OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
September 8, 2021
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 – September 8, 2021

DATE: September 1, 2021

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

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

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Enclosed are the following items related to the September meeting. Material is arranged in order of the agenda.

Call to Order

Public Comment Forum

Action Item – Approval of DUR Board Meeting Minutes – Appendix A

Update on the Medication Coverage Authorization Unit/Pediatric Antipsychotic Monitoring Program Update – Appendix B

Annual Review of the Medication Therapy Management (MTM) Program – Appendix C

Action Item – Approval of July 2021 DUR Board Recommendations – Appendix D

Action Item – Vote to Prior Authorize Qdolo™ (Tramadol 5mg/mL Oral Solution) – Appendix E

Action Item – Vote to Prior Authorize Impeklo® (Clobetasol Propionate 0.05% Lotion) – Appendix F

Action Item – Vote to Update the Approval Criteria for the Ophthalmic Anti-Inflammatory Products – Appendix G

Action Item – Vote to Prior Authorize Nulibry™ (Fosdenopterin) – Appendix H

Action Item – Vote to Prior Authorize Danyelza® (Naxitamab-gqgk) and Truseltiq™ (Infigratinib) – Appendix I

Action Item – Vote to Prior Authorize Feraheme® (Ferumoxytol), Injectafer® (Ferric Carboxymaltose), and Monoferric® (Ferric Derisomaltose) – Appendix J

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

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

Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Herceptin® (Trastuzumab) and Margenza® (Margetuximab-cmkb) – Appendix M

Annual Review of Prostate Cancer Medications and 30-Day Notice to Prior Authorize Orgovyx™ (Relugolix) – Appendix N

Annual Review of Cystadrops® (Cysteamine 0.37% Ophthalmic Solution) and Cystaran® (Cysteamine 0.44% Ophthalmic Solution) – 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 – September 8, 2021 @ 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. Markita Broyles –	participating in person
Dr. Megan Hanner –	participating in person
Dr. Lynn Mitchell –	participating in person
Dr. John Muchmore –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person

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

Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 956 8429 1722
Passcode: 97508217

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 need to 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. 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. Acknowledgment of Speakers for Public Comment

Items to be presented by Dr. Muchmore, Chairman:

3. Action Items – Approval of DUR Board Meeting Minutes – See Appendix A

A. **Action Item –** June 9, 2021 DUR Board Meeting Minutes – Vote
B. June 9, 2021 DUR Board Recommendations Memorandum
C. **Action Item –** July 14, 2021 DUR Board Meeting Minutes – Vote
D. July 14, 2021 DUR Board Recommendations Memorandum

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

4. Update on the Medication Coverage Authorization Unit/Pediatric Antipsychotic Monitoring Program Update – See Appendix B

A. Pharmacy Helpdesk Activity for July 2021
B. Medication Coverage Activity for July 2021
C. Pharmacy Helpdesk Activity for August 2021
D. Medication Coverage Activity for August 2021
E. Pediatric Antipsychotic Monitoring Program Update

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

5. Annual Review of the Medication Therapy Management (MTM) Program – See Appendix C

A. Background
B. Workflow
C. Results
D. Case Study
E. Summary

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

6. Action Items – Approval of July 2021 DUR Board Recommendations – See Appendix D

A. **Action Item –** Vote to Prior Authorize Lybalvi™ (Olanzapine/Samidorphan)
   i. Market News and Updates
   ii. Lybalvi™ (Olanzapine/Samidorphan) Product Summary
   iii. College of Pharmacy Recommendations

B. **Action Item –** Vote to Prior Authorize Azstarys™ (Serdexmethylphenidate/ Dexmethylphenidate), Qelbree™ (Viloxazine), and Xywav® (Calcium/ Magnesium/Potassium/Sodium Oxybates)
   i. Market News and Updates
   ii. Product Summaries
   iii. College of Pharmacy Recommendations

C. **Action Item –** Vote to Prior Authorize Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack) and Pylera® (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline Capsule)
   i. Market News and Updates
   ii. *Helicobacter Pylori* (*H. Pylori*) Product Summaries
   iii. Cost Comparison: *H. Pylori* Regimens
   iv. College of Pharmacy Recommendations

D. **Action Item –** Vote to Prior Authorize Alkindi® Sprinkle (Hydrocortisone Oral Granule), Eysuvis® (Loteprednol 0.25% Ophthalmic Suspension), Gimoti® (Metoclopramide Nasal Spray), Nextstellis® (Drospirenone/Estetrol), Ozobax™ (Baclofen 5mg/mL Oral Solution), Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel), RediTrex™ (Methotrexate Injection), Reltone™ (Ursodiol Capsule), and Thyquidity™ (Levothyroxine Oral Solution)
   i. Introduction
   ii. College of Pharmacy Recommendations

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

7. Action Item – Vote to Prior Authorize Qdolo™ (Tramadol 5mg/mL Oral Solution) – See Appendix E

A. Market News and Updates
B. Qdolo™ (Tramadol 5mg/mL Oral Solution) Product Summary
C. College of Pharmacy Recommendations

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

8. Action Item – Vote to Prior Authorize Impeklo® (Clobetasol Propionate 0.05% Lotion) – See Appendix F

A. Market News and Updates
B. Impeklo® (Clobetasol Propionate 0.05% Lotion) Product Summary
C. College of Pharmacy Recommendations

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

9. Action Item – Vote to Update the Approval Criteria for the Ophthalmic Anti-Inflammatory Products – See Appendix G

A. College of Pharmacy Recommendations

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

10. Action Item – Vote to Prior Authorize Nulibry™ (Fosdenopterin) – See Appendix H

A. Market News and Updates
B. Nulibry™ (Fosdenopterin) Product Summary
C. College of Pharmacy Recommendations

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

11. Action Item – Vote to Prior Authorize Danyelza® (Naxitamab-gqgk) and Truseltiq™ (Infigratinib) – See Appendix I

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

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

12. Action Item – Vote to Prior Authorize Feraheme® (Ferumoxytol), Injectafer® (Ferric Carboxymaltose), and Monoferric® (Ferric Derisomaltose) – See Appendix J

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

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

13. Action Item – Annual Review of Synagis® (Palivizumab) – See Appendix K

A. Current Prior Authorization Criteria
B. Utilization of Synagis® (Palivizumab)
C. Prior Authorization of Synagis® (Palivizumab)
D. Respiratory Syncytial Virus (RSV) Season Comparison
E. Market News and Updates
F. Oklahoma Updates
G. College of Pharmacy Recommendations

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

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

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

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

15. Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Herceptin® (Trastuzumab) and Margenza® (Margetuximab-cmkb) – See Appendix M

A. Introduction

B. Current Prior Authorization Criteria
C. Utilization of Breast Cancer Medications
D. Prior Authorization of Breast Cancer Medications
E. Market News and Updates
F. Margenza® (Margetuximab-cmkb) Product Summary
G. College of Pharmacy Recommendations
H. Utilization Details of Breast Cancer Medications

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

16. Annual Review of Prostate Cancer Medications and 30-Day Notice to Prior Authorize Orgovyx™ (Relugolix) – See Appendix N

A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Prostate Cancer Medications
D. Prior Authorization of Prostate Cancer Medications
E. Market News and Updates
F. Orgovyx™ (Relugolix) Product Summary
G. College of Pharmacy Recommendations
H. Utilization Details of Prostate Cancer Medications

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

17. Annual Review of Cystadrops® (Cysteamine 0.37% Ophthalmic Solution) and Cystaran® (Cysteamine 0.44% Ophthalmic Solution) – See Appendix O

A. Current Prior Authorization Criteria
B. Utilization of Cystadrops® and Cystaran®
C. Prior Authorization of Cystadrops® and Cystaran®
D. Market News and Updates
E. College of Pharmacy Recommendations

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

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

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

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

A. Hepatitis C Medications
B. Ovarian Cancer Medications
C. Spinal Muscular Atrophy (SMA) Medications
D. Targeted Immunomodulator Agents

**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 9, 2021

BOARD MEMBERS:	PRESENT	ABSENT
Stephen Anderson, Pharm.D.		x
Jennifer de los Angeles, Pharm.D., BCOP	x	
Jennifer Boyett, MHS; PA-C	x	
Markita Broyles, D.Ph.; MBA	x	
Theresa Garton, M.D.		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	
Lisa Daniel, Pharm.D.; Pharmacy Resident	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
Brandy Nawaz, Pharm.D.; Clinical Pharmacist	x	
Wynn Phung, Pharm.D.; Clinical Pharmacist		x
Leslie Robinson, D.Ph.; Pharmacy PA Coordinator		x
Vickie Sams, CPhT.; Quality/Training Coordinator	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 State Medicaid Director; 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	
Michael Herndon, D.O.; Chief Medical Officer		x
Jill Ratterman, D.Ph.; Clinical Pharmacist	x	
Paula Root, M.D.; Senior Medical Director	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:	
Jerod Downing, Alkermes	Patrick Harvey, Supernus
Brent Parker, Merck	Chris Stanfield, Supernus
Mark Kaiser, Otsuka	Terry McCurren, Otsuka
Tara McKinley, Otsuka	Kristi Kemp, AbbVie
Joe Garcia, AbbVie	Marc Parker, Sunovion
Donna Birchette, Oncopeptides	Sarah Sanders, Novartis
Burl Beasley, OMES	Frank Alvarado, Johnson and Johnson
Audrey Rattan, Alkermes	Tom Yelle, Xcenda
Jomy Joseph, Sanofi	Andrew Delgado, Bristol Myers Squibb
Rhonda Clark, Indivior	Jason Dickerson, Jazz Pharmaceuticals
Jeff Knappen, Spark Therapeutics	Melanie Curlett, Takeda
Robert Greely, Biogen	Jim Dunlap, Dunlap Consultants
William Eicholzer, Alexion	Shellie Keast, Mercer
Brian Maves, Pfizer	Evan Rushing, Alkermes
Doug Wood, ViiV Healthcare	Glenn Cornish, Alkermes
Christine Dube, AstraZeneca	

PRESENT FOR PUBLIC COMMENT:	
Patrick Harvey	Supernus
Tara McKinley	Otsuka
Jerod Downing	Alkermes

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

A. ROLL CALL

Dr. Muchmore called the meeting to order. Roll call by Dr. Wilcox established the presence of a quorum.

ACTION: NONE REQUIRED

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

A. AGENDA ITEM NO. 12: PATRICK HARVEY

B. AGENDA ITEM NO. 13: TARA MCKINLEY

C. AGENDA ITEM NO. 13: JEROD DOWNING

ACTION: NONE REQUIRED

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

A. MAY 12, 2021 DUR MINUTES – VOTE

B. MAY 12, 2021 DUR RECOMMENDATION MEMORANDUM
Materials included in agenda packet; presented by Dr. Muchmore
Dr. Mitchell moved to approve; seconded by Dr. Broyles
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 4:</u> MEDICATION THERAPY MANAGEMENT (MTM) PROGRAM UPDATE
A. MTM PROGRAM UPDATE
B. FOCUS ON ADHERENCE
C. CASE STUDY
D. SUMMARY
Materials included in agenda packet; presented by Dr. Smith
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 5:</u> UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/USE OF GLUCAGON-LIKE PEPTIDE-1 (GLP-1) AGONISTS/SODIUM-GLUCOSE CO-TRANSPORTER-2 (SGLT-2) INHIBITORS WITH CARDIOVASCULAR (CV) BENEFIT IN MEMBERS WITH TYPE 2 DIABETES (T2D) AND HIGH CV RISK OR ESTABLISHED ATHEROSCLEROTIC CV DISEASE (ASCVD) MAILING UPDATE
A. PHARMACY HELPDESK ACTIVITY FOR MAY 2021
B. MEDICATION COVERAGE ACTIVITY FOR MAY 2021
C. USE OF GLP-1 AGONISTS/SGLT-2 INHIBITORS WITH CV BENEFIT IN MEMBERS WITH T2D AND HIGH CV RISK OR ESTABLISHED ASCVD MAILING UPDATE
Materials included in agenda packet; presented by Dr. Nawaz, Dr. Daniel
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 6:</u> VOTE TO PRIOR AUTHORIZE CABOMETYX® (CABOZANTINIB), FOTIVDA® (TIVOZANIB), JELMYTO® (MITOMYCIN), AND PADCEV® (ENFORTUMAB VEDOTIN-EJFV)
A. MARKET NEWS AND UPDATES
B. PRODUCT SUMMARIES
C. COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Broyles moved to approve; seconded by Dr. Mitchell
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 7:</u> VOTE TO PRIOR AUTHORIZE GEMTESA® (VIBEGRON)
A. INTRODUCTION
B. COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Broyles
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 8:</u> VOTE TO PRIOR AUTHORIZE ZILXI® (MINOCYCLINE 1.5% TOPICAL FOAM)
A. INTRODUCTION
B. COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Broyles
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 9:</u> VOTE TO PRIOR AUTHORIZE KYNMOBI™ (APOMORPHINE) AND ONGENTYS® (OPICAPONE)

A. NEW U.S. FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL(S)
B. PRODUCT SUMMARIES
C. COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Nawaz
Dr. Broyles moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 10:</u> VOTE TO PRIOR AUTHORIZE FETROJA® (CEFIDEROCOL) AND KIMYRSA™ (ORITAVANCIN)
A. NEW U.S. FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL(S)
B. PRODUCT SUMMARIES
C. COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Ha
Dr. Mitchell moved to approve; seconded by Dr. Broyles
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 11:</u> ANNUAL REVIEW OF THE SOONERCARE PHARMACY BENEFIT
A. SUMMARY
B. MEDICAID DRUG REBATE PROGRAM
C. ALTERNATIVE PAYMENT MODELS
D. DRUG APPROVAL TRENDS
E. TRADITIONAL VERSUS SPECIALTY PHARMACY PRODUCTS
F. TOP 10 TRADITIONAL THERAPEUTIC CLASSES BY REIMBURSEMENT
G. TOP 10 SPECIALTY THERAPEUTIC CLASSES BY REIMBURSEMENT
H. TOP 10 MEDICATIONS BY REIMBURSEMENT
I. COST PER CLAIM
J. MARKET PROJECTIONS
K. CONCLUSION
L. TOP 50 REIMBURSED DRUGS BY CALENDAR YEAR
M. TOP 50 MEDICATIONS BY TOTAL NUMBER OF CLAIMS
N. TOP 10 TRADITIONAL AND SPECIALTY THERAPEUTIC CATEGORIES BY CALENDAR YEAR
O. CALENDAR YEAR AGE GROUP COMPARISON
Materials included in agenda packet; presented by Dr. Daniel
ACTION: NONE REQURIED

<u>AGENDA ITEM NO. 12:</u> ANNUAL REVIEW OF ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AZSTARYS™ (SERDEXMETHYLPHENIDATE/ DEXMETHYLPHENIDATE), QELBREE™ (VILOXAZINE), AND XYWAV™ (CALCIUM/MAGNESIUM/POTASSIUM/SODIUM OXYBATES)
A. CURRENT PRIOR AUTHORIZATION CRITERIA
B. UTILIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
C. PRIOR AUTHORIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
D. OKLAHOMA RESOURCES
E. MARKET NEWS AND UPDATES
F. PRODUCT SUMMARIES
G. COLLEGE OF PHARMACY RECOMMENDATIONS
H. UTILIZATION DETAILS OF ADHD AND NARCOLEPSY MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE LYBALVI™ (OLANZAPINE/SAMIDORPHAN)

A. CURRENT PRIOR AUTHORIZATION CRITERIA
B. UTILIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
C. PRIOR AUTHORIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
D. OKLAHOMA RESOURCES
E. MARKET NEWS AND UPDATES
F. LYBALVI™ (OLANZAPINE/SAMIDORPHAN) PRODUCT SUMMARY
G. COLLEGE OF PHARMACY RECOMMENDATIONS
H. UTILIZATION DETAILS OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS

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

<u>AGENDA ITEM NO. 14:</u> ANNUAL REVIEW OF VARIOUS SPECIAL FORMULATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ALKINDI® SPRINKLE (HYDROCORTISONE ORAL GRANULE), EYSUVIS® (LOTEPREDNOL 0.25% OPHTHALMIC SUSPENSION), GIMOTI™ (METOCLOPRAMIDE NASAL SPRAY), NEXTSTELLIS® (DROSPIRENONE/ESTETROL TABLET), OZOBAX® (BACLOFEN 5MG/ML ORAL SOLUTION), PHEXXI® (LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE VAGINAL GEL), REDITREX® (METHOTREXATE INJECTION), RELTONE™ (URSODIOL CAPSULE), AND THYQUIDITY™ (LEVOTHYROXINE ORAL SOLUTION)

A. INTRODUCTION
B. CURRENT PRIOR AUTHORIZATION CRITERIA
C. UTILIZATION OF VARIOUS SPECIAL FORMULATIONS
D. PRIOR AUTHORIZATION OF VARIOUS SPECIAL FORMULATIONS
E. PRODUCT SUMMARIES
F. COLLEGE OF PHARMACY RECOMMENDATIONS
G. UTILIZATION DETAILS OF VARIOUS SPECIAL FORMULATIONS

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

<u>AGENDA ITEM NO. 15:</u> ANNUAL REVIEW OF ANTI-ULCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE HELIDAC® THERAPY (BISMUTH SUBSALICYLATE/METRONIDAZOLE/TETRACYCLINE DOSE PACK) AND PYLERA® (BISMUTH SUBCITRATE POTASSIUM/METRONIDAZOLE/TETRACYCLINE CAPSULE)

A. CURRENT PRIOR AUTHORIZATION CRITERIA
B. UTILIZATION OF ANTI-ULCER MEDICATIONS
C. PRIOR AUTHORIZATION OF ANTI-ULCER MEDICATIONS
D. MARKET NEWS AND UPDATES
E. *HELICOBACTER PYLORI* (*H. PYLORI*) PRODUCT SUMMARIES
F. COST COMPARISON: *H. PYLORI* REGIMENS
G. COLLEGE OF PHARMACY RECOMMENDATIONS
H. UTILIZATION DETAILS OF ANTI-ULCER MEDICATIONS

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

<u>AGENDA ITEM NO. 16:</u> ANNUAL REVIEW OF ISTURISA® (OSILODROSTAT)

A. CURRENT PRIOR AUTHORIZATION CRITERIA
B. UTILIZATION OF ISTURISA® (OSILODROSTAT)
C. PRIOR AUTHORIZATION OF ISTURISA® (OSILODROSTAT)
D. MARKET NEWS AND UPDATES

E. COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Ha
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 17:</u> U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTRATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. Nawaz
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 18:</u> FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
A. INTRAVENOUS (IV) IRON PRODUCTS
B. OPHTHALMIC ANTI-INFLAMMATORY PRODUCTS
C. OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
D. TOPICAL CORTICOSTEROIDS
**Future business subject to change.*
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 19:</u> ADJOURNMENT
The meeting was adjourned at 6:04pm.

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

Memorandum

Date: June 10, 2021

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 9, 2021

Recommendation 1: Medication Therapy Management (MTM) Program Update

NO ACTION REQUIRED.

Recommendation 2: Use of Glucagon-Like Peptide-1 (GLP-1) Agonists or Sodium-Glucose Co-Transporter-2 (SGLT-2) Inhibitors with Cardiovascular (CV) Benefit in Members with Type 2 Diabetes (T2D) and High CV Risk or Established Atherosclerotic CV Disease (ASCVD) Mailing Update

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Cabometyx® (Cabozantinib), Fotivda® (Tivozanib), Jelmyto® (Mitomycin), and Padcev® (Enfortumab Vedotin-ejfv)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Cabometyx® (cabozantinib), Fotivda® (tivozanib), Jelmyto® (mitomycin), and Padcev® (enfortumab vedotin-ejfv) with the following criteria:

Cabometyx® (Cabozantinib) Approval Criteria:

1. For cabozantinib monotherapy:
    a. Diagnosis of advanced renal cell carcinoma (RCC); or
    b. Diagnosis of advanced hepatocellular carcinoma (HCC); and
        i. Member has previously received sorafenib.
2. For cabozantinib in combination with nivolumab:
    a. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with advanced RCC; and
    b. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.

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

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

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

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

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

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

Recommendation 4: Vote to Prior Authorize Gemtesa® (Vibegron)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the placement of Gemtesa® (vibegron) into the Special Prior Authorization (PA) Tier of the Bladder Control Medications Product Based Prior Authorization (PBPA) category, based on net costs, with the following additional criteria:

Gemtesa® (Vibegron) Approval Criteria:

1. An FDA approved indication of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
4. A quantity limit of 30 tablets per 30 days will apply.

Additionally, the College of Pharmacy recommends the placement of VESIcare LS™ (solifenacin oral suspension) into Tier-1 of the bladder control medications PBPA category, based on net costs, with an age restriction of 2 to 10 years of age. Members older than 10 years of age will require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

The College of Pharmacy also recommends the placement of Myrbetriq® (mirabegron granules for oral suspension) into Tier-3 of the bladder control medications PBPA category with an age restriction of 3 years of age and older in members weighing <35kg. Members weighing ≥35kg would require a patient-specific, clinically significant reason why the granule formulation of mirabegron is needed in place of the regular tablet formulation. Current Tier-3 criteria will also apply.

Finally, the College of Pharmacy recommends removing Noctiva™ (desmopressin acetate nasal spray) from the Tier chart based on product discontinuation (additions and changes shown in red):

Bladder Control Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
fesoterodine (Toviaz®)	tolterodine (Detrol®)	darifenacin (Enablex®)	~~**desmopressin acetate nasal spray (Noctiva™)⁺**~~
oxybutynin (Ditropan®)	tolterodine ER (Detrol LA®)	mirabegron (Myrbetriq®)Δ **tablets and granulesβ**	desmopressin acetate SL tablets (Nocdurna®)⁺
oxybutynin ER (Ditropan XL®)		oxybutynin gel (Gelnique®)	oxybutynin patch (Oxytrol®)⁺
solifenacin (VESIcare®)Δ		trospium ER (Sanctura XR®)	**vibegron (Gemtesa®)⁺**
solifenacin oral susp (VESIcare LS™)α			
trospium (Sanctura®)			

ER = extended-release; PA = prior authorization; SL = sublingual; susp = suspension
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

[+]Unique criteria specific to Gemtesa® (vibegron), Oxytrol® (oxybutynin patch), ~~Noctiva™ (desmopressin acetate nasal spray),~~ and Nocdurna® (desmopressin acetate SL tablets) applies.
[Δ]Unique criteria specific to use of Myrbetriq® (mirabegron) in combination with VESIcare® (solifenacin) applies.
[α]An age restriction of 2 to 10 years of age will apply for VESIcare LS™. Members older than 10 years of age will require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.
[β]The Myrbetriq® granule formulation is covered for members 3 years of age or older weighing <35kg. Members weighing ≥35kg will require a patient-specific, clinically significant reason why the granule formulation is needed in place of the regular tablet formulation. Current Tier-3 criteria applies.

Recommendation 5: Vote to Prior Authorize Zilxi® (Minocycline 1.5% Topical Foam)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Zilxi® (minocycline 1.5% topical foam) with the following criteria:

Zilxi® (Minocycline 1.5% Topical Foam) Approval Criteria:

1. An FDA approved diagnosis of inflammatory lesions of rosacea in adults; and
2. Member must be 18 to 20 years of age; and
3. A patient-specific, clinically significant reason why the member cannot utilize clindamycin topical solution (generic), metronidazole topical gel and cream 0.75%, erythromycin topical 2% solution, oral isotretinoin medications, and other generically available preferred oral or topical antibiotic products must be provided; and
4. A quantity limit of 30 grams per 30 days will apply.

Additionally, the College of Pharmacy recommends updating the Aczone® (dapsone gel) approval criteria based on the FDA approved age expansion for the 7.5% gel with the following changes shown in red:

Aczone® (Dapsone Gel) Approval Criteria:

1. An FDA approved indication of acne vulgaris; and
2. For Aczone® 7.5% gel, the member must be 9 years of age or older; and
3. Aczone® is not covered for members older than 20 years of age; and
4. A previous trial of benzoyl peroxide or a patient-specific, clinically significant reason why benzoyl peroxide is not appropriate for the member must be provided; and
5. A previous trial of a topical antibiotic, such as clindamycin or erythromycin, or a patient-specific, clinically significant reason why a topical antibiotic is not appropriate for the member must be provided.

Next, the College of Pharmacy recommends updating the Tazorac® (tazarotene) approval criteria based on net costs and current product availability with the following changes in red:

Tazorac® (Tazarotene Cream and Gel) Approval Criteria:

1. An FDA approved indication of acne vulgaris or plaque psoriasis; and

2. Female members must not be pregnant and must be willing to use an effective method of contraception during treatment; and
~~3. Authorization of tazarotene 0.1% cream will require a patient-specific, clinically significant reason why the member cannot use the other formulations of tazarotene (brand Tazorac® 0.05% cream, 0.05% gel, and 0.1% gel are preferred); and~~
4. For the diagnosis of acne vulgaris, the following must be met:
    a. Member must be 20 years of age or younger; and
    b. ~~Based on current net costs,~~ Tazorac® 0.1% cream, Tazorac® 0.05% gel, Tazorac® 0.1% gel, and tazarotene 0.1% cream will not require prior authorization for members 20 years of age or younger; and
5. A quantity limit of 100 grams per 30 days will apply.

Finally, College of Pharmacy recommends updating the Amzeeq® (minocycline 4% topical foam) approval criteria, based on net costs and to be consistent with the approval criteria for Zilxi®, with the following changes in red:

Amzeeq® (Minocycline 4% Topical Foam) Approval Criteria:

1. An FDA approved indication of inflammatory lesions of non-nodular, moderate-to-severe acne vulgaris; and
2. Member must be 9 years of age or older; and
3. Amzeeq® is not covered for members older than 20 years of age; and
4. A patient-specific, clinically significant reason why the member cannot use erythromycin 2% topical solution~~, or~~ clindamycin 1% topical solution, benzoyl peroxide, brand name Tazorac®, oral isotretinoin medications, and other generically available preferred oral or topical antibiotic products~~, which are available without prior authorization,~~ must be provided; and
5. A quantity limit of 30 grams per 30 days will apply.

Recommendation 6: Vote to Prior Authorize Kynmobi™ (Apomorphine) and Ongentys® (Opicapone)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Kynmobi™ (apomorphine) and Ongentys® (opicapone) with the following criteria:

Kynmobi™ [Apomorphine Sublingual (SL) Film] Approval Criteria:

1. An FDA approved indication of acute, intermittent treatment of "off" episodes in members with Parkinson's disease (PD); and
2. Member must be taking carbidopa/levodopa in combination with Kynmobi™; and
3. Member should be experiencing at least 1 well defined "off" episode per day with a total daily "off" time duration of ≥2 hours during the waking day; and

4. Initial dose titration should occur in an "off" state and in a setting supervised by a health care provider to monitor blood pressure and heart rate; and
5. Member must not use apomorphine concomitantly with 5-HT_3 antagonists (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron); and
6. Prescriber must verify the member has been counseled on separating doses by at least 2 hours; and
7. The maximum single dose approvable is 30mg; and
8. A quantity limit of 5 doses per day will apply.

Ongentys® (Opicapone) Approval Criteria:

1. An FDA approved indication of adjunctive treatment to levodopa/carbidopa in members with Parkinson's disease (PD) experiencing "off" episodes; and
2. Member must be taking levodopa/carbidopa in combination with Ongentys®; and
3. Member must not use non-selective monoamine-oxidase inhibitors (MAOIs) concomitantly with Ongentys®; and
4. Member must not have a history of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms; and
5. Prescriber must verify member has been counseled to avoid eating food 1 hour before and at least 1 hour after taking Ongentys®; and
6. For members with moderate hepatic impairment, the prescriber must verify the dose of Ongentys® will be reduced in accordance with package labeling; and
7. Prescriber must agree to monitor member for changes in heart rate, heart rhythm, and blood pressure in members concurrently taking medications known to be metabolized by catechol-O-methyltransferase (COMT); and
8. A patient-specific, clinically significant reason why the member cannot use entacapone must be provided; and
9. A quantity limit of 30 capsules per 30 days will apply.

Recommendation 7: Vote to Prior Authorize Fetroja® (Cefiderocol) and Kimyrsa™ (Oritavancin)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Fetroja® (cefiderocol) and Kimyrsa™ (oritavancin) with the following criteria:

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 infections (ABSSSI) caused by 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 (beyond convenience) 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).

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 Azstarys™ (Serdexmethylphenidate/Dexmethylphenidate), Qelbree™ (Viloxazine), and Xywav® (Calcium/Magnesium/Potassium/ Sodium Oxybates)

NO ACTION REQUIRED.

Recommendation 10: Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Lybalvi™ (Olanzapine/Samidorphan)

NO ACTION REQUIRED.

Recommendation 11: Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Alkindi® Sprinkle (Hydrocortisone Oral Granule), Eysuvis® (Loteprednol 0.25% Ophthalmic Suspension), Gimoti™ (Metoclopramide Nasal Spray), Nextstellis® (Drospirenone/Estetrol Tablet), Ozobax® (Baclofen 5mg/5mL Oral Solution), Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel), RediTrex® (Methotrexate Injection), Reltone™ (Ursodiol Capsule), and Thyquidity™ (Levothyroxine Oral Solution)

NO ACTION REQUIRED.

Recommendation 12: Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack) and Pylera® (Bismuth Subcitrate Potassium/Metronidazole/ Tetracycline Capsule)

NO ACTION REQUIRED.

Recommendation 13: Annual Review of Isturisa® (Osilodrostat)

NO ACTION REQUIRED.

Recommendation 14: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 15: Future Business

NO ACTION REQUIRED.

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING JULY 14, 2021

DUR BOARD MEMBERS:	PRESENT	ABSENT
Stephen Anderson, Pharm.D.		x
Jennifer de los Angeles, Pharm.D., BCOP		x
Jennifer Boyett, MHS; PA-C		x
Markita Broyles, D.Ph.; MBA	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
Brandy Nawaz, Pharm.D.; Clinical Pharmacist	x	
Wynn Phung, Pharm.D.; Clinical Pharmacist		x
Leslie Robinson, D.Ph.; Pharmacy PA Coordinator		x
Vickie Sams, CPhT.; Quality/Training Coordinator	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): Anmol Abraham	x	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Melody Anthony, Chief State Medicaid Director; 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
Michael Herndon, D.O.; Chief Medical Officer		x
Josh Holloway, J.D.; Deputy General Counsel	x	
Jill Ratterman, D.Ph.; Clinical Pharmacist	x	
Paula Root, M.D.; Senior Medical Director	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:	
Mark Kaiser, Otsuka	Melanie Curlett, Takeda
David Prather, Novo Nordisk	David Condrick, Bridgebio
Burl Beasley, OMES	Jessica Chardoulias, Novo Nordisk
Robert Greely, Biogen	Christopher Voyiatt, Corium
Ron Frost, Astellas	Amara Udokporo, DK Pierce
Brian Maves, Pfizer	Jody Legg, Mirum Pharmaceuticals
Aaron Shaw, Boehringer Ingelheim	Rhonda Clark, Indivior
Brent Parker, Merck	Brandon Ross, Merck
Terry McCurren, Otsuka	Kelli Strother, Otsuka

PRESENT FOR PUBLIC COMMENT:	
N/A	

AGENDA ITEM NO. 1: CALL TO ORDER

A. ROLL CALL

Dr. Muchmore called the meeting to order. Roll call by Dr. Wilcox did not establish the presence of a quorum.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: PUBLIC COMMENT FORUM

ACTION: NONE REQUIRED

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

A. JUNE 9, 2021 DUR MINUTES

B. JUNE 9, 2021 DUR RECOMMENDATION MEMORANDUM

Materials included in agenda packet; presented by Dr. Muchmore

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER 2021

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

A. PHARMACY HELPDESK ACTIVITY FOR JUNE 2021

B. MEDICATION COVERAGE ACTIVITY FOR JUNE 2021

C. CMA PROGRAM UPDATE

Materials included in agenda packet; presented by Dr. Wilson, Dr. Nawaz

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 5:</u> VOTE TO PRIOR AUTHORIZE LYBALVI™ (OLANZAPINE/SAMIDORPHAN)

A. MARKET NEWS AND UPDATES
B. LYBALVI™ (OLANZAPINE/SAMIDORPHAN) PRODUCT SUMMARY
C. COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Nawaz

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER 2021

<u>AGENDA ITEM NO. 6:</u> VOTE TO PRIOR AUTHORIZE AZSTARYS™ (SERDEXMETHYLPHENIDATE/DEXMETHYLPHENIDATE), QELBREE™ (VILOXAZINE), AND XYWAV® (CALCIUM/MAGNESIUM/POTASSIUM/SODIUM OXYBATES)

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

Materials included in agenda packet; presented by Dr. Wilson

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER 2021

<u>AGENDA ITEM NO. 7:</u> VOTE TO PRIOR AUTHORIZE HELIDAC® THERAPY (BISMUTH SUBSALICYLATE/METRONIDAZOLE/TETRACYCLINE DOSE PACK) AND PYLERA® (BISMUTH SUBCITRATE POTASSIUM/METRONIDAZOLE/TETRACYCLINE CAPSULE)

A. MARKET NEWS AND UPDATES
B. *HELICOBACTER PYLORI* (*H. PYLORI*) PRODUCT SUMMARIES
C. COST COMPARISON: *H. PYLORI* REGIMENS
D. COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Ha

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER 2021

<u>AGENDA ITEM NO. 8:</u> VOTE TO PRIOR AUTHORIZE ALKINDI® SPRINKLE (HYDROCORTISONE ORAL GRANULE), EYSUVIS® (LOTEPREDNOL 0.25% OPHTHALMIC SUSPENSION), GIMOTI™ (METOCLOPRAMIDE NASAL SPRAY), NEXTSTELLIS® (DROSPIRENONE/ESTETROL TABLET), OZOBAX™ (BACLOFEN 5MG/ML ORAL SOLUTION), PHEXXI® (LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE VAGINAL GEL), REDITREX™ (METHOTREXATE INJECTION), RELTONE™ (URSODIOL CAPSULE), AND THYQUIDITY™ (LEVOTHYROXINE ORAL SOLUTION)

A. INTRODUCTION
B. COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER 2021

<u>AGENDA ITEM NO. 9:</u> ANNUAL REVIEW OF KOSELUGO™ (SELUMETINIB), PEMAZYRE® (PEMIGATINIB), AND QINLOCK® (RIPRETINIB) AND 30-DAY NOTICE TO PRIOR AUTHORIZE DANYELZA® (NAXITAMAB-GQGK) AND TRUSELTIQ™ (INFIGRATINIB)

A. INTRODUCTION
B. CURRENT PRIOR AUTHORIZATION CRITERIA
C. UTILIZATION OF KOSELUGO™ (SELUMETINIB), PEMAZYRE® (PEMIGATINIB), AND QINLOCK® (RIPRETINIB)
D. PRIOR AUTHORIZATION OF KOSELUGO™ (SELUMETINIB), PEMAZYRE® (PEMIGATINIB), AND QINLOCK® (RIPRETINIB)
E. MARKET NEWS AND UPDATES
F. PRODUCT SUMMARIES

G. COLLEGE OF PHARMACY RECOMMENDATIONS
H. UTILIZATION DETAILS OF KOSELUGO™ (SELUMETINIB), PEMAZYRE® (PEMIGATINIB), AND QINLOCK® (RIPRETINIB)

Materials included in agenda packet; presented by Dr. Borders

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 10:</u> ANNUAL REVIEW OF OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE QDOLO™ (TRAMADOL 5MG/ML ORAL SOLUTION)

A. CURRENT PRIOR AUTHORIZATION CRITERIA
B. UTILIZATION OF OPIOID ANALGESICS AND MAT MEDICATIONS
C. PRIOR AUTHORIZATION OF OPIOID ANALGESICS AND MAT MEDICATIONS
D. MARKET NEWS AND UPDATES
E. QDOLO™ (TRAMADOL 5MG/ML ORAL SOLUTION) PRODUCT SUMMARY
F. COLLEGE OF PHARMACY RECOMMENDATIONS
G. UTILIZATION DETAILS OF OPIOID ANALGESICS
H. UTILIZATION DETAILS OF MAT MEDICATIONS

Materials included in agenda packet; presented by Dr. Chandler

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 11:</u> ANNUAL REVIEW OF TOPICAL CORTICOSTEROIDS AND 30-DAY NOTICE TO PRIOR AUTHORIZE IMPEKLO® (CLOBETASOL PROPIONATE 0.05% LOTION)

A. CURRENT PRIOR AUTHORIZATION CRITERIA
B. UTILIZATION OF TOPICAL CORTICOSTEROIDS
C. PRIOR AUTHORIZATION OF TOPICAL CORTICOSTEROIDS
D. MARKET NEWS AND UPDATES
E. IMPEKLO® (CLOBETASOL PROPIONATE 0.05% LOTION) PRODUCT SUMMARY
F. COLLEGE OF PHARMACY RECOMMENDATIONS
G. UTILIZATION DETAILS OF TOPICAL CORTICOSTEROIDS

Materials included in agenda packet; presented by Dr. Nawaz

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 12:</u> ANNUAL REVIEW OF OPHTHALMIC ANTI-INFLAMMATORY PRODUCTS

A. CURRENT PRIOR AUTHORIZATION CRITERIA
B. UTILIZATION OF OPHTHALMIC ANTI-INFLAMMATORY PRODUCTS
C. PRIOR AUTHORIZATION OF OPHTHALMIC ANTI-INFLAMMATORY PRODUCTS
D. MARKET NEWS AND UPDATES
E. COLLEGE OF PHARMACY RECOMMENDATIONS
F. UTILIZATION DETAILS OF OPHTHALMIC CORTICOSTEROIDS
G. UTILIZATION DETAILS OF OPHTHALMIC NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)

Materials included in agenda packet; presented by Dr. Ha

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 13:</u> 30-DAY NOTICE TO PRIOR AUTHORIZE NULIBRY™ (FOSDENOPTERIN)

A. INTRODUCTION
B. NULIBRY™ (FOSDENOPTERIN) PRODUCT SUMMARY
C. COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Ha

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 14:</u> 30-DAY NOTICE TO PRIOR AUTHORIZE FERAHEME® (FERUMOXYTOL), INJECTAFER® (FERRIC CARBOXYMALTOSE), AND MONOFERRIC® (FERRIC DERISOMALTOSE)

A. INTRODUCTION
B. UTILIZATION OF INTRAVENOUS (IV) IRON PRODUCTS: MEDICAL CLAIMS
C. MARKET NEWS AND UPDATES
D. PRODUCT SUMMARIES
E. RELATIVE RISK OF SERIOUS ADVERSE EFFECTS (SAES)
F. COST COMPARISON
G. COLLEGE OF PHARMACY RECOMMENDATIONS
H. UTILIZATION DETAILS OF IV IRON PRODUCTS

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

<u>AGENDA ITEM NO. 15:</u> U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTRATION (DEA) UPDATES

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

<u>AGENDA ITEM NO. 16:</u> FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)

NO DUR BOARD MEETING SCHEDULED FOR AUGUST 2021.

