OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
July 13, 2022
4:00pm

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

Viewing Access Only:
Please register for the webinar at:
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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 13, 2022

DATE: July 6, 2022

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

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

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Enclosed are the following items related to the 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 Xelstrym™ (Dextroamphetamine Transdermal System) and Update the Approval Criteria for the Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications – Appendix C

Action Item – Vote to Prior Authorize Livtencity™ (Maribavir) – Appendix D

Action Item – Vote to Prior Authorize Quviviq™ (Daridorexant) and Update the Approval Criteria for the Insomnia Medications – Appendix E

Action Item – Vote to Prior Authorize Invega Hafyera™ (Paliperidone Palmitate Injection) and Update the Approval Criteria for the Atypical Antipsychotic Medications – Appendix F

Action Item – Vote to Prior Authorize Ryplazim® (Plasminogen, Human-tvmh) – Appendix G

Action Item – Vote to Prior Authorize Citalopram Capsule, Dartisla ODT™ (Glycopyrrolate Orally Disintegrating Tablet), Fleqsuvy™ (Baclofen Oral Suspension), Lofena™ (Diclofenac Potassium Tablet), Loreev XR™ (Lorazepam Extended-Release Capsule), Norliqva® (Amlodipine Besylate Oral Solution), Seglentis® (Celecoxib/Tramadol Tablet), Sutab® (Sodium Sulfate/Magnesium Sulfate/Potassium Chloride Tablet), Tarpeyo™ (Budesonide Delayed-Release Capsule), Vuity™ (Pilocarpine 1.25% Ophthalmic Solution), and Xipere™ (Triamcinolone Acetonide Injection) – Appendix H

Action Item – Vote to Prior Authorize Camcevi™ (Leuprolide), Pluvicto® (Lutetium Lu 177 Vipivotide Tetraxetan), Tivdak® (Tisotumab Vedotin-tftv), and Welireg™ (Belzutifan) and Update the Approval Criteria for the Genitourinary and Cervical/Endometrial Cancer Medications – Appendix I

Annual Review of Colorectal Cancer Medications and 30-Day Notice to Prior Authorize Alymsys® (Bevacizumab-maly), Lonsurf® (Trifluridine/Tipiracil), and Stivarga® (Regorafenib) – Appendix J

Annual Review of Danyelza® (Naxitamab-gqgk), Koselugo® (Selumetinib), Pemazyre® (Pemigatinib), Qinlock™ (Ripretinib), and Truseltiq™ (Infigratinib) – Appendix K

Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Adlarity® (Donepezil Transdermal System) and Aduhelm™ (Aducanumab-avwa) – Appendix L

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

Annual Review of Various Systemic Antibiotics – Appendix N

Annual Review of Isturisa® (Osilodrostat) and 30-Day Notice to Prior Authorize Recorlev® (Levoketoconazole) – Appendix O

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – July 13, 2022 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

Dr. Stephen Anderson –	participating in person
Dr. Jennifer de los Angeles –	participating in person
Ms. Jennifer Boyett –	participating in person
Dr. Megan Hanner –	participating in person
Dr. Lynn Mitchell –	participating in person
Dr. John Muchmore –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person

Viewing Access Only via Zoom:

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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 8, 2022 DUR Board Meeting Minutes
   B. June 8, 2022 DUR Board Recommendations Memorandum

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

4. **Update on Medication Coverage Authorization Unit/Chronic Medication Adherence (CMA) Program Update – See Appendix B**
   A. Pharmacy Helpdesk Activity for June 2022
   B. Medication Coverage Activity for June 2022
   C. CMA Program Update

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

5. **Action Item – Vote to Prior Authorize Xelstrym™ (Dextroamphetamine Transdermal System) and Update the Approval Criteria for the Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications – See Appendix C**
   A. Market News and Updates
   B. Xelstrym™ (Dextroamphetamine Transdermal System) Product Summary
   C. College of Pharmacy Recommendations

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

6. **Action Item – Vote to Prior Authorize Livtencity™ (Maribavir) – See Appendix D**
   A. Market News and Updates
   B. Livtencity™ (Maribavir) Product Summary
   C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Quviviq™ (Daridorexant) and Update the Approval Criteria for the Insomnia Medications – See Appendix E**
   A. Market News and Updates
   B. Quviviq™ (Daridorexant) Product Summary
   C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Invega Hafyera™ (Paliperidone Palmitate Injection) and Update the Approval Criteria for the Atypical Antipsychotic Medications – See Appendix F**
   A. Market News and Updates
   B. Invega Hafyera™ (Paliperidone Palmitate) Product Summary
   C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Ryplazim® (Plasminogen, Human-tvmh) – See Appendix G**
   A. Market News and Updates
   B. Ryplazim® (Plasminogen, Human-tvmh) Product Summary
   C. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Citalopram Capsule, Dartisla ODT™ (Glycopyrrolate Orally Disintegrating Tablet), Fleqsuvy™ (Baclofen Oral Suspension), Lofena™ (Diclofenac Potassium Tablet), Loreev XR™ (Lorazepam Extended-Release Capsule), Norliqva® (Amlodipine Besylate Oral Solution), Seglentis® (Celecoxib/Tramadol Tablet), Sutab® (Sodium Sulfate/Magnesium Sulfate/Potassium Chloride Tablet), Tarpeyo™ (Budesonide Delayed-Release Capsule), Vuity™ (Pilocarpine 1.25% Ophthalmic Solution), and Xipere™ (Triamcinolone Acetonide Injection) – See Appendix H**
    A. Introduction
    B. Product Summaries and College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Camcevi™ (Leuprolide), Pluvicto® (Lutetium Lu 177 Vipivotide Tetraxetan), Tivdak® (Tisotumab Vedotin-tftv), and Welireg™ (Belzutifan) and Update the Approval Criteria for the Genitourinary and Cervical/Endometrial Cancer Medications – 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. **Annual Review of Colorectal Cancer Medications and 30-Day Notice to Prior authorize Alymsys® (Bevacizumab-maly), Lonsurf® (Trifluridine/Tipiracil), and Stivarga® (Regorafenib) – See Appendix J**
    A. Introduction
    B. Current Prior Authorization Criteria
    C. Utilization of Colorectal Cancer Medications
    D. Prior Authorization of Colorectal Cancer Medications
    E. Market News and Updates
    F. Product Summaries
    G. College of Pharmacy Recommendations
    H. Utilization Details of Colorectal Cancer Medications

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

13. **Annual Review of Danyelza® (Naxitamab-gqgk), Koselugo® (Selumetinib), Pemazyre® (Pemigatinib), Qinlock™ (Ripretinib), and Truseltiq™ (Infigratinib)– See Appendix K**
    A. Introduction
    B. Current Prior Authorization Criteria
    C. Utilization of Danyelza® (Naxitamab-gqgk), Koselugo® (Selumetinib), Pemazyre® (Pemigatinib), Qinlock™ (Ripretinib), and Truseltiq™ (Infigratinib)
    D. Prior Authorization of Danyelza® (Naxitamab-gqgk), Koselugo® (Selumetinib), Pemazyre® (Pemigatinib), Qinlock™ (Ripretinib), and Truseltiq™ (Infigratinib)
    E. Market News and Updates
    F. College of Pharmacy Recommendations
    G. Utilization Details of Danyelza® (Naxitamab-gqgk), Koselugo® (Selumetinib), Pemazyre® (Pemigatinib), Qinlock™ (Ripretinib), and Truseltiq™ (Infigratinib)

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

14. **Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Adlarity® (Donepezil Transdermal System) and Aduhelm™ (Aducanumab-avwa) – See Appendix L**
    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. Aduhelm™ (Aducanumab-avwa) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Alzheimer's Disease Medications

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

15. Annual Review of Testosterone Products and 30-Day Notice to Prior Authorize Tlando® (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. Cost Comparison
F. College of Pharmacy Recommendations
G. Utilization Details of Testosterone Products

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

16. Annual Review of Various Systemic Antibiotics – See Appendix N

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

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

17. Annual Review of Isturisa® (Osilodrostat) and 30-Day Notice to Prior Authorize Recorlev® (Levoketoconazole) – See Appendix O

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

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

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

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

19. Future Business* (Upcoming Product and Class Reviews)
No live DUR Board meeting scheduled for August 2022. August 2022 will be a packet-only meeting.

A. Intravenous (IV) Iron Products
B. Ophthalmic Anti-Inflammatory Products

C. Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications
D. Topical Corticosteroids
*Future product and class reviews subject to change.

20. Adjournment

NOTE: An analysis of the atypical [Aged, Blind, and Disabled (ABD)] patient subgroup of the Oklahoma Medicaid population has been performed pertaining to all recommendations included in this DUR Board meeting packet to ensure fair and knowledgeable deliberation of the potential impact of the recommendations on this patient population.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING JUNE 8, 2022

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

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

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Melody Anthony; Chief Operating Officer		X
Mark Brandenburg, M.D., MSC; Medical Director	X	
Ellen Buettner; Chief of Staff		X
Kevin Corbett, C.P.A.; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	
Josh Holloway, J.D.; Deputy General Counsel	X	

Debra Montgomery, D.O.; Medical Director	X	
Traylor Rains; State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Interim Chief Medical Officer	X	
Kara Smith, J.D.; General Counsel		X
Michelle Tahah, Pharm.D.; Clinical Pharmacist		X
Toney Welborn, M.D., MPH, MS; Medical Director		X

OTHERS PRESENT:	
Kenneth Berry, Alkermes	Lance Lewis, Corium
Brandon Ross, Merck	Frank Alvarado, Johnson & Johnson
Christopher Ngai, Calliditas Therapeutics	Camille Kerr, Regeneron
Brad Burris, Pear Therapeutics	Mark Kaiser, Otsuka
Clint Degner, Novartis	Brent Parker, Merck
Rick Dabner, Alnylam	Madeline Shurtleff, Otsuka
Audrey Rattan, Alkermes	David Prather, Novo Nordisk
Sheri Jepsen, Seagen	Steven Angelcyk, Embecta
Matthew Wright, Artia Solutions	Jenny Ebert, Ascendis
Heather Higgins, Jazz Pharma	David Block, Corium
Chris Stanfield, Supernus	Will Hameline, McDermmot
Ruthel Goss, Biomarin	Lance Lewis, Corium
Kristi Kemp, AbbVie	Rhonda Clark, Indivior
Tom Seignious, Azurity	Aaron Austin, Takeda
Brian Maves, Pfizer	Lori Howarth, Bayer
Marc Parker, Sunovion	Burl Beasley, OMES
Bryan Dillon, Otsuka	Dave Miley, Teva
Jennifer Davis, Gilead	Lindsey Walter, Novartis
Gina Heinen, Novo Nordisk	Nima Nabavi, Amgen
Porscha Showers, Gilead	

PRESENT FOR PUBLIC COMMENT:	
Madeline Shurtleff, Otsuka	Kenneth Berry, Alkermes
Christopher Ngai, Calliditas Therapeutics	

AGENDA ITEM NO. 1: **CALL TO ORDER**
1A: ROLL CALL
Dr. Muchmore called the meeting to order at 4:01pm. Roll call by Dr. Wilcox established the presence of a quorum.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: **PUBLIC COMMENT FORUM**
2A: AGENDA ITEM NO. 15 MADELINE SHURTLEFF
2B: AGENDA ITEM NO. 15 KENNETH BERRY
2C: AGENDA ITEM NO. 17 CHRISTOPHER NGAI
ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: **APPROVAL OF DUR BOARD MEETING MINUTES**
3A: APRIL 13, 2022 DUR MINUTES
3B: MAY 11, 2022 DUR MINUTES
Materials included in agenda packet; presented by Dr. Muchmore

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

<u>AGENDA ITEM NO. 4:</u> UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/SOONERPSYCH AND PEDIATRIC SOONERPSYCH ANTIPSYCHOTIC MONITORING PROGRAM UPDATE

4A: PHARMACY HELPDESK ACTIVITY FOR MAY 2022
4B: MEDICATION COVERAGE ACTIVITY FOR MAY 2022
4C: SOONERPSYCH AND PEDIATRIC SOONERPSYCH ANTIPSYCHOTIC MONITORING PROGRAM UPDATE

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

<u>AGENDA ITEM NO. 5:</u> APPROVAL OF MAY 2022 DUR BOARD RECOMMENDATIONS

5A: VOTE TO PRIOR AUTHORIZE RELEUKO™ (FILGRASTIM-AYOW) AND UPDATE THE APPROVAL CRITERIA FOR THE GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS)
- **I. MARKET NEWS AND UPDATES**
- **II. COST COMPARISON FOR FILGRASTIM PRODUCTS**
- **III. COLLEGE OF PHARMACY RECOMMENDATIONS**

5B: VOTE TO PRIOR AUTHORIZE LAMPIT® (NIFURTIMOX)
- **I. MARKET NEWS AND UPDATES**
- **II. LAMPIT® (NIFURTIMOX) PRODUCT SUMMARY**
- **III. COLLEGE OF PHARMACY RECOMMENDATIONS**

5C: VOTE TO PRIOR AUTHORIZE SKYTROFA® (LONAPEGSOMATROPIN-TCGD) AND VOXZOGO™ (VOSORITIDE) AND UPDATE THE APPROVAL CRITERIA FOR THE GROWTH HORMONE PRODUCTS
- **I. MARKET NEWS AND UPDATES**
- **II. PRODUCT SUMMARIES**
- **III. COLLEGE OF PHARMACY RECOMMENDATIONS**

5D: VOTE TO PRIOR AUTHORIZE PONVORY® (PONESIMOD) AND UPDATE THE APPROVAL CRITERIA FOR THE MULTIPLE SCLEROSIS MEDICATIONS
- **I. MARKET NEWS AND UPDATES**
- **II. PONVORY® (PONESIMOD) PRODUCT SUMMARY**
- **III. COLLEGE OF PHARMACY RECOMMENDATIONS**

5E: VOTE TO PRIOR AUTHORIZE BREXAFEMME® (IBREXAFUNGERP) AND UPDATE THE APPROVAL CRITERIA FOR THE SYSTEMIC ANTIFUNGAL MEDICATIONS
- **I. MARKET NEWS AND UPDATES**
- **II. BREXAFEMME® (IBREXAFUNGERP) PRODUCT SUMMARY**
- **III. COLLEGE OF PHARMACY RECOMMENDATIONS**

5F: VOTE TO PRIOR AUTHORIZE ZYNLONTA™ (LONCASTUXIMAB TESIRINE) AND UPDATE THE APPROVAL CRITERIA FOR THE LYMPHOMA MEDICATIONS
- **I. MARKET NEWS AND UPDATES**
- **II. ZYNLONTA™ (LONCASTUXIMAB TESIRINE-LPLY) PRODUCT SUMMARY**
- **III. COLLEGE OF PHARMACY RECOMMENDATIONS**

Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Mitchell
ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE RYALTRIS™ (MOMETASONE OLOPATADINE NASAL SPRAY) AND UPDATE THE APPROVAL CRITERIA FOR THE NASAL ALLERGY MEDICATIONS**

6A: MARKET NEWS AND UPDATES
6B: RYALTRIS™ (MOMETASONE/OLOPATADINE) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE NEXVIAZYME® (AVALGLUCOSIDASE ALFA-NGPT)**

7A: MARKET NEWS AND UPDATES
7B: NEXVIAZYME® (AVALGLUCOSIDASE ALFA-NGPT) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE KERENDIA® (FINERENONE), REZVOGLAR™ (INSULIN GLARGINE-AGLR), AND SEMGLEE® (INSULIN GLARGINE-YFGN) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTI-DIABETIC MEDICATIONS**

8A: MARKET NEWS AND UPDATES
8B: KERENDIA® (FINERENONE) PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Hanner
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE EXKIVITY® (MOBOCERTINIB), LUMAKRAS™ (SOTORASIB), AND RYBREVANT™ (AMIVANTAMAB-VMJW) AND UPDATE THE APPROVAL CRITERIA FOR THE LUNG CANCER MEDICATIONS**

9A: MARKET NEWS AND UPDATES
9B: PRODUCT SUMMARIES
9C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 10: **ANNUAL REVIEW OF GENITOURINARY AND CERVICAL/ENDOMETRIAL CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE CAMCEVI™ (LEUPROLIDE), PLUVICTO® (LUTETIUM LU 177 VIPIVOTIDE TETRAXETAN), TIVDAK® (TISOTUMAB VEDOTIN-TFTY) AND WELIREG™ (BELZUTIFAN)**

10A: INTRODUCTION
10B: CURRENT PRIOR AUTHORIZATION CRITERIA
10C: UTILIZATION OF GENITOURINARY AND CERVICAL/ENDOMETRIAL CANCER MEDICATIONS
10D: PRIOR AUTHORIZATION OF GENITOURINARY AND CERVICAL/ ENDOMETRIAL CANCER MEDICATIONS
10E: MARKET NEWS AND UPDATES
10F: PRODUCT SUMMARIES

10G: COLLEGE OF PHARMACY RECOMMENDATIONS
10H: UTILIZATION DETAILS OF GENITOURINARY AND CERVICAL/ENDOMETRIAL CANCER MEDICATIONS

Materials included in agenda packet; presented by Dr. Borders

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

<u>AGENDA ITEM NO. 11:</u> ANNUAL REVIEW OF THE SOONERCARE PHARMACY BENEFIT

11A: SUMMARY
11B: MEDICAID DRUG REBATE PROGRAM
11C: ALTERNATIVE PAYMENT MODELS
11D: DRUG APPROVAL TRENDS
11E: TRADITIONAL VERSUS SPECIALTY PHARMACY PRODUCTS
11F: TOP 10 TRADITIONAL THERAPEUTIC CLASSES BY REIMBURSEMENT: CALENDAR YEAR 2021
11G: TOP 10 SPECIALTY THERAPEUTIC CLASSES BY REIMBURSEMENT: CALENDAR YEAR 2021
11H: TOP 10 MEDICATIONS BY REIMBURSEMENT: CALENDAR YEAR 2021
11I: COST PER CLAIM
11J: MARKET PROJECTIONS
11K: CONCLUSION
11L: TOP 50 REIMBURSED DRUGS BY CALENDAR YEAR
11M: TOP 50 MEDICATIONS BY TOTAL NUMBER OF CLAIMS: CALENDAR YEAR 2021
11N: TOP 10 TRADITIONAL AND SPECIALTY THERAPEUTIC CATEGORIES BY CALENDAR YEAR
11O: CALENDAR YEAR AGE GROUP COMPARISON

Materials included in agenda packet; presented by Dr. Teel

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 12:</u> ANNUAL REVIEW OF ATTENTION-DEFICIT/ HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE XELSTRYM™ (DEXTROAMPHETAMINE TRANSDERMAL SYSTEM)

12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
12C: PRIOR AUTHORIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
12D: OKLAHOMA RESOURCES
12E: MARKET NEWS AND UPDATES
12F: COLLEGE OF PHARMACY RECOMMENDATIONS
12G: UTILIZATION DETAILS OF ADHD AND NARCOLEPSY MEDICATIONS

Materials included in agenda packet; presented by Dr. Travers

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

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF ANTIVIRAL MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE LIVTENCITY™ (MARIBAVIR)

13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF ANTIVIRAL MEDICATIONS
13C: PRIOR AUTHORIZATION OF ANTIVIRAL MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: LIVTENCITY™ (MARIBAVIR) PRODUCT SUMMARY
13F: COLLEGE OF PHARMACY RECOMMENDATIONS
13G: UTILIZATON DETAILS OF ANTIVIRAL MEDICATIONS

Materials included in agenda packet; presented by Dr. Ha

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

<u>AGENDA ITEM NO. 14:</u> ANNUAL REVIEW OF INSOMNIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE QUVIVIQ™ (DARIDOREXANT)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF INSOMNIA MEDICATIONS
14C: PRIOR AUTHORIZATION OF INSOMNIA MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: QUVIVIQ™ (DARIDOREXANT) PRODUCT SUMMARY
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZTION DETAILS OF INSOMNIA MEDICATIONS
Materials included in agenda packet; presented by Dr. Ha
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

<u>AGENDA ITEM NO. 15:</u> ANNUAL REVIEW OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE INVEGA HAFYERA™ (PALIPERIDONE PALMITATE INJECTION)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
15C: PRIOR AUTHORIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
15D: OKLAHOMA RESOURCES
15E: MARKET NEWS AND UPDATES
15F: INVEGA HAFYERA™ (PALIPERIDONE PALMITATE INJECTION) PRODUCT SUMMARY
15G: COLLEGE OF PHARMACY RECOMMENDATIONS
15H: 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. 16:</u> 30-DAY NOTICE TO PRIOR AUTHORIZE RYPLAZIM® (PLASMINOGEN, HUMAN-TVMH)
16A: INTRODUCTION
16B: RYPLAZIM® (PLASMINOGEN, HUMAN-TVMH) PRODUCT SUMMARY
16C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

<u>AGENDA ITEM NO. 17:</u> ANNUAL REVIEW OF VARIOUS SPECIAL FORMULATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE CITALOPRAM CAPSULE, DARTISLA ODT™ (GLYCOPYRROLATE ORALLY DISINTEGRATING TABLET), FLEQSUVY™ (BACLOFEN ORAL SUSPENSION), LOFENA™ (DICLOFENAC POTASSIUM TABLET), LOREEV XR™ (LORAZEPAM EXTENDED-RELEASE CAPSULE), NORLIQVA® (AMLODIPINE BESYLATE ORAL SOLUTION), SEGLENTIS® (CELECOXIB/TRAMADOL TABLET), SUTAB® (SODIUM SULFATE/MAGNESIUM SULFATE/POTASSIUM CHLORIDE TABLET), TARPEYO™ (BUDESONIDE DELAYED-RELEASE CAPSULE), VUITY™ (PILOCARPINE 1.25% OPHTHALMIC SOLUTION), AND XIPERE™ (TRIAMCINOLONE ACETONIDE INJECTIONS)
17A: INTRODUCTION
17B: CURRENT PRIOR AUTHORIZATION CRITERIA
17C: UTILIZATION OF VARIOUS SPECIAL FORMULATIONS
17D: PRIOR AUTHORIZATION OF VARIOUS SPECIAL FORMULATIONS
17E: PRODUCT SUMMARIES
17F: COLLEGE OF PHARMACY RECOMMENDATIONS
17G: UTILIZATION DETAILS OF VARIOUS SPECIAL FORMULATIONS

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

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

<u>AGENDA ITEM NO. 19:</u> FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
19A: ALZHEIMER'S DISEASE MEDICATIONS
19B: COLORECTAL CANCER MEDICATIONS
19C: TESTOSTERONE PRODUCTS
19D: VARIOUS SYSTEMIC ANTIBIOTICS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 20:</u> ADJOURNMENT
The meeting was adjourned at 6:07pm.

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

Memorandum

Date: June 10, 2022

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

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

Subject: DUR Board Recommendations from Meeting on June 8, 2022

Recommendation 1: SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update

NO ACTION REQUIRED.

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

MOTION CARRIED by unanimous approval.

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

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

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

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

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

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Granix® (tbo-filgrastim), ~~Neulasta® (pegfilgrastim)~~, Neupogen® (filgrastim), Nyvepria™ (pegfilgrastim-apgf), Zarxio® (filgrastim-sndz), or Ziextenzo® (pegfilgrastim-bmez) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Recommendation 2B: Vote to Prior Authorize Lampit® (Nifurtimox)

MOTION CARRIED by unanimous approval.

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

Lampit® (Nifurtimox) Approval Criteria:

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

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

Recommendation 2C: Vote to Prior Authorize Skytrofa® (Lonapegsomatropin-tcgd) and Voxzogo™ (Vosoritide) and Update the Approval Criteria for the Growth Hormone Products

MOTION CARRIED by unanimous approval.

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

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

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

Skytrofa® (Lonapegsomatropin-tcgd) Approval Criteria:

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

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

Voxzogo™ (Vosoritide) Approval Criteria:

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

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

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

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

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

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

Growth Hormone Tier-2 Approval Criteria:

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

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

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

Discontinuation of Therapy or Transition to Adult Therapy Criteria:

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

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

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

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

Growth Hormone Deficiency (GHD) Approval Criteria:

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

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

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

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

Panhypopituitarism Approval Criteria:

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

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

Neurosecretory Dysfunction Approval Criteria:

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

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

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

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

Idiopathic Short Stature Approval Criteria:

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

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

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

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

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

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

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

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

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

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

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

Short Stature Associated with Noonan Syndrome Approval Criteria:

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

iii. GV <2.5cm/year.

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

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

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

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

iii. GV <2.5cm/year; and

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

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

Small for Gestational Age (SGA) Approval Criteria:

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

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

Recommendation 2D: Vote to Prior Authorize Ponvory® (Ponesimod) and Update the Approval Criteria for the Multiple Sclerosis Medications

MOTION CARRIED by unanimous approval.

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

Ponvory® (Ponesimod) Approval Criteria:

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

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

Zeposia® (Ozanimod) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following in adults:
   a. Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; or
   b. Moderately to severely active ulcerative colitis (UC); and
2. Member must not have any contraindications for use of Zeposia® including:
   a. Experienced myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or

   b. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; or
   c. Have severe untreated sleep apnea; or
   d. Concurrent use of monoamine oxidase inhibitors (MAOIs); and
3. Member must not have received prior treatment with alemtuzumab; and
4. Member must not be concurrently using strong CYP2C8 inhibitors/inducers or breast cancer resistance protein (BCRP) inhibitors; and
5. Verification from the prescriber that member has no active infection(s); and
6. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
7. Prescriber must conduct an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Zeposia®; and
8. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
9. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and
10. Verification from the prescriber that the member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and that the member will be followed with appropriate monitoring per package labeling; and
11. Verification from the prescriber that the member has been assessed for previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Zeposia®; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
13. Female members of reproductive potential must be willing to use effective contraception during treatment with Zeposia® and for at least 3 months after discontinuing treatment; and
14. For the diagnosis of MS, member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; or
15. For the diagnosis of UC, member must have had an inadequate response, loss of response, or intolerance to oral aminosalicylates, corticosteroids, immunomodulators (e.g., 6-mercaptopurine,

azathioprine), and a biologic [e.g., tumor necrosis factor (TNF) blocker]. Tier structure applies; and

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

Recommendation 2E: Vote to Prior Authorize Brexafemme® (Ibrexafungerp) and Update the Approval Criteria for the Systemic Antifungal Medications

MOTION CARRIED by unanimous approval.

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

Brexafemme® (Ibrexafungerp) Approval Criteria:

1. An FDA approved diagnosis of vulvovaginal candidiasis (VVC); and
2. Member must be an adult female or a post-menarchal pediatric female; and
3. Prescriber must verify that female members are not pregnant and are currently using reliable contraception; and
4. Member must not be taking concurrent strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, long-acting barbiturates, bosentan, efavirenz, etravirine); and
5. Authorization consideration requires a patient-specific, clinically significant reason why oral fluconazole and all topical antifungals (prescription and over-the-counter) FDA approved for the treatment of VVC are not appropriate for the member; and
6. A quantity limit of 4 tablets for a 1-day supply will apply.

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

Noxafil® (Posaconazole) Approval Criteria:

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

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

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

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

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

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

Recommendation 2F: Vote to Prior Authorize Zynlonta® (Loncastuximab Tesirine-lply) and Update the Approval Criteria for the Lymphoma Medications

MOTION CARRIED by unanimous approval.

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

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

1. Diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified, or DLBCL arising from low grade lymphoma, or high-grade B-cell lymphoma; and

2. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
3. If previous CD19-directed therapy was used, patient must have a biopsy that shows CD19 protein expression after completion of the CD19-directed therapy; and
4. A patient-specific, clinically significant reason why tafasitamab in combination with lenalidomide is not appropriate for the member must be provided.

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

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

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

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

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

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

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

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

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

~~1. As a single agent; and~~

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

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

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

~~4. For second-line or greater therapy:~~

~~a. As a single agent; and~~

~~b. Tumor expresses programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1]; and~~

~~c. Following disease progression on or after 2 or more lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2-targeted therapy.~~

Recommendation 3: Vote to Prior Authorize Ryaltris™ (Olopatadine/Mometasone Nasal Spray) and Update the Approval Criteria for the Nasal Allergy Medications

MOTION CARRIED by unanimous approval.

