OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
December 14, 2022
4:00pm

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

Viewing Access Only:
Please register for the webinar at:
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The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – December 14, 2022

DATE: December 7, 2022

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

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

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

Call to Order

Public Comment Forum

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

Update on the Medication Coverage Authorization Unit/Academic Detailing Program Update – Appendix B

Action Item – SoonerCare Maintenance Drug List – Appendix C

Action Item – Vote to Prior Authorize Skysona® (Elivaldogene Autotemcel) – Appendix D

Action Item – Vote to Prior Authorize Tezspire® (Tezepelumab-ekko) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications – Appendix E

Action Item – Vote to Prior Authorize Adbry™ (Tralokinumab-ldrm) and Cibinqo™ (Abrocitinib) and Update the Approval Criteria for the Atopic Dermatitis (AD) Medications – Appendix F

Action Item – Vote to Prior Authorize Carvykti™ (Ciltacabtagene Autoleucel) and Tecvayli™ (Teclistamab-cqyv) and Update the Approval Criteria for the Multiple Myeloma Medications – Appendix G

Action Item – Annual Review of Anticoagulants and Platelet Aggregation Inhibitors – Appendix H

Action Item – Annual Review of Crohn's Disease (CD) and Ulcerative Colitis (UC) Medications – Appendix I

Annual Review of Skin Cancer Medications and 30-Day Notice to Prior Authorize Kimmtrak® (Tebentafusp-tebn) and Opdualag™ (Nivolumab/Relatlimab-rmbw) – Appendix J

Annual Review of Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon) and 30-Day Notice to Prior Authorize Vyvgart® (Efgartigimod Alfa-fcab) – Appendix K

Annual Review of Antidepressants and 30-Day Notice to Prior Authorize Auvelity™ (Dextromethorphan/Bupropion) and Venlafaxine 112.5mg Extended-Release (ER) Tablet – Appendix L

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – December 14, 2022 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

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

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https://zoom.us/webinar/register/WN_73z8ERX7Sv-KeQGP3GVqPg
After registering, you will receive a confirmation email containing information about joining the webinar.

Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 952 7560 1667
Passcode: 69395211

Public Comment for Meeting:

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

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. November 9, 2022 DUR Board Meeting Minutes
   B. November 9, 2022 DUR Board Recommendations Memorandum

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

4. **Update on Medication Coverage Authorization Unit/Academic Detailing Program Update – See Appendix B**
   A. Pharmacy Helpdesk Activity for November 2022
   B. Medication Coverage Activity for November 2022
   C. Academic Detailing Program Update

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

5. **SoonerCare Maintenance Drug List – See Appendix C**
   A. Introduction
   B. SoonerCare Maintenance Drug List
   C. College of Pharmacy Recommendations

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

6. **Action Item – Vote to Prior Authorize Skysona® (Elivaldogene Autotemcel) – See Appendix D**
   A. Market News and Updates
   B. Skysona® (Elivaldogene Autotemcel) Product Summary

C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Tezspire® (Tezepelumab-ekko) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications – See Appendix E**

A. Market News and Updates
B. Tezspire® (Tezepelumab-ekko) Product Summary
C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Adbry™ (Tralokinumab-ldrm) and Cibinqo™ (Abrocitinib) and Update the Approval Criteria for the Atopic Dermatitis (AD) Medications – See Appendix F**

A. Market News and Updates
B. Adbry™ (Tralokinumab-ldrm) Product Summary
C. Cibinqo™ (Abrocitinib) Product Summary
D. Cost Comparison
E. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Carvykti™ (Ciltacabtagene Autoleucel) and Tecvayli™ (Teclistamab-cqyv) and Update the Approval Criteria for the Multiple Myeloma Medications – See Appendix G**

A. Market News and Updates
B. Carvykti™ (Ciltacabtagene Autoleucel) Product Summary
C. Tecvayli™ (Teclistamab-cqvy) Product Summary
D. College of Pharmacy Recommendations

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

10. **Action Item – Annual Review of Anticoagulants and Platelet Aggregation Inhibitors – See Appendix H**

A. Current Prior Authorization Criteria
B. Utilization of Anticoagulants and Platelet Aggregation Inhibitors
C. Prior Authorization of Anticoagulants and Platelet Aggregation Inhibitors
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Anticoagulants and Platelet Aggregation Inhibitors

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

11. **Action Item – Annual Review of Crohn's Disease (CD) and Ulcerative Colitis (UC) Medications – See Appendix I**

A. Current Prior Authorization Criteria
B. Utilization of CD and UC Medications
C. Prior Authorization of CD and UC Medications

D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of CD and UC Medications

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

12. Annual Review of Skin Cancer Medications and 30-Day Notice to Prior Authorize Kimmtrak® (Tebentafusp-tebn) and Opdualag™ (Nivolumab/ Relatlimab-rmbw) – See Appendix J