A. BREAST CANCER MEDICATIONS
B. PROSTATE CANCER MEDICATIONS
C. SYNAGIS® (PALIVIZUMAB)
D. TARGETED IMMUNOMODULATOR AGENTS

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

<u>AGENDA ITEM NO. 17:</u> ADJOURNMENT

The meeting was adjourned at 5:10pm.

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

Memorandum

Date: July 16, 2021

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

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

Subject: DUR Board Recommendations from Meeting on July 14, 2021

Recommendation 1: Chronic Medication Adherence (CMA) Program Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Lybalvi™ (Olanzapine/Samidorphan)

VOTE ITEM AT SEPTEMBER MEETING

The College of Pharmacy recommends adding Lybalvi™ (olanzapine/ samidorphan) to Tier-3 of the Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) category; current Tier-3 criteria will apply (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®)

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole lauroxil IM inj (Aristada Initio®)		cariprazine (Vraylar®)
clozapine (Clozaril®)◊		clozapine ODT (Fazaclo®)+
olanzapine (Zyprexa®)		clozapine oral susp (Versacloz®)+
paliperidone IM inj (Invega Sustenna®)		iloperidone (Fanapt®)
paliperidone 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®)		

ER = extended-release; IM = intramuscular; inj = injection; ODT = orally disintegrating tablet; sub-Q = subcutaneous; susp = suspension
*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.
¥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 ER injection (Invega Sustenna®) for at least 4 months.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.

- Tier-1 products are available without prior authorization for members 5 years of age and older. Prior authorization requests for members younger than 5 years of age are reviewed by an Oklahoma Health Care Authority (OHCA)-contracted child psychiatrist.

Atypical Antipsychotic Medications Tier-2 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
   a. Clozapine does not count towards a Tier-1 trial.

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
    a. Clozapine does not count towards a Tier-1 trial; and
2. Trials of all oral Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or
3. A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and
4. Use of Versacloz® (clozapine oral suspension) or Fazaclo® (clozapine orally disintegrating tablet) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
5. Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the oral sublingual tablet formulation. Tier structure rules continue to apply; and
6. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

Recommendation 3: Vote to Prior Authorize Azstarys™ (Serdexmethylphenidate/Dexmethylphenidate), Qelbree™ (Viloxazine), and Xywav® (Calcium/Magnesium/Potassium/ Sodium Oxybates)

VOTE ITEM AT SEPTEMBER MEETING

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

1. The prior authorization of Azstarys™ (serdexmethylphenidate/ dexmethylphenidate) and placement into Tier-3 of the Long-Acting Methylphenidate category of the ADHD Medications PBPA Tier chart; current Tier-3 criteria will apply
2. The prior authorization of Qelbree™ (viloxazine) and placement into Tier-3 of the Non-Stimulants category of the ADHD Medications PBPA Tier chart; the following additional criteria will also apply
3. The prior authorization of Xywav® (calcium/magnesium/potassium/ sodium oxybates) in the Narcolepsy Medications category with criteria similar to the current approval criteria for Xyrem® (sodium oxybate); the following additional criteria will also apply

4. Moving Quillivant XR® (methylphenidate ER suspension) from Tier-2 to Tier-3, moving Adderall XR® from Tier-2 to Tier-1, and moving Metadate ER® (methylphenidate ER tablet), Methylin ER® (methylphenidate ER tablet), and Ritalin SR® (methylphenidate ER tablet) from Tier-3 to Tier-1 of the ADHD Medications PBPA Tier chart based on net costs
5. Moving Kapvay® (clonidine ER tablet) from Tier-3 to Tier-2 of the Non-Stimulants category of the ADHD Medications PBPA Tier chart based on net cost, and updating the following additional criteria for Kapvay®

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

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
methylphenidate ER (Methylin ER®) methylphenidate ER chew tab (QuilliChew ER®) methylphenidate ER (Ritalin LA®) **methylphenidate ER (Ritalin SR®)**		~~**methylphenidate ER (Metadate ER®)**~~ ~~**methylphenidate ER (Methylin ER®)**~~ **methylphenidate ER susp (Quillivant XR®)** ~~**methylphenidate ER (Ritalin SR®)**~~ **serdexmethylphen-idate/dexmethylphe-nidate (Azstarys™)**	
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	**clonidine ER (Kapvay®)Δ**	~~**clonidine ER (Kapvay®)Δ**~~ **viloxazine (Qelbree™)Δ**	

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

ADHD Medications 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 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.
4. A clinical exception may apply for special formulation products when there is a patient-specific, clinically significant reason why the member cannot use the available long-acting lower tiered formulations.
5. ~~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, a long-acting Tier-2 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.~~
6. Qelbree™ [Viloxazine Extended-Release (ER) Capsule] Approval Criteria:
   a. An FDA approved diagnosis; and
   b. Member must be 6 to 17 years of age; and
   c. Previously failed trials (within the last 365 days) with a long-acting Tier-1 stimulant, a long-acting Tier-2 stimulant, Intuniv®, Strattera®, and Kapvay®, unless contraindicated, that did not yield adequate results; 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 and 150mg strengths and 60 capsules per 30 days will apply for the 200mg strength.

7. For 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.

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. Adzenys XR-ODT®, Adzenys ER™, Cotempla XR-ODT®, Dyanavel® XR, and Evekeo ODT™ 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.

ADHD Medications Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum dose are not covered.
2. Prior authorization is required for all tiers for members older than 20 years of age and for members younger than 5 years of age. All prior authorization requests for members younger than 5 years of age must

be reviewed by an Oklahoma Health Care Authority (OHCA)-contracted psychiatrist.

3. For Daytrana® patches, Methylin® oral solution, and QuilliChew ER® chewable tablets, 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), ~~or~~ 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 (OSA) requires concurrent treatment for the OSA; and
7. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the prior authorization request.

Recommendation 4: Vote to Prior Authorize Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack) and Pylera® (Bismuth Subcitrate Potassium/Metronidazole/ Tetracycline Capsule)

VOTE ITEM AT SEPTEMBER MEETING

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

1. Moving rabeprazole tablets and brand name Prevacid® ODT from Tier-2 to Tier-1 based on net costs
2. The prior authorization of Helidac® Therapy (bismuth subsalicylate/ metronidazole/tetracycline) and Pylera® (bismuth subcitrate potassium/metronidazole/tetracycline capsule) and placement into the Special Prior Authorization (PA) Tier with the following additional criteria
3. Updating the current approval criteria for sucralfate suspension unit dose cups based on net costs
4. Removing all ranitidine products from the Tier chart and Special PA criteria based on the FDA-requested market withdrawal
5. Updating the trial requirements for Axid® (nizatidine solution) based on the market withdrawal of ranitidine products

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
dexlansoprazole (Dexilant® caps)	~~**lansoprazole (Prevacid® ODT)**~~	esomeprazole (Nexium® I.V.)	**bismuth subcitrate potassium/ metronidazole/ tetracycline (Pylera® capsule)**
esomeprazole (Nexium® caps)	pantoprazole (Protonix® I.V.)	esomeprazole strontium caps	**bismuth subsalicylate/ metronidazole/ tetracycline (Helidac® Therapy dose pack)**
esomeprazole (Nexium® packet) – **Brand Preferred**	~~**rabeprazole (Aciphex® tabs)**~~	omeprazole (Prilosec® susp, powder)	cimetidine (Tagamet® tabs)

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
lansoprazole (Prevacid® caps)		pantoprazole (Protonix® susp)	esomeprazole kit (ESOMEP-EZS™)
lansoprazole (Prevacid® ODT) – Brand Preferred		rabeprazole (Aciphex® sprinkles)	famotidine (Pepcid® susp)
omeprazole (Prilosec® caps)			glycopyrrolate (Glycate® tabs)
pantoprazole (Protonix® tabs)			nizatidine (Axid® caps & soln)
rabeprazole (Aciphex® tabs)			omeprazole/ amoxicillin/rifabutin (Talicia® caps)
sucralfate susp (Carafate®) – **Brand Preferred**			omeprazole/sodium bicarbonate (Zegerid® caps & pack)
			~~**ranitidine caps**~~
			sucralfate susp **(generic)** ~~**(unit dose cups)**~~

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

Axid® (Nizatidine Capsules) Approval Criteria:

1. A previous 14-day trial of ~~ranitidine and~~ famotidine or a patient-specific, clinically significant reason why ~~ranitidine and~~ famotidine ~~are~~ is not appropriate for the member must be provided.

Axid® (Nizatidine Solution) Approval Criteria:

1. A previous 14-day trial of ~~ranitidine syrup~~ famotidine suspension or a patient-specific, clinically significant reason why ~~ranitidine syrup~~ famotidine suspension is not appropriate for the member must be provided; and
2. Nizatidine solution (Axid®) will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral capsule formulation.

Generic Sucralfate Suspension ~~Unit Dose Cups~~ Approval Criteria:

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

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

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

Pepcid® (Famotidine Suspension) Approval Criteria:

1. ~~A previous 14-day trial of ranitidine syrup or a patient-specific, clinically significant reason why ranitidine syrup is not appropriate for the member must be provided; and~~
2. Famotidine suspension will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral tablet formulation.

~~**Ranitidine Capsules Approval Criteria:**~~

1. ~~A patient-specific, clinically significant reason why the member cannot use ranitidine tablets must be provided~~

Tagamet® (Cimetidine Tablets) Approval Criteria:

1. A previous 14-day trial of ~~ranitidine and~~ famotidine or a patient-specific, clinically significant reason why ~~ranitidine and~~ famotidine ~~are~~ is not appropriate for the member must be provided.

Recommendation 5: Vote to Prior Authorize Alkindi® Sprinkle (Hydrocortisone Oral Granule), Eysuvis® (Loteprednol 0.25% Ophthalmic Suspension), Gimoti™ (Metoclopramide Nasal Spray), Nextstellis® (Drospirenone/Estetrol Tablet), Ozobax® (Baclofen 5mg/5mL Oral Solution), Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel), RediTrex® (Methotrexate Injection), Reltone™ (Ursodiol Capsule), and Thyquidity™ (Levothyroxine Oral Solution)

VOTE ITEM AT SEPTEMBER MEETING

The College of Pharmacy recommends the prior authorization of Alkindi® Sprinkle (hydrocortisone oral granule), Eysuvis® (loteprednol 0.25% ophthalmic suspension), and Gimoti™ (metoclopramide nasal spray) with the following criteria:

Alkindi® Sprinkle (Hydrocortisone Oral Granule) Approval Criteria:

1. An FDA approved indication of replacement therapy in pediatric members with adrenocortical insufficiency; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use hydrocortisone tablets, even when tablets are crushed, must be provided.

Eysuvis® (Loteprednol 0.25% Ophthalmic Suspension) Approval Criteria:

1. An FDA approved indication for the short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease (DED); and
2. A documented trial of intermittent or regular artificial tear use within the past 3 months; and
3. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine 0.05% ophthalmic emulsion), which is available without a prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use Tier-1 ophthalmic corticosteroids including Lotemax® (loteprednol 0.5% suspension) must be provided; and
5. Member must not have any contraindications to Eysuvis®; and
6. A quantity limit of 8.3mL per 15 days will apply (Eysuvis® for the treatment of DED is not indicated for use beyond 15 days).

Gimoti™ (Metoclopramide Nasal Spray) Approval Criteria:

1. An FDA approved indication of acute or recurrent diabetic gastroparesis in adult members; and
2. A patient-specific, clinically significant reason why the member cannot use metoclopramide oral tablets and metoclopramide oral solution must be provided; and
3. For members 65 years of age or older, approvals will not be granted for initiation of metoclopramide therapy; and

4. For members 65 years of age or older requesting to switch from an alternative metoclopramide product to Gimoti™:
    a. Member must be taking a stable dose of metoclopramide 10mg 4 times daily for at least 10 days; and
    b. Duration of current metoclopramide treatment must be provided; and
5. A maximum approval duration of 8 weeks total from all sources will apply; and
6. A quantity limit of 9.8mL per 28 days will apply.

Additionally, the College of Pharmacy recommends the prior authorization of Ozobax® (baclofen 5mg/5mL oral solution), Phexxi® (lactic acid/citric acid/ potassium bitartrate vaginal gel), and Reltone™ (ursodiol capsule) with the following criteria:

Ozobax® (Baclofen 5mg/5mL Oral Solution) Approval Criteria:

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

Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use an over-the-counter (OTC) spermicide and all other forms of contraception (e.g., condoms, oral contraceptives) must be provided. Various OTC spermicides containing nonoxynol 9 are covered by SoonerCare without prior authorization.

Reltone™ (Ursodiol Capsule) Approval Criteria:

1. An FDA approved indication for the dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter or the prevention of gallstone formation in obese members experiencing rapid weight loss; and
2. For the indication of dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter:
    a. Prescriber must confirm member is not a candidate for elective cholecystectomy due to 1 or more of the following:
        i. Increased surgical risk due to systemic disease; or
        ii. Advanced age; or
        iii. Idiosyncratic reaction to general anesthesia; or
        iv. Member refuses surgery; and
    b. Prescriber must confirm the member does not have compelling reasons for cholecystectomy including unremitting acute

cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary-gastrointestinal fistula; and

3. For the indication of prevention of gallstone formation in obese members experiencing rapid weight loss:
   a. Member's baseline body mass index (BMI) and weight must be provided; and
   b. Member's current weight must be provided supporting rapid weight loss compared to baseline; and
4. For both FDA approved indications, a patient-specific, clinically significant reason why the member cannot use other generic formulations of ursodiol must be provided; and
5. Initial approvals for the indication of dissolution of gallstones will be for the duration of 6 months, after which time the prescriber must confirm (via ultrasound imaging) partial or complete dissolution of gallstone(s). Subsequent approvals will be for the duration of 12 months; and
6. Approvals for prevention of gallstone formation in obese members experiencing rapid weight loss will be for 6 months, after which time the member's current weight must be provided to justify continued rapid weight loss and need for preventative treatment; and
7. Treatment duration will be limited to a maximum of 24 months for all diagnoses.

Finally, the College of Pharmacy recommends the addition of Nextstellis® (drospirenone/estetrol tablet) to the current Slynd® (drospirenone tablet) approval criteria, the addition of RediTrex® (methotrexate injection) to the current Otrexup® (methotrexate injection) and Rasuvo® (methotrexate injection) approval criteria along with updates due to net costs and to be consistent with current treatment guidelines, and the addition of Thyquidity™ (levothyroxine oral solution) to the current Tirosint® (levothyroxine capsule) and Tirosint®-SOL (levothyroxine oral solution) approval criteria along with the recommended Drug Utilization Review (DUR) Board update to redefine the dosing for the required 8 week trial of levothyroxine (proposed changes shown in red):

Nextstellis® (Drospirenone/Estetrol Tablet) and Slynd® (Drospirenone Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all alternative formulations of hormonal contraceptives available without a prior authorization must be provided.

Rasuvo®, RediTrex®, and Otrexup® (Methotrexate Injection Solutions) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Adults with severe, active rheumatoid arthritis (RA); or
   b. Children with active polyarticular juvenile idiopathic arthritis (pJIA); or

c. Severe, recalcitrant, disabling psoriasis confirmed by biopsy or dermatologic consultation; and

~~2. Members with a diagnosis of RA or pJIA must have had an adequate trial of full dose nonsteroidal anti-inflammatory drugs (NSAIDs); and~~

3. A patient-specific, clinically significant reason why the oral tablets ~~or~~ and the generic injectable formulation cannot be used must be provided; and
4. Authorization of Otrexup® will also require a patient-specific, clinically significant reason why the member cannot use Rasuvo® or RediTrex®.

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

1. An FDA approved diagnosis of 1 of the following:
   a. Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism; or
   b. Pituitary Thyrotropin (thyroid-stimulating hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer; and
2. A patient-specific, clinically significant reason why the member cannot use all other formulations of levothyroxine must be provided. For the oral solutions, a reason why the member cannot use the levothyroxine tablet, even when the tablets are crushed, must be provided; and
3. Prescriber must verify member has been compliant with levothyroxine tablets at ~~maximum dose~~ a greatly increased dose for at least 8 weeks; and
4. Prescriber must verify that member has not been able to achieve normal thyroid lab levels despite ~~maximum dosing~~ a greatly increased dose and compliance with levothyroxine tablets.

Recommendation 6: Annual Review of Koselugo™ (Selumetinib), Pemazyre® (Pemigatinib), and Qinlock® (Ripretinib) and 30-Day Notice to Prior Authorize Danyelza® (Naxitamab-gqgk) and Truseltiq™ (Infigratinib)

NO ACTION REQUIRED.

Recommendation 7: Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Qdolo™ (Tramadol 5mg/mL Oral Solution)

NO ACTION REQUIRED.

Recommendation 8: Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Impeklo® (Clobetasol Propionate 0.05% Lotion)

NO ACTION REQUIRED.

Recommendation 9: Annual Review of Ophthalmic Anti-Inflammatory Products

NO ACTION REQUIRED.

Recommendation 10: 30-Day Notice to Prior Authorize Nulibry™ (Fosdenopterin)

NO ACTION REQUIRED.

Recommendation 11: 30-Day Notice to Prior Authorize Feraheme® (Ferumoxytol), Injectafer® (Ferric Carboxymaltose), and Monoferric® (Ferric Derisomaltose)

NO ACTION REQUIRED.

Recommendation 12: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

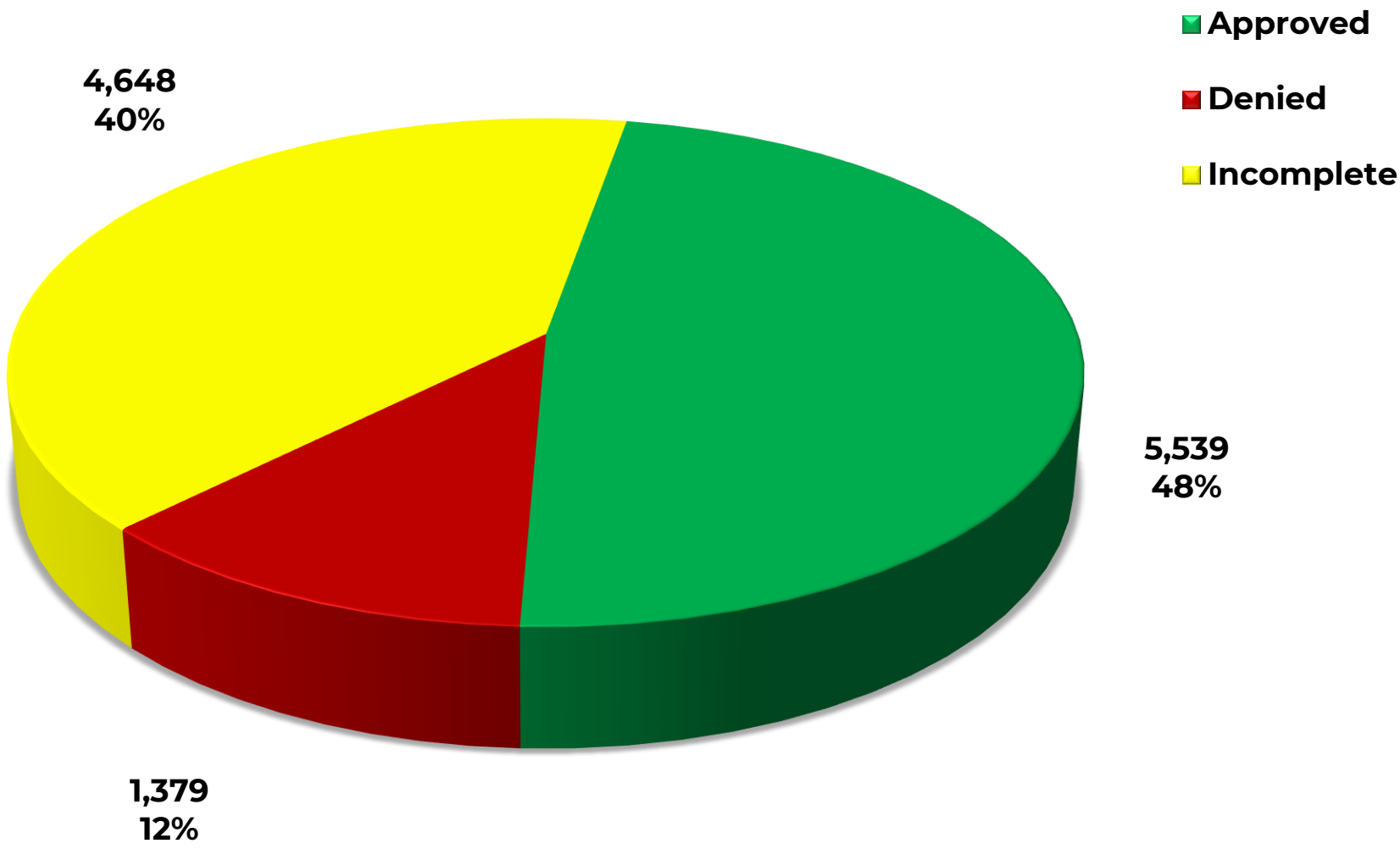
Recommendation 13: Future Business

No DUR Board meeting is scheduled for August 2021. The next scheduled DUR Board meeting will be held on September 8, 2021.

NO ACTION REQUIRED.

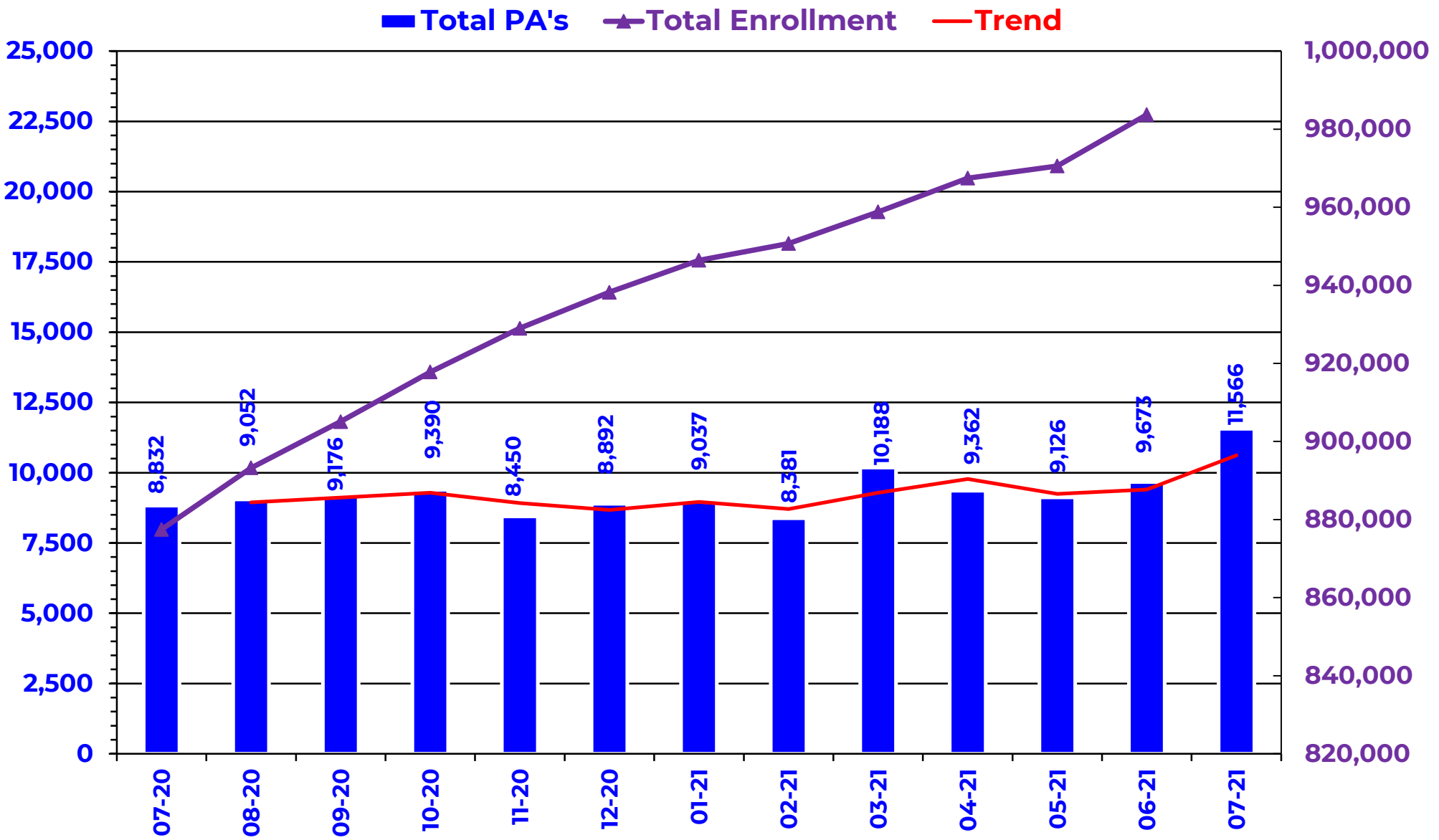
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: JULY 2021



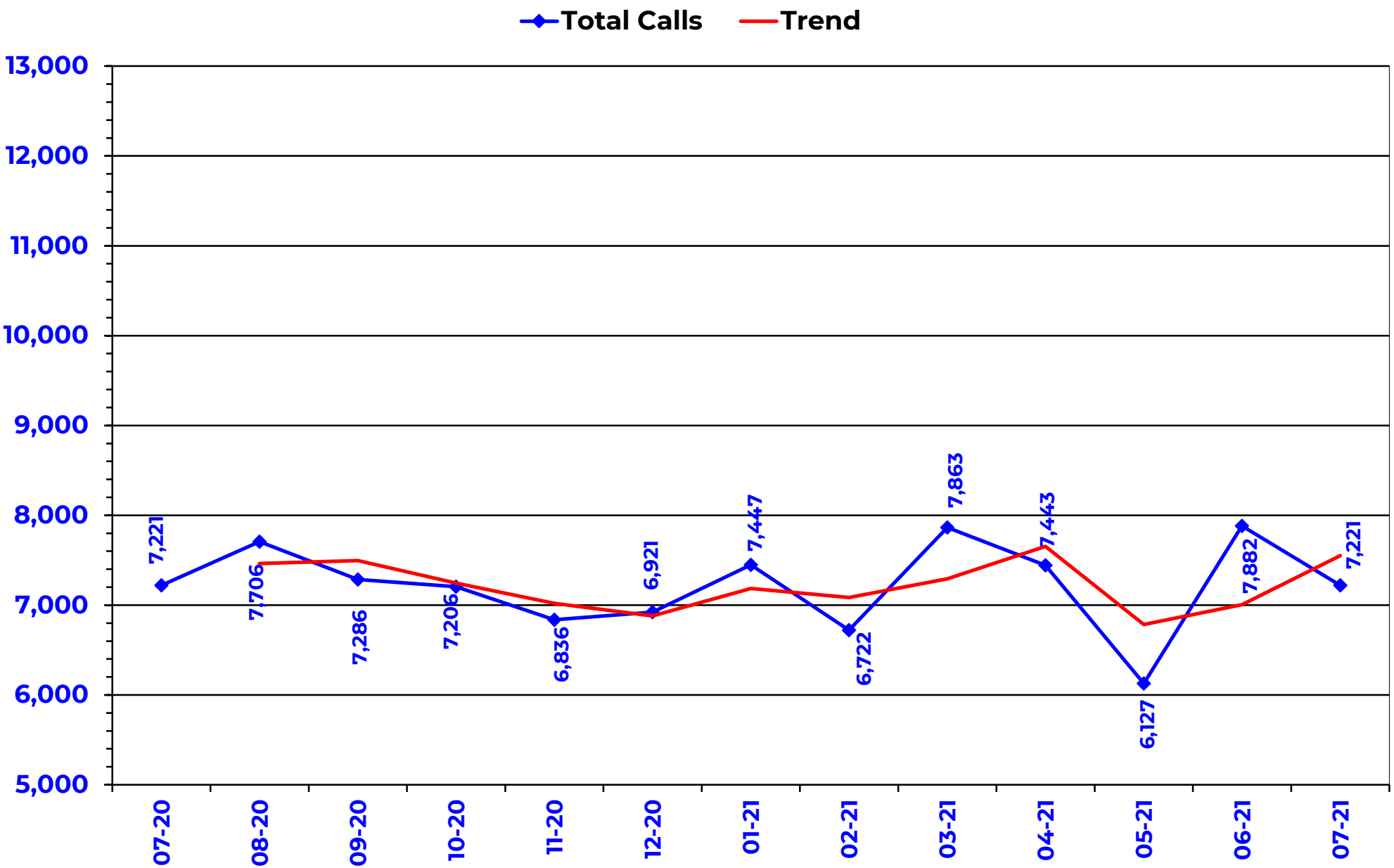
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: JULY 2020 – JULY 2021



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
JULY 2020 – JULY 2021



Prior Authorization Activity
7/1/2021 Through 7/31/2021

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	78	12	5	61	358
Analgesic, NonNarcotic	20	0	5	15	0
Analgesic, Narcotic	270	105	30	135	153
Angiotensin Receptor Antagonist	11	2	0	9	359
Antiasthma	64	19	16	29	291
Antibiotic	43	20	2	21	160
Anticonvulsant	206	98	14	94	301
Antidepressant	395	127	48	220	338
Antidiabetic	791	310	104	377	355
Antigout	18	7	3	8	228
Antihistamine	43	14	8	21	300
Antimalarial Agent	12	7	1	4	73
Antimigraine	285	50	105	130	239
Antineoplastic	174	115	12	47	187
Antiparasitic	16	5	1	10	16
Antiulcers	38	3	11	24	51
Antiviral	10	1	1	8	27
Anxiolytic	26	2	3	21	356
Atypical Antipsychotics	570	339	38	193	354
Benign Prostatic Hypertrophy	11	1	4	6	313
Biologics	261	140	25	96	284
Bladder Control	56	6	18	32	358
Blood Thinners	469	289	17	163	335
Botox	42	28	9	5	309
Buprenorphine Medications	97	30	12	55	87
Calcium Channel Blockers	24	3	3	18	247
Cardiovascular	83	41	6	36	313
Cephalosporins	11	5	0	6	55
Chronic Obstructive Pulmonary Disease	222	50	44	128	341
Contraceptive	33	15	5	13	278
Dermatological	326	110	74	142	160
Diabetic Supplies	1,003	473	117	413	259
Endocrine & Metabolic Drugs	71	33	6	32	164
Erythropoietin Stimulating Agents	21	11	0	10	96
Fibromyalgia	2	0	0	2	0
Fish Oils	21	4	8	9	359
Gastrointestinal Agents	125	35	17	73	177
Genitourinary Agents	15	1	4	10	360
Glaucoma	10	3	0	7	257
Growth Hormones	95	69	7	19	145
Hematopoietic Agents	24	13	2	9	246
Hepatitis C	177	94	25	58	10
HFA Rescue Inhalers	10	0	1	9	0
Insomnia	58	7	17	34	208
Insulin	206	66	19	121	342

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Miscellaneous Antibiotics	23	8	4	11	14
Multiple Sclerosis	54	26	5	23	247
Muscle Relaxant	37	4	10	23	158
Nasal Allergy	74	14	17	43	163
Neurological Agents	134	42	37	55	245
Neuromuscular Agents	11	8	1	2	276
NSAIDs	30	2	5	23	222
Ocular Allergy	27	1	9	17	85
Ophthalmic Anti-infectives	24	5	2	17	16
Ophthalmic Corticosteroid	13	4	3	6	237
Osteoporosis	28	11	5	12	344
Other*	304	81	52	171	272
Otic Antibiotic	32	5	2	25	7
Pediculicide	38	10	0	28	11
Respiratory Agents	53	28	1	24	222
Statins	24	9	8	7	236
Stimulant	1,032	575	69	388	349
Synagis	138	64	37	37	26
Testosterone	69	21	19	29	359
Thyroid	10	5	2	3	357
Topical Antifungal	28	5	4	19	25
Topical Corticosteroids	73	0	49	24	0
Vitamin	82	25	33	24	157
Pharmacotherapy	99	93	0	6	291
Emergency PAs	0	0	0	0	
Total	**9,166**	**3,846**	**1,272**	**4,048**	