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

Additionally, the College of Pharmacy recommends the following changes to the nasal allergy medications PBPA Tier chart based on net costs (updates noted in red):

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

Nasal Allergy Medications		
Tier-1	**Tier-2**	**Tier-3**
azelastine 137mcg, 0.1% (Astelin®)	~~**azelastine 137mcg, 0.1% (Astelin®)**~~	~~**azelastine 205.5mcg, 0.15% (Astepro®)**~~
beclomethasone (Beconase® AQ)	**azelastine 205.5mcg, 0.15% (Astepro®)**	azelastine/fluticasone (Dymista®)
fluticasone (Flonase®)	~~**beclomethasone (Qnasl® 80mcg)**~~	beclomethasone (Qnasl® **80mcg,** 40mcg)
	mometasone (Nasonex®)	ciclesonide (Omnaris®, Zetonna®)
		flunisolide (Nasalide®,
		fluticasone (Veramyst®)
		fluticasone (Xhance®)*
		~~**mometasone (Nasonex®)**~~
		olopatadine (Patanase®)
		olopatadine/mometasone (Ryaltris™)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Xhance®: Unique criteria applies.

Recommendation 4: Vote to Prior Authorize Nexviazyme® (Avalglucosidase Alfa-ngpt)

MOTION CARRIED by unanimous approval.

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

Nexviazyme® (Avalglucosidase Alfa-ngpt) Approval Criteria:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and
2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Prescriber must document presence of symptoms of Pompe disease; and
4. Nexviazyme® must be prescribed by a geneticist or a physician that specializes in the treatment of Pompe disease and/or inherited genetic disorders; and
5. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing; and

6. Initial approval will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent authorizations will be for the duration of 1 year.

Recommendation 5: Vote to Prior Authorize Kerendia® (Finerenone), Rezvoglar™ (Insulin Glargine-aglr), and Semglee® (Insulin Glargine-yfgn) and Update the Approval Criteria for the Anti-Diabetic Medications

MOTION CARRIED by unanimous approval.

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

Kerendia® (Finerenone) Approval Criteria:

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

a. Kerendia® 10mg once daily in members with eGFR 25 to <60mL/min/1.73m²; or
b. Kerendia® 20mg once daily in members with eGFR ≥60mL/min/1.73m².

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

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

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Levemir® (insulin detemir) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

Anti-Diabetic Medications Tier-2 Approval Criteria:

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

Recommendation 6: Vote to Prior Authorize Exkivity® (Mobocertinib), Lumakras™ (Sotorasib), and Rybrevant® (Amivantamab-vmjw) and Update the Approval Criteria for the Lung Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Exkivity® (mobocertinib), Lumakras™ (sotorasib), and Rybrevant® (amivantamab-vmjw) with the following criteria (new criteria noted in red):

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

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

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

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

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

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

The College of Pharmacy recommends implementing the prior authorization of Mvasi® (bevacizumab-awwb) with the following updates and recommends updating the approval criteria for Zirabev® (bevacizumab-bvzr) based on net costs (updates noted in red):

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

1. A patient-specific, clinically significant reason why the member cannot use Avastin® (bevacizumab) or Zirabev® (bevacizumab-bvzr), which ~~is~~ are available without prior authorization, must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.
   ~~*Based on the net cost in comparison to Avastin®, Mvasi® is currently available without prior authorization.~~

Zirabev® (Bevacizumab-bvzr) Approval Criteria*:

1. ~~A patient-specific, clinically significant reason why the member cannot use Avastin® (bevacizumab) must be provided.~~ Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

*Based on the net cost in comparison to available bevacizumab products, Zirabev® is currently available without prior authorization.

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

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

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

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

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

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

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

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

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

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

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

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

1. Diagnosis of NSCLC; and
    a. As adjuvant therapy following tumor resection in members with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations; or
2. Diagnosis of metastatic NSCLC; and
    a. EGFR T790M mutation-positive disease ~~and following progression on erlotinib, afatinib, or gefitinib for asymptomatic disease, symptomatic brain lesions, or multiple symptomatic systemic lesions~~; or
    b. ~~First-line treatment of patients with~~ EGFR exon 19 deletions or exon 21 L858R mutations.

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

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

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

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

Recommendation 7: Annual Review of Genitourinary and Cervical/Endometrial Cancer Medications and 30-Day Notice to Prior Authorize Camcevi™ (Leuprolide), Pluvicto™ (Lutetium Lu 177 Vipivotide Tetraxetan), Tivdak® (Tisotumab Vedotin-tftv), and Welireg™ (Belzutifan)

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

Recommendation 8: Annual Review of the SoonerCare Pharmacy Benefit

NO ACTION REQUIRED.

Recommendation 9: Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Xelstrym™ (Dextroamphetamine Transdermal System)

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

Recommendation 10: Annual Review of Antiviral Medications and 30-Day Notice to Prior Authorize Livtencity™ (Maribavir)

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

Recommendation 11: Annual Review of Insomnia Medications and 30-Day Notice to Prior Authorize Quviviq™ (Daridorexant)

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

Recommendation 12: Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Invega Hafyera™ (Paliperidone Palmitate Injection)

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

Recommendation 13: 30-Day Notice to Prior Authorize Ryplazim® (Plasminogen, Human-tvmh)

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

Recommendation 14: Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Citalopram Capsule, Dartisla ODT™ [Glycopyrrolate Orally Disintegrating Tablet (ODT)], Fleqsuvy™ (Baclofen Oral Suspension), Lofena™ (Diclofenac Potassium Tablet), Loreev XR™ [Lorazepam Extended-Release (ER) Capsule], Norliqva® (Amlodipine Oral Solution), Seglentis® (Celecoxib/Tramadol Tablet), Sutab® (Sodium Sulfate/Magnesium Sulfate/Potassium Chloride Tablet), Tarpeyo™ [Budesonide Delayed-Release (DR) Capsule], Vuity™ (Pilocarpine 1.25% Ophthalmic Solution), and Xipere™ (Triamcinolone Acetonide Injection)

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

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

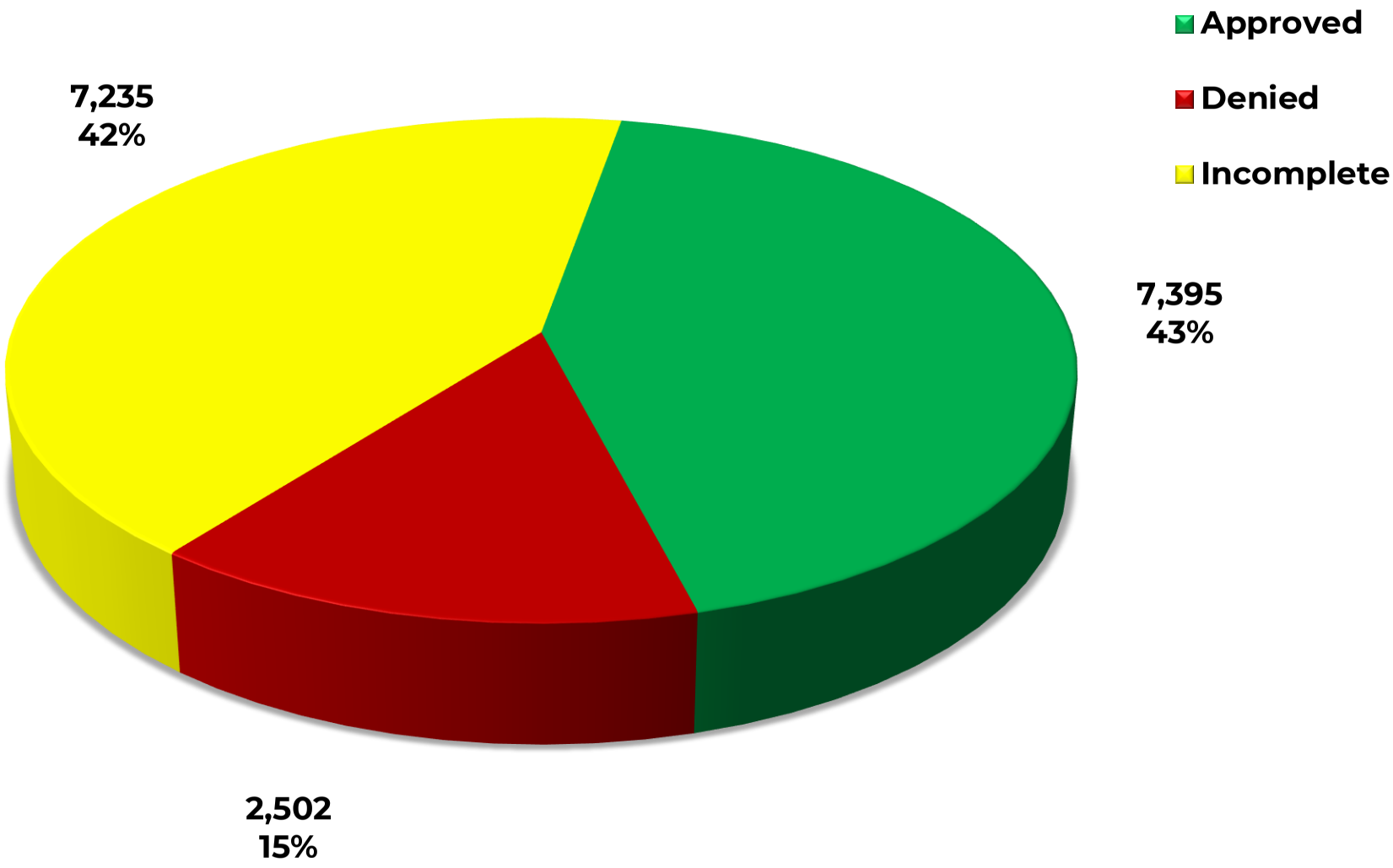
NO ACTION REQUIRED.

Recommendation 16: Future Business

NO ACTION REQUIRED.

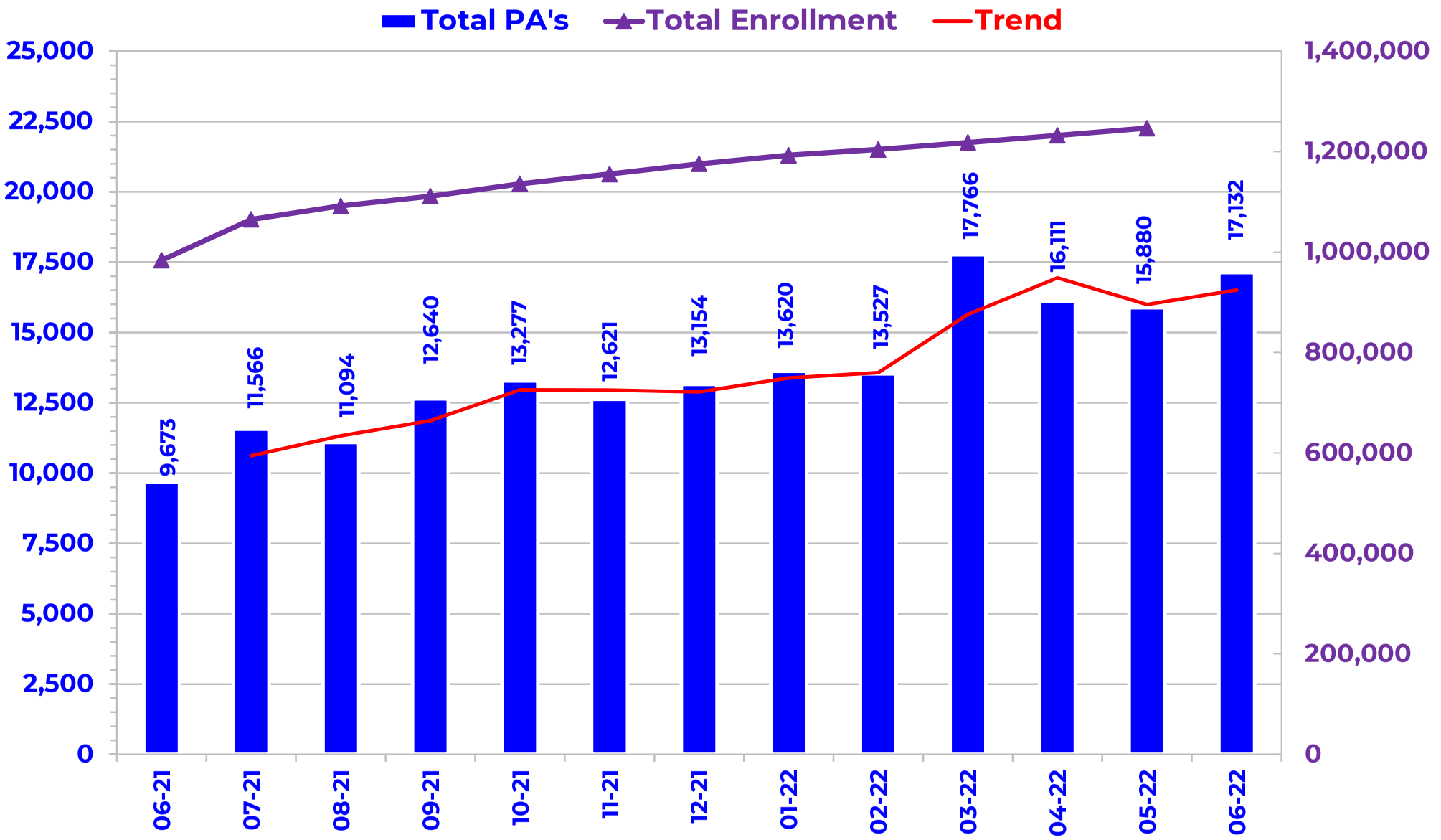
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: JUNE 2022



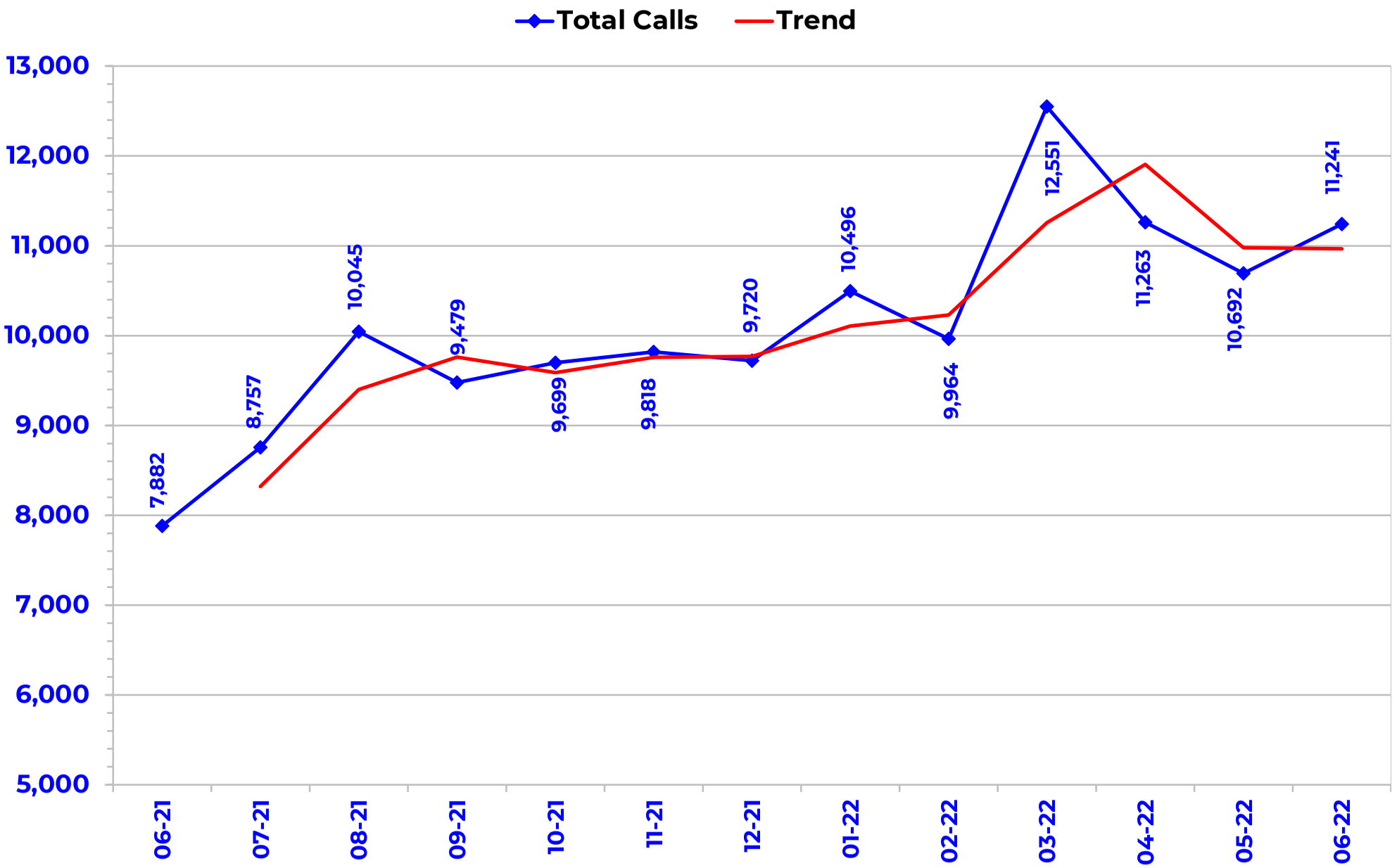
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: JUNE 2021 – JUNE 2022



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
JUNE 2021 – JUNE 2022



Prior Authorization Activity

6/1/2022 Through 6/30/2022

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	115	17	5	93	328
Analgesic - NonNarcotic	17	0	3	14	0
Analgesic, Narcotic	422	160	47	215	153
Angiotensin Receptor Antagonist	10	2	2	6	359
Antiasthma	91	24	36	31	238
Antibiotic	55	20	3	32	269
Anticonvulsant	235	108	21	106	307
Antidepressant	443	91	78	274	338
Antidiabetic	1,700	599	336	765	358
Antigout	16	7	1	8	359
Antihemophilic Factor	21	14	0	7	274
Antihistamine	55	14	15	26	340
Antimalarial Agent	162	110	7	45	352
Antimigraine	643	88	216	339	265
Antineoplastic	259	179	16	64	168
Antiobesity	17	0	15	2	0
Antiparasitic	45	9	10	26	23
Antiulcers	66	8	17	41	95
Anxiolytic	41	3	3	35	220
Atypical Antipsychotics	666	255	95	316	353
Benign Prostatic Hypertrophy	18	2	11	5	359
Biologics	404	191	55	158	268
Bladder Control	131	13	37	81	359
Blood Thinners	814	452	41	321	338
Botox	76	46	17	13	303
Buprenorphine Medications	125	53	12	60	86
Calcium Channel Blockers	19	2	1	16	234
Cardiovascular	129	48	21	60	341
Chronic Obstructive Pulmonary Disease	382	81	103	198	327
Constipation/Diarrhea Medications	296	51	93	152	246
Contraceptive	58	13	13	32	345
Corticosteroid	13	0	3	10	0
Dermatological	505	178	125	202	212
Diabetic Supplies	1,007	357	174	476	251
Endocrine & Metabolic Drugs	128	58	15	55	195
Erythropoietin Stimulating Agents	30	18	6	6	102
Estrogen Derivative	17	0	7	10	0
Fibromyalgia	16	4	3	9	360
Fish Oils	34	3	8	23	360

* 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	333	48	60	225	246
Genitourinary Agents	17	4	4	9	208
Glaucoma	30	2	2	26	133
Growth Hormones	132	91	13	28	146
Hematopoietic Agents	26	13	2	11	210
Hepatitis C	287	199	18	70	9
HFA Rescue Inhalers	20	0	1	19	0
Insomnia	105	4	31	70	178
Insulin	428	126	43	259	347
Miscellaneous Antibiotics	39	8	3	28	33
Multiple Sclerosis	92	37	14	41	192
Muscle Relaxant	59	7	16	36	94
Nasal Allergy	143	42	25	76	111
Neurological Agents	171	57	35	79	241
Neuromuscular Agents	17	7	3	7	257
NSAIDs	64	4	15	45	245
Ocular Allergy	26	2	5	19	57
Ophthalmic	31	2	20	9	358
Ophthalmic Anti-infectives	31	8	4	19	9
Ophthalmic Corticosteroid	14	4	1	9	276
Osteoporosis	35	14	8	13	359
Other*	452	113	58	281	283
Otic Antibiotic	52	10	2	40	9
Pediculicide	13	4	1	8	5
Respiratory Agents	50	34	2	14	275
Smoking Cess.	26	7	11	8	134
Statins	73	13	18	42	198
Stimulant	1,826	1,198	93	535	348
Synagis	65	43	10	12	82
Testosterone	222	56	55	111	333
Thyroid	23	6	1	16	268
Topical Antifungal	54	5	9	40	64
Topical Corticosteroids	94	3	55	36	270
Vitamin	147	28	61	58	167
Pharmacotherapy	85	83	0	2	278
Emergency PAs	0	0	0	0	
Total	**14,563**	**5,560**	**2,370**	**6,633**	

* 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	35	17	4	14	322
Compound	20	15	0	5	10
Cumulative Early Refill	1	0	0	1	0
Diabetic Supplies	9	6	1	2	252
Dosage Change	463	432	6	25	16
High Dose	4	2	1	1	186
IHS-Brand	2	2	0	0	360
Ingredient Duplication	4	2	1	1	177
Lost/Broken Rx	151	144	1	6	20
MAT Override	257	197	8	52	86
NDC vs Age	374	221	51	102	254
NDC vs Sex	12	7	1	4	114
Nursing Home Issue	68	66	0	2	12
Opioid MME Limit	148	58	6	84	118
Opioid Quantity	41	27	1	13	172
Other	76	62	1	13	20
Quantity vs Days Supply	786	495	42	249	256
STBS/STBSM	12	10	0	2	47
Step Therapy Exception	27	16	2	9	359
Stolen	17	14	1	2	17
Third Brand Request	62	42	5	15	14
Overrides Total	**2,569**	**1,835**	**132**	**602**	
Total Regular PAs + Overrides	**17,132**	**7,395**	**2,502**	**7,235**	

Denial Reasons	
Unable to verify required trials.	6,230
Does not meet established criteria.	2,533
Lack required information to process request.	976
Other PA Activity	
Duplicate Requests	1,330
Letters	36,192
No Process	6
Changes to existing PAs	1,215
Helpdesk Initiated Prior Authorizations	1,072
PAs Missing Information	0

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

Chronic Medication Adherence (CMA) Program Update

Oklahoma Health Care Authority
July 2022

Prescriber Mailing: Diabetes and Cardiovascular Maintenance Medications[1]

The CMA educational mailing is processed quarterly and sent to prescribers with members on chronic maintenance medications for diabetes mellitus (DM), blood pressure (BP), and cholesterol. The purpose of the CMA mailing is to encourage medication adherence and improve the quality of care for SoonerCare members receiving these medications. The CMA inclusion criteria at determination of the prescriber mailing list requires the prescriber to have ≥7 SoonerCare members taking DM, BP, and cholesterol medications. 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 in SoonerCare paid pharmacy claims.

Previously, prescribers were selected randomly to receive letters if they met the inclusion criteria for the mailing module. In February 2016, the CMA mailing changed to sending the educational letters to the same consistent prescribers, and in February 2018, the mailing was updated to include both cardiovascular (CV) and DM medications in each mailing rather than alternating mailings. Included 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. Every mailing includes a detailed patient list with each member's PDC, specific medication name and strength, total day supply, and total study days. Each mailing also includes a list of medication adherence

patient resources intended to offer prescribers 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 2020 to the most recent mailing in May 2022:

Date Letter Processed	Total Letters Mailed to Prescribers	Total Members Included
February 2020*	243	7,777
May 2020	242	7,488
August 2020	241	7,262
November 2020	237	7,145
February 2021	214	6,470
May 2021	212	6,311
August 2021	211	6,182
November 2021	193	5,689
February 2022*	236	7,599
May 2022	235	7,200

*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 2021-22 Medicare Star Ratings. However, a rating of 0 stars is exclusive to SoonerCare. The following key is shown to illustrate the star ratings and adherence percentages for each star rating.

- **CV Star Ratings:** CV star ratings address adherence to maintenance renin angiotensin system (RAS) antagonists [i.e., angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), direct renin inhibitors] and 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.

