OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
July 12, 2023
4:00pm

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

Viewing Access Only:
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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 – July 12, 2023

DATE: July 5, 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 July 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/Chronic Medication Adherence (CMA) Program Update – Appendix B

Action Item – Vote to Prior Authorize Altuviiio™ [Antihemophilic Factor (Recombinant), Fc-VMF-XTEN Fusion Protein-ehtl] and Hemgenix® (Etranacogene Dezaparvovec-drlb) – Appendix C

Action Item – 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 – Appendix D

Action Item – 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 – Appendix E

Action Item – 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 – Appendix F

Action Item – Vote to Prior Authorize Daybue™ (Trofinetide) – Appendix G

Action Item – Vote to Prior Authorize Joenja® (Leniolisib) – Appendix H

Action Item – Vote to Prior Authorize Lyvispah™ (Baclofen Oral Granules) and Norgesic®, Norgesic® Forte, and Orphengesic® Forte (Orphenadrine/Aspirin/Caffeine) – Appendix I

Action Item – 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 – Appendix J

Action Item – Annual Review of Colorectal Cancer Medications – Appendix K

Action Item – Annual Review of Allergen Immunotherapies – Appendix L

Annual Review of Testosterone Products and 30-Day Notice to Prior Authorize Kyzatrex® (Testosterone Undecanoate) – Appendix M

30-Day Notice to Prior Authorize Vyjuvek™ (Beremagene Geperpavec-svdt) – Appendix N

Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Leqembi® (Lecanemab-irmb) – Appendix O

Annual Review of Isturisa® (Osilodrostat) and Recorlev® (Levoketoconazole) – Appendix P

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – July 12, 2023 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

Dr. Jennifer de los Angeles –	participating in person
Mr. Kenneth Foster –	participating in person
Dr. Megan Hanner –	participating in person
Dr. Lynn Mitchell –	participating in person
Dr. John Muchmore –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person
Dr. Edna Patatanian –	participating in person
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: 952 7560 1667
Passcode: 69395211

Public Comment for Meeting:

- Speakers who wish to sign up for public comment at the OHCA DUR Board meeting may do so in writing by visiting the DUR Board page on the OHCA website at www.oklahoma.gov/ohca/about/boards-and-committees/drug-utilization-review/dur-board and completing the Speaker Registration Form. Completed Speaker Registration forms should be submitted to DURPublicComment@okhca.org. Forms must be received after the DUR Board agenda has been posted and no later than 24 hours before the meeting.
- The DUR Board meeting will allow public comment and time will be limited to 40 minutes total for all speakers during the meeting. Each speaker will be given 5 minutes to speak at the public hearing. If more than 8 speakers properly request to speak, time will be divided evenly.
- Only 1 speaker per manufacturer will be allowed.
- Any speakers who sign up for public comment must attend the DUR Board meeting in person at OHCA (see above address). Public comment through Zoom will not be allowed for the DUR Board meeting.

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. June 14, 2023 DUR Board Meeting Minutes
   B. June 14, 2023 DUR Board Recommendations Memorandum

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

4. **Update on Medication Coverage Authorization Unit/Chronic Medication Adherence (CMA) Program Update – See Appendix B**
   A. Pharmacy Help Desk Activity for June 2023
   B. Medication Coverage Activity for June 2023
   C. CMA Program Update

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

5. **Action Item – Vote to Prior Authorize Altuviiio™ [Antihemophilic Factor (Recombinant), Fc-VMF-XTEN Fusion Protein-ehtl] and Hemgenix® (Etranacogene Dezaparvovec-drlb) – See Appendix C**
   A. Market News and Updates
   B. Product Summaries
   C. OHCA Recommendations

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

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

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

7. **Action Item – Vote to Prior Authorize Abilify Asimtufii® [Aripiprazole Extended-Release (ER) Injection], Quetiapine 150mg Tablet, Rykindo® (Risperidone ER Injection) and Update the Approval Criteria for the Atypical Antipsychotic Medications – See Appendix E**
   A. Market News and Updates
   B. Cost Comparisons
   C. College of Pharmacy Recommendations

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

8. **Action Item – 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 – See Appendix F**
   A. Introduction
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Daybue™ (Trofinetide) – See Appendix G**
   A. Market News and Updates
   B. Daybue™ (Trofinetide) Product Summary
   C. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Joenja® (Leniolisib) – See Appendix H**
    A. Market News and Updates
    B. Joenja® (Leniolisib) Product Summary
    C. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Lyvispah™ (Baclofen Oral Granules) and Norgesic®, Norgesic® Forte, and Orphengesic® Forte (Orphenadrine/Aspirin/Caffeine)– See Appendix I**
    A. Market News and Updates
    B. Product Summaries
    C. College of Pharmacy Recommendations

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

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

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

13. **Action Item – Annual Review of Colorectal Cancer Medications – See Appendix K**
    A. Current Prior Authorization Criteria
    B. Utilization of Colorectal Cancer Medications
    C. Prior Authorization of Colorectal Cancer Medications
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Colorectal Cancer Medications

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

14. **Action Item – Annual Review of Allergen Immunotherapies – See Appendix L**
    A. Current Prior Authorization Criteria
    B. Utilization of Allergen Immunotherapies
    C. Prior Authorization of Allergen Immunotherapies
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Allergen Immunotherapies

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

15. **Annual Review of Testosterone Products and 30-Day Notice to Prior Authorize Kyzatrex® (Testosterone Undecanoate) – See Appendix M**
    A. Current Prior Authorization Criteria
    B. Utilization of Testosterone Products
    C. Prior Authorization of Testosterone Products
    D. Market News and Updates
    E. Kyzatrex® (Testosterone Undecanoate) Product Summary

F. College of Pharmacy Recommendations
G. Utilization Details of Testosterone Products

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

16. 30-Day Notice to Prior Authorize Vyjuvek™ (Beremagene Geperpavec-svdt) – See Appendix N

A. Introduction
B. Vyjuvek (Beremagene Geperpavec-svdt) Product Summary
C. College of Pharmacy Recommendations

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

17. Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Leqembi® (Lecanemab-irmb) – See Appendix O

A. Current Prior Authorization Criteria
B. Utilization of Alzheimer's Disease Medications
C. Prior Authorization of Alzheimer's Disease Medications
D. Market News and Updates
E. Leqembi® (Lecanemab-irmb) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Alzheimer's Disease Medications

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

18. Annual Review of Isturisa® (Osilodrostat) and Recorlev® (Levoketoconazole) – See Appendix P

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

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

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

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

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.

A. Intravenous (IV) Iron Products
B. Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications
C. Topical Corticosteroids
D. Various Systemic Antibiotics

*Future product and class reviews subject to change.

21. 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 JUNE 14, 2023

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

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

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mark Brandenburg, M.D., MSC; Medical Director	X	
Ellen Buettner; Chief of Staff		X
Kevin Corbett, C.P.A.; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director		X

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

OTHERS PRESENT:	
Kimberly Brackett, AbbVie	John King, AbbVie
Madeline Shurtleff, Otsuka	Craig Irwin, Acadia
Ben Skoog, Acadia	Kenneth Berry, Alkermes
Audrey Rattan, Alkermes	Dave Miley, Teva
Brittany Woller, Indivior	Ralph Rivera, Pharming Healthcare
Gina Heinen, Novo Nordisk	Brent Parker, Merck
Bryan Steffan, Boehringer	Allison Griffin, Cullari Communications
Ed Clasby, Medtronic	David Prather, Novo Nordisk
Melanie Kitto, Biocryst	Brittany Finocchio, Karuna Therapeutics
Scott Symes, Pharming Healthcare	Erik Schindler, Sanofi
Jamie Tobitt, Apellis	Tom Horton, Caris Life Sciences
Gary Parenteau, Dexcom	Robert Greely, Biogen
Shellie Keast, Mercer	Aaron Austin, Takeda
Evan Rushing, Alkermes	Robin Selsor, Aimmune
Lori Howarth, Bayer	Allyson Fonte, Nestle
Richie Crawford, Otsuka	

PRESENT FOR PUBLIC COMMENT:	
Kenneth Berry, Alkermes	Dave Miley, Teva
Brittany Woller, Indivior	Madeline Shurtleff, Otsuka
Benjamin Skoog, Acadia	Ralph Rivera, Pharming Healthcare

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. 17 KENNETH BERRY
2B: AGENDA ITEM NO. 17 DAVE MILEY
2C: AGENDA ITEM NO. 17 BRITTANY WOLLER
2D: AGENDA ITEM NO. 17 MADELINE SHURTLEFF
2E: AGENDA ITEM NO. 18 BENJAMIN SKOOG
2F: AGENDA ITEM NO. 21 RALPH RIVERA

ACTION: NONE REQUIRED

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

3A: APRIL 12, 2023 DUR MINUTES – VOTE

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/OPIOID UTILIZATION AND THE SOONERCARE MORPHINE MILLIGRAM EQUIVALENT (MME) LIMIT

4A: PHARMACY HELP DESK ACTIVITY FOR APRIL 2023
4B: MEDICATION COVERAGE ACTIVITY FOR APRIL 2023
4C: PHARMACY HELP DESK ACTIVITY FOR MAY 2023
4D: MEDICATION COVERAGE ACTIVITY FOR MAY 2023
4E: OPIOID UTILIZATION AND THE SOONERCARE MORPHINE MILLIGRAM EQUIVALENT (MME) LIMIT

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE BRENZAVVY™ (BEXAGLIFLOZIN), MOUNJARO® (TIRZEPATIDE), AND TZIELD™ (TEPLIZUMAB-MZWV) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)

5A: MARKET NEWS AND UPDATES
5B: PRODUCT SUMMARIES
5C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE SYFOVRE™ (PEGCETACOPLAN)

6A: INTRODUCTION
6B: SYFOVRE™ (PEGCETACOPLAN) PRODUCT SUMMARY
6C: 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

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE ANCOBON® (FLUCYTOSINE) AND VIVJOA® (OTESECONAZOLE) AND UPDATE THE APPROVAL CRITERIA FOR THE SYSTEMIC ANTIFUNGAL MEDICATIONS

7A: MARKET NEWS AND UPDATES
7B: VIVJOA® (OTESECONAZOLE) PRODUCT SUMMARY
7C: COST COMPARISON: RECURRENT VULVOVAGINAL CANDIDIASIS (RVVC) TREATMENTS
7D: COLLEGE OF PHARMACY RECOMMENDATIONS

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE DORAL® (QUAZEPAM)

8A: MARKET NEWS AND UPDATES
8B: DORAL® (QUAZEPAM) PRODUCT SUMMARY

8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Kottoor
Dr. Muñoz moved to approve; seconded by Dr. de los Angeles
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE KONVOMEP™ (OMEPRAZOLE/SODIUM BICARBONATE FOR ORAL SUSPENSION) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTI-ULCER MEDICATIONS
9A: MARKET NEWS AND UPDATES
9B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE SKYCLARYS™ (OMAVELOXOLONE)
10A: SKYCLARYS™ (OMAVELOXOLONE) PRODUCT SUMMARY
10B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: VOTE TO PRIOR AUTHORIZE FILSPARI™ (SPARSENTAN)
11A: INTRODUCTION
11B: FILSPARI™ (SPARSENTAN) PRODUCT SUMMARY
11C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: VOTE TO PRIOR AUTHORIZE IMJUDO® (TREMELIMUMAB) AND KRAZATI® (ADAGRASIB) AND UPDATE THE APPROVAL CRITERIA FOR THE LUNG CANCER MEDICATIONS
12A: MARKET NEWS AND UPDATES
12B: PRODUCT SUMMARIES
12C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Baxley
Dr. de los Angeles moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: ANNUAL REVIEW OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ADSTILADRIN® (NADOFARAGENE FIRADENOVAC-VNCG) AND ELAHERE™ (MIRVETUXIMAB SORAVTANSINE-GYNX)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
13C: PRIOR AUTHORIZATION OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: PRODUCT SUMMARIES
13F: COLLEGE OF PHARMACY RECOMMENDATIONS

13G: UTILIZATION DETAILS OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS

Materials included in agenda packet; presented by Dr. Baxley

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

<u>AGENDA ITEM NO. 14:</u> ANNUAL REVIEW OF THE SOONERCARE PHARMACY BENEFIT

14A: SUMMARY
14B: MEDICAID DRUG REBATE PROGRAM
14C: ALTERNATIVE PAYMENT MODELS
14D: DRUG APPROVAL TRENDS
14E: TRADITIONAL VERSUS SPECIALTY PHARMACY PRODUCTS
14F: TOP 10 TRADITIONAL THERAPEUTIC CLASSES BY REIMBURSEMENT
14G: TOP 10 SPECIALTY THERAPEUTIC CLASSES BY REIMBURSEMENT
14H: TOP 10 MEDICATIONS BY REIMBURSEMENT
14I: COST PER CLAIM
14J: MARKET PROJECTIONS
14K: CONCLUSION

Materials included in agenda packet; presented by Dr. Kottoor

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 15:</u> ANNUAL REVIEW OF HEMOPHILIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ALTUVIIIO™ [ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC-VMF-XTEN FUSION PROTEIN-EHTL] AND HEMGENIX® (ETRANACOGENE DEZAPARVOVEC-DRLB)

15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF HEMOPHILIA MEDICATIONS
15C: PRIOR AUTHORIZATION OF HEMOPHILIA MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: PRODUCT SUMMARIES
15F: OHCA RECOMMENDATIONS
15G: UTILIZATION DETAILS OF HEMOPHILIA MEDICATIONS

Materials included in agenda packet; presented by Dr. Ratterman

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

<u>AGENDA ITEM NO. 16:</u> ANNUAL REVIEW OF ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE LAMRYZ™ (SODIUM OXYBATE) AND RELEXXII® [METHYLPHENIDATE EXTENDED-RELEASE (ER) TABLET]

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
16C: PRIOR AUTHORIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
16D: OKLAHOMA RESOURCES
16E: MARKET NEWS AND UPDATES
16F: PRODUCT SUMMARIES
16G: COLLEGE OF PHARMACY RECOMMENDATIONS
16H: UTILIZATION DETAILS OF ADHD AND NARCOLEPSY MEDICATIONS

Materials included in agenda packet; presented by Dr. Wilson

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

<u>AGENDA ITEM NO. 17:</u> ANNUAL REVIEW OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ABILIFY ASIMTUFII® [ARIPIPRAZOLE EXTENDED-RELEASE (ER) INJECTION], QUETIAPINE 150MG

TABLET, RYKINDO® (RISPERIDONE ER INJECTION), AND UZEDY™ (RISPERIDONE ER INJECTION)

17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
17C: PRIOR AUTHORIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
17D: OKLAHOMA RESOURCES
17E: MARKET NEWS AND UPDATES
17F: COST COMPARISON: ARIPIPRAZOLE LONG-ACTING INJECTABLE (LAI) PRODUCTS
17G: COST COMPARISON: QUETIAPINE PRODUCTS
17H: COST COMPARISON: RISPERIDONE LAI PRODUCTS
17I: COLLEGE OF PHARMACY RECOMMENDATIONS
17J: UTILIZATION DETAILS OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS

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

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

<u>AGENDA ITEM NO. 18:</u> 30-DAY NOTICE TO PRIOR AUTHORIZE DAYBUE™ (TROFINETIDE)

18A: INTRODUCTION
18B: DAYBUE™ (TROFINETIDE) PRODUCT SUMMARY
19C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson

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

<u>AGENDA ITEM NO. 19:</u> ANNUAL REVIEW OF MUSCLE RELAXANT MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE LYVISPAH™ (BACLOFEN ORAL GRANULES), NORGESIC®, NORGESIC® FORTE, AND ORPHENGESIC® FORTE (ORPHENADRINE/ASPIRIN/CAFFEINE)

19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF MUSCLE RELAXANT MEDICATIONS
19C: PRIOR AUTHORIZATION OF MUSCLE RELAXANT MEDICATIONS
19D: MARKET NEWS AND UPDATES
19E: PRODUCT SUMMARIES
19F: COLLEGE OF PHARMACY RECOMMENDATIONS
19G: UTILIZATION DETAILS OF MUSCLE RELAXANT MEDICATIONS

Materials included in agenda packet; presented by Dr. Reynolds

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

<u>AGENDA ITEM NO. 20:</u> ANNUAL REVIEW OF VARIOUS SPECIAL FORMULATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ALLOPURINOL 200MG TABLET, APONVIE™ (APREPITANT INJECTABLE EMULSION), ASPRUZYO SPRINKLE™ [RANOLAZINE EXTENDED-RELEASE (ER) GRANULES], AUSTEDO® XR (DEUTETRABENAZINE ER TABLET), ENTADFI® (FINASTERIDE/TADALAFIL CAPSULE), ERMEZA™ (LEVOTHYROXINE ORAL SOLUTION), FUROSCIX® (FUROSEMIDE ON-BODY INFUSOR), IYUZEH™ (LATANOPROST OPHTHALMIC SOLUTION), JYLAMVO® (METHOTREXATE ORAL SOLUTION), PRIMIDONE 125MG TABLET, VERKAZIA® (CYCLOSPORINE OPHTHALMIC SOLUTION), XACIATO™ (CLINDAMYCIN VAGINAL GEL), AND ZOLPIDEM 7.5MG CAPSULE

20A: CURRENT PRIOR AUTHORIZATION CRITERIA
20B: UTILIZATION OF VARIOUS SPECIAL FORMULATIONS
20C: PRIOR AUTHORIZATION OF VARIOUS SPECIAL FORMULATIONS
20D: MARKET NEWS AND UPDATES
20E: PRODUCT SUMMARIES
20F: COLLEGE OF PHARMACY RECOMMENDATIONS

20G: UTILIZATION DETAILS OF VARIOUS SPECIAL FORMUATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

AGENDA ITEM NO. 21: 30-DAY NOTICE TO PRIOR AUTHORIZE JOENJA® (LENIOLISIB)
21A: INTRODUCTION
21B: JOENJA® (LENIOLISIB) PRODUCT SUMMARY
21C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

AGENDA ITEM NO. 22: ANNUAL REVIEW OF RYPLAZIM® (PLASMINOGEN, HUMAN-TVMH)
22A: CURRENT PRIOR AUTHORIZATION CRITERIA
22B: UTILIZATION OF RYPLAZIM® (PLASMINOGEN, HUMAN-TVMH)
22C: PRIOR AUTHORIZATION OF RYPLAZIM® (PLASMINOGEN, HUMAN-TVMH)
22D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 23: 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. 24: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
24A: ALLERGEN IMMUNOTHERAPIES
24B: ALZHEIMER'S DISEASE MEDICATIONS
24C: COLORECTAL CANCER MEDICATIONS
24D: TESTOSTERONE PRODUCTS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 25: ADJOURNMENT
The meeting was adjourned at 6:30 pm.

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

Memorandum

Date: June 16, 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 June 14, 2023

Recommendation 1: Opioid Utilization and the SoonerCare Morphine Milligram Equivalent (MME) Limit

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Brenzavvy™ (Bexagliflozin), Mounjaro® (Tirzepatide), and Tzield® (Teplizumab-mzwv) and Update the Approval Criteria for the Anti-Diabetic Medications and Kerendia® (Finerenone)

MOTION CARRIED by unanimous approval.

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

Tzield® (Teplizumab-mzwv) Approval Criteria:

1. An FDA approved diagnosis of stage 2 Type 1 diabetes mellitus (DM). Diagnosis must be confirmed by the following:
    a. Laboratory testing confirming the presence of ≥2 pancreatic islet autoantibodies; and
        i. Documentation must be submitted with results of autoantibody testing; and

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

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

Anti-Diabetic Medications Tier-3 Approval Criteria:

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

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

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

c. Moving Steglatro® (ertugliflozin) and Segluromet® (ertugliflozin/ metformin) to the Special PA Tier based on net costs; and

5. SGLT-2 Inhibitor/DPP-4 Inhibitor/Biguanides:
   a. Moving Trijardy XR® (empagliflozin/linagliptin/metformin ER) to Tier-1 based on ADA guideline recommendations and net costs after supplemental rebate participation; and
6. Sulfonylureas:
   a. Removing Diabinese® (chlorpropamide) and Orinase® (tolbutamide) due to product discontinuation; and
7. Thiazolidinediones:
   a. Removing Avandaryl® (rosiglitazone/glimepiride) and Avandamet® (rosiglitazone/metformin) due to product discontinuation.

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

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

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

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

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

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

Recommendation 3: Vote to Prior Authorize Vote to Prior Authorize Syfovre™ (Pegcetacoplan)

MOTION CARRIED by unanimous approval.

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

Syfovre™ (Pegcetacoplan) Approval Criteria:

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

Recommendation 4: Vote to Prior Authorize Ancobon® (Flucytosine) and Vivjoa® (Oteseconazole) and Update the Approval Criteria for the Systemic Antifungal Medications

MOTION CARRIED by unanimous approval.

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

Vivjoa® (Oteseconazole) Approval Criteria:

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

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

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

1. An FDA approved indication to reduce the incidence of RVVC; and
2. Member must be an adult female or post-menarchal pediatric female; and
3. Member has a history of RVVC with at least 3 symptomatic episodes of acute vulvovaginal candidiasis (VVC) in the previous 12 months; and
4. Member has experienced a recurrence of VVC during or following 6 months of fluconazole-only maintenance treatment for RVVC or member has a contraindication to fluconazole (e.g., hypersensitivity, drug-drug interactions); and
5. Prescriber must verify member is not pregnant, not lactating, and is currently using reliable contraception and will continue to use throughout the treatment duration and 4 days after last dose; and
6. Member must not be taking concurrent strong CYP3A inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifampin); and
7. A quantity limit of 24 tablets per 180 days will apply.

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

Ancobon® (Flucytosine) Approval Criteria:

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

Recommendation 5: Vote to Prior Authorize Doral® (Quazepam)

MOTION CARRIED by unanimous approval.

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

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

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

Recommendation 6: Vote to Prior Authorize Konvomep™ (Omeprazole/ Sodium Bicarbonate for Oral Suspension) and Update the Approval Criteria for the Anti-Ulcer Medications

MOTION CARRIED by unanimous approval.

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

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

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

sucralfate susp (Carafate®) – ~~**Brand Preferred**~~			**omeprazole/ sodium bicarbonate (Konvomep™ for oral susp)**
			omeprazole/sodium bicarbonate (Zegerid® caps & pack)
			~~**sucralfate susp (generic)**~~

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

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

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

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

~~1. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and~~
~~2. A patient-specific, clinically significant reason why the member cannot use the individual components [bismuth subsalicylate, metronidazole, and tetracycline plus an histamine type 2 receptor (H_2) antagonist], must be provided; and~~
~~3. A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection (e.g., proton pump inhibitor/H_2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and~~
~~4. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and clarithromycin), which are available without prior authorization, must be provided; and~~
~~5. For Helidac® Therapy, a quantity limit of 224 tablets/capsules per 14 days will apply; and~~
~~6. For Pylera®, a quantity limit of 120 capsules per 10 days will apply.~~

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

1. Member must be 18 years of age or older; and

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

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

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components of other triple-therapy regimens approved for the same diagnosis (e.g., omeprazole, amoxicillin, and clarithromycin) or brand name Pylera® (bismuth subcitrate potassium/metronidazole/tetracycline capsules), which are available without prior authorization, must be provided; and
3. A quantity limit of 168 capsules per 14 days will apply.

