OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
June 9, 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:
https://zoom.us/webinar/register/WN_dgGOMPbDRuuDlZWND8TjHQ
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The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – June 9, 2021

DATE: June 1, 2021

NOTE: The DUR Board will meet at 4:00pm. For all DUR Board members, College of Pharmacy presenters, and any speakers who sign up in advance for public comment, this meeting will be held in person at the Oklahoma Health Care Authority (OHCA) at 4345 N. Lincoln Blvd. in Oklahoma City, Oklahoma. In response to COVID-19, temperature checks will be required for all in person attendees. For additional information on OHCA's COVID-19 precautions and protocols for admittance into the Agency, please go to www.oklahoma.gov/ohca.

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

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

Call to Order

Public Comment Forum

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

Medication Therapy Management (MTM) Program Update – Appendix B

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 – Appendix C

Action Item – Vote to Prior Authorize Cabometyx® (Cabozantinib), Fotivda® (Tivozanib), Jelmyto® (Mitomycin), and Padcev® (Enfortumab Vedotin-ejfv) – Appendix D

Action Item – Vote to Prior Authorize Gemtesa® (Vibegron) – Appendix E

Action Item – Vote to Prior Authorize Zilxi® (Minocycline 1.5% Topical Foam) – Appendix F

Action Item – Vote to Prior Authorize Kynmobi™ (Apomorphine) and Ongentys® (Opicapone) – Appendix G

Action Item – Vote to Prior Authorize Fetroja® (Cefiderocol) and Kimyrsa™ (Oritavancin) – Appendix H

Annual Review of the SoonerCare Pharmacy Benefit – Appendix I

Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Azstarys™ (Serdexmethylphenidate/Dexmethylphenidate), Qelbree™ (Viloxazine), and Xywav™ (Calcium, Magnesium, Potassium, and Sodium Oxybates) – Appendix J

Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Lybalvi™ (Olanzapine/Samidorphan) – Appendix K

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) – Appendix L

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) – Appendix M

Annual Review of Isturisa® (Osilodrostat) – Appendix N

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – June 9, 2021 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

NOTE: ***For all DUR Board members, College of Pharmacy presenters, and any speakers who sign up in advance for public comment, this meeting will be held in person at OHCA (see address above). In response to COVID-19, temperature checks will be required for all in person attendees. For additional information on OHCA's COVID-19 precautions and protocols for admittance into the Agency, please go to www.oklahoma.gov/ohca.***

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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. Theresa Garton –	participating in person
Dr. Megan Hanner –	participating in person
Dr. Lynn Mitchell –	participating in person
Dr. John Muchmore –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person

Viewing Access Only via Zoom:

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Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 976 8930 3413
Passcode: 02133264

Public Comment for Meeting:

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

Items to be presented by Dr. Muchmore, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers for Public Comment

Items to be presented by Dr. Muchmore, Chairman:

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

A. May 12, 2021 DUR Minutes – Vote
B. May 12, 2021 DUR Recommendation Memorandum
C. Correspondence

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

4. Medication Therapy Management (MTM) Program Update – See Appendix B

A. MTM Program Update
B. Focus on Adherence
C. Case Study
D. Summary

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

5. 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 – See Appendix C

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

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

6. Action Item – Vote to Prior Authorize Cabometyx® (Cabozantinib), Fotivda® (Tivozanib), Jelmyto® (Mitomycin), and Padcev® (Enfortumab Vedotin-ejfv) – See Appendix D

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

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

7. Action Item – Vote to Prior Authorize Gemtesa® (Vibegron) – See Appendix E

A. Introduction
B. College of Pharmacy Recommendations

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

8. Action Item – Vote to Prior Authorize Zilxi® (Minocycline 1.5% Topical Foam) – See Appendix F

A. Introduction
B. College of Pharmacy Recommendations

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

9. Action Item – Vote to Prior Authorize Kynmobi™ (Apomorphine) and Ongentys® (Opicapone) – See Appendix G

A. New U.S. Food and Drug Administration (FDA) Approval(s)
B. Product Summaries
C. College of Pharmacy Recommendations

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

10. Action Item – Vote to Prior Authorize Fetroja® (Cefiderocol) and Kimyrsa™ (Oritavancin) – See Appendix H

A. New U.S. Food and Drug Administration (FDA) Approval(s)
B. Product Summaries
C. College of Pharmacy Recommendations

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

11. Annual Review of the SoonerCare Pharmacy Benefit – See Appendix I

A. Summary
B. Medicaid Drug Rebate Program
C. Alternative Payment Models
D. Drug Approval Trends
E. Traditional Versus Specialty Pharmacy Products
F. Top 10 Traditional Therapeutic Classes by Reimbursement
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

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

12. 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) – See Appendix J

A. Current Prior Authorization Criteria
B. Utilization of ADHD and Narcolepsy Medications
C. Prior Authorization of ADHD and Narcolepsy Medications
D. Oklahoma Resources
E. Market News and Updates
F. Product Summaries
G. College of Pharmacy Recommendations
H. Utilization Details of ADHD and Narcolepsy Medications

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

13. Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Lybalvi™ (Olanzapine/Samidorphan) – See Appendix K

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

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

14. 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) – See Appendix L

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

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

15. 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) – See Appendix M

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

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

16. Annual Review of Isturisa® (Osilodrostat) – See Appendix N

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

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

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

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

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

A. Intravenous (IV) Iron Products
B. Ophthalmic Anti-Inflammatories
C. Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications
D. Topical Corticosteroids

**Future product and class reviews subject to change.*

19. 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 MAY 12, 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	
Rebekah Bargewell; Administrative Assistant		x
Wendi Chandler, Pharm.D.; Clinical Pharmacist	x	
Andrew Craig; Database Analyst	x	
Lisa Daniel, Pharm.D.; Pharmacy Resident	x	
Erin Ford, Pharm.D.; Clinical Pharmacist		x
Mark Fuelling; Client Support Analyst		x
Thomas Ha, Pharm.D.; Clinical Pharmacist	x	
Katrina Harris, Pharm.D.; Clinical Pharmacist		x
Robert Klatt, Pharm.D.; Clinical Pharmacist	x	
Amy Miller; Operations Coordinator		x
Brandy Nawaz, Pharm.D.; Clinical Pharmacist	x	
Karen O'Neill, 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	
Susan Eads, J.D.; Director of Litigation	x	
Michael Herndon, D.O.; Chief Medical Officer		x
Jill Ratterman, D.Ph.; Clinical Pharmacist	x	
Paula Root, M.D.; Senior Medical Director	x	
Michelle Tahah, Pharm.D.; Clinical Pharmacist	x	

OTHERS PRESENT:	
Brandon Ross, Merck	Janelle Haristy, Novartis
Mark Kaiser, Otsuka	Joe Garcia, AbbVie
Brian Maves, Pfizer	Lindsey Walter, Novartis
Brent Parker, Merck	Evie Knisely, Novartis
Shellie Keast, Mercer	Bob Atkins, Biogen
Nima Nabavi, Amgen	Kristi Kemp, AbbVie
Jomy Joseph, Sanofi	Aaron Shaw, Boehringer-Ingelheim
Robert Pearce, Teva Pharmaceuticals	Gina Heinen, Novo Nordisk
Marc Parker, Sunovion	Kathryne Jensen, Artia Solutions
Robert Firnberg, Gilead	Andrew Delgado, Bristol Myers Squibb
Sarah Keehn, Merck	Keanna Dandridge, Novartis
Robert Greely, Biogen	Melanie Curlett, Takeda
Porscha Showers, Gilead	Jennifer Shumsky, Little Hercules Foundation
Dana Pipkin, Sarepta	Doug Wood, ViiV Health Care

PRESENT FOR PUBLIC COMMENT:	
Brandon Ross	Merck
Janelle Hardisty	Novartis

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

1A: 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**

2A: AGENDA ITEM NO. 7 BRANDON ROSS

2B: AGENDA ITEM NO. 9 JANELLE HARDISTY

ACTION: NONE REQUIRED

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

3A: APRIL 14, 2021 DUR MINUTES – VOTE

3B: APRIL 14, 2021 DUR RECOMMENDATIONS MEMORANDUM

3C: CORRESPONDENCE

Materials included in agenda packet; presented by Dr. Muchmore

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

ACTION: MOTION CARRIED

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

4A: PHARMACY HELPDESK ACTIVITY FOR APRIL 2021

4B: MEDICATION COVERAGE ACTIVITY FOR APRIL 2021

4C: PRENATAL VITAMIN UTILIZATION UPDATE

Materials included in agenda packet; presented by Dr. Chandler, Dr. Ha

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE LYUMJEV™ (INSULIN LISPRO-AABC)**

5A: NEW U.S FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL(S)

5B: NEWS

5C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Nawaz

Dr. Garton moved to approve; seconded by Dr. Broyles

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE AMONDYS 45™ (CASIMERSEN), VILTEPSO® (VILTOLARSEN), AND VYONDYS 53™ (GOLODIRSEN)**

6A: INTRODUCTION

6B: COST COMPARISON: DUCHENNE MUSCULAR DYSTROPHY (DMD) EXON-SKIPPING THERAPIES

6C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Chandler

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE VERQUVO™ (VERICIGUAT)**

7A: NEW U.S. FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL(S)

7B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE BREYANZI® (LISOCABTAGENE MARALEUCEL)**

8A: NEW U.S. FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL(S)

8B: BREYANZI® (LISOCABTAGENE MARALEUCEL) PRODUCT SUMMARY

8C: COST COMPARISON: CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPIES FOR LYMPHOMA

8D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Borders

Dr. Broyles moved to approve; seconded by Dr. Garton

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE COSELA™ (TRILACICLIB), GAVRETO™ (PRALSETINIB), RETEVMO® (SELPERCATINIB), TABRECTA™ (CAPMATINIB), TEPMETKO® (TEPOTINIB), AND ZEPZELCA™ (LURBINECTEDIN)**

9A: NEW U.S. FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL(S) AND INDICATION(S)

9B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Borders
Dr. Broyles moved to approve; seconded by Dr. Garton

ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 10:</u> ANNUAL REVIEW OF BALVERSA® (ERDAFITINIB) AND 30-DAY NOTICE TO PRIOR AUTHORIZE CABOMETYX® (CABOZANTINIB), FOTIVDA® (TIVOZANIB), JELMYTO® (MITOMYCIN), AND PADCEV® (ENFORTUMAB VEDOTIN-EJFV)

10A: INTRODUCTION
10B. CURRENT PRIOR AUTHORIZATION CRITERIA
10C: UTILIZATION OF BALVERSA® (ERDAFITINIB)
10D: PRIOR AUTHORIZATION OF BALVERSA® (ERDAFITINIB)
10E: MARKET NEWS AND UPDATES
10F: PRODUCT SUMMARIES
10G: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Borders

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 11:</u> ANNUAL REVIEW OF BLADDER CONTROL MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE GEMTESA® (VIBEGRON)

11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF BLADDER CONTROL MEDICATIONS
11C: PRIOR AUTHORIZATION OF BLADDER CONTROL MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: GEMTESA® (VIBEGRON) PRODUCT SUMMARY
11F: COLLEGE OF PHARMACY RECOMMENDATIONS
11G: UTILIZATION DETAILS OF BLADDER CONTROL MEDICATIONS

Materials included in agenda packet; presented by Dr. Wilson

ACTION: NONE REQURIED

<u>AGENDA ITEM NO. 12:</u> ANNUAL REVIEW OF TOPICAL ACNE AND ROSACEA PRODUCTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ZILXI® (MINOCYCLINE 1.5% TOPICAL FOAM)

12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF TOPICAL ACNE AND ROSACEA PRODUCTS
12C: PRIOR AUTHORIZATION OF TOPICAL ACNE AND ROSACEA PRODUCTS
12D: MARKET NEWS AND UPDATES
12E: ZILXI® (MINOCYCLINE 1.5% TOPICAL FOAM) PRODUCT SUMMARY
12F: COLLEGE OF PHARMACY RECOMMENDATIONS
12G: UTILIZATION DETAILS OF TOPICAL ACNE AND ROSACEA PRODUCTS

Materials included in agenda packet; presented by Dr. Wilson

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF VARIOUS SYSTEMIC ANTIBIOTICS AND 30-DAY NOTICE TO PRIOR AUTHORIZE FETROJA® (CEFIDEROCOL) AND KIMYRSA™ (ORITAVANCIN)

13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF VARIOUS SYSTEMIC ANTIBIOTICS
13C: PRIOR AUTHORIZATION OF VARIOUS SYSTEMIC ANTIBIOTICS
13D: MARKET NEWS AND UPDATES
13E: FETROJA® (CEFIDEROCOL) PRODUCT SUMMARY
13F: KIMYRSA™ (ORITAVANCIN) PRODUCT SUMMARY

13G: COLLEGE OF PHARMACY RECOMMENDATIONS
13H: UTILIZATION DETAILS OF VARIOUS SYSTEMIC ANTIBIOTICS
Materials included in agenda packet; presented by Dr. Ha
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 14:</u> ANNUAL REVIEW OF PARKINSON'S DISEASE (PD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE KYNMOBI™ (APOMORPHINE) AND ONGENTYS® (OPICAPONE)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF PD MEDICATIONS
14C: PRIOR AUTHORIZATION OF PD MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: KYNMOBI™ (APOMORPHINE) PRODUCT SUMMARY
14F: ONGENTYS® (OPICAPONE) PRODUCT SUMMARY
14G: COLLEGE OF PHARMACY RECOMMENDATIONS
14H: UTILIZATION DETAILS OF PD MEDICATIONS
Materials included in agenda packet; presented by Dr. Nawaz
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 15:</u> ANNUAL REVIEW OF ALZHEIMER'S DISEASE MEDICATIONS
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ALZHEIMER'S DISEASE MEDICATIONS
15C: PRIOR AUTHORIZATION OF ALZHEIMER'S DISEASE MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: COLLEGE OF PHARMACY RECOMMENDATIONS
15F: UTILIZATION DETAILS OF ALZHEIMER'S DISEASE MEDICATIONS
Materials included in agenda packet; presented by Dr. Nawaz
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 16:</u> ANNUAL REVIEW OF ALLERGEN IMMUNOTHERAPIES
16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF ALLERGEN IMMUNOTHERAPIES
16C: PRIOR AUTHORIZATION OF ALLERGEN IMMUNOTHERAPIES
16D: MARKET NEWS AND UPDATES
16E: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Chandler
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. Chandler
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 18:</u> FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
18A: ANNUAL REVIEW OF THE SOONERCARE PHARMACY BENEFIT
18B: ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS
18C: ATYPICAL ANTIPSYCHOTIC MEDICATIONS
18D: OPHTHALMIC ANTI-INFLAMMATORIES
18E: VARIOUS SPECIAL FORMULATIONS

**Future business subject to change.*
Materials included in agenda packet; presented by Dr. Adams

ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: ADJOURNMENT

The meeting was adjourned at 5:31pm.

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

Memorandum

Date: May 14, 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 May 12, 2021

Recommendation 1: Prenatal Vitamin Utilization Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Lyumjev™ (Insulin Lispro-aabc)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Lyumjev™ (insulin lispro-aabc) with the following criteria (changes shown in red):

Admelog® (Insulin Lispro), Insulin Lispro (Generic Humalog® U-100), and Lyumjev™ (Insulin Lispro-aabc 100 Units/mL) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use the brand formulation (Humalog®) must be provided (the brand formulation of Humalog® U-100 is preferred).

Humalog® KwikPen® U-200 (Insulin Lispro 200 Units/mL) and Lyumjev™ (Insulin Lispro-aabc 200 Units/mL) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. Authorization of the 200 units/mL strength requires a patient-specific, clinically significant reason why the member cannot use the 100

units/mL strength (the brand formulation of Humalog® U-100 is preferred).

Additionally, the College of Pharmacy recommends updating the anti-diabetic medications Tier-2 and Tier-3 approval criteria to provide a clinical exception for FDA approved indications for higher tiered medications not covered by lower tiered medications (changes shown in red):

Anti-Diabetic Medications Tier-2 Approval Criteria:

1. A trial of 1 Tier-1 medication (must include a trial of metformin titrated up to maximum dose), or a patient-specific, clinically significant reason why a Tier-1 medication is not appropriate must be provided.
2. For initiation with dual or triple therapy, additional Tier-2 medications may be approved based on current American Association of Clinical Endocrinologists (AACE) or American Diabetes Association (ADA) guidelines.
3. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-1 medications. Tier structure rules for unique FDA approved indications will apply.
4. ~~A clinical exception will apply for medications with an FDA approved indication to reduce the risk of cardiovascular (CV) death in adult patients with type 2 diabetes mellitus (T2DM) and CV disease for patients with the diagnosis of T2DM at high risk for CV events. Tier structure rules for this indication will apply.~~
5. ~~A clinical exception will apply for medications with an FDA approved indication to reduce the risk of end-stage kidney disease, worsening of kidney function, CV death, and heart failure (HF) hospitalization in adults with T2DM and diabetic kidney disease. Tier structure rules for this indication will apply.~~
6. ~~A clinical exception will apply for medications with an FDA approved indication to reduce the risk of hospitalization for HF in adults with T2DM and other CV risk factors. Tier structure rules for this indication will apply.~~

Anti-Diabetic Medications Tier-3 Approval Criteria:

1. Member must have tried 1 Tier-2 medication in the same category and have a documented clinical reason why the Tier-2 medication is not appropriate (for Tier-3 medications that do not have a similar category in Tier-2, a medication from any category in Tier-2 may be used).
2. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-1 and Tier-2 medications. Tier structure rules for unique FDA approved indications will apply.
3. ~~A clinical exception will apply for medications with an FDA approved indication to reduce the risk of cardiovascular (CV) death in adult patients with type 2 diabetes mellitus (T2DM) and CV disease for patients with the diagnosis of T2DM at high risk for CV events. Tier structure rules for this indication will apply.~~

~~4. A clinical exception will apply for medications with an FDA approved indication to reduce the risk of end-stage kidney disease, worsening of kidney function, CV death, and heart failure (HF) hospitalization in adults with T2DM and diabetic kidney disease. Tier structure rules for this indication will apply.~~

~~5. A clinical exception will apply for medications with an FDA approved indication to reduce the risk of hospitalization for HF in adults with T2DM and other CV risk factors. Tier structure rules for this indication will apply.~~

Finally, the College of Pharmacy recommends moving Adlyxin® (lixisenatide) and Rybelsus® (semaglutide) from Tier-3 to the Special Prior Authorization (PA) Tier of the Anti-Diabetic Medications Product Based Prior Authorization (PBPA) Tier Chart based on net cost, removing Bydureon® pen from the Tier Chart based on product discontinuation, and updating the Special PA criteria (changes shown in red):

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

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

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Alpha-Glucosidase Inhibitors			
acarbose (Precose®)		miglitol (Glyset®)	
Amylinomimetics			
			pramlintide (Symlin®)
Biguanides			
metformin (Glucophage®)			metformin ER (Fortamet®, Glumetza®)
metformin SR (Glucophage XR®)			metformin soln (Riomet®)
metformin/glipizide (Metaglip®)			metformin ER susp (Riomet ER™)

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
metformin/ glyburide (Glucovance®)			
DPP-4 Inhibitors			
	linagliptin (Tradjenta®)	alogliptin (Nesina®)	linagliptin/metformin ER (Jentadueto® XR)
	linagliptin/metformin (Jentadueto®)	alogliptin/metformin (Kazano®)	
	sitagliptin (Januvia®)	alogliptin/ pioglitazone (Oseni®)	
	sitagliptin/metformin (Janumet®)	saxagliptin (Onglyza®)	
	sitagliptin/ metformin ER (Janumet XR®)	saxagliptin/ metformin (Kombiglyze®)	
		saxagliptin/ metformin ER (Kombiglyze XR®)	
DPP-4 Inhibitors/SGLT-2 Inhibitors			
	empagliflozin/ linagliptin (Glyxambi®)	dapagliflozin/ saxagliptin (Qtern®)	
		ertugliflozin/ sitagliptin (Steglujan™)	
Dopamine Agonists			
		bromocriptine (Cycloset®)	
Glinides			
repaglinide (Prandin®)	nateglinide (Starlix®)		
	repaglinide/ metformin (Prandimet®)		
GLP-1 Agonists			
	dulaglutide (Trulicity®)	~~**lixisenatide (Adlyxin®)**~~	exenatide ER autoinjector (Bydureon® BCise™)
	exenatide (Byetta®)	semaglutide (Ozempic®)	**lixisenatide (Adlyxin®)**
	~~**exenatide ER (Bydureon®)**~~	~~**semaglutide (Rybelsus®)**~~	**semaglutide (Rybelsus®)**
	liraglutide (Victoza®)		
GLP-1 Agonists/Insulin			
		insulin degludec/ liraglutide (Xultophy® 100/3.6)+	

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
		insulin glargine/ lixisenatide (Soliqua® 100/33)+	
SGLT-2 Inhibitors			
	dapagliflozin (Farxiga®)	canagliflozin (Invokana®)	canagliflozin/metformin ER (Invokamet® XR)
	dapagliflozin/ metformin ER (Xigduo® XR)	canagliflozin/ metformin (Invokamet®)	
	empagliflozin (Jardiance®)	ertugliflozin (Steglatro™)	
	empagliflozin/ metformin (Synjardy®)	ertugliflozin/ metformin (Segluromet™)	
	empagliflozin/ metformin ER (Synjardy® XR)		
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
			dapagliflozin/ saxagliptin/metformin ER (Qternmet® XR)
			empagliflozin/ linagliptin/metformin ER (Trijardy® XR)
Sulfonylureas			
chlorpropamide (Diabinese®)			
glimepiride (Amaryl®)			
glipizide (Glucotrol®)			
glipizide SR (Glucotrol XL®)			
glyburide (Diabeta®)			
glyburide micronized (Micronase®)			
tolbutamide (Orinase®)			
Thiazolidinediones			
pioglitazone (Actos®)		pioglitazone/ glimepiride (Duetact®)	
		pioglitazone/ metformin (Actoplus Met®, Actoplus Met XR®)	
		rosiglitazone (Avandia®)	

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
		rosiglitazone/ glimepiride (Avandaryl®)	
		rosiglitazone/ metformin (Avandamet®)	

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

Recommendation 3: Vote to Prior Authorize Amondys 45™ (Casimersen), Viltepso® (Viltolarsen), and Vyondys 53™ (Golodirsen)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Amondys 45™ (casimersen), Viltepso® (viltolarsen), and Vyondys 53™ (golodirsen) and updating the current Exondys 51® (eteplirsen) criteria with the following changes shown in red:

Amondys 45™ (Casimersen), Exondys 51® (Eteplirsen), Viltepso® (Viltolarsen), and Vyondys 53™ (Golodirsen) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD); and
2. Member must have a confirmed mutation of the *DMD* gene that is amenable to exon skipping for the requested medication (results of genetic testing must be submitted); and
3. Must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and
4. Prescriber must verify the member's renal function will be appropriately assessed prior to initiation of therapy and monitored during treatment; and
5. Member must be on a stable dose of a corticosteroid (at least 3 months in duration) or a patient-specific, clinically significant reason why corticosteroids are not appropriate for the member must be provided; and
6. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
   a. 6-minute walk test (6MWT); or
   b. Forced vital capacity percent predicted (FVCpp); and

7. The requested exon-skipping therapy will not be approved for concurrent use with any other exon-skipping therapies for DMD; and
8. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and
9. Subsequent approvals will be for the duration of 1 year. For yearly approvals, the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and
10. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Recommendation 4: Vote to Prior Authorize Verquvo™ (Vericiguat)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Verquvo™ (vericiguat) with the following criteria:

Verquvo™ (Vericiguat) Approval Criteria:

1. An FDA approved indication to reduce the risk of cardiovascular death and hospitalization for heart failure (HF) in adults with all of the following:
    a. Chronic symptomatic HF [New York Heart Association (NYHA) Class II, III, or IV]; and
    b. Reduced left ventricular ejection fraction (LVEF) <45%; and
    c. Already receiving guideline-directed medical therapy for HF, as documented in member's pharmacy claims history; and
2. Member has evidence of worsening HF (decompensation) demonstrated by at least 1 of the following:
    a. Hospitalization for HF within the past 6 months; or
    b. Received outpatient intravenous (IV) diuretics within the past 3 months; and
3. Member must be 18 years of age or older; and
4. Member must not be taking concomitant soluble guanylate cyclase (sGC) stimulators (e.g., riociguat); and
5. Female members of reproductive potential must not be breastfeeding, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during treatment and for 1 month after the final dose of Verquvo™; and

6. Prescriber must agree to titrate to the target maintenance dose according to package labeling, as tolerated by the member; and
7. Initial approvals will be for the duration of 6 months. Compliance will be checked for continued approval every 6 months; and
8. A quantity limit of 30 tablets per 30 days will apply.

Recommendation 5: Vote to Prior Authorize Breyanzi® (Lisocabtagene Maraleucel)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Breyanzi® (lisocabtagene maraleucel) with the following criteria, including an update based on net cost in comparison to other available CAR T-cell therapies indicated for large B-cell lymphoma [items shown in red are changes from what was included in the March 2021 Drug Utilization Review (DUR) Board packet]:

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma; and
2. Relapsed or refractory disease; and
3. Member must have received at least 2 lines of systemic therapy; and
4. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements; and
5. A patient-specific, clinically significant reason why Kymriah® (tisagenlecleucel) or Yescarta® (axicabtagene) is not appropriate for the member must be provided.

Recommendation 6: Vote to Prior Authorize Cosela™ (Trilaciclib), Gavreto™ (Pralsetinib), Retevmo® (Selpercatinib), Tabrecta™ (Capmatinib), Tepmetko® (Tepotinib), and Zepzelca™ (Lurbinectedin)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Cosela™ (trilaciclib), Gavreto™ (pralsetinib), Retevmo® (selpercatinib), Tabrecta™ (capmatinib), Tepmetko® (tepotinib), and Zepzelca™ (lurbinectedin) with the following criteria (shown in red):

Cosela™ (Trilaciclib) Approval Criteria:

1. Diagnosis of extensive-stage small cell lung cancer (ES-SCLC); and

2. Member is undergoing myelosuppressive chemotherapy with 1 of the following:
    a. Platinum (carboplatin or cisplatin) and etoposide-containing regimen; or
    b. Topotecan-containing regimen; and
3. Cosela™ will not be approved for concomitant use with colony-stimulating factors (CSF) [e.g., granulocyte CSF (G-CSF), pegylated G-CSF (peg-G-CSF), granulocyte-macrophage CSF (GM-CSF)] for primary prophylaxis of febrile neutropenia prior to day 1 cycle 1 of chemotherapy.

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

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

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

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

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

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

Retevmo® (Selpercatinib) Approval Criteria [Thyroid Cancer Diagnosis]:

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

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

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
2. Mesenchymal-epithelial transition (MET) exon 14 skipping positive tumor; and

3. As a single-agent.

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

1. Diagnosis of advanced, metastatic, or unresectable NSCLC; and
2. Mesenchymal-epithelial transition (MET) exon 14 skipping positive tumor; and
3. As a single-agent.

Zepzelca™ (Lurbinectedin) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of metastatic SCLC; and
2. Used following disease progression on or after platinum-based chemotherapy.

Additionally, the College of Pharmacy recommends updating the approval criteria for Alunbrig® (brigatinib), Cyramza® (ramucirumab), Imfinzi® (durvalumab), Keytruda® (pembrolizumab), Libtayo® (cemiplimab-rwlc), Lorbrena® (lorlatinib), Tagrisso® (osimertinib), and Tecentriq® (atezolizumab) based on recent FDA approvals (changes noted in red):

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

1. Diagnosis of metastatic NSCLC; and
2. Anaplastic lymphoma kinase (ALK) positivity~~; and~~
~~3. Progressed on or intolerant to crizotinib; and~~
~~4. Brigatinib must be used as a single-agent only.~~

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

1. Diagnosis of metastatic NSCLC; and
2. First-line in combination with erlotinib; and
   a. Epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation; or
3. Subsequent therapy for metastatic disease; and
   a. In combination with docetaxel.

Imfinzi® (Durvalumab) Approval Criteria [Extensive-Stage Small Cell Lung Cancer (ES-SCLC) Diagnosis]:

1. Diagnosis of ES-SCLC; and
2. In combination with etoposide and either cisplatin or carboplatin followed by single-agent maintenance.

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Basal Cell Carcinoma (BCC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic BCC; and
2. Member has previously been treated with a hedgehog pathway inhibitor (HHI); or

3. Treatment with a HHI is not appropriate for the member.

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of advanced, unresectable, or metastatic NSCLC; and
2. High programmed death ligand 1 (PD-L1) expression [tumor proportion score (TPS) ≥50%]; and
3. No epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or *ROS1* mutations.

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

1. Diagnosis of metastatic NSCLC; and
2. Tumor expresses anaplastic lymphoma kinase (ALK) translocation; and
3. As a single-agent as first-line therapy; or
4. As a single-agent as second-line therapy following disease progression on either alectinib or ceritinib; or
5. As a single-agent as third-line or greater therapy following disease progression on crizotinib and 1 other ALK inhibitor (i.e., ceritinib, alectinib).

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

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

Tecentriq® (Atezolizumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of advanced, unresectable, or metastatic HCC; and
2. Used in combination with bevacizumab; and
3. Member has not received prior systemic therapy.

The College of Pharmacy also recommends the removal of the Imfinzi® (durvalumab) approval criteria for the indication of locally advanced or metastatic bladder cancer based on FDA guided voluntary withdrawal of this indication by the manufacturer.

~~**Imfinzi® (Durvalumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:**~~

~~1. A diagnosis of locally advanced or metastatic urothelial carcinoma; and~~
~~2. Progressed on or following platinum-containing chemotherapy.~~

Finally, the College of Pharmacy recommends updating the approval criteria for Keytruda® (pembrolizumab) based on the National Comprehensive Cancer Network (NCCN) Compendium approval and the recent FDA approved indication (changes and new criteria noted in red; only criteria with updates are listed):

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

1. Diagnosis of locally advanced, recurrent, or metastatic esophageal, gastric, or GEJ carcinoma; and
2. Tumor must have positive programmed death ligand 1 (PD-L1) expression; and
    a. For esophageal carcinoma: Combined positive score (CPS) ≥10; or
    b. For gastric or GEJ carcinoma: CPS ≥1; and
3. For first-line therapy:
    a. Must be used in combination with either oxaliplatin or cisplatin plus a fluoropyrimidine; or
4. For second-line or greater therapy:
    a. Must be used following disease progression after 1 or more prior lines of systemic therapy; and
    b. Tumor must be squamous cell histology; and
    c. Must be used as monotherapy; and
5. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo (nivolumab)].

Recommendation 7: Annual Review of Balversa® (Erdafitinib) and 30-Day Notice to Prior Authorize Cabometyx® (Cabozantinib), Fotivda® (Tivozanib), Jelmyto® (Mitomycin), and Padcev® (Enfortumab Vedotin-ejfv)

NO ACTION REQUIRED.

Recommendation 8: Annual Review of Bladder Control Medications and 30-Day Notice to Prior Authorize Gemtesa® (Vibegron)

NO ACTION REQUIRED.

Recommendation 9: Annual Review of Topical Acne and Rosacea Products and 30-Day Notice to Prior Authorize Zilxi® (Minocycline 1.5% Topical Foam)

NO ACTION REQUIRED.

Recommendation 10: Annual Review of Various Systemic Antibiotics and 30-Day Notice to Prior Authorize Fetroja® (Cefiderocol) and Kimyrsa™ (Oritavancin)

NO ACTION REQUIRED.

Recommendation 11: Annual Review of Parkinson's Disease (PD) Medications and 30-Day Notice to Prior Authorize Kynmobi™ (Apomorphine) and Ongentys® (Opicapone)

NO ACTION REQUIRED.

Recommendation 12: Annual Review of Alzheimer's Disease Medications

NO ACTION REQUIRED.

Recommendation 13: Annual Review of Allergen Immunotherapies

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.

Appendix B

Medication Therapy Management (MTM) Program Update

Oklahoma Health Care Authority
June 2021

MTM Program Update

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. The University of Oklahoma College of Pharmacy: Pharmacy Management Consultants (PMC) collaborates with OHCA to continually identify members who may be at increased risk for poor outcomes due to existing conditions and other factors. SoonerCare members with these high-risk and correspondingly high-cost conditions can improve their health outcomes and reduce cost to the health care system by optimizing their medications through MTM services. An overview of the MTM program can be found in the March 2021 Drug Utilization Review (DUR) Board packet.

As of May 14, 2021, PMC has completed over 1,300 MTM reviews for SoonerCare members since the beginning of the MTM program in December 2019. Now in the second year of the program, PMC continues to work on program innovation to increase member participation. The total number of MTM reviews continues to increase, with >100 reviews completed each month. Starting in April 2021, PMC began outreach to members who completed an MTM review over a year ago, and as a result of the outreach, so far 41 members have chosen to complete a second MTM review, demonstrating that members value the MTM program.

Member 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. Member demographic information is shown in Figure 1 and is based on 811 MTM reviews completed in members with at least 6 months post-MTM observation data.

Figure 1: MTM Program Member Demographics (n=811)	
Age	
Average age (SD)	47.2 ±13.3
18-44	42%
45-64	53%
65+	5%

Figure 1: MTM Program Member Demographics (n=811)	
Gender	
Female	75%
Male	25%
Race	
American Indian or Alaskan native	6%
Asian	1%
Black or African American	19%
Native Hawaiian or other Pacific Islander	<1%
White	65%
More than one race	5%
Charlson Comorbidity Index (CCI)	
Mean total score (SD)	3.3 ± 2.8

MTM = medication therapy management

Focus on Adherence[1]

One key component of a MTM review is a focus on medication adherence. Adherence refers to whether the patient is taking their medications as prescribed. It is estimated that non-adherence to medications costs the health care system nearly $300 billion per year in additional doctor visits, emergency department visits, and hospitalizations.[1] There are several reasons why a SoonerCare member may not take their medications as prescribed including difficulty navigating the health care system, socioeconomic factors such as low health literacy, confusion on directions, concern about side effects, behavioral factors such as forgetfulness, and patient factors such as physical or cognitive impairment. PMC pharmacists use motivational interviewing techniques to identify those reasons and provide tailored solutions for each member.

According to the Pharmacy Quality Alliance (PQA), the preferred method to estimate medication adherence is through measuring the proportion of days covered (PDC), or percentage of days covered by prescription claims. A member is considered adherent if the PDC is ≥80%. The results in both Figure 2 and Figure 3 show the change in PDC for the identified drug classes for members who participated in the MTM program. The results show that PMC's solutions are working for members, as the percentage of members who are adherent (PDC ≥80%) has increased following MTM review.

Figure 2: Medication Adherence – Chronic Disease			
Medication Class	**Antihypertensives (n=319)**	**Statins (n=173)**	**Anti-Diabetics (n=128)**
Adherent (PDC ≥80%)			
Pre-MTM (%)	41.4%	36.6%	39.8%
Post-MTM (%)	55.2%	47.7%	53.9%

% increase in number of members with PDC ≥80%	33.3%	30.2%	35.3%
Mean PDC			
Pre-MTM PDC (SD)	65.5 (30.7)	60.2 (29.4)	62.5 (31.1)
Post-MTM PDC (SD)	73.7 (28.3)	69.14 (28.5)	73.3 (28.4)

*Includes members with at least 180 days in the post-observation period and had at least 1 claim for the medication in the pre and post periods.
MTM = medication therapy management; Pre = before MTM review; Post = after MTM review; PDC = proportion of days covered; SD = standard deviation

Figure 3: Medication Adherence – Behavioral Health		
Medication Class	**Antidepressants (n=299)**	**Antipsychotics (n=115)**
Adherent (PDC ≥80%)		
Pre-MTM (%)	39.1%	40.9%
Post-MTM (%)	46.8%	46.9%
% increase in number of members with PDC ≥80%	19.7%	14.9%
Mean PDC		
Pre-MTM PDC (SD)	62.0 (31.3)	63.8 (31.1)
Post-MTM PDC (SD)	68.5 (29.8)	68.6 (29.9)

*Includes members with at least 180 days in the post-observation period and had at least 1 claim for the medication in the pre and post periods.
MTM = medication therapy management; Pre = before MTM review; Post = after MTM review; PDC = proportion of days covered; SD = standard deviation

Case Study

Member is a 56-year-old female with a diagnosis history of type 2 diabetes, hypertension, acid reflux, depression, anxiety, and chronic obstructive pulmonary disease (COPD).

