OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
September 13, 2023
4:00pm

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

Viewing Access Only:
Please register for the webinar at:
https://www.zoomgov.com/webinar/register/WN_0aEa3CWFRR6lyxMLGdkOvg
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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 – September 13, 2023

DATE: September 6, 2023

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

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

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Enclosed are the following items related to the September 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/Nonalcoholic Fatty Liver Disease (NAFLD) Update – Appendix B

Action Item – Vote to Prior Authorize Leqembi® (Lecanemab-irmb) and Update the Approval Criteria for the Alzheimer's Disease Medications – Appendix C

Action Item – Vote to Prior Authorize Vyjuvek™ (Beremagene Geperpavec-svdt) – Appendix D

Action Item – Vote to Prior Authorize Kyzatrex™ (Testosterone Undecanoate Capsule) and Update the Approval Criteria for the Testosterone Products – Appendix E

Action Item – Vote to Prior Authorize Brixadi™ (Buprenorphine Extended-Release Injection), Nalocet® (Oxycodone/Acetaminophen Tablet), and Prolate™ (Oxycodone/Acetaminophen Oral Solution and Tablet) and Update the Approval Criteria for the Opioid Analgesics and Medication Assisted Treatment (MAT) Medications – Appendix F

Action Item – Vote to Update the Approval Criteria for the Topical Corticosteroids – Appendix G

Action Item – Vote to Update the Approval Criteria for the Intravenous (IV) Iron Products – Appendix H

Action Item – Vote to Prior Authorize Xacduro® (Sulbactam/Durlobactam) and Update the Approval Criteria for the Various Systemic Antibiotics – Appendix I

Action Item – Vote to Vote to Prior Authorize Cuvrior™ (Trientine Tetrahydrochloride) – Appendix J

Action Item – Annual Review of Tepezza® (Teprotumumab-trbw) – Appendix K

Action Item – Annual Review of Oxlumo® (Lumasiran) – Appendix L

Action Item – Annual Review of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators – Appendix M

Action Item – Annual Review of Gattex® [Teduglutide (rDNA origin)] – Appendix N

Action Item – Annual Review of Synagis® (Palivizumab) – Appendix O

Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Orserdu™ (Elacestrant) – Appendix P

Annual Review of Zinplava™ (Bezlotoxumab) and 30-Day Notice to Prior Authorize Rebyota® (Fecal Microbiota, Live-jslm) and Vowst™ (Fecal Microbiota Spores, Live-brpk) – Appendix Q

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – September 13, 2023 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

NOTE: ***The DUR Board will meet at 4:00pm at OHCA (see address above). There will be Zoom access to this meeting; however, Zoom access will be set up in view-only mode with no voting, speaking, video, or chat box privileges. Zoom access will allow for viewing of the presentation slides as well as audio of the presentations and discussion during the meeting; however, the DUR Board meeting will not be delayed or rescheduled due to any technical issues that may arise.***

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Adams

DUR Board Members:

Mr. Kenneth Foster –	participating in person
Dr. Megan Hanner –	participating in person
Dr. John Muchmore –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person
Dr. Edna Patatanian –	participating in person
Dr. Vineetha Thomas –	participating in person
Dr. Beth Walton –	participating in person

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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: 160 522 8313
Passcode: 246928

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. July 12, 2023 DUR Board Meeting Minutes
   B. July 12, 2023 DUR Board Recommendations Memorandum
   C. August 9, 2023 DUR Board Recommendations Memorandum

Items to be presented by Dr. Muchmore, Chairman:

4. **Action Item – Approval of DUR Board Interim Vice Chair**
   A. Nomination and Vote on DUR Board Interim Vice Chair

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

5. **Update on Medication Coverage Authorization Unit/ Nonalcoholic Fatty Liver Disease (NAFLD) Update – See Appendix B**
   A. Pharmacy Help Desk Activity for August 2023
   B. Medication Coverage Activity for August 2023
   C. NAFLD Update

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

6. **Action Item – Vote to Prior Authorize Leqembi® (Lecanemab-irmb) and Update the Approval Criteria for the Alzheimer's Disease Medications – See Appendix C**
   A. Market News and Updates

B. Leqembi® (Lecanemab-irmb) Product Summary
C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Vyjuvek™ (Beremagene Geperpavec-svdt) – See Appendix D**

A. Market News and Updates
B. Vyjuvek™ (Beremagene Geperpavec-svdt) Product Summary
C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Kyzatrex™ (Testosterone Undecanoate Capsule) and Update the Approval Criteria for the Testosterone Products – See Appendix E**

A. Market News and Updates
B. Kyzatrex™ (Testosterone Undecanoate Capsule) Product Summary
C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Brixadi™ (Buprenorphine Extended-Release Injection), Nalocet® (Oxycodone/Acetaminophen Tablet), and Prolate™ (Oxycodone/Acetaminophen Oral Solution and Tablet) and to Update the Approval Criteria for the Opioid Analgesics and Medication Assisted Treatment (MAT) Medications – See Appendix F**

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

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

10. **Action Item – Vote to Update the Approval Criteria for the Topical Corticosteroids – See Appendix G**

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

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

11. **Action Item – Vote to Update the Approval Criteria for the Intravenous (IV) Iron Products – See Appendix H**

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

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

12. **Action Item – Vote to Prior Authorize Xacduro® (Sulbactam/Durlobactam) and Update the Approval Criteria for the Various Systemic Antibiotics – See Appendix I**

A. Market News and Updates

B. Xacduro® (Sulbactam/Durlobactam) Product Summary
C. College of Pharmacy Recommendations

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

13. Action Item – Vote to Prior Authorize Cuvrior™ (Trientine Tetrahydrochloride) – See Appendix J

A. Cuvrior™ (Trientine Tetrahydrochloride) Product Summary
B. College of Pharmacy Recommendations

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

14. Action Item – Annual Review of Tepezza® (Teprotumumab-trbw) – See Appendix K

A. Current Prior Authorization Criteria
B. Utilization of Tepezza® (Teprotumumab-trbw)
C. Prior Authorization of Tepezza® (Teprotumumab-trbw)
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Tepezza® (Teprotumumab-trbw)

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

15. Action Item – Annual Review of Oxlumo® (Lumasiran) – See Appendix L

A. Current Prior Authorization Criteria
B. Utilization of Oxlumo® (Lumasiran)
C. Prior Authorization of Oxlumo® (Lumasiran)
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Oxlumo® (Lumasiran)

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

16. Action Item – Annual Review of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators – See Appendix M

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

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

17. Action Item – Annual Review of Gattex® [Teduglutide (rDNA origin)] – See Appendix N

A. Current Prior Authorization Criteria
B. Utilization of Gattex® [Teduglutide (rDNA origin)]
C. Prior Authorization of Gattex® [Teduglutide (rDNA origin)]
D. Market News and Updates

E. College of Pharmacy Recommendations
F. Utilization Details of Gattex® [Teduglutide (rDNA origin)]

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

18. Action Item – Annual Review of Synagis® (Palivizumab) – See Appendix O

A. Current Prior Authorization Criteria
B. Utilization of Synagis® (Palivizumab)
C. Prior Authorization of Synagis® (Palivizumab)
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Synagis® (Palivizumab)

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

19. Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Orserdu™ (Elacestrant) – See Appendix P

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

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

20. Annual Review of Zinplava™ (Bezlotoxumab) and 30-Day Notice to Prior Authorize Rebyota® (Fecal Microbiota, Live-jslm) and Vowst™ (Fecal Microbiota Spores, Live-brpk) – See Appendix Q

A. Current Prior Authorization Criteria
B. Utilization of Zinplava™ (Bezlotoxumab)
C. Prior Authorization of Zinplava™ (Bezlotoxumab)
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Zinplava™ (Bezlotoxumab)

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

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

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

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

A. Anemia Medications
B. Hepatitis C Medications
C. Muscular Dystrophy Medications
D. Targeted Immunomodulator Agents

*Future product and class reviews subject to change.

23. 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 JULY 12, 2023

DUR BOARD MEMBERS:	PRESENT	ABSENT
Jennifer de los Angeles, Pharm.D., BCOP	X	
Kenneth Foster, MHS, PA-C	X	
Megan A. Hanner, D.O.		X
Lynn Mitchell, M.D.; Vice Chairwoman		X
John Muchmore, M.D.; Ph.D.; Chairman	X	
Lee Muñoz, D.Ph.	X	
James Osborne, Pharm.D.	X	
Edna Patatanian, Pharm.D., FASHP	X	
Beth Walton, Pharm.D.	X	

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Morgan Masterson, Pharm.D; Clinical Pharmacist		X
Mattie Morgan, Pharm.D.; Pharmacy Resident	X	
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist		X
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Jo'Nel Reynolds, Pharm.D.; Clinical Pharmacist	X	
Grant H. Skrepnek, Ph.D.; Associate Professor		X
Peggy Snyder, Pharm.D.; Clinical Pharmacist		X
Ashley Teel, Pharm.D.; Clinical Pharmacist		X
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	X	
Devin Wilcox, D.Ph.; Pharmacy Director	X	
Justin Wilson, Pharm.D.; Clinical Pharmacist	X	
PA Oncology Pharmacists: Tad Autry Pharm.D., BCPS, BCOP		X
Emily Borders, Pharm.D., BCOP	X	
Graduate Students: Rykr Carpenter, Pharm.D.		X
Matthew Dickson, Pharm.D.		X
Victoria Jones, Pharm.D.		X
Michael Nguyen, Pharm.D.		X
Corby Thompson, Pharm.D.		X
Visiting Pharmacy Student(s): N/A		

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

Brandon Keppner; Chief Operating Officer		X
Traylor Rains; State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Interim Chief Medical Officer	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Kara Smith, J.D.; General Counsel		X
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
Toney Welborn, M.D., MPH, MS; Medical Director		X

OTHERS PRESENT:	
Shellie Keast, Mercer	David Shirkey, ALK
Daniel O'Donnell, Axsome	Maggie Shaffer, Alzheimer's Association
Audrey Rattan, Alkermes	Rusty Hailey, Intra-Cellular Therapies
Todd Dickerson, Jazz Pharmaceuticals	Kenneth Berry, Alkermes
Aaron Austin, Takeda	Robert Greely, Biogen
Chrystal Mayes, Sanofi	Bob Atkins, Biogen
Scott Symes, Pharming	Beth Babler, Recordati
Crystal Henderson, Karuna Therapeutics	JJ Roth, Mirum Pharmaceuticals
Seven Tomek, Caris Life Sciences	Stephanie Undernehr, Caris Life Sciences
Rhonda Clark, Indivior	Karen Ward, Krystal Bio
Andi Stratton, Krystal Bio	Madeline Shurtleff, Otsuka
Richie Crawford, Otsuka	Melissa Abbott, Eisai
Mark Kaiser, Otsuka	Todd Ness, AbbVie
Amanda Nowakowski, ViiV	Jonathan Tran, ALK

PRESENT FOR PUBLIC COMMENT:	
Seven Tomek, Caris Life Sciences	Jonathan Tran, ALK
Karen Ward, Krystal Bio	

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

1A: ROLL CALL

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

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO. 13 SEVEN TOMEK

2B: AGENDA ITEM NO. 14 JONATHAN TRAN

2C: AGENDA ITEM NO. 16 KAREN WARD

ACTION: NONE REQUIRED

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

3A: JUNE 14, 2023 DUR MINUTES – VOTE

Materials included in agenda packet; presented by Dr. Muchmore

Dr. Muñoz moved to approve; seconded by Dr. de los Angeles

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/CHRONIC MEDICATION ADHERENCE (CMA) PROGRAM UPDATE**

4A: PHARMACY HELPDESK ACTIVITY FOR JUNE 2023
4B: MEDICATION COVERAGE ACTIVITY FOR JUNE 2023
4C: CMA PROGRAM UPDATE

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

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE ALTUVIIIO™ [ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC-VMF-XTEN FUSION PROTEIN-EHTL] AND HEMGENIX® (ETRANACOGENE DEZAPARVOVEC-DRLB)**

5A: MARKET NEWS AND UPDATES
5B: PRODUCT SUMMARIES
5C: OHCA RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Ratterman
Dr. Muñoz moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE LUMRYZ™ (SODIUM OXYBATE) AND RELEXXII® (METHYLPHENIDATE EXTENDED-RELEASE TABLET) AND UPDATE THE APPROVAL CRITERIA FOR THE ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS**

6A: MARKET NEWS AND UPDATES
6B: PRODUCT SUMMARIES
6C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE ABILIFY ASIMTUFII® [ARIPIPRAZOLE EXTENDED-RELEASE (ER) INJECTION], QUETIAPINE 150MG TABLET, AND RYKINDO® (RISPERIDONE ER INJECTION) AND UPDATE THE APPROVAL CRITERIA FOR THE ATYPICAL ANTIPSYCHOTIC MEDICATIONS**

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

Materials included in agenda packet; presented by Dr. Adams
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE ALLOPURINOL 200MG TABLET, APONVIE™ (APREPITANT INJECTABLE EMULSION), ASPRUZYO SPRINKLE™ [RANOLAZINE EXTENDED-RELEASE (ER) GRANULES], AUSTEDO® XR (DEUTETRABENAZINE ER TABLET), ENTADFI® (FINASTERIDE/TADALAFIL CAPSULE), ERMEZA™ (LEVOTHYROXINE ORAL SOLUTION), FUROSCIX® (FUROSEMIDE ON-BODY INFUSOR), IYUZEH™ (LATANOPROST OPHTHALMIC SOLUTION), JYLAMVO® (METHOTREXATE ORAL SOLUTION), PRIMIDONE 125MG TABLET, VERKAZIA® (CYCLOSPORINE OPHTHALMIC SOLUTION), XACIATO™ (CLINDAMYCIN VAGINAL GEL), AND ZOLPIDEM TARTRATE 7.5MG CAPSULE**

8A: INTRODUCTION
8B: PRODUCT SUMMARIES
8C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss

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

<u>AGENDA ITEM NO. 9:</u> VOTE TO PRIOR AUTHORIZE DAYBUE™ (TROFINETIDE)
9A: MARKET NEWS AND UPDATES
9B: DAYBUE™ (TROFINETIDE) PRODUCT SUMMARY
9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 10:</u> VOTE TO PRIOR AUTHORIZE JOENJA® (LENIOLISIB)
10A: MARKET NEWS AND UPDATES
10B: JOENJA® (LENIOLISIB) PRODUCT SUMMARY
10C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Adams
Dr. Muñoz moved to approve; seconded by Dr. de los Angeles
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 11:</u> VOTE TO PRIOR AUTHORIZE LYVISPAH™ (BACLOFEN ORAL GRANULES) AND NORGESIC®, NORGESIC® FORTE, AND ORPHENGESIC® FORTE (ORPHENADRINE/ASPIRIN/CAFFEINE)
11A: MARKET NEWS AND UPDATES
11B: PRODUCT SUMMARIES
11C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Reynolds
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 12:</u> VOTE TO PRIOR AUTHORIZE ADSTILADRIN® (NADOFARAGENE FIRADENOVAC-VNCG) AND ELAHERE™ (MIRVETUXIMAB SORAVTANSINE-GYNX) AND UPDATE THE APPROVAL CRITERIA FOR THE GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
12A: MARKET NEWS AND UPDATES
12B: PRODUCT SUMMARIES
12C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF COLORECTAL CANCER MEDICATIONS
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF COLORECTAL CANCER MEDICATIONS
13C: PRIOR AUTHORIZATION OF COLORECTAL CANCER MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: COLLEGE OF PHARMACY RECOMMENDATIONS
13F: UTILIZATION DETAILS OF COLORECTAL CANCER MEDICATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: ANNUAL REVIEW OF ALLERGEN IMMUNOTHERAPIES

14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF ALLERGEN IMMUNOTHERAPIES
14C: PRIOR AUTHORIZATION OF ALLERGEN IMMUNOTHERAPIES
14D: MARKET NEWS AND UPDATES
14E: COLLEGE OF PHARMACY RECOMMENDATIONS
14F: UTILIZATION DETAILS OF ALLERGEN IMMUNOTHERAPIES

Materials included in agenda packet; presented by Dr. Reynolds
Mr. Foster moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 15: ANNUAL REVIEW OF TESTOSTERONE PRODUCTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE KYZATREX® (TESTOSTERONE UNDECANOATE)

15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF TESTOSTERONE PRODUCTS
15C: PRIOR AUTHORIZATION OF TESTOSTERONE PRODUCTS
15D: MARKET NEWS AND UPDATES
15E: KYZATREX® (TESTOSTERONE UNDECANOATE) PRODUCT SUMMARY
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF TESTOSTERONE PRODUCTS

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

AGENDA ITEM NO. 16: 30-DAY NOTICE TO PRIOR AUTHORIZE VYJUVEK™ (BEREMAGENE GEPERPAVEC-SVDT)

16A: INTRODUCTION
16B: VYJUVEK™ (BEREMAGENE GEPERPAVEC-SVDT) PRODUCT SUMMARY
16C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 17: ANNUAL REVIEW OF ALZHEIMER'S DISEASE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE LEQEMBI® (LECANEMAB-IRMB)

17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF ALZHEIMER'S DISEASE MEDICATIONS
17C: PRIOR AUTHORIZATION OF ALZHEIMER'S DISEASE MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: LEQEMBI® (LECANEMAB-IRMB) PRODUCT SUMMARY
17F: COLLEGE OF PHARMACY RECOMMENDATIONS
17G: UTILIZATION DETAILS OF ALZHEIMER'S DISEASE MEDICATIONS

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

AGENDA ITEM NO. 18: ANNUAL REVIEW OF ISTURISA® (OSILODROSTAT) AND RECORLEV® (LEVOKETOCONAZOLE)

18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF ISTURISA® (OSILODROSTAT) AND RECORLEV® (LEVOKETOCONAZOLE)
18C: PRIOR AUTHORIZATION OF ISTURISA® (OSILODROSTAT) AND RECORLEV® (LEVOKETOCONAZOLE)
18D: MARKET NEWS AND UPDATES

18E: COLLEGE OF PHARMACY RECOMMENDATIONS
18F: UTILIZATION DETAILS OF ISTURISA® (OSILODROSTAT) AND RECORLEV® (LEVOKETOCONAZOLE)
Materials included in agenda packet; presented by Dr. Reynolds
ACTION: NONE REQUIRED

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. Reynolds
ACTION: NONE REQUIRED

AGENDA ITEM NO. 20: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
NO LIVE DUR BOARD MEETING SCHEDULED FOR AUGUST 2023. AUGUST 2023 WILL BE A PACKET-ONLY MEETING.
20A: INTRAVENOUS (IV) IRON PRODUCTS
20B: OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
20C: TOPICAL CORTICOSTEROIDS
20D: VARIOUS SYSTEMIC ANTIBIOTICS
*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 5:26 pm.

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

Memorandum

Date: July 14, 2023

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

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

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

Recommendation 1: Chronic Medication Adherence (CMA) Program Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Altuviiio™ [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl] and Hemgenix® (Etranacogene Dezaparvovec-drlb)

MOTION CARRIED by unanimous approval.

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

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

1. An FDA approved indication; and
2. Requested medication must be prescribed by a hematologist specializing in rare bleeding disorders or a mid-level practitioner with a supervising physician that is a hematologist specializing in rare bleeding disorders; and

3. A patient-specific, clinically significant reason why the member cannot use the following must be provided:
    a. Hemophilia A: Advate® or current factor VIII replacement product; or
    b. Hemophilia B: Benefix® or current factor IX replacement product; and
4. A half-life study must be performed to determine the appropriate dose and dosing interval; and
5. Initial approvals will be for the duration of the half-life study. If the half-life study shows significant benefit in prolonged half-life, subsequent approvals will be for the duration of 1 year.

Hemgenix® (Etranacogene Dezaparvovec-drlb) Approval Criteria:

1. Diagnosis of severe or moderately severe congenital, X-linked, hemophilia B; and
2. Member must not have a history of an inhibitor or a recent positive screening, defined as ≥0.6 Bethesda units, prior to administration of etranacogene dezaparvovec-drlb; and
3. Member must not have an AAV5 neutralizing antibody titer >700; and
4. Member must be a male 18 years of age or older; and
5. Member must be on prophylactic therapy with continued frequent breakthrough bleeding episodes or has experienced a life-threatening bleeding episode; and
6. Member must have had >150 previous exposure days of treatment with factor IX; and
7. Member must not have active hepatitis B or C; and
8. Members with human immunodeficiency virus (HIV) must be controlled with antiviral therapy; and
9. Member must not have received prior treatment with any gene therapy for hemophilia B; and
10. Prescriber must perform baseline liver health assessment including:
    a. Enzyme testing (ALT, AST, ALP); and
    b. Hepatic ultrasound; and
11. Member's recent weight must be provided (taken within the last month) to ensure appropriate dosing; and
12. Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
13. Must be administered in a clinical setting and monitoring performed for at least 3 hours post-infusion; and
14. Prescriber must monitor liver enzymes weekly for 3 months following administration of etranacogene dezaparvovec-drlb and continue monitoring until liver enzymes return to baseline; and
    a. Prescriber must agree to begin corticosteroids if indicated; and
15. Approvals will be for 1 dose per member per lifetime.

Recommendation 3: Vote to Prior Authorize Lumryz™ (Sodium Oxybate) and Relexxii® (Methylphenidate Extended-Release Tablet) and Update the Approval Criteria for the Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications

MOTION CARRIED by unanimous approval.

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

1. The prior authorization of Relexxii® (methylphenidate ER tablet) and placement into the Special PA Tier of the ADHD Medications PBPA Tier chart; and
2. The prior authorization of Lumryz™ (sodium oxybate) with criteria similar to Xywav® (calcium/magnesium/potassium/sodium oxybates); and
3. Moving Dexedrine Spansules® (dextroamphetamine ER capsule) from the Special PA Tier to Tier-2, moving methylphenidate ER 72mg tablet from Tier-3 to the Special PA Tier, moving Vyvanse® (lisdexamfetamine chewable tablet) from the Special PA Tier to Tier-1, and moving Ritalin LA® (methylphenidate ER capsule) from Tier-1 to Tier-2 based on net costs; and
4. Making Aptensio XR® (methylphenidate ER capsule), Daytrana® (methylphenidate ER patch), and Xyrem® (sodium oxybate solution) brand preferred based on net costs; and
5. Updating the approval criteria for Qelbree® (viloxazine) based on the higher FDA approved maximum dosing in adults.

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			amphetamine ER susp (Adzenys ER™) amphetamine ER ODT (Adenyls XR-ODT®) amphetamine (Evekeo®) amphetamine ODT (Evekeo ODT™) amphetamine/ dextroamphetamine ER (Mydayis®) dextroamphetamine (Dexedrine®)
Short-Acting			
amphetamine/ dextroamphetamine (Adderall®)			
Long-Acting			
amphetamine/ dextroamphetamine ER (Adderall XR®) lisdexamfetamine cap **and chew tab** (Vyvanse®)+	amphetamine ER susp and tab (Dyanavel® XR) **dextroamphetamine ER (Dexedrine Spansules®)**		

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Methylphenidate			
Short-Acting			
dexmethylphenidate (Focalin®) methylphenidate tab and soln (Methylin®) methylphenidate (Ritalin®)			
Long-Acting			
dexmethylphenidate ER (Focalin XR®) – **Brand Preferred** methylphenidate ER (Concerta®) methylphenidate ER (Daytrana®) **– Brand Preferred** methylphenidate ER (Metadate CD®) methylphenidate ER (Metadate ER®) methylphenidate ER (Methylin ER®) ~~**methylphenidate ER (Ritalin LA®)**~~ methylphenidate ER (Ritalin SR®)	dexmethylphenidate ER (generic Focalin XR®) methylphenidate ER (Aptensio XR®) **– Brand Preferred** methylphenidate ER susp (Quillivant XR®) **methylphenidate ER (Ritalin LA®)**	~~**methylphenidate ER 72mg**~~ methylphenidate ER (Adhansia XR®) methylphenidate ER (Jornay PM®) serdexmethylphenidate/dexmethylphenidate (Azstarys®)	
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)Δ		

~~**dextroamphetamine ER (Dexedrine Spansules®)**~~

dextroamphetamine soln (ProCentra®)

dextroamphetamine (Xelstrym™)

dextroamphetamine (Zenzedi®)

~~**lisdexamfetamine chew tab (Vyvanse®)+**~~

methamphetamine (Desoxyn®)

methylphenidate ER 72mg

methylphenidate ER ODT (Cotempla XR-ODT®)

methylphenidate ER (Relexxii®)

methylphenidate chew tab (Methylin®)

methylphenidate ER chew tab (QuilliChew ER®)

viloxazine (Qelbree®)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 Special Prior Authorization (PA) Approval Criteria:

1. Adzenys XR-ODT®, Adzenys ER™, Cotempla XR-ODT®, Evekeo ODT™, QuilliChew ER®, ~~Vyvanse® Chewable Tablets,~~ and Xelstrym™ Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use all other available formulations of stimulant medications that can be used for members who cannot swallow capsules or tablets must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
2. Desoxyn®, Dexedrine®, ~~Dexedrine Spansules®,~~ Evekeo®, Methylphenidate ER 72mg Tablet, ProCentra®, Relexxii®, and Zenzedi® Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
3. Methylin® Chewable Tablets Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use methylphenidate immediate-release tablets or oral solution must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Mydayis® Approval Criteria:
    a. A covered diagnosis; and
    b. Member must be 13 years of age or older; and
    c. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
5. Qelbree® [Viloxazine Extended-Release (ER) Capsule] Approval Criteria:
    a. An FDA approved diagnosis; and
    b. Member must be 6 years of age or older; and
    c. Previously failed trial(s) (within the last 180 days) with atomoxetine or any 2 Tier-1 or Tier-2 ADHD medications, unless contraindicated, that did not yield adequate results; and
        i. Qelbree® will not require a prior authorization and claims will pay at the point of sale if the member has paid claims for atomoxetine or 2 Tier-1 or Tier-2 ADHD medications within the past 180 days of claims history; and
    d. Member must not be taking a monoamine oxidase inhibitor (MAOI) or have taken an MAOI within the last 14 days; and

e. Member must not be taking sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline) concomitantly with Qelbree®; and
~~f. A quantity limit of 30 capsules per 30 days will apply for the 100mg strengths and 60 capsules per 30 days will apply for the 150mg and 200mg strength.~~
g. Quantity limits will apply based on FDA-approved dosing.

ADHD Medications Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum dose are not covered.
2. Prior authorization is required for all tiers for members older than 20 years of age and for members younger than 5 years of age. All prior authorization requests for members younger than 5 years of age must be reviewed by an Oklahoma Health Care Authority (OHCA)-contracted psychiatrist.
3. For Daytrana® patches, Methylin® oral solution, and Vyvanse® chewable tablet, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
   a. Daytrana® patches are brand preferred. Approval of generic methylphenidate transdermal patches will require a patient-specific, clinically significant reason why brand name Daytrana® cannot be used.
4. Vyvanse® (Lisdexamfetamine) Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:
   a. An FDA approved diagnosis of moderate-to-severe BED; and
   b. Member must be 18 years of age or older; and
   c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and
   d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and
   e. A quantity limit of 30 capsules or chewable tablets per 30 days will apply; and
   f. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.

Idiopathic Hypersomnia (IH) Medications Approval Criteria:

1. Diagnosis of IH meeting the following ICSD-3 (International Classification of Sleep Disorders) criteria:
   a. Daily periods of irresistible need to sleep or daytime lapses into sleep for >3 months; and
   b. Absence of cataplexy; and

c. Multiple sleep latency test (MSLT) results showing 1 of the following:
    i. <2 sleep-onset rapid eye movement (REM) periods (SOREMPs); or
    ii. No SOREMPs if the REM sleep latency on the preceding polysomnogram is ≤15 minutes; and
d. At least 1 of the following:
    i. MSLT showing mean sleep latency ≤8 minutes; or
    ii. Total 24-hour sleep time ≥660 minutes on 24-hour polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in association with a sleep log (averaged over ≥7 days with unrestricted sleep); and
e. Insufficient sleep syndrome has been ruled out; and
f. Hypersomnolence or MSLT findings are not better explained by any other sleep disorder, medical or neurologic disorder, mental disorder, medication use, or substance abuse; and

2. Diagnosis must be confirmed by a sleep specialist; and
3. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
    a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; and
4. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
5. Use of Xyrem® (sodium oxybate) or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with at least 4 of the following, unless contraindicated, that did not yield adequate results:
    a. Tier-1 stimulant; or
    b. Tier-2 stimulant; or
    c. Nuvigil®; or
    d. Provigil®; or
    e. Clarithromycin; and
6. Xyrem® is brand preferred. Requests for generic sodium oxybate will require a patient-specific, clinically significant reason why brand name Xyrem® cannot be used; and
7. Xywav® (calcium/magnesium/potassium/sodium oxybates) additionally requires a patient-specific, clinically significant reason why the member cannot use Xyrem®; and
    a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided.

Narcolepsy Medications Approval Criteria:

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

Recommendation 4: Vote to Prior Authorize Abilify Asimtufii® [Aripiprazole Extended-Release (ER) Injection], Quetiapine 150mg Tablet, and Rykindo® (Risperidone ER Injection) and Update the Approval Criteria for the Atypical Antipsychotic Medications

MOTION CARRIED by unanimous approval.

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

1. The prior authorization of Abilify Asimtufii® (aripiprazole ER injection), quetiapine 150mg tablet, and Rykindo® (risperidone ER injection) and placement into Tier-3; and
2. The placement of Uzedy™ (risperidone ER injection) into Tier-1 based on supplemental rebate participation; and
3. Moving Fanapt® (iloperidone) and Invega® (paliperidone ER tablet) to Tier-2 based on net costs; and
4. Moving Risperdal Consta® (risperidone ER injection) to Tier-3 based on net costs; and
5. Updating the Tier-3 approval criteria to clarify the number of Tier-2 trials needed; and
6. Adding Vraylar® (cariprazine) to the approval criteria for atypical antipsychotics as adjunctive treatment for MDD; and
7. Updating the Lybalvi® (olanzapine/samidorphan) approval criteria to be more consistent with clinical practice; and
8. Updating the Rexulti® (brexpiprazole) approval criteria based on the new FDA approved indication for the treatment of agitation associated with dementia due to Alzheimer's disease.

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole (Abilify®)¥	asenapine (Saphris®)	**aripiprazole IM inj (Abilify Asimtufii®)^∞**
aripiprazole IM inj (Abilify Maintena®)^	**iloperidone (Fanapt®)**	aripiprazole tablets with sensor (Abilify MyCite®)~
aripiprazole lauroxil IM inj (Aristada®)^	lurasidone (Latuda®)	asenapine transdermal system (Secuado®)+
aripiprazole lauroxil IM inj (Aristada Initio®)^	**paliperidone (Invega®)**	brexpiprazole (Rexulti®)
clozapine (Clozaril®)◊		cariprazine (Vraylar®)
olanzapine (Zyprexa®)		clozapine (Fazaclo®)+
paliperidone palmitate IM inj (Invega Hafyera)^		clozapine oral susp (Versacloz®)+
paliperidone palmitate IM inj (Invega Sustenna®)^		~~**iloperidone (Fanapt®)**~~
paliperidone palmitate IM inj (Invega Trinza®)^		lumateperone (Caplyta®)
quetiapine (Seroquel®)		olanzapine/fluoxetine (Symbyax®)+
quetiapine ER (Seroquel XR®)		olanzapine/samidorphan (Lybalvi®)β
risperidone (Risperdal®)		~~**paliperidone (Invega®)**~~
~~**risperidone IM inj (Risperdal Consta®)^**~~		**quetiapine 150mg tablets+**

risperidone ER sub-Q inj (Perseris®)^		**risperidone IM inj (Risperdal Consta®)^∞**
risperidone sub-Q inj (Uzedy™)^		**risperidone IM inj (Rykindo®)^∞**
ziprasidone (Geodon®)		

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
ER = extended-release; IM = intramuscular; inj = injection; sub-Q = subcutaneous; susp = suspension
¥Aripiprazole (Abilify®) orally disintegrating tablet (ODT) is considered a special formulation and requires a patient-specific, clinically significant reason why a special formulation product is needed in place of the regular tablet formulation.
◊Clozapine does not count towards a Tier-1 trial.
^Use of a long-acting injectable (LAI) product may require the member to have been adequately treated with another oral or injectable product prior to use and/or during initiation. The package labeling should be referenced for each individual product.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.
ßUnique criteria applies to Lybalvi® (olanzapine/samidorphan).
∞Unique criteria applies to Tier-3 long-acting injectable (LAI) products.

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
   a. Clozapine does not count towards a Tier-1 trial; and
2. Trials of 2 ~~all~~ oral Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or
3. A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and
4. Use of quetiapine 150mg tablet will require a patient-specific, clinically significant reason why the member cannot use the lower-tiered quetiapine products, which are available without a prior authorization; and
5. Use of Fazaclo® (clozapine orally disintegrating tablet) or Versacloz® (clozapine oral suspension) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
6. Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the oral sublingual tablet formulation. Tier structure rules continue to apply; and
7. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

Approval Criteria for Atypical Antipsychotics as Adjunctive Treatment for Major Depressive Disorder (MDD):

1. Authorization of Rexulti® (brexpiprazole), Symbyax® (olanzapine/fluoxetine), or Vraylar® (cariprazine) for a diagnosis of MDD requires current use of an antidepressant and previous trials with at least 2 other antidepressants from both categories (an SSRI and a dual-acting medication) and aripiprazole tablets that did not yield adequate response; and
2. Tier structure rules still apply.

Long-Acting Injectable (LAI) Products Tier-3 Approval Criteria:

1. Use of Tier-3 LAI products will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the lower-tiered LAI products available for the medication being requested, which are available without a prior authorization.

Lybalvi® (Olanzapine/Samidorphan) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. Member must have a positive clinical response to ~~be stable on~~ olanzapine ~~for at least 14 days~~ and ~~be experiencing significant weight gain~~ gained ≥10% from baseline body weight after starting olanzapine (baseline and current weight must be provided); or
4. A patient specific, clinically significant reason why the member cannot use a lower-tiered product with a lower weight gain profile must be provided; and
5. Member must not be taking opioids or undergoing acute opioid withdrawal; and
6. Initial approvals will be for 3 months. For continuation consideration, documentation that the member is responding well to treatment and any increase in body weight is <10% of baseline body weight (current weight must be provided) ~~has had no excessive weight gain~~ while on therapy must be provided.