Recommendation 7: Vote to Prior Authorize Skyclarys™ (Omaveloxolone)

MOTION CARRIED by unanimous approval.

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

Skyclarys™ (Omaveloxolone) Approval Criteria:

1. An FDA approved diagnosis of Friedreich's ataxia (FRDA); and
   a. Diagnosis must be confirmed by genetic testing identifying a mutation in the frataxin (*FXN*) gene; and
2. Member must be 16 years of age or older; and
3. Skyclarys™ must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Member must have a left ventricular ejection fraction of ≥40%; and
5. Member must not be taking concomitant strong or moderate CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin) or the prescriber must verify the dose of Skyclarys™ will be adjusted during concomitant use according to package labeling; and
6. Member must not be taking concurrent strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, long-acting barbiturates, bosentan, efavirenz, etravirine); and
7. Member must not have severe hepatic impairment (Child-Pugh class C); and
8. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Skyclarys™ treatment, every month for the first 3 months of treatment, and periodically thereafter or as clinically indicated; and

9. Prescriber must verify that B-type natriuretic peptide (BNP) will be assessed prior to initiation of Skyclarys™ and cardiac function will be monitored as clinically indicated; and
10. Prescriber must verify lipid parameters will be monitored prior to initiation of Skyclarys™ treatment and periodically thereafter or as clinically indicated; and
11. Female members must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective non-hormonal contraception during therapy and for 28 days after discontinuation of therapy; and
12. Approvals will be for the duration of 1 year. For each subsequent approval, the prescriber must document that the member is responding to the medication, as indicated by slower disease progression and/or other documentation of a positive clinical response to therapy; and
13. A quantity limit of 90 capsules per 30 days will apply.

Recommendation 8: Vote to Prior Authorize Filspari™ (Sparsentan)

MOTION CARRIED by unanimous approval.

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

Filspari™ (Sparsentan) Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy; and
   b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of rapid disease progression as demonstrated by ≥1 of the following, despite 3 months of maximal supportive care:
   a. Urine protein-to-creatinine (UPCR) ratio ≥1.5g/g; or
   b. Proteinuria >0.75g/day; and
6. Member must be on a stable dose of a maximally tolerated angiotensin convert enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and
7. Prescriber must verify the member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin

receptor antagonists (ERAs) prior to initiating treatment with Filspari™; and
8. Member must not be taking strong CYP3A4 inhibitors (e.g., itraconazole) or strong CYP3A4 inducers (e.g., rifampin) concomitantly with Filspari™; and
9. Member must not be taking H2 receptor blockers or proton pump inhibitors (PPIs) concomitantly with Filspari™; and
10. If member is using antacids, they must agree to separate antacid and Filspari™ administration by 2 hours; and
11. Prescriber, pharmacy, and member must be enrolled in the Filspari™ Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. A quantity limit of 30 tablets per 30 days will apply.

Recommendation 9: Vote to Prior Authorize Imjudo® (Tremelimumab-actl) and Krazati® (Adagrasib) and Update the Approval Criteria for the Lung Cancer Medications

MOTION CARRIED by unanimous approval.

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

Imjudo® (Tremelimumab-actl) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:
1. Diagnosis of unresectable HCC; and
2. Used in combination with durvalumab; and
3. Will be approved for a maximum of 1 dose per treatment plan per member.

Imjudo® (Tremelimumab-actl) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of metastatic NSCLC; and
2. No epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS1 mutations; and
3. Used in combination with durvalumab and platinum-based chemotherapy; and
4. Will be approved for a maximum of 5 doses per treatment plan per member.

Krazati® (Adagrasib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
2. Presence of KRAS G12C mutation in tumor or plasma specimen as determined by an FDA approved test; and
3. Member has received at least 1 prior systemic therapy; and

4. As a single agent.

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

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

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

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

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

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

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

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

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

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

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

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

1. Diagnosis of soft tissue sarcoma – IMT; and
2. Member must be 1 year of age or older; and
3. Anaplastic lymphoma kinase (ALK) positive; and
4. Used as a single agent only.

Next, the College of Pharmacy recommends updating the Alunbrig® (brigatinib), Gavreto® (pralsetinib), Rozlytrek® (entrectinib), Tagrisso®

(osimertinib), Vizimpro® (dacomitinib), and Xalkori® (crizotinib) approval criteria to be more consistent with clinical practice and to clarify appropriate use as a single agent (changes shown in red):

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

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

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

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

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

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

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

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

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

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

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

1. Diagnosis of NSCLC; and

a. As adjuvant therapy following tumor resection in members with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations; or

2. Diagnosis of metastatic NSCLC; and
   a. EGFR T790M mutation-positive disease; or
   b. EGFR exon 19 deletions or exon 21 L858R mutations; and
3. As a single agent.

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

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

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

1. Members ~~1 to 21 years of age~~ 1 year of age or older:
   a. Diagnosis of systemic ALCL that is anaplastic lymphoma kinase (ALK)-positive; and
   b. Relapsed or refractory disease; ~~or~~ and

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

3. As a single agent.

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

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

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use Alimta® (pemetrexed; J9305) and other preferred pemetrexed 25mg/mL solution products (J9294 - Hospira, J9296 - Accord, J9314 - Teva) that do not require prior authorization must be provided.

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

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

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

Recommendation 10: Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Adstiladrin® (Nadofaragene Firadenovec-vncg) and Elahere™ (Mirvetuximab Soravtansine-gynx)

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

Recommendation 11: Annual Review of the SoonerCare Pharmacy Benefit

NO ACTION REQUIRED.

Recommendation 12: Annual Review of Hemophilia Medications and 30-Day Notice to Prior Authorize Altuviiio™ [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl] and Hemgenix® (Etranacogene Dezaparvovec-drlb)

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

Recommendation 13: Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Lumryz™ (Sodium Oxybate) and Relexxii® [Methylphenidate Extended-Release (ER) Tablet]

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

Recommendation 14: Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Abilify Asimtufii® [Aripiprazole Extended-Release (ER) Injection], Quetiapine 150mg Tablet, Rykindo® (Risperidone ER Injection), and Uzedy™ (Risperidone ER Injection)

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

Recommendation 15: 30-Day Notice to Prior Authorize Daybue™ (Trofinetide)

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

Recommendation 16: Annual Review of Muscle Relaxant Medications and 30-Day Notice to Prior Authorize Lyvispah™ (Baclofen Oral Granules) and

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

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

Recommendation 17: Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Allopurinol 200mg Tablet, Aponvie™ (Aprepitant Injectable Emulsion), Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules], Austedo® XR (Deutetrabenazine ER Tablet), Entadfi® (Finasteride/ Tadalafil Capsule), Ermeza™ (Levothyroxine Oral Solution), Furoscix® (Furosemide On-Body Infusor), Iyuzeh™ (Latanoprost Ophthalmic Solution), Jylamvo® (Methotrexate Oral Solution), Primidone 125mg Tablet, Verkazia® (Cyclosporine Ophthalmic Solution), Xaciato™ (Clindamycin Vaginal Gel), and Zolpidem Tartrate 7.5mg Capsule

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

Recommendation 18: 30-Day Notice to Prior Authorize Joenja® (Leniolisib)

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

Recommendation 19: Annual Review of Ryplazim® (Plasminogen, Human-tvmh)

NO ACTION REQUIRED.

Recommendation 20: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

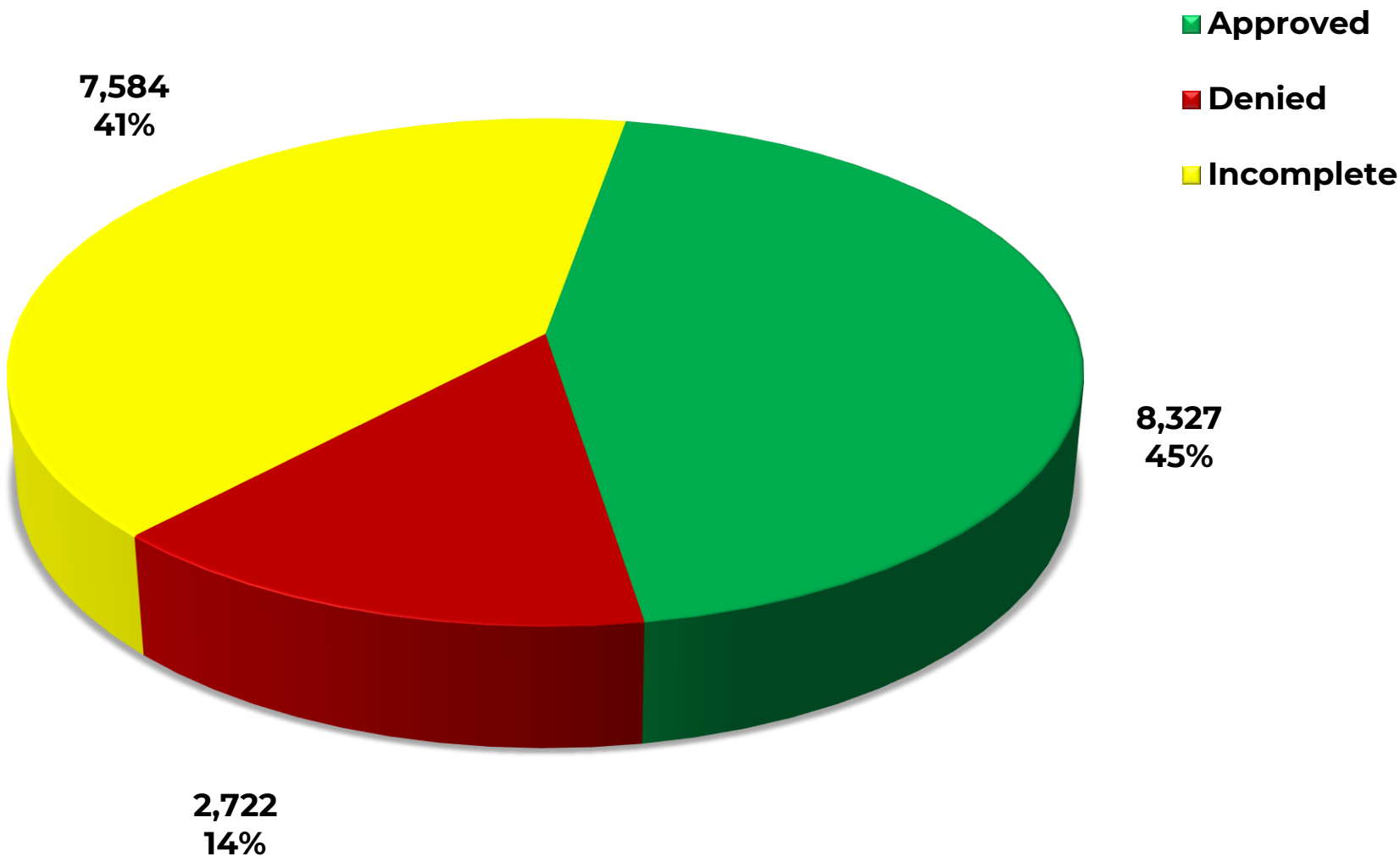
NO ACTION REQUIRED.

Recommendation 21: Future Business

NO ACTION REQUIRED.

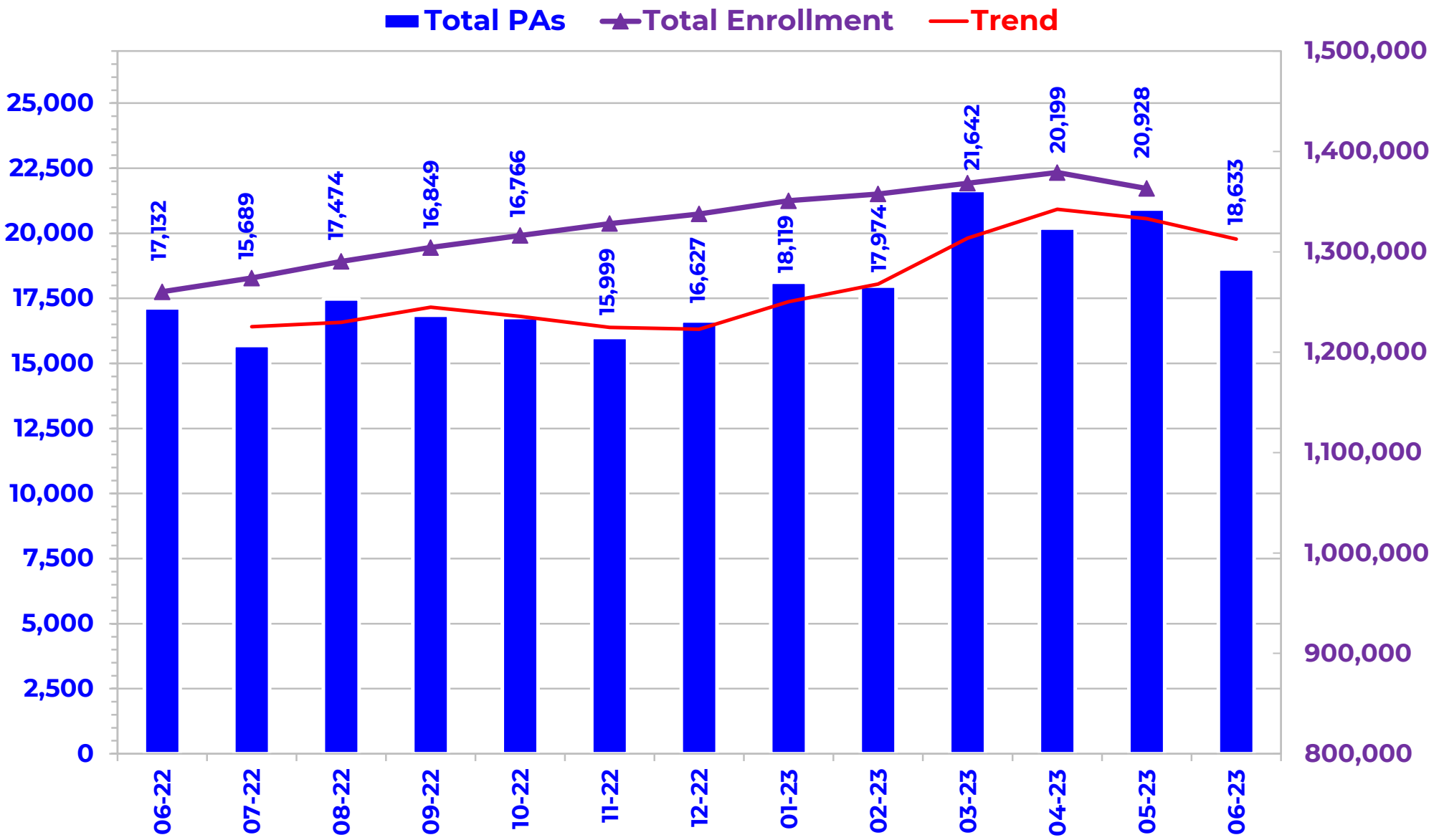
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: JUNE 2023



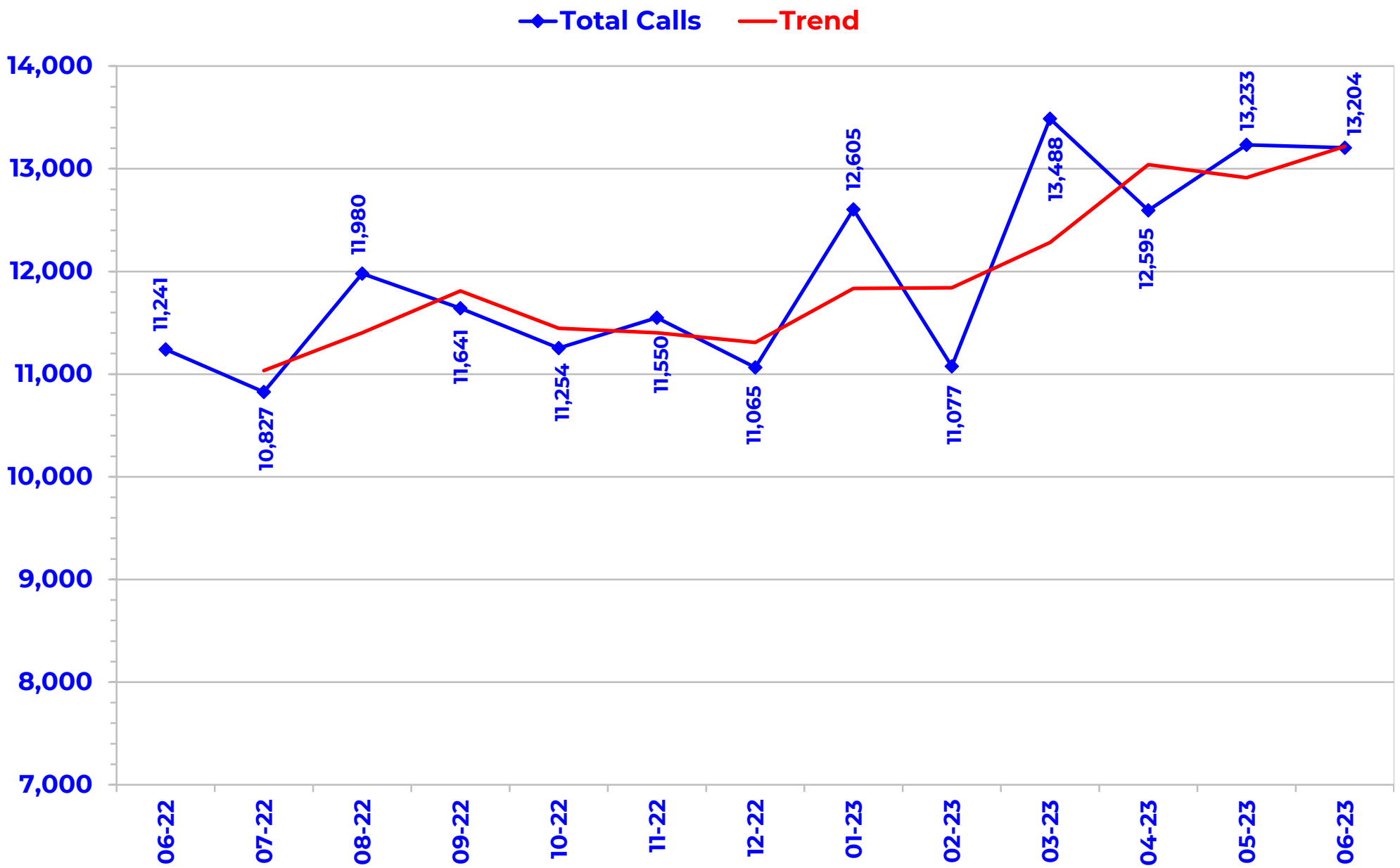
PA totals include approved/denied/incomplete/overrides

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
JUNE 2022 – JUNE 2023



Prior Authorization Activity

6/1/2023 Through 6/30/2023

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	132	41	10	81	350
Analgesic - NonNarcotic	32	1	7	24	179
Analgesic, Narcotic	436	195	40	201	126
Angiotensin Receptor Antagonist	16	2	3	11	361
Anti-inflammatory	26	14	2	10	66
Antiasthma	121	35	32	54	197
Antibiotic	49	22	5	22	211
Anticonvulsant	285	131	19	135	330
Antidepressant	447	101	82	264	314
Antidiabetic	3,339	1,165	777	1,397	350
Antigout	19	11	0	8	344
Antihemophilic Factor	15	11	1	3	313
Antihistamine	43	18	11	14	331
Antimalarial Agent	12	3	0	9	361
Antimigraine	769	132	243	394	272
Antineoplastic	285	181	23	81	172
Antiobesity	70	10	51	9	331
Antiparasitic	32	9	3	20	15
Antiulcers	44	9	9	26	139
Antiviral	14	3	4	7	31
Anxiolytic	40	3	2	35	268
Atypical Antipsychotics	801	296	74	431	353
Benign Prostatic Hypertrophy	10	1	3	6	361
Biologics	503	280	44	179	297
Bladder Control	155	20	43	92	344
Blood Thinners	93	26	3	64	300
Botox	73	45	19	9	353
Buprenorphine Medications	137	51	19	67	107
Calcium Channel Blockers	18	4	1	13	360
Cardiovascular	194	93	22	79	334
Chronic Obstructive Pulmonary Disease	388	81	92	215	350
Constipation/Diarrhea Medications	299	65	79	155	233
Contraceptive	65	21	7	37	315
Corticosteroid	19	5	4	10	168
Dermatological	652	198	170	284	215
Diabetic Supplies	766	324	63	379	253
Endocrine & Metabolic Drugs	80	36	9	35	300
Erythropoietin Stimulating Agents	30	14	5	11	113
Estrogen Derivative	14	3	1	10	361
Fibromyalgia	22	4	6	12	275
Fish Oils	40	7	6	27	351

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Gastrointestinal Agents	229	66	27	136	191
Glaucoma	19	5	3	11	184
Growth Hormones	150	108	9	33	143
Hematopoietic Agents	38	19	3	16	208
Hepatitis C	41	19	7	15	15
HFA Rescue Inhalers	21	2	3	16	181
Insomnia	167	9	48	110	198
Insulin	379	148	30	201	357
Miscellaneous Antibiotics	36	6	4	26	89
Multiple Sclerosis	107	51	12	44	238
Muscle Relaxant	84	12	11	61	225
Nasal Allergy	66	6	14	46	131
Neurological Agents	190	65	32	93	215
Neuromuscular Agents	28	8	6	14	190
NSAIDs	75	1	20	54	85
Ocular Allergy	18	2	2	14	224
Ophthalmic	23	3	7	13	361
Ophthalmic Anti-infectives	35	10	1	24	17
Ophthalmic Corticosteroid	34	8	3	23	217
Osteoporosis	58	22	10	26	351
Other*	452	133	57	262	271
Otic Antibiotic	42	1	9	32	25
Respiratory Agents	39	20	0	19	308
Statins	69	19	17	33	182
Stimulant	2,375	1,650	106	619	351
Testosterone	269	71	62	136	329
Thyroid	26	9	2	15	359
Topical Antifungal	71	8	14	49	72
Topical Corticosteroids	62	5	17	40	228
Vitamin	139	37	74	28	70
Pharmacotherapy	86	74	2	10	292
Emergency PAs	1	1	0	0	
Total	**16,014**	**6,269**	**2,606**	**7,139**	

* 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	102	79	3	20	145
Compound	14	11	0	3	87
Diabetic Supplies	2	2	0	0	256
Dosage Change	463	438	2	23	15
High Dose	6	6	0	0	239
IHS-Brand	1	1	0	0	363
Ingredient Duplication	5	4	0	1	11
Lost/Broken Rx	161	151	1	9	25
MAT Override	337	276	4	57	85
NDC vs Age	324	227	37	60	280
NDC vs Sex	8	8	0	0	173
Nursing Home Issue	48	47	1	0	37
Opioid MME Limit	80	27	4	49	154
Opioid Quantity	50	40	4	6	148
Other	74	46	18	10	27
Quantity vs Days Supply	801	594	28	179	244
STBS/STBSM	11	5	5	1	72
Step Therapy Exception	35	18	6	11	360
Stolen	20	20	0	0	17
Third Brand Request	77	58	3	16	35
Overrides Total	**2,619**	**2,058**	**116**	**445**	
Total Regular PAs + Overrides	**18,633**	**8,327**	**2,722**	**7,584**	

Denial Reasons	
Unable to verify required trials.	6,379
Does not meet established criteria.	2,762
Lack required information to process request.	1,327
Other PA Activity	
Duplicate Requests	1,896
Letters	44,083
No Process	3
Changes to existing PAs	1,308
Helpdesk Initiated Prior Authorizations	1,305
PAs Missing Information	1,947

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

Chronic Medication Adherence (CMA) Program Update

Oklahoma Health Care Authority
July 2023

Prescriber Mailing: Diabetes and Cardiovascular Maintenance Medications[1]

In mid-2015, the College of Pharmacy initiated the CMA program as an educational mailing which is processed quarterly and is sent to prescribers with members on chronic maintenance medications for diabetes mellitus (DM), hypertension (HTN), and cholesterol. The purpose of the CMA mailing is to encourage medication adherence, reduce poor health outcome risk factors, and improve the quality of care for SoonerCare members receiving these medications. The CMA inclusion criteria for each biannual prescriber mailing cohort requires the prescriber to have ≥7 SoonerCare members taking DM, HTN, and cholesterol medications on a regular basis. The review period for each mailing is 1 year, and members are assigned to prescribers and included in the prescriber's patient list if they are the last prescriber of record for a maintenance medication as demonstrated in SoonerCare paid pharmacy claims.