Star Ratings*	RAS Antagonists	Statins	Diabetes Meds
★★★★★ **5 Stars: Excellent**	≥90%	≥88%	≥88%
★★★★☆ **4 Stars: Above Average**	≥88% to <90%	≥86% to <88%	≥85% to <88%
★★★☆☆ **3 Stars: Average**	≥86% to <88%	≥81% to <86%	≥82% to <85%
★★☆☆☆ **2 Stars: Below Average**	≥84% to <86%	≥78% to <81%	≥79% to <82%
★☆☆☆☆ **1 Star: Poor**	≥60% to <84%	≥60% to <78%	≥60% to <79%
☆☆☆☆☆ **0 Stars: Very Poor**	<60%	<60%	<60%

Meds = medications; RAS = renin angiotensin system
*2022 Medicare Star Ratings

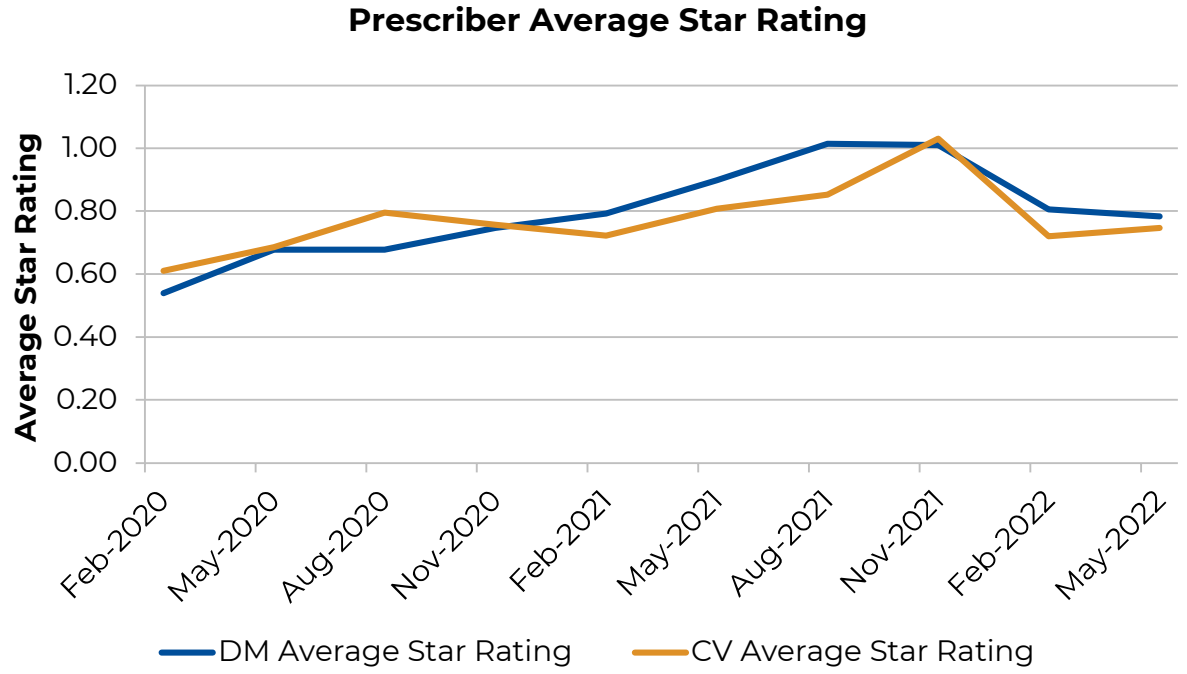
Example Star Rating

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

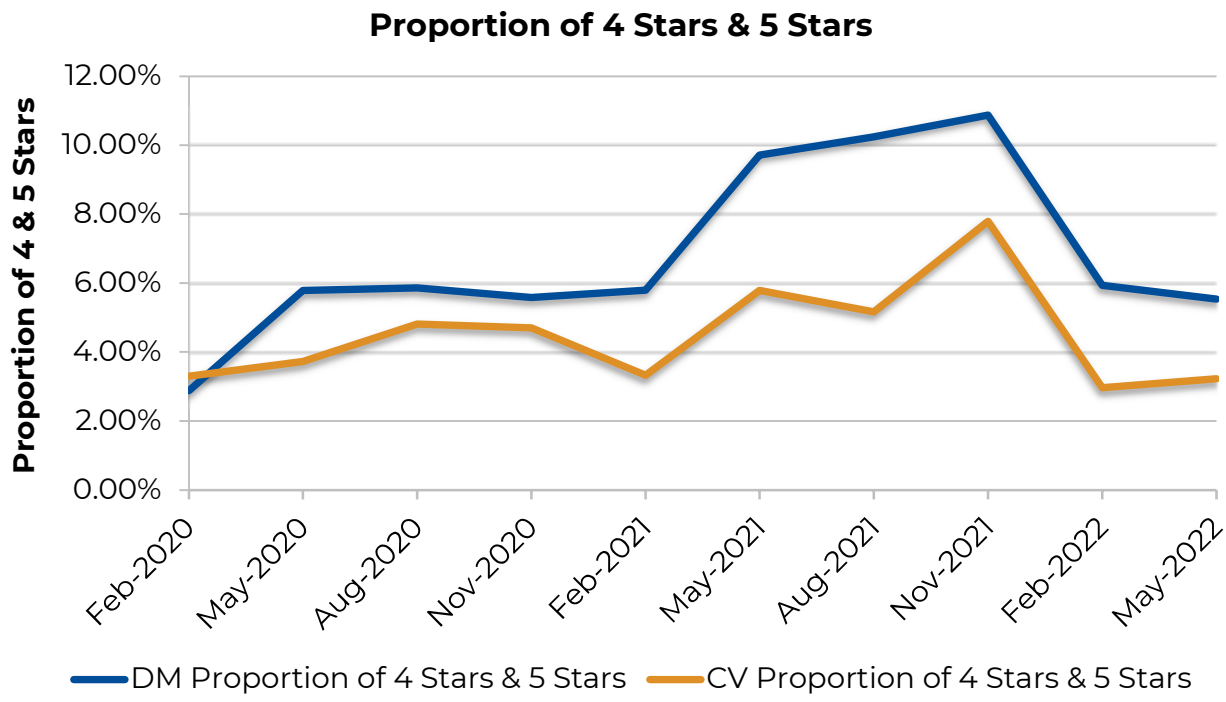
CMA Trends

The following line graph shows trends in the average star rating for prescribers included in the CMA mailing since February 2020. This graph is specific to those prescribers included in the mailings and differentiates

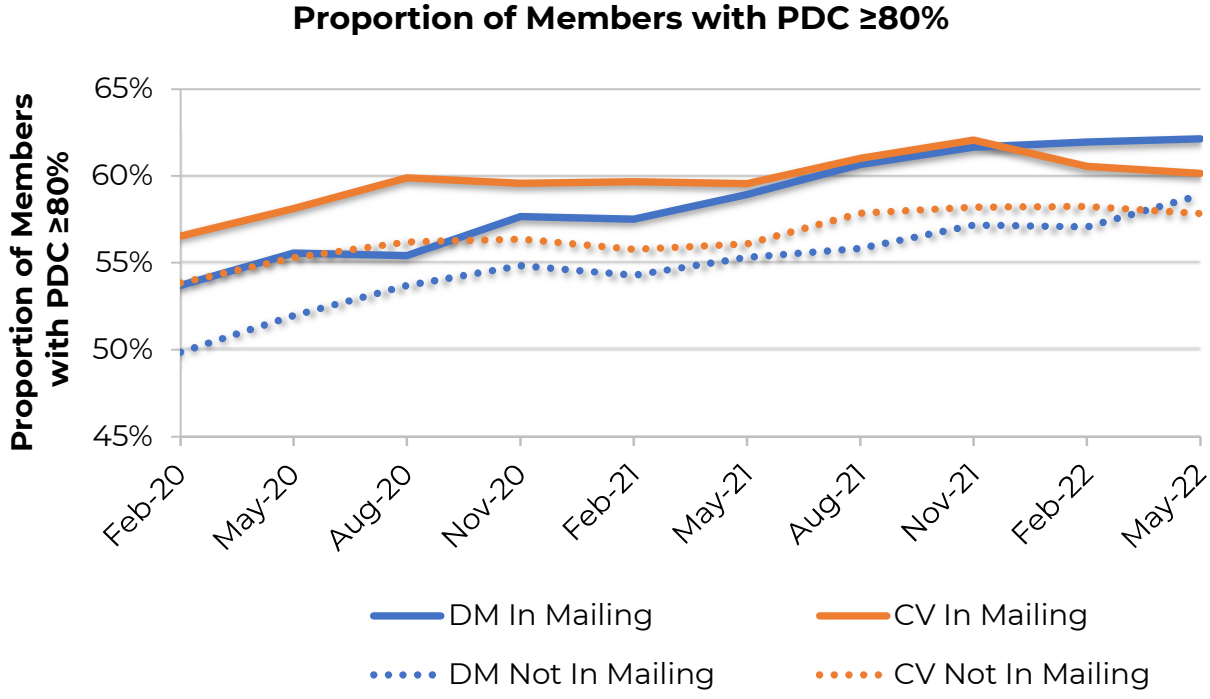
between DM and CV (i.e., statins and RAS antagonists) modules. It is important to note that the prescriber mailing list was updated in February 2020 to include a larger number of prescribers as well as prescribers who were not previously receiving a mailing. An overall increase in the average star rating is seen for the February 2020 through November 2021 mailing cohort for both mailing modules. In February 2022, the mailing list was further updated to include prescribers meeting the current CMS criteria and to remove prescribers no longer meeting the criteria. Approximately 45% of the providers who received the CMA mailings in 2021 will continue receiving the CMA mailings during 2022. 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 2020. An overall increase in the proportion of 4 star and 5 star ratings was seen from February 2020 through November 2021 for both mailing modules. Similar to the average star rating, while overall favorable increases were seen, 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 2020. A member is considered adherent if their PDC is ≥80%. Please note, the vertical axis starts at 45% 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 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, providers 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 2022 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 06/08/2022.

Appendix C

Vote to Prior Authorize Xelstrym™ (Dextroamphetamine Transdermal System) and Update the Approval Criteria for Attention-Deficit/ Hyperactivity Disorder (ADHD) and Narcolepsy Medications

Oklahoma Health Care Authority
July 2022

Market News and Updates[1-10]

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

- **August 2021:** The FDA approved Xywav® (calcium/magnesium/ potassium/sodium oxybates oral solution) for the treatment of idiopathic hypersomnia (IH) in adults. IH is a rare chronic sleep disorder causing excessive sleepiness during the day even after a good night's sleep. This is an expanded indication for Xywav®, which was initially FDA approved in 2020 for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy. Xywav® is a central nervous system (CNS) depressant similar to Xyrem® (sodium oxybate oral solution), but is formulated as a combination of oxybate salts, resulting in 92% less sodium content relative to Xyrem®. Accordingly, the *Prescribing Information* for Xywav® does not contain any warnings about high sodium content. Xywav® is a Schedule III controlled dangerous substance (CDS) and is the first medication to receive FDA approval for the treatment of IH.
- **November 2021:** The FDA approved Dyanavel XR® [amphetamine extended-release (ER) tablets] for the treatment of ADHD in patients 6 years of age and older. This is a new formulation of Dyanavel XR®, initially FDA approved as an ER oral suspension in 2015. Dyanavel XR® is a Schedule II CDS amphetamine product and should not be substituted for other amphetamine products on a milligram-per-milligram basis, because of different amphetamine salt compositions and differing pharmacokinetic profiles.
- **March 2022:** The FDA approved Xelstrym™ (dextroamphetamine transdermal system) for the treatment of ADHD in patients 6 years of age and older. This is the first and only amphetamine-based transdermal product for once daily use. Xelstrym™ is available as 4.5mg, 9mg, 13.5mg, and 18mg transdermal patches to be applied to the hip, upper arm, chest, upper back, or flank and worn during a 9-hour period. Xelstrym™ is a Schedule II CDS dextroamphetamine

product and should not be substituted for other amphetamine products on a milligram-per-milligram basis, because of different amphetamine salt compositions and differing pharmacokinetic profiles.

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

News:

- **September 2021:** The American Academy of Sleep Medicine (AASM) published a clinical practice guideline for the treatment of central disorders of hypersomnolence in which they addressed the treatment of IH in adult patients. They encourage use of modafinil with a strong recommendation. Agents recommended with a conditional recommendation include methylphenidate, clarithromycin, pitolisant, and sodium oxybate. Recommendations build on recent publications assessing diagnostic criteria including biologic and electrophysiological markers as well as a systematic review of treatment options.

Xelstrym™ (Dextroamphetamine Transdermal System) Product Summary[10]

Indication: Xelstrym™ (dextroamphetamine transdermal system) is a CNS stimulant indicated for the treatment of ADHD in patients 6 years of age and older.

Boxed Warning: Abuse and Dependence:

- CNS stimulants, including Xelstrym™, other amphetamine-containing products, and methylphenidate, have a high potential for abuse and dependence. The risk of abuse should be assessed prior to prescribing, and the patient should be monitored for signs of abuse and dependence while on therapy.

How Supplied: Transdermal system available in the following strengths: 4.5mg/9 hours, 9mg/9 hours, 13.5mg/9 hours, and 18mg/9 hours

Dosing and Administration:

- Initial recommended dosage:
  - Pediatric patients 6 to 17 years of age: 4.5mg/9 hours; dosage may be increased in weekly increments of 4.5mg
  - Adult patients: 9mg/9 hours

- Maximum recommended dosage for all ages is 18mg/9 hours
    - Severe renal impairment: Maximum recommended dose is 13.5mg/9 hours
    - End stage renal disease (ESRD): Maximum recommended dose is 9mg/9 hours
- Xelstrym™ should be applied 2 hours before an effect is needed to 1 of the following sites: hip, upper arm, chest, upper back, or flank
- Xelstrym™ should be removed within 9 hours and the site of application should be changed when applying a new transdermal system
- Xelstrym™ should not be substituted for other amphetamine products on a milligram-per-milligram basis because of different amphetamine base compositions and differing pharmacokinetic profiles

Contraindication(s):

- Known hypersensitivity to amphetamine products or Xelstrym™ product components
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days

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

Recommendations

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

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

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

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Non-Stimulants			viloxazine (Qelbree®)
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)Δ		

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

ADHD Medications Tier-2 Approval Criteria:

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

ADHD Medications Tier-3 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response; and

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

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. Adzenys XR-ODT®, Adzenys ER™, Cotempla XR-ODT®, Evekeo ODT™, QuilliChew ER®, Vyvanse® Chewable Tablets, and Xelstrym™ Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use all other available formulations of stimulant medications that can be used for members who cannot swallow capsules or tablets must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
2. Desoxyn®, Dexedrine®, Dexedrine Spansules®, Evekeo®, ProCentra®, and Zenzedi® Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
3. Methylin® Chewable Tablets Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use methylphenidate immediate-release tablets or oral solution must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Mydayis® Approval Criteria:
    a. A covered diagnosis; and
    b. Member must be 13 years of age or older; and
    c. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
5. Qelbree® [Viloxazine Extended-Release (ER) Capsule] Approval Criteria:

a. An FDA approved diagnosis; and
b. Member must be 6 ~~to 17~~ years of age or older; and
c. Previously failed trials (within the last 180 days) with any 2 Tier-1 or Tier-2 ADHD medications, unless contraindicated, that did not yield adequate results; and
    i. Qelbree® will not require a prior authorization and claims will pay at the point of sale if the member has paid claims for 2 Tier-1 or Tier-2 ADHD medications within the past 180 days of claims history; and
d. Member must not be taking a monoamine oxidase inhibitor (MAOI) or have taken an MAOI within the last 14 days; and
e. Member must not be taking sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline) concomitantly with Qelbree®; and
f. A quantity limit of 30 capsules per 30 days will apply for the 100mg strengths and 60 capsules per 30 days will apply for the 150mg and 200mg strength.

ADHD Medications Additional Criteria:

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

f. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.

Narcolepsy Medications Approval Criteria:

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

Idiopathic Hypersomnia (IH) Medications Approval Criteria:

1. Diagnosis of IH meeting the following ICSD-3 (International Classification of Sleep Disorders) criteria:
   a. Daily periods of irresistible need to sleep or daytime lapses into sleep for >3 months; and
   b. Absence of cataplexy; and
   c. Multiple sleep latency test (MSLT) results showing 1 of the following:
      i. <2 sleep-onset rapid eye movement (REM) periods (SOREMPs); or

        ii. No SOREMPs if the REM sleep latency on the preceding polysomnogram is ≤15 minutes; and
    d. At least 1 of the following:
        i. MSLT showing mean sleep latency ≤8 minutes; or
        ii. Total 24-hour sleep time ≥660 minutes on 24-hour polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in association with a sleep log (averaged over ≥7 days with unrestricted sleep); and
    e. Insufficient sleep syndrome has been ruled out; and
    f. Hypersomnolence or MSLT findings are not better explained by any other sleep disorder, medical or neurologic disorder, mental disorder, medication use, or substance abuse; and
2. Diagnosis must be confirmed by a sleep specialist; and
3. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
    a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; and
4. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
5. Use of Xyrem® (sodium oxybate) or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with at least 4 of the following, unless contraindicated, that did not yield adequate results:
    a. Tier-1 stimulant; or
    b. Tier-2 stimulant; or
    c. Nuvigil®; or
    d. Provigil®; or
    e. Clarithromycin; and
6. Xywav® (calcium/magnesium/potassium/sodium oxybates) additionally requires a patient-specific, clinically significant reason why the member cannot use Xyrem®; and
    a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 05/2022. Last accessed 06/22/2022.
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Appendix D

Vote to Prior Authorize Livtencity™ (Maribavir)

Oklahoma Health Care Authority
July 2022

Market News and Updates[1]

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

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

Livtencity™ (Maribavir) Product Summary[2]

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

How Supplied: 200mg oral tablet

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

Warnings/Precautions:

- Maribavir may antagonize the antiviral activity of ganciclovir and valganciclovir, so coadministration is not recommended.
- Due to virologic failure during and after treatment, CMV DNA levels should be monitored, and resistance checking should occur if the patient does not respond to treatment.
- Strong inducers of CYP3A4 are expected to decrease maribavir plasma concentrations and are not recommended to be taken with maribavir,

except for selected anticonvulsants which include carbamazepine, phenytoin, and phenobarbital.
- Maribavir has the potential to increase the drug concentrations of immunosuppressant drugs that are CYP3A4 and/or P-gp substrates (e.g., tacrolimus, cyclosporine, sirolimus). Frequent monitoring of immunosuppressant drug levels throughout treatment is recommended.

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

Contraindication(s): None

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

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

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

Recommendations

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

Livtencity™ (Maribavir) Approval Criteria:
1. An FDA approved indication of the treatment of post-transplant cytomegalovirus (CMV) infection and disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet in adults and pediatric members (12 years of age and older weighing ≥35kg); and
2. A previously failed trial at least 14 days in duration with ganciclovir, valganciclovir, cidofovir, or foscarnet; and

3. Prescriber must verify the member does not have CMV disease involving the central nervous system including the retina (CMV retinitis); and
4. Prescriber must verify member will not receive concurrent treatment with ganciclovir and/or valganciclovir while taking Livtencity™; and
5. Prescriber must verify the member will be monitored for virologic failure during and after treatment with Livtencity™; and
6. Livtencity™ must be prescribed by an oncology, hematology, infectious disease, or transplant specialist (or advanced care practitioner with a supervising physician who is an oncology, hematology, infectious disease, or transplant specialist); and
7. Prescriber must verify Livtencity™ will not be used concomitantly with strong inducers of CYP3A4 (e.g., rifampin, rifabutin, St. John's wort) except carbamazepine, phenobarbital, or phenytoin. Use of carbamazepine, phenobarbital, or phenytoin concomitantly with Livtencity™ will require dose adjustment according to package labeling; and
8. Prescriber must agree to monitor drug concentrations of immunosuppressant drugs that are CYP3A4 and/or P-glycoprotein (P-gp) substrates (e.g., tacrolimus, cyclosporine, sirolimus, everolimus) throughout treatment with Livtencity™ and adjust the dose of immunosuppressant drug(s) as needed; and
9. Approvals will be for a maximum duration of 8 weeks and a quantity limit of 112 tablets per 28 days will apply.

[1] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for Common Type of Post-Transplant Infection that is Resistant to Other Drugs. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-common-type-post-transplant-infection-resistant-other-drugs. Issued 11/23/2021. Last accessed 06/07/2022.
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Appendix E

Vote to Prior Authorize Quviviq™ (Daridorexant) and Update the Approval Criteria for the Insomnia Medications

Oklahoma Health Care Authority
July 2022

Market News and Updates[1,2]

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

- **December 2020:** The FDA approved an expanded indication for Hetlioz® (tasimelteon capsules) for the treatment of patients 16 years of age and older with nighttime sleep disturbances associated with Smith-Magenis Syndrome (SMS) and also approved a new formulation, Hetlioz LQ™ (tasimelteon oral suspension), for use in pediatric patients 3 to 15 years of age with nighttime sleep disturbances associated with SMS. SMS is a rare neurodevelopmental disorder with a defining feature of an inverted circadian rhythm, making it difficult for these patients to sleep during the night. The approval of this new indication was based on a single placebo-controlled efficacy study that included adults taking Hetlioz® capsule and children taking the liquid formulation. The safety profile of Hetlioz® in this study was similar to that seen in the previous studies for Hetlioz® conducted for Non-24-Hour-Sleep-Wake Disorder. Hetlioz® capsules were immediately available for patients with SMS, while Hetlioz LQ™ oral suspension became available for SMS patients in the first quarter of 2021.
- **January 2022:** The FDA approved Quviviq™ (daridorexant) for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. Quviviq™ is a dual orexin receptor antagonist that blocks the binding of the wake-promoting neuropeptides (orexin A and orexin B) and is thought to decrease overactive wakefulness, as opposed to treatments that generally sedate the brain (e.g., zolpidem, temazepam). The approval of Quviviq™ was based on 2 pivotal, multicenter, randomized, double-blind, placebo-controlled studies that included a total of 1,854 patients diagnosed with insomnia. Both studies showed a statistically significant improvement versus placebo on objective measures of sleep onset and sleep maintenance and patient-reported total sleep time. Common adverse reactions from these studies included headache, somnolence, and fatigue.

Quviviq™ (Daridorexant) Product Summary[3]

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

How Supplied: 25mg and 50mg oral tablet

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

Safety:

- Hepatic Impairment: Patients with moderate hepatic impairment should not exceed 25mg per dose.
- Central Nervous System (CNS)-Depressant Effects and Daytime Impairment: Daridorexant is a CNS depressant that can impair daytime wakefulness; co-administration with other CNS depressants can increase CNS depression. The risk of daytime impairment is increased when daridorexant is taken with ≤7 hours of sleep remaining or if a higher than recommended dose is taken.
- Worsening of Depression/Suicidal Ideation: Patients with psychiatric disorders, including insomnia, are at an increased risk of suicide. Worsening of depression and suicidal ideation may occur. As with other hypnotics, daridorexant should be administered with caution in patients exhibiting symptoms of depression. Monitoring of suicide risk and protective manners may be required.
- Sleep Paralysis, Hypnagogic/Hypnopompic Hallucinations, and Cataplexy-Like Symptoms: Sleep paralysis and hypnagogic/ hypnopompic hallucinations can occur with the use of daridorexant. Prescribers should explain the nature of these events to patients when prescribing daridorexant. Symptoms similar to mild cataplexy have been reported with orexin receptor antagonists.
- Complex Sleep Behaviors: Complex sleep behaviors such as sleepwalking, sleep-driving, and engaging in other activities while not fully awake have been reported to occur with the use of hypnotics, including orexin receptor antagonists such as daridorexant. Therapy with daridorexant should be discontinued immediately if this occurs.
- Patients with Compromised Respiratory Function: The effects of daridorexant on respiratory function should be considered if prescribed to patients with compromised respiratory function. Daridorexant has not been studied in patients with moderate obstructive sleep apnea (OSA) requiring continuous positive airway pressure (CPAP) or severe OSA and has not been studied in patients with severe chronic obstructive pulmonary disease (COPD).

- Need to Evaluate for Comorbid Diagnoses: Because sleep disturbances may be the presenting manifestation of a medical and/or psychiatric disorder, treatment of insomnia should only be initiated after careful evaluation of the patient. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated.

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

Contraindication(s): Patients with narcolepsy

Use in Specific Populations:

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

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

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

Recommendations

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

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

3. The prior authorization of Quviviq™ (daridorexant) and placement into the Special PA category of the Insomnia Medications PBPA category

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

CR = controlled release; PA = prior authorization; SL = sublingual
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Medications in the Special PA Tier, including unique dosage formulations, require a special reason for use in place of ~~Tier-1 formulations~~ lower-tiered medications.
+Individual criteria specific to tasimelteon applies.

Hetlioz® (Tasimelteon Capsule) Approval Criteria:

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

Hetlioz LQ™ (Tasimelteon Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) confirmed by a sleep specialist; and
2. Member must be 3 to 15 years of age; and
3. Member must have a failed trial of appropriately timed doses of melatonin; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the Hetlioz LQ™ *Prescribing Information*; and
5. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication.

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[1] FDA Approves Hetlioz® (Tasimelteon) for the Treatment of Nighttime Sleep Disturbances in Smith-Magenis Syndrome. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/fda-approves-hetlioz-tasimelteon-for-the-treatment-of-nighttime-sleep-disturbances-in-smith-magenis-syndrome-301183162.html. Issued 12/01/2021. Last accessed 06/07/2022.

[2] Idorsia Receives U.S. FDA Approval of Quviviq™ (Daridorexant) 25 and 50mg for the Treatment of Adults with Insomnia. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/idorsia-receives-us-fda-approval-of-quviviq-daridorexant-25-and-50-mg-for-the-treatment-of-adults-with-insomnia-301456774.html. Issued 01/10/2022. Last accessed 06/07/2022.

[3] Quviviq™ (Daridorexant) Prescribing Information. Idorsia Pharmaceuticals. Available online at: https://www.idorsia.us/documents/us/label/Quviviq_PI.pdf. Last revised 04/2022. Last accessed 06/07/2022.

Appendix F

Vote to Prior Authorize Invega Hafyera™ (Paliperidone Palmitate Injection) and Update the Approval Criteria for the Atypical Antipsychotic Medications

Oklahoma Health Care Authority
July 2022

Market News and Updates[1,2,3]

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

- **September 2021:** The FDA approved Invega Hafyera™ (paliperidone palmitate) a 6-month intramuscular (IM) injectable medication for the treatment of schizophrenia in adults. The approval was based on a randomized, double-blind, Phase 3 global study that was designed to demonstrate that Invega Hafyera™ was not less effective than Invega Trinza® in delaying time to first relapse in patients who were previously stabilized on doses of Invega Sustenna® or Invega Trinza®.

News:

- **June 2021:** The ENLIGHTEN-2 clinical study evaluated the weight gain profile of Lybalvi® (olanzapine/samidorphan) compared to olanzapine over 6 months in 561 patients with stable schizophrenia. This study met its prespecified co-primary endpoints, demonstrating both a lower mean percentage weight gain from baseline at 6 months compared to the olanzapine group (P=0.003) and a lower proportion of patients who gained 10% or more of their baseline body weight at 6 months compared to the olanzapine group (P=0.003). Patients completing the ENLIGHTEN-2 study were eligible to enroll in the 52-week extension study (ENLIGHTEN-2-EXT) and those on olanzapine were switched to Lybalvi®. These patients had a –0.42kg change in weight throughout the 52-week extension.

Invega Hafyera™ (Paliperidone Palmitate Injection) Product Summary[4]

Indication(s): Invega Hafyera™ (paliperidone palmitate 6-month injection) is an atypical antipsychotic indicated for the treatment of schizophrenia in adults after they have been adequately treated with:

- A once-a-month paliperidone palmitate extended-release (ER) injectable suspension (e.g., Invega Sustenna®) for at least 4 months; or
- An every 3-month paliperidone palmitate ER injectable suspension (e.g., Invega Trinza®) for at least one 3-month cycle

Boxed Warning: Increased Mortality in Elderly Patients with Dementia-Related Psychosis

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
- Invega Hafyera™ is not approved for use in patients with dementia-related psychosis.

How Supplied: 1,092mg/3.5mL and 1,560mg/5mL single-dose prefilled syringes

Dosing:

- Invega Hafyera™ should be administered by gluteal IM injection once every 6 months by a health care professional.
- Invega Hafyera™ should be initiated when the next dose of Invega Sustenna® or Trinza® is scheduled.
- Refer to the Invega Hafyera™ *Prescribing Information* for recommended dosing based on the previous paliperidone palmitate ER injectable suspension used.

Mechanism of Action: Paliperidone palmitate is hydrolyzed to paliperidone. Paliperidone is the major active metabolite of risperidone. The mechanism of action of paliperidone is unclear; however, its efficacy in the treatment of schizophrenia could be mediated through a combination of central dopamine D2 and serotonin 5-HT2A receptor antagonism.

Contraindication(s): Known hypersensitivity to paliperidone, risperidone, or to any excipients in Invega Hafyera™

Warnings and Precautions:

- Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis: Elderly patients utilizing Invega Hafyera™ have an increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack, including fatalities).
- Neuroleptic Malignant Syndrome (NMS): If NMS occurs, it should be managed with immediate discontinuation of Invega Hafyera™ and close monitoring.
- QT Prolongation: Invega Hafyera™ should be avoided with drugs that increase the QT interval and in patients with risk factors for prolonged QT interval.
- Tardive Dyskinesia: If tardive dyskinesia occurs, treatment with Invega Hafyera™ should be discontinued if clinically appropriate.
- Metabolic Changes: Patients should be monitored for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain.

- Orthostatic Hypotension and Syncope: Caution should be taken in patients with known cardiovascular or cerebrovascular disease and patients predisposed to hypotension.
- Leukopenia, Neutropenia, and Agranulocytosis: Complete blood counts (CBC) should be performed in patients with pre-existing low white blood cell count (WBC) or a history of leukopenia or neutropenia. Discontinuing Invega Hafyera™ should be considered if a clinically significant decline in WBC occurs in the absence of other causative factors.
- Hyperprolactinemia: Prolactin elevations may occur and persist during chronic administration of Invega Hafyera™.
- Potential for Cognitive and Motor Impairment: Caution should be taken when operating machinery.
- Seizures: Caution should be taken in patients with a history of seizures or with conditions that lower the seizure threshold.

Adverse Reactions: The most common adverse reactions reported in clinical studies (incidence ≥5%) were upper respiratory tract infection, injection site reaction, weight gain, headache, and parkinsonism.

Efficacy: The safety and efficacy of Invega Hafyera™ were based on a randomized, double-blind, non-inferiority Phase 3 global study that enrolled 702 adults who were previously stabilized with either paliperidone palmitate 1-month injection for at least 4 months or paliperidone 3-month injection for at least one 3-month injection cycle and who had a PANSS score of <70 points. Patients were randomized 2:1 to receive either Invega Hafyera™ or paliperidone palmitate 3-month injection.

- Primary Endpoint: The primary efficacy endpoint was time to first relapse at the end of the 12-month period. Relapse was pre-defined as emergence of 1 or more of the following: psychiatric hospitalization; ≥25% increase (if the baseline score was >40) or a 10-point increase (if the baseline score was ≤40) in total PANSS score on 2 consecutive assessments; or deliberate self-injury, violent behavior, or suicidal/homicidal ideation [a score of ≥5 (if the maximum baseline score was ≤3) or ≥6 (if the maximum baseline score was 4) on 2 consecutive assessments of the specific PANSS items].
- Results: A relapse event was experienced by 7.5% and 4.9% of patients in the Invega Hafyera™ and paliperidone palmitate 3-month injection treatment groups, respectively. The study demonstrated non-inferiority of Invega Hafyera™ to the paliperidone palmitate 3-month injection. An evaluation of population subgroups did not reveal any clinically significant differences in responsiveness based on gender, age, or race.