Rexulti® (Brexpiprazole) Approval Criteria [Agitation Associated with Dementia Due to Alzheimer's Disease Diagnosis]:

1. An FDA approved indication for the treatment of agitation associated with dementia due to Alzheimer's disease; and
2. Diagnosis must be confirmed by the following:
    a. Mini-Mental State Exam (MMSE) score between 5 and 22; and
    b. Documentation of the member's dementia due to Alzheimer's disease diagnosis [i.e., chart notes consistent with findings of a diagnosis of dementia due to Alzheimer's disease as per the National Institute on Aging and the Alzheimer's Association (NIA-AA)]; and

c. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and
d. Neuropsychiatric Inventory (NPI)/NPI-Nursing Home (NH) agitation/aggression score ≥4; and
e. Exhibiting sufficient agitation behaviors warranting the use of pharmacotherapy; and

3. Prescriber must document a baseline evaluation using the Cohen-Mansfield Agitation Inventory (CMAI) total score; and
4. Prescriber must verify member will be closely monitored due to the risk of dementia-related psychosis; and
5. Initial approvals will be for 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the CMAI total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Recommendation 5: Vote to Prior Authorize Allopurinol 200mg Tablet, Aponvie™ (Aprepitant Injectable Emulsion), Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules], Austedo® XR (Deutetrabenazine ER Tablet), Entadfi® (Finasteride/Tadalafil Capsule), Ermeza™ (Levothyroxine Oral Solution), Furoscix® (Furosemide On-Body Infusor), Iyuzeh™ (Latanoprost Ophthalmic Solution), Jylamvo® (Methotrexate Oral Solution), Primidone 125mg Tablet, Verkazia® (Cyclosporine Ophthalmic Solution), Xaciato™ (Clindamycin Vaginal Gel), and Zolpidem Tartrate 7.5mg Capsule

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of allopurinol 200mg tablets with the following criteria (shown in red):

Allopurinol 200mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use 2 allopurinol 100mg tablets in place of allopurinol 200mg must be provided.

The College of Pharmacy recommends the prior authorization of Aponvie™ (aprepitant injectable emulsion) with the following criteria (shown in red):

Aponvie™ (Aprepitant 32mg/4.4mL Vial) Approval Criteria:

1. An FDA approved indication for the prevention of postoperative nausea and vomiting (PONV); and
2. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives for the prevention of PONV (e.g., ondansetron) must be provided.

The College of Pharmacy recommends the prior authorization of Aspruzyo Sprinkle™ (ranolazine ER granules) with the following criteria (shown in red):

Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules] Approval Criteria:

1. An FDA approved diagnosis of chronic angina; and
2. A patient-specific, clinically significant reason why the member cannot use ranolazine ER tablets must be provided.

The College of Pharmacy recommends the prior authorization of Austedo® XR (deutetrabenazine ER tablet) with criteria similar to Austedo® (deutetrabenazine). The College of Pharmacy also recommends updating the approval criteria for Huntington's disease diagnosis for safety and consistency with the approval criteria for tardive dyskinesia as follows (changes shown in red):

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

1. An FDA approved diagnosis of chorea associated with Huntington's disease; and
2. Deutetrabenazine ~~Austedo®~~ must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. A previous trial of Xenazine® (tetrabenazine) or a patient-specific, clinically significant reason why the member cannot use Xenazine® (tetrabenazine) must be provided; and
4. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting deutetrabenazine therapy and throughout treatment; and
5. Member must not have hepatic impairment; and
6. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
7. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
8. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with deutetrabenazine; and
9. For members who are using deutetrabenazine ~~Austedo®~~ concomitantly with other medications that are known to prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval] the prescriber must agree to monitor the

member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures); and
10. Member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and
11. The daily dose of deutetrabenazine ~~Austedo®~~ must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion) or if they are a known poor CYP2D6 metabolizer; and
12. Female members must not be pregnant or breastfeeding; and
13. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea have decreased, and the member is not showing worsening signs of depression.

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

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
   a. Involuntary athetoid or choreiform movements; and
   b. History of treatment with dopamine receptor blocking agent (DRBA); and
   c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Deutetrabenazine ~~Austedo®~~ must be prescribed by a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
4. Member must not have hepatic impairment; and
5. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
6. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
7. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with deutetrabenazine; and
8. For members who are using deutetrabenazine ~~Austedo®~~ concomitantly with other medications that are known to prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval] the prescriber must agree to monitor the member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures); and
9. Member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and

10. The daily dose of deutetrabenazine ~~Austedo®~~ must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion) or if they are a known poor CYP2D6 metabolizer; and
11. Female members must not be pregnant or breastfeeding; and
12. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
13. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

The College of Pharmacy recommends the prior authorization of Entadfi™ (finasteride/tadalafil capsule) with placement into Tier 3 of the Benign Prostatic Hypertrophy (BPH) Medications Product Based Prior Authorization (PBPA) category with the following additional criteria (shown in red):

Entadfi™ (Finasteride 5mg/Tadalafil 5mg) Approval Criteria:

1. An FDA approved diagnosis of benign prostatic hyperplasia (BPH); and
2. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components (finasteride and tadalafil) must be provided; and
4. A quantity limit of 30 capsules per 30 days will apply; and
5. Maximum treatment duration of 26 weeks will apply.

The College of Pharmacy also recommends making Tirosint® (levothyroxine capsule) brand preferred based on net costs and recommends the prior authorization of Ermeza™ (levothyroxine oral solution) with criteria similar to Thyquidity™, Tirosint®, and Tirosint®-SOL as follows (changes shown in red):

Ermeza™ (Levothyroxine Oral Solution), Thyquidity™ (Levothyroxine Oral Solution), Tirosint® (Levothyroxine Capsule), and Tirosint®-SOL (Levothyroxine Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism; or
   b. Pituitary Thyrotropin (thyroid-stimulating hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer; and
2. A patient-specific, clinically significant reason why the member cannot use all other formulations of levothyroxine must be provided. For the

oral solutions, a reason why the member cannot use the levothyroxine tablet formulation, even when the tablets are crushed, must be provided; and
3. Tirosint® (levothyroxine capsule) is brand preferred. Use of generic levothyroxine capsules will require a patient specific, clinically significant reason why the member cannot use the brand formulation; and
4. Prescriber must verify member has been compliant with levothyroxine tablets at a greatly increased dose for at least 8 weeks; and
5. Prescriber must verify that member has not been able to achieve normal thyroid lab levels despite a greatly increased dose and compliance with levothyroxine tablets.

The College of Pharmacy also recommends the prior authorization of Furoscix® (furosemide on-body infusor) with the following criteria (shown in red):

Furoscix® (Furosemide On-Body Infusor) Approval Criteria:

1. An FDA approved indication for the treatment of congestion due to fluid overload in members with NYHA Class II-III heart failure; and
2. Member must be 18 years of age or older; and
3. Furoscix® must be prescribed by, or in consultation with, a cardiologist or a provider trained in managing acute decompensated heart failure (ADHF); and
4. Member is currently showing signs of fluid overload; and
5. Member has been stable and refractory to at least 1 of the following loop diuretics, at maximally indicated doses:
   a. Bumetanide oral tablets; or
   b. Furosemide oral tablets; or
   c. Torsemide oral tablets; and
6. Prescriber must verify the member will discontinue oral diuretics during the treatment with Furoscix® and will transition back to oral diuretic maintenance therapy when practical; and
7. Prescriber must verify the member is stable and suitable for at-home treatment with Furoscix®, as determined by:
   a. Oxygen saturation ≥90% on exertion; and
   b. Respiratory rate <24 breaths per minute; and
   c. Resting heart rate <100 beats per minute; and
   d. Systolic blood pressure >100mmHg; and
8. Member must have an adequate environment for at-home administration and have been trained on the proper use of Furoscix®; and
9. Member must have a creatinine clearance (CrCl) >30mL/min or an estimated glomerular filtration rate (eGFR) >20mL/min/1.73m^2 and no evidence of acute renal failure; and

10. Member must not have any contraindications for use of Furoscix® including anuria, hepatic cirrhosis, or ascites; and
11. Member must not have acute pulmonary edema or other conditions that require immediate hospitalization; and
12. Approvals will be issued per incident of fluid overload; and
13. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of fluid overload.

The College of Pharmacy also recommends the placement of Iyuzeh™ into the Special PA Tier of the Glaucoma Medications PBPA category with the following criteria:

Glaucoma Medications Special Prior Authorization (PA) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 or Tier-2 medication; or
3. Approvals may be granted if there is a documented adverse effect, drug interaction, or contraindication to all Tier-1 and Tier-2 medications; or
4. Approvals may be granted if there is a unique FDA approved indication not covered by all Tier-1 and Tier-2 medications; and
5. The member must have had a comprehensive, dilated eye exam within the last 365-day period as recommended by the National Institutes of Health; and
6. Approvals will be for the duration of 1 year.

The College of Pharmacy recommends the prior authorization of Jylamvo® (methotrexate oral solution) with the following criteria (shown in red):

Jylamvo® (Methotrexate Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen; or
   b. Mycosis fungoides (cutaneous T-cell lymphoma) as a single agent or as part of a combination chemotherapy regimen; or
   c. Relapsed or refractory non-Hodgkin lymphomas as part of a metronomic combination chemotherapy regimen; or
   d. Rheumatoid arthritis; or
   e. Severe psoriasis; and
2. Member must be 18 years of age or older; and
3. A patient-specific clinically significant reason why the oral tablets and the generic injectable formulation cannot be used must be provided.

The College of Pharmacy recommends the prior authorization of primidone 125mg tablet with the following criteria (shown in red):

Primidone 125mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific clinically significant reason why the member cannot split the 250mg tablet to achieve the 125mg dose must be provided.

The College of Pharmacy recommends the prior authorization of Verkazia® (cyclosporine 0.1% ophthalmic emulsion) with the following criteria (shown in red):

Verkazia® (Cyclosporine 0.1% Ophthalmic Emulsion) Approval Criteria:

1. An FDA approved indication of vernal keratoconjunctivitis (VKC); and
2. Member has had 1 recurrence of VKC in the last year; and
3. Verkazia® must be prescribed by, or in consultation with, an allergist, optometrist, or ophthalmologist (or an advanced care practitioner with a supervising physician who is an allergist, optometrist, or ophthalmologist); and
4. Prescriber must verify that environmental factors (e.g., sun, wind, salt water) have been addressed; and
5. Member must have a trial of a topical mast cell stabilizer, antihistamine, or combination product or a patient-specific, clinically significant reason why those products are not appropriate must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use cyclosporine 0.05% ophthalmic emulsion single-use vials, which are available without a prior authorization, must be provided; and
7. A quantity limit of 120 single-use vials per 30 days will apply.

Additionally, the College of Pharmacy recommends the prior authorization of Xaciato™ (clindamycin vaginal gel) with the following criteria (shown in red):

Xaciato™ (Clindamycin Vaginal Gel) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis; and
2. A patient specific, clinically significant reason why the member cannot use clindamycin 2% vaginal cream, Clindesse® (clindamycin phosphate 2% vaginal cream), and Cleocin® vaginal ovules (clindamycin phosphate 2.5g vaginal suppositories), which are available without a prior authorization, must be provided.

Lastly, the College of Pharmacy recommends the prior authorization of zolpidem 7.5mg capsules with placement into the Special PA Tier of the Insomnia Medications PBPA category based on net cost (changes noted in red in the following PBPA Tier chart):

Insomnia Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
estazolam (ProSom®)	zolpidem CR (Ambien® CR)	lemborexant (Dayvigo®)	daridorexant (Quviviq™)
eszopiclone (Lunesta®)		suvorexant (Belsomra®)	doxepin (Silenor®)

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

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

Recommendation 6: Vote to Prior Authorize Daybue™ (Trofinetide)

MOTION CARRIED by unanimous approval.

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

Daybue™ (Trofinetide) Approval Criteria:

1. Diagnosis of typical Rett syndrome confirmed by all of the following:
    a. Prescriber must verify all clinical diagnostic criteria are met supporting a diagnosis of typical Rett syndrome including:
        i. A period of regression followed by recovery or stabilization; and
        ii. Partial or complete loss of acquired purposeful hand skills; and
        iii. Partial or complete loss of acquired spoken language; and
        iv. Gait abnormalities (impaired/dyspraxic or absence of ability); and
        v. Stereotypic hand movements (e.g., hand wringing/squeezing, clapping/tapping, mouthing, washing/rubbing automatisms); and
        vi. Lack of brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection causing neurological problems; and
        vii. Lack of grossly abnormal psychomotor development in the first 6 months of life; and
    b. Genetic testing documenting a disease-causing mutation in the *MECP2* gene (results of genetic testing must be submitted); and

2. Member must be 2 years of age or older; and
3. Daybue™ must be prescribed by a geneticist, neurologist, or other specialist with expertise in the treatment of Rett syndrome; and
4. Prescriber must agree to counsel members and caregivers on the risks of diarrhea and weight loss associated with Daybue™ and agree to monitor appropriately for these adverse effects; and
5. Prescriber must agree to counsel members and caregivers on proper storage and administration of Daybue™, including the use of a calibrated device for measuring each dose; and
6. Prescriber must verify the member does not have moderate or severe renal impairment; and
7. Member's current weight (kg) taken within the past 3 weeks must be provided on initial and subsequent prior authorization requests to ensure accurate weight-based dosing according to package labeling; and
8. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for a duration of 1 year; and
9. A quantity limit of 3,600mL per 30 days will apply.

Recommendation 7: Vote to Prior Authorize Joenja® (Leniolisib)

MOTION CARRIED by unanimous approval.

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

Joenja® (Leniolisib) Approval Criteria:

1. An FDA approved diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS). Diagnosis must be confirmed by the following:
   a. Genetic testing identifying a documented pathogenic variant in either the *PIK3CD* or *PIK3R1* gene (results of genetic testing must be submitted); and
2. Member must be 12 years of age or older and weigh ≥45kg; and
3. Joenja® must be prescribed by, or in consultation with, an immunologist, geneticist, or a specialist with expertise in treatment of APDS; and
4. Female members of reproductive potential must not be breastfeeding, must have a negative pregnancy test prior to initiation, and must agree to use effective contraception during treatment and for 1 week after the final dose of Joenja®; and
5. Member must not have moderate to severe hepatic impairment (Child-Pugh class B or C); and
6. Member must not be taking any of the following medications concomitantly with Joenja®:

a. Strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); and
b. Strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone); and
c. CYP1A2 metabolized drugs with a narrow therapeutic range (e.g., tizanidine, theophylline); and
d. OATP1B1/3 substrates (e.g., statins, bosentan, glyburide, nateglinide, repaglinide, methotrexate, furosemide); and
e. BCRP transporter substrates (e.g., sulfasalazine, ubrogepant, tenofovir); and

7. Initial approvals will be for the duration of 3 months. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
8. A quantity limit of 60 tablets per 30 days will apply.

Recommendation 8: Vote to Prior Authorize Lyvispah™ (Baclofen Oral Granules) and Norgesic®, Norgesic® Forte, and Orphengesic® Forte (Orphenadrine/Aspirin/Caffeine)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Lyvispah™ (baclofen oral granules) and Norgesic®, Norgesic® Forte, and Orphengesic® Forte (orphenadrine/aspirin/caffeine) and placement into the Special PA Tier of the Muscle Relaxant Medications Product Based Prior Authorization (PBPA) category with the following additional criteria (changes and new criteria shown in red):

Fleqsuvy® 25mg/5mL (Baclofen Oral Suspension), Lyvispah™ (Baclofen Oral Granules), and Ozobax® 5mg/5mL (Baclofen Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and
2. Requests for Fleqsuvy® and Ozobax® will require a patient-specific, clinically significant reason why member cannot use Lyvispah™; and
3. Members older than 10 years of age require a patient-specific, clinically significant reason why the member cannot use baclofen oral tablets, even when tablets are crushed.

Norgesic®, Norgesic® Forte, and Orphengesic® Forte (Orphenadrine/Aspirin/Caffeine) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all lower-tiered products must be provided.

Muscle Relaxant Medications*		
Tier-1	**Tier-2**	**Special PA**
baclofen 10mg, 20mg (Lioresal®)	metaxalone (Skelaxin®)	baclofen 5mg (Lioresal®)
chlorzoxazone 500mg (Parafon Forte®)		**baclofen oral granules (Lyvispah™)**
cyclobenzaprine (Flexeril®)		baclofen 5mg/5mL oral soln (Ozobax®)
methocarbamol (Robaxin®)		baclofen 25mg/5mL oral susp (Fleqsuvy®)
orphenadrine (Norflex®)		carisoprodol 250mg (Soma®)
tizanidine tabs (Zanaflex®)		carisoprodol 350mg (Soma®)
		carisoprodol/ASA
		carisoprodol/ASA/codeine
		chlorzoxazone 375mg, 750mg (Lorzone®)
		cyclobenzaprine 7.5mg tabs (Fexmid®)
		cyclobenzaprine ER caps (Amrix®)
		orphenadrine/ASA/caffeine tabs (Norgesic®, Norgesic® Forte, Orphengesic® Forte)
		tizanidine caps (Zanaflex®)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ASA = aspirin; caps = capsules; ER = extended-release; PA = prior authorization; soln = solution; susp = suspension; tabs = tablets.

Recommendation 9: Vote to Prior Authorize Adstiladrin® (Nadofaragene Firadenovac-vncg) and Elahere™ (Mirvetuximab Soravtansine-gynx) and Update the Approval Criteria for the Genitourinary and Gynecologic Cancer Medications

MOTION CARRIED by unanimous approval.

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Diagnosis of locally advanced or metastatic urothelial cancer; and
2. Used in 1 of the following settings:

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

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

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

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

2. Maintenance Treatment of Advanced Disease:
a. Disease must be in a complete or partial response to primary chemotherapy; and
   i. Used as a single-agent in members with a diagnosis of deleterious or suspected deleterious germline BRCA-mutated (*gBRCAm)* or somatic BRCA-mutated (*sBRCAm*), advanced ovarian cancer; or
   ii. Used in combination with bevacizumab following a primary therapy regimen that included bevacizumab; or
b. Complete or partial response to second-line or greater platinum-based chemotherapy (no mutation required); and
c. A quantity limit based on FDA approved dosing will apply.

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

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

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

a. Diagnosis of ~~advanced or~~ recurrent disease; and
b. Disease must be in a complete or partial response to platinum-based chemotherapy; and
c. Positive for a BRCA mutation; and
d. Used as a single agent.

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

~~**1. Treatment of Advanced Recurrent/Refractory Disease as a Single Agent:**~~
~~a. Diagnosis of recurrent or refractory disease; and~~
~~b. Previous treatment with ≥3 prior lines of chemotherapy (prior chemotherapy regimens should be documented on the prior authorization request); and~~
~~c. Diagnosis is associated with homologous recombination deficiency (HRD) positive status defined by either:~~
~~i. Deleterious or suspected deleterious BRCA mutation; or~~
~~ii. Genomic instability and progression >6 months after response to last platinum-based chemotherapy; and~~
~~d. Used as a single agent; or~~

~~**2. Treatment of Advanced Recurrent/Refractory Disease in Combination with Bevacizumab:**~~
~~a. Used in combination with bevacizumab for platinum-sensitive persistent disease or recurrence; and~~
~~b. Meets 1 of the following:~~
~~i. As immediate treatment for serially rising CA-125 in members who previously received chemotherapy; or~~
~~ii. Evidence of radiographic and/or clinical relapse in members with previous complete remission and relapse ≥6 months after completing prior chemotherapy; or~~

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

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

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

1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with a corticosteroid; and

3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

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

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

Recommendation 10: Annual Review of Colorectal Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Alymsys® (bevacizumab-maly) and Mvasi® (bevacizumab-awwb) approval criteria based on the FDA approval of Vegzelma® (bevacizumab-adcd) and net costs, with the following changes (shown in red):

~~Alymsys® (Bevacizumab-maly) and~~ Mvasi® (Bevacizumab-awwb) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Alymsys® (bevacizumab-maly), Avastin® (bevacizumab), Vegzelma® (bevacizumab-adcd), or Zirabev® (bevacizumab-bvzr), which 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.

Additionally, the College of Pharmacy recommends updating the approval criteria for Stivarga® (regorafenib) based on National Comprehensive Cancer Network (NCCN) Guideline changes in osteosarcoma (shown in red):

Stivarga® (Regorafenib) Approval Criteria [Osteosarcoma Diagnosis]:

1. Used for relapsed or refractory disease; and
2. Used in the second line or greater setting; and
3. Used as a single agent.

Recommendation 11: Annual Review of Allergen Immunotherapies

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for Odactra® (house dust mite allergen extract) and Ragwitek® (short ragweed pollen allergen extract) based on the new FDA approved age expansions (changes shown in red):

Odactra® (House Dust Mite Allergen Extract) Approval Criteria:

1. Member must be ~~18~~ 12 to 65 years of age; and
2. Member must have a positive skin test (labs required) to licensed house dust mite allergen extracts or *in vitro* testing for immunoglobulin E (IgE) antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each; and
    b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each; and
6. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
7. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
8. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
9. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and
10. A quantity limit of 1 tablet daily will apply; and
11. Initial approvals will be for the duration of 6 months of therapy, at which time the prescriber must verify the member is responding well to Odactra® therapy. Additionally, compliance will be evaluated for continued approval.

Ragwitek® (Short Ragweed Pollen Allergen Extract) Approval Criteria:

1. Member must be ~~18~~ 5 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific immunoglobulin E (IgE) antibodies to short ragweed pollen; and
3. Member must not have severe uncontrolled asthma; and

4. Member must have failed conservative attempts to control allergic rhinitis symptoms; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
    b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥12 weeks prior to the start of ragweed pollen season (May 15th) and continue throughout the season; and
7. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 12 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
11. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
12. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist).

Recommendation 12: Annual Review of Testosterone Products and 30-Day Notice to Prior Authorize Kyzatrex® (Testosterone Undecanoate)

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

Recommendation 13: 30-Day Notice to Prior Authorize Vyjuvek™ (Beremagene Geperpavec-svdt)

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

Recommendation 14: Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Leqembi® (Lecanemab-irmb)

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

Recommendation 15: Annual Review of Isturisa® (Osilodrostat) and Recorlev® (Levoketoconazole)

NO ACTION REQUIRED.

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

NO ACTION REQUIRED.

Recommendation 17: Future Business

No live DUR Board meeting scheduled for August 2023. August 2023 will be a packet-only meeting.

NO ACTION REQUIRED.

The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: August 11, 2023

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

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

Subject: DUR Board Recommendations from Packet Meeting on August 9, 2023

Recommendation 1: U.S. Food and Drug Administration (FDA) Safety Alerts

NO ACTION REQUIRED.

Recommendation 2: Annual Review of Various Systemic Antibiotics and 30-Day Notice to Prior Authorize Xacduro® (Sulbactam/Durlobactam)

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

Recommendation 3: Annual Review of Intravenous (IV) Iron Products

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

Recommendation 4: Annual Review of Topical Corticosteroids

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

Recommendation 5: Annual Review of Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Brixadi™ (Buprenorphine Extended-Release Injection), Nalocet® (Oxycodone/Acetaminophen Tablet), and Prolate™ (Oxycodone/ Acetaminophen Tablet)

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

Recommendation 6: 30-Day Notice to Prior Authorize Cuvrior™ (Trientine Tetrahydrochloride)

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

Recommendation 7: Annual Review of Camzyos® (Mavacamten)

NO ACTION REQUIRED.

Recommendation 8: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

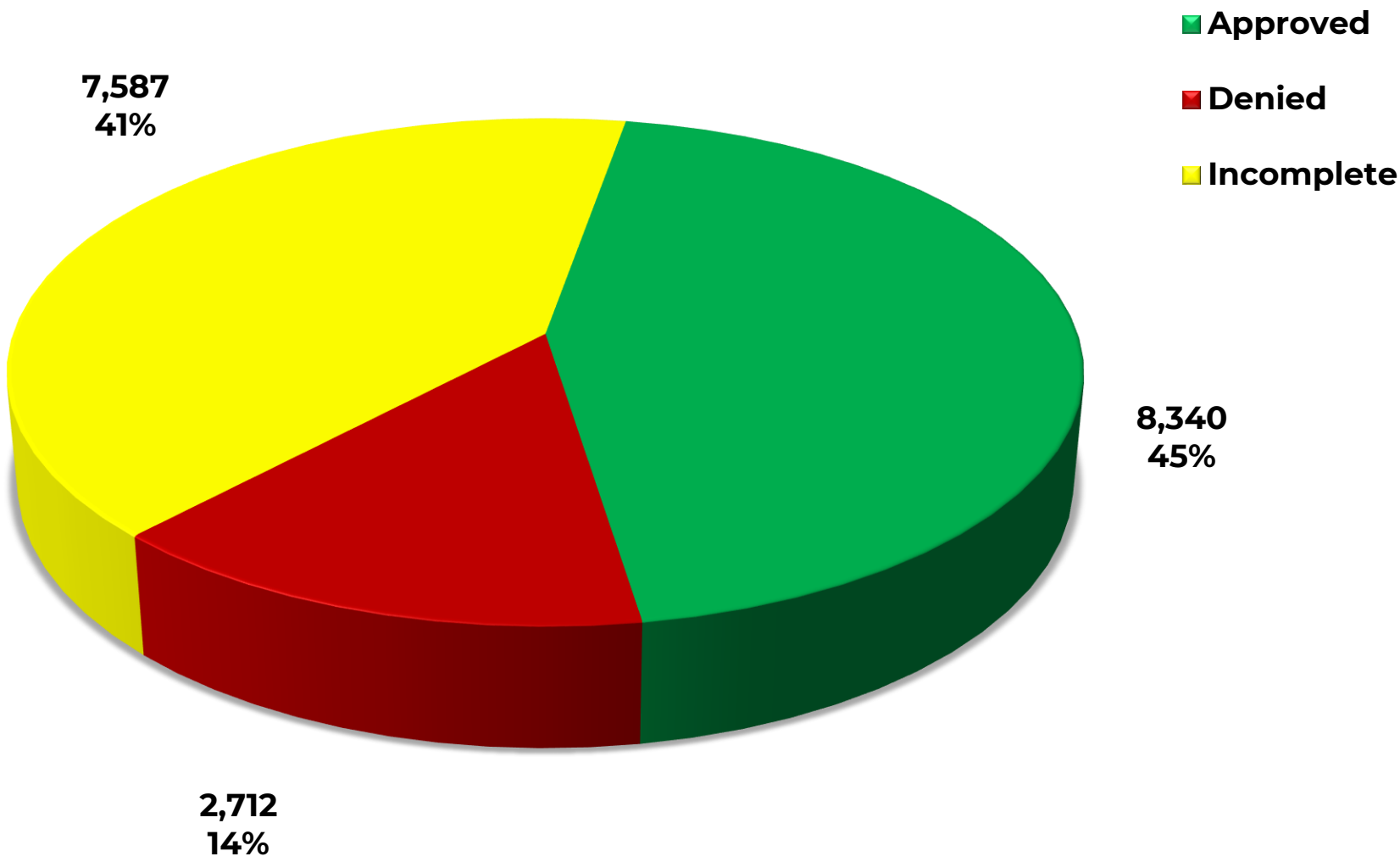
NO ACTION REQUIRED.

Recommendation 9: Future Business

NO ACTION REQUIRED.

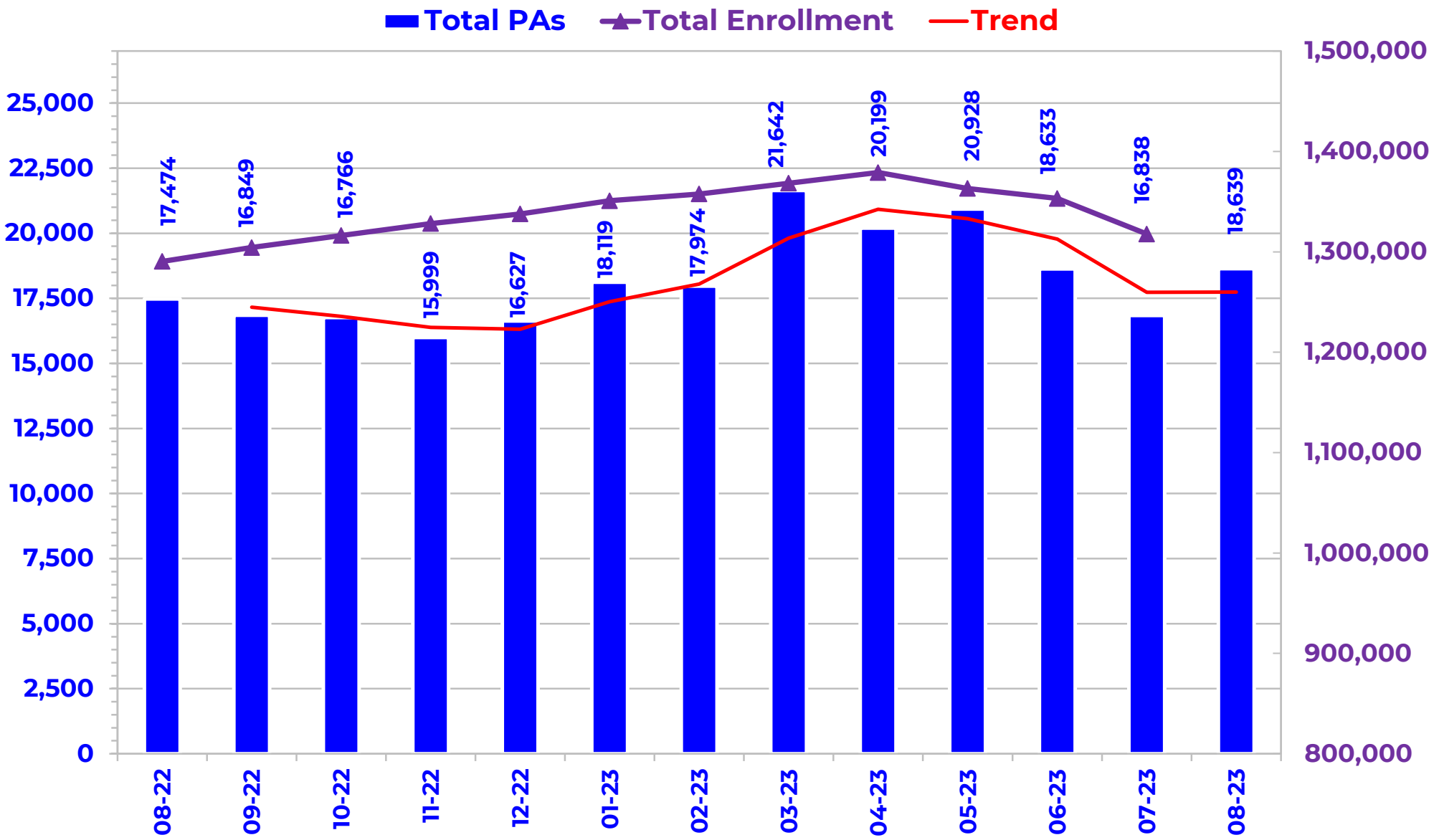
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: AUGUST 2023



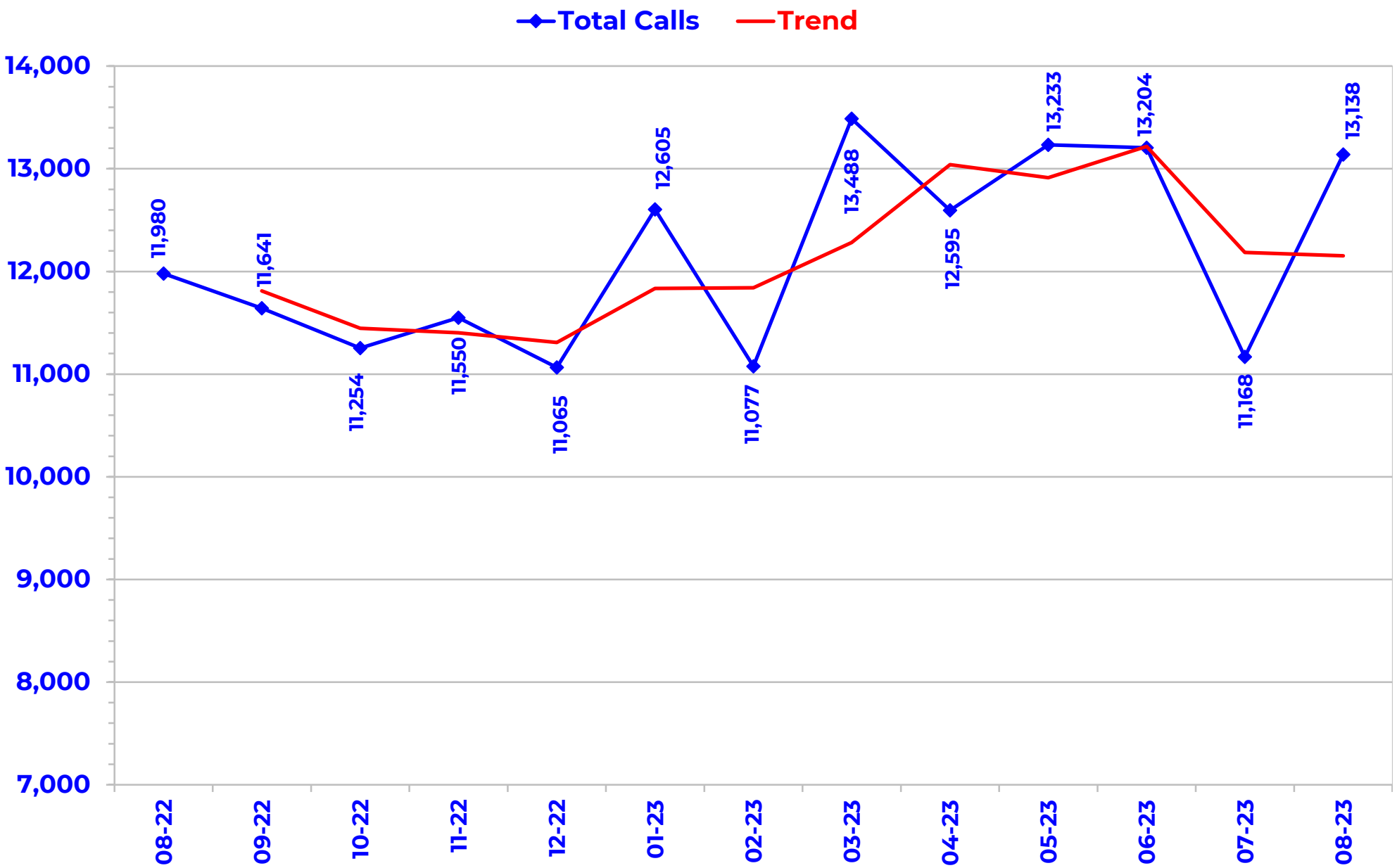
PA totals include approved/denied/incomplete/overrides