A. Current Prior Authorization Criteria
B. Utilization of Skin Cancer Medications
C. Prior Authorization of Skin Cancer Medications
D. Market News and Updates
E. Kimmtrak® (Tebentafusp-tebn) Product Summary
F. Opdualag™ (Nivolumab/Relatlimab-rmbw) Product Summary
G. College of Pharmacy Recommendations
H. Utilization Details of Skin Cancer Medications

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

13. Annual Review of Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon) and 30-Day Notice to Prior Authorize Vyvgart® (Efgartigimod Alfa-fcab) – See Appendix K

A. Current Prior Authorization Criteria
B. Utilization of Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon)
C. Prior Authorization of Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon)
D. Market News and Updates
E. Vyvgart® (Efgartigimod Alfa-fcab) Product Summary
F. Cost Comparison: Generalized Myasthenia Gravis (gMG) Therapies
G. College of Pharmacy Recommendations
H. Utilization Details of Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon)

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

14. Annual Review of Antidepressants and 30-Day Notice to Prior Authorize Auvelity™ (Dextromethorphan/Bupropion) and Venlafaxine 112.5mg Extended-Release (ER) Tablet – See Appendix L

A. Current Prior Authorization Criteria
B. Utilization of Antidepressants
C. Prior Authorization of Antidepressants
D. Market News and Updates

E. Auvelity™ (Dextromethorphan/Bupropion) Product Summary
F. Venlafaxine 112.5mg ER Tablet Product Summary
G. College of Pharmacy Recommendations
H. Utilization Details of Antidepressants

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

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

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

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

A. Amyotrophic Lateral Sclerosis (ALS) Medications
B. Antihyperlipidemics
C. Glaucoma Medications
D. Gonadotropin-Releasing Hormone (GnRH) Medications

*Future product and class reviews subject to change.

17. Adjournment

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

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING NOVEMBER 9, 2022

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

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

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mark Brandenburg, M.D., MSC; Medical Director		X
Ellen Buettner; Chief of Staff		X
Kevin Corbett, C.P.A.; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	
Josh Holloway, J.D.; Deputy General Counsel	X	
Traylor Rains; State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Interim Chief Medical Officer	X	

Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Kara Smith, J.D.; General Counsel		X
Michelle Tahah, Pharm.D.; Clinical Pharmacist		X
Toney Welborn, M.D., MPH, MS; Medical Director	X	

OTHERS PRESENT:	
Kevin Hinthorne, Leo Pharma	Rob Wilson, Boehringer-Ingelheim
Bryan Steffan, Boehringer-Ingelheim	Tom Yelle, Xcenda
Robert Greely, Biogen	Burl Beasley, OMES
Aaron Austin, Takeda	Rhonda Clark, Indivior
Cindy Pennington, Rhythm Pharmaceuticals	Phillip Lohec, Viatris
John Omick, Global Blood Therapeutics	Robert Pearce, Teva
John Stancil, Artia	Joseph Auci, Acer
Kimberly Brackett, AbbVie	Kristi Kemp, AbbVie
Joe Garcia, AbbVie	Collin Verheyden, Vertex
Larry Palmisano, Amgen	Ann Nelson, Vertex
Janie Huff, Amgen	Nima Nabavi, Amgen
Dave Miley, Teva	Marc Bagby, Lilly
Mike Shepherd, Lilly	John Deason, Neurocrine
Brad Willie, Neurocrine	Mark Kaiser, Otsuka
Richie Crawford, Otsuka	Madeline Shurtleff, Otsuka
Brent Parker, Merck	Marc Parker, Sunovion
Crystal Mayes, Sanofi	David Prather, Novo Nordisk
Amanda Nowakowski, ViiV	Robin Selsor, Aimmune

PRESENT FOR PUBLIC COMMENT:	
Mike Shepherd, Lilly	Larry Palmisano, Amgen
John Deason, Neurocrine	Dave Miley, Teva

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

1A: ROLL CALL

Dr. Muchmore called the meeting to order at 4:00 pm. Roll call by Dr. Wilcox established the presence of a quorum.

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO. 7 MIKE SHEPHERD
2B: AGENDA ITEM NO. 7 LARRY PALMISANO
2C: AGENDA ITEM NO. 12 JOHN DEASON
2D: AGENDA ITEM NO. 12 DAVE MILEY
ACTION: NONE REQUIRED

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

3A: OCTOBER 12, 2022 DUR MINUTES – VOTE

Materials included in agenda packet; presented by Dr. Muchmore
Dr. Mitchell moved to approve; seconded by Ms. Boyett

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/IMPACT OF CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGLATOR (CFTR) MODULATORS**