Although criteria for inclusion, frequency of mailing, and types of mailings have changed slightly since program inception, the last substantial change was made in 2018. Since that time, the mailings have included both cardiovascular (CV) and DM medications in each mailing rather than alternating mailings. Cohort prescribers receive 4 letters per year to better inform them of their SoonerCare members using chronic maintenance medications and as a convenient way to track their members' adherence over time, including any improvements or changes. The consistent prescriber list is updated approximately once every 2 years to account for prescribers who move out of state, retire, or no longer contract with SoonerCare. The CMA prescriber list was most recently updated in February 2022.

Each mailing includes a prescriber summary report with a star rating based on the prescriber's overall percentage of members considered adherent to chronic maintenance medications. Adherence is estimated by measuring the proportion of days covered (PDC), or percentage of days in the past year covered by prescription claims. A member is considered adherent if their PDC is ≥80% and is considered non-adherent if their PDC is <80%. A higher prescriber percentage (and corresponding star rating) indicates that more of their SoonerCare members are adherent to chronic maintenance medications. Each mailing also includes a detailed patient list with each member's PDC, specific medication name and strength, total day supply, and total study days. Prescribers also receive a list of medication adherence

resources for patients in hopes prescribers will utilize these methods to improve their patients' adherence.

Mailing Summaries

The following table outlines total letters mailed and total members included in each CMA mailing since February 2021 to the most recent mailing in May 2023:

Date Letter Processed	Total Letters Mailed to Prescribers	Total Members Included
February 2021	214	6,470
May 2021	212	6,311
August 2021	211	6,182
November 2021	196	5,802
February 2022*	236	7,599
May 2022	235	7,200
August 2022	235	6,942
November 2022	232	6,714
February 2023	231	6,572
May 2023	226	6,304

*CMA prescriber list updated

Star Ratings

The star ratings for the percentage of SoonerCare members who are adherent to CV or DM chronic maintenance medications are based on the 2021-23 Medicare Star Ratings. However, a rating of 0 stars is exclusive to SoonerCare. The following descriptions illustrate the star ratings and adherence percentages for each star rating. It is important to note the threshold for each star rating has become increasingly higher with each annual update. Hence the provider star rating may appear to show a trend towards worsening adherence each February, but this may actually reflect a more rigorous standard being applied.

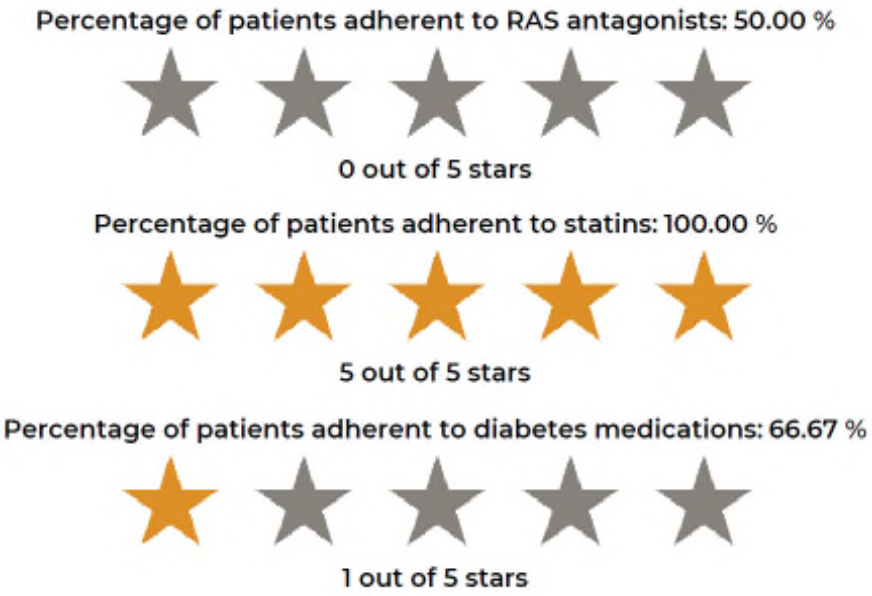
- **CV Star Ratings:**
  CV star ratings address adherence to 2 classes of maintenance medications:
  1. Renin angiotensin system (RAS) antagonists [i.e., angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), direct renin inhibitors]
  2. 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors (i.e., statins)

  Adherence is shown in the Provider Summary Report as a percentage for RAS antagonists and as a percentage for statins, with a corresponding star rating for each CV category.
- **DM Star Ratings:**

DM star ratings address adherence to maintenance medications for DM, excluding insulin and Symlin® (pramlintide). Adherence is shown in the Provider Summary Report as a percentage and corresponding star rating for DM medications.

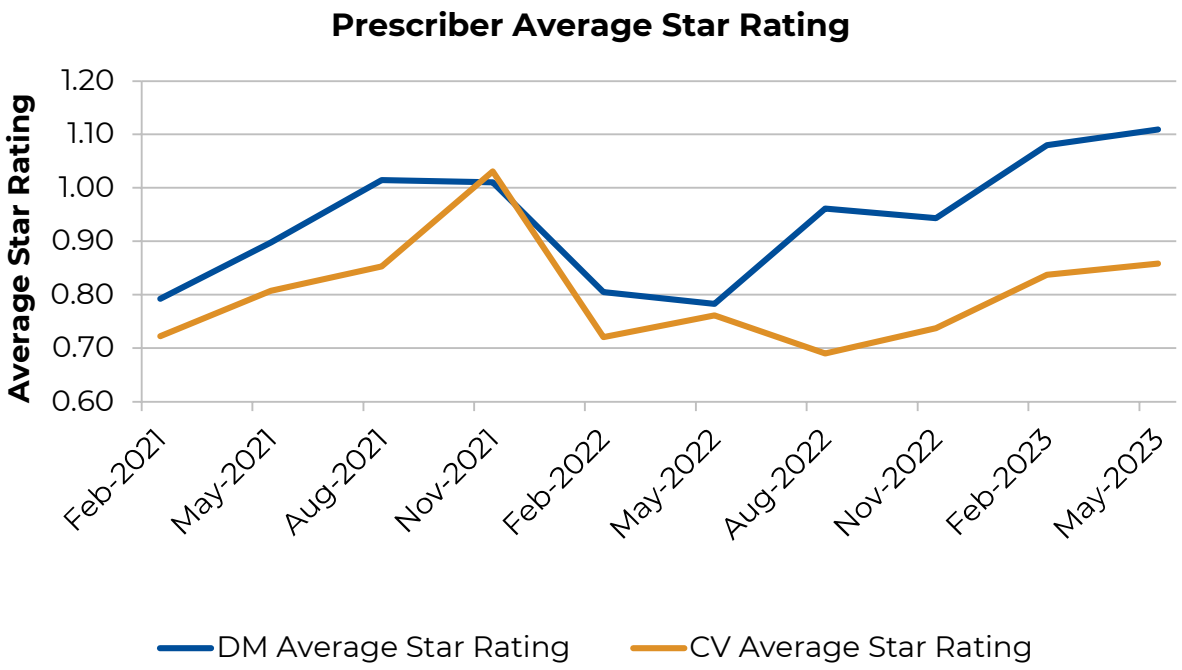
Provider Summary Report

Report date: <Report Date>
Provider: <Provider Name>
NPI: <Prescriber NPI>
SoonerCare Provider ID: <Provider ID>

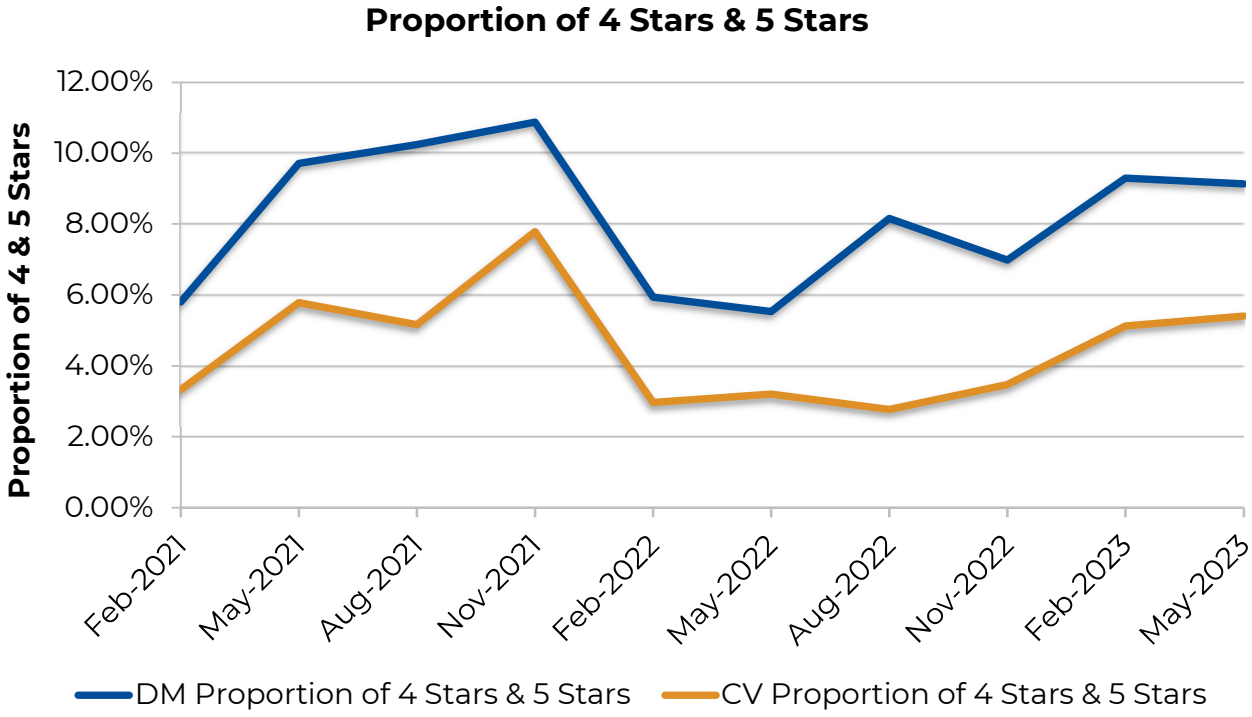


CMA Trends

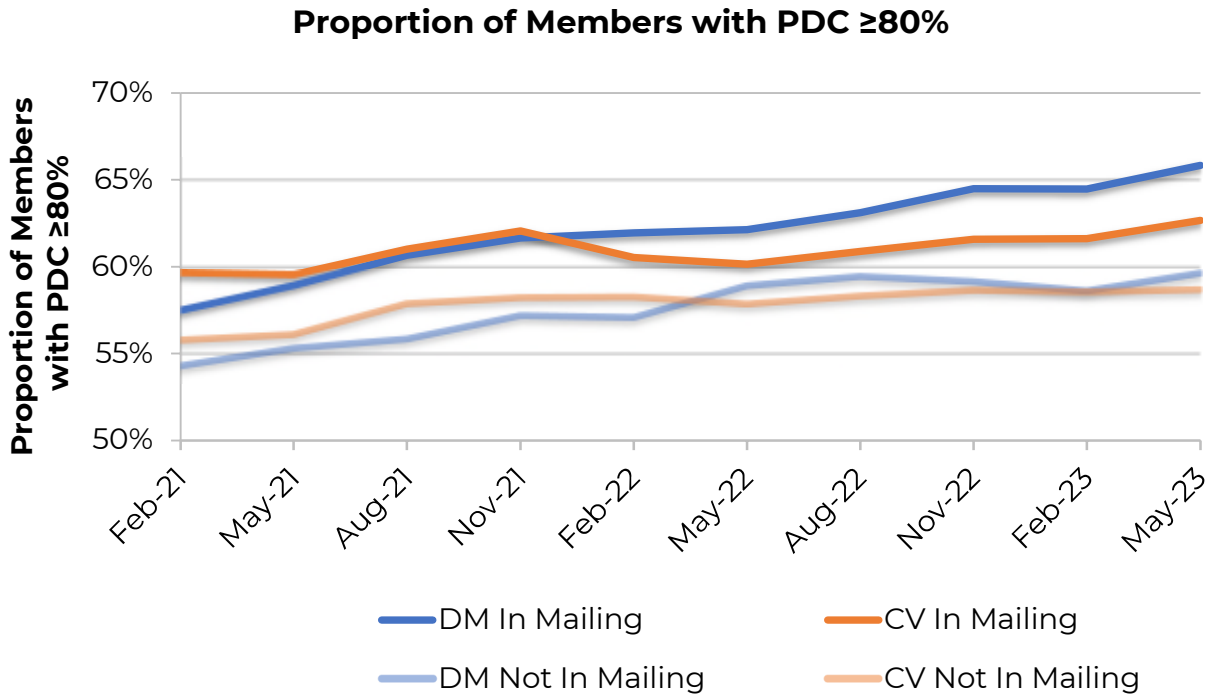
The following line graph shows trends in the average star rating for prescribers included in the CMA mailing since February 2021. As a reminder, February 2022 represents a new cohort of prescribers and a new threshold of star ratings. The mailing list was updated to include prescribers meeting the current CMS criteria and to remove prescribers no longer meeting the criteria. This graph is specific to those prescribers included in the mailings and differentiates between DM and CV (i.e., statins and RAS antagonists) modules. An overall improvement in the average star rating is seen for each February-to-February time period. The DM star ratings tend to be higher than the CV star ratings during the same time period. Approximately 45% of the prescribers who received the CMA mailings in 2021 continued receiving the CMA mailings during 2022-2023. Please note, the vertical axis starts at 0.6 in order to reflect small changes. Despite overall favorable increases in the average star ratings, opportunities for further enhancements continue to exist.



The following line graph shows trends in the proportion of prescribers with 4 star and 5 star ratings included in the CMA mailing since February 2021. An overall increase in the proportion of 4 star and 5 star ratings was seen for each February-to-February time period, similar to the average star ratings above. Also as above, overall favorable increases were seen, but opportunities for further enhancements continue to exist.



The following line graph shows trends in the proportion of members with a PDC ≥80% for those members with prescribers included in the mailing compared to those with prescribers not included in the mailing since February 2021. A member is considered adherent if their PDC is ≥80%. Please note, the vertical axis starts at 50% in order to reflect small changes.



Unlike prescribers included in the mailings, members included in the mailings are not consistent and may change during the calendar year due to medication discontinuations, gaining or losing SoonerCare eligibility, or changing to a prescriber not included in the mailing. Despite member variability, an overall increase in the proportion of members with a PDC ≥80% was seen for both modules for those prescribers included in the recent mailing cohort. The trend is similar when compared to prescribers not included in the mailing. However, prescribers included in the mailing continue to have a higher proportion of members with PDC ≥80% than their peers. This indicates prescriber mailings may have a positive impact on the proportion of members with PDC ≥80%.

Conclusions

Data specific to prescribers in the CMA mailing shows an overall trend toward higher average star ratings and an increase in the prescriber percentage of adherent members using chronic maintenance DM and CV medications. Trends in prescriber specific measures continue to show improvement, and while favorable increases were seen, opportunities for further enhancements continue to exist. The College of Pharmacy will continue to monitor SoonerCare member adherence with the goal of achieving a member PDC of

≥80% and a 5 star rating for the prescriber percentage of adherent members. New interventions will be implemented where appropriate, and results will be reported to the Drug Utilization Review (DUR) Board when available.

[1] Centers for Medicare and Medicaid Services (CMS): *Medicare 2023 Part C & D Star Rating Technical Notes*. Available online at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData. Last revised 02/01/2022. Last accessed 06/05/2023.

Appendix C

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

Oklahoma Health Care Authority
July 2023

Market News and Updates[1,2]

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

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

Altuviiio™ [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl] Product Summary[3]

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

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

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

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

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

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

Cost Comparison:

Product	Cost Per Unit	FDA Approved Prophylactic Dosing	Cost Per 4 Weeks[Ŧ]
Altuviiio™	**$5.11**	**50 IU/kg once weekly**	**$51,100**
Advate® (standard half-life product)	$1.45	20-40 IU/kg every other day	$20,300-$40,600
Eloctate® (extended half-life product)	$2.18	25-65 IU/kg every 3-5 days	$16,625-$63,756

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC), or Specialty Pharmaceutical Acquisition Cost (SPAC).

[Ŧ]Cost per 4 weeks based on a member weighing 50kg using routine prophylaxis therapy.

Hemgenix® (Etranacogene Dezaparvovec-drlb) Product Summary[4]

Therapeutic Class: AAV vector-based gene therapy

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

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

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

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

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

Recommendations

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

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

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

Hemgenix® (Etranacogene Dezaparvovec-drlb) Approval Criteria:

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

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[1] U.S. Food and Drug Administration (FDA). FDA Approves First Gene Therapy to Treat Adults with Hemophilia B. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-treat-adults-hemophilia-b. Issued 11/22/2022. Last accessed 06/26/2023.
[2] U.S. FDA. FDA Approves Altuviiio™ for Hemophilia A Patients. Available online at: https://www.hemophilia.org/news/fda-approves-altuviiiotm-for-hemophilia-a-patients. Issued 02/24/2023. Last accessed 06/26/2023.
[3] Altuviiio™ Prescribing Information. Bioverativ Therapeutics, Inc. Available online at https://www.fda.gov/media/165594/download. Last revised 02/2023. Last accessed 06/26/2023.
[4] Hemgenix® Prescribing information. CSL Behring LLC. Available online at: https://labeling.cslbehring.com/PI/US/Hemgenix/EN/Hemgenix-Prescribing-Information.pdf. Last revised 11/2022. Last accessed 06/26/2023.

Appendix D

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

Oklahoma Health Care Authority
July 2023

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

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

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

News:

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

Lumryz™ (Sodium Oxybate) Product Summary[7]

Therapeutic Class: Central nervous system (CNS) depressant

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

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

Dosing and Administration:

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

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

Relexxii® (Methylphenidate ER) Product Summary[8]

Therapeutic Class: CNS stimulant

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

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

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

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

Cost Comparison:

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

ER = extended-release
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
[+]Cost per 30 days based on the maximum FDA approved dose of 72mg per day for each product.

Recommendations

The College of Pharmacy recommends the following changes to the ADHD and Narcolepsy Medications 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®) ~~**dextroamphetamine ER (Dexedrine Spansules®)**~~ dextroamphetamine soln (ProCentra®) dextroamphetamine (Xelstrym™)
Short-Acting			
amphetamine/ dextroamphetamine (Adderall®)			
Long-Acting			
amphetamine/ dextroamphetamine ER (Adderall XR®) lisdexamfetamine cap **and chew tab** (Vyvanse®)+	amphetamine ER susp and tab (Dyanavel® XR) **dextroamphetamine ER (Dexedrine Spansules®)**		
Methylphenidate			
Short-Acting			
dexmethylphenidate (Focalin®) methylphenidate tab and soln (Methylin®) methylphenidate (Ritalin®)			
Long-Acting			
dexmethylphenidate ER (Focalin XR®) – **Brand Preferred**	dexmethylphenidate ER (generic Focalin XR®)	~~**methylphenidate ER 72mg**~~ methylphenidate ER (Adhansia XR®)	

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
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®)	methylphenidate ER (Aptensio XR®) **– Brand Preferred** methylphenidate ER susp (Quillivant XR®) **methylphenidate ER (Ritalin LA®)**	methylphenidate ER (Jornay PM®) serdexmethylphen-idate/dexmethylphen-idate (Azstarys®)	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
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)Δ		

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

ADHD Medications Tier-2 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response:
   a. Trials should have been within the last 180 days; and
   b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
   c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and

doses should be included along with the signature from the physician; and

3. For Dyanavel® XR oral suspension and Quillivant XR®, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Kapvay® [Clonidine Extended-Release (ER) Tablet] Approval Criteria:
    a. An FDA approved diagnosis; and
    b. Previously failed trials (within the last 180 days) with a long-acting Tier-1 stimulant, Intuniv®, and Strattera®, unless contraindicated, that did not yield adequate results; and
    c. A patient-specific, clinically significant reason why the member cannot use clonidine immediate-release tablets must be provided.