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
AUGUST 2022 – AUGUST 2023



Prior Authorization Activity

8/1/2023 Through 8/31/2023

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	208	108	13	87	360
Analgesic - NonNarcotic	15	0	2	13	0
Analgesic, Narcotic	409	172	47	190	130
Angiotensin Receptor Antagonist	17	2	7	8	361
Anti-inflammatory	17	10	0	7	70
Antiasthma	100	36	18	46	238
Antibiotic	66	38	10	18	240
Anticonvulsant	239	118	11	110	312
Antidepressant	522	140	68	314	308
Antidiabetic	2,666	753	709	1,204	358
Antifungal	10	1	1	8	29
Antigout	23	7	1	15	307
Antihemophilic Factor	23	16	0	7	313
Antihistamine	72	24	19	29	351
Antimigraine	642	103	201	338	277
Antineoplastic	328	226	8	94	173
Antiobesity	84	7	60	17	359
Antiparasitic	41	17	3	21	12
Antiparkinsons	12	0	4	8	0
Antiulcers	78	16	11	51	192
Anxiolytic	55	5	6	44	205
Atypical Antipsychotics	814	330	72	412	352
Benign Prostatic Hypertrophy	10	0	5	5	0
Biologics	486	269	55	162	315
Bladder Control	119	19	33	67	360
Blood Thinners	41	6	1	34	315
Botox	83	47	21	15	351
Buprenorphine Medications	130	43	17	70	82
Calcium Channel Blockers	25	4	6	15	270
Cardiovascular	165	76	17	72	342
Chronic Obstructive Pulmonary	387	86	85	216	351
Constipation/Diarrhea Medications	387	82	108	197	205
Contraceptive	73	27	18	28	335
Corticosteroid	27	3	7	17	148
Dermatological	719	258	176	285	228
Diabetic Supplies	648	293	60	295	185
Endocrine & Metabolic Drugs	101	43	14	44	260
Erythropoietin Stimulating Agents	29	17	4	8	113

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Estrogen Derivative	35	4	5	26	352
Fibric Acid Derivatives	10	0	2	8	0
Fibromyalgia	17	0	2	15	0
Fish Oils	29	1	9	19	362
Gastrointestinal Agents	187	49	29	109	239
Genitourinary Agents	13	2	3	8	224
Glaucoma	16	0	4	12	0
Growth Hormones	129	89	14	26	140
Hematopoietic Agents	32	17	5	10	235
Hepatitis C	33	24	4	5	9
HFA Rescue Inhalers	21	1	0	20	361
Insomnia	154	11	33	110	244
Insulin	327	134	22	171	346
Miscellaneous Antibiotics	25	6	3	16	33
Multiple Sclerosis	104	47	7	50	247
Muscle Relaxant	89	9	12	68	122
Nasal Allergy	34	2	11	21	360
Neurological Agents	229	78	50	101	207
Neuromuscular Agents	29	12	5	12	300
NSAIDs	60	2	17	41	269
Ocular Allergy	22	0	7	15	0
Ophthalmic	18	4	4	10	11
Ophthalmic Anti-infectives	32	8	1	23	11
Ophthalmic Corticosteroid	24	2	3	19	226
Osteoporosis	50	19	11	20	341
Other*	465	139	60	266	266
Otic Antibiotic	47	5	10	32	11
Pediculicide	22	2	3	17	361
Respiratory Agents	37	23	1	13	277
Smoking Cessation	13	1	3	9	23
Statins	67	23	18	26	175
Stimulant	2,885	1,951	127	807	350
Testosterone	232	48	62	122	349
Thyroid	35	11	6	18	335
Topical Antifungal	54	8	11	35	195
Topical Corticosteroids	46	1	14	31	361
Vitamin	188	40	102	46	107
Pharmacotherapy	104	95	0	9	276
Emergency PAs	0	0	0	0	
Total	**15,785**	**6,270**	**2,578**	**6,937**	

* 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	68	39	6	23	165
Compound	1	1	0	0	57
Concurrent Opioid	1	1	0	0	8
Cumulative Early Refill	2	2	0	0	181
Diabetic Supplies	1	1	0	0	359
Dosage Change	1	1	0	0	87
Dosage Change	509	460	2	47	18
High Dose	3	3	0	0	357
IHS-Brand	1	1	0	0	361
Ingredient Duplication	6	4	0	2	53
Lost/Broken Rx	173	147	7	19	18
MAT Override	354	273	9	72	82
NDC vs Age	363	248	37	78	261
NDC vs Sex	8	7	0	1	214
Nursing Home Issue	83	69	2	12	14
Opioid MME Limit	150	40	12	98	124
Opioid Quantity	67	48	3	16	162
Other	62	43	7	12	18
Prescriber Temp Unlock	1	0	0	1	0
Quantity vs. Days Supply	835	575	37	223	255
STBS/STBSM	14	9	3	2	50
Step Therapy Exception	27	14	5	8	360
Stolen	13	10	2	1	21
Third Brand Request	111	74	2	35	55
Overrides Total	**2,854**	**2,070**	**134**	**650**	
Total Regular PAs + Overrides	**18,639**	**8,340**	**2,712**	**7,587**	

Denial Reasons	
Unable to verify required trials.	6,443
Does not meet established criteria.	2,738
Lack required information to process request.	1,101
Other PA Activity	
Duplicate Requests	1,667
Letters	47,643
No Process	5
Changes to existing PAs	1,500
Helpdesk Initiated Prior Authorizations	1,242
PAs Missing Information	1,560

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

Nonalcoholic Fatty Liver Disease (NAFLD) Update

Oklahoma Health Care Authority
September 2023

Introduction[1,2,3,4]

Nonalcoholic fatty liver disease (NAFLD) is a common cause of chronic liver disease and is closely associated with obesity, insulin resistance, type 2 diabetes mellitus (T2DM), hypertension (HTN), and atherogenic dyslipidemia. NAFLD occurs when there is evidence of hepatic steatosis on imaging or histology in the absence of secondary causes (e.g., significant alcohol consumption, chronic use of steatogenic medications, certain genetic disorders). NAFLD can be further classified as either nonalcoholic fatty liver (NAFL) or nonalcoholic steatohepatitis (NASH). NAFL is defined by hepatic steatosis present in ≥5% of hepatocytes without evidence of hepatocellular injury (e.g., hepatocyte ballooning). NASH is a more aggressive form of NAFLD defined by hepatic steatosis present in ≥5% of hepatocytes with the presence of inflammation and hepatocyte injury, with or without fibrosis. NASH can further progress to advanced liver fibrosis, cirrhosis, or hepatocellular carcinoma and is currently the second most common cause of hepatocellular carcinoma, after hepatitis C, among patients waiting for liver transplantation in the United States.

NAFLD is estimated to affect approximately 25% of people globally, of which 12-14% have NASH. The prevalence is even higher among patients with T2DM and obesity, with approximately 25-30% of obese people and 30-40% of people with T2DM having NASH. The prevalence of either form of NAFLD may be as high as 75% among people with T2DM. Despite this, fewer than 5% of patients with NAFLD are aware of their liver disease and many remain asymptomatic even with advanced liver disease related to NAFLD.

T2DM has been identified as a major driver of disease progression in NAFLD and may result in faster disease progression. Approximately one third of people with NAFLD will progress to NASH, 20% of whom will develop liver fibrosis and have a high risk of extrahepatic complications, cirrhosis, and liver failure. All stages of NAFLD are associated with an increased overall risk of mortality and the risk of mortality increases with increased severity of liver disease. Mortality in NAFLD is due primarily to extrahepatic cancer, cirrhosis, cardiovascular disease (CVD), and hepatocellular carcinoma.

Treatment of NAFLD involves treating the liver disease itself as well as the associated co-morbidities, including obesity, T2DM, HTN, and hyperlipidemia.

There are currently no medications approved by the U.S. Food and Drug Administration (FDA) for the treatment of NAFLD or NASH.

Market News and Updates[5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21]

Recent U.S. FDA Action:

- **June 2023:** The FDA issued a Complete Response Letter (CRL) to Intercept Pharmaceuticals for obeticholic acid for the treatment of pre-cirrhotic fibrosis due to NASH. This is the second time the FDA has declined to approve obeticholic acid for NASH, having previously issued a CRL in 2019 for the same indication. The FDA advisory committee voted to defer approval of the drug until additional clinical outcomes data was available, noting that there was uncertainty regarding how the observed changes in surrogate outcomes would translate into changes in clinical outcomes. Additionally, an increased risk of drug-induced liver injury was observed, suggesting that the benefits of treatment may not outweigh the potential risks in this patient population. As a result of the CRL, Intercept announced that they have decided to discontinue all NASH-related investment. Obeticholic acid was previously approved by the FDA in 2016 for the treatment of primary biliary cholangitis and is marketed under the brand name Ocaliva® for that indication.

Guideline Update(s):

- **May 2023:** The American Association for the Study of Liver Diseases (AASLD) published updated guidance on the clinical assessment and management of NAFLD. The AASLD states that a healthy diet and regular exercise form the foundation of treatment for the vast majority of those with NAFLD. Some key guidance statements regarding the nonpharmacologic management of NAFLD include:
  - Patients with NAFLD who are overweight or obese should be prescribed a diet that leads to a caloric deficit. When possible, diets with limited carbohydrates and saturated fat and enriched with high fiber and unsaturated fats (e.g., Mediterranean diet) should be encouraged due to their additional CV benefits.
  - Patients with NAFLD should be strongly encouraged to increase their activity level to the extent possible. Individualized prescriptive exercise recommendations may increase sustainability and have benefits independent of weight loss.
  - Bariatric surgery should be considered as a therapeutic option in patients who meet criteria for metabolic weight loss surgery, as it effectively resolves NAFLD or NASH in the majority of patients without cirrhosis and reduces mortality from CVD and malignancy.

  Additionally, the AASLD provided some guidance statements regarding pharmacologic management of NAFLD, including:

- Semaglutide can be considered for its approved indications (T2DM/obesity) in patients with NASH, as it confers a CV benefit and improves NASH.
- Pioglitazone improves NASH and can be considered for patients with NASH and with T2DM.
- Vitamin E can be considered in select individuals as it improves NASH in some patients without diabetes.

News:

- **June 2023:** The results of a modified Delhi consensus process have been published regarding new nomenclature for NAFLD. A total of 236 participants from 56 countries were involved in the process, which was organized and led by the AASLD and the European Association for Study of the Liver (EASL) in collaboration with the Asociación Latinoamericana para el Estudio del Hígado (ALEH). Many participants felt the new nomenclature was necessary due to the term "nonalcoholic" failing to identify the etiology of the disease, as well as concerns that the term "fatty" is considered stigmatizing by some. The new nomenclature includes steatotic liver disease (SLD) as an umbrella term that includes metabolic dysfunction-associated steatotic liver disease (MASLD) and a new category, MetALD, to describe patients with MASLD who consume greater amounts of alcohol (140-350g/week for females and 210-420g/week for males). MASLD was considered the replacement term for NAFLD. Additionally, metabolic dysfunction-associated steatohepatitis (MASH) was considered the replacement term for NASH. Diagnostic criteria were also updated to require at least 1 cardiometabolic risk factor in addition to hepatic steatosis to satisfy the diagnosis of MASLD. Patients with steatosis but without 1 of the cardiometabolic risk factors will be considered to have cryptogenic SLD according to the new nomenclature.

Pipeline: There is an active pipeline of candidate therapeutic agents for the treatment of NAFLD and NASH. These therapeutic candidates target a variety of mechanisms involved in the pathophysiology of NAFLD, including lipid carbohydrate metabolism, lipotoxicity and cell death, inflammation, and fibrosis. Some pipeline candidates in Phase 3 development for NAFLD include:

- **Belapectin:** Galectin Therapeutics is developing belapectin for the treatment of advanced fibrosis or cirrhosis in NASH. Belapectin is a complex polymer of galacturonic acid, galactose, arabinose, rhamnose, and smaller amounts of other sugars. Belapectin binds to and inhibits galectin-3, which is a protein critical to the pathogenesis of NASH and fibrosis. The Phase 2b/3 NAVIGATE study was initiated in June 2020 and will evaluate the safety and efficacy of belapectin in adult patients with

liver cirrhosis due to NASH, with the primary efficacy endpoint of preventing esophageal varices in these patients with advanced disease. Randomization has been completed for 357 patients as of February 2023, and interim data analysis is expected in the fourth quarter of 2024.

- **Lanifibranor:** Inventiva is developing lanifibranor for the treatment of NASH. Lanifibranor is an oral small molecule agonist of peroxisome proliferator-activated receptor (PPAR) with the ability to activate all 3 isoforms of PPAR, including PPARα, PPARδ, and PPARγ, resulting in anti-fibrotic, anti-inflammatory, and beneficial metabolic changes in the body. The Phase 3 NaTiV3 study was initiated in September 2021 and will evaluate the safety and efficacy of lanifibranor in adults with biopsy-proven non-cirrhotic NASH and F2/F3 stage liver fibrosis, with the primary efficacy outcome being the resolution of NASH and improvement in fibrosis at week 72. In January 2023, Inventiva announced changes to the clinical development program for lanifibranor which will potentially allow for a New Drug Application (NDA) to be submitted for accelerated approval to the FDA. The first visit for the last patient to be enrolled into the NaTiV3 study is expected by the end of 2023.
- **Resmetirom:** Madrigal Pharmaceuticals is developing resmetirom for the treatment of NASH. Resmetirom is an oral thyroid hormone receptor (THR) β-selective agonist. Resmetirom targets the underlying causes of NASH by reducing hepatic steatosis, inflammation, hepatocyte ballooning, and fibrosis. The Phase 3 MAESTRO-NASH and MAESTRO-NAFLD-1 studies are ongoing to evaluate the safety and efficacy of resmetirom both in patients with biopsy-proven NASH (in MAESTRO-NASH) and in patients with NAFLD with presumed NASH (in MAESTRO-NAFLD-1). In July 2023, Madrigal Pharmaceuticals announced they have completed their submission of an NDA for resmetirom for the treatment of adults with NASH with liver fibrosis. The company is seeking accelerated approval for resmetirom, but no Prescription Drug User Fee Act (PDUFA) date has been announced.
- **Semaglutide:** Novo Nordisk is developing semaglutide for the treatment of NASH. Semaglutide is a GLP-1 receptor agonist that was previously FDA approved in 2017 for the treatment of T2DM and in 2021 for obesity. The Phase 3 ESSENCE study is ongoing to evaluate the safety and efficacy of semaglutide for the treatment of adult patients with biopsy-proven NASH without cirrhosis. The primary efficacy endpoints will evaluate the resolution of steatohepatitis (with no worsening of liver fibrosis) and improvement in fibrosis (with no worsening of steatohepatitis) through week 72 of treatment in part 1 of the study. In part 2 of the study, the primary efficacy endpoint will evaluate the time to first liver-related clinical event over 240 weeks of

treatment. In June 2023, the results of a Phase 2 study in patients with NASH-related cirrhosis were published. The study did not demonstrate an improvement in liver fibrosis or NASH resolution in cirrhotic patients treated with semaglutide compared to patients who received placebo after 48 weeks of treatment.

SoonerCare Impact

The International Classification of Diseases, Tenth Revision (ICD-10) includes diagnosis codes K76.0 [Fatty (change of) liver, not elsewhere classified] for reporting NAFLD and K75.81 [Nonalcoholic steatohepatitis (NASH)] for reporting NASH. During fiscal year 2023 (07/01/2022 to 06/30/2023), compared to fiscal year 2022 (07/01/2021 to 06/30/2022), the number of members with a reported diagnosis of NAFLD or NASH increased in both adult and pediatric members. Additionally, the number of members utilizing anti-diabetic medications has increased. Because T2DM has a significant impact on disease progression in NAFLD, the high prevalence of T2DM in Oklahoma suggests that the number of SoonerCare members with NAFLD or NASH is likely to continue to increase. The following table shows a comparison of the number of unique members with a reported NAFLD or NASH diagnosis and the number of unique members with paid pharmacy claims for anti-diabetic medications (excluding insulin) during fiscal year 2023 compared to fiscal year 2022.

	FY 2022	FY 2023	%
	Total Unique Members		Increase
NAFLD diagnosis reported (all ages)	9,917	12,366	24.69%
NAFLD diagnosis reported (0-20 years of age)	1,146	1,250	9.08%
NASH diagnosis reported (all ages)	1,022	1,289	26.13%
NASH diagnosis reported (0-20 years of age)	96	107	11.46%
NAFLD or NASH diagnosis reported (all ages)	10,564	13,171	24.68%
Use of anti-diabetic medications (non-insulin)	26,662	35,800	34.27%

FY = fiscal year; NAFLD = nonalcoholic fatty liver disease; NASH = nonalcoholic steatohepatitis
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Conclusion

The number of SoonerCare members with a reported diagnosis of NAFLD or NASH appears to be increasing, although there are still no FDA approved medications to treat these conditions. The observed increases may be due to actual increased incidence but may also be due in part to increased enrollment in the Medicaid expansion population or increased awareness and screening due to recently published clinical guidelines. The College of Pharmacy will continue to review the number of members with NAFLD or NASH and will continue to monitor the drug development pipeline, clinical practice guidelines, and any future FDA approvals for NAFLD or NASH.

[1] National Institute of Diabetes and Digestive and Kidney Diseases. Nonalcoholic Fatty Liver Disease (NAFLD) & NASH: Definition & Facts of NAFLD and NASH. Available online at: https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash/definition-facts. Last revised 04/2021. Last accessed 08/14/2023.
[2] Chalasani N, Younossi Z, Lavine JE, et al. The Diagnosis and Management of Non-Alcoholic Fatty Liver Disease: Practice Guideline by the American Association for the Study of Liver Diseases, American College of Gastroenterology, and the American Gastroenterological Association. *Hepatology* 2012; 55(6):2005-23.
[3] Chalasani N, Younossi Z, Lavine JE, et al. The Diagnosis and Management of Nonalcoholic Fatty Liver Disease: Practice Guidance from the American Association for the Study of Liver Diseases. *Hepatology* 2018; 67(1):328-357.
[4] Cusi K, Isaacs S, Barb D, et al. American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical Settings: Co-Sponsored by the American Association for the Study of Liver Diseases (AASLD). *Endocr Pract* 2022; 28(5):528-562.
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Appendix C

Vote to Prior Authorize Leqembi™ (Lecanemab-irmb) and Update the Approval Criteria for the Alzheimer's Disease Medications

Oklahoma Health Care Authority
September 2023

Market News and Updates[1,2]

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

- **January 2023:** The FDA approved Leqembi™ (lecanemab-irmb) under the Accelerated Approval Pathway for the treatment of Alzheimer's disease. Leqembi™ is a monoclonal antibody that is directed against soluble and insoluble forms of amyloid beta plaques. The approval was based on Phase 2 data showing that Leqembi™ reduced the accumulation of amyloid beta plaques.
- **July 2023:** The FDA granted traditional approval to Leqembi™ for the treatment of Alzheimer's disease in adults by reducing amyloid plaques in the brain. Leqembi™ is the first amyloid beta-directed antibody to receive traditional FDA approval. Leqembi™ is still indicated in those with mild cognitive impairment or mild dementia stage of Alzheimer's disease. There is no safety or efficacy data on initiating treatment earlier or in later stages of disease per the package labeling.

Leqembi™ (Lecanemab-irmb) Product Summary[3]

Therapeutic Class: Amyloid-beta directed monoclonal antibody

Indication(s): Treatment of Alzheimer's disease in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

- There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied.

How Supplied: 200mg/2mL or 500mg/5mL single dose vials

Dosing and Administration:

- The presence of amyloid beta pathology should be confirmed prior to initiating treatment.
- The recommended dosage is 10mg/kg via intravenous (IV) infusion over approximately 1 hour, once every 2 weeks.

- A recent (within 1 year) brain MRI should be obtained prior to initiating treatment to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA).
- An MRI prior to the 5th, 7th, and 14th infusions should be obtained. If radiographically observed ARIA occurs, treatment recommendations are based on type, severity, and presence of symptoms.
- Refer to the full Leqembi™ *Prescribing Information* for the recommended titration and recommendations for patients with ARIA occurrence.

Cost Comparison:

Product	Cost Per mL	Cost Per Month‡	Cost Per Year‡
Leqembi™ (lecanemab-irmb) SDV	**$127.41**	**$2,038.56⁺**	**$26,501.28⁺**
Aduhelm® (aducanumab-avwa) SDV	$282.00	$2,538.00*	$32,994.00*

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
‡ Cost per month and cost per year based on a member weighing 80kg.
⁺Leqembi™ cost is based on use of (4) 200mg/2mL single dose vials for each dose of 10mg/kg every 2 weeks.
*Aduhelm® cost is based on use of (3) 300mg/3mL single dose vials for each dose of 10mg/kg every 4 weeks.
SDV = single dose vial

Recommendations

The College of Pharmacy recommends the prior authorization of Leqembi™ (lecanemab-irmb) with the following criteria (shown in red):

Leqembi™ (Lecanemab-irmb) Approval Criteria:

1. An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:
   a. Mini-Mental State Exam (MMSE) score between 22 and 30; or
   b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5 or 1; or
   c. Montreal Cognitive Assessment (MoCA) score ≥19; or
   d. Quick Dementia Rating System (QDRS) score ≤5; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Leqembi™ must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and

5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE ε4 status has been completed if appropriate; and
7. Member must not be taking anticoagulant or antiplatelet agents except for aspirin or clopidogrel, and the prescriber must attest that the increased safety risks for developing ARIA with the concomitant use have been discussed and are acceptable to the member prior to initiating Leqembi™; and
8. Member must not have had a stroke, transient ischemic attack (TIA), or unexplained loss of consciousness in the past year; and
9. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
10. Member must not have risk factors for intracerebral hemorrhage, including the following:
    a. Prior cerebral hemorrhage >1cm in greatest diameter; or
    b. >4 microhemorrhages; or
    c. An area of superficial siderosis; or
    d. Evidence of vasogenic edema; or
    e. Evidence of cerebral contusion, aneurysms, vascular malformations, or infective lesions; or
    f. Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Leqembi™ and prior to the 5th, 7th, and 14th infusions; and
12. Prescriber must confirm that the member will be monitored for ARIA during the first 14 weeks and throughout treatment with Leqembi™; and
13. If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation confirming resolution of symptoms, if present, and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H) have been completed; and
14. Leqembi™ must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration; and

    a. Leqembi™ must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and
15. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
16. Initial approvals will be for 6 months. Confirmation that MRIs have been completed and were acceptable to the provider prior to the 5th and 7th infusions is required for continuation; and
17. Subsequent approvals will be for 6 months, and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy for each subsequent approval; and
18. Approval quantities will be dependent on the member's weight and dosing based on package labeling; and
19. The maximum dose approvable is 10mg/kg per 14 days; and
20. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

The College of Pharmacy also recommends updating the Aduhelm® (aducanumab-avwa) approval criteria based on net costs and to be consistent with the approval criteria for Leqembi™ (lecanemab-irmb) (changes shown in red):

Aduhelm® (Aducanumab-avwa) Approval Criteria:

1. An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:
    a. Mini-Mental State Exam (MMSE) score between 24 and 30; or
    b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5; or
    c. Montreal Cognitive Assessment (MoCA) score ≥19; or
    d. Quick Dementia Rating System (QDRS) score ≤5; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Aduhelm® must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and

5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE ε4 status has been completed if appropriate; and
7. Member must not be taking anticoagulant or antiplatelet agents except for aspirin 325mg per day or less, and the prescriber must attest that the increased safety risks for developing ARIA with the concomitant use have been discussed and are acceptable to the member prior to initiating Aduhelm®; and
8. Member must not have had a stroke or transient ischemic attack (TIA) or unexplained loss of consciousness in the past year; and
9. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
10. Member must not have any pre-treatment localized superficial siderosis, ≥10 brain microhemorrhages, or a brain hemorrhage >1cm within 1 year of treatment initiation as safety with Aduhelm® has not been established in patients with these conditions; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Aduhelm® and prior to the 7th infusion (1st dose of 10mg/kg) and 12th infusion (6th dose of 10mg/kg); and
12. The prescriber must confirm that the member will be monitored for ARIA during the first 8 doses of treatment with Aduhelm®, particularly during titration, and also throughout treatment; and
13. If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H); and
14. Aduhelm® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration; and
    a. Aduhelm® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and
~~15. Aduhelm® must be administered by a health care provider; and~~
~~16. Aduhelm® must be shipped via cold chain supply shipping and stored in a refrigerator; and~~
17. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and

18. A patient-specific, clinically significant reason why the member cannot use Leqembi™ (lecanemab-irmb) must be provided; and
19. Initial approvals will be for 6 months. Confirmation that MRI has been completed and is acceptable to the provider prior to 7th infusion is required for continuation; and
20. Subsequent approvals will be for 6 months and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy; and
21. Approval quantities will be dependent on the member's weight and dosing based on package labeling; and
22. The maximum dose approvable is 10mg/kg per 28 days; and
23. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

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[1] Eisai Inc. FDA Approves Leqembi™ (Lecanemab-irmb) Under the Accelerated Approval Pathway for the Treatment of Alzheimer's Disease. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/fda-approves-leqembi-lecanemab-irmb-under-the-accelerated-approval-pathway-for-the-treatment-of-alzheimers-disease-301715691.html. Issued 01/06/2023. Last accessed 08/16/2023.

[2] U.S. Food and Drug Administration (FDA). FDA Converts Novel Alzheimer's Disease Treatment to Traditional Approval. Available online at: https://www.fda.gov/news-events/press-announcements/fda-converts-novel-alzheimers-disease-treatment-traditional-approval. Issued 07/06/2023. Last accessed 08/16/2023.

[3] Leqembi™ (Lecanemab-irmb) Prescribing Information. Eisai Inc. Available online at: https://www.leqembi.com/-/media/Files/Leqembi/Prescribing-Information.pdf. Last revised 01/2023. Last accessed 08/16/2023.

Appendix D

Vote to Prior Authorize Vyjuvek™ (Beremagene Geperpavec-svdt)

Oklahoma Health Care Authority
September 2023

Market News and Updates[1]

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

- **May 2023:** The FDA approved Vyjuvek™ (beremagene geperpavec-svdt) to treat wounds for patients 6 months of age or older with dystrophic epidermolysis bullosa (DEB). Vyjuvek™ is a topical, redosable gene therapy that delivers functional copies of the human *collagen type VII alpha 1 chain (COL7A1)* gene which helps promote wound healing by restoring the skin's ability to make type VII collagen (COL7) protein and form anchoring fibrils. The FDA approved Vyjuvek™ based on 2 clinical trials, GEM-1/2 and GEM-3, which showed improved wound healing with Vyjuvek™ versus placebo both in patients with autosomal recessive DEB (RDEB) and autosomal dominant DEB (DDEB).

Vyjuvek™ (Beremagene Geperpavec-svdt) Product Summary[2]

Therapeutic Class: Herpes-simplex virus type 1 (HSV-1) vector-based gene therapy

Indication(s): Treatment of wounds in patients 6 months of age and older with DEB with mutation(s) in the *COL7A1* gene

How Supplied:

- One carton of Vyjuvek™ contains the following:
  - One Vyjuvek™ biological suspension single dose vial (SDV) which is supplied as a 1mL extractable volume at a nominal concentration of $5x10^9$ plaque forming units (PFU)/mL.
  - One excipient gel vial which is supplied as a 1.5mL fill volume in a separate single use vial.
- The mixture of Vyjuvek™ biological suspension and excipient gel is referred to as Vyjuvek™ gel.
- One carton makes 4 administration syringes of 0.4mL of Vyjuvek™ gel for a total of 1.6mL.

Dosing and Administration

- Vyjuvek™ gel should be prepared at the pharmacy for immediate use within 8 hours of application. If immediate use is not possible,

administration syringes can be stored for up to 48 hours in the refrigerator [2° to 8°C (35.6° to 46.4°F)].

- The maximum recommended dose of Vyjuvek™ gel is based on age (see Figure 1).
- Vyjuvek™ gel is applied topically to wounds once weekly.
- Only a health care professional (HCP) should apply Vyjuvek™ gel either at a health care professional setting (e.g., clinic) or the home setting.
- It may not be possible to apply Vyjuvek™ gel to all the wounds at each treatment visit.
- Vyjuvek™ should be applied to wounds until they are closed before selecting new wound(s) to treat. The provider should prioritize weekly treatment to previously treated wounds if they re-open.
- Vyjuvek™ should be applied to the selected wound(s) in droplets spaced evenly within the wound, approximately 1cm-by-1cm apart.
- Figure 2 provides a reference on dose per approximate size of the wound.

Figure 1: Maximum Weekly Dose by Age

Age Range	Maximum Weekly Dose (PFU)	Maximum Weekly Volume* (mL)
6 months to <3 years	$1.6x10^9$	0.8
≥3 years	$3.2x10^9$	1.6

*Maximum weekly volume is the volume after mixing Vyjuvek™ biological suspension with excipient gel.
mL = milliliter; PFU = plaque forming units

Figure 2: Dose by Wound Size

Wound Area (cm^2)	Dose (PFU)	Volume (mL)
<20	$4x10^8$	0.2
20 to <40	$8x10^8$	0.4
40 to 60	$1.2x10^8$	0.6

For wound area >60cm^2, it is recommended to calculate the total dose based on Figure 2 until the maximum weekly dose in Figure 1 is reached.
mL = milliliter; PFU = plaque forming units

Cost: The Wholesale Acquisition Cost (WAC) of Vyjuvek™ is $24,250 per carton, which supplies the FDA maximum weekly dose of 1.6mL. This results in an estimated annual cost of $1,261,000 for the FDA recommended weekly dosing, which would require one carton per week regardless of dose.

Recommendations

The College of Pharmacy recommends the prior authorization of Vyjuvek™ (beremagene geperpavec-svdt) with the following criteria (shown in red):

Vyjuvek™ (Beremagene Geperpavec-svdt) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB); and
2. Diagnosis must be confirmed by a mutation in the collagen type VII alpha 1 chain (*COL7A1*) gene (results of genetic testing must be submitted); and
3. Vyjuvek™ must be prescribed by a dermatologist or other specialist with expertise in the treatment of DEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB); and
4. Pharmacy or prescriber must confirm Vyjuvek™ will be prepared by a pharmacist trained in the preparation of Vyjuvek™ prior to administration and must confirm Vyjuvek™ will be shipped to the administering provider via cold chain supply and adhere to the storage and handling requirements in the Vyjuvek™ package labeling; and
5. Vyjuvek™ must be administered by a health care professional (HCP) trained in the administration of Vyjuvek™. Approvals will not be granted for self-administration. Prior authorization requests must indicate who will administer Vyjuvek™ and in what setting (i.e., treatment facility, HCP office, home health); and
6. Prescriber must attest that Vyjuvek™ gel will be dosed per package labeling and applied to the same wound(s) until closed before selecting new wound(s) to treat, and that they will prioritize weekly treatment to previously treated wounds if they re-open; and
7. Prescriber must attest member or caregiver(s) have been counseled on the precautions prior to and during treatment with Vyjuvek™ that are listed in the package labeling, including avoiding direct contact with treated wounds and dressings for 24 hours following administration; and
8. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy; and
9. A maximum approval quantity of 1 carton (2.5mL) per week or 4 cartons (10mL) per 28 days will apply; and
10. Initial approvals will be for 3 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is responding well to treatment as indicated by the presence of wound healing.

[1] Krystal Biotech, Inc. Krystal Biotech Receives FDA Approval for the First-Ever Redosable Gene Therapy, Vyjuvek™ (Beremagene Geperpavec-svdt) for the Treatment of Dystrophic Epidermolysis Bullosa. Available online at: https://ir.krystalbio.com/news-releases/news-release-details/krystal-biotech-receives-fda-approval-first-ever-redosable-gene. Issued 05/19/2023. Last accessed 08/09/2023.
[2] Vyjuvek™ Prescribing Information. Krystal Biotech, Inc. Available online at: https://www.fda.gov/media/168350/download. Last revised 05/2023. Last accessed 08/09/2023.

Appendix E

Vote to Prior Authorize Kyzatrex® (Testosterone Undecanoate) and Update the Approval Criteria for the Testosterone Products

Oklahoma Health Care Authority
September 2023

Market News and Updates[1]

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

- **July 2022:** The FDA approved Kyzatrex® (testosterone undecanoate), an oral testosterone replacement therapy, for conditions associated with a deficiency or absence of endogenous testosterone, or hypogonadism, in adult males.

Kyzatrex® (Testosterone Undecanoate) Product Summary[2]

Therapeutic Class: Androgen

Indication(s): For testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone

- Limitation(s) of Use: Safety and efficacy in males younger than 18 years of age have not been established.

How Supplied: 100mg, 150mg, and 200mg oral capsules

Dosing and Administration:

- Recommended starting dose is 200mg twice daily with food
- Serum testosterone should be measured 7 days after initiation (or after dosage adjustment), and dose should be adjusted as necessary
- Minimum recommended dose is 100mg once daily in the morning
- Maximum recommended dose is 400mg twice daily
- See the full *Prescribing Information* for specific dosage adjustment recommendations, based on serum testosterone concentrations

Cost: Cost information for Kyzatrex® is not available at this time.

Recommendations

The College of Pharmacy recommends the following changes to the Testosterone Products PBPA category based on new FDA approvals, product discontinuations, and net costs (changes shown in red in the following Tier chart and approval criteria):

1. The prior authorization and placement of Kyzatrex® (testosterone undecanoate) into the Special Prior Authorization (PA) Tier; and
2. Moving Vogelxo® (testosterone 1% topical gel pump) from Tier-1 to Tier-2; and
3. Moving Axiron® (testosterone topical solution) from Tier-2 to Tier-1; and
4. Removing methyltestosterone powder, Androxy® (fluoxymesterone oral tablet), and Striant® (testosterone buccal tablet) based on product discontinuations.