Cost Comparison:

Medication	Cost Per Unit	Cost Per Year
Invega Sustenna® (paliperidone palmitate) 234mg/1.5mL PFS	$1,987.04	$25,831.52*
Invega Trinza® (paliperidone palmitate) 819mg/2.63mL PFS	$3,392.88	$13,571.52+
Invega Hafyera™ (paliperidone palmitate) 1,560mg/5mL PFS	**$3,718.52**	**$7,437.04ß**

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
PFS = pre-filled syringe; Unit = pre-filled syringe
*Invega Sustenna® cost per year is based on maintenance dose of 234mg once monthly.
+Invega Trinza® cost per year is based on maintenance dose of 819mg once every 3 months.
ß Invega Hafyera™ cost per year is based on maintenance dose of 1,560mg once every 6 months

Recommendations

The College of Pharmacy recommends the placement of Invega Hafyera™ (paliperidone palmitate IM injection) into Tier-1 of the Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) category based on net costs (changes noted in red):

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

quetiapine ER (Seroquel XR®)		olanzapine/samidorphan (Lybalvi™)+
risperidone (Risperdal®)		paliperidone (Invega®)
risperidone IM inj (Risperdal Consta®)		
risperidone ER sub-Q inj (Perseris®)		
ziprasidone (Geodon®)		

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
ER = extended-release; IM = intramuscular; inj = injection; ODT = orally disintegrating tablet; susp = suspension; sub-Q = subcutaneous
¥Aripiprazole (Abilify®) orally disintegrating tablet (ODT) is considered a special formulation and requires a patient-specific, clinically significant reason why a special formulation product is needed in place of the regular tablet formulation.
◊Clozapine does not count towards a Tier-1 trial.
**Use of Invega Trinza® requires members to have been adequately treated with the 1-month paliperidone palmitate injection (Invega Sustenna®) for at least 4 months.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.
^Use of Invega Hafyera™ requires members to have been adequately treated with the 1-month paliperidone palmitate injection (Invega Sustenna®) for at least 4 months or the 3-month paliperidone palmitate injection (Invega Trinza®) for at least one 3-month cycle.

Additionally, the College of Pharmacy recommends adding the following criteria to Lybalvi™ (olanzapine/samidorphan):

Lybalvi™ (Olanzapine/Samidorphan) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. Member must be stable on olanzapine for at least 14 days and be experiencing significant weight gain (baseline and current weight must be provided); or
4. A patient specific, clinically significant reason why the member cannot use a lower tiered product with a lower weight gain profile must be provided; and
5. Member must not be taking opioids or undergoing acute opioid withdrawal; and
6. Approvals will be for 3 months. For continuation consideration, documentation that the member is responding well to treatment and has had no excessive weight gain while on therapy must be provided.

[1] Alkermes. Alkermes Announces FDA Approval of Lybalvi™ for the Treatment of Schizophrenia and Bipolar 1 Disorder. *PR Newswire*. Available online at: https://www.biospace.com/article/releases/alkermes-announces-fda-approval-of-lybalvi-for-the-treatment-of-schizophrenia-and-bipolar-i-disorder/. Issued 06/01/2021. Last accessed 06/27/2022.
[2] Kahn, R. S., Silverman, B. L., DiPetrillo, L., er al. A phase 3, Multicenter Study to Assess the 1-year Safety and Tolerability of a Combination of Olanzapine and Samidorphan in Patients with Schizophrenia: Results from the Enlighten-2 Long-Term Extension. *Schizophrenia Research* 2021; 232:45–53. doi: 10.1016/j.schres.2021.04.009.
[3] Janssen Pharmaceuticals. Janssen Announces U.S. FDA Approval of Invega Hafyera™ (6-Month Paliperidone Palmitate), First and Only Twice-Yearly Treatment for Adults with Schizophrenia. Available online at: https://www.jnj.com/janssen-announces-u-s-fda-approval-of-invega-hafyera-6-month-paliperidone-palmitate-first-and-only-twice-yearly-treatment-for-adults-with-schizophrenia. Issued 09/01/2021. Last accessed 06/13/2022.
[4] Invega Hafyera™ Prescribing Information. Janssen. Available online at: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INVEGA+HAFYERA-pi.pdf. Last revised 08/2021. Last accessed 06/13/2022.

Appendix G

Vote to Prior Authorize Ryplazim® (Plasminogen, Human-tvmh)

Oklahoma Health Care Authority
July 2022

Market News and Updates[1]

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

- **June 2021:** The FDA approved Ryplazim® (plasminogen, human-tvmh) for the treatment of plasminogen deficiency (PLGD) type 1, also referred to as hypoplasminogenemia. Ryplazim® helps increase the plasma level of plasminogen, allowing for a temporary correction of plasminogen deficiency and reduction or resolution of the lesions. Prior to the approval of Ryplazim®, there were no FDA-approved treatment options for patients with plasminogen deficiency type 1.

Ryplazim® (Plasminogen, Human-tvmh) Product Summary[2]

Indication: A plasma-derived human plasminogen indicated for the treatment of patients with PLGD type 1.

How Supplied: 50mL single-dose vial containing 68.8mg of plasminogen as a lyophilized powder

Dosing and Administration:

- The recommended dose is 6.6mg/kg of body weight given intravenously every 2 to 4 days
- The recommended initial dosing frequency is every 3 days
- A trough plasminogen level should be taken 72 hours following the initial dose and prior to the second dose, and the dosing frequency should be adjusted according to plasminogen activity level
- Dosing frequency should be maintained for 12 weeks while treating active lesions
- Refer to the Ryplazim® *Prescribing Information* for full determination of dose and dosing frequency

Mechanism of Action: Ryplazim® is a purified, plasma-derived glu-plasminogen, which is the native circulating form of plasminogen in the blood, and temporarily increases plasminogen levels in the blood.

Contraindication(s):

- Known hypersensitivity to plasminogen or other components of Ryplazim®

Safety:

- Bleeding: Administration may lead to bleeding at lesion sites or may worsen active bleeding. Ryplazim® should be discontinued if serious bleeding occurs. When administering to patients with bleeding diatheses or to patients taking anticoagulants, antiplatelet drugs, or other agents which may interfere with normal coagulation, patients should be monitored during and for 4 hours after infusion.
- Tissue Sloughing: Respiratory distress due to tissue sloughing may occur in patients with mucosal lesions in the tracheobronchial tree following administration. Patients should be monitored appropriately.
- Transmission of Infectious Agents: Ryplazim® is a human blood product and therefore carries a risk of transmitting infectious agents [e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and theoretically, the CJD agent].
- Hypersensitivity Reactions: Hypersensitivity reactions, including anaphylaxis, may occur. If symptoms occur, Ryplazim® should be discontinued and appropriate treatment should be administered.
- Neutralizing Antibodies: Neutralizing antibodies (inhibitors) may develop, although were not observed in clinical studies. If clinical efficacy is not maintained (e.g., development of new or recurrent lesions), then plasminogen activity levels in plasma should be determined.
- Laboratory Abnormalities: Patients receiving Ryplazim® may have elevated blood levels of D-dimer. D-dimer levels will lack interpretability in patients being screened for venous thromboembolism (VTE).

Adverse Reactions: The most common (incidence ≥10%) adverse reactions in clinical studies were abdominal pain, bloating, nausea, fatigue, extremity pain, hemorrhage, constipation, dry mouth, headache, dizziness, arthralgia, and back pain.

Efficacy: The approval of Ryplazim® was based on a single-arm, open-label, Phase 2/3 study which enrolled 15 patients with PLGD type 1 who had a baseline plasminogen activity level of <45%. The study consisted of a 21-day screening period and 3 treatment segments. Only 14 patients completed ≥12 weeks of treatment (5 children and 9 adults).

- Primary Endpoint: The primary endpoint was the number of patients who achieved target trough plasminogen activity levels, defined as an increase of individual plasminogen activity trough level by at least an absolute 10% above baseline, for at least 3 measurements in 12 weeks. Primary endpoint success was defined as at least 80% of evaluable patients achieving target trough plasminogen activity level.
- Results: All 14 patients achieved target trough plasminogen activity levels during the initial 12-week treatment period. In addition, all

patients had >50% improvement in the number and/or size of their lesions by week 48; there were 3 patients who did not have any lesions present at baseline. Among the 14 patients studied, 78% of their external lesions and 75% of their internal lesions were resolved by week 48, and no patients had a new or recurring lesion through week 48. No formal statistical analysis was performed due to the small sample size.

Cost: The Wholesale Acquisition Cost (WAC) of Ryplazim® is $2,064 per 50mL vial. A member weighing 80kg would have an annual cost of $2,014,464 at the recommended dosage of 6.6mg/kg every 3 days.

Recommendations

The College of Pharmacy recommends the prior authorization of Ryplazim® (plasminogen, human-tvmh) with the following criteria:

Ryplazim® (Plasminogen, Human-tvmh) Approval Criteria:

1. An FDA approved indication of plasminogen deficiency type 1 (hypoplasminogenemia) as confirmed by at least 2 of the following:
   a. Genetic testing confirming biallelic mutations in the plasminogen (*PLG*) gene; or
   b. Plasminogen activity level ≤45%; or
   c. Documentation of clinical symptoms and lesions consistent with plasminogen deficiency type 1 (e.g., ligneous conjunctivitis, ligneous gingivitis or gingival overgrowth, vision abnormalities, respiratory distress and/or obstruction, abnormal wound healing); and
2. Ryplazim® must be prescribed by, or in consultation with, a hematologist, pulmonologist, ophthalmologist, geneticist, or other specialist with expertise in the treatment of plasminogen deficiency (or an advanced care practitioner with a supervising physician who is a hematologist, pulmonologist, ophthalmologist, geneticist, or other specialist with expertise in the treatment of plasminogen deficiency); and
3. Prescriber must verify that members at high risk for bleeding and/or confirmed or suspected airway disease will be monitored by a health care provider for 4 hours after receiving the first dose; and
4. Documented vaccination history to hepatitis A and B must be provided or provider must verify member has received the first vaccine dose and is scheduled to receive the second vaccine dose; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and

6. Initial approvals will be for 6 months, after which time the prescriber must document improvement in clinical symptoms, partial or complete lesion resolution, and increased plasminogen activity level; and
7. Subsequent approvals will be for the duration of 1 year and will require documentation from the prescriber that member has not developed new or recurrent lesions while on Ryplazim® and that adequate plasminogen activity trough levels are being maintained.

[1] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for Patients with Plasminogen Deficiency, a Rare Genetic Disorder. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-patients-plasminogen-deficiency-rare-genetic-disorder. Issued 06/04/2021. Last accessed 06/13/2022.
[2] Ryplazim® Prescribing Information. Prometic Biotherapeutics. Available online at: https://www.fda.gov/media/149806/download. Last revised 11/2021. Last accessed 06/13/2022.

Appendix H

Vote to Prior Authorize Citalopram Capsule, Dartisla ODT™ [Glycopyrrolate Orally Disintegrating Tablet (ODT)], Fleqsuvy™ (Baclofen Oral Suspension), Lofena™ (Diclofenac Potassium Tablet), Loreev XR™ [Lorazepam Extended-Release (ER) Capsule], Norliqva® (Amlodipine Oral Solution), Seglentis® (Celecoxib/ Tramadol Tablet), Sutab® (Sodium Sulfate/Magnesium Sulfate/Potassium Chloride Tablet), Tarpeyo™ [Budesonide Delayed-Release (DR) Capsule], Vuity™ (Pilocarpine 1.25% Ophthalmic Solution), and Xipere® (Triamcinolone Acetonide Injection)

Oklahoma Health Care Authority
July 2022

Introduction

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

Citalopram Capsule Product Summary and Recommendations[1]

Citalopram capsule is a selective serotonin reuptake inhibitor (SSRI) indicated for treatment of major depressive disorder (MDD) in adults. The recommended dosing is 30mg once daily, after an initial dose of 20mg once daily with citalopram tablet and dose increases should occur at intervals of no less than 1 week. Citalopram capsule is supplied as a 30mg oral capsule.

- Other Formulation(s) Available: citalopram tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
citalopram 30mg capsule	**$4.90**	**$147.00**
citalopram 10mg tablet	$0.03	$2.70

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on a dose of 30mg daily for both products.
Unit = capsule or tablet

The College of Pharmacy recommends the placement of citalopram capsules into the Special Prior Authorization (PA) Tier of the Antidepressants Product Based Prior Authorization (PBPA) category with the following additional criteria:

Citalopram Capsule Approval Criteria:

1. An FDA approved indication of major depressive disorder (MDD) in adults; and
2. Member must have initiated treatment with citalopram tablets for dose titration up to the 30mg dose; and
3. A patient-specific, clinically significant reason why the member cannot use citalopram tablets, which are available without prior authorization, in place of the capsule formulation must be provided; and
4. Citalopram capsules will not be approved for members 60 years of age or older; and
5. A quantity limit of 30 capsules per 30 days will apply.

Dartisla ODT™ (Glycopyrrolate ODT) Product Summary and Recommendations[2]

Dartisla ODT™ (glycopyrrolate ODT) is an anticholinergic medication indicated to reduce the symptoms of a peptic ulcer as an adjunct to the treatment of peptic ulcer disease (PUD) in adults. Dartisla ODT™ is not indicated as monotherapy for treatment of PUD because effectiveness in peptic ulcer healing has not been established. The recommended dosage is 1.7mg sublingually 2 or 3 times daily, 1 hour before or 2 hours after food. Dartisla ODT™ is not recommended for patients initiating treatment or receiving maintenance treatment with a lower dosage strength of another oral glycopyrrolate product. The maximum recommended daily dosage is 6.8mg. Dartisla ODT™ is supplied as an ODT containing 1.7mg of glycopyrrolate.

- Other Formulation(s) Available: glycopyrrolate tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Dartisla ODT™ (glycopyrrolate 1.7mg ODT)	**$5.56**	**$667.20**
glycopyrrolate 2mg tablet	$0.17	$20.40
glycopyrrolate 1mg tablet	$0.09	$21.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the U.S. Food and Drug Administration (FDA) recommended maximum daily dose for each product.
ODT = orally disintegrating tablet; Unit = tablet or ODT

The College of Pharmacy recommends the placement of Dartisla ODT™ (glycopyrrolate ODT) into the Special PA Tier of the Anti-Ulcer Medications PBPA category with the following additional criteria:

Dartisla ODT™ [Glycopyrrolate Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in members 18 years of age and older; and
2. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without prior authorization, must be provided.
3. A quantity limit of 120 ODTs per 30 days will apply.

Fleqsuvy™ (Baclofen Oral Suspension) Product Summary and Recommendations[3]

Fleqsuvy™ (baclofen oral suspension) is a gamma-aminobutyric acid agonist indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Fleqsuvy™ is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders. Fleqsuvy™ should be initiated at a low dosage, preferably in divided doses with gradual increases based on clinical response and tolerability. The recommended dosing is to initiate treatment at 5mg 3 times daily for 3 days. The dose should be adjusted based on clinical response and tolerability up to a maximum of 80mg per day (20mg 4 times daily). Fleqsuvy™ is supplied as a 25mg/5mL (5mg/mL) grape-flavored oral suspension in 30mL and 120mL bottles. Fleqsuvy™ should be stored at room temperature [20°C to 25°C (68°F to 77°F)], and the unused portion should be discarded 2 months after first opening.

- Other Formulation(s) Available: baclofen (5mg/5mL) oral solution and baclofen tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Fleqsuvy™ (baclofen 5mg/mL oral suspension)	**$5.50**	**$2,640.00**
baclofen 5mg/5mL oral solution	$1.09	$2,616.00
baclofen 20mg tablet	$0.11	$13.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per 30 days based on the maximum FDA recommended dose of 80mg/day.

The College of Pharmacy recommends adding Fleqsuvy™ (baclofen oral suspension) to the current Ozobax® (baclofen oral solution) prior authorization with the changes shown in red:

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

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

Lofena™ (Diclofenac Potassium Tablet) Product Summary and Recommendations[4]

Lofena™ (diclofenac potassium tablet) is a nonsteroidal anti-inflammatory drug (NSAID) indicated for primary dysmenorrhea, mild-to-moderate pain, osteoarthritis (OA), and rheumatoid arthritis (RA). It is recommended to use the lowest effective dose for the shortest duration consistent with individual patient treatment goals. The recommended dosing for primary dysmenorrhea and mild-to-moderate pain is 50mg 3 times a day, for OA 50mg 2 or 3 times a day, and for RA 50mg 3 or 4 times a day. Lofena™ is supplied as 25mg diclofenac potassium film-coated, oral tablets.

- Other Formulation(s) Available: diclofenac potassium 50mg tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Lofena™ (diclofenac potassium 25mg tablet)	**$32.26**	**$7,742.40**
diclofenac potassium 50mg tablet	$0.34	$40.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = tablet
*Cost per 30 days based on the maximum FDA recommended dose of 200mg/day.

The College of Pharmacy recommends the placement of Lofena™ (diclofenac potassium tablet) into the Special PA Tier of the NSAIDs PBPA category with the following additional criteria (changes shown in red):

NSAIDs Special Prior Authorization (PA) Approval Criteria:

1. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or
2. Previous use of at least 2 Tier-1 NSAID products (from different product lines); and

3. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product.
4. Additionally, use of Tivorbex™ will require a patient-specific, clinically significant reason why the member cannot use all other available generic indomethacin products.
5. Additionally, use of Celebrex® (celecoxib) 400mg capsules will require a diagnosis of Familial Adenomatous Polyposis (FAP) and a patient-specific, clinically significant reason why the member cannot use 2 celecoxib 200mg capsules to achieve a 400mg dose.
6. Additionally, use of Lofena™ will require a patient-specific, clinically significant reason why the member cannot use all other available generic diclofenac products.

Loreev XR™ (Lorazepam ER Capsule) Product Summary and Recommendations[5]

Loreev XR™ (lorazepam ER capsule) is a benzodiazepine indicated for the treatment of anxiety disorders in adults who are receiving stable, evenly divided, 3 times daily dosing with lorazepam tablets. The recommended dosing of Loreev XR™ is equal to the patient's current total daily dose of lorazepam tablets (must be 3 times daily dosing) taken once daily in the morning. Loreev XR™ may be swallowed whole or the capsule may be opened, and the contents sprinkled onto applesauce. Loreev XR™ should not be crushed or chewed. For dosage adjustments, Loreev XR™ should be discontinued and the patient should be switched to lorazepam tablets. Loreev XR™ is supplied as lorazepam ER oral capsules in 4 strengths: 1mg, 1.5mg, 2mg, and 3mg.

- Other Formulation(s) Available: lorazepam tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Loreev XR™ (lorazepam 3mg ER tablet)	**$14.17**	**$425.10**
lorazepam 1mg tablet	$0.04	$3.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ER = extended-release; Unit = tablet
*Cost per 30 days based on the FDA recommended dose of 3mg/day.

The College of Pharmacy recommends the prior authorization of Loreev XR™ (lorazepam ER capsule) with the following criteria:

Loreev XR™ [Lorazepam Extended-Release (ER) Capsule] Approval Criteria:

1. An FDA approved diagnosis for the treatment of anxiety disorders; and
2. Member must be 18 years of age or older; and

3. Member must be receiving a stable, evenly divided, 3 times daily dosing regimen of lorazepam tablets; and
4. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation must be provided; and
5. A quantity limit of 30 capsules per 30 days will apply.

Norliqva® (Amlodipine Oral Solution) Product Summary and Recommendations[6]

Norliqva® (amlodipine oral solution) is a calcium channel blocker (CCB) indicated for hypertension (HTN) in adults and pediatric patients 6 years of age and older and for chronic stable angina, vasospastic angina, coronary artery disease (CAD) in adults to reduce the risk of hospitalization for angina and reduce the risk of a coronary revascularization procedure in patients without heart failure (HF) or an ejection fraction (EF) <40%. The recommended dosing for HTN in adults is 5mg to 10mg once daily, for HTN in pediatric patients 6 years of age and older 2.5mg to 5mg once daily, for chronic stable or vasospastic angina in adults 5 to 10mg once daily, and for CAD in adults 5 to 10mg once daily. Norliqva® is supplied as a peppermint-flavored 1mg/mL oral solution in a 150mL glass bottle. Norliqva® should be dispensed in the original packaging and stored at room temperature [20°C to 25°C (68°F to 77°F)].

- Other Formulation(s) Available: amlodipine tablets and Katerzia® (amlodipine oral suspension)

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days
Norliqva® (amlodipine 1mg/mL oral solution)	**$3.43**	**$1,029.00**
Katerzia® (amlodipine 1mg/mL oral suspension)	$3.37	$1,011.00
amlodipine 10mg tablets	$0.01	$0.30

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per 30 days based on the maximum FDA recommended dose of 10mg/day.

The College of Pharmacy recommends the placement of Norliqva® (amlodipine oral solution) into the Special PA Tier of the CCBs PBPA category with criteria similar to Katerzia® (amlodipine oral suspension) as follows (changes shown in red):

Katerzia® (Amlodipine Oral Suspension) and Norliqva® (Amlodipine Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:

a. Hypertension in adults and pediatric members 6 years of age and older; or
b. Coronary artery disease; or
c. Chronic stable angina; or
d. Vasospastic angina; and

2. A patient specific, clinically significant reason the member cannot use amlodipine oral tablets even when the tablets are crushed must be provided; and
3. A quantity limit of 300mL per 30 days will apply.

Seglentis® (Celecoxib/Tramadol Tablet) Product Summary and Recommendations[7]

Seglentis® (celecoxib/tramadol tablet) contains tramadol hydrochloride (an opioid agonist/schedule IV controlled substance) and celecoxib (an NSAID) and is indicated for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Due to the risks of addiction, abuse, and misuse with opioids, Seglentis® should be reserved for use in patients for whom alternative treatment options have not been tolerated, are not expected to be tolerated, and/or have not provided adequate analgesia or are not expected to provide adequate analgesia. Seglentis® is recommended for the shortest duration consistent with individual patient treatment goals. The recommended dose is 2 tablets every 12 hours as needed for pain relief. Seglentis® is supplied as oral, coated tablets containing celecoxib 56mg and tramadol hydrochloride 44mg.

- Other Formulation(s) Available: celecoxib capsules and tramadol tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Seglentis® (celecoxib/tramadol 56mg/44mg tablet)	**$4.23**	**$507.60**
celecoxib 200mg capsule	$0.13	$7.80
tramadol 50mg tablet	$0.02	$4.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = capsule or tablet
*Cost per 30 days based on the maximum FDA recommended dose for acute pain for each product.

The College of Pharmacy recommends the placement of Seglentis® (celecoxib/tramadol) into the Special PA Tier of the Opioid Analgesics PBPA category with the following additional criteria:

Seglentis® (Celecoxib 56mg/Tramadol 44mg) Approval Criteria:

1. An FDA approved indication of acute pain in adults that is severe enough to require an opioid analgesic; and

2. A patient-specific, clinically significant reason why the member cannot use any other opioid medication for treatment of acute pain must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use celecoxib and tramadol individual products in place of Seglentis® must be provided; and
4. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
5. A quantity limit of 28 tablets for a 7-day supply will apply.

Sutab® (Sodium Sulfate/Magnesium Sulfate/Potassium Chloride Tablet) Product Summary and Recommendations[8]

Sutab® (sodium sulfate/magnesium sulfate/potassium chloride tablet) is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults. Administration of 2 doses (24 tablets) are required for a complete preparation for colonoscopy. Twelve tablets are equivalent to 1 dose.

- Split-Dose (2-Day) Regimen:
  - Dose 1 (1 day prior to colonoscopy):
    - Starting evening prior to colonoscopy, 12 tablets should be taken with 16 ounces of water over 15 to 20 minutes
    - One hour after the last tablet is taken, an additional 16 ounces of water should be ingested and 16 ounces of water should be repeated 30 minutes after previous 16 ounces
  - Dose 2 (day of colonoscopy):
    - Starting 5 to 8 hours prior to colonoscopy, 12 tablets should be taken with 16 ounces of water over 15 to 20 minutes
    - One hour after the last tablet is taken, an additional 16 ounces of water should be ingested and 16 ounces of water should be repeated 30 minutes after previous 16 ounces

Sutab® is supplied as a film-coated, oral tablet containing 1.479g sodium sulfate/0.225g magnesium sulfate/0.188g potassium chloride. Sutab® is available in 2 bottles containing 12 tablets each, and 1 container with a 16-ounce fill line is also provided.

- Other Formulation(s) Available: GoLytely® [polyethylene glycol (PEG) 3350/sodium sulfate/sodium bicarbonate/sodium chloride/potassium chloride powder] and MoviPrep® (PEG 3350/sodium sulfate/sodium chloride/potassium chloride/sodium ascorbate/ascorbic acid powder)

Formulation Cost Comparison:

Product	Cost Per Treatment*
Sutab® (sodium sulfate/magnesium sulfate/potassium chloride tablet)	**$148.32**
PEG 3350/sodium sulfate/sodium chloride/potassium chloride/ sodium ascorbate/ascorbic acid powder (generic MoviPrep®)	$76.98
PEG 3350/sodium sulfate/sodium bicarbonate/sodium chloride/ potassium chloride powder packet (generic GoLytely®)	$12.68

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
PEG = polyethylene glycol
*Cost per treatment based on the FDA recommended dose for colonoscopy preparation.

The College of Pharmacy recommends the prior authorization of Sutab® (sodium sulfate/magnesium sulfate/potassium chloride tablet) with criteria similar to other prior authorized bowel preparation medications as follows (changes shown in red):

Clenpiq®, ColPrep Kit®, OsmoPrep®, Plenvu®, Prepopik®, SUPREP®, and Sutab® Approval Criteria:

1. An FDA approved indication for use in cleansing of the colon as a preparation for colonoscopy; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use other bowel preparation medications available without prior authorization must be provided.
3. If the member requires a low volume polyethylene glycol electrolyte lavage solution, MoviPrep® is available without prior authorization. Other medications currently available without a prior authorization include: Colyte®, Gavilyte®, Golytely®, and Trilyte®.

Tarpeyo™ (Budesonide DR Capsule) Product Summary and Recommendations[9]

Tarpeyo™ (budesonide DR capsule) is a corticosteroid indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally with a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g. This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether Tarpeyo™ slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial. The recommended dosing is 16mg once daily, in the morning at least 1 hour before a meal. The recommended duration of therapy is 9 months. When discontinuing therapy, the dosage should be reduced to 8mg once daily for

the last 2 weeks of therapy. Tarpeyo™ is supplied as a DR, oral capsule containing 4mg of budesonide.

- Other Formulation(s) Available: prednisone tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Tarpeyo™ (budesonide 4mg DR capsule)	**$118.00**	**$14,160.00**
budesonide 3mg DR capsule	$0.79	$118.50
prednisone 50mg tablet	$0.24	$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).
DR = delayed-release; Unit = capsule or tablet
*Cost per 30 days based on the FDA recommended dose for Tarpeyo™, budesonide 3mg DR dosing based on dosing similar to Tarpeyo™ for primary immunoglobulin A nephropathy (IgAN), and prednisone dosing based on maximum initial dosing recommended for primary IgAN.

The College of Pharmacy recommends the prior authorization of Tarpeyo™ (budesonide DR capsule) with the following criteria [changes shown in red indicate updates made based on guideline recommendations and Drug Utilization Review (DUR) Board recommendations]:

Tarpeyo™ [Budesonide Delayed Release (DR) Capsule] Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. 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 advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must ~~have a~~ be at risk of rapid disease progression as demonstrated by ≥1 of the following, despite maximal supportive care:
    a. Urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g; or
    b. Proteinuria >0.75g/day; and
6. Member must be on a stable dose of a maximally-tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and
7. A patient-specific, clinically significant reason why ~~the member cannot use~~ a 6-month trial of an alternative formulation of budesonide DR oral capsules (e.g., Entocort® EC) or alternative oral corticosteroids ~~available~~

~~without prior authorization~~ is not appropriate for the member must be provided; and
8. Approval duration will be for 9 months; and
9. A quantity limit of 120 capsules per 30 days will apply.