ADHD Medications Tier-3 Approval Criteria:

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

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

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

[1] Relexxii® (Methylphenidate Hydrochloride Extended-Release) – New Drug Approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_relexxii_2022-0627.pdf. Issued 06/23/2022. Last accessed 06/27/2023.
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Appendix E

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

Oklahoma Health Care Authority
July 2023

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

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

- **December 2022:** The FDA approved Vraylar® (cariprazine) as an adjunctive therapy to antidepressants for major depressive disorder (MDD) in adults. The efficacy of cariprazine for this indication was established in 2 trials in patients with MDD who had an inadequate response to 1-3 prior antidepressant therapies. Vraylar® was previously FDA approved for bipolar I disorder and schizophrenia in adults.
- **January 2023:** The FDA approved Rykindo® (risperidone ER injection) for the treatment of schizophrenia in adults or as monotherapy or adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults. Rykindo® is administered via intramuscular (IM) injection once every 2 weeks. Doses should not exceed 50mg every 2 weeks, and prior to initiation, tolerability with oral risperidone should be established.
- **April 2023:** The FDA approved Uzedy™ (risperidone ER injection) for the treatment of schizophrenia in adults. Uzedy™ is the first subcutaneous (sub-Q), long-acting formulation of risperidone to utilize MedinCell's SteadyTeq™ technology. This new technology helps control the steady release of risperidone allowing therapeutic blood concentrations to be reached within 6-24 hours. Uzedy™ is administered once every month or once every 2 months, with the dose being dependent on the patient's prior oral risperidone therapy.
- **April 2023:** The FDA approved Abilify Asimtufii® (aripiprazole ER injection) for the treatment of schizophrenia or maintenance monotherapy treatment of bipolar I disorder, both in adults. Abilify Asimtufii® is given once every 2 months via IM injection by a health care professional. Tolerability with oral aripiprazole should be established in patients who are naïve to aripiprazole.
- **May 2023:** The FDA approved a new indication for Rexulti® (brexpiprazole) for the treatment of agitation associated with dementia

due to Alzheimer's disease. This is the first FDA approved treatment for this indication. Rexulti® was previously FDA approved for schizophrenia in patients 13 years of age or older and as adjunctive therapy to antidepressants for MDD in adults.

Cost Comparison: Aripiprazole Long-Acting Injectable (LAI) Products

Medication	Cost Per Syringe	Cost Per Year
Abilify Asimtufii® (aripiprazole) 960mg/3.2mL PFS	**$5,438.46**	**$32,630.76ß**
Abilify Maintena® (aripiprazole) 400mg PFS	$2,603.06	$31,236.72*
Aristada® (aripiprazole lauroxil) 1,064mg/3.9mL PFS	$3,454.70	$20,728.20+

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC).
PFS = pre-filled syringe
ßAbilify Asimtufii® cost per year is based on maximum dose of 960mg once every 2 months.
*Abilify Maintena® cost per year is based on maximum dose of 400mg once monthly.
+Aristada® cost per year is based on maximum dose of 1,064mg once every 2 months.

Cost Comparison: Quetiapine Products

Medication	Cost Per Tablet	Cost Per Month*
quetiapine 150mg tablets	**$1.49**	**$44.70**
quetiapine 50mg tablets	$0.04	$3.60
quetiapine 300mg tablets	$0.14	$2.10
quetiapine 100mg tablets	$0.04	$1.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month is based on a dose of 150mg daily.

Cost Comparison: Risperidone LAI Products

Medication	Cost Per Unit	Cost Per Year
Uzedy™ (risperidone) 125mg/0.35mL	**$3,080.00**	**$36,960.00***
Uzedy™ (risperidone) 250mg/0.7mL	**$6,160.00**	**$36,960.00***
Perseris® (risperidone sub-Q inj) 120mg	$2,760.80	$33,129.60ß
Risperdal Consta® (risperidone IM inj) 50mg/2mL	$1,124.80	$29,244.80+

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC).
IM = intramuscular; inj = injection; sub-Q = subcutaneous
Unit = each syringe for Uzedy™, each vial for Risperdal Consta®, and each kit for Perseris®
*Uzedy™ cost per year is based on maximum dose of 125mg once monthly or 250mg once every 2 months.
ßPerseris® cost per year is based on maximum dose of 120mg once monthly.
+Risperdal Consta® cost per year is based on maximum dose of 50mg every 2 weeks.
Please note: There is no cost information for Rykindo® available at this time to allow for comparison.

Recommendations

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

1. The prior authorization of Abilify Asimtufii® (aripiprazole ER injection), quetiapine 150mg tablet, 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 product may require the member to have been adequately treated with another oral or injectable product prior to use and/or during initiation. The package labeling should be referenced for each individual product.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.
βUnique criteria applies to Lybalvi® (olanzapine/samidorphan).
∞Unique criteria applies to long-acting injectable 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 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 of the treatment of agitation associated with dementia due to Alzheimer's disease; and
2. Diagnosis must be confirmed by the following:
    a. Mini-Mental State Exam (MMSE) score between 5 and 22; and
    b. Documentation of the member's dementia due to Alzheimer's disease diagnosis [i.e., chart notes consistent with findings of a diagnosis of dementia due to Alzheimer's disease as per the National Institute on Aging and the Alzheimer's Association (NIA-AA)]; and
    c. 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.

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Appendix F

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

Oklahoma Health Care Authority
July 2023

Introduction

Multiple formulations of medications are made for ease of administration, to increase bioavailability, or as new technologies are created to provide a more efficient treatment response. Some of the new formulations incur greater costs for production, resulting in greater costs for the payer and consumer. A clinical review of each product and its comparative cost to other formulations is provided in the following report for reference.

Allopurinol 200mg Tablet Product Summary and Recommendations[1]

Therapeutic Class: Xanthine oxidase inhibitor

Indication(s): Treatment of gout, recurrent calcium renal calculus, and increased uric acid levels in cancer patients receiving chemotherapy

Dosing and Administration:

- The recommended dosing is based on diagnosis:
  - Gout:
    - The dose of allopurinol varies based on disease severity. It should be dosed to accomplish full control of gout and lower serum uric acid to normal or near normal levels.
      - The minimal effective dose is 100mg to 200mg daily and the maximal recommended dose is 800mg/day.
      - Dosages higher than 300mg should be administered in divided doses.

        - The dose should be titrated by 100mg daily at weekly intervals until serum uric acid level of 6mg/dL or less is attained.
    - Recurrent Calcium Renal Calculus:
        - Initially, 200mg to 300mg orally daily in divided doses or as a single dose
        - The dose may be titrated based on 24 hours urinary urate determination with a maximum dose of 800mg/day.
    - Increased Uric Acid Levels in Cancer Patients:
        - Initially, 600mg to 800mg orally daily for 2 or 3 days together with high fluid intake based on severity of disease with a maximum dose of 800mg/day

Other Formulation(s) Available:

- Allopurinol 100mg and 300mg tablets

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*
allopurinol 200mg tablet (generic)	**$6.61**	**$793.20**
allopurinol 100mg tablet (generic)	$0.04	$9.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the FDA approved maximum daily dose of 800mg.

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.

Aponvie™ (Aprepitant Injectable Emulsion) Product Summary and Recommendations[2,3,4,5]

Therapeutic Class: Substance P/neurokinin-1 (NK_1) receptor antagonist

Indication(s): Prevention of postoperative nausea and vomiting (PONV) in adults

How Supplied: 32mg/4.4mL (7.2mg/mL) injectable emulsion in single-dose vial (SDV)

Dosing and Administration: The recommended dose is 32mg administered as a 30 second intravenous (IV) injection prior to induction of anesthesia.

Other Formulation(s) Available:

- Aprepitant 40mg capsule, ondansetron orally disintegrating tablets (ODTs), and ondansetron injection

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Dose*
Aponvie™ (aprepitant 32mg/4.4mL injectable emulsion)	**$12.23**	**$53.81**
aprepitant 40mg capsule (generic)	$52.16	$52.16
ondansetron 8mg orally disintegrating tablet (generic)	$0.21	$0.42
ondansetron 4mg/2mL injection (generic)	$0.17	$0.34

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = capsule, mL, or tablet
*Cost per dose is based on FDA approved dosing for the prevention of PONV for each product.

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.

Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules] Product Summary and Recommendations[6,7]

Therapeutic Class: Antianginal

Indication(s): Treatment of chronic angina

How Supplied: 500mg and 1,000mg unit-dose sachets containing ranolazine ER granules

Dosing and Administration:

- Initial dose is 500mg orally twice daily; the dose may be increased to 1,000mg orally twice daily, as needed, based on clinical symptoms.
- The maximum recommended daily dose is 1,000mg twice daily.
- Directions for use with soft food (e.g., applesauce, yogurt):
  - Granules should be sprinkled on 1 tablespoonful of soft food and consumed immediately.
  - Granules should not be crushed or chewed.
- Aspruzyo Sprinkle™ may be administered via nasogastric (NG) tube or gastrostomy/gastric (G) tube. Please refer to the package labeling for administration instructions.

Other Formulation(s) Available:

- Ranolazine ER tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Aspruzyo Sprinkle™ (ranolazine ER 1,000mg granules)	**$8.30**	**$498.00**
ranolazine ER 1,000mg tablets (generic)	$0.33	$19.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the FDA approved maximum daily dose of 1000mg twice daily.
Unit = tablet or sachet
ER = extended-release

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.

Austedo® XR (Deutetrabenazine ER Tablet) Product Summary and Recommendations[8]

Therapeutic Class: Vesicular monoamine transporter 2 (VMAT2) inhibitor

Indication(s): Treatment of chorea associated with Huntington's disease and tardive dyskinesia (TD) in adults

How Supplied: 6mg, 12mg, and 24mg ER tablets

Dosing and Administration:

- The recommended starting dose is 12mg with or without food once daily.
- The dose may be titrated at weekly intervals by 6mg per day based on tolerability and the reduction of chorea or TD, up to a maximum recommended daily dose of 48mg.

Other Formulation(s) Available:

- Austedo® (deutetrabenazine tablet)

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*
Austedo® XR (deutetrabenazine 24mg ER) tablet	**$236.02**	**$14,161.20**
Austedo® (deutetrabenazine 12mg) tablet	$113.24	$13,588.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the FDA approved maximum daily dose of 48mg/day.
ER = extended-release

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

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

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

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

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

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

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

Entadfi® (Finasteride/Tadalafil Capsule) Product Summary and Recommendations[9]

Therapeutic Class: Combination of a 5α-reductase inhibitor (finasteride) and a phosphodiesterase 5 (PDE5) inhibitor (tadalafil)

Indication(s): To initiate treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks

- Limitation(s) of Use: Entadfi® is not recommended for more than 26 weeks because the incremental benefit of tadalafil decreased from 4 weeks until 26 weeks, and the incremental benefit beyond 26 weeks is unknown.

How Supplied: Fixed-dose combination of 5/5mg finasteride/tadalafil oral capsules

Dosing and Administration: One capsule orally once daily taken without food at approximately the same time every day for up to 26 weeks

Other Formulation(s) Available:

- Finasteride 5mg tablet and tadalafil 5mg tablet

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*
Entadfi® (finasteride/tadalafil 5/5mg capsule)	**$3.17**	**$95.10**
tadalafil 5mg tablet (generic)	$0.15	$4.50
finasteride 5mg tablet (generic)	$0.06	$1.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the FDA approved once daily dosing.

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

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

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

Ermeza™ (Levothyroxine Oral Solution) Product Summary and Recommendations[10,11,12,13]

Therapeutic Class: Levothyroxine sodium (T4)

Indication(s): Hypothyroidism and pituitary thyrotropin suppression

- Limitation(s) of Use: Ermeza™ is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients nor is it indicated for the treatment of hypothyroidism during the recovery phase of subacute thyroiditis.

How Supplied: 150mcg/5mL (30mcg/mL) oral solution in 75mL or 150mL bottles; the bottle must be used within 90 days of opening

Dosing and Administration: The starting dose will depend on a variety of factors (e.g., age, body weight, cardiovascular status, concomitant medication).

- Administer once daily on an empty stomach, 30 minutes to 1 hour before breakfast.

- Administer at least 4 hours before or after medications that are known to interfere with absorption.
- Administer using the appropriate syringe provided in the original carton. The 5mL syringe should be used for doses up to 5mL. The 10mL syringe should be used for doses >5mL.

Other Formulation(s) Available:

- Levothyroxine tablets, Thyquidity™ (levothyroxine oral solution), and Tirosint®-SOL (levothyroxine oral solution)

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Ermeza™ 150mcg/5mL (levothyroxine oral solution)	**$1.72**	**$86.17**
Tirosint®-SOL 50mcg/mL (levothyroxine oral solution)	$4.44+	$133.20
Thyquidity™ 100mcg/5mL (levothyroxine oral solution)	$1.20	$90.00
levothyroxine 50mcg tablet (generic)	$0.08	$2.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per 30 days based on a dose of 50mcg daily. Cost for Ermeza™, Thyquidity™, and levothyroxine tablets will vary based on dose required.
+Cost per mL is the same for all strengths of Tirosint®-SOL.

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.

Furoscix® (Furosemide On-Body Infusor) Product Summary and Recommendations[14,15,16]

Therapeutic Class: Loop diuretic

Indication(s): Treatment of congestion due to fluid overload in adults with New York Heart Association (NYHA) Class II-III chronic heart failure

- Limitation(s) of Use: Furoscix® is not indicated for emergency situations or in patients with acute pulmonary edema. The on-body infusor will only deliver an 80mg dose of furosemide.

How Supplied: 80mg/10mL injection in a single-dose prefilled cartridge co-packaged with a single-use, on-body infusor

Dosing and Administration: The single-use, on-body infusor is pre-programmed to deliver 30mg of furosemide over the first hour then 12.5mg per hour for the subsequent 4 hours.

- Furoscix® is not for chronic use and should be replaced with oral diuretics as soon as practical.
- Furoscix® is intended for use in a setting where the patient can limit their activity for the duration of administration.

Other Formulation(s) Available:

- Furosemide tablets and furosemide injection

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Incident*
Furoscix® (furosemide 80mg on-body infusor)	**$822.00**	**$6,576.00**
furosemide 10mg/mL injection (generic)	$0.34	$21.76
furosemide 80mg tablet (generic)	$0.05	$0.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = package or mL
*Cost per incident is based on 80mg twice daily for 4 days; however, please note that therapy is individualized according to the patient response.

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.

Iyuzeh™ (Latanoprost Ophthalmic Solution) Product Summary and Recommendations[17,18,19]

Therapeutic Class: Prostaglandin F2α analogue
Indication(s): Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension

How Supplied: Latanoprost 0.005% (50mcg/mL) ophthalmic solution

Dosing and Administration: One drop in the affected eye(s) once daily in the evening

Other Formulation(s) Available:

- Xalatan® 0.005% (latanoprost ophthalmic solution) and Xelpros® 0.005% (latanoprost ophthalmic emulsion)

Formulation Cost Comparison:

Product	Cost Per mL	Cost Per 25 Days*
Xelpros® 0.005% (latanoprost ophthalmic emulsion)	$24.00	$60.00
latanoprost 0.005% ophthalmic solution (generic)	$1.81	$4.53

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Cost information for Iyuzeh™ is currently not available.
*Cost per 25 days based on the FDA approved dose of 1 drop in affected eye(s) once daily, assuming both eyes are affected.

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.

Jylamvo® (Methotrexate Oral Solution) Product Summary and Recommendations[20,21,22,23,24]

Therapeutic Class: Folate analog metabolic inhibitor

Indication(s): Treatment of adults with 1 of the following:

- Acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen
- Mycosis fungoides
- Relapsed or refractory non-Hodgkin lymphoma as part of a metronomic combination regimen
- Rheumatoid arthritis
- Severe psoriasis

How Supplied: 2mg/mL oral solution

Dosing and Administration:

- The recommended dosing is based on diagnosis:
  - ALL: 20mg/m^2 orally once weekly as a part of a combination chemotherapy maintenance regimen
  - Mycosis Fungoides: 25mg to 75mg orally once weekly as monotherapy; 10mg/m^2 orally twice weekly as part of combination chemotherapy
  - Relapsed or Refractory Non-Hodgkin Lymphoma: 2.5mg orally 2 to 4 times per week as part of metronomic combination chemotherapy
  - Rheumatoid Arthritis: 7.5mg orally once weekly; adjust dose to achieve an optimal response
  - Psoriasis: 10mg to 25mg orally once weekly until adequate response is achieved

Other Formulation(s) Available:

- Methotrexate tablet, methotrexate injection, Trexall® tablet, and Xatmep® (methotrexate oral solution)

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days*
Xatmep® 2.5mg/mL (methotrexate oral solution)	$17.38	$208.56
Trexall® (methotrexate tablet) 7.5mg	$28.91	$115.64
methotrexate injection solution 25mg/mL (generic)	$1.93	$15.44⁺
methotrexate tablet 2.5mg (generic)	$0.22	$2.64

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = tablet or mL
Cost information for Jylamvo® is currently not available.
*Cost per 28 days based on weekly dosing of 7.5mg for each product.
⁺Cost per 28 days of methotrexate injection solution based on use of a 2mL single-use vial for each weekly dose.

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.

Primidone 125mg Tablet Product Summary and Recommendations[25]

Therapeutic Class: Anticonvulsant

Indication(s): As monotherapy or concomitantly with other anticonvulsants, in the control of grand mal, psychomotor, and focal epileptic seizures; primidone may control grand mal seizures refractory to other anticonvulsant therapy

Dosing and Administration:

- Usual Dosage:
  - Patients 8 years of age and older who have received no previous treatment may be started on primidone tablets according to the following regimen using either 50mg or scored 250mg primidone tablets:
    - Days 1 to 3: 100mg to 125mg at bedtime
    - Days 4 to 6: 100mg to 125mg twice a day
    - Days 7 to 9: 100mg to 125mg 3 times a day
    - Day 10 to maintenance: 250mg 3 times a day
  - For most adults and children 8 years of age and over, the usual maintenance dose is 250mg 3 or 4 times a day. The dose may be increased if required, but the maximum daily dose should not exceed 2,000mg/day.
  - Dosage should be individualized to provide maximum benefit.
- Patients Already Receiving Other Anticonvulsants:
  - Primidone tablets should be started at 100mg to 125mg at bedtime and gradually increased to maintenance level as the other drug is gradually decreased.

- This regimen should be continued until a satisfactory dosage level is achieved for the combination, or the other medication is completely withdrawn.
- When monotherapy with primidone tablets is the objective, the transition from concomitant therapy should not be completed in less than 2 weeks.

- Pediatric Dosage:
  - For children younger than 8 years of age, the following regimen may be used:
    - Days 1 to 3: 50mg at bedtime
    - Days 4 to 6: 50mg twice a day
    - Days 7 to 9: 100mg twice a day
    - Day 10 to maintenance: 125mg to 250mg 3 times a day
  - For children younger than 8 years of age, the usual maintenance dosage is 125mg to 250mg 3 times daily or 10 to 25mg/kg/day in divided doses.

Other Formulation(s) Available:

- Primidone 50mg tablet and 250mg tablet

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*
primidone 125mg tablet (generic)	**$1.49**	**$134.10**
primidone 250mg tablet (generic)	$0.27	$12.15

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the dosing regimen of 125mg 3 times per day.

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.

Verkazia® (Cyclosporine Ophthalmic Emulsion) Product Summary and Recommendations[26,27]

Therapeutic Class: Calcineurin inhibitor immunosuppressant

Indication(s): Treatment of vernal keratoconjunctivitis (VKC) in children and adults

How Supplied: cyclosporine 0.1% (1mg/mL) ophthalmic emulsion in single-use vials

Dosing and Administration: Instill 1 drop of Verkazia®, 4 times daily (QID; morning, noon, afternoon, and evening) in each affected eye.

Other Formulation(s) Available:

- Cyclosporine 0.05% ophthalmic emulsion

Formulation Cost Comparison:

Product	Cost Per Vial	Cost Per 30 Days
Verkazia® (cyclosporine 0.1% ophthalmic emulsion)	**$12.21**	**$1,465.20**
cyclosporine 0.05% ophthalmic emulsion (generic)	$3.27	$392.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on the use of 1 single-use vial 4 times daily.

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.

Xaciato™ (Clindamycin Vaginal Gel) Product Summary and Recommendations[28,29,30,31]

Therapeutic Class: Lincosamide antibacterial

Indication(s): Treatment of bacterial vaginosis in female patients 12 years of age and older

How Supplied: Clindamycin 2% vaginal gel in an 8g tube. One single-dose, user-filled disposable applicator delivers 5g of gel containing 100mg of clindamycin.

Dosing and Administration:

- Administer 1 applicatorful (5g of gel containing 100mg of clindamycin) once intravaginally as a single dose at any time of the day.
- Not for ophthalmic, dermal, or oral use.

Other Formulation(s) Available:

- Clindamycin 2% vaginal cream, Clindesse® (clindamycin phosphate 2% vaginal cream), and Cleocin® Vaginal Ovules (clindamycin phosphate 2.5g vaginal suppositories)

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment*
Xaciato™ (clindamycin 2% vaginal gel)	**$18.75**	**$150.00**
Cleocin® (clindamycin phosphate 2.5g vaginal suppositories)	$58.94	$176.82
Clindesse® (clindamycin phosphate 2% vaginal cream)	$26.96	$134.80
clindamycin 2% vaginal cream (generic)	$1.62	$64.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = gram or suppository
*Cost per treatment is based on the total package size for each product as 1 package will be dispensed for each treatment course: 8g tube for Xaciato™, 3 suppositories for Cleocin®, 5g tube for Clindesse®, and 40g tube for clindamycin 2% vaginal cream.

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.

Zolpidem Tartrate 7.5mg Capsule Product Summary and Recommendations[32,33]

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

Indication(s): Short-term treatment of transient insomnia characterized by difficulties with sleep initiation in adults younger than 65 years of age

How Supplied: 7.5mg capsule

Dosing and Administration:

- The lowest effective zolpidem tartrate dosage should be used.
  - The recommended starting dose of zolpidem tartrate immediate-release (IR) in females is 5mg once nightly. Another zolpidem tartrate IR product should be used for dosage initiation in females.
  - The recommended starting dose of zolpidem tartrate IR in males is either 5mg, 7.5mg, or 10mg once nightly.
  - In both males and females, if a 5mg once nightly dose is not effective, the dosage may be increased to 7.5mg once nightly or 10mg once nightly.
  - The maximum recommended dose of zolpidem tartrate IR is 10mg once nightly.
  - Zolpidem tartrate 7.5mg capsules are not indicated in geriatric patients (patients older than 65 years of age). Use of zolpidem tartrate 7.5mg capsules should be avoided in geriatric patients because the recommended dose (5mg once nightly) in these patients cannot be achieved with the 7.5mg strength. Another zolpidem tartrate product should be used to achieve the dose for geriatric patients.
  - Zolpidem tartrate 7.5mg capsules should be avoided in patients with mild or moderate hepatic impairment because the recommended dosage (5mg once nightly) in such patients cannot be achieved with the 7.5mg strength.
  - Any zolpidem tartrate use should be avoided in patients with severe hepatic impairment because its use may contribute to encephalopathy.

