OKLAHOMA
Health Care Authority

Drug Utilization Review Board

OHCA Webinar
Wednesday,
June 10, 2020
4:00pm

OHCA Webinar

Register for the meeting using the following website address:
https://okhca.zoom.us/webinar/register/WN_0MkFwBoVQbS6LhOWqnoWzw

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 10, 2020

DATE: May 26, 2020

NOTE: In response to COVID-19, the June 2020 meeting will be held via OHCA webinar at 4:00pm. After registering, you will receive a confirmation email containing information about joining the webinar. Please register for the meeting using the following website address: https://okhca.zoom.us/webinar/register/WN_0MkFwBoVQbS6LhOWqnoWzw

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

Update on Medication Coverage Authorization Unit/Use of Angiotensin Converting Enzyme Inhibitor (ACEI)/Angiotensin Receptor Blocker (ARB)/Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy in Patients with Chronic Heart Failure (HF) Mailing Update – Appendix B

Action Item – Vote to Prior Authorize Ziextenzo® (Pegfilgrastim-bmez) – Appendix C

Action Item – Vote to Prior Authorize Palforzia™ (Peanut Allergen Powder-dnfp) – Appendix D

Action Item – Vote to Prior Authorize Nourianz™ (Istradefylline Tablet) – Appendix E

Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Secuado® (Asenapine Transdermal System) and Caplyta™ (Lumateperone Capsule) – Appendix F

Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Wakix® (Pitolisant) – Appendix G

Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Absorica LD™ (Isotretinoin Capsule), Amzeeq™ (Minocycline 4% Topical Foam), Aprizio Pak™ (Lidocaine/Prilocaine 2.5%/2.5% Kit), Caldolor® (Ibuprofen Injection), Exservan™ (Riluzole Oral Film), Metronidazole 1% Gel, Noritate® (Metronidazole 1% Cream), Procysbi® [Cysteamine Delayed-Release (DR) Granule], Pyridostigmine 30mg Tablet, Quzyttir™ (Cetirizine Injection), Relafen™ DS (Nabumetone Tablet), Slynd™ (Drospirenone Tablet), Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsule), and Tirosint® (Levothyroxine Capsule) – Appendix H

Annual Review of Ophthalmic Anti-Inflammatories and 30-Day Notice to Prior Authorize Iluvien® (Fluocinolone Acetonide Intravitreal Implant), Ozurdex® (Dexamethasone Intravitreal Implant), and Retisert® (Fluocinolone Intravitreal Implant) – Appendix I

30-Day Notice to Prior Authorize Isturisa® (Osilodrostat) – Appendix J

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – June 10, 2020 @ 4:00pm

OHCA Webinar
Register for the meeting here:
https://okhca.zoom.us/webinar/register/WN_0MkFwBoVQbS6LhOWqnoWzw

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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. Skrepnek

Telephone Conference Participants

DUR Board Members:

Dr. Stephen Anderson –	participating via Zoom Teleconference
Dr. Jennifer de los Angeles –	participating via Zoom Teleconference
Ms. Jennifer Boyett –	participating via Zoom Teleconference
Dr. Markita Broyles –	participating via Zoom Teleconference
Dr. Theresa Garton –	participating via Zoom Teleconference
Dr. Megan Hanner –	participating via Zoom Teleconference
Dr. Lynn Mitchell –	participating via Zoom Teleconference
Dr. John Muchmore –	participating via Zoom Teleconference
Dr. Lee Munoz –	participating via Zoom Teleconference
Dr. James Osborne –	participating via Zoom Teleconference

Public Access to Meeting via Zoom:

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Webinar ID: 933 9078 0729

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 www.okhca.org/DUR 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.

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 13, 2020 DUR Minutes – Vote
B. May 13, 2020 DUR Recommendations Memorandum

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

4. Update on Medication Coverage Authorization Unit/Use of Angiotensin Converting Enzyme Inhibitor (ACEI)/Angiotensin Receptor Blocker (ARB)/Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy in Patients with Chronic Heart Failure (HF) Mailing Update – See Appendix B

A. Pharmacy Helpdesk Activity for May 2020
B. Medication Coverage Activity for May 2020
C. Use of ACEI/ARB/ARNI Therapy in Patients with Chronic HF Mailing Summary

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

5. Action Item – Vote to Prior Authorize Ziextenzo® (Pegfilgrastim-bmez) – See Appendix C

A. Introduction
B. College of Pharmacy Recommendations

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

6. Action Item – Vote to Prior Authorize Palforzia™ (Peanut Allergen Powder-dnfp) – See Appendix D

A. Introduction
B. College of Pharmacy Recommendations

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

7. Action Item – Vote to Prior Authorize Nourianz™ (Istradefylline Tablet) – See Appendix E

A. Introduction
B. College of Pharmacy Recommendations

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

8. Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Secuado® (Asenapine Transdermal System) and Caplyta™ (Lumateperone Capsule) – See Appendix F

A. Current Prior Authorization Criteria
B. Medicaid Drug Rebate Program
C. Utilization of Atypical Antipsychotic Medications
D. Prior Authorization of Atypical Antipsychotic Medications
E. Market News and Updates

F. Secuado® (Asenapine) Transdermal System Product Summary
G. Caplyta™ (Lumateperone) Product Summary
H. College of Pharmacy Recommendations
I. Utilization Details of Atypical Antipsychotic Medications

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

9. Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Wakix® (Pitolisant) – See Appendix G

A. Current Prior Authorization Criteria
B. Medicaid Drug Rebate Program
C. Utilization of ADHD and Narcolepsy Medications
D. Prior Authorization of ADHD and Narcolepsy Medications
E. Market News and Updates
F. Wakix® (Pitolisant) Product Summary
G. Cost Comparison
H. College of Pharmacy Recommendations
I. Utilization Details of ADHD and Narcolepsy Medications

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

10. Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Absorica LD™ (Isotretinoin Capsule), Amzeeq™ (Minocycline 4% Topical Foam), Aprizio Pak™ (Lidocaine/Prilocaine 2.5%/2.5% Kit), Caldolor® (Ibuprofen Injection), Exservan™ (Riluzole Oral Film), Metronidazole 1% Gel, Noritate® (Metronidazole 1% Cream), Procysbi® [Cysteamine Delayed-Release (DR) Granule], Pyridostigmine 30mg Tablet, Quzyttir™ (Cetirizine Injection), Relafen™ DS (Nabumetone Tablet), Slynd™ (Drospirenone Tablet), Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsule), and Tirosint® (Levothyroxine Capsule) – See Appendix H

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. Van, Dr. Muchmore, Chairman:

11. Annual Review of Ophthalmic Anti-Inflammatories and 30-Day Notice to Prior Authorize Iluvien® (Fluocinolone Intravitreal Implant), Ozurdex® (Dexamethasone Intravitreal Implant), and Retisert® (Fluocinolone Intravitreal Implant) – See Appendix I

A. Current Prior Authorization Criteria
B. Utilization of Ophthalmic Anti-Inflammatories
C. Prior Authorization of Ophthalmic Anti-Inflammatories
D. Market News and Updates
E. Iluvien® (Fluocinolone Intravitreal Implant) Product Summary
F. Ozurdex® (Dexamethasone Intravitreal Implant) Product Summary
G. Retisert® (Fluocinolone Intravitreal Implant) Product Summary
H. Other Formulations and Cost Comparison
I. College of Pharmacy Recommendations

J. Utilization Details of Ophthalmic NSAIDs
K. Utilization Details of Ophthalmic Corticosteroids

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

12. 30-Day Notice to Prior Authorize Isturisa® (Osilodrostat) – See Appendix J

A. Market News and Updates
B. Isturisa® (Osilodrostat) Product Summary
C. College of Pharmacy Recommendations

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

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

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

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

A. Topical Corticosteroids
B. Opioid Analgesic and Medication-Assisted Treatment (MAT) Medications
C. Amyloidosis Medications
D. Koselugo™ (Selumetinib) and Pemazyre™ (Pemigatinib)

**Future business subject to change.*

15. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES OF MEETING OF MAY 13, 2020

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 Munoz, D.Ph.	x	
James Osborne, Pharm.D.	x	

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; Clinical Pharmacist	x	
Wendi Chandler, Pharm.D.; Clinical Pharmacist	x	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	x	
Erin Ford, Pharm.D.; Clinical Pharmacist	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; Interim Director	x	
Regan Smith, Pharm.D.; Clinical Pharmacist	x	
Ashley Teel, Pharm.D.; Clinical Pharmacist	x	
Brian Thomas, Pharm.D.; Clinical Pharmacist		x
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	x	
Tri Van, Pharm.D.; Pharmacy Resident	x	
PA Oncology Pharmacists: 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): Justin Wilson	x	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Melody Anthony, Chief State Medicaid Director; Chief Operating Officer		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	

Stacey Hale, Drug Rebate Manager	x	
Michael Herndon, D.O.; Chief Medical Officer		x
Paula Root, M.D.; Medical Director	x	
Jill Ratterman, D.Ph.; Clinical Pharmacist	x	
Nathan Valentine, M.D.; Senior Medical Director		x
Kerri Wade, Pharmacy Operations Manager	x	

OTHERS PRESENT:	
Audrey Rattan, Alkermes	John Brunson, Amneal
Doug Wood, ViiV Health Care	Bob Atkins, Biogen
Jim Chapman, Abbvie	Jennifer Shidler, BluePrint Medicines
Tony Salicos, Greenwich	Evie Knisley, Novartis
Janie Huff, Tricida	Tami Sova, Biogen
Bethany Holderread, Mercer	Eric Gardner, Vertex
Shelley Thompson, Alkermes	Nima Nabavi, Amgen
Helen Kim, Aimmune	Rhonda Clark, Indivior
Jason Lurk, Novo Nordisk	Ronald Cain, Pfizer
Charlie Collins, Sanofi-Genzyme	Brent Hildebrand, Gilead Sciences
Brian Maves, Pfizer	Tim Hambacher, Coherus
Matthew Bradley, Novartis	Gina Heinen, Novo Nordisk
Jeff Knappen, Spark Therapeutics	Brett McCabe, Aimmune
Chris DeSimone, Akcea Therapeutics	Scott Stepien, Ipsen
Suzanne Hensley, Xeris	Tom Telly, Ascendis
Doug Whiteman, EMD Serono	Dave Miley, Teva
Terry McCurren, Otsuka	Frances Bauman, Novo Nordisk
Jami Toole, Bayer	Melissa DuVall, Sobi
Roxann Domiguez, Abbvie	D.R. McCale, Akcea Therapeutics
Tara McKinley, Otsuka	Lisa Dunn, Amgen
Dan Joy, Boehringer Ingelheim	Amanda Chancey, Aimmune
Aaron Shaw, Boehringer Ingelheim	CT Hansen, Takeda
Burl Beasley, EGID Health Choice	John Omick, GBT
Shellie Keast, Mercer	Marc Parker, Sunovion
Kelli Amick, Alexion	Kimberly Rinard, Mylan
Lori Howarth, Bayer	Carrie Schaack, Pfizer
Amber Schrantz, Lilly	

PRESENT FOR PUBLIC COMMENT:	
Amanda Chancey	Aimmune
Doug Whiteman	EMD Serono
Tami Sova	Biogen
Jason Lurk	Novo Nordisk

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

1A: ROLL CALL

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

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO. 8 DOUG WHITEMAN

2B: AGENDA ITEM NO. 8 TAMI SOVA

2C: AGENDA ITEM NO. 9 JASON LURK
2D: AGENDA ITEM NO. 16 AMANDA CHANCEY
ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MEETING MINUTES
3A: MARCH 11, 2020 DUR MINUTES – VOTE
3B: MARCH 11, 2020 DUR RECOMMENDATIONS MEMORANDUM
3C: APRIL 8, 2020 DUR RECOMMENDATIONS MEMORANDUM
Materials included in agenda packet; presented by Dr. Muchmore
Dr. Broyles moved to approve; seconded by Dr. Munoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/PIPELINE UPDATE
4A: PHARMACY HELPDESK ACTIVITY FOR APRIL 2020
4B: MEDICATION COVERAGE ACTIVITY FOR APRIL 2020
4C: SPRING 2020 PIPELINE UPDATE
Materials included in agenda packet; presented by Dr. Adams, Dr. Van
ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE KATERZIA™ (AMLODIPINE ORAL SUSPENSION) AND CONJUPRI® (LEVAMLODIPINE TABLET)
5A: INTRODUCTION
5B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Van
Dr. Anderson moved to approve; seconded by Dr. Mitchell
ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE TEPEZZA™ (TEPROTUMUMAB-TRBW)
6A: INTRODUCTION
6B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Adams
Dr. Anderson moved to approve; seconded by Dr. Garton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE DAYVIGO™ (LEMBOREXANT)
7A: INTRODUCTION
7B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Adams
Dr. Broyles moved to approve; seconded by Dr. Garton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE MAYZENT® (SIPONIMOD), MAVENCLAD® (CLADRIBINE), AND VUMERITY® (DIROXIMEL FUMARATE)

8A: INTRODUCTION
8B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Nawaz
Dr. Broyles moved to approve; seconded by Dr. Munoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE QTERNMET® XR [DAPAGLIFLOZIN/SAXAGLIPTIN/METFORMIN EXTENDED-RELEASE (ER) TABLET], RIOMET ER™ (METFORMIN ER ORAL SUSPENSION), RYBELSUS® (SEMAGLUTIDE TABLET), AND TRIJARDY™ XR (EMPAGLIFLOZIN/LINAGLIPTIN/METFORMIN ER TABLET) AND UPDATE THE ANTI-DIABETIC MEDICATIONS PRIOR AUTHORIZATION CRITERIA
9A: INTRODUCTION
9B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Nawaz
Dr. Anderson moved to approve; seconded by Dr. Garton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE AYVAKIT™ (AVAPRITINIB), BYNFEZIA PEN™ (OCTREOTIDE), AND TAZVERIK™ (TAZEMETOSTAT)
10A: INTRODUCTION
10B: PRODUCT SUMMARIES
10C: RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Muchmore requested to add cabergoline to the approval criteria for Bynfezia Pen™ for the treatment of acromegaly; approval criteria was amended to read "Documentation of inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate or cabergoline at maximally tolerated doses"
Dr. Mitchell moved to approve; seconded by Dr. Broyles
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: VOTE TO PRIOR AUTHORIZE ALIQOPA™ (COPANLISIB), BRUKINSA™ (ZANUBRUTINIB), POLIVY™ (POLATUZUMAB VEDOTIN-PIIQ), AND RUXIENCE™ (RITUXIMAB-PVVR)
11A: INTRODUCTION
11B: PRODUCT SUMMARIES
11C: RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Garton moved to approve; seconded by Dr. Munoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: VOTE TO PRIOR AUTHORIZE PEMFEXY™ (PEMETREXED), ROZLYTREK® (ENTRECTINIB), AND ZIRABEV™ (BEVACIZUMAB-BVZR)
12A: INTRODUCTION

12B: PRODUCT SUMMARIES
12C: RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Munoz moved to approve; seconded by Dr. Broyles
ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: ANNUAL REVIEW OF BALVERSA™ (ERDAFITINIB)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF BALVERSA™ (ERDAFITINIB)
13C: PRIOR AUTHORIZATION OF BALVERSA™ (ERDAFITINIB)
13D: MARKET NEWS AND UPDATES
13E: RECOMMENDATIONS
Materials included in agenda packet; Non-presentation; Questions only
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: ANNUAL REVIEW OF THE SOONERCARE PHARMACY BENEFIT
14A: SUMMARY
14B: MEDICAID DRUG REBATE PROGRAM
14C: ALTERNATIVE PAYMENT MODELS
14D: DRUG APPROVAL TRENDS
14E: TRADITIONAL VERSUS SPECIALTY PHARMACY PRODUCTS
14F: TOP 10 THERAPEUTIC CLASSES BY REIMBURSEMENT
14G: TOP 10 MEDICATIONS BY REIMBURSEMENT
14H: COST PER CLAIM
14I: CONCLUSION
14J: TOP 50 REIMBURSED DRUGS BY FISCAL YEAR
14K: TOP 50 MEDICATIONS BY TOTAL NUMBER OF CLAIMS
14L: TOP 10 TRADITIONAL AND SPECIALTY THERAPEUTIC CATEGORIES BY FISCAL YEAR
Materials included in agenda packet; presented by Dr. Teel
ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: ANNUAL REVIEW OF GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS) AND 30-DAY NOTICE TO PRIOR AUTHORIZE ZIEXTENZO® (PEGFILGRASTIM-BMEZ)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF G-CSFS
15C: PRIOR AUTHORIZATION OF G-CSFS
15D: MARKET NEWS AND UPDATES
15E: COLLEGE OF PHARMACY RECOMMENDATIONS
15F: UTILIZATION DETAILS OF G-CSFS
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: **ANNUAL REVIEW OF ALLERGEN IMMUNOTHERAPIES AND 30-DAY NOTICE TO PRIOR AUTHORIZE PALFORZIA™ (PEANUT ALLERGEN POWDER-DNFP)**

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF ALLERGEN IMMUNOTHERAPIES
16C: PRIOR AUTHORIZATION OF ALLERGEN IMMUNOTHERAPIES
16D: MARKET NEWS AND UPDATES
16E: PALFORZIA™ (PEANUT ALLERGEN POWDER-DNFP) PRODUCT SUMMARY
16F: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Chandler

ACTION: NONE REQUIRED

AGENDA ITEM NO. 17: **ANNUAL REVIEW OF PARKINSON'S DISEASE (PD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE NOURIANZ™ (ISTRADEFYLLINE)**

17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF PD MEDICATIONS
17C: PRIOR AUTHORIZATION OF PD MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: NOURIANZ™ (ISTRADEFYLLINE) PRODUCT SUMMARY
17F: COLLEGE OF PHARMACY RECOMMENDATIONS
17G: UTILIZATION DETAILS OF PD MEDICATIONS

Materials included in agenda packet; presented by Dr. Nawaz

ACTION: NONE REQUIRED

AGENDA ITEM NO. 18: **ANNUAL REVIEW OF IDIOPATHIC PULMONARY FIBROSIS (IPF) MEDICATIONS**

18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF IPF MEDICATIONS
18C: PRIOR AUTHORIZATION OF IPF MEDICATIONS
18D: MARKET NEWS AND UPDATES
18E: COLLEGE OF PHARMACY RECOMMENDATIONS
18F: UTILIZATION DETAILS OF IPF MEDICATIONS

Materials included in agenda packet; presented by Dr. Van
Dr. Garton moved to approve; seconded by Dr. Munoz

ACTION: MOTION CARRIED

AGENDA ITEM NO. 19: **ANNUAL REVIEW OF ALDURAZYME® (LARONIDASE) AND NAGLAZYME® (GALSULFASE)**

19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF ALDURAZYME® (LARONIDASE) AND NAGLAZYME® (GALSULFASE)
19C: PRIOR AUTHORIZATION OF ALDURAZYME® (LARONIDASE) AND NAGLAZYME® (GALSULFASE)
19D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; Non-presentation; Questions only

ACTION: NONE REQUIRED

AGENDA ITEM NO. 20: **U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTRATION (DEA) UPDATES**

Materials included in agenda packet; presented by Dr. Adams

ACTION: NONE REQUIRED

AGENDA ITEM NO. 21: **FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)**

21A: ATTENTION DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS

21B: ATYPICAL ANTIPSYCHOTIC MEDICATIONS

21C: VARIOUS SPECIAL FORMULATIONS

21D: OPHTHALMIC ANTI-INFLAMMATORIES

**Future business subject to change.*

Materials included in agenda packet; Non-presentation; Questions only

ACTION: NONE REQUIRED

AGENDA ITEM NO. 22: **ADJOURNMENT**

The meeting was adjourned at 5:36pm.

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

Memorandum

Date: May 14, 2020

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

From: Brandy Nawaz, Pharm.D.
Clinical Pharmacist
Pharmacy Management Consultants

Subject: Drug Utilization Review (DUR) Board Recommendations from Meeting of May 13, 2020

Recommendation 1: Spring 2020 Pipeline Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Katerzia™ (Amlodipine Oral Suspension) and Conjupri® (Levamlodipine Tablet)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Calcium Channel Blocker (CCB) Antihypertensive Medications Product Based Prior Authorization (PBPA) category:

1. Moving Cardene® (nicardipine) from Tier-1 to Tier-2 of the CCB Antihypertensive Medications PBPA tier chart based on the National

Average Drug Acquisition Cost (NADAC). Current Tier-2 criteria will apply.

2. Placement of Katerzia™ (amlodipine oral suspension) and Conjupri® (levamlodipine tablet) into the Special Prior Authorization (PA) Tier of the CCB Antihypertensive Medications PBPA tier chart with the following criteria:

Katerzia™ (Amlodipine Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of hypertension or coronary artery disease; and
2. A patient-specific, clinically significant reason why the member cannot use amlodipine oral tablets, even when crushed, must be provided; and
3. A quantity limit of 300mL per 30 days will apply.

Conjupri® (Levamlodipine Tablet) Approval Criteria:

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

The recommended changes are shown in red in the following CCB PBPA Tier Chart:

Calcium Channel Blockers (CCBs)		
Tier-1	**Tier-2**	**Special PA**
amlodipine (Norvasc®)	amlodipine/atorvastatin (Caduet®)	amlodipine/celecoxib (Consensi™)
diltiazem (Cardizem®)	diltiazem LA (Cardizem® LA, Matzim® LA)	**amlodipine oral suspension (Katerzia™)**
diltiazem (Tiazac®, Taztia XT®)	diltiazem SR (Cardizem® SR)	diltiazem CD 360mg (Cardizem® CD)
diltiazem CD (Cardizem® CD)*	isradipine (Dynacirc®, Dynacirc CR®)	**levamlodipine (Conjupri®)**
diltiazem ER (Cartia XT®, Diltia XT®)	**nicardipine (Cardene®)**	
diltiazem XR (Dilacor® XR)	nicardipine SR (Cardene® SR)	
felodipine (Plendil®)	nisoldipine (Sular®)	
nifedipine (Adalat®, Procardia®)	verapamil (Covera-HS®)	
nifedipine ER (Adalat® CC)	verapamil ER (Verelan®, Verelan® PM)	
nifedipine XL (Nifedical XL®, Procardia XL®)		
nimodipine (Nimotop®)		

Calcium Channel Blockers (CCBs)		
Tier-1	**Tier-2**	**Special PA**
verapamil (Calan®, Isoptin®)		
verapamil SR (Calan® SR, Isoptin® SR)		

XR, XL, ER = extended-release; SR = sustained-release; LA = long-acting; CD = controlled-delivery; PA = prior authorization
*All strengths other than 360mg.

Recommendation 3: Vote to Prior Authorize Tepezza™ (Teprotumumab-trbw)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Tepezza™ (teprotumumab-trbw) with the following criteria with changes noted in red based on recommendations by the Drug Utilization Review (DUR) Board at the March 2020 DUR Board meeting:

Tepezza™ (Teprotumumab-trbw) Approval Criteria:

1. An FDA approved indication for the treatment of thyroid eye disease in adult members 18 years of age and older; and
    a. Member must be experiencing eye symptoms related to thyroid eye disease; and
    b. Member must have thyroid blood levels in the normal range or must be undergoing active treatment working toward normal range; and
2. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
3. Female members of reproductive potential must be willing to use effective contraception prior to initiation, during treatment with Tepezza™, and for at least 6 months after the last dose of Tepezza™; and
4. Member must not have had prior surgical treatment for thyroid eye disease; or
    a. A prior authorization request with patient-specific information may be submitted for consideration of Tepezza™ for members who have had prior surgical treatment for thyroid eye disease, including but not limited to patient-specific, clinically significant information regarding the member's prior surgery and the need for Tepezza™; and

5. Medical supervision by an ophthalmologist in conjunction with an endocrinologist for the treatment of thyroid eye disease; and
    a. The name of the ophthalmologist and endocrinologist recommending treatment with Tepezza™ must be provided on the prior authorization request; and
6. Tepezza™ must be administered as an intravenous (IV) infusion at the recommended infusion rate per package labeling, with appropriate pre-medication(s) based on the member's risk of infusion reactions; and
7. Tepezza™ must be administered by a health care professional. Prior authorization requests must indicate how Tepezza™ will be administered; and
    a. Tepezza™ must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Tepezza™ must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member (or the member's caregiver) must be trained on the proper storage of Tepezza™; and
8. The member's current weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
9. Approvals will be for a maximum of 8 total infusions.

Recommendation 4: Vote to Prior Authorize Dayvigo™ (Lemborexant)

MOTION CARRIED by unanimous approval.

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

1. Placement of Dayvigo™ (lemborexant) into Tier-3; current Tier-3 approval criteria will apply
2. Updating the current approval criteria for Hetlioz® (tasimelteon) based on current clinical practice guidelines for Non-24-Hour Sleep-Wake Disorder

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

PA = prior authorization; CR = controlled-release; SL = sublingual
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Unique dosage formulations require a special reason for use in place of Tier-1 formulations.
+Individual criteria specific to tasimelteon applies.

- Tier-1 medications are available without a prior authorization for all members older than 18 years of age.
- For members 18 years of age or younger, the prescriber will be required to submit a prior authorization for consideration.
- All medications have a quantity limit of 30 units per 30 days.

Insomnia Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. A minimum of a 30-day trial with at least 2 Tier-1 medications and clinical documentation of attempts to correct any primary cause for insomnia; and
3. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and
4. Approvals will be granted for the duration of 6 months.

Insomnia Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. A minimum of a 30-day trial with at least 2 Tier-1 medications and clinical documentation of attempts to correct any primary cause for insomnia; and
3. A minimum of a 30-day trial with at least 2 Tier-2 medications; and
    a. If only 1 Tier-2 medication is available, a minimum of a 30-day trial with 1 Tier-2 medication will be required; and
4. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and
5. Approvals will be granted for the duration of 6 months.

Hetlioz® (Tasimelteon) Approval Criteria:

1. An FDA approved diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24) confirmed by a sleep specialist; and
2. Member must be 18 years of age or older; and
~~3. Member must be totally blind; and~~
4. A failed trial of appropriately timed doses of melatonin; and
~~5. A failed trial of Rozerem® (ramelteon); and~~
6. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication; and
7. A quantity limit of 30 capsules for 30 days will apply.

Recommendation 5: Vote to Prior Authorize Mayzent® (Siponimod), Mavenclad® (Cladribine), and Vumerity® (Diroximel Fumarate)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Mayzent® (siponimod), Mavenclad® (cladribine), and Vumerity® (diroximel fumarate) with the following criteria:

Mayzent® (Siponimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; and
2. Member must have been assessed for CYP2C9 genotype:
    a. Members with a CYP2C9*3/*3 genotype will not generally be approved; or

   b. Members with a CYP2C9*1/*3 or *2/*3 genotype will not be approved for doses exceeding 1mg per day; or
   c. All other genotypes (CYP2C9*1/*1, *1/*2, or *2/*2) will be approved for 2mg per day; and
3. Member must not have any contraindication for use of siponimod including:
   a. CYP2C9*3/*3 genotype; or
   b. Experienced myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or class III/IV HF in the last 6 months; or
   c. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and
4. Member must not have received prior treatment with alemtuzumab; and
5. Verification from the prescriber that member has no active infection(s); and
6. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
7. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
8. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and
9. Verification from the prescriber that the member has been assessed for medications and conditions that cause reduction in heart rate (HR) or AV conduction delays and that the member will be followed with appropriate monitoring per package labeling; and
10. Verification from the prescriber that the member has been assessed for previous confirmed history of chickenpox or vaccination against varicella. Members without history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Mayzent®; and
11. Verification from the prescriber that members with sinus bradycardia (HR <55 beats per minute), first- or second-degree AV block (Mobitz type I), or a history of HF or MI will be monitored following the first dose for a minimum of 6 hours; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and

13. Female members of reproductive potential must be willing to use effective contraception during treatment with Mayzent® and for at least 10 days after discontinuing treatment; and
14. Member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; and
15. Compliance will be checked for continued approval every 6 months; and
16. Quantity limits according to package labeling will apply.

Mavenclad® (Cladribine) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include relapsing remitting disease and active secondary progressive disease in adults; and
2. Requests for use in patients with clinically isolated syndrome will not generally be approved; and
3. Member must have had at least 1 relapse in the previous 12 months; and
4. Member must have had an inadequate response to 2 or more medications indicated for the treatment of MS; and
5. Prescriber must confirm that the member does not have any contraindications for use of cladribine; and
6. Prescriber must confirm that the member does not have an active malignancy; and
7. Prescriber must confirm that females members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
8. Prescriber must attest that female and male members of reproductive potential plan to use effective contraception during cladribine dosing and for 6 months after the last dose in each treatment course; and
9. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
10. Verification from the prescriber that member has no active infection(s); and
11. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
12. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
13. Quantity limits according to package labeling will apply.

Vumerity® (Diroximel Fumarate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; and
2. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
3. Verification from the prescriber that member has no serious active infection(s); and
4. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
5. Serum aminotransferase, alkaline phosphatase, and total bilirubin levels and verification that levels are acceptable to the prescriber; and
6. Verification from the prescriber that member does not have moderate or severe renal impairment; and
7. Verification from the prescriber that the member has been counseled on proper administration of Vumerity® including caloric and fat intake limits at the time of dosing; and
8. Compliance will be checked for continued approval every 6 months; and
9. A quantity limit of 120 capsules per 30 days will apply.

Recommendation 6: Vote to Prior Authorize Qternmet® XR [Dapagliflozin/Saxagliptin/Metformin Extended-Release (ER) Tablet], Riomet ER™ (Metformin ER Oral Suspension), Rybelsus® (Semaglutide Tablet), and Trijardy™ XR (Empagliflozin/Linagliptin/Metformin ER Tablet) and Update the Anti-Diabetic Medications Prior Authorization Criteria

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Anti-Diabetic Medications Product Based Prior Authorization (PBPA) category:

1. Update the Anti-Diabetic Medications Approval Criteria as shown in red to reflect the recent FDA approved indications
2. Place Rybelsus® (semaglutide tablet) into Tier-3 of the Anti-Diabetic Medications PBPA category
    a. Current Tier-3 criteria will apply
3. Place Qternmet® XR (dapagliflozin/saxagliptin/metformin ER tablet), Riomet ER™ (metformin ER oral suspension), and Trijardy™ XR

(empagliflozin/linagliptin/metformin ER tablet) in the Special Prior Authorization (PA) Tier of the Anti-Diabetic Medications PBPA category
   a. Current Special PA Tier criteria will apply

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.
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 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 hospitalization for heart failure (HF) 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.

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 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.
3. 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 hospitalization for heart failure (HF) in

adults with T2DM and diabetic kidney disease. 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 hospitalization for HF in adults with T2DM and other CV risk factors. Tier structure rules for this indication will apply.

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 Bydureon® BCise™ (exenatide ER autoinjector pen) will require a patient-specific, clinically significant reason the member cannot use the vial or pen formulation.

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Alpha-Glucosidase Inhibitors			
acarbose (**Precose®**)		miglitol (**Glyset®**)	
Biguanides			
metformin (**Glucophage®**)			metformin ER (**Fortamet®**, **Glumetza®**)
metformin SR (**Glucophage XR®**)			metformin solution (**Riomet®**)
metformin/glipizide (**Metaglip®**)			**metformin ER suspension (Riomet ER™)**
metformin/ glyburide (**Glucovance®**)			
DPP-4 Inhibitors			
	linagliptin (**Tradjenta®**)	alogliptin (**Nesina®**)	linagliptin/metformin ER (**Jentadueto® XR**)
	linagliptin/ metformin (**Jentadueto®**)	alogliptin/ metformin (**Kazano®**)	

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	sitagliptin (**Januvia®**)	alogliptin/ pioglitazone (**Oseni®**)	
	sitagliptin/ metformin (**Janumet®**)	saxagliptin (**Onglyza®**)	
	sitagliptin/ metformin ER (**Janumet XR®**)	saxagliptin/ metformin (**Kombiglyze®**, **Kombiglyze XR®**)	
DPP-4/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			
	exenatide (**Byetta®**)	albiglutide (**Tanzeium™**)	exenatide ER autoinjector (**Bydureon® BCise™**)
	exenatide ER (**Bydureon®**)	dulaglutide (**Trulicity®**)	
	liraglutide (**Victoza®**)	lixisenatide (**Adlyxin®**)	
		semaglutide oral tablet (Rybelsus®)	
		semaglutide sub-Q injection (**Ozempic®**)	
GLP-1 Agonists/Insulin			

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
		insulin degludec/ liraglutide (**Xultophy® 100/3.6**)+	
		insulin glargine/ lixisenatide (**Soliqua® 100/33**)+	
SGLT-2 Inhibitors			
	dapaglifilozin (**Farxiga®**)	canagliflozin (**Invokana®**)	canagliflozin/metformin ER (**Invokamet® XR**)
	dapaglifilozin/ metformin ER (**Xigduo® XR**)	canagliflozin/ metformin (**Invokamet®**)	
	empagliflozin (**Jardiance®**)	ertugliflozin (**Steglatro™**)	
	empagliflozin/ metformin (**Synjardy®**)	ertugliflozin/metformin (**Segluromet™**)	
	empagliflozin/ metformin ER (**Synjardy® XR**)		
SGLT-2/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®**)			

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
tolbutamide (**Orinase®**)			
Thiazolidinediones			
pioglitazone (**Actos®**)		pioglitazone/ glimepiride (**Duetact®**)	
		pioglitazone/ metformin (**Actoplus Met®**, **Actoplus Met XR®**)	
		rosiglitazone (**Avandia®**)	
		rosiglitazone/ glimepiride (**Avandaryl®**)	
		rosiglitazone/ metformin (**Avandamet®**)	

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

Recommendation 7: Vote to Prior Authorize Ayvakit™ (Avapritinib), Bynfezia Pen™ (Octreotide), and Tazverik™ (Tazemetostat)

MOTION CARRIED by unanimous approval.