Vuity™ (Pilocarpine 1.25% Ophthalmic Solution) Product Summary and Recommendations[10]

Vuity™ (pilocarpine 1.25% ophthalmic solution) is a cholinergic muscarinic receptor agonist indicated for the treatment of presbyopia in adults. The recommended dosing of Vuity™ is 1 drop in each eye once daily. If more than 1 topical ophthalmic product is being used, the products should be administered at least 5 minutes apart. Vuity™ is supplied as a 1.25% (12.5mg/mL) pilocarpine hydrochloride ophthalmic solution available in a 5mL ophthalmic dispenser bottle containing 2.5mL of solution.

- Other Formulation(s) Available: pilocarpine ophthalmic solution

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
Vuity™ (pilocarpine 1.25% ophthalmic solution)	**$28.29**	**$70.73**
pilocarpine 1% ophthalmic solution	$3.47	$52.02
pilocarpine 2% ophthalmic solution	$3.55	$53.25

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL
*Cost per package based on largest package size available for product listed.

The College of Pharmacy recommends the prior authorization of Vuity™ (pilocarpine 1.25% ophthalmic solution) with the following criteria:

Vuity™ (Pilocarpine 1.25% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication of the treatment of presbyopia in adults; and
2. Must be prescribed by an ophthalmologist or optometrist; and
3. Prescriber must verify the member does not have iritis; and
4. Prescriber must verify the member has been counseled on the risk of retinal detachment with use of Vuity™ and when to seek immediate medical care; and
5. Prescriber must verify the member has been advised to use caution with night driving and hazardous occupations in poor illumination as vision may not be clear in these conditions while using Vuity™; and
6. A patient-specific, clinically significant reason the member cannot use corrective lenses must be provided; and

7. A patient-specific, clinically significant reason the member cannot use generic pilocarpine ophthalmic solution (Isopto® Carpine) must be provided.

Xipere® (Triamcinolone Acetonide Injection) Product Summary and Recommendations[11]

Xipere® (triamcinolone acetonide injection) is a corticosteroid indicated for the treatment of macular edema associated with uveitis. The recommended dosing is 4mg (0.1mL) administered as a suprachoroidal injection under controlled aseptic conditions. Adequate anesthesia and a broad-spectrum microbicide applied to the periocular skin, eyelid, and ocular surface are recommended to be given prior to the suprachoroidal injection. Xipere® is supplied as a 40mg/mL triamcinolone acetonide injectable suspension in a single-dose glass vial for use with the supplied SCS Microinjector®.

- Other Formulation(s) Available: Ozurdex® (dexamethasone intravitreal implant) and Triesence® (triamcinolone acetonide injectable suspension)

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Dose*
Xipere® (triamcinolone acetonide 40mg/mL injection)	**$1,650.00**	**$3,300.00**
Ozurdex® (dexamethasone 0.7mg intravitreal implant)	$1,333.00	$2,666.00
Triesence® (triamcinolone acetonide 40mg/mL injection)	$150.41	$300.82

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or implant
*Cost per dose based on the FDA recommended dose for uveitis for each product for the treatment of both eyes.

The College of Pharmacy recommends the prior authorization of Xipere® (triamcinolone acetonide injection) with the following criteria:

Xipere® (Triamcinolone Acetonide Injection) Approval Criteria:

1. An FDA approved indication for the treatment of macular edema associated with non-infectious uveitis; and
2. Member must be 18 years of age or older; and
3. Xipere® must be administered by an ophthalmologist; and
4. Prescriber must confirm that the member does not have an active ocular or periocular infection; and
5. Prescriber must confirm member does not have untreated ocular hypertension or uncontrolled glaucoma; and
6. A patient-specific, clinically significant reason why the member cannot use corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and

7. A patient-specific, clinically significant reason the member cannot use Triesence® must be provided; and
8. Initial authorization will be for 12 weeks, with an additional dose approved at or after 12 weeks if the prescriber documents improvement from baseline in visual acuity.

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[10] Vuity™ Prescribing Information. Allergan. Available online at: https://www.rxabbvie.com/pdf/vuity_pi.pdf. Last revised 10/2021. Last accessed 06/15/2022.
[11] Xipere® Prescribing Information. Clearside Biomedical, Inc. Available online at: https://pi.bauschhealth.com/globalassets/BHC/PI/XIPERE-PI.pdf. Last revised 10/2021. Last accessed 06/15/2022.

Appendix I

Vote to Prior Authorize Camcevi™ (Leuprolide), Pluvicto™ (Lutetium Lu 177 Vipivotide Tetraxetan), Tivdak® (Tisotumab Vedotin-tftv), and Welireg™ (Belzutifan) and Update the Approval Criteria for the Genitourinary and Cervical/Endometrial Cancer Medications

Oklahoma Health Care Authority
July 2022

Market News and Updates[1,2]

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

- **May 2021:** The FDA approved Camcevi™ (leuprolide), a gonadotropin-releasing hormone (GnRH), for the treatment of adult patients with advanced prostate cancer.
- **August 2021:** The FDA approved Welireg™ (belzutifan), a hypoxia-inducible factor inhibitor for the treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery.
- **September 2021:** The FDA approved Cabometyx® (cabozantinib) for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior vascular endothelial growth factor (VEGF)-targeted therapy and who are ineligible or refractory to radioactive iodine.
- **September 2021:** The FDA granted accelerated approval to Tivdak® (tisotumab vedotin-tftv), a tissue factor-directed antibody and microtubule inhibitor conjugate, for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
- **March 2022:** The FDA approved Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan) for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

Product Summaries[3,4,5,6]

Camcevi™ (Leuprolide):

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

Pluvicto™ (Lutetium Lu 177 Vipivotide Tetraxetan):

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

Tivdak® (Tisotumab Vedotin-tftv):

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

Welireg™ (Belzutifan):

- **Therapeutic Class:** Hypoxia-inducible factor inhibitor
- **Indication(s):** VHL disease requiring therapy for associated RCC, CNS hemangioblastomas, or pNET, not requiring immediate surgery
- **How Supplied:** 40mg oral tablets
- **Dose:** 120mg [(3) 40mg tablets] once daily

- **Cost:** The WAC is $293.33 per tablet resulting in a monthly cost of $26,399.70 and an annual cost of $316,796.40 based on the recommended dosing.

Recommendations

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

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

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

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

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

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

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

Welireg™ (Belzutifan) Approval Criteria:

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

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

Cabometyx® (Cabozantinib) Approval Criteria:

1. For cabozantinib monotherapy:
    a. Diagnosis of advanced renal cell carcinoma (RCC); or
    b. Diagnosis of advanced hepatocellular carcinoma (HCC); and
        i. Member has previously received sorafenib; or

c. Diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC) in adults and pediatric members 12 years of age and older; and
    i. Disease has progressed following prior vascular endothelial growth factor (VEGF)-targeted therapy; and
    ii. Disease is radioactive iodine-refractory or member is ineligible for radioactive iodine; or

2. For cabozantinib in combination with nivolumab:
    a. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with advanced RCC; and
    b. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.

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[1] Foresee Pharmaceuticals. Foresee Pharmaceuticals Announces FDA Approval of Camcevi™ for the Treatment of Advanced Prostate Cancer; Accord BioPharma to Head the U.S. Commercialization. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/foresee-pharmaceuticals-announces-fda-approval-of-camcevi-for-the-treatment-of-advanced-prostate-cancer-accord-biopharma-to-head-the-us-commercialization-301300500.html. Issued 05/26/2021. Last accessed 06/13/2022.

[2] U.S. Food and Drug Administration (FDA). Hematology/Oncology (Cancer) Approvals & Safety Notifications. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/hematologyoncology-cancer-approvals-safety-notifications. Last revised 05/31/2022. Last accessed 06/13/2022.

[3] Camcevi™ Prescribing Information. Accord BioPharma, Inc. Available online at: https://www.accordbiopharma.com/our-therapies/camcevi/camcevi_pi.pdf. Last revised 05/2021. Last accessed 06/13/2022.

[4] Pluvicto™ Prescribing Information. Advanced Accelerator Applications USA, Inc. Available online at: https://www.novartis.us/sites/www.novartis.us/files/pluvicto.pdf. Last revised 03/2022. Last accessed 06/13/2022.

[5] Tivdak® Prescribing Information. Seagen, Inc. Available online at: https://seagendocs.com/Tivdak_Full_Ltr_Master.pdf. Last revised 01/2022. Last accessed 06/13/2022.

[6] Welireg™ Prescribing Information. Merck & Co., Inc. Available online at: https://www.merck.com/product/usa/pi_circulars/w/welireg/welireg_pi.pdf. Last revised 05/2022. Last accessed 06/13/2022.

Appendix J

Calendar Year 2021 Annual Review of Colorectal Cancer Medications and 30-Day Notice to Prior Authorize Alymsys® (Bevacizumab-maly), Lonsurf® (Trifluridine/Tipiracil), and Stivarga® (Regorafenib)

Oklahoma Health Care Authority
July 2022

Introduction[1,2,3]

Colorectal cancers are relatively common cancers with approximately 151,030 new cases estimated to be diagnosed in the United States in 2022. Despite therapeutic advances and more individualized treatment approaches, colorectal cancers remain difficult to treat. For 2022, the estimated number of deaths in this patient population are 52,580 with a 65.1% 5-year survival. Screening for colorectal cancers remains the most effective approach at increasing survival as cases are detected at earlier stages and are more likely to be cured. The past 20 years have brought developments to the treatment of metastatic disease. These developments include new active agents against the disease as well as enhanced knowledge about tumor biology in driving therapeutic decision-making. Effective agents include traditional chemotherapy, vascular endothelial growth factors (VEGFs) and VEGF receptor (VEGFR) inhibitors, epidermal growth factor receptor (EGFR) inhibitors, BRAF V600E inhibitors, human epidermal growth factor receptor type 2 (HER2) monoclonal antibodies, and immunotherapy using immune checkpoint inhibitors for patients whose tumors have mismatch repair deficiency or high levels of microsatellite instability. Biomarkers have been identified for patients who are candidates for all of these agents except VEGF inhibitors.

Current Prior Authorization Criteria

Approval criteria for Braftovi® (encorafenib), Keytruda® (pembrolizumab), Opdivo® (nivolumab), and Yervoy® (ipilimumab) for indications other than colorectal cancer can be found in the 2021 Annual Review of Skin Cancer Medications report in the December 2021 Drug Utilization Review (DUR) packet. The complete approval criteria for these medications are reviewed annually with the skin cancer medications. The approval criteria for Cyramza® (ramucirumab), Mvasi® (bevacizumab-awwb), Rozlytrek® (entrectinib), and Zirabev® (bevacizumab-bvzr) for indications other than colorectal cancer can be found in the 2022 Annual Review of Lung Cancer Medications report in the May 2022 DUR packet. The complete approval criteria for these medications

are reviewed annually with the lung cancer medications. The approval criteria for Jemperli (dostarlimab-gxly) for indications other than colorectal cancer can be found in the 2021 Annual Review of Lenvima® (Lenvatinib) and 30-Day Notice to Prior Authorize Jemperli (Dostarlimab-gxly) report in the November 2021 DUR packet. The complete approval criteria for Jemperli is reviewed annually with Lenvima®.

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.

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

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

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

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

Khapzory™ (Levoleucovorin Injection) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Rescue after high-dose methotrexate (MTX) therapy in members with osteosarcoma; or
    b. Diminishing the toxicity associated with overdosage of folic acid antagonists or impaired MTX elimination; or
    c. Treatment of members with metastatic colorectal cancer in combination with fluorouracil; and

2. A patient-specific, clinically significant reason why the member cannot use generic leucovorin injection or generic levoleucovorin calcium injection must be provided.

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.

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

1. Diagnosis of mCRC; and
2. Disease has progressed on treatment with 5-fluorouracil (5-FU), oxaliplatin, and irinotecan; and
3. Tumor is microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR); and
4. Used as a single agent or in combination with ipilimumab.

Opdivo® (Nivolumab) Approval Criteria [Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer (mCRC) Diagnosis]:

1. Diagnosis of MSI-H or dMMR mCRC; and
2. Member has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)]; and
3. Progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

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 has no satisfactory alternative therapy.

Vitrakvi® (Larotrectinib) Approval Criteria [Solid Tumors With Neurotrophic Receptor Tyrosine Kinase (*NTRK*) Gene Fusion Diagnosis]:

1. Diagnosis of a solid tumor with an *NTRK* gene fusion without a known acquired resistance mutation; and

2. Disease is metastatic or surgical resection (or radioactive iodine refractory if thyroid carcinoma) is contraindicated; and
3. Documentation of no satisfactory alternative treatments or progression following acceptable alternative treatments.

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

1. Diagnosis of metastatic CRC; and
2. Disease has progressed on treatment with 5-fluorouracil (5-FU), oxaliplatin, and irinotecan; and
3. Tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and
4. Used in combination with nivolumab.

Utilization of Colorectal Cancer Medications: Calendar Year 2021

The following utilization data includes medications indicated for colorectal cancers; 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
2020	11	26	$386,183.32	$14,853.20	$557.26	2,030	693
2021	8	18	$203,308.02	$11,294.89	$408.25	1,056	498
% Change	**-27.30%**	**-30.80%**	**-47.40%**	**-24.00%**	**-26.70%**	**-48.00%**	**-28.10%**
Change	**-3**	**-8**	**-$182,875.30**	**-$3,558.31**	**-$149.01**	**-974**	**-195**

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

Calendar Year Comparison: Medical Claims

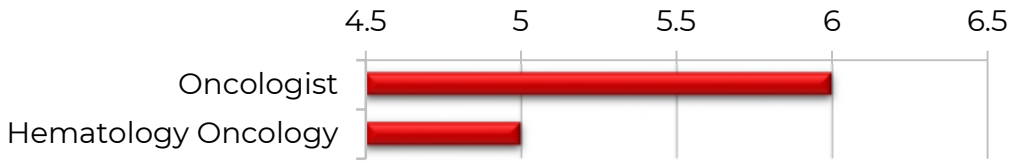
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2020	687	2,861	$16,185,336.37	$5,657.23	4.16
2021	934	3,333	$17,440,050.99	$5,232.54	3.57
% Change	**35.95%**	**16.50%**	**7.75%**	**-7.51%**	**-14.18%**
Change	**247**	**472**	**$1,254,714.62**	**-$424.69**	**-0.59**

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 2021, detailed demographic information could not be provided.

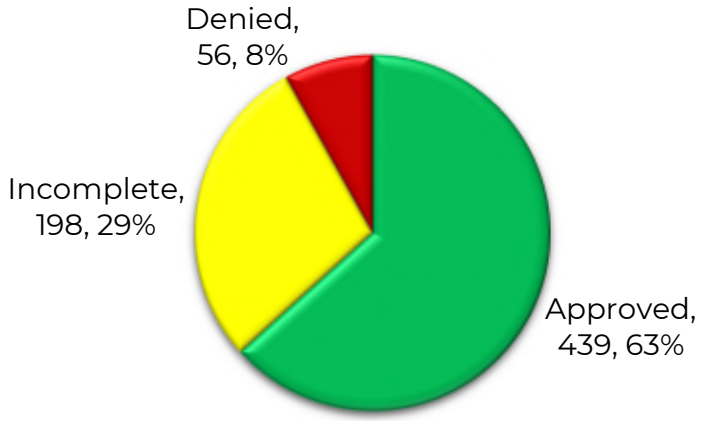
Top Prescriber Specialties of Colorectal Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Colorectal Cancer Medications

There were 693 prior authorization requests submitted for colorectal medications during calendar year 2021. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions



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

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

- **April 2017:** The FDA approved Stivarga® (regorafenib) for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with the drug sorafenib. Stivarga® was first FDA approved in 2012 and is also indicated to treat colorectal cancer and gastrointestinal stromal tumors (GIST) that are no longer responding to previous treatments.
- **August 2017:** The FDA approved Opdivo® (nivolumab) for the treatment of adult and pediatric patients 12 years and older with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Approval for this indication was granted under accelerated approval based on overall response rate (ORR) and duration of response (DOR). In 2018, the

combination of Opdivo® and Yervoy® (ipilimumab) was granted an expanded indication for the treatment of adult and pediatric patients 12 years and older with MSI-H or dMMR mCRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

- **February 2019:** The FDA approved Lonsurf® (trifluridine/tipiracil tablets) for the treatment of adults with metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy. This approval expands the indication for Lonsurf® which includes the treatment of adults with mCRC who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, anti-VEGF biological therapy and, if RAS wild-type, an anti-EGFR therapy. Lonsurf® was originally FDA approved in 2015.
- **June 2020:** The FDA approved Keytruda® (pembrolizumab) for the treatment of uresectable or metastatic MSI-H or dMMR CRC cancer based on improved progression-free survival (PFS) in the frontline setting.
- **April 2022:** The FDA approved Alymsys® (bevacizumab-maly), a biosimilar to Avastin® (bevacizumab). The approval was based on data demonstrating that the biosimilar product and the reference product were highly similar, and that there were no clinically meaningful differences between the agents. Alymsys is a VEGF inhibitor indicated for the treatment of mCRC; unresectable, locally advanced, recurrent, or metastatic non-squamous non-small cell lung cancer (NSCLC); recurrent glioblastoma in adults; metastatic renal cell carcinoma (RCC); persistent, recurrent, or metastatic cervical cancer; and epithelial ovarian, fallopian tube, or primary peritoneal cancer. Alymsys® is not indicated for adjuvant treatment of colon cancer.
- **May 2022:** The FDA approved Opdivo® (nivolumab) in combination with fluoropyrimidine- and platinum-based chemotherapy or Opdivo® in combination with ipilimumab for the first-line treatment of patients with advanced or metastatic esophageal squamous cell carcinoma (ESCC).

Guideline Update(s):

- **February 2022:** The National Comprehensive Caner Network (NCCN) Guidelines for colon cancer recommend the use of Herceptin® (trastuzumab) or its biosimilars in combination with Perjeta® (pertuzumab) or Tykerb® (lapatinib) for use in colon cancer patients with HER2/neu amplified disease who do not have BRAF or RAS mutations. The combination regimens produced a 30% objective response rate in this patient population. Additionally, Enhertu® (fam-trastuzumab deruxtean) is now recommended in patients with HER2/

neu positive and BRAF/RAS wild-type disease in the second-line setting. Median PFS in patients with strong HER2/neu expressing tumors was 6.9 months and overall survival (OS) has not yet been reached.

Product Summaries[11,12,13]

Alymsys® (Bevacizumab-maly):

- **Therapeutic Class:** VEGF inhibitor, biosimilar to Avastin® (bevacizumab)
- **Indication(s):**
  - mCRC:
    - In combination with intravenous (IV) fluorouracil-based chemotherapy for first- or second-line treatment
    - In combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen
  - Unresectable locally advanced, recurrent, or metastatic non-squamous NSCLC, in combination with carboplatin and paclitaxel for first-line treatment
  - Recurrent glioblastoma in adults
  - Metastatic RCC in combination with interferon alfa
  - Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and either cisplatin or topotecan
  - Epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens
  - Limitation(s) of Use: Alymsys® is not indicated for adjuvant treatment of colon cancer.
- **How Supplied:** 100mg/4mL (25mg/mL) or 400mg/16mL (25mg/mL) sterile solution for IV infusion in single-dose vials
- **Dose:** 5mg/kg to 15mg/kg every 2 to 3 weeks based on diagnosis (see Alymsys® *Prescribing Information* for diagnosis dependent dosing regimens)
- **Cost:** The Wholesale Acquisition Cost (WAC) is $179.65 per mL, resulting in a monthly cost of $11,497.60 and annual cost of $149,468.80 based on the recommended dosing of 10mg/kg every 2 weeks for the treatment of mCRC for an 80kg adult.

Lonsurf® (Trifluridine/Tipiracil):

- **Therapeutic Class:** Combination nucleoside metabolic inhibitor and thymidine phosphorylase inhibitor
- **Indication(s):**

    - mCRC previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy
    - GEJ adenocarcinoma previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy
- **How Supplied:** 15mg/6.14mg and 20mg/8.19mg trifluridine/tipiracil oral tablets
- **Dose:** 35mg/m^2 per dose twice daily up to a maximum of 80mg per dose (based on the trifluridine component) on days 1 through 5 and days 8 through 12 of each 28-day cycle
- **Cost:** The WAC is $250.67 per 20mg/8.19mg trifluridine/tipiracil tablet resulting in a monthly cost of $20,053.60 and an annual cost of $260,696.80 based on the maximum recommended dosing.

Stivarga® (Regorafenib):

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):**
    - mCRC previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and if *RAS* wild-type, an anti-EGFR therapy
    - Locally advanced unresectable or metastatic GIST previously treated with imatinib mesylate and sunitinib malate
    - HCC previously treated with sorafenib
- **How Supplied:** 40mg oral tablet
- **Dose:** 160mg [(4) 40mg tablets] once daily for the first 21 days of each 28-day cycle
- **Cost:** The WAC is $243.48 per tablet resulting in a monthly cost of $20,452.32 and an annual cost of $265,880.16 based on the recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Alymsys® (bevacizumab-maly), Lonsurf® (trifluridine/tipiracil), and Stivarga® (regorafenib) with the following criteria listed in red:

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.

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.

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

1. Diagnosis of metastatic, recurrent, or unresectable colorectal cancer; 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 Cancer (HCC) Diagnosis]:

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

Additionally, the College of Pharmacy recommends updating the Enhertu® (fam-trastuzumab deruxtecan-nxki), Herceptin® (trastuzumab), Herzuma®

(trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), Ogivri® (trastuzumab-dkst), Ontruzant® (trastuzumab-dttb), Trazimera® (trastuzumab-qyyp), Keytruda® (pembrolizumab), Opdivo® (nivolumab), Perjeta® (pertuzumab), and Yervoy® (ipilimumab) prior authorization criteria based on FDA approvals and NCCN guideline recommendations (changes noted in red):

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 trastuzumab or lapatinib; and
4. Used in 1 of the following settings:
    a. If first-line therapy, patient should not be a candidate for intensive therapy; or
    b. For the treatment of advanced or metastatic disease following disease progression; and
5. Authorization of Herceptin® (trastuzumab), Herzuma® (trastuzumab-pkrb), or Kanjinti® (trastuzumab-anns) will also require a patient-specific, clinically significant reason why the member cannot use Ogivri® (trastuzumab-dkst), 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. ~~First-line treatment; and~~
3. Metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

Opdivo® (Nivolumab) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) or Esophageal or Gastroesophageal Junction (GEJ) Cancer Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic ESCC; and
    a. Used in the first-line setting; and
    b. Used in combination with 1 of the following:
        i. Fluoropyrimidine- and platinum-based chemotherapy; or
        ii. Ipilimumab; or
2. Diagnosis of esophageal or GEJ cancer; and
    a. Member has received preoperative chemoradiation; and
    b. Member underwent R0 (complete) resection and has residual disease; and
    c. As a single agent; or
3. Palliative therapy for members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease; and
    a. Human epidermal receptor 2 (HER2)-negative disease; and
        i. Used in first-line setting; and
            1. Used in combination with oxaliplatin and fluorouracil or capecitabine; and
            2. Adenocarcinoma pathology; or
        ii. Used in the second-line or greater setting; and
            1. As a single agent; and
            2. Squamous cell pathology.

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

1. Diagnosis of unresectable or metastatic CRC; and
2. ~~Disease has progressed on treatment with 5-fluorouracil (5-FU), oxaliplatin, and irinotecan; and~~
3. Tumor is microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR).~~; and~~
4. ~~Used as a single agent or in combination with ipilimumab.~~

~~**Opdivo® (Nivolumab) Approval Criteria [Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer (mCRC) Diagnosis]:**~~

1. ~~A diagnosis of MSI-H or dMMR mCRC; and~~
2. ~~Member has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)]; and~~
3. ~~Progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.~~

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

1. Diagnosis of human epidermal receptor type 2 (HER2)-positive CRC; and
2. RAS and BRAF mutation-negative; and
3. Used in combination with trastuzumab; and
4. Used in 1 of the following settings:
   a. If first-line therapy, patient should not be a candidate for intensive therapy; or
   b. For the treatment of advanced or metastatic disease following disease progression.

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

1. Diagnosis of unresectable or metastatic CRC; and
2. ~~Disease has progressed on treatment with 5-fluorouracil (5-FU), oxaliplatin, and irinotecan; and~~
3. Tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and
4. Used in combination with nivolumab.

Yervoy® (Ipilimumab) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic ESCC; and
   a. Used in the first-line setting; and
   b. Used in combination with nivolumab.

Utilization Details of Colorectal Cancer Medications: Calendar Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TRIFLURIDINE/TIPIRACIL PRODUCTS					
LONSURF TAB 20/8.19MG	5	3	$52,024.46	1.67	$10,404.89
LONSURF TAB 15/6.14MG	5	3	$32,297.10	1.67	$6,459.42
SUBTOTAL	**10**	**6**	**$84,321.56**	**1.67**	**$8,432.16**
ENCORAFENIB PRODUCTS					
BRAFTOVI CAP 75MG	1	1	$12,687.91	1	$12,687.91
SUBTOTAL	**1**	**1**	**$12,687.91**	**1**	**$12,687.91**
REGORAFENIB PRODUCTS					
STIVARGA TAB 40MG	7	5	$106,298.55	1.4	$474.55
SUBTOTAL	**7**	**5**	**$106,298.55**	**1.4**	**$474.55**
TOTAL	**18**	**8***	**$203,308.02**	**2.25**	**$11,294.89**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
BEVACIZUMAB J9035	1,322	503	$1,447,888.45	2.63	$1,095.23
TRASTUZUMAB J9355	530	87	$2,316,675.42	6.09	$4,371.09
PEMBROLIZUMAB J9271	528	138	$6,725,078.00	3.83	$12,736.89
PERTUZUMAB J9306	366	70	$2,431,654.68	5.23	$6,643.87
BEVACIZUMAB-AWWB Q5107	276	58	$929,912.84	4.76	$3,369.25
NIVOLUMAB J9299	244	56	$2,882,586.15	4.36	$11,813.88
IPILIMUMAB J9228	26	12	$494,363.04	2.17	$19,013.96
RAMUCIRUMAB J9308	22	4	$148,306.60	5.5	$6,741.21
TRASTUZUMAB-ANNS Q5117	17	4	$56,290.45	4.25	$3,311.20
TRASTUZUMAB-QYYP Q5116	1	1	$3,835.52	1	$3,835.52
TRASTUZUMAB-DTTB Q5112	1	1	$3,459.84	1	$3,459.84
TOTAL	**3,333**	**934**	**$17,440,050.99**	**3.57**	**$5,232.54**

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

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Appendix K

Calendar Year 2021 Annual Review of Danyelza® (Naxitamab-gqgk), Koselugo® (Selumetinib), Pemazyre® (Pemigatinib), Qinlock® (Ripretinib), and Truseltiq® (Infigratinib)

Oklahoma Health Care Authority
July 2022

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

Neurofibromatosis is a genetic disorder of the nervous system; types of neurofibromatosis include neurofibromatosis type 1 (NF1), neurofibromatosis type 2 (NF2), and schwannomatosis. NF1 is an autosomal dominant condition, although the estimated new mutation rate is high with approximately 42% of affected individuals having de novo mutations. This syndrome predisposes patients to benign or malignant tumors located in the central and peripheral nervous systems. Patients can present with cutaneous features such as skinfold freckling, cutaneous neurofibromas, or café-au-lait macules (CALMs). Plexiform neurofibromas (PN) are benign tumors of the peripheral nerve sheath affecting 40 to 50% of patients with NF1. PN can lead to pain, disfigurement, local compression, and loss of function of nerves, vessels, and airways, and can also transform into malignant peripheral nerve sheath tumors. Surgical resection can be performed; however, it can be challenging or not feasible in certain areas of the body. Selumetinib remains the only U.S. Food and Drug Administration (FDA) approved medical management for this condition.