Other Formulation(s) Available:

- Zolpidem tartrate 5mg and 10mg tablet

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
zolpidem tartrate 7.5mg capsule (generic)	**$8.33**	**$249.90**
zolpidem tartrate 5mg tablet (generic)	$0.03	$0.90
zolpidem tartrate 10mg tablet (generic)	$0.03	$0.90

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = capsule or tablet
*Cost per 30 days is based on the FDA approved once nightly dose.

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

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Appendix G

Vote to Prior Authorize Daybue™ (Trofinetide)

Oklahoma Health Care Authority
July 2023

Market News and Updates[1]

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

- **March 2023:** The FDA approved Daybue™ (trofinetide) for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older. Daybue™ is the first and only FDA approved medication for this indication.

Daybue™ (Trofinetide) Product Summary[2]

Therapeutic Class: Glycine-proline-glutamate analog

Indication(s): Treatment of Rett syndrome in adults and pediatric patients 2 years of age and older

How Supplied: 200mg/mL oral solution in a 450mL bottle

Dosing and Administration: Recommended dosing regimen is twice daily, with or without food, administered orally or via gastrostomy (G) tube, according to patient weight:

Patient Weight	Dosage	Volume
9kg to <12kg	5,000mg twice daily	25mL twice daily
12kg to <20kg	6,000mg twice daily	30mL twice daily
20kg to <35kg	8,000mg twice daily	40mL twice daily
35kg to <50kg	10,000mg twice daily	50mL twice daily
≥50kg	12,000mg twice daily	60mL twice daily

Cost: The Wholesale Acquisition Cost (WAC) of Daybue™ is $21.10 per milliliter or $9,495 per bottle. This results in an estimated cost of $75,960 per 30 days or $911,520 per year based on the recommended dose for a member weighing ≥50kg.

Recommendations

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

Daybue™ (Trofinetide) Approval Criteria:

1. Diagnosis of typical Rett syndrome confirmed by all of the following:
   a. Prescriber must verify all clinical diagnostic criteria are met supporting a diagnosis of typical Rett syndrome including:

i. A period of regression followed by recovery or stabilization; and
ii. Partial or complete loss of acquired purposeful hand skills; and
iii. Partial or complete loss of acquired spoken language; and
iv. Gait abnormalities (impaired/dyspraxic or absence of ability); and
v. Stereotypic hand movements (e.g., hand wringing/squeezing, clapping/tapping, mouthing, washing/rubbing automatisms); and
vi. Lack of brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection causing neurological problems; and
vii. Lack of grossly abnormal psychomotor development in the first 6 months of life; and

b. Genetic testing documenting a disease-causing mutation in the *MECP2* gene (results of genetic testing must be submitted); and

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

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Appendix H

Vote to Prior Authorize Joenja® (Leniolisib)

Oklahoma Health Care Authority
July 2023

Market News and Updates[1]

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

- **March 2023:** The FDA approved Joenja® (leniolisib) for the treatment of activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS) in adults and pediatric patients 12 years of age and older. This is the first therapy to be FDA approved specifically for APDS.

Joenja® (Leniolisib) Product Summary[2]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of APDS in adult and pediatric patients 12 years of age and older weighing ≥45kg

How Supplied: 70mg oral tablets

Dosing and Administration:

- The recommended dosage is 70mg orally twice daily.
- Pregnancy status should be verified prior to initiating treatment in females of reproductive potential, as leniolisib may cause fetal harm.

Cost: The Wholesale Acquisition Cost (WAC) of Joenja® is $750 per tablet. This results in an estimated cost of $45,000 per month and $540,000 per year based on the recommended dose of 70mg twice daily.

Recommendations

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

Joenja® (Leniolisib) Approval Criteria:

1. An FDA approved diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS). Diagnosis must be confirmed by 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.

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[1] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for Activated Phosphoinositide 3-Kinase Delta Syndrome. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-treatment-activated-phosphoinositide-3-kinase-delta-syndrome. Issued 03/24/2023. Last accessed 06/21/2023.

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Appendix I

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

Oklahoma Health Care Authority
July 2023

Market News and Updates[1,2]

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

- **December 2021:** Saol Therapeutics announced the FDA approval of Lyvispah™ (baclofen oral granules). Lyvispah™ was commercially launched in June 2022 by Amneal Pharmaceuticals.

News:

- **April 2023:** Galt Pharmaceuticals, the current manufacturer of Norgesic®, Norgesic Forte®, and Orphengesic Forte® (orphenadrine/aspirin/caffeine), began participating in the federal Medicaid Drug Rebate Program (MDRP) in April 2023. Orphengesic Forte® was approved by the FDA in 1998 for the treatment of mild to moderate pain associated with musculoskeletal disorders.

Lyvispah™ (Baclofen Oral Granules) Product Summary[3]

Therapeutic Class: Gamma-aminobutyric acid agonist

Indication(s): Treatment of spasticity resulting from multiple sclerosis or spinal cord injuries or diseases, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity

How Supplied: 5mg, 10mg, and 20mg packets of oral granules

Dosing:

- Should be initiated with a low dose, taken orally, preferably in divided doses, increasing gradually based on clinical response and tolerability
- The maximum dose is 80mg daily (20mg 4 times daily).
- The dose may be taken with or without water.
- The oral granules can be mixed with soft food for administration within 2 hours.
- The oral granules can be administered via enteral feeding tube.
- When discontinuing, the dose should be reduced slowly.

Cost Comparison:

Product	Cost Per Unit†	Cost Per Month*
Lyvispah™ (baclofen oral granules) 20mg packet	**$3.28**	**$393.60**
Fleqsuvy™ (baclofen oral suspension) 25mg/5mL	$6.05	$2,904.00
baclofen oral solution 5mg/5mL (generic)	$1.09	$2,616.00
baclofen 20mg oral tablet (generic)	$0.09	$10.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
†Unit = mL, packet, or tablet
*Cost per month is based on a maximum FDA approved dose of 80mg daily for 30 days.

Norgesic®, Norgesic® Forte, and Orphengesic® Forte (Orphenadrine/Aspirin/Caffeine) Product Summary[4,5]

Therapeutic Class: Centrally acting musculoskeletal relaxant

Indication(s): Treatment of mild to moderate pain of acute musculoskeletal disorders as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with painful musculoskeletal conditions

How Supplied:
- Norgesic®: 25/385/30mg orphenadrine/aspirin/caffeine oral tablets
- Norgesic® Forte/Orphengesic® Forte: 50/770/60mg caffeine orphenadrine/aspirin/caffeine oral tablets

Dosing:
- Norgesic®: 1 to 2 tablets 3 to 4 times daily
- Norgesic® Forte/Orphengesic® Forte: 0.5 to 1 tablet 3 to 4 times daily

Cost Comparison: Orphenadrine Products

Product	Cost Per Tablet	Cost Per Day*
orphenadrine/ASA/caffeine 25/385/30mg tab (generic)	**$16.25**	**$130.00**
orphenadrine/ASA/caffeine 50/770/60mg tab (generic)	**$10.65**	**$42.60**
orphenadrine citrate ER 100mg tab (generic)	$0.35	$0.70

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per day is based on the maximum FDA approved dose for each product: 2 tablets 4 times daily for Norgesic®; 1 tablet 4 times daily for Norgesic® Forte and Orphengesic® Forte; 1 tablet twice daily for generic orphenadrine citrate.
ASA = aspirin; ER = extended-release; tab = tablet

Recommendations

The College of Pharmacy recommends the prior authorization of Lyvispah™ (baclofen oral granules) and Norgesic®, Norgesic® Forte, and Orphengesic® Forte (orphenadrine/aspirin/caffeine) and placement into the Special PA Tier

of the Muscle Relaxant Medications Product Based Prior Authorization (PBPA) category with the following additional criteria (changes and new criteria shown in red):

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

1. An FDA approved diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and
2. Requests for Fleqsuvy® and Ozobax® will require a patient-specific, clinically significant reason why 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.

[1] Saol Therapeutics, Inc. Saol Therapeutics Announces FDA Approval of Lyvispah™ (Baclofen) Oral Granules and the Divesture of its Plasma-derived Hyperimmune Portfolio. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/saol-therapeutics-announces-fda-approval-of-lyvispah-baclofen-oral-granules-and-the-divesture-of-its-plasma-derived-hyperimmune-portfolio-301439556.html. Issued 12/07/2021. Last accessed 06/26/2023.

[2] Amneal Pharmaceuticals, Inc. Amneal Launches Lyvispah® (Baclofen) for Spasticity Related to Multiple Sclerosis and Other Spinal Cord Disorders. Available online at: https://investors.amneal.com/news/press-releases/press-release-details/2022/Amneal-Launches-LYVISPAH-baclofen-for-Spasticity-Related-to-Multiple-Sclerosis-and-Other-Spinal-Cord-Disorders/default.aspx. Issued 06/01/2022. Last accessed 06/26/2023.

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[4] Norgesic®, Norgesic Forte® (Orphenadrine/Aspirin/Caffeine) Prescribing Information. Bausch Health US, LLC. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/013416s030lbl.pdf. Last revised 04/2021. Last accessed 06/26/2023.

[5] Orphengesic® Forte (Orphenadrine/Aspirin/Caffeine) Prescribing Information. Galt Pharmaceuticals, Inc. Available online at: https://orphengesicforte.com/assets/documents/Orphengesic-Forte-500523-2021-04-05-clean.pdf. Last revised 04/2021. Last accessed 06/26/2023.

Appendix J

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

Oklahoma Health Care Authority
July 2023

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

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

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

News:

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

Adstiladrin® (Nadofaragene Firadenovec-vncg) Product Summary[14]

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

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

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

Dosing and Administration:

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

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

Elahere™ (Mirvetuximab Soravtansine-gynx) Product Summary[15]

Therapeutic Class: FRα-directed antibody and microtubule inhibitor conjugate

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

How Supplied: 100mg/20mL (5mg/mL) solution in a single-dose vial (SDV)

Dose: 6mg/kg [based on adjusted ideal body weight (AIBW)] once every 3 weeks by IV infusion until disease progression or unacceptable toxicity

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

Recommendations

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

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

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

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

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

Next, the College of Pharmacy recommends updating the approval criteria for Lenvima® (lenvatinib), Lynparza® (olaparib), Nubeqa® (darolutamide), and Padcev® (enfortumab vedotin-ejfv) 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.

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Appendix K

Calendar Year 2022 Annual Review of Colorectal Cancer Medications

Oklahoma Health Care Authority
July 2023

Current Prior Authorization Criteria

Utilization data for Braftovi® (encorafenib), Keytruda® (pembrolizumab), Opdivo® (nivolumab), and Yervoy® (ipilimumab) and approval criteria for indications other than colorectal cancer can be found in the December 2022 Drug Utilization Review (DUR) packet. These medications and criteria are reviewed annually with the skin cancer medications. Utilization data for Cyramza® (ramucirumab) and approval criteria for indications other than colorectal cancer can be found in the April 2023 DUR packet. This medication and criteria are reviewed annually with the lung cancer medications. Utilization data for Enhertu® (fam-trastuzumab deruxtecan-nxki), Herceptin® (trastuzumab), Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), Ogivri® (trastuzumab-dkst), Ontruzant® (trastuzumab-dttb), Perjeta® (pertuzumab), and Trazimera® (trastuzumab-qyyp) and approval criteria for indications other than colorectal cancer can be found in the September 2022 DUR packet. These medications and criteria are reviewed annually with the breast cancer medications.

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

1. A patient-specific, clinically significant reason why the member cannot use Avastin® (bevacizumab) 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.

Braftovi® (Encorafenib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of advanced or metastatic CRC; and
2. BRAF V600E mutation positive; and
3. Used in combination with cetuximab or panitumumab; and
    a. Disease must have progressed following adjuvant therapy within 12 months; or
    b. Used following progression of any line of metastatic therapy.

Cyramza® (Ramucirumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of CRC; and
2. Subsequent therapy for metastatic disease after progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine; and
3. Used in combination with an irinotecan-based regimen.

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.

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, member 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 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 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.

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

1. Diagnosis of unresectable or metastatic CRC; and
2. Metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

Lonsurf® (Trifluridine/Tipiracil) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of metastatic, recurrent, or unresectable CRC; and
2. Previously treated with a fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
3. Previously treated with an anti-vascular endothelial growth factor (VEGF) therapy; and
    a. If RAS wild-type disease, previously treated with an anti-epidermal growth factor receptor (EGFR) therapy; and
4. Used as monotherapy or in combination with bevacizumab.

Lonsurf® (Trifluridine/Tipiracil) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of metastatic gastric or GEJ adenocarcinoma; and
2. Previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, paclitaxel, docetaxel, or irinotecan; and
3. If human epidermal receptor type 2 (HER2)-positive disease, prior treatment should have included HER2 targeted therapy.

Opdivo® (Nivolumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Tumor is microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR).

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, member should not be a candidate for intensive therapy; or
    b. For the treatment of advanced or metastatic disease following disease progression.

Stivarga® (Regorafenib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of metastatic, recurrent, or unresectable CRC; and
2. Previous treatment with a fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
3. Previous treatment with an anti-vascular endothelial growth factor (VEGF) therapy; and

a. If RAS wild-type disease, previously treated with an anti-epidermal growth factor receptor (EGFR) therapy.

Stivarga® (Regorafenib) Approval Criteria [Gastrointestinal Stromal Tumor (GIST) Diagnosis]:

1. Diagnosis of locally advanced unresectable or metastatic GIST; and
2. Previously treated with imatinib and sunitinib.

Stivarga® (Regorafenib) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of HCC; and
2. Previous treatment with sorafenib.

Yervoy® (Ipilimumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and
3. Used in combination with nivolumab.

Utilization of Colorectal Cancer Medications: Calendar Year 2022

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

Calendar Year Comparison: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	7	17	$190,620.11	$11,212.95	$407.31	876	468
2022	15	40	$621,974.72	$15,549.37	$555.33	2,634	1,120
% Change	**114.30%**	**135.30%**	**226.30%**	**38.70%**	**36.30%**	**200.70%**	**139.30%**
Change	**8**	**23**	**$431,354.61**	**$4,336.42**	**$148.02**	**1,758**	**652**

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

Calendar Year Comparison: Medical Claims

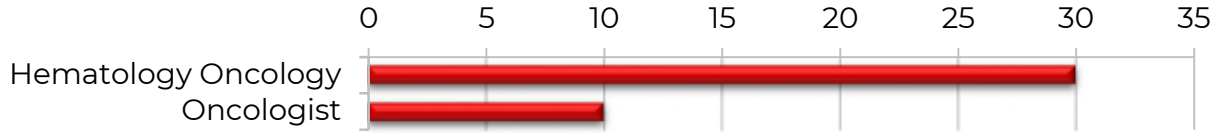
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	551	1,835	$2,377,801.29	$1,295.80	3.33
2022	899	3,155	$2,954,291.43	$936.38	3.51
% Change	**63.16%**	**71.93%**	**24.24%**	**-27.74%**	**5.38%**
Change	**348**	**1,320**	**$576,490.14**	**-$359.42**	**0.18**

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

Demographics of Members Utilizing Colorectal Cancer Medications: Pharmacy Claims

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

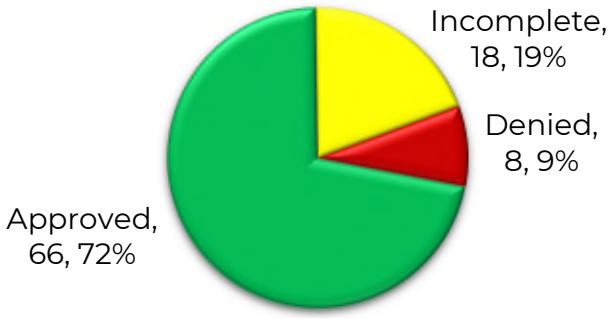
Top Prescriber Specialties of Colorectal Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Colorectal Cancer Medications

There were 92 prior authorization requests submitted for colorectal cancer medications during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



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

Anticipated Patent Expirations

- Stivarga® (regorafenib): July 2032
- Lonsurf® (trifluridine/tipiracil): February 2037

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

- **September 2022:** The FDA approved Vegzelma® (bevacizumab-adcd), a biosimilar for Avastin® (bevacizumab), for the treatment of metastatic colorectal cancer (mCRC); recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC); recurrent glioblastoma; metastatic renal cell carcinoma; persistent, recurrent, or metastatic cervical cancer; and epithelial ovarian, fallopian tube, or primary peritoneal cancer. Vegzelma® contains bevacizumab, which is a vascular endothelial

growth factor (VEGF) inhibitor. Vegzelma® is not indicated for adjuvant treatment of colon cancer.

Guideline Update(s):

- Based on high-level evidence, the National Comprehensive Cancer Network (NCCN) panel recommended updating the bone cancer guidelines to include Stivarga® (regorafenib) as a category 1 recommendation for the treatment of relapsed/refractory osteosarcoma.

Recommendations

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 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.

Utilization Details of Colorectal Cancer Medications: Calendar Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
REGORAFENIB PRODUCTS						
STIVARGA TAB 40MG	23	10	$377,402.99	$16,408.83	2.3	60.68%
SUBTOTAL	**23**	**10**	**$377,402.99**	**$16,408.83**	**2.3**	**60.68%**
TRIFLURIDINE/TIPIRACIL PRODUCTS						
LONSURF TAB 20/8.19MG	11	5	$165,541.41	$15,049.22	2.2	26.62%
LONSURF TAB 15/6.14MG	6	2	$79,030.32	$13,171.72	3	12.71%
SUBTOTAL	**17**	**7**	**$244,571.73**	**$14,386.57**	**2.43**	**39.32%**
TOTAL	**40**	**15***	**$621,974.72**	**$15,549.37**	**2.67**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BEVACIZUMAB J9035	2,611	814	$2,232,655.26	$855.10	3.21
BEVACIZUMAB-AWWB Q5107	439	69	$555,648.33	$1,265.71	6.36
BEVACIZUMAB-BVZR Q5118	105	33	$165,987.84	$1,580.84	3.18
TOTAL	**3,155**	**899**	**$2,954,291.43**	**$936.38**	**3.51**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 06/2023. Last accessed 06/19/2023.
[2] Celltrion USA. Celltrion USA Receives U.S. FDA Approval for Its Oncology Biosimilar Vegzelma® (Bevacizumab-adcd) for the Treatment of Six Types of Cancer. Available online at: https://www.celltrionhealthcare.com/board/en_newslist/95. Issued 09/28/2022. Last accessed 06/21/2023.
[3] Vegzelma® (Bevacizumab-adcd) Prescribing Information. Celltrion. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761268Orig1s000CorrectedIbl.pdf. Last revised 09/2022. Last accessed 06/21/2023.
[4] National Comprehensive Cancer Network (NCCN). NCCN Guidelines: Bone Cancer. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Last revised 04/04/2023. Last accessed 06/26/2023.
[5] Davis LE, Bolejack V, Ryan CW, et al. Randomized Double-Blind Phase II Study of Regorafenib in Patients with Metastatic Osteosarcoma. *J Clin Oncol* 2019; 37:1424-1431. doi: 10.1200/JCO.18.02374

Appendix L

Calendar Year 2022 Annual Review of Allergen Immunotherapies

Oklahoma Health Care Authority
July 2023

Current Prior Authorization Criteria

Grastek® (Timothy Grass Pollen Allergen Extract) Approval Criteria:

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test (labs required) or *in vitro* testing for pollen specific immunoglobulin E (IgE) antibodies for Timothy grass or cross-reactive grass pollen (cool season grasses); 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 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 the grass pollen season (November 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).

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

1. Member must be 18 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.

Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract) Approval Criteria:

1. Member must be 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 1 of the 5 grass pollens contained in Oralair®; 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 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 ≥16 weeks prior to the start of the grass pollen season (October 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 16 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).

Palforzia® (Peanut Allergen Powder-dnfp) Approval Criteria:

1. Member must be 4 to 17 years of age to initiate initial dose escalation (maintenance dosing may be continued for members 4 years of age and older); and
2. Member must have a diagnosis of peanut allergy confirmed by a positive skin test, positive *in vitro* test for peanut-specific immunoglobulin E (IgE), or positive clinician-supervised oral food challenge; and
3. Prescriber must confirm member will use Palforzia® with a peanut-avoidant diet; and
4. Member must not have severe uncontrolled asthma; and
5. Member must not have a history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and
6. Member must not have had severe or life-threatening anaphylaxis within the previous 60 days; and
7. Member or caregiver must be trained in the use of an auto-injectable epinephrine device and have such a device available for immediate use at all times; and
8. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and

9. Prescriber, health care setting, and pharmacy must be certified in the Palforzia® Risk Evaluation and Mitigation Strategy (REMS) program; and
10. Member must be enrolled in the Palforzia® REMS program; and
11. Palforzia must be administered under the direct observation of a health care provider in a REMS certified health care setting with observation duration in accordance with the prescribing information; and
12. After successful completion of initial dose escalation and all levels of up-dosing as documented by the prescriber, initial approvals of maintenance dosing will be for 6 months. For continued approval, member must be compliant, and prescriber must verify member is responding well to treatment.

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

1. Member must be 18 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).

Utilization of Allergen Immunotherapies: Calendar Year 2022

Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	1	2	$898.08	$449.04	$14.97	60	60
2022	1	4	$1,796.16	$449.04	$14.97	120	120
% Change	**0.0%**	**100.0%**	**100.0%**	**0.0%**	**0.0%**	**100.0%**	**100.0%**
Change	**0**	**2**	**$898.08**	**$0.00**	**$0.00**	**60**	**60**

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

Demographics of Members Utilizing Allergen Immunotherapies

- Due to the limited number of members utilizing allergen immunotherapies during calendar year 2022, detailed demographic information could not be provided.

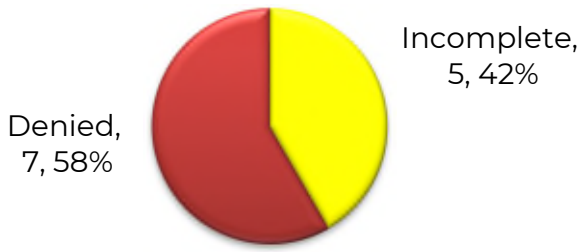
Top Prescriber Specialties of Allergen Immunotherapies by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for allergen immunotherapies during calendar year 2022 was allergist.

Prior Authorization of Allergen Immunotherapies

There were 12 prior authorization requests submitted for 6 unique members for allergen immunotherapies during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



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

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

- **April 2021:** The FDA approved an age expansion for Ragwitek® (short ragweed pollen allergen extract) down to 5 years of age. The initial FDA approval of Ragwitek® in 2014 included patients 18 to 65 years of age.