- The prior authorization of Ayvakit™ (avapritinib), Tazverik™ (tazemetostat), and Bynfezia Pen™ (octreotide) with the following criteria (changes noted in red based on recommendations from the DUR Board at the May DUR meeting):

Ayvakit™ (Avapritinib) Approval Criteria [Gastrointestinal Stromal Tumor (GIST) Diagnosis]:

1. A diagnosis of unresectable or metastatic GIST in adult members; and
2. Member has a *PDGFRA* exon 18 mutation (including *PDGFRA* D842V mutations).

Tazverik™ (Tazemetostat) Approval Criteria [Epithelioid Sarcoma Diagnosis]:

1. A diagnosis of metastatic or locally advanced epithelioid sarcoma; and
2. Member is not eligible for complete resection; and
3. Member must be 16 years of age or older.

Bynfezia Pen™ (Octreotide) Approval Criteria [Metastatic Carcinoid Tumor or Vasoactive Intestinal Peptide-Secreting Tumors (VIPoma) Diagnosis]:*

1. A diagnosis of advanced metastatic carcinoid tumor or VIPoma; and
2. Presence of severe diarrhea or flushing; and
3. A patient-specific, clinically significant reason why the member cannot use other available short-acting injectable formulations of octreotide must be provided.

Bynfezia Pen™ (Octreotide) Approval Criteria [Acromegaly Diagnosis]:*

1. A diagnosis of acromegaly; and
2. Documentation of inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate or cabergoline at maximally tolerated doses; and
3. A patient-specific, clinically significant reason why the member cannot use other available short-acting injectable formulations of octreotide must be provided.

[*The College of Pharmacy will monitor Bynfezia Pen™ (octreotide) pricing as it becomes available and assess prior authorization status based on cost-effectiveness compared to other available short-acting octreotide formulations.]

Recommendation 8: Vote to Prior Authorize Aliqopa™ (Copanlisib), Brukinsa™ (Zanubrutinib), Polivy™ (Polatuzumab Vedotin-piiq), and Ruxience™ (Rituximab-pvvr)

MOTION CARRIED by unanimous approval.

- Update the prior authorization criteria to reflect new FDA approved indications; changes can be seen in the following criteria listed in red (only criteria with updates are listed)
- The prior authorization of Aliqopa™ (copanlisib), Brukinsa™ (zanubrutinib), Polivy™ (polatuzumab vedotin-piiq), and Ruxience™ (rituximab-pvvr) with the following criteria listed in red

Aliqopa™ (Copanlisib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. A diagnosis of relapsed/refractory FL; and
2. Member must have failed at least 2 prior systemic therapies.

Brukinsa™ (Zanubrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. Adult members with a diagnosis of MCL; and
2. Member must have received at least 1 prior therapy.

Keytruda® (Pembrolizumab) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. A diagnosis of high-risk, NMIBC; and
2. Member must have failed therapy with Bacillus Calmette-Guerin (BCG)-therapy; and
3. Member must be ineligible for or has elected not to undergo cystectomy.

Polivy™ (Polatuzumab Vedotin-piiq) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) or High Grade B-Cell Lymphoma Diagnosis]:

1. Relapsed/refractory DLBCL or high grade B-cell lymphoma after at least 2 prior therapies; and
2. Used in combination with bendamustine and rituximab; and
3. Member is not a candidate for transplant.

Ruxience™ (Rituximab-pvvr) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Rituxan® (rituximab) must be provided.

Recommendation 9: Vote to Prior Authorize Pemfexy™ (Pemetrexed), Rozlytrek® (Entrectinib), and Zirabev™ (Bevacizumab-bvzr)

MOTION CARRIED by unanimous approval.

- The prior authorization of Pemfexy™ (pemetrexed), Rozlytrek® (entrectinib), and Zirabev™ (bevacizumab-bvzr) with the following criteria listed in red
- Updating the prior authorization criteria for Imfinzi® (durvalumab) and Tecentriq® (atezolizumab) to reflect new FDA approved indications;

changes and new criteria noted in red (only criteria with updates are listed)

Pemfexy™ (Pemetrexed) Approval Criteria:¥

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use Alimta® (pemetrexed) must be provided.

[¥The College of Pharmacy will monitor Pemfexy™ (pemetrexed) pricing as it becomes available and assess prior authorization status based on cost-effectiveness compared to Alimta® (pemetrexed).]

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

1. Diagnosis of metastatic NSCLC; and
2. *ROS1*-positive.

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

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

Zirabev™ (Bevacizumab-bvzr) Approval Criteria:

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

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

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

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

1. A diagnosis of non-squamous NSCLC; and
   a. First-line therapy for metastatic disease; and
   b. The member does not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) mutations; and

c. In combination with bevacizumab, paclitaxel, and carboplatin (maximum of 6 cycles) or in combination with paclitaxel (protein bound) and carboplatin; and
d. Atezolizumab and bevacizumab may be continued after the above combination in members without disease progression (applies to the bevacizumab/paclitaxel/ carboplatin regimen); or

2. A diagnosis of NSCLC; and
   a. Subsequent therapy for metastatic disease; and
   b. As a single-agent only.

Recommendation 10: Annual Review of Balversa™ (Erdafitinib)

NO ACTION REQUIRED.

Recommendation 11: Annual Review of the SoonerCare Pharmacy Benefit

NO ACTION REQUIRED.

Recommendation 12: Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and 30-Day Notice to Prior Authorize Ziextenzo® (Pegfilgrastim-bmez)

NO ACTION REQUIRED.

Recommendation 13: Annual Review of Allergen Immunotherapies and 30-Day Notice to Prior Authorize Palforzia™ (Peanut Allergen Powder-dnfp)

NO ACTION REQUIRED.

Recommendation 14: Annual Review of Parkinson's Disease (PD) Medications and 30-Day Notice to Prior Authorize Nourianz™ (Istradefylline)

NO ACTION REQUIRED.

Recommendation 15: Annual Review of Idiopathic Pulmonary Fibrosis (IPF) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Esbriet® (pirfenidone) and Ofev® (nintedanib) approval criteria to reflect the new FDA approved indications and updates in the prescribing information (changes shown in red):

Esbriet® (Pirfenidone) Approval Criteria:

1. An FDA approved diagnosis of idiopathic pulmonary fibrosis (IPF); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to the initiation of Esbriet®, monthly for the first 6 months of treatment, and every 3 months thereafter, and as clinically indicated; and
4. Medication must be prescribed by, or in consultation with, a pulmonologist or pulmonary specialist (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
5. A quantity limit of 270 capsules or tablets per 30 days will apply for the 267mg strength capsules and tablets, and a quantity limit of 90 tablets per 30 days will apply for the 801mg strength tablets.

Ofev® (Nintedanib) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Treatment of idiopathic pulmonary fibrosis (IPF); or
   b. Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype; or
   c. Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Ofev® treatment, at regular intervals during the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
4. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy and for at least 3 months after therapy completion; and
5. Medication must be prescribed by, or in consultation with, a pulmonologist or pulmonary specialist (or an advanced care

practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and

6. A quantity limit of 60 capsules per 30 days will apply.

Recommendation 16: Annual Review of Aldurazyme® (Laronidase) and Naglazyme® (Galsulfase)

NO ACTION REQUIRED.

Recommendation 17: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

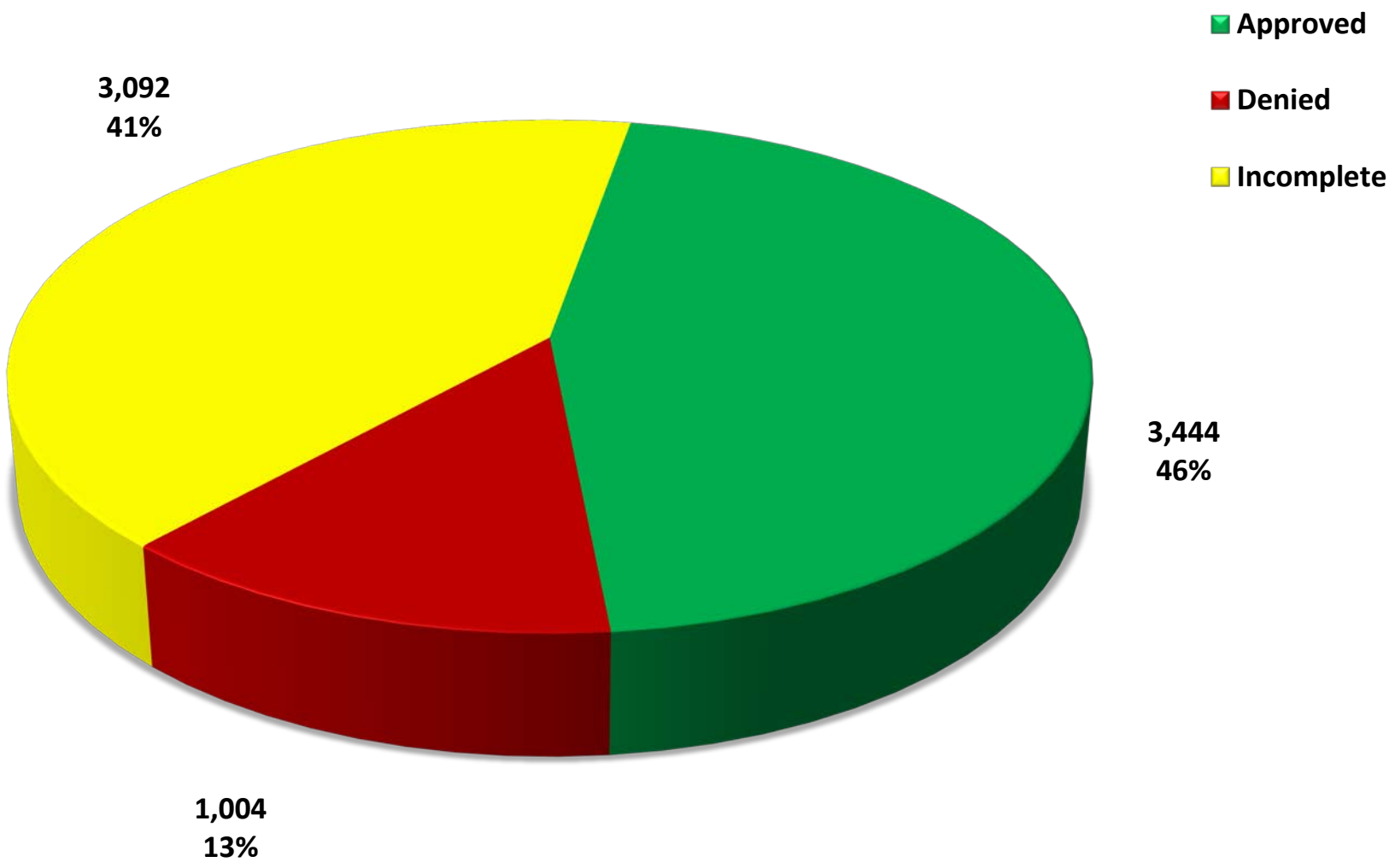
NO ACTION REQUIRED.

Recommendation 18: Future Business

NO ACTION REQUIRED.

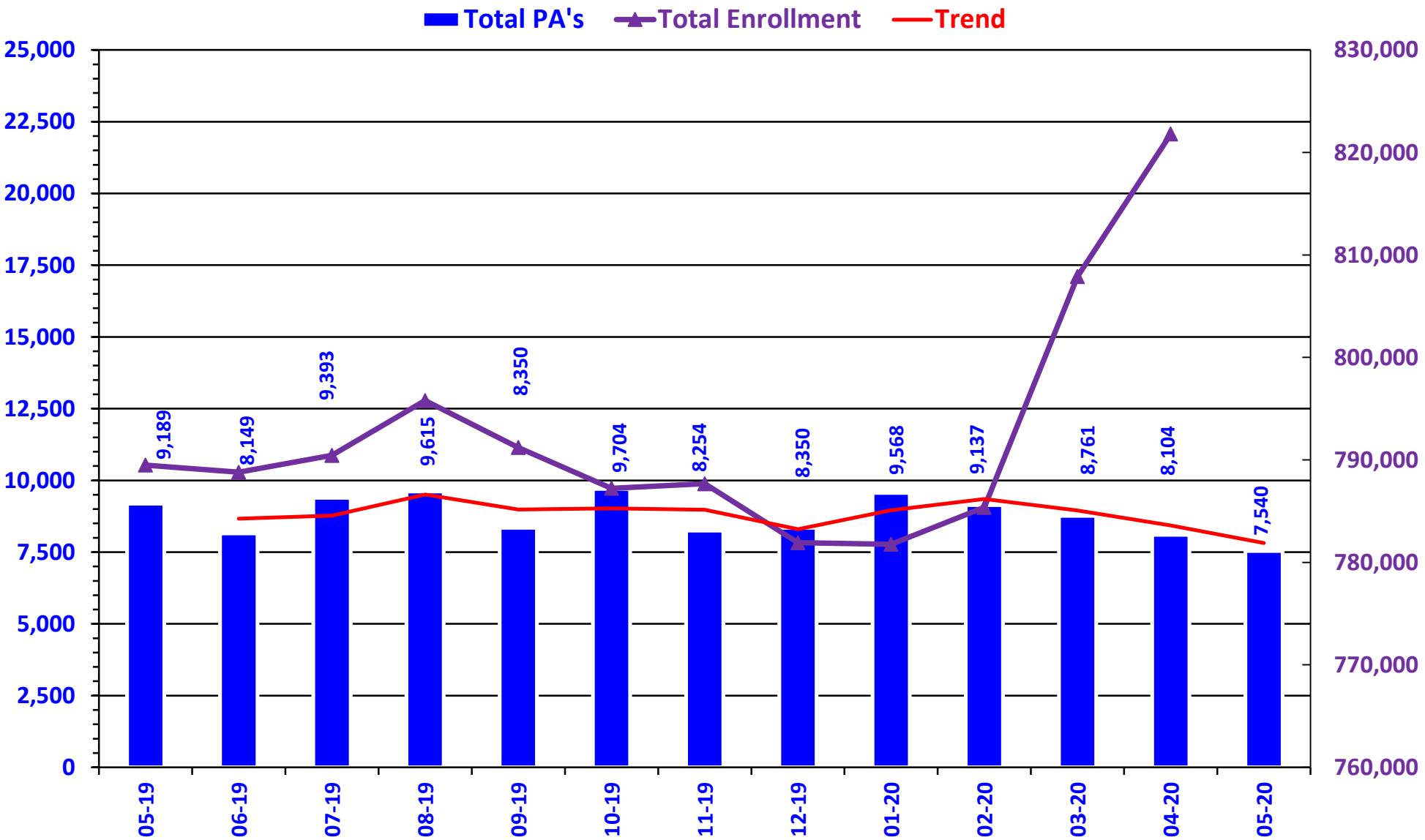
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: MAY 2020



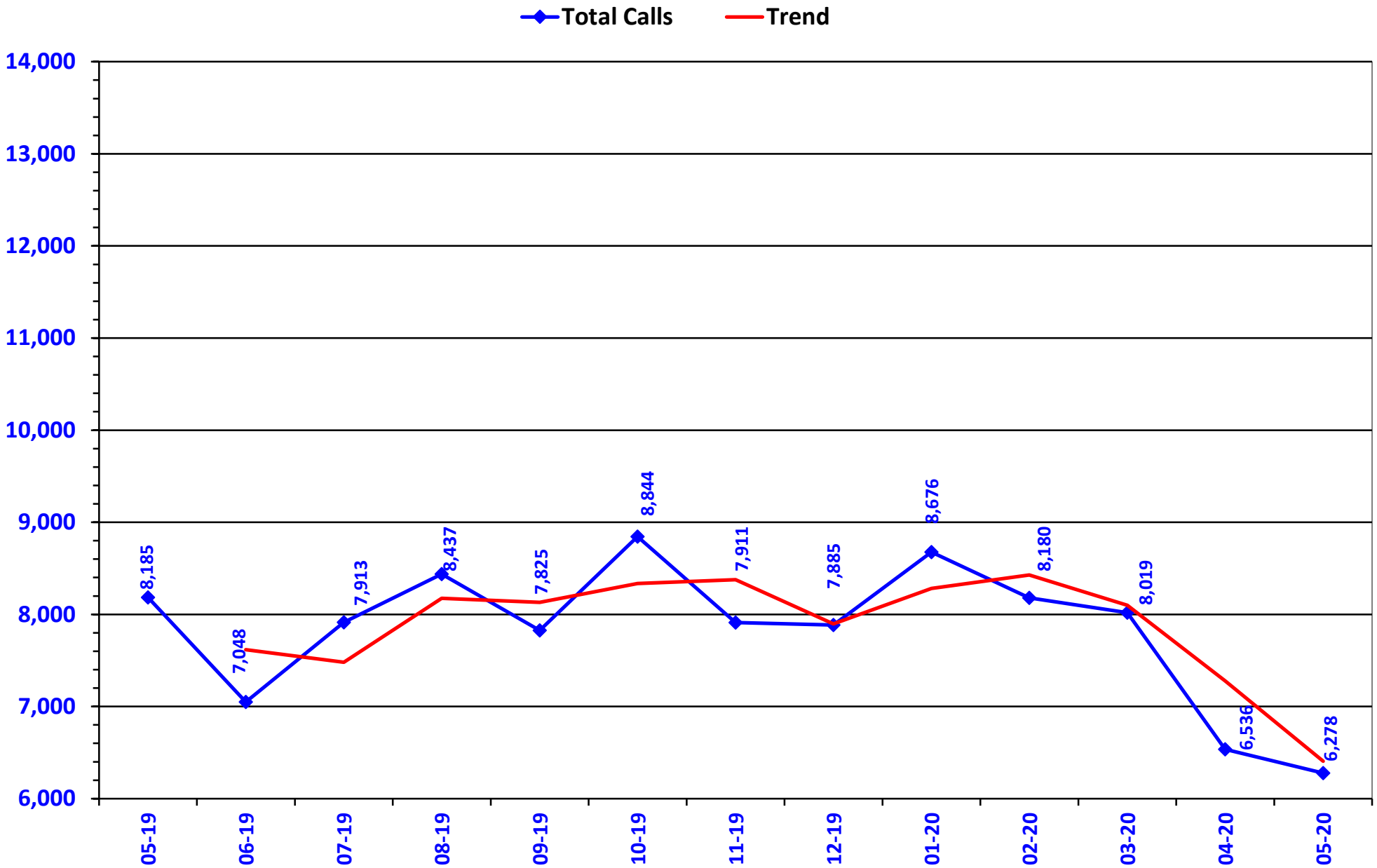
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: MAY 2019 – MAY 2020



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
MAY 2019 – MAY 2020



Prior Authorization Activity

5/1/2020 Through 5/31/2020

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	55	8	7	40	353
Analgesic - NonNarcotic	17	0	2	15	0
Analgesic, Narcotic	327	129	34	164	154
Angiotensin Receptor Antagonist	14	3	2	9	358
Antiasthma	81	9	22	50	299
Antibiotic	18	8	0	10	286
Anticonvulsant	112	49	3	60	292
Antidepressant	171	43	25	103	340
Antidiabetic	264	79	37	148	358
Antihemophilic Factor	13	8	0	5	238
Antihistamine	24	8	5	11	288
Antimalarial Agent	101	76	6	19	337
Antimigraine	178	37	71	70	177
Antineoplastic	88	48	8	32	169
Antiparasitic	16	2	3	11	16
Antiulcers	84	16	22	46	146
Anxiolytic	18	5	0	13	154
Atypical Antipsychotics	288	128	34	126	358
Biologics	157	78	19	60	294
Bladder Control	53	10	20	23	358
Blood Thinners	275	145	24	106	334
Botox	30	16	9	5	294
Buprenorphine Medications	57	8	3	46	69
Calcium Channel Blockers	13	2	2	9	191
Cardiovascular	67	26	8	33	313
Chronic Obstructive Pulmonary Disease	100	13	36	51	293
Constipation/Diarrhea Medications	125	20	40	65	198
Contraceptive	22	14	1	7	316
Dermatological	263	78	67	118	124
Diabetic Supplies	659	352	53	254	237
Endocrine & Metabolic Drugs	93	52	10	31	178
Erythropoietin Stimulating Agents	10	8	0	2	109
Fibromyalgia	16	0	3	13	0
Fish Oils	18	2	11	5	360
Gastrointestinal Agents	118	31	29	58	230
Genitourinary Agents	23	10	3	10	91
Growth Hormones	156	92	10	54	118
Hematopoietic Agents	20	8	2	10	289
Hepatitis C	85	52	6	27	9
HFA Rescue Inhalers	19	0	7	12	0
Insomnia	60	3	22	35	269
Insulin	119	29	14	76	358
Miscellaneous Antibiotics	10	0	1	9	0
Multiple Sclerosis	18	8	6	4	217
Muscle Relaxant	35	8	7	20	121
Nasal Allergy	70	12	23	35	130
Neurological Agents	69	29	9	31	235
NSAIDs	29	3	6	20	153
Ocular Allergy	34	1	15	18	86
Osteoporosis	2	2	0	0	360

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Otic Antibiotic	17	2	6	9	26
Pediculicide	22	4	5	13	18
Respiratory Agents	57	30	1	26	190
Statins	21	4	8	9	243
Stimulant	518	245	46	227	346
Testosterone	44	10	13	21	329
Topical Antifungal	19	4	2	13	61
Topical Corticosteroids	75	1	30	44	360
Vitamin	65	15	34	16	241
Pharmacotherapy	62	59	0	3	253
Emergency PAs	0	0	0	0	
Total	**5,845**	**2,200**	**937**	**2,708**	
Overrides					
Brand	32	14	0	18	171
Compound	10	8	1	1	7
Cumulative Early Refill	1	1	0	0	4
Diabetic Supplies	11	11	0	0	136
Dosage Change	381	352	2	27	13
High Dose	5	4	0	1	90
Ingredient Duplication	9	8	0	1	72
Lost/Broken Rx	100	96	2	2	20
MAT Override	226	188	1	37	73
NDC vs Age	235	134	29	72	206
NDC vs Sex	5	5	0	0	71
Nursing Home Issue	35	30	0	5	8
Opioid MME Limit	103	38	2	63	141
Opioid Quantity	31	22	1	8	160
Other*	53	44	4	5	20
Quantity vs. Days Supply	400	243	23	134	237
STBS/STBSM	14	12	0	2	104
Stolen	5	5	0	0	20
Third Brand Request	38	29	2	7	59
Wrong D.S. on Previous Rx	1	0	0	1	0
Overrides Total	**1,695**	**1,244**	**67**	**384**	
Total Regular PAs + Overrides	**7,540**	**3,444**	**1,004**	**3,092**	

Denial Reasons	
Unable to verify required trials.	2,454
Does not meet established criteria.	1,040
Lack required information to process request.	604
Other PA Activity	
Duplicate Requests	770
Letters	11,588
No Process	5
Changes to existing PAs	553
Helpdesk Initiated Prior Authorizations	624
PAs Missing Information	18

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

Use of Angiotensin Converting Enzyme Inhibitor (ACEI)/Angiotensin Receptor Blocker (ARB)/ Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy in Patients with Chronic Heart Failure (HF) Mailing Update

Oklahoma Health Care Authority
June 2020

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

The 2017 American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America (ACC/AHA/HFSA) updated the 2013 guideline for the management of HF. They reinforced the importance of prescribing ACEIs, ARBs, or ARNIs in conjunction with beta blockers and aldosterone antagonists in chronic HF patients with reduced ejection fraction (HF*r*EF) (EF ≤40%) to reduce morbidity and mortality. The guideline supports the following recommendations:

- **ACEIs and ARBs should be prescribed for patients with prior or current symptoms of chronic HF*r*EF to reduce morbidity and mortality.**
  - ACEIs and ARBs should be started at low doses and titrated upward to doses shown to reduce the risk of cardiovascular (CV) events in clinical trials.
  - If maximal doses are not tolerated, intermediate doses should be tried; abrupt withdrawal of ACEIs and ARBs can lead to clinical deterioration and should be avoided.
- **In patients with chronic symptomatic HF*r*EF New York Heart Association (NYHA) class II or III who tolerate an ACEI or ARB, replacement by an ARNI is recommended to further reduce morbidity and mortality.**
  - In patients not currently taking ACEIs or ARBs or in patients with severe renal impairment or moderate hepatic impairment, an ARNI should be started at a lower than usual recommended dose and titrated upward, with an attempt to use doses shown to reduce the risk of CV events in clinical trials.

- **Cautions:**
  - Patients should not be given ACEIs, ARBs, or ARNIs if they are pregnant or plan to become pregnant.
  - ACEIs, ARBs, and ARNIs should be given with caution to patients with low systemic blood pressure, renal insufficiency, or elevated serum potassium (>5.0mEq/L).
  - ARNIs should not be administered concomitantly with ACEIs or within 36 hours of an ACEI.
  - ARNIs should not be administered to patients with a history of angioedema related to previous ACEI or ARB therapy or in patients with hereditary angioedema. Angioedema occurs more frequently in African Americans and women.

ACEI/ARB/ARNI Therapy in Patients with Chronic HF Mailing Summary

In January 2020, the College of Pharmacy (COP) and the Oklahoma Health Care Authority (OHCA) sent an educational letter to 132 providers of 152 unique members who had a diagnosis of chronic HF and who were not receiving treatment with an ACEI, ARB, or ARNI based on their SoonerCare pharmacy claims history. The purpose of the educational mailing was to encourage providers to evaluate evidence-based prescribing practices for SoonerCare members with chronic HF and determine if they may benefit from therapy with an ACEI, ARB, or ARNI. Providers were selected for this mailing if they were the most recent prescriber for at least 1 patient with a diagnosis of chronic HF in the last year, but without any pharmacy claims for an ACEI, ARB, or ARNI through SoonerCare Pharmacy Services. The letter included information on the current guidelines and a list of the provider's members identified in the claims analysis to evaluate for treatment with an ACEI, ARB, or ARNI based on clinical guidelines.

ACEI/ARB/ARNI Therapy in Patients with Chronic HF Mailing Results

In May 2020, 4 months after the letters were sent out, a second claims analysis was performed. The claims analysis found that 12 members (7.9%) included in the mailing had paid claims for an ACEI, ARB, or ARNI after the letter was sent. There were 12 different providers who received letters regarding the 12 members recently started on an ACEI, ARB, or ARNI. The 12 providers' letters included a total of 17 unique SoonerCare members combined (11.2%), resulting in those members having been potentially evaluated to determine appropriate therapy. Many of the ACEIs and ARBs are

relatively inexpensive; therefore, some members may be paying cash for these medications due to their monthly prescription limit. Pharmacy claims not billed to SoonerCare (e.g., cash claims, private insurance) are not included in the claims analyses.

Conclusions

Although only a moderate increase was observed in the second claims analysis, there was a trend showing that the identified members were potentially being evaluated for appropriate therapy. The purpose of this mailing was not to see all of the members started on ACEI, ARB, or ARNI therapy, but rather to ensure the providers were reviewing these members for appropriate therapy. The COP will continue to work with the OHCA to improve educational mailings with the goal of improving the quality of care for SoonerCare members with chronic HF. New interventions will be implemented where appropriate, and results will be reported to the Drug Utilization Review (DUR) Board when available.

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[1] Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. *J Am Coll Cardiol* 2017; 70(6):776. doi:10.1016/j.jacc.2017.04.025.

[2] Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2013; 62:e147-e239.

[3] Entresto® (Sacubitril/Valsartan) Prescribing Information. Novartis Pharmaceuticals Corporation. Available online at: https://www.novartis.us/sites/www.novartis.us/files/entresto.pdf. Last revised 10/2019. Last accessed 05/20/2020.

[4] Bullo M, Tschumi S, Bucher BS, et al. Pregnancy Outcome Following Exposure to Angiotensin-Converting Enzyme Inhibitors or Angiotensin Receptor Antagonists: A Systematic Review. *Hypertension* 2012; 60(2):444-450.

[5] Einhorn LM, Zhan M, Hsu VD, et al. The Frequency of Hyperkalemia and Its Significance in Chronic Kidney Disease. *Arch Intern Med* 2009; 169:1156-1162.

[6] Woodard-Grice AV, Lucisano AC, Byrd JB, et al. Sex-Dependent and Race-Dependent Association of XPNPEP2 C-2399A Polymorphism with Angiotensin-Converting Enzyme Inhibitor-Associated Angioedema. *Pharmacogenet Genomics* 2010; 20:532-536.

[7] Packer M, Califf RM, Konstam MA, et al. Comparison of Omapatrilat and Enalapril in Patients with Chronic Heart Failure: The Omapatrilat Versus Enalapril Randomized Trial of Utility in Reducing Events (OVERTURE). *Circulation* 2002; 106:920–926.

Appendix C

Vote to Prior Authorize Ziextenzo® (Pegfilgrastim-bmez)

Oklahoma Health Care Authority
June 2020

Introduction[1,2,3]

Ziextenzo® (pegfilgrastim-bmez) was approved by the U.S. Food and Drug Administration (FDA) in November 2019 as a biosimilar to Neulasta® (pegfilgrastim). Ziextenzo® is indicated for the prophylaxis of febrile neutropenia in patients with non-myeloid malignancies who receive myelosuppressive chemotherapy. Neulasta® was first FDA approved in 2002 and is also indicated for hematopoietic subsyndrome of acute radiation syndrome, in addition to the above listed indication for the prophylaxis of febrile neutropenia. Pegfilgrastim is a pegylated derivative of filgrastim and has a longer elimination half-life compared to filgrastim. Ziextenzo® has been approved and marketed in Europe since 2018.

Recommendations

The College of Pharmacy recommends the prior authorization of Ziextenzo® (pegfilgrastim-bmez) with the following criteria (changes shown in red):

Fulphila® (Pegfilgrastim-jmdb), Udenyca™ (Pegfilgrastim-cbqv), and Ziextenzo® (Pegfilgrastim-bmez) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Neulasta® (pegfilgrastim) or Neupogen® (filgrastim) must be provided.

[1] Novartis. Sandoz Receives U.S. FDA Approval for Long-Acting Oncology Supportive Care Biosimilar Ziextenzo® (Pegfilgrastim-bmez). Available online at: https://www.novartis.com/news/media-releases/sandoz-receives-us-fda-approval-long-acting-oncology-supportive-care-biosimilar-ziextenzo-pegfilgrastim-bmez. Issued 11/05/2019. Last accessed 05/20/2020.

[2] Ziextenzo® (Pegfilgrastim-bmez) Prescribing Information. Novartis. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7dada041-6528-4acf-809c-62d271538c9a. Last revised 11/11/2019. Last accessed 05/20/2020.

[3] Neulasta® (Pegfilgrastim) Prescribing Information. Amgen. Available online at: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/neulasta/neulasta_pi_hcp_english.pdf. Last revised 01/2020. Last accessed 05/20/2020.

Appendix D

Vote to Prior Authorize Palforzia™ (Peanut Allergen Powder-dnfp)

Oklahoma Health Care Authority
June 2020

Introduction[1,2]

- **Palforzia™ (Peanut Allergen Powder-dnfp):** Palforzia™ was approved by the U.S. Food and Drug Administration (FDA) in January 2020 as an oral immunotherapy for the mitigation of allergic reactions, including anaphylaxis, which may occur with accidental exposure to peanut. Palforzia™ is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial dose escalation may be administered to patients 4 through 17 years of age. Up-dosing and maintenance may be continued in patients 4 years of age and older. Palforzia™ is to be used in conjunction with a peanut-avoidant diet. Palforzia™ is supplied as 0.5mg, 1mg, 10mg, 20mg, and 100mg capsules or 300mg sachets containing powder for oral administration. The capsule or sachet should be opened and the entire contents emptied into a few spoonfuls of refrigerated or room temperature semisolid food (e.g., applesauce, yogurt, pudding), mixed well, and the entire prepared mixture consumed promptly. The capsules should not be swallowed nor the powder inhaled. Treatment with Palforzia™ is administered in 3 sequential phases: initial dose escalation (single-day dosing), up-dosing [(11) 2-week intervals], and maintenance. It is recommended that the patient progresses through each level of the initial dose escalation and up-dosing, and then begin maintenance dosing of 300mg daily. The patient should be observed after each dose increase in accordance with the *Prescribing Information*. Palforzia™ is contraindicated in patients with uncontrolled asthma and a history of eosinophilic esophagitis and other eosinophilic gastrointestinal (GI) disease. Palforzia™ has a *Boxed Warning* for anaphylaxis, which may be life-threatening and can occur at any time during Palforzia™ therapy. Injectable epinephrine should be prescribed, and patients should be instructed and trained on its appropriate use. Dose modifications may be necessary following an anaphylactic reaction. Because of the risk of anaphylaxis, Palforzia™ is available only through the Palforzia™ Risk Evaluation and Mitigation

Strategy (REMS) program. The Wholesale Acquisition Cost (WAC) of the initial dose escalation kit is $30.03 which includes 13 capsules of various strengths for dosing of levels A through E and is administered in a single day (day 1 of treatment). The WAC for the up-dosing kits ranges from $444.60 to $445.20 (per 2-week supply), with an estimated total cost to complete the 11 levels of up-dosing of $4,895.10. The WAC for the maintenance dose kit is $890.10 per 30-day supply, resulting in an annual maintenance dose cost of $10,681.20.