Drug-related problems (DRPs) identified by pharmacist:

- Member was dosing her Humulin® R (insulin human) U-500 on her own sliding scale
- Victoza® (liraglutide) never titrated up, as instructed by prescriber
- Member had difficulty using her Victoza® (liraglutide) because she was legally blind
- Uncontrolled diabetes with recent HgA1c around 10% and blood glucose levels ranging from 200-400mg/dL
- Not currently taking a statin

DRPs resolved by pharmacist:

- Counseled patient on proper dosing of both anti-diabetic medications
- Recommended 90-day supplies of chronic medications to help with adherence and member copays

DRPs resolved by provider after recommendations sent by pharmacist:

- Discontinued Victoza® (liraglutide) daily dosing regimen; changed to Trulicity® (dulaglutide) weekly dosing regimen
- Discontinued Humulin® R (insulin human) U-500 sliding scale regimen; changed to basal/bolus regimen with Lantus® (insulin glargine) and NovoLog® (insulin aspart)
- Atorvastatin 40mg was started
- New prescriptions for 90-day supplies sent to pharmacy for chronic medications

Summary

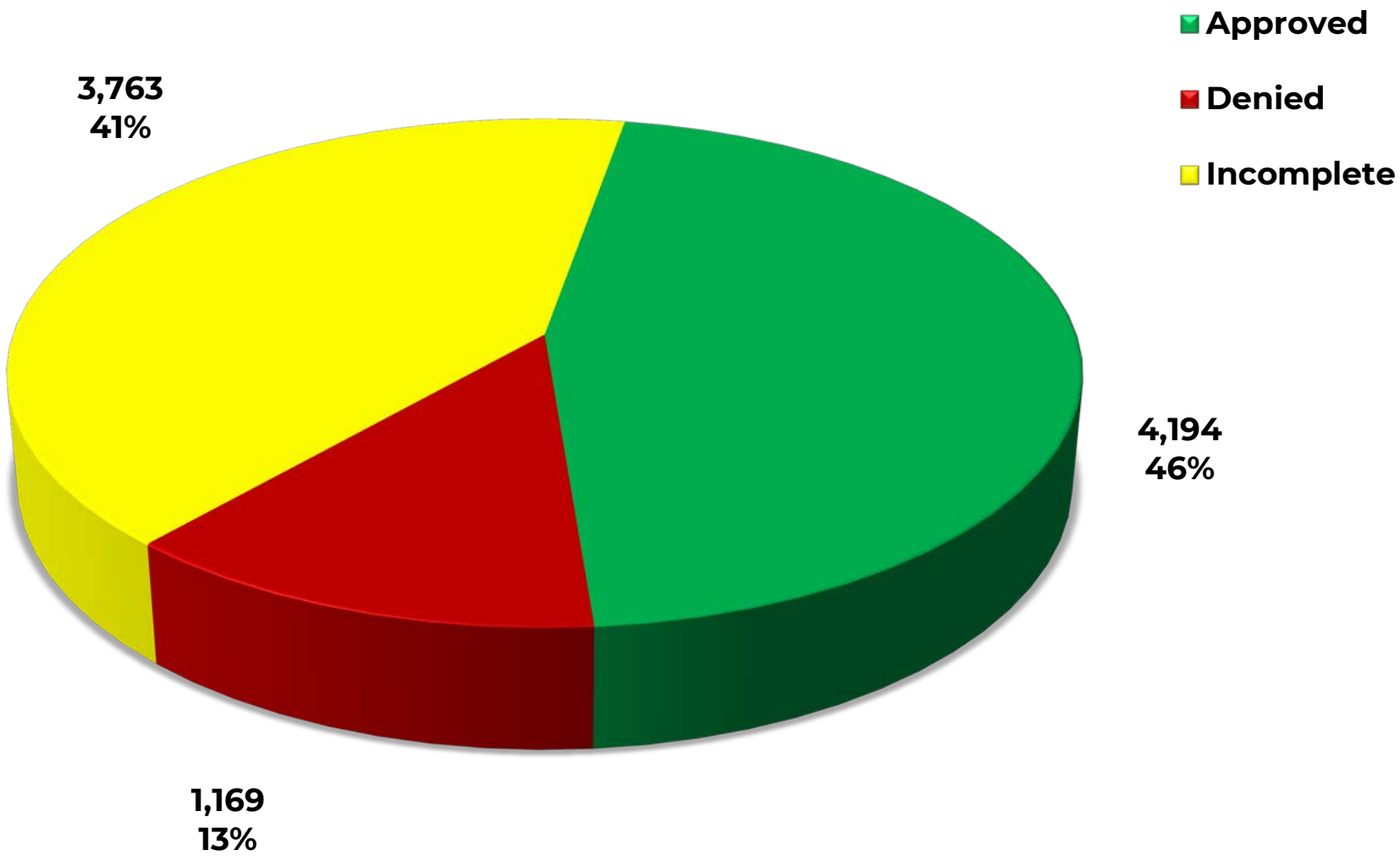
Medication adherence is essential for positive therapeutic outcomes, and as the cost associated with non-adherence to medication therapy continues to increase, PMC is dedicated to finding innovative solutions to this health care issue. Non-adherence can be difficult to manage because there are usually multiple reasons a member does not take their medications as prescribed, and non-adherence may lead to false medication failure, resulting in unnecessary dose increases or medication changes or additions, disease complications, and increased health care costs. MTM services provide a unique approach to non-adherence because solutions can be tailored to the individual. Members who participate in the MTM program have shown an increase in adherence, demonstrating these solutions are effective.

PMC will continue to work with OHCA to identify members who may benefit from MTM services with the goal of promoting the evidence-based use of medications for SoonerCare members. Future results of the MTM services will be reviewed with the OHCA Drug Utilization Review (DUR) Board as they become available.

[1] American Heart Association. Medication Adherence – Taking Your Meds as Directed. Available online at: https://www.heart.org/en/health-topics/consumer-healthcare/medication-information/medication-adherence-taking-your-meds-as-directed. Last accessed 05/25/2021.

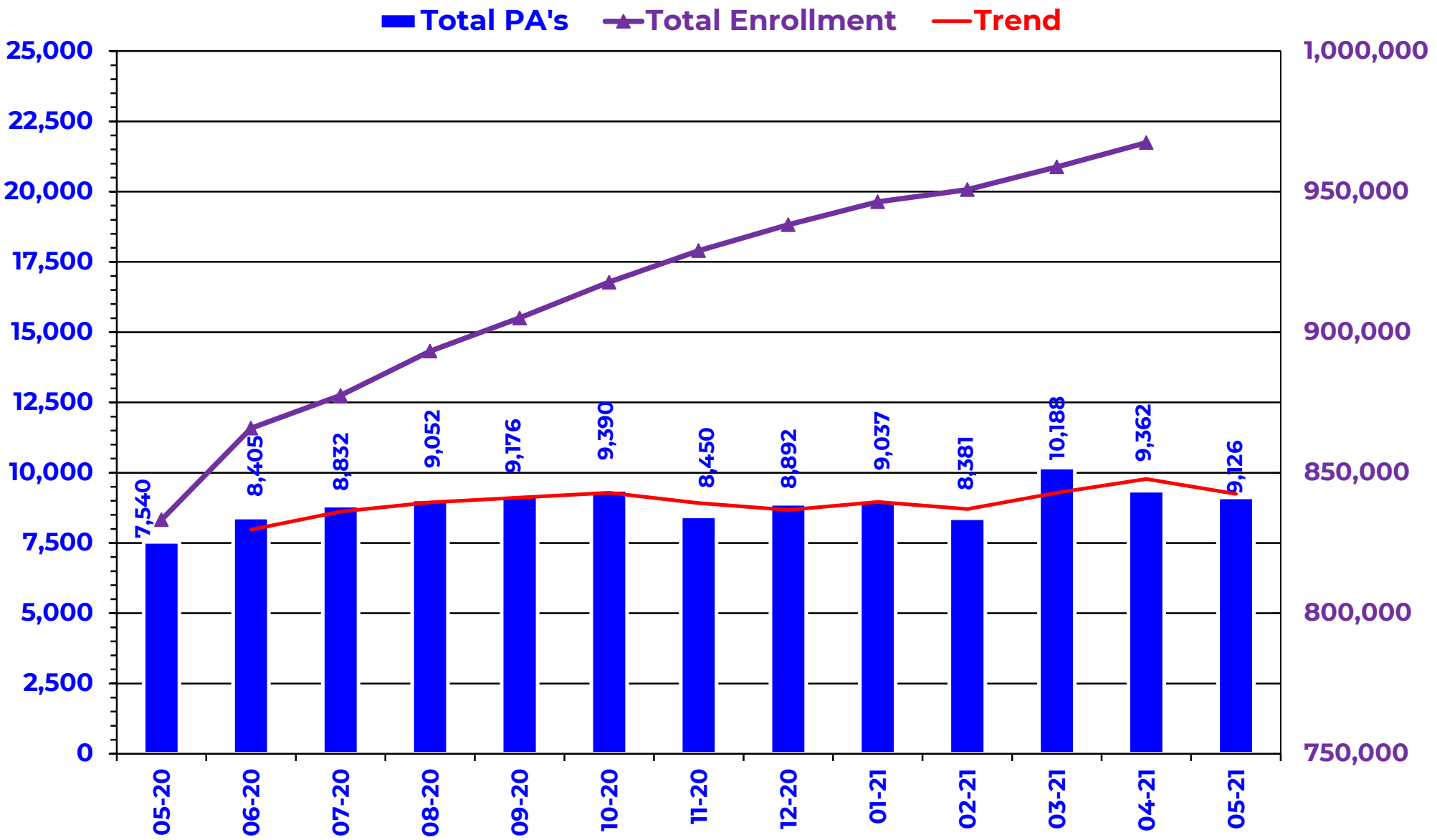
Appendix C

PRIOR AUTHORIZATION ACTIVITY REPORT: MAY 2021



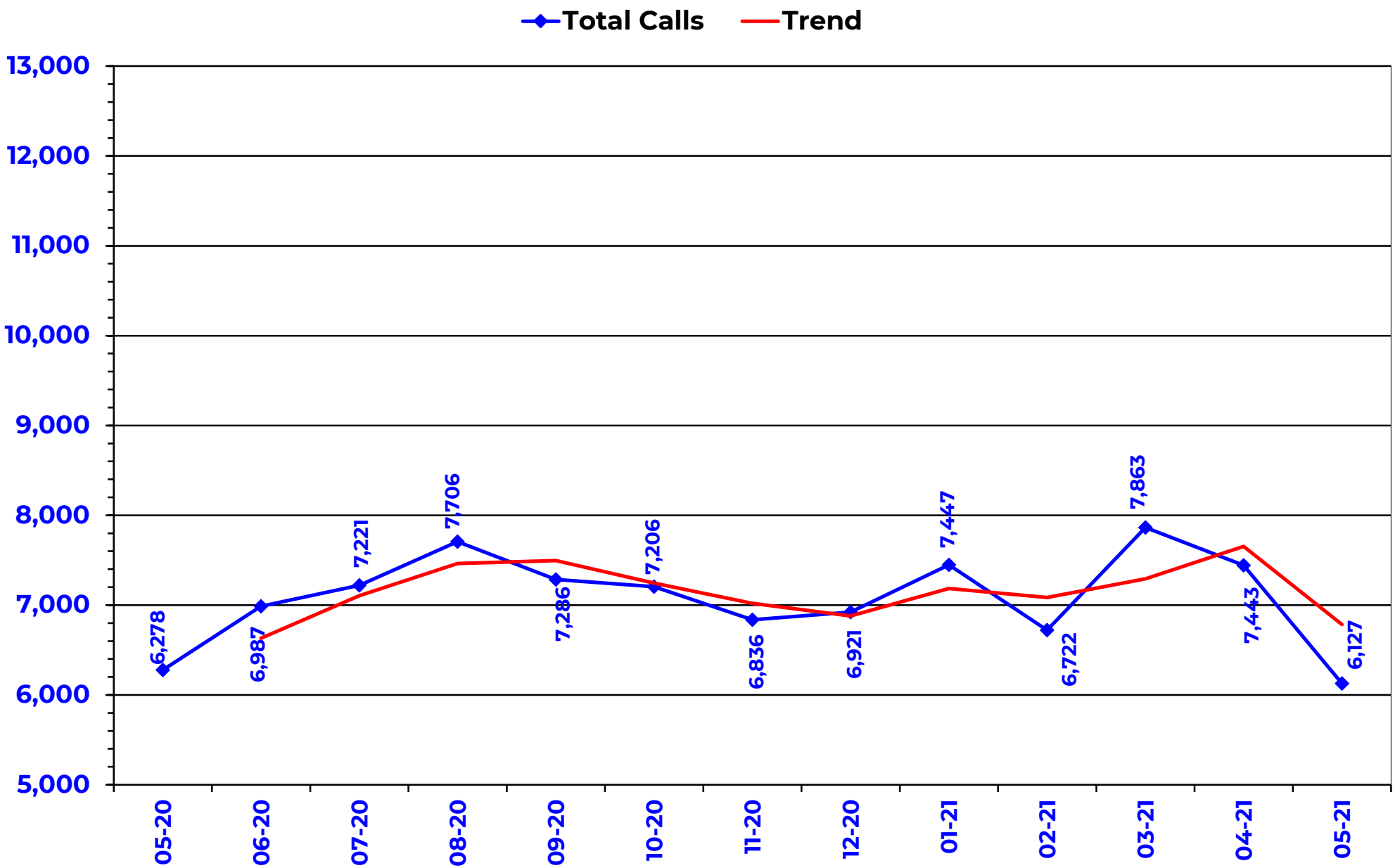
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: MAY 2020 – MAY 2021



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
MAY 2020 – MAY 2021



Prior Authorization Activity

5/1/2021 Through 5/31/2021

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	62	18	5	39	355
Analgesic - NonNarcotic	12	1	2	9	198
Analgesic, Narcotic	233	85	24	124	161
Antiasthma	54	17	10	27	294
Antibiotic	54	27	4	23	195
Anticonvulsant	194	88	10	96	308
Antidepressant	187	42	25	120	322
Antidiabetic	403	130	65	208	355
Antihistamine	52	17	6	29	278
Antimigraine	245	43	94	108	246
Antineoplastic	78	42	16	20	169
Antiulcers	59	11	16	32	108
Anxiolytic	19	0	3	16	0
Atypical Antipsychotics	329	141	35	153	354
Biologics	200	96	25	79	297
Bladder Control	39	11	8	20	358
Blood Thinners	338	196	18	124	340
Botox	42	30	9	3	301
Buprenorphine Medications	64	19	5	40	81
Cardiovascular	59	30	8	21	300
Chronic Obstructive Pulmonary Disease	211	34	56	121	330
Constipation/Diarrhea Medications	119	27	28	64	195
Contraceptive	18	7	1	10	282
Dermatological	336	95	94	147	201
Diabetic Supplies	954	491	83	380	258
Endocrine & Metabolic Drugs	104	61	8	35	184
Erythropoietin Stimulating Agents	22	10	2	10	86
Fibromyalgia	2	0	1	1	0
Fish Oils	20	6	4	10	359
Gastrointestinal Agents	162	43	31	88	243
Glaucoma	14	5	1	8	226
Growth Hormones	111	77	11	23	151
Hematopoietic Agents	13	5	2	6	155
Hepatitis C	146	71	18	57	8
HFA Rescue Inhalers	11	0	2	9	0
Insomnia	52	5	10	37	177
Insulin	156	80	5	71	355
Miscellaneous Antibiotics	15	1	1	13	11
Multiple Sclerosis	63	27	7	29	239
Nasal Allergy	57	12	20	25	131
Neurological Agents	85	28	16	41	255
NSAIDs	25	3	4	18	358
Ocular Allergy	42	2	14	26	85
Ophthalmic Anti-infectives	18	2	5	11	19

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Ophthalmic Corticosteroid	14	5	1	8	290
Osteoporosis	16	5	4	7	357
Other*	363	93	48	222	286
Pediculicide	16	3	1	12	17
Respiratory Agents	50	34	0	16	275
Statins	22	4	5	13	220
Stimulant	817	398	106	313	350
Testosterone	73	21	12	40	358
Thyroid	13	9	1	3	301
Topical Antifungal	30	2	7	21	50
Topical Corticosteroids	62	1	34	27	116
Vitamin	82	20	37	25	150
Pharmacotherapy	71	62	0	9	285
Emergency PAs	0	0	0	0	
Total	**7,153**	**2,798**	**1,077**	**3,278**	
Overrides					
Brand	22	17	0	5	288
Compound	11	9	0	2	16
Cumulative Early Refill	3	2	0	1	21
Diabetic Supplies	26	25	0	1	144
Dosage Change	349	315	0	34	11
High Dose	8	6	0	2	224
Ingredient Duplication	7	6	0	1	15
Lost/Broken Rx	98	86	1	11	15
MAT Override	240	171	4	65	64
NDC vs. Age	321	212	37	72	245
NDC vs. Sex	5	1	2	2	85
Nursing Home Issue	51	44	0	7	15
Opioid MME Limit	135	45	10	80	120
Opioid Quantity	44	34	1	9	167
Other*	49	38	1	10	13
Quantity vs. Days Supply	554	352	34	168	252
STBS/STBSM	12	6	1	5	57
Step Therapy Exception	2	1	1	0	358
Stolen	4	4	0	0	24
Overrides Total	**1,973**	**1,396**	**92**	**485**	
Total Regular PAs + Overrides	**9,126**	**4,194**	**1,169**	**3,763**	

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

Denial Reasons	
Unable to verify required trials.	3,113
Does not meet established criteria.	1,199
Lack required information to process request.	610
Other PA Activity	
Duplicate Requests	999
Letters	16,445
No Process	7
Changes to existing PAs	650
Helpdesk Initiated Prior Authorizations	783
PAs Missing Information	1

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

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

Oklahoma Health Care Authority
June 2021

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

Atherosclerotic cardiovascular disease (ASCVD) is the leading cause of morbidity and mortality for individuals with diabetes, and an estimated $37.3 billion is spent annually on CV-related issues associated with diabetes. Co-existing conditions like hypertension (HTN) and hyperlipidemia (HLD) are risk factors for ASCVD, while diabetes itself confers independent risk. The 2021 American Diabetes Association (ADA) *Standards of Medical Care in Diabetes* guidelines include a dedicated decision pathway for individuals with indicators of high CV risk or established ASCVD. For these individuals, either a GLP-1 agonist or an SGLT-2 inhibitor with known CV benefit should be considered independent of baseline hemoglobin A1C target or metformin use. Per the ADA guidelines, indicators of high CV risk include an age of 55 years or older with left ventricular hypertrophy or with >50% coronary, carotid, or lower-extremity artery stenosis. The GLP-1 agonists with U.S. Food and Drug Administration (FDA) approved CV benefit include Victoza® (liraglutide), Trulicity® (dulaglutide), and Ozempic® (injectable semaglutide). The SGLT-2 inhibitors with FDA approved CV benefit include Jardiance® (empagliflozin), Farxiga® (dapagliflozin), and Invokana® (canagliflozin).

Mailing Summary

In late February 2021, the College of Pharmacy (COP) and the Oklahoma Health Care Authority (OHCA) sent an educational letter to 120 providers regarding 944 unique members with a diagnosis of T2D with high CV risk or established ASCVD who were not receiving treatment with 1 of the above GLP-1 agonists or SGLT-2 inhibitors based on their SoonerCare pharmacy claims history. The number of members associated with these top 120 providers ranged from 39 members to 3 members per provider. High CV risk was determined using the indicators suggested in the ADA guidelines (55 years of age or older with left ventricular hypertrophy or with >50% coronary, carotid, or lower-extremity artery stenosis) or a diagnosis of HTN and HLD as evidenced in the member's SoonerCare claims history. The purpose of the

educational mailing was to encourage providers to evaluate evidence-based prescribing practices for SoonerCare members with diabetes and high CV risk or established ASCVD and determine if they may benefit from therapy with a GLP-1 agonist or SGLT-2 inhibitor with FDA approved CV benefit. Providers were selected for this mailing if they were the most recent prescriber for at least 1 SoonerCare member with concurrent diagnoses of T2DM and ASCVD or high CV risk factors in the last year who did not have any SoonerCare pharmacy paid claims for a GLP-1 agonist or SGLT-2 inhibitor with CV benefit. Members with a diagnosis of end-stage renal disease (ESRD), heart failure (HF), and pregnancy were excluded.

Mailing Results

In May 2021, 2.5 months after the letters were sent out, a second claims analysis was performed. The claims analysis found 23 members (2.44%) included in the mailing had a paid claim for a GLP-1 agonist or SGLT-2 inhibitor with CV benefit after the letter was sent. There were 20 different providers who received letters regarding the 23 members recently started on the new therapy. The 20 providers encompass 16.7% of the total 120 providers who received a mailing, and the 20 providers' letters included a total of 169 unique SoonerCare members combined. Therefore 17.9% of the 944 members included in the mailing were potentially evaluated to determine appropriate therapy. Pharmacy claims not billed to SoonerCare (e.g., cash claims, office samples, commercial insurance) were not included in the claims analyses.

Conclusions

Although only a 2.44% increase was observed in the second claims analysis, there was evidence showing that 169 identified members (17.9%) were potentially evaluated for appropriate therapy. It is important to note that a major limitation of this retrospective drug utilization review (retroDUR) project is that only 2.5 months had passed between the letter being mailed out and the second claims analysis. These 2.5 months also occurred during a global pandemic in which members may not have been seen by their primary care provider. In addition, the 2.5 months is also shorter than a 90-day medication supply; therefore, some members may not have been due for a prescription refill. It is anticipated that the 2.44% increase will continue to rise as more time passes. Additionally, it is important to note that the recommended GLP-1 agonists and SGLT-2 inhibitors with CV benefit require prior authorization that could delay the time to filling the medication. However, while these medications do require prior authorization, there is a clinical exception that applies for members who require the medication for its CV benefit (tier structure still applies). Overall, the purpose of this mailing was not to see all of the members started on therapy with a GLP-1 agonist or SGLT-2 inhibitor with CV benefit, but rather to ensure the providers were

evaluating these members for appropriate therapy. The COP will continue to work with OHCA to improve educational mailings with the goal of improving the quality of care for SoonerCare members with T2D. New interventions will be implemented where appropriate, and results will be reported to the DUR Board when available.

[1] Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes – 2021. *Diabetes Care* 2021; 44(1):S125–S150.
[2] Marso SP, Daniels GH, Brown-Frandsen K, et al; LEADER Steering Committee; LEADER Trial Investigators. Liraglutide and Cardiovascular Outcomes in Type 2 Diabetes. *N Engl J Med* 2016; 375:311-322.
[3] Gerstein HC, Colhoun HM, Dagenais GR, et al; REWIND Investigators. Dulaglutide and Cardiovascular Outcomes in Type 2 Diabetes (REWIND): a Double-blind, Randomized Placebo-controlled Trial. *Lancet* 2019; 394:121-130.
[4] Marso SP, Bain SC, Consoli A, et al.; SUSTAIN-6 Investigators. Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes. *N Engl J Med* 2016; 375:1834-1844.
[5] Zinman B, Wanner C, Lachin JM, et al.; EMPGA-REG OUTCOME Investigators. Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes. *N Engl J Med* 2015; 373:2117-2128.
[6] Wiviott SD, Raz I, Bonaca MP, et al. Dapagliflozin and Cardiovascular Outcomes in Type 2 Diabetes. *N Engl J Med* 2019; 380:347-357.
[7] Neal B, Perkovic V, Mahaffey KW, et al; CANVAS Program Collaborative Group. Canagliflozin and Cardiovascular and Renal Events in Type 2 Diabetes. *N Engl J Med* 2017; 377:644-657.

Appendix D

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

Oklahoma Health Care Authority
June 2021

Market News and Updates[1]

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

- **December 2019:** The FDA granted accelerated approval to Padcev® (enfortumab vedotin-ejfv) for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-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.
- **April 2020:** The FDA approved Jelmyto® (mitomycin) for the treatment of adult patients with low-grade upper tract urothelial cancer.
- **January 2021:** The FDA approved the combination of Opdivo® (nivolumab) and Cabometyx® (cabozantinib) as first-line treatment for adult patients with advanced renal cell carcinoma (RCC). Cabometyx® was originally approved by the FDA in April 2016 for the treatment of adult patients with advanced RCC who have received prior antiangiogenic therapy. Additionally, in January 2019, Cabometyx® received FDA approval for the treatment of adult patients with hepatocellular carcinoma (HCC) who have been previously treated with Nexavar® (sorafenib).
- **March 2021:** The FDA approved Fotivda® (tivozanib) for the treatment of adult patients with relapsed or refractory advanced RCC following 2 or more prior systemic therapies.

Product Summaries[2,3,4,5]

Cabometyx® (Cabozantinib):

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):**
  - Advanced RCC
  - Advanced RCC as a first-line treatment in combination with nivolumab
  - HCC in patients previously treated with sorafenib
- **How Supplied:** 20mg, 40mg, and 60mg oral tablets
- **Dose:**
  - Advanced RCC as a single-agent: 60mg once daily

    - Advanced RCC in combination with nivolumab: 40mg once daily with nivolumab 240mg every 2 weeks or 480mg every 4 weeks for up to 2 years
    - HCC: 60mg once daily
- **Cost:** The Wholesale Acquisition Cost (WAC) is $722.09 per 60mg tablet, resulting in a cost per 30 days of $21,662.70 for the recommended dose of 60mg daily

Fotivda® (Tivozanib):
- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):** Relapsed or refractory advanced RCC following 2 or more prior systemic therapies
- **How Supplied:** 1.34mg and 0.89mg oral capsules
- **Dose:** 1.34mg once daily for 21 days followed by 7 days off treatment (28-day cycle)
    - For moderate hepatic impairment, dose reduction to 0.89mg once daily for 21 days on and 7 days off (28-day cycle) is recommended
- **Cost:** The WAC is $1,150 for the 1.34mg capsule, resulting in a cost per 21 days of $24,150 for the recommended dose of 1.34mg daily

Jelmyto® (Mitomycin):
- **Therapeutic Class:** Alkylating drug
- **Indication(s):** LG-UTUC
- **How Supplied:** A single-dose carton containing the following:
    - (2) 40mg single-dose vials (SDVs) of mitomycin for pyelocalyceal solution
    - (1) 20mL vial of sterile hydrogel for reconstitution
- **Dose:**
    - 4mg/mL instilled once weekly for 6 weeks via ureteral catheter or nephrostomy tube, with total instillation volume not to exceed 15mL (60mg of mitomycin)
    - For patients with a complete response 3 months after therapy initiation, instillations may be administered once a month for a maximum of 11 additional instillations
- **Cost:** The WAC is $21,376 per single-dose carton containing (2) 40mg SDVs of mitomycin, resulting in a cost per 6 weeks of $128,256 based on the recommended once weekly dosing

Padcev® (Enfortumab Vedotin-ejfv):
- **Therapeutic Class:** Nectin-4-directed antibody and microtubule inhibitor conjugate
- **Indication(s):** Locally advanced or metastatic urothelial cancer after previous treatment with PD-1 or PD-L1 inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced, or metastatic setting

- **How Supplied:** 20mg and 30mg lyophilized powder for reconstitution in SDVs
- **Dose:** 1.25mg/kg (up to a maximum dose of 125mg) via intravenous (IV) infusion on days 1, 8, and 15 of a 28-day cycle
- **Cost:** The WAC is $2,277.00 per 20mg vial and $3,415.50 per 30mg vial, resulting in a cost per 28 days of $30,739.50 for an adult patient weighing 70kg

Recommendations

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.

[1] U.S. Food and Drug Administration (FDA). Hematology/Oncology (Cancer) Approvals & Safety Notifications. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/hematologyoncology-cancer-approvals-safety-notifications. Last revised 05/05/2021. Last accessed 05/12/2021.
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[3] Fotivda® Prescribing Information. AVEO Pharmaceuticals, Inc. Available online at: https://www.fotivda.com/fotivdapi.pdf. Last revised 03/2021. Last accessed 05/12/2021.
[4] Jelmyto® Prescribing Information. UroGen Pharma, Inc. Available online at: https://www.urogen.com/download/pdf/jelmyto_prescribing.pdf. Last revised 01/2021. Last accessed 05/12/2021.
[5] Padcev® Prescribing Information. Astellas Pharma US, Inc. Available online at: https://astellas.us/docs/PADCEV_label.pdf. Last revised 03/2021. Last accessed 05/12/2021.

Appendix E

Vote to Prior Authorize Gemtesa® (Vibegron)

Oklahoma Health Care Authority
June 2021

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

VESIcare LS™ (solifenacin oral suspension) was approved by the U.S. Food and Drug Administration (FDA) in May 2020 for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 2 years of age and older. VESIcare LS™ is available as a 5mg/5mL oral suspension. The recommended dose for NDO is weight-based and ranges from 2mg to 10mg per day (refer to the full *Prescribing Information* for the complete weight-based dosing recommendations for this indication, including the starting dose and maximum dose by weight range). The Wholesale Acquisition Cost (WAC) of VESIcare LS™ is $1.71 per mL.

Myrbetriq® (mirabegron tablet) was approved by the FDA in March 2021 for a new indication for the treatment of NDO in pediatric patients 3 years of age and older weighing ≥35kg. Additionally, the FDA approved a new formulation of **Myrbetriq® (mirabegron granules for oral suspension)** which can be used in pediatric patients with NDO 3 years of age or older weighing <35kg. The tablet and granule formulations of Myrbetriq® are not substitutable on a milligram-per-milligram basis. Myrbetriq® granules will be available in bottles containing 830mg of mirabegron, resulting in an 8mg/mL oral suspension after reconstitution with 100mL of water. The recommended dose for NDO in patients weighing <35kg is weight-based and ranges from 24mg to 64mg per day. For patients weighing ≥35kg, either formulation of mirabegron may be used, but the recommended dosing varies depending on which formulation is selected (refer to the full *Prescribing Information* for the complete dosing recommendations for this indication, including the starting dose and maximum dose by weight range and formulation). The FDA granted a 6-month pediatric exclusivity period for Myrbetriq®. Astellas plans to launch the new granule formulation of Myrbetriq® in the United States by the end of 2021. Cost information for the granule formulation is not yet available.

Gemtesa® (vibegron) was approved by the FDA in December 2020 for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence (UUI), urgency, and urinary frequency in adults. Vibegron is a selective beta-3 adrenergic agonist. When activated, beta-3 receptors in the bladder increase the bladder's capacity by causing a relaxation of the detrusor smooth muscle during bladder filling. Gemtesa® is supplied as a 75mg oral tablet, and the recommended dose is 75mg once daily with or without food, swallowed whole with a glass of water. Alternatively, in adults,

the tablets may be crushed, mixed with approximately 15mL of applesauce, and taken immediately with a glass of water. The safety and efficacy of vibegron have not been established in pediatric patients. The FDA approval of Gemtesa® for the treatment of OAB was based on data from the Phase 3 EMPOWUR study, a 12-week, double-blind, randomized, placebo- and active-controlled study in adult patients 18 years of age or older with OAB. Patients were randomized 5:5:4 to receive vibegron 75mg, placebo, or tolterodine extended-release (ER) 4mg once daily for 12 weeks. Tolterodine ER was included as an active control in the study, but no formal statistical comparisons were conducted between vibegron and tolterodine ER. The co-primary endpoints were change from baseline in average daily number of micturitions and average daily number of UUI episodes at week 12. After 12 weeks of treatment, the average daily number of micturitions was reduced by 1.8 for patients receiving vibegron and 1.3 for patients receiving placebo [treatment difference: -0.5; P<0.001; 95% confidence interval (CI): -0.8, -0.2]. The average daily number of UUI episodes was reduced by 2 for patients receiving vibegron and 1.4 for patients receiving placebo (treatment difference: -0.6; P<0.0001; 95% CI: -0.9, -0.3).

Cost Comparison:

Product	Cost Per Unit*	Cost Per Month⁺
Gemtesa® (vibegron) 75mg tablet	**$15.28**	**$458.40**
Myrbetriq® (mirabegron) 50mg tablet	$13.34	$400.20
tolterodine 4mg ER capsule (generic)	$1.31	$39.30
oxybutynin 15mg ER tablet (generic)	$0.26	$15.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unit = 1 capsule or tablet
⁺Cost per month based on the maximum FDA approved dose for each product.
ER = extended-release

Recommendations

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®)$^{\Delta}$ **tablets and granules$^{\beta}$**	desmopressin acetate SL tablets (Nocdurna®)⁺
oxybutynin ER (Ditropan XL®)		oxybutynin gel (Gelnique®)	oxybutynin patch (Oxytrol®)⁺
solifenacin (VESIcare®)$^{\Delta}$		trospium ER (Sanctura XR®)	**vibegron (Gemtesa®)⁺**
solifenacin oral susp (VESIcare LS™)$^{\alpha}$			
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.
$^{\Delta}$Unique criteria specific to use of Myrbetriq® (mirabegron) in combination with VESIcare® (solifenacin) applies.
$^{\alpha}$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.
$^{\beta}$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.

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Appendix F

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

Oklahoma Health Care Authority
June 2021

Introduction[1,2,3]

Aczone® (dapsone 7.5% gel) was approved by the U.S. Food and Drug Administration (FDA) in September 2019 for an expanded indication to include patients 9 to 11 years of age. Aczone® 7.5% gel was previously FDA approved in February 2016 for patients 12 years of age and older for the treatment of inflammatory and non-inflammatory acne. The expanded approval was based on data from an open-label safety study to assess safety, pharmacokinetics, and treatment effect of Aczone® 7.5% gel in 101 patients 9 to 11 years of age with acne vulgaris. Based on the results of the study, Aczone® 7.5% gel was determined to be safe and effective in this age range.

Zilxi® (minocycline 1.5% topical foam) was FDA approved in May 2020 for the treatment of inflammatory lesions of rosacea in adults. Zilxi® is the first minocycline-containing product approved by the FDA for rosacea. Zilxi® is supplied as a 1.5% topical foam (containing 15mg minocycline per gram) in a 30g pressurized aluminum aerosol can. The FDA approval was based on data from (2) 12-week, multicenter, double-blind, vehicle-controlled Phase 3 studies in 1,522 adult patients with moderate-to-severe facial papulopustular rosacea. The co-primary endpoints were absolute change from baseline in inflammatory lesion count and Investigator Global Assessment (IGA) treatment success at week 12. Both studies met the co-primary endpoints, demonstrating significantly greater reduction in inflammatory lesions and a higher proportion of patients with IGA treatment success at week 12 with Zilxi® compared to vehicle.

Cost Comparison:

Product	Cost Per Unit*	Cost Per Package⁺
Zilxi® (minocycline) 1.5% topical foam	**$16.17**	**$485.10**
Amzeeq® (minocycline) 4% topical foam	$15.51	$465.30
metronidazole 0.75% topical cream (generic)	$0.99	$44.55
metronidazole 0.75% topical gel (generic)	$0.73	$32.85
clindamycin 1% topical solution (generic)	$0.22	$13.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unit = 1 gram or mL
⁺Cost per package based on the largest package size available for each product listed (30g for Zilxi® and Amzeeq®, 45g for metronidazole 0.75% cream and metronidazole 0.75% gel, and 60mL for clindamycin 1% topical solution)

Recommendations

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 be 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.

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[3] Zilxi® (Minocycline Topical Foam) Prescribing Information. Vyne Therapeutics, Inc. Available online at: https://zilxi.com/sites/default/files/documents/prescribing-information.pdf. Last revised 01/2021. Last accessed 05/26/2021.

Appendix G

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

Oklahoma Health Care Authority
June 2021

New U.S. Food and Drug Administration (FDA) Approval(s)[1,2]

- **April 2020:** The FDA approved Ongentys® (opicapone) 25mg and 50mg capsules as an add-on treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes. As the disease progresses, patients taking levodopa/carbidopa may begin to experience "off" time between treatment doses, during which an increase in PD motor symptoms such as tremor, slowed movement, and difficulty walking occur. Ongentys® increases "on" time, the time when the motor symptoms of a patient with PD are better controlled, without troublesome dyskinesia. Ongentys® is an oral, selective catechol-O-methyltransferase (COMT) inhibitor that helps block the COMT enzyme which breaks down levodopa, the gold standard therapy for controlling motor symptoms in patients with PD. Ongentys® protects levodopa by reducing its breakdown in the blood, making more levodopa available to reach the brain, prolonging its clinical effects and helping patients achieve motor symptom control. The FDA approval of Ongentys® is supported by data from 38 clinical studies, including 2 multinational Phase 3 clinical studies (BIPARK-1 and BIPARK-2), with >1,000 PD patients treated with Ongentys®. Both studies included a 1-year, open-label extension. Data from both studies showed that Ongentys® 50mg significantly reduced "off" time from baseline to week 14 or 15 compared to placebo. "On" time without troublesome dyskinesia also increased from baseline to week 14 or 15 compared to placebo.
- **May 2020:** The FDA approved Kynmobi™ (apomorphine) sublingual (SL) film for the acute, intermittent treatment of "off" episodes in patients with PD. Kynmobi™ SL film, a novel formulation of apomorphine, a dopamine agonist, is the first and only SL therapy for the fast-acting, on-demand treatment of "off" episodes associated with PD. Kynmobi™ may be used up to 5 times a day. Phase 3 clinical study results, published in *Lancet Neurology,* demonstrated that patients with PD receiving Kynmobi™ experienced significant improvements in motor symptoms at 30 minutes after dosing at week 12, with a mean reduction of 7.6 points, compared to placebo, on the Movement Disorder Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part III score. Higher scores indicate increased severity. Initial

clinical improvements were seen at 15 minutes post-administration. Additionally, a significantly higher percentage of patients treated with Kynmobi™ had a patient-rated full "on" response within 30 minutes at week 12, compared with patients receiving placebo.

Kynmobi™ (Apomorphine) Product Summary[3,4]

- **Therapeutic Class:** Non-ergoline dopamine agonist
- **Indication(s):** Acute, intermittent treatment of "off" episodes in patients with PD
- **How Supplied:** 10mg, 15mg, 20mg, 25mg, and 30mg SL films
- **Dose:**
    - Dose initiation should be supervised by a health care provider.
    - The dose range for Kynmobi™ is 10mg to 30mg per dose administered as needed. The maximum single dose of Kynmobi™ is 30mg, and Kynmobi™ administration should not exceed >5 doses per day.
    - Kynmobi™ doses should be separated by at least 2 hours. If a single dose of Kynmobi™ is ineffective for a particular "off" episode, a second dose should not be given for that "off" episode. The efficacy and safety of administering a second dose for a single "off" episode have not been studied.
    - Kynmobi™ should be administered whole and will disintegrate in approximately 3 minutes. Kynmobi™ should not be cut, chewed, or swallowed.
    - Due to the high incidence of nausea and vomiting with Kynmobi™ administration at recommended doses, concomitant treatment with an antiemetic (e.g., trimethobenzamide) is recommended, beginning 3 days prior to the initial dose of Kynmobi™; however, concomitant use of an 5-HT_3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron) with Kynmobi™ is contraindicated due to the risk of profound hypotension and altered consciousness. Treatment with the antiemetic should only be continued as long as necessary to control nausea and vomiting, and generally no longer than 2 months after initiation of treatment with Kynmobi™.
- **Cost:** The Wholesale Acquisition Cost (WAC) is $47,250.00 per year for Kynmobi™ 30mg dosed 5 times per day.

Ongentys® (Opicapone) Product Summary[5,6]

- **Therapeutic Class:** COMT inhibitor
- **Indication(s):** Adjunctive treatment to levodopa/carbidopa in patients with PD experiencing "off" episodes

- **How Supplied:** 25mg and 50mg oral capsules
- **Dose:**
  - The recommended dosage is 50mg administered orally once daily at bedtime. Patients should not eat food 1 hour before and at least 1 hour after taking Ongentys®.
  - The recommended dosage in patients with moderate hepatic impairment is 25mg orally once daily at bedtime. Ongentys® should be avoided in patients with severe hepatic impairment.
- **Cost:** The WAC is $7,081.20 per year for Ongentys® 50mg once daily.