- **January 2023:** The FDA approved an age expansion for Odactra® (house dust mite allergen extract) down to 12 years of age. The initial FDA approval of Odactra® in 2017 was for patients 18 to 65 years of age.

News:

- **July 2023:** ALK-Abello, Inc., the current manufacturer of Grastek® (Timothy grass pollen allergen extract), Odactra®, and Ragwitek®, began participating in the federal Medicaid Drug Rebate Program (MDRP) in July 2023.

Pipeline:

- **Viaskin™ Peanut:** DBV Technologies' peanut protein topical patches have gone through Phase 3 clinical trials and show some promise in alternative treatment options for children with food allergies to peanuts. The trial included children down to 4 years of age.
- **Viaskin™ Milk:** Cow's milk allergy is also being investigated by DBV Technologies. Eosinophilic esophagitis (EoE) is thought to be connected to cow's milk allergy which is also going through Phase 2 clinical trials along with the Viaskin™ Milk cow milk allergy patch trials.
- **REGN5713-5714-5715:** Regeneron Pharmaceuticals' birch tree pollen allergen anti-Bet v 1 monoclonal antibodies given subcutaneously or intravenously as a single dose is currently in Phase 3 clinical trials looking into the effectiveness over time.

Recommendations

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).

Utilization Details of Allergen Immunotherapies: Calendar Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ORALAIR SUB 300 IR TAB	4	1	$1,796.16	$449.04	4	100%
TOTAL	**4**	**1***	**$1,796.16**	**$449.04**	**4**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
IR = index of reactivity; SUB = sublingual; TAB = tablet

[1] ALK, Inc. U.S. FDA Approves ALK’s Ragwitek® (Short Ragweed Pollen Allergen Extract) Tablet for Sublingual Use as Immunotherapy for Children and Adolescents with Short Ragweed Pollen-Induced Allergic Rhinitis With or Without Conjunctivitis. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/us-fda-approves-alks-ragwitek-short-ragweed-pollen-allergen-extract-tablet-for-sublingual-use-as-immunotherapy-for-children-and-adolescents-with-short-ragweed-pollen-induced-allergic-rhinitis-with-or-without-conjunctivitis-301270945.html. Issued 04/19/2021. Last accessed 06/26/2023.
[2] ALK, Inc. U.S. FDA Approves ALK’s Odactra® (House Dust Mite Allergen Extract) Tablet for Sublingual Use as Immunotherapy for Adolescents. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/us-fda-approves-alks-odactra-house-dust-mite-allergen-extract-tablet-for-sublingual-use-as-immunotherapy-for-adolescents-301729972.html. Issued 01/25/2023. Last accessed 06/26/2023.
[3] Fleischer D, Greenhawt M, Sussman G, et al. Effect of Epicutaneous Immunotherapy vs Placebo on Reaction to Peanut Protein Ingestion Among Children with Peanut Allergy. The PEPITES Randomized Clinical Trial. *JAMA* 2019; 321(10):946-955. doi:10.1001/jama.2019.1113.
[4] DBV Technologies. Our Pipeline. Available online at: https://dbv-technologies.com/pipeline/. Last accessed 06/28/2023.
[5] DBV Technologies. Development Program: Viaskin™ Peanut. Available online at: https://dbv-technologies.com/pipeline/viaskin-peanut/. Last accessed 6/28/2023.
[6] DBV Technologies. DBV Technologies Announces Results from Phase II Study of Viaskin Milk in Milk Allergic Patients. Available online at: https://dbv-technologies.com/wp-content/uploads/ir/4511-pr-miles-final_eng-pdf.pdf. Issued 02/26/2018. Last accessed 06/21/2023.
[7] DBV Technologies. Development Program: Viaskin™ Milk. Available online at: https://dbv-technologies.com/pipeline/viaskin-milk/. Last accessed 6/28/2023.
[8] Regeneron Pharmaceuticals. Investigational Pipeline. Available online at: https://www.regeneron.com/pipeline-medicines/investigational-pipeline. Last accessed 6/28/2023
[9] Atanasio A, Franklin MC, Kamat V, et al. Targeting Immunodominant Bet v 1 Epitopes with Monoclonal Antibodies Prevents the Birch Allergic Response. *J Allergy Clin Immunol* 2022; 149(1):200-211. doi: 10.1016/j.jaci.2021.05.038.

Appendix M

Calendar Year 2022 Annual Review of Testosterone Products and 30-Day Notice to Prior Authorize Kyzatrex® (Testosterone Undecanoate)

Oklahoma Health Care Authority
July 2023

Current Prior Authorization Criteria

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% (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 2% pump (Fortesta®)	testosterone undecanoate oral cap (Jatenzo®, Tlando®)
	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

Initial Approval Criteria for All Testosterone Products:

1. An FDA approved diagnosis of 1 of the following:
    a. Testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchiectomy; or
    b. Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation; or
    c. Delayed puberty; or
    d. Advanced inoperable metastatic mammary cancer in females 1 to 5 years postmenopausal, or premenopausal females with breast

cancer benefitting from oophorectomy and have been determined to have a hormone-responsive tumor; and

2. The prescriber must verify the member has been evaluated for the presence of a pituitary tumor as the potential cause of low testosterone and the member will receive appropriate follow-up and/or treatment as necessary; and
3. Must include 2 labs showing pre-medication, morning testosterone (total testosterone) levels <300ng/dL; and
4. Must include 1 lab showing abnormal gonadotropins and/or other information necessary to demonstrate diagnosis; or
5. Testosterone and gonadotropin labs are not required for authorization of testosterone therapy if documentation is provided for established hypothalamic pituitary or gonadal disease, if the pituitary gland or testes has/have been removed, or for postmenopausal females with advanced inoperable metastatic mammary cancer or premenopausal females with breast cancer benefitting from oophorectomy and that have been determined to have a hormone-responsive tumor.

Testosterone Products Tier-2 Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. Member must have a trial of at least 2 Tier-1 products (must include at least 1 injectable and 1 topical formulation) at least 12 weeks in duration; or
3. A patient-specific, clinically significant reason why member cannot use all available Tier-1 products must be provided; or
4. Prior stabilization on a Tier-2 product (within the past 180 days); and
5. Approvals will be for the duration of 1 year; and
6. For Xyosted® [testosterone enanthate subcutaneous (sub-Q) auto-injector]:
    a. Member must be trained by a health care professional on sub-Q administration and storage of Xyosted® sub-Q auto-injector.

Testosterone Products Special Prior Authorization (PA) Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. A patient-specific, clinically significant reason why member cannot use all other available formulations of testosterone must be provided; and
3. Approvals will be for the duration of 1 year.

Utilization of Testosterone Products: Calendar Year 2022

Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	239	1,052	$103,658.16	$98.53	$2.81	15,704	36,880
2022	453	1,958	$226,594.46	$115.73	$3.36	31,422	67,491
% Change	**89.50%**	**86.10%**	**118.60%**	**17.50%**	**19.60%**	**100.10%**	**83.00%**
Change	**214**	**906**	**$122,936.30**	**$17.20**	**$0.55**	**15,718**	**30,611**

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

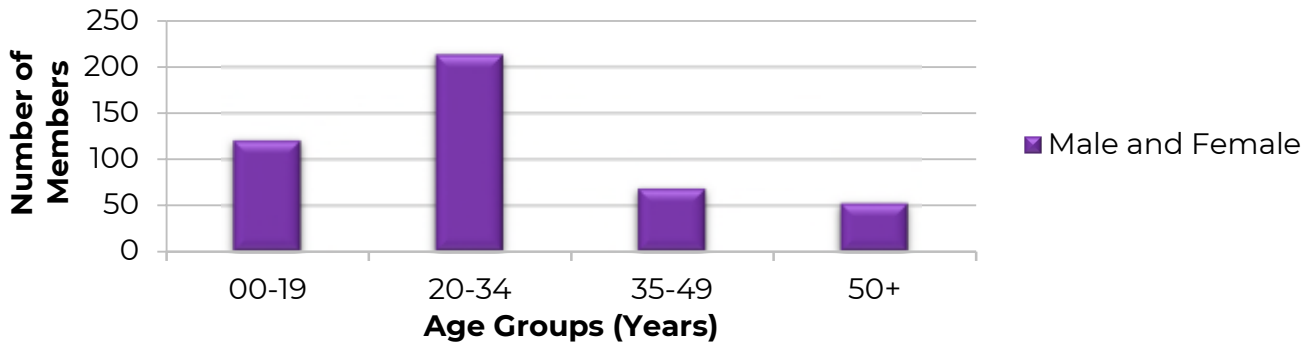
Comparison of Calendar Years: Medical Claims

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	15	32	$65.19	$2.04	2.13
2022	14	49	$172.74	$3.53	3.5
% Change	**-6.67%**	**53.13%**	**164.98%**	**72.81%**	**64.32%**
Change	**-1**	**17**	**$107.55**	**$1.49**	**1.37**

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

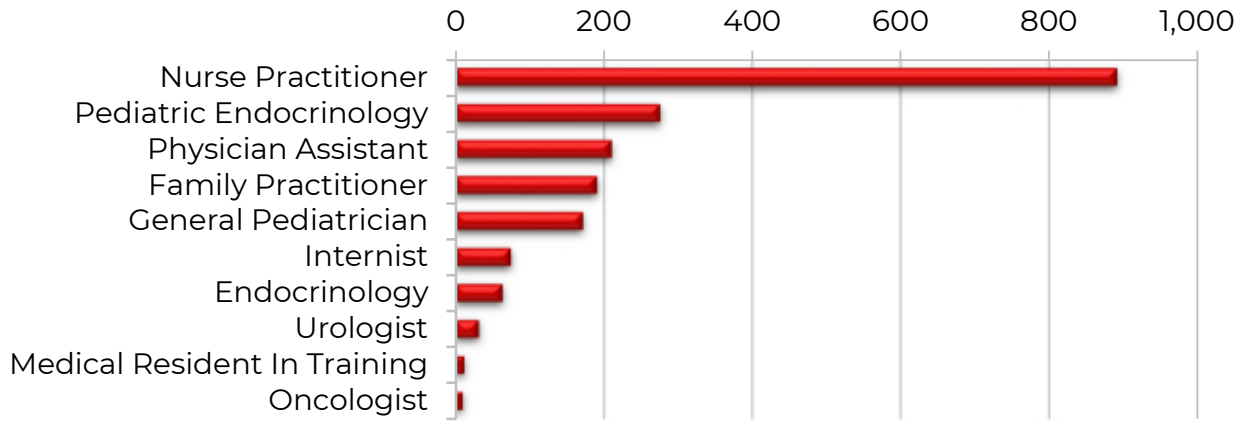
- The Testosterone Products Product Based Prior Authorization (PBPA) category is influenced by supplemental rebates. Some brand name testosterone products are preferred over available generic products due to a lower net cost compared to generics, after taking into account federal and/or supplemental rebate participation. These rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.
  - Aggregate drug rebates collected during calendar year 2022 for Testosterone Products: $146,449.06[Δ]

Demographics of Members Utilizing Testosterone Products: Pharmacy Claims



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

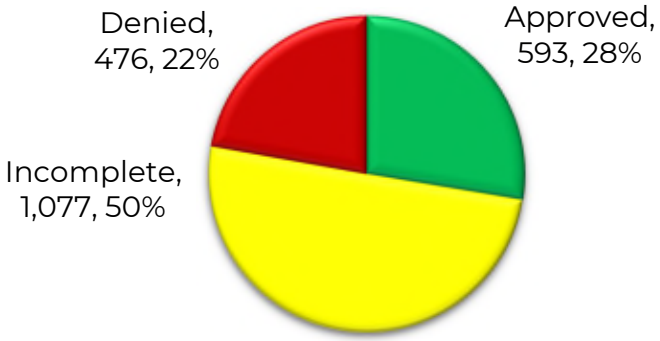
Top Prescriber Specialties of Testosterone Products by Number of Claims: Pharmacy Claims



Prior Authorization of Testosterone Products

There were 2,146 prior authorization requests submitted for testosterone products during calendar year 2022. All testosterone products require prior authorization regardless of tier status in order to evaluate diagnosis and submitted labs. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Testim® (testosterone topical gel): January 2025
- Androgel® (testosterone topical gel): October 2026
- Aveed® [testosterone undecanoate intramuscular (IM) injection]: May 2027
- Axiron® (testosterone topical solution): September 2027
- Kyzatrex® (testosterone undecanoate oral capsule): March 2033
- Vogelxo® (testosterone topical gel): February 2034

- Natesto® (testosterone nasal gel): March 2034
- Xyosted® [testosterone enanthate subcutaneous (sub-Q) auto-injector]: August 2038
- Jatenzo® (testosterone undecanoate oral capsule): April 2039
- Tlando® (testosterone undecanoate oral capsule): April 2041

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[3]

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

Utilization Details of Testosterone Products: Calendar Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TESTOSTERONE INJECTABLE PRODUCTS						
TESTOST CYP INJ 200MG/ML	1,597	370	$60,608.62	$37.95	4.32	26.75%
TESTOST CYP INJ 100MG/ML	32	17	$1,458.27	$45.57	1.88	0.64%
DEPO-TESTOST INJ 200MG/ML	18	18	$706.10	$39.23	1	0.31%
TESTOST ENAN INJ 200MG/ML	14	8	$1,006.86	$71.92	1.75	0.44%
XYOSTED INJ 100MG/0.5ML	12	1	$4,979.74	$414.98	12	2.20%
SUBTOTAL	**1,673**	**389***	**$68,759.59**	**$41.10**	**4.3**	**30.34%**
TESTOSTERONE TOPICAL PRODUCTS						
ANDROGEL GEL 1.62%	206	68	$127,682.05	$619.82	3.03	56.35%
TESTOSTERONE GEL 1% (50MG)	34	9	$6,412.60	$188.61	3.78	2.83%
ANDROGEL GEL 1% (50MG)	10	7	$7,540.98	$754.10	1.43	3.33%
TESTOSTERONE SOL 30MG/ACT	7	1	$701.15	$100.16	7	0.31%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TESTOSTERONE GEL 1.62%	7	3	$368.65	$52.66	2.33	0.16%
ANDRODERM DIS 4MG/24HR	6	3	$3,049.81	$508.30	2	1.35%
TESTOSTERONE GEL PUMP 1%	2	1	$307.86	$153.93	2	0.14%
ANDROGEL GEL 1% (25MG)	1	1	$634.48	$634.48	1	0.28%
SUBTOTAL	**273**	**83***	**$146,697.58**	**$537.35**	**3.29**	**64.74%**
TESTOSTERONE ORAL PRODUCTS						
JATENZO CAP 237MG	12	1	$11,137.29	$928.11	12	4.92%
SUBTOTAL	**12**	**1***	**$11,137.29**	**$928.11**	**12**	**4.92%**
TOTAL	**1,958**	**453***	**$226,594.46**	**$115.73**	**4.32**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = actuation; CAP = capsule; CYP = cypionate; DIS = patch; ENAN = enanthate; INJ = injection; SOL = solution; TESTOST = testosterone

Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TESTOSTERONE CYPIONATE INJ J1071	49	14	$172.74	$3.53	3.5
TOTAL	**49**	**14**	**$172.74**	**$3.53**	**3.5**

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

[1] 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 06/2023. Last Accessed 06/16/2023.
[2] 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 06/20/2023.
[3] 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 06/20/2023.

Appendix N

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

Oklahoma Health Care Authority
July 2023

Introduction[1,2,3,4]

Dystrophic epidermolysis bullosa (DEB) is 1 of the 4 major types of epidermolysis bullosa, a group of rare inherited disorders that cause the skin to become fragile and blister easily. The type of epidermolysis bullosa can be determined by the location within the skin layers the blisters occur and the gene mutation identified. DEB is caused by a mutation in the *collagen type VII alpha 1 chain* (*COL7A1*) gene that is responsible for encoding the type VII collagen (COL7) protein. The COL7 protein provides the main component of anchoring fibrils which bind the dermis and epidermis together. A lack of COL7 protein leads to a reduction in the number of working anchoring fibrils, causing the skin to easily separate when exposed to any type of friction such as itching, rubbing, or minor trauma.

There are 2 main subtypes of DEB: autosomal dominant (DDEB) and autosomal recessive (RDEB). Together, the prevalence of both types is estimated to be 3.3 per million people. RDEB is the most common subtype and can be the most severe, however clinical severity varies between affected patients. Mild cases include blisters affecting the hands, feet, knees, and elbows. In the most severe cases, mainly those with RDEB, blisters can affect large areas of the body and mucous membranes in the lining of the mouth and digestive tract. Once the blisters heal, scarring can make it difficult to chew and swallow leading to malnutrition and slow growth. Scarring may also lead to the fusion of the skin between fingers and toes, loss of nails, joint deformities restricting movement, and eye inflammation leading to vision loss. Additionally, these individuals have a higher risk of squamous cell carcinoma due to the recurring blistering and inflammation. There is currently no cure for DEB. Treatment is focused on symptom management including wound care, managing pain, and treating complications.

In May 2023, the U.S. Food and Drug Administration (FDA) approved Vyjuvek™ (beremagene geperpavec-svdt) to treat wounds for patients 6 months of age or older with DEB. Vyjuvek™ is a topical, redosable gene therapy that delivers functional copies of the human *COL7A1* gene which helps promote wound healing by restoring the skin's ability to make 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 RDEB and DDEB.

Vyjuvek™ (Beremagene Geperpavec-svdt) Product Summary[5]

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 dispensing 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 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.

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[1] National Institute of Arthritis and Musculoskeletal and Skin Diseases. Epidermolysis Bullosa. Available online at: https://www.niams.nih.gov/health-topics/epidermolysis-bullosa. Last revised 03/2020. Last accessed 06/21/2023.
[2] Krystal Biotech, Inc. Vyjuvek™ Patient Brochure. Available online at: https://www.vyjuvek.com/pdf/patient-brochure.pdf. Last accessed 06/21/2023.
[3] 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 06/21/2023.
[4] National Library of Medicine: Medline Plus. Dystrophic Epidermolysis Bullosa. Available online at: https://medlineplus.gov/genetics/condition/dystrophic-epidermolysis-bullosa/#frequency. Last accessed 06/21/2023.
[5] Vyjuvek™ Prescribing Information. Krystal Biotech, Inc. Available online at: https://www.fda.gov/media/168350/download. Last revised 05/2023. Last accessed 06/16/2023.

Appendix O

Calendar Year 2022 Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Leqembi™ (Lecanemab-irmb)

Oklahoma Health Care Authority
July 2023

Current Prior Authorization Criteria

Alzheimer's Disease Medications Approval Criteria:

1. Special formulation products including oral solutions, transdermal patches, and other convenience formulations require prior authorization with the following approval criteria:
    a. A patient-specific, clinically significant reason why the special formulation is necessary in place of the standard formulation.
2. An age restriction for ages 0 to 50 years applies to all Alzheimer's medications. Members older than 50 years of age can receive formulations without prior authorization. Members younger than 50 years of age will require prior authorization with the following criteria:
    a. An FDA approved diagnosis; or
    b. Other patient-specific, clinically significant information supporting the use of the medication.

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. Member must not be taking anticoagulant or antiplatelet agents except for aspirin 325mg per day or less; and
7. Member must not have had a stroke or transient ischemic attack (TIA) or unexplained loss of consciousness in the past year; and
8. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
9. 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
10. 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
11. The prescriber must confirm that the member will be monitored for amyloid-related imaging abnormalities (ARIA) during the first 8 doses of treatment with Aduhelm®, particularly during titration, and also throughout treatment; and
12. 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
13. Aduhelm® must be administered by a health care provider; and
14. Aduhelm® must be shipped via cold chain supply shipping and stored in a 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 MRI has been completed and is acceptable to the provider prior to 7th infusion 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; 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 28 days.

Namenda XR® [Memantine Extended-Release (ER) Capsules] Approval Criteria:

1. An FDA approved diagnosis for the treatment of moderate-to-severe Alzheimer's type dementia; and
2. A patient-specific, clinically significant reason why the member cannot use memantine immediate-release tablets must be provided.

Namzaric® [Memantine Extended-Release (ER)/Donepezil] Approval Criteria:

1. Member must have a patient-specific, clinically significant reason why the separate immediate-release products which do not require prior authorization cannot be used over this combination product; and
2. A quantity limit of 30 capsules per 30 days will apply.