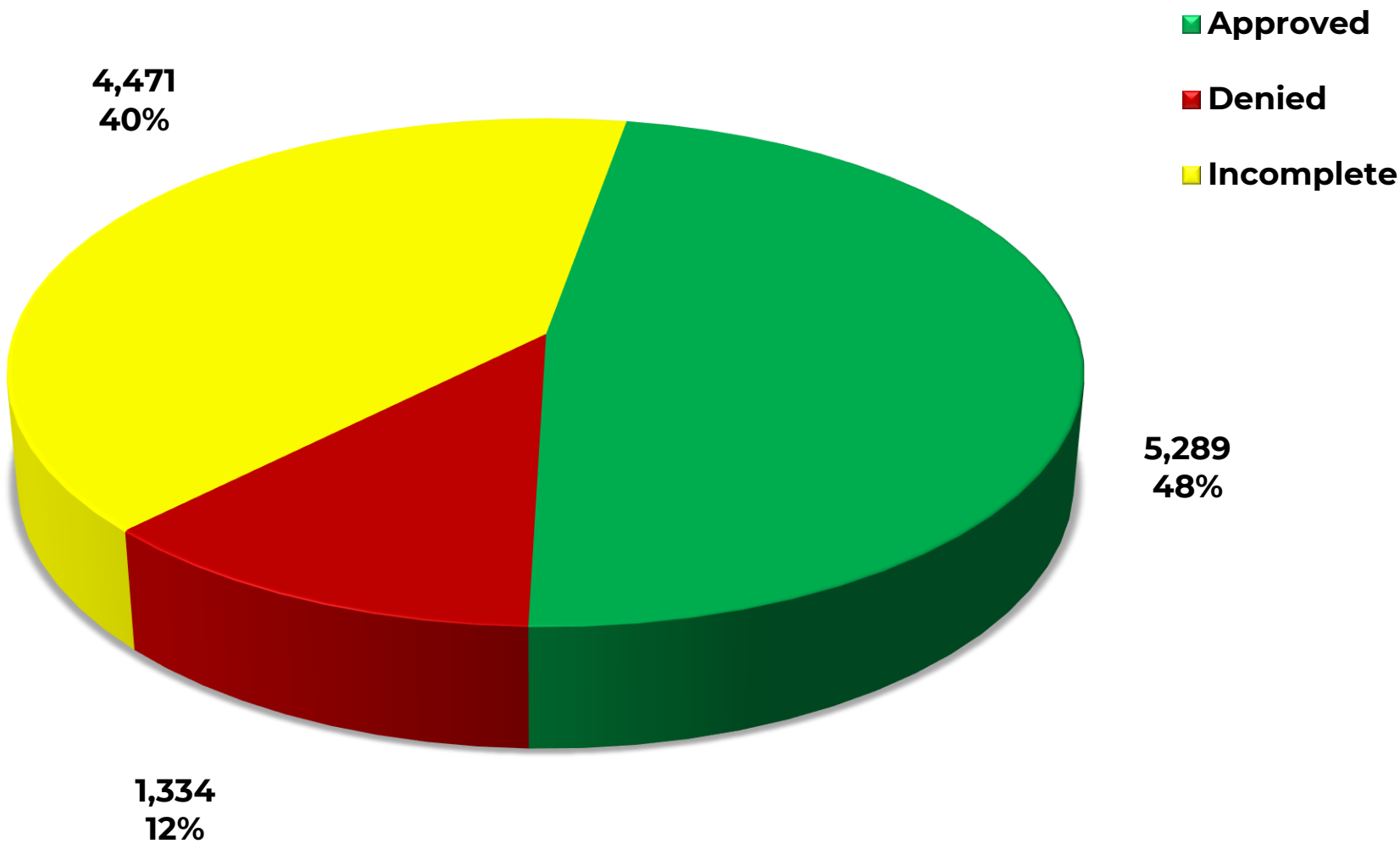
* Includes any therapeutic category with less than 10 prior authorizations for the month.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	27	17	0	10	302
Compound	12	9	0	3	19
Cumulative Early Refill	1	1	0	0	180
Diabetic Supplies	21	18	0	3	207
Dosage Change	341	313	1	27	12
High Dose	8	6	1	1	299
IHS-Brand	1	1	0	0	360
Ingredient Duplication	1	0	0	1	0
Lost/Broken Rx	107	97	1	9	14
MAT Override	270	196	4	70	68
NDC vs. Age	574	398	49	127	296
NDC vs. Sex	14	8	1	5	126
Nursing Home Issue	119	89	0	30	18
Opioid MME Limit	140	41	11	88	132
Opioid Quantity	40	26	3	11	168
Other	83	62	1	20	12
Quantity vs. Days Supply	579	365	33	181	241
STBS/STBSM	20	15	0	5	74
Step Therapy Exception	3	2	1	0	221
Stolen	8	7	1	0	11
Third Brand Request	31	22	0	9	10
Overrides Total	**2,400**	**1,693**	**107**	**600**	
Total Regular PAs + Overrides	**11,566**	**5,539**	**1,379**	**4,648**	

Denial Reasons	
Unable to verify required trials.	3,881
Does not meet established criteria.	1,402
Lack required information to process request.	736
Other PA Activity	
Duplicate Requests	1,053
Letters	22,588
No Process	6
Changes to existing PAs	774
Helpdesk Initiated Prior Authorizations	806
PAs Missing Information	5

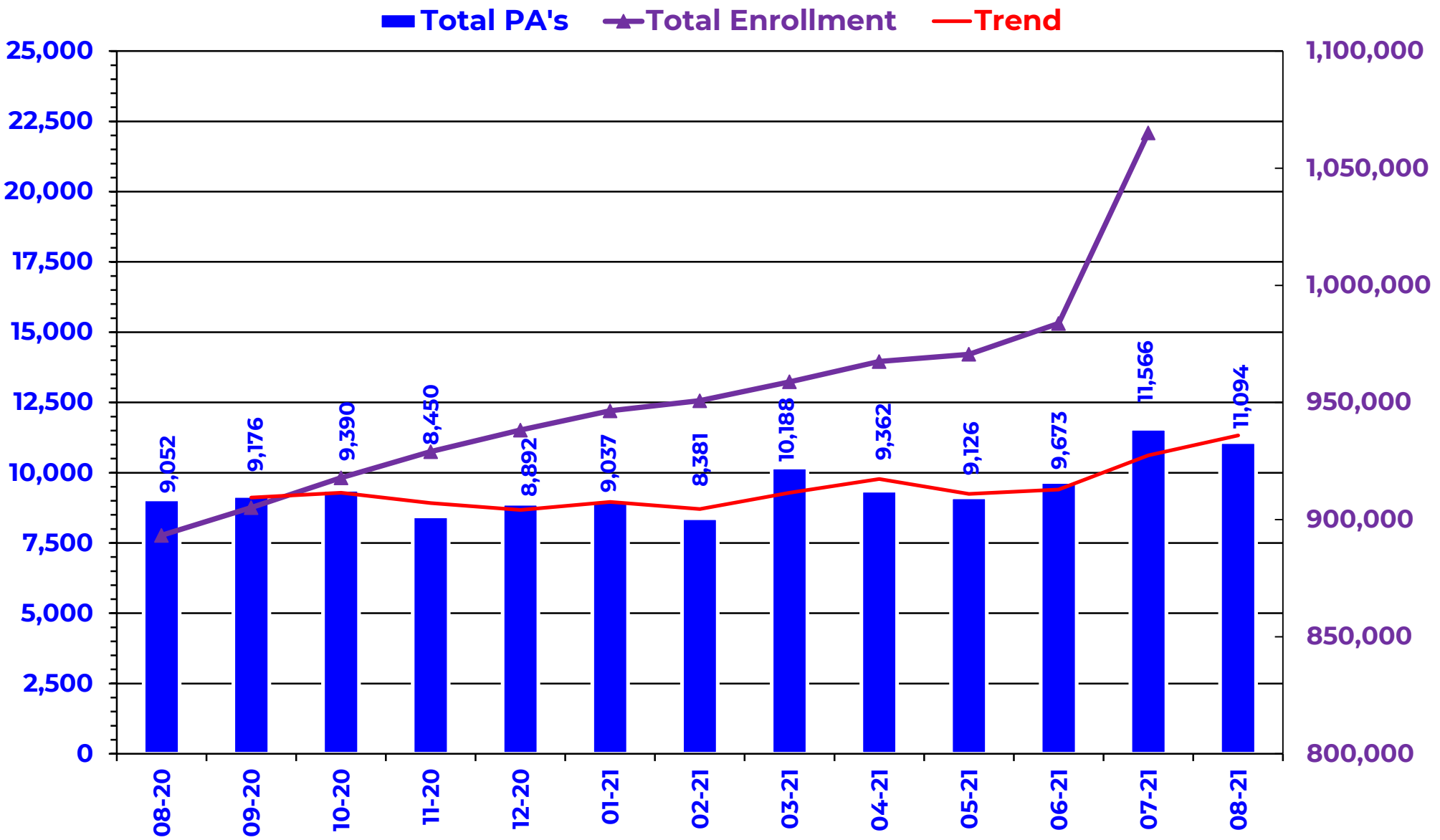
* Includes any therapeutic category with less than 10 prior authorizations for the month.

PRIOR AUTHORIZATION ACTIVITY REPORT: AUGUST 2021*



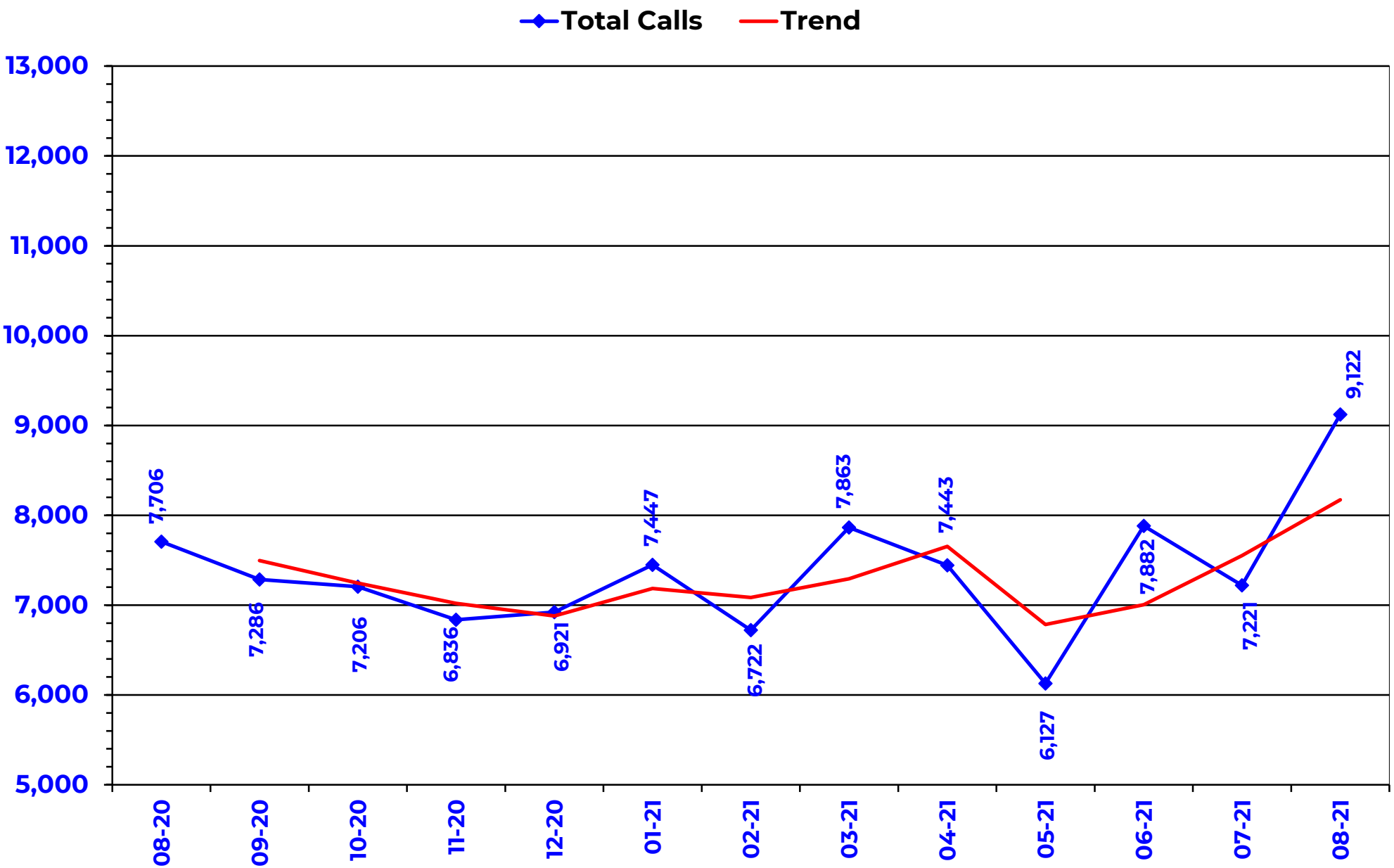
PA totals include approved/denied/incomplete/overrides
**Current as of August 30, 2021*

PRIOR AUTHORIZATION REPORT: AUGUST 2020 – AUGUST 2021*



PA totals include approved/denied/incomplete/overrides
**Current as of August 30, 2021*

CALL VOLUME MONTHLY REPORT: AUGUST 2020 – AUGUST 2021*



*Current as of August 30, 2021

Prior Authorization Activity

8/1/2021 Through 8/30/2021

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	81	25	9	47	347
Analgesic, Narcotic	243	88	25	130	158
Angiotensin Receptor Antagonist	10	3	1	6	358
Anti-inflammatory	11	2	3	6	357
Antiasthma	54	15	14	25	282
Antibiotic	48	22	6	20	243
Anticonvulsant	190	90	12	88	295
Antidepressant	284	93	36	155	343
Antidiabetic	828	338	110	380	357
Antihemophilic Factor	12	7	1	4	271
Antihistamine	29	11	5	13	283
Antimigraine	305	51	96	158	256
Antineoplastic	143	101	7	35	175
Antiulcers	46	7	5	34	91
Antiviral	12	3	2	7	57
Anxiolytic	28	2	0	26	131
Atypical Antipsychotics	501	304	34	163	347
Biologics	225	124	26	75	296
Bladder Control	65	13	20	32	343
Blood Thinners	549	313	22	214	333
Botox	46	31	9	6	281
Buprenorphine Medications	103	38	7	58	76
Cardiovascular	66	25	6	35	334
Chronic Obstructive Pulmonary Disease	284	56	66	162	358
Constipation/Diarrhea Medications	175	41	52	82	263
Contraceptive	21	9	4	8	356
Corticosteroid	14	3	2	9	146
Dermatological	302	82	91	129	187
Diabetic Supplies	1,005	463	115	427	256
Endocrine & Metabolic Drugs	90	48	13	29	192
Erythropoietin Stimulating Agents	30	18	2	10	103
Fibric Acid Derivatives	11	3	2	6	360
Fibromyalgia	3	0	0	3	0
Fish Oils	14	3	4	7	358
Gastrointestinal Agents	116	31	18	67	229
Genitourinary Agents	11	1	3	7	115
Glaucoma	12	2	0	10	208
Growth Hormones	92	64	9	19	151
Hepatitis C	171	91	35	45	9
HFA Rescue Inhalers	10	3	1	6	122
Insomnia	88	11	13	64	211
Insulin	232	76	21	135	342
Miscellaneous Antibiotics	20	5	3	12	22
Multiple Sclerosis	85	33	11	41	223

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Muscle Relaxant	43	4	9	30	122
Nasal Allergy	79	20	18	41	127
Neurological Agents	106	32	30	44	256
NSAIDs	35	1	4	30	358
Ocular Allergy	14	0	5	9	0
Ophthalmic Anti-infectives	19	6	0	13	24
Osteoporosis	39	12	6	21	332
Other*	370	105	50	215	274
Otic Antibiotic	17	1	6	10	11
Respiratory Agents	31	14	0	17	207
Smoking Cessation	38	10	19	9	89
Statins	16	3	3	10	263
Stimulant	1,211	778	69	364	348
Synagis	76	42	13	21	21
Testosterone	92	28	22	42	325
Thyroid	13	3	3	7	267
Topical Antifungal	31	1	8	22	117
Topical Corticosteroids	66	0	44	22	0
Vitamin	64	18	23	23	155
Pharmacotherapy	47	43	0	4	250
Emergency PAs	0	0	0	0	
Total	**9,072**	**3,870**	**1,253**	**3,949**	

* 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	26	16	0	10	250
Compound	19	15	0	4	61
Diabetic Supplies	12	11	0	1	194
Dosage Change	360	328	1	31	14
High Dose	8	5	0	3	291
Ingredient Duplication	4	2	0	2	20
Lost/Broken Rx	96	85	1	10	16
MAT Override	265	193	6	66	68
NDC vs. Age	293	177	27	89	254
NDC vs. Sex	10	7	0	3	74
Nursing Home Issue	42	40	0	2	17
Opioid MME Limit	167	47	16	104	125
Opioid Quantity	48	34	3	11	156
Other*	54	45	0	9	12
Prescriber Temp Unlock	1	0	0	1	0
Quantity vs. Days Supply	556	375	24	157	267
STBS/STBSM	18	11	1	6	37
Step Therapy Exception	5	2	0	3	82
Stolen	15	9	0	6	17
Temporary Unlock	1	1	0	0	7
Third Brand Request	22	16	2	4	14
Overrides Total	**2,022**	**1,419**	**81**	**522**	
Total Regular PAs + Overrides	**11,094**	**5,289**	**1,334**	**4,471**	

Denial Reasons	
Unable to verify required trials.	3,656
Does not meet established criteria.	1,372
Lack required information to process request.	776
Other PA Activity	
Duplicate Requests	1,081
Letters	20,610
No Process	3
Changes to existing PAs	722
Helpdesk Initiated Prior Authorizations	869
PAs Missing Information	6

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

Pediatric Antipsychotic Monitoring Program Update

Oklahoma Health Care Authority
September 2021

Background[1]

The Oklahoma Health Care Authority (OHCA) is responsible for establishing and maintaining a program to monitor and manage appropriate utilization of antipsychotic medications for all children, including children in the foster care system, as part of a requirement by the Centers for Medicare and Medicaid Services (CMS). To accomplish these purposes, the College of Pharmacy developed the Pediatric Antipsychotic Monitoring Program (PAMP) in October 2019. The PAMP is updated twice per year and includes providers for pediatric members receiving antipsychotic medications. The specific provider focus alternates on a semi-annual basis between all children and those children in the foster care system. Providers meeting criteria for all pediatric members receive mailings and educational offerings each December. Providers meeting criteria for pediatric members in the foster care system receive mailings and educational offerings each June. The PAMP evaluates prescribing patterns and medical claims across 4 topics: medication adherence, target diagnosis, metabolic monitoring, and polypharmacy as described below:

- Adherence: Poor medication adherence is defined as members whose proportion of days covered (PDC), or adherence, was <80%. Adherence is calculated from pharmacy claims history for antipsychotic medications.
- Diagnosis: Inappropriate diagnosis is defined as members whose recent 12-month medical claims history does not include a diagnosis with a strong indication for prescribing an antipsychotic medication. Diagnoses with a strong indication for prescribing an antipsychotic include:
  - Schizophrenia
  - Bipolar disorder
  - Delusional disorders
  - Other nonorganic psychoses
  - Autism spectrum disorder
  - Mood disorder*
  - Obsessive-compulsive disorder
  - Severe depression with or without psychotic features

  **Mood disorder was added based on input from Oklahoma SoonerCare providers and psychiatrists.*
- Metabolic Monitoring: Poor metabolic monitoring is defined as members whose recent 12-month medical claims history does not include glucose testing. Metabolic monitoring also evaluates the recent

12-month medical claims history for lipid testing for members with a diagnosis of hyperlipidemia.

- Polypharmacy: Polypharmacy is defined as members whose pharmacy claims history indicated concurrent use of 2 or more antipsychotic medications for >90 days.

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

Providers received an educational mailing and member list if they were the last prescriber of record for an antipsychotic medication and were in the most concerning cohort of prescribers. Following receipt of the PAMP mailings, providers were offered an in-person or virtual visit by an academic detailing pharmacist and/or a consultation with an OHCA-contracted child psychiatrist. Further, providers were encouraged to participate in the pediatric psychiatry Project ECHO (Extension for Community Health Care Outcomes) for medical education and care collaboration. Providers also received the comprehensive, multidisciplinary Oklahoma Pediatric Psychotropic Medication Resource Guide. Additional services through OHCA Care Management and Behavioral Health Care Management were also encouraged.

PAMP Trends[2]

The following tables show the 2020 baseline values as determined in May 2020 and the resultant changes observed through May 2021. Provider numbers have been assigned to preserve the privacy of providers. In all tables, a lower number indicates improvement. Improvements were observed in all topics, with the most notable improvement seen in the area of metabolic monitoring. All of the providers meeting metabolic monitoring criteria in 2020 no longer met criteria in 2021. This is particularly compelling as the most recent report by the Office of the Inspector General cited inappropriate metabolic monitoring as the most prevalent cause for concern for pediatric Medicaid members receiving antipsychotic medications.

With the exception of polypharmacy, at least 2 of the previous providers from each category were able to improve to the degree that they no longer met criteria for the 2021 mailing cohort. The initial polypharmacy cohort criteria required providers to have 2 or more members in foster care with polypharmacy. Only 2 providers met the 2020 criteria. During 2021 there were no providers with 2 or more members in foster care with polypharmacy, and the threshold was lowered to 1 member in foster care with polypharmacy to reflect the improved care. The initial 2 providers met the lowered threshold,

but had improved their care for members in foster care by 50% from the previous year.

Medication adherence appeared to worsen from 121 total members to 161 members with PDC <80%. However, the PAMP educational materials emphasize the appropriate use of antipsychotic medications for appropriate diagnoses. Lowering the dose and/or frequency (i.e., tapering) of these medications with eventual discontinuation is suggested for members who do not meet diagnostic criteria. With this in mind, some intentional medication tapering may be represented as poor adherence in SoonerCare pharmacy claims history.

The following tables (Tables 1-4) show the total number of pediatric members per category for each cohort provider. Cohort providers were identified based on paid claims for pediatric members in foster care. Provider letters included member lists for those in foster care and for those not in foster care. For reporting purposes, all pediatric members with paid claims from cohort providers have been included.

The following table (Table 1) shows the number of pediatric members having poor adherence (PDC <80%) to antipsychotic medication(s) for each cohort provider.

Table 1: PAMP Trends – Adherence

Provider #	2020 Adherence	2021 Adherence
9	27	*
19	*	63
23	15	21
27	*	10
32	42	39
40	20	*
41	17	*
47	*	28
Total◊	**121**	**161**

*Did not meet cohort criteria
◊ Lower number indicates improvement

Table 2 shows the number of pediatric members without a diagnosis supporting the use of antipsychotic medications for each cohort provider.

Table 2: PAMP Trends – Diagnosis

Provider #	2020 Diagnosis	2021 Diagnosis
6	*	31
16	20	*
19	42	51
28	21	*
32	95	76
35	*	11
38	*	18
40	15	*
Total◊	**193**	**187**

*Did not meet cohort criteria
◊ Lower number indicates improvement

The following table (Table 3) shows the number of pediatric members receiving antipsychotic medication(s) without metabolic monitoring for each cohort provider.

Table 3: PAMP Trends – Metabolic Monitoring

Provider #	2020 Metabolic Monitoring	2021 Metabolic Monitoring
1	*	1
4	*	3
9	1	*
19	3	*
23	2	*
29	*	1
30	*	1
32	4	*
41	6	*
42	*	1
Total◊	**16**	**7**

*Did not meet cohort criteria
◊ Lower number indicates improvement

Table 4 shows the number of members receiving 2 or more antipsychotic medications for >90 days for each cohort provider.

Table 4: PAMP Trends – Polypharmacy‡

Provider #	2020 Polypharmacy	2021 Polypharmacy
11	3	5
23	*	6
19	*	5
33	14	14
41	*	5
Total◊	**17**	**35**

*Did not meet cohort criteria
‡Criteria threshold lowered from 2020 to 2021
◊ Lower number indicates improvement

Conclusions

The first year of foster care-focused PAMP trends indicate overall improvements in the areas of diagnosis, metabolic monitoring, and polypharmacy. Improvements in the area of adherence are more difficult to determine, owing to the likely co-occurrence of true poor adherence and intentional tapering. The greatest improvements were seen in the areas of metabolic monitoring and polypharmacy. In the case of metabolic monitoring, none of the original cohort met the inclusion criteria at the end of the first year. Polypharmacy improvements also resulted in all providers no longer meeting initial cohort criteria at the end of the first year. Overall results indicate the foster care-focused PAMP targeted mailing and educational offerings are likely leading to improvements in antipsychotic medication management, resulting in a lower risk of overprescribing and increased rates of recommended metabolic monitoring. The College of Pharmacy will continue to work with OHCA to identify providers who may benefit from PAMP activities with the goal of promoting evidence-based use of antipsychotic medications for pediatric members. Future results of the PAMP activities will be reviewed with the Drug Utilization Review (DUR) Board as they become available.

[1] 115th U.S. Congress (2017-2018). H.R.6 – SUPPORT for Patients and Communities Act. Available online at: https://www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf. Issued 10/24/2018. Last accessed 08/09/2021.
[2] Department of Health and Human Services: Office of the Inspector General. Second-Generation Antipsychotic Drug Use Among Medicaid-Enrolled Children: Quality-of-Care Concerns (Report OEI-07-12-00320). Available online at: http://oig.hhs.gov/oei/reports/oei-07-12-00320.pdf. Issued 03/2015. Last accessed 08/09/2021.

Appendix C

Fiscal Year 2021 Annual Review of the Medication Therapy Management (MTM) Program

Oklahoma Health Care Authority
September 2021

Background[1]

The Oklahoma Health Care Authority (OHCA) is responsible for controlling costs of state-purchased health care while continuing to protect and improve the health of Oklahoma SoonerCare members. OHCA collaborated with the University of Oklahoma College of Pharmacy: Pharmacy Management Consultants (PMC) to develop and implement an MTM program for SoonerCare members. MTM is defined by the Centers for Disease Control and Prevention (CDC) as a "distinct service or group of services provided by health care providers, including pharmacists, to ensure the best therapeutic outcomes for patients." The SoonerCare MTM program started in December 2019, and since that time, over 1,500 SoonerCare members have completed an MTM review with a PMC clinical pharmacist.

The MTM program uses a data-driven approach to perform medication reconciliation, evaluate any opportunities to further optimize medications, address barriers to access, and improve quality measures. PMC clinical pharmacists perform telephonic MTM services for SoonerCare members across the state of Oklahoma. As part of the MTM review, clinical pharmacists provide counseling to members regarding any medication issues identified and address any medication-related questions or concerns.

The goals of the SoonerCare MTM program include:

- Increased member understanding of and adherence to medication therapy
- Optimized therapeutic outcomes
- Decreased medication-related adverse effects
- Reduced overall health care spending

Clinical pharmacists assist members with:

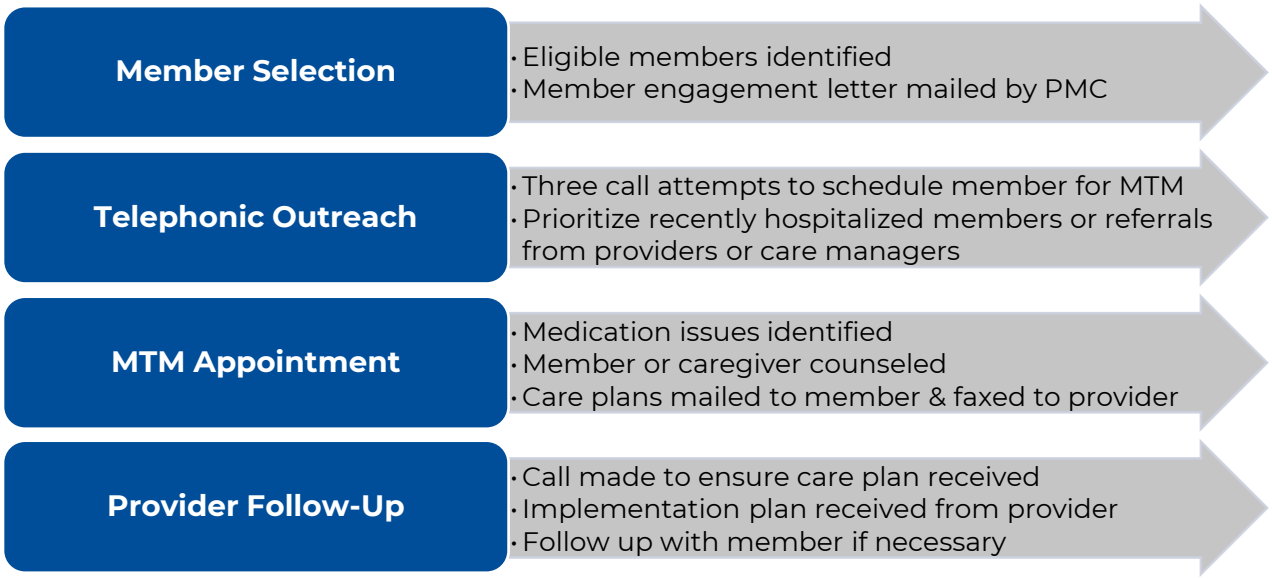
- Maximizing their prescription limit
- Navigating preferred formulary options
- Identifying medication-related problems
- Counseling on disease state management
- Connecting them with OHCA's Care Coordination program
- Answering any questions the members may have about their medications

Workflow[2]

The following figure (Figure 1) describes the workflow for MTM services. Once the members are selected, telephonic outreach begins to members to schedule a review with a clinical pharmacist at PMC. During the review, the clinical pharmacist identifies any drug-related problems (DRPs) and counsels the member or caregiver appropriately.

After the review is complete, care plans are sent to both the member and provider. The member report includes an updated medication list and a summary of the discussion that occurred during the MTM review. The provider care plan contains an updated medication list and a report of the DRPs identified. Each DRP contains both an evidence-based assessment and recommendation for the provider.

Figure 1: MTM Workflow



The DRPs identified are organized into categories that are based on the Pharmacy Quality Alliance (PQA) Medication Therapy Problem Categories Framework, which are listed below:

- Adherence refers to whether the patient is taking the medication as prescribed and addressing any barriers that may be preventing them from taking their medication correctly.
- Effectiveness refers to a medication being ineffective, dosage too low, or additional patient monitoring needed to establish effectiveness (e.g., blood glucose monitoring).
- Indication refers to unnecessary medication therapy or patient need for additional medication therapy.

- Safety refers to adverse drug reactions, dosage too high, or additional patient monitoring needed to establish safety (e.g., serum potassium monitoring for diuretics).

The following 2 categories were added to the existing PQA framework to address current public health concerns and include:

- Preventative care refers to vaccinations, cancer screenings, nutrition counseling, diabetes screening, and cholesterol screenings, among other recommended preventative care measures.
- SoonerCare resources refers to prior authorization assistance, information regarding covered medications, referral to the Care Coordination program, referral to a specialist, or referral to member services to resolve eligibility issues and/or primary care provider selection.

To assess the percentage of care plan implementation by providers, each DRP report asks providers to indicate their planned implementation of the suggested changes. After a reasonable time, providers are contacted to ensure the reports have been received by the provider and reviewed. Upon verification of receipt and review, clinical pharmacists at PMC review the planned provider changes and communicate new information to members as necessary. Changes in prescription drug regimens are verified in each member's pharmacy claims history.

Results

In fiscal year (FY) 2021, PMC clinical pharmacists completed 936 MTM reviews for SoonerCare members. Figure 2 represents program engagement. On average, 6.5 DRPs were identified per member completing an MTM review and 1,056 unique providers received MTM reports. Providers stated their intention to implement 75% of the changes recommended by PMC clinical pharmacists.

Figure 2: FY 2021 Program Engagement	
Total number of outreach calls to members	25,551
Unique members receiving outreach calls	9,812
Percentage of members answering outreach calls	38%
Total number of members scheduling and/or rescheduling MTM services	1,770
Total number of members completing MTM services	936
Total number of unique DRPs identified	6,046
Average number of unique DRPs per member [mean (SD)]	6.5 (3.6)
Total number of unique providers receiving MTM reports	1,056
Percentage of DRPs implemented by providers*	75%

*Implementation of 56% of all recommendations sent through 06/30/2021 are currently being assessed through validation of claims or follow up.
DRP = drug-related problem; FY 2021 = fiscal year 2021 (07/01/2020 to 06/30/2021); MTM = medication therapy management; SD = standard deviation

Figure 3 shows the top 5 disease areas and the total number of DRPs identified for each disease area listed. Figure 4 includes the number of DRPs identified for each of the 6 medication therapy problem categories. As previously mentioned, 936 SoonerCare members completed an MTM review during FY 2021. From those 936 reviews, 6,047 unique DRPs were identified with an average of 6.5 unique DRPs per member. DRPs are sent to the member, their primary care provider, and the member's specialists, if applicable; therefore, 1 DRP may be sent multiple times. The total number of DRPs sent to both the members and providers in FY 2021 was 11,824. The numbers below are categorized based on the total number of DRPs sent.

Figure 3: Recommendations Sent to Members & Providers – Disease Areas

Disease Area	Total Number of DRPs
Preventative Health	2,020
Diabetes	1,566
Cardiovascular Disease	1,236
Behavioral Health	1,219
Asthma/COPD	1,022

COPD = chronic obstructive pulmonary disease; DRPs = drug-related problems

Figure 4: Recommendations Sent to Members & Providers – Category

Medication Therapy Problem Category	Total Number of DRPs
Preventative Care	3,911
Adherence	2,706
Indication	2,339
Safety	1,028
SoonerCare Resources	708
Effectiveness	285

DRPs = drug-related problems

Selection criteria for the MTM program includes SoonerCare members 18 years of age or older who are currently receiving ≥4 chronic medications or have had ≥1 inpatient or emergency department admission(s) in the preceding 12 months. Of the 936 reviews completed during FY 2021, 517 of those members were included in the following results (Figures 5-8). The 517 members selected for analysis had to have at least 3 months follow up data after the MTM review and be eligible for SoonerCare at least 6 months before and 3 months after the MTM review. Member demographic information is shown in Figure 5. The average age of SoonerCare members receiving MTM services in FY 2021 was 46 years.

Figure 5: SoonerCare MTM Program Member Demographics	
Characteristic	**Percent**
Gender	
Female	76.2%
Male	23.8%
Race	
American Indian or Alaskan Native	5.6%
Asian	0.8%
Black or African American	17.8%
White	67.3%
More than one race	5.8%
Unspecified	2.7%
Age	
18-44	44.9%
45-64	52.2%
65+	2.9%
Charlson Comorbidity Index (CCI)	
Average score [mean (SD)]	2.91 (2.47)

MTM = medication therapy management; SD = standard deviation

According to PQA, the preferred method to measure medication adherence is through the proportion of days covered (PDC). A member is considered adherent if the PDC is ≥80%. The results in Figure 6 and Figure 7 show the change in PDC for the identified medication classes before and after MTM reviews. The analysis is based on paid SoonerCare pharmacy claims and does not include whether a member is paying cash for inexpensive medications, receiving office samples, or receiving their medications through a non-SoonerCare source (e.g., Indian Health Services, private insurance, free clinics).

Figure 6: Medication Adherence – Chronic Disease			
Medication Class	**Antihypertensives (n=172)**	**Statins (n=82)**	**Anti-Diabetics (n=58)**
Adherent (PDC ≥80%)			
Pre MTM	76	26	26
Post MTM	90	33	30
Change in number of members with PDC ≥ 80% (percent change)	14 (18.4%)	7 (26.9%)	4 (15.4%)
Mean PDC			
Pre MTM PDC (SD)	65.5 (31.8)	59.3 (28.8)	63.7 (33.1)
Post MTM PDC (SD)	70.9 (30.6)	63.2 (30.0)	73.6 (26.5)
Percent change in mean PDC	8.2%	6.6%	15.5%

*Includes members with ≥90 days in the post-observation period and who had ≥1 claim for the medication in the pre and post MTM periods.
MTM = medication therapy management; PDC = proportion of days covered; SD = standard deviation

Figure 7: Medication Adherence – Behavioral Health		
Medication Class	**Antidepressants (n=162)**	**Antipsychotics (n=55)**
Adherent (PDC ≥80%)		
Pre MTM	65	21
Post MTM	72	20
Change in number of members with PDC ≥ 80% (percent change)	7 (10.8%)	-1 (-4.8%)
Mean PDC		
Pre MTM PDC (SD)	62.7 (31.6)	61.9 (31.1)
Post MTM PDC (SD)	67.0 (30.5)	63.3 (30.2)
Percent change in mean PDC	6.9%	2.3%

*Includes members with ≥90 days in the post-observation period and who had ≥1 claim for the medication in the pre and post MTM periods.
MTM = medication therapy management; PDC = proportion of days covered; SD = standard deviation

Figure 8 shows the change in total inpatient (IP) admissions and emergency department (ED) visits for the 517 members included in the analysis. The rate of IP admissions and ED visits has decreased post MTM review. Part of the MTM review process involves connecting the member to OHCA's Care Coordination program and to primary care providers.

Figure 8: IP Admissions and ED Visits	
Total IP Admissions	
Pre MTM	250
Post MTM	79
Percent change in IP admissions per member per month	-39.4%
Total ED Visits	
Pre MTM	1,446
Post MTM	459
Percent change in ED admissions per member per month	-39.2%

ED = emergency department; IP = inpatient; MTM = medication therapy management

Case Study

Member is a 64-year-old male with hypertension, chronic obstructive pulmonary disease (COPD), hypothyroidism, emphysema, atherosclerotic cardiovascular disease (ASCVD), hyperlipidemia, major depressive disorder (MDD), anxiety, and gastroesophageal reflux disease (GERD). The member is currently on 13 medications. The member completed an initial MTM review in April 2020 and completed a second review in June 2021. The following is a summary of his initial review in April 2020.