Recommendations

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.

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[2] Sunovion Pharmaceuticals, Inc. Sunovion Announces U.S. FDA Approval of Kynmobi™ (Apomorphine Hydrochloride) Sublingual Film for the Treatment of Parkinson's Disease Off Episodes. *Business Wire*. Available online at: https://news.sunovion.com/press-releases/press-releases-details/2020/Sunovion-Announces-US-FDA-Approval-of-KYNMOBI-apomorphine-hydrochloride-Sublingual-Film-for-the-Treatment-of-Parkinsons-Disease-OFF-Episodes/default.aspx. Issued 05/21/2020. Last accessed 05/17/2021.

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Appendix H

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

Oklahoma Health Care Authority
June 2021

New U.S. Food and Drug Administration (FDA) Approval(s)[1,2,3,4,5]

Fetroja® (cefiderocol) was approved by the FDA in November 2019 for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by susceptible gram-negative microorganisms. In September 2020, the FDA expanded the indication for Fetroja® to include treatment of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) caused by susceptible gram-negative microorganisms. The safety and efficacy of Fetroja® for cUTI, including pyelonephritis, and HABP/VABP were assessed in 2 active-controlled, double-blind, randomized, Phase 3 trials in hospitalized patients 18 years of age and older. In the first trial, Fetroja® was compared to imipenem/cilastatin for the treatment of cUTI, including pyelonephritis, while the second trial compared Fetroja® to meropenem for the treatment of HABP/VABP. In both trials, Fetroja® was shown to be non-inferior to both active-controlled groups.

Kimyrsa™ (oritavancin) was approved by the FDA in March 2021 for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of designated gram-positive microorganisms, including methicillin-resistant *Staphylococcus aureus* (MRSA), in adult patients. The safety and efficacy of Kimyrsa™ for ABSSSI were established in the SOLO clinical trials with another oritavancin product, Orbactiv®. The FDA approval of Kimyrsa™ was based on an open-label, pharmacokinetic study which compared Kimyrsa™ infused over 1 hour to Orbactiv® infused over 3 hours. Kimyrsa™ was shown to be comparable to Orbactiv® with a favorable safety profile.

Fetroja® (Cefiderocol) Product Summary[6]

- **Therapeutic Class:** Cephalosporin antibiotic
- **Indication(s):** Treatment of patients 18 years of age and older with the following infections caused by susceptible gram-negative microorganisms:
  - **cUTI, including pyelonephritis:** *Escherichia coli, Enterobacter cloacae* complex, *Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa*

    - **HABP/VABP:** *Acinetobacter baumannii* complex, *Escherichia coli*, *Enterobacter cloacae* complex, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Serratia marcescens*
- **How Supplied:** 1 gram lyophilized powder for reconstitution in a single-dose vial (SDV)
- **Dose:**
    - 2 grams every 8 hours via intravenous (IV) infusion over 3 hours for 7 to 14 days
    - Treatment duration to be guided by patient's clinical status
    - Dose adjustments are required for patients with renal impairment
- **Cost:** The Wholesale Acquisition Cost (WAC) of Fetroja® is $189.75 per SDV, resulting in a cost of $1,138.50 per day of therapy at the recommended dose of 2 grams every 8 hours.

Kimyrsa™ (Oritavancin) Product Summary[7]

- **Therapeutic Class:** Lipoglycopeptide antibiotic
- **Indication(s):** Treatment of adult patients with ABSSSI caused by or suspected to be caused by susceptible isolates of designated gram-positive microorganisms:
    - *Staphylococcus aureus* (including methicillin-resistant isolates), *Streptococcus agalactiae*, *Streptococcus anginosus group (*includes *S. anginosus*, *S. intermedius*, and *S. constellatus)*, *Streptococcus dysgalactiae*, *Streptococcus pyogenes*, and *Enterococcus faecalis* (vancomycin-susceptible isolates only)
- **How Supplied:** 1,200mg lyophilized powder for reconstitution in a SDV
- **Dose:** 1,200mg as a single dose given by IV infusion over 1 hour
- **Cost:** Pricing information is not available at this time. Melinta Therapeutics is planning to launch Kimyrsa™ in summer 2021.

Recommendations

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).

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[1] U.S. Food and Drug Administration. FDA Approves New Antibacterial Drug to Treat Complicated Urinary Tract Infections as Part of Ongoing Efforts To Address Antimicrobial Resistance. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-new-antibacterial-drug-treat-complicated-urinary-tract-infections-part-ongoing-efforts. Issued 11/14/2019. Last accessed 05/14/2021.

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Appendix I

Calendar Year 2020 Annual Review of the SoonerCare Pharmacy Benefit

Oklahoma Health Care Authority
June 2021

Summary[1,2,3,4,5,6]

During calendar year (CY) 2020, prescription drugs accounted for $592.5 million of the approximately $5.28 billion in total SoonerCare spending. According to the Centers for Medicare and Medicaid Services (CMS), the national health expenditure is projected to grow at an average rate of 5.4% annually, and Medicaid expenditures are expected to grow at a rate of 5.7% annually. Comparing SoonerCare pharmacy data from CY 2019, the total reimbursement increased 4.6% from CY 2019 to CY 2020, less than the CMS-estimated Medicaid expenditure increase. The annual pharmacy cost per member decreased from $701.32 in CY 2019 to $666.15 in CY 2020, which is a 5% decrease. Although there was a decrease in reimbursement per member, the specialty pharmaceutical products total pharmacy reimbursement continues to be on the incline as a result of orphan drug approvals for rare diseases, as well as numerous new oncology medications and the high costs associated with these therapies.

Indian Health Service (IHS) reimbursement was updated in 2017 to the Federal Office of Management and Budget encounter rate; therefore, in order to more accurately compare CY 2020 with previous years, IHS data was excluded from this analysis. Additionally, costs in this report do not reflect the federal and state supplemental rebates that are provided by medication manufacturers. The coverage and prior authorization criteria of many medications, particularly the anti-infective, attention-deficit/hyperactivity disorder (ADHD), antipsychotic, endocrine, and analgesic classes, are significantly influenced by supplemental rebates, and net costs are substantially lower than the total reimbursement to pharmacies included in this analysis.

Total Pharmacy State Fiscal Year (SFY) Comparison							
SFY	**Claims**	**Members**	**Utilizers***	**Reimbursement**	**Cost/Claim**	**Cost/Member**	**Cost/Day**
2018⁺	5,802,025	1,020,726	535,823	$543,569,067	$93.70	$532.62	$3.61
2019⁺	5,508,417	998,209	516,569	$555,643,845	$100.87	$556.64	$3.80
2020	5,292,429	822,271◊	495,722	$576,735,805	$108.97	$701.39	$3.95

◊Average monthly enrollment as obtained from OHCA Fast Facts reports
*Total number of unduplicated utilizers.
Reimbursement does not reflect rebated costs or net costs.
State Fiscal Year = July 1 to June 30
⁺Utilization data as listed in the previous annual review of the SoonerCare pharmacy benefit report

Total Pharmacy Calendar Year (CY) Comparison							
CY	**Claims**	**Members◊**	**Utilizers***	**Reimbursement**	**Cost/Claim**	**Cost/Member**	**Cost/Day**
2018	5,662,452	816,009	529,885	$554,467,343	$97.92	$679.49	$3.73
2019	5,467,453	807,530	518,167	$566,334,267	$103.58	$701.32	$3.88
2020	5,056,276	889,437	469,039	$592,497,789	$117.18	$666.15	$4.02

◊Average monthly enrollment as obtained from OHCA Fast Facts reports
*Total number of unduplicated utilizers
Reimbursement does not reflect rebated costs or net costs.

The per member per year (PMPY) value reflects the total pharmacy cost divided by the unduplicated number of members (total enrollees) for each time period. In order to reflect an accurate PMPY value, average monthly enrollment was used in place of annual enrollment, and dual eligible (members eligible for Medicare and Medicaid) and IHS members were excluded. The PMPY value is used across benefit plans with similar populations to accurately assess health care spending. The following table contains the overall PMPY values for the past few years.

Overall PMPY Calendar Year Comparison			
Calendar Year (CY)	**CY 2018***	**CY 2019***	**CY 2020**
Overall PMPY Value◊	$803	$856	$872

PMPY = per member per year
◊PMPY value calculated using average monthly enrollment, excluding dual eligible and IHS members.
*PMPY values as listed in the previous annual review of the SoonerCare pharmacy benefit report

Oklahoma currently uses a fee-for-service (FFS) pharmacy benefit for the SoonerCare program. Pharmacy benefit managers (PBMs) are used by some states for their FFS pharmacy programs, contracting out services such as claims processing and payment, prior authorization processing, drug utilization review (DUR), and formulary management. Similarly, Medicaid managed care organizations (MCOs) frequently subcontract the management of the pharmacy benefit to a separate PBM. The Oklahoma Health Care Authority (OHCA) currently contracts with Pharmacy Management Consultants (PMC), a department within the University of Oklahoma College of Pharmacy, for many of these services.

To measure the success of the SoonerCare pharmacy benefit management, Oklahoma's Medicaid statistics were compared to the Medicaid statistics of the largest PBM in the United States, Express Scripts (ESI). For CY 2020, ESI's Medicaid PMPY was $1,214, making it 39% higher than OHCA's $872. At the ESI PMPY rate, it would have cost OHCA over $232.8 million more than the $592.5 million spent during CY 2020 for pharmacy reimbursement.

Medicaid PMPY Comparison			
Calendar Year	**ESI**	**OHCA**	**Percent Difference**
2018*	$1,342	$803	-67%
2019*	$1,373	$856	-60%
2020	$1,214	$872	-39%

ESI = Express Scripts; OHCA = Oklahoma Health Care Authority; PMPY = per member per year
PMPY costs do not reflect rebated prices or net costs.
*PMPY values as listed in the previous annual review of the SoonerCare pharmacy benefit report

SoonerCare prior authorization policies, coupled with quantity limits and monthly prescription limits, yield better than average results while still providing a comprehensive pharmacy benefit for approximately 900,000 SoonerCare members. Looking at the cost to manage the pharmacy benefit, the OHCA pharmacy department has a cost of about $1 million. OHCA's partner, PMC, spent approximately $5 million of their contract in CY 2020. As a return on investment (ROI), using the overage generated by the ESI PMPY rate, for CY 2020 it is $39 to $1.

Medicaid Drug Rebate Program[7,8,9]

Medicaid coverage of a drug requires the manufacturer to have a federal rebate agreement with the Secretary of Health and Human Services (HHS). Participation in the federal drug rebate program requires Medicaid coverage with limited exceptions (e.g., cosmetic medications, fertility medications). Rebate amounts are based on the "best price" for each drug. Best price refers to the lowest price paid to a manufacturer for a drug by any commercial payer. Best prices are reported to CMS by the manufacturer but are not publicly available.

If a drug's price increases more quickly than inflation, an additional rebate penalty is included based on the change in price compared with the consumer price index (CPI). The CPI penalty of the federal rebate is designed to keep Medicaid net cost relatively flat despite increases in drug prices. Until the first quarter of 2017, the CPI penalty only applied to brand medications; however, following a Senate vote in October 2015 in response to increasing generic drug prices, the Medicaid CPI penalty was extended to generic drugs with an effective date of January 1, 2017. The cost increases found in this report do not reflect net cost increases.

Additionally, many states have negotiated supplemental rebate agreements with manufacturers to produce added rebates. In CY 2020, OHCA collected $386 million in federal and state supplemental rebates, resulting in a total increase from CY 2019 ($365 million in federal and state rebates). These rebates are collected after reimbursement for the medication and are not reflected in this report.

Alternative Payment Models[10,11,12,13,14,15,16]

The introduction of a greater number of costly specialty medications, finite Medicaid budgets, Medicaid policy, and access requirements has resulted in alternative payment arrangements as particularly compelling opportunities. Medicaid programs must provide comprehensive care to vulnerable individuals while operating under limited budgets and regulatory requirements. An alternative payment model (APM) is an agreement between a payer and manufacturer that is intended to provide improved patient care or increased access to evidence-based therapies while lowering costs or improving health outcomes. In general, there are 2 types of APMs:

- **Financial APM:** Caps or discounts are used to provide predictability or limit spending; these type of contracts are intended to lower costs and expand access. Data collection for financial APMs is minimal, making them easier to administer.
  - Examples: Price volume agreements, market share, patient level utilization caps, manufacturer funded treatment initiation
- **Health Outcome-Based APM:** Payments for medications are tied to clinical outcomes or measurements; these type of contracts are often referred to as "value-based contracts." Health outcome-based APMs require additional planning and data collection, but do have the potential to increase the quality and value of treatments.
  - Examples: Outcomes guarantee, conditional coverage, PMPY guarantees, event avoidance (e.g., hospitalizations)

Since October 2016, PMC and OHCA have been engaged in negotiations with pharmaceutical manufacturers regarding pharmacy value-based contracts. PMC and OHCA have initiated talks with more than 25 companies regarding APMs and have established 7 APM contracts with pharmaceutical manufacturers following CMS approval to participate in value-based payment arrangements in June 2018. Oklahoma was the first Medicaid state to receive approval from CMS to participate in value-based payment arrangements. Future considerations include the expectation that initial value-based contracts will set the precedent for further collaboration among manufacturers and state Medicaid agencies.

Overview of Established APM Contracts	
Manufacturer	**Details**
Alkermes	▪ Long-acting injectable (LAI) antipsychotic – adherence
Amgen	▪ Tumor necrosis factor (TNF) inhibitor – utilization and cost ▪ Focus on population characterizations to inform future value-based contracts
Avexis	▪ Spinal muscular atrophy (SMA) medication – utilization
Janssen	▪ LAI antipsychotic – adherence; phase 2 will include additional clinical outcomes

Overview of Established APM Contracts	
Manufacturer	**Details**
Lilly	▪ Anti-migraine medication [calcitonin gene-related peptide (CGRP) antagonist] – utilization and cost
UCB	▪ Anticonvulsant medication – health resource utilization

APM = alternative payment model

Drug Approval Trends[17,18,19]

During CY 2020, the U.S. Food and Drug Administration (FDA) approved the first generic product of several key medications that may have a significant impact on SoonerCare reimbursement. Key first-time generics approved by the FDA in CY 2020 included Butrans® (buprenorphine transdermal patch), Sklice® (ivermectin lotion), Ciprodex® (ciprofloxacin/ dexamethasone otic suspension), and Saphris® (asenapine sublingual tablet).

A total of 53 novel drugs were approved by the FDA during CY 2020. The active ingredient or ingredients in a novel drug have never before been approved in the United States. Of the novel drugs approved by the FDA in CY 2020, 19 were considered first-in-class and 34 were approved to treat rare or "orphan" diseases. Select novel drugs approved during CY 2020 that are expected to be highly utilized or have a particular impact in the SoonerCare population are included in the following table.

Select Novel Drugs FDA Approved During Calendar Year 2020			
Drug Name	**Date Approved**	**FDA-Approved Indication**	**Estimated Annual Cost Per Member***
Viltepso® (viltolarsen)	08/12/2020	Treatment of DMD	$586,560 for member weighing 25kg
Evrysdi™ (risdiplam)	08/07/2020	Treatment of SMA	$335,112
Zeposia® (ozanimod)	03/25/2020	Treatment of relapsing forms of MS	$88,639
Nurtec® ODT (rimegepant)	02/27/2020	Treatment of acute migraine with or without aura	$19,260
Vyepti™ (eptinezumab-jjmr)	02/21/2020	Preventative treatment of migraine	$5,980 – $17,940

*Costs do not include rebated or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
DMD = Duchenne muscular dystrophy; MS = multiple sclerosis; ODT = orally disintegrating tablet; SMA = spinal muscular atrophy

Traditional Versus Specialty Pharmacy Products

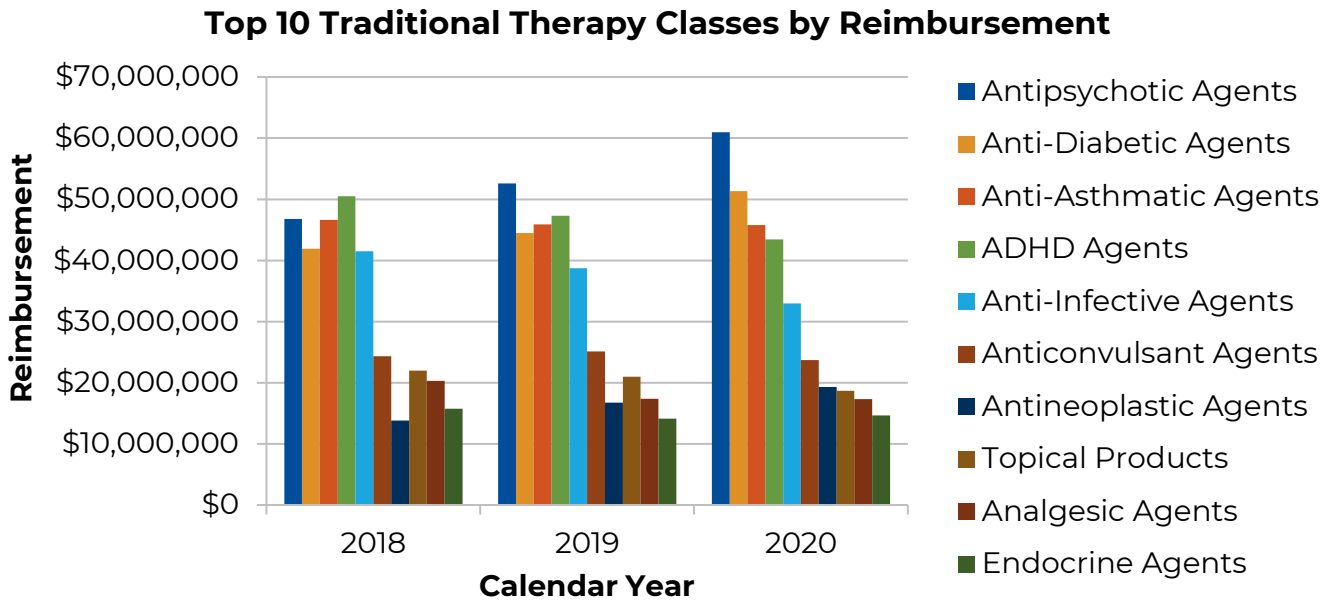
Traditional pharmaceuticals include products that are typically non-injectable and do not require special transportation, storage, administration, and are not typically indicated for rare diseases requiring unique management. These products treat many common chronic diseases such as diabetes, hypertension, and chronic obstructive pulmonary disease. Traditional pharmaceuticals carried the bulk of the reimbursement costs, accounting for 68.5% of the total pharmacy reimbursement and more than 99% of utilizers, in CY 2020.

Specialty products, in contrast, are typically injectable and require special handling such as refrigerated transport and special administration techniques or are indicated for rare diseases requiring unique management. These products include treatments for cystic fibrosis (CF), hemophilia, rheumatoid arthritis, and genetic deficiencies. Specialty pharmaceuticals have become a larger part of reimbursement over the last 5 years. Newly FDA approved therapies for spinal muscular atrophy (SMA) and CF led to an increase in specialty pharmaceutical expenditures for CY 2020.

Top 10 Traditional Therapeutic Classes by Reimbursement: CY 2020

2018	2019	2020	Therapeutic Class
$46,791,370	$52,616,527	**$60,984,666**	**Antipsychotic Agents**
$41,908,481	$44,467,095	**$51,313,829**	**Anti-Diabetic Agents**
$46,618,211	$45,871,626	**$45,776,987**	**Anti-Asthmatic Agents**
$50,497,704	$47,318,535	**$43,457,614**	**ADHD Agents**
$41,515,371	$38,735,389	**$32,950,196**	**Anti-Infective Agents**
$24,320,286	$25,110,543	**$23,702,828**	**Anticonvulsant Agents**
$13,808,895	$16,730,921	**$19,305,175**	**Antineoplastic Agents**
$21,957,332	$20,981,253	**$18,663,423**	**Topical Products**
$20,318,753	$17,361,647	**$17,312,286**	**Analgesic Agents**
$15,737,526	$14,138,973	**$14,669,985**	**Endocrine Agents**

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



The top 10 traditional pharmaceutical classes that showed the most significant change from CY 2019 to 2020, include the antipsychotic and anti-diabetic agents. Other traditional classes saw minor fluctuations.

- Reimbursement increased by more than $6.8 million in the anti-diabetic agents, which can be attributed to increased utilization of Tier-2 medications, including glucagon-like peptide 1 (GLP-1) agonists and sodium-glucose cotransporter-2 (SGLT-2) inhibitors, many of which have significant supplemental rebates. Reimbursement in this report does not reflect rebated prices or net costs.
- Antipsychotic agents' reimbursement increased by $8.4 million; the antipsychotic agents' reimbursement totals include first-generation (typical) and second-generation (atypical) antipsychotics. The increase in reimbursement in this class can be accounted for by increased utilization of long-acting injectable atypical antipsychotics as well as utilization of brand formulation oral medications. It is important to note that many medications in the atypical antipsychotic class have supplemental rebates in place with Oklahoma Medicaid and net cost increases are not reflected in this analysis.
- The ADHD agents saw a $3.86 million spending decrease from CY 2019, which could be attributed to school occuring online and at home due to COVID-19-related closures and adjusted schedules. Many of these products have significant federal rebates designed to keep Medicaid net cost relatively flat and many products in this class also have supplemental rebates; however, rebates are not accounted for in this analysis.

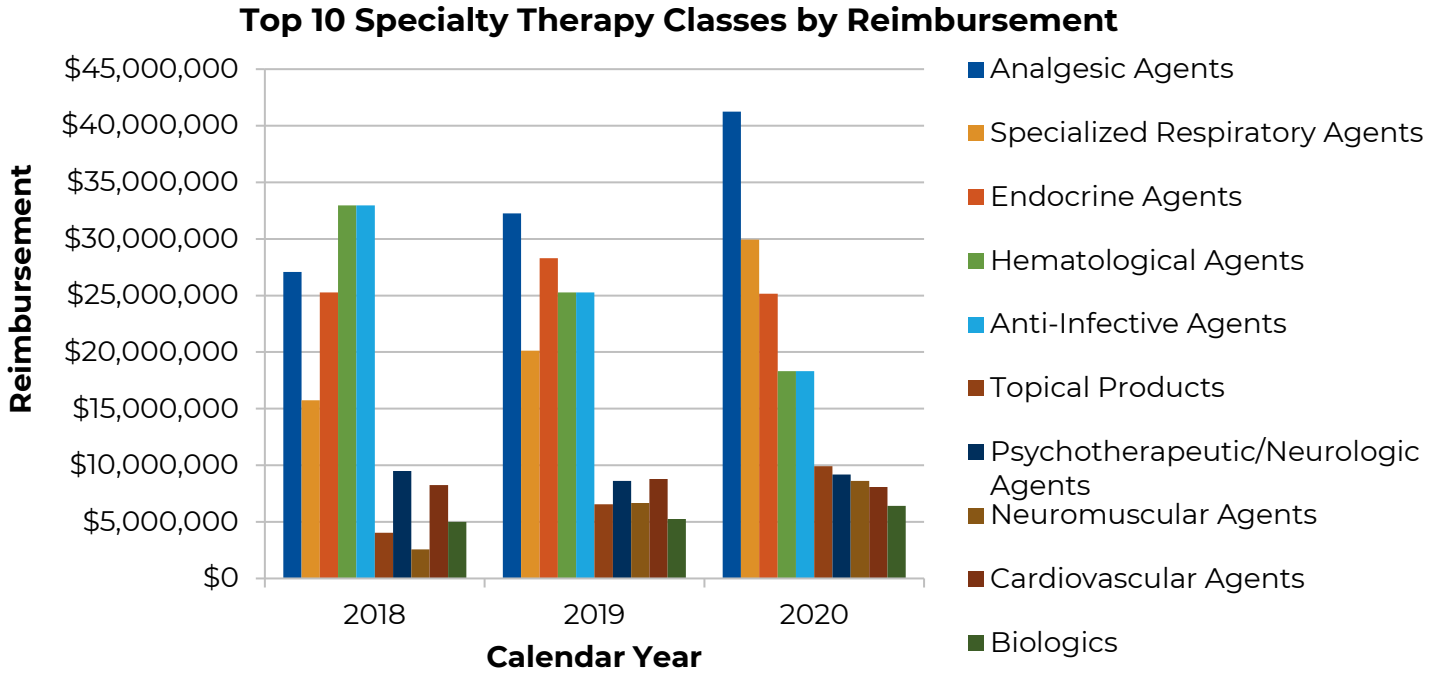
Costs in this report do not reflect the federal and state supplemental rebates that are provided by medication manufacturers. Many branded agents,

particularly anti-infective, ADHD, antipsychotic, endocrine, and analgesic medications are significantly influenced by supplemental rebates and net costs are substantially lower than the total reimbursement paid to pharmacies included in this analysis.

Top 10 Specialty Therapeutic Classes by Reimbursement: CY 2020

2018	2019	2020	Therapeutic Class
$27,087,807	$32,260,764	**$41,244,853**	**Analgesic Agents**
$15,746,918	$20,128,396	**$29,933,715**	**Specialized Respiratory Agents**
$25,281,278	$28,291,082	**$25,153,127**	**Endocrine Agents**
$24,533,816	$23,108,404	**$20,803,778**	**Hematological Agents**
$32,965,335	$25,285,075	**$18,313,938**	**Anti-Infective Agents**
$4,047,085	$6,549,815	**$9,928,919**	**Topical Products**
$9,493,022	$8,631,900	**$9,182,134**	**Psychotherapeutic/Neurologic Agents**
$2,573,311	$6,664,209	**$8,605,724**	**Neuromuscular Agents**
$8,250,814	$8,799,008	**$8,092,050**	**Cardiovascular Agents**
$4,986,592	$5,262,976	**$6,415,482**	**Biologics**

Reimbursement does not reflect rebated prices or net costs.



The cost of specialty therapeutic products is high, largely in part due to biologic therapies and therapies focused on rare diseases, including CF, hemophilia, and SMA. Continuous review and management of biological agents and psychotherapeutic/neurologic agents has promoted minimal reimbursement increases, other than expected yearly price increases by

product manufacturers, and has resulted in declines in reimbursement for hematological, endocrine, anti-infective, and cardiovascular agents.

- The cost of specialty analgesic agents increased this year, with a $9 million increase in anti-inflammatory agents. Reimbursement in this class is largely attributed to targeted immunomodulatory agents such as Humira® (adalimumab), Enbrel® (etanercept), Ilaris® (canakinumab), Orencia® (abatacept), Simponi® (golimumab), Xeljanz® (tofacitinib), Otezla® (apremilast), and Kineret® (anakinra). The majority of utilization was seen in Tier-2 medications (Humira® and Enbrel®), which are supplementally rebated medications. The supplementally rebated prices and net costs are not reflected in this analysis.
- Respiratory agents saw a $9.8 million increase in reimbursement from CY 2019 to CY 2020. This class includes medications indicated for the treatment of CF. Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) was FDA approved in October 2019 and contributed to the CY 2020 increase.

Top 10 Medications by Reimbursement: CY 2020

Many of the top 10 medications by reimbursement are still branded at this time and not available in a generic formulation. The top 3 medications by reimbursement have been consistent over the past 3 years; however, in CY 2020, adalimumab moved from the 3rd ranked medication by reimbursement to the top medication by reimbursement. The top products typically come from highly utilized classes such as atypical antipsychotics, ADHD therapies, respiratory medications (including rescue and maintenance therapies), and the anti-infective class (including antiviral medications for hepatitis C). Top drug reimbursement rankings only slightly change from year to year for several reasons: high use, broad use between age demographics, and high costs of new therapies such as those indicated for CF.

Top 10 Medications by Reimbursement*			
Rank	**2018**	**2019**	**2020**
1	lisdexamfetamine	lisdexamfetamine	**adalimumab**
2	paliperidone inj	paliperidone inj	**paliperidone inj**
3	adalimumab	adalimumab	**lisdexamfetamine**
4	albuterol	albuterol	**elexacaftor/tezacaftor/ivacaftor**
5	sofosbuvir/ledipasvir	sofosbuvir/velpatasvir	**lurasidone**
6	lurasidone	lurasidone	**sofosbuvir/velpatasvir**
7	oseltamivir	somatropin inj	**albuterol**
8	sofosbuvir/velpatasvir	insulin glargine inj	**somatropin inj**
9	methylphenidate	fluticasone HFA	**insulin glargine inj**
10	fluticasone HFA	methylphenidate	**fluticasone HFA**

*Includes brand and generic where applicable.
Rank does not reflect rebated prices or net costs.
Medications are listed by generic name, but may include both generic and brand formulations.
inj = injection; HFA = hydrofluoroalkane

Cost Per Claim

Claims for generic medications made up 84.4% of the volume while only accounting for 23.7% of the reimbursement amount. The SoonerCare cost per claim of traditional medications increased by 12% in CY 2020 in comparison to CY 2019, and the cost per specialty medication claim decreased by 3.5%. As mentioned previously, specialty costs are largely driven by the significant cost associated with medications for rare diseases.

Cost Per Claim			
Drug Class	**CY 2018**	**CY 2019**	**CY 2020**
Traditional	$69.12	$72.03	$80.66
Specialty	$7,336.86	$7,043.67	$6,798.85

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

Market Projections[14]

Specialty medications, including gene therapies, will continue to influence reimbursements. Zolgensma® (onasemnogene abeparvovec-xioi), a gene therapy for SMA FDA approved in May 2019, was utilized by more than 1 SoonerCare member in CY 2020. Tecartus® (brexucabtagene autoleucel), a chimeric antigen receptor (CAR) T-cell therapy, was FDA approved in July 2020 for the treatment of refractory or relapsed mantle cell lymphoma. There are other gene therapies in the pipeline for hemophilia and DMD, among other diseases. Oncology and autoimmune anti-inflammatory medications that were FDA approved in the third and fourth quarter of CY 2020 for various indications, as shown in the following table, will likely influence future reimbursement trends in CY 2021. With new oncology agents continually entering the market, assessment of the oncology medication classes will need frequent reevaluation.

Oncology Medications FDA Approved in Calendar Year 2020			
Brand	**Generic**	**Indication(s)**	**Approval Date**
Ayvakit™	avapritinib	unresectable or metastatic GIST	January 2020
Tazverik®	tazemetostat	epithelioid sarcoma	January 2020
Sarclisa®	isatuximab-irfc	multiple myeloma	March 2020
Tukysa®	tucatinib	advanced unresectable or HER2-positive MBC	April 2020
Pemazyre®	pemigatinib	cholangiocarcinoma	April 2020
Trodelvy®	sacituzumab govitecan-hziy	triple-negative MBC in patients who received ≥2 prior therapies for metastatic disease	April 2020
Tabrecta®	capmatinib	NSCLC	May 2020
Retevmo®	selpercatinib	lung and thyroid cancers	May 2020
Qinlock™	ripretinib	advanced GIST	May 2020

Oncology Medications FDA Approved in Calendar Year 2020			
Brand	**Generic**	**Indication(s)**	**Approval Date**
Zepzelca™	lurbinectedin	metastatic SCLC	June 2020
Monjuvi®	tafasitamab-cxix	relapsed or refractory DLBCL	July 2020
Gavreto™	pralsetinib	NSCLC	September 2020
Orgovyx™	relugolix	advanced prostate cancer	December 2020

DLBCL = diffuse large B-cell lymphoma; FDA = U.S. Food and Drug Administration; GIST = gastrointestinal stromal tumor; HER2 = human epithelial growth factor receptor 2; MBC = metastatic breast cancer; NSCLC = non-small cell lung cancer; SCLC = small cell lung cancer

Conclusion

New prior authorization categories and continuous evaluation of categories such as oncology and hemophilia medications, along with new respiratory and anti-diabetic medications that continue to be FDA approved, ensure the most clinically appropriate, cost-effective measures are taken. Modifications to Tier structures and other generic categories reduced elevated spending on high-priced generic products. When new drugs are FDA approved and become available on the market, a cost-effectiveness analysis is performed to minimize spending while ensuring appropriate clinical care. The goal of the SoonerCare program is to provide SoonerCare members with the most appropriate health care in a fiscally responsible manner. For the pharmacy benefit, this is accomplished through DUR services, using prior authorization criteria, quantity limits, monthly total prescription limits and brand name prescription limits for non-institutionalized adult members, continuous product pricing maintenance, and provider outreach and education. Constant market review and response to changes, including evolving gene therapies, growth of the specialty market, and introduction of biosimilars, is necessary. SoonerCare will continue to strive to bring value-based pharmacy services to its members.

Top 50 Reimbursed Drugs by Calendar Year

Generic	Brand	CY 2020		CY 2019	
		Rank	Amount Paid	Rank	Amount Paid
adalimumab	Humira®	1	**$26,820,571**	3	$20,238,412
paliperidone inj	Multiple	2	**$24,433,216**	2	$21,553,240
lisdexamfetamine	Vyvanse®	3	**$23,475,202**	1	$24,670,183
elexacaftor/tezacaftor/ivacaftor	Trikafta®	4	**$16,766,241**	94	$1,267,084
lurasidone	Latuda®	5	**$14,472,541**	6	$11,936,600
sofosbuvir/velpatasvir	Epclusa®	6	**$11,848,522**	5	$13,836,412
albuterol	Multiple	7	**$11,343,733**	4	$14,035,234
somatropin	Multiple	8	**$11,055,496**	7	$10,833,029
insulin glargine	Multiple	9	**$10,799,671**	8	$9,644,102
fluticasone	Flovent®	10	**$9,394,049**	9	$9,452,013
dexmethylphenidate	Multiple	11	**$8,297,993**	13	$8,906,477
etanercept	Enbrel®	12	**$8,092,955**	15	$7,246,795
fluticasone/salmeterol	Multiple	13	**$8,010,461**	12	$7,961,041
insulin aspart	NovoLog®	14	**$7,794,606**	14	$7,792,242
methylphenidate	Multiple	15	**$6,930,474**	10	$8,678,336
emicizumab-kxwh	Hemlibra®	16	**$6,865,928**	32	$3,297,671
aripiprazole tab	Abilify®	17	**$6,806,344**	19	$6,341,768
buprenorphine/naloxone	Multiple	18	**$6,392,949**	21	$5,636,730
lacosamide	Vimpat®	19	**$5,529,466**	24	$4,925,623
insulin lispro	Humalog®	20	**$5,484,888**	26	$4,906,369
ciprofloxacin/dexamethasone	Ciprodex®	21	**$5,217,241**	20	$6,149,532
insulin detemir	Levemir®	22	**$5,128,327**	23	$5,107,493
tiotropium	Spiriva®	23	**$4,682,525**	30	$3,582,142
budesonide/formoterol	Symbicort®	24	**$4,104,585**	51	$2,463,803
liraglutide	Victoza®	25	**$4,022,335**	39	$3,019,861
tezacaftor/ivacaftor	Symdeko®	26	**$4,016,726**	11	$8,113,058
hydroxyprogesterone	Makena®	27	**$3,892,441**	17	$6,679,715
blood glucose test strips	Multiple	28	**$3,835,436**	27	$4,076,588
onasemnogene abeparvovec-xioi	Zolgensma®	29	**$3,787,872**	44	$2,840,904
palivizumab	Synagis®	30	**$3,713,086**	36	$3,090,814
apixaban	Eliquis®	31	**$3,712,834**	49	$2,569,474
dupilumab	Dupixent®	32	**$3,707,435**	65	$1,789,396
palbociclib	Ibrance®	33	**$3,702,275**	45	$2,838,229
dornase alfa	Pulmozyme®	34	**$3,687,134**	31	$3,323,036
nusinersen	Spinraza®	35	**$3,574,524**	29	$3,772,094
vigabatrin	Multiple	36	**$3,524,038**	37	$3,043,400
pancrelipase	Multiple	37	**$3,517,255**	35	$3,128,996
oseltamivir	Tamiflu®	38	**$3,455,792**	16	$7,185,520

Generic	Brand	CY 2020		CY 2019	
		Rank	Amount Paid	Rank	Amount Paid
ustekinumab	Stelara®	39	**$3,402,711**	52	$2,417,449
everolimus	Afinitor®	40	**$3,244,559**	34	$3,179,554
aripiprazole inj	Multiple	41	**$3,182,597**	54	$2,265,643
cariprazine	Vraylar®	42	**$3,116,474**	78	$1,577,009
sitagliptin	Januvia®	43	**$3,088,429**	41	$2,929,671
cannabidiol	Epidiolex®	44	**$3,063,397**	73	$1,664,825
valbenazine	Ingrezza®	45	**$2,966,909**	58	$2,126,192
bictegravir/emtricitabine/tenofovir	Biktarvy®	46	**$2,928,801**	68	$1,732,073
lumacaftor/ivacaftor	Orkambi®	47	**$2,867,498**	28	$3,904,072
antihemophilic factor recombinant (rFVII)	Kogenate®	48	**$2,786,349**	38	$3,034,830
glecaprevir/pibrentasvir	Mavyret™	49	**$2,756,997**	48	$2,600,596
darunavir/cobicistat/ emtricitabine/tenofovir	Symtuza®	50	**$2,723,582**	91	$1,307,368

Includes brand and generic where applicable.
Reimbursement does not reflect rebated costs or net costs.
CY = calendar year; inj = injection; tab = tablet

Top 50 Medications by Total Number of Claims: Calendar Year 2020

Top 50 Medications by Total Number of Claims								
Rank	**Generic Name**	**Claims**	**Members**	**Cost**	**Units/Day**	**Claims/Member**	**Cost/Claim**	**% Cost**
1	albuterol	191,585	75,200	$11,343,733.12	1.97	2.55	$59.21	10.56%
2	cetirizine	181,967	73,406	$2,082,525.51	2.93	2.48	$11.44	1.94%
3	amoxicillin	132,627	106,835	$1,727,232.49	11.20	1.24	$13.02	1.61%
4	montelukast	122,477	32,463	$1,777,059.49	1.00	3.77	$14.51	1.65%
5	hydrocodone/APAP	102,789	39,573	$1,542,034.13	3.81	2.60	$15.00	1.44%
6	gabapentin	91,393	18,630	$1,514,510.84	3.10	4.91	$16.57	1.41%
7	fluticasone nasal	83,738	40,361	$1,243,574.52	0.42	2.07	$14.85	1.16%
8	clonidine	80,497	14,129	$919,909.94	1.46	5.70	$11.43	0.86%
9	sertraline	80,261	20,044	$1,025,574.42	1.16	4.00	$12.78	0.95%
10	lisdexamfetamine	78,831	14,014	$23,475,201.97	1.00	5.63	$297.79	21.86%
11	methylphenidate ER	68,947	10,723	$6,930,473.90	1.30	6.43	$100.52	6.45%
12	trazodone	66,544	15,052	$791,782.99	1.22	4.42	$11.90	0.74%
13	azithromycin	64,690	51,697	$1,097,514.75	2.59	1.25	$16.97	1.02%
14	fluoxetine	63,017	14,370	$831,361.54	1.24	4.39	$13.19	0.77%
15	omeprazole	62,182	20,100	$768,729.75	1.22	3.09	$12.36	0.72%
16	ibuprofen	60,051	40,406	$749,288.67	3.03	1.49	$12.48	0.70%
17	guanfacine	56,294	8,605	$1,194,693.72	1.00	6.54	$21.22	1.11%
18	ondansetron	55,956	41,827	$839,640.24	2.41	1.34	$15.01	0.78%
19	levothyroxine	49,422	10,435	$1,210,652.34	0.99	4.74	$24.50	1.13%
20	prednisone	48,328	34,847	$525,673.48	1.79	1.39	$10.88	0.49%
21	oseltamivir	47,912	45,757	$3,455,791.79	11.77	1.05	$72.13	3.22%
22	lisinopril	47,331	13,674	$511,942.79	1.09	3.46	$10.82	0.48%
23	aripiprazole	46,186	9,344	$6,806,343.62	0.97	4.94	$147.37	6.34%
24	quetiapine	46,039	8,048	$737,314.04	1.44	5.72	$16.01	0.69%
25	cephalexin	44,749	38,810	$730,993.41	8.84	1.15	$16.34	0.68%
26	escitalopram	43,427	11,238	$595,844.83	1.07	3.86	$13.72	0.55%

Top 50 Medications by Total Number of Claims								
Rank	**Generic Name**	**Claims**	**Members**	**Cost**	**Units/Day**	**Claims/Member**	**Cost/Claim**	**% Cost**
27	amphetamine/ dextroamphetamine	43,170	6,886	$1,389,322.66	1.47	6.27	$32.18	1.29%
28	hydroxyzine	41,980	16,096	$550,576.98	3.36	2.61	$13.12	0.51%
29	cefdinir	41,870	34,588	$880,978.50	6.49	1.21	$21.04	0.82%
30	triamcinolone	40,947	28,763	$608,336.37	4.52	1.42	$14.86	0.57%
31	atorvastatin	39,875	11,618	$546,575.76	1.00	3.43	$13.71	0.51%
32	amoxicillin/ clavulanate	39,778	34,673	$918,227.56	7.41	1.15	$23.08	0.85%
33	loratadine	39,490	15,967	$452,051.40	2.70	2.47	$11.45	0.42%
34	fluticasone HFA	39,365	14,213	$9,394,049.29	0.33	2.77	$238.64	8.75%
35	risperidone	37,747	6,161	$891,603.35	1.53	6.13	$23.62	0.83%
36	buspirone	37,260	9,641	$547,295.30	2.26	3.86	$14.69	0.51%
37	alprazolam	37,128	5,641	$411,368.13	2.25	6.58	$11.08	0.38%
38	metformin	36,234	10,727	$398,578.66	2.03	3.38	$11.00	0.37%
39	oxycodone/APAP	34,936	13,294	$724,957.63	3.70	2.63	$20.75	0.68%
40	mupirocin	34,247	28,949	$523,467.91	2.40	1.18	$15.29	0.49%
41	dexmethylphenidate	34,178	4,999	$8,297,992.92	1.16	6.84	$242.79	7.73%
42	cyclobenzaprine	33,709	14,720	$348,480.06	2.34	2.29	$10.34	0.32%
43	levetiracetam	33,653	5,027	$971,451.64	5.38	6.69	$28.87	0.90%
44	sulfamethoxazole/ trimethoprim	33,537	27,050	$550,644.17	6.51	1.24	$16.42	0.51%
45	bupropion	31,550	8,066	$629,325.57	1.22	3.91	$19.95	0.59%
46	lamotrigine	29,958	5,148	$1,005,930.78	1.88	5.82	$33.58	0.94%
47	duloxetine	29,954	7,250	$452,546.88	1.27	4.13	$15.11	0.42%
48	atomoxetine	29,931	5,846	$1,786,340.03	1.11	5.12	$59.68	1.66%
49	pantoprazole	29,703	9,799	$396,570.34	1.15	3.03	$13.35	0.37%
50	amlodipine	29,130	8,519	$291,361.78	1.04	3.42	$10.00	0.27%

APAP = acetaminophen; ER = extended-release; HFA = hydrofluoroalkane
Includes brand and generic where applicable.
Reimbursement does not reflect rebated costs or net costs.