- **Montelukast *Boxed Warning*:** In March 2020, the FDA required a *Boxed Warning* for montelukast (sold under the brand name Singulair® and in generic form) to strengthen an existing warning about the risk of neuropsychiatric events associated with the drug, which is used to treat asthma and allergic rhinitis. The warning follows the FDA's review of available data regarding continued reports of neuropsychiatric events with montelukast, such as agitation, depression, sleeping problems, and suicidal thoughts and actions. The *Boxed Warning* advises health care providers to avoid prescribing montelukast for patients with mild symptoms, particularly those with allergic rhinitis. The FDA determined the risks of montelukast may outweigh the benefits in some patients, particularly when the symptoms of the disease are mild and can be adequately treated with alternative therapies

Recommendations

The College of Pharmacy recommends the prior authorization of Palforzia™ (peanut allergen powder-dnfp) with the following criteria (additions to clarify approval duration are shown in red):

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

1. Member must be 4 to 17 years of age to initiate initial dose escalation (maintenance dosing may be continued for members 4 years of age and older); and
2. Member must have a diagnosis of peanut allergy confirmed by a positive skin test, positive *in vitro* test for peanut-specific IgE, or positive clinician-supervised oral food challenge; and
3. Prescriber must confirm member will use Palforzia™ with a peanut-avoidant diet; and
4. Member must not have severe uncontrolled asthma; and

5. Member must not have a history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and
6. Member must not have had severe or life-threatening anaphylaxis within the previous 60 days; and
7. Member or caregiver must be trained in the use of an auto-injectable epinephrine device and have such a device available for immediate use at all times; and
8. Prescriber must be an allergist, immunologist, or be an advanced care practitioner with a supervising physician that is an allergist or immunologist; and
9. Prescriber, health care setting, and pharmacy must be certified in the Palforzia™ Risk Evaluation and Mitigation Strategy (REMS) program; and
10. Member must be enrolled in the Palforzia™ REMS program; and
11. Palforzia™ must be administered under the direct observation of a health care provider in a REMS certified health care setting with an observation duration in accordance with the prescribing information; and
12. After successful completion of initial dose escalation and all levels of up-dosing as documented by the prescriber, initial approvals of maintenance dosing will be for 6 months. For continued approval, the member must be compliant and prescriber must verify the member is responding well to treatment.

Additionally, the College of Pharmacy recommends updating the current Allergen Immunotherapies approval criteria to remove the montelukast trial requirement based on the recent FDA *Boxed Warning* (changes are shown in red):

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

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test (labs required) or *in vitro* testing for pollen specific IgE antibodies for Timothy grass or cross-reactive grass pollen (cool season grasses); and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and

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

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

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific IgE antibodies to 1 of the 5 grass pollens contained in Oralair®; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):

a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
~~b. **Montelukast:** (1) 14-day trial during a previous season in combination with an antihistamine; and~~
c. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and

6. Treatment must begin ≥16 weeks prior to the start of the grass pollen season (October 15th) and continue throughout the season; and
7. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 16 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
11. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
12. Prescriber must be an allergist, immunologist, or be an advanced care practitioner with a supervising physician that is an allergist or immunologist.

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

1. Member must be 18 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific IgE antibodies to short ragweed pollen; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
   a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
   ~~b. **Montelukast:** (1) 14-day trial during a previous season in combination with an antihistamine; and~~

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

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

1. Member must be 18 to 65 years of age; and
2. Member must have a positive skin test (labs required) to licensed house dust mite allergen extracts or *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
   a. **Antihistamines:** Trials of 2 different products for 14 days each; and
   ~~b. **Montelukast:** (1) 14-day trial in combination with an antihistamine; and~~
   c. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each; and
6. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and

7. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as “allergy shots”; and
8. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
9. Prescriber must be an allergist, immunologist, or be an advanced care practitioner with a supervising physician that is an allergist or immunologist; and
10. A quantity limit of 1 tablet daily will apply; and
11. Initial approvals will be for the duration of 6 months of therapy, at which time the prescriber must verify the patient is responding well to Odactra® therapy. Additionally, compliance will be evaluated for continued approval.

*Current prior authorization criteria is only applicable to allergen immunotherapies with a current federal drug rebate agreement. All criteria, regardless of coverage, are provided in this report for informational purposes.

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[1] Palforzia™ Prescribing Information. Aimmune Therapeutics. Available online at: https://www.palforzia.com/static/pi_palforzia.pdf. Last revised 01/2020. Last accessed 05/11/2020.
[2] U.S. Food and Drug Administration (FDA). FDA Requires *Boxed Warning* About Serious Mental Health Side Effects for Asthma and Allergy Drug Montelukast (Singulair); Advises Restricting Use for Allergic Rhinitis. Available online at: https://www.fda.gov/drugs/fda-requires-boxed-warning-about-serious-mental-health-side-effects-asthma-and-allergy-drug. Issued 03/11/2020. Last accessed 05/11/2020.

Appendix E

Vote to Prior Authorize Nourianz™ (Istradefylline Tablet)

Oklahoma Health Care Authority
June 2020

Introduction[1,2]

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

- **Nourianz™ (Istradefylline Tablet):** In August 2019, the FDA approved Nourianz™ (istradefylline tablet) as an add-on treatment to carbidopa/levodopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes. An "off" episode is a time when a patient's medications are not working well, causing an increase in PD symptoms, such as tremor and difficulty walking. Nourianz™ is available as a 20mg and 40mg oral tablet that may be taken with or without food. The recommended dosage of Nourianz™ is 20mg once daily and may be increased to a maximum of 40mg once daily. The maximum recommended dosage in patients with moderate hepatic impairment is 20mg once daily. Use of Nourianz™ in patients with severe hepatic impairment should be avoided. For patients who smoke ≥20 cigarettes per day (or the equivalent of another tobacco product), the recommended dosage is 40mg once daily. The effectiveness of Nourianz™ was shown in (4) 12-week, placebo-controlled, clinical studies that included a total of 1,143 patients. In all 4 studies, patients treated with Nourianz™ experienced a statistically significant decrease from baseline in daily "off" time compared to patients receiving placebo. The most common adverse reactions observed in patients taking Nourianz™ were dyskinesia, dizziness, constipation, nausea, hallucination, and insomnia. Patients taking Nourianz™ should be monitored for the development of dyskinesia or exacerbation of existing dyskinesia. If hallucinations, psychotic behavior, or impulsive/compulsive behavior occurs, a dosage reduction or discontinuation of Nourianz™ should be considered. Use of Nourianz™ during pregnancy is not recommended. Women of childbearing potential should be advised to use contraception during treatment with Nourianz™. The annual cost of once daily Nourianz™ is $18,000.00 for either the 20mg or 40mg strength.

Recommendations

The College of Pharmacy recommends the prior authorization of Nourianz™ (istradefylline tablet) with the following criteria:

Nourianz™ (Istradefylline Tablet) Approval Criteria:

1. An FDA approved diagnosis of Parkinson's disease (PD); and
2. Member must be taking carbidopa/levodopa in combination with istradefylline (istradefylline has not been shown to be effective as monotherapy for the treatment of PD); and
3. Prescriber must verify that the dose is appropriate for the member based on degree of hepatic impairment, concomitant strong CYP3A4 inhibitors, and smoking status of the member; and
4. Member must be experiencing at least 2 hours of "off" time per day; and
5. A quantity limit of 1 tablet per day will apply.

[1] U.S. Food and Drug Administration (FDA) News Release. FDA Approves New Add-On Drug to Treat off Episodes in Adults with Parkinson's Disease. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-new-add-drug-treat-episodes-adults-parkinsons-disease. Issued 08/27/2019. Last accessed 05/20/2020.

[2] Nourianz™ Prescribing Information. Kyowa Kirin, Inc. Available online at: https://nourianz.com/assets/pdf/nourianz-full-prescribing-information.pdf. Last revised 08/2019. Last accessed 05/20/2020.

Appendix F

Calendar Year 2019 Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Secuado® (Asenapine Transdermal System) and Caplyta™ (Lumateperone Capsule)

Oklahoma Health Care Authority
June 2020

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®)	brexpiprazole (Rexulti®)
aripiprazole lauroxil IM inj (Aristada®)		cariprazine (Vraylar®)
aripiprazole lauroxil IM inj (Aristada Initio®)		clozapine (Fazaclo®)+
clozapine (Clozaril®)◊		clozapine oral susp (Versacloz®)+
olanzapine (Zyprexa®)		iloperidone (Fanapt®)
paliperidone IM inj (Invega Sustenna®)		olanzapine/fluoxetine (Symbyax®)^
paliperidone IM inj (Invega Trinza®)**		paliperidone (Invega®)
quetiapine (Seroquel®)		
quetiapine ER (Seroquel XR®)		
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), or Wholesale Acquisition Costs (WAC) if NADAC unavailable. Placement of products shown in blue is based on net cost after 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.

Approval Criteria for Atypical Antipsychotic Medications as Adjunctive Treatment for 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.

Medicaid Drug Rebate Program[1,2,3]

Medicaid coverage of a drug requires the manufacturer to have a federal rebate agreement with the Secretary of Health and Human Services (HHS). 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 payer. Best prices

are reported to the Centers for Medicare and Medicaid Services (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. As average wholesale price (AWP) increases, the rebated amount per unit (RAPU) increases as well, resulting in minimal effect on Medicaid net cost.

Additionally, many states have negotiated supplemental rebate agreements with manufacturers to produce added rebates. The Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) category is heavily influenced by supplemental rebates. In calendar year 2019, the Oklahoma Health Care Authority (OHCA) collected $33,598,409.73 in aggregate drug rebates for atypical antipsychotic medications. 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.

Utilization of Atypical Antipsychotic Medications: Calendar Year 2019

Comparison of Calendar Years: Atypical Antipsychotic Medications

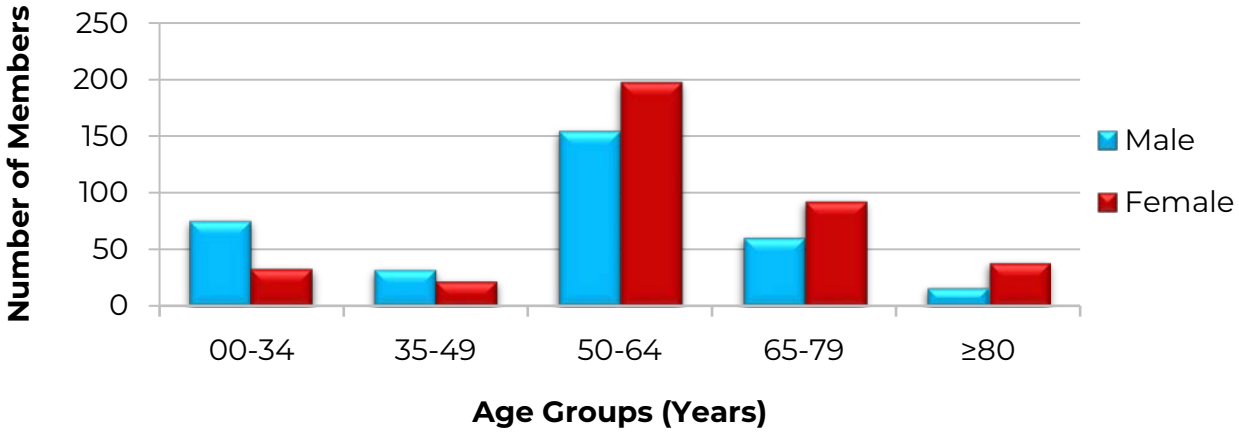
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	27,071	191,614	$44,746,109.64	$233.52	$7.47	7,626,999	5,987,601
2019	27,134	193,721	$50,756,273.76	$262.01	$8.29	7,680,177	6,120,337
% Change	**0.20%**	**1.10%**	**13.40%**	**12.20%**	**11.00%**	**0.70%**	**2.20%**
Change	**63**	**2,107**	**$6,010,164.12**	**$28.49**	**$0.82**	**53,178**	**132,736**

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

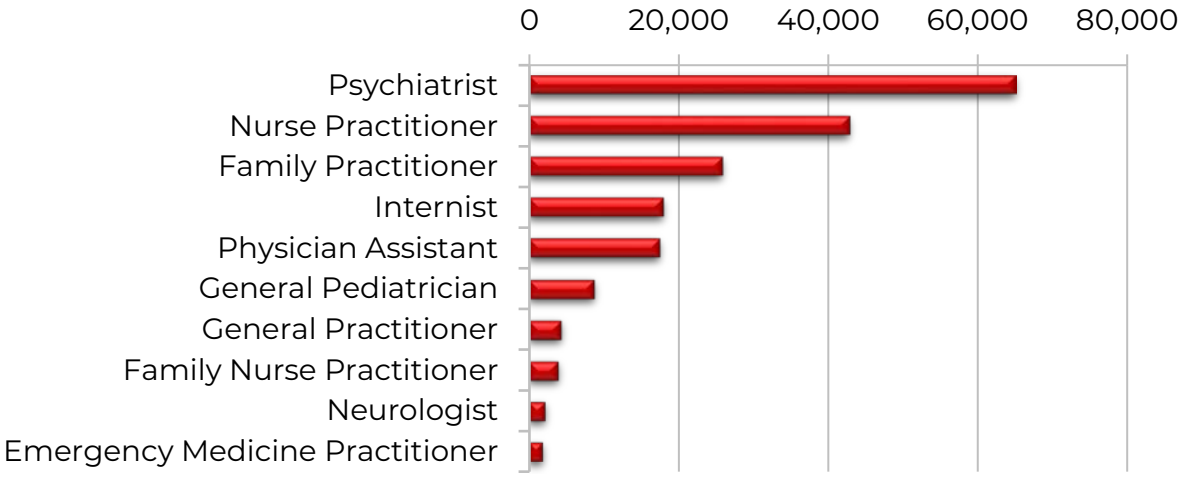
- Aggregate drug rebates collected during calendar year 2019 for atypical antipsychotic medications: $33,598,409.73[Δ]

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

Demographics of Members Utilizing Atypical Antipsychotic Medications



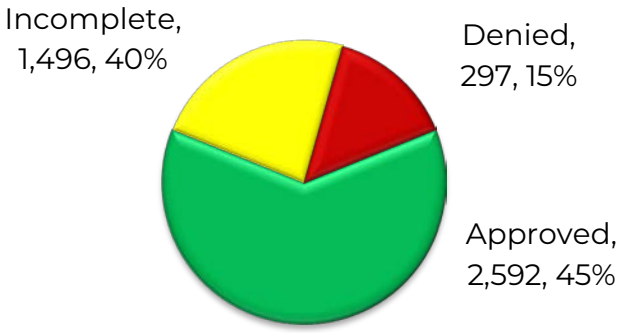
Top Prescriber Specialties of Atypical Antipsychotic Medications by Number of Claims



Prior Authorization of Atypical Antipsychotic Medications

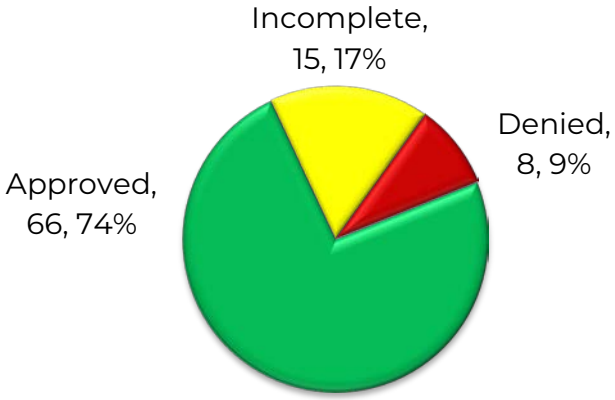
There were 4,385 prior authorization requests submitted for atypical antipsychotic medications during calendar year 2019. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2019.

Status of Petitions



There were 89 prior authorization requests submitted for a total of 68 unique members for atypical antipsychotic medications during calendar year 2019 that were referred for a psychiatric consultation. Most requests were for children 3 and 4 years of age. The following chart shows the status of the submitted petitions that were referred for a psychiatric consultation for calendar year 2019.

Status of Psychiatric Consultations



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

Anticipated Patent Expiration(s):

- Risperdal Consta® [risperidone intramuscular (IM) injection]: November 2020
- Rexulti® (brexpiprazole tablet): April 2026
- 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 IM injection): January 2031

- Fanapt® (iloperidone tablet): December 2031
- Secuado® (asenapine transdermal system): July 2033
- Abilify MyCite® (aripiprazole tablet with sensor): October 2033
- Abilify Maintena® (aripiprazole IM injection): March 2034
- Caplyta™ (lumateperone capsule): December 2034
- Aristada® (aripiprazole lauroxil IM injection): March 2035
- Invega Trinza® (paliperidone IM injection): April 2036

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

- **October 2019:** The FDA approved Secuado® (asenapine transdermal system), the first and only transdermal patch formulation for the treatment of adult patients with schizophrenia. Secuado® is a once daily transdermal formulation that provides sustained concentrations of asenapine over 24 hours. Asenapine is also available as a SL tablet, (Saphris®), which was first FDA approved in 2009. The systemic safety profile of Secuado® was consistent with what is known for SL asenapine.
- **December 2019:** The FDA approved once daily Caplyta™ (lumateperone capsule) for the treatment of schizophrenia in adult patients. The exact mechanism of action of Caplyta™ in the treatment of schizophrenia is unknown; however, it may be mediated through a combination of antagonist activity at central serotonin 2A (5-HT_{2A}) receptors and postsynaptic antagonist activity at central dopamine 2 (D2) receptors. In pooled data from short term studies, mean changes from baseline in weight gain, fasting glucose, triglycerides, and total cholesterol were similar between Caplyta™ and placebo. The incidence of extrapyramidal symptoms was 6.7% for Caplyta™ and 6.3% for placebo. Caplyta™ is also being developed for the treatment of bipolar depression, behavioral disturbances in patients with dementia (including Alzheimer's disease), depression, and other neuropsychiatric and neurological disorders. In March 2020, Intra-Cellular Therapies announced that Caplyta™ is now available to pharmacies.

News:

- **January 2020:** The FDA released a Drug Safety Communication strengthening an existing warning that untreated constipation caused by clozapine can lead to serious bowel complications that can lead to hospitalization or even death if constipation is not diagnosed and treated quickly. Constipation is a frequent and known side effect of clozapine, but serious and fatal events continue to be reported.

Clozapine affects how the intestines function in a majority of patients and produces effects ranging from constipation to serious but uncommon bowel problems, including complete blockage of the bowels. The FDA found that because of the way clozapine works, this risk is greater with clozapine than with the other schizophrenia medications in its drug class. The risk is further increased at higher doses of clozapine and when it is co-prescribed with anticholinergics or opioids, which can slow the movement in the intestines and cause constipation.

Pipeline:

- **SEP-363856:** SEP-363856 is a novel trace amine-associated receptor 1 (TAAR1) agonist with serotonin 1A ($5\text{-}HT_{1A}$) agonist activity that is being evaluated in patients with schizophrenia. SEP-363856 does not bind to D2 or $5\text{-}HT_{2A}$ receptors, which are thought to mediate the effects of currently available atypical antipsychotic medications. SEP-363856 is being studied in the DIAMOND (Developing Innovative Approaches for Mental Disorders) Phase 3 global development program for schizophrenia with additional indications under consideration. The FDA granted SEP-363856 Breakthrough Therapy designation for the treatment of schizophrenia in May 2019. In April 2020, results of a 4-week pivotal study (SEP361-201) evaluating the safety and efficacy of SEP-363856 in patients with schizophrenia were published online in the *New England Journal of Medicine*. In this study, once daily, flexible-dose (50-75mg) treatment with SEP-363856 demonstrated a statistically significant and clinically meaningful improvement in the Positive and Negative Syndrome Scale (PANSS) total score compared to placebo after 4 weeks of treatment (-17.2 vs. -9.7, respectively; P=0.001). Patients treated with SEP-363856 also showed improvement in the overall severity of illness as assessed by the Clinical Global Impression Scale-Severity (CGI-S) (P<0.001). In addition, improvement was observed in all major PANSS (positive, negative, and general psychopathology) subscales (P<0.02). SEP-363856 was well tolerated throughout the study and the overall discontinuation rate was comparable for SEP-363856 and placebo.
- **KarXT:** KarXT is an oral co-formulation of xanomeline (a novel muscarinic receptor agonist) and trospium (a muscarinic receptor antagonist) designed to treat psychosis and related symptoms through preferential stimulation of muscarinic receptors in the central nervous

system (CNS). This combination has the potential to be a new option for treating the difficult symptoms of debilitating CNS disorders, such as schizophrenia, without subjecting patients to the problematic side effects associated with current antipsychotic standard of care therapies. In November 2019, results from the Phase 2 clinical study of KarXT for the treatment of acute psychosis in patients with schizophrenia were announced. In the clinical study, KarXT demonstrated a statistically significant and clinically meaningful -11.6 point mean reduction in total PANSS score compared to placebo ($P<0.0001$) and also demonstrated good overall tolerability. A statistically significant reduction in the secondary endpoints of PANSS-Positive and PANSS-Negative scores were also observed ($P<0.001$). KarXT was well tolerated in the Phase 2 study, with similar discontinuation rates between KarXT (20%) and placebo (21%). The number of discontinuations due to treatment emergent adverse events were equal in the KarXT and placebo arms (N=2 in each group). Karuna Therapeutics plans to initiate a Phase 3 clinical study of KarXT in patients with schizophrenia by the end of 2020. Karuna also plans to further analyze these results to better understand the potential of KarXT in patients with schizophrenia experiencing negative and cognitive symptoms and to explore other CNS disorders that could benefit from this approach, such as psychosis in Alzheimer's disease as well as pain management.

Secuado® (Asenapine Transdermal System) Product Summary[11,12]

Indication(s): Secuado® (asenapine) is an atypical antipsychotic indicated for the treatment of adults with schizophrenia.

Dosing:

- Secuado® is supplied in 3 strengths: 3.8mg/24 hours, 5.7mg/24 hours, and 7.6mg/24 hours.
- The recommended regimen is 1 transdermal system applied every 24 hours.
- Secuado® is for transdermal use only and may be applied to 1 of the following sites: hip, abdomen, upper arm, or upper back area.
- The recommended starting dose of Secuado® is 3.8mg/24 hours. The strength may be increased to 5.7mg/24 hours or 7.6mg/24 hours after 1 week.

- Based on the average exposure (area under the curve; AUC) of asenapine, Secuado® 3.8mg/24 hours corresponds to 5mg twice daily of SL asenapine and Secuado® 7.6mg/24 hours corresponds to 10mg twice daily of SL asenapine.

Mechanism of Action: The mechanism of action of asenapine in schizophrenia is unclear. However, its efficacy in schizophrenia could be mediated through a combination of antagonist activity at dopamine and serotonin receptors.

Contraindication(s):

- Severe hepatic impairment (Child-Pugh C)
- Known hypersensitivity to Secuado® or to any components in the transdermal system

Boxed Warning: Increased Mortality in Elderly Patients with Dementia-Related Psychosis
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Secuado® is not approved for the treatment of patients with dementia-related psychosis.

Safety:

- **Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis:** Asenapine may cause an increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack).
- **Neuroleptic Malignant Syndrome (NMS):** NMS, a potentially fatal symptom complex, has been reported in association with administration of antipsychotic drugs. Clinical manifestations of NMS may include hyperpyrexia, muscle rigidity, altered mental status, evidence of autonomic instability, elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Management of NMS should include immediate discontinuation and close monitoring.
- **Tardive Dyskinesia (TD):** TD, a syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs, including asenapine. The risk of developing TD and the likelihood that it will become irreversible increases with the

duration of treatment and the cumulative dose. Asenapine should be discontinued if clinically appropriate.

- **Metabolic Changes:** The prescriber should monitor the patient for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain while taking asenapine.
- **Orthostatic Hypotension:** Atypical antipsychotics may cause orthostatic hypotension and syncope. Generally, the risk is greatest during initial dose titration and when increasing the dose. Prescribers should monitor heart rate (HR) and blood pressure (BP) in patients taking asenapine. Additionally, prescribers should warn patients with known cardiovascular (CV) or cerebrovascular disease and patients at risk of dehydration or syncope of the risks associated with taking asenapine.
- **Leukopenia, Neutropenia, and Agranulocytosis:** Complete blood counts (CBC) should be performed in patients taking asenapine with pre-existing low white blood cell count (WBC) or a history of leukopenia or neutropenia. Discontinuation of asenapine should be considered if a clinically significant decline in WBC occurs in the absence of other causative factors.
- **QT Prolongation:** Increases in QT interval may occur with asenapine; use should be avoided with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval.
- **Seizures:** Caution should be used in patients taking asenapine who have a history of seizures or conditions that lower the seizure threshold. In the placebo-controlled study, there were no reports of seizures in adult patients treated with doses of 3.8mg/24 hours and 7.6mg/24 hours of transdermal asenapine. During adult pre-marketing clinical studies with SL asenapine, including long term studies without comparison to placebo, seizures were reported in 0.3% (5 out of 1,953) of patients treated with SL asenapine. As with other antipsychotic drugs, transdermal asenapine should be used with caution in patients who have a history of seizures or conditions that potentially lower the seizure threshold.
- **Potential for Cognitive and Motor Impairment:** While taking asenapine, caution should be used when operating machinery. Transdermal asenapine, like other antipsychotics, has the potential to impair judgment, thinking, or motor skills. Somnolence was reported in patients treated with transdermal asenapine. In the short-term, fixed-dose, placebo-controlled schizophrenia adult study, somnolence was

reported in 4.4% (9 out of 204) of patients on the 3.8mg/24 hours dose and in 3.4% (7 out of 204) of patients on the 7.6mg/24 hours dose compared to 1.5% (3 out of 206) of placebo patients. There were no reports of somnolence that led to discontinuation in the placebo-controlled study. During adult pre-marketing clinical studies with SL asenapine, including long term studies without comparison to placebo, somnolence was reported in 18% (358 out of 1,953) of patients treated with SL asenapine.

- **External Heat:** Exposing Secuado® to external heat sources during wear should be avoided because both the rate and extent of absorption are increased.
- **Application Site Reactions:** During wear time or immediately after removal of Secuado®, local skin reactions may occur. Patients should be instructed to select a different transdermal system application site each day to limit the occurrence of skin reactions.

Adverse Reactions: Commonly observed adverse reactions (incidence ≥5% and at least twice that for placebo) in patients treated with Secuado® include extrapyramidal disorder, application site reaction, and weight gain.

Efficacy: The efficacy of Secuado® was established, in part, on the basis of efficacy data from studies with the SL formulation of asenapine (Saphris®). In addition, the efficacy of Secuado® was evaluated in a 6-week, fixed-dose, randomized, double-blind, placebo-controlled study of 607 adult patients with schizophrenia. The PANSS rating scale was used as the primary efficacy measure. The placebo-subtracted difference in the change from baseline in the PANSS total score was -6.6 [95% confidence interval (CI): -9.81, -3.40] for Secuado® 3.8mg/24 hours and -4.8 (95% CI: -8.06, -1.64) for Secuado® 7.6mg/24 hours, vs. placebo.

Cost Comparison:

Medication	Cost Per Unit	Cost Per Month	Cost Per Year
Secuado® (asenapine) transdermal system all strengths	**$40.00**	**$1,200.00**	**$14,400.00**
Saphris® (asenapine) 10mg sublingual tablet	$19.16	$1,149.60[+]	$13,795.20[+]

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
Unit = transdermal patch or tablet
[+] Cost based on a maximum FDA recommended dose of 10mg twice daily.

Caplyta™ (Lumateperone Capsule) Product Summary[13,14]

Indication(s): Caplyta™ (lumateperone) is an atypical antipsychotic indicated for the treatment of adults with schizophrenia.

Dosing:

- Caplyta™ is available as a 42mg oral capsule.
- The recommended regimen is 42mg once daily with food.
- Lumateperone does not require dose titration.

Mechanism of Action: The mechanism of action of lumateperone in the treatment of schizophrenia is unknown. However, the efficacy of lumateperone may be mediated through a combination of antagonist activity at central serotonin 5-HT_{2A} receptors and postsynaptic antagonist activity at central dopamine D2 receptors.

Contraindication(s):

- Known hypersensitivity to lumateperone or any components of Caplyta™

Boxed Warning: Increased Mortality in Elderly Patients with Dementia-Related Psychosis
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Caplyta™ is not approved for the treatment of patients with dementia-related psychosis.

Safety:

- **Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis:** Lumateperone may cause an increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack).
- **NMS:** NMS, a potentially fatal symptom complex, has been reported in association with administration of antipsychotic drugs. Clinical manifestations of NMS may include hyperpyrexia, muscle rigidity, altered mental status, evidence of autonomic instability, elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Management of NMS should include immediate discontinuation and close monitoring.
- **TD:** TD, a syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs,

including lumateperone. The risk of developing TD and the likelihood that it will become irreversible increases with the duration of treatment and the cumulative dose. Lumateperone should be discontinued if clinically appropriate.

- **Metabolic Changes:** The prescriber should monitor the patient for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain while taking lumateperone.
- **Orthostatic Hypotension:** The prescriber should monitor HR and BP and warn patients with known CV or cerebrovascular disease or patients at risk of dehydration or syncope of the risks associated with taking lumateperone.
- **Leukopenia, Neutropenia, and Agranulocytosis:** CBC should be performed in patients taking lumateperone with pre-existing low WBC or a history of leukopenia or neutropenia. Discontinuation of lumateperone should be considered if a clinically significant decline in WBC occurs in the absence of other causative factors.
- **QT Prolongation:** Increases in QT interval may occur with lumateperone; use should be avoided with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval.
- **Seizures:** Like other antipsychotic drugs, lumateperone may cause seizures. The risk is greatest in patients with a history of seizures or with conditions that lower the seizure threshold. Conditions that lower the seizure threshold may be more prevalent in older patients.
- **Potential for Cognitive and Motor Impairment:** Lumateperone, like other antipsychotics, may cause somnolence and has the potential to impair judgment, thinking, and motor skills. In short term (i.e., 4- to 6-week) placebo-controlled clinical studies of patients with schizophrenia, somnolence and sedation were reported in 24% of lumateperone-treated patients, compared to 10% of placebo-treated patients.

Adverse Reactions: The most common adverse reactions observed in clinical studies (incidence >5% and greater than twice that of placebo) in patients treated with lumateperone were somnolence/sedation and dry mouth.

Efficacy: The efficacy of lumateperone was established in (2) 4-week, randomized, double-blind, placebo-controlled, multi-center studies in adult patients with a diagnosis of schizophrenia. In both studies, the primary efficacy measure was the change in the PANSS total score at day 28. The PANSS measures symptoms of schizophrenia.

- Study 1: A total of 335 patients were randomly assigned to receive lumateperone 42mg, lumateperone 84mg, an active comparator (risperidone), or placebo once daily. The study was not designed to allow for efficacy comparison of lumateperone and the active comparator (risperidone). After 28 days of treatment, patients treated with lumateperone 42mg demonstrated a statistically significantly greater mean change in PANSS compared to placebo (-13.2 points vs. -7.4 points, respectively). When compared to placebo, the lumateperone 84mg group was not statistically different.
- Study 2: A total of 450 patients were randomly assigned to receive lumateperone 28mg, lumateperone 42mg, or placebo once daily. After 28 days of treatment, patients treated with lumateperone 42mg demonstrated a statistically significantly greater mean change in PANSS compared to placebo (-14.5 points vs. -10.3 points, respectively). When compared to placebo, the lumateperone 28mg group was not statistically different.

Cost Comparison:

Medication	Cost Per Unit	Cost Per Month	Cost Per Year
Caplyta™ (lumateperone) 42mg capsule	**$44.00**	**$1,320.00**	**$15,840.00**
risperidone 3mg tablet	$0.07	$4.20⁺	$50.40⁺

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
Unit = capsule or tablet
⁺ Cost based on risperidone 6mg per day.

Recommendations

The College of Pharmacy recommends the placement of Secuado® (asenapine transdermal system) and Caplyta™ (lumateperone capsule) into Tier-3 of the Atypical Antipsychotic Medications PBPA Tier chart. Current Tier-3 criteria will apply, and Secuado® will also require additional criteria (changes shown in red in the following Tier chart and Tier-3 Approval 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), or Wholesale Acquisition Costs (WAC) if NADAC unavailable. Placement of products shown in blue is based on net cost after 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.