DRPs identified by PMC clinical pharmacist:

- Incorrect administration of levothyroxine
- Reported using his rescue inhaler [Ventolin® HFA (albuterol)] daily
- Prescribed Trelegy™ Ellipta® (fluticasone furoate/umeclidinium/ vilanterol) but was having difficulty using it
- No prior authorization request had been submitted for Trelegy™ Ellipta®
- Taking pravastatin 10mg once daily; based on diagnosis history, a high-intensity statin is recommended
- Currently smoking 1 pack per day; interested in smoking cessation
- Non-adherent to medications due to cost/prescription limit issues
- Missing key vaccinations – influenza, zoster, and pneumococcal

DRPs resolved by provider:

- Pravastatin was discontinued and atorvastatin 40mg was started
- Prior authorization request was submitted for Trelegy™ Ellipta®
- Submitted 90-day prescriptions for chronic maintenance medications

DRPs resolved by PMC clinical pharmacist:

- Counseled member on appropriate administration of levothyroxine
- Counseled member on how to use Trelegy™ Ellipta® inhaler
- Counseled member on smoking cessation and available covered smoking cessation products through SoonerCare
- Counseled member on recommended vaccines

During the member's second MTM review in June 2021, the member indicated he had stopped smoking. He felt more comfortable using his Trelegy™ Ellipta® inhaler and was able to refill it on time after the prior authorization was approved. Utilization of his rescue inhaler (Ventolin® HFA) decreased from daily use to only using a couple times per week. He is refilling his chronic maintenance medications for a 90-day supply, and his overall adherence has increased. He received his zoster, influenza, and pneumococcal vaccinations. He also reported receiving both doses of the COVID-19 vaccine. He reported feeling better and appreciated the PMC clinical pharmacist's help through SoonerCare MTM services. Also during the second review, a drug interaction was identified between omeprazole and clopidogrel. Clopidogrel was recently started after the member had a stent placed. The concurrent use of clopidogrel and omeprazole significantly reduces the anti-platelet activity of clopidogrel. After consulting with the provider, the member's omeprazole was switched to pantoprazole, which does not interact with clopidogrel.

Summary[3]

OHCA's mission includes "to analyze and recommend strategies for optimizing the accessibility and quality of health care; and, to cultivate relationships to improve the health outcomes of Oklahomans." The results described in this report demonstrate how the SoonerCare MTM program is working to help achieve this mission. The MTM program provides access to extra care for high-risk members who may need additional support. By developing relationships with members, providers, and care mangers, the MTM program is improving the quality of care for Oklahoma SoonerCare members. The MTM program is well accepted by members as evidenced by the 936 members completing MTM reviews in FY 2021. Members are receiving care that is more closely aligned with the existing evidence as demonstrated by the identification of 6.5 DRPs per member. Providers value the service as evidenced by their 75% acceptance rate of changes recommended by PMC clinical pharmacists.

PMC continues to complete MTM reviews on a daily basis. Since reporting these results, additional reviews have been completed totaling more than 1,500 MTM reviews since December 2019. PMC will continue to work with OHCA to identify members who may benefit from MTM services with the goal of promoting evidence-based use of medications and improving the quality of care for Oklahoma SoonerCare members. Future results of the MTM program will be reviewed with the Drug Utilization Review (DUR) Board as they become available.

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[1] Centers for Disease Control and Prevention (CDC). Community Pharmacists and Medication Therapy Management. Available online at: https://www.cdc.gov/dhdsp/pubs/guides/best-practices/pharmacist-mtm.htm. Last accessed 08/12/2021.

[2] Pharmacy Quality Alliance (PQA). PQA Medication Therapy Problem Categories Framework. Available online at: https://pqa.memberclicks.net/assets/Measures/PQA_MTP_Categories_Framework.pdf. Last revised 08/2017. Last accessed 08/12/2021.

[3] Oklahoma Health Care Authority (OHCA). About Us: Our Mission Statement and Goals. Available online at: https://oklahoma.gov/ohca/about.html. Last accessed 08/20/2021.

Appendix D

Vote to Prior Authorize Lybalvi™ (Olanzapine/ Samidorphan)

Oklahoma Health Care Authority
September 2021

Market News and Updates[1]

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

- **June 2021:** The FDA approved Lybalvi™ (olanzapine/samidorphan) for the treatment of adults with schizophrenia, for the treatment of adults with bipolar I disorder as maintenance monotherapy, and for the acute treatment of adults with manic or mixed episodes of bipolar I disorder as monotherapy or as an adjunct to lithium or valproate. Lybalvi™ is a once-daily, oral medication composed of olanzapine, an established atypical antipsychotic agent, and samidorphan, a new chemical entity that is an opioid antagonist. The FDA approved Lybalvi™ under the 505(b)(2) regulatory pathway based on data from 27 clinical studies, including 18 studies evaluating Lybalvi™ and 9 studies evaluating samidorphan alone, as well as the FDA's findings of safety and effectiveness of olanzapine in the treatment of schizophrenia and bipolar I disorder. The efficacy of Lybalvi™ in the treatment of schizophrenia was evaluated in the ENLIGHTEN clinical development program, which included ENLIGHTEN-2 that compared the weight gain profile of Lybalvi™ 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). The most common adverse effects (AEs) reported in the Lybalvi™ treatment group were weight gain, somnolence, and dry mouth; the most common AEs reported in the olanzapine treatment group were weight gain, somnolence, and increased appetite.

Lybalvi™ (Olanzapine/Samidorphan) Product Summary[2]

- **Therapeutic Class:** An atypical antipsychotic (olanzapine) combined with an opioid antagonist (samidorphan) to mitigate weight gain associated with the AEs of the atypical antipsychotic
- **Indication(s):**
  - Schizophrenia in adults; or
  - Bipolar I disorder in adults, including:

    - Maintenance monotherapy treatment; or
    - Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
- **How Supplied:** 5/10mg, 10/10mg, 15/10mg, and 20/10mg olanzapine/samidorphan oral bilayer tablets
- **Dosing and Administration:**
    - Lybalvi™ should be administered once daily with or without food. Lybalvi™ tablets should not be combined or divided.
    - The recommended starting dosage is 5/10mg once daily in patients who have a predisposition to hypotensive reactions, have potential for slower metabolism of olanzapine, or may be more pharmacodynamically sensitive to olanzapine.
    - Dosage may be adjusted at weekly intervals of 5mg (based on the olanzapine component of Lybalvi™), depending upon clinical response and tolerability, up to the maximum recommended dosage of 20/10mg once daily.
    - Refer to the full *Prescribing Information* for the recommended titration and maximum recommended dosage specific to each indication.
    - Lybalvi™ can precipitate opioid withdrawal in patients who are dependent on opioids; concomitant use of Lybalvi™ with opioids is contraindicated. Prior to initiating Lybalvi™, there should be at least a 7-day opioid-free interval from the last use of short-acting opioids and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal.
- **Cost:** The cost information for Lybalvi™ is not available at this time. Lybalvi™ is anticipated to be available in the fourth quarter of 2021.

Recommendations

The College of Pharmacy recommends adding Lybalvi™ (olanzapine/ samidorphan) to Tier-3 of the Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) category (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®)+

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
olanzapine (Zyprexa®)		clozapine oral susp (Versacloz®)+
paliperidone IM inj (Invega Sustenna®)		iloperidone (Fanapt®)
paliperidone 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®)		

ER = extended-release; IM = intramuscular; inj = injection; ODT = orally disintegrating tablet; sub-Q = subcutaneous; susp = suspension
*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.
¥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 ER injection (Invega Sustenna®) for at least 4 months.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.

- Tier-1 products are available without prior authorization for members 5 years of age and older. Prior authorization requests for members younger than 5 years of age are reviewed by an Oklahoma Health Care Authority (OHCA)-contracted child psychiatrist.

Atypical Antipsychotic Medications Tier-2 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
    a. Clozapine does not count towards a Tier-1 trial.

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and

   a. Clozapine does not count towards a Tier-1 trial; and
2. Trials of all oral Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or
3. A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and
4. Use of Versacloz® (clozapine oral suspension) or Fazaclo® (clozapine orally disintegrating tablet) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
5. Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the oral sublingual tablet formulation. Tier structure rules continue to apply; and
6. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

[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 08/13/2021.
[2] Lybalvi™ Prescribing Information. Alkermes. Available online at: https://www.alkermes.com/Alkermes2/media/Graphics/downloadables/lybalvi-pi-2021.pdf. Last revised 05/2021. Last accessed 08/13/2021.

Vote to Prior Authorize Azstarys™ (Serdexmethylphenidate/Dexmethylphenidate), Qelbree™ (Viloxazine), and Xywav® (Calcium/ Magnesium/Potassium/Sodium Oxybates)

Oklahoma Health Care Authority
September 2021

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

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

- **July 2020:** The FDA approved Xywav® (calcium/magnesium/ potassium/sodium oxybates) oral solution for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy. Xywav® is a central nervous system (CNS) depressant similar to Xyrem® (sodium oxybate), 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).
- **March 2021:** The FDA approved Azstarys™ (serdexmethylphenidate/ dexmethylphenidate), a once-daily CNS stimulant, for the treatment of attention-deficit/hyperactivity disorder (ADHD) in patients 6 years of age and older. Azstarys™ capsules are formulated to contain 70% serdexmethylphenidate, a prodrug of dexmethylphenidate, and 30% immediate-release dexmethylphenidate. Azstarys™ is a Schedule II CDS and should not be substituted for other methylphenidate-containing products on a milligram-per-milligram basis. Azstarys™ became available in the United States in July 2021.
- **April 2021:** The FDA approved Qelbree™ (viloxazine) for the treatment of ADHD in pediatric patients 6 to 17 years of age. Viloxazine is a selective norepinephrine reuptake inhibitor and is the first novel, non-stimulant medication for ADHD approved by the FDA since 2002. Supernus launched Qelbree™ in May 2021.

Product Summaries[6,7,8,9]

Azstarys™ (Serdexmethylphenidate/Dexmethylphenidate):

- **Indication(s):** Azstarys™ (serdexmethylphenidate/ dexmethylphenidate) 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 Azstarys™, other methylphenidate-containing products, and amphetamines, 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:** 26.1mg/5.2mg, 39.2mg/7.8mg, and 52.3mg/10.4mg serdexmethylphenidate/dexmethylphenidate oral capsules
- **Dosing and Administration:**
  - Pediatric patients 6 to 12 years of age: Initial dose of 39.2mg/7.8mg once daily in the morning; dose may be increased to 52.3mg/10.4mg once daily or decreased to 26.1mg/5.2mg once daily after 1 week depending on response and tolerability
  - Adults and pediatric patients 13 to 17 years of age: Initial dose of 39.2mg/7.8mg once daily in the morning; dose may be increased to 52.3mg/10.4mg once daily after 1 week
  - Maximum recommended dose: 52.3mg/10.4mg once daily
  - May be taken with or without food; capsules may be swallowed whole, opened and sprinkled onto applesauce, or opened and added to water
  - To avoid substitution errors and overdosage, Azstarys™ should not be substituted for other methylphenidate products on a milligram-per-milligram basis; when switching from other methylphenidate products, the previous medication should be discontinued and the initial dose titration schedule for Azstarys™ should be followed
- **Contraindication(s):**
  - Known hypersensitivity to serdexmethylphenidate, dexmethylphenidate, or product components
  - Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days
- **Cost:** The Wholesale Acquisition Cost (WAC) for Azstarys™ is $12.90 per capsule for each strength, resulting in a cost per 30 days of $387.00.

Qelbree™ (Viloxazine):

- **Indication(s):** Qelbree™ (viloxazine) is a selective norepinephrine reuptake inhibitor indicated for the treatment of ADHD in pediatric patients 6 to 17 years of age.

Boxed Warning: Suicidal Thoughts and Behaviors

- In clinical studies, higher rates of suicidal thoughts and behavior were reported in pediatric patients with ADHD treated with Qelbree™ than patients treated with placebo. All Qelbree™-treated patients should be closely monitored for clinical worsening and for the emergence of suicidal thoughts and behaviors.

- **How Supplied:** 100mg, 150mg, and 200mg extended-release (ER) oral capsules
- **Dosing and Administration:**
  - Pediatric patients 6 to 11 years of age: Initial dose of 100mg once daily; may titrate in 100mg increments weekly to the maximum recommended dose of 400mg once daily
  - Pediatric patients 12 to 17 years of age: Initial dose of 200mg once daily; may titrate after 1 week, by an increment of 200mg, to the maximum recommended dose of 400mg once daily
  - Capsules may be swallowed whole or opened and sprinkled onto a teaspoonful of applesauce
- **Contraindication(s):**
  - Concomitant administration of MAOIs or within 14 days after discontinuing an MAOI
  - Concomitant administration of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range
- **Cost:** The WAC for Qelbree™ is $9.97 per capsule, resulting in a maximum cost per 30 days of $598.20 at the maximum FDA approved dose of 400mg once daily.

Xywav® (Calcium/Magnesium/Potassium/Sodium Oxybates):

- **Indication(s):** Xywav® (calcium/magnesium/potassium/sodium oxybates) is a CNS depressant indicated for the treatment of cataplexy or EDS in patients 7 years of age and older with narcolepsy.

Boxed Warning: CNS Depression and Abuse and Misuse

- Xywav® is a CNS depressant. Clinically significant respiratory depression and obtundation may occur in patients treated with Xywav® at recommended doses. Many patients who received Xywav® during clinical studies in narcolepsy were receiving CNS stimulants.
- The active moiety of Xywav® is oxybate or gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death.
- Because of the risks of CNS depression and abuse and misuse, Xywav® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Xywav® and Xyrem® REMS.

- **How Supplied:** 0.5g/mL oral solution (equivalent to 0.413g/mL of oxybate)
- **Dosing and Administration:**
  - Administered as 2 divided doses nightly (taken at bedtime and then 2.5 to 4 hours later); dose should be titrated to effect

    - Adults: Initiate at 4.5g per night (2.25g per dose); recommended dosage range: 6g to 9g per night
    - Children 7 years of age and older: Recommended starting dose, titration regimen, and maximum nightly dose is based on body weight (refer to the full Xywav® *Prescribing Information* for the complete weight-based dosing recommendations for pediatric patients)
  - Doses >9g per night have not been studied and ordinarily should not be administered
  - Patients should take the first nightly dose at least 2 hours after eating and should take each dose while in bed and lie down after dosing
  - For patients with hepatic impairment, the recommended dose is one-half the original dosage per night
- **Contraindication(s):**
  - Combination with sedative hypnotics or alcohol
  - Use in patients with succinic semialdehyde dehydrogenase deficiency
- **Cost:** The WAC is $28.39 per mL, resulting in a cost per 180mL bottle of $5,110.20 and a cost per 30 days of $15,330.60 for an adult using the maximum FDA approved dose of 9g per night.

Recommendations

The College of Pharmacy recommends the following changes to the ADHD and Narcolepsy Medications product based prior authorization (PBPA) category (changes noted in red in the following PBPA Tier chart and approval criteria):

1. The prior authorization of Azstarys™ (serdexmethylphenidate/ dexmethylphenidate) and placement into Tier-3 of the Long-Acting Methylphenidate category of the ADHD Medications PBPA Tier chart; current Tier-3 criteria will apply
2. The prior authorization of Qelbree™ (viloxazine) and placement into Tier-3 of the Non-Stimulants category of the ADHD Medications PBPA Tier chart; the following additional criteria will also apply
3. The prior authorization of Xywav® (calcium/magnesium/potassium/ sodium oxybates) in the Narcolepsy Medications category with criteria similar to the current approval criteria for Xyrem® (sodium oxybate); the following additional criteria will also apply
4. Moving Quillivant XR® (methylphenidate ER suspension) from Tier-2 to Tier-3, moving Adderall XR® from Tier-2 to Tier-1, and moving Metadate ER® (methylphenidate ER tablet), Methylin ER® (methylphenidate ER tablet), and Ritalin SR® (methylphenidate ER tablet) from Tier-3 to Tier-1 of the ADHD Medications PBPA Tier chart based on net costs

5. Moving Kapvay® (clonidine ER tablet) from Tier-3 to Tier-2 of the Non-Stimulants category of the ADHD Medications PBPA Tier chart based on net cost, and updating the following additional criteria for Kapvay®

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

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
methylphenidate ER chew tab (QuilliChew ER®) methylphenidate ER (Ritalin LA®) **methylphenidate ER (Ritalin SR®)**		**~~methylphenidate ER (Methylin ER®)~~** **methylphenidate ER susp (Quillivant XR®)** **~~methylphenidate ER (Ritalin SR®)~~** **serdexmethylphen-idate/dexmethylphe-nidate (Azstarys™)**	
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	**clonidine ER (Kapvay®)Δ**	**~~clonidine ER (Kapvay®)Δ~~** **viloxazine (Qelbree™)Δ**	

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

ADHD Medications 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 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.
4. A clinical exception may apply for special formulation products when there is a patient-specific, clinically significant reason why the member cannot use the available long-acting lower tiered formulations.
5. ~~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, a long-acting Tier-2 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.~~
6. Qelbree™ [Viloxazine Extended-Release (ER) Capsule] Approval Criteria:
   a. An FDA approved diagnosis; and
   b. Member must be 6 to 17 years of age; and
   c. Previously failed trials (within the last 365 days) with a long-acting Tier-1 stimulant, a long-acting Tier-2 stimulant, Intuniv®, Strattera®, and Kapvay®, unless contraindicated, that did not yield adequate results; 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 and 150mg strengths and 60 capsules per 30 days will apply for the 200mg strength.

7. For 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.

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. Adzenys XR-ODT®, Adzenys ER™, Cotempla XR-ODT®, Dyanavel® XR, and Evekeo ODT™ 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.

ADHD Medications Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum dose are not covered.
2. Prior authorization is required for all tiers for members older than 20 years of age and for members younger than 5 years of age. All prior

authorization requests for members younger than 5 years of age must be reviewed by an Oklahoma Health Care Authority (OHCA)-contracted psychiatrist.

3. For Daytrana® patches, Methylin® oral solution, and Quillichew ER® chewable tablets, 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), ~~or~~ 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 (OSA) requires concurrent treatment for the OSA; and
7. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the prior authorization request.

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[1] Jazz Pharmaceuticals. Jazz Pharmaceuticals Announces U.S. FDA Approval of Xywav® (Calcium, Magnesium, Potassium, and Sodium Oxybates) Oral Solution for Cataplexy or Excessive Daytime Sleepiness Associated with Narcolepsy. Available online at: https://investor.jazzpharma.com/news-releases/news-release-details/jazz-pharmaceuticals-announces-us-fda-approval-xywavtm-calcium. Issued 07/22/2020. Last accessed 08/04/2021.
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[4] Supernus Pharmaceuticals, Inc. Supernus Announces FDA Approval of Qelbree™ (SPN-812) for the Treatment of ADHD. Available online at: https://ir.supernus.com/news-releases/news-release-details/supernus-announces-fda-approval-qelbreetm-spn-812-treatment-adhd. Issued 04/02/2021. Last accessed 08/04/2021.
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[8] Qelbree™ (Viloxazine) Prescribing Information. Supernus Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211964s000lbl.pdf. Last revised 04/2021. Last accessed 08/04/2021.
[9] Xywav® (Calcium, Magnesium, Potassium, and Sodium Oxybates) Prescribing Information. Jazz Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021196s035,212690s001s002lbl.pdf. Last revised 02/2021. Last accessed 08/04/2021.

Vote to Prior Authorize Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack) and Pylera® (Bismuth Subcitrate Potassium/ Metronidazole/Tetracycline Capsule)

Oklahoma Health Care Authority
September 2021

Market News and Updates[1]

News:

- **April 2020:** The U.S. Food and Drug Administration (FDA) has requested all manufacturers withdraw all prescription and over-the-counter (OTC) ranitidine products from the market immediately due to a contaminant known as N-nitrosodimethylamine (NDMA). NDMA is a probable human carcinogen and third-party laboratories have confirmed that NDMA levels increase in ranitidine over time, even under normal storage conditions. Ranitidine stored at higher temperatures, including temperatures the product may be exposed to during distribution and handling, have been shown to have significantly higher NMDA levels. To date, testing done by the FDA for famotidine, cimetidine, esomeprazole, lansoprazole, and omeprazole have not found any NDMA contaminants.

Helicobacter Pylori (*H. Pylori*) Product Summaries[2,3]

Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack):

- **Indication(s):** The components of Helidac® Therapy (bismuth subsalicylate/metronidazole/tetracycline dose pack), in combination with a histamine type 2 receptor (H_2) antagonist, are indicated for the eradication of *H. pylori* for treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or a history of duodenal ulcer).

Boxed Warning: Potential for Carcinogenicity

- Metronidazole has been shown to be carcinogenic in mice and rats. It is unknown whether metronidazole is associated with carcinogenicity in humans.

- **Dosing and Administration:**
  - The recommended dosing for Helidac® Therapy is bismuth subsalicylate [(2) 262.4mg chewable tablets], metronidazole [(1) 250mg tablet], and tetracycline [(1) 500mg capsule] taken 4 times

daily for 14 days plus an H_2 antagonist approved for the treatment of acute duodenal ulcer (e.g., famotidine).
- Helidac® Therapy doses should be taken at mealtimes and at bedtime. The bismuth subsalicylate tablets should be chewed and swallowed. The metronidazole tablet and tetracycline capsule should be swallowed whole with 8 ounces of water. Concomitantly prescribed H_2 antagonist therapy should be taken as directed.
- Helidac® Therapy is supplied in a carton containing 14 blister cards, each card containing 8 bismuth subsalicylate 262.4mg chewable tablets, 4 metronidazole 250mg tablets, and 4 tetracycline 500mg capsules.

Pylera® (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline Capsule) Product Summary:

- **Indication(s):** Pylera® (bismuth subcitrate potassium/metronidazole/ tetracycline capsule) is a combination of metronidazole, tetracycline, and bismuth subcitrate potassium indicated for use, in combination with omeprazole, for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate *H. pylori*.

Boxed Warning: Potential for Carcinogenicity

- Metronidazole has been shown to be carcinogenic in mice and rats. It is unknown whether metronidazole is associated with carcinogenicity in humans.

- **Dosing and Administration:**
  - The recommended dosing for Pylera® is 3 capsules 4 times a day (after meals and at bedtime) for 10 days.
  - Pylera® should be administered with omeprazole 20mg twice daily (after the morning and evening meals).
  - Each capsule of Pylera® contains 140mg of bismuth subcitrate potassium, 125mg of metronidazole, and 125mg of tetracycline. Pylera® is supplied in a 120 count bottle or blister pack for 10 days of therapy.

Cost Comparison: *H. Pylori* Regimens[4]

Product	Cost Per Unit	Cost Per Regimen*
Helidac® Therapy (bismuth subsalicylate/ metronidazole/tetracycline dose pack)	**$4.31**	**$965.44**
Pylera® (bismuth subcitrate potassium/ metronidazole/tetracycline capsule)	**$7.33**	**$879.60**
bismuth subsalicylate 262mg chewable tablet (generic)	$0.16+	$17.92+

Product	Cost Per Unit	Cost Per Regimen*
metronidazole 250mg tablet (generic)	$0.12	$6.72
tetracycline 500mg capsule (generic)	$1.54	$86.24
omeprazole 20mg capsule (generic)	$0.03	$0.84
famotidine 20mg tablet (generic)	$0.04	$1.12

Unit = capsule, chewable tablet, or tablet
*Cost per regimen based on recommended dosing duration for *H. Pylori* treatment for product listed.
⁺Cost for over-the-counter bismuth subsalicylate 262mg chewable tablets based on price available as of 08/10/2021 on Walgreens.com for store-brand product.
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).

Recommendations

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

1. Moving rabeprazole tablets and brand name Prevacid® ODT from Tier-2 to Tier-1 based on net costs
2. The prior authorization of Helidac® Therapy (bismuth subsalicylate/ metronidazole/tetracycline) and Pylera® (bismuth subcitrate potassium/metronidazole/tetracycline capsule) and placement into the Special Prior Authorization (PA) Tier with the following additional criteria
3. Updating the current approval criteria for sucralfate suspension unit dose cups based on net costs
4. Removing all ranitidine products from the Tier chart and Special PA criteria based on the FDA-requested market withdrawal
5. Updating the trial requirements for Axid® (nizatidine solution) based on the market withdrawal of ranitidine products

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
dexlansoprazole (Dexilant® caps)	~~**lansoprazole (Prevacid® ODT)**~~	esomeprazole (Nexium® I.V.)	**bismuth subcitrate potassium/ metronidazole/ tetracycline (Pylera® capsule)**
esomeprazole (Nexium® caps)	pantoprazole (Protonix® I.V.)	esomeprazole strontium caps	**bismuth subsalicylate/ metronidazole/ tetracycline (Helidac® Therapy dose pack)**

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
esomeprazole (Nexium® packet) – **Brand Preferred**	~~**rabeprazole (Aciphex® tabs)**~~	omeprazole (Prilosec® susp, powder)	cimetidine (Tagamet® tabs)
lansoprazole (Prevacid® caps)		pantoprazole (Protonix® susp)	esomeprazole kit (ESOMEP-EZS™)
lansoprazole (Prevacid® ODT) – Brand Preferred		rabeprazole (Aciphex® sprinkles)	famotidine (Pepcid® susp)
omeprazole (Prilosec® caps)			glycopyrrolate (Glycate® tabs)
pantoprazole (Protonix® tabs)			nizatidine (Axid® caps & soln)
rabeprazole (Aciphex® tabs)			omeprazole/ amoxicillin/rifabutin (Talicia® caps)
sucralfate susp (Carafate®) – **Brand Preferred**			omeprazole/sodium bicarbonate (Zegerid® caps & pack)
			~~**ranitidine caps**~~
			sucralfate susp **(generic)** ~~**(unit dose cups)**~~

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

Axid® (Nizatidine Capsules) Approval Criteria:

1. A previous 14-day trial of ~~ranitidine and~~ famotidine or a patient-specific, clinically significant reason why ~~ranitidine and~~ famotidine ~~are~~ is not appropriate for the member must be provided.

Axid® (Nizatidine Solution) Approval Criteria:

1. A previous 14-day trial of ~~ranitidine syrup~~ famotidine suspension or a patient-specific, clinically significant reason why ~~ranitidine syrup~~ famotidine suspension is not appropriate for the member must be provided; and
2. Nizatidine solution (Axid®) will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral capsule formulation.

Generic Sucralfate Suspension ~~Unit Dose Cups~~ Approval Criteria:

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

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

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

Pepcid® (Famotidine Suspension) Approval Criteria:

1. ~~A previous 14-day trial of ranitidine syrup or a patient-specific, clinically significant reason why ranitidine syrup is not appropriate for the member must be provided; and~~
2. Famotidine suspension will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral tablet formulation.

~~**Ranitidine Capsules Approval Criteria:**~~

1. ~~A patient-specific, clinically significant reason why the member cannot use ranitidine tablets must be provided~~

Tagamet® (Cimetidine Tablets) Approval Criteria:

1. A previous 14-day trial of ~~ranitidine and~~ famotidine or a patient-specific, clinically significant reason why ~~ranitidine and~~ famotidine ~~are~~ is not appropriate for the member must be provided.

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Vote to Prior Authorize Alkindi® Sprinkle (Hydrocortisone Oral Granule), Eysuvis® (Loteprednol 0.25% Ophthalmic Suspension), Gimoti® (Metoclopramide Nasal Spray), Nextstellis® (Drospirenone/Estetrol Tablet), Ozobax® (Baclofen 5mg/5mL Oral Solution), Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel), RediTrex® (Methotrexate Injection), Reltone™ (Ursodiol Capsule), and Thyquidity™ (Levothyroxine Oral Solution)

Oklahoma Health Care Authority
September 2021

Introduction[1,2,3,4,5,6,7,8,9]

Alkindi® Sprinkle (hydrocortisone oral granule) is a corticosteroid indicated as replacement therapy in pediatric patients with adrenocortical insufficiency. Alkindi® Sprinkle is supplied as oral granules contained within capsules available as 0.5mg, 1mg, 2mg, and 5mg strengths. The capsules should not be swallowed, nor the granules chewed or crushed. The capsule should be opened and its contents placed directly into the patient's mouth or sprinkled onto soft food and given immediately. The dose should be individualized, using the lowest possible dosage with a recommended starting dose of 8 to 10mg/m^2 daily. The total daily dose should be divided into 3 doses and administered 3 times daily.

- Other Formulation(s) Available: hydrocortisone tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days
Alkindi® Sprinkle 2mg (hydrocortisone oral granule)	**$27.95**	**$2,515.50***
hydrocortisone 5mg tablet (generic)	$0.18	$16.20[+]

Unit = granule-filled capsule or tablet
*Cost per 30 days for Alkindi® Sprinkle based on the U.S. Food and Drug Administration (FDA) recommended dose of 10mg/m^2 (divided into 3 doses/day) for a pediatric patient with a body surface area of 0.6m^2.
[+]Cost per 30 days for hydrocortisone generic tablet based on American Academy of Pediatrics guideline recommended pediatric fixed-dosing of 5mg 3 times daily.
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).

Eysuvis® (loteprednol 0.25% ophthalmic suspension) is a corticosteroid indicated for short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease. Eysuvis® is supplied as 8.3mL of 0.25% sterile loteprednol etabonate ophthalmic suspension in a 10mL dropper bottle. After shaking the suspension, it is recommended to instill 1 to 2 drops of Eysuvis® into each eye 4 times daily for up to 2 weeks.

- Other Formulation(s) Available: Lotemax® (loteprednol 0.5% ophthalmic suspension) and Restasis® (cyclosporine 0.05% ophthalmic emulsion)

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
Eysuvis® (loteprednol 0.25% ophthalmic suspension)	**$56.02**	**$464.97**
Lotemax® (loteprednol 0.5% ophthalmic suspension)€	$52.94	$794.10
Restasis® (cyclosporine 0.05% ophthalmic emulsion)€	$9.83	$589.80

Unit = milliliter (mL) or single-use vial
€Brand name Lotemax® 0.5% suspension and Restasis® have supplemental rebates and are currently covered without prior authorization.
*Cost per package based on largest package size available for product listed.
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).

Gimoti® (metoclopramide nasal spray) is a dopamine-2 (D_2) antagonist indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. The recommended dosing for adults younger than 65 years of age is 1 spray (15mg) in 1 nostril, 30 minutes before each meal and at bedtime (maximum of 4 sprays daily) for 2 to 8 weeks, depending on symptomatic response. For adults 65 years of age or older, Gimoti® is not recommended as initial therapy; if receiving an alternative metoclopramide product at a stable dosage of 10mg 4 times daily, the patient can be switched to Gimoti® at the recommended dose and duration. Gimoti® is supplied as a metoclopramide solution in a 10mL amber glass bottle fitted with a metered spray pump attachment that delivers 15mg of metoclopramide in each 70mcL spray. Each bottle contains 9.8mL which is sufficient for 4 weeks of 4 times daily use.

- Other Formulation(s) Available: metoclopramide tablets and metoclopramide oral solution

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 8 Weeks*
Gimoti® (metoclopramide nasal spray)	**$178.57**	**$3,499.97**
metoclopramide 5mg/5mL oral solution (generic)	$0.03	$67.20
metoclopramide 10mg tablet (generic)	$0.04	$8.96

Unit = mL or tablet
*Cost per 8 weeks based on the maximum FDA recommended dosing for diabetic gastroparesis.
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).

Nextstellis® (drospirenone/estetrol tablet) is a combination of drospirenone (a progestin) and estetrol (an estrogen) indicated for use by females of reproductive potential to prevent pregnancy. The recommended dose is 1 tablet by mouth at the same time every day for 28 consecutive days. Nextstellis® is supplied in a 28-day blister card with 24 pink, active film-coated tablets containing 3mg drospirenone/14.2mg estetrol and 4 white inert film-coated tablets.

- Other Formulation(s) Available: drospirenone/ethinyl estradiol (EE) 3mg/0.02mg tablets and drospirenone/EE 3mg/0.03mg tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Pack
Nextstellis® (drospirenone 3mg/estetrol 14.2mg tablet)	**$6.79**	**$190.12**
drospirenone 3mg/EE 0.02mg tablet (generic)	$0.40	$11.20
drospirenone 3mg/EE 0.03mg tablet (generic)	$0.31	$8.68

Unit = tablet; EE = ethinyl estradiol
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).

Ozobax® (baclofen 5mg/5mL oral solution) is a gamma-aminobutyric acid (GABA) 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; may also be of some value in patients with spinal cord injuries and other spinal cord diseases. 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). Ozobax® is supplied as a 5mg/5mL grape-flavored oral solution in a 473mL stock bottle. Ozobax® must be stored refrigerated [2°C to 8°C (36°F to 46°F)].

- Other Formulation(s) Available: baclofen tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Ozobax® (baclofen 5mg/5mL oral solution)	**$1.73**	**$4,152.00**
baclofen 20mg tablet (generic)	$0.14	$16.80

Unit = mL or tablet
*Cost per 30 days based on the maximum FDA recommended dosing for baclofen.
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).

Phexxi® (lactic acid/citric acid/potassium bitartrate vaginal gel) is a combination of lactic acid, citric acid, and potassium bitartrate indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception. The recommended dosing is to

administer 1 pre-filled single-dose applicator of Phexxi® (5 grams) vaginally immediately before (or up to 1 hour before) each act of vaginal intercourse. Phexxi® is supplied as vaginal gel containing 1.8% lactic acid, 1% citric acid, and 0.4% potassium bitartrate in individually wrapped 5 gram pre-filled single-dose vaginal applicators in sealed foil pouches along with a plunger. Phexxi® is available in a box containing 12 single doses.

- Other Formulation(s) Available: VCF® (nonoxynol 9 vaginal 28% film) and VCF® (nonoxynol 9 vaginal 12.5% foam)

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
Phexxi® (lactic acid/citric acid/potassium bitartrate vaginal gel)	**$4.28**	**$256.80**
VCF® (nonoxynol 9 vaginal 28% film)	$1.28	$11.52
VCF® (nonoxynol 9 vaginal 12.5% foam)	$0.67	$11.39

Unit = gram or film
*Cost per package based on largest package size available for product listed.
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).

RediTrex® (methotrexate injection) is a folate analog metabolic inhibitor indicated for the management of patients with severe, active rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), or severe, recalcitrant, disabling psoriasis. RediTrex® is supplied in single-dose pre-filled syringes delivering sterile methotrexate solution for subcutaneous (sub-Q) injection in 8 strengths: 7.5mg/0.3mL, 10mg/0.4mL, 12.5mg/0.5mL, 15mg/0.6mL, 17.5mg/0.7mL, 20mg/0.8mL, 22.5mg/0.9mL, and 25mg/mL. The recommended dose for RediTrex® is once weekly via sub-Q administration in the abdomen or thigh. The recommended starting doses based on indication are as follows, for RA 7.5mg once weekly, for pJIA 10mg/m^2 once weekly, and for psoriasis 10mg to 25mg once weekly.

- Other Formulation(s) Available: methotrexate tablets and methotrexate injection

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 4 Weeks*
RediTrex® (10mg/0.4mL methotrexate injection)	**$75.00**	**$300.00**
Otrexup® (10mg/0.4mL methotrexate injection)	$162.44	$649.76
Rasuvo® (10mg/0.2mL methotrexate injection)	$123.25	$493.00
methotrexate 25mg/mL injection (generic)	$3.23±	$6.46±
methotrexate 2.5mg tablet (generic)	$0.23	$2.76

Unit = pre-filled syringe, auto-injector, mL, or tablet
±Cost for methotrexate 25mg/mL injection based on use of multi-dose 2mL vial.
*Cost per 4 weeks is based on the FDA recommended dose for psoriasis (10mg once weekly).
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).

Reltone™ (ursodiol capsule) is a bile acid indicated for the dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter in whom elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to systemic disease, advanced age, idiosyncratic reaction to general anesthesia, or for those patients who refuse surgery and prevention of gallstone formation in obese patients with rapid weight loss. The recommended dosing is based on diagnosis. For dissolution of radiolucent, noncalcified gallstones, the recommended dose is 8 to 10mg/kg/day given by mouth in 2 or 3 divided doses. For prevention of gallstone formation, the recommended dose is 600mg by mouth daily. Reltone™ is supplied in 2 strengths: 200mg and 400mg capsules. Safety of Reltone™ use beyond 24 months has not been established.

- Other Formulation(s) Available: ursodiol capsules and ursodiol tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Reltone™ 200mg (ursodiol capsule)	**$19.00**	**$1,710.00**
ursodiol 500mg tablet (generic)	$1.16	$69.60
ursodiol 300mg capsule (generic)	$0.58	$34.80

Unit = tablet or capsule
*Cost per 30 days based on the FDA recommended dose of 8mg/kg/day (2 or 3 divided doses) for gallstone dissolution for a 75kg adult patient.
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).