Neuroblastomas are tumors that have been associated with NF1, but can arise anywhere in the sympathetic nervous system. The adrenal gland is the most common primary site (40%), followed by abdominal (25%), thoracic (15%), cervical (5%), and pelvic sympathetic ganglia (5%). Neuroblastoma is almost exclusively a disease of children. It is the third most common childhood cancer, after leukemia and brain tumors, and is the most common solid extracranial tumor in children. More than 600 cases are diagnosed in the United States each year, and neuroblastoma accounts for approximately 15% of all pediatric cancer fatalities. The median age at diagnosis is 17.3 months, and 40% of patients are diagnosed before 1 year of age. Neuroblastomas are the most common extracranial solid malignant tumor diagnosed during the first 2 years of life and the most common cancer among infants younger than 12 months, in whom the incidence rate is almost twice that of leukemia (58 versus 37 per 1 million infants). Disialoganglioside (GD2) is a neuroblastoma cell-specific antigen and is highly expressed in most neuroblastoma cells.

Based on the overall response rates (ORR) from 2 clinical studies (45% and 34%) and a duration of response (DOR) of >6 months in the same 2 studies (30% and 23%), naxitamab-gqgk, a monoclonal antibody that targets GD2, was granted accelerated approval by the FDA in 2020 for the treatment of relapsed or refractory high-risk neuroblastoma.

Cholangiocarcinomas originate in the epithelium of the bile duct and can be divided into intrahepatic or extrahepatic cholangiocarcinomas. Complete resection is the only potentially curative treatment for patients with resectable disease, although many patients are not candidates for this due to the presence of advanced disease at diagnosis. Systemic treatment with chemotherapy can be given to patients not eligible for resection or with metastatic disease. There is an increasing role for molecular profiling of cholangiocarcinomas looking at *IDH1/IDH2* mutations, *KRAS* mutation, *BAP1* mutation, human epidermal growth factor receptor 2 (HER2) gene amplification, and fibroblast growth factor (FGF) receptor 2 (FGFR2) fusions. FGFR2 fusions are found in 8 to 14% of intrahepatic cholangiocarcinomas. FGF receptor mutations may be associated with a favorable prognosis, and pemigatinib, an FGF receptor inhibitor, was FDA approved in 2020 for the treatment of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or other rearrangement. Based on the ORR (23%) and a DOR of >6 months (32%), infigratinib, another FGF receptor inhibitor, was granted accelerated approval by the FDA in 2021 for the treatment of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or other rearrangement.

Gastrointestinal stromal tumors (GIST) are the most common type of soft-tissue sarcoma of the gastrointestinal (GI) tract. Surgery and targeted therapies are the cornerstones of treatment of GIST, as traditional chemotherapy has been largely ineffective. *KIT* and *PDGFRA* are common activating mutations involved in the pathogenesis of GIST. Approximately 80% of all GIST are positive for *KIT* mutation and another 5 to 10% possess *PDGFRA* mutation, making these mutations rational therapeutic targets. Tyrosine kinase inhibitors (TKIs) specific for these mutations have improved 2-year overall survival to approximately 80%. Ripretinib, a TKI that inhibits both wild type and mutant forms of *KIT* and *PDGRA*, was FDA approved for advanced GIST in 2020.

Current Prior Authorization Criteria

Danyelza® (Naxitamab-gqgk) Approval Criteria [Neuroblastoma Diagnosis]:

1. Diagnosis of relapsed or refractory high-risk neuroblastoma in adult and pediatric members 1 year of age and older; and

2. Disease in the bone or bone marrow demonstrating a partial response, minor response, or stable disease to prior therapy (i.e., no progressive disease following most recent therapy); and
3. Must be given in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF) according to package labeling (GM-CSF dosed at 250mcg/m^2/day daily starting 5 days prior to Danyelza® therapy and 500mcg/m^2/day daily on days 1 to 5 of Danyelza® therapy); and
4. Prescriber must agree to provide the member appropriate premedication for pain management and neuropathic pain (e.g., oral opioids, gabapentin); and
5. Prescriber must agree to provide the member appropriate premedication for infusion-related reactions and nausea/vomiting including an intravenous (IV) corticosteroid, a histamine 1 (H_1) antagonist, an H_2 antagonist, acetaminophen, and an antiemetic.

Koselugo® (Selumetinib) Approval Criteria [Neurofibromatosis Type 1 (NF1) Diagnosis]:

1. Diagnosis of NF1 with symptomatic, inoperable plexiform neurofibromas.

Pemazyre® (Pemigatinib) Approval Criteria [Cholangiocarcinoma Diagnosis]:

1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma; and
2. Must have failed 1 or more prior therapies; and
3. Disease is positive for a fibroblast growth factor receptor 2 (FGFR2) fusion or other FGFR rearrangement.

Qinlock® (Ripretinib) Approval Criteria [Gastrointestinal Stromal Tumor (GIST) Diagnosis]:

1. Diagnosis of advanced GIST; and
2. Previously received ≥3 kinase inhibitors, including imatinib; and
3. As a single agent.

Truseltiq® (Infigratinib) Approval Criteria [Cholangiocarcinoma Diagnosis]:

1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma; and
2. Presence of fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement; and
3. Disease has progressed on at least 1 prior systemic therapy; and
4. As a single agent.

Utilization of Danyelza® (Naxitamab-gqgk), Koselugo® (Selumetinib), Pemazyre® (Pemigatinib), Qinlock® (Ripretinib), and Truseltiq® (Infigratinib): Calendar Year 2021

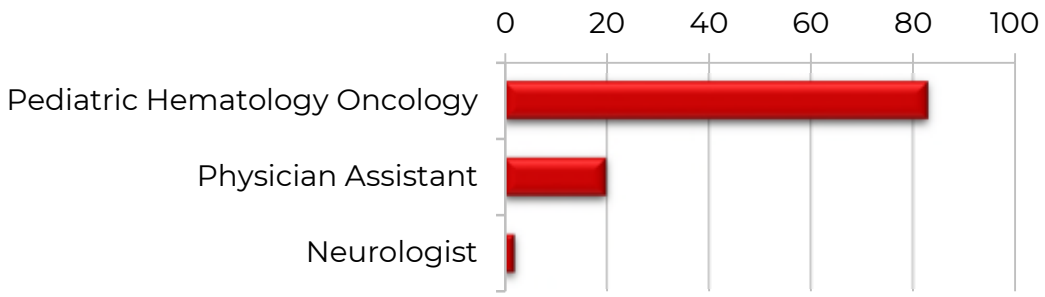
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	9	48	$580,693.68	$12,097.79	$420.79	5,280	1,380
2021	13	105	$1,377,223.65	$13,116.42	$450.07	11,580	3,060
% Change	**44.40%**	**118.80%**	**137.20%**	**8.40%**	**7.00%**	**119.30%**	**121.70%**
Change	**4**	**57**	**$796,529.97**	**$1,018.63**	**$29.28**	**6,300**	**1,680**

Demographics of Members Utilizing Danyelza® (Naxitamab-gqgk), Koselugo® (Selumetinib), Pemazyre® (Pemigatinib), Qinlock® (Ripretinib), and Truseltiq® (Infigratinib)

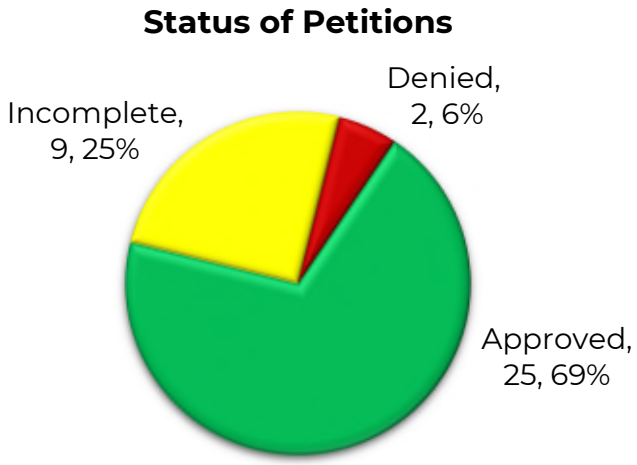
- Due to the limited number of members utilizing Danyelza®, Koselugo®, Pemazyre®, Qinlock®, and Truseltiq® during calendar year 2021, detailed demographic information could not be provided.

Top Prescriber Specialties of Utilizing Danyelza® (Naxitamab-gqgk), Koselugo® (Selumetinib), Pemazyre® (Pemigatinib), Qinlock® (Ripretinib), and Truseltiq® (Infigratinib) by Number of Claims



Prior Authorization of Danyelza® (Naxitamab-gqgk), Koselugo® (Selumetinib), Pemazyre® (Pemigatinib), Qinlock® (Ripretinib), and Truseltiq® (Infigratinib)

There were 36 prior authorization requests submitted for Danyelza®, Koselugo®, Pemazyre®, Qinlock®, and Truseltiq® during calendar year 2021. The following chart shows the status of the submitted petitions for calendar year 2021.



Market News and Updates[8]

Anticipated Patent Expiration(s):

- Koselugo® (selumetinib): December 2026
- Truseltiq® (infigratinib): December 2034
- Pemazyre® (pemigatinib): January 2035
- Qinlock® (ripretinib): December 2040

Recommendations

The College of Pharmacy does not recommend any changes to the current prior authorization criteria for Danyelza® (naxitamab-gqgk), Koselugo® (selumetinib), Pemazyre® (pemigatinib), Qinlock® (ripretinib), and Truseltiq® (infigratinib) at this time.

Utilization Details of Danyelza® (Naxitamab-gqgk), Koselugo® (Selumetinib), Pemazyre® (Pemigatinib), Qinlock® (Ripretinib), and Truseltiq® (Infigratinib): Calendar Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
KOSELUGO CAP 25MG	57	8	$836,217.67	$14,670.49	7.13
KOSELUGO CAP 10MG	48	10	$541,005.98	$11,270.96	4.8
TOTAL	**105**	**13***	**$1,377,223.65**	**$13,116.42**	**8.08**

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

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Appendix L

Calendar Year 2021 Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Adlarity® (Donepezil Transdermal System) and Aduhelm® (Aducanumab-avwa)

Oklahoma Health Care Authority
July 2022

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.

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.

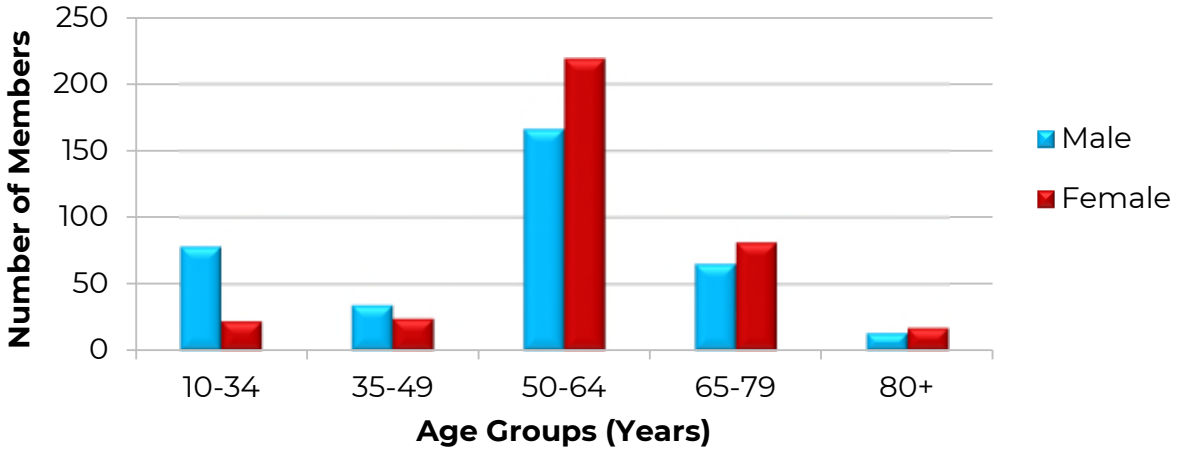
Utilization of Alzheimer's Disease Medications: Calendar Year 2021

Comparison of Calendar Years: Pharmacy Claims

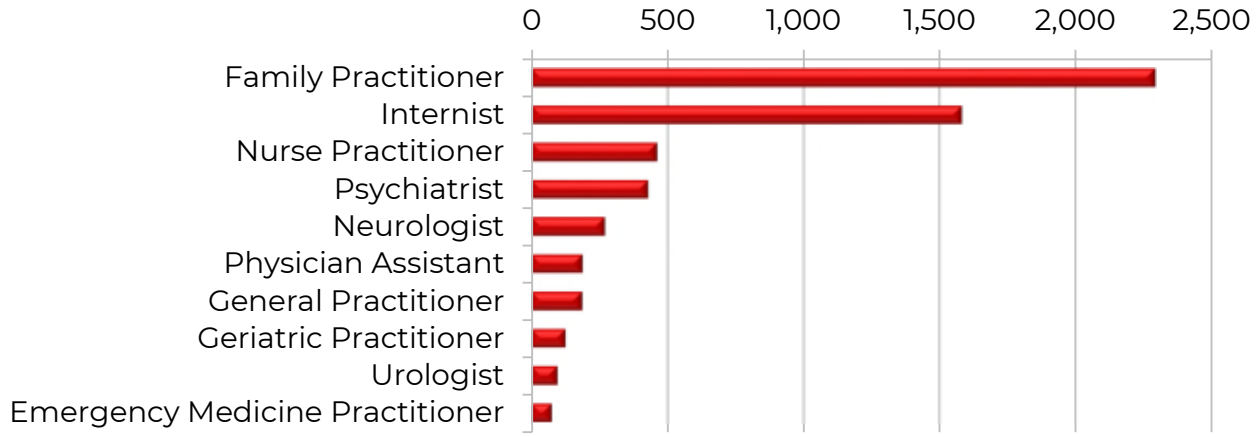
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	684	6,166	$114,085.37	$18.50	$0.57	313,197	200,758
2021	719	5,855	$100,022.99	$17.08	$0.51	306,946	196,730
% Change	**5.1%**	**-5.0%**	**-12.3%**	**-7.7%**	**-10.5%**	**-2.0%**	**-2.0%**
Change	**35**	**-311**	**-$14,062.38**	**-$1.42**	**-$0.06**	**-6,251**	**-4,028**

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

Demographics of Members Utilizing Alzheimer's Disease Medications

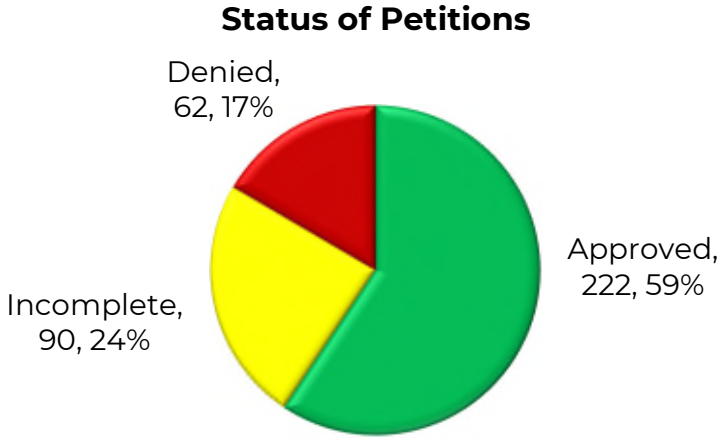


Top Prescriber Specialties of Alzheimer's Disease Medications by Number of Claims



Prior Authorization of Alzheimer's Disease Medications

There were 374 prior authorization requests submitted for Alzheimer's disease medications during calendar year 2021. The following chart shows the status of the submitted petitions for calendar year 2021.



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

Anticipated Patent Expiration(s):

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

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

- **June 2021:** The FDA approved Aduhelm® (aducanumab-avwa) for the treatment of Alzheimer's disease through the accelerated approval pathway. Aduhelm® is the first new treatment approved for Alzheimer's disease since 2003 and the first therapy that targets the fundamental pathophysiology of the disease by reducing amyloid beta plaques in the brain. The efficacy of Aduhelm® was evaluated in 3 Phase 3 clinical studies, EMERGE (study 1), ENGAGE (study 2) and PRIME (study 3), in patients with early stages of Alzheimer's disease (mild cognitive impairment and mild dementia) with confirmed presence of amyloid pathology. In these studies, Aduhelm® consistently showed a dose- and time-dependent effect on the lowering of amyloid beta plaques [by 59% ($P<0.0001$) in ENGAGE, 71% ($P<0.0001$) in EMERGE, and 61% ($P<0.0001$) in PRIME]. Continued approval for Aduhelm® may be contingent upon verification of clinical benefit in confirmatory studies.
- **March 2022:** The FDA approved Adlarity® (donepezil transdermal system) as a treatment for patients with mild, moderate, or severe dementia of the Alzheimer's type. This is the first and only once-weekly

patch of donepezil. It uses Corium's proprietary CORPLEX transdermal technology that was developed to deliver continuous, controlled, and sustained release of a drug over a defined time. Adlarity® was approved through the FDA 505(b)(2) regulatory pathway and was shown to have bioequivalence to donepezil tablets. It will be supplied as a 5mg/day and 10mg/day patch and should be applied to the patient's back, thigh, or buttocks. Adlarity® is expected to be available in early fall 2022.

News:

- **December 2021:** Biogen Inc. announced that effective January 1, 2022, the wholesale acquisition cost (WAC) of Aduhelm® will be reduced by approximately 50%. The goal is the lowering of out-of-pocket expenses for patients and reducing the potential financial implications for the United States health care system. The reduced price is part of the company's ongoing commitment to further inform treatment choices. Biogen recently presented new p-tau181 biomarker data at the Clinical Trials on Alzheimer's Disease (CTAD) conference and announced its plan to complete the Phase 4 confirmatory post-marketing study of Aduhelm® in an accelerated timeline of 4 years.
- **January 2022:** The Centers for Medicare and Medicaid Services (CMS) intends to limit coverage of the Alzheimer's drug, Aduhelm® via a special program, intended to help assess how well this expensive medication works. CMS has proposed a National Coverage Determination (NCD) that will pay for Aduhelm® under its coverage with evidence development (CED) mechanism and only if patients are enrolled in qualifying clinical studies. If the NCD is finalized, CMS will review each submitted clinical study to determine whether it meets specific criteria. Studies must address whether using anti-amyloid antibodies in Alzheimer's results in a statistically significant and clinically meaningful difference in decline in cognition and function, in addition to studying adverse events associated with treatment. In addition to CMS-approved studies, National Institutes of Health (NIH)-sponsored clinical studies also would be covered under the proposed determination. Medicare patients in the studies would be eligible to receive coverage of the drug, related services, and other routine costs, including positron emission tomography (PET) scans.
- **February 2022:** The American Academy of Neurology (AAN) has released an "evidence-in-focus" report to help neurologists, patients, and their families digest the current evidence on the controversial Alzheimer's drug, Aduhelm®. The authors reviewed data from 4 clinical studies – 1 rated class I and 3 rated class II. Results from the class I study showed that single doses of Aduhelm® up to 30mg/kg were safe and well tolerated. All 3 class II studies provided evidence that 3mg/kg to 10mg/kg doses of Aduhelm® decreased amyloid plaques in the brain

compared with placebo. However, it was unclear what effect the drug had on symptoms of Alzheimer's disease. More research is needed regarding many aspects of Aduhelm® treatment, including whether the drug can slow Alzheimer's disease progression, how often brain imaging is needed to monitor for brain swelling and bleeding, the optimal duration of treatment, and the criteria for when to discontinue use of the drug. Until new research is available, AAN hopes their evidence-in-focus report will increase understanding of the current data to help doctors, patients, and families discuss and make decisions on whether to pursue treatment with Aduhelm®.

- **March 2022:** New data released by Biogen showed that long-term treatment with Aduhelm® continues to reduce the underlying pathologies of Alzheimer's disease after more than 2 years of treatment. Patients receiving Aduhelm® in the long-term extension phase of two Phase 3 studies (ENGAGE and EMERGE) continued to experience significant reductions in amyloid beta plaque levels ($P<0.001$) out to week 132 and plasma p-tau181 levels ($P<0.001$) out to week 128. In both studies, at 78 weeks, patients with a reduction in plasma p-tau181, an exploratory endpoint, had less clinical progression across all 4 clinical endpoints measuring cognition and function than patients whose plasma p-tau181 levels were not reduced. Biogen is expecting to start screening patients in May 2022 for the Phase 4 confirmatory study with the primary readout of data expected 4 years later.

Pipeline:

- **Donanemab:** Donanemab is a monoclonal antibody similar to aducanumab-avwa but designed to target a form of amyloid beta present only in amyloid plaques called N3pG. Due to its specific action, Eli Lilly has suggested that donanemab may be a more effective anti-amyloid agent. The FDA has granted Breakthrough Therapy designation for donanemab based on the Phase 2 study that studied the efficacy and safety of donanemab in patients with early symptomatic Alzheimer's disease. Eli Lilly intends to submit a biologics license application (BLA) for donanemab under the accelerated approval pathway later this year based on data from the study. The safety, tolerability, and efficacy of donanemab are also being evaluated in the ongoing Phase 3 study.
- **Lecanemab:** Eisai has requested Priority Review of its BLA for lecanemab, a monoclonal antibody, for the treatment of mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease (collectively known as early Alzheimer's disease) with confirmed presence of amyloid pathology in the brain. If the FDA accepts the BLA, the Prescription Drug User Fee Act (PDUFA) action date will be set. While Eisai has currently submitted the BLA for lecanemab under the

accelerated approval pathway, results of the Phase 3 confirmatory clinical study, Clarity AD, will be released in the fall of 2022.

- **Gantenerumab:** Gantenerumab is a subcutaneously administered investigational IgG1 antibody designed to bind to aggregated forms of beta-amyloid and remove brain amyloid plaques, and it was granted Breakthrough Therapy designation by the FDA. The pivotal GRADUATE studies are investigating the effect of gantenerumab on amyloid load and downstream biomarkers of disease progression as well as the safety and efficacy of gantenerumab in patients with early (prodromal-to-mild) Alzheimer's disease. Both studies are expected to be completed in the second half of 2022.

Aduhelm® (Aducanumab-avwa) Product Summary[12,13]

Indication(s): An amyloid beta-directed antibody indicated for the 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 studies.

- Continued approval for this indication is contingent upon verification of clinical benefit in confirmatory studies.

How Supplied: 170mg/1.7mL and 300mg/3mL solution in a single dose vial

Dosing and Administration:

- The presence of amyloid beta pathology should be confirmed prior to initiating treatment.
- A recent (within 1 year) magnetic resonance imaging (MRI) should be obtained prior to treatment initiation.
- The recommended maintenance dosage is 10mg/kg via intravenous (IV) infusion over 1 hour every 4 weeks following a dose titration.
- An MRI should be obtained prior to the 5th, 7th, 9th, and 12th infusions. If amyloid-related imaging abnormalities (ARIA) occurs, treatment recommendations are based on type, severity, and presence of symptoms.
- Refer to the full Aduhelm® *Prescribing Information* for the recommended titration and recommendations for patients with occurrence of ARIA.

Mechanism of Action: Aducanumab-avwa is a human, immunoglobulin gamma (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta and thereby reduces amyloid beta plaques in the brain. The accumulation of amyloid beta plaques is a defining pathophysiological feature of Alzheimer's disease.

Contraindication(s): None

Warnings and Precautions:

- ARIA: Enhanced clinical vigilance for ARIA should be performed during the first 8 doses of treatment with Aduhelm®, particularly during titration. If a patient experiences symptoms which could be suggestive of ARIA, clinical evaluation should be performed, including MRI testing if indicated.
- Hypersensitivity reactions: Angioedema and urticaria have occurred. If a hypersensitivity reaction occurs, the infusion of Aduhelm® should be discontinued and appropriate therapy should be initiated.

Adverse Reactions: The most common adverse reactions reported in clinical studies (incidence ≥10%) were ARIA-edema (ARIA-E), headache, ARIA-hemosiderin deposition (ARIA-H) microhemorrhage, ARIA-H superficial siderosis, and fall.

Efficacy: The efficacy of Aduhelm® was evaluated in 3 double-blind, randomized, placebo-controlled studies in patients with Alzheimer's disease confirmed by the presence of amyloid pathology and mild cognitive impairment or mild dementia stage of disease. In studies 1 and 2, patients were randomized to receive Aduhelm® low dose [3 or 6mg/kg for apolipoprotein E (ApoE) 4 carriers and noncarriers, respectively], Aduhelm® high dose (10mg/kg), or placebo every 4 weeks for 18 months, followed by an optional, dose-blind, long-term extension period. In study 3, 197 patients were randomized to receive a fixed dose of Aduhelm® 1mg/kg, 3mg/kg, 6mg/kg, 10mg/kg, titration to 10mg/kg over 44 weeks, or placebo for 12 months.

- **Study 1:**
  - Primary Endpoint: The primary efficacy endpoint was the change from baseline on the Clinical Dementia Rating-Sum of Boxes (CDR-SB) at week 78. Additionally, sub-studies were conducted to assess the reduction of amyloid beta plaques biomarkers.
  - Results: Treatment with Aduhelm® high dose reduced clinical decline, as shown by a statistically significant treatment effect on change from baseline in CDR-SB compared to placebo [-0.39 (-22%), P=0.0120]. Differences from placebo observed in the low dose group numerically favored Aduhelm® but were not statistically significant. Biomarker results for Aduhelm® showed a significant dose-and-time dependent reduction of amyloid beta plaques [-60.8 (-71%), P<0.0001].
- **Study 2:**
  - Primary Endpoint: The primary efficacy endpoint was the change from baseline on the CDR-SB at week 78. Additionally, sub-studies were conducted to assess the reduction of amyloid beta plaques biomarkers.

- Results: No statistically significant differences were seen between Aduhelm®-treated and placebo-treated patients on the primary efficacy endpoint. Biomarker results for Aduhelm® showed a statistically significant dose-and-time dependent reduction of amyloid beta plaques [-54.0 (-59%), P<0.0001].

- **Study 3:**
  - Primary Endpoint: The primary outcome was the number of patients with adverse effects from baseline to Week 518 and to evaluate the safety and tolerability of multiple doses. A key exploratory endpoint was the measure of clinical decline on the CDR-SB and Mini-Mental State Examination (MMSE) scores.
  - Results: Results for clinical assessments were exploratory and directionally aligned with the findings from study 1, with less change from baseline in CDR-SB and MMSE scores at 1 year in the Aduhelm® 10mg/kg fixed-dose group than in patients on placebo [CDR-SB: -1.26, 95% confidence interval (CI): -2.356, -0.163; MMSE: 1.9, 95% CI: 0.06, 3.75]. The most common adverse events seen in the long-term extension study were fall, headache, and ARIA. The majority of ARIA events occurred early during treatment and were typically mild, asymptomatic, and resolved or stabilized within 4-12 weeks, with most patients continuing treatment.

Cost: The WAC of Aduhelm® is $282 per mL, or $846 per 300mg/3mL single dose vial. A member weighing 80kg would have an annual cost of $32,994 at the recommended dosage of 10mg/kg every 4 weeks.

Recommendations

The College of Pharmacy recommends the prior authorization of Adlarity® (donepezil transdermal system) as a special formulation product. The following criteria will apply:

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.

Additionally, the College of Pharmacy recommends the prior authorization of Aduhelm® (aducanumab-avwa) with the following criteria:

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 the Aduhelm® *Prescribing Information*.
19. The maximum dose approvable is 10mg/kg per 28 days.