Utilization of Alzheimer's Disease Medications: Calendar Year 2022

Comparison of Calendar Years: Pharmacy Claims

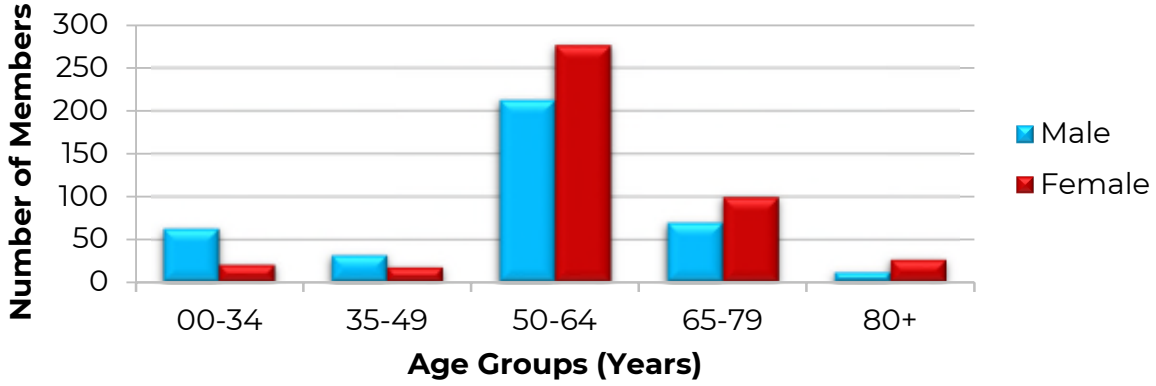
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	719	5,855	$100,022.99	$17.08	$0.51	306,946	196,730
2022	823	5,852	$88,541.44	$15.13	$0.43	309,867	205,146
% Change	**14.50%**	**-0.10%**	**-11.50%**	**-11.40%**	**-15.70%**	**1.00%**	**4.30%**
Change	**104**	**-3**	**-$11,481.55**	**-$1.95**	**-$0.08**	**2,921**	**8,416**

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

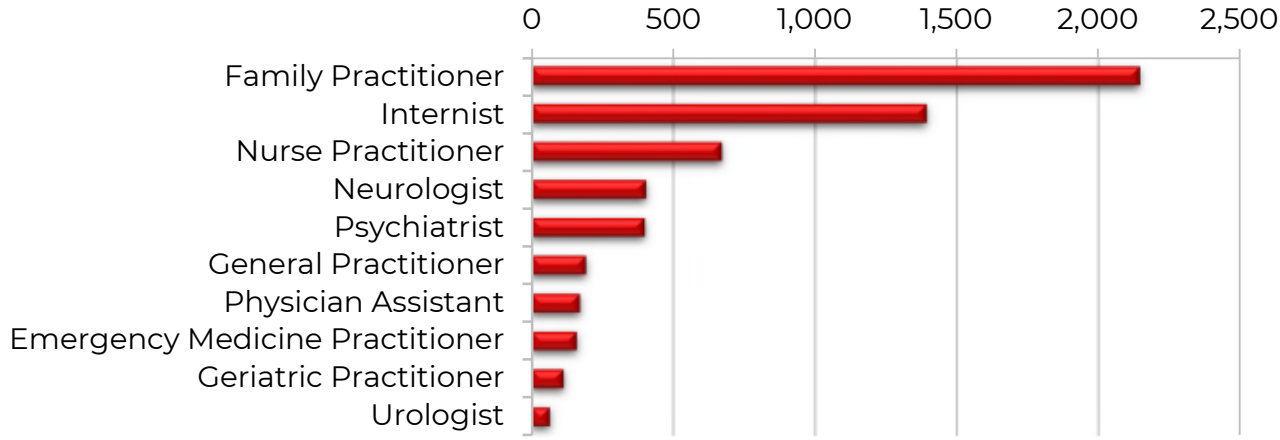
- There were no paid medical claims for the Alzheimer's disease medications during calendar year 2021 or 2022.
- Aggregate drug rebates collected during calendar year 2022 for the Alzheimer's disease medications: $5,018.93.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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

Demographics of Members Utilizing Alzheimer's Disease Medications



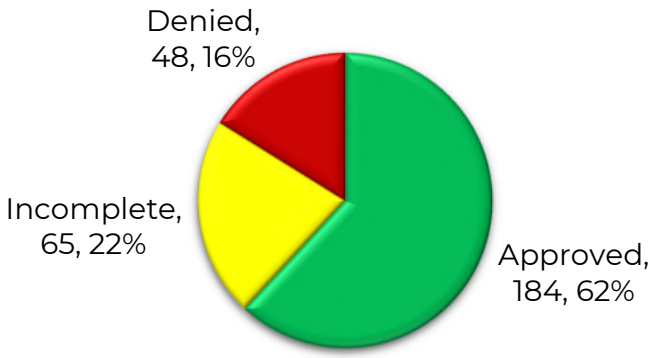
Top Prescriber Specialties of Alzheimer's Disease Medications by Number of Claims



Prior Authorization of Alzheimer's Disease Medications

There were 297 prior authorization requests submitted for Alzheimer's disease medications during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Namenda XR® [memantine extended-release (ER) capsules]: September 2029, however, after litigation settlements, generic versions are currently available in the United States
- Namzaric® (memantine ER/donepezil capsules): December 2029

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

News:

- **July 2022:** The FDA granted Breakthrough Device designation to the Elecsys® Amyloid Plasma Panel. Elecsys® is a test that can detect and measure Alzheimer's disease biomarkers in the blood plasma, including the phosphorylated Tau (pTau) 181 protein assay and apolipoprotein (APOE) E4 assay, to indicate if a patient needs further confirmatory testing. Elevations in pTau occur in early stages of Alzheimer's, while the presence of APOE E4 is one of the most common genetic risk factors for Alzheimer's disease. Patients testing negative with the Elecsys® Amyloid Plasma Panel are unlikely to be amyloid positive and should be investigated for other causes of cognitive decline. Elecsys® is intended to be used in conjunction with other clinical information.
- **December 2022:** The Elecsys® beta-amyloid (1-42) cerebrospinal fluid (CSF) II (Abeta42) and Elecsys® phospho-tau (181P) CSF (pTau181) assays were granted FDA 510(k) clearance with the intent to increase diagnosis accuracy. The Elecsys® CSF assays achieve 90% concordance with the Amyloid positron emission tomography (PET) scan. Elecsys® will also offer detection of multiple biomarkers from 1 draw, with no radiation and the potential to detect Alzheimer's pathology in early stages of disease. The Elecsys® assay generates a pTau181/Abeta42 ratio value that is consistent with a negative Amyloid PET scan if the result ≤0.023pg/mL, and if the ratio is >0.023pg/mL, then it is comparable to a positive Amyloid PET scan. A positive ratio, however, does not establish the diagnosis of Alzheimer's disease but is intended to be used in addition to other clinical evaluations.
- **February 2023:** The Centers for Medicare and Medicaid Services (CMS) announced that at this time it will not be reconsidering the national coverage determination (NCD) for the FDA approved anti-amyloid monoclonal antibodies for the treatment of Alzheimer's disease. This

decision was made based on not having enough evidence meeting the criteria for reconsideration when the letter was submitted. If an anti-amyloid monoclonal antibody receives traditional FDA approval, CMS will provide broader coverage under the Coverage with Evidence Development (CED). Coverage through CED will include registry-based studies that reflect real-world care. CMS has stated they will review any new evidence that becomes available that may lead to changes in the NCD.

- **March 2023:** Eli Lilly announced results from the anti-amyloid treatment in asymptomatic Alzheimer's disease (A4) study did not show a slow in cognitive decline or a reduction in the risk of progression to symptomatic Alzheimer's disease in patients taking solanezumab. Solanezumab only targets soluble amyloid beta plaque and does not help remove deposited amyloid plaques. Based on these results, Eli Lilly has decided to end their clinical development of solanezumab and focus on their other investigational monoclonal antibodies that are currently in Phase 3 development.
- **March 2023:** The U.S. Veterans' Health Administration (VHA) announced the coverage of Leqembi™ for veterans with early stages of Alzheimer's disease. VHA health care providers meeting the criteria set by the VHA can prescribe Leqembi™ to veterans meeting the VHA's criteria and the current FDA label.
- **June 2023:** CMS announced that if traditional approval is granted to the current FDA approved anti-amyloid monoclonal antibodies, then Medicare will cover them in the appropriate settings. Broader Medicare coverage would begin on the same day as the traditional approval. Currently 2 drugs, Aduhelm® and Leqembi™ have received accelerated approval from the FDA, but no product has received traditional approval. In order to obtain Medicare coverage after the traditional approval, patients will need to be enrolled in Medicare Part B, be diagnosed with mild cognitive impairment or early dementia caused by Alzheimer's disease, and have a qualified physician participating in a registry with appropriate follow up care. This is in addition to any FDA label requirements as well. The registry allows the qualified physicians to submit their collection of real-world evidence of how these drugs are working through a nationwide, CMS-facilitated portal that is available when any product gains traditional approval. CMS is working with multiple organizations that are getting ready to open their own registries and more information will be released as it becomes available.
- **June 2023:** The FDA's Peripheral and Central Nervous System Drugs Advisory Committee has unanimously endorsed the efficacy and clinical benefit of Leqembi™ for the process of receiving a traditional approval. The decision was made based on the supplemental Biologics

License Application (sBLA) that included data from the Phase 3 Clarity AD clinical trial showing a statistically significant slowing of cognitive and functional decline compared to placebo. The next regulatory step toward traditional approval of the treatment is FDA review. The FDA has accepted the sBLA and has granted Priority Review to Leqembi™ for the traditional approval application, with required action from the agency by July 6, 2023.

- **June 2023:** Another Elecsys® CSF assay received 510(k) clearance from the FDA. The Elecsys® beta-amyloid (1-42) CSF II (Abeta42) and Elecsys total-tau CSF assays (tTau) will join the previous assay that was approved in December 2022 that measures the pTau181/Abeta42 ratio. The tTau/Abeta42 ratio will show concordance with a negative amyloid PET scan if ≤0.28pg/mL; if the ratio is >0.28pg/mL, it will be comparable to a positive amyloid PET scan. Similar to the previous approval, this assay is indicated to be used in addition to other clinical evaluations to make the Alzheimer's disease diagnosis.

Pipeline:

- **ALZ-801 (Valiltramiprosate):** Valiltramiprosate is a potential oral disease modifying therapy for the treatment of Alzheimer's disease. It is differentiated from the current approved anti-amyloid monoclonal antibodies by its novel mechanism of action, oral administration, and potential efficacy in a genetically-targeted population. Valiltramiprosate has been shown to fully inhibit the formation of neurotoxic soluble beta amyloid oligomers. These oligomers are associated with the onset of cognitive symptoms and progression of Alzheimer's disease. Valiltramiprosate received Fast Track designation from the FDA and is currently in Phase 3 trials focusing on early Alzheimer's disease patients with the APO4/4 genotype. Future trials are intended to expand the treatment and prevention of those who are homozygous for the APOE4 gene and noncarriers. Submission of a New Drug Application (NDA) is anticipated in 2024 with a potential approval by 2025.
- **ALZT-OP1:** ALZT-OP1 is a combination of inhaled cromolyn and oral ibuprofen that provide a daily dose to potentially suppress the brain's neuroinflammatory response. The combination uses a unique approach of attacking the neuroinflammation that leads to neuronal death by shifting the brain's microglial immune cells to a neuroprotective state. Phase 3 trials in early Alzheimer's disease have been completed, and ALZT-OP1 qualifies for a 505(b)2 FDA approval process.
- **Donanemab:** Donanemab is an investigational monoclonal antibody for the treatment of early Alzheimer's disease that binds to the deposited amyloid plaques in the brain. An accelerated approval application was submitted to the FDA, and in January 2023, a Complete

Response Letter (CRL) was issued due to the limited number of patients that had 12 months of exposure to the drug, but no other deficiencies were noted. The FDA requested that the data show at least 100 patients who had a minimum of 12 months of continued treatment with donanemab prior to resubmission. In March 2023, Phase 3 results showed slowed cognitive and functional decline in those with early symptomatic Alzheimer's disease. In the Phase 3 TRAILBLAZER-ALZ 2 study, 47% of patients on donanemab versus 29% on placebo had no clinical progression at 1 year. Based on these results, a new submission to the FDA is anticipated mid-2023.

Leqembi™ (Lecanemab-irmb) Product Summary[19]

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.
- This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Leqembi™. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

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**	**$2,293.38+**	**$29,813.94+**
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 (2) 2mL and (1) 5mL single dose vials for each dose of 10mg/kg every 2 weeks.
*Aduhelm® cost is based on use of (3) 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 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. 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. 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 amyloid-related imaging abnormalities (ARIA) with the concomitant use have been discussed and are acceptable to the member prior to initiating Leqembi™; and
7. Member must not have had a stroke, transient ischemic attack (TIA), or unexplained loss of consciousness in the past year; and

8. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
9. 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
10. 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
11. Prescriber must confirm that the member will be monitored for ARIA during the first 14 weeks and throughout treatment with Leqembi™; and
12. 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
13. 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
14. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
15. 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
16. 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

17. Approval quantities will be dependent on the member's weight and dosing based on package labeling; and
18. The maximum dose approvable is 10mg/kg per 14 days; and
19. 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. 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 amyloid-related imaging abnormalities (ARIA) with the concomitant use have been discussed and are acceptable to the member prior to initiating Aduhelm®; and
7. Member must not have had a stroke or transient ischemic attack (TIA) or unexplained loss of consciousness in the past year; and
8. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
9. 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

10. 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
11. 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
12. 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
13. 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
~~14. Aduhelm® must be administered by a health care provider; and~~
~~15. Aduhelm® must be shipped via cold chain supply shipping and stored in a refrigerator; and~~
16. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
17. A patient-specific, clinically significant reason why the member cannot use Leqembi™ (lecanemab-irmb) must be provided; and
18. 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
19. 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
20. Approval quantities will be dependent on the member's weight and dosing based on package labeling; and
21. The maximum dose approvable is 10mg/kg per 28 days; and
22. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

Utilization Details of Alzheimer's Disease Medications: Calendar Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MEMANTINE PRODUCTS						
MEMANTINE TAB HCL 10MG	2,720	407	$40,884.64	$15.03	6.68	46.18%
MEMANTINE TAB HCL 5MG	717	169	$10,819.51	$15.09	4.24	12.22%
MEMANTINE HCL CAP 28MG ER	169	16	$6,450.91	$38.17	10.56	7.29%
MEMANTINE TAB 10MG	19	18	$335.66	$17.67	1.06	0.38%
MEMANTINE TAB 5MG	13	3	$209.72	$16.13	4.33	0.24%
MEMANT TITRA PACK 5-10MG	3	3	$81.28	$27.09	1	0.09%
MEMANTINE HCL CAP 14MG ER	2	1	$83.41	$41.71	2	0.09%
SUBTOTAL	**3,643**	**617**	**$58,865.13**	**$16.16**	**5.9**	**66.49%**
DONEPEZIL PRODUCTS						
DONEPEZIL TAB 10MG	1,278	239	$15,485.23	$12.12	5.35	17.49%
DONEPEZIL TAB 5MG	799	216	$9,500.10	$11.89	3.7	10.73%
DONEPEZIL TAB 23MG	2	1	$164.54	$82.27	2	0.19%
SUBTOTAL	**2,079**	**456**	**$25,149.87**	**$12.10**	**4.56**	**28.41%**
RIVASTIGMINE PRODUCTS						
RIVASTIGMINE CAP 3MG	38	3	$896.57	$23.59	12.67	1.01%
RIVASTIGMINE CAP 1.5MG	22	6	$554.70	$25.21	3.67	0.63%
RIVASTIGMINE PATCH 4.6MG/24HR	21	4	$1,843.19	$87.77	5.25	2.08%
RIVASTIGMINE CAP 6MG	6	1	$159.71	$26.62	6	0.18%
RIVASTIGMINE CAP 4.5MG	1	1	$17.13	$17.13	1	0.02%
SUBTOTAL	**88**	**15**	**$3,471.30**	**$39.45**	**5.87**	**3.92%**
GALANTAMINE PRODUCTS						
GALANTAMINE TAB 4MG	33	4	$868.67	$26.32	8.25	0.98%
GALANTAMINE TAB 8MG	9	1	$186.47	$20.72	9	0.21%
SUBTOTAL	**42**	**5**	**$1,055.14**	**$25.12**	**8.4**	**1.19%**
TOTAL	**5,852**	**823***	**$88,541.44**	**$15.13**	**7.11**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; ER = extended-release; HCL = hydrochloride; HR = hour; TAB = tablet; TITRA = titration

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Appendix P

Calendar Year 2022 Annual Review of Isturisa® (Osilodrostat) and Recorlev® (Levoketoconazole)

Oklahoma Health Care Authority
July 2023

Current Prior Authorization Criteria

Isturisa® (Osilodrostat) Approval Criteria:

1. An FDA approved indication for the treatment of adult members with Cushing's disease for whom pituitary or adrenal surgery is not an option or has not been curative; and
2. Member must be 18 years of age or older; and
3. Prescriber must document that the member has had an inadequate response to pituitary or adrenal surgery or is not a candidate for pituitary or adrenal surgery; and
4. Prescriber must verify that hypokalemia and hypomagnesemia are corrected prior to starting Isturisa®; and
5. Prescriber must agree to perform and monitor electrocardiogram (ECG) at baseline, 1 week after treatment initiation, and as clinically indicated thereafter; and
6. Prescriber must verify that dose titration will be followed according to package labeling; and
7. If the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin) or strong CYP3A4 and/or CYP2B6 inducers (e.g., carbamazepine, rifampin, phenobarbital), the prescriber must verify that the Isturisa® dose will be adjusted according to the package labeling; and
8. For female members, prescriber must verify that the member is not breastfeeding; and
9. Isturisa® must be prescribed by, or in consultation with, an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
10. A patient-specific, clinically significant reason why the member cannot use ketoconazole tablets and metyrapone capsules must be provided; and
11. Initial authorizations will be for the duration of 3 months after which time, compliance and 24-hour urine free cortisol levels within the normal range (to demonstrate the effectiveness of this medication) will be required for continued approval. Subsequent approvals will be for the duration of 1 year and will require the prescriber to verify the member is still not a candidate for pituitary or adrenal surgery.

Recorlev® (Levoketoconazole) Approval Criteria:

1. An FDA approved indication for the treatment of adult members with Cushing's disease for whom pituitary or adrenal surgery is not an option or has not been curative; and
2. Member must be 18 years of age or older; and
3. Recorlev® must be prescribed by, or in consultation with, an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
4. Prescriber must document that the member has had an inadequate response to pituitary or adrenal surgery or is not a candidate for pituitary or adrenal surgery; and
5. Prescriber agrees to obtain baseline liver test and electrocardiogram (ECG) prior to initiating treatment; and
6. Prescriber agrees to monitor liver enzymes and bilirubin weekly for at least 6 weeks after initiating treatment, every 2 weeks for the next 6 weeks, monthly for the next 3 months, and then as clinically indicated; and
7. Prescriber must verify that hypokalemia and hypomagnesemia are corrected prior to starting Recorlev®; and
8. Member must not be taking medications that cause QT prolongation associated with ventricular arrhythmias, including torsades de pointes (e.g., dofetilide, dronedarone, methadone, quinidine, ranolazine); and
9. Member must not be taking medications that are sensitive substrates of CYP3A4 and/or P-gp (e.g., digoxin, lovastatin, simvastatin, tacrolimus, triazolam); and
10. If the member is taking medications that are strong CYP3A4 inhibitors (e.g., ritonavir, mifepristone) or strong CYP3A4 inducers (e.g., isoniazid, carbamazepine, rifampicin, phenytoin), the prescriber must verify the medication will be stopped 2 weeks before and during treatment with Recorlev® per package labeling; and
11. For female members, prescriber must verify that the member is not breastfeeding; and
12. A patient-specific, clinically significant reason why the member cannot use ketoconazole tablets and metyrapone capsules must be provided; and
13. Initial authorizations will be for the duration of 3 months. Continued authorization at that time will require the prescriber to provide a recent 24-hour urine free cortisol (UFC) level within the normal range to demonstrate the effectiveness of this medication, and compliance will also be checked at that time. Subsequent approvals will be for the duration of 1 year and will require the prescriber to verify the member is still not a candidate for pituitary or adrenal surgery.

Utilization of Isturisa® (Osilodrostat) and Recorlev® (Levoketoconazole): Calendar Year 2022

Calendar Year 2022 Utilization

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	1	3	$50,636.49	$16,878.83	$723.38	360	70

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Please note: There were no paid pharmacy claims during calendar year 2021 to allow for a calendar year comparison.

Demographics of Members Utilizing Isturisa® (Osilodrostat) and Recorlev® (Levoketoconazole)

- Due to the limited number of members utilizing Isturisa® (osilodrostat) and Recorlev® (levoketoconazole) detailed demographic information could not be provided.

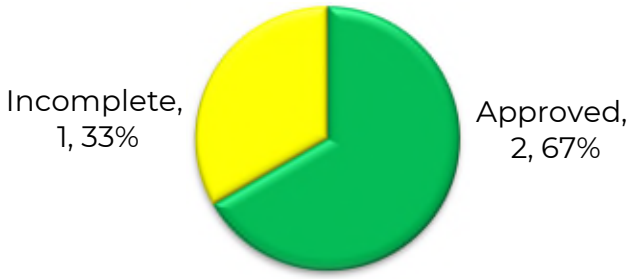
Top Prescriber Specialties of Isturisa® (Osilodrostat) and Recorlev® (Levoketoconazole) by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for Isturisa® (osilodrostat) during calendar year 2022 was endocrinologist.

Prior Authorization of Isturisa® (Osilodrostat) and Recorlev® (Levoketoconazole)

There were 3 prior authorization requests submitted for 1 unique member for Isturisa® (osilodrostat) and Recorlev® (levoketoconazole) during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Isturisa® (osilodrostat): October 2035
- Recorlev® (levoketoconazole): March 2040

Pipeline:

- **Relacorilant:** Relacorilant is a selective glucocorticoid receptor modulator that is showing promising results for lowering blood pressure and glucose levels in Cushing's disease. Cushing's disease is a condition where excess cortisol is produced that can lead to multitude of health issues, some being hypertension, weight gain, and increased blood glucose levels. The current treatment option on the market, Korlym® (mifepristone), works similarly by blocking extra cortisol from being used in the body; however, is not selective which affects progesterone activity. Corcept Therapeutics has published the results of their open label Phase 2 clinical trial that showed reductions in hypertension and hyperglycemia. A Phase 3 trial has started for endogenous Cushing syndrome and hypercortisolism associated with adrenal adenoma or hyperplasia. Relacorilant's lack of progesterone involvement could indicate this may be a viable option for more patients than what is currently approved.

Recommendations

The College of Pharmacy does not recommend any changes to the current Isturisa® (osilodrostat) and Recorlev® (levoketoconazole) prior authorization criteria at this time.

Utilization Details of Isturisa® (Osilodrostat) and Recorlev® (Levoketoconazole): Calendar Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OSILODROSTAT PRODUCTS						
ISTURISA TAB 1MG	3	1	$50,636.49	$16,878.83	3	100%
TOTAL	**3**	**1***	**$50,636.49**	**$16,878.83**	**3**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 06/2023. Last accessed 06/26/2023.
[2] Pivonello R, Bancos I, Feelders RA, et al. Relacorilant, A Selective Glucocorticoid Receptor Modulator, Induces Clinical Improvements in Patients with Cushing Syndrome: Results from A Prospective, Open-Label Phase 2 Study. *Front Endocrinol* 2021; 12:662865. doi:10.3389/fendo.2021.662865.
[3] Corcept Therapeutics. Pipeline and Clinical Trials. Available online at: https://www.corcept.com/research-pipeline/pipeline/. Last accessed 6/28/2023.

Appendix Q

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: June 29, 2023

FDA Approves First Gene Therapy for Adults with Severe Hemophilia A

The FDA approved Roctavian™ (valoctocogene roxaparvovec-rvox), an adeno-associated virus vector-based gene therapy for the treatment of adults with severe hemophilia A without pre-existing antibodies to adeno-associated virus serotype 5 detected by an FDA-approved test.

Roctavian™ is a one-time gene therapy product administered as a single dose by intravenous infusion. Roctavian™ consists of a viral vector carrying a gene for clotting Factor VIII. The gene is expressed in the liver to increase blood levels of FVIII and reduce the risk of uncontrolled bleeding.

The safety and effectiveness of Roctavian™ were evaluated in a multinational study in adult men 18 to 70 years of age with severe Hemophilia A who were previously treated with Factor VIII replacement therapy. Effectiveness was established based on results from a cohort of 112 patients followed up for at least 3 years after Roctavian™ treatment. Following the infusion, the mean annualized bleeding rate decreased from 5.4 bleeds per year at baseline to 2.6 bleeds per year. The majority of patients who received Roctavian™ received corticosteroids to suppress the immune system for the gene therapy to be effective and safe. Treatment response to Roctavian™ may decrease over time.