Thyquidity™ (levothyroxine oral solution) is a levothyroxine sodium (T4) oral solution indicated for hypothyroidism and pituitary thyrotropin suppression. The recommended dosing for Thyquidity™ is once daily, preferably on an empty stomach, 30 minutes to 1 hour before breakfast and at least 4 hours before or after drugs that are known to interfere with absorption. The starting dose depends on a variety of factors, including age, body weight, cardiovascular status, concomitant medical conditions, concomitant medications, co-administered food, and the specific nature of the condition being treated. Peak therapeutic effect may not be attained for 4-6 weeks. Thyquidity™ is supplied as 100mcg/5mL (20mcg/mL) oral solution in 100mL bottles. The bottle must be used within 8 weeks of opening.

- Other Formulation(s) Available: levothyroxine tablets and Tirosint®-SOL (levothyroxine oral solution)

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Thyquidity™ 100mcg/5mL (levothyroxine oral solution)	**$1.10**	**$110.00α**
Tirosint®-SOL 50mcg/mL (levothyroxine oral solution)	$4.44+	$133.20
levothyroxine 50mcg tablet (generic)	$0.21	$6.30

Unit = mL or tablet
*Cost per 30 days based on a dose of 50mcg daily. Cost for Thyquidity™ and levothyroxine tablets will vary based on dose required.
+Cost per mL is the same for all strengths of Tirosint®-SOL.
αThyquidity™ cost per 30 days for 50mcg daily requires the use of a 100mL bottle (as supplied), as it must be used within 8 weeks of opening.
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).

Recommendations

The College of Pharmacy recommends the prior authorization of Alkindi® Sprinkle (hydrocortisone oral granule), Eysuvis® (loteprednol 0.25% ophthalmic suspension), and Gimoti® (metoclopramide nasal spray) with the following criteria:

Alkindi® Sprinkle (Hydrocortisone Oral Granule) Approval Criteria:

1. An FDA approved indication of replacement therapy in pediatric members with adrenocortical insufficiency; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use hydrocortisone tablets, even when tablets are crushed, must be provided.

Eysuvis® (Loteprednol 0.25% Ophthalmic Suspension) Approval Criteria:

1. An FDA approved indication for the short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease (DED); and
2. A documented trial of intermittent or regular artificial tear use within the past 3 months; and
3. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine 0.05% ophthalmic emulsion), which is available without a prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use Tier-1 ophthalmic corticosteroids including Lotemax® (loteprednol 0.5% suspension) must be provided; and
5. Member must not have any contraindications to Eysuvis®; and
6. A quantity limit of 8.3mL per 15 days will apply (Eysuvis® for the treatment of DED is not indicated for use beyond 15 days).

Gimoti® (Metoclopramide Nasal Spray) Approval Criteria:

1. An FDA approved indication of acute or recurrent diabetic gastroparesis in adult members; and

2. A patient-specific, clinically significant reason why the member cannot use metoclopramide oral tablets and metoclopramide oral solution must be provided; and
3. For members 65 years of age or older, approvals will not be granted for initiation of metoclopramide therapy; and
4. For members 65 years of age or older requesting to switch from an alternative metoclopramide product to Gimoti®:
    a. Member must be taking a stable dose of metoclopramide 10mg 4 times daily for at least 10 days; and
    b. Duration of current metoclopramide treatment must be provided; and
5. A maximum approval duration of 8 weeks total from all sources will apply; and
6. A quantity limit of 9.8mL per 28 days will apply.

Additionally, the College of Pharmacy recommends the prior authorization of Ozobax® (baclofen 5mg/5mL oral solution), Phexxi® (lactic acid/citric acid/ potassium bitartrate vaginal gel), and Reltone™ (ursodiol capsule) with the following criteria:

Ozobax® (Baclofen 5mg/5mL Oral Solution) Approval Criteria:

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

Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use an over-the-counter (OTC) spermicide and all other forms of contraception (e.g., condoms, oral contraceptives) must be provided. Various OTC spermicides containing nonoxynol 9 are covered by SoonerCare without prior authorization.

Reltone™ (Ursodiol Capsule) Approval Criteria:

1. An FDA approved indication for the dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter or the prevention of gallstone formation in obese members experiencing rapid weight loss; and
2. For the indication of dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter:
    a. Prescriber must confirm member is not a candidate for elective cholecystectomy due to 1 or more of the following:

        i. Increased surgical risk due to systemic disease; or
        ii. Advanced age; or
        iii. Idiosyncratic reaction to general anesthesia; or
        iv. Member refuses surgery; and
    b. Prescriber must confirm the member does not have compelling reasons for cholecystectomy including unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary-gastrointestinal fistula; and
3. For the indication of prevention of gallstone formation in obese members experiencing rapid weight loss:
    a. Member's baseline body mass index (BMI) and weight must be provided; and
    b. Member's current weight must be provided supporting rapid weight loss compared to baseline; and
4. For both FDA approved indications, a patient-specific, clinically significant reason why the member cannot use other generic formulations of ursodiol must be provided; and
5. Initial approvals for the indication of dissolution of gallstones will be for the duration of 6 months, after which time the prescriber must confirm (via ultrasound imaging) partial or complete dissolution of gallstone(s). Subsequent approvals will be for the duration of 12 months; and
6. Approvals for prevention of gallstone formation in obese members experiencing rapid weight loss will be for 6 months, after which time the member's current weight must be provided to justify continued rapid weight loss and need for preventative treatment; and
7. Treatment duration will be limited to a maximum of 24 months for all diagnoses.

Finally, the College of Pharmacy recommends the addition of Nextstellis® (drospirenone/estetrol tablet) to the current Slynd® (drospirenone tablet) approval criteria, the addition of RediTrex® (methotrexate injection) to the current Otrexup® (methotrexate injection) and Rasuvo® (methotrexate injection) approval criteria along with updates due to net costs and to be consistent with current treatment guidelines, and the addition of Thyquidity™ (levothyroxine oral solution) to the current Tirosint® (levothyroxine capsule) and Tirosint®-SOL (levothyroxine oral solution) approval criteria along with the recommended Drug Utilization Review (DUR) Board update to redefine the dosing for the required 8 week trial of levothyroxine (proposed changes shown in red):

Nextstellis® (Drospirenone/Estetrol Tablet) and Slynd® (Drospirenone Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all alternative formulations of hormonal contraceptives available without a prior authorization must be provided.

Rasuvo®, RediTrex®, and Otrexup® (Methotrexate Injection Solutions) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Adults with severe, active rheumatoid arthritis (RA); or
    b. Children with active polyarticular juvenile idiopathic arthritis (pJIA); or
    c. Severe, recalcitrant, disabling psoriasis confirmed by biopsy or dermatologic consultation; and
2. ~~Members with a diagnosis of RA or pJIA must have had an adequate trial of full dose nonsteroidal anti-inflammatory drugs (NSAIDs); and~~
3. A patient-specific, clinically significant reason why the oral tablets ~~or~~ and the generic injectable formulation cannot be used must be provided; and
4. Authorization of Otrexup® will also require a patient-specific, clinically significant reason why the member cannot use Rasuvo® or RediTrex®.

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

1. An FDA approved diagnosis of 1 of the following:
    a. Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism; or
    b. Pituitary Thyrotropin (thyroid-stimulating hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer; and
2. A patient-specific, clinically significant reason why the member cannot use all other formulations of levothyroxine must be provided. For the oral solutions, a reason why the member cannot use the levothyroxine tablet, even when the tablets are crushed, must be provided; and
3. Prescriber must verify member has been compliant with levothyroxine tablets at ~~maximum dose~~ a greatly increased dose for at least 8 weeks; and
4. Prescriber must verify that member has not been able to achieve normal thyroid lab levels despite ~~maximum dosing~~ a greatly increased dose and compliance with levothyroxine tablets.

[1] Alkindi® Sprinkle Prescribing Information. Eton Pharmaceuticals, Inc. Available online at: https://www.alkindisprinkle.com/. Last revised 03/2021. Last accessed 08/09/2021.
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[3] Gimoti® Prescribing Information. Evoke Pharma, Inc. Available online at: https://evokepharma.com/wp-content/uploads/Prescribing-Information-Gimoti-metoclopramide-nasal-spray.pdf. Last revised 01/2021. Last accessed 08/09/2021.
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Appendix E

Vote to Prior Authorize Qdolo™ (Tramadol 5mg/mL Oral Solution)

Oklahoma Health Care Authority
September 2021

Market News and Updates[1]

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

- **September 2020:** The FDA approved Qdolo™ (tramadol 5mg/mL oral solution), an opioid agonist indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Qdolo™ (Tramadol 5mg/mL Oral Solution) Product Summary[2,3]

- **Indication(s):** Qdolo™ (tramadol 5mg/mL oral solution) is a schedule IV narcotic/opioid agonist indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
  - Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, Qdolo™ should be reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics) have not been tolerated or are not expected to be tolerated and in whom alternative treatment options have not provided adequate analgesia or are not expected to provide adequate analgesia.

Boxed Warning:

- Accidental ingestion
- Addiction, abuse, and misuse
- Interactions with drugs affecting cytochrome P450 isoenzymes
- Life-threatening respiratory depression
- Neonatal opioid withdrawal syndrome
- Risk Evaluation and Mitigation Strategy (REMS)
- Risks from concomitant use with benzodiazepines or other central nervous system (CNS) depressants
- Risk of medication errors
- Ultra-rapid metabolism of tramadol and other risk factors for life-threatening respiratory depression in children

- **How Supplied:** Tramadol 5mg/mL grape-flavored oral solution supplied in 473mL white, opaque plastic bottles

- **Dosing and Administration:**
  - The recommended starting dose is 25mg/day and may be titrated in 25mg increments as separate doses every 3 days up to 100mg/day (25mg 4 times a day).
  - Thereafter, the total daily dose may be increased by 50mg as tolerated every 3 days up to 200mg/day (50mg 4 times a day).
  - After titration, Qdolo™ 50mg to 100mg can be administered as needed for pain relief every 4 to 6 hours, not to exceed 400mg/day.
  - Using the lowest effective dosage for the shortest duration consistent with individual patient treatment goals is recommended.
  - Patients should be advised to always use a calibrated oral syringe or other oral dosing device with metric units of measurements (i.e., mL) to correctly measure the prescribed amount of medication.
- **Contraindication(s):**
  - Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
  - Children younger than 12 years of age
  - Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days
  - Hypersensitivity to tramadol, any other component of this product, or opioids
  - Known or suspected gastrointestinal obstruction, including paralytic ileus
  - Postoperative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy
  - Significant respiratory depression
- **Cost:** The cost information for Qdolo™ is not yet available.

Recommendations

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

1. Placement of Qdolo™ (tramadol 5mg/mL oral solution) into the Short-Acting Special Prior Authorization (PA) category of the Opioid Analgesics Tier chart
2. Removal of Combunox™ (oxycodone/ibuprofen tablet), Embeda® [morphine/naltrexone extended-release (ER) capsule], Oxecta® (oxycodone tablet), Primlev™ [oxycodone/acetaminophen (APAP) tablet], Vantrela™ ER (hydrocodone ER tablet), and Xolox® (oxycodone/APAP tablet) from the Opioid Analgesics Tier chart due to product discontinuation

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
buprenorphine patch (Butrans®) – **Brand Preferred**	fentanyl patch (Duragesic®)	buprenorphine ER buccal film (Belbuca®)	oxycodone/APAP ER tab (Xartemis® XR)
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab
	~~**morphine/ naltrexone ER cap (Embeda®)**~~	hydrocodone ER tab (Hysingla® ER)	tramadol ER cap (ConZip®)
	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	~~**hydrocodone ER tab (Vantrela™ ER)**~~	
	tramadol ER tab (Ultram ER®, Ryzolt®)	hydromorphone ER tab (Exalgo®)	
		methadone tab and oral soln (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
		morphine ER tab (Arymo™ ER)	
		morphine ER tab (MorphaBond™)	
		oxycodone ER cap (Xtampza® ER)	
		oxycodone/ naltrexone ER cap (Troxyca® ER)	
Short-Acting			
APAP/butalbital/ caff/codeine cap (Fioricet® with Codeine)	oxymorphone IR tab (Opana®)	benzhydrocodone/ APAP tab (Apadaz®)	levorphanol tab
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	tapentadol IR tab (Nucynta®)	dihydrocodeine/ APAP/caff cap (Trezix®)	tramadol 100mg tab

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Short-Acting			
codeine tab		hydrocodone/ APAP oral soln (Zamicet®, Liquicet®)	**tramadol oral soln (Qdolo™)**
codeine/APAP tab (Tylenol® with Codeine)		hydrocodone/ APAP tab (Xodol®)	
dihydrocodeine/ ASA/caff cap (Synalgos-DC®)		~~**oxycodone/APAP tab (Primlev™, Xolox®)**~~	
hydrocodone/ APAP tab (Norco®)		oxycodone tab (Oxaydo®)	
hydrocodone/IBU tab (Vicoprofen®, Ibudone®, Reprexain™)		~~**oxycodone tab (Oxecta®)**~~	
hydromorphone tab (Dilaudid®)		oxycodone tab (RoxyBond™)	
morphine IR tab (MSIR®)			
oxycodone/APAP tab (Percocet®)			***Oncology Only:***
oxycodone/ASA tab (Percodan®)			fentanyl buccal film (Onsolis®)
~~**oxycodone/IBU tab (Combunox™)**~~			fentanyl buccal tab (Fentora®)
oxycodone IR cap (Oxy IR®)			fentanyl nasal spray (Lazanda®)
oxycodone IR tab (Roxicodone®)			fentanyl SL spray (Subsys®)
tramadol 50mg tab (Ultram®)			fentanyl SL tab (Abstral®)
tramadol/APAP tab (Ultracet®)			fentanyl transmucosal lozenge (Actiq®)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
APAP = acetaminophen; ASA = aspirin; caff = caffeine; cap = capsule; ER = extended-release; IBU = ibuprofen; IR = immediate-release; PA = prior authorization; SL = sublingual; soln = solution; tab = tablet

Opioid Analgesics Special Prior Authorization (PA) Approval Criteria:

1. Abstral®, Actiq®, Fentora®, Lazanda®, Onsolis®, and Subsys® are approved for oncology-related diagnoses only.
2. Unique Strengths of Hydrocodone/Acetaminophen (APAP) Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) must be provided.
3. ConZip® [Tramadol Extended-Release (ER) Capsule] Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use the ER tablet formulation must be provided. Tier structure rules apply.
4. Xartemis® XR (Oxycodone/APAP ER Tablet) Approval Criteria:
    a. An acute pain condition requiring around-the-clock opioid treatment; and
    b. A patient-specific, clinically significant reason must be provided for all of the following:
        i. Why the member cannot use any other opioid medication for treatment of acute pain; and
        ii. Why the member requires a long-acting medication for an acute pain condition; and
        iii. Why the member cannot use Oxycontin® (oxycodone ER) and over-the-counter (OTC) APAP individual products in place of this combination product; and
    c. A quantity limit of 4 tablets per day will apply with a maximum approval duration of 10 days; and
    d. The member must not exceed 3,250mg of APAP per day from all sources; and
    e. Tier structure rules still apply.
5. Levorphanol Tablet Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use alternative treatment options for pain (e.g., non-opioid analgesics, lower-tiered opioid analgesics) must be provided.
6. Tramadol 100mg Tablet Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose must be provided; and
    b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age.

7. Qdolo™ (Tramadol 5mg/mL Oral Solution) Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use tramadol 50mg tablets, even when tablets are crushed, must be provided; and
    b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the prescriber must provide patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
    c. A quantity limit of 2,400mL per 30 days will apply.

Additionally, the College of Pharmacy recommends the following changes to the Medication Assisted Treatment (MAT) medications approval criteria (changes noted in red in the following criteria; only criteria with changes are listed):

1. Removal of Cassipa® [buprenorphine/naloxone sublingual (SL) film] and Probuphine® (buprenorphine implant) based on product discontinuation

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

1. Generic buprenorphine/naloxone SL tablet is the preferred product. Authorization consideration of Bunavail®, Zubsolv®, ~~Cassipa®,~~ and Suboxone® films (brand and generic) requires a patient-specific, clinically significant reason why generic buprenorphine/naloxone SL tablets are not appropriate.
2. Subutex® (buprenorphine) 2mg and 8mg SL tablets will only be approved if the member is pregnant or has a documented serious allergy or adverse reaction to naloxone; and
~~3. For Cassipa®, the member must have been titrated to a dose of 16mg buprenorphine using another buprenorphine product prior to approval; and~~
4. Buprenorphine products FDA approved for a diagnosis of opioid abuse/dependence must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and
5. Member must have an FDA approved diagnosis of opioid abuse/dependence; and

6. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
7. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
8. The following limitations will apply:
    a. Bunavail® 2.1mg/0.3mg buccal films: A quantity limit of 90 buccal films per 30 days will apply.
    b. Bunavail® 4.2mg/0.7mg buccal films: A quantity limit of 60 buccal films per 30 days will apply.
    c. Bunavail® 6.3mg/1mg buccal films: A quantity limit of 30 buccal films per 30 days will apply.
    ~~d. Cassipa® 16mg/4mg SL films: A quantity limit of 30 SL films per 30 days will apply.~~
    e. Suboxone® 2mg/0.5mg and 4mg/1mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    f. Suboxone® 8mg/2mg SL tablets and films: A quantity limit of 60 SL units per 30 days will apply.
    g. Suboxone® 12mg/3mg SL films: A quantity limit of 30 SL films per 30 days will apply.
    h. Subutex® 2mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    i. Subutex® 8mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
    j. Zubsolv® 0.7mg/0.18mg, 1.4mg/0.36mg, and 2.9mg/0.71mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    k. Zubsolv® 5.7mg/1.4mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
    l. Zubsolv® 8.6mg/2.1mg and 11.4mg/2.9mg SL tablets: A quantity limit of 30 SL tablets per 30 days will apply.

~~**Probuphine® (Buprenorphine Implant) Approval Criteria:**~~

~~1. An FDA approved indication of maintenance treatment of opioid dependence; and~~
~~2. Member must be currently on a maintenance dose of ≤8mg per day of a Subutex® or Suboxone® sublingual tablet or its transmucosal buprenorphine product equivalent; and~~
~~3. Member must have been stable on current transmucosal buprenorphine dose (of ≤8mg per day) for 3 months or longer without any need for supplemental dosing or adjustments; and~~
~~4. Member must have had no positive urine toxicology results or paid claims for opioids within the last 3 months. Concomitant treatment with opioids (including tramadol) will be denied; and~~
~~5. Probuphine® must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA)~~

and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and

6. Prescribers must verify they have considered the following factors in determining clinical stability and suitability for Probuphine®:
   a. Period free from illicit opioid drug use; and
   b. Stability of living environment; and
   c. Participation in a structured activity/job; and
   d. Consistency in participation in recommended behavioral therapy/peer support program; and
   e. Consistency in compliance with clinic visit requirements; and
   f. Minimal to no desire or need to use illicit opioids; and
   g. Period without episodes of hospitalizations (addiction or mental health issues), emergency room visits, or crisis interventions; and
   h. Social support system; and
7. The prescriber must verify enrollment in the Probuphine® Risk Evaluation and Mitigation Strategy (REMS) program; and
8. Approvals will be for 1 kit (4 implants) per 6 months. Reauthorizations for an additional 6 months may be granted if the member does not have ongoing use of supplemental dosing with transmucosal buprenorphine or opioid analgesics while utilizing Probuphine®.

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[1] Athena Bioscience. U.S. FDA Approves Athena Bioscience's New Drug Application (NDA) for QDOLO™ (Tramadol Hydrochloride) Oral Solution. *BioSpace*. Available online at: https://www.biospace.com/article/releases/u-s-fda-approves-athena-bioscience-s-new-drug-application-nda-for-qdolo-tramadol-hydrochloride-oral-solution/. Issued 09/08/2020. Last accessed 08/09/2021.

[2] Qdolo™ Prescribing Information. Athena Bioscience, LLC. Available online at: https://qdolo.com/wp-content/uploads/2020/10/QDOLO-Prescribing-Information.pdf. Last revised 09/2020. Last accessed 08/09/2021.

[3] Qdolo™ (Tramadol) – New Drug Approval. *OptumRx*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_qdolo_2020-0904.pdf. Issued 2020. Last accessed 08/09/2021.

Appendix F

Vote to Prior Authorize Impeklo® (Clobetasol Propionate 0.05% Lotion)

Oklahoma Health Care Authority
September 2021

Market News and Updates[1]

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

- **May 2020:** The FDA approved Impeklo® (clobetasol propionate 0.05% lotion) for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in adults 18 years of age and older. Impeklo® is the first and only metered-dose clobetasol lotion formulation available. Clobetasol is generically available in various other formulations, including as a lotion (generic Clobex® lotion), cream, foam, gel, spray, ointment, shampoo, and solution.

Impeklo® (Clobetasol Propionate 0.05% Lotion) Product Summary[2]

- **Therapeutic Class:** Topical corticosteroid (TCS)
- **Indication(s):** For relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 18 years of age or older
- **Limitation(s) of Use:**
  - Impeklo® should not be used in the treatment of rosacea or perioral dermatitis.
  - Impeklo® should not be used in patients younger than 18 years of age due to numerically high rates of hypothalamic-pituitary-adrenal (HPA) axis suppression.
- **How Supplied:** Impeklo® is available as a 0.05% weight per weight (w/w) lotion in a 68g bottle with a metered-dose pump having an integral pump locking feature. Each pump actuation delivers on average 0.15mg of clobetasol propionate, USP in 0.3g of lotion.
- **Dosing and Administration:**
  - Impeklo® lotion is for topical use only and is not for ophthalmic, oral, or intravaginal use.
  - Impeklo® lotion should be applied to the affected skin areas twice daily and rubbed in gently and completely. Patients should avoid contact with eyes and wash hands after each application.
  - The total dosage should not exceed 50g per week because of the potential for the drug to suppress the HPA axis.

- The maximum dose is 10 pump actuations per application twice daily or 20 pump actuations per day for 7 days; the maximum recommended dose should not be exceeded.
- Impeklo® lotion contains a TCS; therefore, treatment should be limited to 2 consecutive weeks for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses and up to 2 additional weeks in localized lesions (<10% body surface area) of moderate to severe plaque psoriasis that have not sufficiently improved after the initial 2 weeks of treatment. Impeklo® should be discontinued when control is achieved.
- Impeklo® should not be used with occlusive dressings unless directed by a physician.

- **Adverse Reactions:** The most common adverse reactions (incidence >1%) were skin atrophy, telangiectasia, discomfort of skin, and dry skin.
- **Cost Comparison:**

Medication	Cost Per Unit	Cost Per Package
Impeklo® (clobetasol propionate 0.05% lotion) with metered-dose pump	**$7.35/g**	**$499.80/68g**
clobetasol propionate 0.05% lotion (generic)	$0.58/mL	$68.44/118mL

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).

Recommendations

The College of Pharmacy recommends moving clobetasol propionate 0.05% lotion (Clobex®) from Tier-2 to Tier-1 and recommends adding Impeklo® (clobetasol propionate 0.05% lotion) to Tier-3 of the Ultra-High to High Potency Topical Corticosteroids Product Based Prior Authorization (PBPA) category; current Tier-3 criteria will apply for Impeklo® (changes noted in red in the following Tier chart):

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (Diprolene AF®)	C,G	amcinonide 0.1%	C,L	clobetasol propionate 0.05% (Clobex®)	Sh,Spr
clobetasol propionate 0.05% (Clobex®)	**L**	augmented betamethasone dipropionate 0.05% (Diprolene®)	L,O	clobetasol propionate 0.05% (Olux®, Olux-E®, Tovet®)	F

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
clobetasol propionate 0.05% (Temovate®)	C,O, So	betamethasone dipropionate 0.05% (Diprosone®)	C,O	**clobetasol propionate 0.05% (Impeklo®)**	**L**
fluocinonide 0.05%	C,O,So	~~**clobetasol propionate 0.05% (Clobex®)**~~	~~**L**~~	desoximetasone 0.25% (Topicort®)	C,O,Spr
halobetasol propionate 0.05% (Ultravate®)	C	clobetasol propionate 0.05% (Temovate®)	G	diflorasone diacetate 0.05% (Apexicon®)	C,O
		desoximetasone 0.05% (Topicort®)	G	diflorasone diacetate/ emollient 0.05% (Apexicon E®)	C
		fluocinonide 0.05%	G	halobetasol propionate 0.01% (Bryhali®)	L
		fluocinonide 0.1% (Vanos®)	C	halobetasol propionate 0.05% (Lexette®)	F
		flurandrenolide tape 0.05% (Cordran®)	Tape		
		halcinonide 0.1% (Halog®)	C,O,So		
		halobetasol propionate 0.05% (Ultravate®)	L,O		
		halobetasol propionate/lactic acid 0.05%/10% (Ultravate X®)	C		
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	L	betamethasone dipropionate/ calcipotriene 0.064%/0.005% (Taclonex®)	O,Spr, Sus	hydrocortisone valerate 0.2% (Westcort®)	C,O
betamethasone valerate 0.1% (Beta-Val®)	C,L,O	betamethasone dipropionate/ calcipotriene 0.064%/0.005% (Enstilar® Foam)	F		

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
fluticasone propionate 0.05% (Cutivate®)	C,O	betamethasone valerate 0.12% (Luxiq®)	F		
mometasone furoate 0.1% (Elocon®)	C,L,O, So	clocortolone pivalate 0.1% (Cloderm®)	C		
triamcinolone acetonide 0.025%	O	desoximetasone 0.05% (Topicort LP®)	C,O		
triamcinolone acetonide 0.1%	C,L,O	fluocinolone acetonide 0.025% (Synalar®)	C,O		
triamcinolone acetonide 0.5%	C,O	fluocinonide emollient 0.05% (Lidex E®)	C		
		flurandrenolide 0.05%	C,L,O		
		fluticasone propionate 0.05% (Cutivate®)	L		
		hydrocortisone butyrate 0.1%	C,L,O, So		
		hydrocortisone probutate 0.1% (Pandel®)	C		
		prednicarbate 0.1% (Dermatop®)	C,O		
		triamcinolone acetonide 0.147mg/g (Kenalog®)	Spr		
		triamcinolone acetonide 0.05% (Trianex®)	O		
Low Potency					
desonide 0.05% (Desonate®)	G	alclometasone dipropionate 0.05% (Aclovate®)	C,O	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®)	Oil
fluocinolone acetonide 0.01% (Capex®)	Sh	fluocinolone acetonide 0.01% (Synalar®)	C,So	desonide 0.05%	L
hydrocortisone acetate 1%	C,O	hydrocortisone 2.5% (Texacort®)	So	desonide emollient 0.05%	C,O

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
hydrocortisone acetate 2.5%	C,L,O	hydrocortisone/ pramoxine 1%/1% (Pramosone®)	C,L		
hydrocortisone/urea 1%/10% (U-Cort®)	C				
triamcinolone acetonide 0.025%	C,L				

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
C = cream; F = foam; G = gel; L = lotion; O = ointment; Sh = shampoo; So = solution; Spr = spray; Sus = suspension

Topical Corticosteroids Tier-3 Approval Criteria:

1. Documented trials of all Tier-1 and Tier-2 topical corticosteroids of similar potency in the past 90 days that did not yield adequate relief; and
2. If Tier-1 and Tier-2 trials are completed and do not yield adequate relief, a patient-specific, clinically significant reason for requesting a Tier-3 medication in the same potency instead of trying a higher potency medication must be provided; and
3. When the same medication is available in Tier-1 or Tier-2, a patient-specific, clinically significant reason must be provided for using a special dosage formulation of that medication in Tier-3 (e.g., foams, shampoos, sprays, kits); and
4. Topical corticosteroid kits require tier trials and a patient-specific, clinically significant reason for use of the kit over other standard formulations.

[1] Impeklo® (Clobetasol Propionate) – New Drug Approval. *OptumRx*®. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_impeklo_2020-0526.pdf. Issued 2020. Last accessed 08/10/2021.
[2] Impeklo® (Clobetasol Propionate) Prescribing Information. Mylan. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213691s000lbl.pdf. Last revised 05/2020. Last accessed 08/10/2021.

Appendix G

Vote to Update the Approval Criteria for the Ophthalmic Anti-Inflammatory Products

Oklahoma Health Care Authority
September 2021

Recommendations

The College of Pharmacy recommends the following changes to the ophthalmic corticosteroids and ophthalmic non-steroidal anti-inflammatory drugs (NSAIDs) Product Based Prior Authorization (PBPA) categories (changes noted in red in the following PBPA Tier charts):

1. Moving brand name Lotemax® (loteprednol) 0.5% gel and 0.5% ointment from Tier-2 to Tier-1 in the Ophthalmic Corticosteroids PBPA Tier chart based on net costs
2. Moving Ilevro® (nepafenac) 0.3% suspension from Tier-1 to Tier-2 in the Ophthalmic NSAIDs PBPA Tier chart based on net costs; current Tier-2 criteria will apply

Ophthalmic Corticosteroids	
Tier-1	**Tier-2**
dexamethasone 0.1% sus (Maxidex®)	fluorometholone 0.25% sus (FML Forte®)
dexamethasone sodium phosphate 0.1% sol	fluorometholone 0.1% oint (FML S.O.P®)
difluprednate 0.05% emu (Durezol®)	loteprednol 1% sus (Inveltys®)
fluorometholone 0.1% sus (Flarex®)	~~**loteprednol 0.5% gel (Lotemax®)**~~
fluorometholone 0.1% sus (FML Liquifilm®)	~~**loteprednol 0.5% oint (Lotemax®)**~~
loteprednol 0.5% **gel, oint,** sus (Lotemax®) – **Brand Preferred**	loteprednol 0.38% gel (Lotemax® SM)
prednisolone acetate 1% sus (Omnipred®)	prednisolone acetate 1% sus (Pred Forte®)
prednisolone acetate 0.12% sus (Pred Mild®)	
prednisolone sodium phosphate 1% sol	

emu = emulsion; oint = ointment; sol = solution; sus = suspension
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

Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	
Tier-1	**Tier-2**
diclofenac 0.1% sol (Voltaren®)	bromfenac 0.09% sol (Bromday®)
flurbiprofen 0.03% sol[Δ] (Ocufen®)	bromfenac 0.075% sol (BromSite®)
ketorolac 0.5% sol (Acular®)	bromfenac 0.07% sol (Prolensa®)
~~**nepafenac 0.3% sus (Ilevro®)**~~	ketorolac 0.4% sol (Acular LS®)
	ketorolac 0.45% sol (Acuvail®)
	nepafenac 0.1% sus (Nevanac®)
	nepafenac 0.3% sus (Ilevro®)

sol = solution; sus = suspension
[Δ]Not a required Tier-1 trial; does not have to be attempted for approval of a Tier-2 medication.
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).

Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Tier-2 Approval Criteria:

1. Documented trials of all Tier-1 ophthalmic NSAIDs (from different medication lines) in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
2. Contraindication(s) to all lower tiered medications; or
3. A unique indication for which the Tier-1 ophthalmic NSAIDs lack.

Appendix H

Vote to Prior Authorize Nulibry™ (Fosdenopterin)

Oklahoma Health Care Authority
September 2021

Market News and Updates[1]

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

- **February 2021:** The FDA approved Nulibry™ (fosdenopterin) to reduce the risk of death due to molybdenum cofactor deficiency (MoCD) Type A. Prior to the approval of Nulibry™, the only treatment options were supportive care and therapies directed towards the complications caused by the disease. Patients with MoCD Type A lack a substance known as cyclic pyranopterin monophosphate (cPMP). Nulibry™ is an intravenous (IV) replacement for the missing cPMP, and patients treated with Nulibry™ in clinical trials had a survival rate of 84% at 3 years, compared to 55% for untreated patients in a natural history cohort. The most common adverse reactions were catheter-related complications, fever, respiratory infections, vomiting, and diarrhea. Patients treated with Nulibry™ should avoid sunlight and wear sunscreen and protective clothing when exposed to the sun.

Nulibry™ (Fosdenopterin) Product Summary[2]

Indication(s): To reduce the risk of mortality in patients with MoCD Type A

How Supplied: 9.5mg of fosdenopterin as a lyophilized powder in a single-dose vial (SDV) for reconstitution

Dosing and Administration:

- 1 year of age or older: 0.9mg/kg given as an IV infusion once daily
- Younger than 1 year of age: Refer to the following table for the recommended dosage given as an IV infusion once daily:

Titration Schedule	Preterm Neonates (GSA <37 weeks)	Term Neonates (GSA >37 weeks)
Initial Dosage	0.4mg/kg once daily	0.55mg/kg once daily
Dosage at Month 1	0.7mg/kg once daily	0.75mg/kg once daily
Dosage at Month 3 and Thereafter	0.9mg/kg once daily	0.9mg/kg once daily

GSA = gestational age

- Nulibry™ is intended for administration by a health care provider. If deemed appropriate by a health care provider, Nulibry™ may be administered at home by the patient's caregiver.
- Administration of Nulibry™ must be completed within 4 hours of reconstitution.

Cost: The Wholesale Acquisition Cost (WAC) of Nulibry™ is $1,369.86 per SDV. The estimated annual cost for a patient 1 year of age or older weighing <10.5kg would be $499,998.90.

Recommendations

The College of Pharmacy recommends the prior authorization of Nulibry™ (fosdenopterin) with the following criteria:

Nulibry™ (Fosdenopterin) Approval Criteria:

1. An FDA approved indication to reduce the risk of mortality in members with molybdenum cofactor deficiency (MoCD) Type A; and
2. MoCD Type A must be confirmed by genetic testing; and
    a. If the member is presumed to have MoCD Type A, Nulibry™ can be approved for 1 month until genetic testing can be performed; and
    b. Nulibry™ will be discontinued if genetic testing results do not confirm MoCD Type A; and
3. Nulibry™ must be administered by a health care provider or the prescriber must verify the member or member's caregiver has been trained by a health care professional on proper storage, preparation, and intravenous (IV) administration of Nulibry™; and
4. Member's weight (kg) must be provided and must have been taken within the last 4 weeks to ensure accurate weight-based dosing according to package labeling; and
5. Approval quantities will be dependent on the member's age, weight, and dosing based on the Nulibry™ *Prescribing Information*.

[1] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for Molybdenum Cofactor Deficiency Type A. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-molybdenum-cofactor-deficiency-type. Issued 02/26/2021. Last accessed 08/10/2021.

[2] Nulibry™ Prescribing Information. Origin Biosciences, Inc. Available online at: https://www.nulibry.com/pdfs/nulibry-prescribing-information-v2.pdf. Last revised 02/2021. Last accessed 08/10/2021.

Appendix I

Vote to Prior Authorize Danyelza® (Naxitamab-gqgk) and Truseltiq™ (Infigratinib)

Oklahoma Health Care Authority
September 2021

Market News and Updates[1]

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

- **November 2020:** The FDA granted accelerated approval to Danyelza® (naxitamab-gqgk) in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF) for adult patients and pediatric patients 1 year of age and older with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow demonstrating a partial response, minor response, or stable disease to prior therapy.
- **May 2021:** The FDA granted accelerated approval to Truseltiq™ (infigratinib) for adults with previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement.

Product Summaries[2,3]

Danyelza® (Naxitamab-gqgk):

- **Therapeutic Class:** Disialoganglioside (GD2)-binding monoclonal antibody
- **Indication(s):** For use in combination with a GM-CSF, for the treatment of adult patients and pediatric patients 1 year of age and older with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease on prior therapy
- **How Supplied:** Sterile, preservative-free 40mg/10mL (4mg/mL) solution in single-dose vials (SDVs)
- **Dose:**
  - 3mg/kg/day (up to 150mg/day), via intravenous (IV) infusion on days 1, 3, and 5 of each treatment cycle (4 weeks) until complete or partial response, followed by 5 additional cycles every 4 weeks; subsequent cycles may be repeated every 8 weeks
- **Cost:** The Wholesale Acquisition Cost (WAC) is $20,368 per SDV, resulting in a cost of $244,416 every 4 weeks for the maximum dose of 150mg/day on cycle days 1, 3, and 5.

