1,273.27	0.13%
REXULTI TAB 0.25MG	9	5	$13,685.02	1.8	$1,520.56	0.02%
SUBTOTAL	**1,206**	**376**	**$1,658,443.09**	**3.21**	**$1,375.16**	**2.14%**
ILOPERIDONE PRODUCTS						
FANAPT TAB 6MG	99	20	$144,819.94	4.95	$1,462.83	0.19%
FANAPT TAB 4MG	97	14	$106,570.94	6.93	$1,098.67	0.14%
FANAPT TAB 8MG	91	17	$153,516.52	5.35	$1,686.99	0.20%
FANAPT TAB 12MG	84	12	$216,061.48	7	$2,572.16	0.28%
FANAPT TAB 10MG	59	8	$150,873.69	7.38	$2,557.18	0.20%
FANAPT TAB 2MG	31	6	$31,102.71	5.17	$1,003.31	0.04%
FANAPT TAB 1MG	1	1	$1,551.42	1	$1,551.42	0.00%
FANAPT TAB 1/2/4/6MG PACK	1	1	$206.97	1	$206.97	0.00%
SUBTOTAL	**463**	**79**	**$804,703.67**	**5.86**	**$1,738.02**	**1.05%**
CLOZAPINE ORALLY DISENTEGRATING PRODUCTS						
CLOZAPINE 100MG ODT	171	15	$64,686.73	11.4	$378.28	0.08%
CLOZAPINE 150MG ODT	104	11	$89,364.73	9.45	$859.28	0.12%
CLOZAPINE 200MG ODT	46	5	$77,229.86	9.2	$1,678.91	0.10%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIM/ MEMBER	COST/ CLAIM	% COST
CLOZAPINE 25MG ODT	28	4	$6,084.39	7	$217.30	0.01%
SUBTOTAL	**349**	**35**	**$237,365.71**	**9.97**	**$680.13**	**0.31%**
LUMATEPERONE PRODUCTS						
CAPLYTA CAP 42MG	305	64	$407,908.69	4.77	$1,337.41	0.53%
SUBTOTAL	**305**	**64**	**$407,908.69**	**4.77**	**$1,337.41**	**0.53%**
OLANZAPINE/FLUOXETINE COMBINATION PRODUCTS						
OLANZA/FLUOX CAP 12-50MG	22	2	$16,768.08	11	$762.19	0.02%
OLANZA/FLUOX CAP 12-25MG	12	1	$6,375.00	12	$531.25	0.01%
OLANZA/FLUOX CAP 6-50MG	11	1	$3,039.30	11	$276.30	0.00%
OLANZA/FLUOX CAP 6-25MG	11	1	$2,713.76	11	$246.71	0.00%
OLANZA/FLUOX CAP 3-25MG	1	1	$121.15	1	$121.15	0.00%
SUBTOTAL	**57**	**6**	**$29,017.29**	**9.50**	**$509.08**	**0.03%**
OLANZAPINE/SAMIDORPHAN COMBINATION PRODUCTS						
LYBALVI TAB 20-10MG	1	1	$1,397.41	1	$1,397.41	0.00%
LYBALVI TAB 10-10MG	1	1	$1,401.41	1	$1,401.41	0.00%
SUBTOTAL	**2**	**2**	**$2,798.82**	**1**	**$1,399.41**	**0.00%**
PALIPERIDONE PALMITATE INJECTABLE PRODUCTS						
INVEGA HAFYE INJ 1560MG/5ML	1	1	$17,651.46	1	$17,651.46	0.02%
SUBTOTAL	**1**	**1**	**$17,651.46**	**1**	**$17,651.46**	**0.02%**
TIER-3 SUBTOTAL	**7,672**	**1,903**	**$8,320,515.32**	**4.03**	**$1,084.53**	**10.80%**
TOTAL	**224,333**	**36,020***	**$76,887,732.02**	**6.23**	**$324.74**	**100%**

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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[4] Otsuka America Pharmaceutical. Otsuka and Lundbeck Announce FDA Approval of Supplemental New Drug Application for REXULTI® (Brexpiprazole) to Treat Schizophrenia in Pediatric Patients Ages 13-17. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20220106005229/en/Otsuka-and-Lundbeck-Announce-FDA-Approval-of-Supplemental-New-Drug-Application-for-REXULTI%C2%AE-brexpiprazole-to-Treat-Schizophrenia-in-Pediatric-Patients-Ages-13-17. Issued 01/06/2022. Last accessed 05/17/2022.

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Appendix N

30-Day Notice to Prior Authorize Ryplazim® (Plasminogen, Human-tvmh)

Oklahoma Health Care Authority
June 2022

Introduction[1,2]

Plasminogen deficiency type I, also known as plasminogen deficiency (PLGD) or hypoplasminogenemia (HPG), is an ultra-rare, genetic, multisystem disease in which individuals develop thick growths, or lesions, on the mucous membranes of their body (e.g., respiratory, gastrointestinal, and genitourinary tracts; oropharynx; middle ear; skin; central nervous system).

Individuals with PLGD have a mutation in the *PLG* gene, which encodes the protein plasminogen. Typically, plasminogen is broken down into plasmin, which then has multiple functions throughout the body including breaking down fibrin. Since individuals with PLGD lack plasminogen, fibrin accumulates and causes inflammation and woody lesions throughout the body's mucous membranes; it is currently unknown why fibrin accumulates in mucous membranes and not in the blood vessels. The manifestations of PLGD are highly individualized, but the mucous membranes that line the mouth and the inside of the eyelid (i.e., conjunctiva) are generally most affected. The lesions may be painful and can cause severe and potentially life-threatening complications such as tooth loss, vision loss, hearing loss, airway obstruction, and hydrocephalus.

The prevalence of PLGD is estimated at 1.6 per 1 million people in the general population, and there is currently no screening test available for PLGD. Diagnosis generally relies on clinical symptoms, family medical history, and confirmatory molecular genetic testing. PLGD is highly individualized, so while some infants and children may show early manifestations, others may not have symptoms until adulthood.

Until recently there was no standardized treatment for individuals with PLGD due to the rarity of the disease. Many reported therapies have only anecdotal evidence to support efficacy or were only used in a single person. Therapies that have been tried in PLGD include corticosteroids, immunosuppressants (e.g., cyclosporine), antivirals, and heparin. The lesions can be surgically removed but usually grow back. Replacing plasminogen has been the only treatment modality in PLGD shown to improve symptoms and prevent recurrence.

In June 2021, the U.S. Food and Drug Administration (FDA) approved Ryplazim® (plasminogen, human-tvmh) for the treatment of patients with PLGD type 1. This is the first therapy FDA approved for PLGD.

Ryplazim® (Plasminogen, Human-tvmh) Product Summary[3,4,5]

Indication: A plasma-derived human plasminogen indicated for the treatment of patients with PLGD type 1.

How Supplied: Single-dose 50mL vial containing 68.8mg of plasminogen as a lyophilized powder

Dosing and Administration:

- The recommended dose is 6.6mg/kg of body weight given intravenously every 2 to 4 days
- The recommended initial dosing frequency is every 3 days
- A trough plasminogen level should be taken 72 hours following the initial dose and prior to the second dose, and the dosing frequency should be adjusted according to plasminogen activity level
- Dosing frequency should be maintained for 12 weeks while treating active lesions
- Refer to the Ryplazim® *Prescribing Information* for full determination of dose and dosing frequency

Mechanism of Action: Ryplazim® is a purified, plasma-derived Glu-plasminogen, which is the native circulating form of plasminogen in the blood, and temporarily increases plasminogen levels in the blood.

Contraindication(s):

- Known hypersensitivity to plasminogen or other components of Ryplazim®

Safety:

- Bleeding: Administration may lead to bleeding at lesion sites or may worsen active bleeding. Ryplazim® should be discontinued if serious bleeding occurs. When administering to patients with bleeding diatheses or to patients taking anticoagulants, antiplatelet drugs, or other agents which may interfere with normal coagulation, patients should be monitored during and for 4 hours after infusion.
- Tissue Sloughing: Respiratory distress due to tissue sloughing may occur in patients with mucosal lesions in the tracheobronchial tree following administration. Patients should be monitored appropriately.
- Transmission of Infectious Agents: Ryplazim® is a human blood product and therefore carries a risk of transmitting infectious agents [e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and theoretically, the CJD agent].

- Hypersensitivity Reactions: Hypersensitivity reactions, including anaphylaxis, may occur. If symptoms occur, Ryplazim® should be discontinued and appropriate treatment should be administered.
- Neutralizing Antibodies: Neutralizing antibodies (inhibitors) may develop, although were not observed in clinical studies. If clinical efficacy is not maintained (e.g., development of new or recurrent lesions), then plasminogen activity levels in plasma should be determined.
- Laboratory Abnormalities: Patients receiving Ryplazim® may have elevated blood levels of D-dimer. D-dimer levels will lack interpretability in patients being screened for venous thromboembolism (VTE).

Adverse Reactions: The most common (incidence ≥10%) adverse reactions in clinical studies were abdominal pain, bloating, nausea, fatigue, extremity pain, hemorrhage, constipation, dry mouth, headache, dizziness, arthralgia, and back pain.

Efficacy: The approval of Ryplazim® was based on a single-arm, open-label, Phase 2/3 study which enrolled 15 patients who had a baseline plasminogen activity level of <45%. The study consisted of a 21-day screening period and 3 treatment segments. Only 14 patients completed ≥12 weeks of treatment (5 children and 9 adults).