The most common adverse reactions associated with Roctavian™ included mild changes in liver function, headache, nausea, vomiting, fatigue, abdominal pain and infusion-related reactions. Close monitoring for infusion-related reactions and liver enzyme elevation is advised with Roctavian™ administration. In some cases, treatment with Roctavian™ was observed to increase FVIII activity levels above the normal limits. An increase in FVIII activity may increase the risk of thromboembolic events. Introduction of the Roctavian™ product's DNA sequence may carry the theoretical risk of developing hepatocellular carcinoma or other cancers. No instances of thromboembolic events or cancers associated with Roctavian™ were observed in clinical studies.

Roctavian™ is approved with the AAV5 DetectCDx™, a companion diagnostic test intended to help health care providers identify patients who may benefit from receiving Roctavian™ to treat hemophilia A. The test was proven effective in detecting pre-existing anti-AAV5 antibodies, which may render the gene therapy less effective or ineffective. Clinical study data from hemophilia A patients who received Roctavian™ after being identified as eligible by the AAV5 DetectCDx™ (patients without pre-existing anti-AAV5 antibodies), supported the safety and effectiveness of the AAV5 DetectCDx™ for its intended use as a companion diagnostic to Roctavian™. The FDA granted approval of the AAV5 DetectCDx™ to ARUP Laboratories.

This application received Orphan, Breakthrough Therapy, Regenerative Medicine Advanced Therapy, and Priority Review designations. The FDA granted approval of Roctavian™ to BioMarin Pharmaceutical Inc.

FDA NEWS RELEASE

For Immediate Release: June 28, 2023

FDA Approves First Cellular Therapy to Treat Patients with Type 1 Diabetes

The FDA approved Lantidra™ (donislecel-jujn), the first allogeneic (donor) pancreatic islet cellular therapy made from deceased donor pancreatic cells for the treatment of type 1 diabetes. Lantidra™ is approved for the treatment of adults with type 1 diabetes who are unable to approach target glycated hemoglobin because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education.

The primary mechanism of action of Lantidra™ is believed to be the secretion of insulin by the infused allogeneic islet beta cells. In some patients with type 1 diabetes, these infused cells can produce enough insulin, so the patient no longer needs to take insulin (by injections or pump) to control their blood sugar levels. Lantidra™ is administered as a single infusion into the hepatic portal vein. An additional infusion of Lantidra™ may be performed depending on the patient's response to the initial dose.

The safety and effectiveness of Lantidra™ was evaluated in two non-randomized, single-arm studies in which a total of 30 participants with type 1 diabetes and hypoglycemic unawareness received at least one infusion and a maximum of three infusions. Overall, 21 participants did not need to take insulin for a year or more, with 11 participants not needing insulin for one to five years and 10 participants not needing insulin for more than five years. Five participants did not achieve any days of insulin independence.

Adverse reactions associated with Lantidra™ varied with each participant depending on the number of infusions they received and the length of time they were followed and may not reflect the rates observed in practice The most common adverse reactions included nausea, fatigue, anemia, diarrhea, and abdominal pain. A majority of participants experienced at least one serious adverse reaction related to the procedure for infusing Lantidra™ into the hepatic portal vein and the use of immunosuppressive medications needed to maintain the islet cell viability. Some serious adverse reactions required discontinuation of immunosuppressive medications, which resulted in the loss of islet cell function and insulin independence. These adverse events should be considered when assessing the benefits and risks of Lantidra™ for each patient. Lantidra™ is approved with patient-directed labeling to inform patients with type 1 diabetes about benefits and risks of Lantidra™.

The FDA granted approval of Lantidra™ to CellTrans Inc.

FDA NEWS RELEASE

For Immediate Release: June 23, 2023

FDA Issues First Draft Guidance on Clinical Trials with Psychedelic Drugs

The FDA published a new draft guidance to highlight fundamental considerations to researchers investigating the use of psychedelic drugs for potential treatment of medical conditions, including psychiatric or substance use disorders. This is the first FDA draft guidance that presents considerations to industry for designing clinical trials for psychedelic drugs.

There has been growing interest in the therapeutic potential of psychedelic drugs in recent years. They are being evaluated for use in the potential treatment of conditions such as depression, post-traumatic stress disorder, substance use disorders and other conditions. However, designing clinical studies to evaluate the safety and effectiveness of

these compounds presents a number of unique challenges that require careful consideration.

The purpose of the draft guidance is to advise researchers on study design and other considerations as they develop medications that contain psychedelics. Within the draft guidance, the term psychedelics refers to "classic psychedelics," typically understood to be drugs such as psilocybin and lysergic acid diethylamide (LSD) that act on the brain's serotonin system, as well as "entactogens" or "empathogens" such as methylenedioxymethamphetamine (MDMA).

The document describes basic considerations throughout the drug development process including trial conduct, data collection, subject safety and new drug application requirements. For example, psychedelic drugs may produce psychoactive effects such as mood and cognitive changes, as well as hallucinations. As a result, there is the potential for abuse of these drugs, which is a drug safety issue that requires careful consideration and putting sufficient safety measures in place for preventing misuse throughout clinical development. For psychedelics that are currently Schedule I controlled substances, the draft guidance notes that activities associated with investigations under an Investigational New Drug Application must comply with applicable Drug Enforcement Administration regulatory requirements.

The evidentiary standard for establishing effectiveness of psychedelic drugs is the same as for all other drugs. However, there are unique factors investigators may need to consider when designing their clinical trials if those trials are to be considered adequate and well-controlled. The draft guidance also addresses the role of psychotherapy in psychedelic drug development, considerations for safety monitoring and the importance of characterizing dose-response and the durability of any treatment effect.

FDA NEWS RELEASE

For Immediate Release: June 22, 2023

FDA Approves First Gene Therapy for Treatment of Certain Patients with Duchenne Muscular Dystrophy

The FDA approved Elevidys™, the first gene therapy for the treatment of pediatric patients 4 through 5 years of age with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene who do not have a pre-existing medical reason preventing treatment with this therapy.

DMD is a rare and serious genetic condition which worsens over time, leading to weakness and wasting away of the body's muscles. The disease occurs due to a defective gene that results in absence of dystrophin, a protein that helps keep the body's muscle cells intact.

Elevidys™ is a recombinant gene therapy designed to deliver into the body a gene that leads to production of Elevidys™ micro-dystrophin, a shortened protein (138 kDa, compared to the 427 kDa dystrophin protein of normal muscle cells) that contains selected domains of the dystrophin protein present in normal muscle cells. The product is administered as a single intravenous dose.

Elevidys™ was approved through the Accelerated Approval pathway. The FDA granted approval based on an evaluation of data submitted by the sponsor. In one study which involved two parts, individuals in part 1 – which was randomized, double-blind, and placebo-controlled – were treated with either Elevidys™ or placebo and followed for 48 weeks. In part 2 of the study, individuals who received placebo during part 1 were treated with Elevidys™, and individuals treated with Elevidys™ during part 1 received a placebo. All individuals were followed for an additional 48 weeks.

The accelerated approval of Elevidys™ was based on data from the randomized clinical trial that established that Elevidys™ increased the expression of the Elevidys™ micro-dystrophin protein observed in Elevidys-treated individuals aged 4 to 5 years with DMD. The FDA concluded that the data submitted by the applicant demonstrated that an increase in this surrogate endpoint (expression of Elevidys™ micro-dystrophin) is reasonably likely to predict clinical benefit in individuals 4 to 5 years of age with DMD who do not have significant pre-existing antibody titers against the AAV rh74 vector or have other contraindications based on the inclusion criteria of the clinical trials.

A clinical benefit of Elevidys™, including improved motor function, has not been established. As a condition of approval, the FDA is requiring the company to complete a clinical study to confirm the drug's clinical benefit. The required study is designed to assess whether Elevidys™ improves physical function and mobility in ambulatory DMD patients with a confirmed mutation in the DMD gene. The study is ongoing and fully enrolled. The agency will review the data from this trial as quickly as possible to consider if further action, such as a revised indication or withdrawal of Elevidys™, may be necessary.

The most commonly reported side effects by individuals who received Elevidys™ were vomiting, nausea, acute liver injury, pyrexia and thrombocytopenia. Patients' liver function should be monitored before treatment with Elevidys™, and weekly for the first three months after treatment. Patients given Elevidys™ may also be at risk for severe immune-mediated myositis. Additionally, myocarditis and elevations of troponin-I have been observed following use of Elevidys™ in clinical trials. Troponin-I levels should be monitored before administration of Elevidys™ and weekly for the first month after treatment.

The FDA granted accelerated approval of Elevidys™ to Sarepta Therapeutics, Inc.

FDA NEWS RELEASE

For Immediate Release: June 20, 2023

FDA Approves New Class of Medicines to Treat Pediatric Type 2 Diabetes

The FDA approved Jardiance® (empagliflozin) and Synjardy® (empagliflozin/metformin hydrochloride) as additions to diet and exercise to improve blood sugar control in children 10 years of age and older with type 2 diabetes. These approvals provide a new class of medications taken by mouth to treat pediatric type 2 diabetes. Metformin, the only other oral therapy available for the treatment of children with type 2 diabetes, was first approved for pediatric use in 2000.

Based on information from the SEARCH for Diabetes in Youth study, the incidence of type 2 diabetes in children increased by 4.8% per year from 2002 to 2015 and is expected to continue increasing. As of 2017, there were approximately 28,000 cases of type 2 diabetes in children in the United States. By 2060, if current trends continue, that number is predicted to be approximately 220,000, with the majority of cases occurring in minority racial and ethnic groups such as Non-Hispanic Blacks and Hispanics.

Empagliflozin, the active ingredient in Jardiance® and Synjardy®, works by increasing the excretion of glucose in the urine. Synjardy® also contains metformin. The safety and efficacy of empagliflozin in children were studied in a double-blind, randomized, placebo-controlled trial in 157 patients 10 to 17 years of age with inadequately controlled type 2 diabetes. Participants were randomly assigned to 1 of 3 treatment arms for 26 weeks: empagliflozin, a dipeptidyl peptidase 4 (DPP-4) inhibitor (linagliptin), or placebo. At the beginning of the trial, 51% of patients were taking metformin alone, 40% of patients were taking a combination of metformin and insulin, 3% of patients were taking insulin alone, and 6% of patients were not taking other

medicines for diabetes. The trial found that, at week 26, treatment with empagliflozin was superior in reducing hemoglobin A1c compared to placebo. The 52 patients treated with empagliflozin had an average 0.2% decrease in hemoglobin A1c compared with an average 0.7% increase in hemoglobin A1c in the 53 patients taking placebo, representing a 0.8% decrease in hemoglobin A1c with empagliflozin as compared to placebo. Patients treated with empagliflozin also had reductions in fasting plasma glucose as compared to patients taking placebo.

Common side effects in children treated with empagliflozin were generally similar to those reported in adults, except there was a higher risk of hypoglycemia among pediatric patients 10 years of age and older taking empagliflozin compared to placebo, regardless of whether they were taking other therapies for diabetes.

The most common side effects in adults treated with empagliflozin include urinary tract infections and female fungal infections. The most common side effects in patients treated with metformin include diarrhea, nausea, and upset stomach. Jardiance® and Synjardy® are not recommended in patients with type 1 diabetes because of an increased risk of diabetic ketoacidosis. Jardiance® and Synjardy® are also not recommended for use to improve blood sugar control in patients with severe kidney problems and should not be used in patients who previously have had a serious allergic reaction to them. Synjardy® must not be used in patients with metabolic acidosis or diabetic ketoacidosis.

Jardiance® was originally approved by the FDA in 2014 as an addition to diet and exercise to improve blood sugar control in adults with type 2 diabetes. Jardiance® is also approved to reduce the risk of cardiovascular death in adults with type 2 diabetes and established cardiovascular disease, and to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.

Synjardy® was originally approved by the FDA in 2015 as an addition to diet and exercise to improve glucose control in adults with type 2 diabetes. Empagliflozin, when used as a component of Synjardy®, is approved to reduce the risk of cardiovascular death in adults with type 2 diabetes and established cardiovascular disease and to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.

Jardiance® and Synjardy® received priority review designations for these approvals. The FDA granted these approvals of Jardiance® and Synjardy® to Boehringer Ingelheim.

FDA NEWS RELEASE

For Immediate Release: June 20, 2023

FDA Launches Pilot Program to Help Reduce Risks Associated with Using Laboratory Developed Tests to Identify Cancer Biomarkers

The FDA announced a new voluntary pilot program for certain oncology drug products used with certain corresponding in vitro diagnostic tests to help clinicians select appropriate cancer treatments for patients.

Under current FDA policy, an in vitro companion diagnostic test is 1 that provides information essential for the safe and effective use of a corresponding treatment. In oncology, for example, specific tests may be used to identify patients, such as those with a particular genetic mutation, who may or may not benefit from certain cancer treatments.

The current policy also provides that, in certain limited circumstances, the FDA may decide to approve a life-saving treatment that requires use of an in vitro companion diagnostic even if a corresponding in vitro companion diagnostic has not yet received marketing authorization. In these cases, tests offered as laboratory developed tests (LDTs)

are being used for patient treatment decisions. LDTs are diagnostics that have generally been under an enforcement discretion approach (such that the FDA generally has not enforced applicable requirements with respect to most LDTs) and are not generally reviewed by the FDA for safety or effectiveness. The FDA has not applied this general enforcement discretion approach in certain circumstances, such as during declared public health emergencies.

The FDA has become increasingly concerned that some tests made by laboratories and not authorized by the FDA may not provide accurate and reliable test results or perform as well as FDA authorized tests. This may negatively impact treatment decisions. This pilot program is one step that may be helpful in reducing the risk of using LDTs for oncology drug treatment decisions while we continue to work on a broader approach for LDTs, including moving forward with rulemaking.

Through the pilot program, the FDA will request, from drug manufacturers, performance information for the tests used to enroll patients into the clinical trials that support drug approval. Based on an assessment of that information, the FDA will post to the FDA website the minimum performance characteristics recommended for similar tests that may be used to select patients for treatment with the approved drug. Laboratories may use this information to guide their development of LDTs to identify specific biomarkers used for selecting cancer treatment. This transparency aims to help facilitate better and more consistent performance of these tests, resulting in better drug selection and improved care for patients with cancer.

As discussed in the guidance, the initial phase of the pilot program is anticipated to last up to 1 year, during which the FDA will evaluate no more than 9 drug sponsors for possible acceptance into the pilot. The minimum recommended performance characteristics for in vitro diagnostic tests used with each approved drug product under the pilot, based on the clinical trial assays, will be made publicly available on the FDA's website following drug approval.

FDA NEWS RELEASE

For Immediate Release: June 06, 2023

FDA Permits Marketing of First COVID-19 At-Home Test Using Traditional Premarket Review Process

The FDA granted marketing authorization for the Cue™ COVID-19 Molecular Test. The product is a molecular nucleic acid amplification test (NAAT) that is intended to detect genetic material from SARS-CoV-2 virus present in nasal swabs from adults with signs and symptoms of upper respiratory infection. This test is the first at-home over-the-counter (OTC) test for COVID-19 to be granted marketing authorization using a traditional premarket review pathway and the first ever at-home test authorized using a traditional premarket review pathway for any respiratory illness.

The Cue™ COVID-19 Molecular Test consists of a single-use Cue™ COVID-19 test cartridge, a single-use Cue™ sample wand (nasal swab), and the Cue™ cartridge reader (sold separately). The test also uses the Cue™ Health app, which displays results when the test is complete. The reusable, battery-operated Cue™ Cartridge Reader runs the Cue™ Test Cartridge and communicates results directly to the app in about 20 minutes. In a study reviewed by the FDA, this test correctly identified 98.7% of negative and 92.9% of positive samples in individuals with signs and symptoms of upper respiratory infection.

As with all rapid tests, there is a risk of false positive and false negative results. Individuals who test positive for SARS-CoV-2 should take appropriate precautions to avoid spreading the virus and should seek follow-up care with their physician or health care

provider as additional testing may be necessary. Negative results should be confirmed by a lab-based molecular test if necessary for patient management. Individuals who test negative and continue to experience symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 or another respiratory infection and should seek follow up care with their health care provider.

Along with this De Novo authorization, the FDA is establishing criteria called special controls that define the requirements related to labeling and performance testing. When met, the special controls, in combination with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action also creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through the FDA's 510(k) pathway, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device.

The FDA granted the marketing authorization to Cue™ Health Inc.

FDA NEWS RELEASE

For Immediate Release: June 06, 2023

FDA Announces Additional Steps to Modernize Clinical Trials

The FDA announced the availability of a draft guidance with updated recommendations for good clinical practices (GCPs) aimed at modernizing the design and conduct of clinical trials, making them more agile without compromising data integrity or participant protections. The updates are intended to help pave the way for more efficient clinical trials to facilitate the development of medical products. The draft guidance is adopted from the International Council for Harmonisation's (ICH) recently updated E6(R3) draft guideline that was developed to enable the incorporation of rapidly developing technological and methodological innovations into the clinical trial enterprise.

GCPs are essential to help ensure the safety of trial participants, as well as the integrity of the data generated from trials. Over the years, the clinical trial enterprise has been viewed as costly, inefficient, and constrained by inadequate collaboration and insufficient utilization of technology, data sources, and innovations in design and conduct. The COVID-19 pandemic highlighted many of these challenges, while also spurring the development of new approaches.

This draft guidance, once finalized, would update the existing guidance titled, E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) (March 2018). The revised draft recommendations are designed to be applicable to a broad range of clinical trials including those with innovative design elements. These elements have the potential to make trials more efficient and less burdensome. Additionally, the modernized GCP recommendations encourage the use of fit-for-purpose innovative digital health technologies (DHTs). DHTs, such as wearable sensors could potentially facilitate more agile data collection and assist with patient recruitment.

The FDA recently issued other documents that complement these draft recommendations. The FDA supports the adoption of innovative trial designs, when appropriate, and in May released draft guidance proposing recommendations for the implementation of decentralized clinical trials. Regarding DHTs, the FDA also recently released a DHT framework document to guide the use of DHT-derived data in regulatory decision-making for drugs and biological products.

In addition to the recommendations supporting the modernization of trials, the principles outlined in the draft recommendations aim to make trials more efficient and potentially accelerate evidence generation for medical products by:

- Emphasizing the use of risk-based and proportionate approaches across the lifecycle of a clinical trial (e.g., data collection, monitoring, quality management). With this approach, investigators are encouraged to determine which data and clinical trial processes are most important to participant safety and data integrity, and focus efforts accordingly. This helps ensure investigators are allocating resources and efforts toward collecting and analyzing key data for the trial; and
- Encouraging sponsors to be proactive when it comes to a trial's quality considerations. Quality considerations include attributes of a trial which are fundamental to the protection of participants, the reliability of trial results and the decisions made based on those trial results. Having an early focus on these factors helps ensure trials are designed efficiently, avoiding possible delays from unnecessary complexities and burdens.

As part of the FDA's established process, this draft guidance will be open for public comment for 60 days. The ICH Expert Working Group will review and consider comments on this draft guidance, as well as feedback from other ICH member countries before finalizing the ICH guideline.

Current Drug Shortages Index (as of June 28, 2023):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma. Additional information regarding drug shortages can be found on the FDA website at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

0.9% Sodium Chloride Irrigation	***Currently in Shortage***
Albuterol Sulfate Inhalation Solution, 0.5%	***Currently in Shortage***
Alprostadil (Muse) Suppository	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acids	***Currently in Shortage***
Amoxapine Tablets	***Currently in Shortage***
Amoxicillin Oral Powder for Suspension	***Currently in Shortage***
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine for Injection	***Currently in Shortage***
Azithromycin (Azasite) Ophthalmic Solution 1%	***Currently in Shortage***
Bacteriostatic 0.9% Sodium Chloride Injection	***Currently in Shortage***
Bacteriostatic Water for Injection	***Currently in Shortage***
Belatacept (Nulojix) Lyophilized Powder for Injection	***Currently in Shortage***
Belladonna and Opium Suppositories	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride and Epinephrine Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Capecitabine Tablets	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefixime Oral Capsules	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloramphenicol Sodium Succinate Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Chlorothiazide Oral Suspension	***Currently in Shortage***
Cisplatin Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablets	***Currently in Shortage***
Collagenase Ointment	***Currently in Shortage***
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container	***Currently in Shortage***
Conjugated Estrogens/Bazedoxifene (Duavee) Tablet, Film Coated	***Currently in Shortage***
Cyclopentolate Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***
Desmopressin Acetate Nasal Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Injection	***Currently in Shortage***
Dextrose 10% Injection	***Currently in Shortage***
Dextrose 25% Injection	***Currently in Shortage***
Dextrose 5% Injection	***Currently in Shortage***
Dextrose 50% Injection	***Currently in Shortage***
Diazepam Rectal Gel	***Currently in Shortage***
Diflunisal Tablets	***Currently in Shortage***

Difluprednate Ophthalmic Emulsion	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Dimercaprol (Bal in Oil) Injection	***Currently in Shortage***
Disopyramide Phosphate (Norpace) Capsules	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide (Trulicity) Injection	***Currently in Shortage***
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution	***Currently in Shortage***
Edetate Calcium Disodium Injection	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Injection, 0.1mg/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***
Lorazepam Injection	***Currently in Shortage***
Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto) Injection	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***
Mepivacaine Hydrochloride Injection	***Currently in Shortage***
Methamphetamine Hydrochloride Tablets	***Currently in Shortage***
Methotrexate Injection	***Currently in Shortage***
Methyldopa Tablets	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Neomycin Sulfate Tablets	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Oxybutynin Chloride Syrup	***Currently in Shortage***

Oxytocin Injection	***Currently in Shortage***
Palifermin (Kepivance) Lyophilized Powder for Injection	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Parathyroid Hormone 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***
Rivaroxaban Oral Suspension	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Semaglutide (Ozempic) Injection	***Currently in Shortage***
Semaglutide (Wegovy) Injection	***Currently in Shortage***
Sincalide (Kinevac) Lyophilized Powder for Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection Bags	***Currently in Shortage***
Sodium Chloride 14.6% Injection	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection, 0.9% Vials and Syringes	***Currently in Shortage***
Sodium Phosphates Injection	***Currently in Shortage***
Somatropin Injection	***Currently in Shortage***
Sterile Water for Injection	***Currently in Shortage***
Sterile Water for Irrigation	***Currently in Shortage***
Streptozocin (Zanosar) Sterile Powder	***Currently in Shortage***
Sucralfate Tablets	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Sulfasalazine Tablets	***Currently in Shortage***
Technetium TC-99M Mebrofenin Injection	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injectable Suspension	***Currently in Shortage***
Triamcinolone Hexacetonide Injectable suspension	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsules	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***