Truseltiq™ (Infigratinib):

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):** Previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or other rearrangement
- **How Supplied:** 25mg and 100mg oral capsules supplied in 21-day blister pack dose presentations as follows:
  - 50mg daily dose: (42) 25mg capsules
  - 75mg daily dose: (63) 25mg capsules
  - 100mg daily dose: (21) 100mg capsules
  - 125mg daily dose: (21) 100mg capsules and (21) 25mg capsules
- **Dose:**
  - 125mg once daily for 21 consecutive days followed by 7 days off therapy in 28-day cycles
  - Dose reduction is recommended for mild or moderate hepatic impairment, mild or moderate renal impairment, and adverse reactions
- **Cost:** The WAC per capsule ranges from $341.27 to $1,023.81, resulting in an approximate cost of $21,500 per 21-day blister pack.

Recommendations

The College of Pharmacy recommends the prior authorization of Danyelza® (naxitamab-gqgk) and Truseltiq™ (infigratinib) with the following 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.

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.

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[1] U.S. Food and Drug Administration (FDA). Hematology/Oncology (Cancer) Approvals & Safety Notifications. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/hematologyoncology-cancer-approvals-safety-notifications. Last revised 08/04/2021. Last accessed 08/09/2021.

[2] Danyelza® Prescribing Information. Y-mAbs Therapeutics, Inc. Available online at: https://labeling.ymabs.com/danyelza. Last revised 11/2020. Last accessed 08/09/2021.

[3] Truseltiq™ Prescribing Information. QED Therapeutics, Inc. Available online at: https://www.truseltiq.com/pdfs/prescribing-information.pdf. Last revised 05/2021. Last accessed 08/09/2021.

Appendix J

Vote to Prior Authorize Feraheme® (Ferumoxytol), Injectafer® (Ferric Carboxymaltose), and Monoferric® (Ferric Derisomaltose)

Oklahoma Health Care Authority
September 2021

Market News and Updates[1,2]

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

- **January 2020:** The FDA approved Monoferric® (ferric derisomaltose injection) for the treatment of iron deficiency anemia (IDA) in adult patients with an intolerance or unsatisfactory response to oral iron or with non-hemodialysis dependent chronic kidney disease (CKD). Monoferric® was approved as a single-dose treatment option for IDA. The approval of Monoferric® was based on data from 2 randomized, open-label studies in 3,050 adults with IDA which demonstrated that Monoferric® was noninferior to iron sucrose for the primary efficacy endpoint, change in hemoglobin from baseline to week 8.
- **April 2021:** The FDA approved Injectafer® (ferric carboxymaltose injection) for a new single-dose regimen. Patients weighing ≥50kg may now receive a 15mg/kg dose, up to a maximum of 1,000mg, as a single-dose treatment course. The previous FDA approved regimen for Injectafer® for patients weighing ≥50kg was (2) 750mg doses separated by at least 7 days for a total of 1,500mg per treatment course. The approval of the new single-dose regimen was based on data from 2 randomized, open-label studies evaluating the safety and tolerability of Injectafer® as a single dose up to a maximum of 1,000mg in patients weighing ≥50kg. The manufacturer of Injectafer® plans to launch a new 1,000mg single-dose vial (SDV) for use with the new regimen.

Product Summaries[3,4,5]

Feraheme® (Ferumoxytol Injection):

- **Indication(s):** Feraheme® (ferumoxytol injection) is indicated for the treatment of IDA in adult patients with:
  - Intolerance or unsatisfactory response to oral iron; or
  - CKD

Boxed Warning: Risk for Serious Hypersensitivity/Anaphylaxis Reactions

- Fatal and serious hypersensitivity reactions including anaphylaxis have occurred in patients receiving Feraheme®. Initial symptoms may include hypotension, syncope, unresponsiveness, and cardiac/ cardiorespiratory arrest.
  - Feraheme® should only be administered as an intravenous (IV) infusion over at least 15 minutes and only when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.
  - Patients should be observed for signs or symptoms of hypersensitivity reactions during and for at least 30 minutes following Feraheme® infusion including monitoring of blood pressure and pulse during and after administration.
  - Hypersensitivity reactions have occurred in patients in whom a previous Feraheme® dose was tolerated.

- **How Supplied:** SDV containing 510mg/17mL (30mg/mL) of elemental iron
- **Dosing and Administration:**
  - (2) 510mg doses administered 3 to 8 days apart
  - Should be administered as an IV infusion in 50-200mL 0.9% sodium chloride or 5% dextrose over at least 15 minutes
  - Hematologic response (e.g., hemoglobin, ferritin, iron, transferrin saturation) should be evaluated at least 1 month after the second dose of Feraheme®
  - May be readministered to patients with persistent or recurrent IDA
  - For patients receiving hemodialysis, Feraheme® should be administered once the blood pressure is stable and after at least 1 hour of hemodialysis has been completed; signs and symptoms of hypotension should be monitored following each Feraheme® infusion
- **Contraindication(s):**
  - Known hypersensitivity to Feraheme® or any of its components
  - History of allergic reaction to any IV iron product

Injectafer® (Ferric Carboxymaltose Injection):

- **Indication(s):** Injectafer® (ferric carboxymaltose injection) is indicated for the treatment of IDA in adult patients with:
  - Intolerance or unsatisfactory response to oral iron; or
  - Non-dialysis dependent CKD
- **How Supplied:** SDVs containing 750mg/15mL or 1,000mg/20mL (50mg/mL) of elemental iron

- **Dosing and Administration:**
  - Patients weighing ≥50kg:
    - (2) 750mg doses administered at least 7 days apart; or
    - 15mg/kg, up to a maximum of 1,000mg, as a single dose
  - Patients weighing <50kg:
    - (2) 15mg/kg doses administered at least 7 days apart
  - May be administered by IV infusion or as an undiluted slow IV push
  - For IV infusion, up to 1,000mg of Injectafer® should be diluted in ≤250mL 0.9% sodium chloride with a concentration ≥2mg of iron per mL and should be administered over at least 15 minutes
  - For IV push, Injectafer® 750mg should be administered at the rate of approximately 100mg (2mL) per minute and the 1,000mg dose should be administered slowly over 15 minutes; patients should be monitored for extravasation and use of the administration site should be discontinued if extravasation occurs
  - May be repeated if IDA reoccurs
- **Contraindication(s):**
  - History of hypersensitivity to Injectafer® or any of its components

Monoferric® (Ferric Derisomaltose Injection):

- **Indication(s):** Monoferric® (ferric derisomaltose injection) is indicated for the treatment of IDA in adult patients with:
  - Intolerance or unsatisfactory response to oral iron; or
  - Non-hemodialysis dependent CKD
- **How Supplied:** SDV containing 1,000mg/10mL (100mg/mL) of elemental iron
- **Dosing and Administration:**
  - Patients weighing ≥50kg:
    - 1,000mg as a single dose
  - Patients weighing <50kg:
    - 20mg/kg as a single dose
  - Should be diluted in 100 to 500mL 0.9% sodium chloride to a final concentration >1mg of iron per mL and administered by IV infusion over at least 20 minutes
  - May be repeated if IDA reoccurs
- **Contraindication(s):**
  - Serious hypersensitivity to Monoferric® or any of its components

Cost Comparison

Product	Cost Per mg	Cost Per Treatment Course*
Monoferric® (ferric derisomaltose inj) 1,000mg/10mL	**$2.46**	**$2,460.00**
Injectafer® (ferric carboxymaltose inj) 750mg/15mL	**$1.13**	**$1,695.00**
Feraheme® (ferumoxytol inj) 510mg/17mL	**$0.95**	**$969.00**
Infed® (iron dextran inj) 100mg/2mL	$0.32	$315.80
Venofer® (iron sucrose inj) 200mg/2mL	$0.22	$220.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per treatment course based on 1,000mg for Monoferric®, (2) 750mg doses for Injectafer®, (2) 510mg doses for Feraheme®, 1,000mg for Infed®, and (5) 200mg doses for Venofer®
inj = injection

Recommendations

The College of Pharmacy recommends the prior authorization of Feraheme® (ferumoxytol injection), Injectafer® (ferric carboxymaltose injection), and Monoferric® (ferric derisomaltose injection) with the following criteria:

Feraheme® (Ferumoxytol) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Iron deficiency anemia (IDA); or
   b. IDA with chronic kidney disease (CKD); and
2. Documented lab results verifying IDA; and
3. Documentation of intolerance or inadequate response to oral iron therapy after at least 3 months at recommended dosing; and
4. Prescriber must verify the member does not have a previous history of allergic reaction to any intravenous iron medications; and
5. A recent, failed trial of Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Infed® and Venofer® must be provided.

Injectafer® (Ferric Carboxymaltose) Approval Criteria:

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

Monoferric® (Ferric Derisomaltose) Approval Criteria:

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

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[1] Park B. Monoferric® Injection Approved for Iron Deficiency Anemia. *MPR*. Available online at: https://www.empr.com/home/news/monoferric-injection-approved-for-iron-deficiency-anemia/. Issued 01/30/2020. Last accessed 08/10/2021.

[2] Daiichi Sankyo, Inc. Injectafer® (Ferric Carboxymaltose Injection) Receives FDA Approval for Single Dose Option for the Treatment of Adult Patients with Iron Deficiency Anemia. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/injectafer-ferric-carboxymaltose-injection-receives-fda-approval-for-single-dose-option-for-the-treatment-of-adult-patients-with-iron-deficiency-anemia-301285079.html. Issued 05/06/2021. Last accessed 08/10/2021.

[3] Feraheme® (Ferumoxytol) Prescribing Information. AMAG Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022180s024lbl.pdf. Last revised 09/2020. Last accessed 08/10/2021.

[4] Injectafer® (Ferric Carboxymaltose) Prescribing Information. American Regent, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/203565s014lbl.pdf. Last revised 04/2021. Last accessed 08/10/2021.

[5] Monoferric® (Ferric Derisomaltose) Prescribing Information. Pharmacosmos Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208171s001lbl.pdf. Last revised 09/2020. Last accessed 08/10/2021.

Appendix K

Fiscal Year 2021 Annual Review of Synagis® (Palivizumab)

Oklahoma Health Care Authority
September 2021

Current Prior Authorization Criteria[1]

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

Synagis® (Palivizumab) Approval Criteria:

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

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

B. Length of Treatment: Palivizumab is approved for use only during RSV season. Approval dates will be November 1st through March 31st.
C. Units Authorized: The maximum duration of therapy is 5 doses, with a dose to be administered no more often than every 30 days. Members given doses more frequently than every 30 days will not be authorized for additional doses. Doses administered prior to the member's discharge from a hospital will be counted as 1 of the approved total.
D. Dose-Pooling: To avoid unnecessary risk to the patient, multiple patients are not to be treated from a single vial. Failure to follow this recommendation will result in referral of the provider to the Quality Assurance Committee of the Oklahoma Health Care Authority.

Utilization of Synagis® (Palivizumab): Fiscal Year 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	333	1,539	$3,781,909.64	$2,457.38	$81.93	1,329	46,158
2021	291	1,283	$3,186,343.30	$2,483.51	$82.78	1,108	38,490
% Change	**-12.60%**	**-16.60%**	**-15.70%**	**1.10%**	**1.00%**	**-16.60%**	**-16.60%**
Change	**-42**	**-256**	**-$595,566.34**	**$26.13**	**$0.85**	**-221**	**-7,668**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Pharmacy Claim Details for Fiscal Year 2021: [November 2020 – March 2021 Respiratory Syncytial Virus (RSV) Season]

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PALIVIZUMAB PRODUCTS						
SYNAGIS INJ 100MG/ML	839	270	$2,520,571.71	$3,004.26	3.11	79.11%
SYNAGIS INJ 50MG/0.5ML	444	205	$665,771.59	$1,499.49	2.17	20.89%
TOTAL	**1,283**	**291***	**$3,186,343.30**	**$2,483.51**	**4.41**	**100%**

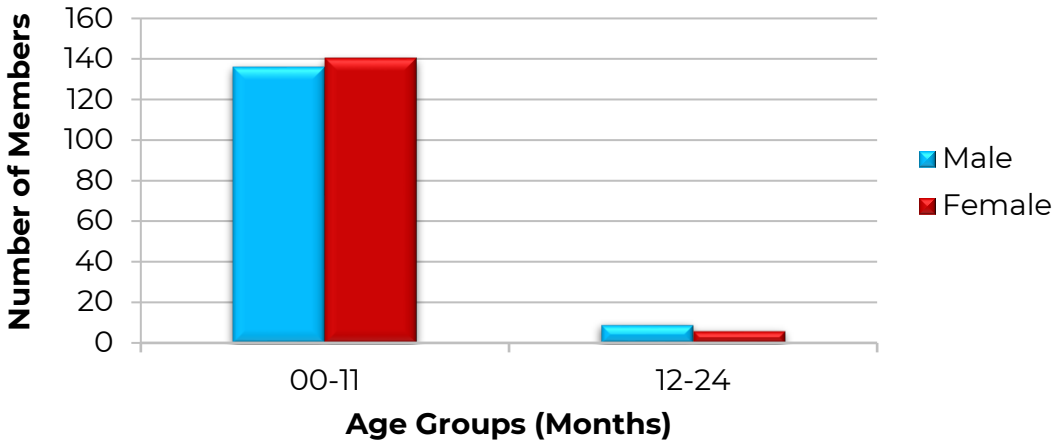
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection

Cost Per Vial

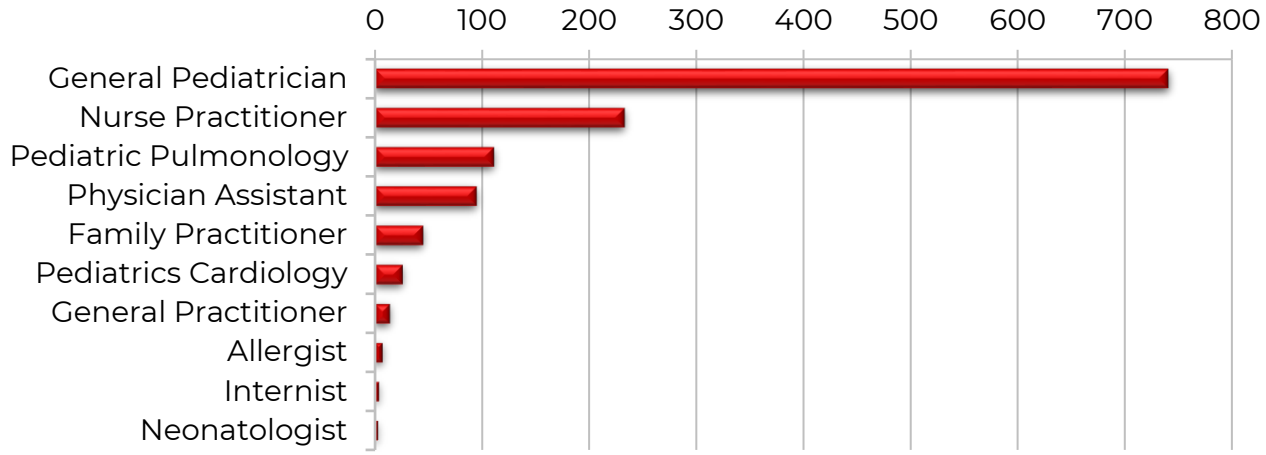
Vial Size	Cost Per Vial
Synagis® (palivizumab) 100mg/mL vial	$3,013.16
Synagis® (palivizumab) 50mg/0.5mL vial	$1,595.62

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

Demographics of Members Utilizing Synagis® (Palivizumab)

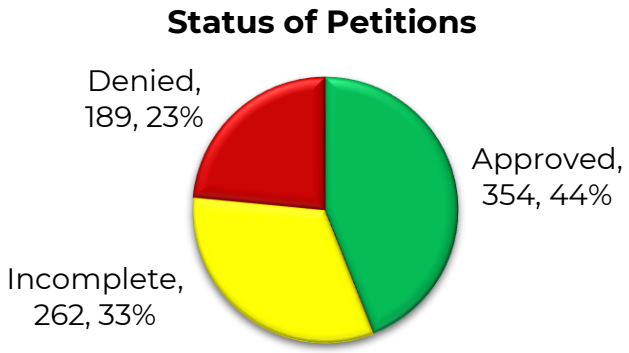


Top Prescriber Specialties of Synagis® (Palivizumab) by Number of Claims

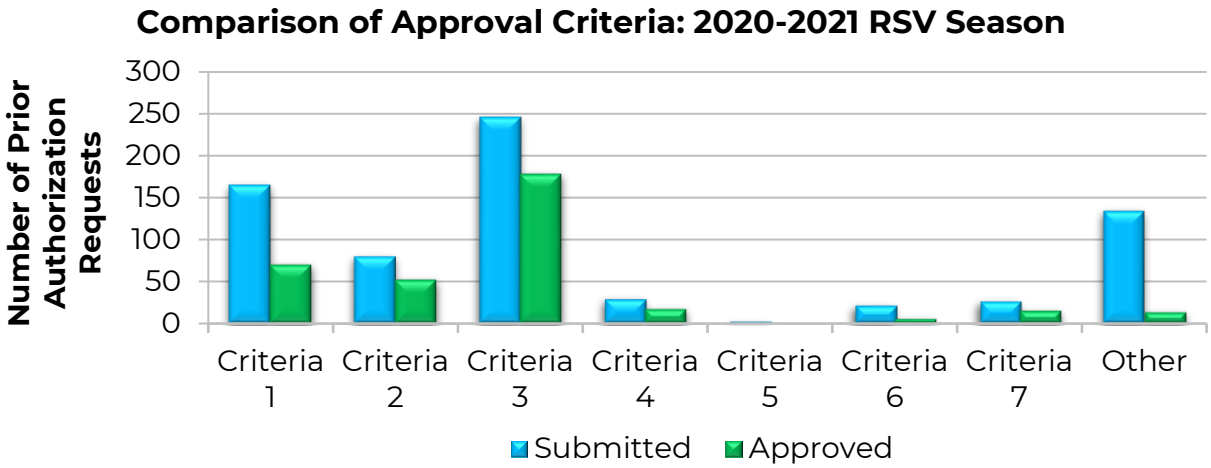


Prior Authorization of Synagis® (Palivizumab)

There were 805 palivizumab prior authorization requests submitted for 444 unique members during fiscal year 2021. This is a decrease in both submitted petitions and number of members requesting palivizumab compared to fiscal year 2020 when there were 1,081 palivizumab prior authorization requests submitted for 521 unique members. The following chart shows the status of the submitted petitions for fiscal year 2021.



The following graph shows the number of submissions and approvals for each prior authorization criteria. The graph is followed by a numbered list in which the list number corresponds to the criteria number in the graph. The most commonly requested and approved criteria selection during the 2020 to 2021 RSV season was criteria number 3: infants born before 29 weeks, 0 days gestation. Infants born before 32 weeks, 0 days gestation and who had chronic lung disease (CLD) of prematurity was also a commonly requested and approved criteria selection (criteria number 1).



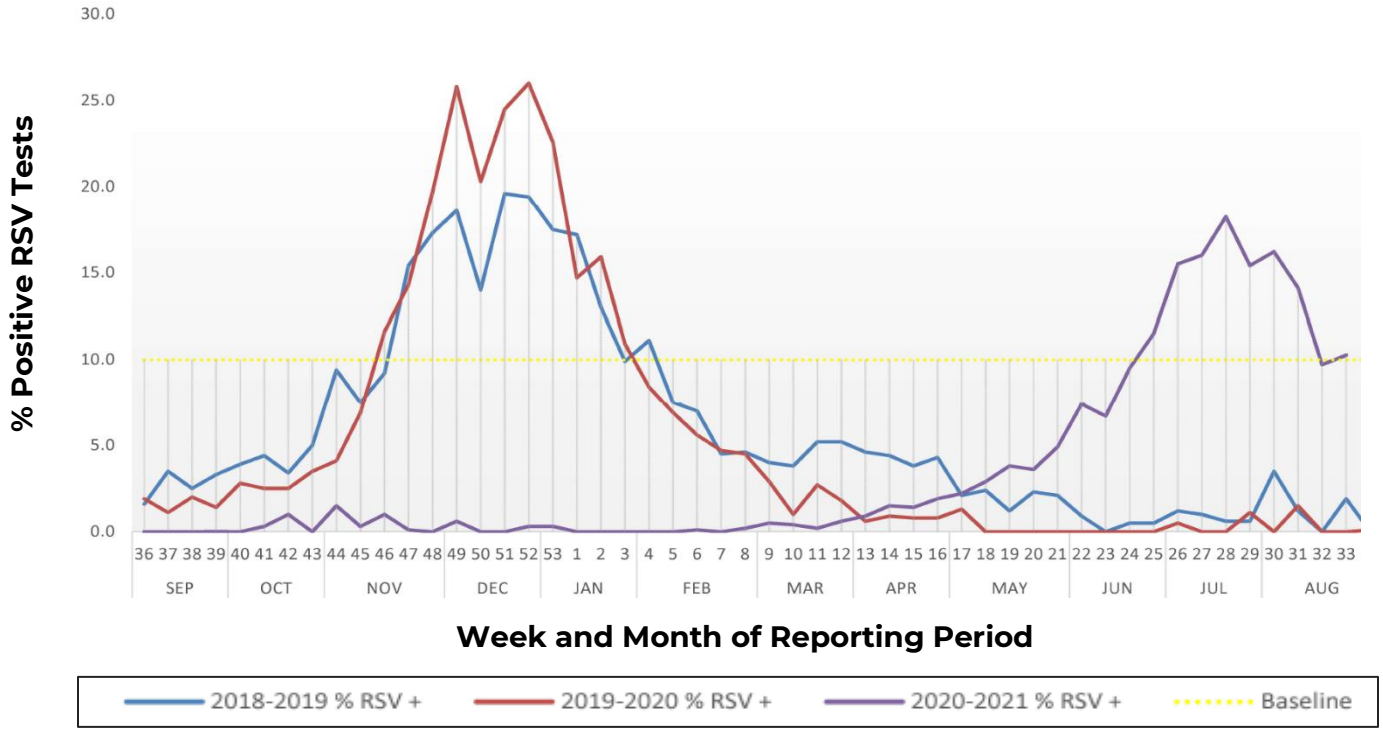
Criteria List:

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

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

The following chart contains the weekly percentage of laboratory positive RSV tests in Oklahoma as reported by the Oklahoma State Department of Health (OSDH) Viral Respiratory Illness Sentinel Surveillance System. The chart is included to compare RSV seasons since 2018. RSV is determined to be in season once the percentage of positive tests is >10% for 2 consecutive weeks. Similarly, the season is determined to be at an end when the percentage of positive tests is <10% for 2 consecutive weeks. RSV seasons appear to be similar with a peak typically in December or January and a season end by late March. SoonerCare palivizumab prior authorization approvals are initiated with a start date of November 1st and continue to March 31st; this approval window corresponds to the following state monitoring graph as well as with state data reported by the Centers for Disease Control and Prevention (CDC). For the 2020 to 2021 RSV season in Oklahoma, the percentage of positive antigen detection tests did not exceed the 10% threshold during the typical months of November 2020 through March 2021. Additional information about the recent atypical RSV season in Oklahoma is addressed in the Oklahoma Updates section of this report.

OSDH: Weekly Percentage of Laboratory Positive RSV Tests 2018-2021

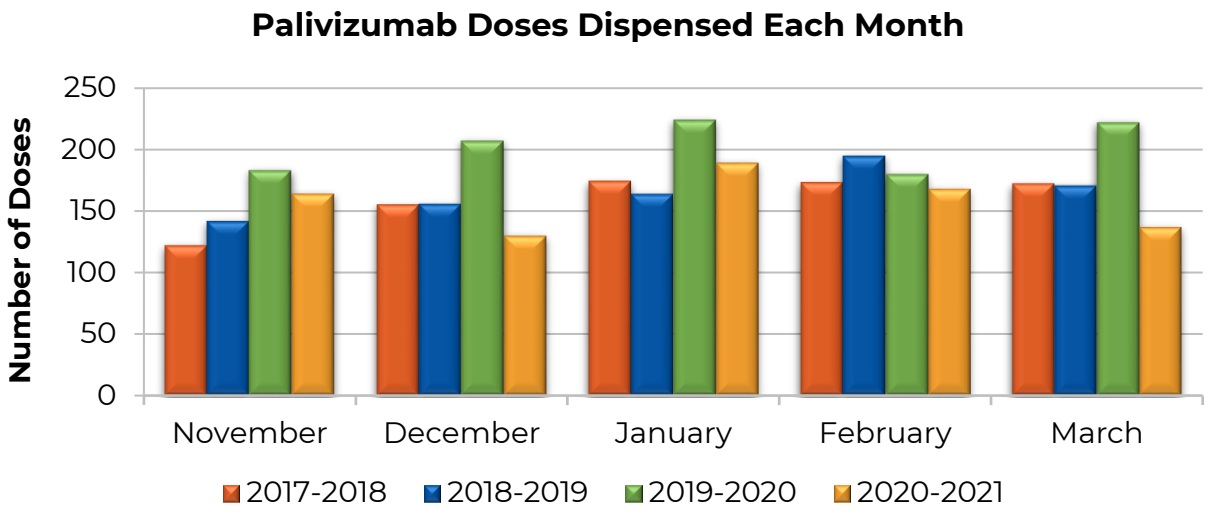


The CDC reported seasonality by using RSV polymerase chain reaction (PCR) laboratory detections. Laboratories are shifting away from antigen-based RSV testing, and since 2014, the majority of RSV detections among reporting laboratories were determined by PCR. RSV season onset, when evaluated by

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

> "During the 6 RSV seasons from July 2007 to January 2013, the median duration of the RSV season ranged from 13 to 23 weeks, with median peak activity from mid-December to early February, with the exception of Florida and Alaska. Within the 10 Health and Human Services Regions, in the few regions when the RSV season began in October, the season ended in March or early April. In regions where the RSV season began in November or December, the season ended by April or early May. Because 5 monthly doses of palivizumab at 15mg/kg per dose will provide more than 6 months of serum palivizumab concentrations above the desired serum concentration for most infants, administration of more than 5 monthly doses is not recommended within the continental United States."

The following bar graph shows the number of palivizumab doses reimbursed for by SoonerCare for each month during the last 4 typical RSV seasons. The number of doses dispensed each month was lower during the typical 2020-2021 RSV season compared to the 2019-2020 RSV season, corresponding with the lower number of prior authorization requests submitted.



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

News:

- **June 2021:** The CDC Health Alert Network (HAN) issued a health advisory to notify clinicians and caregivers about increased interseasonal RSV activity across parts of the southern United States, including Oklahoma. Based on this observed increase in RSV activity, the CDC has encouraged broader testing for RSV in patients who present with acute respiratory illness who test negative for SARS-CoV-2, the virus that causes COVID-19. Additionally, the advisory reminded health care personnel, childcare providers, and staff of long-term care facilities to avoid reporting to work while acutely ill, even if they test negative for SARS-CoV-2.
- **July 2021:** In the *Morbidity and Mortality Weekly Report (MMWR)*, the CDC reported that non-pharmaceutical interventions, such as masking and social distancing, introduced to mitigate the impact of COVID-19 have reduced the transmission of many common respiratory viruses in the United States. Circulation of RSV and other respiratory viruses decreased in early 2020 and did not increase again until spring 2021. Specifically for RSV, the weekly percentage of positive RSV tests in the United States decreased from 15.3% to 1.4% between January and April 2020. During the subsequent year, RSV circulation remained at historically low levels, with <1% of tests positive for RSV. Since April 2021, RSV activity has been increasing in the United States. During October 2020 – April 2021, the cumulative incidence of RSV-associated hospitalization was 0.3 per 100,000 persons, compared with 27.1 and 33.4 per 100,000 persons during the previous 2 RSV seasons. The duration of the effect of non-pharmaceutical interventions related to the COVID-19 pandemic on the circulation of other respiratory viruses is currently unknown.

- **August 2021:** The AAP released *Interim Guidance for Use of Palivizumab Prophylaxis to Prevent Hospitalization from Severe Respiratory Syncytial Virus Infection during the Current Atypical Interseasonal RSV Spread*. In regions experiencing high rates of RSV circulation, the AAP strongly supports consideration for the use of palivizumab in patients who would be candidates based on the eligibility recommendations outlined in the current 2014 AAP guidelines for palivizumab prophylaxis. Additionally, the need for palivizumab administration to these eligible infants during the atypical season should be supported where RSV activity approaches the fall-winter season and should be reassessed at least monthly. This interim guidance is not intended to supplant typical seasonal palivizumab administration guidance.

Pipeline:

- **EDP-938:** Enanta Pharmaceuticals is developing EDP-938, an N-protein inhibitor that targets RSV replication, for the treatment of RSV infection. The Phase 2b RSVP study of EDP-938 in adult outpatients with RSV is ongoing, with data expected in the first half of 2022. Additionally, in 2021, Enanta initiated 2 additional clinical studies: the Phase 2b RSVTx study in adult hematopoietic cell transplant recipients with RSV infection and the Phase 2 RSVPEDs study in pediatric patients with RSV.
- **GSK3844766A:** GlaxoSmithKline (GSK) is developing GSK3844766A, a vaccine candidate for the prevention of RSV in older adults. GSK3844766A contains a recombinant subunit pre-fusion RSV antigen (RSVPreF3) combined with a proprietary adjuvant (AS01), which is also used in GSK's shingles vaccine. In a previous Phase 1/2 study in young and older adults, GSK3844766A elicited robust humoral and cellular immunity compared with baseline, indicating the vaccine candidate can stimulate the immune system in older adults to produce a similar level of antibodies as young adults. In February 2021, GSK announced patient dosing has begun in the Phase 3 AReSVi 004 study, a randomized, open-label study which will assess the safety, reactogenicity, immunogenicity, and long-term persistence of immune response up to 3 years following vaccination with GSK3844766A in adults 60 years of age and older. GSK plans to enroll more than 10,000 patients in Phase 3 studies of GSK3844766A in older adults.
- **GSK3888550A:** GSK is also developing GSK3888550A, a vaccine candidate for the prevention of medically assessed RSV lower respiratory tract infection (LRTI) in infants during the first 6 months of life. GSK3888550A is being developed for maternal immunization to provide transfer of maternal antibodies, potentially allowing infants to be born with protection due to the passive transfer of neutralizing

antibodies from the mother to the unborn child in the last weeks of pregnancy. In November 2020, GSK announced patient dosing had begun in the Phase 3 GRACE study, a double-blind study in pregnant women 18 to 49 years of age for the prevention of medically assessed RSV LRTI in their newborn infants. Interim results from the study are expected by the second half of 2022.

- **IVX-121:** Icosavax is developing IVX-121, a novel, experimental RSV vaccine which incorporates a stabilized prefusion F antigen (DS-Cav1) licensed from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). Previously, DS-Cav1 showed early promise in a Phase 1 clinical study. An interim analysis of study data showed that 1 dose of DS-Cav1 prompted large increases in RSV-neutralizing antibodies in healthy adults that were sustained for several months. Icosavax plans to combine the prefusion F antigen with their virus-like-particle (VLP) technology, which may further enhance the magnitude, quality, and durability of the response to the prefusion RSV F antigen. Icosavax plans to initiate a new Phase 1 study of IVX-121 in the second half of 2021.
- **mRNA-1345:** Moderna is developing mRNA-1345 as a vaccine against RSV in vulnerable populations, including young children and older adults. mRNA-1345 encodes for a prefusion F glycoprotein, which elicits a superior neutralizing antibody response compared to the postfusion state, and is developed using the same lipid nanoparticle (LNP) as Moderna's COVID-19 vaccine. A Phase 1 study of mRNA-1345 to evaluate tolerability and reactogenicity in younger adults, older adults, and children is ongoing. In August 2021, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to mRNA-1435 as a vaccine against RSV in adults older than 60 years of age.
- **MVA-BN® RSV:** Bavarian Nordic is developing MVA-BN® RSV, a universal RSV vaccine. The vaccine incorporates 5 different RSV antigens to stimulate a broad immune response against both RSV subtypes (A and B), thus mimicking the immune response observed following a natural response to an RSV infection. The Phase 2 study in elderly patients included a revaccination of patients after 1 year, following which the immune responses were rapidly and significantly increased. Phase 2 study results have demonstrated that the vaccine induced broad and durable antibody and T-cell responses against RSV, as well as mucosal immune responses. A Phase 3 study, originally planned to start in 2021, has been postponed until 2022 due to the lower prevalence of RSV seen during the COVID-19 pandemic.
- **Nirsevimab (MEDI8897):** AstraZeneca is developing nirsevimab, an extended half-life RSV F monoclonal antibody (mAb) for the prevention of LRTI caused by RSV. Nirsevimab is being developed for use in late preterm and healthy full-term infants and is being developed so that it

may only require 1 dose during a typical 5-month RSV season. The FDA previously granted nirsevimab Breakthrough Therapy and Fast Track designations. In April 2021, AstraZeneca announced nirsevimab met its primary efficacy endpoint in the Phase 3 MELODY study of nirsevimab in healthy infants entering their first RSV season. Compared with placebo, the incidence of medically-attended RSV LRTI was statistically significantly lower in healthy late preterm and term infants who received nirsevimab during their first RSV season. In June 2021, AstraZeneca also announced results from the Phase 2/3 MEDLEY study which evaluated the safety and tolerability of nirsevimab compared to Synagis® in infants at high risk of RSV during their first RSV season. The study included infants with CLD, congenital heart disease, and/or prematurity and found the occurrence of treatment emergent adverse events or treatment emergent serious adverse events was similar between the 2 groups. With the results from MELODY, MEDLEY, and a previous Phase 2b study, AstraZeneca plans to submit for FDA approval of nirsevimab during the first half of 2022.

- **RSVpreF:** Pfizer is developing RSVpreF, a bivalent protein-based vaccine candidate for the prevention of RSV in adults. In July 2021, Pfizer provided an update on a Phase 2a virus challenge study evaluating the safety, immunogenicity, and efficacy of RSVpreF. In healthy adults 18 to 50 years of age, RSVpreF showed 100% efficacy against mild-to-moderate symptomatic RSV infection, with no serious vaccine-related adverse events observed. Pfizer plans to release additional data from the study at a future date, and a global Phase 3 study of RSVpreF in adults is expected to begin in September 2021.
- **Sisunatovir (RV521):** ReViral is developing sisunatovir, a potent, orally available inhibitor of the RSV F protein, for the treatment of RSV infection in pediatric, elderly, and immunocompromised patients. The FDA previously granted Fast Track designation to sisunatovir for the treatment of serious RSV infection in August 2020. The Phase 2 REVIRAL 1 and 2 studies are currently ongoing in pediatric and adult high-risk patients, respectively. In June 2021, ReViral announced that Part A of the REVIRAL 1 study had been completed and, following a review by the Data Safety Monitoring Committee, would advance to Part B of the study. REVIRAL 1 is a 3-part adaptive study which will evaluate the safety, tolerability, pharmacokinetic profile, antiviral effects, and clinical effects of single and multiple oral doses of sisunatovir in otherwise healthy infants from 1 to 36 months of age hospitalized with complications from RSV LRTI. In Part B of the study, patients will receive sisunatovir or placebo twice daily for 5 days.

Oklahoma Updates[7,22]

During the typical RSV season months of November 2020 through March 2021, the percentage of positive antigen detection tests in Oklahoma did not exceed the 10% threshold used to determine RSV season onset, likely due to nonpharmacological interventions (e.g., masking, social distancing, decreased travel) related to the ongoing COVID-19 pandemic. However, a delayed increase in positive RSV tests has been observed, with the current level of positive RSV tests in Oklahoma indicating an atypical RSV season onset. This delayed onset of the RSV season has been documented in other countries and other regions of the United States as well, and coincides with the relaxation of some COVID-19-related restrictions and interventions. Based on this information and data from OSDH indicating the percentage of positive RSV tests exceeded the 10% threshold, the Oklahoma Health Care Authority began covering Synagis® for RSV prophylaxis on 07/01/2021. Prior authorization requests for Synagis® during this new atypical RSV season are currently being reviewed on a month-to-month basis, with 07/01/2021 considered the start date of the new atypical season. Upon meeting the approval criteria, a prior authorization for 1 month can be issued. The OSDH RSV surveillance data is being reviewed regularly to determine the duration of this atypical season, and previously approved requests for Synagis® will be extended by an additional month, as necessary, while the percentage of positive RSV tests continues to exceed 10% in Oklahoma.