Testosterone Products		
Tier-1*	**Tier-2**	**Special PA**
~~**methyltestosterone powder**~~	testosterone enanthate sub-Q auto-injector (Xyosted®)	~~**fluoxymesterone oral tab (Androxy®)**~~
testosterone cypionate IM inj (Depo Testosterone®)	testosterone nasal gel (Natesto®)	methyltestosterone oral tab/cap (Android®, Methitest®, Testred®)
testosterone enanthate IM inj (Delatestryl®)	testosterone patch (Androderm®)	~~**testosterone buccal tab (Striant®)**~~
testosterone topical gel 1% **packet, tube** (Testim®, Vogelxo®)	testosterone topical gel 1%, 1.62% packet (Androgel®)	testosterone pellets (Testopel®)
testosterone topical gel 1.62% pump (Androgel®) – **Brand Preferred**	**testosterone topical gel 1% pump (Vogelxo®)**	testosterone undecanoate oral cap (Jatenzo®, **Kyzatrex®,** Tlando®)
testosterone topical solution (Axiron®)	testosterone topical gel 2% pump (Fortesta®)	
	~~**testosterone topical solution (Axiron®)**~~	
	testosterone undecanoate IM inj (Aveed®)	

*Tier-1 products include generic injectable products and supplementally rebated topical products.
cap = capsule; IM = intramuscular; inj = injection; PA = prior authorization; sub-Q = subcutaneous; tab = tablet

[1] Marius Pharmaceuticals. Marius Pharmaceuticals Receives FDA Approval of Kyzatrex®, an Oral Testosterone Replacement Therapy. *BioSpace*. Available online at: https://www.biospace.com/article/releases/marius-pharmaceuticals-receives-fda-approval-of-kyzatrex-an-oral-testosterone-replacement-therapy/. Issued 08/02/2022. Last accessed 08/23/2023.
[2] Kyzatrex® (Testosterone Undecanoate) Prescribing Information. Marius Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/213953s000lbl.pdf. Last revised 07/2022. Last accessed 08/23/2023.

Appendix F

Vote to Prior Authorize Brixadi™ (Buprenorphine Extended-Release Injection), Nalocet® (Oxycodone/ Acetaminophen Tablet), and Prolate™ (Oxycodone/ Acetaminophen Oral Solution and Tablet) and Update the Approval Criteria for the Opioid Analgesics and Medication Assisted Treatment (MAT) Medications

Oklahoma Health Care Authority
September 2023

Market News and Updates[1,2]

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

- **May 2023:** The FDA approved Brixadi™ [buprenorphine extended-release (ER) injection] for the treatment of moderate-to-severe opioid use disorder (OUD) in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. Brixadi™ is an ER formulation of buprenorphine given weekly or monthly via subcutaneous (sub-Q) injection. Brixadi™ will be available through a risk evaluation and mitigation strategy (REMS) program to be administered by a health care provider in a health care setting.

News:

- **January 2023:** The federal requirement for prescribers to qualify for a waiver and be assigned a Drug Enforcement Administration (DEA) X number to prescribe medications, such as buprenorphine, for the treatment of OUD has been removed. Section 1262 of the 2023 Consolidated Appropriations Act, also known as the Omnibus Bill, allows all providers with a current DEA registration to prescribe Schedule III medications to now prescribe buprenorphine for the treatment of OUD if permitted by state law.
- **April 2023:** Forte BioPharma, the current manufacturer of Nalocet® and Prolate® [oxycodone/acetaminophen (APAP)] products, began participating in the federal Medicaid Drug Rebate Program (MDRP) in April 2023.

Brixadi™ (Buprenorphine ER Injection) Product Summary[3]

Therapeutic Class: Partial opioid agonist

Indication(s): Treatment of moderate-to-severe OUD in patients who have started treatment with a transmucosal buprenorphine product or who are already being treated with buprenorphine

- Brixadi™ should be used as part of a complete treatment plan that includes counseling and psychosocial support.

How Supplied: Pre-filled single-dose syringe in the following strengths:

- Weekly Injections: 8mg/0.16mL, 16mg/0.32mL, 24mg/0.48mL, and 32mg/0.64mL
- Monthly Injections: 64mg/0.18mL, 96mg/0.27mL, and 128mg/0.36mL

Dosing and Administration:

- Should be administered as a single sub-Q injection into the buttock, thigh, abdomen, or upper arm
- Should be administered by a health care professional in a health care setting
- Brixadi™ (weekly) should be administered in 7-day intervals.
- Brixadi™ (monthly) should be administered in 28-day intervals.
- Refer to package labeling for specific dosing recommendations for patients not currently receiving buprenorphine treatment, patients switching from transmucosal buprenorphine-containing products, and patients transitioning between Brixadi™ weekly and Brixadi™ monthly.

Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days*
Brixadi™ (buprenorphine ER inj) 128mg/0.36mL	**$4,430.56**	**$1,595.00**
Brixadi™ (buprenorphine ER inj) 32mg/0.64mL	**$648.44**	**$1,660.01**
Sublocade® (buprenorphine ER inj) 300mg/1.5mL	$1,280.33	$1,920.50
buprenorphine/naloxone SL tablet 8/2mg (generic)	$1.04	$62.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 28 days based on 1 injection for Brixadi™ 128mg and Sublocade® 300mg, 4 weekly injections for Brixadi™ 32mg, or 2 tablets per day for buprenorphine/naloxone SL tablet
Unit = mL or tablet
ER = extended-release; inj = injection; SL = sublingual

Nalocet® and Prolate® (Oxycodone/APAP) Product Summary[4,5,6]

Therapeutic Class: Opioid agonist (oxycodone); analgesic/antipyretic (APAP)

Indication(s): Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate

How Supplied:

- Nalocet®: Oxycodone/APAP 2.5mg/300mg oral tablets
- Prolate®: Oxycodone/APAP 10mg/300mg/5mL oral solution and 5mg/300mg, 7.5mg/300mg, 10mg/300mg tablets

Dosing and Administration:

- Usual adult dose:
  - Nalocet®: 1 to 2 tablets every 6 hours
  - Prolate® Tablet: 1 tablet every 6 hours
  - Prolate® Oral Solution: 5mL every 6 hours
  - Total daily dose of APAP should not exceed 4g

Cost Comparison:

Product	Cost Per Unit	Cost Per Day*
Nalocet® (oxycodone/APAP) 2.5/300mg tablet	**$31.73**	**$126.92**
Prolate® (oxycodone/APAP) 5/300mg tablet	**$27.76**	**$111.04**
Prolate® (oxycodone/APAP) 10/300mg/5mL oral solution	**$10.94**	**$218.80**
oxycodone/APAP 5/325mg tablet (generic)	$0.08	$0.32

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per day based on 1 tablet or 5mL every 6 hours.
Unit = mL or tablet
APAP = acetaminophen

Recommendations

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

1. Adding Nalocet® and Prolate® to Tier-3 of the Short-Acting Opioid Analgesics category based on net costs; and
2. Moving Nucynta® and Nucynta® ER 50mg to Tier-1 based on net costs; and
3. Moving Nucynta® ER 100mg, 150mg, 200mg, and 250mg to Tier-2 based on net costs and morphine milligram equivalent (MME); and
4. Removing Arymo™ ER, Lazanda®, MorphaBond™, Subsys®, Synalgos-DC®, Troxyca® ER, and Xartemis® XR due to product discontinuations.

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
buprenorphine patch (Butrans®) – **Brand Preferred**	fentanyl patch (Duragesic®)	buprenorphine ER buccal film (Belbuca®)	~~**oxycodone/APAP ER tab (Xartemis® XR)**~~

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab
tapentadol ER tab 50mg (Nucynta® ER)	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER)	tramadol ER cap (ConZip®)
	tapentadol ER tab 100mg, 150mg, 200mg, 250mg (Nucynta® ER)	hydromorphone ER tab (Exalgo®)	
	tramadol ER tab (Ultram ER®, Ryzolt®)	methadone tab and oral soln (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
		~~**morphine ER tab (Arymo™ ER)**~~	
		~~**morphine ER tab (MorphaBond™)**~~	
		oxycodone ER cap (Xtampza® ER)	
		~~**oxycodone/ naltrexone ER cap (Troxyca® ER)**~~	
		~~**tapentadol ER tab (Nucynta® ER)**~~	
Short-Acting			
APAP/butalbital/ caff/codeine cap (Fioricet® with Codeine)	hydrocodone/IBU tab 10/200mg (Ibudone®, Reprexain™)	benzhydrocodone/ APAP tab (Apadaz®)	levorphanol tab

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	oxymorphone IR tab (Opana®)	dihydrocodeine/ APAP/caff cap (Trezix®)	tramadol 100mg tab
codeine tab	~~**tapentadol IR tab (Nucynta®)**~~	hydrocodone/ APAP oral soln (Zamicet®, Liquicet®)	tramadol oral soln (Qdolo™)
codeine/APAP tab (Tylenol® with Codeine)		hydrocodone/ APAP tab (Xodol®)	celecoxib 56mg/tramadol 44mg (Seglentis®)
~~**dihydrocodeine/ ASA/caff cap (Synalgos-DC®)**~~		**oxycodone/APAP tab (Nalocet®)**	
hydrocodone/ APAP tab (Norco®)		**oxycodone/APAP tab and oral soln (Prolate®)**	
hydrocodone/IBU tab 5/200mg, 7.5/200mg only (Vicoprofen®, Ibudone®, Reprexain™)		oxycodone tab (Oxaydo®)	
hydromorphone tab (Dilaudid®)		oxycodone tab (RoxyBond™)	
morphine IR tab (MSIR®)			
oxycodone/APAP tab (Percocet®)			***Oncology Only:***
oxycodone/ASA tab (Percodan®)			fentanyl buccal film (Onsolis®)
oxycodone IR cap (Oxy IR®)			fentanyl buccal tab (Fentora®)
oxycodone IR tab (Roxicodone®)			~~**fentanyl nasal spray (Lazanda®)**~~
tapentadol IR (Nucynta®)			~~**fentanyl SL spray (Subsys®)**~~
tramadol 50mg tab (Ultram®)			fentanyl SL tab (Abstral®)

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
tramadol/APAP (Ultracet®)			fentanyl transmucosal lozenge (Actiq®)

*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).
APAP = acetaminophen; ASA = aspirin; caff = caffeine; cap = capsule; ER = extended-release; IBU = ibuprofen; IR = immediate-release; PA = prior authorization; SL = sublingual; soln = solution; tab = tablet

Opioid Analgesics Special Prior Authorization (PA) Approval Criteria:

1. Abstral®, Actiq®, Fentora®, ~~Lazanda®,~~ and Onsolis®~~, and Subsys®~~ are approved for oncology-related diagnoses only.
2. ConZip® [Tramadol Extended-Release (ER) Capsule] Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use the ER tablet formulation must be provided. Tier structure rules apply.
3. Hydrocodone/Acetaminophen (APAP) Unique Strengths Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) must be provided.
4. Levorphanol Tablet Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use alternative treatment options for pain (e.g., non-opioid analgesics, lower-tiered opioid analgesics) must be provided.
5. Qdolo™ (Tramadol 5mg/mL Oral Solution) Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use tramadol 50mg tablets, even when tablets are crushed, must be provided; and
   b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the prescriber must provide patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
   c. A quantity limit of 2,400mL per 30 days will apply.
6. Seglentis® (Celecoxib 56mg/Tramadol 44mg) Approval Criteria:
   a. An FDA approved indication of acute pain in adults that is severe enough to require an opioid analgesic; and
   b. A patient-specific, clinically significant reason why the member cannot use any other opioid medication for treatment of acute pain must be provided; and
   c. A patient-specific, clinically significant reason why the member cannot use celecoxib and tramadol individual products in place of Seglentis® must be provided; and

d. 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
e. A quantity limit of 28 tablets for a 7-day supply will apply.

7. Tramadol 100mg Tablet Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose must be provided; and
   b. 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.

~~8. Xartemis® XR (Oxycodone/APAP ER Tablet) Approval Criteria:~~
   ~~a. An acute pain condition requiring around-the-clock opioid treatment; and~~
   ~~b. A patient-specific, clinically significant reason must be provided for all of the following:~~
      ~~i. Why the member cannot use any other opioid medication for treatment of acute pain; and~~
      ~~ii. Why the member requires a long-acting medication for an acute pain condition; and~~
      ~~iii. Why the member cannot use Oxycontin® (oxycodone ER) and over-the-counter (OTC) APAP individual products in place of this combination product; and~~
   ~~c. A quantity limit of 4 tablets per day will apply with a maximum approval duration of 10 days; and~~
   ~~d. The member must not exceed 3,250mg of APAP per day from all sources; and~~
   ~~e. Tier structure rules still apply.~~

The College of Pharmacy also recommends the following changes to the MAT medications approval criteria (changes noted in red in the following criteria):

1. The prior authorization of Brixadi™ with criteria similar to Sublocade®; and
2. Updating the approval criteria for Brixadi™ and Sublocade® to be consistent with clinical practice regarding concomitant treatment with transmucosal buprenorphine; and
3. Updating the approval criteria for Sublocade®, Suboxone®, Subutex®, and Zubsolv® to remove the DEA X requirement based on the 2023 Consolidated Appropriations Act.

Brixadi™ [Buprenorphine Extended-Release (ER) Injection] and Sublocade® (Buprenorphine ER Injection) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe opioid use disorder; and
2. ~~Sublocade® must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and~~
3. For Sublocade®, member must have initiated treatment with a transmucosal buprenorphine-containing product for a minimum of 7 days; ~~and~~ or
4. For Brixadi™, member must have initiated treatment with a single dose of a transmucosal buprenorphine product or is currently treated with buprenorphine; and
5. Concomitant treatment with opioids (including tramadol) will be denied; and
6. ~~Sublocade®~~ Medication should only be prepared and administered by a health care provider; and
7. A patient-specific, clinically significant reason why the member cannot use the preferred buprenorphine product(s) (buprenorphine/naloxone sublingual tablets) must be provided; and
8. In general, concomitant treatment with transmucosal buprenorphine will not be approved long term; and
9. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
10. A quantity limit of 1 monthly dose ~~(300mg or 100mg)~~ per 28 days or 4 weekly doses per 28 days will apply.

Suboxone® [Buprenorphine/Naloxone Sublingual (SL) Tablet and Film], Subutex® (Buprenorphine SL Tablet), and Zubsolv® (Buprenorphine/ Naloxone SL Tablet) Approval Criteria:

1. Generic buprenorphine/naloxone SL tablet is the preferred product. Authorization consideration of Zubsolv® and Suboxone® films (brand and generic) requires a patient-specific, clinically significant reason why generic buprenorphine/naloxone SL tablets are not appropriate; and
2. Subutex® (buprenorphine) 2mg and 8mg SL tablets will only be approved if the member is pregnant or has a documented serious allergy or adverse reaction to naloxone; and
3. ~~Buprenorphine products FDA approved for a diagnosis of opioid abuse/ dependence must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the~~

~~intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and~~

4. Member must have an FDA approved diagnosis of opioid abuse/ dependence; and
5. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
6. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
7. The following limitations will apply:
    a. Suboxone® 2mg/0.5mg and 4mg/1mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    b. Suboxone® 8mg/2mg SL tablets and films: A quantity limit of 60 SL units per 30 days will apply.
    c. Suboxone® 12mg/3mg SL films: A quantity limit of 30 SL films per 30 days will apply.
    d. Subutex® 2mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    e. Subutex® 8mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
    f. Zubsolv® 0.7mg/0.18mg, 1.4mg/0.36mg, and 2.9mg/0.71mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    g. Zubsolv® 5.7mg/1.4mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
    h. Zubsolv® 8.6mg/2.1mg and 11.4mg/2.9mg SL tablets: A quantity limit of 30 SL tablets per 30 days will apply.

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[1] U.S. FDA. FDA Approves New Buprenorphine Treatment Option for Opioid Use Disorder. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-new-buprenorphine-treatment-option-opioid-use-disorder. Issued 05/23/2023. Last accessed 07/26/2023.
[2] Substance Abuse and Mental Health Services Administration (SAMHSA). Waiver Elimination (MAT Act). Available online at: https://www.samhsa.gov/medications-substance-use-disorders/waiver-elimination-mat-act. Last revised 06/07/2023. Last accessed 07/26/2023.
[3] Brixadi™ (Buprenorphine) Prescribing Information. Braeburn, Inc. Available online at: https://braeburnrx.com/wp-content/uploads/2023/05/brixadi-prescribing-information.pdf. Last revised 05/2023. Last accessed 07/26/2023.
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[5] Prolate® (Oxycodone/Acetaminophen Tablet) Prescribing Information. Forte Bio-Pharma LLC. Available online at: https://fortebiopharma.com/wp-content/uploads/2021/09/Revised-PI-1143C00-06-21-Prolate.pdf. Last revised 06/2021. Last accessed 07/26/2023.
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Appendix G

Vote to Update the Approval Criteria for the Topical Corticosteroids

Oklahoma Health Care Authority
September 2023

Recommendations

The College of Pharmacy recommends the following changes to the Topical Corticosteroids Product Based Prior Authorization (PBPA) Tier chart based on net costs (changes are shown in red in the following Tier chart):

1. Ultra-High to High Potency:
    a. Move clobetasol propionate 0.05% foam (Olux®) from Tier-3 to Tier-1
    b. Move clobetasol propionate 0.05% shampoo (Clobex®) from Tier-3 to Tier-2
2. Medium-High to Medium Potency:
    a. Move triamcinolone acetonide 0.147mg/g spray (Kenalog®) from Tier-2 to Tier-3
3. Low Potency:
    a. Move hydrocortisone 2.5% solution (Texacort®) from Tier-2 to Tier-3

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (Diprolene®) Diprolene AF®)	C,O	amcinonide 0.1%	C,L	clobetasol propionate 0.05% (Clobex®)	~~Sh,~~Spr
betamethasone dipropionate 0.05% (Diprosone®)	C,O	augmented betamethasone dipropionate 0.05% (Diprolene®)	G,L	clobetasol propionate 0.05% (~~Olux®,~~ Olux-E®, Tovet®)	F
clobetasol propionate 0.05% (Olux®)	**F**	clobetasol propionate 0.05% (Clobex®)	L**,Sh**	Clobetasol propionate 0.05% (Impeklo®)	L
clobetasol propionate 0.05% (Temovate®)	C,O,So	clobetasol propionate 0.05% (Temovate®)	G	desoximetasone 0.25% (Topicort®)	Spr
desoximetasone 0.25% (Topicort®)	C,O	desoximetasone 0.05% (Topicort®)	G	diflorasone diacetate 0.05% (Apexicon®)	C,O

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
fluocinonide 0.05%	C,O,So	fluocinonide 0.05%	G	diflorasone diacetate 0.05% (Apexicon E®)	C
fluocinonide 0.1% (Vanos®)	C	flurandrenolide tape 0.05% (Cordran®)	Tape	halobetasol propionate 0.01% (Bryhali®)	L
halobetasol propionate 0.05% (Ultravate®)	C,O	halcinonide 0.1% (Halog®)	C,O,So	halobetasol propionate 0.05%	F
		halobetasol propionate 0.05% (Ultravate®)	L		
		halobetasol propionate/lactic acid 0.05%/10% (Ultravate X®)	C		
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	L	betamethasone dipropionate/calcipotriene 0.064%/0.005% (Taclonex®)	O,Spr, Sus	desoximetasone 0.05% (Topicort LP®)	C,O
betamethasone valerate 0.1% (Beta-Val®)	C,O	betamethasone valerate 0.12% (Luxiq®)	F	hydrocortisone valerate 0.2% (Westcort®)	C,O
fluticasone propionate 0.005% (Cutivate®)	O	betamethasone valerate 0.1% (Beta-Val®)	L	**triamcinolone acetonide 0.147mg/g (Kenalog®)**	**Spr**
fluticasone propionate 0.05% (Cutivate®)	C	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (Enstilar®)	F		
mometasone furoate 0.1% (Elocon®)	C,L,O, So	clocortolone pivalate 0.1% (Cloderm®)	C		
triamcinolone acetonide 0.025%	O	fluocinolone acetonide 0.025% (Synalar®)	C,O		
triamcinolone acetonide 0.1%	C,L,O	fluocinonide emollient 0.05% (Lidex E®)	C		
triamcinolone acetonide 0.5%	C,O	flurandrenolide 0.05%	C,L,O		

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
		fluticasone propionate 0.05% (Cutivate®)	L		
		hydrocortisone butyrate 0.1%	C,L,O, So		
		hydrocortisone probutate 0.1% (Pandel®)	C		
		prednicarbate 0.1% (Dermatop®)	C,O		
		~~**triamcinolone acetonide 0.147mg/g (Kenalog®)**~~	~~**Spr**~~		
		triamcinolone acetonide 0.05% (Trianex®)	O		
Low Potency					
desonide emollient 0.05%	C,O	alclometasone dipropionate 0.05% (Aclovate®)	C	alclometasone dipropionate 0.05% (Aclovate®)	O
fluocinolone acetonide 0.01% (Capex®)	Sh	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®) – **Brand Preferred**	Oil	desonide 0.05%	L
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Synalar®)	C	desonide 0.05% (Desonate®)	G
hydrocortisone acetate 1%	C,O	~~**hydrocortisone 2.5% (Texacort®)**~~	~~**So**~~	**hydrocortisone 2.5% (Texacort®)**	**So**
hydrocortisone acetate 2.5%	C,L,O	hydrocortisone/pramoxine 1%/1% (Pramosone®)	C,L		
hydrocortisone/urea 1%/10% (U-Cort®)	C				
triamcinolone acetonide 0.025%	C,L				

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).
C = cream; F = foam; G = gel; L= lotion; O = ointment; Sh = shampoo; So = solution; Spr = spray; Sus = suspension

Appendix H

Vote to Update the Approval Criteria for the Intravenous (IV) Iron Products

Oklahoma Health Care Authority
September 2023

Market News and Updates[1,2]

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

- **May 2023:** The FDA approved Injectafer® (ferric carboxymaltose injection) for a new indication for the treatment of iron deficiency in adult patients with New York Heart Association class II-III heart failure (HF) to improve exercise capacity. The FDA approved dosing for this indication is an initial dose of 500mg or 1,000mg given on day 1 with a potential second dose given at week 6 (the recommended dose and number of doses is based on the patient's weight and hemoglobin level). Subsequent maintenance doses of 500mg may be given at 12, 24, and 36 weeks if serum ferritin is <100ng/mL (or 100-300ng/mL if transferrin saturation is <20%).

Cost Comparison: IV Iron Products

Product	Cost Per mg	Cost Per Treatment Course*
Monoferric® (ferric derisomaltose inj) 1,000mg/10mL	$2.06	$2,060
Injectafer® (ferric carboxymaltose inj) 1,000mg/20mL	$1.13	$1,130
Feraheme® (ferumoxytol inj) 510mg/17mL	$0.50	$510
Infed® (iron dextran inj) 100mg/2mL	$0.34	$340
Venofer® (iron sucrose inj) 200mg/2mL	$0.21	$210

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 course based on 1,000mg for Monoferric®, Injectafer®, and Infed®, (2) 510mg doses for Feraheme®, and (5) 200mg doses for Venofer®.
inj = injection

Recommendations

The College of Pharmacy recommends updating the Injectafer® (ferric carboxymaltose) approval criteria based on recent FDA approved indication for iron deficiency in patients with HF (new criteria and changes shown in red):

Injectafer® (Ferric Carboxymaltose) Approval Criteria [Iron Deficiency Diagnosis]:

1. An FDA approved indication of iron deficiency in adult members with New York Heart Association (NYHA) class II-III heart failure (HF) to improve exercise capacity; and
2. Member must be 18 years of age or older; and
3. Documented lab results verifying iron deficiency; and
4. Prescriber must verify member is already receiving optimal background therapy for HF; and
5. Member must have left ventricular ejection fraction (LVEF) <45%; and
6. Member's current weight (kg) and hemoglobin (Hb) (g/dL) must be provided to ensure appropriate dosing according to package labeling; and
7. A recent trial of Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Infed® and Venofer® must be provided; and
8. Initial approvals will be for 1 or 2 doses only (depending on member's weight and Hb) according to package labeling; and
9. Subsequent requests for maintenance doses at weeks 12, 24, and 36 will require submission of updated lab results verifying continued iron deficiency for each dose and will be approved for (1) 500mg dose at a time.

Injectafer® (Ferric Carboxymaltose) Approval Criteria [Iron Deficiency Anemia (IDA) Diagnosis]:

1. An FDA approved indication of 1 of the following:
   a. IDA; or
   b. IDA in members with non-dialysis dependent chronic kidney disease (CKD); and
2. Documented lab results verifying IDA; and
3. Documentation of intolerance or inadequate response to oral iron therapy after at least 3 months at recommended dosing; and
4. A recent trial of Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Infed® and Venofer® must be provided.

Additionally, the College of Pharmacy recommends updating the Monoferric® (ferric derisomaltose) approval criteria based on net cost (changes shown in red):

Monoferric® (Ferric Derisomaltose) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Iron deficiency anemia (IDA); or
   b. IDA in members with non-dialysis dependent chronic kidney disease (CKD); and

2. Documented lab results verifying IDA; and
3. Documentation of intolerance or inadequate response to oral iron therapy after at least 3 months at recommended dosing; and
4. A recent trial of Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Infed® and Venofer® must be provided; and
5. A patient-specific, clinically significant reason why the member cannot utilize Feraheme® (ferumoxytol) and Injectafer® (ferric carboxymaltose) must be provided.

[1] Daiichi Sankyo, Inc. Injectafer® Approved in the U.S. for the Treatment of Iron Deficiency in Adult Patients with Heart Failure. Available online at: https://www.businesswire.com/news/home/20230605005213/en/INJECTAFER%C2%AE-Approved-in-the-U.S.-for-the-Treatment-of-Iron-Deficiency-in-Adult-Patients-with-Heart-Failure. Issued 06/05/2023. Last accessed 08/23/2023.
[2] Injectafer® (Ferric Carboxymaltose) Prescribing Information. American Regent, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/203565s020lbl.pdf. Last revised 05/2023. Last accessed 08/23/2023.

Appendix I

Vote to Prior Authorize Xacduro® (Sulbactam/ Durlobactam) and Update the Approval Criteria for the Various Systemic Antibiotics

Oklahoma Health Care Authority
September 2023

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

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

- **June 2020:** The FDA approved an expanded indication for Recarbrio™ (imipenem/cilastatin/relebactam) to treat hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) in adult patients 18 years of age and older. Previously, Recarbrio™ was only FDA approved to treat patients with complicated intra-abdominal infections (cIAI) and complicated urinary tract infections (cUTI) who had limited or no treatment options.
- **July 2021:** The FDA approved an expanded indication for Solosec® (secnidazole oral granules) to include treatment of trichomoniasis in adults. Previously, Solosec® was only FDA approved to treat bacterial vaginosis (BV) in adult women.
- **April 2022:** The FDA approved Zerbaxa® (ceftolozane/tazobactam) for the treatment of cIAI and cUTI in pediatric patients (birth to younger than 18 years of age). Previously, Zerbaxa® was only approved in adults and is still only approved in adults for the treatment of HABP/VABP.
- **May 2023:** The FDA approved Xacduro® (sulbactam/durlobactam) for the treatment of HABP/VABP caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex in patients 18 years of age and older. It is the first pathogen-targeted therapy addressing *Acinetobacter,* including resistant strains.

Guideline Update(s):

- **Infectious Diseases Society of America (IDSA) 2023 Guideline Update:** In June 2023, the IDSA released updated guidance on the treatment of antimicrobial resistant gram-negative infections including guidance on the treatment of infections caused by extended-spectrum beta-lactamase-producing Enterobacterales (ESBL-E), AmpC beta-lactamase-producing Enterobacterales (AmpC-E), carbapenem-resistant Enterobacterales (CRE), *Pseudomonas aeruginosa* with difficult-to-treat resistance (DTR-*P. aeruginosa*), carbapenem-resistant *Acinetobacter baumannii* species (CRAB), and *Stenotrophomonas maltophilia*.

Xacduro® (Sulbactam/Durlobactam) Product Summary[6]

Therapeutic Class: Dual beta-lactamase inhibitor and beta-lactam antibacterial

Indication(s): Treatment of HABP/VABP caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex in patients 18 years of age and older

- Limitation(s) of Use: Xacduro® is not indicated for the treatment of HABP/VABP caused by pathogens other than susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

How Supplied: Xacduro® is a 1g/1g sulbactam/durlobactam co-packaged kit containing the following 2 components as sterile powders for reconstitution:

- 1 clear single-dose vial (SDV) of 1g of sulbactam for injection
- 2 amber SDVs of 0.5g of durlobactam for injection

Dosing and Administration: The recommended dose of Xacduro® is 1g of sulbactam and 1g of durlobactam every 6 hours administered by intravenous (IV) infusion over 3 hours in adults with creatinine clearance (CrCl) of 45 to 120mL/min. Refer to the package labeling for dose adjustments for patients with CrCl <45mL/min or ≥130mL/min. The recommended duration of treatment with Xacduro® is 7 to 14 days depending on patient's clinical status.

Cost: The Wholesale Acquisition Cost (WAC) of Xacduro® is $475 per kit. This results in an estimated cost of $26,600 per 14-day treatment.

Recommendations

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

Xacduro® (Sulbactam/Durlobactam) Approval Criteria:

1. An FDA approved diagnosis of hospital-acquired bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use a carbapenem, ampicillin/sulbactam, polymyxin B, or other cost effective therapeutic equivalent alternative(s); or
4. For members with carbapenem-resistant *Acinetobacter baumannii* (CRAB), a patient-specific, clinically significant reason why the member cannot use high dose ampicillin/sulbactam in combination with polymyxin B, minocycline, or tigecycline must be provided; and
5. The prescriber must confirm that the member will be treated for other pathogens present, if applicable; and

6. Approval quantity will be based on Xacduro® package labeling and FDA approved dosing regimen(s).

Additionally, the College of Pharmacy recommends updating the current approval criteria for Fetroja® (cefiderocol), Kimyrsa™ (oritavancin), Recarbrio™ (imipenem/cilastatin/relebactam), Solosec® (secnidazole oral granules), and Zerbaxa® (ceftolozane/tazobactam) to be consistent with the FDA approved indications (changes shown in red):

Fetroja® (Cefiderocol) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
   a. Complicated urinary tract infection (cUTI), including pyelonephritis; or
   b. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. Member must be 18 years of age or older; and
~~3. The prescriber must verify that limited or no alternative treatment options are available; and~~
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime), or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Kimyrsa™ (Oritavancin) Approval Criteria:

1. An FDA approved indication for the treatment of acute bacterial skin and skin structure infection (ABSSSI) caused or suspected to be caused by susceptible isolates of designated gram-positive microorganisms; and
2. Member must be 18 years of age or older; and
~~3. The prescriber must verify that limited or no alternative treatment options are available; and~~
4. A patient-specific, clinically significant reason why the member cannot use Orbactiv® (oritavancin) or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Recarbrio™ (Imipenem/Cilastatin/Relebactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:

a. Complicated intra-abdominal infection (cIAI); or
b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and

2. Member must be 18 years of age or older; and
3. ~~The prescriber must verify that limited or no alternative treatment options are available; and~~
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. A quantity limit of 56 vials per 14 days will apply.

Solosec® (Secnidazole Oral Granules) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis or trichomoniasis; and
2. A patient-specific, clinically significant reason why the member cannot use metronidazole, tinidazole, or other cost effective therapeutic equivalent alternative(s) must be provided; and
3. A quantity limit of 1 packet per 30 days will apply.

Zerbaxa® (Ceftolozane/Tazobactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
   a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or
   b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
   c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. For the diagnosis of HABP/VABP, member must be 18 years of age or older; and
3. For the diagnosis of cIAI, Zerbaxa® must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and

5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Finally, the College of Pharmacy recommends removing the prior authorization of amoxicillin 500mg tablets based on net costs (changes shown in red):

Oral Antibiotic Special Formulation Approval Criteria:

1. Member must have a patient-specific, clinically significant reason why the immediate-release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.
2. The following oral antibiotics currently require prior authorization and the special formulation approval criteria will apply:
   - ~~Amoxicillin 500mg tablets~~
   - Amoxicillin/clavulanate potassium extended-release (ER) tablets (Augmentin XR®)
   - Cephalexin 250mg and 500mg tablets
   - Cephalexin 750mg capsules
   - Doxycycline hyclate 75mg and 150mg tablets (Acticlate®)
   - Doxycycline hyclate 50mg tablet (Targadox®)
   - Doxycycline hyclate delayed-release (DR) tablets (Doryx®)
   - Doxycycline monohydrate 150mg capsules and tablets
   - Doxycycline monohydrate DR 40mg capsules (Oracea®)
   - Minocycline ER capsules (Ximino®)
   - Minocycline ER tablets (Minolira™)
   - Minocycline ER tablets (Solodyn®)

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[1] U.S. Food and Drug Administration (FDA). FDA Approves Antibiotic to Treat Hospital-Acquired Bacterial Pneumonia and Ventilator Associated Bacterial Pneumonia. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-antibiotic-treat-hospital-acquired-bacterial-pneumonia-and-ventilator-associated. Issued 06/04/2020. Last accessed 08/09/2023.
[2] Lupin Pharmaceuticals, Inc. Lupin Announces FDA Approval of Supplemental New Drug Application for Solosec® (Secnidazole) for the Treatment of Trichomoniasis. Available online at: https://www.lupin.com/lupin-announces-fda-approval-of-supplemental-new-drug-application-for-solosec-secnidazole-for-the-treatment-of-trichomoniasis/. Issued on 07/01/2021. Last accessed 08/09/2023.
[3] Park, B. Zerbaxa® Approved for Complicated Pediatric Intra-abdominal, Urinary Tract Infections. *Medical Professionals Reference*. Available online at: https://www.empr.com/home/news/zerbaxa-approved-for-complicated-pediatric-intra-abdominal-urinary-tract-infections/. Issued 04/26/2022. Last accessed 08/09/2023.
[4] Innoviva, Inc. Innoviva Specialty Therapeutics Announces FDA Approval for Xacduro® (Sulbactam for Injection; Durlobactam for Injection), Co-packaged for Intravenous Use. Available online at: https://investor.inva.com/news-releases/news-release-details/innoviva-specialty-therapeutics-announces-fda-approval-xacduror. Issued 05/23/2023. Last accessed 08/09/2023.
[5] Tamma PD, Aitken SL, Bonomo RA, et al. Infectious Disease Society of American Antimicrobial-Resistant Treatment Guidance: Gram-Negative Bacterial Infections. *IDSA* 2023. Available online at: https://www.idsociety.org/practice-guideline/amr-guidance/#Carbapenem-ResistantAcinetobacterbaumannii%C2%A0. Issued 06/07/2023. Last accessed 08/09/2023.
[6] Xacduro® (Sulbactam/Durlobactam) Prescribing Information. Entasis Therapeutics Inc. Available online at: https://xacduro-assets.s3.amazonaws.com/prescribing-information.pdf. Last revised 05/2023. Last accessed 08/09/2023.

Appendix J

Vote to Prior Authorize Cuvrior™ (Trientine Tetrahydrochloride)

Oklahoma Health Care Authority
September 2023

Market News and Updates[1,2]

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

- **May 2022:** Cuvrior™ (trientine tetrahydrochloride) was FDA approved for the treatment of stable Wilson's disease in adults who are de-coppered and tolerant to penicillamine.