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) and 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 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-1 PRODUCTS						
ARIPIPRAZOLE INJECTABLE PRODUCTS						
ABILIFY MAIN INJ 400MG	1,586	339	$3,397,210.97	$74.45	$2,142.00	6.69%
ABILIFY MAIN INJ 400MG	664	172	$1,424,784.00	$75.09	$2,145.76	2.81%
ABILIFY MAIN INJ 300MG	234	54	$379,688.63	$56.35	$1,622.60	0.75%
ABILIFY MAIN INJ 300MG	118	40	$190,557.11	$55.30	$1,614.89	0.38%
SUBTOTAL	**2,602**	**605**	**$5,392,240.71**	**$72.10**	**$2,072.34**	**10.63%**
ARIPIPRAZOLE LAUROXIL INJECTABLE PRODUCTS						
ARISTADA INJ 882MG	495	97	$1,228,711.82	$83.02	$2,482.25	2.42%
ARISTADA INJ 1064MG	200	85	$591,555.16	$51.41	$2,957.78	1.17%
ARISTADA INJ 662MG	142	46	$264,903.70	$64.61	$1,865.52	0.52%
ARISTADA INJ 441MG	68	26	$83,917.18	$43.17	$1,234.08	0.17%
ARISTADA INJ INITIO 675MG	49	46	$96,555.10	$89.32	$1,970.51	0.19%
SUBTOTAL	**954**	**300**	**$2,265,642.96**	**$67.77**	**$2,374.89**	**4.47%**
ARIPIPRAZOLE ORAL PRODUCTS						
ARIPIPRAZOLE TAB 5MG	13,080	4,202	$233,994.18	$0.56	$17.89	0.46%
ARIPIPRAZOLE TAB 10MG	10,245	3,205	$187,302.80	$0.56	$18.28	0.37%
ARIPIPRAZOLE TAB 15MG	6,263	1,744	$109,525.09	$0.54	$17.49	0.22%
ARIPIPRAZOLE TAB 2MG	4,650	1,628	$85,784.18	$0.56	$18.45	0.17%
ARIPIPRAZOLE TAB 20MG	3,899	995	$88,230.89	$0.71	$22.63	0.17%
ARIPIPRAZOLE TAB 30MG	2,263	469	$50,576.85	$0.67	$22.35	0.10%
ARIPIPRAZOLE SOL 1MG/ML	247	52	$138,488.09	$14.91	$560.68	0.27%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
ABILIFY TAB 20MG	15	2	$25,643.54	$40.70	$1,709.57	0.05%
ABILIFY TAB 5MG	12	1	$10,400.01	$28.89	$866.67	0.02%
ARIPIPRAZOLE TAB 10MG ODT	6	2	$5,333.85	$29.63	$888.98	0.01%
ABILIFY TAB 10MG	4	1	$6,895.64	$28.73	$1,723.91	0.01%
ABILIFY TAB 30MG	2	1	$7,339.02	$40.77	$3,669.51	0.01%
SUBTOTAL	**40,686**	**12,302**	**$949,514.14**	**$0.72**	**$23.34**	**1.86%**
CLOZAPINE PRODUCTS						
CLOZAPINE TAB 100MG	4,848	430	$245,848.90	$2.19	$50.71	0.48%
CLOZAPINE TAB 200MG	1,852	168	$138,782.44	$3.33	$74.94	0.27%
CLOZAPINE TAB 50MG	1,723	176	$64,367.03	$1.72	$37.36	0.13%
CLOZAPINE TAB 25MG	1,143	133	$28,347.57	$1.20	$24.80	0.06%
CLOZARIL TAB 100MG	24	2	$29,014.87	$45.76	$1,208.95	0.06%
SUBTOTAL	**9,590**	**909**	**$506,360.81**	**$2.35**	**$52.80**	**1.00%**
OLANZAPINE PRODUCTS						
OLANZAPINE TAB 20MG	6,756	1,247	$109,254.35	$0.51	$16.17	0.22%
OLANZAPINE TAB 10MG	6,198	1,636	$86,187.91	$0.44	$13.91	0.17%
OLANZAPINE TAB 5MG	3,643	1,206	$48,177.68	$0.41	$13.22	0.09%
OLANZAPINE TAB 15MG	2,462	618	$38,938.72	$0.47	$15.82	0.08%
OLANZAPINE TAB 2.5MG	1,020	372	$13,232.49	$0.43	$12.97	0.03%
OLANZAPINE TAB 7.5MG	592	171	$8,509.85	$0.44	$14.37	0.02%
OLANZAPINE TAB 10MG ODT	391	110	$12,583.95	$1.06	$32.18	0.02%
OLANZAPINE TAB 5MG ODT	307	108	$8,636.91	$0.97	$28.13	0.02%
OLANZAPINE TAB 20MG ODT	270	69	$13,049.71	$1.31	$48.33	0.03%
OLANZAPINE TAB 15MG ODT	126	33	$5,372.84	$1.28	$42.64	0.01%
ZYPREXA TAB 5MG	20	2	$7,142.76	$12.11	$357.14	0.01%
ZYPREXA TAB 15MG	12	1	$10,088.10	$28.02	$840.68	0.02%
ZYPREXA TAB 10MG	4	1	$7,543.92	$20.96	$1,885.98	0.01%
SUBTOTAL	**21,801**	**5,574**	**$368,719.19**	**$0.51**	**$16.91**	**0.73%**
PALIPERIDONE INJECTABLE PRODUCTS						
INVEGA SUST INJ 234MG/1.5ML	4,130	814	$10,599,799.32	$90.00	$2,566.54	20.88%
INVEGA SUST INJ 156MG/ML	1,792	557	$3,075,652.09	$59.94	$1,716.32	6.06%
INVEGA TRINZ INJ 819MG	702	251	$5,384,181.55	$87.91	$7,669.77	10.61%
INVEGA SUST INJ 117MG/0.75ML	453	109	$587,041.84	$45.23	$1,295.90	1.16%
INVEGA TRINZ INJ 546MG	293	99	$1,501,360.20	$58.69	$5,124.10	2.96%
INVEGA TRINZ INJ 410MG	69	30	$265,700.10	$44.19	$3,850.73	0.52%
INVEGA SUST INJ 78MG/0.5ML	39	14	$40,444.47	$35.79	$1,037.04	0.08%
INVEGA TRINZ INJ 273MG	33	12	$83,404.36	$29.08	$2,527.40	0.16%
INVEGA SUST INJ 39MG/0.25ML	30	6	$13,075.34	$15.35	$435.84	0.03%
SUBTOTAL	**7,541**	**1,892**	**$21,550,659.27**	**$1,986.79**	**$2,857.80**	**42.46%**
QUETIAPINE PRODUCTS						
QUETIAPINE TAB 100MG	11,061	2,937	$144,546.50	$0.41	$13.07	0.28%
QUETIAPINE TAB 50MG	8,516	2,604	$109,827.57	$0.41	$12.90	0.22%
QUETIAPINE TAB 200MG	7,422	1,781	$114,137.22	$0.47	$15.38	0.22%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
QUETIAPINE TAB 300MG	6,202	1,328	$107,361.72	$0.52	$17.31	0.21%
QUETIAPINE TAB 25MG	5,911	1,909	$72,452.82	$0.39	$12.26	0.14%
QUETIAPINE TAB 400MG	5,571	1,053	$103,273.00	$0.56	$18.54	0.20%
QUETIAPINE TAB 300MG ER	845	197	$24,863.93	$0.93	$29.42	0.05%
QUETIAPINE TAB 400MG ER	834	138	$29,710.64	$1.08	$35.62	0.06%
QUETIAPINE TAB 150MG ER	550	168	$12,815.13	$0.69	$23.30	0.03%
QUETIAPINE TAB 50MG ER	467	171	$10,171.87	$0.71	$21.78	0.02%
QUETIAPINE TAB 200MG ER	385	115	$9,074.97	$0.71	$23.57	0.02%
SEROQUEL TAB 400MG	12	1	$13,558.62	$37.66	$1,129.89	0.03%
SEROQUEL XR TAB 400MG	12	1	$18,183.04	$49.82	$1,515.25	0.04%
SUBTOTAL	**47,788**	**12,403**	**$769,977.03**	**$0.50**	**$16.11**	**1.52%**
RISPERIDONE INJECTABLE PRODUCTS						
RISPERDAL CONSTA INJ 50MG	266	34	$408,264.11	$60.55	$1,534.83	0.91%
RISPERDAL CONSTA INJ 25MG	96	14	$62,689.82	$31.07	$653.02	0.14%
RISPERDAL CONSTA INJ 37.5MG	94	16	$114,122.39	$45.87	$1,214.07	0.26%
RISPERDAL CONSTA INJ 12.5MG	32	7	$12,646.04	$15.55	$395.19	0.03%
SUBTOTAL	**483**	**68**	**$648,434.12**	**$55.44**	**$1,342.51**	**1.29%**
RISPERIDONE ORAL PRODUCTS						
RISPERIDONE TAB 1MG	11,118	2,482	$131,672.36	$0.38	$11.84	0.26%
RISPERIDONE TAB 0.5MG	9,841	2,314	$116,563.50	$0.38	$11.84	0.23%
RISPERIDONE TAB 2MG	6,479	1,370	$76,702.30	$0.38	$11.84	0.15%
RISPERIDONE TAB 0.25MG	5,362	1,384	$62,335.34	$0.38	$11.63	0.12%
RISPERIDONE TAB 3MG	3,325	625	$40,421.44	$0.39	$12.16	0.08%
RISPERIDONE TAB 4MG	1,673	299	$20,747.10	$0.38	$12.40	0.04%
RISPERIDONE SOL 1MG/ML	914	178	$28,266.53	$0.94	$30.93	0.06%
RISPERIDONE TAB 0.5MG ODT	165	53	$8,521.43	$1.72	$51.65	0.02%
RISPERIDONE TAB 1MG ODT	128	41	$6,313.34	$1.76	$49.32	0.01%
RISPERIDONE TAB 2MG ODT	91	19	$4,968.82	$1.86	$54.60	0.01%
RISPERIDONE TAB 0.25MG ODT	84	23	$12,608.24	$4.96	$150.10	0.02%
RISPERIDONE TAB 4MG ODT	31	5	$3,501.02	$3.27	$112.94	0.01%
RISPERIDONE TAB 3MG ODT	16	5	$3,063.07	$6.66	$191.44	0.01%
RISPERDAL TAB 2MG	12	1	$10,606.26	$29.46	$883.86	0.02%
RISPERDAL SOL 1MG/ML	11	2	$11,196.53	$33.93	$1,017.87	0.02%
RISPERDAL TAB 3MG	10	1	$10,472.48	$34.91	$1,047.25	0.02%
SUBTOTAL	**39,260**	**8,802**	**$547,959.76**	**$0.45**	**$13.96**	**1.08%**
ZIPRASIDONE PRODUCTS						
ZIPRASIDONE CAP 40MG	2,092	620	$50,623.74	$0.78	$24.20	0.10%
ZIPRASIDONE CAP 80MG	1,991	345	$45,895.80	$0.74	$23.05	0.09%
ZIPRASIDONE CAP 20MG	1,973	647	$40,223.54	$0.67	$20.39	0.08%
ZIPRASIDONE CAP 60MG	1,497	314	$41,526.22	$0.87	$27.74	0.08%
GEODON INJ 20MG	5	4	$551.69	$78.81	$110.34	0.00%
SUBTOTAL	**7,558**	**1,930**	**$178,820.99**	**$0.76**	**$23.66**	**0.35%**
TIER-1 SUBTOTAL	**178,263**	**44,785**	**$33,178,328.98**	**$5.86**	**$185.12**	**65.39%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-2 PRODUCTS						
LURASIDONE PRODUCTS						
LATUDA TAB 40MG	2,790	882	$3,441,837.39	$38.73	$1,233.63	6.78%
LATUDA TAB 20MG	1,881	696	$2,265,683.81	$38.34	$1,204.51	4.46%
LATUDA TAB 80MG	1,786	406	$2,457,517.46	$43.22	$1,375.99	4.84%
LATUDA TAB 60MG	1,772	473	$2,179,207.04	$38.52	$1,229.80	4.29%
LATUDA TAB 120MG	862	176	$1,592,353.95	$58.27	$1,847.28	3.14%
SUBTOTAL	**9,091**	**2,633**	**$11,936,599.65**	**$41.34**	**$1,313.01**	**23.51%**
ASENAPINE PRODUCTS						
SAPHRIS SUB 10MG	706	137	$662,343.34	$30.32	$938.16	1.30%
SAPHRIS SUB 5MG	359	121	$332,144.06	$30.16	$925.19	0.65%
SAPHRIS SUB 2.5MG	104	36	$90,923.07	$29.38	$874.26	0.18%
SUBTOTAL	**1,169**	**294**	**$1,085,410.47**	**$30.19**	**$928.49**	**2.13%**
TIER-2 SUBTOTAL	**10,260**	**2,927**	**$13,022,010.12**	**$40.11**	**$1,269.20**	**25.64%**
TIER-3 PRODUCTS						
BREXPIPRAZOLE PRODUCTS						
REXULTI TAB 2MG	307	106	$358,105.41	$35.55	$1,166.47	0.71%
REXULTI TAB 3MG	207	48	$238,146.82	$36.64	$1,150.47	0.47%
REXULTI TAB 1MG	152	72	$163,153.38	$36.24	$1,073.38	0.32%
REXULTI TAB 4MG	145	34	$179,987.54	$36.96	$1,241.29	0.35%
REXULTI TAB 0.5MG	60	17	$66,191.78	$37.19	$1,103.20	0.13%
REXULTI TAB 0.25MG	5	1	$5,632.45	$37.55	$1,126.49	0.01%
SUBTOTAL	**876**	**278**	**$1,011,217.38**	**$36.28**	**$1,154.36**	**1.99%**
CARIPRAZINE PRODUCTS						
VRAYLAR CAP 3MG	466	163	$592,957.57	$40.29	$1,272.44	1.17%
VRAYLAR CAP 6MG	379	73	$452,397.20	$38.11	$1,193.66	0.89%
VRAYLAR CAP 1.5MG	244	119	$293,061.96	$38.54	$1,201.07	0.58%
VRAYLAR CAP 4.5MG	212	80	$238,304.69	$37.40	$1,124.08	0.47%
VRAYLAR CAP 1.5-3MG	1	1	$287.60	$41.09	$287.60	0.00%
SUBTOTAL	**1,302**	**436**	**$1,577,009.02**	**$38.87**	**$1,211.22**	**3.11%**
CLOZAPINE ORALLY DISINTEGRATING PRODUCTS						
CLOZAPINE TAB 100MG ODT	108	13	$52,787.18	$18.94	$488.77	0.10%
CLOZAPINE TAB 150MG ODT	85	9	$92,647.79	$40.42	$1,089.97	0.18%
CLOZAPINE TAB 200MG ODT	72	8	$101,012.73	$49.81	$1,402.95	0.20%
CLOZAPINE TAB 25MG ODT	41	4	$9,047.41	$7.36	$220.67	0.02%
SUBTOTAL	**306**	**34**	**$255,495.11**	**$30.65**	**$834.95**	**0.50%**
ILOPERIDONE PRODUCTS						
FANAPT TAB 12MG	150	18	$311,963.17	$69.71	$2,079.75	0.61%
FANAPT TAB 6MG	141	21	$185,252.95	$45.19	$1,313.85	0.36%
FANAPT TAB 8MG	102	16	$105,969.29	$45.93	$1,038.91	0.21%
FANAPT TAB 4MG	101	14	$89,452.97	$31.68	$885.67	0.18%
FANAPT TAB 10MG	72	13	$139,545.39	$64.60	$1,938.13	0.27%
FANAPT TAB 2MG	54	10	$44,471.83	$24.71	$823.55	0.09%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
FANAPT TAB 1MG	16	5	$16,263.43	$30.12	$1,016.46	0.03%
SUBTOTAL	**636**	**97**	**$892,919.03**	**$49.05**	**$1,403.96**	**1.75%**
OLANZAPINE/FLUOXETINE COMBINATION PRODUCTS						
OLANZA/FLUOX CAP 12-50MG	22	2	$14,206.74	$21.59	$645.76	0.03%
OLANZA/FLUOX CAP 3-25MG	13	2	$2,047.21	$5.25	$157.48	0.00%
OLANZA/FLUOX CAP 6-25MG	13	1	$2,827.23	$7.25	$217.48	0.01%
OLANZA/FLUOX CAP 12-25MG	11	1	$2,614.33	$7.92	$237.67	0.01%
OLANZA/FLUOX CAP 6-50MG	9	1	$1,631.19	$6.04	$181.24	0.00%
SUBTOTAL	**68**	**7**	**$23,326.70**	**$11.45**	**$343.04**	**0.05%**
PALIPERIDONE ORAL PRODUCTS						
PALIPERIDONE TAB ER 6MG	963	179	$373,519.89	$12.22	$387.87	0.74%
PALIPERIDONE TAB ER 9MG	553	100	$251,639.74	$13.57	$455.04	0.50%
PALIPERIDONE TAB ER 3MG	419	111	$147,344.12	$9.85	$351.66	0.29%
PALIPERIDONE TAB ER 1.5MG	74	25	$22,317.03	$10.42	$301.58	0.04%
INVEGA TAB 6MG	1	1	$1,146.64	$38.22	$1,146.64	0.00%
SUBTOTAL	**2,010**	**416**	**$795,967.42**	**$12.02**	**$396.00**	**1.57%**
TIER-3 SUBTOTAL	**5,198**	**1,268**	**$4,555,934.66**	**$27.90**	**$876.48**	**8.97%**
TOTAL	**193,721**	**27,134***	**$50,756,273.76**	**$8.29**	**$262.01**	**100%**

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

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Appendix G

Calendar Year 2019 Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Wakix® (Pitolisant)

Oklahoma Health Care Authority
June 2020

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) Daytrana® (methylphenidate ER) Desoxyn® (methamphetamine) Dexedrine® (dextroamphetamine) Dexedrine Spansules® (dextroamphetamine ER) Dyanavel® XR (amphetamine ER susp)
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) Ritalin® (methylphenidate)			
Long-Acting			
Aptensio XR® (methylphenidate ER) Focalin XR® brand name only (dexmethylphenidate ER)	dexmethylphenidate ER (generic Focalin XR®) Quillivant XR® (methylphenidate ER susp)	Adhansia XR™ (methylphenidate ER) Concerta® (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)		Jornay PM™ (methylphenidate ER) Metadate ER® (methylphenidate ER) Methylin ER® (methylphenidate ER) methylphenidate ER 72mg Ritalin SR® (methylphenidate ER)	Evekeo® (amphetamine) Evekeo ODT™ (amphetamine ODT) Methylin® (methylphenidate soln and 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), or Wholesale Acquisition Costs (WAC) if NADAC unavailable. Placement of products shown in blue is based on net cost after 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; PA = prior authorization; ER = extended-release; SR = sustained-release; cap = capsule; ODT = orally disintegrating tablet; chew tab = chewable tablet; soln = solution; susp = suspension

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. 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.
2. Adzenys XR-ODT®, Adzenys ER™, Cotempla XR-ODT™, Daytrana®, 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.
3. Methylin® Chewable Tablets and Solution Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use methylphenidate immediate-release tablets must be provided; and
   c. Use of Methylin® chewable tablets or generic Methylin® solution will require a patient-specific, clinically significant reason why the member cannot use the brand formulation of Methylin® solution (brand name Methylin® solution is the preferred product); and
   d. 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. 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; and
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; and
4. Use of Sunosi™ (solriamfetol) 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 the 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.

Medicaid Drug Rebate Program[1,2]

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). Federal 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 the Centers for Medicare and Medicaid Services (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. As average wholesale price (AWP) increases, the rebated amount per unit (RAPU) increases as well, resulting in minimal effect on Medicaid net cost.

Additionally, many states have negotiated supplemental rebate agreements with manufacturers to produce added rebates. 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. In calendar year 2019, the Oklahoma Health Care Authority (OHCA) collected $33,670,810.57 in aggregate drug rebates for ADHD and narcolepsy medications. 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.

Utilization of ADHD and Narcolepsy Medications: Calendar Year 2019

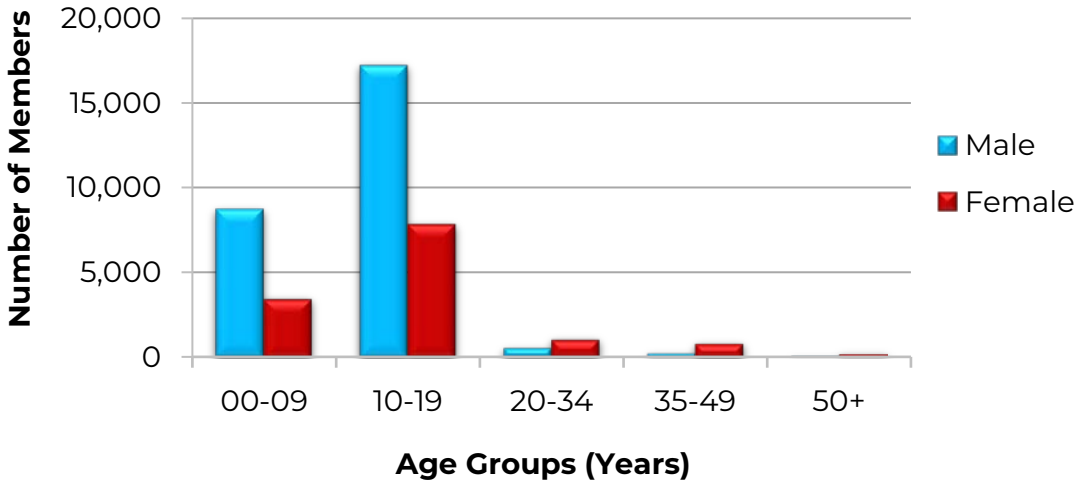
Comparison of Calendar Years: ADHD and Narcolepsy Medications

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	41,147	335,120	$50,744,587.08	$151.42	$5.10	11,715,456	9,952,636
2019	40,300	332,243	$47,727,417.00	$143.65	$4.84	11,519,445	9,863,637
% Change	**-2.10%**	**-0.90%**	**-5.90%**	**-5.10%**	**-5.10%**	**-1.70%**	**-0.90%**
Change	**-847**	**-2,877**	**-$3,017,170.08**	**-$7.77**	**-$0.26**	**-196,011**	**-88,999**

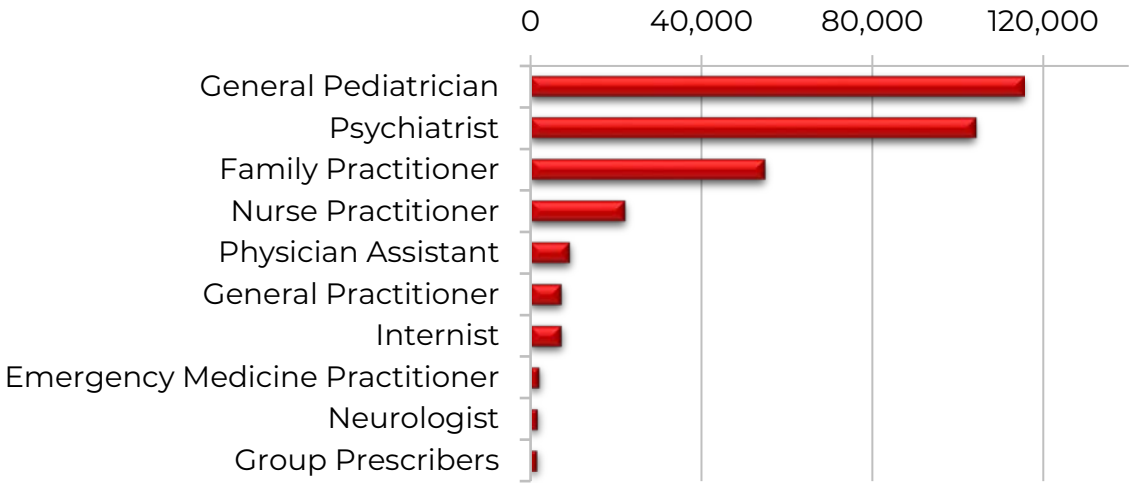
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

- Aggregate drug rebates collected during calendar year 2019 for ADHD and narcolepsy medications: $33,670,810.57[Δ]

Demographics of Members Utilizing ADHD and Narcolepsy Medications



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

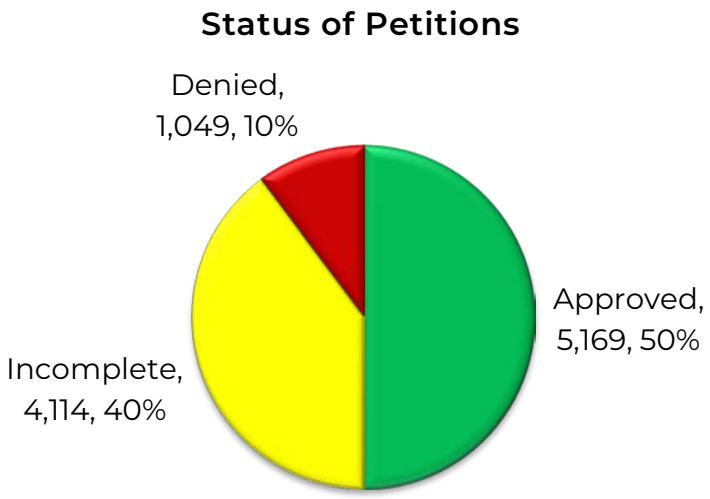


Prior Authorization of ADHD and Narcolepsy Medications

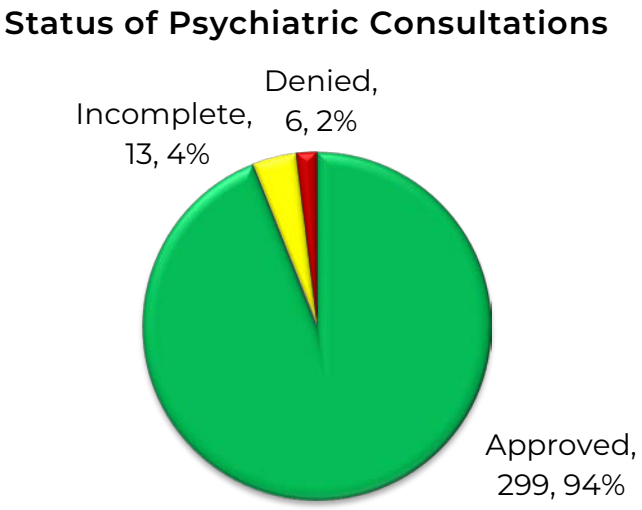
There were 10,332 prior authorization requests submitted for ADHD and narcolepsy medications during calendar year 2019. Computer edits are in place to detect lower tiered ADHD medications in a member's recent claims history and generate automated prior authorizations where possible. The

[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.

following chart shows the status of the submitted petitions for calendar year 2019.



There were 318 prior authorization requests submitted for a total of 223 unique members for ADHD and narcolepsy medications during calendar year 2019 that were referred for a psychiatric consultation. Most requests were for children 3 and 4 years of age. The following chart shows the status of the submitted petitions referred for psychiatric consultation for calendar year 2019.



Market News and Updates[3,4,5]

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
- QuilliChew ER® (methylphenidate ER chewable tablet): August 2033
- Xyrem® (sodium oxybate solution): September 2033
- Adhansia XR™ (methylphenidate ER capsule): October 2035
- Evekeo ODT™ (amphetamine ODT): March 2037
- Sunosi™ (solriamfetol tablet): September 2037

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

- **August 2019:** The FDA approved Wakix® (pitolisant), a first-in-class medication, for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy. Pitolisant is a selective histamine 3 (H_3) receptor antagonist/inverse agonist that works through a novel mechanism of action to increase the synthesis and release of histamine, a wake-promoting neurotransmitter in the brain. Pitolisant is the first and only treatment approved by the FDA for patients with narcolepsy that is not classified as a controlled substance by the U.S. Drug Enforcement Administration (DEA).

News:

- **ADHD Clinical Practice Guideline:** The American Academy of Pediatrics (AAP) updated clinical practice guidelines for the diagnosis, evaluation, and treatment of ADHD in children and adolescents in 2019. Since the release of the previous 2011 guideline, the *Diagnostic and Statistical Manual of Mental Disorders* has been

revised to the fifth edition (*DSM-5*) and new ADHD-related research has been published. However, the new research and *DSM-5* do not support dramatic changes to the previous guideline. Key updates to the recommendations include:

- The addition of a Key Action Statement (KAS) about the diagnosis and treatment of coexisting or comorbid conditions in children and adolescents with ADHD; the subcommittee uses the term "comorbid" to be consistent with the *DSM-5*
- The addition of a Process of Care Algorithm (PoCA) for the diagnosis and treatment of children and adolescents with ADHD:
    - Provides recommendations for implementing the guideline steps
    - The section on evaluating and treating comorbidities in the PoCA document has been expanded
- The addition of a companion article on systemic barriers to the care of children and adolescents with ADHD intended to assist pediatricians and other primary care clinicians; the procedures recommended necessitate the following:
    - Spending more time with patients and their families
    - Developing a care management system of contacts with school or other community stakeholders
    - Providing continuous, coordinated care to the patient and his/her family
- To make a diagnosis of ADHD, the primary care clinician should determine that the *DSM-5* criteria have been met and should rule out any alternative cause
- Preschool-aged children may experience mood lability and dysphoria with stimulant medications; none of the non-stimulants have FDA approval for use in preschool-aged children
- For elementary school-aged children, the evidence is particularly strong for stimulant medications and is sufficient, but less strong for atomoxetine, guanfacine ER, and clonidine ER (in that order)

Wakix® (Pitolisant) Product Summary[6]

Indication(s): Wakix® (pitolisant) is an H_3 antagonist/inverse agonist indicated for the treatment of EDS in adult patients with narcolepsy.

Dosing:

- Wakix® is supplied as 4.45mg and 17.8mg oral tablets.
- The recommended dosage range for pitolisant is 17.8mg to 35.6mg administered once daily in the morning upon awakening. The dosage should be titrated as follows:
    - Week 1: Initiate with a dosage of 8.9mg [(2) 4.45mg tablets] once daily.
    - Week 2: Increase dosage to 17.8mg once daily.
    - Week 3: Dosage may be increased to the maximum recommended dosage of 35.6mg [(2) 17.8mg tablets] once daily.
- Dosage may be adjusted based on tolerability. It may take up to 8 weeks for some patients to achieve a clinical response.
- The maximum recommended dosage of pitolisant in patients with moderate (Child-Pugh class B) hepatic impairment is 17.8mg once daily. Pitolisant is contraindicated in patients with severe (Child-Pugh class C) hepatic impairment.
- The maximum recommended dosage of pitolisant in patients with moderate [estimated glomerular filtration rate (eGFR) 30 to 59mL/min/1.73m^2] or severe (eGFR 15 to 29mL/min/1.73m^2) renal impairment is 17.8mg once daily. Pitolisant is not recommended in patients with end stage renal disease (ESRD; eGFR <15mL/min/1.73m^2).
- Dosage adjustment is recommended for concomitant use of pitolisant with strong CYP2D6 inhibitors or strong CYP3A4 inducers. In patients known to be poor CYP2D6 metabolizers, the maximum recommended dosage of pitolisant is 17.8mg once daily (*refer to Wakix® Prescribing Information for specific recommendations regarding drug interactions*).

Mechanism of Action: The mechanism of action of pitolisant in EDS in adult patients with narcolepsy is unclear; however, its efficacy could be mediated through its activity as an antagonist/inverse agonist of the H_3 receptor. Pitolisant binds to the H_3 receptor with a high affinity and has no appreciable binding to other histamine receptors.

Contraindication(s): Pitolisant is contraindicated in patients with severe hepatic impairment.

Safety:

- **QT Interval Prolongation:** Pitolisant prolongs the QT interval. The use of pitolisant should be avoided in patients with known QT prolongation

or in combination with other drugs known to prolong the QT interval. Pitolisant should be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of torsade de pointes or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and the presence of congenital prolongation of the QT interval. The risk of QT prolongation may be greater in patients with hepatic or renal impairment due to higher concentrations of pitolisant. Dosage modification is recommended and patients with hepatic or renal impairment should be monitored for increased QTc. Pitolisant is contraindicated in patients with severe hepatic impairment and is not recommended in patients with ESRD.

- **Hepatic Impairment:** Pitolisant is contraindicated in patients with severe (Child-Pugh class C) hepatic impairment as it has not been studied in this population. Pitolisant is extensively metabolized by the liver, and there is a significant increase in pitolisant exposure in patients with moderate (Child-Pugh class B) hepatic impairment. Patients with moderate (Child-Pugh class B) hepatic impairment should be monitored and the dose of pitolisant should be adjusted. Patients with mild (Child-Pugh class A) hepatic impairment should be monitored; however, no dosage adjustment of pitolisant is recommended in patients with mild hepatic impairment.
- **Renal Impairment:** The pharmacokinetics of pitolisant in patients with ESRD (eGFR <15mL/min/1.73m^2) is unknown; therefore, pitolisant is not recommended in patients with ESRD. Dosage adjustment of pitolisant is recommended in patients with moderate (eGFR 30 to 59mL/min/1.73m^2) and severe (eGFR 15 to 29mL/min/1.73m^2) renal impairment.
- **CYP2D6 Poor Metabolizers:** Dosage reduction is recommended in patients known to be poor CYP2D6 metabolizers because these patients have higher pitolisant concentrations than normal CYP2D6 metabolizers.
- **Pregnancy:** Available case reports from clinical trials and post-marketing reports with pitolisant use in pregnant women have not determined a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. In animal reproductive studies, administration of pitolisant during organogenesis caused maternal and embryofetal toxicity in rats and rabbits at doses ≥13 and >4 times the maximum recommended human dose (MRHD) of 35.6mg based on

mg/m^2 body surface area, respectively. There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are exposed to pitolisant during pregnancy (*refer to Wakix® Prescribing Information for additional details regarding the pitolisant pregnancy registry*).