Recommendations

The College of Pharmacy recommends the following changes to the current Synagis® (palivizumab) prior authorization criteria based on recent variations in the RSV season in Oklahoma (changes noted in red):

Synagis® (Palivizumab) Approval Criteria:

A. Member Selection:
   1. Infants younger than 12 months of age at the start of respiratory syncytial virus (RSV) season:
      a. Born before 29 weeks, 0 days gestation; or
      b. Born before 32 weeks, 0 days gestation and develop chronic lung disease (CLD) of prematurity (require >21% oxygen supplementation for ≥28 days after birth); or
      c. Have hemodynamically significant congenital heart disease [acyanotic heart disease and receiving medication to control congestive heart failure (CHF) and will require surgical procedures, or have moderate-to-severe pulmonary hypertension]; or
      d. May be considered for:

i. Infants with neuromuscular disease or a congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough; or
ii. Infants who undergo cardiac transplantation during RSV season; or
iii. Infants who are profoundly immunocompromised during RSV season; or
iv. Infants with cystic fibrosis with clinical evidence of CLD and/or are nutritionally compromised; or

2. Infants 12 to 24 months of age at the start of RSV season:
   a. Born before 32 weeks, 0 days gestation and have CLD of prematurity (required ≥28 days of oxygen after birth) and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6 months before the start of the RSV season; or
   b. May be considered for:
      i. Infants who undergo cardiac transplantation during RSV season; or
      ii. Infants who are profoundly immunocompromised during RSV season; or
      iii. Infants with cystic fibrosis with manifestations of severe lung disease or weight for length less than the 10th percentile.

B. Length of Treatment: Palivizumab is approved for use only during RSV season in Oklahoma as determined by the Oklahoma State Department of Health (OSDH) Viral Respiratory Illness Sentinel Surveillance System or other credible statewide monitoring system. The threshold for determining RSV seasonality is 10% of positive tests. RSV is determined to be in season once the percentage of positive tests is >10%; however, due to a potential lag in reporting data, palivizumab coverage will begin when the percentage of positive tests is consistently increasing and approaching the 10% threshold. RSV season is determined to be at an end when the percentage of positive tests is consistently <10%. ~~Approval dates will be November 1st through March 31st.~~ Initial approvals will be for the duration of 3 months from the determined RSV season start date in Oklahoma. Subsequent approvals will be for the duration of 1 month until RSV season end. A separate prior authorization request will be required for consideration of initial approval and for each subsequent approval.

C. Units Authorized: The member's current weight (taken within the last 3 weeks) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling. ~~The maximum duration of therapy is 5 doses, with a~~ Doses are to be administered no more often than every 30 days.

Members given doses more frequently than every 30 days will not be authorized for additional doses. Doses administered prior to the member's discharge from a hospital will be counted as 1 of the approved total.

D. Dose-Pooling: To avoid unnecessary risk to the patient, multiple patients are not to be treated from a single vial. Failure to follow this recommendation will result in referral of the provider to the Quality Assurance Committee of the Oklahoma Health Care Authority.

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Appendix L

Fiscal Year 2021 Annual Review of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators

Oklahoma Health Care Authority
September 2021

Current Prior Authorization Criteria

Kalydeco® (Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) with a mutation in the CF transmembrane conductance regulator *(CFTR)* gene detected by genetic testing that is responsive to ivacaftor based on clinical and/or *in vitro* assay data; and
2. Documentation must be submitted with results of *CFTR* genetic testing; and
3. Member must be 4 months of age or older; and
4. A quantity limit of 2 tablets or granule packets per day or 56 tablets or granule packets per 28 days will apply; and
5. An age restriction of 4 months to younger than 6 years of age will apply to Kalydeco® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
6. Initial approval will be for the duration of 3 months, after which time compliance will be required for continued approval. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval.

Orkambi® (Lumacaftor/Ivacaftor) Approval Criteria:

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

6. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Orkambi®, every 3 months during the first year of treatment, and annually thereafter; and
7. Member must not be taking any of the following medications concomitantly with Orkambi®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort; and
8. A quantity limit of 4 tablets per day or 112 tablets per 28 days will apply or a quantity limit of 2 granule packets per day or 56 packets per 28 days will apply; and
9. An age restriction of 2 years to younger than 6 years of age will apply to Orkambi® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
10. Initial approval will be for the duration of 3 months, after which time compliance will be required for continued approval. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval.

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

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation or who have at least 1 mutation in the CF transmembrane conductance regulator *(CFTR)* gene detected by genetic testing that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence; and
2. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and
3. Member must be 6 years of age or older; and
4. Members using Symdeko® must be supervised by a pulmonary specialist; and
5. If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) and experiencing adverse effects associated with Orkambi® use, the prescriber must indicate that information on the prior authorization request; and
6. Prescriber must verify that member has been counseled on proper administration of Symdeko® including taking with a fat-containing food; and
7. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Symdeko®, every 3 months during the first year of treatment, and annually thereafter; and

8. Member must not be taking any of the following medications concomitantly with Symdeko®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort; and
9. A quantity limit of 2 tablets per day or 56 tablets per 28 days will apply; and
10. Initial approval will be for the duration of 3 months, after which time compliance will be required for continued approval. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events must be provided for members who switched from Orkambi® to Symdeko®.

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

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

11. A quantity limit of 3 tablets per day or 84 tablets per 28 days will apply; and
12. Initial approval will be for the duration of 3 months, after which time compliance will be required for continued approval. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor).

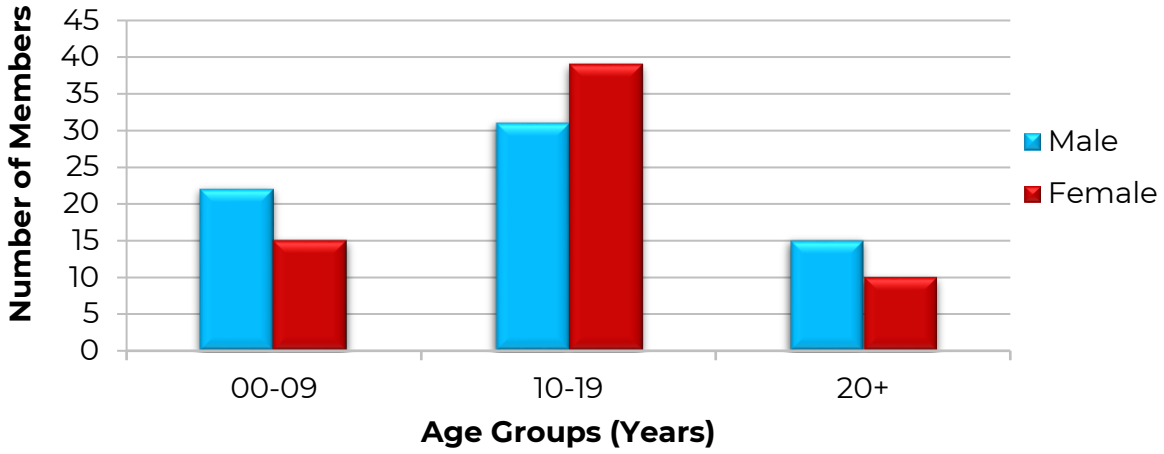
Utilization of CFTR Modulators: Fiscal Year 2021

Comparison of Fiscal Years:

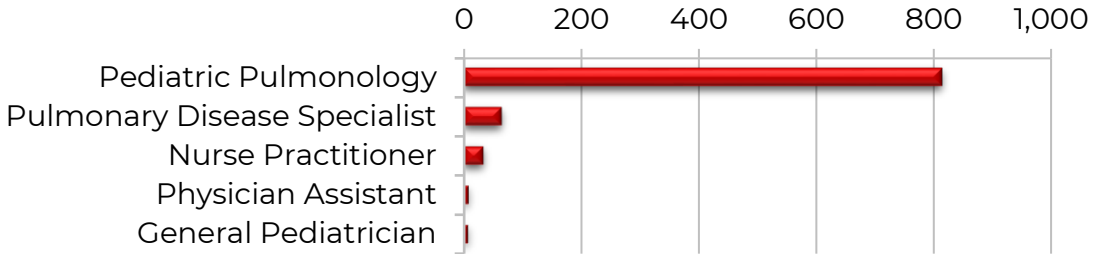
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	108	926	$20,670,236.40	$22,322.07	$797.22	65,100	25,928
2021	132	1,182	$26,612,806.14	$22,515.06	$804.11	88,060	33,096
% Change	**22.20%**	**27.60%**	**28.70%**	**0.90%**	**0.90%**	**35.30%**	**27.60%**
Change	**24**	**256**	**$5,942,569.74**	**$192.99**	**$6.89**	**22,960**	**7,168**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing CFTR Modulators



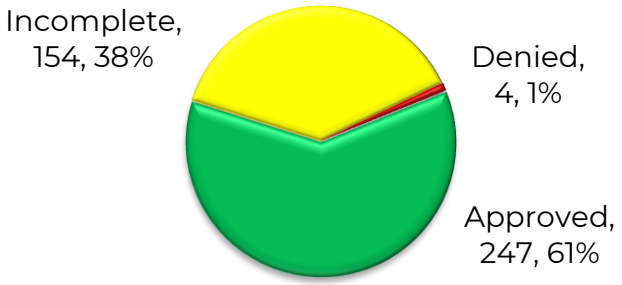
Top Prescriber Specialties of CFTR Modulators by Number of Claims



Prior Authorization of CFTR Modulators

There were 405 prior authorization requests submitted for CFTR modulators during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Kalydeco® (ivacaftor tablets): August 2029
- Orkambi® (lumacaftor/ivacaftor tablets and granules): December 2030
- Kalydeco® (ivacaftor granules): February 2033
- Symdeko® (tezacaftor/ivacaftor and ivacaftor tablets): April 2035
- Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor tablets): December 2037

News:

- **December 2020:** The U.S. Food and Drug Administration (FDA) expanded the eligibility for Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) to include patients with cystic fibrosis (CF) 12 years of age and older with certain mutations in the *CFTR* gene that are responsive to Trikafta® based on *in vitro* data. Symdeko® (tezacaftor/ivacaftor and ivacaftor) and Kalydeco® (ivacaftor) also received approvals to include additional responsive mutations in patients with CF 6 years of age and older and 4 months of age and older, respectively. These approvals

allow more than 600 patients with CF not previously eligible for these medications an opportunity to potentially benefit from treatment that targets the underlying cause of their disease. Trikafta® was previously approved for patients with at least 1 *F508del* mutation and is now approved for 177 additional mutations; Symdeko® is now approved for 127 additional mutations, for a total of 154 Symdeko®-responsive mutations; Kalydeco® is now approved for an additional 59 mutations, for a total of 97 Kalydeco®-responsive mutations. In addition, for certain patients with CF who are currently eligible for Kalydeco®, this approval allows them to also be eligible for Symdeko® or Trikafta®; similarly, for those who are currently eligible for Symdeko®, this approval allows them to also be eligible for treatment with Trikafta®.

- **June 2021:** Vertex Pharmaceuticals announced the FDA approved the expanded use of Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) to include children with CF ages 6 through 11 years of age who have at least 1 *F508del* mutation in the *CFTR* gene or a mutation in the *CFTR* gene that is responsive to Trikafta® based on *in vitro* data. Trikafta® was previously approved by the FDA for use in patients with CF 12 years of age and older with at least 1 copy of the *F508del* mutation or 1 copy of a mutation that is responsive *in vitro*. An additional dosage strength of Trikafta® tablets is now available (elexacaftor 50mg/tezacaftor 25mg/ivacaftor 37.5mg and ivacaftor 75mg) in connection with this approval. Vertex completed a 24-week Phase 3 open-label, multicenter study which enrolled 66 children ages 6 through 11 years of age with CF who have either 2 copies of the *F508del* mutation or 1 copy of the *F508del* mutation and 1 minimal function mutation to evaluate the safety, pharmacokinetics, and efficacy of Trikafta®. The regimen was generally well tolerated, and safety data was similar to that observed in previous studies of patients 12 years of age and older. The full data from this study was recently published in *American Journal of Respiratory and Critical Care Medicine*.

Pipeline:

- **ARCT-032:** Arcturus Therapeutics announced in December 2020 that it has selected ARCT-032, an aerosolized LUNAR® messenger RNA (mRNA)-based therapeutic candidate, as a development candidate for CF. ARCT-032 will utilize Arcturus' LUNAR® lipid-mediated aerosolized platform to deliver CFTR mRNA to the lungs; expression of a functional copy of the CFTR mRNA in the lungs of CF patients has the potential to restore normal lung CFTR activity. The ARCT-032 program is supported by preclinical data in CFTR deficient murine model, ferrets, and nonhuman primates. LUNAR®-CFTR was shown to be efficiently delivered to epithelial cells in the airways and restore chloride channel activity in a CFTR knockout mice model following intranasal

administration of LUNAR®-CFTR. An mRNA-based replacement therapy for CF, if successfully developed, has the potential to deliver a fully functional copy of CFTR into the lungs, independent of the underlying CF genotype. The expression of functional CFTR protein is expected to restore chloride channel efflux in the airways, reducing mucus accumulation, tissue scarring, and minimizing the progressive respiratory dysfunction observed in CF patients.

- **Lenabasum:** Corbus Pharmaceuticals announced topline results from its failed 28-week Phase 2b study of lenabasum in patients with CF. The study enrolled patients in the United States, Canada, and Europe at high risk for recurrent pulmonary exacerbations (PEx). Patients received lenabasum or placebo added to their background treatments for CF. The CF-002 Phase 2b study did not meet the primary endpoint of a statistically significant reduction in rate of new PEx per patient per 28 weeks. Lenabasum treatment had a favorable safety profile and was well tolerated. CF-002 was a multinational, double-blind, randomized, placebo-controlled Phase 2b study evaluating the efficacy and safety of lenabasum in CF, with dosing of lenabasum at 5mg twice daily, lenabasum 20mg twice daily, or placebo twice daily for 28 weeks, with 4 weeks safety follow-up off active treatment. The primary efficacy endpoint was the event rate of new PEx per patient per 28 weeks; new PEx was defined as physician diagnosis of PEx, prescription of new antibiotics for that PEx starting more than 28 days after completion of the last antibiotic course for any previous PEx, and 4 out of 12 Fuchs criteria for PEx (predefined signs or symptoms to identify an exacerbation state) present in the patient. The Phase 2b CF study was funded in part by a Development Award for up to $25 million from the Cystic Fibrosis Foundation.
- **MRT5005:** Translate Bio announced results from the second interim analysis from the first-in-human Phase 1/2 clinical study evaluating the safety and tolerability of single- and multiple-ascending doses of MRT5005 in patients with CF. MRT5005 is designed to address the underlying cause of CF, regardless of genetic mutation, by delivering mRNA encoding fully functional CFTR protein to cells in the lungs through nebulization. Results from the second interim analysis build on the previously reported single-ascending dose (SAD) data (8, 16, and 24mg dose groups) with new data from a subsequently added 20mg SAD group, as well as data from multiple-ascending dose (MAD) groups (5 once-weekly doses of 8, 12, and 16mg) through 1 month follow-up post treatment. In evaluating safety and tolerability, the primary outcome measure of the Phase 1/2 study, repeat dosing of MRT5005 was generally safe and well tolerated with no serious adverse events and treatment-emergent adverse events (TEAEs) were mild-to-moderate. Transient, mild-to-moderate symptoms of a febrile reaction

such as fever, headache, and chills occurred in 3 patients after the first dose of MRT5005 and did not recur with subsequent dosing in the 2 patients who continued dosing; however, the third patient discontinued MRT5005 due to the febrile reaction. The percent predicted forced expiratory volume in 1 second ($ppFEV_1$), a measure of lung function, was assessed as a safety measure at pre-defined time points throughout the study; there was no pattern of increases in $ppFEV_1$. The Phase 1/2 clinical study is ongoing, and the company anticipates reporting the findings from the clinical study, including an additional MAD dose group (20mg) and a daily dosing cohort (4mg once daily for 5 days), at a future medical meeting. The FDA has granted MRT5005 Orphan Drug, Fast Track, and Rare Pediatric Disease designations.

- **VX-121/Tezacaftor/Deutivacaftor (VX-561):** Vertex Pharmaceuticals announced in July 2021 the company will initiate a Phase 3 development program for the new once daily investigational triple combination of VX-121/tezacaftor/deutivacaftor in the second half of 2021. The combination of VX-121/tezacaftor/deutivacaftor was first identified as having potential for increased efficacy based on its ability to drive higher levels of chloride transport compared to Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) in human bronchial epithelial cells *in vitro*. The combination of VX-121/tezacaftor/ deutivacaftor was evaluated in a Phase 2 study in patients with CF ages 18 years of age and older with 1 *F508del* mutation and 1 minimal function mutation (F/MF) and in patients with CF 18 years of age and older with 2 *F508del* mutations (F/F). The regimen was generally well tolerated, and the study met the primary efficacy endpoint of absolute change from baseline in $ppFEV_1$ and met all secondary efficacy endpoints including absolute change from baseline in sweat chloride concentration in both patient populations. Taken together, this data suggests the triple combination holds the potential to restore CFTR function in patients with CF to even higher levels than seen with other Vertex CFTR modulators and thereby provide enhanced clinical benefit. The Phase 3 program consists of 2 randomized, double-blind, active-controlled 48-week trials which will evaluate the safety and efficacy of VX-121 20mg/tezacaftor 100mg/deutivacaftor 250mg in comparison to Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor). The first study will enroll approximately 350 patients with CF 12 years of age and older with F/MF and the second study will enroll approximately 450 patients with CF 12 years of age and older with F/F or with 1 *F508del* mutation and a second mutation responsive to CFTR modulators. The primary endpoint in both studies is the absolute change from baseline in $ppFEV_1$, which will be analyzed for non-inferiority to Trikafta®. Both

studies will also assess absolute change from baseline in ppFEV$_1$ and sweat chloride concentration for superiority to Trikafta®.

Recommendations

The College of Pharmacy recommends updating the FDA approved indication and age restriction of Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) based on the new FDA approvals with the following criteria (changes and new criteria shown in red):

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

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

a. Members 6 to 11 years of age weighing <30kg will be approved for Trikafta® (elexacaftor 50mg/tezacaftor 25mg/ivacaftor 37.5mg and ivacaftor 75mg) upon meeting approval criteria; or
b. Members 6 to 11 years of age weighing ≥30kg and members 12 years of age and older will be approved for Trikafta® (elexacaftor 100mg/tezacaftor 50mg/ivacaftor 75mg and ivacaftor 150mg) upon meeting approval criteria; and

12. A quantity limit of 3 tablets per day or 84 tablets per 28 days will apply; and
13. Initial approval will be for the duration of 3 months, after which time compliance will be required for continued approval. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor).

Utilization Details of CFTR Modulators: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
IVACAFTOR PRODUCTS						
KALYDECO TAB 150MG	54	6	$1,290,971.16	$853.82	$23,906.87	4.85%
KALYDECO PAK 75MG	10	1	$239,075.40	$853.84	$23,907.54	0.90%
KALYDECO PAK 50MG	4	2	$95,630.16	$853.84	$23,907.54	0.36%
SUBTOTAL	**68**	**9**	**$1,625,676.72**	**$853.82**	**$23,907.01**	**6.11%**
TEZACAFTOR/IVACAFTOR AND IVACAFTOR COMBINATION PRODUCTS						
SYMDEKO TAB 50-75MG	118	16	$2,644,546.38	$800.41	$22,411.41	9.94%
SYMDEKO TAB 100-150MG	68	11	$1,370,365.24	$719.73	$20,152.43	5.15%
SUBTOTAL	**186**	**27**	**$4,014,911.62**	**$770.91**	**$21,585.55**	**15.09%**
LUMACAFTOR/IVACAFTOR COMBINATION PRODUCTS						
ORKAMBI GRA 150-188MG	113	14	$2,365,162.32	$747.52	$20,930.64	8.89%
ORKAMBI GRA 100-125MG	35	6	$690,900.26	$705.00	$19,740.01	2.60%
ORKAMBI TAB 100-125MG	2	2	$36,631.47	$654.13	$18,315.74	0.14%
SUBTOTAL	**150**	**22**	**$3,092,694.05**	**$736.36**	**$20,617.96**	**11.63%**
ELEXACAFTOR/TEZACAFTOR/IVACAFTOR AND IVACAFTOR COMBINATION PRODUCTS						
TRIKAFTA TAB 100-50-75/150MG	773	86	$17,759,986.05	$820.55	$22,975.40	66.73%
TRIKAFTA TAB 50-25-37.5/75MG	5	5	$119,537.70	$853.84	$23,907.54	0.45%
SUBTOTAL	**778**	**91**	**$17,879,523.75**	**$820.76**	**$22,981.39**	**67.18%**
TOTAL	**1,182**	**132***	**$26,612,806.14**	**$804.11**	**$22,515.06**	**100%**

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

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[2] Vertex Pharmaceuticals. Vertex Announces U.S. FDA Approval for Trikafta® (Elexacaftor/Tezacaftor/Ivacaftor and Ivacaftor) in Children with Cystic Fibrosis Ages 6 through 11 with Certain Mutations. *Business Wire*. Available online at: https://investors.vrtx.com/news-releases/news-release-details/vertex-announces-us-fda-approval-trikaftar. Issued 06/09/2021. Last accessed 08/10/2021.
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[6] Translate Bio. Translate Bio Announces Results from Second Interim Data Analysis from Ongoing Phase 1/2 Clinical Trial of MRT5005 in Patients with Cystic Fibrosis (CF). *Globe Newswire*. Available online at: http://investors.translate.bio/news-releases/news-release-details/translate-bio-announces-results-second-interim-data-analysis. Issued 03/17/2021. Last accessed 08/10/2021.
[7] Vertex Pharmaceuticals. Vertex to Initiate Phase 3 Development Program for New Once-Daily Triple Combination Regimen in People with Cystic Fibrosis. *Business Wire*. Available online at: https://investors.vrtx.com/news-releases/news-release-details/vertex-initiate-phase-3-development-program-new-once-daily. Issued 07/28/2021. Last accessed 08/10/2021.

Appendix M

Fiscal Year 2021 Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Herceptin® (Trastuzumab) and Margenza® (Margetuximab-cmkb)

Oklahoma Health Care Authority
September 2021

Introduction[1,2,3,4]

According to the National Cancer Institute, in 2021, there will be an estimated 281,550 new cases of breast cancer, making it the second most common cancer diagnosed in women in the United States after skin cancer. Additionally, it is estimated there will be 43,600 breast cancer deaths in 2021. The most common type of breast cancer is ductal carcinoma, which begins in the cells of the ducts. Breast cancer can also begin in the cells of the lobules and in other tissues in the breast. Invasive breast cancer is breast cancer that has spread from where it began in the ducts or lobules to surrounding tissues. About 8 of 10 invasive breast cancers are invasive ductal carcinomas. There are several different types of treatments available for patients with breast cancer, including surgery, radiation, hormone therapy, and traditional chemotherapy. Additionally, targeted therapy using drugs or other substances (e.g., targeted radiation) to identify and attack specific cancer cells without harming normal cells is being used. Types of targeted therapy used for breast cancer include monoclonal antibodies, tyrosine kinase inhibitors, cyclin-dependent kinase inhibitors, mammalian target of rapamycin (mTOR) inhibitors, and poly [adenosine diphosphate (ADP)-ribose] polymerase (PARP) inhibitors. Additionally, biosimilar agents for use in breast cancer have been approved by the U.S. Food and Drug Administration (FDA) in recent years.

Use of evidence-based expert consensus guidelines is imperative in the treatment of cancers. The National Comprehensive Cancer Network (NCCN) Compendium contains authoritative, scientifically derived information designed to support decision making about the appropriate use of drugs and biologics in patients with cancer. These evidence-based guidelines should be used for optimal outcomes of cancer patients.

Current Prior Authorization Criteria

Approval criteria for Tecentriq® (atezolizumab) for indications other than breast cancer diagnoses can be found in the April 2021 Drug Utilization Review (DUR) Board packet. Atezolizumab approval criteria are reviewed

annually with the lung cancer medications. Approval criteria for Keytruda® (pembrolizumab) for indications other than breast cancer diagnoses can be found in the December 2020 DUR Board packet. Pembrolizumab approval criteria are reviewed annually with the skin cancer medications.

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

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

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

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

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

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

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

1. Diagnosis of advanced RCC; and
2. Failure of treatment with sunitinib or sorafenib; and
3. Everolimus may also be approved to be used in combination with lenvatinib for advanced RCC.

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

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

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

1. Diagnosis of TSC-associated partial-onset seizures; and
2. Initial prescription must be written by a neurologist or neuro-oncologist; and
3. Failure of ≥3 other medications commonly used for seizures; and

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

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

1. Adult members with unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
2. Member has received ≥2 prior anti-HER2-based regimens in the metastatic setting.

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

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

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

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

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
2. A patient-specific, clinically significant reason why the member cannot use Herceptin® (trastuzumab) 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.

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic gastric or gastroesophageal junction adenocarcinoma; and
2. A patient-specific, clinically significant reason why the member cannot use Herceptin® (trastuzumab) 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.

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

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

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

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

a. In combination with capecitabine after failure of an anthracycline and a taxane (must have failed combination taxane and anthracycline therapy unless anthracyclines not indicated); or
b. Monotherapy after failure of an anthracycline, a taxane, and capecitabine.

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

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

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

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

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

1. Diagnosis of locally recurrent, unresectable, or metastatic triple-negative breast cancer; and
2. Tumors express programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥10.

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

1. Hormone receptor (HR) positive; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. If used in combination with an aromatase inhibitor:
   a. Diagnosis of advanced or metastatic breast cancer, as initial therapy; or
4. If used in combination with fulvestrant:
   a. Diagnosis of advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy; and
   b. Must be used in postmenopausal women only.

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

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

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

1. Diagnosis of metastatic breast cancer; and
2. Progression on previous chemotherapy in any setting; and
3. Positive test for a germline BRCA-mutation (*gBRCAm*); and
4. Members with hormone receptor (HR) positive disease must have failed prior endocrine therapy or are considered to not be a candidate for endocrine therapy.

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

1. **Treatment of Advanced Recurrent/Refractory Ovarian Cancer:**
    a. Diagnosis of deleterious or suspected deleterious germline BRCA mutated (*gBRCAm*), advanced ovarian cancer; and
    b. Previous treatment with ≥2 prior lines of chemotherapy. Prior chemotherapy regimens should be documented on the prior authorization request; and
    c. A quantity limit based on FDA approved dosing will apply; or
2. **Maintenance Treatment of Advanced Ovarian Cancer:**
    a. Disease must be in complete or partial response to primary chemotherapy; and
        i. Used as a single agent in members with a diagnosis of deleterious or suspected deleterious *gBRCAm*, advanced ovarian cancer; or
        ii. Used in combination with bevacizumab following a primary therapy regimen that included bevacizumab; or
    b. Complete or partial response to second-line or greater platinum-based based chemotherapy (no mutation required); and
    c. A quantity limit based on FDA approved dosing will apply.

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

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

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

1. For adjuvant treatment in early-stage breast cancer; and

2. Human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
3. Neratinib must be used to follow adjuvant trastuzumab-based therapy.

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

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

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

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

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

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

b. Adjuvant treatment of members with early breast cancer; or
c. In combination with docetaxel for members with metastatic disease.

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

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

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

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

Tecentriq® (Atezolizumab) Approval Criteria [Breast Cancer Diagnosis]:

1. Unresectable locally advanced or metastatic triple-negative breast cancer; and
2. Used in combination with nab-paclitaxel (Abraxane®); and
3. Positive expression of programmed death ligand-1 (PD-L1); and
4. Member has not failed other immunotherapy(ies).

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

1. Diagnosis of triple-negative breast cancer; and
2. Metastatic disease; and
3. Member must have received ≥2 therapies for metastatic disease.

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

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

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

1. Diagnosis of metastatic or recurrent breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive; and

3. Lapatinib must be used in combination with 1 of the following:
    a. Trastuzumab; or
    b. Capecitabine; or
    c. An aromatase inhibitor (e.g., exemestane, letrozole, anastrozole) if also estrogen receptor (ER) positive.

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

1. Used in 1 of the following settings:
    a. In combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women; or
    b. In combination with fulvestrant with disease progression following endocrine therapy in advanced or metastatic breast cancer; or
    c. As monotherapy for disease progression following endocrine therapy and prior chemotherapy in metastatic breast cancer; and
2. All the following criteria must be present:
    a. Advanced or metastatic breast cancer; and
    b. Progressed after endocrine therapy when used with fulvestrant or as initial therapy in combination with an aromatase inhibitor; and
    c. Hormone receptor (HR) positive; and
    d. Human epidermal growth factor receptor 2 (HER2)-negative.

Utilization of Breast Cancer Medications: Fiscal Year 2021

Fiscal Year Comparison: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	74	513	$7,758,164.18	$15,123.13	$551.05	17,938	14,079
2021	87	559	$9,091,731.90	$16,264.28	$582.54	25,646	15,607
% Change	**17.60%**	**9.00%**	**17.20%**	**7.50%**	**5.70%**	**43.00%**	**10.90%**
Change	**13**	**46**	**$1,333,567.72**	**$1,141.15**	**$31.49**	**7,708**	**1,528**

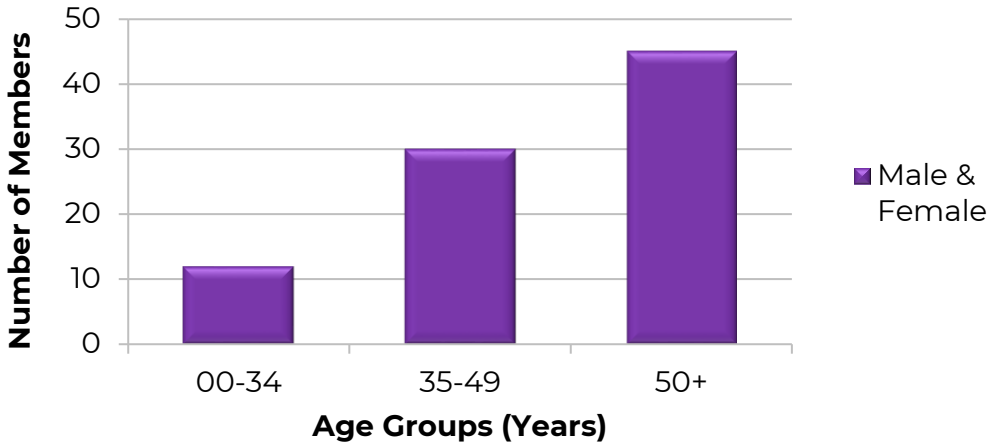
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year Comparison: Medical Claims

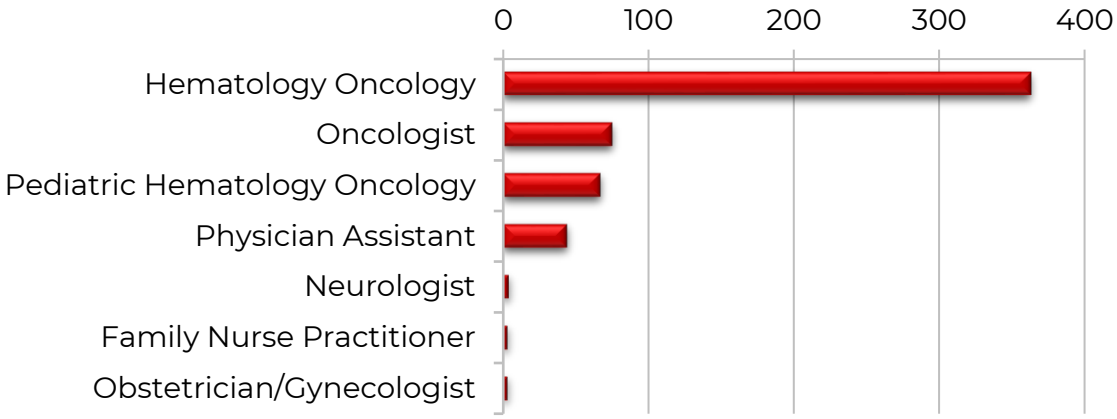
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2020	173	829	$9,258,902.82	$11,168.76	209,544
2021	228	1,273	$12,910,175.19	$10,141.54	383,846
% Change	**31.79%**	**53.56%**	**39.44%**	**-9.20%**	**83.18%**
Change	**55**	**444**	**$3,651,272.37**	**-$1,027.22**	**174,302**

*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Costs do not reflect rebated prices or net costs.
Please note: Some members may be utilizing medications concomitantly.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Breast Cancer Medications: Pharmacy Claims

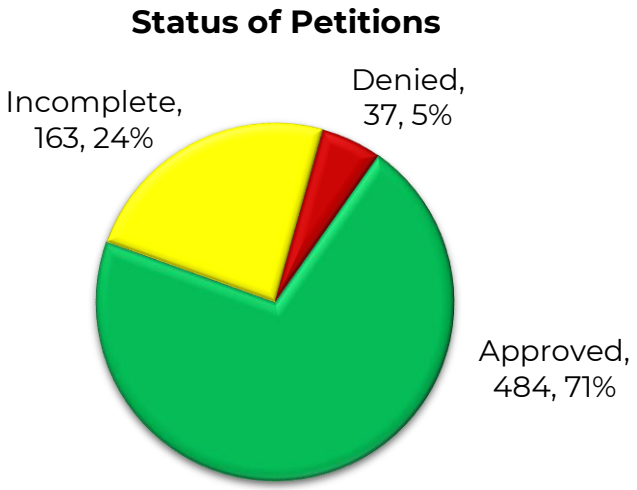


Top Prescriber Specialties of Breast Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Breast Cancer Medications

There were 684 prior authorization requests submitted for breast cancer medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.



Market News and Updates[5,6,7]

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

- **December 2020:** The FDA approved Margenza® (margetuximab-cmkb) in combination with chemotherapy for the treatment of adult patients with metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received 2 or more prior anti-HER2 regimens, at least 1 of which was for metastatic disease.
- **January 2021:** The FDA approved Enhertu® (fam-trastuzumab deruxtecan-nxki) for the treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen.
- **April 2021:** The FDA approved Trodelvy® (sacituzumab govitecan-hziy) for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received 2 or more prior systemic therapies, at least 1 of which was for metastatic disease.
- **April 2021:** The FDA granted accelerated approval to Trodelvy® (sacituzumab govitecan-hziy) for the treatment of adult patients with locally advanced or metastatic urothelial cancer who previously received a platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or a programmed death-ligand 1 (PD-L1) inhibitor.
- **July 2021:** The FDA approved Keytruda® (pembrolizumab) for the treatment of adult patients with high-risk, early-stage, triple-negative breast cancer in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.

News:

- **August 2021:** Genentech announced the voluntarily withdrawal of the FDA's accelerated approval for Tecentriq® (atezolizumab) in combination with chemotherapy (Abraxane®, nab-paclitaxel) for the treatment of adults with unresectable, locally advanced or mTNBC whose tumors express PD-L1. This decision was made in consultation with the FDA and was based on the agency's assessment of the current mTNBC treatment landscape and in accordance with the requirements of the accelerated approval program. This withdrawal does not impact other FDA approved Tecentriq® indications.

Guideline Update(s):

- The NCCN Compendium guideline recommendations were updated to include the use of Ibrance® (palbociclib) with letrozole or any aromatase inhibitor. The combination therapy showed a benefit in progression-free survival in both younger and older women with breast cancer.

Margenza® (Margetuximab-cmkb) Product Summary[8]

- **Therapeutic Class:** HER2/neu receptor antagonist
- **Indication(s):** In combination with chemotherapy for the treatment of adult patients with metastatic HER2-positive breast cancer who have received 2 or more prior anti-HER2 regimens, at least 1 of which was for metastatic disease
- **How Supplied:** 250mg/10mL (25mg/mL) solution in single-dose vials (SDVs)
- **Dose:** 15mg/kg, via intravenous (IV) infusion every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity
- **Cost:** The Wholesale Acquisition Cost (WAC) is $2,077 per SDV, resulting in a cost of $10,385 every 3 weeks based on the recommended dosing for an adult patient weighing 80kg.

Recommendations

The College of Pharmacy recommends the prior authorization of Margenza® (margetuximab-cmkb) with the following criteria:

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

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

Additionally, the College of Pharmacy recommends the prior authorization of Herceptin® (trastuzumab) and updating the prior authorization criteria for Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), Ogivri® (trastuzumab-dkst), Ontruzant® (trastuzumab-dttb), and Trazimera™ (trastuzumab-qyyp) based on net costs (changes noted in red):

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
2. 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 ~~Herceptin® (trastuzumab)~~ 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.

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic gastric or gastroesophageal junction adenocarcinoma; and
2. 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 ~~Herceptin® (trastuzumab)~~ 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.

The College of Pharmacy also recommends updating the approval criteria for Enhertu® (fam-trastuzumab deruxtecan-nxki), Keytruda® (pembrolizumab), and Trodelvy® (sacituzumab govitecan-hziy) based on recent FDA approvals (changes and new criteria noted in red; only criteria with updates are listed):

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

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

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

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

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

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

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

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

Further, the College of Pharmacy recommends updating the prior authorization criteria for Ibrance® (palbociclib) based on NCCN Compendium approval (changes noted in red):

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

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

c. An aromatase inhibitor or fulvestrant in male patients.