News:

- **April 2023:** PantherRx Rare announced the launch of Cuvrior™ in the United States.

Cuvrior™ (Trientine Tetrahydrochloride) Product Summary[3]

Therapeutic Class: Copper chelator

Indication(s): Treatment of adults with stable Wilson's disease who are de-coppered and tolerant to penicillamine

How Supplied: 300mg functionally scored oral tablets

Dosing and Administration:

- The starting total daily dosage of Cuvrior™ is 300mg up to 3,000mg taken in divided doses (twice daily). The total daily dosage of Cuvrior™ should not exceed 3,000mg.
- If the number of Cuvrior™ tablets prescribed per day cannot be equally divided among doses, then the total daily dosage should be divided such that the higher number of tablets is taken with the first daily dose.
- Cuvrior™ should be swallowed without crushing, chewing, or dissolving and should be taken on an empty stomach.
- Cuvrior™ is not substitutable on a milligram-per-milligram basis with other trientine products.
- Refer to the package labeling for the recommended conversion table when switching from penicillamine or other trientine products to Cuvrior™.

Cost Comparison:

Product	Cost Per Unit	Cost Per Month
Cuvrior™ (trientine tetrahydrochloride) 300mg tablet	**$191.00**	**$57,300.00***
penicillamine 250mg capsule (generic)	$80.42^	$19,300.80±
penicillamine 250mg tablet (generic)	$46.53	$11,167.20±
trientine hydrochloride 250mg capsule (generic)	$18.87^	$4,528.80+
Galzin® (zinc acetate) 50mg capsule	$3.46	$311.40β

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = tablet or capsule
*Cuvrior™ cost is based on the maximum FDA recommended dose of 3,000mg daily.
±Penicillamine cost is based on the maximum FDA recommended dose of 2,000mg daily.
+Trientine hydrocholoride cost is based on the maximum FDA recommended dose of 2,000mg daily.
βGalzin® cost is based on the maximum FDA recommended dose of 50mg 3 times daily.
^Cost per capsule varies per NDC.

Recommendations

The College of Pharmacy recommends the prior authorization of Cuvrior™ (trientine tetrahydrochloride) with the following criteria:

Cuvrior™ (Trientine Tetrahydrochloride) Approval Criteria:

1. An FDA approved diagnosis of Wilson's disease; and
   a. Diagnosis must be confirmed by a Leipzig score ≥4; and
2. Member must be 18 years of age or older; and
3. Cuvrior™ must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of Wilson's disease (or an advanced care practitioner with a supervising physician who is gastroenterologist, hepatologist, or other specialist with expertise in the treatment of Wilson's disease); and
4. Member must be clinically stable, de-coppered, and tolerant to penicillamine as indicated by 1 of the following:
   a. Serum non-ceruloplasmin copper (NCC) level 25-150mcg/L; or
   b. Urinary copper excretion (UCE) level 200-500mcg/24 hours; and
5. Prescriber must verify the member will discontinue therapy with penicillamine or other copper chelating agents prior to starting therapy with Cuvrior™; and
6. A patient-specific, clinically significant reason why the member cannot use penicillamine, generic trientine hydrochloride, and Galzin® (zinc acetate), which are available without a prior authorization, must be provided; and
7. A quantity limit of 288 tablets per 28 days will apply.

[1] Orphalan SA. Orphalan Announces FDA Approval of Cuvrior™ for the Treatment of Adult Patients with Stable Wilson's Disease who are De-coppered and Tolerant to Penicillamine. Available online at: https://www.orphalan.com/orphalan-announces-fda-approval-of-cuvrior/. Issued 05/02/2022. Last accessed 08/16/2023.

[2] PantherRx® Rare. PantherRx® Rare Announces Release of Cuvrior™ (Trientine Tetrahydrochloride) to Treat Wilson Disease. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/pantherx-rare-announces-release-of-cuvrior-trientine-tetrahydrochloride-to-treat-wilson-disease-301802534.html. Issued 04/19/2023. Last accessed 08/16/2023.

[3] Cuvrior™ (Trientine Tetrahydrochloride) Prescribing Information. Orphalan SA. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215760s000lbl.pdf. Last revised 04/2022. Last accessed 08/16/2023.

Appendix K

Fiscal Year 2023 Annual Review of Tepezza® (Teprotumumab-trbw)

Oklahoma Health Care Authority
September 2023

Current Prior Authorization Criteria

Tepezza® (Teprotumumab-trbw) Approval Criteria:

1. An FDA approved indication for the treatment of thyroid eye disease in adult members 18 years of age and older; and
    a. Member must be experiencing eye symptoms related to thyroid eye disease; and
    b. Member must have thyroid blood levels in the normal range or must be undergoing active treatment working toward normal range; and
2. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
3. Female members of reproductive potential must be willing to use effective contraception prior to initiation, during treatment with Tepezza®, and for at least 6 months after the last dose of Tepezza®; and
4. Member must not have had prior surgical treatment for thyroid eye disease; and
    a. A prior authorization request with patient-specific information may be submitted for consideration of Tepezza® for members who have had prior surgical treatment for thyroid eye disease, including but not limited to patient-specific, clinically significant information regarding the member's prior surgery and the need for Tepezza®; and
5. Medical supervision by an ophthalmologist in conjunction with an endocrinologist for the treatment of thyroid eye disease; and
    a. The name of the ophthalmologist and endocrinologist recommending treatment with Tepezza® must be provided on the prior authorization request; and
6. Tepezza® must be administered as an intravenous (IV) infusion at the recommended infusion rate per package labeling, with appropriate pre-medication(s) based on the member's risk of infusion reactions; and
7. Tepezza® must be administered by a health care professional. Prior authorization requests must indicate how Tepezza® will be administered; and
    a. Tepezza® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or

b. Tepezza® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member (or the member's caregiver) must be trained on the proper storage of Tepezza®; and

8. The member's current weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
9. Approvals will be for a maximum of 8 total infusions.

Utilization of Tepezza® (Teprotumumab-trbw): Fiscal Year 2023

Comparison of Fiscal Years: Medical Claims

Fiscal Year	Total Members*	Total Claims†	Total Cost	Cost/ Claim	Total Units
2022	15	83	$4,432,744.04	$53,406.55	14,033
2023	9	34	$1,954,176.48	$57,475.78	6,050
% Change	**-40.00%**	**-59.04%**	**-55.92%**	**7.62%**	**-56.89%**
Change	**-6**	**-49**	**-$2,478,567.56**	**$4,069.23**	**-7,983**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note: There were no paid pharmacy claims for Tepezza® during fiscal year 2022 or 2023.

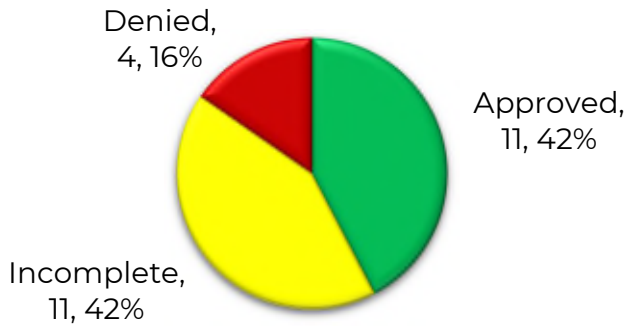
Demographics of Members Utilizing Tepezza® (Teprotumumab-trbw)

- Due to the limited number of members utilizing Tepezza® during fiscal year 2023, detailed demographic information could not be provided.

Prior Authorization of Tepezza® (Teprotumumab-trbw)

There were 26 prior authorization requests submitted for Tepezza® (teprotumumab-trbw) for 11 unique members during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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

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

- **April 2023:** The FDA approved a new expanded indication for Tepezza® (teprotumumab-trbw) to include the treatment of patients with thyroid eye disease (TED) regardless of disease activity or duration. This approval comes from the positive results of the Phase 4 clinical study. This study included a broader group of participants with chronic TED and low clinical activity score (CAS), which is a measure of disease activity. The study included patients with a TED diagnosis duration from 2 years to less than 10 years with a CAS score of ≤1. The primary endpoint of reduction in proptosis was statistically and clinically significant compared to placebo, with a reduction of ≥2mm. Previous Phase 2 and 3 studies for Tepezza® included patients with active TED diagnosed within the last 9 months and a CAS score of ≥4 with a lid retraction ≥2mm and proptosis ≥3mm with diplopia.

Pipeline:

- **Linsitinib:** Linsitinib is an oral insulin-like growth factor 1 receptor (IGF-1R) inhibitor. Sling Therapeutics is conducting a Phase 2b clinical study to evaluate the safety and efficacy of linsitinib for the treatment of active, moderate-to-severe TED. The primary endpoint is the percentage of patients who are proptosis responders after 24 weeks of treatment. Linsitinib has also been evaluated in Phase 2 and Phase 3 studies for cancer-related diagnoses.

Recommendations

The College of Pharmacy recommends updating the current Tepezza® (teprotumumab-trbw) approval criteria based on the FDA approved expanded indication (changes shown in red):

Tepezza® (Teprotumumab-trbw) Approval Criteria:

1. An FDA approved indication for the treatment of thyroid eye disease in adult members 18 years of age and older; and
   ~~a. Member must be experiencing eye symptoms related to thyroid eye disease; and~~
   b. Member must have thyroid blood levels in the normal range or must be undergoing active treatment working toward normal range; and
2. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
3. Female members of reproductive potential must be willing to use effective contraception prior to initiation, during treatment with Tepezza®, and for at least 6 months after the last dose of Tepezza®; and

4. Member must not have had prior surgical treatment for thyroid eye disease; and
    a. A prior authorization request with patient-specific information may be submitted for consideration of Tepezza® for members who have had prior surgical treatment for thyroid eye disease, including but not limited to patient-specific, clinically significant information regarding the member's prior surgery and the need for Tepezza®; and
5. Medical supervision by an ophthalmologist in conjunction with an endocrinologist for the treatment of thyroid eye disease; and
    a. The name of the ophthalmologist and endocrinologist recommending treatment with Tepezza® must be provided on the prior authorization request; and
6. Tepezza® must be administered as an intravenous (IV) infusion at the recommended infusion rate per package labeling, with appropriate pre-medication(s) based on the member's risk of infusion reactions; and
7. Tepezza® must be administered by a health care professional. Prior authorization requests must indicate how Tepezza® will be administered; and
    a. Tepezza® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Tepezza® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member (or the member's caregiver) must be trained on the proper storage of Tepezza®; and
8. The member's current weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
9. Approvals will be for a maximum of 8 total infusions.

Utilization Details of Tepezza® (Teprotumumab-trbw): Fiscal Year 2023

Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J3241 TEPROTUMUMAB-TRBW INJ 500MG	34	9	$1,954,176.48	$57,475.78	3.78
TOTAL	**34**	**9**	**$1,954,176.48**	**$57,475.78**	**3.78**

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

[1] Horizon Therapeutics plc. Horizon Therapeutics plc Announces Positive Topline Data from Tepezza® (Teprotumumab-trbw) Phase 4 Clinical Trial in Patients with Chronic/Low Clinical Activity Score (CAS) Thyroid Eye Disease (TED). Available online at: https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-positive-topline-data. Issued 04/10/2023. Last accessed 08/11/2023.

[2] Horizon Therapeutics plc. Additional Data from Phase 4 Tepezza® (Teprotumumab-trbw) Clinical Trial Presented at the Endocrine Society Annual Meeting Reinforces Efficacy in People with Thyroid Eye Disease (TED) Regardless of Disease Activity or Duration. Available online at: https://ir.horizontherapeutics.com/news-releases/news-release-details/additional-data-phase-4-tepezzar-teprotumumab-trbw-clinical. Issued 06/17/2023. Last accessed 08/18/2023.

[3] U.S. FDA Approves Label Update for Horizon's Tepezza® TED Drug. *Pharmaceutical Technology*. Available online at: https://www.pharmaceutical-technology.com/news/fda-horizon-tepezza-ted-drug/. Issued 04/17/2023. Last accessed 08/11/2023.

[4] Sling Therapeutics. Sling Therapeutics Initiates Enrollment in Phase 2b LIDS Clinical Trial Evaluating Linsitinib in Thyroid Eye Disease. Available online at: https://www.prnewswire.com/news-releases/sling-therapeutics-initiates-enrollment-in-phase-2b-lids-clinical-trial-evaluating-linsitinib-in-thyroid-eye-disease-301592193.html. Issued 07/25/2022. Last accessed 08/21/2023.

Appendix L

Fiscal Year 2023 Annual Review of Oxlumo® (Lumasiran)

Oklahoma Health Care Authority
September 2023

Current Prior Authorization Criteria

Oxlumo® (Lumasiran) Approval Criteria:

1. An FDA approved indication for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels. Diagnosis of PH1 must be confirmed by:
   a. Molecular genetic testing identifying biallelic pathogenic variants in the *AGXT* gene; or
   b. Liver biopsy confirming alanine-glyoxylate aminotransferase (AGT) catalytic deficiency if the results of genetic testing are not diagnostic; and
2. Oxlumo® must be prescribed by a nephrologist, geneticist, or other specialist with expertise in the treatment of PH1 (or an advanced care practitioner with a supervising physician who is a nephrologist, geneticist, or other specialist with expertise in the treatment of PH1); and
3. Prescriber must verify the member has an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m^2 prior to starting Oxlumo® and must agree to monitor renal function regularly during treatment with Oxlumo®; and
4. Member must not have a history of liver transplant; and
5. Member must not have evidence of systemic oxalosis; and
6. Prescriber must verify that Oxlumo® will be administered by a health care professional; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a reduction in urinary oxalate excretion.

Utilization of Oxlumo® (Lumasiran): Fiscal Year 2023

There was no SoonerCare utilization of Oxlumo® (lumasiran) during fiscal year 2023 (07/01/2022 to 06/30/2023).

Prior Authorization of Oxlumo® (Lumasiran)

There were no prior authorization requests submitted for Oxlumo® (lumasiran) during fiscal year 2023.

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

Anticipated Patent Expiration(s):

- Oxlumo® (lumasiran): November 2038

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

- **October 2022:** The FDA approved a supplemental New Drug Application (sNDA) for Oxlumo® (lumasiran) for the treatment of patients with advanced primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels. The approval was based on data from the Phase 3 ILLUMINATE-C study which was a multi-center, single-arm study that enrolled patients with advanced PH1 with an estimated glomerular filtration rate (eGFR) ≤45mL/min/1.73m^2 (or an elevated serum creatinine for age in patients younger than 12 months of age), including patients on hemodialysis. The results of the study demonstrated reductions in plasma oxalate both in patients who did and who did not require hemodialysis. Oxlumo® was initially FDA approved in November 2020 for a more limited indication to lower urinary (but not plasma) oxalate levels, based on initial Phase 3 studies of lumasiran which were conducted in PH1 patients with relatively preserved renal function and no evidence of systemic oxalosis.

Pipeline:

- **Nedosiran:** Nedosiran is a small interfering ribonucleic acid (siRNA) therapy targeting lactate dehydrogenase A (LDHA) that is being evaluated for the treatment of PH1, primary hyperoxaluria type 2 (PH2), and primary hyperoxaluria type 3 (PH3). LDHA catalyzes the final step in oxalate synthesis in the liver and may be a successful target for patients with all 3 subtypes of the disorder. Phase 1 and 2 studies in patients with all subtypes have been published, although the results were inconclusive in patients with PH2. Novo Nordisk submitted for FDA approval of nedosiran for the treatment of PH1 in the third quarter of 2022. A Prescription Drug User Fee Act (PDUFA) date has not been announced.

Recommendations

The College of Pharmacy recommends updating the Oxlumo® (lumasiran) approval criteria based on the recent FDA approval and to be consistent with clinical practice (changes shown in red):

Oxlumo® (Lumasiran) Approval Criteria:

1. An FDA approved indication for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels. Diagnosis of PH1 must be confirmed by:
    a. Molecular genetic testing identifying biallelic pathogenic variants in the *AGXT* gene (results of genetic testing must be submitted); or
    b. Liver biopsy confirming alanine-glyoxylate aminotransferase (AGT) catalytic deficiency if the results of genetic testing are not diagnostic (results of liver biopsy must be submitted); and
2. Oxlumo® must be prescribed by a nephrologist, geneticist, or other specialist with expertise in the treatment of PH1 (or an advanced care practitioner with a supervising physician who is a nephrologist, geneticist, or other specialist with expertise in the treatment of PH1); and
~~3. Prescriber must verify the member has an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m² prior to starting Oxlumo® and must agree to monitor renal function regularly during treatment with Oxlumo®; and~~
4. Member must not have a history of liver transplant; and
~~5. Member must not have evidence of systemic oxalosis; and~~
6. Prescriber must verify that Oxlumo® will be administered by a health care professional; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a reduction in urinary oxalate excretion or plasma oxalate levels.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 07/2023. Last accessed 07/28/2023.
[2] Alnylam Pharmaceuticals, Inc. Alnylam Announces FDA Approval of Supplemental New Drug Application for Oxlumo® (Lumasiran) in Advanced Primary Hyperoxaluria Type 1. Available online at: https://www.businesswire.com/news/home/20221006006075/en/Alnylam-Announces-FDA-Approval-of-Supplemental-New-Drug-Application-for-OXLUMO%C2%AE-lumasiran-in-Advanced-Primary-Hyperoxaluria-Type-1. Issued 10/06/2022. Last accessed 07/28/2023.
[3] Oxlumo® (Lumasiran) Prescribing Information. Alnylam Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214103s003lbl.pdf. Last revised 10/2022. Last accessed 07/28/2023.
[4] Michael M, Groothoff JW, Shasha-Lavsky H, et al. Lumasiran for Advanced Primary Hyperoxaluria Type 1: Phase 3 ILLUMINATE-C Trial. *Am J Kidney Dis* 2023; 81(2):145-155.e1. doi: 10.1053/j.ajkd.2022.05.012.
[5] Novo Nordisk. Science & Technology: R&D Pipeline. Available online at: https://www.novonordisk.com/science-and-technology/r-d-pipeline.html. Last accessed 08/15/2023.
[6] Baum MA, Langman C, Cochat P, et al. PHYOX2: A Pivotal Randomized Study of Nedosiran in Primary Hyperoxaluria Type 1 or 2. *Kidney Int* 2023; 103(1):207-217. doi: 10.1016/j.kint.2022.07.025.
[7] Goldfarb DS, Liese JC, Groothoff J, et al. Nedosiran in Primary Hyperoxaluria Subtype 3: Results from a Phase I, Single-Dose Study (PHYOX4). *Urolithiasis* 2023; 51(1):80. doi: 10.1007/s00240-023-01453-3.
[8] Novo Nordisk. Investor Presentation First Nine Months of 2022. Available online at: https://www.novonordisk.com/content/dam/nncorp/global/en/investors/pdfs/financial-results/2022/Q3-2022-investor-presentation.pdf. Issued 11/02/2022. Last accessed 08/15/2023.

Appendix M

Fiscal Year 2023 Annual Review of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators

Oklahoma Health Care Authority
September 2023

Current Prior Authorization Criteria

Kalydeco® (Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) with a mutation in the CF transmembrane conductance regulator (*CFTR*) gene detected by genetic testing that is responsive to ivacaftor based on clinical and/or *in vitro* assay data; and
2. Documentation must be submitted with results of *CFTR* genetic testing; and
3. Member must be 4 months of age or older; and
4. A quantity limit of 2 tablets or 2 granule packets per day or 56 tablets or granule packets per 28 days will apply; and
5. An age restriction of 4 months to 5 years of age will apply to Kalydeco® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
6. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
7. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
8. Subsequent approvals will be for 1 year.

Orkambi® (Lumacaftor/Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation in the CF transmembrane conductance regulator *(CFTR)* gene detected by genetic testing; and
2. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene; and
3. Orkambi® will not be approved for members with CF other than those homozygous for the *F508del* mutation; and
4. Member must be 12 months of age or older; and

5. Members using Orkambi® must be supervised by a pulmonary disease specialist; and
6. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Orkambi®, every 3 months during the first year of treatment, and annually thereafter; and
7. Member must not be taking any of the following medications concomitantly with Orkambi®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
8. A quantity limit of 4 tablets per day or 112 tablets per 28 days will apply or a quantity limit of 2 granule packets per day or 56 packets per 28 days will apply; and
9. An age restriction of 12 months to 5 years of age will apply to Orkambi® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
10. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
11. Initial approvals will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
12. Subsequent approvals will be for the duration of 1 year.

Symdeko® (Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation or who have at least 1 mutation in the CF transmembrane conductance regulator *(CFTR)* gene detected by genetic testing that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence; and
2. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and
3. Member must be 6 years of age or older; and
4. Members using Symdeko® must be supervised by a pulmonary disease specialist; and
5. If the member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) and experiencing adverse effects associated with Orkambi® use, the prescriber must indicate that information on the prior authorization request; and

6. Prescriber must verify the member has been counseled on proper administration of Symdeko® including taking with a fat-containing food; and
7. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Symdeko®, every 3 months during the first year of treatment, and annually thereafter; and
8. Member must not be taking any of the following medications concomitantly with Symdeko®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
9. A quantity limit of 2 tablets per day or 56 tablets per 28 days will apply; and
10. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
11. Initial approvals will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events must be provided for members who switched from Orkambi® to Symdeko®; and
12. Subsequent approvals will be for the duration of 1 year.

Trikafta® (Elexacaftor/Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 *F508del* mutation in the CF transmembrane conductance regulator *(CFTR)* gene or a mutation in the *CFTR* gene that is responsive based on *in vitro* data; and
2. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and
3. Member must be 6 years of age or older; and
4. Members using Trikafta® must be supervised by a pulmonary disease specialist; and
5. If the member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi® or Symdeko® use, the prescriber must indicate that information on the prior authorization request; and

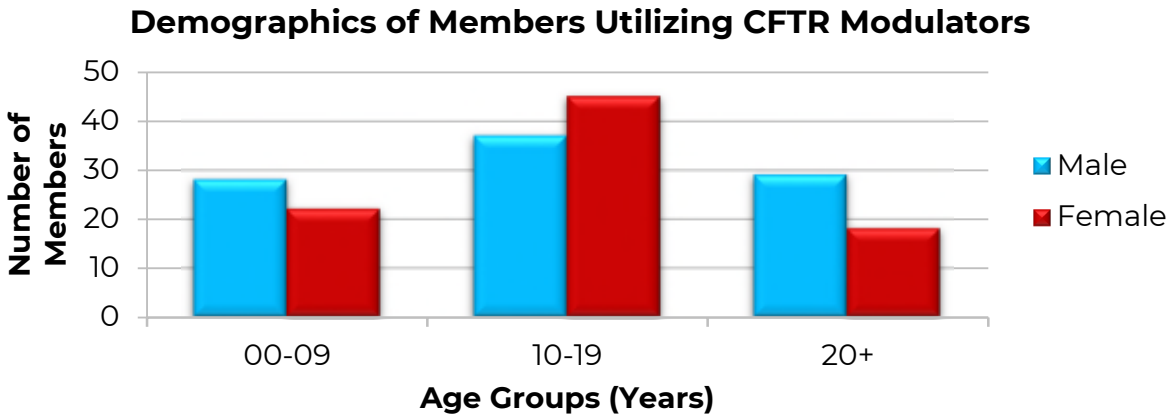
6. Prescriber must verify the member has been counseled on proper administration of Trikafta® including taking with a fat-containing food; and
7. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Trikafta®, every 3 months during the first year of treatment, and annually thereafter; and
8. Prescriber must verify the member does not have severe hepatic impairment; and
9. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
10. Member must not be taking any of the following medications concomitantly with Trikafta®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
11. A quantity limit of 3 tablets per day or 84 tablets per 28 days will apply; and
12. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
13. Initial approvals will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® or Symdeko® to Trikafta®; and
14. Subsequent approvals will be for the duration of 1 year.

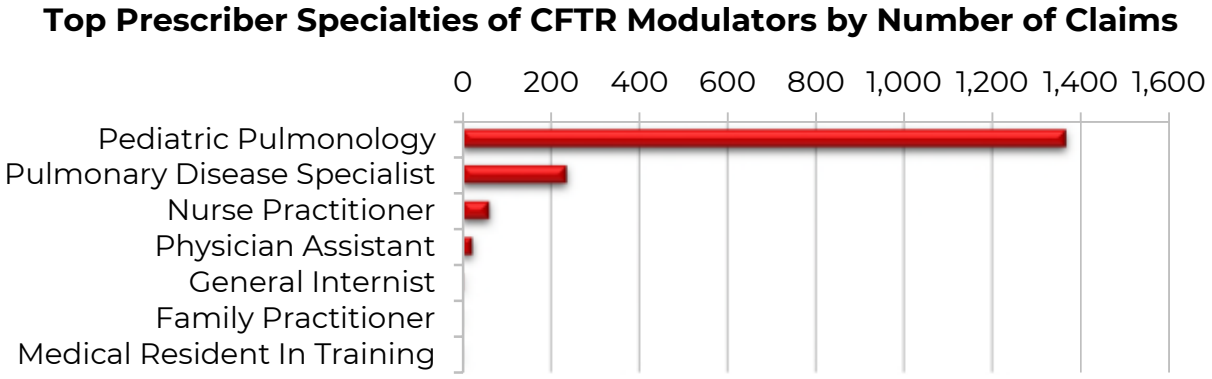
Utilization of CFTR Modulators: Fiscal Year 2023

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	152	1,500	$34,769,675.50	$23,179.78	$825.33	120,064	42,128
2023	179	1,695	$39,896,009.50	$23,537.47	$840.00	136,465	47,495
% Change	**17.80%**	**13.00%**	**14.70%**	**1.50%**	**1.80%**	**13.70%**	**12.70%**
Change	**27**	**195**	**$5,126,334.00**	**$357.69**	**$14.67**	**16,401**	**5,367**

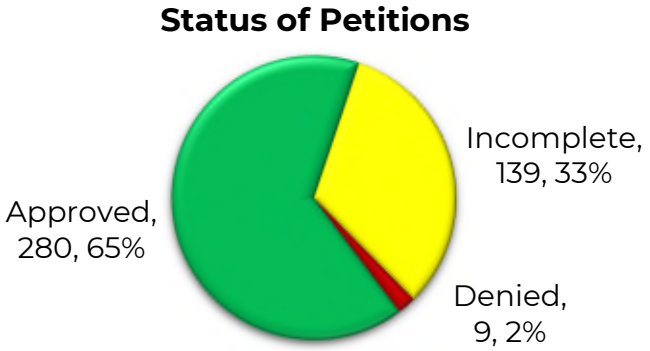
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023





Prior Authorization of CFTR Modulators

There were 428 prior authorization requests submitted for CFTR modulators during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



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

Anticipated Patent Expiration(s):

- Kalydeco® (ivacaftor tablets): August 2029
- Orkambi® (lumacaftor/ivacaftor tablets and granules): December 2030
- Kalydeco® (ivacaftor granules): February 2033

- Symdeko® (tezacaftor/ivacaftor and ivacaftor tablets): April 2035
- Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor tablets and granules): December 2037

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

- **April 2023:** Vertex Pharmaceuticals announced the FDA approval of an age expansion for Trikafta® to include children 2 to 5 years of age who have at least 1 *F508del* mutation in the *CFTR* gene or a mutation in the *CFTR* gene that is responsive to Trikafta® based on *in vitro* data. Trikafta® was previously approved for use in children 6 years of age and older.
- **May 2023:** The FDA approved an age expansion for Kalydeco® (ivacaftor) down to 1 month of age for infants with cystic fibrosis (CF) who have a mutation in the *CFTR* gene that is responsive to ivacaftor. Kalydeco® was previously approved for use in infants 4 months of age and older.

News:

- **November 2022:** The Simplify study was a 6-week study conducted to assess whether patients with CF who are 12 years of age or older and taking Trikafta® experienced a change in their lung function after discontinuing either hypertonic saline or dornase alfa. The results showed that stopping either of the inhaled therapies while on Trikafta® did not lead to a reduction in their lung function. Although longer studies are needed to better understand the impact on long-term health effects, this study is a step towards helping minimize the burden of various medications that CF patients need to manage their disease. Other studies assessing longer-term effects are also currently being conducted.

Pipeline:

- **Vanzacaftor/Tezacaftor/Deutivacaftor:** Vanzacaftor/tezacaftor/deutivacaftor is an investigational triple therapy that will be given once daily for patients with CF that have certain mutations in the *CFTR* gene. Enrollment for the 2 Phase 3 trials, SKYLINE 102 and SKYLINE 103, has been completed and the trials will compare the safety and efficacy of vanzacaftor/tezacaftor/deutivacaftor to Trikafta® in CF patients 12 years of age and older.
- **VX-522:** An Investigational New Drug (IND) application was cleared for VX-522, a messenger ribonucleic acid (mRNA) therapy. VX-522 targets the underlying cause of CF, offering an alternative to CF patients who cannot use a CFTR modulator. VX-522 is delivered to the lungs by lipid nanoparticles and when delivered to the target cells can produce functional copes of the *CFTR* protein. VX-522 is currently in Phase 1 of a

single dose escalation study in patients 18 years of age or older which is expected to be completed in 2023.

Recommendations

The College of Pharmacy recommends updating the approval criteria for the CFTR modulators based on the recent FDA approved age expansions and to be more consistent with clinical practice (changes shown in red):

Kalydeco® (Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) with a mutation in the CF transmembrane conductance regulator (*CFTR*) gene detected by genetic testing that is responsive to ivacaftor based on clinical and/*or in vitro* assay data; and
2. Documentation must be submitted with results of *CFTR* genetic testing; and
3. Member must be 1 ~~4~~ month~~s~~ of age or older; and
4. Members using Kalydeco® must be supervised by a pulmonary disease specialist; and
5. Prescriber must verify the member has been counseled on proper administration of Kalydeco® including taking with a fat-containing food; and
6. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Kalydeco®, every 3 months during the first year of treatment, and annually thereafter; and
7. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
8. Member must not be taking any of the following medications concomitantly with Kalydeco®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
9. For members 1 month to younger than 6 months of age:
    a. Member must not have any level of hepatic impairment; and
    b. Member must not be taking concomitant moderate or strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); and
10. A quantity limit of 2 tablets or 2 granule packets per day or 56 tablets or granule packets per 28 days will apply; and
11. An age restriction of 1 ~~4~~ month~~s~~ to 5 years of age will apply to Kalydeco® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
12. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable.

For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
13. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
14. Subsequent approvals will be for 1 year.

Orkambi® (Lumacaftor/Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation in the CF transmembrane conductance regulator *(CFTR)* gene detected by genetic testing; and
2. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene; and
3. Orkambi® will not be approved for members with CF other than those homozygous for the *F508del* mutation; and
4. Member must be 12 months of age or older; and
5. Members using Orkambi® must be supervised by a pulmonary disease specialist; and
6. Prescriber must verify the member has been counseled on proper administration of Orkambi® including taking with a fat-containing food; and
7. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Orkambi®, every 3 months during the first year of treatment, and annually thereafter; and
8. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
9. Member must not be taking any of the following medications concomitantly with Orkambi®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
10. A quantity limit of 4 tablets per day or 112 tablets per 28 days will apply or a quantity limit of 2 granule packets per day or 56 packets per 28 days will apply; and
11. An age restriction of 12 months to 5 years of age will apply to Orkambi® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
12. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

13. Initial approvals will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
14. Subsequent approvals will be for the duration of 1 year.

Symdeko® (Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation or who have at least 1 mutation in the CF transmembrane conductance regulator *(CFTR)* gene detected by genetic testing that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence; and
2. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and
3. Member must be 6 years of age or older; and
4. Members using Symdeko® must be supervised by a pulmonary disease specialist; and
5. If the member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) and experiencing adverse effects associated with Orkambi® use, the prescriber must indicate that information on the prior authorization request; and
6. Prescriber must verify the member has been counseled on proper administration of Symdeko® including taking with a fat-containing food; and
7. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Symdeko®, every 3 months during the first year of treatment, and annually thereafter; and
8. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
9. Member must not be taking any of the following medications concomitantly with Symdeko®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
10. A quantity limit of 2 tablets per day or 56 tablets per 28 days will apply; and
11. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
12. Initial approvals will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be

required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events must be provided for members who switched from Orkambi® to Symdeko®; and

13. Subsequent approvals will be for the duration of 1 year.

Trikafta® (Elexacaftor/Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 *F508del* mutation in the CF transmembrane conductance regulator *(CFTR)* gene or a mutation in the *CFTR* gene that is responsive based on *in vitro* data; and
2. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and
3. Member must be 2 ~~6~~ years of age or older; and
4. Members using Trikafta® must be supervised by a pulmonary disease specialist; and
5. If the member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi® or Symdeko® use, the prescriber must indicate that information on the prior authorization request; and
6. Prescriber must verify the member has been counseled on proper administration of Trikafta® including taking with a fat-containing food; and
7. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Trikafta®, every 3 months during the first year of treatment, and annually thereafter; and
8. Prescriber must verify the member does not have severe hepatic impairment; and
9. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
10. Member must not be taking any of the following medications concomitantly with Trikafta®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
11. ~~A quantity limit of 3 tablets per day or 84 tablets per 28 days will apply; and~~
12. The following quantity limits will apply:
    a. Oral tablets: A quantity limit of 3 tablets per day or 84 tablets per 28 days; or

b. Oral granules: A quantity limit of 2 packets per day or 56 packets per 28 days; and

13. For Trikafta® oral granules, an age restriction of 2 years to 5 years of age will apply. Members 6 years of age or older will require a patient-specific, clinically significant reason why the Trikafta® tablets cannot be used; and
14. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
15. Initial approvals will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® or Symdeko® to Trikafta®; and
16. Subsequent approvals will be for the duration of 1 year.