- Primary Endpoint: The primary endpoint was the number of patients who achieved target trough plasminogen activity levels, defined as an increase of individual plasminogen activity trough level by at least an absolute 10% above baseline, for at least 3 measurements in 12 weeks. Primary endpoint success was defined as at least 80% of evaluable patients achieving target trough plasminogen activity level.
- Results: All 14 patients achieved target trough plasminogen activity levels during the initial 12-week treatment period. In addition, all patients had >50% improvement in the number and/or size of their lesions by week 48; there were 3 patients who did not have any lesions present at baseline. Among the 14 patients studied, 78% of their external lesions and 75% of their internal lesions were resolved by week 48, and no patients had a new or recurring lesion through week 48. No formal statistical analysis was performed due to the small sample size.

Cost: The Wholesale Acquisition Cost (WAC) of Ryplazim® is $2,064 per 50mL vial. A member weighing 80kg would have an annual cost of $2,014,464 at the recommended dosage of 6.6mg/kg every 3 days.

Recommendations

The College of Pharmacy recommends the prior authorization of Ryplazim® (plasminogen, human-tvmh) with the following criteria:

Ryplazim® (Plasminogen, Human-tvmh) Approval Criteria:

1. An FDA approved indication of plasminogen deficiency type 1 (hypoplasminogenemia) as confirmed by the following:
    a. Genetic testing confirming biallelic mutations in the plasminogen (*PLG*) gene; and
    b. Plasminogen activity level ≤45%; and
    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 who have 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 there is no development of new or recurrent lesions while on Ryplazim® and that adequate plasminogen activity trough levels are being maintained.

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Appendix O

Calendar Year 2021 Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Citalopram Capsule, Dartisla ODT™ [Glycopyrrolate Orally Disintegrating Tablet (ODT)], Fleqsuvy™ (Baclofen Oral Suspension), Lofena™ (Diclofenac Potassium Tablet), Loreev XR™ [Lorazepam Extended-Release (ER) Capsule], Norliqva® (Amlodipine Oral Solution), Seglentis® (Celecoxib/Tramadol Tablet), Sutab® (Sodium Sulfate/Magnesium Sulfate/Potassium Chloride Tablet), Tarpeyo™ [Budesonide Delayed-Release (DR) Capsule], Vuity™ (Pilocarpine 1.25% Ophthalmic Solution), and Xipere™ (Triamcinolone Acetonide Injection)

Oklahoma Health Care Authority
June 2022

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 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 *Prescribing Information*; 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.

Alkindi® Sprinkle (Hydrocortisone Oral Granule) Approval Criteria:

1. An FDA approved indication of replacement therapy in pediatric members with adrenocortical insufficiency; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use hydrocortisone tablets, even when tablets are crushed, must be provided.

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.

Ozobax® (Baclofen 5mg/5mL 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 (beyond convenience) why the member cannot use baclofen oral tablets, even when tablets are crushed.

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.

Quzyttir® (Cetirizine Injection) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use an oral formulation of cetirizine (e.g., tablets, oral solution) must be provided.

Rasuvo®, RediTrex®, and Otrexup® (Methotrexate Injection Solutions) 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.

Sinuva® (Mometasone Furoate Sinus Implant) Approval Criteria:

1. An FDA approved indication of nasal polyps in adults 18 years of age and older who have had ethmoid sinus surgery; and
2. Date of ethmoid sinus surgery must be provided; and
3. Sinuva® must be prescribed and implanted by a physician specializing in otolaryngology; and
4. Failure of intranasal corticosteroids after at least a 3 month trial at the maximum recommended dose in combination with a 14-day trial of oral corticosteroids within the last 6 months (if not contraindicated); and

5. Prescriber must confirm the member has recurrent nasal obstruction/congestion symptoms and recurrent bilateral sinusitis or chronic sinusitis due to nasal polyps; and
6. A quantity limit of 2 implants per member will apply.

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. The reduction in 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.

Sorilux® (Calcipotriene 0.005% Foam) Approval Criteria:

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

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, 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.

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 2021

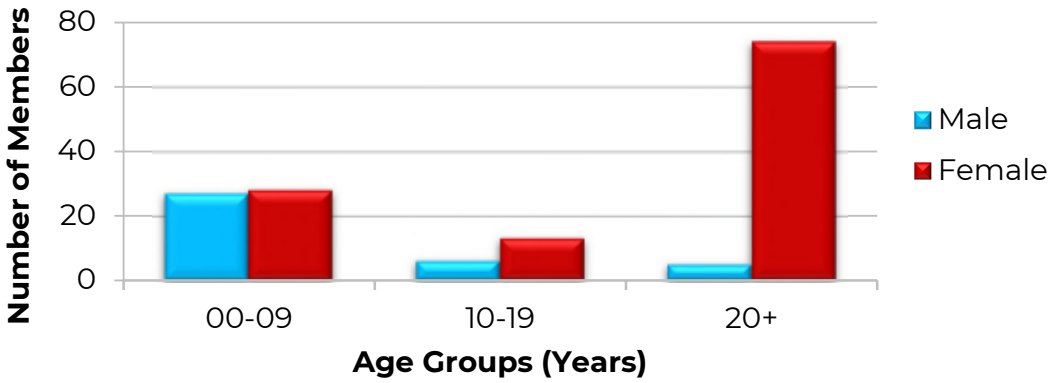
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	146	693	$341,325.15	$492.53	$13.05	36,111	26,153
2021	153	773	$382,896.66	$495.34	$13.51	43,943	28,332
% Change	**4.80%**	**11.50%**	**12.20%**	**0.60%**	**3.50%**	**21.70%**	**8.30%**
Change	**7**	**80**	**$41,571.51**	**$2.81**	**$0.46**	**7,832**	**2,179**

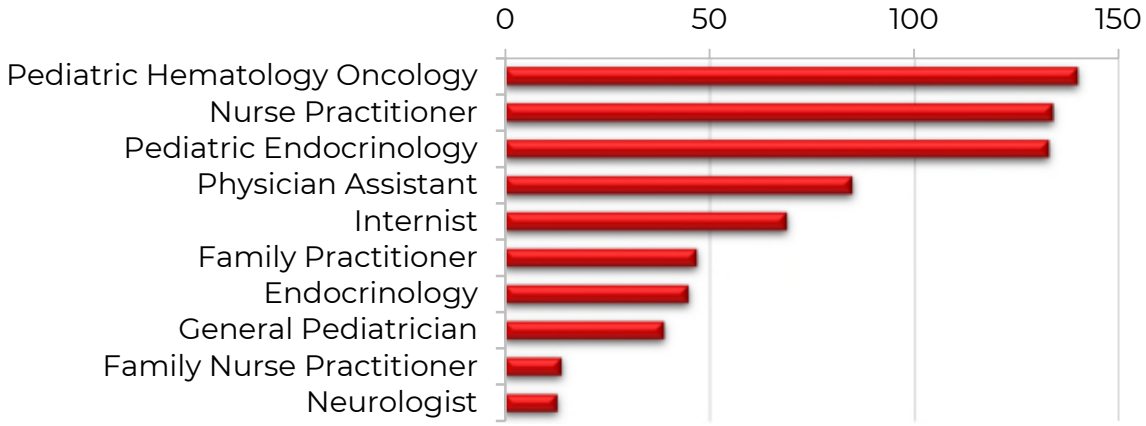
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

- 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 2021.

Demographics of Members Utilizing Various Special Formulations



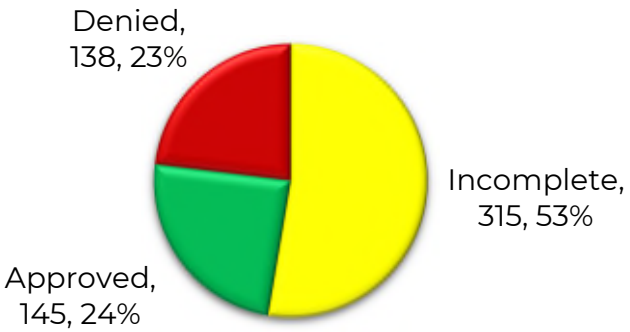
Top Prescriber Specialties of Various Special Formulations by Number of Claims



Prior Authorization of Various Special Formulations

There were 598 prior authorization requests submitted for various special formulations during calendar year 2021. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions



Citalopram Capsule Product Summary[1,2]

Indication(s): Citalopram capsule is a selective serotonin reuptake inhibitor (SSRI) indicated for treatment of major depressive disorder (MDD) in adults.

Dosing and Administration:

- The recommended dosing is 30mg once daily, after an initial dose of 20mg once daily with citalopram tablet
- Dose increases should occur at intervals of no less than 1 week
- Citalopram capsule is supplied as a 30mg oral capsule

Boxed Warning: Suicidal Thoughts and Behaviors
In short-term studies, antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients. All antidepressant-treated patients should be closely monitored for clinical worsening and emergence of suicidal thoughts and behaviors. Citalopram capsule is not approved for use in pediatric patients.

Other Formulation(s) Available:

- Citalopram Tablet:
  - Like citalopram capsules, citalopram tablets are indicated for the treatment of MDD in adults.
  - Citalopram tablets have the same *Boxed Warning* as the capsules.
  - The initial dosage of citalopram tablets is 20mg once daily; after 1 week the dose may be increased to a maximum of 40mg once daily.
  - Citalopram tablets are scored and available in 3 strengths: 10mg, 20mg, and 40mg.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
citalopram 30mg capsule	**$4.90**	**$147.00**
citalopram 10mg tablet	$0.03	$2.70

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 30 days based on a dose of 30mg daily for both products.
Unit = tablet

Calendar Year 2021 Utilization: There was no SoonerCare utilization of citalopram capsule during calendar year 2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
CITALOPRAM TAB 20MG	14,554	5,412	$142,343.50	$0.23	2.69	$9.78
CITALOPRAM TAB 40MG	8,903	2,638	$90,426.53	$0.23	3.37	$10.16
CITALOPRAM TAB 10MG	7,545	2,938	$75,959.70	$0.26	2.57	$10.07
TOTAL	**31,002**	**9,556***	**$308,729.73**	**$0.24**	**3.24**	**$9.96**

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

Dartisla ODT™ [Glycopyrrolate Orally Disintegrating Tablet (ODT)] Product Summary[3,4]

Indication(s): Dartisla ODT™ is an anticholinergic medication indicated to reduce the symptoms of a peptic ulcer as an adjunct to the treatment of peptic ulcer disease (PUD) in adults.