Top 10 Traditional and Specialty Therapeutic Categories by Calendar Year

Top 10 Specialty Therapeutic Categories by Calendar Year*						
	2020			2019		
	Total Claims	Total Paid	Cost/Member	Total Claims	Total Paid	Cost/Member
ANALGESIC AGENTS	**7,759**	**$41,244,853.26**	**$33,918.46**	**6,113**	**$32,260,764.11**	**$30,492.22**
Analgesics - Anti-Inflammatory	6,633	$40,523,255.00	$42,432.73	5,544	$31,928,507.27	$36,741.67
Migraine Products	942	$567,908.02	$3,036.94	375	$219,670.31	$2,052.99
Analgesics - Narcotics	113	$151,679.47	$6,067.18	117	$110,668.75	$3,952.46
Local Anesthetics - Parenteral	71	$2,010.77	$41.04	77	$1,917.78	$35.51
SPECIALIZED RESPIRATORY AGENTS	**2,244**	**$29,933,714.55**	**$163,572.21**	**1,807**	**$20,128,395.96**	**$110,595.58**
Misc. Respiratory	2,244	$29,933,714.55	$163,572.21	1,807	$20,128,395.96	$110,595.58
ENDOCRINE AGENTS	**5,178**	**$25,153,126.89**	**$27,701.68**	**6,227**	**$28,291,082.45**	**$23,400.40**
Misc. Endocrine	3,773	$21,260,685.61	$46,319.58	3,867	$21,615,393.57	$44,023.20
Progestins	1,405	$3,892,441.28	$8,669.13	2,360	$6,675,688.88	$9,297.62
HEMATOLOGICAL AGENTS	**1,439**	**$20,803,777.92**	**$111,848.27**	**1,269**	**$23,108,404.16**	**$132,048.02**
Misc. Hematological	880	$19,149,424.37	$189,598.26	743	$21,364,019.83	$237,378.00
Hematopoietic Agents	559	$1,654,353.55	$19,462.98	526	$1,744,384.33	$20,522.17
ANTI-INFECTIVE AGENTS	**1,283**	**$18,313,937.62**	**$36,554.77**	**1,464**	**$25,285,075.02**	**$42,071.67**
Antiviral	752	$16,324,829.05	$48,441.63	1,014	$23,621,738.61	$53,202.11
Aminoglycosides	429	$1,128,160.48	$8,116.26	393	$1,158,986.54	$8,398.45
Misc. Anti-Infectives	86	$781,975.21	$37,236.91	57	$504,349.87	$26,544.73
Antifungals	16	$78,972.88	$19,743.22	---	---	---
TOPICAL AGENTS	**1,792**	**$9,928,918.72**	**$37,048.20**	**1,094**	**$6,549,814.70**	**$36,186.82**
Dermatological	1,792	$9,928,918.72	$37,048.20	1,094	$6,549,814.70	$36,186.82
PSYCHOTHERAPEUTIC/ NEUROLOGICAL AGENTS	**1,452**	**$9,182,133.74**	**$46,609.82**	**1,434**	**$8,631,899.95**	**$39,962.50**
Misc. Psychotherapeutic & Neurological Agents	1,452	$9,182,133.74	$46,609.82	1,434	$8,631,899.95	$39,962.50
NEUROMUSCULAR AGENTS	**78**	**$8,605,724.21**	**$344,228.97**	**38**	**$6,664,209.14**	**$392,012.30**
Neuromuscular Agents	78	$8,605,724.21	$358,571.84	38	$6,664,209.14	$392,012.30

Top 10 Specialty Therapeutic Categories by Calendar Year*						
	2020			2019		
	Total Claims	Total Paid	Cost/Member	Total Claims	Total Paid	Cost/Member
CARDIOVASCULAR AGENTS	**1,924**	**$8,092,050.35**	**$31,364.54**	**1,663**	**$8,799,008.04**	**$38,256.56**
Misc. Cardiovascular	1,831	$7,987,904.64	$33,847.05	1,576	$8,592,380.56	$40,916.10
Vasopressors	4	$67,223.23	$67,223.23	10	$155,765.92	$155,765.92
Antihyperlipidemic	80	$36,448.12	$2,144.01	59	$49,886.84	$3,325.79
Antihypertensive	9	$474.36	$118.59	18	$974.72	$243.68
BIOLOGICAL AGENTS	**2,733**	**$6,415,482.37**	**$8,463.70**	**2,351**	**$5,262,975.60**	**$6,961.61**
Passive Immunizing Agents	2,733	$6,415,482.37	$8,463.70	2,351	$5,262,975.60	$6,961.61
TOTAL	**25,882**	**$177,673,719.63**	**$39,483.05**	**23,460**	**164,981,629**	**$35,671.70**

*Table contains top 10 specialty therapeutic categories and is not an all-inclusive list.
Reimbursement does not reflect rebated costs or net costs.

Top 10 Traditional Therapeutic Categories by Calendar Year*						
	2020			2019		
	Total Claims	Total Paid	Cost/Member	Total Claims	Total Paid	Cost/Member
ANTIPSYCHOTICS & ANTIMANIC AGENTS	**219,372**	**$60,984,665.88**	**$2,085.02**	**215,320**	**$52,616,527.90**	**$1,795.54**
Antipsychotics	219,372	$60,984,665.88	$2,085.02	215,320	$52,616,527.90	$1,795.54
ANTI-DIABETIC AGENTS	**129,360**	**$51,313,828.78**	**$2,912.08**	**126,997**	**$44,467,095.48**	**$2,567.38**
Anti-Diabetic	129,360	$51,313,828.78	$2,912.08	126,997	$44,467,095.48	$2,567.38
ANTI-ASTHMATIC & BRONCHODILATOR AGENTS	**428,594**	**$45,776,987.84**	**$481.23**	**469,646**	**$45,871,626.19**	**$404.29**
Anti-Asthmatic & Bronchodilatory Agents	428,594	$45,776,987.84	$481.23	469,646	$45,871,626.19	$404.29
ADHD AGENTS	**313,037**	**$43,457,614.79**	**$1,136.68**	**332,236**	**$47,318,535.90**	**$1,173.90**
ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants	313,037	$43,457,614.79	$1,136.68	332,236	$47,318,535.90	$1,173.90
ANTI-INFECTIVE AGENTS	**565,116**	**$32,950,196.05**	**$78.11**	**749,710**	**$38,735,389.30**	**$71.46**
Antiviral	69,972	$18,733,547.04	$339.63	90,975	$20,292,185.83	$277.92

Top 10 Traditional Therapeutic Categories by Calendar Year*						
	2020			2019		
	Total Claims	Total Paid	Cost/Member	Total Claims	Total Paid	Cost/Member
Misc. Anti-Infectives	87,615	$4,996,028.90	$83.74	94,985	$5,496,194.35	$83.40
Penicillins	179,903	$2,932,581.63	$21.58	272,506	$4,478,813.74	$23.91
Cephalosporins	91,214	$1,980,461.57	$27.17	122,577	$2,745,125.86	$29.25
Macrolide Antibiotics	66,797	$1,651,484.62	$31.26	97,500	$2,378,873.56	$32.01
Antifungals	25,486	$1,271,901.65	$74.07	25,330	$1,850,640.56	$105.16
Tetracyclines	22,646	$653,185.01	$45.20	23,860	$464,106.34	$30.52
Anthelmintic	2,172	$303,712.88	$164.88	2,328	$559,929.46	$288.62
Fluoroquinolones	12,934	$190,674.68	$18.77	14,674	$216,706.27	$18.93
Antimalarial	5,552	$165,404.26	$113.21	4,251	$191,858.27	$165.25
Antimycobacterial Agents	410	$45,352.86	$298.37	363	$31,141.90	$213.30
Aminoglycosides	389	$20,664.21	$141.54	344	$24,392.33	$161.54
Sulfonamides	24	$4,630.84	$1,157.71	12	$4,070.22	$1,017.56
Amebicides	2	$565.90	$282.95	5	$1,350.61	$337.65
ANTICONVULSANTS	**314,119**	**$23,702,828.42**	**$557.39**	**312,722**	**$25,110,543.62**	**$584.54**
Anticonvulsants	314,119	$23,702,828.42	$557.39	312,722	$25,110,543.62	$584.54
ANTINEOPLASTICS	**10,369**	**$19,305,175.19**	**$8,142.21**	**10,472**	**$16,730,921.48**	**$7,140.81**
Antineoplastics	10,369	$19,305,175.19	$8,142.21	10,472	$16,730,921.48	$7,140.81
TOPICAL PRODUCTS	**266,572**	**$18,663,423.30**	**$113.46**	**305,238**	**$20,981,253.63**	**$107.74**
Dermatological	176,106	$10,208,675.04	$105.11	193,837	$11,902,840.81	$108.54
Otic	23,408	$5,370,118.03	$273.02	27,813	$6,306,637.74	$278.37
Ophthalmic	45,789	$2,670,594.00	$86.24	60,069	$2,309,741.81	$52.96
Mouth/Throat/Dental Agents	19,958	$331,265.25	$21.15	22,168	$363,315.57	$20.48
Anorectal	1,311	$82,770.98	$77.65	1,351	$98,717.70	$92.17
ANALGESIC AGENTS	**383,848**	**$17,312,285.85**	**$124.23**	**412,008**	**$17,361,647.15**	**$111.40**
Analgesics - Narcotic	233,888	$14,718,140.44	$227.06	255,220	$14,828,246.19	$196.17
Analgesics - Anti-Inflammatory	127,747	$1,964,419.00	$29.69	133,318	$1,885,238.51	$26.49
Migraine Products	11,360	$405,316.33	$81.05	11,026	$318,326.09	$63.99

Top 10 Traditional Therapeutic Categories by Calendar Year*						
	2020			2019		
	Total Claims	Total Paid	Cost/Member	Total Claims	Total Paid	Cost/Member
Gout	5,617	$113,845.26	$87.17	5,571	$166,364.58	$122.60
Analgesics - Non-Narcotic	5,072	$108,356.77	$56.09	6,720	$161,315.44	$61.57
Local Anesthetics - Parenteral	164	$2,208.05	$17.25	153	$2,156.34	$16.59
ENDOCRINE AGENTS	**299,929**	**$14,669,985.42**	**$110.99**	**347,168**	**$14,138,973.69**	**$85.33**
Contraceptives	96,152	$6,085,738.58	$215.98	90,734	$5,636,581.41	$203.15
Misc. Endocrine	15,769	$4,305,524.27	$1,268.57	16,978	$3,311,821.06	$871.07
Corticosteroids	119,514	$1,865,871.10	$22.05	173,229	$2,721,801.65	$23.03
Thyroid	54,079	$1,408,508.99	$125.03	52,172	$1,380,272.91	$123.61
Estrogens	7,739	$709,890.45	$356.37	7,739	$735,779.63	$354.76
Progestin	5,823	$177,091.37	$71.96	5,466	$185,750.11	$76.92
Androgen-Anabolic	735	$80,906.82	$496.36	718	$124,949.53	$730.70
Oxytocics	118	$36,453.84	$319.77	132	$42,017.39	$325.72
TOTAL	**2,930,316**	**$328,136,991.52**	**$302.99**	**3,281,517**	**$323,332,514.34**	**$247.96**
GRAND TOTAL (TOP 10 SPECIALTY & TRADITIONAL)	**2,956,198**	**$505,810,711.15**	**$465.11**	**3,304,977**	**$488,314,143.47**	**$373.15**

*Table contains top 10 traditional therapeutic categories and is not an all-inclusive list.
Reimbursement does not reflect rebated costs or net costs.

Calendar Year Age Group Comparison

Specialty Pharmacy Reimbursement by Age Group Comparison by Calendar Year			
Age Group (Years)	**2018**	**2019**	**2020**
Age 0 to 2	$9,092,792.21	$11,612,209.65	$10,150,583.46
Age 3 to 5	$6,787,409.80	$10,110,090.56	$8,514,078.39
Age 6 to 9	$10,796,096.09	$10,034,038.95	$16,987,282.65
Age 10 to 14	$23,252,655.29	$27,722,518.29	$32,562,986.35
Age 15 to 18	$19,922,881.62	$22,866,402.89	$30,128,624.82
Age 19 to 25	$16,640,363.32	$14,583,198.35	$13,872,096.27
Age 26 to 34	$17,056,661.61	$17,867,757.94	$17,030,226.89
Age 35 to 54	$34,233,521.78	$35,813,690.77	$37,403,135.82
Age 55 to 64	$24,446,051.11	$21,647,289.23	$18,637,437.98
Age 65+	$2,373,946.34	$2,017,339.17	$1,586,502.20
Total (All Ages)	**$164,602,379.17**	**$174,274,535.80**	**$186,872,954.83**

Reimbursement does not reflect rebated costs or net costs.

Traditional Pharmacy Reimbursement by Age Group Comparison by Calendar Year			
Age Group (Years)	**2018**	**2019**	**2020**
Age 0 to 2	$12,314,763.76	$11,397,193.22	$9,716,285.73
Age 3 to 5	$19,242,138.14	$17,342,568.64	$14,487,831.82
Age 6 to 9	$42,319,723.23	$41,144,487.75	$35,432,461.76
Age 10 to 14	$59,077,880.29	$57,246,708.50	$56,068,019.25
Age 15 to 18	$39,976,103.52	$39,019,105.14	$39,523,270.29
Age 19 to 25	$22,698,506.72	$23,201,603.84	$27,557,479.49
Age 26 to 34	$36,083,970.91	$36,313,761.82	$40,700,793.05
Age 35 to 54	$87,539,287.18	$91,100,536.47	$102,783,813.23
Age 55 to 64	$61,779,772.61	$65,153,558.47	$68,234,587.50
Age 65+	$8,830,547.04	$10,139,832.60	$11,121,940.67
Total (All Ages)	**$389,864,964.05**	**$392,060,731.09**	**$405,628,220.26**

Reimbursement does not reflect rebated costs or net costs.

Total Enrollment by Age Group Comparison by Calendar Year*			
Age Group (Years)	**2018**	**2019**	**2020**
Age 0 to 2	93,532	90,859	94,553
Age 3 to 5	87,962	87,317	92,513
Age 6 to 9	114,299	111,656	118,793
Age 10 to 14	135,601	137,051	146,397
Age 15 to 18	87,627	88,283	97,109
Age 19 to 25	39,511	37,208	49,258

Total Enrollment by Age Group Comparison by Calendar Year*			
Age Group (Years)	**2018**	**2019**	**2020**
Age 26 to 34	54,062	51,992	63,963
Age 35 to 54	78,607	76,076	87,749
Age 55 to 64	43,909	44,619	46,254
Age 65+	61,491	63,889	65,652
Total (All Ages)	**796,603**	**788,958**	**863,073**

*Average monthly enrollment as obtained from OHCA Fast Facts reports

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Appendix J

Calendar Year 2020 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)

Oklahoma Health Care Authority
June 2021

Current Prior Authorization Criteria

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			Adzenys ER™ (amphetamine ER susp) Adzenys XR-ODT® (amphetamine ER-ODT) Cotempla XR-ODT® (methylphenidate ER ODT) Desoxyn® (methamphetamine) Dexedrine® (dextroamphetamine) Dexedrine Spansules® (dextroamphetamine ER) Dyanavel® XR (amphetamine ER susp) Evekeo® (amphetamine)
Short-Acting			
Adderall® (amphetamine/ dextroamphetamine)			
Long-Acting			
Vyvanse® (lisdexamfetamine cap and chew tab)+	Adderall XR® (amphetamine/ dextroamphetamine ER)		
Methylphenidate			
Short-Acting			
Focalin® (dexmethylphenidate) Methylin® (methylphenidate tab and soln) Ritalin® (methylphenidate)			
Long-Acting			
Daytrana® (methylphenidate ER) Focalin XR® brand name only (dexmethylphenidate ER)	Concerta® (methylphenidate ER) dexmethylphenidate ER (generic Focalin XR®)	Adhansia XR® (methylphenidate ER) Aptensio XR® (methylphenidate ER)	

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Metadate CD® (methylphenidate ER) QuilliChew ER® (methylphenidate ER chew tab) Ritalin LA® (methylphenidate ER)	Quillivant XR® (methylphenidate ER susp)	Jornay PM® (methylphenidate ER) Metadate ER® (methylphenidate ER) Methylin ER® (methylphenidate ER) methylphenidate ER 72mg Ritalin SR® (methylphenidate ER)	Evekeo ODT™ (amphetamine ODT) Methylin® (methylphenidate chew tab) Mydayis® (amphetamine/ dextroamphetamine ER) ProCentra® (dextroamphetamine) Zenzedi® (dextroamphetamine)
Non-Stimulants			
Intuniv® (guanfacine ER) Strattera® (atomoxetine)		Kapvay® (clonidine ER)[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).
[Δ]Unique 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.

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 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.

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 or Methylin® oral solution, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Vyvanse® (Lisdexamfetamine) Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:
   a. An FDA approved diagnosis of moderate-to-severe BED; and
   b. Member must be 18 years of age or older; and
   c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and
   d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and
   e. A quantity limit of 30 capsules or chewable tablets per 30 days will apply; and

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

Narcolepsy Medications Approval Criteria:

1. An FDA approved diagnosis; and
2. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
   a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; or
3. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; or
4. Use of Sunosi® (solriamfetol), Wakix® (pitolisant), or Xyrem® (sodium oxybate) 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. The diagnosis of obstructive sleep apnea requires concurrent treatment for obstructive sleep apnea; and
6. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the prior authorization request.

Utilization of ADHD and Narcolepsy Medications: Calendar Year 2020

Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	40,300	332,243	$47,727,417.00	$143.65	$4.84	11,519,445	9,863,637
2020	38,217	313,063	$44,254,702.45	$141.36	$4.75	10,853,585	9,309,262
% Change	**-5.20%**	**-5.80%**	**-7.30%**	**-1.60%**	**-1.90%**	**-5.80%**	**-5.60%**
Change	**-2,083**	**-19,180**	**-$3,472,714.55**	**-$2.29**	**-$0.09**	**-665,860**	**-554,375**

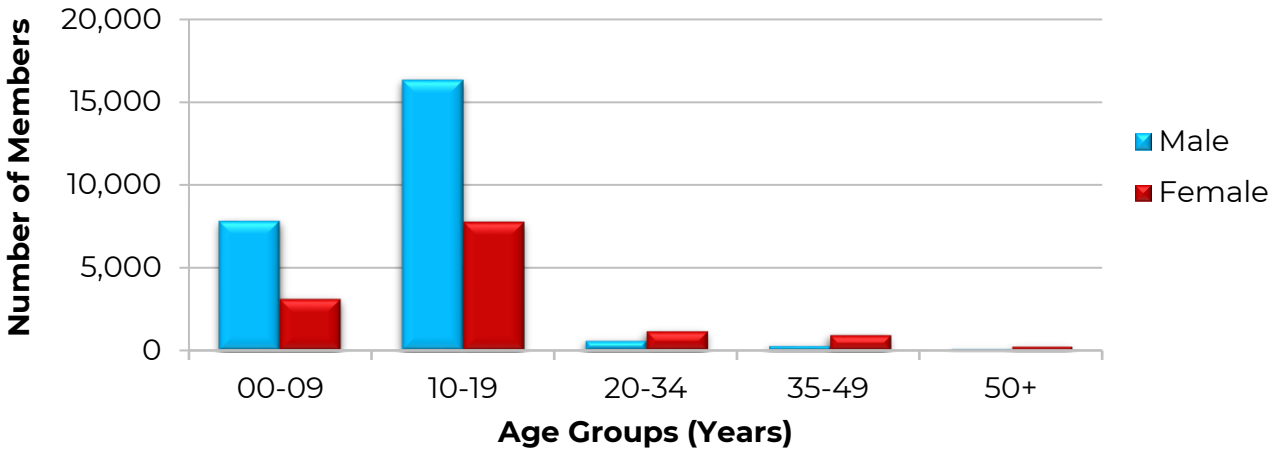
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.

- The ADHD and Narcolepsy Medications Product Based Prior Authorization (PBPA) category is heavily influenced by supplemental rebates. Some brand name ADHD and narcolepsy products are preferred over available generic products due to a lower net cost compared to generics, after taking into account federal and/or supplemental rebate participation. These rebates are collected after

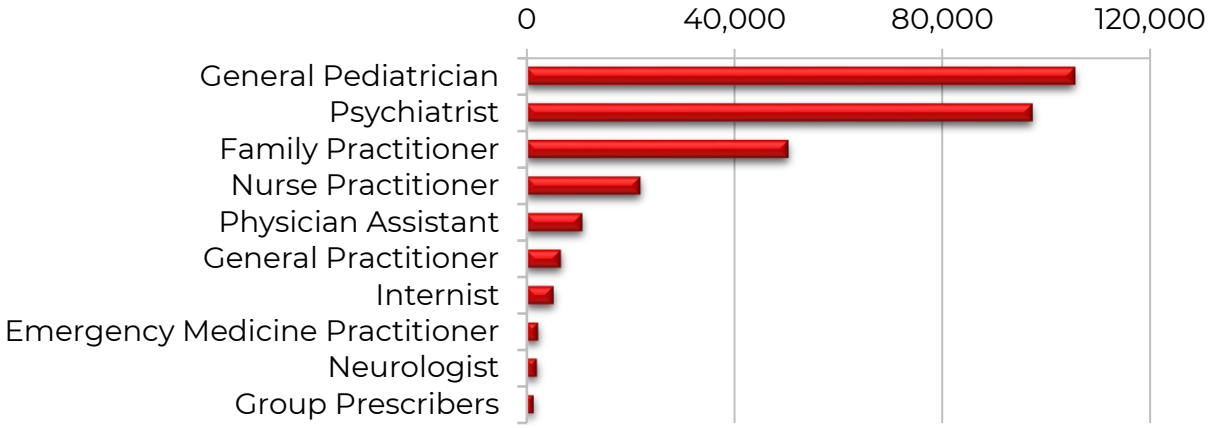
reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

- Aggregate drug rebates collected during calendar year 2020 for ADHD and narcolepsy medications: $33,252,520.50[Δ]

Demographics of Members Utilizing ADHD and Narcolepsy Medications



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

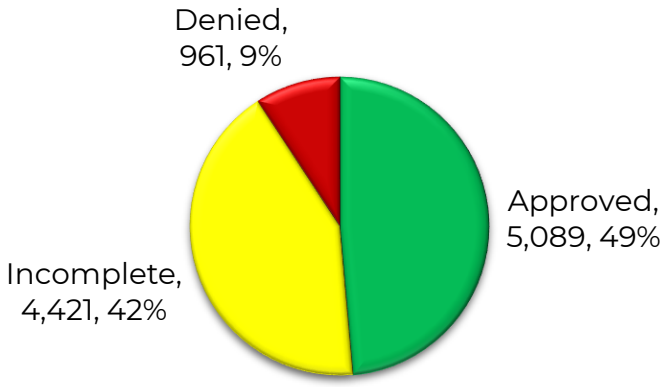


Prior Authorization of ADHD and Narcolepsy Medications

There were 10,471 prior authorization requests submitted for ADHD and narcolepsy medications during calendar year 2020. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2020.

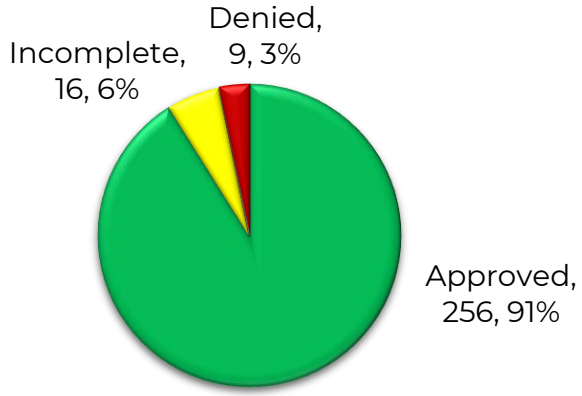
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Status of Petitions



There were 281 prior authorization requests submitted for a total of 193 unique members for ADHD and narcolepsy medications during calendar year 2020 that were referred for a psychiatric consultation. Most requests were for children 3 or 4 years of age. The following chart shows the status of the submitted petitions referred for psychiatric consultation for calendar year 2020.

Status of Psychiatric Consultations



Oklahoma Resources

The following list includes local resources available to prescribers, specifically regarding psychotropic medications:

- **Consultation with a Child Psychiatrist:** For children with especially challenging symptoms, a consultation with a child psychiatrist is available. If you would like to speak with a psychiatrist, please call 1-405-522-7597 to schedule a consultation.
- **Care Management (Including Behavioral Health):** If additional services are needed for SoonerCare members, please contact *Care Management* at 1-877-252-6002 or *Behavioral Health Care Management* at 1-800-652-2010.

- **Project ECHO:** Project ECHO (Extension for Community Health Care Outcomes) is available online for medical education and care management for chronic and complex medical conditions at: https://health.okstate.edu/echo/index.html.
- **Oklahoma Pediatric Psychotropic Medication Resource Guide:** The Department of Psychiatry and Behavioral Sciences at Oklahoma State University Center for Health Sciences has provided a psychotropic medication resource guide that can assist in the management of pediatric patients in the state of Oklahoma and can be found at: https://medicine.okstate.edu/academics/psychiatry/index.html.

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

Anticipated Patent Expiration(s):

- Vyvanse® (lisdexamfetamine capsule and chewable tablet): February 2023
- Daytrana® [methylphenidate extended-release (ER) transdermal patch]: October 2025
- Dyanavel® XR (amphetamine ER suspension): March 2029
- Mydayis® (amphetamine/dextroamphetamine ER capsule): August 2029
- Wakix® (pitolisant tablet): September 2029
- Quillivant XR® (methylphenidate ER suspension): February 2031
- Jornay PM® (methylphenidate ER capsule): March 2032
- Adzenys XR-ODT® [amphetamine ER orally disintegrating tablet (ODT)]: June 2032
- Adzenys ER™ (amphetamine ER suspension): June 2032
- Cotempla XR-ODT® (methylphenidate ER ODT): June 2032
- Qelbree™ (viloxazine ER capsule): February 2033
- Xywav™ (calcium/magnesium/potassium/sodium oxybates oral solution): March 2033
- QuilliChew ER® (methylphenidate ER chewable tablet): August 2033
- Xyrem® (sodium oxybate solution): September 2033
- Evekeo ODT™ (amphetamine ODT): March 2037
- Azstarys™ (serdexmethylphenidate/dexmethylphenidate capsule): December 2037
- Adhansia XR® (methylphenidate ER capsule): November 2038
- Sunosi® (solriamfetol tablet): March 2040

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

- **October 2020:** The FDA approved Wakix® (pitolisant) for a new indication for the treatment of cataplexy in adult patients with narcolepsy. Wakix® was previously approved by the FDA in August 2019 for the treatment of EDS in adults with narcolepsy. Approval for the new indication was supported by data from the HARMONY CTP and HARMONY 1 studies. Wakix® is the first medication that is not scheduled as a CDS to be approved by the FDA for narcolepsy.
- **March 2021:** The FDA approved Azstarys™ (serdexmethylphenidate/ dexmethylphenidate), a once-daily CNS stimulant, for the treatment of ADHD in patients 6 years of age or 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. Corium plans to launch Azstarys™ in the second half of 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.

News:

- **Society for Developmental and Behavioral Pediatrics (SDBP):** In February 2020, the SDBP published the *Clinical Practice Guideline for the Assessment and Treatment of Children and Adolescents with Complex ADHD*. This guideline is intended to supplement the American Academy of Pediatrics (AAP) clinical practice guidelines for ADHD. The AAP guidelines state that some primary care providers may not be confident to successfully diagnose and treat ADHD in certain children due to their age, coexisting conditions, or other concerns, and the AAP recommends referral to a pediatric or mental health specialist in these cases. The SDBP guidelines are intended to provide a framework for assessing and treating these patients with complex ADHD by clinicians with specialized training or expertise. For the purposes of the SDBP guideline, complex ADHD is defined as any of the following:

- Younger than 4 years of age or older than 12 years of age at the time of initial presentation of symptoms or impairment
- Presence or suspicion of coexisting disorders and complicating factors (refer to the full SDBP guidelines for a list of coexisting disorders and complicating factors which should be considered)
- Moderate-to-severe functional impairments in important aspects of daily living
- Diagnostic uncertainty on the part of the primary care clinician
- Inadequate response to treatment (or uncertainty about treatment planning)

The SDBP guidelines recommend comprehensive assessment by a clinician with specialized training or expertise for any child or adolescent through 18 years of age with complex ADHD. Behavioral and educational interventions should also be provided to all children and adolescents with complex ADHD. Additionally, recommendations are made regarding the pharmacologic treatment of complex ADHD with a variety of coexisting conditions, including learning disorder, autism spectrum disorder, intellectual disability, tics, substance use disorder, internalizing disorders (e.g., anxiety, depression), disruptive behavior disorders, and sociodemographic disadvantage.

Pipeline:

- **Amphetamine Transdermal System (ATS):** Noven is conducting Phase 2 studies of its ATS, a transdermal patch formulation of dextroamphetamine. The ATS is being studied in 4 dosage strengths, 4.5mg/9 hours, 9mg/9 hours, 13.5mg/9 hours, and 18mg/9 hours. In February 2021, Noven submitted a New Drug Application (NDA) to the FDA for the ATS for the treatment of ADHD in patients 6 years of age and older. The NDA submission is supported by data from a Phase 2 multicenter, laboratory classroom study in 110 pediatric patients with ADHD who were not adequately controlled with a current ADHD medication. In the study, patients treated with transdermal dextroamphetamine experienced statistically significant improvements in ADHD symptoms on the Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) total score relative to placebo (least-squares mean difference: -5.87; $P<0.001$). The safety profile was consistent with what is seen with oral amphetamine products. If the NDA is approved, the ATS would be the first amphetamine-based transdermal patch approved by the FDA for the treatment of ADHD.
- **Centanafadine:** Otsuka is conducting Phase 3 studies evaluating the use of centanafadine in adult patients with ADHD. Centanafadine is a serotonin-norepinephrine-dopamine triple-reuptake inhibitor. In June 2020, Otsuka announced positive topline results from 2 Phase 3 studies of centanafadine in approximately 900 adult patients with ADHD,

ranging from 18 to 55 years of age. Patients were randomized 1:1:1 to receive centanafadine 100mg, centanafadine 200mg, or placebo twice daily for 6 weeks. The primary endpoint, change from baseline to day 42 on the adult ADHD investigator symptom rating scale (AISRS) total score, was met in both studies demonstrating statistically significant improvement relative to placebo for both doses of centanafadine ($P<0.05$ in study 1; $P<0.01$ in study 2). A long-term safety and tolerability study of centanafadine is currently ongoing. Otsuka also plans to investigate the use of centanafadine in pediatric patients with ADHD.

- **Qelbree™ (Viloxazine):** Supernus is conducting Phase 3 studies evaluating the use of viloxazine for the treatment of adult patients with ADHD. In December 2020, positive topline results were announced from a Phase 3 study of viloxazine in adults with ADHD. Patients were randomized to receive viloxazine (titrated up to a maximum of 600mg) or placebo once daily. The primary endpoint was the change from baseline to the end of the study at 6 weeks in the AISRS. The study met its primary endpoint relative to placebo, demonstrating a statistically significant reduction in ADHD symptoms from baseline to week 6 (15.5 point reduction for viloxazine vs. 11.7 point reduction for placebo; $P=0.0040$). Supernus plans to submit a supplemental NDA (sNDA) for Qelbree™ to the FDA for the treatment of adults with ADHD in the second half of 2021.

Azstarys™ (Serdexmethylphenidate/Dexmethylphenidate) Product Summary[14,15]

Indication: 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 oral capsules

- The combined molar dose of serdexmethylphenidate and dexmethylphenidate in each dosage form is equivalent to 20mg, 30mg, and 40mg of dexmethylphenidate hydrochloride, respectively.

Dosing and Administration:

- Patients 6 to 12 years of age: Initial dose of 39.2mg/7.8mg once daily in the morning; 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
- Patients 13 to 17 years of age: Initial dose of 39.2mg/7.8mg once daily in the morning; increase the dose 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
- If switching from other methylphenidate products, the previous medication should be discontinued and the initial dose titration schedule for Azstarys™ should be followed
- To avoid substitution errors and overdosage, Azstarys™ should not be substituted for other methylphenidate products on a milligram-per-milligram basis

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

Use in Specific Populations:

- Pregnancy: There is no data available on the use of serdexmethylphenidate/dexmethylphenidate in pregnant women to evaluate the risk of birth defects, miscarriage, or adverse maternal or fetal outcomes. Published studies and postmarketing reports on methylphenidate use during pregnancy have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. No evidence of developmental effects were found in an embryo-fetal development study with oral administration of serdexmethylphenidate in rabbits during organogenesis at doses up to approximately 49 times the maximum recommended human dose (MRHD) of 52mg/day of serdexmethylphenidate.
- Lactation: There is no data available on the presence of serdexmethylphenidate in human milk, the effects on the breastfed infant, or the effects on milk production. Limited published literature reports that methylphenidate is present in human milk. There are no reports of adverse effects on the breastfed infants and no effects on milk production. Long-term neurodevelopmental effects on infants from stimulant exposure are unknown.