- **Lactation:** There are no data on the presence of pitolisant in human milk, the effects on the breastfed infant, or the effects on milk production. Pitolisant is present in the milk of lactating rats. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for pitolisant and any potential adverse effects on the breastfed child from pitolisant or from the underlying maternal condition.
- **Females and Males of Reproductive Potential:** Pitolisant may reduce the effectiveness of hormonal contraceptives. Patients using hormonal contraceptives should be advised to use an alternative non-hormonal contraceptive method during treatment with pitolisant and for at least 21 days after discontinuing treatment.
- **Pediatric Use:** The safety and effectiveness of pitolisant have not been established in pediatric patients. Limited pharmacokinetic data from 24 pediatric patients with narcolepsy (ages 7 years to younger than 18 years) receiving a single dose of pitolisant suggest that pediatric patients have higher exposure to pitolisant than adults.
- **Geriatric Use:** Limited pharmacokinetic data are available in healthy elderly subjects. A pharmacokinetic study that compared 12 elderly patients (ages 68 to 82 years) to 12 healthy adult patients (ages 18 to 45 years) did not reveal any significant differences in drug exposure. Of the total number of patients with narcolepsy in clinical studies of pitolisant, 14 patients (5%) were 65 years of age or older. No overall differences in safety or effectiveness were observed between these patients and younger patients in clinical trials, but greater sensitivity of some older patients cannot be ruled out.

Adverse Reactions: In randomized, placebo-controlled clinical studies, the most common adverse reactions (occurred ≥2% of patients and more frequently than placebo) following treatment with pitolisant were headache, insomnia, nausea, upper respiratory tract infection, musculoskeletal pain, anxiety, increased heart rate, hallucinations, irritability, abdominal pain, sleep disturbance, decreased appetite, cataplexy, dry mouth, and rash.

Efficacy: The efficacy of pitolisant for the treatment of EDS in adult patients with narcolepsy was evaluated in 2 multicenter, randomized, double-blind, placebo-controlled clinical studies (Study 1 and Study 2) in patients 18 years of age or older who met the International Classification of Sleep Disorders (ICSD-2) criteria for narcolepsy and who had an Epworth Sleepiness Scale (ESS) score ≥14. EDS was assessed using the ESS, an 8-item questionnaire by which patients rate their perceived likelihood of falling asleep during usual daily life activities. Each of the 8 items on the ESS is rated from 0 (would never doze) to 3 (high chance of dozing); the maximum score is 24. Study 1 and Study 2 included an 8-week treatment period, consisting of a 3-week dose titration phase followed by a 5-week stable dose phase, and both studies compared pitolisant to a placebo and an active control. The primary endpoint in both studies was the least square mean final ESS score compared to placebo. Both studies included an active control (modafinil); however, the primary efficacy endpoint in both studies only compared the efficacy of pitolisant to placebo.

- Study 1 included 95 patients who were randomized to pitolisant, placebo, or active control (modafinil). The dose of pitolisant was initiated at 8.9mg once daily and could be increased at weekly intervals to 17.8mg or 35.6mg, based on efficacy response and tolerability; 61% of patients reached a stable dose of 35.6mg. No dose adjustments were permitted during the 5-week stable dose phase. The median age in Study 1 was 37 years, and approximately 80% of patients in Study 1 had a history of cataplexy. In Study 1, pitolisant demonstrated statistically significantly greater improvement in the least square mean final ESS score compared to placebo (*see efficacy results in the following table, Table 1*).
- Study 2 included 166 patients who were randomized to pitolisant, placebo, or active control (modafinil). The dose of pitolisant was initiated at 4.45mg once daily and could be increased at weekly intervals to 8.9mg or 17.8mg, based on efficacy response and tolerability; 76% of patients reached a stable dose of 17.8mg. No dose adjustments were permitted during the 5-week stable dose phase. The median age in Study 2 was 40 years, and approximately 75% of patients in Study 2 had a history of cataplexy. In Study 2, pitolisant demonstrated statistically significantly greater improvement in the least square mean final ESS score compared to placebo (*see efficacy results in the following table, Table 1*).

Table 1. Pitolisant Efficacy Results for ESS in Patients with Narcolepsy (Study 1 and Study 2)

Study	Treatment Group (N)	Baseline ESS Score Mean (SD)	Final ESS Score[c] LS Mean at Week 8 (SE)	Placebo Subtracted Difference[d] (95% CI) at Week 8
Study 1[a]	pitolisant (N=31)	17.8 (2.5)	12.4 (1.01)	-3.1* (-5.73, -0.46)
	placebo (N=30)	18.9 (2.5)	15.5 (1.03)	n/a
Study 2[b]	pitolisant (N=66)	18.3 (2.4)	13.3 (1.19)	-2.2* (-4.17, -0.22)
	placebo (N=32)	18.2 (2.3)	15.5 (1.32)	n/a

ESS = Epworth Sleepiness Scale; N = number; SD = standard deviation; LS mean = least squares mean; SE = standard error; CI = confidence interval; n/a = not applicable
[a]Maximum dose randomized to was 35.6mg.
[b]Maximum dose randomized to was 17.8mg.
[c]A lower score on the ESS represents improvement; scores range from 0 (no symptoms) to 24 (worst symptoms).
[d]A negative value for the placebo subtracted difference represents improvement.
*Statistically significant

Cost: The Wholesale Acquisition Cost (WAC) of Wakix® (pitolisant) is $94.75 per 4.45mg tablet and $189.50 per 17.8mg tablet, resulting in an annual cost of $11,370.00 at the maximum dose of 35.6mg [(2) 17.8mg tablets] once daily.

Cost Comparison

Medication	Cost Per Unit	Cost Per Month*
methylphenidate 5mg chewable tablet	$1.98	$118.80
methylphenidate 5mg/5mL oral solution	$0.13	$39.00
methylphenidate 5mg tablet	$0.10	$6.00
dexmethylphenidate 5mg tablet	$0.16	$9.60
methylphenidate 10mg chewable tablet	$4.92	$295.20
methylphenidate 10mg/5mL oral solution	$0.09	$27.00
methylphenidate 10mg tablet	$0.13	$7.80
dexmethylphenidate 10mg tablet	$0.30	$18.00

Unit = chewable tablet, milliliter, or tablet
*Cost per month is based on twice daily (BID) dosing (5mg BID for the 5mg strengths and 10mg BID for the 10mg strengths).
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Recommendations

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

1. The prior authorization of Wakix® (pitolisant) in the Narcolepsy Medications category
   a. Criteria similar to the current approval criteria for Sunosi™ (solriamfetol) and Xyrem® (sodium oxybate) will apply
2. Moving methylphenidate oral solution to Tier-1 in the ADHD Medications Tier chart based on cost
   a. The brand formulation of Methylin® oral solution will no longer be preferred over the generic formulation
   b. 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-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) Daytrana® (methylphenidate ER) Desoxyn® (methamphetamine) Dexedrine® (dextroamphetamine)
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)			

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Long-Acting			Dexedrine Spansules® (dextroamphetamine ER) Dyanavel® XR (amphetamine ER susp) Evekeo® (amphetamine) Evekeo ODT™ (amphetamine ODT) Methylin® (methylphenidate ~~soln and~~ chew tab) Mydayis® (amphetamine/ dextroamphetamine ER) ProCentra® (dextroamphetamine) Zenzedi® (dextroamphetamine)
Aptensio XR® (methylphenidate ER) Focalin XR® brand name only (dexmethylphenidate ER) Metadate CD® (methylphenidate ER) QuilliChew ER® (methylphenidate ER chew tab) Ritalin LA® (methylphenidate ER)	dexmethylphenidate ER (generic Focalin XR®) Quillivant XR® (methylphenidate ER susp)	Adhansia XR™ (methylphenidate ER) Concerta® (methylphenidate ER) Jornay PM™ (methylphenidate ER) Metadate ER® (methylphenidate ER) Methylin ER® (methylphenidate ER) methylphenidate ER 72mg Ritalin SR® (methylphenidate ER)	
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), or Wholesale Acquisition Costs (WAC) if NADAC unavailable. Placement of products shown in blue is based on net cost after 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; PA = prior authorization; ER = extended-release; SR = sustained-release; cap = capsule; tab = tablet; ODT = orally disintegrating tablet; chew tab = chewable tablet; soln = solution; susp = suspension

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. 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.
2. Adzenys XR-ODT®, Adzenys ER™, Cotempla XR-ODT™, Daytrana®, 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.
3. Methylin® Chewable Tablets ~~and Solution~~ 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. Use of Methylin® chewable tablets or generic Methylin® solution will require a patient-specific, clinically significant reason why the member cannot use the brand formulation of Methylin® solution (brand name Methylin® solution is the preferred product); and~~
   d. 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 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; and

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; and
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 the 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 Details of ADHD and Narcolepsy Medications: Calendar Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LISDEXAMFETAMINE PRODUCTS						
VYVANSE CAP 30MG	21,010	5,243	$5,950,425.48	$283.22	4.01	12.47%
VYVANSE CAP 40MG	16,740	3,683	$4,722,267.32	$282.09	4.55	9.89%
VYVANSE CAP 20MG	15,775	4,568	$4,446,857.32	$281.89	3.45	9.32%
VYVANSE CAP 50MG	11,032	2,250	$3,083,627.71	$279.52	4.9	6.46%
VYVANSE CAP 60MG	6,714	1,262	$1,894,328.34	$282.15	5.32	3.97%
VYVANSE CAP 70MG	5,991	958	$1,703,047.33	$284.27	6.25	3.57%
VYVANSE CAP 10MG	5,404	2,159	$1,492,406.58	$276.17	2.5	3.13%
VYVANSE CHW 20MG	1,840	616	$520,785.18	$283.04	2.99	1.09%
VYVANSE CHW 10MG	1,522	628	$428,511.37	$281.54	2.42	0.90%
VYVANSE CHW 30MG	1,007	324	$281,114.16	$279.16	3.11	0.59%
VYVANSE CHW 40MG	369	116	$98,488.04	$266.91	3.18	0.21%
VYVANSE CHW 50MG	88	31	$25,446.93	$289.17	2.84	0.05%
VYVANSE CHW 60MG	73	17	$22,877.35	$313.39	4.29	0.05%
SUBTOTAL	**87,565**	**21,855**	**$24,670,183.11**	**$281.74**	**4.01**	**51.69%**
METHYLPHENIDATE PRODUCTS						
METHYLPHENID TAB 10MG	9,328	2,173	$184,406.42	$19.77	4.29	0.39%
METHYLPHENID TAB 5MG	7,462	2,105	$128,275.75	$17.19	3.54	0.27%
METHYLPHENID CAP 20MG	7,111	2,027	$588,903.08	$82.82	3.51	1.23%
METHYLPHENID CAP 30MG	6,690	1,587	$594,647.13	$88.89	4.22	1.25%
METHYLPHENID CAP 40MG	4,766	1,064	$532,356.50	$111.70	4.48	1.12%
METHYLPHENID TAB 20MG	3,988	790	$92,137.36	$23.10	5.05	0.19%
METHYLPHENID TAB 36MG	3,131	651	$720,886.10	$230.24	4.81	1.51%
METHYLPHENID CAP 10MG	3,048	1,189	$249,321.88	$81.80	2.56	0.52%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
METHYLPHENID TAB 54MG	2,883	522	$566,281.44	$196.42	5.52	1.19%
METHYLPHENID CAP 50MG	2,230	439	$268,500.90	$120.40	5.08	0.56%
APTENSIO XR CAP 20MG	1,968	664	$467,485.35	$237.54	2.96	0.98%
APTENSIO XR CAP 30MG	1,811	545	$426,218.99	$235.35	3.32	0.89%
METHYLPHENID TAB 54MG	1,665	299	$253,490.39	$152.25	5.57	0.53%
METHYLPHENID CAP 60MG	1,613	285	$198,873.69	$123.29	5.66	0.42%
METHYLPHENID TAB 36MG	1,544	327	$300,820.30	$194.83	4.72	0.63%
APTENSIO XR CAP 40MG	1,401	397	$328,845.01	$234.72	3.53	0.69%
METHYLPHENID CAP 20MG	1,212	419	$124,232.14	$102.50	2.89	0.26%
METHYLPHENID TAB 27MG	1,165	291	$170,355.93	$146.23	4	0.36%
APTENSIO XR CAP 10MG	1,157	554	$281,268.03	$243.10	2.09	0.59%
APTENSIO XR CAP 60MG	982	211	$224,797.40	$228.92	4.65	0.47%
METHYLPHENID CAP 30MG	896	278	$107,362.12	$119.82	3.22	0.22%
APTENSIO XR CAP 15MG	858	300	$206,603.96	$240.80	2.86	0.43%
QUILLICHEW CHW 20MG	828	272	$249,958.07	$301.88	3.04	0.52%
APTENSIO XR CAP 50MG	823	210	$189,140.69	$229.82	3.92	0.40%
METHYLPHENID TAB 18MG	807	244	$128,435.95	$159.15	3.31	0.27%
METHYLPHENID CAP 40MG	672	160	$70,707.35	$105.22	4.2	0.15%
METHYLPHENID TAB 27MG	501	139	$67,486.23	$134.70	3.6	0.14%
METHYLPHENID TAB 20MG	494	88	$35,949.41	$72.77	5.61	0.08%
METHYPHENID CAP 10MG	440	179	$97,788.67	$222.25	2.46	0.20%
QUILLICHEW CHW 30MG	413	107	$134,541.90	$325.77	3.86	0.28%
METHYLPHENID SOL 5MG/5ML	373	122	$15,868.19	$42.54	3.06	0.03%
METHYLPHENID CHW 5MG	356	125	$55,694.30	$156.44	2.85	0.12%
METHYLPHENID TAB 18MG	293	86	$45,435.66	$155.07	3.41	0.10%
METHYLPHENID SOL 10MG/5ML	265	62	$21,922.63	$82.73	4.27	0.05%
QUILLIVANT SUS 25MG/5ML	224	47	$81,853.60	$365.42	4.77	0.17%
METHYLPHENID CAP 40MG	221	161	$26,541.25	$120.10	1.37	0.06%
METHLPHENID CHW 2.5MG	213	81	$26,156.78	$122.80	2.63	0.05%
CONCERTA TAB 36MG	199	64	$63,415.43	$318.67	3.11	0.13%
QUILLICHEW CHW 40MG	177	44	$56,597.95	$319.76	4.02	0.12%
METHYLPHENID CHW 10MG	174	47	$46,291.22	$266.04	3.7	0.10%
CONCERTA TAB 54MG	163	51	$51,732.26	$317.38	3.2	0.11%
METHYLIN SOL 5MG/5ML	133	42	$7,654.46	$57.55	3.17	0.02%
DAYTRANA DIS 30MG/9HR	122	20	$37,601.72	$308.21	6.1	0.08%
RITALIN LA CAP 30MG	108	27	$35,032.08	$324.37	4	0.07%
METHYLPHENID TAB 72MG	100	21	$50,200.45	$502.00	4.76	0.11%
RITALIN LA CAP 20MG	84	24	$25,250.41	$300.60	3.5	0.05%
METHYLPHENID TAB 10MG	81	20	$4,257.95	$52.57	4.05	0.01%
RITALIN LA CAP 10MG	77	33	$20,704.50	$268.89	2.33	0.04%
RITALIN LA CAP 40MG	54	19	$17,390.37	$322.04	2.84	0.04%
DAYTRANA DIS 10MG/9HR	52	12	$14,262.24	$274.27	4.33	0.03%
DAYTRANA DIS 20MG/9HR	49	10	$16,875.53	$344.40	4.9	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
METHYLIN SOL 10MG/5ML	41	16	$3,033.04	$73.98	2.56	0.01%
CONCERTA TAB 27MG	33	15	$7,417.93	$224.79	2.2	0.02%
DAYTRANA DIS 15MG/9HR	24	8	$6,436.17	$268.17	3	0.01%
JORNAY PM CAP 40MG ER	22	14	$7,708.13	$350.37	1.57	0.02%
JORNAY PM CAP 20MG ER	17	15	$6,341.95	$373.06	1.13	0.01%
METHYLPHENID CAP 60MG	15	8	$3,948.12	$263.21	1.88	0.01%
JORNAY PM CAP 60MG ER	12	9	$3,765.23	$313.77	1.33	0.01%
COTEMPLA TAB 25.9MG	7	2	$2,256.30	$322.33	3.5	0.00%
COTEMPLA TAB 17.3MG	6	1	$2,202.18	$367.03	6	0.00%
JORNAY PM CAP 80MG ER	6	3	$2,287.38	$381.23	2	0.00%
RITALIN TAB 20MG	5	1	$804.92	$160.98	5	0.00%
CONCERTA TAB 18MG	4	1	$188.84	$47.21	4	0.00%
COTEMPLA TAB 8.6MG	4	1	$1,384.71	$346.18	4	0.00%
JORNAY PM CAP 100MG ER	2	1	$762.82	$381.41	2	0.00%
SUBTOTAL	**75,603**	**19,729**	**$8,759,354.84**	**$115.86**	**3.83**	**18.35%**
GUANFACINE EXTENDED-RELEASE (ER) PRODUCTS						
GUANFACINE TAB 2MG ER	18,935	4,210	$394,339.69	$20.83	4.5	0.83%
GUANFACINE TAB 1MG ER	14,005	4,344	$300,844.09	$21.48	3.22	0.63%
GUANFACINE TAB 3MG ER	12,253	2,296	$256,238.42	$20.91	5.34	0.54%
GUANFACINE TAB 4MG ER	10,762	1,608	$229,012.00	$21.28	6.69	0.48%
INTUNIV TAB 3MG	80	8	$23,254.00	$290.68	10	0.05%
INTUNIV TAB 4MG	30	3	$7,274.10	$242.47	10	0.02%
INTUNIV TAB 2MG	22	4	$6,239.59	$283.62	5.5	0.01%
INTUNIV TAB 1MG	14	2	$3,832.93	$273.78	7	0.01%
SUBTOTAL	**56,101**	**12,475**	**$1,221,034.82**	**$21.76**	**4.5**	**2.56%**
AMPHETAMINE/DEXTROAMPHETAMINE PRODUCTS						
AMPHET/DEXTR TAB 10MG	11,288	2,584	$308,877.25	$27.36	4.37	0.65%
AMPHET/DEXTR TAB 20MG	7,946	1,495	$240,855.92	$30.31	5.32	0.50%
AMPHET/DEXTR TAB 5MG	7,465	2,055	$207,367.19	$27.78	3.63	0.43%
AMPHET/DEXTR TAB 30MG	3,706	612	$121,453.85	$32.77	6.06	0.25%
AMPHET/DEXTR TAB 15MG	3,489	740	$102,699.39	$29.44	4.71	0.22%
AMPHET/DEXTR CAP 30MG	3,279	520	$187,133.06	$57.07	6.31	0.39%
AMPHET/DEXTR CAP 20MG	3,146	654	$181,849.37	$57.80	4.81	0.38%
AMPHET/DEXTR CAP 10MG	1,575	450	$82,672.00	$52.49	3.5	0.17%
AMPHET/DEXTR CAP 15MG	1,555	381	$87,366.75	$56.18	4.08	0.18%
AMPHET/DEXTR CAP 25MG	1,178	212	$60,584.03	$51.43	5.56	0.13%
AMPHET/DEXTR TAB 7.5MG	1,023	253	$41,581.15	$40.65	4.04	0.09%
AMPHET/DEXTR CAP 5MG	273	97	$14,762.21	$54.07	2.81	0.03%
AMPHET/DEXTR TAB 12.5MG	236	68	$9,414.51	$39.89	3.47	0.02%
ADDERALL XR CAP 30MG	38	9	$8,135.66	$214.10	4.22	0.02%
ADDERALL XR CAP 10MG	30	6	$4,932.67	$164.42	5	0.01%
ADDERALL XR CAP 20MG	27	8	$4,545.57	$168.35	3.38	0.01%
AMPHETAMINE TAB 5MG	26	21	$656.33	$25.24	1.24	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AMPHETAMINE TAB 7.5MG	14	8	$546.29	$39.02	1.75	0.00%
MYDAYIS CAP 12.5MG	11	3	$2,430.93	$220.99	3.67	0.01%
ADDERALL XR CAP 25MG	9	2	$1,925.09	$213.90	4.5	0.00%
MYDAYIS CAP 37.5MG	6	1	$1,650.93	$275.16	6	0.00%
MYDAYIS CAP 25MG	6	4	$1,447.56	$241.26	1.5	0.00%
SUBTOTAL	**46,326**	**10,183**	**$1,672,887.71**	**$36.11**	**4.55**	**3.51%**
DEXMETHYLPHENIDATE PRODUCTS						
DEXMETHYLPH TAB 10MG	6,715	1,246	$211,202.32	$31.45	5.39	0.44%
DEXMETHYLPH TAB 5MG	5,638	1,320	$132,236.06	$23.45	4.27	0.28%
FOCALIN XR CAP 20MG	4,397	984	$1,669,754.09	$379.75	4.47	3.50%
FOCALIN XR CAP 10MG	3,994	1,212	$1,474,343.92	$369.14	3.3	3.09%
FOCALIN XR CAP 15MG	3,358	838	$1,277,808.53	$380.53	4.01	2.68%
FOCALIN XR CAP 30MG	2,820	517	$1,032,533.56	$366.15	5.45	2.16%
FOCALIN XR CAP 25MG	1,845	368	$738,174.80	$400.09	5.01	1.55%
FOCALIN XR CAP 5MG	1,552	639	$556,338.63	$358.47	2.43	1.17%
DEXMETHYLPH TAB 2.5MG	1,421	477	$28,825.44	$20.29	2.98	0.06%
FOCALIN XR CAP 40MG	1,265	196	$530,437.63	$419.32	6.45	1.11%
FOCALIN XR CAP 35MG	536	94	$228,148.55	$425.65	5.7	0.48%
FOCALIN TAB 10MG	195	66	$13,287.09	$68.14	2.95	0.03%
FOCALIN TAB 5MG	160	58	$7,946.91	$49.67	2.76	0.02%
FOCALIN TAB 2.5MG	34	22	$1,035.33	$30.45	1.55	0.00%
DEXMETHYLPH CAP ER 15MG	20	6	$1,644.30	$82.22	3.33	0.00%
DEXMETHYLPHE CAP ER 20MG	12	3	$391.25	$32.60	4	0.00%
DEXMETHYLPHE CAP ER 10MG	11	5	$588.97	$53.54	2.2	0.00%
DEXMETHYLPHE CAP ER 35MG	10	1	$976.14	$97.61	10	0.00%
DEXMETHYLPHE CAP ER 25MG	6	2	$417.09	$69.52	3	0.00%
DEXMETHYLPH CAP ER 30MG	3	2	$351.78	$117.26	1.5	0.00%
DEXMETHYLPHE CAP ER 5MG	1	1	$34.50	$34.50	1	0.00%
SUBTOTAL	**33,993**	**8,057**	**$7,906,476.89**	**$232.59**	**4.22**	**16.57%**
ATOMOXETINE PRODUCTS						
ATOMOXETINE CAP 40MG	7,995	2,190	$623,595.54	$78.00	3.65	1.31%
ATOMOXETINE CAP 25MG	7,730	2,256	$691,936.27	$89.51	3.43	1.45%
ATOMOXETINE CAP 60MG	4,547	987	$385,474.07	$84.78	4.61	0.81%
ATOMOXETINE CAP 18MG	3,970	1,431	$353,532.93	$89.05	2.77	0.74%
ATOMOXETINE CAP 10MG	3,273	1,226	$307,090.70	$93.83	2.67	0.64%
ATOMOXETINE CAP 80MG	2,719	571	$258,991.33	$95.25	4.76	0.54%
ATOMOXETINE CAP 100MG	854	185	$81,000.13	$94.85	4.62	0.17%
STRATTERA CAP 40MG	23	4	$9,924.83	$431.51	5.75	0.02%
STRATTERA CAP 10MG	19	4	$7,722.37	$406.44	4.75	0.02%
STRATTERA CAP 25MG	12	3	$4,562.24	$380.19	4	0.01%
STRATTERA CAP 80MG	8	2	$3,766.30	$470.79	4	0.01%
STRATTERA CAP 18MG	4	1	$1,625.08	$406.27	4	0.00%
STRATTERA CAP 100MG	2	1	$770.57	$385.29	2	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**31,156**	**8,861**	**$2,729,992.36**	**$87.62**	**3.52**	**5.72%**
CLONIDINE ER PRODUCTS						
CLONIDINE TAB 0.1MG ER	794	119	$107,263.26	$135.09	6.67	0.22%
KAPVAY TAB 0.1 MG	1	1	$857.98	$857.98	1	0.00%
SUBTOTAL	**795**	**120**	**$108,121.24**	**$136.00**	**6.63**	**0.23%**
MODAFINIL PRODUCTS						
MODAFINIL TAB 200MG	177	30	$6,844.66	$38.67	5.9	0.01%
MODAFINIL TAB 100MG	9	2	$444.49	$49.39	4.5	0.00%
PROVIGIL TAB 200MG	8	1	$25,812.64	$3,226.58	8	0.05%
SUBTOTAL	**194**	**33**	**$33,101.79**	**$170.63**	**5.88**	**0.07%**
ARMODAFINIL PRODUCTS						
NUVIGIL TAB 250MG	74	13	$56,521.88	$763.81	5.69	0.12%
NUVIGIL TAB 150MG	73	12	$65,812.14	$901.54	6.08	0.14%
NUVIGIL TAB 200MG	16	4	$12,663.32	$791.46	4	0.03%
ARMODAFINIL TAB 150MG	8	1	$316.00	$39.50	8	0.00%
NUVIGIL TAB 50MG	1	1	$271.37	$271.37	1	0.00%
SUBTOTAL	**172**	**31**	**$135,584.71**	**$788.28**	**5.55**	**0.28%**
AMPHETAMINE PRODUCTS						
ADZENYS XR TAB 12.5MG	34	5	$10,872.65	$319.78	6.8	0.02%
ADZENYS XR TAB 9.4MG	31	8	$10,300.90	$332.29	3.88	0.02%
ADZENYS XR TAB 15.7 MG	26	5	$8,740.81	$336.19	5.2	0.02%
ADZENYS XR TAB 6.3MG	24	3	$8,195.16	$341.47	8	0.02%
ADZENYS XR TAB 18.8MG	24	6	$8,241.44	$343.39	4	0.02%
ADZENYS XR TAB 3.1MG	7	1	$2,385.74	$340.82	7	0.00%
DYANAVEL XR SUS 2.5MG/ML	6	2	$1,751.97	$292.00	3	0.00%
AMPHETAMINE TAB 10MG	2	1	$949.45	$474.73	2	0.00%
EVEKEO TAB 10MG	2	2	$935.26	$467.63	1	0.00%
EVEKEO TAB 5MG	1	1	$376.48	$376.48	1	0.00%
SUBTOTAL	**157**	**34**	**$52,749.86**	**$335.99**	**4.62**	**0.11%**
DEXTROAMPHETAMINE PRODUCTS						
DEXTROAMPHET CAP 15MG ER	59	7	$8,889.52	$150.67	8.43	0.02%
DEXTROAMPHET TAB 10MG	32	5	$1,157.62	$36.18	6.4	0.00%
DEXTROAMPHET CAP 10MG ER	16	4	$646.94	$40.43	4	0.00%
DEXTROAMPHET TAB 5MG	10	2	$224.02	$22.40	5	0.00%
DEXTROAMPHET CAP 5MG ER	8	3	$374.92	$46.87	2.67	0.00%
ZENZEDI TAB 30MG	6	1	$2,445.96	$407.66	6	0.01%
DEXTROAMPHET SOL 5MG/5ML	6	2	$3,587.69	$597.95	3	0.01%
SUBTOTAL	**137**	**24**	**$17,326.67**	**$126.47**	**5.71**	**0.04%**
SODIUM OXYBATE PRODUCTS						
XYREM SOL 500MG/ML	36	5	$414,884.84	$11,524.58	7.2	0.87%
SUBTOTAL	**36**	**5**	**$414,884.84**	**$11,524.58**	**7.2**	**0.87%**
METHAMPHETAMINE PRODUCTS						
METHAMPHETAM TAB 5MG	8	1	$5,718.16	$714.77	8	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**8**	**1**	**$5,718.16**	**$714.77**	**8**	**0.01%**
TOTAL	**332,243**	**40,300***	**$47,727,417.00**	**$143.65**	**8.24**	**100%**

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

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Appendix H

Calendar Year 2019 Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Absorica LD™ (Isotretinoin Capsule), Amzeeq™ (Minocycline 4% Topical Foam), Aprizio Pak™ (Lidocaine/Prilocaine 2.5%/2.5% Kit), Caldolor® (Ibuprofen Injection), Exservan™ (Riluzole Oral Film), Metronidazole 1% Gel, Noritate® (Metronidazole 1% Cream), Procysbi® [Cysteamine Delayed-Release (DR) Granule], Pyridostigmine 30mg Tablet, Quzyttir™ (Cetirizine Injection), Relafen™ DS (Nabumetone Tablet), Slynd™ (Drospirenone Tablet), Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsule), and Tirosint® (Levothyroxine Capsule)

Oklahoma Health Care Authority
June 2020

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

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

1. An FDA approved indication to increase tear production in patients 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.

~~**Erythromycin 2% Swabs Approval Criteria:**~~

1. ~~Approval consideration requires a trial of erythromycin 2% topical solution or gel.~~

Erythromycin 2% Swabs and 2% Topical Gel Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use erythromycin 2% topical solution must be provided.

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 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 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 patients with osteosarcoma; or
    b. Diminishing the toxicity associated with overdosage of folic acid antagonists or impaired MTX elimination; or
    c. Treatment of patients 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 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 Vaginal 1.3% 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.

~~**Potassium Chloride 25mEq Packet (Klor-Con®, Epiklor®) Approval Criteria:**~~

~~1. A patient-specific, clinically significant reason why the member cannot use other non-prior authorized formulations of potassium chloride 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.

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.

Rayos® (Prednisone Delayed-Release Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use immediate-release corticosteroid medications 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.

Seconal Sodium® (Secobarbital Sodium Capsule) Approval Criteria:

1. An FDA approved indication for 1 of the following:
   a. Short-term treatment of insomnia; or
   b. As a pre-anesthetic; and
2. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives must be provided; and
3. For the short-term treatment of insomnia, a quantity limit of 1 capsule per day not to exceed 14 capsules per 30 days will apply.

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.

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 patients 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®-SOL (Levothyroxine Sodium 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 in the place of the oral solution, even when the tablets are crushed, must be provided.

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

1. An FDA approved indication of 1 of the following:
   a. Treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as a component of a combination chemotherapy maintenance regimen; or
   b. Management of pediatric patients 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.

Utilization of Various Special Formulations: Calendar Year 2019

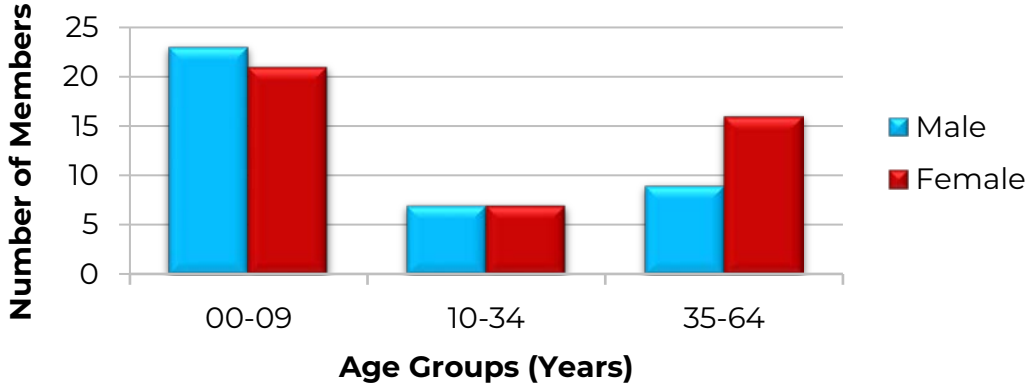
Comparison of Calendar Years: Various Special Formulations

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	138	338	$221,895.14	$656.49	$22.85	20,972	9,711
2019	83	343	$274,559.81	$800.47	$21.96	21,554	12,504
% Change	**-39.90%**	**1.50%**	**23.70%**	**21.90%**	**-3.90%**	**2.80%**	**28.80%**
Change	**-55**	**5**	**$52,664.67**	**$143.98**	**-$0.89**	**582**	**2,793**

*Total number of unduplicated 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.