- Limitation(s) of Use: Dartisla ODT™ is not indicated as monotherapy for treatment of PUD because effectiveness in peptic ulcer healing has not been established.

Dosing and Administration:

- The recommended dosage is 1.7mg sublingually 2 or 3 times daily, 1 hour before or 2 hours after food.
- Dartisla ODT™ is not recommended for patients initiating treatment or receiving maintenance treatment with a lower dosage strength of another oral glycopyrrolate product.
- The maximum recommended daily dosage is 6.8mg.
- Dartisla ODT™ is supplied as an ODT containing 1.7mg of glycopyrrolate.

Other Formulation(s) Available:

- Glycopyrrolate Tablet:
  - Glycopyrrolate tablets have an indication similar to Dartisla ODT™, for use as adjunctive treatment of PUD; however, glycopyrrolate tablets are indicated for use in patients 12 years of age and older.
  - Dosing for glycopyrrolate tablets should be adjusted based on patient response.
  - The recommended initial dosing for glycopyrrolate 1mg tablet is 1 tablet 3 times daily. For maintenance dosing, 1 tablet twice daily may be adequate.
  - For glycopyrrolate 2mg tablet, the recommended dosing is 1 tablet 2 or 3 times daily. The maximum recommended dose is 8mg/day.
  - Glycopyrrolate tablets are scored and supplied in 2 strengths: 1mg and 2mg.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Dartisla ODT™ (glycopyrrolate 1.7mg ODT)	**$5.56**	**$667.20**
glycopyrrolate 2mg tablet	$0.17	$20.40
glycopyrrolate 1mg tablet	$0.09	$21.60

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 U.S. Food and Drug Administration (FDA) recommended maximum daily dose for each product.
ODT = orally disintegrating tablet; Unit = tablet or ODT

Calendar Year 2021 Utilization: There was no SoonerCare utilization of Dartisla ODT™ during calendar year 2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
GLYCOPYRROL TAB 1MG	1,465	278	$32,520.12	$0.74	5.27	$22.20
GLYCOPYRROL TAB 2MG	866	121	$25,892.12	$1.02	7.16	$29.90
TOTAL	**2,331**	**382***	**$58,412.24**	**$0.85**	**6.1**	**$25.06**

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

Fleqsuvy™ (Baclofen Oral Suspension) Product Summary[5,6,7]

Indication(s): Fleqsuvy™ is a gamma-aminobutyric acid agonist indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.

- Limitation(s) of Use: Fleqsuvy™ is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.

Dosing and Administration:

- Fleqsuvy™ should be initiated at a low dosage, preferably in divided doses with gradual increases based on clinical response and tolerability.
- The recommended dosing is to initiate treatment at 5mg 3 times daily for 3 days. The dose should be adjusted based on clinical response and tolerability up to a maximum of 80mg per day (20mg 4 times daily).
- Fleqsuvy™ is supplied as a 25mg/5mL (5mg/mL) grape-flavored oral suspension in 30mL and 120mL bottles.
- Fleqsuvy™ should be stored at room temperature [20°C to 25°C (68°F to 77°F)], and the unused portion should be discarded 2 months after first opening.

Other Formulation(s) Available:

- Baclofen (5mg/5mL) Oral Solution and Baclofen Tablet:
  - Baclofen oral solution and tablets have the same indication and *Limitation(s) of Use* as Fleqsuvy™. Baclofen tablets have an additional limitation that the efficacy of baclofen tablets in stroke, cerebral palsy, and Parkinson's disease has not been established and, therefore, it is not recommended for these conditions.
  - The recommended dosing for baclofen oral solution and tablets is also the same as Fleqsuvy™.
  - Baclofen oral solution is supplied as a 5mg/5mL grape-flavored oral solution in a 473mL stock bottle. It must be stored refrigerated [2°C to 8°C (36°F to 46°F)].
  - Baclofen tablets are supplied in 3 strengths: 5mg, 10mg, and 20mg.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Fleqsuvy™ (baclofen 5mg/mL oral suspension)	**$5.50**	**$2,640.00**
baclofen 5mg/5mL oral solution	$1.09	$2,616.00
baclofen 20mg tablet	$0.11	$13.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per 30 days based on the maximum FDA recommended dose of 80mg/day.

Calendar Year 2021 Utilization: There was no SoonerCare utilization of Fleqsuvy™ during calendar year 2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
BACLOFEN TAB 10MG	14,086	4,054	$208,335.59	$0.52	3.47	$14.79
BACLOFEN TAB 20MG	5,768	1,212	$117,377.08	$0.70	4.76	$20.35
BACLOFEN TAB 5MG	57	20	$4,004.47	$2.40	2.85	$70.25
OZOBAX SOL 5MG/5ML	9	2	$6,402.10	$26.35	4.5	$711.34
TOTAL	**19,920**	**5,096***	**$336,119.24**	**$0.59**	**3.91**	**$16.87**

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

Lofena™ (Diclofenac Potassium Tablet) Product Summary[8,9]

Indication(s): Lofena™ is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the following:

- Primary dysmenorrhea
- Mild to moderate pain
- Osteoarthritis (OA)
- Rheumatoid arthritis (RA)

Dosing and Administration:

- It is recommended to use the lowest effective dose for the shortest duration consistent with individual patient treatment goals.
- The recommended dosing is based on indication as follows:
  - Primary dysmenorrhea and mild to moderate pain: 50mg 3 times a day
  - OA: 50mg 2 or 3 times a day
  - RA: 50mg 3 or 4 times a day
- Lofena™ is supplied as 25mg diclofenac potassium film-coated, oral tablets.

Boxed Warning: Risk of Serious Cardiovascular (CV) and Gastrointestinal (GI) Events

- NSAIDs cause an increased risk of serious CV thrombotic events, including myocardial infarction and stroke, which can be fatal.
- NSAIDs cause an increased risk of serious GI adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal.

Other Formulation(s) Available:

- Diclofenac Potassium 50mg Tablet:
  - Diclofenac potassium 50mg tablets have the same indications and *Boxed Warning* as Lofena™.
  - The recommended dosing for diclofenac potassium 50mg tablets is also the same as Lofena™.
  - Diclofenac potassium 50mg tablets are supplied as sugar-coated, oral tablets.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Lofena™ (diclofenac potassium 25mg tablet)	**$32.26**	**$7,742.40**
diclofenac potassium 50mg tablet	$0.34	$40.80

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 = tablet
*Cost per 30 days based on the maximum FDA recommended dose of 200mg/day.

Calendar Year 2021 Utilization: There was no SoonerCare utilization of Lofena™ during calendar year 2021. For diclofenac potassium 50mg tablets, there were 188 claims for 144 unduplicated utilizing members with a total cost of $7,333.39. The cost per day was $1.62 with a cost per claim of $39.01. These costs do not reflect rebated prices or net costs.

Loreev XR™ [Lorazepam Extended-Release (ER) Capsule] Product Summary[10,11]

Indication(s): Loreev XR™ is a benzodiazepine indicated for the treatment of anxiety disorders in adults who are receiving stable, evenly divided, 3 times daily dosing with lorazepam tablets.

Dosing and Administration:

- The recommended dosing of Loreev XR™ is equal to the patient's current total daily dose of lorazepam tablets (must be 3 times daily dosing) taken once daily in the morning.
- Loreev XR™ may be swallowed whole or the capsule may be opened and the entire contents sprinkled onto applesauce. Loreev XR™ should not be crushed or chewed.
- For dosage adjustments, Loreev XR™ should be discontinued and the patient should be switched to lorazepam tablets to adjust the dosage.
- Loreev XR™ is supplied as oral lorazepam ER capsules in 4 strengths: 1mg, 1.5mg, 2mg, and 3mg.

Boxed Warning: Risks from Concomitant Use with Opioids; Abuse, Misuse, and Addiction; Dependence and Withdrawal

- Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death.
- The use of benzodiazepines, including Loreev XR™, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death.
- Abrupt discontinuation or rapid dosage reduction of Loreev XR™ after continued use may precipitate acute withdrawal reactions, which can be life-threatening.

Other Formulation(s) Available:

- Lorazepam Tablet:
  - Lorazepam tablets are indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety or anxiety associated with depressive symptoms.
  - Lorazepam tablets have a *Boxed Warning* similar to Loreev XR™.
  - The usual dosing range for lorazepam tablets is 2 to 6mg/day given in divided doses, but the daily dosage may vary from 1 to 10mg/day.
  - For anxiety, most patients require an initial dose of 2 to 3mg/day given 2 or 3 times a day. For insomnia due to anxiety or transient situational stress, a single daily dose of 2 to 4mg may be given, usually at bedtime.
  - Lorazepam tablets are supplied in 3 strengths: 0.5mg, 1mg, and 2mg.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Loreev XR™ (lorazepam 3mg ER tablet)	**$14.17**	**$425.10**
lorazepam 1mg tablet	$0.04	$3.60

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).
ER = extended release; Unit = tablet
*Cost per 30 days based on the FDA recommended dose of 3mg/day.