- Geriatric Use: Clinical studies of serdexmethylphenidate/ dexmethylphenidate did not include any patients 65 years of age or older.

Efficacy: The efficacy of Azstarys™ for the treatment of ADHD in pediatric patients 6 to 12 years of age was determined based on data from a Phase 3 randomized, double-blind, placebo-controlled, parallel group, analog classroom study in 150 pediatric patients with ADHD. After a washout period of previous ADHD medications, all patients received open-label serdexmethylphenidate/dexmethylphenidate during a 3-week dose-optimization period until an optimal dose or the maximum dose was reached. After the dose-optimization period, patients were randomly assigned to receive either the optimized dose of serdexmethylphenidate/ dexmethylphenidate or placebo for 1 week. On day 7 of the treatment period, patients were evaluated in a laboratory classroom setting over a period of 13 hours. The primary efficacy endpoint was the change in the SKAMP rating scale from baseline at randomization to the mean SKAMP-Combined scores averaged across the test day (day 7) at 0.5, 1, 2, 4, 8, 10, 12, and 13 hours post-dose. The results of the study showed a statistically significant decrease in SKAMP-Combined scores in patients treated with serdexmethylphenidate/ dexmethylphenidate relative to placebo. The efficacy of serdexmethylphenidate/dexmethylphenidate in adults and pediatric patients 13 to 17 years of age was established by pharmacokinetic bridging between the 52.3mg/10.4mg dose and dexmethylphenidate hydrochloride ER capsules.

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

Qelbree™ (Viloxazine) Product Summary[16]

Indication: 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 ER oral capsules

Dosing and Administration:

- 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
- 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

Safety:

- Suicidal Thoughts and Behaviors: Higher rates of suicidal thoughts and behavior were reported in pediatric patients with ADHD treated with viloxazine than with placebo. Suicidal ideation or behavior was reported in 9 out of 1,019 patients (0.9%) treated with viloxazine vs. 2 out of 463 patients (0.4%) who received placebo. No completed suicides occurred during the clinical studies of viloxazine. Patients receiving viloxazine should be monitored for clinical worsening or emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy and during dosage changes. Discontinuation of viloxazine should be considered in patients who experience emergent suicidal thoughts and behaviors.
- Blood Pressure (BP) and Heart Rate (HR) Increases: Viloxazine can cause an increase in HR and diastolic BP. HR and BP should be assessed prior to initiating treatment with viloxazine, following increases in dosage, and periodically throughout treatment.
- Activation of Mania or Hypomania: Noradrenergic drugs, including viloxazine, may induce a manic or mixed episode in patients with bipolar disorder. Patients should be screened prior to initiating treatment with viloxazine to determine if they are at risk for bipolar disorder.
- Somnolence and Fatigue: Viloxazine can cause somnolence and fatigue. In clinical studies of viloxazine, somnolence and fatigue were reported in 16% and 6% of patients treated with viloxazine, respectively, compared to 4% and 2% of patients who received placebo. Patients should not perform activities requiring mental alertness, such as operating a motor vehicle or hazardous machinery, until they know how they will be affected by viloxazine.

- Drug Interactions: Coadministration of viloxazine with an MAOI may lead to potentially life-threatening hypertensive crisis. Additionally, viloxazine is a strong CYP1A2 inhibitor. Concomitant use of viloxazine and an MAOI or sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline) is contraindicated.
- Pregnancy: Viloxazine may cause maternal harm when used during pregnancy based on animal reproduction studies. Data from case series with viloxazine use in pregnant women are insufficient to determine the drug-associated risk of major birth defects, miscarriage, or adverse maternal outcomes. Viloxazine should be discontinued when pregnancy is recognized unless the benefits of therapy outweigh the potential risk to the mother.
- Lactation: There is no data available on the presence of viloxazine in human milk, the effects on the breastfed infant, or the effects on milk production. Viloxazine is likely present in rat milk; therefore, viloxazine would likely be present in human milk as well.
- Pediatric Use: The safety and effectiveness of viloxazine have been established in pediatric patients 6 to 17 years of age with ADHD.
- Geriatric Use: Clinical studies of viloxazine for the treatment of ADHD did not include sufficient numbers of patients 65 years of age and older to determine whether or not they respond differently from younger patients.
- Renal Impairment: Viloxazine exposure increases in patients with renal impairment. No dosage adjustment is recommended in patients with mild or moderate renal impairment [estimated glomerular filtration rate (eGFR) 30 to 89mL/min/1.73m^2]. Dosage reduction is recommended in patients with severe renal impairment (eGFR <30mL/min/1.73m^2).
    - Dose Adjustment for Severe Renal Impairment: Initial dose of 100mg once daily; may titrate in weekly increments of 50mg to 100mg once daily to the maximum recommended dose of 200mg once daily
- Hepatic Impairment: The effect of hepatic impairment on the pharmacokinetics of viloxazine is unknown. Use of viloxazine is not recommended in patients with hepatic impairment.

Adverse Reactions: The most common adverse reactions (occurring in ≥5% and at least twice the placebo rate for any dose) were somnolence, decreased appetite, fatigue, nausea, vomiting, insomnia, and irritability. Approximately 3% of patients receiving viloxazine in clinical studies discontinued treatment due to adverse reactions. The most common adverse reactions leading to treatment discontinuation were somnolence, nausea, headache, irritability, tachycardia, fatigue, and decreased appetite.

Efficacy: The efficacy of viloxazine for the treatment of ADHD in pediatric patients 6 to 17 years of age was determined based on data from (3) Phase 3, short-term, multicenter, randomized, double-blind, placebo-controlled, monotherapy studies. The primary endpoint for all 3 studies was the change from baseline to the end of the study period on the total score of the ADHD Rating Scale 5th Edition (ADHD-RS-5). Higher ADHD-RS-5 scores reflect more severe ADHD symptoms. Additionally, all studies included the Clinical Global Impression-Improvement (CGI-I) score at the end of the study as a secondary endpoint.

- Study 1 included patients 6 to 11 years of age with ADHD, randomized to receive viloxazine 100mg, viloxazine 200mg, or placebo once daily for 6 weeks of treatment (including a 1-week titration period).
- Study 2 included patients 6 to 11 years of age with ADHD, randomized to receive viloxazine 200mg, viloxazine 400mg, or placebo once daily for 8 weeks of treatment (including a 3-week titration period).
- Study 3 included patients 12 to 17 years of age with ADHD, randomized to receive viloxazine 200mg, viloxazine 400mg, or placebo once daily for 6 weeks of treatment (including a 1-week titration period).

The primary efficacy endpoint was met in all 3 studies, demonstrating a statistically significant reduction in ADHD-RS-5 total scores in patients treated with viloxazine relative to placebo (*see efficacy results in the following table, Table 1*).

Table 1. Viloxazine Primary Efficacy Results for Change from Baseline in ADHD-RS-5 Total Score in Pediatric Patients with ADHD

Study Number (Age Range)	Treatment Group	Mean Baseline Score (SD)	LS Mean Change from Baseline (SE)	Placebo-subtracted Difference (95% CI)
Study 1 (6 to 11 Years)	100mg/day 200mg/day placebo	45.0 (6.53) 44.0 (6.80) 43.6 (7.05)	-16.6 (1.16) -17.7 (1.12) -10.9 (1.14)	-5.8 (-8.9, -2.6)* -6.9 (-10.0, -3.8)* --
Study 2 (6 to 11 Years)	200mg/day 400mg/day placebo	43.8 (6.54) 45.0 (6.55) 43.5 (6.79)	-17.6 (1.43) -17.5 (1.52) -11.7 (1.48)	-6.0 (-10.0, -1.9)* -5.8 (-9.9, -1.7)* --
Study 3 (12 to 17 Years)	200mg/day 400mg/day placebo	39.9 (7.22) 39.4 (7.59) 40.5 (6.79)	-16.0 (1.45) -16.5 (1.38) -11.4 (1.37)	-4.5 (-8.4, -0.6)* -5.1 (-8.9, -1.3)* --

ADHD-RS-5 = Attention-Deficit/Hyperactivity Disorder Rating Scale 5th Edition; SD = standard deviation; SE = standard error; LS Mean = least-squares mean; CI = confidence interval
*Statistically significantly superior to placebo after multiplicity adjustment

Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days[+]
Qelbree™ (viloxazine) 200mg capsule	**$9.97**	**$598.20**
atomoxetine 100mg capsule (generic)	$1.79	$53.70
guanfacine ER 4mg tablet (generic)	$0.24	$7.20

ER = extended-release
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
[+]Cost per 30 days based on the maximum FDA approved dose for each product: 400mg [(2) 200mg capsules] once daily for Qelbree™, 100mg once daily for atomoxetine, and 4mg once daily for guanfacine ER.

Xywav™ (Calcium/Magnesium/Potassium/Sodium Oxybates) Product Summary[17]

Indication: 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 *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 Comparison:

Product	Cost Per mL	Cost Per Package[+]
Xywav™ (calcium/magnesium/potassium/sodium oxybates) 0.5g/mL oral solution	**$28.39**	**$5,110.20**
Xyrem® (sodium oxybate) 0.5g/mL oral solution	$30.80	$5,544.00

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).
[+]Both products are available as a 180mL bottle.

Recommendations

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

1. 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
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			Adzenys ER™ (amphetamine ER susp) Adzenys XR-ODT® (amphetamine ER-ODT) Cotempla XR-ODT® (methylphenidate ER ODT) Desoxyn® (methamphetamine) Dexedrine® (dextroamphetamine) Dexedrine Spansules® (dextroamphetamine ER) Dyanavel® XR (amphetamine ER susp) Evekeo® (amphetamine) Evekeo ODT™ (amphetamine ODT) Methylin® (methylphenidate chew tab) Mydayis® (amphetamine/ dextroamphetamine ER) ProCentra® (dextroamphetamine) Zenzedi® (dextroamphetamine)
Short-Acting			
Adderall® (amphetamine/ dextroamphetamine)			
Long-Acting			
Vyvanse® (lisdexamfetamine cap and chew tab)+ **Adderall XR® (amphetamine/ dextroamphetamine ER)**	~~**Adderall XR® (amphetamine/ dextroamphetamine ER)**~~		
Methylphenidate			
Short-Acting			
Focalin® (dexmethylphenidate) Methylin® (methylphenidate tab and soln) Ritalin® (methylphenidate)			
Long-Acting			
Daytrana® (methylphenidate ER) Focalin XR® brand name only (dexmethylphenidate ER) Metadate CD® (methylphenidate ER) **Metadate ER® (methylphenidate ER)** **Methylin ER® (methylphenidate ER)** QuilliChew ER® (methylphenidate ER chew tab)	Concerta® (methylphenidate ER) dexmethylphenidate ER (generic Focalin XR®) ~~**Quillivant XR® (methylphenidate ER susp)**~~	Adhansia XR® (methylphenidate ER) Aptensio XR® (methylphenidate ER) **Azstarys™ (serdexmethylphenidate/dexmethylphenidate)** Jornay PM® (methylphenidate ER) ~~**Metadate ER® (methylphenidate ER)**~~	

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Ritalin LA® (methylphenidate ER) **Ritalin SR® (methylphenidate ER)**		**~~Methylin ER® (methylphenidate ER)~~** methylphenidate ER 72mg **Quillivant XR® (methylphenidate ER susp)** **~~Ritalin SR® (methylphenidate ER)~~**	
Non-Stimulants			
Intuniv® (guanfacine ER) Strattera® (atomoxetine)	**Kapvay® (clonidine ER)Δ**	**~~Kapvay® (clonidine ER)Δ~~** **Qelbree™ (viloxazine)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 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 or Methylin® oral solution, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Vyvanse® (Lisdexamfetamine) Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:
    a. An FDA approved diagnosis of moderate-to-severe BED; and
    b. Member must be 18 years of age or older; and
    c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and
    d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and
    e. A quantity limit of 30 capsules or chewable tablets per 30 days will apply; and
    f. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.

Narcolepsy Medications Approval Criteria:

1. An FDA approved diagnosis; and
2. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
    a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; or
3. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; or
4. Use of Sunosi® (solriamfetol), Wakix® (pitolisant), ~~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 requires concurrent treatment for the obstructive sleep apnea; and
7. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the prior authorization request.

Utilization Details of ADHD and Narcolepsy Medications: Calendar Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LISDEXAMFETAMINE PRODUCTS						
VYVANSE CAP 30MG	18,171	4,415	$5,428,024.06	$298.72	4.12	12.27%
VYVANSE CAP 40MG	14,873	3,141	$4,438,320.54	$298.41	4.74	10.03%
VYVANSE CAP 20MG	13,482	4,047	$4,010,658.86	$297.48	3.33	9.06%
VYVANSE CAP 50MG	10,305	1,967	$3,054,753.82	$296.43	5.24	6.90%
VYVANSE CAP 60MG	6,048	1,059	$1,818,781.55	$300.72	5.71	4.11%
VYVANSE CAP 70MG	5,487	860	$1,645,287.13	$299.85	6.38	3.72%
VYVANSE CAP 10MG	4,778	1,929	$1,408,508.61	$294.79	2.48	3.18%
VYVANSE CHW 20MG	1,967	613	$577,357.65	$293.52	3.21	1.30%
VYVANSE CHW 10MG	1,576	629	$465,978.37	$295.67	2.51	1.05%
VYVANSE CHW 30MG	1,309	359	$385,944.70	$294.84	3.65	0.87%
VYVANSE CHW 40MG	592	149	$170,692.30	$288.33	3.97	0.39%
VYVANSE CHW 50MG	166	41	$46,797.28	$281.91	4.05	0.11%
VYVANSE CHW 60MG	77	24	$24,097.10	$312.95	3.21	0.05%
SUBTOTAL	**78,831**	**14,014***	**$23,475,201.97**	**$297.79**	**5.63**	**53.05%**
METHYLPHENIDATE PRODUCTS						
METHYLPHENID TAB 10MG	8,482	1,915	$157,343.36	$18.55	4.43	0.36%
METHYLPHENID TAB 5MG	6,545	1,843	$106,975.91	$16.34	3.55	0.24%
METHYLPHENID CAP 20MG	6,315	1,729	$453,246.14	$71.77	3.65	1.02%
METHYLPHENID CAP 30MG	5,966	1,337	$474,811.59	$79.59	4.46	1.07%
METHYLPHENID CAP 40MG ER	4,183	924	$410,773.00	$98.20	4.53	0.93%
METHYLPHENID TAB 20MG	3,873	735	$81,345.11	$21.00	5.27	0.18%
METHYLPHENID TAB 36MG ER	3,107	595	$337,739.07	$108.70	5.22	0.76%
METHYLPHENID TAB 54MG ER	2,999	500	$286,321.65	$95.47	6	0.65%
METHYLPHENID CAP 10MG	2,702	977	$183,195.76	$67.80	2.77	0.41%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
METHYLPHENID CAP 50MG	2,149	401	$221,789.86	$103.21	5.36	0.50%
METHYLPHENID CAP 60MG	1,658	275	$168,739.42	$101.77	6.03	0.38%
APTENSIO XR CAP 30MG	1,595	463	$385,462.00	$241.67	3.44	0.87%
APTENSIO XR CAP 20MG	1,441	518	$361,013.05	$250.53	2.78	0.82%
APTENSIO XR CAP 40MG	1,295	347	$311,961.29	$240.90	3.73	0.70%
QUILLICHEW CHW 20MG ER	1,293	405	$401,842.98	$310.78	3.19	0.91%
METHYLPHENID CAP 20MG ER	1,160	346	$77,986.21	$67.23	3.35	0.18%
METHYLPHENID TAB 27MG ER	1,042	260	$76,673.06	$73.58	4.01	0.17%
APTENSIO XR CAP 60MG	954	175	$222,467.77	$233.19	5.45	0.50%
METHYLPHENID CAP 30MG ER	844	231	$57,765.32	$68.44	3.65	0.13%
METHYLPHENID TAB 18MG ER	840	241	$62,037.87	$73.85	3.49	0.14%
APTENSIO XR CAP 10MG	785	377	$196,564.06	$250.40	2.08	0.44%
APTENSIO XR CAP 50MG	733	176	$179,532.42	$244.93	4.16	0.41%
METHYLPHENID CAP 40MG ER	701	156	$48,346.98	$68.97	4.49	0.11%
QUILLICHEW CHW 30MG ER	662	174	$230,621.34	$348.37	3.8	0.52%
METHYLPHENID TAB 36MG ER	643	182	$84,943.59	$132.11	3.53	0.19%
APTENSIO XR CAP 15MG	620	200	$150,656.13	$242.99	3.1	0.34%
METHYLPHENID TAB 54MG ER	537	154	$64,930.22	$120.91	3.49	0.15%
METHYLPHENID CAP 10MG ER	436	181	$45,217.52	$103.71	2.41	0.10%
METHYLPHENID CAP 20MG ER	387	189	$82,689.18	$213.67	2.05	0.19%
METHYLPHENID SOL 5MG/5ML	365	141	$12,468.45	$34.16	2.59	0.03%
QUILLIVANT SUS 25MG/5ML	364	71	$144,239.99	$396.26	5.13	0.33%
METHYLPHENID CAP 30MG ER	359	202	$78,754.54	$219.37	1.78	0.18%
QUILLICHEW CHW 40MG ER	331	74	$109,598.06	$331.11	4.47	0.25%
METHYLPHENID CHW 5MG	327	118	$34,235.76	$104.70	2.77	0.08%
METHYLPHENID CAP 40MG ER	298	135	$64,193.53	$215.41	2.21	0.15%
METHYLPHENID TAB 20MG ER	245	50	$14,801.11	$60.41	4.9	0.03%
METHYLPHENID CAP 10MG ER	239	146	$49,276.48	$206.18	1.64	0.11%
METHYLPHENID CAP 60MG ER	224	91	$47,570.47	$212.37	2.46	0.11%
METHYLPHENID SOL 10MG/5ML	205	61	$8,583.34	$41.87	3.36	0.02%
METHYLPHENID TAB 27MG ER	199	74	$16,260.79	$81.71	2.69	0.04%
METHYLPHENID CAP 50MG ER	194	89	$41,580.05	$214.33	2.18	0.09%
METHYLPHENID CAP 15MG ER	183	83	$39,208.59	$214.25	2.2	0.09%
METHYLPHENID CHW 10MG	179	51	$41,055.33	$229.36	3.51	0.09%
METHYLPHENID CHW 2.5MG	171	77	$13,113.11	$76.68	2.22	0.03%
METHYLPHENID TAB 72MG ER	151	32	$67,840.62	$449.28	4.72	0.15%
METHYLIN SOL 5MG/5ML	136	44	$5,365.91	$39.46	3.09	0.01%
JORNAY PM CAP 40MG ER	135	30	$45,331.12	$335.79	4.5	0.10%
JORNAY PM CAP 60MG ER	106	20	$30,562.19	$288.32	5.3	0.07%
METHYLPHENID TAB 18MG ER	106	36	$8,764.50	$82.68	2.94	0.02%
DAYTRANA DIS 30MG/9HR	97	20	$30,864.93	$318.20	4.85	0.07%
CONCERTA TAB 36MG	92	24	$35,470.59	$385.55	3.83	0.08%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
METHYLPHENID CAP 60MG LA	66	19	$17,394.21	$263.55	3.47	0.04%
RITALIN LA CAP 10MG	66	22	$20,209.66	$306.21	3	0.05%
DAYTRANA DIS 10MG/9HR	57	14	$20,318.31	$356.46	4.07	0.05%
JORNAY PM CAP 80MG ER	38	11	$10,360.75	$272.65	3.45	0.02%
RITALIN LA CAP 30MG	32	12	$9,902.69	$309.46	2.67	0.02%
DAYTRANA DIS 20MG/9HR	31	8	$11,717.94	$378.00	3.88	0.03%
CONCERTA TAB 54MG	25	13	$4,716.18	$188.65	1.92	0.01%
RITALIN LA CAP 40MG	25	6	$8,131.00	$325.24	4.17	0.02%
METHYLPHENID TAB 10MG ER	24	7	$1,056.49	$44.02	3.43	0.00%
METHYLIN SOL 10MG/5ML	23	10	$691.37	$30.06	2.3	0.00%
RITALIN LA CAP 20MG	18	10	$5,394.78	$299.71	1.8	0.01%
JORNAY PM CAP 100MG ER	17	4	$6,099.36	$358.79	4.25	0.01%
DAYTRANA DIS 15MG/9HR	16	6	$6,246.00	$390.38	2.67	0.01%
JORNAY PM CAP 20MG ER	16	12	$5,317.15	$332.32	1.33	0.01%
CONCERTA TAB 27MG	16	10	$4,341.08	$271.32	1.6	0.01%
RITALIN TAB 20MG	12	2	$1,717.43	$143.12	6	0.00%
COTEMPLA TAB 25.9MG	7	1	$2,896.65	$413.81	7	0.01%
COTEMPLA TAB 17.3MG	5	1	$2,072.60	$414.52	5	0.00%
ADHANSIA XR CAP 25MG	5	2	$1,569.77	$313.95	2.5	0.00%
ADHANSIA XR CAP 35MG	3	1	$962.43	$320.81	3	0.00%
ADHANSIA XR CAP 55MG	3	1	$977.43	$325.81	3	0.00%
CONCERTA TAB 18MG	1	1	$54.51	$54.51	1	0.00%
ADHANSIA XR CAP 70MG	1	1	$311.22	$311.22	1	0.00%
SUBTOTAL	**69,160**	**10,746***	**$7,004,590.33**	**$101.28**	**6.44**	**15.83%**
GUANFACINE ER PRODUCTS						
GUANFACINE TAB 2MG ER	19,204	3,825	$407,483.33	$21.22	5.02	0.92%
GUANFACINE TAB 1MG ER	13,368	3,777	$277,385.09	$20.75	3.54	0.63%
GUANFACINE TAB 3MG ER	12,493	2,150	$266,745.64	$21.35	5.81	0.60%
GUANFACINE TAB 4MG ER	11,101	1,520	$206,392.19	$18.59	7.3	0.47%
INTUNIV TAB 3MG	56	7	$15,954.20	$284.90	8	0.04%
INTUNIV TAB 4MG	46	5	$13,683.92	$297.48	9.2	0.03%
INTUNIV TAB 2MG	25	3	$6,757.68	$270.31	8.33	0.02%
INTUNIV TAB 1MG	1	1	$291.67	$291.67	1	0.00%
SUBTOTAL	**56,294**	**8,605***	**$1,194,693.72**	**$21.22**	**6.54**	**2.70%**
AMPHETAMINE/DEXTROAMPHETAMINE PRODUCTS						
AMPHET/DEXTR TAB 10MG	10,288	2,276	$273,477.60	$26.58	4.52	0.62%
AMPHET/DEXTR TAB 20MG	8,175	1,462	$235,420.97	$28.80	5.59	0.53%
AMPHET/DEXTR TAB 5MG	6,366	1,749	$161,337.56	$25.34	3.64	0.36%
AMPHET/DEXTR TAB 30MG	3,987	618	$122,283.31	$30.67	6.45	0.28%
AMPHET/DEXTR TAB 15MG	3,405	662	$94,658.94	$27.80	5.14	0.21%
AMPHET/DEXTR CAP 30MG ER	2,868	458	$131,667.72	$45.91	6.26	0.30%
AMPHET/DEXTR CAP 20MG ER	2,495	545	$118,508.14	$47.50	4.58	0.27%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AMPHET/DEXTR CAP 15MG ER	1,481	337	$76,866.72	$51.90	4.39	0.17%
AMPHET/DEXTR CAP 10MG ER	1,254	358	$54,811.82	$43.71	3.5	0.12%
AMPHET/DEXTR CAP 25MG ER	1,045	211	$41,972.50	$40.17	4.95	0.09%
AMPHET/DEXTR TAB 7.5MG	835	207	$29,047.83	$34.79	4.03	0.07%
AMPHETAMINE TAB 5MG	282	78	$7,355.35	$26.08	3.62	0.02%
AMPHET/DEXTR TAB 12.5MG	250	56	$8,510.45	$34.04	4.46	0.02%
AMPHET/DEXTR CAP 5MG ER	210	78	$10,058.13	$47.90	2.69	0.02%
AMPHETAMINE TAB 7.5MG	108	37	$3,560.11	$32.96	2.92	0.01%
ADDERALL XR CAP 20MG	31	7	$2,876.54	$92.79	4.43	0.01%
ADDERALL XR CAP 25MG	26	5	$4,938.67	$189.95	5.2	0.01%
ADDERALL XR CAP 30MG	25	5	$5,283.64	$211.35	5	0.01%
MYDAYIS CAP 25MG	13	2	$2,753.55	$211.81	6.5	0.01%
ADDERALL XR CAP 10MG	9	4	$1,389.62	$154.40	2.25	0.00%
ADDERALL XR CAP 15MG	9	3	$475.45	$52.83	3	0.00%
MYDAYIS CAP 37.5MG	5	2	$1,443.74	$288.75	2.5	0.00%
MYDAYIS CAP 50MG	2	1	$582.44	$291.22	2	0.00%
ADDERALL XR CAP 5MG	1	1	$41.86	$41.86	1	0.00%
SUBTOTAL	**43,170**	**6,886***	**$1,389,322.66**	**$32.18**	**6.27**	**3.14%**
DEXMETHYLPHENIDATE PRODUCTS						
DEXMETHYLPHE TAB 10MG	6,172	1,111	$143,690.35	$23.28	5.56	0.32%
DEXMETHYLPHE TAB 5MG	5,412	1,270	$98,841.79	$18.26	4.26	0.22%
FOCALIN XR CAP 20MG	4,652	998	$1,784,561.67	$383.61	4.66	4.03%
FOCALIN XR CAP 10MG	4,000	1,264	$1,489,054.18	$372.26	3.16	3.36%
FOCALIN XR CAP 15MG	3,633	878	$1,400,064.12	$385.37	4.14	3.16%
FOCALIN XR CAP 30MG	2,739	525	$1,021,409.24	$372.91	5.22	2.31%
FOCALIN XR CAP 25MG	2,145	395	$868,298.84	$404.80	5.43	1.96%
FOCALIN XR CAP 5MG	1,669	637	$611,159.64	$366.18	2.62	1.38%
DEXMETHYLPHE TAB 2.5MG	1,562	466	$26,998.05	$17.28	3.35	0.06%
FOCALIN XR CAP 40MG	1,368	206	$579,558.00	$423.65	6.64	1.31%
FOCALIN XR CAP 35MG	617	104	$262,131.61	$424.85	5.93	0.59%
FOCALIN TAB 10MG	97	29	$6,171.43	$63.62	3.34	0.01%
FOCALIN TAB 5MG	63	18	$4,159.33	$66.02	3.5	0.01%
FOCALIN TAB 2.5MG	13	9	$474.88	$36.53	1.44	0.00%
DEXMETHYLPHE CAP 10MG ER	13	5	$407.09	$31.31	2.6	0.00%
DEXMETHYLPHE CAP 20MG ER	12	3	$517.73	$43.14	4	0.00%
DEXMETHYLPHE CAP 25MG ER	8	3	$350.76	$43.85	2.67	0.00%
DEXMETHYLPHE CAP 15MG ER	2	2	$106.67	$53.34	1	0.00%
DEXMETHYLPHE CAP 5MG ER	1	1	$37.54	$37.54	1	0.00%
SUBTOTAL	**34,178**	**4,999***	**$8,297,992.92**	**$242.79**	**6.84**	**18.75%**
ATOMOXETINE PRODUCTS						
ATOMOXETINE CAP 40MG	8,063	2,122	$475,623.96	$58.99	3.8	1.07%
ATOMOXETINE CAP 25MG	7,462	2,095	$487,982.37	$65.40	3.56	1.10%
ATOMOXETINE CAP 60MG	4,278	910	$226,996.10	$53.06	4.7	0.51%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ATOMOXETINE CAP 18MG	3,897	1,281	$229,623.74	$58.92	3.04	0.52%
ATOMOXETINE CAP 10MG	3,029	1,092	$150,293.26	$49.62	2.77	0.34%
ATOMOXETINE CAP 80MG	2,308	496	$133,172.88	$57.70	4.65	0.30%
ATOMOXETINE CAP 100MG	829	169	$58,942.31	$71.10	4.91	0.13%
STRATTERA CAP 40MG	28	4	$11,893.68	$424.77	7	0.03%
STRATTERA CAP 80MG	15	2	$7,095.25	$473.02	7.5	0.02%
STRATTERA CAP 10MG	7	3	$2,847.67	$406.81	2.33	0.01%
STRATTERA CAP 100MG	3	2	$1,403.99	$468.00	1.5	0.00%
SUBTOTAL	**29,919**	**5,841***	**$1,785,875.21**	**$59.69**	**5.12**	**4.04%**
CLONIDINE ER PRODUCTS						
CLONIDINE TAB 0.1MG ER	849	137	$56,901.10	$67.02	6.2	0.13%
SUBTOTAL	**849**	**137***	**$56,901.10**	**$67.02**	**6.2**	**0.13%**
ARMODAFINIL PRODUCTS						
NUVIGIL TAB 250MG	84	18	$68,988.39	$821.29	4.67	0.16%
NUVIGIL TAB 150MG	70	12	$58,077.95	$829.69	5.83	0.13%
NUVIGIL TAB 200MG	26	4	$22,153.28	$852.05	6.5	0.05%
ARMODAFINIL TAB 150MG	5	2	$230.81	$46.16	2.5	0.00%
ARMODAFINIL TAB 250MG	3	1	$115.28	$38.43	3	0.00%
SUBTOTAL	**188**	**32***	**$149,565.71**	**$795.56**	**5.88**	**0.34%**
MODAFINIL PRODUCTS						
MODAFINIL TAB 200MG	156	24	$5,426.18	$34.78	6.5	0.01%
MODAFINIL TAB 100MG	12	2	$382.77	$31.90	6	0.00%
PROVIGIL TAB 200MG	9	1	$30,745.31	$3,416.15	9	0.07%
SUBTOTAL	**177**	**27***	**$36,554.26**	**$206.52**	**6.56**	**0.08%**
AMPHETAMINE PRODUCTS						
ADZENYS XR TAB 18.8MG	25	4	$9,294.15	$371.77	6.25	0.02%
ADZENYS XR TAB 6.3MG	23	3	$8,553.26	$371.88	7.67	0.02%
ADZENYS XR TAB 9.4MG	19	3	$7,088.45	$373.08	6.33	0.02%
ADZENYS XR TAB 15.7 MG	18	2	$6,751.24	$375.07	9	0.02%
ADZENYS XR TAB 12.5MG	17	2	$6,138.12	$361.07	8.5	0.01%
DYANAVEL XR SUS 2.5MG/ML	14	3	$2,637.55	$188.40	4.67	0.01%
AMPHETAMINE TAB 10MG	2	1	$856.72	$428.36	2	0.00%
SUBTOTAL	**118**	**16***	**$41,319.49**	**$350.17**	**7.38**	**0.09%**
DEXTROAMPHETAMINE PRODUCTS						
DEXTROAMPHET CAP 15MG ER	65	7	$9,133.87	$140.52	9.29	0.02%
DEXTROAMPHET TAB 10MG	30	3	$962.98	$32.10	10	0.00%
DEXTROAMPHET CAP 10MG ER	16	3	$693.19	$43.32	5.33	0.00%
DEXTROAMPHET SOL 5MG/5ML	2	1	$2,678.80	$1,339.40	2	0.01%
SUBTOTAL	**113**	**12***	**$13,468.84**	**$119.19**	**9.42**	**0.03%**
SODIUM OXYBATE PRODUCTS						
XYREM SOL 500MG/ML	63	9	$788,122.72	$12,509.88	7	1.78%
SUBTOTAL	**63**	**9***	**$788,122.72**	**$12,509.88**	**7**	**1.78%**
CALCIUM/MAGNESIUM/POTASSIUM/SODIUM OXYBATES PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
XYWAV SOL 0.5GM/ML	2	1	$20,455.30	$10,227.65	2	0.05%
SUBTOTAL	**2**	**1***	**$20,455.30**	**$10,227.65**	**2**	**0.05%**
SOLRIAMFETOL PRODUCTS						
SUNOSI TAB 150MG	1	1	$638.22	$638.22	1	0.00%
SUBTOTAL	**1**	**1***	**$638.22**	$638.22	**1**	0.00%
TOTAL	**313,063**	**38,217***	**$44,254,702.45**	**$141.36**	**8.19**	**100.00%**

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

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Appendix K

Calendar Year 2020 Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Lybalvi™ (Olanzapine/Samidorphan)

Oklahoma Health Care Authority
June 2021

Current Prior Authorization Criteria

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

ER = extended-release; IM = intramuscular; inj = injection; susp = suspension; sub-Q = subcutaneous
*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.
^In addition to the Tier-3 criteria requirements, approval of olanzapine/fluoxetine (Symbyax®) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

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.

Approval Criteria for Atypical Antipsychotic Medications as Adjunctive Treatment of Major Depressive Disorder:

1. Authorization of Symbyax® (olanzapine/fluoxetine) or Rexulti® (brexpiprazole) for a diagnosis of major depressive disorder requires current use of an antidepressant, previous trials with at least 2 other antidepressants [including 1 trial with a selective serotonin reuptake

inhibitor (SSRI) and 1 trial with duloxetine], and a trial of aripiprazole tablets that did not yield adequate response. Tier structure rules continue to apply.

Abilify MyCite® (Aripiprazole Tablet with Sensor) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must not have dementia-related psychosis; and
3. A patient-specific, clinically significant reason why the member cannot use all oral or injectable Tier-1 or Tier-2 medications must be provided. Tier structure rules continue to apply. Please note, the ability of Abilify MyCite® to improve patient compliance or modify aripiprazole dosage has not been established; and
4. Previous use of aripiprazole tablets and a reason why the Tier-1 aripiprazole tablets are no longer appropriate for the member must be provided; and
5. The prescriber agrees to closely monitor patient adherence; and
6. Patients should be capable and willing to use the MyCite® App and follow the *Instructions for Use* and ensure the MyCite® App is compatible with their specific smartphone; and
7. Initial approval will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and patient compliance greater than 80% with prescribed therapy must be provided. In addition, a patient-specific, clinically significant reason why the member cannot transition to oral aripiprazole tablets or to any of the oral or injectable Tier-1 or Tier-2 medications must be provided. Tier structure rules continue to apply.

Utilization of Atypical Antipsychotic Medications: Calendar Year 2020

Comparison of Calendar Years

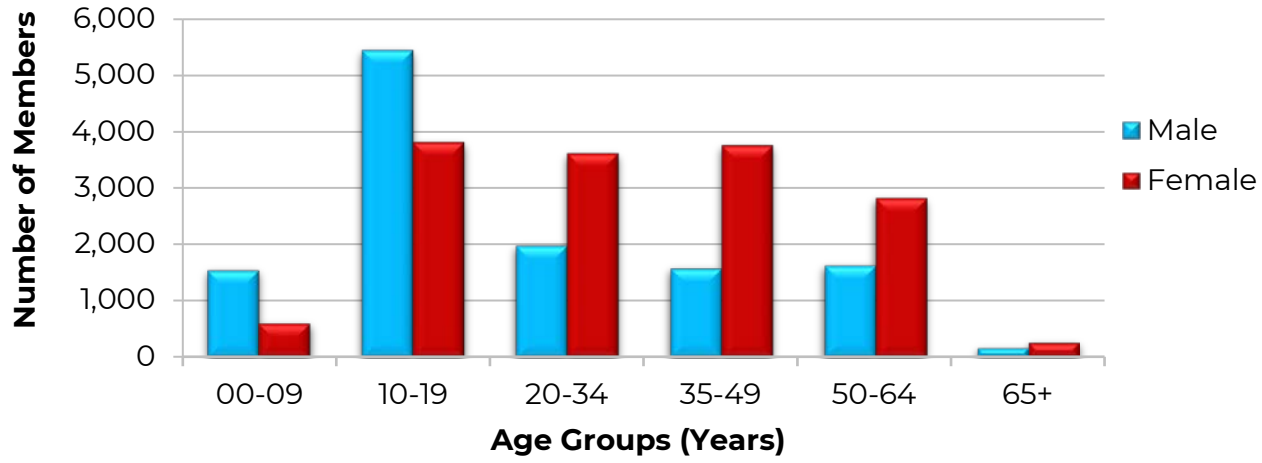
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	27,137	193,725	$50,758,895.75	$262.02	$8.29	7,680,267	6,120,454
2020	27,186	197,988	$59,273,940.39	$299.38	$9.15	7,996,247	6,476,052
% Change	**0.20%**	**2.20%**	**16.80%**	**14.30%**	**10.40%**	**4.10%**	**5.80%**
Change	**49**	**4,263**	**$8,515,044.64**	**$37.36**	**$0.86**	**315,980**	**355,598**

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

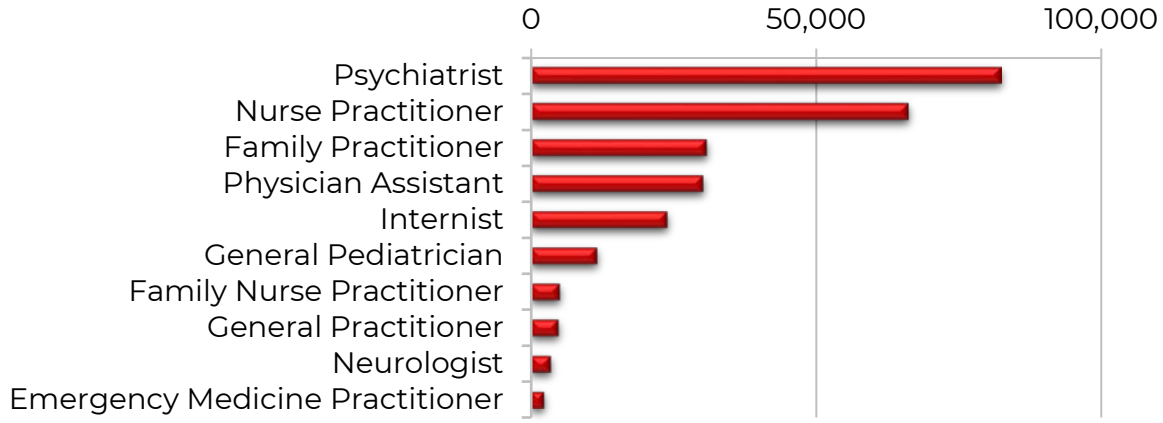
- The Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) category is heavily influenced by supplemental rebates. These rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

- Aggregate drug rebates collected during calendar year 2020 for atypical antipsychotic medications: $40,474,005.15[Δ]

Demographics of Members Utilizing Atypical Antipsychotic Medications



Top Prescriber Specialties of Atypical Antipsychotic Medications by Number of Claims

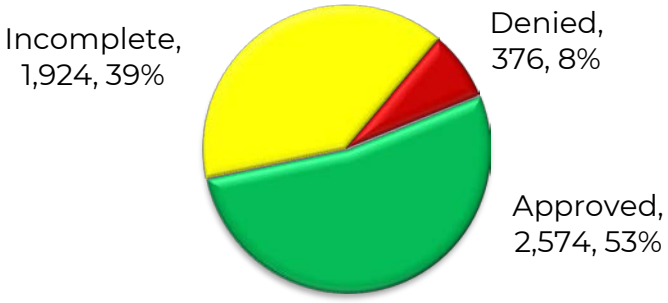


Prior Authorization of Atypical Antipsychotic Medications

There were 4,874 prior authorization requests submitted for atypical antipsychotic medications during calendar year 2020. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2020.