Demographics of Members Utilizing Various Special Formulations

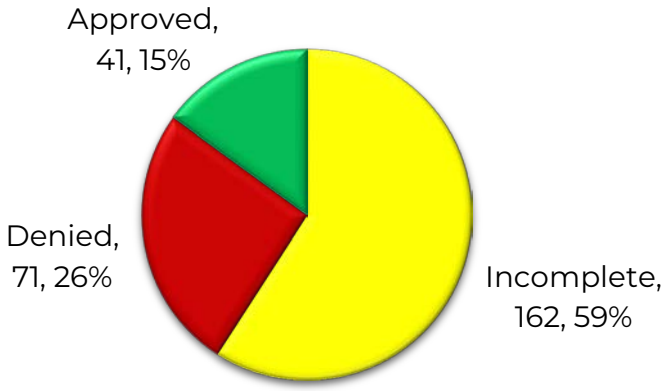


Top Prescriber Specialties of Various Special Formulations by Number of Claims

Prior Authorization of Various Special Formulations

There were 274 prior authorization requests submitted for various special formulations during calendar year 2019. The following chart shows the status of the submitted petitions for calendar year 2019.

Status of Petitions



Absorica LD™ (Isotretinoin Capsule) Product Summary[1,2]

Indication(s): Absorica LD™ (isotretinoin capsule) is a retinoid indicated for the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5mm or greater.

Limitation(s) of Use: If a second course of Absorica LD™ therapy is needed, it is not recommended before a 2-month waiting period because the patient's acne may continue to improve following a 15- to 20-week course of therapy.

Dosing and Administration:

- Absorica LD™ is supplied as liquid-filled, oral capsules containing micronized isotretinoin in suspension available in 6 strengths: 8mg, 16mg, 20mg, 24mg, 28mg, and 32mg.
- The recommended dose is 0.4 to 0.8mg/kg/day given in 2 divided doses for 15 to 20 weeks.
- Adult patients with very severe disease (e.g., scarring, trunk involvement) may increase dosage to 1.6mg/kg/day in divided doses.
- Absorica LD™ may be taken with or without a meal.
- Absorica LD™ is not substitutable with Absorica® because of different bioavailability and recommended dosage.
- Lipid abnormalities and hepatoxicity have been reported with isotretinoin use. Due to these risks, a fasting lipid profile and liver function tests are recommended prior initiating treatment with Absorica LD™ and at regular intervals during treatment.

Boxed Warning: Embryo-Fetal Toxicity – Contraindicated in Pregnancy
Absorica LD™ can cause life-threatening birth defects and is contraindicated in pregnancy. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. Absorica LD™ is available only through a Risk Evaluation and Mitigation Strategy (REMS) program called the iPLEDGE REMS.

Other Formulation(s) Available:

- Isotretinoin Capsules:
  - The indication and dose duration (15 to 20 weeks) for generic isotretinoin capsules are the same as Absorica LD™ with a similar *Boxed Warning*.
  - Generic isotretinoin capsules should be taken with a meal and the recommended dosing is 0.5 to 1mg/kg/day given in 2 divided doses with dose adjustments up to 2mg/kg/day, as tolerated for adults with severe disease.
  - Generic isotretinoin capsules are liquid-filled like Absorica LD™ but are available in 4 strengths: 10mg, 20mg, 30mg, and 40mg.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days	Cost Per 20 Weeks
Absorica LD™ (isotretinoin) 24mg capsule	**$38.13**	**$4,270.56**	**$21,352.80**
isotretinoin 30mg capsule (generic)	$5.12	$573.44	$2,867.20

Unit = capsule
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
Cost for both products based on maximum FDA recommended dose for a 60kg patient.

Calendar Year 2019 Utilization: There was no SoonerCare utilization of Absorica LD™ during calendar year 2019. For other isotretinoin capsule products, there were 1,554 claims for 427 unduplicated members with a total cost of $301,354.68. The cost per day was $6.50 with a cost per claim of $193.92. These costs do not reflect rebated prices or net costs.

Amzeeq™ (Minocycline 4% Topical Foam) Product Summary[3,4,5]

Indication(s): Amzeeq™ (minocycline 4% topical foam) is a tetracycline-class drug indicated to treat inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients 9 years of age and older.

Limitation(s) of Use: This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Amzeeq™ should be used only as indicated.

Dosing and Administration:

- Amzeeq™ is supplied as a 4% topical foam available in a 30g aluminum can. Each gram of Amzeeq™ contains 40mg of minocycline equivalent to 43mg of minocycline hydrochloride.
- The recommended dosing is to apply a small amount of topical foam onto the fingertips of the hand and then into acne-affected parts of the face. If acne is present on other parts of the patient's body (neck, shoulders, arms, back, or chest), additional amounts of topical foam should also be applied to these areas.
- The topical foam should be applied at approximately the same time each day at least 1 hour before bedtime.
- It is recommended to shake the can well prior to use.

Other Formulation(s) Available:

- Erythromycin 2% Topical Solution and Clindamycin 1% Topical Solution:
  - Similar to Amzeeq™, generic erythromycin 2% topical solution and clindamycin 1% topical solution are indicated for the topical treatment of acne vulgaris; however, unlike Amzeeq™, the safety and effectiveness of erythromycin 2% topical solution in pediatric patients have not been established. For clindamycin 1% topical solution, the safety and effectiveness in pediatric patients younger than 12 years of age have not been established.
  - The recommended dosing for erythromycin 2% topical solution is to apply over the affected area(s) (face, neck, shoulders, chest, and back) twice daily (morning and evening) after the skin is thoroughly washed with warm water and soap and patted dry. Clindamycin 1% topical solution is also applied to the affected area(s) twice daily.
  - Generic erythromycin 2% topical solution is supplied in a 60mL applicator bottle, and generic clindamycin 1% topical solution is supplied in 30mL and 60mL applicator bottles.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
Amzeeq™ (minocycline) 4% topical foam	**$15.59**	**$467.70**
erythromycin 2% topical solution (generic)	$0.46	$27.60
clindamycin 1% topical solution (generic)	$0.23	$13.80

Unit = gram or milliliter (mL)
*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) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Calendar Year 2019 Utilization: There was no SoonerCare utilization of Amzeeq™ during calendar year 2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
CLINDAMYCIN SOL 1%	1,388	840	$39,219.69	$1.12	1.65	$28.26
ERYTHROMYCIN SOL 2%	276	170	$11,608.10	$1.75	1.62	$42.06
TOTAL	**1,664**	**1,009***	**$50,827.79**	**$1.22**	**1.65**	**$30.55**

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

Aprizio Pak™ (Lidocaine/Prilocaine 2.5%/2.5% Kit) Product Summary[6,7]

Indication(s): Aprizio Pak™ (lidocaine/prilocaine 2.5%/2.5% kit) is indicated as a topical anesthetic for use on the following:

- Normal intact skin for local analgesia
- Genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia

Dosing and Administration:

- Aprizio Pak™ is supplied as a kit containing (3) 30g tubes of lidocaine/prilocaine 2.5%/2.5% cream, (20) 6x7cm frame style transparent dressings, and 1 pair of disposable medical scissors.
- The recommended dosing is based on the procedure, location of the procedure, and patient age (patient weight is also considered for pediatric patients):
  - Adult patients-intact skin: Apply a thick layer to intact skin and cover with an occlusive dressing.
  - Minor dermal procedures: Apply 2.5g over 20 to 25cm^2 of skin and allow to remain in contact with the skin at least 1 hour prior to procedure.
  - Major dermal procedures: Apply 2g per 10cm^2 of skin and allow to remain in contact with the skin for at least 2 hours prior to procedure.
  - Adult male patients-genital skin: As an adjunct prior to local anesthetic infiltration, apply a thick layer (1g/10cm^2) to the skin for 15 minutes prior to procedure.
  - Adult female patients-genital mucous membranes: For minor procedures as well as for use as pretreatment for anesthetic infiltration, apply a thick layer (5 to 10g) 5 to 10 minutes prior to procedure.
  - Pediatric patients-intact skin: Maximum application amount (1 to 20g), application area (10 to 200cm^2), and application duration (1 to 4 hours) is based on patient age and body weight.

Other Formulation(s) Available:

- Lidocaine/Prilocaine 2.5%/2.5% Cream:
  - Generic lidocaine/prilocaine 2.5%/2.5% cream has the same indications and recommended dosing as Aprizio Pak™.

- Generic lidocaine/prilocaine 2.5%/2.5% cream is supplied as individually packaged 5g and 30g tubes or as a pack containing (5) 5g tubes.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
Aprizio Pak™ (lidocaine/prilocaine) 2.5%/2.5% kit	**$1,350.86**	**$1,350.86**
lidocaine/prilocaine 2.5%/2.5% cream (generic)	$0.25	$22.50

Unit = gram
*Cost per package for lidocaine/prilocaine 2.5%/2.5% cream (generic) based on (3) 30g tubes as supplied in Aprizio Pak™.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Calendar Year 2019 Utilization: There was no SoonerCare utilization of Aprizio Pak™ during calendar year 2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
LIDO/PRILOCN CRE 2.5-2.5%	1,516	813	$27,505.07	$0.60	1.86	$18.14
TOTAL	**1,516**	**813***	**$27,505.07**	**$0.60**	**1.86**	**$18.14**

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

Caldolor® (Ibuprofen Injection) Product Summary[8,9,10]

Indication(s): Caldolor® [ibuprofen (IBU) injection] is a non-steroidal anti-inflammatory drug (NSAID) indicated in adult and pediatric patients 6 months of age and older for the following:

- Management of mild-to-moderate pain and the management of moderate-to-severe pain as an adjunct to opioid analgesics
- Reduction of fever

Dosing and Administration:

- Caldolor® is supplied as an injection for intravenous (IV) use and is available in 800mg/8mL single-dose vials (SDV), which require dilution before use, and 800mg/200mL single-dose, ready-to-use, polypropylene flexible bags.
- The recommended dose varies based on patient age and indication, as follows:

- Adult patients (pain): 400mg to 800mg IV over 30 minutes every 6 hours as needed
- Adult patients (fever): 400mg IV over 30 minutes, followed by 400mg every 4 to 6 hours or 100 to 200mg every 4 hours as needed
- Pediatric patients 12 to 17 years of age (pain and fever): 400mg IV over 10 minutes every 4 to 6 hours as needed
- Pediatric patients 6 months to 12 years of age (pain and fever): 10mg/kg IV over 10 minutes up to a maximum single dose of 400mg every 4 to 6 hours as needed

- It is recommended to use the lowest effective dosage for shortest duration consistent with individual patient treatment goals.

Boxed Warning: Risk of Serious Cardiovascular (CV) and Gastrointestinal (GI) Adverse Events

- NSAIDs cause an increased risk of serious CV thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. Caldolor® is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.
- NSAIDs cause an increased risk of serious GI adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms.

Other Formulation(s) Available:

- IBU tablets [prescription (Rx) and over-the-counter (OTC) strengths]:
  - Generic Rx IBU tablets, like Caldolor®, are indicated for the relief of mild-to-moderate pain. Additionally, Rx IBU tablets are indicated for relief of the signs and symptoms of rheumatoid arthritis (RA) and osteoarthritis (OA), and for the treatment of primary dysmenorrhea.
  - Like Caldolor®, the lowest effective dose for the shortest duration is recommended. A maximum daily dose of 3,200mg is recommended for Rx IBU tablets.
  - Rx IBU tablets are supplied as 3 strengths: 400mg, 600mg, and 800mg.
  - The recommended dose for adults for mild-to-moderate pain is 400mg every 4 to 6 hours as needed; for RA and OA, the

recommended dose is 1,200mg to 3,200mg daily in divided doses; for primary dysmenorrhea, the recommended dose is 400mg every 4 hours as needed.

- Rx IBU tablets have the same *Boxed Warning* as Caldolor®.
- Safety and effectiveness of Rx IBU tablets in pediatric patients have not been established.
- In children, OTC IBU is used for fever reduction and relief of minor aches and pains due to the common cold, influenza, sore throat, headaches, and toothaches.
- In adults, OTC IBU is used for fever reduction and relief of minor aches and pains due to headache, muscular aches, minor pain of arthritis, toothache, backache, the common cold, and menstrual cramps.
- OTC IBU tablets are indicated for patients 12 years of age and older, the chewable tablets and oral suspension for patients 2 to 11 years of age, and the oral infant drops for patients 6 months to 23 months of age.
- OTC IBU tablets and chewable tablets are available in 200mg and 100mg strengths, respectively. The oral suspension is available as 100mg/5mL and oral infant drops are available as 50mg/1.25mL.
- The directions for use for OTC IBU tablets are 1 to 2 tablets every 4 to 6 hours as needed, and for children 6 months to 11 years of age, the dosing is weight-based and administered every 6 to 8 hours.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Day*
Caldolor® (IBU) injection 800mg/8mL SDV	**$17.36**	**$69.44**
IBU 800mg tablet (Rx)	$0.09	$0.36
IBU 400mg tablet (Rx)	$0.05	$0.40
IBU 200mg tablet (OTC)	$0.06⁺	$0.96⁺

IBU = ibuprofen; SDV = single-dose vial; Unit = SDV or tablet; Rx = prescription strength; OTC = over-the-counter strength

*Cost per day based on maximum recommended adult dose of 3,200mg.

⁺Cost for ibuprofen 200mg tablet (OTC) based on price available as of 05/15/2020 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) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Calendar Year 2019 Utilization: There were no pharmacy claims for Caldolor® during calendar year 2019; however, there were 13 medical claims for

Caldolor® in calendar year 2019 with a total cost of $273.36. For the RX IBU tablets, there were 63,870 claims for 43,661 unduplicated members with a total cost of $746,467.21. The cost per day was $0.69 with a cost per claim of $11.69. OTC IBU is not covered by SoonerCare. These costs do not reflect rebated prices or net costs.

Exservan™ (Riluzole Oral Film) Product Summary[11,12,13]

Indication(s): Exservan™ (riluzole oral film) is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

Dosing and Administration:

- Exservan™ is supplied as a rectangular-shaped, orally-dissolving film containing 50mg of riluzole.
- The recommended dose is 50mg twice daily, 1 hour before or 2 hours after a meal.
- Exservan™ should be applied to the top of the tongue to adhere and dissolve; films should not be cut or split.
- Exservan™ should not be administered with liquids and patient should refrain from chewing, spitting, or talking as film dissolves.

Other Formulation(s) Available:

- Riluzole Tablet and Tiglutik® (Riluzole Oral Suspension):
  - Riluzole tablets and Tiglutik®, like Exservan™, are both indicated for the treatment of ALS.
  - Riluzole tablets are supplied as 50mg film-coated, capsule-shaped tablets, while Tiglutik® is supplied as a 50mg/10mL oral suspension.
  - Both riluzole tablets and Tiglutik® have the same recommended dosing as Exservan™, 50mg twice daily.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Exservan™ (riluzole) 50mg oral film	**Unavailable**	**Unavailable**
Tiglutik® (riluzole) 50mg/10mL oral suspension	$5.41	$3,246.00
riluzole 50mg tablet (generic)	$1.40	$84.00

Unit = film, mL, tablet

*Cost per 30 days based on recommended dosing of 50mg twice daily.

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Calendar Year 2019 Utilization: There was no SoonerCare utilization of Exservan™ during calendar year 2019 as it is not yet available.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
RILUZOLE TAB 50MG	23	5	$1,899.57	$2.75	4.6	$82.59
TOTAL	**23**	**5***	**$1,899.57**	**$2.75**	**4.6**	**$82.59**

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

Metronidazole 1% Gel[14,15]

Indication(s): Metronidazole 1% gel is indicated for the topical treatment of inflammatory lesions of rosacea.

Dosing and Administration:

- Metronidazole 1% gel is supplied as a clear, colorless to pale yellow gel containing 10mg of metronidazole per gram. It is available in a 60g tube and a 55g pump.
- Both the 60g tube and 55g pump are available as generics.
- The recommended dosing is to apply a thin layer to the affected area(s) once daily.

Other Formulation(s) Available:

- Metronidazole 0.75% Gel:
  - Metronidazole 0.75% gel has the same indication as metronidazole 1% gel.
  - Metronidazole 0.75% gel contains 7.5mg of metronidazole per gram of gel and is available in a 45g tube.
  - The recommended dosing of metronidazole 0.75% gel is to apply and rub in a thin layer to the affected area(s) twice daily, morning and evening.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
metronidazole 1% gel (generic)	**$1.70**	**$102.00**
metronidazole 0.75% gel (generic)	$0.96	$43.20

Unit = gram
*Cost per package based 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) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Calendar Year 2019 Utilization: There was 1 claim for 1 unduplicated member utilizing metronidazole 1% gel with a total cost of $122.64 for calendar year 2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
METRONIDAZOL GEL 0.75%	54	40	$2,680.15	$2.31	1.35	$49.63
TOTAL	**54**	**40***	**$2,680.15**	**$2.31**	**1.35**	**$49.63**

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

Noritate® (Metronidazole 1% Cream)[16,17]

Indication(s): Noritate® (metronidazole 1% cream) is indicated for the topical treatment of inflammatory lesions and erythema of rosacea.

Dosing and Administration:

- Noritate® is an emollient cream with each gram containing 10mg of micronized metronidazole and is supplied in a 60g tube.
- The recommended dosing is to apply and rub in a thin layer to the affected area(s) once daily.

Other Formulation(s) Available:

- Metronidazole 0.75% Cream:
  - Metronidazole 0.75% cream has the same indication as Noritate®.
  - Metronidazole 0.75% cream is an emollient cream with each gram containing 7.5mg of metronidazole, and it is supplied in a 45g tube.
  - The recommended dosing is to apply and rub in a thin layer to the affected area(s) twice daily, in the morning and evening.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
Noritate® (metronidazole) 1% cream	**$32.61**	**$1,956.60**
metronidazole 0.75% cream (generic)	$1.12	$50.40

Unit = gram
*Cost per package based 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) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Calendar Year 2019 Utilization: There was no SoonerCare utilization of Noritate® during calendar year 2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
METRONIDAZOL CRE 0.75%	57	51	$3,494.27	$2.74	1.12	$61.30
TOTAL	**57**	**51***	**$3,494.27**	**$2.74**	**1.12**	**$61.30**

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

Procysbi® [Cysteamine Delayed-Release (DR) Granule][18,19]

Indication(s): Procysbi® (cysteamine DR granule) is a cystine-depleting agent indicated for the treatment of nephropathic cystinosis in adults and pediatric patients 1 year of age and older.

Dosing and Administration:

- Procysbi® DR granules are supplied in single-use packets available in cartons containing of 60 or 120 packets.
- Procysbi® DR granules are available in 2 strengths: 75mg and 300mg; doses should be rounded to allow use of available strengths.
- Procysbi® treatment should begin promptly after the diagnosis is confirmed.
- The recommended dosing varies based on factors such as dose initiation, dose maintenance, switching from the immediate-release (IR) formulation, medication effectiveness, patient's age, and patient's weight.
- The recommended maintenance dose is 1.3g/m^2/day in 2 divided doses given every 12 hours with a maximum recommended dose of 1.95g/m^2/day. Dosing tables are provided in the *Prescribing Information* for detailed dosing recommendations.
- Prior to administration, the granules should be sprinkled onto applesauce, berry jelly, or fruit juice (except grapefruit juice), and mixed.
- For patients with a gastrostomy tube, the oral granules can be mixed in applesauce and administered via a gastrostomy tube.
- The entire contents should be consumed within 30 minutes of mixing, and the granules should not be crushed or chewed.

Other Formulation(s) Available:

- Procysbi® DR Capsule and Cystagon® IR Capsule:
  - Procysbi® DR capsules and Cystagon® IR capsules have the same indication as Procysbi® DR granules.
  - Procysbi® DR capsules are supplied in 2 strengths: 25mg and 75mg.
  - Cystagon® IR capsules are supplied in 2 strengths: 50mg and 150mg.

- Procysbi® DR capsule has the same recommended dosing and maximum recommended dose as Procysbi® DR granules.
- The recommended maintenance dose for Cystagon® IR capsule for children up to 12 years of age is 1.3g/m^2/day in 4 divided doses. Patients older than age 12 and weighing >110 pounds should receive 2g/day, divided 4 times daily. The maximum recommended dose is the same as Procysbi®.
- Cystagon® IR capsules are not recommended for children younger than 6 years of age due to risk of aspiration.
- Procysbi® DR capsule should be swallowed whole and not chewed or crushed.
- Both Procysbi® DR capsules and Cystagon® IR capsules can be opened and the contents mixed with food if the patient is unable to swallow capsules.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Procysbi® (cysteamine) 300mg DR granule	**$405.28**	**$48,633.60**
Procysbi® (cysteamine) 75mg DR capsule	$101.32	$48,633.60
Cystagon® (cysteamine) 150mg IR capsule	$1.28	$307.20

Unit = granule packet or capsule
*Cost per 30 days based on recommended maintenance dose from dosing charts in the *Prescribing Information* for a 23kg (50lb) patient.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Calendar Year 2019 Utilization: There was no SoonerCare utilization of Procysbi® DR granules or Cystagon® IR capsules during calendar year 2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
PROCYSBI CAP	1	1	$4,881.01	$162.70	1	$4,881.01
PROCYSBI CAP	1	1	$984.89	$32.83	1	$984.89
TOTAL	**1**	**1***	**$5,865.90**	**$97.77**	**2**	**$2,932.95**

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

Pyridostigmine 30mg Tablet[20,21]

Indication(s): Pyridostigmine 30mg tablet is indicated for the treatment of myasthenia gravis.

Dosing and Administration:

- The recommended dose is 600mg/day [(20) 30mg tablets] spaced throughout the day to provide maximum relief.
- Severe cases may require a dose of 1,500mg/day [(50) 30mg tablets], while mild cases may be treated with 60mg to 360mg/day.
- The strength and frequency of the dosage should be adjusted to meet the needs of each individual patient.

Other Formulation(s) Available:

- Pyridostigmine 60mg Tablet:
  - The indication and recommended dosing for pyridostigmine 60mg tablets are the same as those for pyridostigmine 30mg tablets.
  - Pyridostigmine 60mg tablets are supplied as white to off white, round, flat-faced tablets with a quadrisect score on one side.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
pyridostigmine 30mg tablet (generic)	**$6.96**	**$4,176.00**
pyridostigmine 60mg tablet (generic)	$0.37	$111.00

Unit = tablet
*Cost per 30 days is based on the recommended dose of 600mg per day.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Calendar Year 2019 Utilization: There was no SoonerCare utilization of pyridostigmine 30mg tablets during calendar year 2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
PYRIDOSTIGM TAB 60MG	148	25	$9,395.85	$2.19	5.92	$63.49
TOTAL	**148**	**25***	**$9,395.85**	**$2.19**	**5.92**	**$63.49**

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

Quzyttir™ (Cetirizine Injection)[22,23,24]

Indication(s): Quzyttir™ (cetirizine injection) is a histamine-1 (H1) receptor antagonist indicated for the treatment of acute urticaria in adults and children 6 months of age and older.

Limitation(s) of Use: Quzyttir™ is not recommended in pediatric patients younger than 6 years of age with impaired renal or hepatic function.

Dosing and Administration:

- Quzyttir™ is supplied as 10mg/mL aqueous solution for IV administration (via IV push over 1 to 2 minutes) and is available in 2mL SDVs.
- The recommended dose is once every 24 hours as needed as follows:
  - Adults and adolescents 12 years of age and older: 10mg every 24 hours
  - Children 6 to 11 years of age: 5mg or 10mg every 24 hours depending on symptom severity
  - Children 6 months to 5 years of age: 2.5mg every 24 hours

Other Formulation(s) Available:

- Cetirizine 5mg and 10mg Tablet and Cetirizine 1mg/mL Oral Solution:
  - Cetirizine 5mg and 10mg tablets and cetirizine 1mg/mL oral solution are indicated for the following:
    - Relief of symptoms associated with seasonal allergic rhinitis in adults and children 2 years of age and older
    - Relief of symptoms associated with perennial allergic rhinitis in adults and children 6 months of age and older
    - Treatment of the uncomplicated skin manifestations of chronic, idiopathic urticaria in adults and children 6 months of age and older
  - The recommended dose of oral cetirizine is once daily with dosing similar to Quzyttir™. For adults and children 12 years of age and older, the recommended dose varies slightly and is 5 to 10mg daily. The dose for children 6 to 11 years of age is the same as Quzyttir™. For children 12 months to 5 years of age the initial dose is the same, but may be increased to 5mg daily (given every 12 hours). For children 6 months of age to younger than 12 months of age, the dose is 2.5mg daily.
  - Current treatment guidelines for acute urticaria indicate that in some cases the dosing of second-generation H1 antihistamines, such as cetirizine, may be titrated to 2 or 4 times the normal dose to control symptoms.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Dose*
Quzyttir™ (cetirizine) 10mg/mL injection	**$300.00**	**$300.00**
cetirizine 10mg tablet (generic)	$0.07	$0.28
cetirizine 5mg tablet (generic)	$0.06	$0.48
cetirizine 1mg/mL oral solution (generic)	$0.04	$1.60

Unit = mL or tablet
*Cost per dose based on maximum recommended adult dose for acute urticaria (per guidelines for generic tablets and solution, per *Prescribing Information* for Quzyttir™).
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Calendar Year 2019 Utilization: There was no SoonerCare utilization of Quzyttir™ during calendar year 2019. For other cetirizine products, there were 210,359 claims for 92,074 unduplicated members with a total cost of $2,382,717.69. The cost per day was $0.35 with a cost per claim of $11.33. These costs do not reflect rebated prices or net costs.

Relafen™ DS (Nabumetone Tablet)[25,26]

Indication(s): Relafen™ DS (nabumetone tablet) is an NSAID indicated for the relief of signs and symptoms of OA and RA in adults.

Dosing and Administration:

- Relafen™ DS is supplied as 1,000mg white, coated, modified capsule-shaped tablets that are scored on 1 side.
- The recommended starting dose is 1,000mg taken as a single dose with or without food. The dose may be increased to 1,500mg per day or to a maximum recommended dose of 2,000mg per day given in either a single or twice-daily dose.
- The lowest effective dose for the shortest duration consistent with individual patient treatment goals is recommended.
- Relafen™ DS has a *Boxed Warning* for risk of serious CV and GI adverse events (*refer to the Boxed Warning for NSAIDs available in the Caldolor® Product Summary for additional information).*

Other Formulation(s) Available:

- Nabumetone 500mg and 750mg Tablet:

- Nabumetone 500mg and 750mg tablets have the same indications, recommended dosing, and *Boxed Warning* as Relafen™ DS tablets.
- Nabumetone 500mg and 750mg tablets are supplied as white, oval-shaped, biconvex, film-coated tablets.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Relafen™ DS (nabumetone) 1,000mg tablet	**$40.32**	**$1,814.40**
nabumetone 750mg tablet (generic)	$0.34	$20.40
nabumetone 500mg tablet (generic)	$0.24	$21.60

Unit = tablet
*Cost per 30 days based on dose of 1,500mg per day.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Calendar Year 2019 Utilization: There was no SoonerCare utilization of Relafen™ DS during calendar year 2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
NABUMETONE TAB 750MG	1,393	527	$27,891.54	$0.69	2.64	$20.02
NABUMETONE TAB 500MG	1,001	445	$17,163.50	$0.64	2.25	$17.15
TOTAL	**2,394**	**958***	**$45,055.04**	**$0.67**	**2.5**	**$18.82**

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

Slynd™ (Drospirenone Tablet)[27,28]

Indication(s): Slynd™ (drospirenone tablet) is a progestin-only oral contraceptive indicated for use by females of reproductive potential to prevent pregnancy.

Dosing and Administration:

- Slynd™ is supplied as white round, active film-coated tablets, each containing 4mg of drospirenone and green round, inert film-coated tablets that do not contain drospirenone. The tablets are available in blister cards that hold 24 active tablets and 4 inactive tablets.
- The recommended dose is to take 1 tablet daily for 28 consecutive days at the same time each day.

Other Formulation(s) Available:

- Norethindrone 0.35mg Tablet:
  - Norethindrone 0.35mg tablets have the same indication as Slynd™.
  - Norethindrone 0.35mg tablets are supplied in a dispenser card, dose pack containing 28 active tablets.
  - The recommended dosing is 1 tablet daily, at the same time each day. Administration is continuous, with no interruption between dose packs.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Pack
Slynd™ (drospirenone) 0.4mg tablet	**$6.61**	**$185.08**
norethindrone 0.35mg tablet (generic)	$0.22	$6.16

Unit = tablet
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Calendar Year 2019 Utilization: There were 3 claims for 1 unduplicated member utilizing Slynd™ with a total cost of $616.23 for calendar year 2019. For norethindrone 0.35mg tablets, there were 5,729 claims for 2,633 unduplicated members with a total cost of $103,488.07; the cost per day was $0.38 with a cost per claim of $18.06. These costs do not reflect rebated prices or net costs.

Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsule)[29,30]

Indication(s): Talicia® (omeprazole/amoxicillin/rifabutin capsule) is a 3-drug combination of omeprazole (a proton pump inhibitor), amoxicillin (a penicillin-class antibacterial), and rifabutin (a rifamycin antibacterial) indicated for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults.

Dosing and Administration:

- Talicia® is supplied as DR capsules containing omeprazole 10mg, amoxicillin 250mg, and rifabutin 12.5mg.
- The recommended dosing is 4 capsules every 8 hours for 14 days with food. Each dose (4 capsules) includes omeprazole 40mg, amoxicillin 1,000mg, and rifabutin 50mg.
- The capsules should be swallowed whole and should be taken with a full glass of water.

Other Formulation(s) Available*:

- Omeprazole 20mg DR Capsule, Amoxicillin 500mg Capsule, and Clarithromycin 500mg Tablet[+]:
  - Omeprazole DR capsules include an indication for *H. pylori* eradication for the reduction of the risk of duodenal ulcer recurrence when used as triple-therapy in combination with amoxicillin and clarithromycin.
  - Additionally, omeprazole DR capsules are indicated for *H. pylori* as double-therapy in combination with clarithromycin.
  - The following regimen is recommended for triple-therapy: omeprazole 20mg plus clarithromycin 500mg plus amoxicillin 1,000mg each given twice daily for 10 days.
  - For double-therapy the regimen is as follows: omeprazole 40mg once daily plus clarithromycin 500mg 3 times daily for 14 days.
  - Omeprazole DR capsules, amoxicillin capsules, and clarithromycin tablets are available in variety of strengths. For the purposes of comparison to Talicia®, only the strengths previously listed are included in the following cost comparison table.

* Due to their multiple indications/dosing regimens, the medications listed in the Talicia® Product Summary under *Other Formulation(s) Available* will only be reviewed for indications and dosing recommendations applicable to *H. pylori* GI tract infection.
[+]Clarithromycin 500mg tablet is being reviewed in place of rifabutin as rifabutin alone is only available as a 150mg capsule which is not currently indicated for the treatment of *H. pylori* infection.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Regimen[¥]
Talicia® (omeprazole/amoxicillin/rifabutin) capsule	**$3.87**	**$650.16**
omeprazole 20mg capsule (generic)	$0.04	$0.80
amoxicillin 500mg capsule (generic)	$0.06	$2.40
clarithromycin 500mg tablet (generic)	$0.54	$10.80

Unit = capsule or tablet
[¥]Cost per regimen based on recommended dosing duration for *H. Pylori* treatment for product listed. Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Calendar Year 2019 Utilization: There was no SoonerCare utilization of Talicia® during calendar year 2019. The following utilization data includes medications indicated for triple-therapy treatment of *H. pylori*; the data does not differentiate between triple-therapy treatment of *H. pylori* and other diagnoses, for which use may be appropriate.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
AMOXICILLIN CAP 500MG	44,029	38,141	$506,720.87	$1.29	1.15	$11.51
OMEPRAZOLE CAP 20MG	34,729	12,769	$392,649.11	$0.29	1.28	$11.31
CLARITHROMYC TAB 500MG	1,049	962	$23,523.72	$1.79	1.09	$22.42
TOTAL	**79,807**	**48,772***	**$922,893.70**	**$0.52**	**1.64**	**$11.56**

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

Tirosint® (Levothyroxine Capsule)[31,32]

Indication(s): Tirosint® (levothyroxine capsule) is L-thyroxine (T_4) indicated for the following:

- Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism
- 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

Limitation(s) of Use: Tirosint® is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients or for the treatment of transient hypothyroidism during the recovery phase of subacute thyroiditis.

Dosing and Administration:

- Tirosint® is supplied as amber-colored, round/biconvex capsules that are imprinted with a dosage strength specific letter on 1 side and contain a viscous amber-colored liquid.
- Tirosint® is available in a box consisting of 3 blister packs with 10 capsules each for a total of 30 capsules per box. The dosage strength on each box is clearly identified in several locations and is associated with a distinct color.
- Tirosint® is available in 12 strengths ranging from 13mcg to 200mcg. The recommended dosing is once daily, on an empty stomach, 1/2 to 1 hour before breakfast. It should be administered at least 4 hours before or after drugs that are known to interfere with absorption.
- Tirosint® starting dose depends on a variety of factors, including age, body weight, CV status, concomitant medical conditions, concomitant medications, co-administered food, and the specific nature of the

condition being treated. Peak therapeutic effect may not be attained for 4 to 6 weeks.
- Tirosint® capsules should be swallowed whole and should not be cut, crushed, or chewed.