Utilization Details of CFTR Modulators: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ELEXACAFTOR/TEZACAFTOR/IVACAFTOR AND IVACAFTOR COMBINATION PRODUCTS					
TRIKAFTA TAB 100-50-75/150MG	1,140	125	$27,479,896.65	$24,105.17	9.12
TRIKAFTA TAB 50-25-37.5/75MG	313	36	$7,833,237.27	$25,026.32	8.69
TRIKAFTA PAK 100-50-75/75MG	8	6	$102,860.18	$12,857.52	1.33
TRIKAFTA PAK 80-40-60/59.5MG	8	5	$200,627.60	$25,078.45	1.6
SUBTOTAL	**1,469**	**172**	**$35,616,621.70**	**$24,245.49**	**8.54**
LUMACAFTOR/IVACAFTOR COMBINATION PRODUCTS					
ORKAMBI GRA 100-125MG	78	10	$1,519,868.20	$19,485.49	7.8
ORKAMBI GRA 150-188MG	65	9	$1,230,954.10	$18,937.76	7.22
ORKAMBI TAB 100-125MG	21	3	$411,694.65	$19,604.51	7
ORKAMBI GRA 75-94MG	6	2	$131,734.08	$21,955.68	3
SUBTOTAL	**170**	**24**	**$3,294,251.03**	**$19,377.95**	**7.08**
IVACAFTOR PRODUCTS					
KALYDECO PAK 50MG	20	2	$238,687.90	$11,934.40	10
KALYDECO PAK 75MG	13	1	$326,019.85	$25,078.45	13
KALYDECO TAB 150MG	10	2	$250,752.50	$25,075.25	5
KALYDECO PAK 25MG	2	1	$2,278.30	$1,139.15	2
SUBTOTAL	**45**	**6**	**$817,738.55**	**$18,171.97**	**7.5**
TEZACAFTOR/IVACAFTOR AND IVACAFTOR COMBINATION PRODUCTS					
SYMDEKO TAB 100-150MG	8	2	$96,871.19	$12,108.90	4

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SYMDEKO TAB 50-75MG	3	1	$70,527.03	$23,509.01	3
SUBTOTAL	**11**	**3**	**$167,398.22**	**$15,218.02**	**3.67**
TOTAL	**1,695**	**179***	**$39,896,009.50**	**$23,537.47**	**9.47**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 08/2023. Last accessed 08/15/2023.
[2] Cystic Fibrosis Foundation. Simplify Study Indicates Potential to Reduce Medication Burden for People With CF Taking Trikafta®. Available online at: https://www.cff.org/news/2022-11/simplify-study-indicates-potential-reduce-medication-burden-people-cf-taking-trikafta. Issued 11/04/2022. Last accessed 08/15/2023.
[3] Vertex Pharmaceuticals Inc. Vertex Announces U.S. FDA Approval for Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) in Children with Cystic Fibrosis Ages 2 Through 5 With Certain Mutations. Available online at: https://investors.vrtx.com/news-releases/news-release-details/vertex-announces-us-fda-approval-trikaftar-0. Issued 04/26/2023. Last accessed 08/15/2023.
[4] Cystic Fibrosis Foundation. FDA Approves Kalydeco® for Infants as Young as 1 Month. Available online at: https://www.cff.org/news/2023-05/fda-approves-kalydeco-infants. Issued 05/03/2023. Last accessed 08/15/2023.
[5] Vertex Pharmaceuticals Inc. R&D Pipeline. Available online at: https://www.vrtx.com/our-science/pipeline/. Last accessed 08/15/2023.
[6] Vertex Pharmaceuticals Inc. Vertex Reports Fourth Quarter and Full Year Financial 2022 Results. Available online at: https://investors.vrtx.com/node/30231/pdf. Issued 02/07/2023. Last accessed 08/15/2023.
[7] Vertex Pharmaceuticals Inc. Vertex Announces Investigational New Drug (IND) Application for VX-522, mRNA Therapy for People with Cystic Fibrosis, Cleared by FDA. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20221208005977/en/. Issued 12/12/2022. Last accessed 08/15/2023.

Appendix N

Fiscal Year 2023 Annual Review of Gattex® [Teduglutide (rDNA Origin)]

Oklahoma Health Care Authority
September 2023

Current Prior Authorization Criteria

Gattex® [Teduglutide (rDNA Origin)] Approval Criteria:

1. An FDA approved diagnosis of severe short bowel syndrome; and
2. Member must have required parenteral nutrition at least 3 times per week, every week, for the past 12 months; and
3. Documentation of all of the following:
   a. Prior use of supportive therapies (e.g., anti-motility agents, proton pump inhibitors, bile acid sequestrants, octreotide); and
   b. Colonoscopy within the previous 6 months, with removal of polyps if present; and
   c. Gastrointestinal malignancy has been ruled out; and
4. Approval will be for the duration of 3 months, after which time, prescriber must verify benefit of medication by documented reduction of at least 20% in parenteral support. Subsequent approvals will be for the duration of 1 year.

Utilization of Gattex® [Teduglutide (rDNA Origin)]: Fiscal Year 2023

Comparison of Fiscal Years

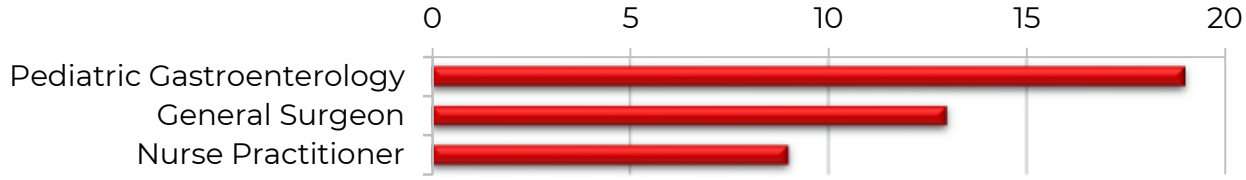
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	6	41	$1,734,921.06	$42,315.15	$1,410.50	41	1,230
2023	6	41	$1,696,155.34	$41,369.64	$1,378.99	41	1,230
% Change	**0.00%**	**0.00%**	**-2.20%**	**-2.20%**	**-2.20%**	**0.00%**	**0.00%**
Change	**0**	**0**	**-$38,765.72**	**-$945.51**	**-$31.51**	**0**	**0**

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

Demographics of Members Utilizing Gattex® [Teduglutide (rDNA Origin)]

- Due to the limited number of members utilizing Gattex® [teduglutide (rDNA Origin)] during fiscal year 2023, detailed demographic information could not be provided.

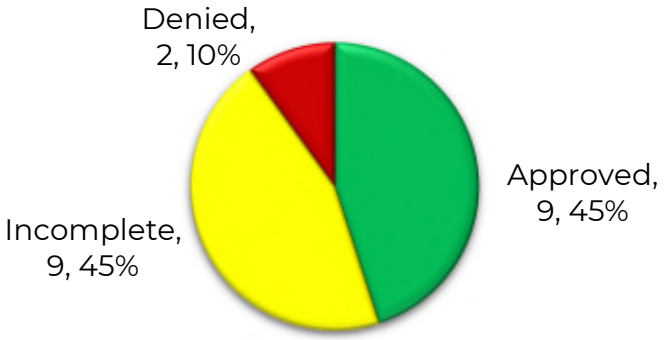
Top Prescriber Specialties of Gattex® [Teduglutide (rDNA Origin)] by Number of Claims



Prior Authorization of Gattex® [Teduglutide (rDNA Origin)]

There were 20 prior authorization requests submitted for Gattex® [teduglutide (rDNA origin)] for 7 unique members during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Gattex® [teduglutide (rDNA origin)]: May 2026

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

- **May 2019:** The FDA approved Gattex® [teduglutide (rDNA origin)] for an age expansion for the treatment of short bowel syndrome in patients 1 to 17 years of age who are dependent on parenteral support. Gattex® was previously only approved for use in adult patients with this indication. The label expansion trial recruited patients who were 0 to 17 years of age, had a current diagnosis of short bowel syndrome, and those who were stable on parenteral nutrition that accounted for at least 30% of their caloric or fluid and electrolyte needs. Due to similarities in the adverse event profiles between pediatric and adult populations and the previously identified risk of colorectal polyps in the adult population, it is recommended that pediatric patients undergo fecal occult blood testing prior to initiating treatment with Gattex® and

if unexplained blood is found, a follow-up colonoscopy/sigmoidoscopy is recommended.

Pipeline:

- **ZP-1848 (Glepaglutide):** Glepaglutide is a long-acting glucagon-like peptide-2 (GLP-2) analog that is being evaluated for the treatment of short bowel syndrome. In a Phase 2 crossover trial, patients experienced an increase in absorption after 6 weeks of treatment with once daily subcutaneous injections of glepaglutide. The Phase 3 EASE-SBS 1 trial randomized patients to once or twice weekly glepaglutide or placebo with the primary outcome measure being a reduction in weekly parenteral support volume. EASE-SBS 1 was completed in July 2022 and an extension was granted in May 2023. Two trials are ongoing to further determine the safety and efficacy of glepaglutide in the adult population with short bowel syndrome. Both the Phase 2 and 3 trials only enrolled adult patients with no active studies investigating use in pediatric patients.

Recommendations

The College of Pharmacy recommends the following changes to the Gattex® [teduglutide (rDNA origin] approval criteria based on the FDA approved age expansion and label updates (changes shown in red):

Gattex® [Teduglutide (rDNA Origin)] Approval Criteria:

1. An FDA approved diagnosis of severe short bowel syndrome; and
2. Member must require parenteral nutrition (PN) as indicated by the following:
    a. For adult members: Must require PN at least 3 times per week, every week, for the past 12 months; or
    b. For pediatric members: PN accounts for at least 30% of caloric and/or fluid/electrolyte needs; and
3. Documentation of all of the following:
    a. Prior use of supportive therapies (e.g., anti-motility agents, proton pump inhibitors, bile acid sequestrants, octreotide); and
    b. For adult members, ~~C~~colonoscopy within the previous 6 months, with removal of polyps if present; and
    c. For pediatric members, a fecal occult blood test within the previous 6 months; and
        i. If there is unexpected blood in the stool, a colonoscopy/ sigmoidoscopy was performed; and
    d. Gastro-intestinal malignancy has been ruled out; and
4. Approval will be for the duration of 3 months, after which time, prescriber must verify benefit of medication by documented reduction

of at least 20% in parenteral support. Subsequent approvals will be for the duration of 1 year.

Utilization Details of Gattex® [Teduglutide (rDNA Origin)]: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GATTEX KIT 5MG	41	6	$1,696,155.34	$41,369.64	6.83	100%
TOTAL	**41**	**6***	**$1,696,155.34**	**$41,369.64**	**6.83**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 08/2023. Last accessed 08/15/2023.
[2] U.S. FDA. New Pediatric Labeling Information Database – Detail. Available online at https://www.accessdata.fda.gov/scripts/sda/sdDetailNavigation.cfm?sd=labelingdatabase&id=8DBBF863015E1625E053564DA8C07639&rownum=14. Issued 05/15/2019. Last accessed 08/15/2023.
[3] Gattex® [Teduglutide (rDNA Origin)] Prescribing Information. Takeda. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203441s013lbl.pdf. Last revised 05/2019. Last accessed 08/15/2023.
[4] A 24-Week, Double-Blind, Safety, Efficacy, and Pharmacodynamic Study Investigating Two Doses of Teduglutide in Pediatric Subjects Through 17 Years of Age with Short Bowel Syndrome Who are Dependent on Parenteral Support. *ClinicalTrials.gov*. Available Online at: https://clinicaltrials.gov/study/NCT02682381. Last revised 06/09/2021. Last accessed 08/25/2023.
[5] A Phase 3, International, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Glepaglutide Subcutaneous Injections in Patients with Short Bowel Syndrome (SBS). *ClinicalTrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT03690206. Last revised 05/30/2023. Last accessed 08/25/2023.
[6] Naimi R, Hvistendahl M, Enevoldsen L, et al. Glepaglutide, a Novel Long-Acting Glucagon-Like Peptide-2 Analogue, for Patients with Short Bowel Syndrome: a Randomized Phase 2 Trial. *Lancet Gastroenterol Hepatol* 2019; 4(5):354-363. doi: 10.1016/S2468-1253(19)30077-9.

Appendix O

Fiscal Year 2023 Annual Review of Synagis® (Palivizumab)

Oklahoma Health Care Authority
September 2023

Current Prior Authorization Criteria[1]

A prior authorization is required for all members who receive palivizumab in an outpatient setting. Palivizumab is approved for members who meet the established prior authorization criteria, which is based on the American Academy of Pediatrics (AAP) 2014 guidelines for palivizumab prophylaxis.

Synagis® (Palivizumab) Approval Criteria:

A. Member Selection:
   1. Infants younger than 12 months of age at the start of respiratory syncytial virus (RSV) season:
      a. Born before 29 weeks, 0 days gestation; or
      b. Born before 32 weeks, 0 days gestation and develop chronic lung disease (CLD) of prematurity (require >21% oxygen supplementation for ≥28 days after birth); or
      c. Have hemodynamically significant congenital heart disease [acyanotic heart disease and receiving medication to control congestive heart failure (CHF) and will require surgical procedures, or have moderate-to-severe pulmonary hypertension]; or
      d. May be considered for:
         i. Infants with neuromuscular disease or a congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough; or
         ii. Infants who undergo cardiac transplantation during RSV season; or
         iii. Infants who are profoundly immunocompromised during RSV season; or
         iv. Infants with cystic fibrosis with clinical evidence of CLD and/or who are nutritionally compromised; or
   2. Infants 12 to 24 months of age at the start of RSV season:
      a. Born before 32 weeks, 0 days gestation and have CLD of prematurity (required ≥28 days of oxygen after birth) and continue to require medical support (i.e., chronic corticosteroid therapy, diuretic therapy, supplemental oxygen) during the 6 months before the start of the RSV season; or

b. May be considered for:
    i. Infants who undergo cardiac transplantation during RSV season; or
    ii. Infants who are profoundly immunocompromised during RSV season; or
    iii. Infants with cystic fibrosis with manifestations of severe lung disease or weight for length less than the 10th percentile.

B. Length of Treatment: Palivizumab is approved for use only during RSV season in Oklahoma as determined by the Oklahoma State Department of Health (OSDH) Viral Respiratory Illness Sentinel Surveillance System or other credible statewide monitoring system. The threshold for determining RSV seasonality is 10% of positive tests. RSV is determined to be in season once the percentage of positive tests is >10%; however, due to a potential lag in reporting data, palivizumab coverage will begin when the percentage of positive tests is consistently increasing and approaching the 10% threshold. RSV season is determined to be at an end when the percentage of positive tests is consistently <10%. Initial approvals will be for the duration of 3 months from the determined RSV season start date in Oklahoma. Subsequent approvals will be for the duration of 1 month until RSV season end. A separate prior authorization request will be required for consideration of initial approval and for each subsequent approval.
C. Units Authorized: The member's current weight (taken within the last 3 weeks) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling. Doses are to be administered no more often than every 30 days. Members given doses more frequently than every 30 days will not be authorized for additional doses. Doses administered prior to the member's discharge from a hospital will be counted as 1 of the approved total.
D. Dose-Pooling: To avoid unnecessary risk to the member, multiple members are not to be treated from a single vial. Failure to follow this recommendation will result in referral of the provider to the Quality Assurance Committee of the Oklahoma Health Care Authority.

Utilization of Synagis® (Palivizumab): Fiscal Year 2023

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	312	1,214	$3,161,700.09	$2,604.37	$86.83	1,052	36,414
2023	254	840	$2,331,515.31	$2,775.61	$92.54	730	25,194
% Change	**-18.60%**	**-30.80%**	**-26.30%**	**6.60%**	**6.60%**	**-30.60%**	**-30.80%**
Change	**-58**	**-374**	**-$830,184.78**	**$171.24**	**$5.71**	**-322**	**-11,220**

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

Fiscal Year 2023 Utilization: Medical Claims

Fiscal Year	*Total Members	⁺Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2023	1	3	$11,504.71	$3,834.90	3

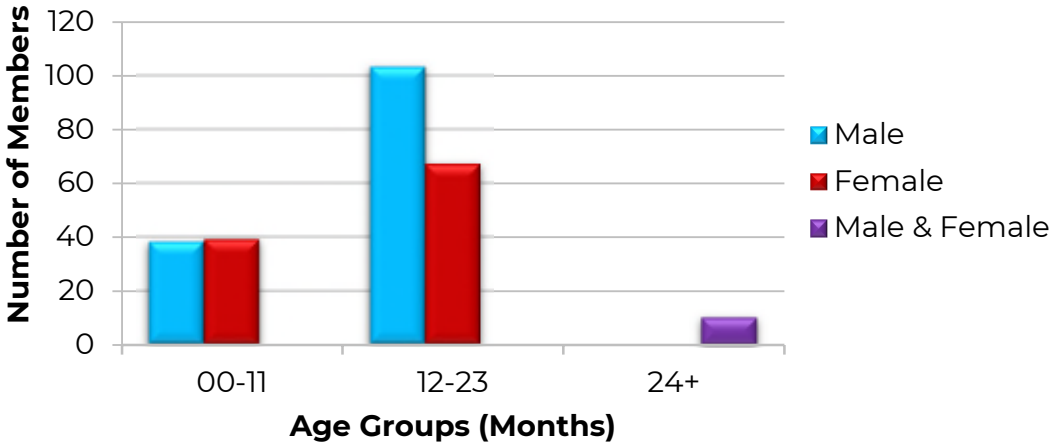
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Total number of unduplicated claims.
Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note: There were no paid medical claims for Synagis® during fiscal year 2022 (07/01/2021 to 06/30/2022) to allow for a fiscal year comparison.

Cost Per Vial

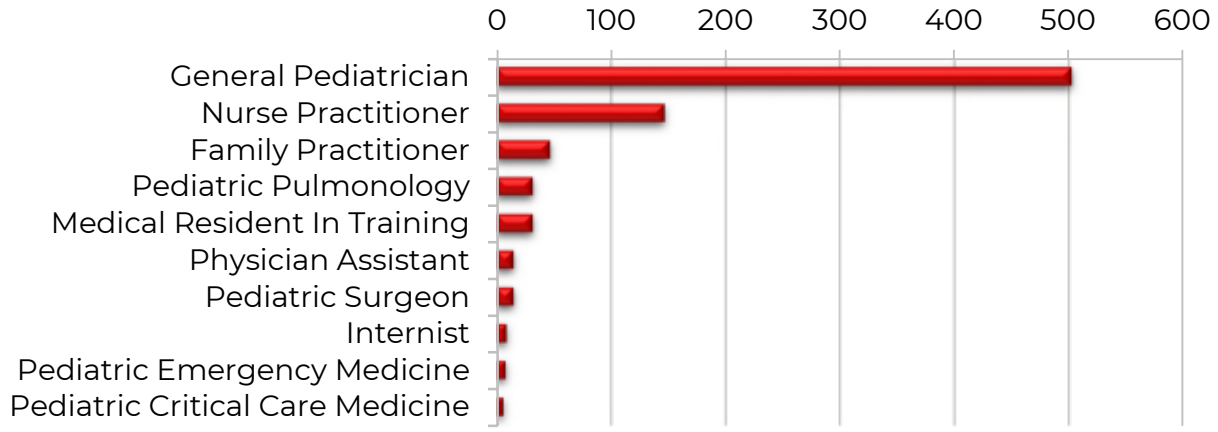
Vial Size	Cost Per Vial
Synagis® (palivizumab) 100mg/mL vial	$3,369.16
Synagis® (palivizumab) 50mg/0.5mL vial	$1,784.25

Costs do not reflect rebated prices or net costs.
Costs based on specialty pharmaceutical allowable cost (SPAC).

Demographics of Members Utilizing Synagis® (Palivizumab)



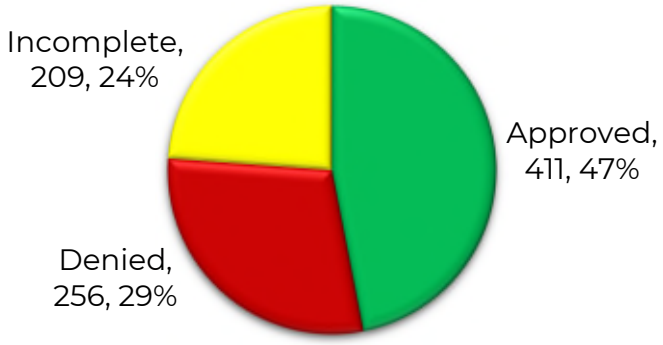
Top Prescriber Specialties of Synagis® (Palivizumab) by Number of Claims



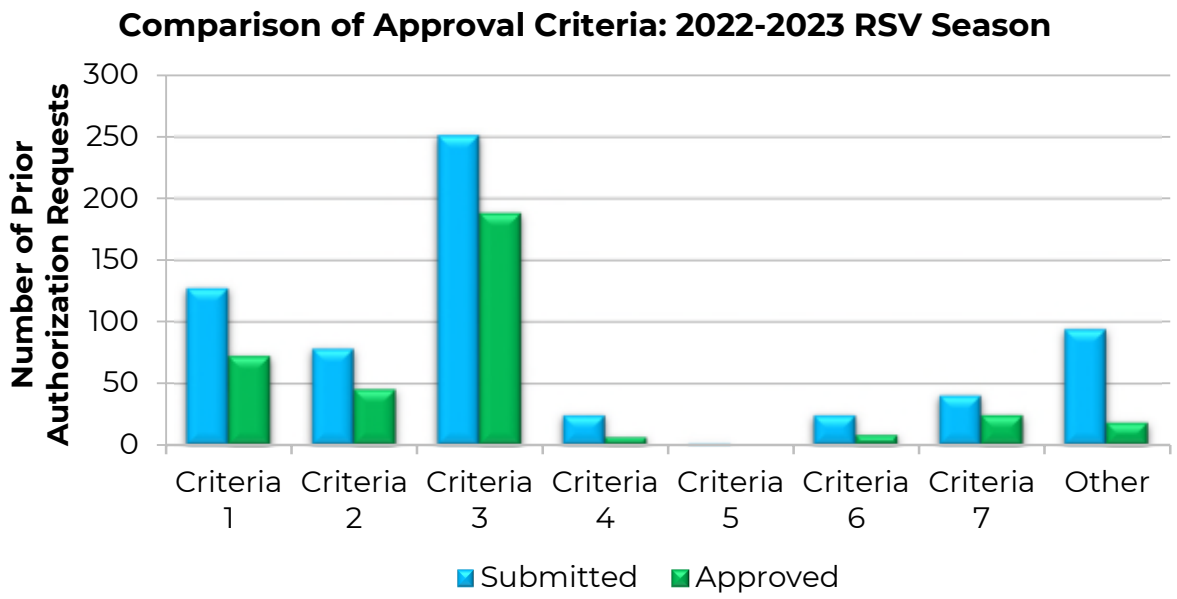
Prior Authorization of Synagis® (Palivizumab)

There were 876 palivizumab prior authorization requests submitted for 389 unique members during fiscal year 2023. This is a decrease in both submitted petitions and number of members requesting palivizumab compared to fiscal year 2022 when there were 1,299 palivizumab prior authorization requests submitted for 461 unique members. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



The following graph shows the number of submissions and approvals for each prior authorization criteria. The graph is followed by a numbered list in which the list number corresponds to the criteria number in the graph. The most commonly requested and approved criteria selection during the 2022 to 2023 respiratory syncytial virus (RSV) season was criteria number 3: infants born before 29 weeks, 0 days gestation. Infants born before 32 weeks, 0 days gestation and who had chronic lung disease (CLD) of prematurity was also a commonly requested and approved criteria selection (criteria number 1).



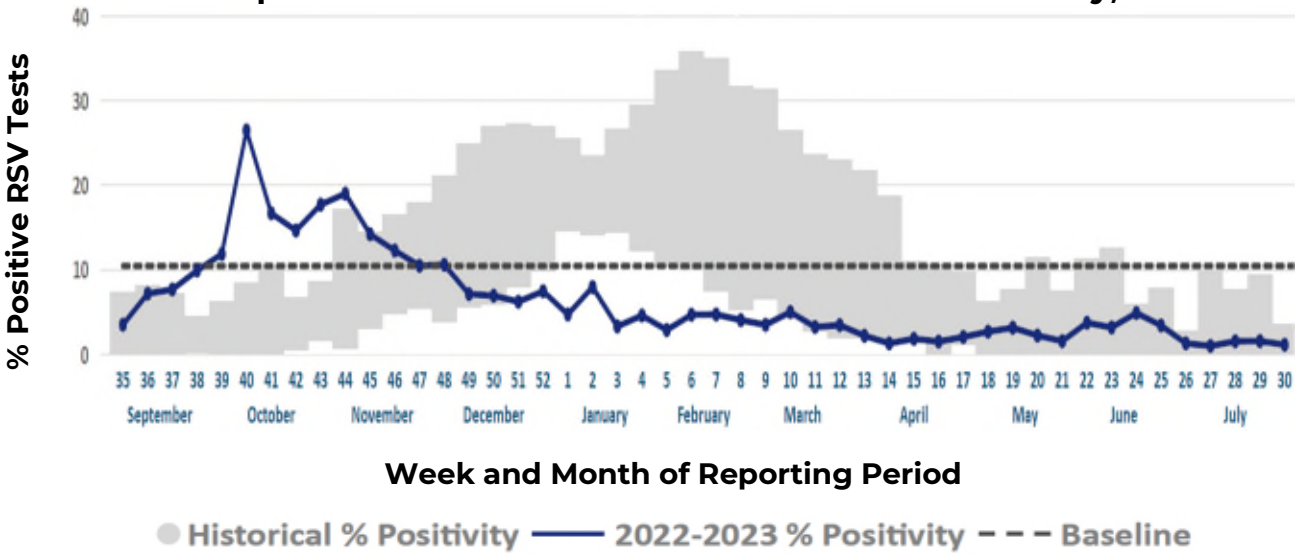
Criteria List:

1. Infants 0 to 24 months of age at the start of RSV season born before 32 weeks, 0 days gestation and have CLD of prematurity
2. Infants who have hemodynamically significant congenital heart disease and will require surgical procedures, or have moderate-to-severe pulmonary hypertension
3. Infants born before 29 weeks, 0 days gestation
4. Infants with neuromuscular disease or a congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough
5. Infants who undergo cardiac transplantation during RSV season
6. Infants who are profoundly immunocompromised during RSV season
7. Infants with cystic fibrosis with clinical evidence of CLD and/or are nutritionally compromised

RSV Season Comparison[2,3,4,5,6,7,8]

The following chart contains the weekly percentage of laboratory positive RSV tests in Oklahoma as reported by the Oklahoma State Department of Health (OSDH) Viral Respiratory Illness Sentinel Surveillance System. The chart shows the percent positivity for the 2022-2023 RSV season compared to a 10-year historical average. RSV is determined to be in season once the percentage of positive tests is >10% for 2 consecutive weeks. Similarly, the season is determined to be at an end when the percentage of positive tests is <10% for 2 consecutive weeks.

OSDH: Percent of Positive RSV Tests Reported by Sentinel Providers by Week Compared to Ten-Year Historical RSV Percent Positivity, 2022-2023



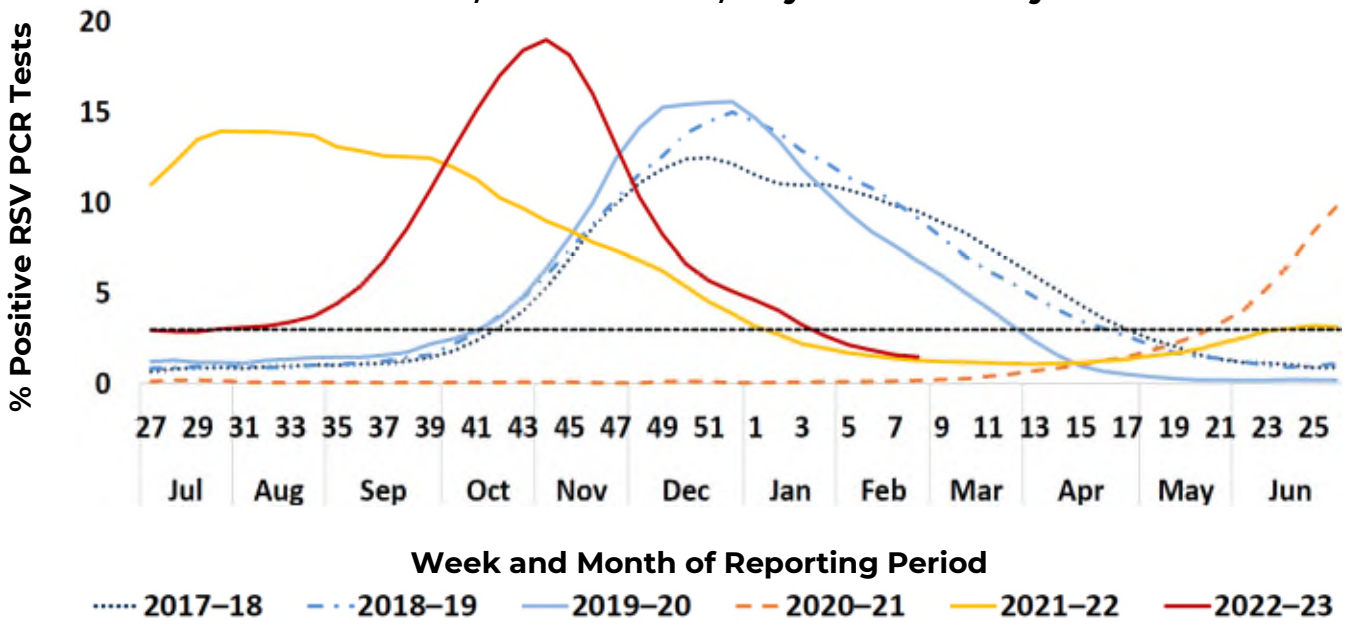
The Centers for Disease Control and Prevention (CDC) reports seasonality by using RSV polymerase chain reaction (PCR) laboratory detections. Laboratories are shifting away from antigen-based RSV testing, and since 2014, the majority of RSV detections among reporting laboratories were determined by PCR. RSV season onset, when evaluated by PCR detections and a new statistical method determined by the CDC, was defined as the second of 2 consecutive weeks when the slope, or normalized 5-week moving average of RSV detections between subsequent weeks, exceeded 10 standardized detections per week. Season offset was determined as the last week when the standardized detections exceeded the standardized detections at onset. These changes were done to reflect the adoption of a statistical method rather than a threshold or percentage positive which can be influenced by volume of tests performed. The CDC cautioned that the statistical detection method used captures a high proportion of RSV detection for retrospectively determining seasonality but cannot be used to determine seasonal onset and offset in real time and can only be used after the season is at an end. The CDC advises that surveillance data collected by state and local health departments might be more accurate to describe local RSV circulation trends. The OSDH currently reports RSV testing data as a mixture of antigen and PCR testing. PCR testing is not separately reported by the OSDH to evaluate local trends specific to the state of Oklahoma. The *Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection* released by the AAP in 2014 states the following with regard to RSV seasonality:

> "During the 6 RSV seasons from July 2007 to January 2013, the median duration of the RSV season ranged from 13 to 23 weeks, with median peak

activity from mid-December to early February, with the exception of Florida and Alaska. Within the 10 Health and Human Services Regions, in the few regions when the RSV season began in October, the season ended in March or early April. In regions where the RSV season began in November or December, the season ended by April or early May. Because 5 monthly doses of palivizumab at 15mg/kg per dose will provide more than 6 months of serum palivizumab concentrations above the desired serum concentration for most infants, administration of more than 5 monthly doses is not recommended within the continental United States."

When looking at the United States as a whole and comparing RSV seasons since 2017, in April 2023, the CDC reported that there was historically low RSV circulation during the 2020-2021 season, which was followed by large epidemics and atypical seasonality during the following 2 seasons. The 2021-2022 season began in late spring and lasted longer than pre-pandemic seasons. The 2022-2023 season began later than the 2021-2022 season, but earlier than in pre-pandemic years. The CDC has interpreted this as being suggestive of a return toward pre-pandemic seasonality with peaks occurring during the winter months, but clinicians should be aware that atypical RSV circulation might continue, and they should consider testing for multiple respiratory pathogens when indicated.

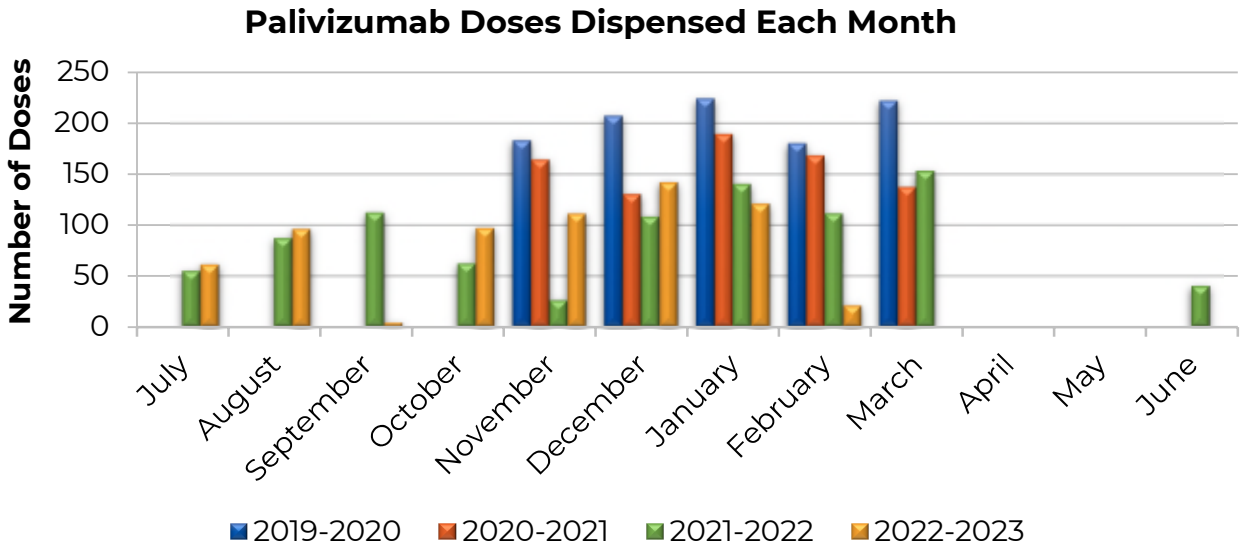
CDC: Changes in Seasonality of RSV Transmission Following SARS-CoV2 Introduction, United States, July 2017-February 2023



Historically, in Oklahoma, RSV seasons were similar with a peak typically in December or January and a season end by late March. Beginning in 2020, the percentage of positive tests in Oklahoma did not exceed 10% during the typical RSV season months, likely due to nonpharmacological interventions

(e.g., masking, social distancing, decreased travel) related to the COVID-19 pandemic. However, atypical RSV circulation was observed beginning in June 2021, coinciding with the relaxation of some COVID-19-related restrictions and interventions. As a result of the atypical RSV season onset and offset, the palivizumab approval criteria was updated by the Drug Utilization Review (DUR) Board in September 2021 to allow coverage based on RSV positivity in Oklahoma, rather than only during specific months. Currently, SoonerCare coverage of palivizumab is determined based on the percentage of positive tests, as reported by the OSDH. During fiscal year 2023 in Oklahoma, the percentage of positive antigen and PCR detection tests exceeded the 10% threshold during portions of October 2022 and November 2022.