Calendar Year 2021 Utilization: There was no SoonerCare utilization of Loreev XR™ during calendar year 2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
LORAZEPAM TAB 1MG	4,615	1,484	$103,908.26	$0.93	3.11	$22.52
LORAZEPAM TAB 0.5MG	3,608	1,246	$78,536.64	$0.89	2.9	$21.77
LORAZEPAM TAB 2MG	1,195	334	$20,152.99	$0.68	3.58	$16.86
TOTAL	**9,418**	**2,842***	**$202,597.89**	**$0.88**	**3.31**	**$21.51**

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

Norliqva® (Amlodipine Oral Solution) Product Summary[12,13,14]

Indication(s): Norliqva® is a calcium channel blocker (CCB) indicated for the following:

- Adults and pediatric patients 6 years of age and older:
  - Hypertension (HTN)
- Adults:
  - Chronic stable angina
  - Vasospastic angina
  - Coronary artery disease (CAD); to reduce the risk of hospitalization for angina and reduce the risk of a coronary revascularization procedure in patients without heart failure (HF) or an ejection fraction (EF) <40%

Dosing and Administration:

- The recommended dosing is as follows:
  - HTN in adults: 5mg once daily up to a maximum of 10mg once daily
  - HTN in pediatric patients 6 years of age and older: 2.5mg to 5mg once daily
  - Chronic stable or vasospastic angina in adults: 5 to 10mg once daily
  - CAD in adults: 5 to 10mg once daily
- Norliqva® is supplied as a peppermint-flavored 1mg/mL oral solution in a 150mL glass bottle. Norliqva® should be dispensed in the original

packaging and stored at room temperature [20°C to 25°C (68°F to 77°F)].

Other Formulation(s) Available:

- Amlodipine Tablet and Katerzia® (Amlodipine Oral Suspension):
  - Amlodipine tablets and Katerzia® have the same indications as Norliqva® as well as the same recommended dosing based on age and diagnosis.
  - Amlodipine tables are supplied in 3 strengths: 2.5mg, 5mg, and 10mg
  - Katerzia® is supplied as a 1mg/ml oral suspension as 150mL in a 185mL bottle. Katerzia® must be stored refrigerated [2°C to 8°C (36°F to 46°F)] and shaken well before use.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days
Norliqva® (amlodipine 1mg/mL oral solution)	**$3.43**	**$1,029.00**
Katerzia® (amlodipine 1mg/mL oral suspension)	$3.37	$1,011.00
amlodipine 10mg tablets	$0.01	$0.30

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 the maximum FDA recommended dose of 10mg/day.

Calendar Year 2021 Utilization: There was no SoonerCare utilization of Norliqva® during calendar year 2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
AMLODIPINE TAB 10MG	20,009	7,372	$199,921.34	$0.17	2.71	$9.99
AMLODIPINE TAB 5MG	15,766	6,260	$153,705.71	$0.18	2.52	$9.75
AMLODIPINE TAB 2.5MG	2,333	913	$23,516.69	$0.21	2.56	$10.08
KATERZIA SUS 1MG/ML	212	50	$83,940.14	$12.52	4.24	$395.94
TOTAL	**38,320**	**13,451***	**$461,083.88**	**$0.21**	**2.85**	**$12.03**

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

Seglentis® (Celecoxib/Tramadol Tablet) Product Summary[15,16,17]

Indication(s): Seglentis® contains tramadol hydrochloride (an opioid agonist/ schedule IV controlled substance) and celecoxib (an NSAID) and is indicated for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Limitation(s) of Use: Due to the risks of addiction, abuse, and misuse with opioids, even at recommended doses, Seglentis® should be

reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics) have not been tolerated, are not expected to be tolerated, and/or have not provided adequate analgesia or are not expected to provide adequate analgesia.

Dosing and Administration:

- For use of Seglentis®, it recommended to use the shortest duration consistent with individual patient treatment goals.
- The recommended dose is 2 tablets every 12 hours as needed for pain relief.
- Seglentis® is supplied as oral, coated tablets containing celecoxib 56mg and tramadol hydrochloride 44mg.

Boxed Warning: Addiction, Abuse, and Misuse; Risk Evaluation and Mitigation Strategy (REMS); Life-Threatening Respiratory Depression; Accidental Ingestion; CV Thrombotic Events; GI Bleeding, Ulceration, and Perforation; Ultra-Rapid Metabolism of Tramadol and Other Risk Factors for Life-Threatening Respiratory Depression in Children; Neonatal Opioid Withdrawal Syndrome; Interactions with Drugs Affecting Cytochrome P450 Isoenzymes; Risks From Concomitant Use with Benzodiazepines or Other Central Nervous System (CNS) Depressants

- Seglentis® exposes users to the risks of addiction, abuse, and misuse, which can lead to overdose and death.
- To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the FDA has required a REMS program for these products.
- Serious, life-threatening, or fatal respiratory depression may occur.
- Accidental ingestion of Seglentis®, especially by children, can result in a fatal overdose of tramadol.
- NSAIDs cause an increased risk of serious CV thrombotic events which can be fatal.
- NSAIDs cause an increased risk of serious GI adverse events which can be fatal.
- Life-threatening respiratory depression and death have occurred in children who received tramadol.
- Seglentis® is contraindicated in children younger than 12 years of age and in children younger than 18 years of age following tonsillectomy and/or adenoidectomy.
- Prolonged use of Seglentis® during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening.
- Concomitant use of opioids with benzodiazepines or other CNS depressants, may result in profound sedation, respiratory depression, coma, and death.

Other Formulation(s) Available:

- Celecoxib Capsule and Tramadol Tablet:
  - Celecoxib capsules are indicated for OA, RA, juvenile rheumatoid arthritis (JRA) in patients 2 years of age and older, ankylosing spondylitis (AS), acute pain, and primary dysmenorrhea.
  - The recommended dosing for celecoxib capsules is as follows:
    - OA: 200mg once daily or 100mg twice daily
    - RA: 100mg to 200mg twice daily
    - JRA: 50mg twice daily in patients 10kg to 25kg; 100mg twice daily in patients >25 kg
    - AS: 200mg once daily single dose or 100mg twice daily
    - Acute pain and primary dysmenorrhea: 400 mg initially, followed by 200mg if needed on first day; 200mg twice daily as needed thereafter
  - Celecoxib capsules have a *Boxed Warning* similar to Seglentis® in regard to the NSAID warnings.
  - Celecoxib capsules are supplied in 4 strengths: 50mg, 100mg, 200mg, and 400mg.
  - Tramadol tablets have the same indication and *Limitation(s) of Use* as Seglentis®.
  - The recommended dosing for tramadol tablets is to start at 25mg/day and titrate in 25mg increments every 3 days to reach 100mg/day (25mg 4 times a day). Thereafter, the total daily dose may be increased by 50mg as tolerated every 3 days to reach 200mg/day (50mg 4 times a day). After titration, 50 to 100mg can be administered as needed every 4 to 6 hours, not to exceed 400mg/day.
  - Tramadol tablets have a *Boxed Warning* similar to Seglentis® in regard to the opioid warnings.
  - Tramadol tablets are supplied in 2 strengths: 50mg and 100mg.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Seglentis® (celecoxib/tramadol 56mg/44mg tablet)	**$4.23**	**$507.60**
celecoxib 200mg capsule	$0.13	$7.80
tramadol 50mg tablet	$0.02	$4.80

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 = cap or tablet
*Cost per 30 days based on the maximum FDA recommended dose for acute pain for each product.

Calendar Year 2021 Utilization: There was no SoonerCare utilization of Seglentis® during calendar year 2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
TRAMADOL HCL TAB 50MG	25,632	10,000	$274,382.01	$0.56	2.56	$10.70
CELECOXIB CAP 200MG	6,432	2,835	$108,355.79	$0.49	2.27	$16.85
CELECOXIB CAP 100MG	2,605	1,116	$39,742.57	$0.50	2.33	$15.26
CELECOXIB CAP 50MG	53	42	$945.12	$0.64	1.26	$17.83
TOTAL	**34,722**	**13,396***	**$423,425.49**	**$0.53**	**2.59**	**$12.19**

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

Sutab® (Sodium Sulfate/Magnesium Sulfate/Potassium Chloride Tablet) Product Summary[18,19,20]

Indication(s): Sutab® is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults

Dosing and Administration:

- Administration of 2 doses (24 tablets) are required for a complete preparation for colonoscopy. Twelve tablets are equivalent to 1 dose.
- Split-Dose (2-Day) Regimen:
  - Dose 1 (1 day prior to colonoscopy):
    - Starting evening prior to colonoscopy, 12 tablets should be taken with 16 ounces of water over 15 to 20 minutes
    - One hour after the last tablet is taken, an additional 16 ounces of water should be ingested and 16 ounces of water should be repeated 30 minutes after previous 16 ounces
  - Dose 2 (day of colonoscopy):
    - Starting 5 to 8 hours prior to colonoscopy, 12 tablets should be taken with 16 ounces of water over 15 to 20 minutes
    - One hour after the last tablet is taken, an additional 16 ounces of water should be ingested and 16 ounces of water should be repeated 30 minutes after previous 16 ounces
- Sutab® is supplied as a film-coated, oral tablet containing 1.479g sodium sulfate/0.225g magnesium sulfate/0.188g potassium chloride. Sutab® is available in 2 bottles containing 12 tablets each and 1 container with a 16-ounce fill line is also provided.