Other Formulation(s) Available:

- Levothyroxine Tablets:
  - Levothyroxine tablets have the same indications and dosing as Tirosint®, but are supplied in a tablet formulation.
  - Levothyroxine tablets do not include the limitations of use associated with Tirosint®.
  - Additional indications for levothyroxine tablets include the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's thyroiditis), and multinodular goiters.
  - Levothyroxine tablets are available in 12 different strengths which differ from Tirosint® with the exclusion of 13mcg and the inclusion of 300mcg.
  - Levothyroxine tablets can be crushed and mixed in a small amount (5mL to 10mL) of water for those unable to swallow tablets.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days
Tirosint® (levothyroxine) capsule	**$4.24 - $4.44**	**$127.20 - $133.20**
levothyroxine tablet (generic)	$0.23 - $0.52	$6.90 - $15.60

Unit = capsule or tablet
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Calendar Year 2019 Utilization: There were 281 claims for 72 unduplicated members utilizing Tirosint® with a total cost of $51,848.31 for calendar year 2019. For levothyroxine tablet products, there were 47,629 claims for 10,352 unduplicated members with a total cost of $1,086,438.36; the cost per day was $0.49 with a cost per claim of $22.81. These costs do not reflect rebated prices or net costs.

Recommendations

The College of Pharmacy recommends the following changes to current Various Special Formulations approval criteria based on cost and product availability (changes are shown in red in the *Current Prior Authorization* section):

1. Adding erythromycin 2% swabs to the current erythromycin 2% topical gel approval criteria based on Wholesale Acquisition Cost (WAC); and
2. Removing the potassium chloride 25mEq packet (Klor-Con®, Epiklor®) approval criteria based on product discontinuation.

Additionally, the College of Pharmacy recommends the prior authorization of Absorica LD™ (isotretinoin capsule), Amzeeq™ (minocycline 4% topical foam), and Aprizio Pak™ (lidocaine/prilocaine 2.5%/2.5% kit) with the following criteria:

Absorica LD™ (Isotretinoin Capsule) Approval Criteria:

1. An FDA approved diagnosis of severe recalcitrant nodular acne in non-pregnant patients 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. A recent patient weight must be provided on the prior authorization request in order to authorize the appropriate amount of medication according to drug labeling.

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, which are available without prior authorization, must be provided; and

5. A quantity limit of 30 grams per 30 days will apply.

Aprizio Pak™ (Lidocaine/Prilocaine 2.5%/2.5% Kit) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the standard formulation of lidocaine/prilocaine 2.5%/2.5% cream, which is available without prior authorization, must be provided.

Additionally, the College of Pharmacy recommends the placement of Caldolor® (ibuprofen injection) and Relafen™ DS (nabumetone tablet) into the Special Prior Authorization (PA) Tier of the Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Product Based Prior Authorization (PBPA) category. Current Special PA criteria will apply. The proposed changes are shown in red in the following NSAIDs Tier Chart:

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
celecoxib (Celebrex®) 50mg, 100mg, & 200mg caps	diclofenac potassium (Cataflam®)	celecoxib (Celebrex®) 400mg caps
diclofenac epolamine (Flector® Patch) - brand name preferred	diclofenac sodium/ misoprostol (Arthrotec®)	diclofenac (Zorvolex®)
diclofenac ER (Voltaren® XR)	diclofenac sodium (Voltaren®) 25mg tabs	diclofenac potassium (Cambia®) powder pack
diclofenac sodium (Voltaren®) 50mg & 75mg tabs	etodolac (Lodine®) 200mg & 300mg caps	diclofenac potassium (Zipsor®) caps
diclofenac sodium 1% (Voltaren® Gel)	etodolac ER (Lodine® XL)	diclofenac sodium (Dyloject™)
etodolac (Lodine®) 400mg & 500mg tabs	naproxen sodium (Anaprox®) 275mg & 550mg tabs	diclofenac sodium (Pennsaid®) topical drops
flurbiprofen (Ansaid®)	oxaprozin (Daypro®)	fenoprofen (Nalfon®)
ibuprofen (Motrin®)	piroxicam (Feldene®)	**ibuprofen injection (Caldolor®)**
indomethacin IR capsules (Indocin® 25 & 50mg only)	tolmetin (Tolectin®)	ibuprofen/famotidine (Duexis®)
ketoprofen (Orudis®)		indomethacin (Indocin®) susp & ER caps
meloxicam (Mobic®)		indomethacin (Tivorbex®)
nabumetone (Relafen®)		ketoprofen ER (Oruvail®)

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
naproxen (Naprosyn®)		ketorolac tromethamine (Sprix®) nasal spray
naproxen EC (Naprosyn®)		meclofenamate (Meclomen®)
sulindac (Clinoril®)		mefenamic acid (Ponstel®)
		meloxicam (Vivlodex®) caps
		meloxicam orally disintegrating tablet (Qmiiz ODT™)
		nabumetone 1,000mg (Relafen DS®)
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)

ER = extended-release; EC = enteric coated; caps = capsules; tabs = tablets; susp = suspension; IR = immediate-release; PA = prior authorization
Tier structure based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

NSAIDs Special Prior Authorization (PA) Approval Criteria:

1. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or
2. Previous use of at least 2 Tier-1 NSAID products (from different product lines); and
3. A patient-specific, clinically-significant reason why a special formulation is needed over a Tier-1 product must be provided.
4. Additionally, use of Tivorbex™ will require a patient-specific, clinically significant reason why the member cannot use all other available generic indomethacin products.
5. Additionally, use of Celebrex® (celecoxib) 400mg capsules will require a diagnosis of Familial Adenomatous Polyposis (FAP) and a patient-specific, clinically significant reason why the member cannot use 2 celecoxib 200mg capsules to achieve a 400mg dose.

The College of Pharmacy also recommends the addition of Exservan™ (riluzole oral film) to the current Tiglutik® (riluzole oral suspension) approval criteria and the addition of Procysbi® (cysteamine DR granule) to the current Procysbi® (cysteamine DR capsule) approval criteria (proposed changes shown in red):

Exservan™ (Riluzole Oral Film) and Tiglutik® (Riluzole Oral Suspension) Approval Criteria:

1. An FDA approved indication for the treatment of amyotrophic lateral sclerosis (ALS); and
2. A patient-specific, clinically significant reason why the member cannot use riluzole tablets, even when tablets are crushed, must be provided; and
3. A quantity limit of 20mL per day or 600mL per 30 days will apply for Tiglutik®; and
4. A quantity limit of 2 films per day or 60 films per 30 days will apply for Exservan™.

Procysbi® (Cysteamine Bitartrate) Delayed-Release Capsule and Granule Approval Criteria:

1. An FDA approved diagnosis of nephropathic cystinosis; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation Cystagon® (cysteamine bitartrate) must be provided; and
3. Use of Procysbi® granules will require a patient-specific, clinically significant reason why the member cannot use the capsule formulation of Procysbi®.

Further, the College of Pharmacy recommends the prior authorization of metronidazole 1% gel, Noritate® (metronidazole 1% cream), and pyridostigmine 30mg tablet with the following criteria:

Metronidazole 1% Gel Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use metronidazole 0.75% gel, which is available without prior authorization, must be provided.

Noritate® (Metronidazole 1% Cream) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use metronidazole 0.75% cream, which is available without prior authorization, must be provided.

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.

The College of Pharmacy also recommends the prior authorization of Quzyttir™ (cetirizine injection), Slynd™ (drospirenone tablet), and Talicia® (omeprazole/amoxicillin/rifabutin capsule) with the following criteria:

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.

Slynd™ (Drospirenone Tablet) Approval Criteria:

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

Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsule) 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 treatments 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.

Finally, the College of Pharmacy recommends adding Tirosint® (levothyroxine capsule) to the current Tirosint®-SOL (levothyroxine oral solution) approval criteria (proposed changes are shown in red):

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 formulation, even when the tablets are crushed, must be provided.

Utilization Details of Various Special Formulations: Calendar Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
CALCIPOTRIENE PRODUCTS					
SORILUX AER 0.005%	48	19	$49,761.96	$1,036.71	2.53
SUBTOTAL	**48**	**19**	**$49,761.96**	**$1,036.71**	**2.53**
ERYTHROMYCIN PRODUCTS					
ERYTHROMYCIN GEL 2%	1	1	$67.92	$67.92	1
SUBTOTAL	**1**	**1**	**$67.92**	**$67.92**	**1**
GABAPENTIN PRODUCTS					
HORIZANT TAB 600MG ER	3	1	$1,127.78	$375.93	3
SUBTOTAL	**3**	**1**	**$1,127.78**	**$375.93**	**3**
LACTULOSE PRODUCTS					
KRISTALOSE PAK 20GM	9	2	$2,048.67	$227.63	4.5
KRISTALOSE PAK 10GM	8	1	$1,790.42	$223.80	8
SUBTOTAL	**17**	**3**	**$3,839.09**	**$225.83**	**5.67**
LEVOTHYROXINE PRODUCTS					
TIROSINT-SOL SOL 8MCG/ML	6	2	$749.40	$124.90	3
TIROSINT-SOL SOL 50MCG/ML	5	3	$697.45	$139.49	1.67
TIROSINT-SOL SOL 75MCG/ML	3	2	$346.43	$115.48	1.5
TIROSINT-SOL SOL 25MCG/ML	2	1	$278.44	$139.22	2
SUBTOTAL	**16**	**8**	**$2,071.72**	**$129.48**	**2**
MERCAPTOPURINE PRODUCTS					
PURIXAN SUS 20MG/ML	157	32	$164,982.79	$1,050.85	4.91
SUBTOTAL	**157**	**32**	**$164,982.79**	**$1,050.85**	**4.91**
METHOTREXATE PRODUCTS					
XATMEP SOL 2.5MG/ML	70	22	$40,968.06	$585.26	3.18
OTREXUP INJ 12.5MG/0.4ML	7	1	$4,598.71	$656.96	7
OTREXUP INJ 15MG/0.4ML	3	1	$1,983.03	$661.01	3
OTREXUP INJ 20MG/0.4ML	2	1	$1,321.30	$660.65	2
RASUVO INJ 25MG/0.5ML	2	1	$988.37	$494.19	2
RASUVO INJ 15MG/0.3ML	2	1	$914.16	$457.08	2
RASUVO INJ 12.5MG/0.25ML	1	1	$504.41	$504.41	1
SUBTOTAL	**87**	**28**	**$51,278.04**	**$589.40**	**3.11**
METOCLOPRAMIDE PRODUCTS					
METOCLOPRAM TAB 5MG	2	1	$471.08	$235.54	2
SUBTOTAL	**2**	**1**	**$471.08**	**$235.54**	**2**
NORETHINDRONE/ESTRADIOL PRODUCTS					
TAYTULLA CAP 1MG/20MCG	1	1	$190.16	$190.16	1
SUBTOTAL	**1**	**1**	**$190.16**	**$190.16**	**1**
POTASSIUM CHLORIDE PRODUCTS					

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
POT CHLORIDE POW 20MEQ	6	3	$281.44	$46.91	2
KLOR-CON PAK 20MEQ	5	2	$487.83	$97.57	2.5
SUBTOTAL	**11**	**5**	**$769.27**	**$69.93**	**2.2**
TOTAL	**343**	**83***	**$274,559.81**	**$800.47**	**4.13**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
The prior authorization for Sorilux® (calcipotriene 0.005% foam) was voted on by the Drug Utilization Review (DUR) board in October 2019 and implemented in December 2019. The utilization shown in the table above occurred prior to implementation.

- There were no SoonerCare paid pharmacy claims for calendar year 2019 for the following various special formulation products: Cequa™ (cyclosporine 0.09% ophthalmic solution), erythromycin 2% swabs, GoNitro™ (nitroglycerin sublingual powder), Gralise® [gabapentin extended-release (ER) tablet], Khapzory™ (levoleucovorin injection), Lyrica® CR (pregabalin ER capsule), Nuvessa™ (metronidazole 1.3% vaginal gel), potassium chloride 25mEQ packet (Klor-Con®, Epiklor®), Rayos® (prednisone DR tablet), Restasis MultiDose® (cyclosporine 0.05% ophthalmic emulsion), Seconal Sodium® (secobarbital sodium capsule), Sinuva™ (mometasone furoate sinus implant), and Soltamox® (tamoxifen citrate 10mg/5mL oral solution).

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Appendix I

Calendar Year 2019 Annual Review of Ophthalmic Anti-Inflammatories and 30-Day Notice to Prior Authorize Iluvien® (Fluocinolone Intravitreal Implant), Ozurdex® (Dexamethasone Intravitreal Implant), and Retisert® (Fluocinolone Intravitreal Implant)

Oklahoma Health Care Authority
June 2020

Current Prior Authorization Criteria

Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	
Tier-1	**Tier-2**
diclofenac (Voltaren®) 0.1% soln	bromfenac (Bromday®) 0.09% soln
flurbiprofen (Ocufen®) 0.03% soln$^{\Delta}$	bromfenac (BromSite™) 0.075% soln
ketorolac (Acular®) 0.5% soln	bromfenac (Prolensa®) 0.07% soln
nepafenac (Ilevro®) 0.3% susp	ketorolac (Acular LS®) 0.4% soln
	ketorolac (Acuvail®) 0.45% soln
	nepafenac (Nevanac®) 0.1% susp

soln = solution; susp = suspension
$^{\Delta}$ Not a required Tier-1 trial; does not have to be attempted for approval of a Tier-2 medication.
Tier structure based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

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

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

Ophthalmic Corticosteroids	
Tier-1	**Tier-2**
dexamethasone (Maxidex®) 0.1% susp	fluorometholone (FML Forte®) 0.25% susp
dexamethasone sodium phosphate 0.1% soln	fluorometholone (FML S.O.P.®) 0.1% oint
difluprednate (Durezol®) 0.05% emul	loteprednol (Inveltys™) 1% susp
fluorometholone (Flarex®) 0.1% susp	loteprednol (Lotemax®) 0.5% gel
fluorometholone (FML Liquifilm®) 0.1% susp	loteprednol (Lotemax®) 0.5% oint
loteprednol (Lotemax®) 0.5% susp	loteprednol (Lotemax® SM) 0.38% gel
prednisolone acetate (Omnipred®) 1% susp	prednisolone acetate (Pred Forte®) 1% susp
prednisolone acetate (Pred Mild®) 0.12% susp	
prednisolone sodium phosphate 1% soln	

soln = solution; susp = suspension; emul = emulsion; oint = ointment
Tier structure based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Ophthalmic Corticosteroids Tier-2 Approval Criteria:

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

Dextenza® (Dexamethasone Ophthalmic Insert) Approval Criteria:

1. An FDA approved indication of the treatment of ocular pain following ophthalmic surgery; and
2. Prescriber must verify that Dextenza® will be placed by a physician immediately following ophthalmic surgery; and
3. Date of ophthalmic surgery must be provided; and
4. A patient-specific, clinically significant reason why corticosteroid ophthalmic preparations, such as solution or suspension, typically used following ophthalmic surgery are not appropriate for the member must be provided; and
5. A quantity limit of 2 inserts per 30 days will apply.

Oxervate™ (Cenegermin-bkbj Ophthalmic Solution) Approval Criteria:

1. An FDA approved diagnosis of neurotrophic keratitis; and
2. Oxervate™ must be prescribed by, or in consultation with, an ophthalmologist; and

3. Prescriber must verify that the member has persistent epithelial defect (PED) (stage 2 disease) or corneal ulceration (stage 3 disease) of at least 2 weeks duration that is refractory to 1 or more conventional non-surgical treatments for neurotrophic keratitis; and
    a. Specific non-surgical treatments and dates of trials must be listed on the prior authorization request; and
4. Prescriber must verify that the member has evidence of decreased corneal sensitivity within the area of the PED or corneal ulcer and outside of the area of the defect in at least 1 corneal quadrant; and
5. Prescriber must verify the member has been counseled on the proper administration and storage of Oxervate™; and
6. Approvals will be for a maximum duration of 8 weeks of total therapy per eye; and
7. A quantity limit of 2 weekly kits per 14 days will apply. A quantity limit override will be approved for 4 weekly kits per 14 days with prescriber documentation of treatment in both eyes.

Yutiq™ (Fluocinolone Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of chronic, non-infectious uveitis affecting the posterior segment of the eye; and
2. Yutiq™ must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure and cataract development; and
4. A patient-specific, clinically significant reason why the member requires Yutiq™ in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
5. A quantity limit of 1 implant per eye every 36 months will apply.

Utilization of Ophthalmic Anti-Inflammatories: Calendar Year 2019

Comparison of Calendar Years: Ophthalmic NSAIDs (Pharmacy Claims)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	541	733	$41,555.04	$56.69	$2.30	3,712	18,031
2019	548	741	$44,606.74	$60.20	$2.52	3,744	17,687
% Change	**1.3%**	**1.1%**	**7.3%**	**6.2%**	**9.6%**	**0.9%**	**-1.9%**
Change	**7**	**8**	**$3,051.70**	**$3.51**	**$0.22**	**32**	**-344**

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

- Please note: Some Tier-1 ophthalmic NSAID products participate in supplemental rebates; therefore, costs shown do not reflect net costs.

Comparison of Calendar Years: Ophthalmic Corticosteroids (Pharmacy Claims)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	1,965	2,918	$246,583.68	$84.50	$3.26	19,552	75,599
2019	1,993	2,852	$244,863.25	$85.86	$3.29	19,035	74,367
% Change	**1.4%**	**-2.3%**	**-0.7%**	**1.6%**	**0.9%**	**-2.6%**	**-1.6%**
Change	**28**	**-66**	**-$1,720.43**	**$1.36**	**$0.03**	**-517**	**-1,232**

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

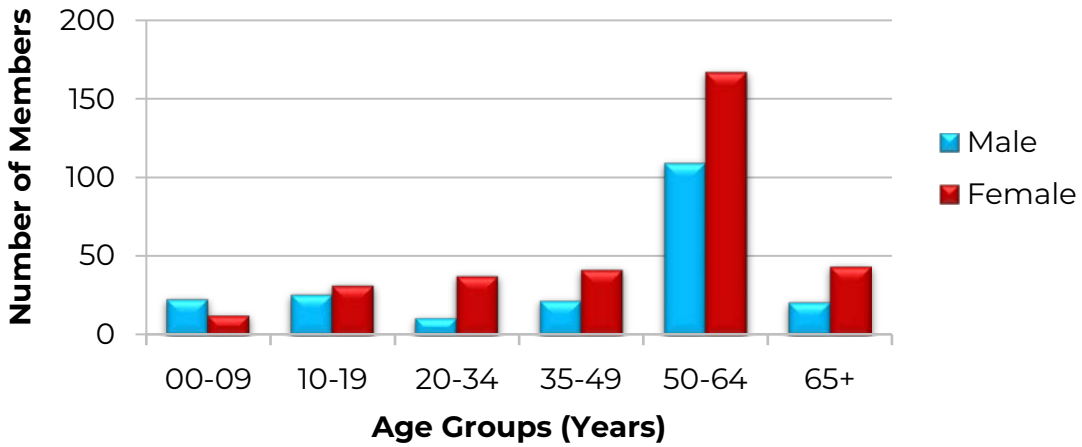
- Please note: Some Tier-1 ophthalmic corticosteroid products participate in supplemental rebates; therefore, costs shown do not reflect net costs.

Calendar Year 2019 Utilization: Ophthalmic Corticosteroids (Medical Claims)

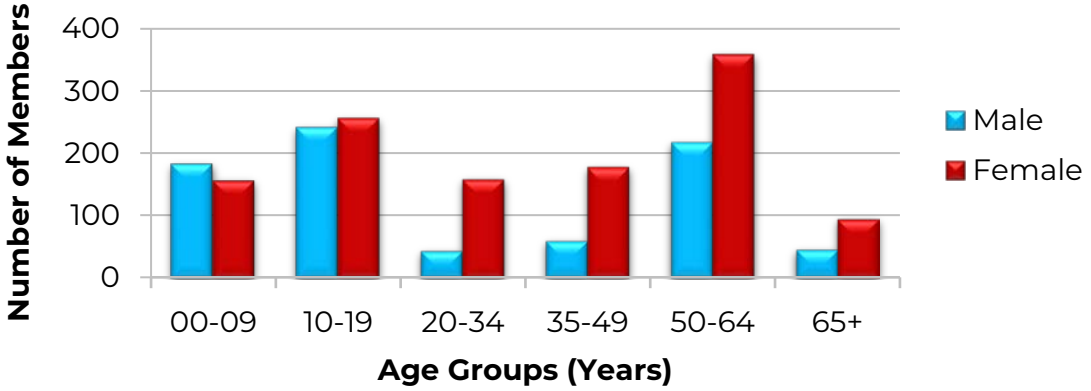
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2019	15	23	$45,455.69	$1,976.33	1.53

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

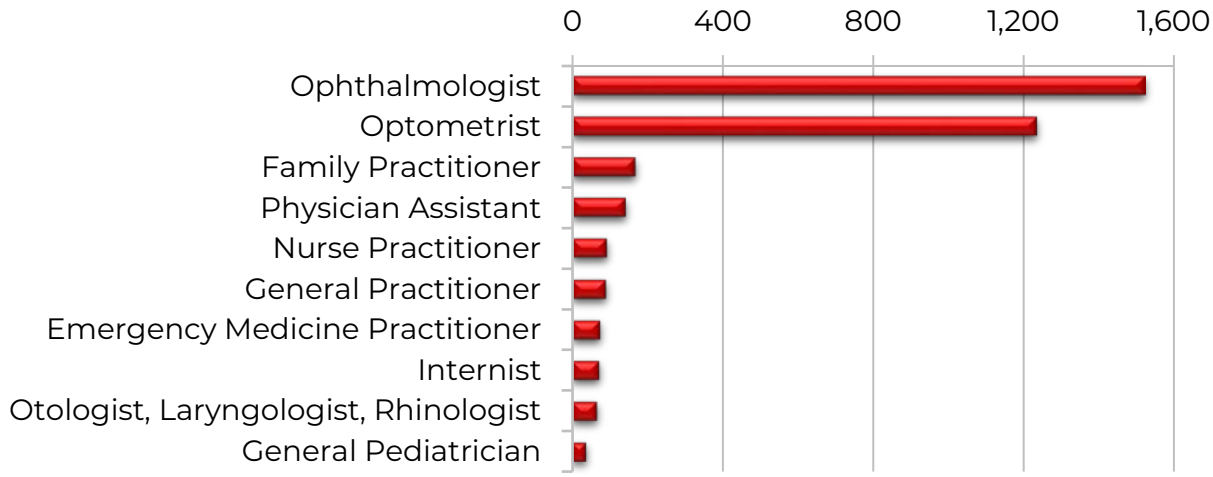
Demographics of Members Utilizing Ophthalmic NSAIDs (Pharmacy Claims)



Demographics of Members Utilizing Ophthalmic Corticosteroids (Pharmacy Claims)



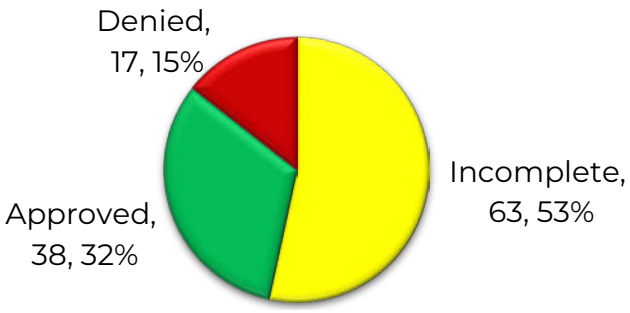
Top Prescriber Specialties of Ophthalmic Anti-Inflammatories by Number of Claims (Pharmacy Claims)



Prior Authorization of Ophthalmic Anti-Inflammatories

There were 118 prior authorization requests submitted for ophthalmic anti-inflammatories during calendar year 2019. The following chart shows the status of the submitted petitions for calendar year 2019.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Ozurdex® (dexamethasone intravitreal implant): November 2023
- Nevanac® (nepafenac 0.1% ophthalmic suspension): January 2027
- Iluvien® (fluocinolone intravitreal implant): August 2027
- Yutiq™ (fluocinolone intravitreal implant): August 2027
- Acular LS® (ketorolac 0.4% ophthalmic solution): November 2027
- Acuvail® (ketorolac 0.45% ophthalmic solution): August 2029
- BromSite™ (bromfenac 0.075% ophthalmic solution): August 2029
- Dextenza® (dexamethasone ophthalmic insert): May 2030
- Ilevro® (nepafenac 0.3% ophthalmic suspension): March 2032
- Inveltys™ (loteprednol 1% ophthalmic suspension): May 2033
- Prolensa® (bromfenac 0.07% ophthalmic solution): November 2033
- Lotemax® SM (loteprednol 0.38% ophthalmic gel): December 2036

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

- **June 2019:** Ocular Therapeutix announced that the FDA approved a supplemental New Drug Application (sNDA) for Dextenza® (dexamethasone ophthalmic insert) to include the treatment of ocular inflammation following ophthalmic surgery as an additional indication. Dextenza® is the first FDA-approved intracanalicular insert, a novel route of administration that delivers drug to the surface of the eye without the need for eye drops. Dextenza® originally received FDA approval in November 2018 for the treatment of ocular pain following ophthalmic surgery.
- **June 2019:** Alembic Pharmaceuticals announced that the FDA has approved its Abbreviated New Drug Application (ANDA) for bromfenac 0.09% ophthalmic solution for the treatment of postoperative inflammation and pain. The approved ANDA is therapeutically equivalent to the reference listed drug, Bromday® 0.09% ophthalmic solution.

Pipeline:

- **January 2020:** Kala Pharmaceuticals announced positive topline results from STRIDE (Short Term Relief In Dry Eye) 3, a Phase 3 clinical trial evaluating KPI-121 0.25%, which Kala plans to commercialize under the brand name Eysuvis™. STRIDE 3 met both of its primary efficacy endpoints, demonstrating a statistically significant improvement in the symptom endpoint of ocular discomfort severity (ODS) at day 15 in the

overall intent-to-treat (ITT) population (P=0.0002) and in the predefined subgroup of ITT patients with more severe ocular discomfort at baseline (P=0.0007). Statistical significance was also achieved in the key secondary endpoints of conjunctival hyperemia at day 15 in the ITT population (P<0.0001) and ODS at day 8 in the ITT population (P=0.0282). Significant results were also observed for total corneal staining at day 15 in the ITT population (P=0.0042). Eysuvis™ was well tolerated, with adverse events and intraocular pressure increases comparable to vehicle. Kala plans to utilize these data as the basis for a Class 2 resubmission of the New Drug Application (NDA) for Eysuvis™ in the second quarter of 2020, with an expected 6-month review timeline by the FDA.

Iluvien® (Fluocinolone Intravitreal Implant) Product Summary[7]

FDA Approval Date: 2014

Indication(s): Iluvien® (fluocinolone intravitreal implant) contains a corticosteroid and is indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (IOP).

Dosing and Administration:

- Iluvien® is supplied as a non-bioerodable intravitreal implant in a drug delivery system containing 0.19mg fluocinolone acetonide, designed to release fluocinolone acetonide at an initial rate of 0.25mcg/day and lasting 36 months.
- Iluvien® is for ophthalmic intravitreal injection only and should be carried out under aseptic conditions.
- Following the intravitreal injection, patients should be monitored for elevation in IOP, endophthalmitis, and cataract development.

Ozurdex® (Dexamethasone Intravitreal Implant) Product Summary[8]

FDA Approval Date: 2009

Indication(s): Ozurdex® (dexamethasone intravitreal implant) is a corticosteroid indicated for:

- The treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO); and

- The treatment of non-infectious uveitis affecting the posterior segment of the eye; and
- The treatment of diabetic macular edema.

Dosing and Administration:

- Ozurdex® is supplied as a 0.7mg dexamethasone in the NOVADUR® solid polymer drug delivery system.
- Ozurdex® is for ophthalmic intravitreal injection only and should be carried out under aseptic conditions.
- Following the intravitreal injection, patients should be monitored for elevation in IOP, endophthalmitis, and cataract development.

Retisert® (Fluocinolone Intravitreal Implant) Product Summary[9]

FDA Approval Date: 2004

Indication(s): Retisert® (fluocinolone intravitreal implant) is a corticosteroid indicated for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye.

Dosing and Administration:

- Retisert® is supplied as an intravitreal implant containing a 0.59mg fluocinolone acetonide tablet encased in a silicone elastomer cup containing a release orifice, and is designed to release fluocinolone acetonide at an initial rate of 0.6mcg/day, decreasing over the first month to a steady state between 0.3-0.4mcg/day over approximately 30 months.
- Retisert® is for ophthalmic intravitreal injection only and should be carried out under aseptic conditions.
- Following the intravitreal injection, patients should be monitored for elevation in IOP, endophthalmitis, and cataract development.

Other Formulations and Cost Comparison[10,11]

Dextenza® (dexamethasone ophthalmic insert) is a corticosteroid indicated for the treatment of ocular inflammation and pain following ophthalmic surgery.

- Dextenza® is supplied as an ophthalmic intracanalicular insert containing 0.4mg dexamethasone in a polyethylene glycol based hydrogel conjugated with fluorescein, and is designed to release a 0.4mg dose of dexamethasone for up to 30 days following insertion.

- Dextenza® is for insertion in the lower lacrimal punctum and into the canaliculus.
- Following the insertion, patients should be monitored for change in IOP.

Yutiq™ (fluocinolone intravitreal implant) contains a corticosteroid and is indicated for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye.

- Yutiq™ is supplied as a non-bioerodible intravitreal implant in a drug delivery system containing 0.18mg fluocinolone acetonide, designed to release fluocinolone acetonide at an initial rate of 0.25mcg/day and last 36 months.
- Yutiq™ is for ophthalmic intravitreal injection only and should be carried out under aseptic conditions.
- Following the injection, patients should be monitored for change in IOP and for endophthalmitis.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Iluvien® (fluocinolone) 0.19mg intravitreal implant	**$8,800.00**	**$244.44**
Ozurdex® (dexamethasone) 0.7mg intravitreal implant	**$1,333.00**	**$333.25-$444.33**
Retisert® (fluocinolone) 0.59mg intravitreal implant	**$19,025.00**	**$634.17**
Dextenza® (dexamethasone) 0.4mg ophthalmic insert	$538.83	$538.83
Yutiq™ (fluocinolone) 0.18mg intravitreal implant	$8,340.00	$231.67

Unit = intravitreal implant or ophthalmic insert

*Please note: The duration of treatments vary. Iluvien® and Yutiq™ are intended to last 36 months per implant, Retisert® 30 months per implant, Ozurdex® 3 to 4 months per implant, and Dextenza® 30 days per insert.

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Recommendations

The College of Pharmacy recommends the prior authorization of Iluvien® (fluocinolone intravitreal implant), Ozurdex® (dexamethasone intravitreal implant), and Retisert® (fluocinolone intravitreal implant) with the following criteria:

Iluvien® (Fluocinolone Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of diabetic macular edema (DME) in patients who have been previously treated with a course of

corticosteroids and did not have a clinically significant rise in intraocular pressure; and
2. Iluvien® must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. A patient-specific, clinically significant reason why the member requires Iluvien® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
5. A quantity limit of 1 implant per eye every 36 months will apply.

Ozurdex® (Dexamethasone Intravitreal Implant) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. The treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO); or
    b. The treatment of non-infectious uveitis affecting the posterior segment of the eye; or
    c. The treatment of diabetic macular edema; and
2. Ozurdex® must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. Prescriber must agree to periodically monitor the integrity of the implant by visual inspection; and
5. A patient-specific, clinically significant reason why the member requires Ozurdex® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
6. A quantity limit of 1 implant per eye every 3 months will apply.

Retisert® (Fluocinolone Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of chronic, non-infectious posterior uveitis; and
2. Retisert® must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. Prescriber must agree to periodically monitor the integrity of the implant by visual inspection; and
5. A patient-specific, clinically significant reason why the member requires Retisert® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and

6. A patient-specific, clinically significant reason why the member requires Retisert® in place of Ozurdex® or Yutiq™ must be provided; and
7. A quantity limit of 1 implant per eye every 30 months will apply.

Additionally, the College of Pharmacy recommends the following changes to the current Dextenza® (dexamethasone ophthalmic insert) and Yutiq™ (fluocinolone intravitreal implant) approval criteria based on new FDA approved indication(s) and net costs (changes shown in red):

Dextenza® (Dexamethasone Ophthalmic Insert) Approval Criteria:

1. An FDA approved indication of the treatment of ocular inflammation and pain following ophthalmic surgery; and
2. Prescriber must verify that Dextenza® will be placed by a physician immediately following ophthalmic surgery; and
3. Date of ophthalmic surgery must be provided; and
4. A patient-specific, clinically significant reason why corticosteroid ophthalmic preparations, such as solution or suspension, typically used following ophthalmic surgery are not appropriate for the member must be provided; and
5. A quantity limit of 2 inserts per 30 days will apply.