The following bar graph shows the number of palivizumab doses reimbursed for by SoonerCare for each month during the last 4 RSV seasons. The use of palivizumab outside the typical RSV season months (November through March) was allowed for the first time during fiscal year 2022 (shown in green) due to atypical RSV season onset and offset. During fiscal year 2023, although RSV circulation continued to be somewhat atypical, the overall number of doses dispensed decreased significantly compared to fiscal year 2022, corresponding with the decreased number of prior authorization requests submitted during fiscal year 2023.



Market News and Updates[9,10,11,12,13,14,15,16,17,18,19,20,21,22,23]

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

- **May 2023:** The FDA approved Arexvy (RSV vaccine, adjuvanted) for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 60 years of age and older. Arexvy is the first RSV vaccine to be FDA approved in the United States.

In the clinical trial used to demonstrate efficacy and safety, Arexvy reduced the risk of RSV-associated LRTD by 82.6% and reduced the risk of developing severe RSV-associated LRTD by 94.1% compared to participants who received placebo. Arexvy is supplied as a lyophilized powder (antigen component) in a single-dose vial and a single-dose vial of adjuvant suspension for reconstitution. The recommended dosing is a single 0.5mL dose administered by intramuscular (IM) injection.

- **May 2023:** The FDA approved Abrysvo™ (RSV vaccine) for active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older. In the clinical trial, Abrysvo™ was 66.7% effective against RSV-associated LRTD with ≥2 signs or symptoms and 85.7% effective against RSV-associated LRTD with ≥3 signs or symptoms. Abrysvo™ is supplied as a single dose of lyophilized antigen component in a vial and a prefilled syringe containing sterile water diluent for reconstitution. The recommended dosing is a single 0.5mL dose administered by IM injection.
- **July 2023:** The FDA approved Beyfortus™ (nirsevimab-alip), a long-acting RSV F protein-directed fusion inhibitor, for the prevention of RSV LRTD in neonates and infants born during or entering their first RSV season or in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. The safety and efficacy of Beyfortus™ were assessed in 3 clinical trials (Trial 03, Trial 04, and Trial 05). Trial 03 enrolled preterm infants born at gestational age (GA) 29 to <35 weeks and found that Beyfortus™ was 70.1% effective against medically attended RSV-associated lower respiratory tract infection (MA RSV LRTI) at 150 days post dose. Trial 04 enrolled term and late preterm infants born at GA ≥35 weeks entering their first RSV season and found that Beyfortus™ was 74.9% effective against MA RSV LRTI at 150 days post dose. Trial 05 was not powered to evaluate efficacy, but enrolled preterm infants born at GA <35 weeks and infants with chronic lung disease (CLD) of prematurity or hemodynamically significant congenital heart disease (CHD). Infants with CLD or CHD could continue in the trial for a second RSV season. Participants were randomized 2:1 to receive 1 dose of Beyfortus™ (followed by 4 monthly placebo doses) or 5 monthly doses of palivizumab. In the first RSV season, the incidence of MA RSV LRTI was 0.6% in the Beyfortus™ group and 1.0% in the palivizumab group. In the second RSV season, no cases of MA RSV LRTI were reported through 150 days post dose for either the Beyfortus™ or palivizumab group. Beyfortus™ is supplied as a 50mg/0.5mL or 100mg/mL single-dose prefilled syringe for IM injection. The recommended dosing is based on the RSV season (first or second) and weight:
    - Neonates and infants born during or entering their first RSV season: 50mg dose (if <5kg) or 100mg dose (if ≥5kg)

    - Children who remain vulnerable through their second RSV season: 200mg dose [(2) 100mg injections]
- **August 2023:** The FDA approved Abrysvo™ for a new indication for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age. In the clinical trial supporting FDA approval for this indication, in the subset of individuals who were 32 through 36 weeks gestational age when vaccinated, Abrysvo™ was 91.1% effective against severe RSV LRTD at 90 days after birth and 76.5% effective against severe RSV LRTD at 180 days after birth. The recommended dosing is a single 0.5mL dose administered by IM injection to pregnant individuals at 32 through 36 weeks gestational age.

Guideline Update(s):

- **November 2022:** The AAP released updated guidance for the use of palivizumab prophylaxis to prevent hospitalization from severe RSV infection during the 2022-2023 RSV season. In response to the changing patterns of RSV circulation, the AAP stated that some regions that began administering palivizumab during the summer or fall of 2022 may experience a period of RSV disease activity lasting longer than the usual 6-month duration. In these regions, the AAP supports providing more than 5 doses of palivizumab to eligible children, depending on the duration of RSV circulation in that region. The AAP will continue to monitor interseasonal RSV circulation trends and provide updated guidance as needed.
- **June 2023:** The AAP published a new technical report titled *Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection* which reviews literature published since 2014 regarding palivizumab prophylaxis. Based on this review, the Committee on Infectious Diseases (COID) determined that the literature and data support a reaffirmation of the 2014 AAP recommendations for palivizumab prophylaxis. Additionally, the AAP noted that several new options for RSV prevention, which are currently under review, may significantly impact RSV prophylaxis recommendations in the near future.

News:

- **August 2023:** Following a vote by the Advisory Committee on Immunization Practices (ACIP), the CDC now recommends 1 dose of nirsevimab for all infants younger than 8 months of age born during or entering their first RSV season. Additionally, the CDC recommends 1 dose of nirsevimab for children 8-19 months of age who are at increased risk of severe RSV disease in their second RSV season. ACIP

also voted to add nirsevimab to the Vaccines for Children (VFC) program, and the CDC is currently working to make nirsevimab available through the VFC program, which provides vaccines and immunizations at no cost to eligible children in the United States.

- **August 2023:** The AAP released recommendations for the use of nirsevimab for the prevention of RSV disease, including the following recommendations regarding palivizumab vs. nirsevimab administration:
  - If nirsevimab is administered, palivizumab should not be administered later that season.
  - If palivizumab was administered initially for the season and <5 doses were administered, the infant should receive 1 dose of nirsevimab. No further palivizumab should be administered.
  - If palivizumab was administered in season 1 and the child is eligible for RSV prophylaxis in season 2, the child should receive nirsevimab in season 2, if available. If nirsevimab is not available, palivizumab should be administered as previously recommended.

  Additionally, children who qualify for the use of nirsevimab when entering their second RSV season include:
  - Children with CLD of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season
  - Children who are severely immunocompromised
  - Children with cystic fibrosis who have manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or have weight-for-length that is <10th percentile
  - American Indian and Alaska Native children (note that this is a new group for whom second-season prophylaxis is recommended in contrast to the current palivizumab recommendations).

Pipeline:

- **mRNA-1345:** Moderna is developing mRNA-1345 as a vaccine against RSV in vulnerable populations, including young children and older adults. mRNA-1345 encodes for a prefusion F glycoprotein, which elicits a higher neutralizing antibody response compared to the postfusion state and is developed using the same lipid nanoparticle (LNP) as Moderna's COVID-19 vaccine. In July 2023, Moderna announced the initiation of the rolling submission process for a Biologics License Application (BLA) to the FDA for the prevention of RSV-associated LRTD in adults 60 years of age or older. The FDA previously granted Breakthrough Therapy and Fast Track designations for this indication.

Recommendations

The College of Pharmacy recommends updating the Synagis® (palivizumab) approval criteria based on the FDA approval of Beyfortus™ (nirsevimab-alip) and CDC and AAP recommendations (changes shown in red):

Synagis® (Palivizumab) Approval Criteria:

A. Member Selection:
   1. Infants younger than 12 months of age at the start of respiratory syncytial virus (RSV) season:
      a. Born before 29 weeks, 0 days gestation; or
      b. Born before 32 weeks, 0 days gestation and develop chronic lung disease (CLD) of prematurity (require >21% oxygen supplementation for ≥28 days after birth); or
      c. Have hemodynamically significant congenital heart disease [acyanotic heart disease and receiving medication to control congestive heart failure (CHF) and will require surgical procedures, or have moderate-to-severe pulmonary hypertension]; or
      d. May be considered for:
         i. Infants with neuromuscular disease or a congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough; or
         ii. Infants who undergo cardiac transplantation during RSV season; or
         iii. Infants who are profoundly immunocompromised during RSV season; or
         iv. Infants with cystic fibrosis with clinical evidence of CLD and/or who are nutritionally compromised; or
   2. Infants 12 to 24 months of age at the start of RSV season:
      a. Born before 32 weeks, 0 days gestation and have CLD of prematurity (required ≥28 days of oxygen after birth) and continue to require medical support (i.e., chronic corticosteroid therapy, diuretic therapy, supplemental oxygen) during the 6 months before the start of the RSV season; or
      b. May be considered for:
         i. Infants who undergo cardiac transplantation during RSV season; or
         ii. Infants who are profoundly immunocompromised during RSV season; or
         iii. Infants with cystic fibrosis with manifestations of severe lung disease or weight for length less than the 10th percentile.

B. Product Selection: A patient-specific, clinically significant reason why the member cannot receive Beyfortus™ (nirsevimab-alip), as recommended by the CDC, must be provided. Additionally, the prescriber must confirm the member has not already received Beyfortus™ for the current RSV season. Concomitant use with Beyfortus™ will not be approved.
C. Length of Treatment: Palivizumab is approved for use only during RSV season in Oklahoma as determined by the Oklahoma State Department of Health (OSDH) Viral Respiratory Illness Sentinel Surveillance System or other credible statewide monitoring system. The threshold for determining RSV seasonality is 10% of positive tests. RSV is determined to be in season once the percentage of positive tests is >10%; however, due to a potential lag in reporting data, palivizumab coverage will begin when the percentage of positive tests is consistently increasing and approaching the 10% threshold. RSV season is determined to be at an end when the percentage of positive tests is consistently <10%. ~~Initial approvals will be for the duration of 3 months from the determined RSV season start date in Oklahoma.~~ Initial and subsequent approvals will be for the duration of 1 month until RSV season end. A separate prior authorization request will be required for consideration of initial approval and for each subsequent approval. Members initially approved for palivizumab will require a patient-specific, clinically significant reason why the member still cannot receive Beyfortus™ (nirsevimab-alip).
D. Units Authorized: The member's current weight (taken within the last 3 weeks) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling. Doses are to be administered no more often than every 30 days. Members given doses more frequently than every 30 days will not be authorized for additional doses. Doses administered prior to the member's discharge from a hospital will be counted as 1 of the approved total.
E. Dose-Pooling: To avoid unnecessary risk to the member, multiple members are not to be treated from a single vial. Failure to follow this recommendation will result in referral of the provider to the Quality Assurance Committee of the Oklahoma Health Care Authority.

Utilization Details of Synagis® (Palivizumab): Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PALIVIZUMAB PRODUCTS						
SYNAGIS INJ 100MG/ML	604	236	$1,931,716.38	$3,198.21	2.56	82.85%
SYNAGIS INJ 50MG/0.5ML	236	140	$399,798.93	$1,694.06	1.69	17.15%
TOTAL	**840**	**254***	**$2,331,515.31**	**$2,775.61**	**3.31**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PALIVIZUMAB INJ 50MG (90378)	3	1	$11,504.71	$3,834.90	3
TOTAL	**3†**	**1***	**$11,504.71**	**$3,834.90**	**3**

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

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Appendix P

Fiscal Year 2023 Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Orserdu™ (Elacestrant)

Oklahoma Health Care Authority
September 2023

Current Prior Authorization Criteria

Utilization data for Keytruda® (pembrolizumab) and approval criteria for indications other than breast cancer can be found in the December 2022 Drug Utilization Review (DUR) Board packet. This medication and criteria are reviewed annually with the skin cancer medications. Utilization data for Lynparza® (olaparib) and approval criteria for indications other than breast cancer can be found in the June 2023 DUR Board packet. This medication and criteria are reviewed annually with the genitourinary and gynecologic cancer medications.

Afinitor® (Everolimus) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. Hormone receptor (HR) positive; and
4. Used in combination with exemestane, fulvestrant, or tamoxifen; and
5. Member must have failed treatment with, have a contraindication to, or be intolerant to letrozole or anastrozole.

Afinitor® (Everolimus) Approval Criteria [Neuroendocrine Tumors (NET) of Pancreatic (PNET), Gastrointestinal, or Lung Origin Diagnosis]:

1. Diagnosis of unresectable, locally advanced, or metastatic NET of pancreatic (PNET), gastrointestinal, or lung origin; and
2. Progressive disease from a previous treatment.

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

1. Diagnosis of renal AML and TSC; and
2. Not requiring immediate surgery; and
3. Used in pediatric and adult members 1 year of age and older.

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.

Afinitor® (Everolimus) Approval Criteria [Subependymal Giant Cell Astrocytoma (SEGA) with Tuberous Sclerosis Complex (TSC) Diagnosis]:

1. Diagnosis of SEGA with TSC; and
2. Requires therapeutic intervention but cannot be curatively resected.

Afinitor® (Everolimus) Approval Criteria [Tuberous Sclerosis Complex (TSC)-Associated Partial-Onset Seizures Diagnosis]:

1. Diagnosis of TSC-associated partial-onset seizures; and
2. Initial prescription must be written by a neurologist or neuro-oncologist; and
3. Failure of ≥3 other medications commonly used for seizures; and
4. Must be used as adjunctive treatment; and
5. Member must not be taking any P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, clarithromycin) concurrently with Afinitor®; and
6. Member must not be taking St. John's wort concurrently with Afinitor®; and
7. Prescriber must verify that Afinitor® trough levels and adverse reactions (e.g., non-infectious pneumonitis, stomatitis, hyperglycemia, dyslipidemia, thrombocytopenia, neutropenia, febrile neutropenia) will be monitored and dosing changes or discontinuations will correspond with recommendations in the package labeling; and
8. Prescriber must verify that female members are not pregnant and will use contraception while receiving Afinitor® therapy and for 8 weeks after the last dose of Afinitor® and that male members with female partners of reproductive potential will use contraception while receiving Afinitor® therapy and for 4 weeks after the last dose of Afinitor®; and
9. The member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Breast Cancer Diagnosis]:

1. Adult members with unresectable or metastatic disease; and
    a. For human epidermal growth factor receptor 2 (HER2)-positive disease, must meet the following:
        i. Member received prior therapy in the metastatic, neoadjuvant, or adjuvant setting and developed disease recurrence during or within 6 months of completing therapy; and

ii. Member has received ≥1 prior anti-HER2-based regimen; or

b. For HER-2 low [immunohistochemistry (IHC) 1+ or IHC 2+/in situ hybridization (ISH)-] disease, must meet the following:
    i. Member received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of advanced or metastatic disease; and
2. Disease has progressed on prior therapy; and
3. Human epidermal receptor type 2 (HER2) amplified disease; and
4. RAS and BRAF mutation negative; and
5. Used as a single agent.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic gastric or GEJ adenocarcinoma; and
2. Human epidermal growth factor receptor 2 (HER2)-positive disease; and
3. Member has received at least 1 prior trastuzumab-based regimen.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of unresectable or metastatic NSCLC; and
2. Disease is human epidermal growth factor receptor 2 (HER2)-positive; and
3. Member must have received a prior systemic therapy.

Halaven® (Eribulin) Approval Criteria [Recurrent or Metastatic Breast Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic breast cancer; and
2. Used in 1 of the following settings:
    a. Previously received ≥2 chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting; or
    b. In combination with trastuzumab for human epidermal growth factor receptor 2 (HER2)-positive disease that is:
        i. Hormone receptor (HR) negative; or
        ii. HR positive with or without endocrine therapy; or
    c. As a single-agent for HER2-negative disease that is:
        i. HR negative; or

ii. HR positive with visceral crisis or endocrine therapy refractory.

Halaven® (Eribulin) Approval Criteria [Liposarcoma Diagnosis]:

1. Diagnosis of unresectable or metastatic liposarcoma; and
2. Previously received an anthracycline-containing chemotherapy regimen.

Herceptin® (Trastuzumab), Herceptin Hylecta™ (Trastuzumab/ Hyaluronidase-oysk), Herzuma® (Trastuzumab-pkrb), Kanjinti® (Trastuzumab-anns), Ogivri® (Trastuzumab-dkst), Ontruzant® (Trastuzumab-dttb), and Trazimera® (Trastuzumab-qyyp) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
2. Preferred trastuzumab products include Ontruzant® (trastuzumab-dttb) and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), Herceptin Hylecta™ (trastuzumab/hyaluronidase-oysk), Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), or Ogivri® (trastuzumab-dkst)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [Ontruzant® (trastuzumab-dttb) or Trazimera® (trastuzumab-qyyp)]. 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.

Herceptin® (Trastuzumab), Herzuma® (Trastuzumab-pkrb), Kanjinti® (Trastuzumab-anns), Ogivri® (Trastuzumab-dkst), Ontruzant® (Trastuzumab-dttb), and Trazimera® (Trastuzumab-qyyp) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of human epidermal receptor type 2 (HER2)-positive CRC; and
2. RAS and BRAF mutation negative; and
3. Used in combination with pertuzumab or lapatinib; and
4. Used in 1 of the following settings:
    a. If first-line therapy, patient should not be a candidate for intensive therapy; or
    b. For the treatment of advanced or metastatic disease following disease progression; and
5. Preferred trastuzumab products include Ontruzant® (trastuzumab-dttb) and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), or Ogivri®

(trastuzumab-dkst)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [Ontruzant® (trastuzumab-dttb) or Trazimera® (trastuzumab-qyyp)]. 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.

Herceptin® (Trastuzumab), Herzuma® (Trastuzumab-pkrb), Kanjinti® (Trastuzumab-anns), Ogivri® (Trastuzumab-dkst), Ontruzant® (Trastuzumab-dttb), and Trazimera® (Trastuzumab-qyyp) Approval Criteria [Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma Diagnosis]:

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic gastric or gastroesophageal junction adenocarcinoma; and
2. Preferred trastuzumab products include Ontruzant® (trastuzumab-dttb) and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), or Ogivri® (trastuzumab-dkst)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [Ontruzant® (trastuzumab-dttb) or Trazimera® (trastuzumab-qyyp)]. 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.

Ibrance® (Palbociclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced, metastatic, hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
2. Used in combination with:
    a. An aromatase inhibitor in postmenopausal women; or
    b. Fulvestrant in female members with disease progression following endocrine therapy; or
    c. An aromatase inhibitor or fulvestrant in male members.

Ixempra® (Ixabepilone) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of metastatic or locally advanced breast cancer; and
2. Used in combination with capecitabine; and
    a. After failure of an anthracycline and a taxane unless anthracycline contraindicated; or
3. Used as a single agent; and
    a. Used in 1 of the following settings:

        i. After failure of capecitabine, an anthracycline, and a taxane; or
        ii. In members with no response to preoperative systemic therapy; or
        iii. After at least 1 line of therapy for recurrent unresectable (local or regional) disease; or
        iv. Disease is human epidermal growth factor receptor 2 (HER2)-negative; or
4. Used in combination with trastuzumab; and
    a. Disease is HER2-positive; and
    b. Third-line or subsequent therapy.

Kadcyla® (Ado-Trastuzumab Emtansine) Approval Criteria [Early Stage or Locally Advanced Breast Cancer Diagnosis]:

1. Diagnosis of early stage or locally advanced breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive; and
3. Used as adjuvant treatment in members with residual invasive disease after neoadjuvant therapy with taxane and trastuzumab-based treatment; and
4. Maximum duration of a total of 14 cycles.

Kadcyla® (Ado-Trastuzumab Emtansine) Approval Criteria [Metastatic Breast Cancer Diagnosis]:

1. Diagnosis of metastatic breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive; and
3. Previously received trastuzumab and a taxane, separately or in combination; and
4. Members should also have either:
    a. Received prior therapy for metastatic disease; or
    b. Developed disease recurrence during or within 6 months of completing adjuvant therapy.

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

1. Diagnosis of locally recurrent unresectable or metastatic triple-negative breast cancer; and
    a. Tumors express programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥10; and
    b. Used in combination with chemotherapy; or
2. Diagnosis of early stage triple-negative breast cancer; and
    a. Disease is considered high-risk; and
    b. Used in combination with chemotherapy as neoadjuvant therapy.

Kisqali® (Ribociclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Hormone receptor (HR) positive; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and

3. Used in 1 of the following settings:
    a. Diagnosis of advanced or metastatic breast cancer, as initial therapy; and
        i. In combination with an aromatase inhibitor; or
    b. Diagnosis of advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy; and
        i. In combination with fulvestrant; and
        ii. Must be used in postmenopausal women only.

Kisqali® Femara® Co-Pack (Ribociclib/Letrozole) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer, as initial therapy; and
2. Hormone receptor (HR) positive; and
3. Human epidermal growth factor receptor 2 (HER2)-negative.

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

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

Margenza® (Margetuximab-cmkb) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of metastatic breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive; and
3. Member has received 2 or more prior anti-HER2 regimens, at least 1 of which was for metastatic disease; and
4. Used in combination with chemotherapy (capecitabine, eribulin, gemcitabine, or vinorelbine).

Nerlynx® (Neratinib) Approval Criteria [Non-Metastatic Breast Cancer Diagnosis]:

1. For adjuvant treatment in early-stage breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and

3. Neratinib must be used to follow adjuvant trastuzumab-based therapy.

Nerlynx® (Neratinib) Approval Criteria [Recurrent or Metastatic Breast Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic breast cancer; and
2. Member must have human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
3. Used in combination with capecitabine; or
4. Used in combination with capecitabine or paclitaxel if brain metastases are present.

Perjeta® (Pertuzumab) Approval Criteria [Breast Cancer Diagnosis]:

1. Human epidermal growth factor receptor 2 (HER2)-positive; and
2. Used in 1 of the following settings:
    a. Metastatic breast cancer in members who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease:
        i. Used in combination with trastuzumab and chemotherapy; or
    b. Neoadjuvant treatment of members with locally advanced, inflammatory, or early stage breast cancer (either >2cm in diameter or node positive):
        i. Used in combination with trastuzumab and chemotherapy; or
    c. Adjuvant systemic therapy for members with node positive, HER2-positive tumors or members with high-risk node negative tumors [tumor >1cm; tumor 0.5 to 1cm with histologic or nuclear grade 3; estrogen receptor (ER)/progesterone receptor (PR) negative; or younger than 35 years of age]:
        i. Used in combination with trastuzumab and chemotherapy; or
        ii. Used in combination with trastuzumab and docetaxel following doxorubicin/cyclophosphamide (AC); or
        iii. Used in combination with docetaxel/carboplatin/trastuzumab (TCH); or
        iv. Used in combination with trastuzumab following neoadjuvant therapy with paclitaxel/docetaxel/carboplatin/ trastuzumab/pertuzumab (pTCHP).

Perjeta® (Pertuzumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of human epidermal receptor type 2 (HER2)-positive CRC; and
2. RAS and BRAF mutation-negative; and
3. Used in combination with trastuzumab; and
4. Used in 1 of the following settings:

a. If first-line therapy, patient should not be a candidate for intensive therapy; or
b. For the treatment of advanced or metastatic disease following disease progression.

Phesgo® (Pertuzumab/Trastuzumab/Hyaluronidase-zzxf) Approval Criteria [Breast Cancer Diagnosis]:

1. Human epidermal growth factor receptor 2 (HER2)-positive disease; and
2. Used in 1 of the following settings:
   a. Neoadjuvant treatment of members with locally advanced, inflammatory, or early stage breast cancer; or
   b. Adjuvant treatment of members with early breast cancer; or
   c. In combination with docetaxel for members with metastatic disease.

Piqray® (Alpelisib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer that has progressed on or after an endocrine-based regimen in men or in postmenopausal women; and
2. Hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-negative; and
3. PIK3CA-mutated disease; and
4. In combination with fulvestrant.

Talzenna® (Talazoparib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. Presence of BRCA1/BRCA2-germline mutated disease; and
4. Disease is hormone receptor (HR) negative or is HR positive and endocrine therapy refractory; and
5. Patient has symptomatic visceral disease; and
6. Must be used as a single-agent.

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

1. Diagnosis of triple-negative breast cancer; and
   a. Unresectable locally advanced or metastatic disease; and
   b. Member must have received ≥2 prior therapies, at least 1 of which was for metastatic disease.

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.

Tukysa® (Tucatinib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced unresectable or metastatic breast cancer; and
2. Used in combination with trastuzumab and capecitabine; and
3. Disease is human epidermal growth factor receptor 2 (HER2)-positive; and
4. Following progression of ≥1 prior anti-HER2 regimen(s) in the metastatic setting.

Tykerb® (Lapatinib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of metastatic or recurrent breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive; and
3. Lapatinib must be used in combination with 1 of the following:
    a. Trastuzumab; or
    b. Capecitabine; or
    c. An aromatase inhibitor (e.g., exemestane, letrozole, anastrozole) if also estrogen receptor (ER) positive.

Verzenio® (Abemaciclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer; and
    a. Hormone receptor positive disease; and
    b. Human epidermal receptor 2 (HER2)-negative disease; and
        i. Used in 1 of the following settings:
            1. In combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women; or
            2. In combination with fulvestrant with disease progression following endocrine therapy; or
            3. As monotherapy for disease progression following endocrine therapy and prior chemotherapy; or
2. Diagnosis of early-stage breast cancer; and
    a. Hormone receptor positive disease; and
    b. HER2-negative disease; and
    c. Node-positive disease high risk for recurrence with Ki-67 ≥20%; and
    d. Used as adjuvant treatment in combination with endocrine therapy.

Utilization of Breast Cancer Medications: Fiscal Year 2023

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

Fiscal Year Comparison: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	100	666	$11,003,027.67	$16,521.06	$584.21	28,699	18,834
2023	126	770	$12,540,568.86	$16,286.45	$573.47	32,226	21,868
% Change	**26.00%**	**15.60%**	**14.00%**	**-1.40%**	**-1.80%**	**12.30%**	**16.10%**
Change	**26**	**104**	**$1,537,541.19**	**-$234.61**	**-$10.74**	**3,527**	**3,034**

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

Fiscal Year Comparison: Medical Claims

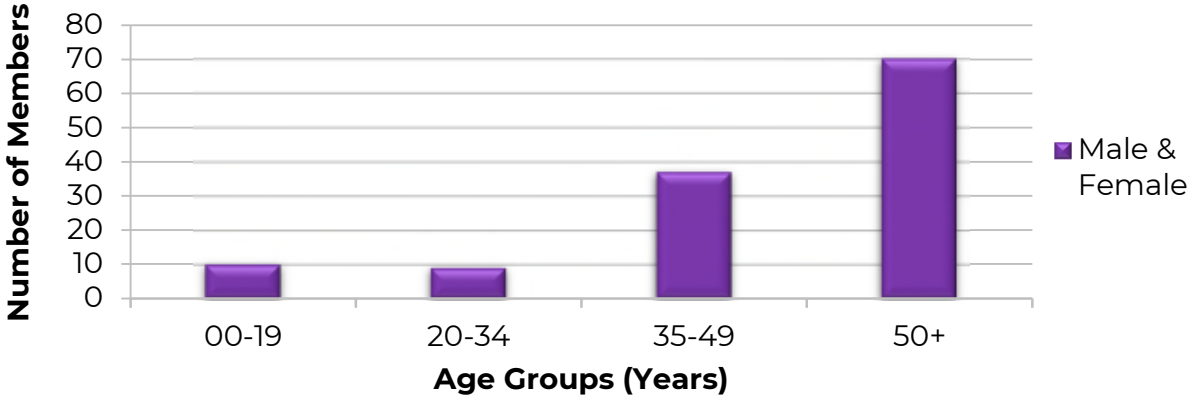
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	111	1,182	$5,584,827.72	$4,724.90	10.65
2023	129	1,311	$6,800,228.64	$5,187.05	10.16
% Change	**16.22%**	**10.91%**	**21.76%**	**9.78%**	**-4.60%**
Change	**18**	**129**	**$1,215,400.92**	**$462.16**	**-0.49**

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

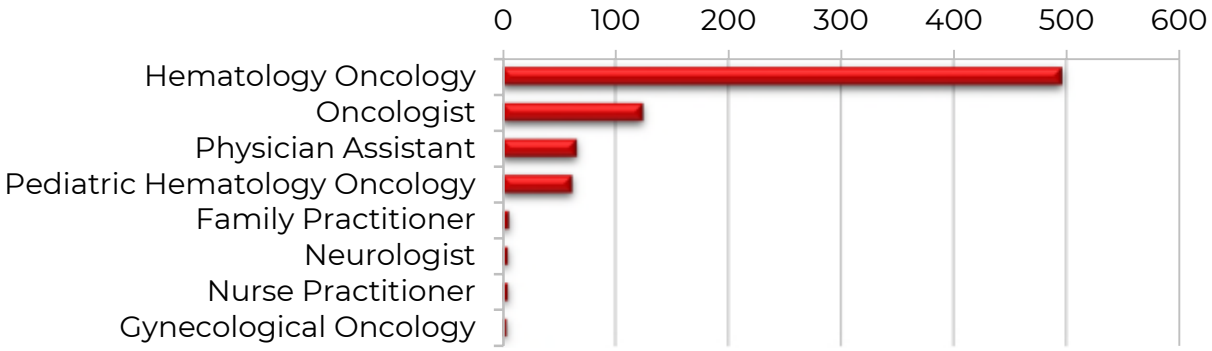
- Aggregate drug rebates collected during calendar year 2022 for Breast Cancer Medications totaled $4,341,514.91.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, calendar year 2022 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2023 (7/1/2022 to 6/30/2023) are still being collected at this time. The costs included in this report do not reflect net costs.

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

Demographics of Members Utilizing Breast Cancer Medications: Pharmacy Claims



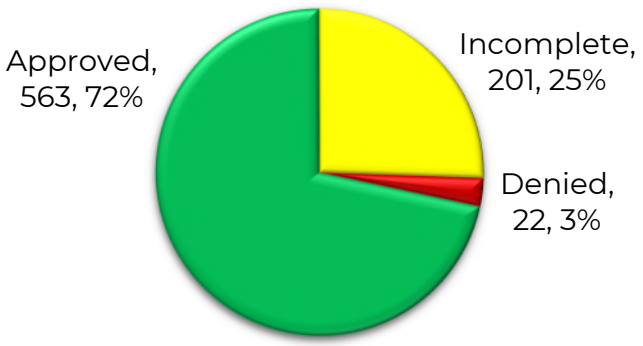
Top Prescriber Specialties of Breast Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Breast Cancer Medications

There were 786 prior authorization requests submitted for breast cancer medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Ixempra® (ixabepilone): February 2025
- Halaven® (eribulin): July 2027
- Afinitor® (everolimus): July 2028
- Tykerb® (lapatinib): September 2029
- Verzenio® (abemaciclib): December 2029
- Nerlynx® (neratinib): July 2031
- Talzenna® (talazoparib): October 2031
- Piqray® (alpelisib): April 2033
- Ibrance® (palbociclib capsule): February 2034
- Kisqali® (ribociclib): April 2036
- Kisqali® Femara® Co-Pack (ribociclib/letrozole): April 2036
- Ibrance® (palbociclib tablet): May 2036
- Orserdu™ (elacestrant): January 2038
- Tukysa® (tucatinib): April 2038

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

- **December 2022:** The FDA approved Ibrance® (palbociclib) for an expanded indication for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy. This indication was previously limited to use in postmenopausal women or men, but the postmenopausal restriction has now been removed.
- **January 2023:** The FDA granted accelerated approval to Tukysa® (tucatinib) for a new indication in combination with trastuzumab for RAS wild-type HER2-positive unresectable or metastatic colorectal cancer that has progressed following fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
- **January 2023:** The FDA approved Orserdu™ (elacestrant) for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, HER2-negative, estrogen receptor 1 (ESR1)-mutated advanced or metastatic breast cancer with disease progression following at least 1 line of endocrine therapy.
- **February 2023:** The FDA approved Trodelvy® (sacituzumab govitecan-hziy) for a new indication for the treatment of patients with unresectable locally advanced or metastatic HR-positive, HER2-negative breast cancer who have received endocrine-based therapy and at least 2 additional systemic therapies in the metastatic setting.
- **March 2023:** The FDA approved an expanded indication for Verzenio® (abemaciclib) with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with HR-positive,

HER2-negative, node-positive, early breast cancer at high risk of recurrence. This approval removes the requirement for the patient to also have a Ki-67 score ≥20%.
- **June 2023:** The FDA approved Talzenna® (talazoparib) for a new indication in combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

Guideline Update(s):
- **April 2023:** The current National Comprehensive Cancer Network (NCCN) Guidelines support the use of lapatinib or tucatinib in colon or rectal cancer for HER2-amplified, RAS and BRAF wild-type disease, in combination with trastuzumab, if not previously treated with a HER2 inhibitor based on positive response rates in 2 Phase 2 trials.

Orserdu™ (Elacestrant) Product Summary[11]

Therapeutic Class: ER antagonist

Indication(s): Treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least 1 line of endocrine therapy

How Supplied: 86mg and 345mg oral tablets

Dose: Recommended dose is 345mg once daily

Cost: The Wholesale Acquisition Cost (WAC) is $712.30 per 345mg tablet, resulting in a cost of $21,369 per month or $256,428 per year based on the recommended dosing.

Recommendations

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

Orserdu™ (Elacestrant) Approval Criteria [Breast Cancer Diagnosis]:
1. Diagnosis of advanced or metastatic breast cancer; and
2. Estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease; and
3. Tumor is positive for ESR1-mutation; and
4. Female members must be postmenopausal; and
5. Has progressed after at least 1 prior endocrine therapy.

The College of Pharmacy also recommends updating the approval criteria for Ibrance® (palbociclib), Talzenna® (talazoparib), Trodelvy® (sacituzumab govitecan-hziy), Tukysa® (tucatinib), and Verzenio® (abemaciclib) based on recent FDA approvals (changes and new criteria noted in red):

Ibrance® (Palbociclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced, metastatic, hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
2. In combination with:
    a. An aromatase inhibitor in female members ~~postmenopausal women~~; or
    b. Fulvestrant in women with disease progression following endocrine therapy; or
    c. An aromatase inhibitor or fulvestrant in male patients.

Talzenna® (Talazoparib) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of metastatic, castration-resistant prostate cancer; and
2. Disease is homologous recombination repair (HRR) gene-mutated; and
3. Used in combination with enzalutamide.

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

1. Diagnosis of triple-negative breast cancer; and
    a. Unresectable locally advanced or metastatic disease; and
    b. Member must have received ≥2 prior therapies, at least 1 of which was for metastatic disease; or
2. Diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
    a. Unresectable locally advanced or metastatic disease; and
    b. Member has previously received endocrine-based therapy and ≥2 additional systemic therapies in the metastatic setting.

Tukysa® (Tucatinib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of RAS wild-type HER2-positve unresectable or metastatic CRC; and
2. Has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy; and
3. Used in combination with trastuzumab.