Other Formulation(s) Available:

- GoLytely® [polyethylene glycol (PEG) 3350/sodium sulfate/sodium bicarbonate/sodium chloride/potassium chloride powder] and MoviPrep® (PEG 3350/sodium sulfate/sodium chloride/potassium chloride/sodium ascorbate/ascorbic acid powder):
  - GoLytely® and MoviPrep® have the same indication as Sutab® with an additional indication for GoLytely® of preparation for barium enema X-ray examination in adults.

- Prior to starting GoLytely® therapy, the product must be reconstituted with 1 gallon of water and shaken vigorously.
- The recommended dosing for GoLytely®, starting the day prior to colonoscopy, is to ingest 8 ounces of reconstituted solution every 10 minutes until 1 gallon is completed or rectal effluent is clear.
- GoLytely® is supplied as a powder for reconstitution to an oral solution as follows:
    - In a disposable jug containing 236g PEG 3350, 22.74g sodium sulfate, 6.74g sodium bicarbonate, 5.86g sodium chloride, and 2.97g potassium chloride.
    - In a packet containing 227.1g PEG 3350, 21.5g sodium sulfate, 6.36g sodium bicarbonate, 5.53g sodium chloride, and 2.82g potassium chloride.
- MoviPrep® must be reconstituted in water prior to ingestion.
- MoviPrep® can be administered as a 1-day or 2-day dosing regimen with the 2-day regimen being preferred.
    - 1-day regimen: At least 3.5 hours prior to bedtime the evening before the colonoscopy, thoroughly mix the contents of the 2 packets provided with 32 ounces of water and ingest 8 ounces every 15 minutes. This should be repeated at least 1.5 hours after the initial dose.
    - 2-day regimen: The evening before the colonoscopy (10-12 hours before the second dose), thoroughly mix the contents of the 2 packets with 32 ounces of water and ingest 8 ounces every 15 minutes. This should be repeated the next morning, on the day of the colonoscopy, approximately 12 hours after the first dose and at least 3.5 hours prior to colonoscopy.
- MoviPrep® is supplied as a lemon-flavored powder for reconstitution to an oral solution in 2 pouches. One pouch contains 100g PEG 3350, 7.5g sodium sulfate, 2.691g sodium chloride, and 1.015g potassium chloride, and the second pouch contains 4.7g ascorbic acid and 5.9g sodium ascorbate. A mixing container for reconstitution is also provided.

Formulation Cost Comparison:

Product	Cost Per Treatment*
Sutab® (sodium sulfate/magnesium sulfate/potassium chloride tablet)	**$148.32**
PEG 3350/sodium sulfate/sodium chloride/potassium chloride/ sodium ascorbate/ascorbic acid powder (generic MoviPrep®)	$76.98
PEG 3350/sodium sulfate/sodium bicarbonate/sodium chloride/ potassium chloride powder packet (generic GoLytely®)	$12.68

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per treatment based on the FDA recommended dose for colonoscopy preparation.

Calendar Year 2021 Utilization: There were 3 claims for 3 unduplicated utilizing members for Sutab® with a total cost of $452.43 during calendar year 2021. This cost does not reflect rebated prices or net costs.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
PEG-3350 SOL ELECTROL	1,125	1,075	$22,208.68	$9.62	1.05	$19.74
PEG/NASUL/NACL/POT SOL	269	259	$24,795.80	$40.65	1.04	$92.18
MOVIPREP SOL	101	100	$12,195.18	$115.05	1.01	$120.74
GOLYTELY SOL	3	3	$70.37	$2.20	1	$23.46
TOTAL	**1,498**	**1,437**	**$59,270.03**	**$14.71**	**1.04**	**$39.57**

Costs do not reflect rebated prices or net costs.
ELECTROL = electrolytes; NASUL = sodium sulfate; NACL = sodium chloride; PEG = polyethylene glycol; POT = potassium chloride; SOL= solution

Tarpeyo™ [Budesonide Delayed-Release (DR) Capsule] Product Summary[21,22]

Indication(s): Tarpeyo™ is a corticosteroid indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally with a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g.

- This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether Tarpeyo™ 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.

Dosing and Administration:

- The recommended dosing is 16mg once daily, in the morning at least 1 hour before a meal.
- The recommended duration of therapy is 9 months. When discontinuing therapy, the dosage should be reduced to 8mg once daily for the last 2 weeks of therapy
- Tarpeyo™ is supplied as a DR, oral capsule containing 4mg of budesonide.

Other Formulation(s) Available:

- Prednisone Tablet:
  - Prednisone tablets are indicated for endocrine disorders, rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases, respiratory diseases, hematologic disorders, neoplastic diseases, edematous states, GI diseases, and nervous system diseases.
  - The initial dosage of prednisone may vary from 5mg to 60mg per day depending on the specific diagnosis being treated. The initial dosage should be maintained or adjusted until a satisfactory

response is noted. Dosage requirements are variable and should be individualized to each patient and disease state.
- Prednisone tablets are supplied in 6 strengths: 1mg, 2.5mg, 5mg, 10mg, 20mg, and 50mg.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Tarpeyo™ (budesonide 4mg DR capsule)	**$118.00**	**$14,160.00**
prednisone 10mg tablet	$0.07	$2.10

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).
DR = delayed release; Unit = cap or tablet
*Cost per 30 days based on the FDA recommended dose for Tarpeyo™ and prednisone dosing based on its use in clinical trials for primary immunoglobulin A nephropathy.

Calendar Year 2021 Utilization: There was no SoonerCare utilization of Tarpeyo™ during calendar year 2021. For prednisone tablet products, there were 70,766 claims for 52,330 unduplicated utilizing members with a total cost of $705,952.79. The cost per day was $1.16 with a cost per claim of $9.98. These costs do not reflect rebated prices or net costs.

Vuity™ (Pilocarpine 1.25% Ophthalmic Solution) Product Summary[23,24]

Indication(s): Vuity™ is a cholinergic muscarinic receptor agonist indicated for the treatment of presbyopia in adults.

Dosing and Administration:
- The recommended dosing of Vuity™ is 1 drop in each eye once daily.
- If more than 1 topical ophthalmic product is being used, the products should be administered at least 5 minutes apart.
- Vuity™ is supplied as a 1.25% (12.5mg/mL) pilocarpine hydrochloride ophthalmic solution available in a 5mL ophthalmic dispenser bottle containing 2.5mL of solution.

Other Formulation(s) Available:
- Pilocarpine Ophthalmic Solution:
  - Pilocarpine ophthalmic solution is a muscarinic cholinergic agonist indicated for the following:
    - Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension
    - Management of acute angle-closure glaucoma
    - Prevention of postoperative elevated IOP associated with laser surgery
    - Induction of miosis

- The recommended dosing of pilocarpine ophthalmic solution is 1 drop in the eye(s) up to 4 times daily.
- Pilocarpine ophthalmic solution is supplied in 3 strengths: 1%, 2% and 4%. All strengths are available in 15mL ophthalmic Droptainer® dispensers.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
Vuity™ (pilocarpine 1.25% ophthalmic solution)	**$28.29**	**$70.73**
pilocarpine 1% ophthalmic solution	$3.47	$52.02
pilocarpine 2% ophthalmic solution	$3.55	$53.25

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 = cap or tablet
*Cost per package based on largest package size available for product listed.

Calendar Year 2021 Utilization: There was no SoonerCare utilization of Vuity™ during calendar year 2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
PILOCARPINE SOL 4% OP	4	1	$289.14	$0.96	4	$72.29
PILOCARPINE SOL 1% OP	1	1	$70.16	$0.94	1	$70.16
TOTAL	**5**	**1**	**$359.30**	**$0.96**	**5**	**$71.86**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
OP = ophthalmic; SOL = solution

Xipere™ (Triamcinolone Acetonide Injection) Product Summary[25,26,27]

Indication(s): Xipere™ is a corticosteroid indicated for the treatment of macular edema associated with uveitis.

Dosing and Administration:

- The recommended dosing is 4mg (0.1mL) administered as a suprachoroidal injection under controlled aseptic conditions.
- Adequate anesthesia and a broad-spectrum microbicide applied to the periocular skin, eyelid, and ocular surface are recommended to be given prior to the suprachoroidal injection.
- Xipere™ is supplied as a 40mg/mL triamcinolone acetonide injectable suspension in a single-dose glass vial for use with the supplied SCS Microinjector®.

Other Formulation(s) Available:

- Ozurdex® (Dexamethasone Intravitreal Implant) and Triesence® (Triamcinolone Acetonide Injectable Suspension)

- Ozurdex® is a corticosteroid indicated for macular edema following branch retinal vein occlusion or central retinal vein occlusion, non-infectious uveitis affecting the posterior segment of the eye, and diabetic macular edema.
    - The recommended dosing of Ozurdex® is an 0.7mg implant administered as an intravitreal injection under controlled aseptic conditions with adequate anesthesia and a broad-spectrum microbicide given prior to injection.
    - One implant can be administered per eye every 3 months.
    - Ozurdex® is supplied as an intravitreal implant containing dexamethasone 0.7mg in the Novadur® solid polymer drug delivery system.
- Triesence® is a synthetic corticosteroid indicated for sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroid, as well as visualization during vitrectomy.
    - The initial recommended dosing for all indications except visualization is 4mg per ophthalmic injection with subsequent dosage as needed over the course of treatment.
    - The recommended dose for visualization is 1 to 4mg administered intravitreally.
    - Each dose should be administered under controlled aseptic conditions with adequate anesthesia and a broad-spectrum microbicide given prior to injection.
    - Triesence® is supplied as 1mL of a 40mg/mL sterile triamcinolone acetonide suspension in a single-use glass vial.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Dose*
Xipere™ (triamcinolone acetonide 40mg/mL injection)	**$1,650.00**	**$3,300.00**
Ozurdex® (dexamethasone 0.7mg intravitreal implant)	$1,333.00	$2,666.00
Triesence® (triamcinolone acetonide 40mg/mL injection)	$150.41	$300.82

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
*Cost per dose based on the FDA recommended dose for uveitis for each product for the treatment of both eyes.