Utilization Details of Alzheimer's Disease Medications: Calendar Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIM/ MEMBER	COST/ CLAIM	% COST
MEMANTINE PRODUCTS						
MEMANTINE TAB HCL 10MG	3,077	406	$50,137.87	7.58	$16.29	50.13%
MEMANTINE TAB HCL 5MG	619	127	$9,918.88	4.87	$16.02	9.92%
MEMANTINE HCL CAP 28MG ER	212	19	$11,197.01	11.16	$52.82	11.19%
NAMENDA XR CAP 28MG	4	1	$1,700.56	4	$425.14	1.70%
MEMANTINE TAB 10MG	3	3	$40.56	1	$13.52	0.04%
MEMANTINE TAB 5MG	2	1	$37.95	2	$18.98	0.04%
MEMANTINE HCL CAP 14MG ER	2	1	$100.32	2	$50.16	0.10%
SUBTOTAL	**3,919**	**558**	**$73,133.15**	**7.02**	**$18.66**	**73.12%**
DONEPEZIL PRODUCTS						
DONEPEZIL TAB 10MG	1,263	211	$15,677.31	5.99	$12.41	15.67%
DONEPEZIL TAB 5MG	585	145	$6,866.78	4.03	$11.74	6.87%
DONEPEZIL TAB HCL 23MG	1	1	$67.07	1	$67.07	0.07%
SUBTOTAL	**1,849**	**357**	**$22,611.16**	**5**	**$12.23**	**22.61%**
RIVASTIGMINE PRODUCTS						
RIVASTIGMINE CAP 3MG	24	2	$661.84	12	$27.58	0.66%
RIVASTIGMINE PATCH 4.6MG/24MG	21	3	$2,304.21	7	$109.72	2.30%
RIVASTIGMINE CAP 1.5MG	8	2	$233.09	4	$29.14	0.23%
RIVASTIGMINE CAP 6MG	8	1	$232.27	8	$29.03	0.23%
RIVASTIGMINE CAP 4.5MG	1	1	$20.48	1	$20.48	0.02%
SUBTOTAL	**62**	**9**	**$3,451.89**	**6.89**	**$55.68**	**3.44%**
GALANTAMINE PRODUCTS						
GALANTAMINE TAB 4MG	25	3	$826.79	8.33	$33.07	0.83%
SUBTOTAL	**25**	**3**	**$826.79**	**8.33**	**$33.07**	**0.83%**
TOTAL	**5,855**	**719***	**$100,022.99**	**8.14**	**$17.08**	**100%**

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

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Appendix M

Calendar Year 2021 Annual Review of Testosterone Products and 30-Day Notice to Prior Authorize Tlando® (Testosterone Undecanoate)

Oklahoma Health Care Authority
July 2022

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 (Androgel® 1%, 1.62%) – **Brand Preferred**	testosterone topical gel (Fortesta®, Testim®, Vogelxo®)	testosterone pellets (Testopel®)
	testosterone topical solution (Axiron®)	testosterone undecanoate oral cap (Jatenzo®)
	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. Must include 2 labs showing pre-medication, morning testosterone (total testosterone) levels <300ng/dL; and
3. Must include 1 lab showing abnormal gonadotropins and/or other information necessary to demonstrate diagnosis; or

4. 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 2021

Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	158	719	$79,963.33	$111.21	$2.89	11,864	27,677
2021	239	1,052	$103,658.16	$98.53	$2.81	15,704	36,880
% Change	**51.30%**	**46.30%**	**29.60%**	**-11.40%**	**-2.80%**	**32.40%**	**33.30%**
Change	**81**	**333**	**$23,694.83**	**-$12.68**	**-$0.08**	**3,840**	**9,203**

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

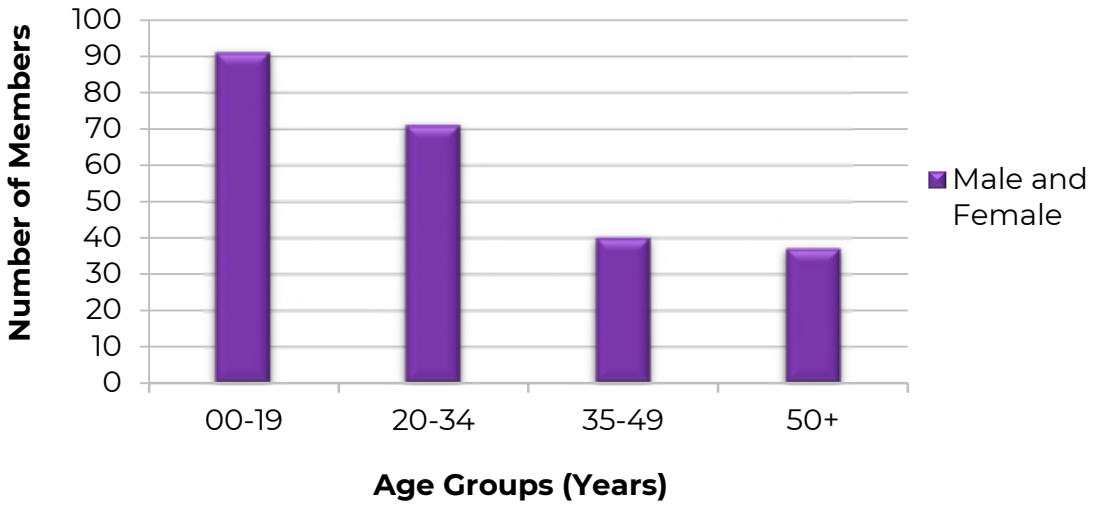
Comparison of Calendar Years: Medical Claims

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2020	77	18	$206.26	$2.68	4.28
2021	32	15	$65.19	$2.04	2.13
% Change	**-58.44%**	**-16.67%**	**-68.39%**	**-23.88%**	**-50.23%**
Change	**-45**	**-3**	**-$141.07**	**-0.64**	**-2.15**

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

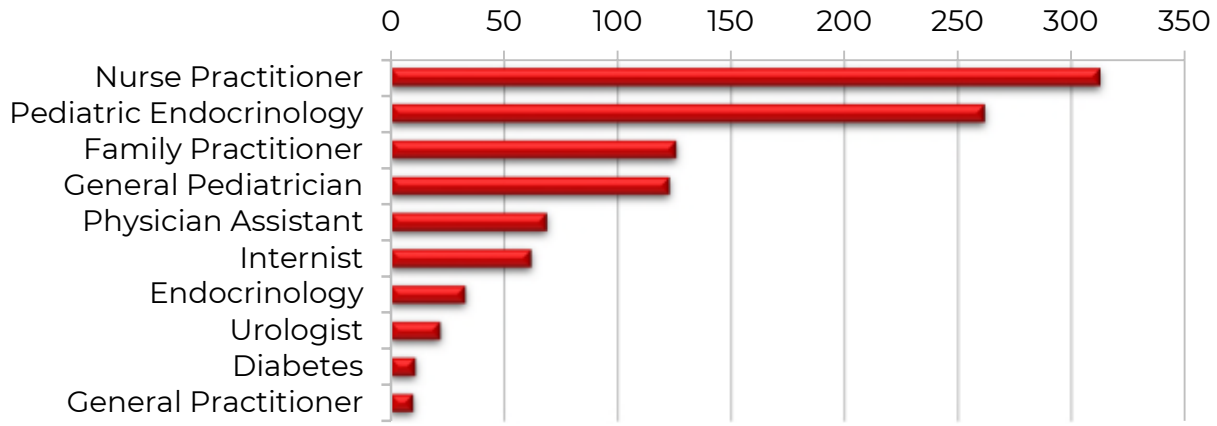
- The Testosterone Products Product Based Prior Authorization (PBPA) category is influenced by supplemental rebates. Some brand name testosterone products are preferred over available generic products due to a lower net cost compared to generics, after taking into account federal and/or supplemental 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 2021 for Testosterone Products: $61,199.47[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 1,047 prior authorization requests submitted for 550 unique members for testosterone products during calendar year 2021. 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 2021.

Status of Petitions

Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Natesto® (testosterone nasal gel): February 2024
- 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
- Tlando® (testosterone undecanoate oral capsule): November 2030

- Jatenzo® (testosterone undecanoate oral capsule): December 2030
- Vogelxo® (testosterone topical gel): February 2034
- Xyosted® [testosterone enanthate subcutaneous (sub-Q) auto-injector]: August 2038

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

- **March 2022:** The FDA approved Tlando® (testosterone undecanoate), an oral testosterone replacement therapy, for conditions associated with a deficiency or absence of endogenous testosterone or hypogonadism in adult males. Tlando® is supplied as 112.5mg testosterone undecanoate oral capsules and is not substitutable with other oral testosterone undecanoate products. The recommended dosing is 225mg twice daily with food. The approval of Tlando® was based on data from a multicenter, open-label, single-arm Phase 3 study, which evaluated the efficacy and safety of Tlando® in 95 adult hypogonadal male patients. Patients received 225mg orally twice daily with food for approximately 24 days; no titration was performed to adjust the dosage. Results demonstrated that the trial met the primary endpoint with 80% (95% confidence interval: 72, 88) of patients achieving a 24-hour average serum testosterone concentration (Cavg0-24h) within the normal range of 300-1080ng/dL on the final visit of the study. The safety and efficacy of Tlando® in males younger than 18 years of age have not been established.

Cost Comparison

Product	Cost Per Unit	Cost Per Month*
Tlando® (testosterone undecanoate 112.5mg cap)	**$5.79**	**$694.80**
Jatenzo® (testosterone undecanoate 198mg cap)	$8.02	$962.40
testosterone cypionate 200mg/mL inj (Depo-Testosterone®)	$14.64	$58.56

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 capsule
cap = capsule; inj = injection
*Cost per 30 days of the maximum FDA recommended dosing for each product.

Recommendations

The College of Pharmacy recommends the placement of Tlando® (testosterone undecanoate) into the Special Prior Authorization (PA) Tier of the testosterone products Product Based Prior Authorization (PBPA) category.

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 (Androgel® 1%, 1.62%) – **Brand Preferred**	testosterone topical gel (Fortesta®, Testim®, Vogelxo®)	testosterone pellets (Testopel®)
	testosterone topical solution (Axiron®)	testosterone undecanoate oral cap (Jatenzo®, **Tlando®**)
	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 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TESTOSTERONE INJECTABLE PRODUCTS						
TESTOST CYP INJ 200MG/ML	906	199	$37,197.22	$41.06	4.55	35.88%
TESTOST CYP INJ 100MG/ML	22	10	$1,020.47	$46.39	2.2	0.98%
TESTOST ENAN INJ 200MG/ML	8	5	$607.00	$75.88	1.6	0.59%
DEPO-TESTOST INJ 100MG/ML	6	2	$421.28	$70.21	3	0.41%
XYOSTED INJ 100MG/0.5ML	6	1	$1,297.50	$216.25	6	1.25%
DEPO-TESTOST INJ 200MG/ML	4	3	$108.78	$27.20	1.33	0.10%
SUBTOTAL	**952**	**215***	**$40,652.25**	**$42.70**	**4.43**	**39.22%**
TESTOSTERONE TOPICAL PRODUCTS						
ANDROGEL GEL 1% (50MG)	32	7	$27,101.45	$846.92	4.57	26.15%
ANDROGEL GEL 1.62%	31	12	$19,161.95	$618.13	2.58	18.49%
ANDROGEL GEL 1% (25MG)	11	6	$6,967.28	$633.39	1.83	6.72%
TESTOSTERONE GEL 1% (50MG)	11	2	$2,433.01	$221.18	5.5	2.35%
TESTOSTERONE GEL 1.62%	4	1	$279.08	$69.77	4	0.27%
ANDROGEL GEL 1.62%	3	2	$1,186.90	$395.63	1.5	1.15%
TESTOSTERONE GEL 1% (25MG)	1	1	$205.39	$205.39	1	0.20%
ANDRODERM DIS 4MG/24HR	1	1	$596.89	$596.89	1	0.58%
ANDROGEL GEL 1.62%	1	1	$630.46	$630.46	1	0.61%
SUBTOTAL	**95**	**31***	**$58,562.41**	**$616.45**	**3.06**	**56.50%**
TESTOSTERONE ORAL PRODUCTS						
JATENZO CAP 237MG	5	1	$4,443.50	$888.70	5	4.29%
SUBTOTAL	**5**	**1***	**$4,443.50**	**$888.70**	**5**	**4.29%**
TOTAL	**1,052**	**239***	**$103,658.16**	**$98.53**	**4.4**	**100%**

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

Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TESTOSTERONE CYPIONATE INJ J1071	32	15	$65.19	$2.04	2.13
TOTAL	**32**	**15**	**$65.19**	**$2.04**	**2.13**

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 06/2022. Last Accessed 06/15/2022.
[2] Park B. FDA Approves Oral Testosterone Replacement Therapy Tlando. *MPR*. Available online at: https://www.empr.com/home/news/fda-approves-oral-testosterone-replacement-therapy-tlando/. Issued 03/30/2022. Last accessed 06/15/2022.
[3] Tlando® Prescribing Information. Antares Pharma, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208088s000lbl.pdf. Last revised 03/2022. Last accessed 06/15/2022.

Appendix N

Calendar Year 2021 Annual Review of Various Systemic Antibiotics

Oklahoma Health Care Authority
July 2022

Current Prior Authorization Criteria

Oral Antibiotic Special Formulation Approval Criteria:

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

Arikayce® (Amikacin Liposome Inhalation Suspension) Approval Criteria:

1. An FDA approved indication for the treatment of *Mycobacterium avium* complex (MAC) lung disease in adult members who have limited or no alternative treatment options; and
2. Member must have had a minimum of 6 consecutive months of a multidrug background regimen therapy used compliantly and have not achieved negative sputum cultures within the last 12 months. Dates of previous treatments and regimens must be listed on the prior authorization request; and
   a. If claims for a multidrug background regimen are not in the member's claims history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the prescriber; and

3. Member must continue a multidrug background regimen therapy while on Arikayce®, unless contraindicated, or provide reasoning why continuation of a multidrug background regimen is not appropriate for the member; and
4. A patient-specific, clinically significant reason why the member requires an inhaled aminoglycoside in place of an intravenous or intramuscular aminoglycoside (e.g., amikacin, streptomycin) must be provided; and
5. Arikayce® will not be approved for members with non-refractory MAC lung disease; and
6. Arikayce® must be prescribed by, or in consultation with, a pulmonary disease or infectious disease specialist (or an advanced care practitioner with a supervising physician who is a pulmonary disease or infectious disease specialist); and
7. Initial approvals will be for the duration of 6 months after which time the prescriber must document the member is responding to treatment for continued approval; and
8. A quantity limit of 28 vials per 28 days will apply.

Avycaz® (Ceftazidime/Avibactam) Approval Criteria:

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

Baxdela® (Delafloxacin) Tablet and Vial Approval Criteria [Acute Bacterial Skin and Skin Structure Infection (ABSSSI) Diagnosis]:

1. An FDA approved diagnosis of ABSSSI caused by designated susceptible bacteria; and

2. A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid, doxycycline, trimethoprim/sulfamethoxazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
3. Approval quantity will be based on Baxdela® *Prescribing Information* and FDA approved dosing regimen(s); and
    a. For Baxdela® vials, an initial quantity limit of 6 vials for a 3-day supply will apply. Continued authorization will require a patient-specific, clinically significant reason why the member cannot switch to the oral tablets for the remainder of therapy.

Baxdela® (Delafloxacin) Tablet and Vial Approval Criteria [Community-Acquired Bacterial Pneumonia (CABP) Diagnosis]:

1. An FDA approved diagnosis of CABP caused by designated susceptible bacteria; and
2. A patient-specific, clinically significant reason why the member cannot use an appropriate beta lactam (e.g., ceftriaxone, cefotaxime, ceftaroline, ertapenem, ampicillin/sulbactam) in combination with a macrolide (e.g., azithromycin, clarithromycin) or doxycycline, monotherapy with a respiratory fluoroquinolone (e.g., levofloxacin, moxifloxacin, gemifloxacin), or other cost-effective therapeutic equivalent alternative(s) must be provided; and
3. Approval quantity will be based on Baxdela® *Prescribing Information* and FDA approved dosing regimen(s); and
    a. For Baxdela® vials, an initial quantity limit of 6 vials for a 3-day supply will apply. Continued authorization will require a patient-specific, clinically significant reason why the member cannot switch to the oral tablets for the remainder of therapy.

Ciprofloxacin 100mg Tablet Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member cannot use alternative strengths of ciprofloxacin tablets, levofloxacin tablets, moxifloxacin tablets, or other cost-effective therapeutic equivalent alternative(s).

Ciprofloxacin 500mg and 1,000mg Extended-Release (ER) Tablet Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member cannot use the immediate-release formulation of ciprofloxacin tablets, levofloxacin tablets, moxifloxacin tablets, or other cost-effective therapeutic equivalent alternative(s).

Ciprofloxacin 250mg/mL and 500mg/mL Oral Suspension and Levofloxacin 25mg/mL Oral Solution:

1. Members older than 6 years of age require a patient-specific, clinically significant reason why the oral tablet formulations cannot be used.

Dalvance® (Dalbavancin) Approval Criteria:

1. An indicated diagnosis or infection known to be susceptible to requested agent and resistant to the cephalosporin-class of antibiotics and other antibiotics commonly used for diagnosis or infection; and
2. A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid, or other cost effective therapeutic equivalent medication(s) must be provided; and
3. A quantity limit of 3 vials per 7 days will apply.

Fetroja® (Cefiderocol) Approval Criteria:

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

Kimyrsa™ (Oritavancin) Approval Criteria:

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

5. Approval quantity will be based on Kimyrsa™ *Prescribing Information* and FDA approved dosing regimen(s).

Minocycline (50, 75, 100mg) Immediate-Release (IR) Tablet:

1. Approval requires a patient-specific, clinically significant reason why the member requires the IR tablet formulation and cannot use the IR capsule formulation and/or other cost effective therapeutic equivalent medication(s).

Nuzyra® (Omadacycline) Approval Criteria [Acute Bacterial Skin and Skin Structure Infection (ABSSSI) Diagnosis]:

1. An FDA approved diagnosis of ABSSSI caused by designated susceptible microorganisms; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid, doxycycline, trimethoprim/sulfamethoxazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. Use of Nuzyra® vials will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
5. Approval quantity will be based on Nuzyra® *Prescribing Information* and FDA approved dosing regimen(s).

Nuzyra® (Omadacycline) Approval Criteria [Community-Acquired Bacterial Pneumonia (CABP) Diagnosis]:

1. An FDA approved diagnosis of CABP caused by designated susceptible microorganisms; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use an appropriate beta-lactam (e.g., ceftriaxone, cefotaxime, ceftaroline, ertapenem ampicillin/sulbactam) in combination with a macrolide (e.g., azithromycin, clarithromycin) or doxycycline, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. Approval quantity will be based on Nuzyra® *Prescribing Information* and FDA approved dosing regimen(s).
    a. For Nuzyra® vials, an initial quantity limit of 4 vials for a 3-day supply will apply. Continued authorization will require a patient-specific, clinically significant reason why the member cannot switch to the oral tablet formulation for the remainder of therapy.

Ofloxacin 300mg and 400mg Tablet Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member cannot use ciprofloxacin tablets, levofloxacin tablets,

moxifloxacin tablets, or other cost-effective therapeutic equivalent alternative(s).

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

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
   a. Complicated intra-abdominal infection (cIAI); or
   b. Complicated urinary tract infection (cUTI), including pyelonephritis; and
2. Member must be 18 years of age or older; and
3. The prescriber must verify that limited or no alternative treatment options are available; and
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. A quantity limit of 56 vials per 14 days will apply.

Seysara® (Sarecycline) Approval Criteria:

1. An FDA approved diagnosis of inflammatory lesions of non-nodular, moderate-to-severe acne vulgaris; and
2. Member must be 9 years of age or older; and
3. Seysara® is not covered for members older than 20 years of age; and
4. A patient-specific, clinically significant reason why the member cannot use minocycline, doxycycline, tetracycline, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate strength according to package labeling; and
6. A quantity limit of 30 tablets per 30 days will apply.

Sivextro® (Tedizolid) Tablet and Vial Approval Criteria:

1. An indicated diagnosis or infection known to be susceptible to requested agent and resistant to the cephalosporin class of antibiotics and other antibiotics commonly used for diagnosis or infection; and
2. A patient-specific, clinically significant reason why the member cannot use linezolid or other cost effective therapeutic equivalent medication(s) must be provided; and
3. A quantity limit of 6 tablets or vials per 6 days will apply.

Solosec® (Secnidazole Oral Granules) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis; and

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

Suprax® (Cefixime) and Cedax® (Ceftibuten) Approval Criteria:

1. An indicated diagnosis or infection known to be susceptible to requested agent; and
2. A patient-specific, clinically significant reason why the member cannot use cephalexin, cefdinir, or other cost effective therapeutic equivalent medication(s) must be provided.

Tetracycline 250mg and 500mg Capsule Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member requires tetracycline and cannot use doxycycline, minocycline capsules, and/or other cost effective therapeutic equivalent medication(s).

Vabomere® (Meropenem/Vaborbactam Injection) Approval Criteria:

1. An FDA approved diagnosis of complicated urinary tract infection (cUTI) or pyelonephritis; and
2. A patient-specific, clinically significant reason why the member cannot use piperacillin/tazobactam or other cost effective therapeutic equivalent alternative(s) must be provided; and
3. Approval quantity will be based on Vabomere® *Prescribing Information* and FDA approved dosing regimen(s).

Xenleta® (Lefamulin) Approval Criteria:

1. An FDA approved diagnosis of community-acquired bacterial pneumonia (CABP) caused by designated susceptible microorganisms; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use an appropriate beta-lactam (e.g., ceftriaxone, cefotaxime, ceftaroline, ertapenem, ampicillin/sulbactam) in combination with a macrolide (e.g., azithromycin, clarithromycin) or doxycycline, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. Approval quantity will be based on Xenleta® *Prescribing Information* and FDA approved dosing regimen(s).

Xerava™ (Eravacycline) Approval Criteria:

1. An FDA approved diagnosis of complicated intra-abdominal infection (cIAI) caused by designated susceptible microorganisms; and
2. Member must be 18 years of age or older; and

3. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Zemdri® (Plazomicin) Approval Criteria:

1. An FDA approved diagnosis of complicated urinary tract infection (cUTI), including pyelonephritis, caused by designated susceptible microorganisms; and
2. A patient-specific, clinically significant reason why the member cannot use an appropriate alternative aminoglycoside (e.g., gentamicin, tobramycin) or other cost-effective therapeutic equivalent alternative(s) must be provided; and
3. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Zerbaxa® (Ceftolozane/Tazobactam) Approval Criteria:

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

Utilization of Various Systemic Antibiotics: Calendar Year 2021

Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	222	328	$447,983.61	$1,365.80	$100.81	37,647	4,444
2021	269	407	$271,918.45	$668.10	$53.87	41,218	5,048
% Change	**21.2%**	**24.1%**	**-39.3%**	**-51.1%**	**-46.6%**	**9.5%**	**13.6%**
Change	**47**	**79**	**-$176,065.16**	**-$697.70**	**-46.94**	**3,571**	**604**

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

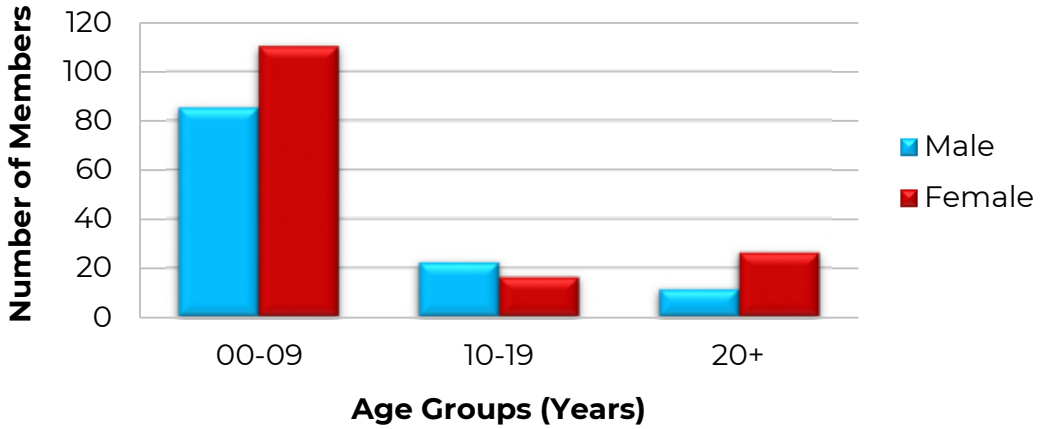
Comparison of Calendar Years: Medical Claims

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2020	3	3	$13,653.00	$4,551.00	1.00
2021	8	17	$77,498.00	$4,558.71	2.13
% Change	**166.67%**	**466.67%**	**467.63%**	**0.17%**	**113%**
Change	**5**	**14**	**$63,845.00**	**$7.71**	**1.13**

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

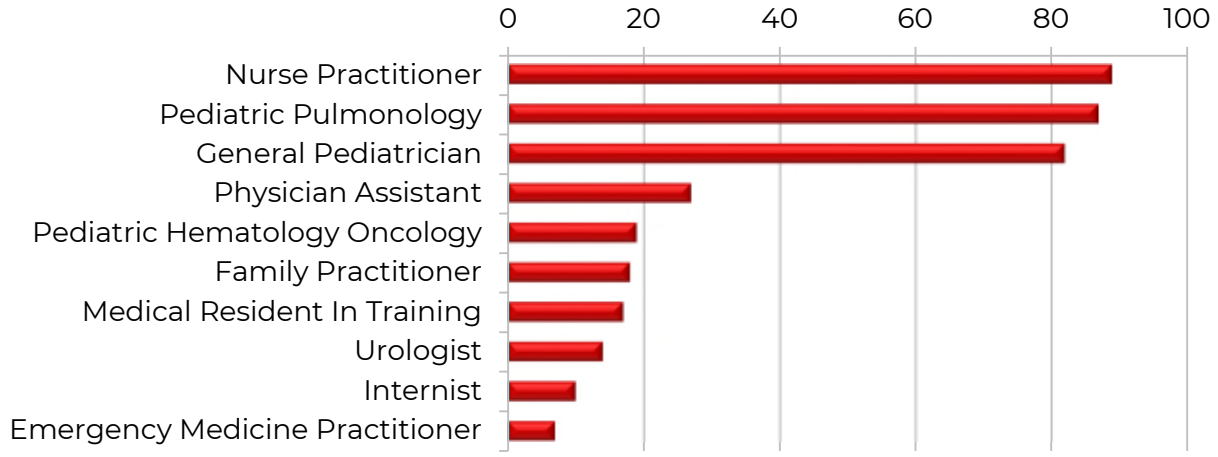
- The Various Systemic Antibiotics medication category is influenced by federal rebates. These rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.
  - Aggregate drug rebates collected during calendar year 2021 for the Systemic Antibiotics: $85,650.52[Δ]

Demographics of Members Utilizing Various Systemic Antibiotics



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

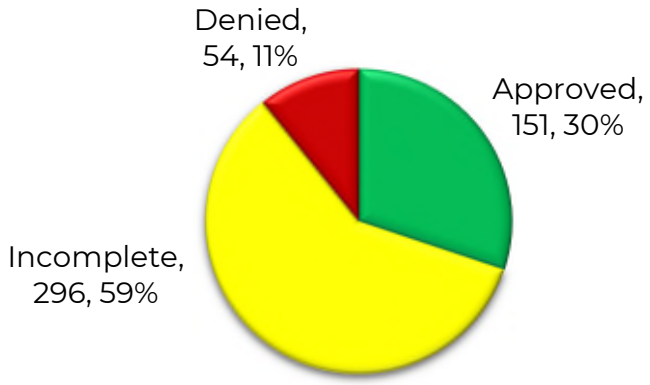
Top Prescriber Specialties of Various Systemic Antibiotics by Number of Claims



Prior Authorization of Various Systemic Antibiotics

There were 501 prior authorization requests submitted for various systemic antibiotics during calendar year 2021. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Dalvance® [dalbavancin vial for intravenous (IV) infusion]: December 2023
- Ximino® [minocycline extended-release (ER) capsule]: April 2027
- Doryx® [doxycycline hyclate delayed-release (DR) tablet]: February 2028
- Suprax® (cefixime 500mg/5mL oral suspension): December 2028
- Xenleta® (lefamulin vial for IV infusion): January 2029
- Recarbrio™ (imipenem/cilastatin/relebactam vial for IV infusion): November 2029

- Sivextro® (tedizolid tablet and vial for IV infusion): February 2030
- Xenleta® (lefamulin tablet): May 2031
- Baxdela® (delafloxacin tablet): June 2031
- Zemdri® (plazomicin vial for IV infusion): June 2031
- Vabomere® (meropenem/vaborbactam vial for IV infusion): August 2031
- Solodyn® (minocycline ER tablet): November 2031
- Avycaz® (ceftazidime/avibactam vial for IV infusion): June 2032
- Baxdela® (delafloxacin vial for IV infusion): February 2033
- Seysara® (sarecycline tablet): February 2033
- Orbactiv® (oritavancin vial for IV infusion): July 2035
- Zerbaxa® (ceftolozane/tazobactam vial for IV infusion): August 2035
- Fetroja® (cefiderocol vial for IV infusion): September 2035
- Nuzyra® (omadacycline tablet and vial for IV infusion): October 2037
- Xerava™ (eravacycline vial for IV infusion): October 2037

Pipeline:

- **Tebipenem:** In May 2022, Spero Therapeutics announced it would immediately defer current commercialization activities for tebipenem based on feedback from the U.S. Food and Drug Administration (FDA) regarding Spero's New Drug Application (NDA). Tebipenem is an oral carbapenem for the treatment of adult patients with complicated urinary tract infections (cUTI), including acute pyelonephritis (AP), and would be the first oral carbapenem on the U.S. market. In a Phase 3 study, oral tebipenem was shown to be statistically noninferior to IV ertapenem in patients with cUTI and AP. Feedback from the FDA indicated that the data package submitted in the NDA for tebipenem may be insufficient to support approval. In response to this, Spero Therapeutics will be undertaking a reduction in its workforce by approximately 75% and reallocating its resources to other clinical development programs, while continuing to engage with the FDA on the appropriate path forward for tebipenem.
- **Exebacase:** Currently in a Phase 3 study, exebacase is a lysin that has the potential to be the first-in-class of a new treatment for patients with *Staphylococcus aureus* bacteremia. Exebacase works by dissolving the bacterial cell wall and was shown to have better efficacy when used in combination with either vancomycin or daptomycin in animal models of disease when compared to treatment with these antibiotics or exebacase alone.