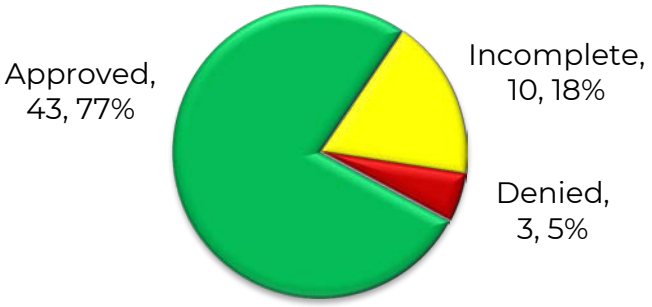
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Status of Petitions



There were 56 prior authorization requests submitted for a total of 45 unique members for atypical antipsychotic medications during calendar year 2020 that were referred for a psychiatric consultation. Most requests were for children 3 or 4 years of age. The following chart shows the status of the submitted petitions that were referred for a psychiatric consultation for calendar year 2020.

Status of Psychiatric Consultations



Oklahoma Resources

The following list includes local resources available to prescribers, specifically regarding psychotropic medications:

- **Consultation with a Child Psychiatrist:** For children with especially challenging symptoms, a consultation with a child psychiatrist is available. If you would like to speak with a psychiatrist, please call 1-405-522-7597 to schedule a consultation.
- **Care Management (Including Behavioral Health):** If additional services are needed for SoonerCare members, please contact *Care Management* at 1-877-252-6002 or *Behavioral Health Care Management* at 1-800-652-2010.
- **Project ECHO:** Project ECHO (Extension for Community Health Care Outcomes) is available online for medical education and care

management for chronic and complex medical conditions at: https://health.okstate.edu/echo/index.html.

- **Oklahoma Pediatric Psychotropic Medication Resource Guide:** The Department of Psychiatry and Behavioral Sciences at Oklahoma State University Center for Health Sciences has provided a psychotropic medication resource guide that can assist in the management of pediatric patients in the state of Oklahoma and can be found at: https://medicine.okstate.edu/academics/psychiatry/index.html.

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

Anticipated Patent Expiration(s):

- Saphris® [asenapine sublingual (SL) tablet]: October 2026
- Perseris® [risperidone extended-release (ER) subcutaneous (sub-Q) injection]: February 2028
- Vraylar® (cariprazine capsule): September 2029
- Invega Sustenna® [paliperidone intramuscular (IM) injection]: January 2031
- Fanapt® (iloperidone tablet): December 2031
- Rexulti® (brexpiprazole tablet): October 2032
- Secuado® (asenapine transdermal system): July 2033
- Abilify MyCite® (aripiprazole tablet with sensor): October 2033
- Abilify Maintena® (aripiprazole IM injection): March 2034
- Aristada® (aripiprazole lauroxil IM injection): March 2035
- Invega Trinza® (paliperidone IM injection): April 2036
- Caplyta® (lumateperone capsule): August 2039

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 and for the treatment of adults with bipolar I disorder, as a maintenance monotherapy or for the acute treatment of manic or mixed episodes, as monotherapy or as an adjunct to lithium or valproate. Lybalvi™ is a once-daily, oral atypical antipsychotic composed of olanzapine, an established 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 bipolar I disorder and schizophrenia. Alkermes expects to launch Lybalvi™ in the fourth quarter of 2021.

Guideline Update(s):

- **September 2020:** The American Psychiatric Association (APA) released a new evidence-based practice guideline to enhance the treatment of patients with schizophrenia. The goals are to reduce the mortality, morbidity, and significant psychosocial and health consequences of this psychiatric condition. The guideline recommends that patients with schizophrenia have a documented, comprehensive, and person-centered treatment plan that includes evidence-based nonpharmacological and pharmacological treatments. The guideline also recommends or suggests several treatment options for side effects associated with antipsychotic medication. The guideline was approved by the APA Board of Trustees at the December 2019 meeting. It was developed using a systematic process that is intended to be consistent with the recommendations of the Institute of Medicine and the Council of Medical Specialty Societies. Pharmacotherapy recommendations include:
  - Antipsychotic medication with monitoring for effectiveness and side effects; continuation of medications for those whose symptoms have improved
  - Clozapine for patients with treatment-resistant schizophrenia or those with substantial risk of suicide or suicide attempts
  - Long-acting injectable (LAI) antipsychotics for those who prefer them.

News:

- **July 2020:** LAI antipsychotics significantly increased time to first hospitalization in patients with early-phase schizophrenia, according to a study published in *JAMA Psychiatry,* the Prevention of Relapse in Schizophrenia (PRELAPSE) study. Many patients with schizophrenia struggle with relapse and hospitalization. One factor in this struggle may be treatment non-compliance, and LAI antipsychotics have the potential to increase compliance in patients with schizophrenia. However, many physicians may be reluctant to prescribe LAIs until after patients with schizophrenia have experienced multiple hospitalizations and relapses. It may be beneficial to start LAI antipsychotics earlier in the course of schizophrenia, as patients are less responsive to the same treatment after a second episode of psychosis. Randomized clinical trials have provided conflicting data on the beneficial effect of LAI antipsychotics in first episode and early-phase schizophrenia. The conflicting data may result from greater treatment adherence in patients enrolled in clinical trials than patients in the general population. The PRELAPSE study used cluster randomization at the clinical level to more closely represent adherence in the general population of schizophrenia patients. Researchers collected data from

19 clinics that provided LAI antipsychotic treatment with aripiprazole monohydrate LAI once monthly and from 20 clinics that provided antipsychotic medication treatment as usual. The inclusion criteria for participants (N=489; 75.3% men) included a schizophrenia diagnosis confirmed by the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, 5th (DSM-5), Research Version (SCID-5), <5 years of lifetime antipsychotic use, age of 18 to 35 years, and ability to give consent. Patients were followed for 2 years, during which time data on hospitalizations and emergency department and crisis unit use was collected via monthly phone interviews and confirmed via hospital records or other sources. Overall, treatment with aripiprazole monohydrate LAI increased the time to first hospitalization and reduced the total number of hospitalizations compared to the standard antipsychotic treatment. The mean survival time until first hospitalization was greater with aripiprazole monohydrate LAI treatment (613.7 days; 95% confidence interval (CI): 582.3, 645.1 days) than with standard care (530.6 days; 95% CI: 497.3, 563.9 days). This difference indicated superiority of treatment with LAI aripiprazole monohydrate [hazard ratio (HR) 0.56; 95% CI: 0.34, 0.92; P=0.02]. The number needed to treat was 7 when comparing aripiprazole monohydrate LAI with standard of care. Limitations to the study included potential selection effects caused by the cluster randomization design and the use of only 1 formulation for comparison. The study concluded LAI antipsychotic use by patients with early-phase schizophrenia can significantly delay time to hospitalization, a personally and economically important outcome, and clinicians should more broadly consider LAI antipsychotic treatment for patients with early-phase illness.

- **July 2020:** Data presented at the European Psychiatric Association (EPA) 2020 Congress virtual meeting suggest Vraylar® (cariprazine) is more effective than risperidone in treating patients with schizophrenia and persistent negative symptoms (PNS). A post-hoc analysis of the efficacy of cariprazine vs. risperidone in treating acute and primary negative symptoms in schizophrenia was presented. The first study was a 6-week placebo- and risperidone-controlled study of patients with acute symptoms of schizophrenia. A full sample analysis was conducted of participants with baseline Positive and Negative Syndrome Scale (PANSS) total scores of between 80 and 120. A subgroup analysis of patients with PNS included 145 who were randomly assigned to receive cariprazine 4.5mg per day, 67 to receive risperidone 4mg per day, and 148 to receive placebo. The second study was a 26-week risperidone-controlled study in patients with PNS of at least 6 months' duration and who were stable in terms of their psychotic symptoms. In this study, 35 patients were randomly assigned

to receive cariprazine 4.5mg per day, 16 to risperidone 4mg per day, and 35 to placebo. Results showed that both cariprazine 4.5mg per day and risperidone 4mg per day significantly reduced PANSS total scores from baseline vs. placebo, with a least squared mean difference (LSMD) of -10.57 (P<0.0001) and -13.17 (P<0.0001), respectively. There was no significant difference between the 2 treatment groups for PANSS total scores (P=0.4071). However, only cariprazine was associated with a significant reduction in PANSS factor score for negative symptoms (PANSS-FSNS) in patients with PNS, at an LSMD of -1.98 (P<0.001) vs. -0.813 for risperidone (P=0.368). Among patients with persistent PNS, 26 weeks of treatment with cariprazine was also associated with a greater reduction in PANSS-FSNS scores vs. placebo, at an LSMD of -2.73 (P=0.038) vs. -1.56 for risperidone (P=0.361). There were no significant differences between the drugs in reduction of positive symptoms, depression, or movement scores. In September 2017, Allergan announced it received a Refusal to File (RTF) letter from the FDA regarding its supplemental New Drug Application (sNDA) to include negative symptoms of schizophrenia. The FDA stated that its preliminary appraisal found the sNDA for treatment of negative symptoms was not sufficiently complete to permit a substantive review.

Pipeline:

- **LYN-005 (risperidone once-weekly ER capsule):** In April 2021, Lyndra Therapeutics announced results from its Phase 2 study of LYN-005, an investigational oral, ultra-long-acting, risperidone ER capsule, in development for the weekly treatment of schizophrenia. The data, from the first repeat dose Phase 2 study in patients, demonstrated that LYN-005 provided sustained therapeutic levels of risperidone over the 1-week dosing intervals and reduced peak drug exposure relative to immediate release (IR) risperidone. The Phase 2 multiple-dose, randomized, parallel group, placebo-controlled study assessed the safety, tolerability, and pharmacokinetics of LYN-005 in 32 clinically stable patients with a primary diagnosis of schizophrenia or schizoaffective disorder. Although treatment assignment was blinded, the dose level was not blinded. The study included a lead-in period in which patients received IR risperidone tablets (2mg or 4mg) for 13 days in order to achieve a steady therapeutic state. Following the lead-in, patients were randomized 3:1 to receive weekly LYN-005 (14mg or 28mg) with daily IR risperidone-matched placebo or daily IR risperidone (2mg or 4mg) with weekly ER risperidone-matched placebo for 3 weeks. The primary endpoints were incidence of treatment emergent adverse events and plasma concentrations of active moiety after repeat doses of LYN-005, relative to IR risperidone. The company

plans to conduct an end of Phase 2 meeting with the FDA in the summer of 2021 and initiate a pivotal study of LYN-005 in schizophrenia in the second half of 2021.

- **SEP-4199:** In July 2020, Sunovion Pharmaceuticals announced topline results from SEP380-201, a global, multicenter, randomized, double-blind, placebo-controlled clinical study designed to evaluate the efficacy, safety, and tolerability of treatment with SEP-4199, an investigational oral medication for the treatment of major depressive episodes associated with bipolar I disorder (bipolar I depression). SEP-4199 is a non-racemic ratio of amisulpride enantiomers with increased potency for serotonin 5-HT_7 receptors relative to dopamine D_2 receptors. According to the topline results for the primary endpoint, which included data from Europe and the United States in patients with bipolar I depression, SEP-4199 showed numerical improvement in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score compared to placebo after 6 weeks of treatment [200mg: -19.5 vs. -16.2, 400mg: -19.3 vs. -16.2 respectively, both dose groups vs. placebo, P=0.054; 200mg group effect size (ES): -0.31 and 400mg group ES: -0.29]. While the study did not meet its primary endpoint, a relatively large improvement in MADRS total score was observed in the placebo group, which may have contributed to the trend level findings of the primary analysis. In a pre-specified exploratory analysis of data from all 337 intent-to-treat patients, including those enrolled in Japan, the least squares (LS) mean reduction from baseline at week 6 in MADRS total score was -18.0 and -17.7 for the SEP-4199 200mg and 400mg doses, respectively, and -14.3 for placebo, resulting in LSMD from placebo of -3.7 and -3.4, for the 200mg and 400mg doses, respectively (unadjusted P-values <0.025, ES: -0.34 and -0.31, respectively). These results suggest that patients with bipolar I depression treated with SEP-4199 in both dose groups experienced clinically meaningful improvements over the study period. SEP-4199 was well tolerated by patients enrolled in the study, with relatively low rates of adverse events. The most commonly reported adverse events occurring more frequently in the SEP-4199 treatment group than in the placebo group and in at least 2% of patients included QT prolongation (observed in the 400mg arm), somnolence, constipation, galactorrhea, nausea, akathisia, dizziness, hypomania, and diarrhea. Serious adverse events were reported by 2 patients in the study, including 1 patient treated with SEP-4199 and 1 patient who received placebo. The company stated the results of this study will guide them as they consider plans to start Phase 3 studies.

Lybalvi™ (Olanzapine/Samidorphan) Product Summary[14,14]

Indication(s): Lybalvi™ (olanzapine/samidorphan) is a combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist, indicated for the treatment of:

- Schizophrenia in adults; or
- Bipolar I disorder in adults, including:
    - Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate; or
    - Maintenance monotherapy treatment.

Dosing:

- Lybalvi™ (olanzapine/samidorphan) is supplied as oral tablets in the following strengths: 5/10mg, 10/10mg, 15/10mg, and 20/10mg.
- Lybalvi™ should be administered once daily with or without food. Do not divide tablets or combine strengths.
- See the full *Prescribing Information* for the recommended titration and maximum recommended dosage specific to each indication.
- 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.

Mechanism of Action: The mechanism of action of olanzapine is unclear; however, its efficacy in the treatment of schizophrenia or bipolar I disorder could be mediated through a combination of dopamine and serotonin type 2 ($5HT_2$) antagonism. The mechanism of action of samidorphan could be mediated through opioid receptor antagonism.

Contraindication(s):

- Patients using opioids
- Patients undergoing acute opioid withdrawal
- If Lybalvi™ is administered with lithium or valproate, refer to the lithium or valproate *Prescribing Information* for the contraindications specific to those products

Warnings and Precautions:

- Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis: Lybalvi™ may cause an increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack, including fatalities).
- Precipitation of Opioid Withdrawal in Patients who are Dependent on Opioids: Lybalvi™ can precipitate opioid withdrawal in patients who are dependent on opioids. 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.

- Vulnerability to Life-Threatening Opioid Overdose:
    - Risk of Opioid Overdose from Attempts to Overcome Lybalvi™ Opioid Blockade: Attempts to overcome Lybalvi™ opioid blockade with high or repeated doses of opioids may lead to fatal opioid intoxication, particularly if Lybalvi™ therapy is interrupted or discontinued.
    - Risk of Resuming Opioids in Patients with Prior Opioid Use: Patients with a history of chronic opioid use prior to Lybalvi™ treatment may have decreased opioid tolerance if Lybalvi™ therapy is interrupted or discontinued.
- Neuroleptic Malignant Syndrome (NMS): NMS should be managed with immediate discontinuation of Lybalvi™ and close monitoring.
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): If DRESS is suspected, Lybalvi™ should be discontinued.
- Metabolic Changes: Patients taking Lybalvi™ should be monitored for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain.
- Tardive Dyskinesia: In cases of tardive dyskinesia, if clinically appropriate, Lybalvi™ should be discontinued.
- Orthostatic Hypotension and Syncope: Atypical antipsychotics cause orthostatic hypotension and syncope. Orthostatic vital signs in patients taking Lybalvi™ who are vulnerable to hypotension (e.g., elderly patients, patients with dehydration, hypovolemia, patients with known cardiovascular disease) or who have cerebrovascular disease should be monitored.
- Leukopenia, Neutropenia, and Agranulocytosis: Complete blood counts (CBC) should be performed in patients with a history of a clinically significant low white blood cell (WBC) count. Discontinuation of Lybalvi™ should be considered if a clinically significant decline in WBC occurs in the absence of other causative factors.
- Seizures: Lybalvi™ should be used cautiously in patients with a history of seizures or with conditions that lower the seizure threshold.
- Potential for Cognitive and Motor Impairment: Lybalvi™, like other antipsychotics, may cause somnolence and has the potential to impair judgment, thinking, or motor skills. Lybalvi™ should be used with caution when operating hazardous machinery.
- Anticholinergic (Antimuscarinic) Effects: Lybalvi™ should be used with caution with other anticholinergic drugs and in patients with urinary retention, prostatic hypertrophy, constipation, paralytic ileus or related conditions.
- Hyperprolactinemia: Lybalvi™ elevates prolactin levels, and the elevation can persist during chronic administration. Long-standing

hyperprolactinemia when associated with hypogonadism may lead to decreased bone density in both female and male patients.

Adverse Reactions: The most common adverse reactions (incidence ≥5% and at least twice that of placebo) include the following:

- Schizophrenia (Lybalvi™): weight increased, somnolence, dry mouth, and headache
- Bipolar I disorder, manic or mixed episodes (olanzapine): asthenia, dry mouth, constipation, increased appetite, somnolence, dizziness, and tremor
- Bipolar I disorder, manic or mixed episodes, adjunct to lithium or valproate (olanzapine): dry mouth, dyspepsia, weight gain, increased appetite, dizziness, back pain, constipation, speech disorder, increased salivation, amnesia, and paresthesia

Efficacy: The efficacy of Lybalvi™ in the treatment of schizophrenia in adults is based, in part, upon adequate and well-controlled studies of orally administered olanzapine. The efficacy of Lybalvi™ in the treatment of schizophrenia was also evaluated in the ENLIGHTEN clinical development program which includes 2 key studies: ENLIGHTEN-1 and ENLIGHTEN-2. The efficacy of Lybalvi™ in the treatment of adult patients with bipolar I disorder has been established based on adequate and well-controlled studies of orally administered olanzapine.

- ENLIGHTEN-1 evaluated the antipsychotic efficacy, safety, and tolerability of Lybalvi™ compared to placebo over 4 weeks in 403 patients experiencing an acute exacerbation of schizophrenia. This study met its prespecified primary endpoint, with Lybalvi™ demonstrating statistically significant reductions from baseline in PANSS scores compared to placebo ($P<0.001$). An olanzapine comparator arm was also included, which achieved similar improvements from baseline PANSS scores compared to placebo ($P=0.004$). The most common adverse events (AEs) for both the Lybalvi™ and olanzapine treatment groups were weight gain, somnolence, and dry mouth.
- ENLIGHTEN-2 evaluated the weight gain profile of Lybalvi™ compared to olanzapine over 6 months in 561 patients with stable schizophrenia. This study met its prespecified co-primary endpoints, demonstrating both a lower mean percent 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 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.

- The ENLIGHTEN program also included supportive studies to evaluate the pharmacokinetic and metabolic profile and long-term safety of Lybalvi™, as well as pharmacokinetic bridging studies comparing Lybalvi™ and Zyprexa® (olanzapine).

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 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 (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; susp = suspension; sub-Q = subcutaneous

*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.
^In addition to the Tier-3 criteria requirements, approval of olanzapine/fluoxetine (Symbyax®) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

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.

Utilization Details of Atypical Antipsychotic Medications: Calendar Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-1 PRODUCTS						
ARIPIPRAZOLE INJECTABLE PRODUCTS						
ABILIFY MAIN INJ 400MG PS	2,066	382	$4,485,654.46	$75.61	$2,171.18	7.57%
ABILIFY MAIN INJ 400MG	352	84	$753,344.61	$73.44	$2,140.18	1.27%
ABILIFY MAIN INJ 300MG PS	204	53	$331,978.61	$56.42	$1,627.35	0.56%
ABILIFY MAIN INJ 300MG	178	41	$291,069.05	$57.01	$1,635.22	0.49%
SUBTOTAL	**2,800**	**560**	**$5,862,046.73**	**$72.75**	**$2,093.59**	**9.89%**
ARIPIPRAZOLE LAUROXIL INJECTABLE PRODUCTS						
ARISTADA INJ 882MG	723	157	$1,863,222.48	$87.02	$2,577.07	3.14%
ARISTADA INJ 1,064MG	249	86	$780,290.49	$52.95	$3,133.70	1.32%
ARISTADA INJ 662MG	146	37	$281,138.43	$66.34	$1,925.61	0.47%
ARISTADA INJ INITIO 675MG	81	74	$158,163.06	$105.23	$1,952.63	0.27%
ARISTADA INJ 441MG	77	17	$99,782.29	$45.05	$1,295.87	0.17%
SUBTOTAL	**1,276**	**371**	**$3,182,596.75**	**$72.16**	**$2,494.20**	**5.37%**
ARIPIPRAZOLE ORAL PRODUCTS						
ARIPIPRAZOLE TAB 5MG	13,661	4,197	$234,261.62	$0.52	$17.15	0.40%
ARIPIPRAZOLE TAB 10MG	10,962	3,271	$179,737.40	$0.49	$16.40	0.30%
ARIPIPRAZOLE TAB 15MG	6,708	1,732	$107,033.56	$0.48	$15.96	0.18%
ARIPIPRAZOLE TAB 2MG	4,633	1,505	$77,571.35	$0.51	$16.74	0.13%
ARIPIPRAZOLE TAB 20MG	4,446	1,026	$89,528.43	$0.61	$20.14	0.15%
ARIPIPRAZOLE TAB 30MG	2,606	506	$51,212.19	$0.59	$19.65	0.09%
ARIPIPRAZOLE SOL 1MG/ML	328	64	$134,778.38	$11.24	$410.91	0.23%
ABILIFY TAB 20MG	16	2	$27,873.76	$42.23	$1,742.11	0.05%
ABILIFY TAB 5MG	12	1	$10,433.26	$28.98	$869.44	0.02%
ARIPIPRAZOLE TAB 10MG ODT	8	2	$15,914.69	$37.89	$1,989.34	0.03%
ABILIFY TAB 30MG	4	1	$14,922.48	$41.45	$3,730.62	0.03%
ARIPIPRAZOLE TAB 15MG ODT	1	1	$1,016.83	$33.89	$1,016.83	0.00%
SUBTOTAL	**43,385**	**12,308**	**$944,283.95**	**$0.66**	**$21.77**	**1.61%**
CLOZAPINE PRODUCTS						
CLOZAPINE TAB 100MG	4,854	408	$247,623.48	$2.23	$51.01	0.42%
CLOZAPINE TAB 200MG	1,916	164	$139,473.65	$3.33	$72.79	0.24%
CLOZAPINE TAB 50MG	1,642	163	$59,000.26	$1.64	$35.93	0.10%
CLOZAPINE TAB 25MG	979	114	$24,057.70	$1.05	$24.57	0.04%
CLOZARIL TAB 100MG	23	2	$29,084.35	$43.54	$1,264.54	0.05%
SUBTOTAL	**9,414**	**851**	**$499,239.44**	**$2.35**	**$53.03**	**0.85%**
OLANZAPINE ORAL PRODUCTS						
OLANZAPINE TAB 10MG	7,111	1,827	$88,929.84	$0.39	$12.51	0.15%
OLANZAPINE TAB 20MG	6,809	1,201	$99,572.09	$0.45	$14.62	0.17%
OLANZAPINE TAB 5MG	4,251	1,360	$50,968.36	$0.37	$11.99	0.09%
OLANZAPINE TAB 15MG	2,633	629	$36,741.65	$0.42	$13.95	0.06%
OLANZAPINE TAB 2.5MG	1,238	457	$15,931.70	$0.40	$12.87	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
OLANZAPINE TAB 7.5MG	637	182	$7,947.20	$0.37	$12.48	0.01%
OLANZAPINE TAB 10MG ODT	459	134	$13,886.45	$0.96	$30.25	0.02%
OLANZAPINE TAB 5MG ODT	396	147	$10,745.84	$0.87	$27.14	0.02%
OLANZAPINE TAB 20MG ODT	337	65	$11,075.10	$1.00	$32.86	0.02%
OLANZAPINE TAB 15MG ODT	165	37	$5,627.21	$1.02	$34.10	0.01%
ZYPREXA TAB 5MG	23	2	$10,024.47	$14.53	$435.85	0.02%
ZYPREXA TAB 15MG	9	1	$8,488.62	$31.44	$943.18	0.01%
ZYPREXA TAB 10MG	4	1	$7,707.51	$21.41	$1,926.88	0.01%
ZYPREXA ZYDI TAB 5MG	1	1	$473.11	$15.77	$473.11	0.00%
SUBTOTAL	**24,073**	**6,044**	**$368,119.15**	**$0.47**	**$15.29**	**0.62%**
OLANZAPINE INJECTABLE PRODUCTS						
OLANZAPINE INJ 10MG	2	2	$83.00	$41.50	$41.50	0.00%
ZYPREXA INJ 300MG	1	1	$849.81	$60.70	$849.81	0.00%
SUBTOTAL	**3**	**3**	**$932.81**	**$58.30**	**$310.94**	**0.00%**
PALIPERIDONE INJECTABLE PRODUCTS						
INVEGA SUST INJ 234MG	4,621	787	$12,431,880.35	$94.57	$2,690.30	20.97%
INVEGA SUST INJ 156MG	1,847	511	$3,299,384.91	$62.49	$1,786.35	5.57%
INVEGA TRINZA INJ 819MG	780	246	$6,199,521.84	$90.99	$7,948.10	10.46%
INVEGA SUST INJ 117MG	414	94	$574,218.44	$48.58	$1,387.00	0.97%
INVEGA TRINZA INJ 546MG	287	93	$1,548,872.35	$61.48	$5,396.77	2.61%
INVEGA TRINZA INJ 410MG	58	25	$237,744.41	$46.67	$4,099.04	0.40%
INVEGA SUST INJ 78MG	40	13	$36,408.81	$30.85	$910.22	0.06%
INVEGA TRINZA INJ 273MG	36	13	$90,659.88	$28.49	$2,518.33	0.15%
INVEGA SUST INJ 39MG	31	9	$14,524.90	$16.28	$468.55	0.02%
SUBTOTAL	**8,114**	**1,791**	**$24,433,215.89**	**$81.51**	**$3,011.24**	**41.21%**
QUETIAPINE PRODUCTS						
QUETIAPINE TAB 100MG	10,893	2,747	$140,669.08	$0.38	$12.91	0.24%
QUETIAPINE TAB 50MG	8,619	2,534	$109,761.16	$0.38	$12.73	0.19%
QUETIAPINE TAB 200MG	6,913	1,636	$107,371.84	$0.46	$15.53	0.18%
QUETIAPINE TAB 300MG	5,797	1,217	$102,145.45	$0.50	$17.62	0.17%
QUETIAPINE TAB 25MG	5,441	1,724	$67,341.95	$0.37	$12.38	0.11%
QUETIAPINE TAB 400MG	5,250	953	$97,689.61	$0.53	$18.61	0.16%
QUETIAPINE TAB 300MG ER	826	176	$22,953.80	$0.83	$27.79	0.04%
QUETIAPINE TAB 400MG ER	760	136	$27,213.62	$1.03	$35.81	0.05%
QUETIAPINE TAB 150MG ER	639	180	$13,241.97	$0.59	$20.72	0.02%
QUETIAPINE TAB 50MG ER	491	178	$9,254.45	$0.54	$18.85	0.02%
QUETIAPINE TAB 200MG ER	360	100	$8,221.01	$0.65	$22.84	0.01%
SEROQUEL TAB 400MG	12	1	$13,563.48	$37.68	$1,130.29	0.02%
SEROQUEL XR TAB 400MG	12	1	$17,539.97	$48.72	$1,461.66	0.03%
SUBTOTAL	**46,013**	**11,583**	**$736,967.39**	**$0.47**	**$16.02**	**1.24%**
RISPERIDONE INJECTABLE PRODUCTS						
RISPERDAL INJ 50MG	234	26	$370,958.43	$67.45	$1,585.29	0.63%
PERSERIS INJ 120MG	126	37	$302,757.66	$83.54	$2,402.84	0.51%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
RISPERDAL INJ 25MG	79	13	$62,440.14	$34.36	$790.38	0.11%
RISPERDAL INJ 37.5MG	48	8	$65,174.66	$51.16	$1,357.81	0.11%
PERSERIS INJ 90MG	39	19	$70,429.49	$62.00	$1,805.88	0.12%
RISPERDAL INJ 12.5MG	15	5	$6,410.02	$15.95	$427.33	0.01%
SUBTOTAL	**541**	**108**	**$878,170.40**	**$63.85**	**$1,623.24**	**1.49%**
RISPERIDONE ORAL PRODUCTS						
RISPERIDONE TAB 1MG	10,993	2,348	$132,589.28	$0.37	$12.06	0.22%
RISPERIDONE TAB 0.5MG	9,588	2,214	$113,467.69	$0.37	$11.83	0.19%
RISPERIDONE TAB 2MG	6,265	1,322	$76,736.76	$0.37	$12.25	0.13%
RISPERIDONE TAB 0.25MG	4,151	1,002	$49,035.87	$0.36	$11.81	0.08%
RISPERIDONE TAB 3MG	3,199	602	$38,805.95	$0.36	$12.13	0.07%
RISPERIDONE TAB 4MG	1,745	295	$20,167.19	$0.34	$11.56	0.03%
RISPERIDONE SOL 1MG/ML	1,057	180	$25,215.25	$0.68	$23.86	0.04%
RISPERIDONE TAB 0.5MG ODT	154	43	$7,249.28	$1.67	$47.07	0.01%
RISPERIDONE TAB 1MG ODT	136	39	$6,306.19	$1.67	$46.37	0.01%
RISPERIDONE TAB 0.25 ODT	117	35	$11,682.24	$3.32	$99.85	0.02%
RISPERIDONE TAB 2MG ODT	93	21	$5,209.24	$1.78	$56.01	0.01%
RISPERIDONE TAB 4MG ODT	34	5	$3,555.16	$3.11	$104.56	0.01%
RISPERIDONE TAB 3MG ODT	30	8	$8,388.26	$8.85	$279.61	0.01%
RISPERDAL TAB 2MG	13	1	$11,475.38	$29.42	$882.72	0.02%
RISPERDAL SOL 1MG/ML	7	1	$8,532.46	$40.63	$1,218.92	0.01%
SUBTOTAL	**37,582**	**8,116**	**$518,416.20**	**$0.42**	**$13.79**	**0.86%**
ZIPRASIDONE PRODUCTS						
ZIPRASIDONE CAP 40MG	1,958	536	$39,584.63	$0.62	$20.22	0.07%
ZIPRASIDONE CAP 80MG	1,790	285	$47,533.63	$0.80	$26.56	0.08%
ZIPRASIDONE CAP 20MG	1,747	558	$35,059.74	$0.64	$20.07	0.06%
ZIPRASIDONE CAP 60MG	1,364	277	$35,021.09	$0.77	$25.68	0.06%
ZIPRASIDONE INJ 20MG	1	1	$105.41	$105.41	$105.41	0.00%
SUBTOTAL	**6,861**	**1,658**	**$157,837.05**	**$0.71**	**$23.00**	**0.27%**
TIER-1 SUBTOTAL	**180,062**	**43,393**	**$37,581,825.76**	**$6.67**	**$208.72**	**63.41%**
TIER-2 PRODUCTS						
LURASIDONE PRODUCTS						
LATUDA TAB 40MG	3,239	967	$4,171,044.72	$39.75	$1,287.76	7.04%
LATUDA TAB 20MG	2,330	849	$2,966,257.51	$39.84	$1,273.07	5.00%
LATUDA TAB 60MG	2,004	504	$2,722,453.00	$40.43	$1,358.51	4.59%
LATUDA TAB 80MG	1,972	412	$2,836,783.90	$44.01	$1,438.53	4.79%
LATUDA TAB 120MG	891	160	$1,776,001.54	$60.24	$1,993.27	3.00%
SUBTOTAL	**10,436**	**2,892**	**$14,472,540.67**	**$42.48**	**$1,386.79**	**24.42%**
ASENAPINE PRODUCTS						
SAPHRIS SUB 10MG	723	138	$676,602.71	$30.38	$935.83	1.14%
SAPHRIS SUB 5MG	352	134	$318,518.18	$30.18	$904.88	0.54%
SAPHRIS SUB 2.5MG	137	47	$130,643.65	$32.66	$953.60	0.22%
ASENAPINE SUB 10MG	1	1	$1,088.14	$36.27	$1,088.14	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
ASENAPINE SUB 5MG	1	1	$0.00	$0.00	$0.00	0.00%
SUBTOTAL	**1,214**	**321**	**$1,126,852.68**	**$30.55**	**$928.21**	**1.90%**
TIER-2 SUBTOTAL	**11,650**	**3,213**	**$15,599,393.35**	**$41.32**	**$1,339.00**	**26.32%**
TIER-3 PRODUCTS						
BREXPIPRAZOLE PRODUCTS						
REXULTI TAB 2MG	298	84	$363,504.58	$37.43	$1,219.81	0.61%
REXULTI TAB 3MG	203	47	$243,005.14	$37.02	$1,197.07	0.41%
REXULTI TAB 1MG	183	61	$234,878.15	$37.40	$1,283.49	0.40%
REXULTI TAB 4MG	159	33	$215,071.45	$37.44	$1,352.65	0.36%
REXULTI TAB 0.5MG	81	22	$91,094.55	$37.55	$1,124.62	0.15%
REXULTI TAB 0.25MG	8	1	$9,037.52	$37.66	$1,129.69	0.02%
SUBTOTAL	**932**	**248**	**$1,156,591.39**	**$37.35**	**$1,240.98**	**1.95%**
CARIPRAZINE PRODUCTS						
VRAYLAR CAP 3MG	952	270	$1,221,959.22	$38.94	$1,283.57	2.06%
VRAYLAR CAP 1.5MG	565	199	$736,135.19	$39.09	$1,302.89	1.24%
VRAYLAR CAP 6MG	539	91	$666,668.11	$38.70	$1,236.86	1.12%
VRAYLAR CAP 4.5MG	391	98	$491,414.28	$39.08	$1,256.81	0.83%
VRAYLAR CAP 1.5-3MG	1	1	$297.20	$42.46	$297.20	0.00%
SUBTOTAL	**2,448**	**659**	**$3,116,474.00**	**$0.03**	**$1,273.07**	**5.25%**
CLOZAPINE ORALLY DISINTEGRATING PRODUCTS						
CLOZAPINE TAB 100MG ODT	133	14	$66,644.75	$18.22	$501.09	0.11%
CLOZAPINE TAB 150MG ODT	69	7	$77,324.47	$41.28	$1,120.64	0.13%
CLOZAPINE TAB 25MG ODT	40	4	$8,840.18	$7.37	$221.00	0.01%
CLOZAPINE TAB 200MG ODT	27	5	$39,260.13	$56.09	$1,454.08	0.07%
SUBTOTAL	**269**	**30**	**$192,069.53**	**$25.85**	**$714.01**	**0.32%**
ILOPERIDONE PRODUCTS						
FANAPT TAB 6MG	140	23	$176,325.91	$42.99	$1,259.47	0.30%
FANAPT TAB 12MG	120	16	$254,411.33	$71.14	$2,120.09	0.43%
FANAPT TAB 4MG	109	16	$107,320.99	$35.24	$984.60	0.18%
FANAPT TAB 8MG	106	23	$137,629.95	$48.41	$1,298.40	0.23%
FANAPT TAB 10MG	79	17	$165,220.47	$70.49	$2,091.40	0.28%
FANAPT TAB 2MG	45	14	$38,202.83	$25.78	$848.95	0.06%
FANAPT TAB 1MG	17	3	$18,193.23	$35.67	$1,070.19	0.03%
SUBTOTAL	**616**	**112**	**$897,304.71**	**$50.12**	**$1,456.66**	**1.51%**
OLANZAPINE/FLUOXETINE COMBINATION PRODUCTS						
OLANZ/FLUOX CAP 12-50MG	23	2	$17,231.55	$24.97	$749.20	0.03%
OLANZ/FLUOX CAP 6-25MG	12	1	$2,535.99	$7.04	$211.33	0.00%
OLANZ/FLUOX CAP 12-25MG	11	1	$5,766.15	$17.47	$524.20	0.01%
OLANZ/FLUOX CAP 3-25MG	11	1	$1,691.03	$5.12	$153.73	0.00%
OLANZ/FLUOX CAP 6-50MG	11	1	$3,539.72	$10.73	$321.79	0.01%
SUBTOTAL	**68**	**6**	**$30,764.44**	**$15.08**	**$452.42**	**0.05%**
PALIPERIDONE ORAL PRODUCTS						
PALIPERIDONE TAB ER 6MG	920	148	$279,023.60	$9.45	$303.29	0.47%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
PALIPERIDONE TAB ER 9MG	528	76	$193,695.98	$11.39	$366.85	0.33%
PALIPERIDONE TAB ER 3MG	333	79	$87,404.07	$7.55	$262.47	0.15%
PALIPERIDONE TAB ER 1.5MG	66	21	$16,622.55	$8.20	$251.86	0.03%
INVEGA TAB 6MG	3	1	$3,508.32	$38.98	$1,169.44	0.01%
INVEGA TAB 9MG	3	1	$5,267.48	$58.53	$1,755.83	0.01%
INVEGA TAB 3MG	2	1	$6,907.87	$38.38	$3,453.94	0.01%
SUBTOTAL	**1,855**	**327**	**$592,429.87**	**$9.79**	**$319.37**	**1.01%**
LUMATEPERONE ORAL PRODUCTS						
CAPLYTA CAP 42MG	88	31	$107,087.34	$40.87	$1,216.90	0.18%
SUBTOTAL	**88**	**31**	**$107,087.34**	**$40.87**	**$1,216.90**	**0.18%**
TIER-3 SUBTOTAL	**6,276**	**1,413**	**$6,092,721.28**	**$12.21**	**$970.80**	**10.27**
TOTAL	**197,988**	**27,186***	**$59,273,940.39**	**$9.15**	**$299.38**	**100%**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
PS = prefilled syringe; INJ = injection; MAIN = Maintena; TAB = tablet; SOL = solution; ODT = orally disintegrating tablet; SUST = Sustenna; ER/XR = extended release; CAP = capsule; SUB = sublingual; OLANZ/FLUOX = olanzapine/fluoxetine

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 05/2021. Last accessed 05/19/2021.
[2] APA Releases New Practice Guideline on Treatment of Patients with Schizophrenia. American Psychiatric Association. Available online at: https://www.psychiatry.org/newsroom/news-releases/apa-releases-new-practice-guideline-on-treatment-of-patients-with-schizophrenia. Issued 09/01/2020. Last accessed 05/19/2021.
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Appendix L

Calendar Year 2020 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)

Oklahoma Health Care Authority
June 2021

Introduction

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

Current Prior Authorization Criteria

Absorica LD™ (Isotretinoin Capsule) Approval Criteria:

1. An FDA approved diagnosis of severe recalcitrant nodular acne in non-pregnant members 12 years of age and older with multiple inflammatory nodules with a diameter of 5mm or greater; and
2. Prescriber must verify member is enrolled in the iPLEDGE REMS program; and
3. Prescriber must verify lipid profile and liver function tests will be monitored prior to initiation of Absorica LD™ and at regular intervals during treatment in accordance with the *Prescribing Information*; and
4. A patient-specific, clinically significant reason why the member cannot use other isotretinoin capsules available without prior authorization must be provided; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of medication according to package labeling.