Calendar Year 2021 Utilization: There was no SoonerCare utilization of Xipere™ during calendar year 2021.

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
DEXAMETHASONE IMPLANT J7312	38	19	$53,369.34	2	$1,404.46

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TRIAMCINOLONE PF INJ J3300	13	6	$2,016.40	2.17	$155.11
TOTAL	**51**	**25**	**$55,385.74**	**2.04**	**$1,085.99**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection; PF = preservative free

Recommendations

The College of Pharmacy recommends the placement of citalopram capsules into the Special Prior Authorization (PA) Tier of the Antidepressants Product Based Prior Authorization (PBPA) category with the following additional criteria:

Citalopram Capsule Approval Criteria:

1. An FDA approved indication of major depressive disorder (MDD) in adults; and
2. Member must have initiated treatment with citalopram tablets for dose titration up to the 30mg dose; and
3. A patient-specific, clinically significant reason why the member cannot use citalopram tablets, which are available without prior authorization, in place of the capsule formulation must be provided; and
4. Citalopram capsules will not be approved for members 60 years of age or older; and
5. A quantity limit of 30 capsules per 30 days will apply.

The College of Pharmacy also recommends the placement of Dartisla ODT™ (glycopyrrolate ODT) into the Special PA Tier of the Anti-Ulcer Medications PBPA category with the following additional criteria:

Dartisla ODT™ [Glycopyrrolate Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in members 18 years of age and older; and
2. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without prior authorization, must be provided.
3. A quantity limit of 120 tablets per 30 days will apply.

The College of Pharmacy recommends the prior authorization of Fleqsuvy™ (baclofen oral suspension) with the following criteria:

Fleqsuvy™ 25mg/5mL (Baclofen Oral Suspension) 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.

Additionally, the College of Pharmacy recommends the placement of Lofena™ (diclofenac potassium tablet) into the Special PA Tier of the NSAIDs PBPA category with the following additional criteria (changes shown in red):

NSAIDs Special Prior Authorization (PA) Approval Criteria:

1. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or
2. Previous use of at least 2 Tier-1 NSAID products (from different product lines); and
3. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product.
4. Additionally, use of Tivorbex™ will require a patient-specific, clinically significant reason why the member cannot use all other available generic indomethacin products.
5. Additionally, use of Celebrex® (celecoxib) 400mg capsules will require a diagnosis of Familial Adenomatous Polyposis (FAP) and a patient-specific, clinically significant reason why the member cannot use 2 celecoxib 200mg capsules to achieve a 400mg dose.
6. Additionally, use of Lofena™ will require a patient-specific, clinically significant reason why the member cannot use all other available generic diclofenac products.

The College of Pharmacy also recommends the placement of Norliqva® (amlodipine oral solution) into the Special PA Tier of the CCBs PBPA category with criteria similar to Katerzia® (amlodipine oral suspension) as follows (changes shown in red):

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

1. An FDA approved diagnosis of 1 of the following:
    a. Hypertension in adults and pediatric members 6 years of age and older; or
    b. Coronary artery disease; or
    c. Chronic stable angina; or

    d. Vasospastic angina; and
2. A patient specific, clinically significant reason the member cannot use amlodipine oral tablets even when crushed must be provided; and
3. A quantity limit of 300mL per 30 days will apply.

Additionally, the College of Pharmacy also recommends the placement of Seglentis® (celecoxib/tramadol) into the Special PA Tier of the Opioid Analgesics PBPA category with the following additional criteria:

Seglentis® (Celecoxib 56mg/Tramadol 44mg) Approval Criteria:

1. An FDA approved indication of acute pain in adults that is severe enough to require an opioid analgesic; and
2. A patient-specific, clinically significant reason why the member cannot use any other opioid medication for treatment of acute pain must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use celecoxib and tramadol individual products in place of Seglentis® must be provided; and
4. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
5. A quantity limit of 28 tablets for a 7-day supply will apply.

Finally, the College of Pharmacy recommends the prior authorization of Loreev XR™ (lorazepam ER capsule), Sutab® (sodium sulfate/magnesium sulfate/potassium chloride tablet), Tarpeyo™ (budesonide DR capsule), Vuity™ (pilocarpine 1.25% ophthalmic solution), and Xipere™ (triamcinolone acetonide injection) with the following criteria (changes and new criteria shown in red):

Loreev XR™ [Lorazepam Extended-Release (ER) Capsule] Approval Criteria:

1. An FDA approved diagnosis for the treatment of anxiety disorders; and
2. Member must be 18 years of age or older; and
3. Member must be receiving a stable, evenly divided, 3 times daily dosing of lorazepam tablets; and
4. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation must be provided; and
5. A quantity limit of 30 capsules per 30 days will apply.

Clenpiq®, ColPrep Kit®, OsmoPrep®, Plenvu®, Prepopik®, SUPREP®, and Sutab® Approval Criteria:

1. An FDA approved indication for use in cleansing of the colon as a preparation for colonoscopy; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use other bowel preparation medications available without prior authorization must be provided.
3. If the member requires a low volume polyethylene glycol electrolyte lavage solution, MoviPrep® is available without prior authorization. Other medications currently available without a prior authorization include: Colyte®, Gavilyte®, Golytely®, and Trilyte®.

Tarpeyo™ [Budesonide Delayed Release (DR) Capsule] Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. Member must be 18 years of age or older; and
3. Member must have a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g; and
4. Member must be on a stable dose of a maximally-tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and
5. A patient-specific, clinically significant reason why the member cannot use other oral corticosteroids available without prior authorization must be provided; and
6. A quantity limit of 120 capsules per 30 days will apply.

Vuity™ (Pilocarpine 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 the member cannot use corrective lenses must be provided; and
7. A patient-specific, clinically significant reason the member cannot use generic pilocarpine ophthalmic solution (Isopto® Carpine) must be provided.

Xipere™ (Triamcinolone Acetonide Injection) Approval Criteria:

1. An FDA approved indication for the treatment of macular edema associated with non-infectious uveitis; and
2. Member must be 18 years of age or older; and
3. Xipere™ must be administered by an ophthalmologist; and
4. Prescriber must confirm that the member does not have an active ocular or periocular infection; and
5. Prescriber must confirm member does not have untreated ocular hypertension or uncontrolled glaucoma; and
6. A patient-specific, clinically significant reason why the member cannot use corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
7. A patient-specific, clinically significant reason the member cannot use Triesence® must be provided; and
8. Initial authorization will be for 12 weeks, with an additional dose approved at or after 12 weeks if the prescriber documents improvement from baseline in visual acuity.

Utilization Details of Various Special Formulations: Calendar Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LEVOTHYROXINE PRODUCTS					
TIROSINT CAP 50MCG	42	7	$7,583.03	$180.55	6
TIROSINT CAP 75MCG	37	9	$8,057.93	$217.78	4.11
TIROSINT CAP 125MCG	35	7	$5,338.31	$152.52	5
TIROSINT-SOL SOL 50MCG/ML	25	7	$3,615.25	$144.61	3.57
TIROSINT-SOL SOL 25MCG/ML	24	6	$3,470.64	$144.61	4
TIROSINT CAP 100MCG	23	5	$6,228.56	$270.81	4.6
LEVOTHYROXINE CAP 75MCG	22	8	$3,730.96	$169.59	2.75
TIROSINT CAP 200MCG	21	4	$2,828.38	$134.68	5.25
LEVOTHYROXINE CAP 100MCG	20	4	$2,965.78	$148.29	5
TIROSINT CAP 25MCG	19	3	$2,883.49	$151.76	6.33
TIROSINT CAP 137MCG	18	4	$4,535.73	$251.99	4.5
TIROSINT-SOL SOL 100MCG	16	4	$2,217.87	$138.62	4
TIROSINT CAP 13MCG	13	2	$2,826.79	$217.45	6.5
TIROSINT CAP 150MCG	13	4	$3,592.09	$276.31	3.25
TIROSINT CAP 112MCG	9	4	$2,021.23	$224.58	2.25
LEVOTHYROXINE CAP 88MCG	9	2	$1,498.15	$166.46	4.5
LEVOTHYROXINE CAP 50MCG	9	6	$1,486.15	$165.13	1.5
TIROSINT-SOL SOL 112MCG	8	1	$1,156.88	$144.61	8
LEVOTHYROXINE CAP 200MCG	8	2	$803.74	$100.47	4
TIROSINT CAP 88MCG	6	1	$1,213.18	$202.20	6
TIROSINT-SOL SOL 75MCG/ML	6	4	$801.06	$133.51	1.5
TIROSINT-SOL SOL 88MCG/ML	5	1	$723.05	$144.61	5