Recommendations

The College of Pharmacy does not recommend any changes to the current prior authorization criteria for the various systemic antibiotics at this time.

Utilization Details of Various Systemic Antibiotics: Calendar Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LEVOFLOXACIN PRODUCTS					
LEVOFLOXACIN SOL 25MG/ML	163	110	$18,332.68	$112.47	1.48
SUBTOTAL	**163**	**110**	**$18,332.68**	**$112.47**	**1.48**
CIPROFLOXACIN PRODUCTS					
CIPRO 10% SUS 500MG/5ML	79	48	$12,701.45	$160.78	1.65
CIPRO 5% SUS 250MG/5ML	78	68	$13,160.71	$168.73	1.15
CIPROFLOXACN SUS 500MG/5ML	2	1	$251.14	$125.57	2
SUBTOTAL	**159**	**117**	**$26,113.30**	**$164.23**	**1.36**
CEFIXIME PRODUCTS					
CEFIXIME SUS 200MG/5ML	16	5	$6,198.58	$387.41	3.2
CEFIXIME CAP 400MG	8	5	$1,099.97	$137.50	1.6
CEFIXIME SUS 100MG/5ML	1	1	$166.27	$166.27	1
SUBTOTAL	**25**	**11**	**$7,464.82**	**$298.59**	**2.27**
TETRACYCLINE PRODUCTS					
TETRACYCLINE CAP 500MG	23	21	$1,816.48	$78.98	1.1
TETRACYCLINE CAP 250MG	1	1	$68.16	$68.16	1
SUBTOTAL	**24**	**22**	**$1,884.64**	**$78.53**	**1.09**
OMADACYCLINE PRODUCTS					
NUZYRA TAB 150MG	9	5	$92,384.03	$10,264.89	1.8
SUBTOTAL	**9**	**5**	**$92,384.03**	**$10,264.89**	**1.8**
AMIKACIN PRODUCTS					
ARIKAYCE SUS 590MG/8.4ML	6	2	$74,358.54	$12,393.09	3
SUBTOTAL	**6**	**2**	**$74,358.54**	**$12,393.09**	**3**
AMOXICILLIN PRODUCTS					
AMOX-POT CLA TAB ER 1000-62.5MG	4	3	$1,152.82	$288.21	1.33
AMOXICILLIN TAB 500MG	2	2	$29.42	$14.71	1
SUBTOTAL	**6**	**5**	**$1,182.24**	**$197.04**	**1.20**
SECNIDAZOLE PRODUCTS					
SOLOSEC GRA 2GM	4	3	$1,135.51	$283.88	1.33
SUBTOTAL	**4**	**3**	**$1,135.51**	**$283.88**	**1.33**
CEFTAZIDIME/AVIBACTAM PRODUCTS					
AVYCAZ INJ 2-0.5GM	3	3	$22,639.20	$7,546.40	1
SUBTOTAL	**3**	**3**	**$22,639.20**	**$7,546.40**	**1**
DALBAVANCIN PRODUCTS					
DALVANCE SOL 500MG	3	2	$11,149.53	$3,716.51	1.5
SUBTOTAL	**3**	**2**	**$11,149.53**	**$3,716.51**	**1.5**
DOXYCYCLINE PRODUCTS					
DOXYCYCLINE HYCLATE TAB 200MG DR	3	1	$3,149.94	$1,049.98	3
SUBTOTAL	**3**	**1**	**$3,149.94**	**$1,049.98**	**3**
TEDIZOLID PRODUCTS					

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SIVEXTRO TAB 200MG	1	1	$12,064.91	$12,064.91	1
SUBTOTAL	**1**	**1**	**$12,064.91**	**$12,064.91**	**1**
MINOCYCLINE PRODUCTS					
MINOCYCLINE TAB 100MG	1	1	$59.11	$59.11	1
SUBTOTAL	**1**	**1**	**$59.11**	**$59.11**	**1**
TOTAL	**407**	**269***	**$271,918.45**	**$688.10**	**1.51**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AMOX-POT CLA = amoxicillin/clavulanate potassium; CAP = capsule; DR = delayed-release;
ER = extended-release; GRA = granules; INJ = injection; SOL = solution; SUS = suspension; TAB = tablet

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
DALBAVANCIN INJ 5MG (J0875)	17	8	$77,498.00	$4,558.71	2.13
TOTAL	**17+**	**8***	**$77,498.00**	**$4,558.71**	**2.13**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
+Total number of unduplicated claims.
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/default.cfm?resetfields=1. Last revised 06/2022. Last accessed 06/15/2022.
[2] Spero Therapeutics Announces New Strategic Direction Focusing on Advancing Promising Clinical-Stage Pipeline. *Globe Newswire*. Available online at: https://www.globenewswire.com/en/news-release/2022/05/03/2434399/0/en/Spero-Therapeutics-Announces-New-Strategic-Direction-Focusing-on-Advancing-Promising-Clinical-Stage-Pipeline.html. Issued 05/03/2022. Last accessed 06/16/2022.
[3] ContraFect. Pipeline: Exebacase. Available online at: https://www.contrafect.com/pipeline/exebacase. Last accessed 06/16/2022.

Appendix O

Calendar Year 2021 Annual Review of Isturisa® (Osilodrostat) and 30-Day Notice to Prior Authorize Recorlev® (Levoketoconazole)

Oklahoma Health Care Authority
July 2022

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 surgery is not an option or has not been curative;
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 surgery or is not a candidate for pituitary 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. For female members, prescriber must verify that the member is not breastfeeding; and
8. 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
9. A patient-specific, clinically significant reason why the member cannot use ketoconazole tablets must be provided; and
10. 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 surgery.

Utilization of Isturisa® (Osilodrostat): Calendar Year 2021

There was no SoonerCare utilization of Isturisa® (osilodrostat) during calendar year 2021.

Prior Authorization of Isturisa® (Osilodrostat)

There were no prior authorization requests submitted for Isturisa® (osilodrostat) during calendar year 2021.

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

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

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

- **December 2021:** The FDA approved Recorlev® (levoketoconazole) for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome (CS) for whom surgery is not an option or has not been curative. CS is a rare and serious endocrine disease caused by elevated cortisol level exposure often due to a benign tumor of the pituitary gland. This disease is most common in adults 30-50 years of age and affects women 3 times more than men. Metabolic changes such as diabetes, high blood pressure, high cholesterol, and psychological disturbances such as depression can occur in these patients. If untreated, the 5-year survival rate is approximately 50%. Recorlev® is a pure 2S,4R enantiomer of ketoconazole and works by inhibiting cortisol synthesis. The approval of Recorlev® was based on 2 Phase 3 trials in 166 patients with CS. Both studies met their primary and key secondary endpoints which included reducing and normalizing mean urinary free cortisol concentrations without a dose increase and normalizing and maintaining therapeutic response compared to placebo.

Recorlev® (Levoketoconazole) Product Summary[3]

Indication(s): Treatment of endogenous hypercortisolemia in adult patients with CS for whom surgery is not an option or has not been curative

How Supplied: 150mg oral tablet

Dosing

- The initial dosage is 150mg orally twice daily. Dosage may be titrated by 150mg daily, no more frequently than every 2-3 weeks.
- The maximum recommended dosage is 1,200mg daily, administered as 600mg [(4) 150mg tablets] twice daily.

Boxed Warning: Hepatotoxicity and QT Prolongation

- Hepatotoxicity:
  - Cases of hepatotoxicity with a fatal outcome or requiring liver transplantation have been reported with use of oral ketoconazole.
  - Liver enzymes should be evaluated prior to and during treatment.
- QT Prolongation:
  - Recorlev® is associated with a dose-related QT interval prolongation and may lead to life-threatening ventricular dysrhythmias.
  - A baseline electrocardiogram should be obtained prior to initiating therapy.

Warnings/Precautions:

- **Hypocortisolism:** Dosage reduction or interruption may be necessary if urine free cortisol or morning serum or plasma cortisol levels fall below the target range. Exogenous glucocorticoid replacement therapy should be administered if cortisol levels are below target range and signs and/or symptoms of adrenal insufficiency or hypocortisolism are present.
- **Risks Related to Decreased Testosterone:** Decreased testosterone may be seen in both men and women. Potential clinical manifestations of decreased testosterone concentrations in men may include gynecomastia, impotence, and oligospermia. Potential clinical manifestations of decreased testosterone in women include decreased libido and mood changes.

Mechanism of Action: Levoketoconazole inhibits key steps in the synthesis of cortisol and testosterone, principally mediated by CYP11B1, CYP11A1, and CYP17A1.

Contraindication(s):

- Cirrhosis, acute liver disease, or poorly controlled chronic liver disease, baseline AST or ALT >3 times the upper limit of normal (ULN), recurrent symptomatic cholelithiasis, a prior history of drug induced liver injury due to any azole antifungal therapy that required discontinuation of treatment, or extensive metastatic liver disease
- Taking drugs that cause QT prolongation associated with ventricular arrhythmias, including torsades de pointes
- Prolonged QTcF interval >470msec at baseline, history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, or prolonged QT syndrome

- Taking certain drugs that are sensitive substrates of CYP3A4 and/or P-gp (e.g., ritonavir, mifepristone, isoniazid, carbamazepine, phenytoin)

Use in Specific Populations:

- Pregnancy: There is insufficient data to evaluate the drug associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. In animal reproduction studies, embryotoxic effects were observed in pregnant mice, rats, and rabbits, and fetal malformations were observed in rats.
- Pediatric Use: The safety and efficacy of levoketoconazole have not been established in pediatric patients younger than 18 years of age.
- Geriatric Use: Of the 166 patients in the clinical studies, 12 patients (7%) were 65 years of age and older. There was an insufficient number of patients 65 years of age and older to determine whether they responded differently from younger adult patients.

Adverse Reactions: The most common adverse reactions reported in clinical studies (incidence >20%) were nausea/vomiting, hypokalemia, hemorrhage/ contusion, systemic hypertension, headache, hepatic injury, abnormal uterine bleeding, erythema, fatigue, abdominal pain/dyspepsia, arthritis, upper respiratory infection, myalgia, arrhythmia, back pain, insomnia/sleep disturbances, and peripheral edema.

Efficacy: The safety and efficacy of levoketoconazole were assessed in 2 Phase 3 open-label studies in 166 patients with CS. Study 1 consisted of an open-label dose titration and maintenance phase (up to 19 weeks), followed by an 8-week double-blind, placebo-controlled, randomized withdrawal phase. Study 2 was a multicenter, single-arm, open-label study that consisted of 3 study phases (dose titration, maintenance, and extended evaluation) for a total estimated treatment duration of up to 73 weeks. Both studies included patients with persistent or recurrent disease despite surgery, previously medically treated patients, and previously untreated patients. Patients with pituitary or adrenal carcinoma were excluded from the studies.

- **Study 1:**
  - Intervention: 79 patients were started on levoketoconazole in the dose titration and maintenance phase for 14-19 weeks. Only 39 of these patients from the initial phase achieved a stable therapeutic dose and entered the randomized withdrawal phase, in addition to 5 patients directly from study 2. Therapeutic dose was defined as a dose at which mean urinary free cortisol (mUFC) level was ≤ULN, maximum dose of 1,200mg/day had been reached, or a clinically meaningful partial response based on clinical judgement and the maximum tolerated dose had been reached. These 44 patients entered the randomized withdrawal phase and were then

randomized 1:1 to either continue levoketoconazole or placebo for 8 weeks or until early rescue was necessary.
    - Endpoints: The primary endpoint was the number of patients with loss of therapeutic response to levoketoconazole upon withdrawing to placebo compared with those who continued treatment. A key secondary endpoint was the proportion of patients with mUFC normalization at the end of the randomized withdrawal phase, which was defined as a patient with mUFC at or below the ULN at the end of randomized withdrawal phase without meeting a requirement for early rescue during the randomized withdrawal phase.
    - Results: The number and percentage of patients who had a normal mUFC at the end of the randomized withdrawal phase was 11/21 (52.4%) in treatment group and 1/18 (5.6%) in placebo group. Primary endpoint results were not available.
- **Study 2:**
    - Intervention: 94 patients were started on levoketoconazole in the dose titration phase (2-21 weeks) with only 77 patients entering the maintenance phase once a therapeutic dose (as previously defined in Study 1) was achieved. The patients in the maintenance phase were followed for 6 months and of these 77 patients, only 60 patients entered the extended evaluation phase in which treatment was continued for 6 additional months.
    - Endpoints: The primary endpoint was the proportion of patients with normalization of mUFC at the end of the 6-month maintenance phase, without an increase in dose at any time during the maintenance phase.
    - Results: At the end of the maintenance phase, 29/34 patients (30.9%) met the primary endpoint of normalization of mUFC at the end of the maintenance phase.

Cost Comparison:

Medication	Cost Per Tablet	Cost Per Year
Recorlev® (levoketoconazole) 150mg tablet	**$270.00**	**$777,600.00**
Isturisa® (osilodrostat) 10mg tablet	$529.12	$1,142,899.20
ketoconazole 200mg tablet	$0.78	$1,684.80

Costs do not reflect rebated prices or net costs.
Cost of therapy calculated based on wholesale acquisition cost (WAC).
*Cost per year based on maximum recommended dosage of 1,200mg per day for Recorlev® and ketoconazole and 60mg per day for Isturisa®.

Recommendations

The College of Pharmacy recommends the prior authorization of Recorlev® levoketoconazole with the following criteria:

Recorlev® (Levoketoconazole) Approval Criteria:

1. An FDA approved indication for the treatment of adult members with Cushing's disease for whom pituitary 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 surgery or is not a candidate for pituitary 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. For female members, prescriber must verify that the member is not breastfeeding; and
9. A patient-specific, clinically significant reason why the member cannot use ketoconazole tablets must be provided; and
10. 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 surgery.

[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/default.cfm?resetfields=1. Last revised 06/2022. Last accessed 06/10/2022.

[2] Xeris Biopharma Announces U.S. FDA Approval of Recorlev® (Levoketoconazole) for the Treatment of Endogenous Hypercortisolemia in Adult Patients with Cushing's Syndrome. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20211230005308/en/Xeris-Biopharma-Announces-U.S.-FDA-Approval-of-Recorlev%C2%AE-levoketoconazole-for-the-Treatment-of-Endogenous-Hypercortisolemia-in-Adult-Patients-With-Cushing%E2%80%99s-Syndrome. Issued 12/30/2021. Last accessed 06/13/2022.

[3] Recorlev® (Levoketoconazole) Prescribing Information. Xeris Pharmaceuticals. Available online at: https://www.recorlev.com/full-prescribing-information.pdf. Last revised 12/2021. Last accessed 06/15/2022.

Appendix P

U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates (additional information can be found at http://www.fda.gov/Drugs/default.htm)

FDA NEWS RELEASE

For Immediate Release: June 17, 2022

Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age

The FDA authorized emergency use of the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine for the prevention of COVID-19 to include use in children as young as 6 months of age. For the Moderna COVID-19 vaccine, the FDA amended the emergency use authorization (EUA) to include use of the vaccine in individuals 6 months through 17 years of age. This vaccine had previously been authorized for use in adults 18 years of age and older. For the Pfizer-BioNTech COVID-19 vaccine, the FDA amended the EUA to include use of the vaccine in individuals 6 months through 4 years of age. This vaccine had previously been authorized for use in individuals 5 years of age and older.

The most commonly reported side effects of the Moderna COVID-19 vaccine in the clinical trial participants for 6 months to 17 years of age include, pain, redness and swelling at the injection site, tiredness, headache, muscle pain, chills, joint pain, underarm swollen lymph nodes in the same arm as the injection, nausea and vomiting, and fever. The most commonly reported side effects of the Pfizer-BioNTech COVID-19 vaccine in clinical trial participants 6 months through 23 months of age who received the vaccine were irritability, decreased appetite, fever and pain, and tenderness, redness, and swelling at the injection site. These side effects were also reported for the vaccine recipients 2 years through 4 years of age, in addition to fever, headache, and chills.

As part of their original EUA requests, both ModernaTX, Inc. and Pfizer, Inc. submitted plans to continue to monitor the safety of the vaccines as they are used under the EUA. These plans for monitoring the overall safety of the vaccines and ensuring that any safety concerns are identified and evaluated in a timely manner, and which include monitoring for myocarditis and pericarditis, have been updated to include the newly authorized populations. In addition, longer-term safety follow-up monitoring is ongoing for participants enrolled in the clinical trials for both vaccines. Furthermore, the FDA and the Centers for Disease Control (CDC) have several systems in place to continually monitor COVID-19 vaccine safety and allow for the timely detection and investigation of potential safety concerns.

FDA NEWS RELEASE

For Immediate Release: June 13, 2022

FDA Approves First Systemic Treatment for Alopecia Areata

The FDA approved Olumiant® (baricitinib) oral tablets to treat adult patients with severe alopecia areata, a disorder that often appears as patchy baldness and affects more than 300,000 people in the United States each year. This marks the first FDA approval of a systemic treatment for alopecia areata.

Alopecia areata, commonly referred to as alopecia, is an autoimmune disorder in which the body attacks its own hair follicles, causing hair to fall out, often in clumps.

Olumiant® is a Janus kinase (JAK) inhibitor which blocks the activity of 1 or more of a specific family of enzymes, interfering with the pathway that leads to inflammation.

The efficacy and safety of Olumiant® in alopecia areata was studied in 2 randomized, double-blind, placebo-controlled trials (Trial AA-1 and Trial AA-2) with patients who had at least 50% scalp hair loss as measured by the Severity of Alopecia Tool for more than 6 months. Patients in these trials received either a placebo, Olumiant® 2mg, or Olumiant® 4mg every day. The primary measurement of efficacy for both trials was the proportion of patients who achieved at least 80% scalp hair coverage at week 36.

In Trial AA-1, 22% of the 184 patients who received Olumiant® 2mg and 35% of the 281 patients who received Olumiant® 4mg achieved adequate scalp hair coverage, compared to 5% of the 189 patients who received a placebo. In Trial AA-2, 17% of the 156 patients who received Olumiant® 2mg and 32% of the 234 patients who received Olumiant® 4mg achieved adequate scalp hair coverage, compared to 3% of the 156 patients who received a placebo.

The most common side effects associated with Olumiant® include upper respiratory tract infections, headache, acne, hyperlipidemia, increase in creatinine phosphokinase, urinary tract infections, liver enzyme elevations, folliculitis, fatigue, lower respiratory tract infections, nausea, genital Candida infections, anemia, neutropenia, abdominal pain, shingles, and weight gain.

FDA NEWS RELEASE

For Immediate Release: May 20, 2022

FDA Approves First Treatment for Eosinophilic Esophagitis

The FDA approved Dupixent® (dupilumab) to treat eosinophilic esophagitis (EoE) in adults and pediatric patients 12 years of age and older weighing at least 40kg. This marks the first FDA approval of a treatment for EoE.

EoE is a chronic inflammatory disorder in which eosinophils are found in the tissue of the esophagus. In adults and adolescent patients with EoE, common symptoms include difficulty swallowing, difficulty eating, and food getting stuck in the esophagus. Dupixent® is a monoclonal antibody that acts to inhibit part of the inflammatory pathway.

The efficacy and safety of Dupixent® in EoE was studied in a randomized, double-blind, parallel-group, multicenter, placebo-controlled trial, that included two 24-week treatment periods (part A and part B) that were conducted independently in separate groups of patients. In part A and part B, patients received either placebo or 300mg of Dupixent® every week. The 2 primary measurements of efficacy were the proportion of patients who achieved a certain level of reduced eosinophils in the esophagus at week 24, as determined by assessing patients' esophageal tissue under a microscope, and the change in the patient-reported Dysphagia Symptom Questionnaire (DSQ) score from baseline to week 24. The DSQ is a questionnaire designed to measure difficulty swallowing associated with EoE, with total scores ranging from 0 to 84; higher DSQ scores indicate worse symptoms.

In part A of the trial, 60% of the 42 patients who received Dupixent® achieved the pre-determined level of reduced eosinophils in the esophagus compared to 5% of the 39 patients who received a placebo. Patients in part A who received Dupixent® experienced an average improvement of 22 points in their DSQ score compared to 10 points in patients who received placebo. In part B, 59% of the 80 patients who received Dupixent® achieved the pre-determined level of reduced eosinophils in the esophagus compared to 6% of the 79 patients who received a placebo. Patients in part B who received Dupixent®

experienced an average improvement of 24 points in their DSQ score compared to 14 points in patients who received placebo. Assessments incorporating the perspectives from patients with EoE supported that the DSQ score improvement in patients who received Dupixent® in the clinical trial was representative of clinically meaningful improvement in dysphagia.

The most common side effects associated with Dupixent® include injection site reactions, upper respiratory tract infections, joint pain, and herpes viral infections.

FDA NEWS RELEASE

For Immediate Release: May 19, 2022

New FDA Draft Guidance Aims to Increase Safety Information About Dietary Supplement Marketplace

The FDA announced the availability of a draft guidance aimed at increasing the amount of safety information the agency has about the dietary supplement marketplace by providing the industry an opportunity to submit late new dietary ingredient (NDI) notifications.

This draft guidance, if finalized, will advise the dietary supplement industry that the FDA intends to exercise enforcement discretion, for a limited time and in limited circumstances, to encourage manufacturers and distributors to correct any past failures to submit a required NDI notification. By providing industry with an opportunity to correct past failures to submit required safety information, the FDA can gain more safety information about the dietary supplement marketplace and better protect public health.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) requires manufacturers and distributors who wish to market a dietary supplement containing an NDI to notify the FDA before marketing, unless a legal exception applies. The notification must contain the safety information that a manufacturer relied upon to conclude the dietary supplement containing the NDI is reasonably expected to be safe. The NDI notification process is the FDA's only chance to evaluate the safety of a dietary supplement before it becomes available to consumers. For dietary supplements that do not contain an NDI, the law does not require manufacturers to submit safety information to the FDA before marketing. The FDA is aware that in the more than 27 years since the requirement was established, some dietary supplement firms have marketed products for which a premarket NDI notification was required, but never submitted.

The enforcement discretion policy proposed in this draft guidance relates solely to the failure to submit an NDI notification. For example, it would not extend to NDI-containing dietary supplements that are adulterated for safety reasons or that violate any other regulatory requirements that pertain to dietary supplements. This temporary policy also should help facilitate enforcement actions against those that remain out of compliance with the NDI notification requirements after the enforcement discretion period ends.

If the draft guidance is finalized without change, the enforcement discretion period to submit a late notification would start when the guidance is published, would last 180 days, and would apply only to products on the market when the Federal Register notice announcing the draft guidance was published. Along with this draft guidance, the FDA is also developing a new submission type through the CFSAN Online Submission Module to provide a dedicated pathway for stakeholders to electronically submit their late notifications.

Current Drug Shortages Index (as of June 30, 2022):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma.

Acetazolamide Injection	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acids	***Currently in Shortage***
Amoxapine Tablets	***Currently in Shortage***
Amphetamine Oral Suspension, Extended Release	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine for Injection	***Currently in Shortage***
Azithromycin (Azasite) Ophthalmic Solution 1%	***Currently in Shortage***
Bacteriostatic 0.9% Sodium Chloride Injection	***Currently in Shortage***
Bacteriostatic Water for Injection	***Currently in Shortage***
Belatacept (Nulojix) Lyophilized Powder for Injection	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride and Epinephrine Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Calcium Disodium Versenate Injection	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Cefazolin Injection	***Currently in Shortage***
Cefixime Oral Capsules	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chlordiazepoxide Hydrochloride Capsules	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container	***Currently in Shortage***
Continuous Renal Replacement Therapy (CRRT) Solutions	***Currently in Shortage***
Cortisone Acetate Tablets	***Currently in Shortage***
Cyclopentolate Ophthalmic Solution	***Currently in Shortage***
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***
Digoxin Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Disopyramide Phosphate (Norpace) Capsules	***Currently in Shortage***

Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Injection, 0.1 mg/mL	***Currently in Shortage***
Epinephrine Injection, Auto-Injector	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Floxuridine for Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Fluorescein Injection	***Currently in Shortage***
Fluvoxamine ER Capsules	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Guanfacine Hydrochloride Tablets	***Currently in Shortage***
Heparin Sodium and Sodium Chloride 0.9% Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert	***Currently in Shortage***
Ibutilide Fumarate Injection	***Currently in Shortage***
Iodixanol (Visipaque) Injection	***Currently in Shortage***
Iohexol (Omnipaque) Injection	***Currently in Shortage***
Iopromide (Ultravist) Injection	***Currently in Shortage***
Isoniazid Injection	***Currently in Shortage***
Ketamine Injection	***Currently in Shortage***
Ketoprofen Capsules	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Lyophilized Powder for Injection	***Currently in Shortage***
Leuprolide Acetate Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine	***Currently in Shortage***
Lipid Injection	***Currently in Shortage***
Lithium Oral Solution	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Lutetium Lu 177 Dotatate (LUTATHERA) Injection	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***
Mepivacaine Hydrochloride Injection	***Currently in Shortage***
Methyldopa Tablets	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***

Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Paclitaxel Injection (protein-bound particles)	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Parathyroid Hormone (Natpara) Injection	***Currently in Shortage***
Pentostatin Injection	***Currently in Shortage***
Physostigmine Salicylate Injection	***Currently in Shortage***
Potassium Acetate Injection	***Currently in Shortage***
Potassium Chloride Concentrate Injection	***Currently in Shortage***
Promethazine (Phenergan) Injection	***Currently in Shortage***
Propofol Injectable Emulsion	***Currently in Shortage***
Protamine Sulfate Injection	***Currently in Shortage***
Rifampin Capsules	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablets	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Semaglutide (Wegovy) Injection	***Currently in Shortage***
Sincalide (Kinevac) Lyophilized Powder for Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection Bags	***Currently in Shortage***
Sodium Chloride 14.6% Injection	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection USP, 0.9% Vials and Syringes	***Currently in Shortage***
Sodium Phosphates Injection	***Currently in Shortage***
Sterile Water for Injection	***Currently in Shortage***
Streptozocin Powder for Injection	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Sulfasalazine Tablets	***Currently in Shortage***
Technetium TC-99M Mebrofenin Injection	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Teprotumumab-trbw	***Currently in Shortage***
Thiothixene Capsules	***Currently in Shortage***
Triamcinolone Acetonide Injectable Suspension	***Currently in Shortage***
Triamcinolone Hexacetonide Injectable suspension	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsules	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***