Yutiq™ (Fluocinolone Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of chronic, non-infectious uveitis affecting the posterior segment of the eye; and
2. Yutiq™ must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure and cataract development; and
4. A patient-specific, clinically significant reason why the member requires Yutiq™ in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
5. A patient-specific, clinically significant reason why the member requires Yutiq™ in place of Ozurdex® must be provided; and
6. A quantity limit of 1 implant per eye every 36 months will apply.

Utilization Details of Ophthalmic NSAIDs: Calendar Year 2019 (Pharmacy Claims)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
KETOROLAC PRODUCTS						
KETOROLAC SOL 0.5%	545	422	$10,064.99	$0.83	$18.47	22.56%
SUBTOTAL	**545**	**422**	**$10,064.99**	**$0.83**	**$18.47**	**22.56%**
NEPAFENAC PRODUCTS						
ILEVRO DROP 0.3%	124	91	$33,403.41	$8.43	$269.38	74.88%
SUBTOTAL	**124**	**91**	**$33,403.41**	**$8.43**	**$269.38**	**74.88%**
DICLOFENAC PRODUCTS						
DICLOFENAC SOL 0.1%	72	49	$1,138.34	$0.74	$15.81	2.55%
SUBTOTAL	**72**	**49**	**$1,138.34**	**$0.74**	**$15.81**	**2.55%**
TOTAL	**741**	**548***	**$44,606.74**	**$2.52**	**$60.20**	**100%**

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

Utilization Details of Ophthalmic Corticosteroids: Calendar Year 2019 (Pharmacy Claims)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-1 MEDICATIONS						
PREDNISOLONE PRODUCTS						
PREDNISOLONE SUS	1,898	1,395	$97,992.92	$1.94	$51.63	40.02%
PRED MILD SUS 0.12%	7	7	$1,480.91	$11.85	$211.56	0.60%
PRED SOD PHO SOL 1%	2	2	$107.76	$4.49	$53.88	0.04%
OMNIPRED SUS 1% OP	1	2	$124.86	$1.86	$124.86	0.05%
SUBTOTAL	**1,908**	**1,403**	**$99,706.45**	**$1.96**	**$52.26**	**40.71%**
DIFLUPREDNATE PRODUCTS						
DUREZOL EMU 0.05%	318	194	$60,633.91	$7.08	$190.67	24.76%
SUBTOTAL	**318**	**194**	**$60,633.91**	**$7.08**	**$190.67**	**24.76%**
FLUOROMETHOLONE PRODUCTS						
FLUOROMETH SUS 0.1%	153	115	$13,974.47	$3.32	$91.34	5.71%
FML LIQUIFLM SUS 0.1%	15	11	$2,972.94	$8.08	$198.20	1.21%
FLAREX SUS 0.1%	14	10	$1,508.36	$4.19	$107.74	0.62%
SUBTOTAL	**182**	**134**	**$18,455.77**	**$3.74**	**$101.41**	**7.54%**
DEXAMETHASONE PRODUCTS						
DEXAMETH PHOS SOL 0.1%	248	215	$14,532.40	$3.43	$58.60	5.93%
MAXIDEX SUS 0.1%	7	7	$594.64	$7.93	$84.95	0.24%
SUBTOTAL	**255**	**222**	**$15,127.04**	**$3.51**	**$59.32**	**6.17%**
LOTEPREDNOL PRODUCTS						
LOTEMAX SUS 0.5%	151	107	$42,385.56	$9.09	$280.70	17.31%
LOTEPREDNOL SUS	26	21	$5,610.84	$7.62	$215.80	2.29%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SUBTOTAL	**177**	**124**	**$47,996.40**	**$8.89**	**$271.17**	**19.60%**
TIER-1 SUBTOTAL	**2,840**	**1,990**	**$241,919.57**	**$3.27**	**$85.18**	**98.78%**
TIER-2 MEDICATIONS						
LOTEPREDNOL PRODUCTS						
LOTEMAX OIN 0.5%	7	3	$1,883.61	$11.42	$269.09	0.77%
LOTEMAX GEL 0.5%	4	2	$776.25	$12.32	$194.06	0.32%
SUBTOTAL	**11**	**5**	**$2,659.86**	**$11.67**	**$241.81**	**1.09%**
PREDNISOLONE PRODUCTS						
PRED FORTE SUS 1%	1	1	$283.82	**$1.89**	$283.82	0.12%
SUBTOTAL	**1**	**1**	**$283.82**	**$1.89**	$283.82	0.12%
TIER-2 SUBTOTAL	**12**	**6**	**$2,943.68**	**$7.79**	**$245.31**	**1.21%**
TOTAL	**2,852**	**1,993***	**$244,863.25**	**$3.29**	**$85.86**	**100%**

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

Utilization Details of Ophthalmic Corticosteroids: Calendar Year 2019 (Medical Claims)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM
OZURDEX IMPLANT J7312	20	12	$26,602.63	$1,330.13
ILUVIEN IMPLANT J7313	3	3	$18,853.06	$6,284.35
TOTAL	**23⁺**	**15***	**$45,455.69**	**$1,976.33**

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

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Appendix J

30-Day Notice to Prior Authorize Isturisa® (Osilodrostat)

Oklahoma Health Care Authority
June 2020

Market News and Updates[1]

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

- **March 2020:** Recordati announced the FDA approval of Isturisa® (osilodrostat) for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. Isturisa® was granted Orphan Drug designation by the FDA.

Isturisa® (Osilodrostat) Product Summary[2]

Indication(s): Isturisa® (osilodrostat) is a cortisol synthesis inhibitor indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

Dosing:

- Isturisa® is available in 1mg, 5mg, and 10mg oral tablets.
- Hypokalemia and hypomagnesemia should be corrected and baseline electrocardiogram should be obtained prior to starting osilodrostat.
- The initial recommended dosage of osilodrostat is 2mg twice daily, taken with or without food.
- The dosage of osilodrostat should be titrated by 1 to 2mg twice daily no more frequently than every 2 weeks based on the rate of cortisol changes, individual tolerability, and improvement in signs and symptoms.
- The maximum recommended dosage of osilodrostat is 30mg twice daily.
- The starting dosage of osilodrostat should be adjusted for patients with hepatic impairment:
    - Child-Pugh B: Recommended starting dose is 1mg twice daily.
    - Child-Pugh C: Recommended starting dose is 1mg once daily in the evening.
- Dosage adjustment may be necessary for concomitant use of osilodrostat with strong CYP3A4 inhibitors or strong CYP3A4 and/or

CYP2B6 inducers (*refer to Isturisa® Prescribing Information for specific recommendations regarding drug interactions*).

Mechanism of Action: Osilodrostat is a cortisol synthesis inhibitor; osilodrostat inhibits 11 beta-hydroxylase (CYP11B1), the enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland.

Contraindication(s): None

Safety:

- **Hypocortisolism:** Osilodrostat lowers cortisol levels and can lead to hypocortisolism and sometimes life-threatening adrenal insufficiency. Hypocortisolism can occur at any time during treatment with osilodrostat. Prescribers should monitor 24-hour urine free cortisol (UFC), serum cortisol, or plasma cortisol and the patient's signs and symptoms periodically during osilodrostat treatment. Osilodrostat dosage should be decreased or temporarily discontinued if UFC levels fall below the target range, there is a rapid decrease in cortisol levels, and/or patients report symptoms of hypocortisolism. Osilodrostat should be stopped and exogenous glucocorticoid replacement therapy should be administered if serum or plasma cortisol levels are below target range and patients have symptoms of adrenal insufficiency. Osilodrostat should be re-initiated at a lower dose when UFC, serum cortisol, or plasma cortisol levels are within target range, and/or patients' symptoms have resolved. Patients should be educated on the symptoms associated with hypocortisolism and advised to contact a health care provider if they occur.
- **QTc Prolongation:** Osilodrostat is associated with a dose-dependent QT interval prolongation. Prescribers should perform an electrocardiogram (ECG) to obtain a baseline QTc interval measurement prior to initiating therapy with osilodrostat and should monitor for an effect on the QTc interval thereafter. Hypokalemia and/or hypomagnesemia should be corrected prior to osilodrostat initiation and patients should be monitored periodically during treatment with osilodrostat. Electrolyte abnormalities should be corrected if indicated. Temporary discontinuation of osilodrostat should be considered in the case of an increase in QTc interval >480 milliseconds. Caution should be used in patients with risk factors for QT prolongation and more frequent ECG monitoring should be considered.

- **Elevations in Adrenal Hormone Precursors and Androgens:** Osilodrostat blocks cortisol synthesis and may increase circulating levels of cortisol and aldosterone precursors (11-deoxy cortisol and 11-deoxycorticosterone) and androgens. Elevated 11-deoxycorticosterone levels may activate mineralocorticoid receptors and cause hypokalemia, edema, and hypertension (HTN). Hypokalemia should be corrected prior to initiating osilodrostat. Patients treated with osilodrostat should be monitored for hypokalemia, worsening of HTN, and edema. Osilodrostat-induced hypokalemia should be treated with intravenous or oral potassium supplementation based on event severity. If hypokalemia persists despite potassium supplementation, the addition of mineralocorticoid antagonists should be considered and dose reduction or discontinuation of osilodrostat may be necessary. Accumulation of androgens may lead to hirsutism, hypertrichosis, and acne. Patients should be informed of the symptoms associated with hyperandrogenism and advised to contact a health care provider if they occur.
- **Pregnancy:** There are no available data on osilodrostat use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There are risks to the mother and fetus associated with active Cushing's syndrome during pregnancy.
- **Lactation:** There are no available data on the presence of osilodrostat in human or animal milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions (such as adrenal insufficiency) in the breastfed infant, patients should be advised that breastfeeding is not recommended during treatment with osilodrostat and for 1 week after the final dose.
- **Pediatric:** The safety and effectiveness of osilodrostat in pediatric patients have not been established.
- **Geriatric:** Of the 167 patients in clinical trials with osilodrostat, 10 (6%) were 65 years of age and older. Based on the available data on the use of osilodrostat in patients older than 65 years of age, no dosage adjustment is required.

Adverse Reactions: In randomized, placebo-controlled clinical studies, the most common adverse reactions (incidence >20%) following treatment with osilodrostat were adrenal insufficiency, fatigue, nausea, headache, and edema.

Efficacy: The safety and efficacy of osilodrostat was assessed in a 48-week, multicenter study that consisted of 4 study periods as follows:

- Period 1: 12-week, open-label, dose titration period
- Period 2: 12-week, open-label, maintenance treatment period
- Period 3: 8-week, double-blind, placebo-controlled, randomized withdrawal treatment period which provided the data for the primary efficacy endpoint
- Period 4: open-label treatment period of 14 to 24 weeks duration

The trial enrolled Cushing's disease patients with persistent or recurrent disease despite pituitary surgery or de novo patients for whom surgery was not indicated or who had refused surgery. Persistence or recurrence of Cushing's disease was evidenced by the mean of (3) 24-hour UFC levels (mUFC) >1.5 times the upper limit of normal (ULN). The median mUFC at baseline was 476nmol/24hr, which corresponds to approximately 3.5 times the ULN. During Period 3, 71 patients were considered responders and were randomized 1:1 to continue receiving osilodrostat (N = 36) or to switch to placebo (N = 35) for 8 weeks. Patients were stratified at randomization according to dose received at week 24 (≤5mg twice daily vs. 5mg twice daily) and history of pituitary irradiation. The primary efficacy endpoint of the study was to compare the percentage of complete responders at the end of the 8-week randomized withdrawal period (Period 3) between patients randomized to continue Isturisa® versus the patients switched to placebo. A complete responder was defined as a patient who had mUFC ≤ ULN and who neither discontinued randomized treatment or the study nor had any dose increase above their week 26 dose. The following table (Table 1) summarizes the efficacy results.

Table 1. Percentage of Cushing's Disease Patients with Normal mUFC at End of Period 3 (8-Week Randomized Withdrawal Period)

Primary Endpoint	osilodrostat (N = 36) n (%)	placebo (N = 34) n (%)	Complete Responder Rate Difference* (Differences in Percentages)
Complete responder rate at the end of the 8-week randomized withdrawal period (week 34)	31 (86)	10 (29)	57 (38, 76)
95% CI	(71, 95)	(15, 47)	2- sided P-value <0.001

N = number; CI = confidence interval
*osilodrostat vs. placebo

Cost: The Wholesale Acquisition Cost (WAC) of Isturisa® (osilodrostat) is $110, $400, and $475 per 1mg, 5mg, and 10 mg tablet, respectively. Treatment cost will vary depending on dose based on the rate of cortisol changes, individual tolerability, and improvement in signs and symptoms. The annual cost of treatment with Isturisa® at the maximum recommended dose of 30mg twice daily is $1,026,000.

Recommendations

The College of Pharmacy recommends the prior authorization of Isturisa® (osilodrostat) with the following criteria:

Isturisa® (Osilodrostat) Approval Criteria:

1. An FDA approved indication for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative; and
2. Member must be 18 years of age or older; and
3. 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. Prescriber must verify that female member is not breastfeeding; and
8. Isturisa® must be prescribed by, or in consultation with, an endocrinologist (or be an advanced care practitioner with a supervising physician who is an endocrinologist); and
9. 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.

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Appendix K

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 16, 2020

Coronavirus (COVID-19) Update: FDA Authorizes First Standalone At-home Sample Collection Kit that can be used with Certain Authorized Tests

The FDA has authorized an at-home sample collection kit that can then be sent to specified laboratories for COVID-19 diagnostic testing. Specifically, the FDA issued an emergency use authorization (EUA) to Everlywell, Inc. for the Everlywell COVID-19 Test Home Collection Kit. Everlywell's kit is authorized to be used by individuals at home who have been screened using an online questionnaire that is reviewed by a health care provider. This allows an individual to self-collect a nasal sample at home using Everlywell's authorized kit. The FDA has also authorized 2 COVID-19 diagnostic tests, performed at specific laboratories, for use with samples collected using the Everlywell COVID-19 Test Home Collection Kit. These tests have been authorized under separate, individual EUAs. Additional tests may be authorized for use with the Everlywell at-home collection kit in the future, provided data are submitted in an EUA request that demonstrate the accuracy of each test when used with the Everlywell at-home collection kit.

Today's EUA for the Everlywell COVID-19 Test Home Collection Kit permits testing of a sample collected from inside the patient's nose using the authorized self-collection kit that contains nasal swabs to collect a sample and a tube filled with saline to transport the sample back to a specified lab. Once patients self-swab to collect their nasal sample, they will ship the sample overnight to a specific CLIA-certified lab that is running 1 of the in vitro diagnostic molecular tests authorized under a separate EUA for use with the Everlywell at-home sample collection kit. The labs authorized to test specimens collected using the Everlywell at-home collection kit are Fulgent Therapeutics and Assurance Scientific Laboratories. Results will be returned to the patient through Everlywell's independent physician network and their online portal.

This announcement follows 2 recent EUAs for diagnostic tests that also use at-home specimen collection: 1 that uses a sample collected from the patient's nose with a nasal swab and transported in saline and another that permits testing of a saliva sample collected by the patient at home. Everlywell's EUA request leveraged data from studies supported by The Bill and Melinda Gates Foundation and UnitedHealth Group to demonstrate stability of specimens during shipping. The data from these studies are freely available to support other EUA requests, alleviating each test developer of the burden of recreating the same study.

The Everlywell home-collection kit is currently the only authorized COVID-19 at-home sample collection kit for use with multiple authorized COVID-19 diagnostic tests. The kit and associated tests are available by prescription only. The authorization is limited

to the Everlywell COVID-19 test for at-home collection of nasal swab specimens for analysis by COVID-19 diagnostic tests specifically authorized under separate EUAs for use with specimens collected with the Everlywell at-home collection kit. It is important to note that this is not a general authorization for at-home collection of patient samples using other collection kits, swabs, media, or tests, or for tests fully conducted at home.

FDA NEWS RELEASE

For Immediate Release: May 15, 2020

FDA Approves First Drug for Fourth-Line Treatment of Advanced Gastrointestinal Stromal Tumors

As part of Project Orbis, the FDA approved Qinlock (ripretinib) tablets as the first new drug specifically approved as a fourth-line treatment for advanced gastrointestinal stromal tumor (GIST), a type of tumor that originates in the gastrointestinal (GI) tract. Qinlock is indicated for adult patients who have received prior treatment with 3 or more kinase inhibitor therapies, including imatinib.

Each year, approximately 4,000 to 6,000 adults in the United States are diagnosed with a GIST. GISTs arise when abnormal cells form in the tissues of the GI tract. GISTs most commonly occur in the stomach, small intestine, and large intestine but can start anywhere along the GI tract.

Qinlock is a kinase inhibitor, meaning it works by blocking a type of enzyme called a kinase, which helps keep the cancer cells from growing. Qinlock's approval was based on the results of an international, multi-center, randomized, double-blind, placebo-controlled clinical trial that enrolled 129 patients with advanced GIST who had received prior treatment with other FDA-approved targeted therapies, imatinib, sunitinib, and regorafenib. The trial compared patients who were randomized to receive Qinlock to patients who were randomized to receive placebo, to determine whether progression free survival (PFS), the time from initial treatment in the clinical trial to growth of the cancer or death, was longer in the Qinlock group compared to the placebo group. During treatment in the trial, patients received Qinlock or placebo once a day in 28-day cycles, repeated until tumor growth was found, or the patient experienced intolerable side effects. After disease progression, patients who were randomized to placebo were given the option of switching to Qinlock. On average, the PFS rate in patients in the Qinlock group was 6.3 months, compared to 1 month for patients in the placebo group. The most common side effects with Qinlock were alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, palmar-plantar erythrodysesthesia syndrome, and vomiting. Qinlock can also cause serious side effects including skin cancer, hypertension (HTN), and cardiac dysfunction manifested as ejection fraction (EF) decrease. Health care providers should routinely check for symptoms and signs of these and other risks of Qinlock. Qinlock may cause harm to a developing fetus or a newborn baby. Health care professionals should advise pregnant women of this risk and should advise both females of reproductive potential and male patients with female partners of reproductive potential, to use effective contraception during treatment and for 1 week after the last dose. Patients should be advised not to breastfeed while taking Qinlock.

The FDA granted this application Priority Review and Fast Track designations, as well as Breakthrough Therapy designation, which expedites the development and review of drugs that are intended to treat a serious condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies. Qinlock also received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases. This review used the Real-Time Oncology Review, which streamlined data submission prior to the filing of the entire clinical application, and the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

FDA NEWS RELEASE

For Immediate Release: May 8, 2020

FDA Approves First Therapy for Patients with Lung and Thyroid Cancers with a Certain Genetic Mutation or Fusion

The FDA approved Retevmo (selpercatinib) capsules to treat 3 types of tumors in patients whose tumors have a mutation or fusion in a specific gene known as rearranged during transfection (RET). Retevmo is the first therapy approved specifically for cancer patients with the RET gene alterations. Specifically, the cancers that Retevmo is approved to treat are non-small cell lung cancer (NSCLC) that has spread in adults, advanced medullary thyroid cancer (MTC) or MTC that has spread, in patients 12 years of age and older who require systemic therapy, and advanced RET fusion-positive thyroid cancer in those age 12 and older that requires systemic therapy that has stopped responding to radioactive iodine therapy or is not appropriate for radioactive iodine therapy.

Retevmo is a kinase inhibitor and helps prevent the cancer cells from growing. Before beginning treatment, the identification of a RET gene alteration must be determined using laboratory testing. The FDA approved Retevmo on the results of a clinical trial involving patients with each of the 3 types of tumors. During the clinical trial, patients received 160mg Retevmo orally twice daily until disease progression or unacceptable toxicity. The major efficacy outcome measures were overall response rate (ORR), which reflects the percentage of patients that had a certain amount of tumor shrinkage, and duration of response (DOR).

Efficacy for NSCLC was evaluated in 105 adult patients with RET fusion-positive NSCLC who were previously treated with platinum chemotherapy. The ORR for the 105 patients was 64%. For 81% of patients who had a response to the treatment, their response lasted at least 6 months. Efficacy was also evaluated in 39 patients with RET fusion-positive NSCLC who had never undergone treatment. The ORR for these patients was 84%. For 58% of patients who had a response to the treatment, their response lasted at least 6 months.

Efficacy for MTC in adults and pediatric patients was evaluated in those 12 years of age and older with RET-mutant MTC. The study enrolled 143 patients with advanced or metastatic RET-mutant MTC who had been previously treated with cabozantinib, vandetanib or both, and patients with advanced or metastatic RET-mutant MTC who had not received prior treatment with cabozantinib or vandetanib. The ORR for the 55

previously treated patients was 69%. For 76% of patients who had a response to the treatment, their response lasted at least 6 months. Efficacy was also evaluated in 88 patients who had not been previously treated with an approved therapy for MTC. The ORR for these patients was 73%. For 61% of patients who had a response to the treatment, their response lasted at least 6 months.

Efficacy for RET fusion-positive thyroid cancer was evaluated in adults and pediatric patients 12 years of age and older. The study enrolled 19 patients with RET fusion-positive thyroid cancer who were radioactive iodine-refractory (RAI, if an appropriate treatment option) and had received another prior systemic treatment, and 8 patients with RET fusion-positive thyroid cancer who were RAI-refractory and had not received any additional therapy. The ORR for the 19 previously treated patients was 79%. For 87% of patients who had a response to the treatment, their response lasted at least 6 months. Efficacy was also evaluated in 8 patients who had not received therapy other than RAI. The ORR for these patients was 100%. For 75% of patients who had a response to the treatment, their response lasted at least 6 months. The most common side effects with Retevmo were increased aspartate aminotransferase (AST) and alanine aminotransferase (ALT) enzymes in the liver, increased blood sugar, decreased white blood cell count, decreased albumin in the blood, decreased calcium in the blood, dry mouth, diarrhea, increased creatinine, increased alkaline phosphatase, HTN, fatigue, swelling in the body or limbs, low blood platelet count, increased cholesterol, rash, constipation, and decreased sodium in the blood.

Retevmo can cause serious side effects including hepatotoxicity, elevated blood pressure, QT prolongation, bleeding, and allergic reactions. If a patient experiences hepatotoxicity, Retevmo should be withheld, dose reduced or permanently discontinued. Patients undergoing surgery should tell their doctor as drugs similar to Retevmo have caused problems with wound healing. Retevmo may cause harm to a developing fetus or a newborn baby. Health care professionals should advise pregnant women of this risk and should advise both females of reproductive potential and males patients with female partners of reproductive potential to use effective contraception during treatment with Retevmo and for 1 week after the last dose. Additionally, women should not breastfeed while on Retevmo.

Retevmo was approved under the Accelerated Approval pathway, which provides for the approval of drugs that treat serious or life-threatening diseases and generally provide a meaningful advantage over existing treatments. The FDA also granted this application Priority Review, Breakthrough Therapy, and Orphan Drug designations.

FDA NEWS RELEASE

For Immediate Release: May 6, 2020

FDA Approves First Targeted Therapy to Treat Aggressive Form of Lung Cancer

The FDA approved Tabrecta (capmatinib) for the treatment of adult patients with NSCLC that has spread to other parts of the body. Tabrecta is the first FDA-approved therapy to treat NSCLC with specific mutations that lead to mesenchymal-epithelial transition or MET exon 14 skipping. The FDA also approved the FoundationOne CDx assay

(F1CDx) as a companion diagnostic for Tabrecta today. Most patients had tumor samples that were tested for mutations that lead to MET exon 14 skipping using local tests and confirmed with the F1CDx, which is a next-generation sequencing based in vitro diagnostic device that is capable of detecting several mutations, including mutations that lead to MET exon 14 skipping.

NSCLC is a disease in which malignant cancer cells form in the tissues of the lung. It is the most common type of lung cancer with up to 90% of all lung carcinomas falling into the non-small cell category. NSCLC occurs when healthy cells become abnormal and grow rapidly. One danger of this form of cancer is that there's a high likelihood that the cancer cells will spread from the lungs to other organs and body parts. Cancer metastasis consists of a sequential series of events, and MET exon 14 skipping is recognized as a critical event for metastasis of carcinomas. Mutations leading to MET exon 14 skipping are found in 3-4% of patients with lung cancer.

Tabrecta is a kinase inhibitor, meaning it functions by blocking a key enzyme that results in helping to stop the tumor cells from growing. The FDA approved Tabrecta based on the results of a clinical trial involving patients with NSCLC with mutations that lead to MET exon 14 skipping, epidermal growth factor receptor (EGFR) wild-type and anaplastic lymphoma kinase (ALK) negative status, and at least 1 measurable lesion. During the clinical trial, participants received Tabrecta 400mg orally twice daily until disease progression or unacceptable toxicity. The major efficacy outcome measure was ORR. An additional efficacy outcome measure was DOR. The efficacy population included 28 patients who had never undergone treatment for NSCLC and 69 previously treated patients. The ORR for the 28 participants was 68%, with 4% having a complete response and 64% having a partial response. The ORR for the 69 participants was 41%, with all having a partial response. Of the responding participants who had never undergone treatment for NSCLC, 47% had a duration of response lasting 12 months or longer compared to 32.1% of the responding participants who had been previously treated. Common side effects for patients taking Tabrecta are peripheral edema, nausea, fatigue, vomiting, dyspnea, and decreased appetite. Tabrecta may cause serious side effects including interstitial lung disease or pneumonitis. Tabrecta should be permanently discontinued in patients with these side effects. Tabrecta may also cause hepatotoxicity, and health care professionals should monitor a patient's liver function tests prior to starting and when taking Tabrecta. If a patient experiences hepatotoxicity, Tabrecta should be withheld, dose reduced, or permanently discontinued. Based on a clear positive signal for phototoxicity in laboratory studies in cells, patients may be more sensitive to sunlight and should be advised to take precautions to cover their skin and use sunscreen and not to tan while taking Tabrecta. Tabrecta may cause harm to a developing fetus or newborn baby. Health care professionals should advise pregnant women of this risk and should advise both females of reproductive potential and male patients with female partners of reproductive potential to use effective contraception during treatment with Tabrecta and for 1 week after the last dose.

Tabrecta was approved under the Accelerated Approval pathway. The FDA granted this application Breakthrough Therapy, Priority Review, Orphan Drug designations.

FDA NEWS RELEASE

For Immediate Release: May 5, 2020

FDA Approves New Treatment for a Type of Heart Failure

The FDA approved Farxiga (dapagliflozin) oral tablets for adults with heart failure (HF) with reduced EF to reduce the risk of cardiovascular (CV) death and hospitalization for HF. HF occurs when the heart does not pump enough blood to support the body's needs, and this type of HF happens when the heart's main pumping chamber, the left ventricle, is weakened. With the approval, Farxiga is the first in this particular drug class, sodium-glucose co-transporter 2 (SGLT2) inhibitors, to be approved to treat adults with New York Heart Association's functional class II-IV HF with reduced EF. Farxiga was shown in a clinical trial to improve survival and reduce the need for hospitalization in adults with HF with reduced EF. Farxiga is also FDA-approved to improve glycemic control in adults with type 2 diabetes in addition to diet and exercise, and to reduce the risk of hospitalization for HF among adults with type 2 diabetes and known CV disease or other risk factors.

Farxiga's safety and effectiveness were evaluated in a randomized, double-blind, placebo-controlled study of 4,744 participants. The average age of participants was 66 years and more participants were male (77%) than female. To determine the drug's effectiveness, investigators examined the occurrence of CV death, hospitalization for HF, and urgent HF visits. Participants were randomly assigned to receive a once-daily dose of either 10mg of Farxiga or a placebo. After about 18 months, people who received Farxiga had fewer CV deaths, hospitalizations for HF, and urgent HF visits than those receiving the placebo.

Farxiga can cause dehydration, serious urinary tract infections, and genital yeast infections. Elderly patients, patients with kidney problems, those with low blood pressure, and patients on diuretics should be assessed for their volume status and kidney function prior to treatment. Patients with signs and symptoms of metabolic acidosis or ketoacidosis should also be assessed prior to treatment. Farxiga can cause serious cases of necrotizing fasciitis of the perineum in people with diabetes and low blood glucose when combined with insulin.

This application received Priority Review designation, meaning the agency planned to take action on the application within 6 months, because the drug, if approved, would significantly improve the safety or effectiveness of treating, diagnosing or preventing a serious condition.

Current Drug Shortages Index (as of May 21, 2020):

The information provided in this section is provided voluntarily by manufacturers.

Alogliptin Tablets	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Aminophylline Injection, USP	***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***
AVYCAZ® (ceftazidime and avibactam) for Injection, 2 grams/0.5 grams	***Currently in Shortage***
Azithromycin Tablets	***Currently in Shortage***
Belatacept (Nulojix) Lyophilized Powder for Injection	***Currently in Shortage***
Bumetanide Injection, USP	***Currently in Shortage***
Bupivacaine Hydrochloride and Epinephrine Injection, USP	***Currently in Shortage***
Bupivacaine Hydrochloride Injection, USP	***Currently in Shortage***
Calcitriol Injection USP 1MCG /ML	***Currently in Shortage***
Calcium Chloride Injection, USP	***Currently in Shortage***
Capreomycin Injection, USP	***Currently in Shortage***
Cefazolin Injection	***Currently in Shortage***
Cefepime Injection	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Cefoxitin for Injection, USP	***Currently in Shortage***
Cisatracurium Besylate Injection	***Currently in Shortage***
Continuous Renal Replacement Therapy (CRRT) Solutions	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Injection	***Currently in Shortage***
Dextrose 25% Injection	***Currently in Shortage***
Dextrose 50% Injection	***Currently in Shortage***
Dicyclomine Oral Tablets/Capsules	***Currently in Shortage***
Diltiazem Hydrochloride	***Currently in Shortage***
Dimercaprol (Bal in Oil) Injection USP	***Currently in Shortage***
Diphenhydramine Injection	***Currently in Shortage***
Disulfiram Tablets	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dorzolamide Hydrochloride and Timolol Maleate (Cosopt) Ophthalmic Solution	***Currently in Shortage***
Dorzolamide Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution	***Currently in Shortage***

Enalaprilat Injection, USP	***Currently in Shortage***
Epinephrine Injection, 0.1 mg/mL	***Currently in Shortage***
Epinephrine Injection, Auto-Injector	***Currently in Shortage***
Erythromycin Lactobionate for Injection, USP	***Currently in Shortage***
Erythromycin Ophthalmic Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Famotidine Injection	***Currently in Shortage***
Famotidine Tablets	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Fluorescein Injection	***Currently in Shortage***
Fluorescein Strips	***Currently in Shortage***
Flurazepam Hydrochloride Capsules	***Currently in Shortage***
Fluvoxamine ER Capsules	***Currently in Shortage***
Furosemide Injection, USP	***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***
Hydrocortisone Tablets, USP	***Currently in Shortage***
Hydromorphone Hydrochloride Injection, USP	***Currently in Shortage***
Hydroxychloroquine Sulfate Tablets	***Currently in Shortage***
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert	***Currently in Shortage***
Hydroxyzine Pamoate Oral Capsules	***Currently in Shortage***
Imipenem and Cilastatin for Injection, USP	***Currently in Shortage***
Ketamine Injection	***Currently in Shortage***
Ketoprofen Capsules	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Labetalol Hydrochloride Injection	***Currently in Shortage***
Letermovir (Prevymis) Injection	***Currently in Shortage***
Leucovorin Calcium Lyophilized Powder for Injection	***Currently in Shortage***
Levetiracetam Extended-Release Oral Tablets, USP	***Currently in Shortage***
Levetiracetam Immediate-Release Oral Tablets, USP	***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, USP	***Currently in Shortage***
Loxapine Capsules	***Currently in Shortage***
Methadone Hydrochloride Injection	***Currently in Shortage***

Methyldopa Tablets	***Currently in Shortage***
Methylphenidate Hydrochloride (QUILLIVANT XR) Extended-Release Oral Suspension	***Currently in Shortage***
Metoprolol Tartrate Injection, USP	***Currently in Shortage***
Metronidazole Injection, USP	***Currently in Shortage***
Midazolam Injection, USP	***Currently in Shortage***
Morphine Sulfate Injection, USP	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Nalbuphine Hydrochloride Injection	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Ondansetron Hydrochloride Injection	***Currently in Shortage***
Oxytocin Injection, USP Synthetic	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Parathyroid Hormone (Natpara) Injection	***Currently in Shortage***
Physostigmine Salicylate Injection, USP	***Currently in Shortage***
Pindolol Tablets	***Currently in Shortage***
Potassium Acetate Injection, USP	***Currently in Shortage***
Procainamide Hydrochloride Injection, USP	***Currently in Shortage***
Promethazine (Phenergan) Injection	***Currently in Shortage***
Propofol Injectable Emulsion	***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, USP	***Currently in Shortage***
Sodium Bicarbonate Injection, USP	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection USP, 0.9% Vials and Syringes	***Currently in Shortage***
Sulfasalazine Tablets	***Currently in Shortage***
Tacrolimus Capsules	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Thiothixene Capsules	***Currently in Shortage***
Timolol Maleate Tablets	***Currently in Shortage***
Triamcinolone Acetonide (Triesence) Injection, Suspension	***Currently in Shortage***
Trifluridine Ophthalmic Solution	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***