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TIROSINT-SOL SOL 62.5MCG/ML	5	2	$723.05	$144.61	2.5
TIROSINT-SOL SOL 200MCG	5	2	$723.05	$144.61	2.5
TIROSINT CAP 175MCG	5	3	$1,698.29	$339.66	1.67
LEVOTHYROXINE CAP 125MCG	4	4	$962.20	$240.55	1
TIROSINT-SOL SOL 150MCG	2	2	$418.42	$209.21	1
TIROSINT-SOL SOL 125MCG	2	2	$281.72	$140.86	1
TIROSINT-SOL SOL 44MCG/ML	2	1	$289.22	$144.61	2
LEVOTHYROXINE CAP 13MCG	2	2	$656.82	$328.41	1
TIROSINT-SOL SOL 13MCG/ML	1	1	$122.41	$122.41	1
LEVOTHYROXINE CAP 175MCG	1	1	$391.99	$391.99	1
SUBTOTAL	**417**	**115**	**$75,845.42**	**$181.88**	**3.63**
MERCAPTOPURINE PRODUCTS					
PURIXAN SUS 20MG/ML	169	29	$211,270.98	$1,250.12	5.83
SUBTOTAL	**169**	**29**	**$211,270.98**	**$1,250.12**	**5.83**
METHOTREXATE PRODUCTS					
XATMEP SOL 2.5MG/ML	85	18	$56,680.66	$666.83	4.72
OTREXUP INJ 25MG	7	1	$4,600.33	$657.19	7
SUBTOTAL	**92**	**19**	**$61,280.99**	**$666.10**	**4.84**
POTASSIUM PRODUCTS					
POT CHLORIDE POW 20MEQ	15	5	$1,598.56	$106.57	3
KLOR-CON PAK 20MEQ	6	3	$476.51	$79.42	2
SUBTOTAL	**21**				
GABAPENTIN PRODUCTS					
HORIZANT TAB 600MG ER	13	2	$5,543.00	$426.38	6.5
GRALISE TAB 600MG	7	1	$1,982.44	$283.21	7
SUBTOTAL	**20**	**3**	**$7,525.44**	**$376.27**	**6.67**
LACTULOSE PRODUCTS					
KRISTALOSE PAK 10GM	19	3	$6,529.86	$343.68	6.33
KRISTALOSE PAK 20GM	1	1	$254.13	$254.13	1
SUBTOTAL	**20**	**4**	**$6,783.99**	**$339.20**	**5**
DROSPIRENONE PRODUCTS					
SLYND TAB 4MG	17	8	$6,706.71	$394.51	2.13
SUBTOTAL	**17**	**8**	**$6,706.71**	**$394.51**	**2.13**
BACLOFEN PRODUCTS					
OZOBAX SOL 5MG/5ML	9	2	$6,402.10	$711.34	4.5
SUBTOTAL	**9**	**2**	**$6,402.10**	**$711.34**	**4.5**
LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE PRODUCTS					
PHEXXI GEL	3	3	$1,093.80	$364.60	1
SUBTOTAL	**3**	**3**	**$1,093.80**	**$364.60**	**1**
ISOTRETINOIN PRODUCTS					
ABSORICA LD CAP 24MG	1	1	$2,413.63	$2,413.63	1
ABSORICA LD CAP 16MG	1	1	$1,127.74	$1,127.74	1
SUBTOTAL	**2**	**2**	**$3,541.37**	**$1,770.69**	**1**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
NORETHINDRONE ACE/ETHINYL ESTRADIOL/FE PRODUCTS					
GEMMILY CAP 1/20	2	1	$181.84	$90.92	2
SUBTOTAL	**2**	**1**	**$181.84**	**$90.92**	**2**
METRONIDAZOLE PRODUCTS					
NUVESSA GEL 1.3%	1	1	$188.95	$188.95	1
SUBTOTAL	**1**	**1**	**$188.95**	**$188.95**	**1**
TOTAL	**773**	**153***	**$382,896.66**	**$495.34**	**5.05**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACE = acetate; CAP = capsule; ER = extended release; FE = iron; INJ = injection; PAK = packet; POW = powder; SOL = solution; SUS = suspension; TAB = tablet

- There were no SoonerCare paid pharmacy claims for calendar year 2021 for the following various special formulation products: Alkindi® Sprinkle (hydrocortisone oral granule), Gimoti® (metoclopramide nasal spray), GoNitro™ (nitroglycerin sublingual powder), Khapzory™ (levoleucovorin injection), Lyrica® CR (pregabalin ER capsule), Metozolv® ODT [metoclopramide orally disintegrating tablet (ODT)], Nextstellis® (drospirenone/estetrol tablet), pyridostigmine 30mg tablet, Quzyttir® (cetirizine injection), Rasuvo® (methotrexate injection), Reltone™ (ursodiol capsule), Sinuva™ (mometasone furoate sinus implant) Soltamox® (tamoxifen citrate 10mg/5mL oral solution), Sorilux® (calcipotriene 0.005% foam), and Thyquidity™ (levothyroxine oral solution).

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Appendix P

U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates (additional information can be found at http://www.fda.gov/Drugs/default.htm)

FDA NEWS RELEASE

For Immediate Release: May 17, 2022

Coronavirus (COVID-19) Update: FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Vaccine Booster Dose to Children 5 through 11 Years

The FDA amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine, authorizing the use of a single booster dose for administration to individuals 5 through 11 years of age at least 5 months after completion of a primary series with the Pfizer-BioNTech COVID-19 vaccine.

The EUA for a single booster dose of the Pfizer-BioNTech COVID-19 vaccine for children 5 through 11 years of age is based on FDA's analysis of immune response data in a subset of children from the ongoing randomized placebo-controlled trial that supported the October 2021 authorization of the Pfizer-BioNTech COVID-19 vaccine primary series in this age group. Antibody responses were evaluated in 67 study participants who received a booster dose 7 to 9 months after completing a 2-dose primary series of the Pfizer-BioNTech COVID-19 vaccine. The antibody level against the Coronavirus 1 month after the booster dose was increased compared to the pre-booster antibody level.

The safety of a single booster dose of the Pfizer-BioNTech COVID-19 vaccine in this age group was assessed in approximately 400 children who received a booster dose at least 5 months (range 5 to 9 months) after completing a 2-dose primary series. The most commonly reported side effects were pain, redness and swelling at the injection site, as well as fatigue, headache, muscle or joint pain and chills, and fever.

FDA NEWS RELEASE

For Immediate Release: May 16, 2022

Coronavirus (COVID-19) Update: FDA Authorizes First COVID-19 Test Available without a Prescription That Also Detects Flu and RSV

The FDA authorized the Labcorp Seasonal Respiratory Virus RT-PCR DTC Test for use without a prescription by individuals with symptoms of respiratory viral infection consistent with COVID-19. This product is the first direct-to-consumer (non-prescription) multi-analyte COVID-19 test authorized by FDA and allows an individual to self-collect a nasal swab sample at home and then send that sample to Labcorp for testing. The test can identify and differentiate multiple respiratory viruses at the same time, detecting influenza A and B, respiratory syncytial virus (RSV), and SARS-CoV-2. Results are delivered through an online portal, with follow-up from a health care provider for positive or invalid test results.

This home sample collection kit can be purchased online or in a store without a prescription. The samples can be self-collected by individuals 18 years of age and older, self-collected by individuals 14 years of age and older with adult supervision, or collected with adult assistance for individuals 2 years of age and older. This will enable consumers to more easily determine whether they may be infected with COVID-19, flu, or RSV, which

can aid in assessing the need for self-isolation and in assisting with health care professional discussions and decisions.

FDA NEWS RELEASE

For Immediate Release: May 13, 2022

FDA Approves Novel, Dual-Targeted Treatment for Type 2 Diabetes

The FDA approved Mounjaro™ (tirzepatide) injection to improve blood glucose control in adults with type 2 diabetes, as an addition to diet and exercise. Mounjaro™ was effective at improving blood glucose and was more effective than the other diabetes therapies with which it was compared in clinical studies. Mounjaro™ received priority review designation from the FDA for this indication.

Glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP) are hormones involved in blood glucose control. Mounjaro™ is a first-in-class medicine that activates both the GLP-1 and GIP receptors. Mounjaro™ is administered by subcutaneous injection once weekly, with the dose adjusted as tolerated to meet blood glucose goals.

Three different doses of Mounjaro™ (5mg, 10mg, and 15mg) were evaluated in 5 clinical trials as either a stand-alone therapy or as an add-on to other diabetes medicines. The efficacy of Mounjaro™ was compared to placebo, a GLP-1 receptor agonist (semaglutide), and 2 long-acting insulin analogs. On average, patients randomized to receive the maximum recommended dose of Mounjaro™ (15mg) had lowering of their hemoglobin A1c (HbA1c) level by 1.6% more than placebo when used as stand-alone therapy and by 1.5% more than placebo when used in combination with a long-acting insulin. In trials comparing Mounjaro™ to other diabetes medications, patients who received the maximum recommended dose of Mounjaro™ had lowering of their HbA1c by 0.5% more than semaglutide, 0.9% more than insulin degludec, and 1.0% more than insulin glargine.

Mounjaro™ can cause nausea, vomiting, diarrhea, decreased appetite, constipation, upper abdominal discomfort, and abdominal pain. Mounjaro™ causes thyroid C-cell tumors in rats. It is unknown whether Mounjaro™ causes such tumors, including medullary thyroid cancer, in humans. Mounjaro™ should not be used in patients with a personal or family history of medullary thyroid cancer or in patients with multiple endocrine neoplasia syndrome type 2. Mounjaro™ has not been studied in patients with a history of pancreatitis, and it is not indicated for use in patients with type 1 diabetes.

FDA NEWS RELEASE

For Immediate Release: May 5, 2022

Coronavirus (COVID-19) Update: FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals

The FDA has limited the authorized use of the Janssen COVID-19 vaccine to individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 vaccine because they would otherwise not receive a COVID-19 vaccine.