Finally, the College of Pharmacy recommends the removal of the Tecentriq® (atezolizumab) approval criteria for the indication of unresectable locally advanced or mTNBC based on FDA-guided voluntary withdrawal of this indication by the manufacturer (changes noted in red):

~~**Tecentriq® (Atezolizumab) Approval Criteria [Breast Cancer Diagnosis]:**~~

~~1. Unresectable locally advanced or metastatic triple-negative breast cancer; and~~
~~2. Used in combination with nab-paclitaxel (Abraxane®); and~~
~~3. Positive expression of programmed death ligand 1 (PD-L1); and~~
~~4. Member has not failed other immunotherapy(ies).~~

Utilization Details of Breast Cancer Medications: Fiscal Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
PALBOCICLIB PRODUCTS					
IBRANCE TAB 125MG	151	30	$1,929,203.99	5.03	$12,776.19
IBRANCE TAB 100MG	44	11	$555,086.98	4	$12,615.61
IBRANCE CAP 125MG	33	8	$418,588.38	4.13	$12,684.50
IBRANCE CAP 100MG	27	6	$341,364.82	4.5	$12,643.14
IBRANCE TAB 75MG	18	2	$227,980.86	9	$12,665.60
IBRANCE CAP 75MG	8	2	$94,322.80	4	$11,790.35
SUBTOTAL	**281**	**59**	**$3,566,547.83**	**4.76**	**$12,692.34**
EVEROLIMUS PRODUCTS					
AFINITOR DIS TAB 5MG	36	4	$1,336,042.06	9	$37,112.28
AFINITOR DIS TAB 3MG	29	3	$1,041,610.58	9.67	$35,917.61
AFINITOR TAB 10MG	23	4	$361,480.76	5.75	$15,716.55
EVEROLIMUS TAB 7.5MG	13	1	$142,431.27	13	$10,956.25
EVEROLIMUS TAB 5MG	9	3	$75,460.68	3	$8,384.52
AFINITOR DIS TAB 2MG	5	2	$119,587.77	2.5	$23,917.55
EVEROLIMUS TAB 2.5MG	4	1	$25,723.36	4	$6,430.84
AFINITOR TAB 5MG	2	1	$31,436.24	2	$15,718.12
SUBTOTAL	**121**	**19**	**$3,133,772.72**	**6.37**	**$25,898.95**
ABEMACICLIB PRODUCTS					
VERZENIO TAB 150MG	33	11	$397,672.37	3	$12,050.68
VERZENIO TAB 100MG	12	3	$152,716.12	4	$12,726.34
VERZENIO TAB 50MG	11	3	$141,693.51	3.67	$12,881.23
SUBTOTAL	**56**	**17**	**$692,082.00**	**3.29**	**$12,358.61**
TUCATINIB PRODUCTS					
TUKYSA TAB 150MG	34	7	$656,530.94	4.86	$19,309.73
SUBTOTAL	**34**	**7**	**$656,530.94**	**4.86**	**$19,309.73**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
ALPELISIB PRODUCTS					
PIQRAY TAB 300MG	18	5	$315,126.62	3.6	$17,507.03
PIQRAY TAB 250MG	3	1	$52,525.77	3	$17,508.59
SUBTOTAL	**21**	**6**	**$367,652.39**	**3.5**	**$17,507.26**
RIBOCICLIB PRODUCTS					
KISQALI FEMARA CO-PACK	11	2	$146,701.73	5.5	$13,336.52
KISQALI TAB 600MG DOSE PACK	9	1	$123,892.31	9	$13,765.81
SUBTOTAL	**20**	**3**	**$270,594.04**	**6.67**	**$13,529.70**
NERATINIB PRODUCTS					
NERLYNX TAB 40MG	14	3	$231,040.38	4.67	$16,502.88
SUBTOTAL	**14**	**3**	**$231,040.38**	**4.67**	**$16,502.88**
OLAPARIB PRODUCTS					
LYNPARZA TAB 150MG	9	2	$130,130.70	4.5	$14,458.97
LYNPARZA TAB 100MG	3	1	$43,380.90	3	$14,460.30
SUBTOTAL	**12**	**3**	**$173,511.60**	**4**	**$14,459.30**
TOTAL	**559**	**87***	**$9,091,731.90**	**6.43**	**$16,264.28**

CAP = capsule; DIS = Disperz (oral tablet for suspension); TAB = tablet
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM
J9355 TRASTUZUMAB INJ	550	80	$2,829,575.69	$5,144.68
J9271 PEMBROLIZUMAB INJ	439	91	$5,279,444.12	$12,026.07
J9306 PERTUZUMAB INJ	410	61	$2,701,007.02	$6,587.82
J9022 ATEZOLIZUMAB INJ	108	35	$1,082,672.24	$10,024.74
J9354 ADO-TRASTUZUMAB INJ	91	20	$664,343.84	$7,300.48
J9179 ERIBULIN MESYLATE INJ	28	7	$92,504.96	$3,303.75
J9317 SACITUZUMAB GOVITECAN-HZIY INJ	17	4	$190,135.08	$11,184.42
Q5117 TRASTUZUMAB-ANNS INJ	10	1	$39,535.10	$3,953.51
J9358 FAM-TRASTUZUMAB INJ	8	2	$19,435.56	$2,429.45
J9207 IXABEPILONE INJ	3	2	$11,521.58	$3,840.53
TOTAL	**1,273**	**228**	**$12,910,175.19**	**$10,141.54**

INJ = injection
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Please note: Some members may be utilizing medications concomitantly.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

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[7] Genentech. Genentech Provides Update on Tecentriq® U.S. Indication for PD-L1-Positive, Metastatic Triple-Negative Breast Cancer. Available online at: https://www.gene.com/media/press-releases/14927/2021-08-27/genentech-provides-update-on-tecentriq-u. Issued 08/27/2021. Last accessed 08/31/2021.
[8] Margenza® Prescribing Information. MacroGenics, Inc. Available online at: https://www.margenza.com/pdf/prescribing-information.pdf. Last revised 12/2020. Last accessed 08/10/2021.

Appendix N

Fiscal Year 2021 Annual Review of Prostate Cancer Medications and 30-Day Notice to Prior Authorize Orgovyx™ (Relugolix)

Oklahoma Health Care Authority
September 2021

Introduction[1,2,3]

According to the National Cancer Institute, in 2021, an estimated 248,530 men will be diagnosed with prostate cancer, making prostate cancer approximately 10.6% of all new cancer cases in the United States. Additionally, it is estimated there will be 34,130 prostate cancer deaths in 2021. Prostate cancer is the second leading cause of cancer death in men. The incidence of prostate cancer is closely correlated with trends in screening practices. Prostate specific antigen (PSA) is a protein produced by cells of the prostate gland, and elevations in PSA levels may indicate prostate cancer. PSA has been used as a screening marker for prostate cancer over the last 3 decades with its peak utilization occurring in the early 1990s and gradually declining since that time. Following the same trend, the incidence rates of prostate cancer were highest in 1992 and have slowly decreased from that date. Physicians have reduced recommending generalized PSA screening for the average risk male, primarily because the mortality associated with prostate cancer is very low with an estimated 98% survival at 5 years. Early detection of prostate cancer can lead to overtreatment of cancers that do not impact life expectancy, which may result in unwarranted side effects, reduced quality of life, and increased cost. Prostate cancer detection and progression models estimate that 23% to 42% of all screen-detected cancers are overtreated.

The most common type of prostate cancer is adenocarcinoma, which accounts for 99% of tumors in the prostate. Sarcomas, transitional, small, and squamous cell carcinomas are rare. The treatment principles for prostate cancer have largely remained the same over the past 50 years with surgery, radiation, and androgen deprivation therapy (ADT) making up the main components of therapy. Androgens, the most common of which is testosterone, promote the growth of prostate cancers. ADT involves medications that reduce the body's level of androgens or surgery to remove the testicles (orchiectomy), which ultimately can decrease and slow the growth of prostate cancers. Early stage (stage I and II localized) prostate cancer is typically treated with either surgery, radiation therapy, or active surveillance. Stage III prostate cancer treatment often involves a combination of radiation therapy with ADT and surgery. ADT is usually recommended for initial treatment of men with metastatic (stage IV) prostate cancer and is

often combined with chemotherapy. Other treatment strategies for advanced prostate cancer include immunotherapy and radiation. Advanced prostate cancer is incurable but treatment can help to control the tumor burden for long periods of time.

Current Prior Authorization Criteria

Approval criteria for Lynparza® (olaparib) for indications other than prostate cancer diagnoses can be found in the 2021 Annual Review of Breast Cancer Medications report, which is also being presented at the September 2021 Drug Utilization Review (DUR) Board meeting. Lynparza® approval criteria are reviewed annually with the breast cancer medications.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Diagnosis of metastatic CRPC; and
2. Symptomatic bone metastases; and
3. No known visceral metastatic disease; and
4. Prescriber must verify radium-223 dichloride will not be used in combination with chemotherapy; and

5. Absolute neutrophil count ≥1.5 x 10^9/L, platelet count ≥100 x 10^9/L, and hemoglobin ≥10g/dL; and
6. Approvals will be for a maximum duration of 6 months.

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

1. Diagnosis of CRPC.

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

1. Diagnosis of metastatic CSPC.

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

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

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

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

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

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

Utilization of Prostate Cancer Medications: Fiscal Year 2021

Fiscal Year Comparison: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	14	78	$757,056.81	$9,705.86	$323.53	7,080	2,340
2021	22	120	$1,161,112.98	$9,675.94	$324.33	12,100	3,580
% Change	**57.10%**	**53.80%**	**53.40%**	**-0.30%**	**0.20%**	**70.90%**	**53.00%**
Change	**8**	**42**	**$404,056.17**	**-$29.92**	**$0.80**	**5,020**	**1,240**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year Comparison: Medical Claims

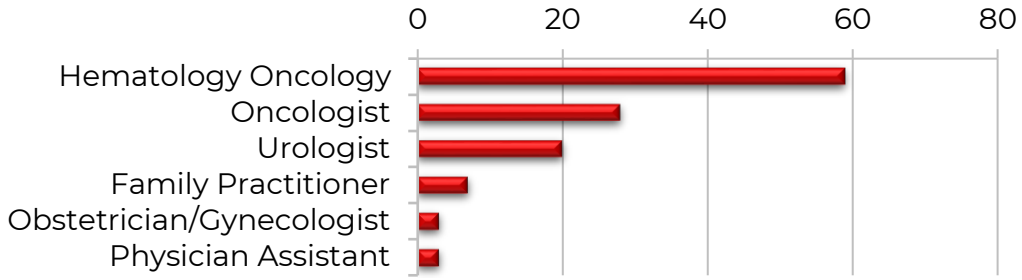
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2020	6	33	$432,849.10	$13,116.64	2,478
2021	5	22	$256,841.20	$11,674.60	1,408
% Change	**-16.67%**	**-33.33%**	**-40.66%**	**-10.99%**	**-43.18%**
Change	**-1**	**-11**	**-$176,007.90**	**-$1,442.04**	**-1,070**

*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Prostate Cancer Medications: Pharmacy Claims

- Due to the limited number of members utilizing prostate cancer medications during fiscal year 2021, detailed demographic information could not be provided. All members were 50 years of age or older.

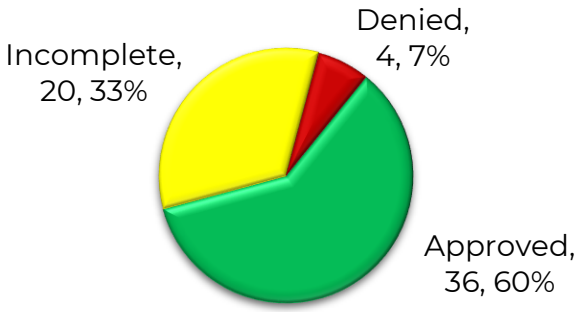
Top Prescriber Specialties of Prostate Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Prostate Cancer Medications

There were 60 prior authorization requests submitted for prostate cancer medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates[4]

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

- **December 2020:** The FDA approved the first oral gonadotropin-releasing hormone (GnRH) receptor antagonist, Orgovyx™ (relugolix), for the treatment of adult patients with advanced prostate cancer.

Orgovyx™ (Relugolix) Product Summary[5]

- **Therapeutic Class:** GnRH receptor antagonist
- **Indication(s):** Treatment of adult patients with advanced prostate cancer
- **How Supplied:** 120mg oral tablets
- **Dose:** A loading dose of 360mg [(3) 120mg tablets] on the first day of treatment followed by 120mg taken once daily
- **Cost:** The Wholesale Acquisition Cost (WAC) is $77.10 per tablet resulting in an initial monthly cost of $2,467.20 at the recommended dosing of 360mg on the first day followed by 120mg once daily and a subsequent monthly cost of $2,313 at 120mg once daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Orgovyx™ (relugolix) with the following criteria listed in red:

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

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

Utilization Details of Prostate Cancer Medications: Fiscal Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
ABIRATERONE PRODUCTS					
ZYTIGA TAB 500MG	37	5	$392,538.65	7.4	$10,609.15
ABIRATERONE TAB 250MG	23	6	$6,444.23	3.83	$280.18
SUBTOTAL	**60**	**11**	**$398,982.88**	**5.45**	**$6,649.71**
ENZALUTAMIDE PRODUCTS					
XTANDI CAP 40MG	35	6	$423,481.13	5.83	$12,099.46

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
SUBTOTAL	**35**	**6**	**$423,481.13**	**5.83**	**$12,099.46**
APALUTAMIDE PRODUCTS					
ERLEADA TAB 60MG	13	4	$165,137.37	3.25	$12,702.87
SUBTOTAL	**13**	**4**	**$165,137.37**	**3.25**	**$12,702.87**
OLAPARIB PRODUCTS					
LYNPARZA TAB 150MG	9	2	$130,130.70	4.5	$14,458.97
LYNPARZA TAB 100MG	3	1	$43,380.90	3	$14,460.30
SUBTOTAL	**12**	**3**	**$173,511.60**	**4**	**$14,459.30**
TOTAL	**120**	**22***	**$1,161,112.98**	**5.45**	**$9,675.94**

CAP = capsule; TAB = tablet
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM
J9043 CABAZITAXEL INJECTION	22	5	$256,841.20	$11,674.60
TOTAL	**22**	**5**	**$256,841.20**	**$11,674.60**

+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

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[1] National Cancer Institute. Surveillance, Epidemiology, and End Results (SEER) Program Cancer Statistics. Available online at: https://seer.cancer.gov/statfacts/html/prost.html. Last accessed 08/13/2021.
[2] Draisma G, Etzioni R, Tsodikov A, et al. Lead Time and Overdiagnosis in Prostate-Specific Antigen Screening: Importance of Methods and Context. *J Natl Cancer Inst* 2009; 101(6):374-83.
[3] National Comprehensive Cancer Network (NCCN). *NCCN Clinical Practice Guidelines in Oncology (Prostate Cancer)*. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Last accessed 08/13/2021.
[4] 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 08/04/2021. Last accessed 08/10/2021.
[5] Orgovyx™ Prescribing Information. Myovant Sciences, Inc. Available online at: https://www.myovant.com/wp-content/uploads/2020/12/NDA-214621-Final-USPIandPI.pdf. Last revised 12/2020. Last accessed 08/10/2021.

Appendix O

Fiscal Year 2021 Annual Review of Cystadrops® (Cysteamine 0.37% Ophthalmic Solution) and Cystaran® (Cysteamine 0.44% Ophthalmic Solution)

Oklahoma Health Care Authority
September 2021

Current Prior Authorization Criteria

Cystadrops® (Cysteamine 0.37% Ophthalmic Solution) and Cystaran® (Cysteamine 0.44% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication for the treatment of corneal cystine crystal accumulation in members with cystinosis; and
2. The requested medication must be prescribed by, or in consultation with, an ophthalmologist; and
3. Prescriber must verify that the member has been counseled on the proper storage of the requested medication; and
4. For Cystadrops®, a patient-specific, clinically significant reason (beyond convenience) why the member cannot use Cystaran® must be provided; and
5. A quantity limit of 4 bottles per month will apply.

Utilization of Cystadrops® and Cystaran®: Fiscal Year 2021

- There was no SoonerCare utilization of Cystadrops® or Cystaran® during fiscal year 2021 (07/01/2020 to 06/30/2021).

Prior Authorization of Cystadrops® and Cystaran®

- There were no prior authorization requests submitted for Cystadrops® or Cystaran® during fiscal year 2021.

Market News and Updates[1]

Anticipated Exclusivity Expiration(s):

- Cystadrops® (Cysteamine 0.37% Ophthalmic Solution): August 2023

Recommendations

The College of Pharmacy does not recommend any changes to the current Cystadrops® or Cystaran® approval criteria at this time.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 08/2021. Last accessed 08/02/2021.

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: August 23, 2021

FDA Approves First COVID-19 Vaccine

The FDA has approved the first COVID-19 vaccine, known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty®, for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA) for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

Since December 11, 2020, the Pfizer-BioNTech COVID-19 Vaccine has been available under EUA in individuals 16 years of age and older, and the authorization was expanded to include those 12 through 15 years of age on May 10, 2021. EUAs can be used by the FDA during public health emergencies to provide access to medical products that may be effective in preventing, diagnosing, or treating a disease, provided that the FDA determines that the known and potential benefits of a product, when used to prevent, diagnose, or treat the disease, outweigh the known and potential risks of the product.

FDA-approved vaccines undergo the agency's standard process for reviewing the quality, safety and effectiveness of medical products. For all vaccines, the FDA evaluates data and information included in the manufacturer's submission of a biologics license application (BLA). A BLA is a comprehensive document that is submitted to the agency providing very specific requirements. For Comirnaty®, the BLA builds on the extensive data and information previously submitted that supported the EUA, such as preclinical and clinical data and information, as well as details of the manufacturing process, vaccine testing results to ensure vaccine quality, and inspections of the sites where the vaccine is made. The agency conducts its own analyses of the information in the BLA to make sure the vaccine is safe and effective and meets the FDA's standards for approval.

Comirnaty® contains messenger RNA (mRNA) that is used by the body to make a mimic of one of the proteins in the virus that causes COVID-19. The result of a person receiving this vaccine is that their immune system will ultimately react defensively to the virus that causes COVID-19. The mRNA in Comirnaty® is only present in the body for a short time and is not incorporated into - nor does it alter - an individual's genetic material. Comirnaty® has the same formulation as the EUA vaccine and is administered as a series of two doses, three weeks apart.

FDA Evaluation of Safety and Effectiveness Data for Approval for 16 Years of Age and Older

The first EUA, issued December 11, for the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years of age and older was based on safety and effectiveness data from a randomized, controlled, blinded ongoing clinical trial of thousands of individuals.

To support the FDA's approval decision, the FDA reviewed updated data from the clinical trial which supported the EUA and included a longer duration of follow-up in a larger clinical trial population.

Specifically, in the FDA's review for approval, the agency analyzed effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients ages 16 and older who did not have evidence of the COVID-19 virus infection within a week of receiving the second dose. The safety of Comirnaty® was evaluated in approximately 22,000 people who received the vaccine and 22,000 people who received a placebo 16 years of age and older. Based on results from the clinical trial, the vaccine was 91% effective in preventing COVID-19 disease.

More than half of the clinical trial participants were followed for safety outcomes for at least 4 months after the second dose. Overall, approximately 12,000 recipients have been followed for at least 6 months.

The most commonly reported side effects by those clinical trial participants who received Comirnaty® were pain, redness and swelling at the injection site, fatigue, headache, muscle or joint pain, chills, and fever. The vaccine is effective in preventing COVID-19 and potentially serious outcomes including hospitalization and death.

Additionally, the FDA conducted a rigorous evaluation of the post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine and has determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes. The Comirnaty® *Prescribing Information* includes a warning about these risks.

Ongoing Safety Monitoring

The FDA and Centers for Disease Control and Prevention (CDC) have monitoring systems in place to ensure that any safety concerns continue to be identified and evaluated in a timely manner. In addition, the FDA is requiring the company to conduct post marketing studies to further assess the risks of myocarditis and pericarditis following vaccination with Comirnaty®. These studies will include an evaluation of long-term outcomes among individuals who develop myocarditis following vaccination with Comirnaty®. In addition, although not FDA requirements, the company has committed to additional post-marketing safety studies, including conducting a pregnancy registry study to evaluate pregnancy and infant outcomes after receipt of Comirnaty® during pregnancy.

FDA NEWS RELEASE

For Immediate Release: August 12, 2021

FDA Grants First of its Kind Indication for Chronic Sleep Disorder Treatment

The FDA approved a new indication for Xywav® for idiopathic hypersomnia (IH) in adults. IH is an uncommon chronic sleep disorder that causes people to be excessively sleepy during the day even after a good night's sleep. Xywav® (calcium/magnesium/potassium/sodium oxybates) oral solution is already approved for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy.

The effectiveness of Xywav® was evaluated in a double-blind placebo-controlled randomized-withdrawal study in 154 adult patients (ages 19 to 75 years) with IH. In the clinical study, patients who were randomized to switch from Xywav® to placebo

experienced worsening on measures of sleepiness and symptoms of IH compared to patients randomized to continue treatment with Xywav®.

In the clinical study for IH, the most common adverse events as a result of the treatment observed in the study included nausea (21.4%), headache (16.2%), dizziness (11.7%), anxiety (10.4%) and vomiting (10.4%).

Xywav® has a *Boxed Warning* for central nervous system depression and abuse and misuse. The active moiety of Xywav® is oxybate, also known as gamma-hydroxybutyrate (GHB), a Schedule I controlled substance. Abuse or misuse of illicit GHB has been associated with serious side effects including seizures, trouble breathing, changes in alertness, coma, and death. Clinically significant respiratory depression and reduced level of alertness has occurred in adult patients taking sodium oxybate.

Because of the potential risks associated with Xywav®, it is subject to strict safety controls on prescribing and dispensing under a program called a Risk Evaluation and Mitigation Strategy (REMS).

Specifically, under the Xywav® REMS, it can be prescribed only by a certified prescriber, and dispensed only to an enrolled patient by a certified pharmacy. Only a certified pharmacy that ships directly to patients can dispense Xywav®. Xywav® will not be available in retail pharmacies.

FDA NEWS RELEASE

For Immediate Release: August 6, 2021

FDA Approves New Treatment for Pompe Disease

The FDA approved Nexviazyme® (avalglucosidase alfa-ngpt) for intravenous (IV) infusion to treat patients 1 year of age and older with late-onset Pompe disease.

Patients with Pompe disease have an enzyme deficiency that leads to the accumulation of glycogen in skeletal and heart muscles, which cause muscle weakness and premature death from respiratory or heart failure. Normally, glycogen breaks down to release glucose into the bloodstream to be used as fuel for the cells.

Nexviazyme®, an enzyme replacement therapy, is an IV medication that helps reduce glycogen accumulation. The effectiveness of Nexviazyme® for the treatment of Pompe disease was demonstrated in a study of 100 patients who were randomized to take Nexviazyme® or another FDA-approved enzyme replacement therapy for Pompe disease. Treatment with Nexviazyme® improved lung function similar to the improvement seen with the other therapy.

The most common side effects included headache, fatigue, diarrhea, nausea, arthralgia, dizziness, myalgia, pruritus, vomiting, dyspnea, erythema, paresthesia, and skin urticaria. Serious reactions included hypersensitivity reactions like anaphylaxis and infusion-associated reactions, including respiratory distress, chills, and raised body temperature. Patients susceptible to fluid volume overload or with compromised cardiac or respiratory function may be at risk for serious acute cardiorespiratory failure.

FDA NEWS RELEASE

For Immediate Release: July 28, 2021

FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes

The FDA approved the first interchangeable biosimilar insulin product, indicated to improve glycemic control in adults and pediatric patients with Type 1 diabetes mellitus and in adults with Type 2 diabetes mellitus. Semglee® (insulin glargine-yfgn) is both biosimilar to, and interchangeable with (can be substituted for), its reference product

Lantus® (insulin glargine), a long-acting insulin analog. Semglee® (insulin glargine-yfgn) is the first interchangeable biosimilar product approved in the United States for the treatment of diabetes. Approval of these insulin products can provide patients with additional safe, high-quality, and potentially cost-effective options for treating diabetes.

Biological products include medications for treating many serious illnesses and chronic health conditions, including diabetes. A biosimilar is a biological product that is highly similar to, and has no clinically meaningful differences from, a biological product already approved by the FDA (also called the reference product). This means you can expect the same safety and effectiveness from the biosimilar as you would the reference product.

An interchangeable biosimilar product may be substituted for the reference product without the intervention of the prescriber. The substitution may occur at the pharmacy, a practice commonly called "pharmacy-level substitution" – much like how generic drugs are substituted for brand name drugs, subject to state pharmacy laws, which vary by state. Biosimilar and interchangeable biosimilar products have the potential to reduce health care costs, similar to how generic drugs have reduced costs. Biosimilars marketed in the United States typically have launched with initial list prices 15% to 35% lower than comparative list prices of the reference products.

All biological products are approved only after they meet the FDA's rigorous approval standards. The approval of Semglee® (insulin glargine-yfgn) as biosimilar to and interchangeable with Lantus® (insulin glargine) is based on evidence that showed the products are highly similar and that there are no clinically meaningful differences between Semglee® (insulin glargine-yfgn) and Lantus® (insulin glargine) in terms of safety and effectiveness. It also showed that Semglee® (insulin glargine-yfgn) can be expected to produce the same clinical result as Lantus® (insulin glargine) in any given patient and that the risks in terms of safety or diminished efficacy of switching between Semglee® (insulin glargine-yfgn) and Lantus® (insulin glargine) is not greater than the risk of using Lantus® (insulin glargine) without such switching.

Semglee® (insulin glargine-yfgn), offered in 10mL vials and 3mL prefilled pens, is administered subcutaneously once daily. Dosing of Semglee® (insulin glargine-yfgn), like Lantus®, should be individualized based on the patient's needs and should not be used during episodes of hypoglycemia or in patients with hypersensitivity to insulin glargine products. Also like Lantus®, Semglee® (insulin glargine-yfgn) is not recommended for treating diabetic ketoacidosis. Semglee® (insulin glargine-yfgn) may cause serious side effects, including hypoglycemia, severe allergic reactions, hypokalemia, and heart failure. The most common side effects associated with insulin glargine products other than hypoglycemia include edema, lipodystrophy, weight gain, and allergic reactions, such as injection site reactions, rash, redness, pain, and severe itching.

FDA NEWS RELEASE

For Immediate Release: July 8, 2021

Joint CDC and FDA Statement on Vaccine Boosters

The United States is fortunate to have highly effective vaccines that are widely available for those 12 years of age and older. People who are fully vaccinated are protected from severe disease and death, including from the variants currently circulating in the country such as Delta. People who are not vaccinated remain at risk. Virtually all COVID-19 hospitalizations and deaths are among those who are unvaccinated. We encourage Americans who have not yet been vaccinated to get vaccinated as soon as possible to protect themselves and their community.

Americans who have been fully vaccinated do not need a booster shot at this time. The FDA, CDC, and National Institutes of Health (NIH) are engaged in a science-based, rigorous process to consider whether or when a booster might be necessary. This process takes into account laboratory data, clinical trial data, and cohort data – which can include data from specific pharmaceutical companies, but does not rely on those data exclusively. The FDA and CDC will continue to review any new data as it becomes available and will keep the public informed. Booster doses will be recommended if and when the science demonstrates that they are needed.

FDA NEWS RELEASE

For Immediate Release: June 30, 2021

FDA Approves Component of Treatment Regimen for Most Common Childhood Cancer

The FDA approved Rylaze™ [asparaginase erwinia chrysanthemi (recombinant)-rywn] as a component of a chemotherapy regimen to treat acute lymphoblastic leukemia and lymphoblastic lymphoma in adult and pediatric patients who are allergic to the *E. coli*-derived asparaginase products used most commonly for treatment. The only other FDA-approved drug for such patients with allergic reactions, Erwinaze® (asparaginase erwinia chrysanthemi), has been in global shortage for years.

Acute lymphoblastic leukemia occurs in approximately 5,700 patients annually, about half of whom are children. It is the most common type of childhood cancer. One component of the chemotherapy regimen is an enzyme called asparaginase that kills cancer cells by depriving them of substances needed to survive. An estimated 20% of patients are allergic to the standard *E. coli*-derived asparaginase and need an alternative their bodies can tolerate.

The efficacy of Rylaze™ was evaluated in a study of 102 patients who either had a hypersensitivity to *E. coli*-derived asparaginases or experienced silent inactivation. The main measurement was whether patients achieved and maintained a certain level of asparaginase activity. The study found that the recommended dosage would provide the target level of asparaginase activity in 94% of patients. The most common side effects of Rylaze™ include hypersensitivity reactions, pancreatic toxicity, blood clots, hemorrhage, and liver toxicity.

FDA NEWS RELEASE

For Immediate Release: June 24, 2021

Coronavirus (COVID-19) Update: FDA Authorizes Drug for Treatment of COVID-19

The FDA issued an emergency use authorization (EUA) for the drug Actemra® (tocilizumab) for the treatment of hospitalized adults and pediatric patients 2 years of age and older who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Actemra® is not authorized for use in outpatients with COVID-19.

In clinical trials of hospitalized patients with COVID-19, Actemra® in addition to the routine care patients receive for treatment of COVID-19, which included corticosteroid therapy, was shown to reduce the risk of death through 28 days of follow-up and decrease the amount of time patients remained hospitalized. The risk of patients being placed on ventilators or death through 28 days of follow-up was also decreased.

Actemra® is a monoclonal antibody that reduces inflammation by blocking the interleukin-6 receptor. In the case of COVID-19 infection, the immune system can become hyperactive, which may result in worsening of disease. Actemra® does not directly target

SARS-COV-2. Actemra® is a prescription medication given by IV infusion that is FDA-approved for multiple inflammatory diseases, including rheumatoid arthritis. Under today's EUA, the FDA is authorizing the emergency use of Actemra® for the treatment of certain hospitalized patients with COVID-19. Actemra® is not approved as a treatment for COVID-19.

The issuance of an EUA is different than an FDA approval. In determining whether to issue an EUA, the FDA evaluates the totality of available scientific evidence and carefully balances any known or potential risks with any known or potential benefits of the product for use during an emergency. Based on the FDA's review of the totality of the scientific evidence available, the agency has determined that it is reasonable to believe that Actemra® may be effective in treating COVID-19 for the authorized population. And, when used to treat COVID-19 for the authorized population, the known and potential benefits of Actemra® outweigh the known and potential risks for the drug. There are no adequate, approved, and available alternative treatments to Actemra® for the treatment of COVID-19 in hospitalized adults and pediatric patients 2 years of age or older who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.

The data supporting this EUA for Actemra® are based on 4 clinical trials. These included 1 randomized, controlled, open-label, platform trial (RECOVERY) and 3 randomized, double-blind, placebo-controlled trials (EMPACTA, COVACTA, and REMDACTA). While all 4 clinical trials contribute to the FDA's understanding of Actemra® for the treatment of COVID-19, the most important scientific evidence on the potential benefit of Actemra® for its authorized use came from the RECOVERY and EMPACTA trials.

In the RECOVERY trial, 4,116 hospitalized patients with severe COVID-19 pneumonia were randomized to receive either Actemra® in addition to usual care (2,022 patients) or usual care alone (2,094 patients). The primary endpoint evaluated death through 28 days of follow-up, and the results of the primary analysis were statistically significant. The probabilities of death by day 28 were estimated to be 30.7% for patients receiving Actemra® and 34.9% for patients receiving usual care alone. The median time to hospital discharge was 19 days for patients receiving Actemra® and more than 28 days for patients receiving usual care alone.

In the EMPACTA trial, 389 hospitalized patients with COVID-19 pneumonia were randomized to receive Actemra® (249 patients) or placebo (128 patients). The primary endpoint evaluated the need for mechanical ventilation or death through 28 days of follow-up. For patients receiving Actemra®, there was an observed reduction in progression to mechanical ventilation or death compared to patients who received placebo, with the primary analysis results being statistically significant. The proportion of patients who required mechanical ventilation or died by day 28 was estimated to be 12% for patients receiving Actemra® and 19.3% for patients receiving placebo.

In the COVACTA trial, 452 hospitalized patients with severe COVID-19 pneumonia were randomized to receive Actemra® (294 patients) or placebo (144 patients). The primary endpoint was clinical status through 28 days of follow-up assessed on a 7-category ordinal scale. While there was no statistically significant difference observed in clinical status on the 7-category ordinal scale at day 28 between treatment groups, the COVACTA trial contributed to the assessment of the safety for Actemra® when used for the treatment of COVID-19.

In the REMDACTA trial, 649 hospitalized patients with severe COVID-19 pneumonia were randomized to receive Actemra® in combination with remdesivir (430 patients) or placebo in combination with remdesivir (210 patients). The primary endpoint was time to

hospital discharge or “ready for discharge” through 28 days of follow-up. Additionally, while there were no statistically significant differences observed between treatment groups with respect to time to hospital discharge or “ready for discharge” through 28 days of follow-up, the REMDACTA trial contributed to the assessment of the safety for Actemra® when used for the treatment of COVID-19.

Current Drug Shortages Index (as of September 1, 2021):

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

Acetazolamide Injection	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acids	***Currently in Shortage***
Amoxapine Tablets	***Currently in Shortage***
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Atropine Sulfate Ophthalmic Ointment	***Currently in Shortage***
Azacitidine 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***
Calcitriol Injection 1MCG/ML	***Currently in Shortage***
Calcium Disodium Versenate Injection	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Cefazolin Injection	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Cefoxitin for Injection	***Currently in Shortage***
Ceftazidime and Avibactam (Avycaz) for Injection, 2 grams/0.5 grams	***Currently in Shortage***
Ceftolozane and Tazobactam (Zerbaxa) Injection	***Currently in Shortage***
Chlordiazepoxide Hydrochloride Capsules	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Continuous Renal Replacement Therapy (CRRT) Solutions	***Currently in Shortage***
Cortisone Acetate Tablets	***Currently in Shortage***
Crisantaspase (Erwinase)	***Currently in Shortage***
Cyclopentolate Ophthalmic Solution	***Currently in Shortage***
Cysteamine Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Desmopressin Acetate Nasal Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Injection	***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***
Famotidine Injection	***Currently in Shortage***
Famotidine Tablets	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Floxuridine for Injection	***Currently in Shortage***
Fluvoxamine ER Capsules	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gemifloxacin Mesylate (Factive) Tablets	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Guanfacine Hydrochloride Tablets	***Currently in Shortage***
Heparin Sodium and Sodium Chloride 0.9% Injection	***Currently in Shortage***
Histreline Acetate Implant	***Currently in Shortage***
Hydrocortisone Tablets	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert	***Currently in Shortage***
Imipenem and Cilastatin for 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***
Letermovir (Prevymis) 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***
Lithium Oral Solution	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Loxapine Capsules	***Currently in Shortage***
Mepivacaine Hydrochloride Injection	***Currently in Shortage***
Methohexital Sodium (Brevital) Injection	***Currently in Shortage***
Methyldopa Tablets	***Currently in Shortage***
Midazolam Injection	***Currently in Shortage***
Misoprostol Tablets	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Nefazodone Hydrochloride Tablets	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Ondansetron Hydrochloride Injection	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Parathyroid Hormone (Natpara) Injection	***Currently in Shortage***
Physostigmine Salicylate Injection	***Currently in Shortage***
Pindolol Tablets	***Currently in Shortage***

Potassium Acetate Injection	***Currently in Shortage***
Promethazine (Phenergan) Injection	***Currently in Shortage***
Propofol Injectable Emulsion	***Currently in Shortage***
Protamine Sulfate Injection	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablets	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Sclerosol Intrapleural Aerosol	***Currently in Shortage***
Sincalide (Kinevac) Lyophilized Powder for Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate 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***
Succimer (Chemet) Capsules	***Currently in Shortage***
Sulfasalazine Tablets	***Currently in Shortage***
Tacrolimus Capsules	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Teprotumumab-trbw	***Currently in Shortage***
Thiothixene Capsules	***Currently in Shortage***
Timolol Maleate Ophthalmic Gel Forming Solution	***Currently in Shortage***
Tocilizumab Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injectable suspension	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsules	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Varenicline Tartrate (Chantix) Tablets	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***