Verzenio® (Abemaciclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer; and
    a. Hormone receptor positive disease; and
    b. Human epidermal receptor 2 (HER2)-negative disease; and
        i. Used in 1 of the following settings:

1. In combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women; or
2. In combination with fulvestrant with disease progression following endocrine therapy in advanced or metastatic breast cancer; or
3. As monotherapy for disease progression following endocrine therapy and prior chemotherapy in metastatic breast cancer; ~~and~~ or

2. Diagnosis of early-stage breast cancer; and
   a. Hormone receptor positive disease; and
   b. HER2-negative disease; and
   c. Node-positive disease high risk for recurrence ~~with Ki-67 ≥20%~~; and
   d. Used as adjuvant treatment in combination with endocrine therapy.

Additionally, the College of Pharmacy recommends updating the Tykerb® (lapatinib) approval criteria based on NCCN recommendations for use in colorectal cancer (new criteria noted in red):

Tykerb® (Lapatinib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable, advanced, or metastatic disease; and
2. Member has human epidermal receptor 2 (HER2)-amplified disease; and
3. Member has wild-type RAS and BRAF disease; and
4. Member meets 1 of the following:
   a. Has tried at least 1 chemotherapy regimen; or
   b. Is not a candidate for intensive therapy, according to the prescriber; and
5. Used in combination with trastuzumab; and
6. Member has not been previously treated with a HER2-inhibitor.

Lastly, the College of Pharmacy recommends updating the approval criteria for the trastuzumab products based on NCCN recommendations and net costs (changes shown in red):

Herceptin® (Trastuzumab), Herceptin Hylecta™ (Trastuzumab/ Hyaluronidase-oysk), Herzuma® (Trastuzumab-pkrb), Kanjinti® (Trastuzumab-anns), Ogivri® (Trastuzumab-dkst), Ontruzant® (Trastuzumab-dttb), and Trazimera® (Trastuzumab-qyyp) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
2. Preferred trastuzumab products include Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), ~~Ontruzant® (trastuzumab-dttb)~~ and

Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), Herceptin Hylecta™ (trastuzumab/hyaluronidase-oysk), ~~Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), or~~ Ogivri® (trastuzumab-dkst), or Ontruzant® (trastuzumab-dttb)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), ~~Ontruzant® (trastuzumab-dttb)~~, or Trazimera® (trastuzumab-qyyp)]. 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.

Herceptin® (Trastuzumab), Herzuma® (Trastuzumab-pkrb), Kanjinti® (Trastuzumab-anns), Ogivri® (Trastuzumab-dkst), Ontruzant® (Trastuzumab-dttb), and Trazimera® (Trastuzumab-qyyp) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of human epidermal receptor type 2 (HER2)-positive CRC; and
2. RAS and BRAF mutation negative; and
3. Used in combination with pertuzumab, ~~or~~ lapatinib, or tucatinib; and
4. Used in 1 of the following settings:
    a. If first-line therapy, patient should not be a candidate for intensive therapy; or
    b. For the treatment of advanced or metastatic disease following disease progression; and
5. Preferred trastuzumab products include Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), ~~Ontruzant® (trastuzumab-dttb)~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), ~~Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), or~~ Ogivri® (trastuzumab-dkst), or Ontruzant® (trastuzumab-dttb)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), ~~Ontruzant® (trastuzumab-dttb)~~, or Trazimera® (trastuzumab-qyyp)]. 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.

Herceptin® (Trastuzumab), Herzuma® (Trastuzumab-pkrb), Kanjinti® (Trastuzumab-anns), Ogivri® (Trastuzumab-dkst), Ontruzant® (Trastuzumab-dttb), and Trazimera® (Trastuzumab-qyyp) Approval Criteria [Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma Diagnosis]:

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic gastric or gastroesophageal junction adenocarcinoma; and
2. Preferred trastuzumab products include Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), ~~Ontruzant® (trastuzumab-dttb)~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), ~~Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), or~~ Ogivri® (trastuzumab-dkst), or Ontruzant® (trastuzumab-dttb)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), ~~Ontruzant® (trastuzumab-dttb)~~, or Trazimera® (trastuzumab-qyyp)]. 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.

Utilization Details of Breast Cancer Medications: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PALBOCICLIB PRODUCTS						
IBRANCE TAB 125MG	197	32	$2,858,460.89	$14,509.95	6.16	22.79%
IBRANCE TAB 100MG	62	16	$902,351.13	$14,554.05	3.88	7.20%
IBRANCE TAB 75MG	30	8	$442,679.83	$14,755.99	3.75	3.53%
IBRANCE CAP 100MG	27	4	$390,755.83	$14,472.44	6.75	3.12%
IBRANCE CAP 75MG	14	2	$204,612.38	$14,615.17	7	1.63%
IBRANCE CAP 125MG	13	2	$188,431.31	$14,494.72	6.5	1.50%
SUBTOTAL	**343**	**64**	**$4,987,291.37**	**$14,540.21**	**5.36**	**39.77%**
EVEROLIMUS PRODUCTS						
AFINITOR DIS TAB 5MG	41	6	$1,291,726.09	$31,505.51	6.83	10.30%
EVEROLIMUS DIS TAB 3MG	34	4	$1,055,343.28	$31,039.51	8.5	8.42%
EVEROLIMUS TAB 5MG	21	5	$100,642.17	$4,792.48	4.2	0.80%
AFINITOR DIS TAB 2MG	19	2	$363,999.61	$19,157.87	9.5	2.90%
EVEROLIMUS DIS TAB 5MG	16	5	$596,625.44	$37,289.09	3.2	4.76%
EVEROLIMUS TAB 7.5MG	13	3	$82,707.28	$6,362.10	4.33	0.66%
EVEROLIMUS TAB 10MG	13	5	$72,673.20	$5,590.25	2.6	0.58%
EVEROLIMUS DIS TAB 2MG	5	3	$90,321.91	$18,064.38	1.67	0.72%
AFINITOR DIS TAB 3MG	1	1	$17,425.68	$17,425.68	1	0.14%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**163**	**34**	**$3,671,464.66**	**$22,524.32**	**4.79**	**29.28%**
ABEMACICLIB PRODUCTS						
VERZENIO TAB 150MG	78	22	$1,060,877.44	$13,600.99	3.55	8.46%
VERZENIO TAB 100MG	33	6	$467,043.91	$14,152.85	5.5	3.72%
VERZENIO TAB 50MG	9	3	$130,133.63	$14,459.29	3	1.04%
VERZENIO TAB 200MG	1	1	$13,787.41	$13,787.41	1	0.11%
SUBTOTAL	**121**	**32**	**$1,671,842.39**	**$13,816.88**	**3.78**	**13.33%**
RIBOCICLIB PRODUCTS						
KISQALI TAB 600MG DOSE	74	20	$1,145,221.53	$15,475.97	3.7	9.13%
KISQALI TAB 200MG DOSE	12	3	$60,804.96	$5,067.08	4	0.48%
KISQALI TAB 400MG DOSE	12	3	$154,428.99	$12,869.08	4	1.23%
SUBTOTAL	**98**	**26**	**$1,360,455.48**	**$13,882.20**	**3.77**	**10.85%**
TUCATINIB PRODUCTS						
TUKYSA TAB 150MG	12	2	$266,752.92	$22,229.41	6	2.13%
SUBTOTAL	**12**	**2**	**$266,752.92**	**$22,229.41**	**6**	**2.13%**
NERATINIB PRODUCTS						
NERLYNX TAB 40MG	12	3	$230,971.92	$19,247.66	4	1.84%
SUBTOTAL	**12**	**3**	**$230,971.92**	**$19,247.66**	**4**	**1.84%**
ALPELISIB PRODUCTS						
PIQRAY TAB 300MG	8	4	$153,209.58	$19,151.20	2	1.22%
PIQRAY TAB 200MG	1	1	$18,729.89	$18,729.89	1	0.15%
PIQRAY TAB 250MG	1	1	$18,729.89	$18,729.89	1	0.15%
SUBTOTAL	**10**	**6**	**$190,669.36**	**$19,066.94**	**1.67**	**1.52%**
ELACESTRANT PRODUCTS						
ORSERDU TAB 345MG	4	1	$85,505.64	$21,376.41	4	0.68%
SUBTOTAL	**4**	**1**	**$85,505.64**	**$21,376.41**	**4**	**0.68%**
RIBOCICLIB/LETROZOLE PRODUCTS						
KISQALI FEMARA PAK 400/2.5MG	3	1	$36,411.87	$12,137.29	3	0.29%
SUBTOTAL	**3**	**1**	**$36,411.87**	**$12,137.29**	**3**	**0.29%**
LAPATINIB PRODUCTS						
LAPATINIB TAB 250MG	3	1	$21,677.77	$7,225.92	3	0.17%
SUBTOTAL	**3**	**1**	**$21,677.77**	**$7,225.92**	**3**	**0.17%**
TALAZOPARIB PRODUCTS						
TALZENNA CAP 1MG	1	1	$17,525.48	$17,525.48	1	0.14%
SUBTOTAL	**1**	**1**	**$17,525.48**	**$17,525.48**	**1**	**0.14%**
TOTAL	**770**	**126***	**$12,540,568.86**	**$16,286.45**	**6.11**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DIS = Disperz (oral tablet for suspension); PAK = Co-Pack; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9306 PERTUZUMAB INJ	372	66	$2,427,053.96	$6,524.34	5.64
Q5114 TRASTUZUMAB-DKST INJ	184	30	$391,130.75	$2,125.71	6.13
J9354 ADO-TRASTUZUMAB INJ	182	26	$1,260,140.72	$6,923.85	7
Q5116 TRASTUZUMAB-QYYP INJ	175	30	$259,446.09	$1,482.55	5.83
Q5112 TRASTUZUMAB-DTTB INJ	146	30	$374,371.46	$2,564.19	4.87
J9358 FAM-TRASTUZUMAB DERUXTECAN-NXKI INJ	121	20	$1,347,927.54	$11,139.90	6.05
J9355 TRASTUZUMAB INJ	57	9	$199,051.78	$3,492.14	6.33
J9317 SACITUZUMAB GOVITECAN-HZIY INJ	42	7	$426,159.84	$10,146.66	6
Q5117 TRASTUZUMAB-ANNS INJ	14	5	$19,106.30	$1,364.74	2.8
J9179 ERIBULIN MESYLATE INJ	9	3	$27,179.20	$3,019.91	3
J9316 PERTUZUMAB/TRASTUZUMAB/ HYALURONIDASE-ZZXF INJ	7	1	$58,125.60	$8,303.66	7
J9207 IXABEPILONE INJ	2	1	$10,535.40	$5,267.70	2
TOTAL	**1,311**	**129**	**$6,800,228.64**	**$5,187.05**	**10.16**

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

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Appendix Q

Fiscal Year 2023 Annual Review of Zinplava™ (Bezlotoxumab) and 30-Day Notice to Prior Authorize Rebyota™ (Fecal Microbiota, Live-jslm) and Vowst™ (Fecal Microbiota Spores, Live-brpk)

Oklahoma Health Care Authority
September 2023

Current Prior Authorization Criteria

Zinplava™ (Bezlotoxumab) Approval Criteria:

1. An FDA approved diagnosis of *Clostridium difficile* infection (CDI) in members 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence; and
    a. Prescriber must document the member has ≥1 of the following risk factor(s) for high risk of CDI recurrence:
        i. Age 65 years or older; or
        ii. One or more episodes of CDI within the 6 months prior to the episode under treatment; or
        iii. Need for ongoing therapy with concomitant antibiotics during treatment for CDI; or
        iv. Severe underlying medical disorders; or
        v. Immunocompromised; or
        vi. Clinically severe CDI (Zar score ≥2); and
2. Current or planned antibacterial drug for CDI must be provided on the prior authorization request to ensure medication is within standard of care; and
3. Prescriber must document that Zinplava™ (bezlotoxumab) will be administered while the member is receiving antibacterial drug treatment of CDI; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Utilization of Zinplava™ (Bezlotoxumab): Fiscal Year 2023

Comparison of Fiscal Years: Medical Claims

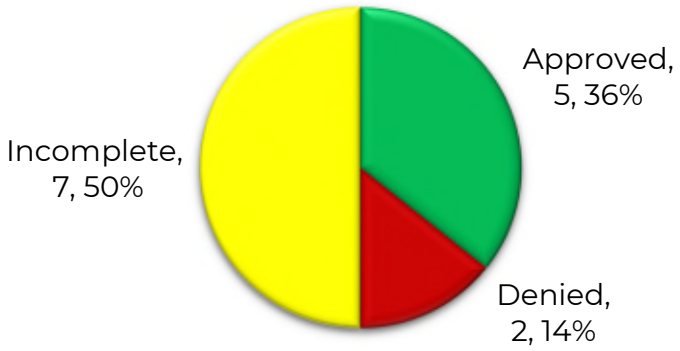
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	4	4	$13,918.50	$3,479.63	1
2023	1	1	$1,875.30	$1,875.30	1
% Change	**-75.00%**	**-75.00%**	**-86.53%**	**-46.11%**	**0.00%**
Change	**-3**	**-3**	**-$12,043.20**	**-$1,604.33**	**0**

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

Prior Authorization of Zinplava™ (Bezlotoxumab)

There were 14 prior authorization requests submitted for Zinplava™ (bezlotoxumab) for 7 unique members during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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

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

- **November 2022:** The FDA approved Rebyota™ (fecal microbiota, live-jslm) for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in adults 18 years of age and older who have completed antibiotic treatment for recurrent CDI. Rebyota™ is the first fecal microbiota product approved by the FDA and is administered rectally.
- **April 2023:** The FDA approved Vowst™ (fecal microbiota spores, live-brpk) for the prevention of recurrence of CDI in adults 18 years of age and older following antibacterial treatment for recurrent CDI. Vowst™ is the first fecal microbiota product that is taken orally.

- **May 2023:** The FDA approved Zinplava™ (bezlotoxumab) in pediatric patients 1 year of age and older. Previously, Zinplava™ (bezlotoxumab) was only approved for adults.

Pipeline:

- **LMN-201:** In May 2023, the FDA granted Fast Track designation for LMN-201, an investigational, oral drug used to treat and prevent CDI. LMN-201 contains 4 therapeutic proteins that work together to neutralize both the *C. difficile* bacterium and the toxin that causes its virulence directly in the patient's gastrointestinal (GI) tract. It is taken orally with standard of care antibiotics and then 8 weeks after to provide protection from reinfection while commensal bacteria recolonize the GI tract. A Phase 2/3 trial of LMN-201 will begin enrolling patients later this year.
- **VE303:** In May 2023, the FDA granted Fast Track designation for VE303 used for the prevention of recurrent CDI. VE303 is an orally administered drug that consists of 8 types of clonal human bacteria strains selected for their ability to provide colonization resistance to *C. difficile*. It is produced from pure, clonal bacterial cell banks, which produces a standardized drug product and bypasses the need to rely on direct sourcing of donor fecal material. The Phase 2 trial met its primary endpoint of preventing CDI recurrence at 8 weeks. A Phase 3 trial is planned to start in 2023.

Rebyota™ (Fecal Microbiota, Live-jslm) Product Summary[7]

Therapeutic Class: Fecal microbiota transplantation (FMT) agent

Indication(s): Prevention of the recurrence of CDI in individuals 18 years of age and older following antibiotic treatment for recurrent CDI.

- Limitation(s) of Use: Rebyota™ is not indicated for the treatment of CDI.

How Supplied: 150mL rectal suspension

Dosing and Administration:

- The recommended dosage is a single 150mL dose administered rectally.
- Rebyota™ should be administered 24 to 72 hours after the last dose of antibiotics for CDI.

Vowst™ (Fecal Microbiota Spores, Live-brpk) Product Summary[8]

Therapeutic Class: FMT agent

Indication(s): Prevention of the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for the recurrent CDI.

- Limitation(s) of Use: Vowst™ is not indicated for the treatment of CDI.

How Supplied: Oral capsule

Dosing and Administration:

- Prior to taking the first dose:
  - Antibacterial treatment for recurrent CDI should be completed 2 to 4 days before initiating treatment with Vowst™.
  - The patient should drink 296mL (10oz) of magnesium citrate on the day before and at least 8 hours prior to taking the first dose of Vowst™. In clinical studies, participants with impaired kidney function received polyethylene glycol electrolyte solution (250mL GoLYTELY®, not approved for this use).
- The recommended dosage of Vowst™ is 4 capsules taken orally once daily for 3 consecutive days.
- Each dose should be taken on an empty stomach prior to the first meal of the day.

Cost Comparison

Product	Cost Per Unit	Cost Per Treatment
Vowst™ (fecal microbiota spores, live-brpk) capsule	**$1,458.33**	**$17,499.96***
Rebyota™ (fecal microbiota, live-jslm) 150mL	**$60.00**	**$9,000.00***
Zinplava™ (bezlotoxumab) 1,000mg/40mL	$95.00	$3,800.00⁺

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 mL
*Cost per treatment course is based on the FDA approved dosing for each product.
⁺Cost per treatment course is based on the FDA approved dosing of 10mg/kg as a single dose for a 100kg patient.

Recommendations

The College of Pharmacy recommends the prior authorization of Rebyota™ (fecal microbiota, live-jslm) and Vowst™ (fecal microbiota spores, live-brpk) with the following criteria (shown in red):

Rebyota™ (Fecal Microbiota, Live-jslm) Approval Criteria:

1. An FDA approved indication for the prevention of recurrence of *Clostridium difficile* infection (CDI) in members 18 years of age or older; and
2. Member must have a diagnosis of at least 2 recurrent CDI episodes (≥3 total CDI episodes); and
3. The most recent CDI episode must be confirmed by a positive stool test for *C. difficile* toxin; and
4. The current CDI episode must be controlled (<3 unformed/loose stools/day for 2 consecutive days); and

5. The prescriber must verify that administration of Rebyota™ will occur 24-72 hours following completion of antibiotic course for CDI treatment; and
6. Rebyota™ must be prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or a specialist with expertise in the treatment of CDI; and
7. For members at high risk for recurrent CDI (e.g., age ≥65, immunocompromised, clinically severe CDI upon presentation), a patient specific, clinically specific reason why the member cannot use Zinplava™ (bezlotoxumab) must be provided; and
8. The member must not be using Rebyota™ in combination with Vowst™ (fecal microbiota spores, live-brpk) or Zinplava™ (bezlotoxumab); and
9. Initial approvals will be for 1 treatment course, a second treatment course may be considered following a confirmed treatment failure within 8 weeks.

Vowst™ (Fecal Microbiota Spores, Live-brpk) Approval Criteria:

1. An FDA approved indication for the prevention of recurrence of *Clostridium difficile* infection (CDI) in members 18 years of age or older; and
2. Member must have a diagnosis of at least 2 recurrent CDI episodes (≥3 total CDI episodes); and
3. The most recent CDI episode must be confirmed by a positive stool test for *C. difficile* toxin; and
4. The current CDI episode must be controlled (<3 unformed/loose stools/day for 2 consecutive days) following 10 to 21 days of antibiotic therapy; and
5. The prescriber must verify that administration of Vowst™ will occur 2 to 4 days following completion of antibiotic course for CDI treatment; and
6. The member must agree to bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst™; and
7. Vowst™ must be prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or a specialist with the expertise in the treatment of CDI; and
8. A patient specific, clinically specific reason (beyond convenience) why the member cannot use Rebyota™ (fecal microbiota, live-jslm) must be provided; and
9. For members at high risk for recurrent CDI (e.g., age ≥65, immunocompromised, clinically severe CDI on presentation), a patient specific, clinically specific reason why the member cannot use Zinplava™ (bezlotoxumab) must be provided; and

10. The member must not be using Vowst™ in combination with Rebyota™ (fecal microbiota, live-jslm) or Zinplava™ (bezlotoxumab); and
11. A quantity limit of 12 capsules for 3 days for 1 treatment course will apply.

Additionally, the College of Pharmacy recommends updating the current approval criteria for Zinplava™ based on the FDA approved age expansion and to be more consistent with clinical practice (changes shown in red):

Zinplava™ (Bezlotoxumab) Approval Criteria:

1. An FDA approved diagnosis of *Clostridium difficile* infection (CDI) in members ~~18~~ 1 year of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence; and
    a. Prescriber must document the member has ≥1 of the following risk factor(s) for high risk of CDI recurrence:
        i. Age 65 years or older; or
        ii. One or more episodes of CDI within the 6 months prior to the episode under treatment; or
        iii. Need for ongoing therapy with concomitant antibiotics during treatment for CDI; or
        iv. Severe underlying medical disorders; or
        v. Immunocompromised; or
        vi. Clinically severe CDI (Zar score ≥2); and
2. Current or planned antibacterial drug for CDI must be provided on the prior authorization request to ensure medication is within standard of care; and
3. Prescriber must document that Zinplava™ (bezlotoxumab) will be administered while the member is receiving antibacterial drug treatment of CDI; and
4. Zinplava™ must be prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or a specialist with expertise in the treatment of CDI; and
5. The member must not be using Zinplava™ in combination with Rebyota™ (fecal microbiota, live-jslm) or Vowst™ (fecal microbiota spores, live-brpk); and
6. 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
7. Approvals will be for 1 treatment course.

Utilization Details of Zinplava™ (Bezlotoxumab): Fiscal Year 2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J0565 BEZLOTOXUMAB INJ	1	1	$1,875.30	$1,875.30	1
TOTAL	**1**	**1**	**$1,875.30**	**$1,875.30**	**1**

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

[1] U.S. Food and Drug Administration (FDA). FDA Approves First Fecal Microbiota Product. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-fecal-microbiota-product. Issued 11/30/2022. Last accessed 07/31/2023.
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Appendix R

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

***Additional information, including the full news release, on the following FDA and DEA updates can be found on the FDA website at: https://www.fda.gov/news-events/fda-newsroom/press-announcements.**

FDA NEWS RELEASE

For Immediate Release: August 24, 2023

FDA Approves First Biosimilar to Treat Multiple Sclerosis

The FDA approved Tyruko® (natalizumab-sztn), the first biosimilar to Tysabri® (natalizumab) injection for the treatment of adults with relapsing forms of multiple sclerosis (MS). Tyruko®, like Tysabri®, is also indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's Disease (CD) with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and tumor necrosis factor alpha (TNF-α) inhibitors.

Tyruko® is approved to treat relapsing forms of MS, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. The approval of Tyruko®, a biosimilar to Tysabri® (natalizumab), is based on evidence that showed there are no clinically meaningful differences between the 2 products in terms of safety, purity, and potency (i.e., safety and effectiveness).

The *Prescribing Information* for natalizumab products (including Tyruko® and Tysabri®) contains a *Boxed Warning* to inform health care professionals and patients about the increased risk of progressive multifocal leukoencephalopathy (PML), a viral infection of the brain that usually leads to death or severe disability. Risk factors for the development of PML include the presence of anti-JC virus (JCV) antibodies, longer duration of therapy, and prior use of immunosuppressants. These factors should be considered in the context of expected benefit when initiating and continuing treatment with natalizumab products, and health care providers should monitor patients and withhold treatment immediately at the first sign or symptom suggestive of PML.

Because of the risks of PML, natalizumab products are available only through a restricted drug distribution program, under a risk evaluation and mitigation strategy (REMS). The REMS requires health care professionals who prescribe natalizumab products, and pharmacies that dispense them, to be specially certified in the REMS, and that patients be enrolled in the REMS. As part of the REMS requirements, prescribers must evaluate patients 3 and 6 months after the first infusion, every 6 months thereafter, as well as immediately and 6 months after discontinuing treatment.

Additional warnings in the *Prescribing Information* include risks regarding herpes infections, thrombocytopenia, immunosuppression, serious hypersensitivity reactions such as anaphylaxis, and hepatotoxicity. The most common side effects associated with natalizumab products are headache and fatigue. Other common side effects are arthralgia, urinary tract infection, lower respiratory tract infection, gastroenteritis, vaginitis, depression, pain in extremity, abdominal discomfort, diarrhea, and rash.

The FDA granted approval of Tyruko®, the first biosimilar to Tysabri® to Sandoz Inc.

FDA NEWS RELEASE

For Immediate Release: August 21, 2023

FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants

The FDA approved Abrysvo™ (respiratory syncytial virus vaccine), the first vaccine approved for use in pregnant individuals to prevent lower respiratory tract disease (LRTD)

and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age. Abrysvo™ is approved for use at 32 through 36 weeks gestational age of pregnancy. Abrysvo™ is administered as a single dose injection into the muscle. The FDA approved Abrysvo™ in May for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

RSV is a highly contagious virus that causes respiratory infections in individuals of all age groups. It is the most frequent cause of lower respiratory tract illness in infants worldwide. In most parts of the United States, RSV circulation is seasonal, typically starting during the fall and peaking in the winter. The virus is especially common in children, and most individuals can be expected to be infected with RSV by the time they reach 2 years of age. While RSV most often causes cold-like symptoms in infants and young children, it can also lead to serious LRTD such as pneumonia and bronchiolitis. In infants and children, the risk of RSV-associated LRTD is highest during the first year of life. According to the Centers for Disease Control and Prevention, RSV is the leading cause of infant hospitalization in the United States.

The safety and effectiveness of Abrysvo™ for immunization of pregnant individuals to prevent LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age was evaluated in ongoing, randomized, placebo-controlled international clinical studies. A clinical study evaluated the effectiveness of Abrysvo™ to prevent LRTD and severe LRTD caused by RSV in infants born to individuals who were vaccinated during pregnancy. Among approximately 3,500 pregnant individuals who received Abrysvo™, compared to approximately 3,500 pregnant individuals who received placebo, Abrysvo™ reduced the risk of severe LRTD by 81.8% within 90 days after birth, and 69.4% within 180 days after birth. In a subgroup of pregnant individuals who were 32 through 36 weeks gestational age, of whom approximately 1,500 received Abrysvo™ and 1,500 received placebo, Abrysvo™ reduced the risk of LRTD by 34.7%, and reduced the risk of severe LRTD by 91.1% within 90 days after birth when compared to placebo. Within 180 days after birth, Abrysvo™ reduced the risk of LRTD by 57.3% and by 76.5% for severe LRTD, when compared to placebo.

The safety of Abrysvo™ was evaluated in 2 studies. In 1 study, approximately 3,600 pregnant individuals received a single dose of Abrysvo™ and approximately 3,600 pregnant individuals received a placebo. In the second study, approximately 100 pregnant individuals received Abrysvo™ and approximately 100 pregnant individuals received placebo.

The most commonly reported side effects by pregnant individuals who received Abrysvo™ were pain at the injection site, headache, muscle pain, and nausea. In addition, although not commonly reported, a dangerous hypertensive disorder, known as pre-eclampsia, occurred in 1.8% of pregnant individuals who received Abrysvo™ compared to 1.4% of pregnant individuals who received placebo. In the safety studies, low birth weight and jaundice in infants occurred at a higher rate in the pregnant Abrysvo™ recipients compared to pregnant placebo recipients.

The *Prescribing Information* for Abrysvo™ includes a warning to inform that a numerical imbalance in preterm births in Abrysvo™ recipients (5.7%) occurred compared to those who received placebo (4.7%). The available data are insufficient to establish or exclude a causal relationship between preterm birth and Abrysvo™. Specifically, the warning informs health care providers that to avoid the potential risk of preterm birth with use of Abrysvo™ before 32 weeks of gestation, administer Abrysvo™ as indicated in pregnant individuals at 32 through 36 weeks gestational age. Pregnant individuals who

were at increased risk of preterm birth were generally excluded from clinical studies of Abrysvo™.

The FDA is requiring the company to conduct postmarketing studies to assess the signal of serious risk of preterm birth and to assess hypertensive disorders of pregnancy, including pre-eclampsia.

The application was granted Priority Review status and Fast Track and Breakthrough Therapy designations. The FDA granted approval of Abrysvo™ to Pfizer Inc.

FDA NEWS RELEASE

For Immediate Release: August 04, 2023

FDA Approves First Oral Treatment for Postpartum Depression

The FDA approved Zurzuvae™ (zuranolone), the first oral medication indicated to treat postpartum depression (PPD) in adults. PPD is a major depressive episode that typically occurs after childbirth but can also begin during the later stages of pregnancy. Until now, treatment for PPD was only available as an intravenous (IV) injection given by a health care provider in certain health care facilities.

As with other forms of depression, PPD is characterized by sadness and/or loss of interest in activities that one used to enjoy and a decreased ability to feel pleasure. It can present with symptoms such as cognitive impairment, feelings of sadness or inadequacy, loss of energy or suicidal ideation.

The efficacy of Zurzuvae™ for the treatment of PPD in adults was demonstrated in 2 randomized, double-blind, placebo-controlled, multicenter studies. The trial participants were women with PPD who met the Diagnostic and Statistical Manual of Mental Disorders criteria for a major depressive episode and whose symptoms began in the third trimester or within 4 weeks of delivery. In Study 1, patients received 50mg of Zurzuvae™ or placebo once daily in the evening for 14 days. In Study 2, patients received another zuranolone product that was approximately equal to 40mg of Zurzuvae™ or placebo, also for 14 days. Patients in both studies were monitored for at least 4 weeks after the 14-day treatment. The primary endpoint of both studies was the change in depressive symptoms using the total score from the 17-item Hamilton depression rating scale (HAMD-17), measured at day 15. Patients in the Zurzuvae™ groups showed significantly more improvement in their symptoms compared to those in the placebo groups. The treatment effect was maintained at Day 42 – 4 weeks after the last dose of Zurzuvae™.

The labeling contains a *Boxed Warning* noting that Zurzuvae™ can impact a person's ability to drive and perform other potentially hazardous activities. Patients also may not be able to assess their degree of impairment. To reduce the risk of harm, patients should not drive or operate heavy machinery for at least 12 hours after taking Zurzuvae™.

The most common side effects include drowsiness, dizziness, diarrhea, fatigue, nasopharyngitis, and urinary tract infection. Use of Zurzuvae™ may cause suicidal thoughts and behavior. Zurzuvae™ may cause fetal harm. Women should use effective contraception while taking, and for 1 week after taking, Zurzuvae™.

The daily recommended dose for Zurzuvae™ is 50mg. It should be taken once every day, for 14 days, in the evening with a fatty meal.

The FDA granted this application Priority Review and Fast Track designation. Approval of Zurzuvae™ was granted to Sage Therapeutics, Inc.

Current Drug Shortages Index (as of August 25, 2023):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma. Additional information regarding drug shortages can be found on the FDA website at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

0.9% Sodium Chloride Irrigation	***Currently in Shortage***
Albuterol Sulfate Inhalation Solution, 0.5%	***Currently in Shortage***
Alprostadil (Muse) Suppository	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acids	***Currently in Shortage***
Amoxapine Tablets	***Currently in Shortage***
Amoxicillin Oral Powder for Suspension	***Currently in Shortage***
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine for Injection	***Currently in Shortage***
Bacteriostatic 0.9% Sodium Chloride Injection	***Currently in Shortage***
Bacteriostatic Water for Injection	***Currently in Shortage***
Belatacept (Nulojix) Lyophilized Powder for Injection	***Currently in Shortage***
Belladonna and Opium Suppositories	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride and Epinephrine Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Capecitabine Tablets	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefixime Oral Capsules	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloramphenicol Sodium Succinate Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Chlorothiazide Oral Suspension	***Currently in Shortage***
Cisplatin Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablets	***Currently in Shortage***
Collagenase Ointment	***Currently in Shortage***
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container	***Currently in Shortage***
Conjugated Estrogens/Bazedoxifene (Duavee) Tablet, Film Coated	***Currently in Shortage***
Cyclopentolate Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***
Desmopressin Acetate Nasal Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***

Dexmedetomidine Injection	***Currently in Shortage***
Dextrose 10% Injection	***Currently in Shortage***
Dextrose 25% Injection	***Currently in Shortage***
Dextrose 5% Injection	***Currently in Shortage***
Dextrose 50% Injection	***Currently in Shortage***
Diazepam Rectal Gel	***Currently in Shortage***
Difluprednate Ophthalmic Emulsion	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Dimercaprol (Bal in Oil) Injection	***Currently in Shortage***
Disopyramide Phosphate (Norpace) Capsules	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide (Trulicity) Injection	***Currently in Shortage***
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution	***Currently in Shortage***
Edetate Calcium Disodium Injection	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Injection, 0.1mg/mL	***Currently in Shortage***
Erythromycin Ophthalmic Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Fluorescein Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsules	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Guanfacine Hydrochloride Tablets	***Currently in Shortage***
Heparin Sodium and Sodium Chloride 0.9% Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert	***Currently in Shortage***
Ibutilide Fumarate Injection	***Currently in Shortage***
Indigotindisulfonate Sodium Injection	***Currently in Shortage***
Isoniazid Injection	***Currently in Shortage***
Isoniazid Tablets	***Currently in Shortage***
IV Fat Emulsion	***Currently in Shortage***
Ketamine Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Viscous) Oral Topical Solution	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine	***Currently in Shortage***

Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsules	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto) Injection	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***
Mepivacaine Hydrochloride Injection	***Currently in Shortage***
Methamphetamine Hydrochloride Tablets	***Currently in Shortage***
Methotrexate Injection	***Currently in Shortage***
Methotrexate Tablets	***Currently in Shortage***
Methyldopa Tablets	***Currently in Shortage***
Methylphenidate Hydrochloride Extended Release Tablets	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Neomycin Sulfate Tablets	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Oxybutynin Chloride Syrup	***Currently in Shortage***
Palifermin (Kepivance) Lyophilized Powder for Injection	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Penicillin G Benzathine Injectable Suspension	***Currently in Shortage***
Physostigmine Salicylate Injection	***Currently in Shortage***
Potassium Acetate Injection	***Currently in Shortage***
Potassium Chloride Concentrate Injection	***Currently in Shortage***
Quinapril and Hydrochlorothiazide Tablets	***Currently in Shortage***
Quinapril Hydrochloride Tablets	***Currently in Shortage***
Remifentanil Injection	***Currently in Shortage***
Rifampin Capsules	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablets	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Semaglutide (Ozempic) Injection	***Currently in Shortage***
Semaglutide (Wegovy) Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection Bags	***Currently in Shortage***
Sodium Chloride 14.6% Injection	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection, 0.9% Vials and Syringes	***Currently in Shortage***
Sodium Phosphates Injection	***Currently in Shortage***

Somatropin Injection	***Currently in Shortage***
Sterile Water for Injection	***Currently in Shortage***
Sterile Water for Irrigation	***Currently in Shortage***
Streptozocin (Zanosar) Sterile Powder	***Currently in Shortage***
Sucralfate Tablets	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Sulfasalazine Tablets	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injectable Suspension	***Currently in Shortage***
Triamcinolone Hexacetonide Injectable suspension	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsules	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***