After conducting an updated analysis, evaluation and investigation of reported cases, the FDA has determined that the risk of thrombosis with thrombocytopenia syndrome (TTS), a syndrome of rare and potentially life-threatening blood clots in combination with low levels of blood platelets with onset of symptoms approximately 1 to

2 weeks following administration of the Janssen COVID-19 vaccine, warrants limiting the authorized use of the vaccine.

The FDA has determined that the known and potential benefits of the vaccine for the prevention of COVID-19 outweigh the known and potential risks for individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and for individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.

The FDA and the Centers for Disease Control and Prevention (CDC) have continuously monitored for and investigated all suspected cases of TTS reported to the Vaccine Adverse Event Reporting System (VAERS). In an updated analysis of TTS cases following administration of the Janssen COVID-19 vaccine that were reported to VAERS through March 18, 2022, the FDA and CDC have identified 60 confirmed cases, including 9 fatal cases. The FDA has determined that the reporting rate of TTS is 3.23 per million doses of vaccine administered, and the reporting rate of TTS deaths is 0.48 per million doses of vaccine administered.

In making the determination to limit the authorized use of the Janssen COVID-19 vaccine, the agency considered that reporting rates of TTS and TTS deaths following administration of the Janssen COVID-19 vaccine are not appreciably lower than previously reported. Furthermore, the factors that put an individual at risk for TTS following administration of Janssen COVID-19 vaccine remain unknown. The FDA also considered that individuals with TTS may rapidly deteriorate, despite prompt diagnosis and treatment, that TTS can lead to long-term and debilitating health consequences and that TTS has a high death rate. The agency also considered the availability of alternative authorized and approved COVID-19 vaccines which provide protection from COVID-19 and have not been shown to present a risk for TTS.

Examples of individuals who may still receive the Janssen COVID-19 vaccine include: individuals who experienced an anaphylactic reaction after receipt of an mRNA COVID-19 vaccine, individuals who have personal concerns with receiving mRNA vaccines and would otherwise not receive a COVID-19 vaccine, and individuals who would remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines.

The FDA has a robust safety surveillance system in place to monitor the safety of COVID-19 vaccines approved and authorized for emergency use. The FDA is monitoring COVID-19 vaccine safety through both passive and active safety surveillance systems in collaboration with the CDC, the Centers for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs, and other academic and large non-government health care data systems.

FDA NEWS RELEASE

For Immediate Release: May 4, 2022

FDA Permits Marketing for New Test to Improve Diagnosis of Alzheimer's Disease

The FDA permitted marketing for the first *in vitro* diagnostic test for early detection of amyloid plaques associated with Alzheimer's disease. The Lumipulse® G β-Amyloid Ratio (1-42/1-40) test is intended to be used in adult patients, 55 years of age and older, presenting with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline.

The Lumipulse® test is intended to measure the ratio of β-amyloid 1-42 and β-amyloid 1-40 (specific proteins that can accumulate and form plaques) concentrations found in human cerebral spinal fluid (CSF), which can help physicians determine whether

a patient is likely to have amyloid plaques, a hallmark sign of Alzheimer's disease. Results must be interpreted in conjunction with other patient clinical information.

A positive Lumipulse® G β-amyloid Ratio (1-42/1-40) test result is consistent with the presence of amyloid plaques, similar to what would be seen in a PET scan. A negative result is consistent with a negative amyloid PET scan result. A negative test result reduces the likelihood that a patient's cognitive impairment is due to Alzheimer's disease, enabling physicians to pursue other causes of cognitive decline and dementia. The test is not intended as a screening or stand-alone diagnostic assay. There is also the possibility that a positive test result could be seen in patients with other types of neurologic conditions, as well as in older cognitively healthy people, which underscores the importance of using this test in conjunction with other clinical evaluations.

The FDA evaluated the safety and effectiveness of this test in a clinical study of 292 CSF samples from the Alzheimer's Disease Neuroimaging Initiative sample bank. The samples were tested by the Lumipulse® G β-amyloid Ratio (1-42/1-40) and compared with amyloid PET scan results. In this clinical study, 97% of individuals with Lumipulse® G β-amyloid Ratio (1-42/1-40) positive results had the presence of amyloid plaques by PET scan and 84% of individuals with negative results had a negative amyloid PET scan.

The risks associated with the Lumipulse® G β-amyloid Ratio (1-42/1-40) test are mainly the possibility of false positive and false negative test results. False positive results, in conjunction with other clinical information, could lead to an inappropriate diagnosis of, and unnecessary treatment for, Alzheimer's disease. This could lead to psychological distress, delay in receiving a correct diagnosis as well as expense and the risk for side effects from unnecessary treatment. False negative test results could result in additional unnecessary diagnostic tests and potential delay in effective treatment.

FDA NEWS RELEASE

For Immediate Release: May 4, 2022

FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products

The FDA issued warning letters to 5 companies for selling products labeled as containing delta-8 tetrahydrocannabinol (delta-8 THC) in ways that violate the Federal Food, Drug, and Cosmetic Act (FD&C Act). This action is the first time the FDA has issued warning letters for products containing delta-8 THC. Delta-8 THC has psychoactive and intoxicating effects and may be dangerous to consumers. The FDA has received reports of adverse events experienced by patients who have consumed these products.

There are no FDA-approved drugs containing delta-8 THC. Any delta-8 THC product claiming to diagnose, cure, mitigate, treat, or prevent diseases is considered an unapproved new drug. The FDA has not evaluated whether these unapproved drug products are effective for the uses manufacturers claim, what an appropriate dose might be, how they could interact with FDA-approved drugs or other products, or whether they have dangerous side effects or other safety concerns.

The warning letters address the illegal marketing of unapproved delta-8 THC products by companies as unapproved treatments for various medical conditions or for other therapeutic uses. The letters also cite violations related to drug misbranding (e.g., the products lack adequate directions for use) and the addition of delta-8 THC in foods, such as gummies, chocolate, caramels, chewing gum, and peanut brittle.

The FDA recently published a consumer update expressing serious concerns about the potential health effects of delta-8 THC products. The FDA has received adverse event reports involving products containing delta-8 THC from consumers, health care

practitioners, and law enforcement, some of which resulted in the need for hospitalization or emergency room treatment. The agency is also aware of an increasing number of exposure cases involving products containing delta-8 THC received by national poison control centers and alerts issued by state poison control centers describing safety concerns and adverse events with products containing delta-8 THC.

Current Drug Shortages Index (as of May 24, 2022):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma.

Acetazolamide Injection	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acids	***Currently in Shortage***
Amoxapine Tablets	***Currently in Shortage***
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets	***Currently in Shortage***
Amphetamine Oral Suspension, Extended Release	***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***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride and Epinephrine Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Calcium Disodium Versenate Injection	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Cefazolin Injection	***Currently in Shortage***
Cefixime Oral Capsules	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chlordiazepoxide Hydrochloride Capsules	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Conivaptan Hydrochloride (Vaprisol®) in 5% Dextrose Plastic Container	***Currently in Shortage***
Continuous Renal Replacement Therapy (CRRT) Solutions	***Currently in Shortage***
Cortisone Acetate Tablets	***Currently in Shortage***
Cyclopentolate Ophthalmic Solution	***Currently in Shortage***
Cysteamine Hydrochloride 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***
Diflunisal Tablets	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Disopyramide Phosphate (Norpace®) Capsules	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Injection, 0.1 mg/mL	***Currently in Shortage***
Epinephrine Injection, Auto-Injector	***Currently in Shortage***
Fentanyl Citrate (Sublimaze®) Injection	***Currently in Shortage***
Floxuridine for Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Fluorescein Injection	***Currently in Shortage***
Fluvoxamine ER Capsules	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gemifloxacin Mesylate (Factive®) Tablets	***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 Tablets	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxypropyl (Lacrisert®) Cellulose Ophthalmic Insert	***Currently in Shortage***
Ibutilide Fumarate Injection	***Currently in Shortage***
Imipenem and Cilastatin for Injection	***Currently in Shortage***
Iodixanol (Visipaque) Injection	***Currently in Shortage***
Iohexol (Omnipaque) Injection	***Currently in Shortage***
Isoniazid Injection	***Currently in Shortage***
Ketamine Injection	***Currently in Shortage***
Ketoprofen Capsules	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Lyophilized Powder for Injection	***Currently in Shortage***
Leuprolide Acetate Injection	***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***
Lipid Injection	***Currently in Shortage***
Lithium Oral Solution	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Loxapine Capsules	***Currently in Shortage***
Lutetium Lu 177 Dotatate (Lutathera®) Injection	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***
Mepivacaine Hydrochloride 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***
Nefazodone Hydrochloride Tablets	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Paclitaxel Injection (protein-bound particles)	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Parathyroid Hormone (Natpara®) Injection	***Currently in Shortage***
Pentostatin Injection	***Currently in Shortage***
Physostigmine Salicylate Injection	***Currently in Shortage***
Potassium Acetate Injection	***Currently in Shortage***
Potassium Chloride Concentrate Injection	***Currently in Shortage***
Promethazine (Phenergan®) Injection	***Currently in Shortage***
Propofol Injectable Emulsion	***Currently in Shortage***
Protamine Sulfate Injection	***Currently in Shortage***
Rifampin Capsules	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablets	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Sclerosol Intrapleural Aerosol	***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 USP, 0.9% Vials and Syringes	***Currently in Shortage***
Sodium Phosphates Injection	***Currently in Shortage***

Sterile Water for Injection	***Currently in Shortage***
Streptozocin Powder for Injection	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Sulfasalazine Tablets	***Currently in Shortage***
Technetium TC-99M Mebrofenin Injection	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Teprotumumab-trbw	***Currently in Shortage***
Thiothixene Capsules	***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***
Varenicline Tartrate (Chantix™) Tablets	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***