Cequa™ (Cyclosporine 0.09% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication to increase tear production in members with keratoconjunctivitis sicca (dry eye); and
2. 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
3. A quantity limit of 60 single-use vials (1 box) per 30 days will apply.

GoNitro™ (Nitroglycerin Sublingual Powder) Approval Criteria:

1. An FDA approved indication of acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease; and
2. A patient-specific, clinically significant reason why the member cannot use nitroglycerin sublingual tablets or nitroglycerin lingual spray must be provided.

Gralise® [Gabapentin Extended-Release (ER) Tablet] Approval Criteria:

1. An FDA approved indication of postherpetic neuralgia (PHN); and
2. Documented treatment attempts, at recommended dosing, with at least 1 agent from 2 of the following drug classes that did not yield adequate relief:
    a. Tricyclic antidepressants; or
    b. Anticonvulsants; or
    c. Topical or oral analgesics; and
3. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.

Horizant® [Gabapentin Enacarbil Extended-Release (ER) Tablet] Approval Criteria:

1. For the FDA approved indication of restless leg syndrome:
    a. Member must be 18 years of age or older; and
    b. Documented treatment attempts at recommended dosing with at least 2 of the following medications that did not yield adequate relief:
        i. Carbidopa/levodopa; or
        ii. Pramipexole; or
        iii. Ropinirole; and
    c. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.
2. For the FDA approved indication of postherpetic neuralgia (PHN):
    a. Member must be 18 years of age or older; and
    b. Documented treatment attempts, at recommended dosing, with at least 1 agent from 2 of the following drug classes that did not yield adequate relief:

i. Tricyclic antidepressants; or
ii. Anticonvulsants; or
iii. Topical or oral analgesics; and

c. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.

Khapzory™ (Levoleucovorin Injection) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Rescue after high-dose methotrexate (MTX) therapy in members with osteosarcoma; or
   b. Diminishing the toxicity associated with overdosage of folic acid antagonists or impaired MTX elimination; or
   c. Treatment of members with metastatic colorectal cancer in combination with fluorouracil; and
2. A patient-specific, clinically significant reason why the member cannot use generic leucovorin injection or generic levoleucovorin calcium injection must be provided.

Klor-Con® 20mEq Packet (Potassium Chloride) Approval Criteria:

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

Kristalose® (Lactulose Packet for Oral Solution) Approval Criteria:

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

Lyrica® CR [Pregabalin Extended-Release (ER) Capsule] Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Neuropathic pain associated with diabetic peripheral neuropathy (DPN); or
   b. Neuropathic pain associated with postherpetic neuralgia (PHN); and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation of pregabalin must be provided; and
3. Requests exceeding once daily dosing will not be approved.

Metozolv® ODT [Metoclopramide Orally Disintegrating Tablet (ODT)] Approval Criteria:

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

Nuvessa™ (Metronidazole 1.3% Vaginal Gel) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis in non-pregnant women; and

2. A patient-specific, clinically significant reason why the member cannot use MetroGel-Vaginal® 0.75% (metronidazole 0.75% vaginal gel) or the generic metronidazole oral tablets must be provided.

Purixan® (Mercaptopurine Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of acute lymphoblastic leukemia (ALL); and
2. An age restriction for members older than 10 years of age applies. Purixan® does not require prior authorization for members 10 years of age and younger; and
3. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

Pyridostigmine 30mg Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use pyridostigmine 60mg tablets, which are available without prior authorization, must be provided.

Quzyttir® (Cetirizine Injection) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use an oral formulation of cetirizine (e.g., tablets, oral solution) must be provided.

Rasuvo® and Otrexup® (Methotrexate Injection) 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 the generic injectable formulation cannot be used must be provided.

Restasis MultiDose® (Cyclosporine 0.05% Ophthalmic Emulsion) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Restasis® in the individual dosage formulation (single-use vials) must be provided.

Sinuva® (Mometasone Furoate Sinus Implant) Approval Criteria:

1. An FDA approved indication of nasal polyps in adults 18 years of age and older who have had ethmoid sinus surgery; and
2. Date of ethmoid sinus surgery must be provided; and
3. Sinuva® must be prescribed and implanted by a physician specializing in otolaryngology; and

4. Failure of intranasal corticosteroids after at least a 3 month trial at the maximum recommended dose in combination with a 14-day trial of oral corticosteroids within the last 6 months (if not contraindicated); and
5. Prescriber must confirm the member has recurrent nasal obstruction/congestion symptoms and recurrent bilateral sinusitis or chronic sinusitis due to nasal polyps; and
6. A quantity limit of 2 implants per member will apply.

Slynd® (Drospirenone Tablet) Approval Criteria:

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

Soltamox® (Tamoxifen Citrate 10mg/5mL Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of metastatic breast cancer in women and men; or
    b. Adjuvant treatment of node-positive breast cancer in postmenopausal women and for the adjuvant treatment of axillary node-negative breast cancer in women following total mastectomy or segmental mastectomy, axillary dissection, and breast irradiation; or
    c. The reduction in risk of invasive breast cancer in women with ductal carcinoma in situ (DCIS), following breast surgery and radiation; or
    d. To reduce the incidence of breast cancer in women at high risk for breast cancer; and
2. A patient-specific, clinically significant reason why the member cannot use tamoxifen oral tablets must be provided.

Sorilux® (Calcipotriene 0.005% Foam) Approval Criteria:

1. An FDA approved indication for the topical treatment of plaque psoriasis of the scalp and body in members 12 years of age and older; and
2. A patient-specific, clinically significant reason why the member cannot use the generic formulations of topical calcipotriene, which are available without a prior authorization, must be provided; and
3. A quantity limit of 120g per 30 days will apply.

Taytulla® (Norethindrone Acetate/Ethinyl Estradiol Capsule and Ferrous Fumarate Capsule) Approval Criteria:

1. An FDA approved indication to prevent pregnancy in women; and
2. A patient-specific, clinically significant reason why the member cannot use all other generic formulations of norethindrone acetate/ethinyl estradiol tablets with ferrous fumarate tablets must be provided.

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 solution, 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 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 and compliance with levothyroxine tablets.

Xatmep® (Methotrexate 2.5mg/mL Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of pediatric members with acute lymphoblastic leukemia (ALL) as a component of a combination chemotherapy maintenance regimen; or
    b. Management of pediatric members with active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant of or had an inadequate response to first-line therapy; and
2. A patient-specific, clinically significant reason why the oral tablets or generic injectable formulation cannot be used must be provided.

Xiidra® (Lifitegrast 5% Ophthalmic Solution) Approval Criteria:

1. Member must be 17 years of age or older and have an FDA approved diagnosis of dry eye disease (DED); and
2. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
3. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
4. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine ophthalmic emulsion), which is available without a prior authorization, must be provided; and
5. A quantity limit of 2 vials per day will apply.

Utilization of Various Special Formulations: Calendar Year 2020

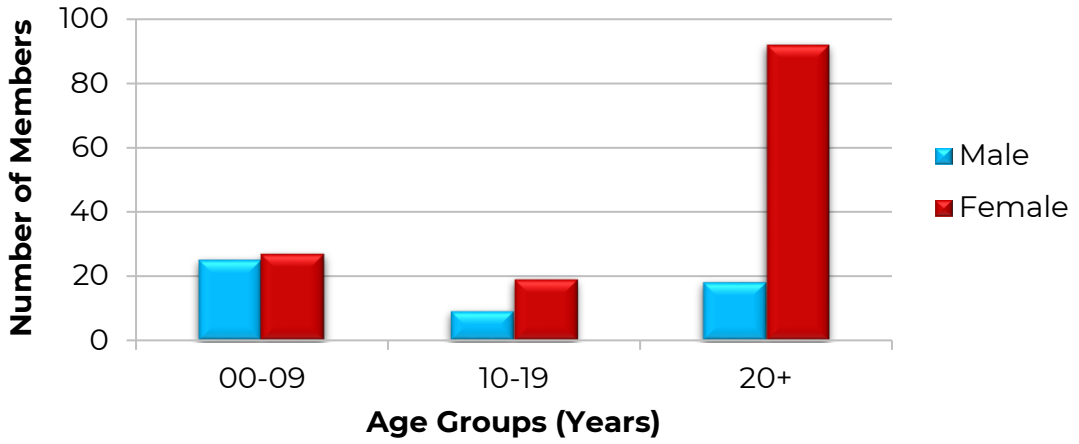
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	201	720	$374,210.67	$519.74	$14.01	39,543	26,717
2020	190	808	$401,877.21	$497.37	$13.58	42,911	29,591
% Change	**-5.50%**	**12.20%**	**7.40%**	**-4.30%**	**-3.10%**	**8.50%**	**10.80%**
Change	**-11**	**88**	**$27,666.54**	**-$22.37**	**$0.43**	**3,368**	**2,874**

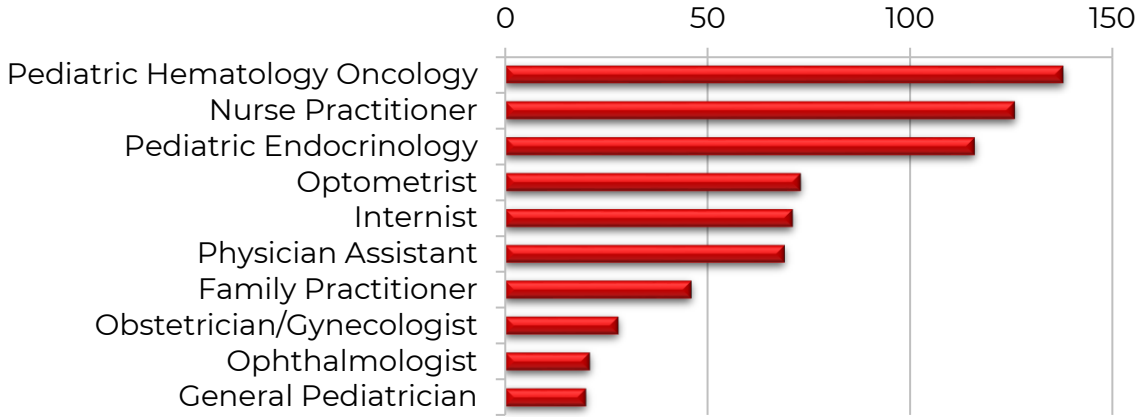
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.

- Due to the evolving nature of this category, calendar year comparisons may not reflect the same product utilization from year to year.
- There were no paid medical claims for various special formulations during calendar year 2020.

Demographics of Members Utilizing Various Special Formulations

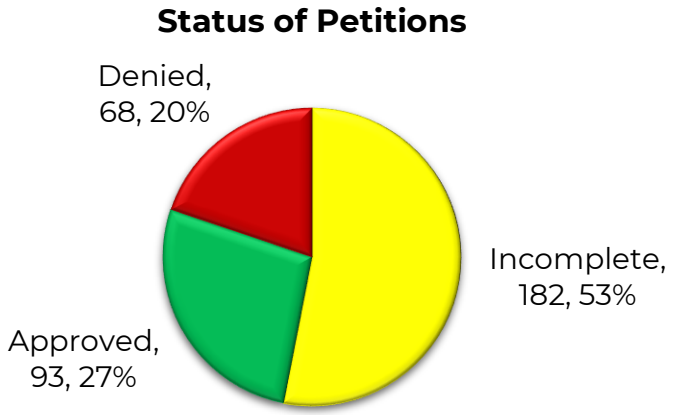


Top Prescriber Specialties of Various Special Formulations by Number of Claims



Prior Authorization of Various Special Formulations

There were 343 prior authorization requests submitted for various special formulations during calendar year 2020. The following chart shows the status of the submitted petitions for calendar year 2020.



Alkindi® Sprinkle (Hydrocortisone Oral Granule) Product Summary[1,2]

Indication(s): Alkindi® Sprinkle (hydrocortisone oral granule) is a corticosteroid indicated as replacement therapy in pediatric patients with adrenocortical insufficiency.

Dosing and Administration:

- The dose should be individualized, using the lowest possible dosage with a recommended starting dose of 8 to 10mg/m^2 daily. Higher doses may be needed based on patient's age and symptoms of the disease.
- The dose should be rounded to the nearest 0.5mg or 1mg which may require more than 1 capsule to supply the required dose.
- The total daily dose should be divided into 3 doses and administered 3 times daily.
- 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.

Other Formulation(s) Available:

- Hydrocortisone Tablet:
  - Hydrocortisone tablets have various indications including endocrine disorders, rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases,

respiratory diseases, hematologic disorders, neoplastic diseases, and others.
- The initial dosage of hydrocortisone tablets varies from 20mg to 240mg per day depending on the specific disease entity being treated. In situations of less severity, lower doses will generally suffice while in selected patients, higher initial doses may be required.
- Hydrocortisone tablets are scored and available in 3 strengths: 5mg, 10mg, and 20mg.

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 three 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).

Calendar Year 2020 Utilization: There was no SoonerCare utilization of Alkindi® Sprinkle during calendar year 2020. For generic hydrocortisone tablets, there were 1,719 claims for 323 unduplicated utilizing members with a total cost of $47,102.46. The cost per day was $1.03 with a cost per claim of $27.40. These costs do not reflect rebated prices or net costs.

Eysuvis® (Loteprednol 0.25% Ophthalmic Suspension) Product Summary[3,4,5]

Indication(s): Eysuvis® (loteprednol 0.25% ophthalmic suspension) is a corticosteroid indicated for the short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease.

Dosing and Administration:
- 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.
- This product should only be renewed after examination under magnification and evaluation of the patient's intraocular pressure.

Other Formulation(s) Available:

- Lotemax® (Loteprednol 0.5% Ophthalmic Suspension) & Restasis® (Cyclosporine 0.05% Ophthalmic Emulsion):
  - Lotemax® (Loteprednol 0.5% Ophthalmic Suspension):
    - Lotemax® is indicated for the treatment of steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, and selected infective conjunctivitides, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation. It is also indicated for treatment of post-operative inflammation following ocular surgery.
    - The recommended dosing is to instill 1 to 2 drops into the affected eye 4 times daily.
    - Lotemax® is supplied as loteprednol 5mg/mL ophthalmic suspension in 5mL, 10mL, and 15mL dropper bottles.
  - Restasis® (Cyclosporine 0.05% Ophthalmic Emulsion):
    - Restasis® is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.
    - The recommended dosing is to instill 1 drop twice a day in each eye approximately 12 hours apart.
    - Restasis® is supplied as cyclosporine 0.5mg/mL ophthalmic emulsion packaged in sterile, preservative-free, single-use vials.

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 Lotemax® 0.5% suspension and Restasis® have supplemental rebates and do not require 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).

Calendar Year 2020 Utilization: There was no SoonerCare utilization of Eysuvis® during calendar year 2020.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
RESTASIS EMU 0.05%	741	242	$390,250.44	$18.32	3.06	$526.65
LOTEMAX SUS 0.5%	96	67	$29,032.39	$10.12	1.43	$302.42
LOTEPREDNOL SUS 0.5%	50	38	$9,816.02	$6.44	1.32	$196.32
TOTAL	**887**	**334***	**$429,098.85**	**$16.70**	**2.66**	**$483.76**

EMU = emulsion; SUS = suspension
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.

Gimoti™ (Metoclopramide Nasal Spray) Product Summary[6,7,8]

Indication(s): 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.

Limitations of Use:

- Gimoti™ is not recommend for use in the following:
  - Pediatric patients due to the risk of tardive dyskinesia (TD) and other extrapyramidal symptoms as well as the risk of methemoglobinemia in neonates
  - Moderate or severe hepatic impairment (Child-Pugh B or C), moderate or severe renal impairment (creatinine clearance <60 mL/minute), and patients concurrently using strong CYP2D6 (e.g., quinidine, bupropion, fluoxetine, paroxetine) inhibitors due to the risk of increased drug exposure and adverse reactions

Dosing and Administration:

- Adults younger than 65 years of age: The recommended dosage 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.
- Adults 65 years of age and 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 1 spray (15mg) in 1 nostril, 30 minutes before each meal and at bedtime (maximum 4 times daily) for 2 to 8 weeks, depending on symptomatic response.
- 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.

Boxed Warning: Tardive Dyskinesia (TD)
Metoclopramide can cause TD, a serious movement disorder that is often irreversible. The risk of developing TD increases with duration of treatment and total cumulative dosage. Gimoti™ should be discontinued if signs or symptoms of TD develop. Treatment with all dosage forms of metoclopramide for longer than 12 weeks should be avoided due to the risk of developing TD with longer-term use.

Other Formulation(s) Available:

- Metoclopramide Tablet and Metoclopramide Oral Solution:
  - Like Gimoti™, metoclopramide tablets and oral solution are both indicated for relief of symptoms in adults with acute and recurrent diabetic gastroparesis.
  - Metoclopramide tablets and oral solution have an additional indication of short-term (4 to 12 weeks) therapy for adults with symptomatic, documented gastroesophageal reflux disease (GERD) who fail to respond to conventional therapy.
  - Both metoclopramide tablets and oral solution have the same *Boxed Warning* and *Limitations of Use* as Gimoti™.
  - The recommended dosing for metoclopramide tablets and oral solution for GERD is 10 to 15mg 30 minutes before each meal and at bedtime (maximum of 60mg per day) for 4 to 12 weeks.
  - The recommended dosing for metoclopramide tablets and oral solution for diabetic gastroparesis is 10mg, 30 minutes before each meal and at bedtime (maximum of 40mg per day) for 2 to 8 weeks.
  - Metoclopramide tablets are supplied as 2 strengths: 5mg and 10mg.
  - Metoclopramide oral solution is supplied as a 5mg/5mL 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).

Calendar Year 2020 Utilization: There was no SoonerCare utilization of Gimoti™ during calendar year 2020. For generic metoclopramide tablets and oral solution, there were 4,950 claims for 2,774 unduplicated utilizing

members with a total cost of $57,735.79. The cost per day was $0.56 with a cost per claim of $11.66. These costs do not reflect rebated prices or net costs.

Nextstellis® (Drospirenone/Estetrol Tablet) Product Summary[9,10,11]

Indication(s): 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.

Limitations of Use: Nextstellis® may be less effective in females with a body mass index (BMI) of ≥30kg/m^2. In females with BMI ≥30kg/m^2, decreasing effectiveness may be associated with increasing BMI.

Dosing and Administration:

- 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.

Boxed Warning: Cigarette Smoking and Serious Cardiovascular Events
Females older than 35 years of age who smoke should not use Nextstellis®. Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use.

Other Formulation(s) Available:

- Drospirenone/Ethinyl Estradiol (EE) 3mg/0.02mg Tablet and Drospirenone/EE 3mg/0.03mg Tablet:
  - Both drospirenone/EE 3mg/0.02mg tablets and drospirenone/EE 3mg/0.03mg tablets have the same indication as Nextstellis®.
  - Drospirenone/EE 3mg/0.02mg tablets have additional indications for the treatment of symptoms of premenstrual dysphoric disorder (PMDD) for females who choose to use an oral contraceptive for contraception and for the treatment of moderate acne for females 14 years of age and older (only if the patient desires an oral contraceptive for birth control).
  - Both products have the same recommended dosing as Nextstellis® and the same *Boxed Warning*.
  - Drospirenone/EE 3mg/0.02mg tablets are supplied in a 28-day blister card with 24 light pink active tablets and 4 white inert tablets.
  - Drospirenone/EE 3mg/0.03mg tablets are supplied in a 28-day blister card with 21 yellow active tablets and 7 white inert 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).

Calendar Year 2020 Utilization: There was no SoonerCare utilization of Nextstellis® during calendar year 2020. For generic drospirenone/EE 3mg/0.02mg tablets and drospirenone/EE 3mg/0.03mg tablets, there were 4,093 claims for 1,155 unduplicated utilizing members with a total cost of $114,218.07. The cost per day was $0.63 with a cost per claim of $27.91. These costs do not reflect rebated prices or net costs.

Ozobax® (Baclofen 5mg/5mL Oral Solution) Product Summary[12,13]

Indication(s): 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.

Limitations of Use: Not indicated for the treatment of skeletal muscle spasm resulting from rheumatic disorders.

Dosing and Administration:

- 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 Tablet:
  - Baclofen tablets have the same indication and *Limitations of Use* as Ozobax® with an additional limitation that the efficacy of baclofen tablets in stroke, cerebral palsy, and Parkinson's disease has not been established and, therefore, it is not recommended for these conditions.
  - The recommended dosing for baclofen tablets is also the same as Ozobax®. Baclofen tablets are supplied in 3 strengths: 5mg, 10mg, and 20mg.

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).

Calendar Year 2020 Utilization: There was no SoonerCare utilization of Ozobax® during calendar year 2020.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
BACLOFEN TAB 10MG	12,209	3,182	$185,626.62	$0.53	3.84	$15.20
BACLOFEN TAB 20MG	5,575	1,046	$122,461.97	$0.76	5.33	$21.97
BACLOFEN TAB 5MG	68	14	$3,883.51	$2.00	4.86	$57.11
TOTAL	**17,852**	**4,079***	**$311,972.10**	**$0.61**	**4.38**	**$17.48**

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

Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel) Product Summary[14,15,16]

Indication(s): 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.

Limitations of Use: Phexxi® is not effective for the prevention of pregnancy when administered after intercourse.

Dosing and Administration:

- 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):

- VCF® (nonoxynol 9 vaginal 28% film) and VCF® (nonoxynol 9 vaginal 12.5% foam) are both over-the-counter (OTC) products for the prevention of pregnancy.
- The recommended dosing of VCF® (nonoxynol 9 vaginal 28% film) is to insert 1 film into the vagina against the cervix not <15 minutes and not >3 hours before intercourse. One film should be used before each act of intercourse.
- The recommended dosing of VCF® (nonoxynol 9 vaginal 12.5% foam) is to instill 1 applicator full of foam into the vagina not >1 hour before each act of intercourse.
- VCF® (nonoxynol 9 vaginal 28% film) is supplied in a box containing 9 individually sealed vaginal films.
- VCF® (nonoxynol 9 vaginal 12.5% foam) is supplied in an aerosol can containing 17g of foam with an applicator.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
Phexxi® (lactic acid/citric acid/potassium bitartrate vaginal gel)	**$4.46**	**$267.60**
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).

Calendar Year 2020 Utilization: There was 1 claim for 1 unduplicated utilizing member utilizing Phexxi® with a total cost of $278.91 for calendar year 2020.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
VCF VAGINAL MIS CONTRACP	1	1	$9.96	$1.11	1	$9.96
TOTAL	**1**	**1***	**$9.96**	**$1.11**	**1**	**$9.96**

MIS CONTRACP = miscellaneous contraceptive/film
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.

RediTrex® (Methotrexate Injection) Product Summary[17,18,19]

Indication(s): 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.

Limitations of Use: RediTrex® is not indicated for the treatment of neoplastic diseases.

Dosing and Administration:

- The recommended dose for RediTrex® is once weekly via subcutaneous (sub-Q) administration in the abdomen or thigh.
- Patients who require doses <7.5mg per week or doses >25mg per week should use other formulations of methotrexate.
- The following are starting doses of methotrexate based on indication:
  - RA: 7.5mg once weekly
  - pJIA: 10mg/m^2 once weekly
  - Psoriasis: 10mg to 25mg once weekly
- Doses may be adjusted gradually to achieve an optimal response.
- RediTrex® is supplied in single-dose pre-filled syringes delivering sterile methotrexate solution for 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.

Boxed Warning: Severe Toxic Reactions, Including Embryofetal Toxicity and Death

- Serious toxic reactions and death have been reported with the use of methotrexate. Patients should be closely monitored for bone marrow, liver, lung, skin, and kidney toxicities.
- Methotrexate can cause embryo-fetal toxicity, including fetal death. Use is contraindicated during pregnancy. Males and females of reproductive potential should be advised to use effective contraception during and after treatment with methotrexate.
- Unexpectedly severe bone marrow suppression, aplastic anemia, and gastrointestinal toxicity have been reported with concomitant administration of methotrexate along with some nonsteroidal anti-inflammatory drugs (NSAIDs).
- Hepatotoxicity, fibrosis, and cirrhosis may occur after prolonged use.
- Methotrexate may cause interstitial pneumonitis at any time during therapy and has been reported at low doses. Pulmonary symptoms may require interruption of treatment and careful investigation.
- Diarrhea, ulcerative stomatitis, hemorrhagic enteritis, and death from intestinal perforation may occur.
- Severe, occasionally fatal, skin reactions have been reported.
- Potentially fatal opportunistic infections may occur.

Other Formulation(s) Available:

- <u>Methotrexate Tablet and Methotrexate Injection:</u>
  - Methotrexate tablets and methotrexate injection are indicated for the treatment neoplastic disease or maintenance therapy in combination with other chemotherapeutic agents. Like RediTrex®, these products are also indicated for severe psoriasis, RA, or pJIA.

- Methotrexate tablets and methotrexate injection solution have the same *Boxed Warning* as RediTrex®.
- Dosing varies based on the disease being treated. Methotrexate tablets are generically available in a 2.5mg strength. Methotrexate 25mg/mL injection is available generically in 2mL and 10mL vials. Procedures for proper handling of anticancer drugs should be considered when handling injection solution and tablets, including crushing and cutting tablets.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 4 weeks*
RediTrex® (7.5mg/0.3mL methotrexate injection)	**$75.00**	**$300.00**
methotrexate 25mg/mL injection (generic)	$3.23±	$6.46±
methotrexate 2.5mg tablet (generic)	$0.23	$2.76

Unit = pre-filled syringe, 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 rheumatoid arthritis (7.5mg 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).

Calendar Year 2020 Utilization: There was no SoonerCare utilization of RediTrex® during calendar year 2020. For generic methotrexate 25mg/mL injection and methotrexate 2.5mg tablets, there were 3,445 claims for 878 unduplicated utilizing members with a total cost of $75,641.22. The cost per day was $0.58 with a cost per claim of $21.96. These costs do not reflect rebated prices or net costs.

Reltone™ (Ursodiol Capsule) Product Summary[20,21,22]

Indication(s): Reltone™ (ursodiol capsule) is a bile acid indicated for the following:

- 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.
- Prevention of gallstone formation in obese patients with rapid weight loss.

Dosing and Administration:

- The recommended dosing is based on diagnosis:
  - Dissolution of radiolucent, noncalcified gallstones: 8 to 10mg/kg/day given by mouth in 2 or 3 divided doses
  - Prevention of gallstone formation: 600mg by mouth daily

- Gallstone dissolution with Reltone™ treatment requires months of therapy. Complete dissolution does not occur in all patients and recurrence of gallstones within 5 years has been observed in up to 50% of patients who do achieve gallstone dissolution on bile acid therapy. Patients should be carefully selected for therapy with ursodiol, and alternative therapies should be considered.
- Safety of Reltone™ use beyond 24 months has not been established.
- Reltone™ is supplied in 2 strengths: 200mg and 400mg capsules.

Other Formulation(s) Available:

- Ursodiol Capsule and Ursodiol Tablet:
  - Ursodiol capsules have the same FDA approved indications and diagnosis-specific recommended dosing as Reltone™.
  - The *Prescribing Information* for ursodiol capsule also includes the same information on the duration of treatment and efficacy as Reltone™.
  - Ursodiol tablets are indicated for the treatment of patients with primary biliary cirrhosis (PBC).
  - The recommended dosing for ursodiol tablets for the treatment of PBC is 13 to 15mg/kg/day administered in 2 to 4 divided doses.
  - Ursodiol capsules are supplied in 1 strength, 300mg.
  - Ursodiol tablets are supplied in 250mg tablets and 500mg scored 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).

Calendar Year 2020 Utilization: There was no SoonerCare utilization of Reltone™ during calendar year 2020.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
URSODIOL CAP 300MG	513	211	$29,348.86	$1.92	2.43	$57.21
URSODIOL TAB 250MG	345	72	$25,035.20	$2.41	4.79	$72.57
URSODIOL TAB 500MG	137	38	$10,861.36	$2.32	3.61	$79.28
TOTAL	**995**	**315***	**$65,245.42**	**$2.15**	**3.16**	**$65.57**

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

Thyquidity™ (Levothyroxine Oral Solution) Product Summary[23,24,25]

Indication(s): Thyquidity™ (levothyroxine oral solution) is a levothyroxine sodium (T4) oral solution indicated for hypothyroidism and pituitary thyrotropin suppression.

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

Dosing and Administration:

- 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, and 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 Tablet and Tirosint®-SOL (Levothyroxine Oral Solution):
  - Levothyroxine tablets and Tirosint®-SOL have the same indications and dosing as Thyquidity™.
  - Levothyroxine tablets and Tirosint®-SOL also include the same *Boxed Warning* and *Limitations of Use* as Thyquidity™.
  - Levothyroxine tablets are available in 12 strengths: 25mcg, 50mcg, 75mcg, 88mcg, 100mcg, 112mcg, 125mcg, 137mcg, 150mcg, 175mcg, 200mcg, or 300mcg.
  - Levothyroxine tablets can be crushed and mixed in a small amount (5mL to 10mL) of water for those unable to swallow tablets.
  - Tirosint®-SOL is supplied as an oral solution in 1mL unit-dose ampules and is available in 12 strengths which differ from levothyroxine tablets with the exclusion of 300mcg and the addition of 13mcg.
  - The contents of the Tirosint®-SOL ampule can be mixed with a glass of water prior to administration, emptied onto a spoon and consumed, or administered directly into the mouth.

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).

Calendar Year 2020 Utilization: There was no SoonerCare utilization of Thyquidity™ during calendar year 2020. For levothyroxine tablet products and Tirosint®-SOL, there were 49,026 claims for 10,395 unduplicated utilizing members with a total cost of $1,083,989.81. The cost per day was $0.46 with a cost per claim of $22.11. These costs do not reflect rebated prices or net costs.

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 and 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.

Finally, the College of Pharmacy recommends the addition of Nextstellis® (drospirenone/estetrol tablet) to the current Slynd® (drospirenone tablets) approval criteria, the addition of RediTrex® (methotrexate injection) to the current Otrexup® (methotrexate injection) and Rasuvo® (methotrexate injection) approval criteria along with updates 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 (proposed changes shown in red):

Nextstellis® (Drospirenone/Estetrol Tablet) and Slynd® (Drospirenone Tablets) 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.

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 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 and compliance with levothyroxine tablets.

Utilization Details of Various Special Formulations: Calendar Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LEVOTHYROXINE PRODUCTS					
TIROSINT CAP 75MCG	59	15	$12,584.34	$213.29	3.93
TIROSINT CAP 50MCG	47	10	$8,580.54	$182.56	4.7
TIROSINT CAP 100MCG	35	7	$7,504.16	$214.40	5
TIROSINT CAP 150MCG	34	12	$7,924.82	$233.08	2.83
TIROSINT CAP 25MCG	31	12	$5,308.93	$171.26	2.58
TIROSINT CAP 125MCG	29	8	$6,312.54	$217.67	3.63
TIROSINT-SOL SOL 100MCG/ML	25	3	$2,559.71	$102.39	8.33
TIROSINT-SOL SOL 75MCG/ML	18	4	$1,666.58	$92.59	4.5
TIROSINT CAP 200MCG	15	3	$2,279.98	$152.00	5
TIROSINT CAP 88MCG	14	5	$2,749.79	$196.41	2.8
TIROSINT CAP 13MCG	13	5	$3,065.41	$235.80	2.6
TIROSINT CAP 137MCG	9	3	$2,028.92	$225.44	3
TIROSINT-SOL SOL 25MCG/ML	9	3	$1,297.99	$144.22	3
TIROSINT-SOL SOL 50MCG/ML	8	3	$1,156.88	$144.61	2.67
TIROSINT CAP 112MCG	8	4	$2,505.83	$313.23	2
TIROSINT CAP 175MCG	7	6	$1,295.07	$185.01	1.17
TIROSINT-SOL SOL 13MCG/ML	5	1	$723.05	$144.61	5
TIROSINT-SOL SOL 88MCG/ML	3	1	$433.83	$144.61	3
LEVOTHYROXINE CAP 100MCG	3	2	$414.81	$138.27	1.5
TIROSINT-SOL SOL 200MCG	2	1	$281.22	$140.61	2
LEVOTHYROXINE CAP 13MCG	1	1	$138.27	$138.27	1
LEVOTHYROXINE CAP 75MCG	1	1	$138.27	$138.27	1
LEVOTHYROXINE CAP 200MCG	1	1	$50.00	$50.00	1
LEVOTHYROXINE CAP 50MCG	1	1	$138.27	$138.27	1
SUBTOTAL	**378**	**112**	**$71,139.21**	**$188.20**	**3.38**
MERCAPTOPURINE PRODUCTS					
PURIXAN SUS 20MG/ML	166	31	$198,871.38	$1,198.02	5.35
SUBTOTAL	**166**	**31**	**$198,871.38**	**$1,198.02**	**5.35**
METHOTREXATE PRODUCTS					
XATMEP SOL 2.5MG/ML	87	22	$44,616.69	$512.84	3.95
OTREXUP INJ 25MG	9	1	$5,914.71	$657.19	9
RASUVO INJ 12.5MG	7	1	$3,530.87	$504.41	7
RASUVO INJ 25MG	6	1	$2,927.76	$487.96	6
OTREXUP INJ 12.5MG	4	1	$2,628.76	$657.19	4
OTREXUP INJ 10MG	1	1	$657.19	$657.19	1
OTREXUP INJ 15MG	1	1	$661.19	$661.19	1
SUBTOTAL	**115**	**28**	**$60,937.17**	**$529.89**	**4.11**
LIFITEGRAST PRODUCTS					
XIIDRA DRO 5%	111	45	$59,106.76	$532.49	2.47
SUBTOTAL	**111**	**45**	**$59,106.76**	**$532.49**	**2.47**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LACTULOSE PRODUCTS					
KRISTALOSE PAK 10GM	16	4	$4,417.67	$276.10	4
SUBTOTAL	**16**	**4**	**$4,417.67**	**$276.10**	**4**
DROSPIRENONE PRODUCTS					
SLYND TAB 4MG	11	2	$2,544.82	$231.35	5.5
SUBTOTAL	**11**	**2**	**$2,544.82**	**$231.35**	**5.5**
GABAPENTIN PRODUCTS					
HORIZANT TAB 600MG ER	7	1	$2,883.20	$411.89	7
SUBTOTAL	**7**	**1**	**$2,883.20**	**$411.89**	**7**
CYCLOSPORINE PRODUCTS					
CEQUA SOL 0.09%	4	2	$1,977.00	$494.25	2
SUBTOTAL	**4**	**2**	**$1,977.00**	**$494.25**	**2**
TOTAL	**808**	**190***	**$401,877.21**	**$497.37**	**4.25**

CAP = capsule; DRO = drop; ER = extended-release; INJ = injection; PAK = packet; SOL = solution; SUS = suspension; TAB = tablet

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

The prior authorization (PA) for Tirosint® (levothyroxine capsule) was voted on by the Drug Utilization Review (DUR) board in July 2020 and implemented in December 2020. A portion of the utilization of Tirosint® shown in the table above occurred prior to implementation of the PA requirement.

- There were no SoonerCare paid pharmacy claims for calendar year 2020 for the following various special formulation products: Absorica LD™ (isotretinoin capsule), Cequa™ (cyclosporine 0.09% ophthalmic solution), GoNitro™ (nitroglycerin sublingual powder), Gralise® [gabapentin extended-release (ER) tablet], Khapzory™ (levoleucovorin injection), Klor-Con® 20mEq packet (potassium chloride), Lyrica® CR (pregabalin ER capsule), Metozolv® ODT [metoclopramide orally disintegrating tablet (ODT)], Nuvessa™ (metronidazole 1.3% vaginal gel), Pyridostigmine 30mg tablet, Quzyttir® (cetirizine injection), Restasis MultiDose® (cyclosporine 0.05% ophthalmic emulsion), Soltamox® (tamoxifen citrate 10mg/5mL oral solution), Sorilux® (calcipotriene 0.005% foam), and Taytulla® (norethindrone acetate/ethinyl estradiol capsule and ferrous fumarate capsule).

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Appendix M

Calendar Year 2020 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)

Oklahoma Health Care Authority
June 2021

Current Prior Authorization Criteria

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
dexlansoprazole (Dexilant® caps)	lansoprazole (Prevacid® ODT)	esomeprazole (Nexium® I.V.)	cimetidine (Tagamet® tabs)
esomeprazole (Nexium® caps)	pantoprazole (Protonix® I.V.)	esomeprazole strontium caps	esomeprazole kit (ESOMEP-EZS™)
esomeprazole (Nexium® packet) – **brand preferred**	rabeprazole (Aciphex® tabs)	omeprazole (Prilosec® susp, powder)	famotidine (Pepcid® susp)
lansoprazole (Prevacid® caps)		pantoprazole (Protonix® susp)	glycopyrrolate (Glycate® tabs)
omeprazole (Prilosec® caps)		rabeprazole (Aciphex® sprinkles)	nizatidine (Axid® caps & soln)
pantoprazole (Protonix® tabs)			omeprazole/ amoxicillin/rifabutin (Talicia® caps)
sucralfate susp (Carafate®) – **brand preferred**			omeprazole/sodium bicarbonate (Zegerid® caps & pack)
			ranitidine caps
			sucralfate susp (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.

Anti-Ulcer Medications Tier-2 Approval Criteria:

1. A 14-day trial of all available Tier-1 medications titrated up to the recommended dose that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication(s) to all available Tier-1 medications; or
3. An indication not covered by lower tiered medications.

Anti-Ulcer Medications Tier-3 Approval Criteria:

1. A 14-day trial of all available Tier-1 and Tier-2 medications that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication(s) to all available Tier-1 and Tier-2 medications; or
3. An indication not covered by lower tiered medications; and
4. Special formulations including orally disintegrating tablets (ODTs), sprinkle capsules, granules, suspensions, and intravenous (IV) solutions require special reasoning for use.

Proton Pump Inhibitors for Pediatric Members Approval Criteria:

1. A recent 14-day trial of an H_2 receptor antagonist that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Recurrent or severe disease such as:
    a. Gastrointestinal (GI) bleed; or
    b. Zollinger-Ellison Syndrome or similar disease; and
3. Tier structure rules still apply.

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 not appropriate for the member must be provided.

Axid® (Nizatidine Solution) 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. Nizatidine solution 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.

Esomep-EZS™ (Esomeprazole Kit) Approval Criteria:

1. A previous 14-day trial of esomeprazole magnesium and a patient-specific, clinically significant reason why other lower tiered proton pump inhibitors, including omeprazole and esomeprazole, along with over-the-counter (OTC) pill swallowing spray are not appropriate for the member must be provided; and

2. Current Tier structure rules will also apply.

Glycate® (Glycopyrrolate Tablets) Approval Criteria:

1. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in members 12 years of age and older; and
2. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without a prior authorization, must be provided.

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

Sucralfate Suspension Unit Dose Cups Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use the bulk medication 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 not appropriate for the member must be provided.

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

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

Zegerid® (Omeprazole/Sodium Bicarbonate Capsules) Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use omeprazole and over-the-counter (OTC) sodium bicarbonate must be provided.

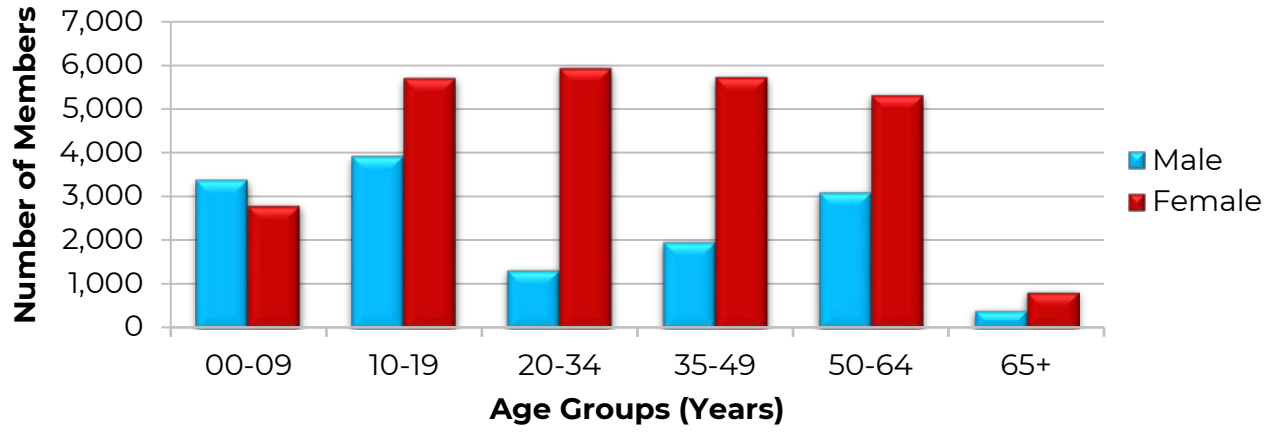
Utilization of Anti-Ulcer Medications: Calendar Year 2020

Comparison of Calendar Years

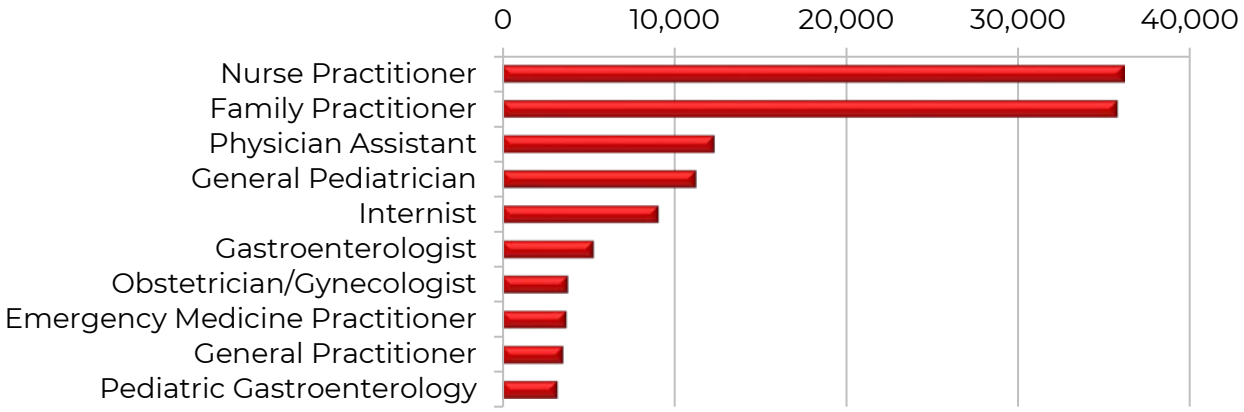
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	43,843	145,260	$3,558,413.47	$24.50	$0.67	9,799,178	5,339,987
2020	40,479	136,748	$4,557,838.04	$33.33	$0.83	8,238,004	5,517,408
% Change	**-7.7%**	**-5.9%**	**28.1%**	**36.0%**	**23.9%**	**-15.9%**	**3.3%**
Change	**-3,364**	**-8,512**	**$999,424.57**	**$8.83**	**$0.16**	**-1,561,174**	**177,421**

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

Demographics of Members Utilizing Anti-Ulcer Medications

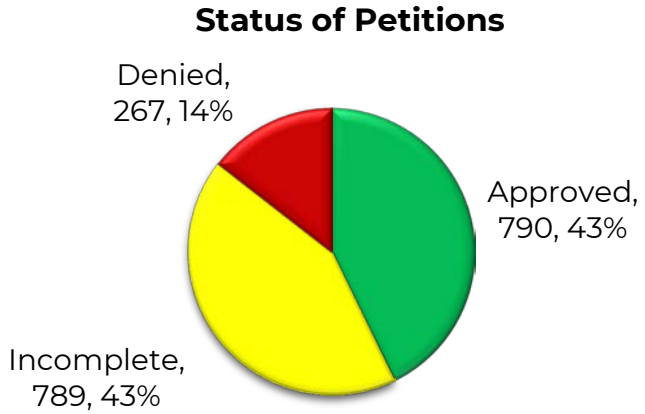


Top Prescriber Specialties of Anti-Ulcer Medications by Number of Claims



Prior Authorization of Anti-Ulcer Medications

There were 1,846 prior authorization requests submitted for anti-ulcer medications during calendar year 2020. The following chart shows the status of the submitted petitions for calendar year 2020.



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Dexilant® (dexlansoprazole capsule): September 2030
- Talicia® (omeprazole/amoxicillin/rifabutin capsule): February 2034

News:

- **April 2020:** The U.S. Food and Drug Administration (FDA) has requested all manufacturers withdraw all prescriptions 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[3,4]

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).
- **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 262.4g chewable tablets, 4 metronidazole 250mg tablets, and 4 tetracycline 500mg capsules.

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.

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*.
- **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 metronidazole, and 125mg of tetracycline. Pylera® is supplied in 120 count bottle or blister pack for 10 days of therapy.

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.

Cost Comparison: *H. Pylori* Regimens[5]

Product	Cost Per Unit	Cost Per Regimen*
Helidac® Therapy (bismuth subsalicylate/ metronidazole/tetracycline)	**$4.31**	**$965.44**
Pylera® (bismuth subcitrate potassium/ metronidazole/tetracycline capsule)	**$7.42**	**$890.40**
bismuth subsalicylate 262mg chewable tablet (generic)	$0.16[+]	$17.92[+]
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 05/18/2021 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 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 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
5. Updating the trial requirements for Axid® (nizatidine solution)

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)
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**~~
			generic sucralfate susp ~~**(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 must be provided.

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.

Utilization Details of Anti-Ulcer Medications: Calendar Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TIER-1 UTILIZATION					
OMEPRAZOLE PRODUCTS					
OMEPRAZOLE CAP 20MG	35,260	12,085	$415,286.78	$11.78	2.92
OMEPRAZOLE CAP 40MG	23,252	7,760	$304,848.70	$13.11	3
OMEPRAZOLE CAP 10MG	2,386	915	$33,322.62	$13.97	2.61
SUBTOTAL	**60,898**	**20,760**	**$753,458.10**	**$12.37**	**2.93**
PANTOPRAZOLE PRODUCTS					
PANTOPRAZOLE TAB 40MG	25,089	8,424	$324,856.30	$12.95	2.98
PANTOPRAZOLE TAB 20MG	4,486	1,612	$56,818.23	$12.67	2.78
SUBTOTAL	**29,575**	**10,036**	**$381,674.53**	**$12.91**	**2.95**
FAMOTIDINE PRODUCTS					
FAMOTIDINE TAB 20MG	10,733	5,480	$128,923.02	$12.01	1.96
FAMOTIDINE TAB 40MG	3,035	1,549	$39,652.93	$13.07	1.96
FAMOTIDINE INJ 10MG/ML	115	6	$1,959.52	$17.04	19.17
FAMOTIDINE INJ 200MG/20ML	32	3	$202.89	$6.34	10.67
FAMOTIDINE INJ 40MG/4ML	5	1	$72.66	$14.53	5
FAMOTIDINE INJ 20MG/2ML	1	1	$10.40	$10.40	1
PEPCID TAB 40MG	1	1	$1,987.20	$1,987.20	1
SUBTOTAL	**13,922**	**7,041**	**$172,808.62**	**$12.41**	**1.98**
SUCRALFATE PRODUCTS					
SUCRALFATE TAB 1GM	5,344	2,785	$139,087.50	$26.03	1.92
SUCRALFATE SUS 1GM/10ML	860	485	$219,531.07	$255.27	1.77
CARAFATE SUS 1GM/10ML	487	197	$155,673.30	$319.66	2.47
SUBTOTAL	**6,691**	**3,467**	**$514,291.87**	**$76.86**	**1.93**
ESOMEPRAZOLE PRODUCTS					
ESOMEPRAZOLE CAP 40MG DR	1,942	615	$38,408.71	$19.78	3.16
ESOMEPRAZOLE CAP 20MG DR	891	359	$18,378.56	$20.63	2.48
NEXIUM GRA 10MG DR	468	149	$137,866.13	$294.59	3.14
NEXIUM GRA 5MG DR	233	97	$63,377.15	$272.00	2.4
NEXIUM GRA 20MG DR	211	54	$65,051.67	$308.30	3.91

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
NEXIUM GRA 2.5MG DR	111	61	$31,808.29	$286.56	1.82
NEXIUM GRA 40MG DR	101	25	$28,961.15	$286.74	4.04
ESOMEPRAZOLE GRA 10MG DR	20	8	$4,320.12	$216.01	2.5
NEXIUM CAP 40MG	10	1	$3,546.33	$354.63	10
ESOMEPRAZOLE GRA 40MG DR	8	2	$1,302.76	$162.85	4
ESOMEPRAZOLE GRA 20MG DR	7	2	$2,205.24	$315.03	3.5
SUBTOTAL	**4,002**	**1,373**	**$395,226.11**	**$98.76**	**2.91**
DEXLANSOPRAZOLE PRODUCTS					
DEXILANT CAP 60MG DR	2,795	512	$794,456.48	$284.24	5.46
DEXILANT CAP 30MG DR	681	155	$196,497.84	$288.54	4.39
SUBTOTAL	**3,476**	**667**	**$990,954.32**	**$285.08**	**5.21**
RANIDITINE PRODUCTS					
RANITIDINE SYP 75MG/5ML	1,837	1,202	$33,144.09	$18.04	1.53
RANITIDINE TAB 150MG	1,074	654	$13,943.23	$12.98	1.64
RANITIDINE TAB 300MG	133	84	$2,200.45	$16.54	1.58
RANITIDINE SYP 15MG/ML	18	17	$284.19	$15.79	1.06
RANITIDINE INJ 50MG/2ML	8	1	$1,989.81	$248.73	8
RANITIDINE CAP 150MG	2	1	$53.38	$26.69	2
SUBTOTAL	**3,072**	**1,959**	**$51,615.15**	**$16.80**	**1.57**
LANSOPRAZOLE PRODUCTS					
LANSOPRAZOLE CAP 30MG DR	1,963	528	$30,601.47	$15.59	3.72
LANSOPRAZOLE CAP 15MG DR	520	207	$11,399.76	$21.92	2.51
SUBTOTAL	**2,483**	**735**	**$42,001.23**	**$16.92**	**3.38**
GLYCOPYRROLATE PRODUCTS					
GLYCOPYRROLATE TAB 1MG	1,318	229	$32,461.98	$24.63	5.76
GLYCOPYRROLATE TAB 2MG	829	115	$30,506.83	$36.80	7.21
SUBTOTAL	**2,147**	**344**	**$62,968.81**	**$29.33**	**6.24**
CIMETIDINE PRODUCTS					
CIMETIDINE SOL 300MG/5ML	398	230	$9,657.18	$24.26	1.73
SUBTOTAL	**398**	**230**	**$9,657.18**	**$24.26**	**1.73**
TIER-1 SUBTOTAL	**126,664**	**46,612**	**$3,374,655.92**	**$26.64**	**2.72**
TIER-2 UTILIZATION					
LANSOPRAZOLE PRODUCTS					
LANSOPRAZOLE 30MG ODT	334	54	$70,787.27	$211.94	6.19
LANSOPRAZOLE 15MG ODT	316	60	$77,169.66	$244.21	5.27
PREVACID 15MG ODT	70	13	$27,982.77	$399.75	5.38
PREVACID 30MG ODT	60	7	$24,048.90	$400.82	8.57
SUBTOTAL	**780**	**134**	**$199,988.60**	**$256.40**	**5.82**
RABEPRAZOLE PRODUCTS					
RABEPRAZOLE TAB 20MG	248	45	$4,859.87	$19.60	5.51
SUBTOTAL	**248**	**45**	**$4,859.87**	**$19.60**	**5.51**
PANTOPRAZOLE PRODUCTS					
PANTOPRAZOLE INJ SOD 40MG	29	3	$1,131.89	$39.03	9.67

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PROTONIX INJ 40MG	1	1	$46.41	$46.41	1
SUBTOTAL	**30**	**4**	**$1,178.30**	**$39.28**	**7.50**
TIER-2 SUBTOTAL	**1,058**	**183**	**$206,026.77**	**$194.73**	**5.78**
TIER-3 UTILIZATION					
OMEPRAZOLE PRODUCTS					
PRILOSEC POW 10MG	30	5	$15,136.98	$504.57	6
PRILOSEC POW 2.5MG	24	8	$11,941.48	$497.56	3
SUBTOTAL	**54**	**13**	**$27,078.46**	**$501.45**	**4.15**
PANTOPRAZOLE PRODUCTS					
PROTONIX PAK 40MG	23	2	$10,655.78	$463.29	11.5
PANTOPRAZOLE PAK 40MG	1	1	$860.83	$860.83	1
SUBTOTAL	**24**	**3**	**$11,516.61**	**$479.86**	**8.00**
RABEPRAZOLE PRODUCTS					
ACIPHEX SPR CAP 10MG	8	1	$6,123.58	$765.45	8
SUBTOTAL	**8**	**1**	**$6,123.58**	**$765.45**	**8**
TIER-3 SUBTOTAL	**86**	**17**	**$44,718.65**	**$519.98**	**5.06**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION					
FAMOTIDINE PRODUCTS					
FAMOTIDINE SUS 40MG/5ML	8,388	3,536	$866,464.52	$103.30	2.37
SUBTOTAL	**8,388**	**3,536**	**$866,464.52**	**$103.30**	**2.37**
NIZATIDINE PRODUCTS					
NIZATIDINE SOL 15MG/ML	451	266	$61,040.32	$135.34	1.7
NIZATIDINE CAP 150MG	6	3	$143.20	$23.87	2
SUBTOTAL	**457**	**269**	**$61,183.52**	**$133.88**	**1.70**
CIMETIDINE PRODUCTS					
CIMETIDINE TAB 400MG	35	18	$1,276.98	$36.49	1.94
CIMETIDINE TAB 300MG	32	12	$786.29	$24.57	2.67
CIMETIDINE TAB 800MG	17	9	$1,083.29	$63.72	1.89
CIMETIDINE TAB 200MG	9	5	$319.28	$35.48	1.8
SUBTOTAL	**93**	**44**	**$3,465.84**	**$37.27**	**2.11**
TRIPLE THERAPY COMBINATIONS					
TALICIA 10/250/12.5MG CAP	2	2	$1,322.82	$661.41	1
SUBTOTAL	**2**	**2**	**$1,322.82**	**$661.41**	**1**
SPECIAL PA SUBTOTAL	**8,940**	**3,851**	**$932,436.70**	**$104.30**	**2.32**
TOTAL	**136,748**	**40,479***	**$4,557,838.04**	**$33.33**	**3.38**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
CAP = capsule; DR = delayed-release; GRA = granules; INJ = injection; ODT = orally disintegrating tablet; PAK = pack; POW = powder; SOD = sodium; SOL = solution; SPR = sprinkle; SUS = suspension; SYP = syrup; TAB = tablet

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 05/2021. Last accessed 05/20/2021.
[2] U.S. FDA. FDA Requests Removal of All Ranitidine Products (Zantac) from the Market. Available online at: https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market. Issued 04/01/2020. Last accessed 05/20/2021.
[3] Helidac® Therapy Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=eb651905-007d-4a56-b010-db4a4f7c405d. Last revised 06/2020. Last accessed 05/18/2021.
[4] Pylera® Prescribing Information. Allergan. Available online at: https://media.allergan.com/actavis/actavis/media/allergan-pdf-documents/product-prescribing/Pylera-Final-PI-10_2018.pdf. Last revised 03/2021. Last accessed 05/19/2021.
[5] Chey WD, Leontiadis GI, Howden CW, et al. ACG Clinical Guideline: Treatment of Helicobacter Pylori Infection. *Am J Gastroenterol* 2017; 112(2):212-239.

Appendix N

Calendar Year 2020 Annual Review of Isturisa® (Osilodrostat)

Oklahoma Health Care Authority
June 2021

Current Prior Authorization Criteria

Isturisa® (Osilodrostat) Approval Criteria:

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

Utilization of Isturisa® (Osilodrostat): Calendar Year 2020

There was no SoonerCare utilization of Isturisa® (osilodrostat) during calendar year 2020.

Prior Authorization of Isturisa® (Osilodrostat)

There were no prior authorization requests submitted for Isturisa® (osilodrostat) during calendar year 2020.

Market News and Updates[1,23]

Anticipated Patent Expiration(s):

- Isturisa® (osilodrostat tablet): October 2035

News:

- **March 2021:** Recordati Rare Diseases announced positive results from their Phase 3 LINC4 study of Isturisa® (osilodrostat) in patients with Cushing's disease. The LINC4 study enrolled patients with persistent or recurrent Cushing's disease or those with *de novo* disease who were ineligible for surgery. LINC4 was a multicenter, randomized, double-blind, 48-week study with an initial 12-week placebo-controlled period that compared Isturisa® to placebo with a primary endpoint of achieving a normal mean urinary free cortisol (mUFC) level. A significantly higher proportion of patients achieved normal mUFC levels with Isturisa® than with placebo at the end of the 12 week placebo-controlled phase (77% vs. 8%, P<0.0001). All patients received Isturisa® after the initial 12 week placebo-controlled phase until the end of the study at 48 weeks.
- **May 2021:** Data from the LINC3 and LINC4 Phase 3 studies of osilodrostat suggest that a more gradual increase in osilodrostat was better tolerated among patients with Cushing's disease and reduced the risk of hypocortisolism-related adverse events. These adverse events included glucocorticoid deficiency, adrenocortical insufficiency, steroid withdrawal syndrome, and decreased cortisol. In the LINC3 study, osilodrostat was titrated up once every 2 weeks to a maximum dose of 30mg twice daily, while in the LINC4 study, the dose was titrated up once every 3 weeks to a maximum dose of 20mg twice daily. When comparing the number of patients who experienced a hypocortisolism-related adverse event, 51% of the patients in the LINC3 study experienced a hypocortisolism-related adverse event compared to 27% in the LINC4 study. Despite the differences in the dose titration schedules, the time to the first mUFC level normalization was similar between the 2 studies.

Recommendations

The College of Pharmacy does not recommend any changes to the current prior authorization criteria for Isturisa® (osilodrostat) 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/default.cfm?resetfields=1. Last revised 05/2021. Last accessed 05/19/2021.

[2] Recordati Rare Diseases. Positive Results from the Phase III LINC 4 Study Presented Today at the Endocrine Society's Annual Meeting Reinforce the Efficacy and Safety of Isturisa® (Osilodrostat) in Cushing's Disease. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20210323005021/en/Recordati-Rare-Diseases-Positive-Results-From-the-Phase-III-LINC-4-Study-Presented-Today-at-the-Endocrine-Society%E2%80%99s-Annual-Meeting-Reinforce-the-Efficacy-and-Safety-of-Isturisa%C2%AE-osilodrostat-in-Cushing%E2%80%99s-Disease. Issued 03/23/2021. Last accessed 05/19/2021.

[3] Monaco, K. Slow and Steady With Osilodrostat. *Medpage Today*. Available online at: https://www.medpagetoday.com/meetingcoverage/aace/92824?xid=nl_mpt_DHE_2021-05-28&eun=g1080562d0r&utm_source=Sailthru&utm_medium=email&utm_campaign=Daily%20Headlines%20Top%20Cat%20HeC%20%202021-05-28&utm_term=NL_Daily_DHE_dual-gmail-definition. Issued 05/27/2021. Last accessed 05/27/2021.

Appendix O

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

FDA NEWS RELEASE

For Immediate Release: May 21, 2021

FDA Approves First Targeted Therapy for Subset of Non-Small Cell Lung Cancer

The FDA approved Rybrevant (amivantamab-vmjw) as the first treatment for adult patients with non-small cell lung cancer (NSCLC) whose tumors have specific types of genetic mutations: epidermal growth factor receptor (EGFR) exon 20 insertion mutations. The FDA also approved the Guardant360 CDx (Guardant Health Inc.) as a companion diagnostic for Rybrevant today.

Approximately 2% to 3% of patients with NSCLC will have EGFR exon 20 insertion mutations, which are a group of mutations on a protein that causes rapid cell growth, and consequently, helps cancer spread. EGFR exon 20 insertion mutations are the third most common type of EGFR mutation.

Researchers evaluated Rybrevant's efficacy in a study of 81 patients with NSCLC and EGFR exon 20 insertion mutations whose disease had progressed on or after platinum-based chemotherapy. The main outcome measured was overall response rate. In the trial population in which all patients received Rybrevant, the overall response rate was 40%. The median duration of response was 11.1 months, with 63% of patients having a duration of response of ≥6 months.

The most common side effects of Rybrevant include rash, infusion-related reactions, skin infections around the fingernails or toenails, muscle and joint pain, shortness of breath, nausea, fatigue, swelling in the lower legs or hands or face, sores in the mouth, cough, constipation, vomiting, and changes in certain blood tests. Rybrevant should be withheld if patients develop symptoms of interstitial lung disease and permanently discontinued if interstitial lung disease is confirmed. Patients taking Rybrevant should limit sun exposure during and for 2 months after treatment. Rybrevant may cause problems with vision. Rybrevant can also cause fetal harm when administered to a pregnant woman; therefore, the pregnancy status of females of reproductive potential should be confirmed before treatment is started.

Rybrevant received Priority Review and Breakthrough Therapy designation for this indication.

FDA NEWS RELEASE

For Immediate Release: May 19, 2021

FDA Authorizes Longer Time for Refrigerator Storage of Thawed Pfizer-BioNTech COVID-19 Vaccine Prior to Dilution, Making Vaccine More Widely Available

Based on a review of recent data submitted by Pfizer Inc. today, the FDA is authorizing undiluted, thawed Pfizer-BioNTech COVID-19 Vaccine vials to be stored in the refrigerator at 2°C to 8°C (35°F to 46°F) for up to 1 month. Previously, thawed, undiluted vaccine vials could be stored in the refrigerator for up to 5 days.

Pfizer Inc. submitted data to the FDA to demonstrate that undiluted, thawed vials of its COVID-19 vaccine are stable at refrigerator temperatures for up to 1 month. The updated Fact Sheet for Health Care Providers Administering Vaccine is intended to help

frontline workers understand the revised storage time. The Fact Sheet is available on the FDA's web site.

FDA NEWS RELEASE

For Immediate Release: May 19, 2021

FDA Advises Against Use of SARS-CoV-2 Antibody Test Results to Evaluate Immunity or Protection from COVID-19, Including After Vaccination

The FDA issued a safety communication informing the public that results from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antibody tests should not be used to evaluate immunity or protection from COVID-19 at any time, and especially after the person received a COVID-19 vaccination.

The authorized vaccines for prevention of COVID-19 induce antibodies to specific viral protein targets; post-vaccination antibody test results will be negative in individuals without a history of previous natural infection if the test used does not detect the type of antibodies induced by the vaccine.

Currently authorized SARS-CoV-2 antibody tests are not validated to evaluate immunity or protection from COVID-19 infection. SARS-CoV-2 antibody tests should be ordered only by health care providers who are familiar with the use and limitations of the test.

FDA NEWS RELEASE

For Immediate Release: May 18, 2021

The FDA Announced the Following Actions Taken in its Ongoing Response Effort to the COVID-19 Pandemic:

- On May 17, 2021, the FDA provided summary information about the status of CytoDyn, Inc.'s development program for the monoclonal antibody investigational drug, leronlimab, for the treatment of COVID-19. The data currently available from recent CytoDyn clinical trials do not support the clinical benefit of leronlimab for the treatment of COVID-19.
- The Janssen (Johnson & Johnson) COVID-19 Vaccine Fact Sheet for Recipients and Caregivers has been updated and is available in multiple languages.
- Testing updates:
  - Currently, 374 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). These include 272 molecular tests and sample collection devices, 78 antibody and other immune response tests, and 24 antigen tests. There are 50 molecular authorizations and 1 antibody authorization that can be used with home-collected samples. There is 1 molecular prescription at-home test, 2 antigen prescription at-home tests, 4 antigen over-the-counter (OTC) at-home tests, and 2 molecular OTC at-home tests.
  - The FDA has authorized 9 antigen tests and 4 molecular tests for serial screening programs.
  - The FDA has also authorized 505 revisions to EUA authorizations.

FDA NEWS RELEASE

For Immediate Release: May 17, 2021

FDA Provides Guidance on Master Protocols for Evaluating Prevention, Treatment Options for COVID-19

The FDA issued a final guidance entitled, "COVID-19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention Guidance for Industry." This guidance describes the FDA's current recommendations to sponsors of master protocols evaluating drugs for the treatment or prevention of COVID-19. A master protocol is defined as a protocol designed with multiple substudies, which involve coordinated efforts to evaluate 1 or more investigational drugs, in 1 or more disease subtypes, with 1 or more objectives, all within the same overall trial structure.

This guidance focuses on the design, conduct, and statistical considerations of master protocols intended to generate or contribute to substantial evidence of effectiveness and adequate characterization of safety of drugs for the treatment or prevention of COVID-19. Additionally, this guidance provides administrative and procedural recommendations to sponsors of master protocols for COVID-19 drugs.

FDA NEWS RELEASE

For Immediate Release: May 10, 2021

FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Adolescents in Another Important Action in Fight Against Pandemic

The FDA expanded the EUA for the Pfizer-BioNTech COVID-19 vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 to include adolescents 12 through 15 years of age. The FDA amended the EUA originally issued on December 11, 2020 for administration in individuals 16 years of age and older.

From March 1, 2020 through April 30, 2021, approximately 1.5 million COVID-19 cases in individuals 11 to 17 years of age have been reported to the Centers for Disease Control and Prevention (CDC). Children and adolescents generally have a milder COVID-19 disease course as compared to adults. The Pfizer-BioNTech COVID-19 vaccine is administered as a series of 2 doses, 3 weeks apart, the same dosage and dosing regimen for 16 years of age and older.

The FDA has determined that Pfizer-BioNTech COVID-19 vaccine has met the statutory criteria to amend the EUA, and that the known and potential benefits of this vaccine in individuals 12 years of age and older outweigh the known and potential risks, supporting the vaccine's use in this population.

The FDA has updated the Fact Sheets for Health Care Providers Administering the Vaccine and for Recipients and Caregivers with information to reflect the use of the vaccine in the adolescent population, including the benefits and risks of the Pfizer-BioNTech COVID-19 vaccine.

The EUA amendment for the Pfizer-BioNTech COVID-19 Vaccine was issued to Pfizer, Inc. The issuance of an EUA is not an FDA approval of a vaccine. The EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biologics for prevention and treatment of COVID-19 is terminated, and may be revised or revoked if it is determined the EUA no longer meets the statutory criteria for issuance or to protect public health or safety.

FDA Evaluation of Available Safety Data

The available safety data to support the EUA in adolescents down to 12 years of age, includes 2,260 patients ages 12 through 15 years enrolled in an ongoing randomized, placebo-controlled clinical trial in the United States. Of these, 1,131 adolescent patients

received the vaccine and 1,129 received a saline placebo. More than half of the patients were followed for safety for at least 2 months following the second dose.

The most commonly reported side effects in the adolescent clinical trial patients, which typically lasted 1-3 days, were pain at the injection site, tiredness, headache, chills, muscle pain, fever, and joint pain. With the exception of pain at the injection site, more adolescents reported these side effects after the second dose than after the first dose, so it is important for vaccination providers and recipients to expect that there may be some side effects after either dose, but even more so after the second dose. The side effects in adolescents were consistent with those reported in clinical trial patients 16 years of age and older. It is important to note that as a general matter, while some individuals experience side effects following any vaccination, not every individual's experience will be the same and some people may not experience side effects.

The Pfizer-BioNTech COVID-19 vaccine should not be given to anyone with a known history of a severe allergic reaction, including anaphylaxis, to any component of the vaccine. Since its authorization for emergency use, rare severe allergic reactions, including anaphylaxis, have been reported following administration of the Pfizer-BioNTech COVID-19 vaccine in some recipients.

FDA Evaluation of Available Effectiveness Data

The effectiveness data to support the EUA in adolescents down to 12 years of age is based on immunogenicity and an analysis of COVID-19 cases. The immune response to the vaccine in 190 patients, 12 through 15 years of age, was compared to the immune response of 170 patients, 16 through 25 years of age. In this analysis, the immune response of adolescents was non-inferior to the immune response of the older patients. An analysis of cases of COVID-19 occurring among patients, 12 through 15 years of age, 7 days after the second dose was also conducted. In this analysis, among patients without evidence of prior infection with SARS-CoV-2, no cases of COVID-19 occurred among 1,005 vaccine recipients and 16 cases of COVID-19 occurred among 978 placebo recipients; the vaccine was 100% effective in preventing COVID-19. At this time, there are limited data to address whether the vaccine can prevent transmission of the virus from person to person. In addition, at this time, data are not available to determine how long the vaccine will provide protection.

Ongoing Safety Monitoring

As part of the original EUA request, Pfizer, Inc. submitted a plan to continue monitoring the safety of the vaccine as it is used under EUA. This plan has been updated to include the newly authorized adolescent population, and includes longer-term safety follow-up for patients enrolled in ongoing clinical trials, as well as other activities aimed at monitoring the safety of the Pfizer-BioNTech COVID-19 vaccine and ensuring that any safety concerns are identified and evaluated in a timely manner.

It is mandatory for Pfizer, Inc. and vaccination providers to report the following to the Vaccine Adverse Event Reporting System (VAERS) for Pfizer-BioNTech COVID-19 vaccine: all vaccine administration errors, serious adverse events, cases of multisystem inflammatory syndrome and cases of COVID-19 that result in hospitalization or death.

FDA NEWS RELEASE

For Immediate Release: April 30, 2021

FDA Approves Treatment for Chronic Kidney Disease

The FDA approved Farxiga (dapagliflozin) oral tablets to reduce the risk of kidney function decline, kidney failure, cardiovascular (CV) death and hospitalization for heart failure in adults with chronic kidney disease (CKD) who are at risk of disease progression.

The efficacy of Farxiga to improve kidney outcomes and reduce CV death in patients with CKD was evaluated in a multicenter, double-blind study. In this study, 4,304 patients were randomly assigned to receive either Farxiga or a placebo. The study compared the 2 groups for the number of patients whose disease progressed to a composite endpoint that included at least a 50% reduction in kidney function, progression to kidney failure, or CV or kidney death. Results showed that 197 of the 2,152 patients who received Farxiga had at least 1 of the composite endpoint events compared to 312 of the 2,152 patients who received a placebo. The study also compared the 2 groups for the number of patients who were hospitalized for heart failure or died from CV disease. A total of 100 patients who received Farxiga were hospitalized or died compared to 138 patients who received a placebo.

Farxiga was not studied, nor is expected to be effective, in treating CKD among patients with autosomal dominant or recessive polycystic kidney disease or among patients who require or have recently used immunosuppressive therapy to treat kidney disease.

Patients should not use Farxiga if they have a history of serious hypersensitivity reactions to the medication or if they are on dialysis treatment. Serious, life-threatening cases of Fournier's Gangrene have occurred in patients with diabetes taking Farxiga. Patients should consider a lower dose of insulin or insulin secretagogue to reduce the risk of hypoglycemia if they are also taking Farxiga. Farxiga can cause dehydration, serious urinary tract infections, genital yeast infections, and metabolic acidosis or ketoacidosis. Patients should be assessed for their volume status and kidney function before starting Farxiga.

Farxiga was originally approved in 2014 to improve glycemic control in adults with type 2 diabetes in addition to diet and exercise.

FDA NEWS RELEASE

For Immediate Release: April 30, 2021

FDA Approves Higher Dosage of Naloxone Nasal Spray to Treat Opioid Overdose

The FDA announced the approval of a higher dose naloxone hydrochloride nasal spray product, Kloxxado, to treat opioid overdose. The newly approved product delivers 8mg of naloxone into the nasal cavity. The FDA had previously approved 2mg and 4mg naloxone nasal spray products.

Over the last several years, the FDA has taken a number of steps to improve availability of naloxone products, including: encouraging manufacturers to pursue approval of over-the-counter naloxone products; requiring drug manufacturers for all opioid pain relievers and medicines to treat opioid use disorder to add new recommendations about naloxone to the *Prescribing Information*; and extending the shelf life of naloxone nasal spray from 24 months to 36 months.

The FDA is committed to using its regulatory authority to address the opioid crisis with a focus on: decreasing exposure to opioids and preventing new addiction; fostering the development of novel pain treatment therapies; supporting treatment of those with opioid use disorder; and improving enforcement and assessing benefit-risk.

The use of naloxone in patients who are opioid-dependent may result in opioid withdrawal characterized by body aches, diarrhea, increased heart rate, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure.

The FDA granted approval of Kloxxado to Hikma Pharmaceuticals through the 505(b)(2) approval pathway that relied, in part, on the FDA's finding of safety and effectiveness for naloxone hydrochloride (Narcan injection) to support approval. The applicant demonstrated that reliance on the FDA's finding of safety and effectiveness for Narcan was scientifically justified and provided Kloxxado-specific pharmacokinetic data to establish the drug's safety and efficacy for its approved use.

Current Drug Shortages Index (as of May 21, 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***
Anagrelide Hydrochloride Capsules	***Currently in Shortage***
Asparaginase Erwinia Chrysanthemi (Erwinaze)	***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***
Cisatracurium Besylate Injection	***Currently in Shortage***
Continuous Renal Replacement Therapy (CRRT) Solutions	***Currently in Shortage***
Cortisone Acetate Tablets	***Currently in Shortage***
Cyclopentolate Ophthalmic Solution	***Currently in Shortage***
Cysteamine Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Desmopressin Acetate Nasal Spray	***Currently in Shortage***

Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Dimercaprol (Bal in Oil) Injection	***Currently in Shortage***
Disopyramide Phosphate (Norpace) Capsules	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Injection, 0.1mg/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***
Fluorescein Strips	***Currently in Shortage***
Fluvoxamine ER Capsules	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gemifloxacin Mesylate (Factive) Tablets	***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***
Hydralazine Hydrochloride Injection	***Currently in Shortage***
Hydrocortisone Tablets	***Currently in Shortage***
Hydrocortisone Tablets, USP	***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***
Methadone 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***
Nalbuphine Hydrochloride Injection	***Currently in Shortage***
Nefazodone Hydrochloride Tablets	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Ondansetron Hydrochloride Injection	***Currently in Shortage***
Oxytocin Injection (Synthetic)	***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***
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***
Triamcinolone Hexacetonide Injectable suspension	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsules	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***