4A: PHARMACY HELPDESK ACTIVITY FOR OCTOBER 2022
4B: MEDICATION COVERAGE ACTIVITY FOR OCTOBER 2022
4C: IMPACT OF CFTR MODULATORS
Materials included in agenda packet; presented by Dr. Chandler, Dr. O'Halloran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: 2023 DUR BOARD MEETING DATES
5A: 2023 DUR BOARD MEETING DATES
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Mitchell moved to approve; seconded by Ms. Boyett
ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE ENJAYMO™ (SUTIMLIMAB-JOME), PYRUKYND® (MITAPIVAT), AND ZYNTEGLO® (BETIBEGLOGENE AUTOTEMCEL) AND UPDATE THE APPROVAL CRITERIA FOR THE ANEMIA MEDICATIONS
6A: MARKET NEWS AND UPDATES
6B: PRODUCT SUMMARIES
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. de los Angeles moved to approve; seconded by Ms. Boyett
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE SOTYKTU™ (DEUCRAVACITINIB), SPEVIGO® (SPESOLIMAB-SBZO), AND TAVNEOS® (AVACOPAN) AND UPDATE THE APPROVAL CRITERIA FOR THE TARGETED IMMUNOMODULATOR AGENTS
7A: MARKET NEWS AND UPDATES
7B: PRODUCT SUMMARIES
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Mitchell moved to approve; seconded by Dr. de los Angeles
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE XENPOZYME® (OLIPUDASE ALFA-RPCP)
8A: MARKET NEWS AND UPDATES
8B: XENPOZYME® (OLIPUDASE ALFA-RPCP) PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Kottoor
Dr. de los Angeles moved to approve; seconded by Ms. Boyett
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE BESREMI® (ROPEGINTERFERON ALFA-2B-NJFT) AND VONJO™ (PACRITINIB)
9A: MARKET NEWS AND UPDATES
9B: PRODUCT SUMMARIES
9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Mitchell moved to approve; seconded by Dr. Hanner
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: ANNUAL REVIEW OF IMCIVREE™ (SETMELANOTIDE)
10A: CURRENT PRIOR AUTHORIZATION CRITERIA

10B: UTILIZATION OF IMCIVREE™ (SETMELANOTIDE)
10C: PRIOR AUTHORIZATION OF IMCIVREE™ (SETMELANOTIDE)
10D: MARKET NEWS AND UPDATES
10E: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Chandler
Dr. Hanner moved to approve; seconded by Dr. de los Angeles
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 11:</u> ANNUAL REVIEW OF LAMBERT-EATON MYASTHENIC SYNDROME (LEMS) MEDICATIONS
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF LEMS MEDICATIONS
11C: PRIOR AUTHORIZATION OF LEMS MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: COLLEGE OF PHARMACY RECOMMENDATIONS
11F: UTILIZATION DETAILS OF LEMS MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
Ms. Boyett moved to approve; seconded by Dr. de los Angeles
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 12:</u> ANNUAL REVIEW OF VESICULAR MONOAMINE TRANSPORTER 2 (VMAT2) INHIBITOR MEDICATIONS
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF VMAT2 INHIBITOR MEDICATIONS
12C: PRIOR AUTHORIZATION OF VMAT2 INHIBITOR MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: COLLEGE OF PHARMACY RECOMMENDATIONS
12F: UTILIZATION DETAILS OF VMAT2 INHIBITOR MEDICATIONS
Materials included in agenda packet; presented by Dr. Kottoor
Dr. de los Angeles moved to approve; seconded by Dr. Mitchell
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF MULTIPLE MYELOMA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE CARVYKTI™ (CILTACABTAGENE AUTOLEUCEL) AND TECVAYLI™ (TECLISTAMAB-CQYV)
13A: INTRODUCTION
13B: CURRENT PRIOR AUTHORIZATION CRITERIA
13C: UTILIZATION OF MULTIPLE MYELOMA MEDICATIONS
13D: PRIOR AUTHORIZATION OF MULTIPLE MYELOMA MEDICATIONS
13E: MARKET NEWS AND UPDATES
13F: PRODUCT SUMMARIES
13G: COLLEGE OF PHARMACY RECOMMENDATIONS
13H: UTILIZATION DETAILS OF MULTIPLE MYELOMA MEDICATIONS
Materials included in agenda packet; presented by Dr. Borders
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

<u>AGENDA ITEM NO. 14:</u> ANNUAL REVIEW OF ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHROIZE TEZSPIRE® (TEZEPELUMAB-EKKO)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATON OF ASTHMA AND COPD MAINTENANCE MEDICATIONS
14C: PRIOR AUTHORIZATION OF ASTHMA AND COPD MAINTENANCE MEDICATIONS
14D: MARKET NEWS AND UPDATES

14E: TEZSPIRE® (TEZEPELUMAB-EKKO) PRODUCT SUMMARY
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF ASTHMA AND COPD MAINTENANCE MEDICATIONS
14H: UTILIZATION DETAILS OF ASTHMA-INDICATED MONOCLONAL ANTIBODIES
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 15: ANNUAL REVIEW OF ATOPIC DERMATITIS (AD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ADBRY™ (TRALOKINUMAB-LDRM) AND CIBINQO™ (ABROCITINIB)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF AD MEDICATIONS
15C: PRIOR AUTHORIZATION OF AD MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: PRODUCT SUMMARIES
15F: COST COMPARISON
15G: COLLEGE OF PHARMACY RECOMMENDATIONS
15H: UTILIZATION DETAILS OF AD MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 16: 30-DAY NOTICE TO PRIOR AUTHORIZE SKYSONA® (ELIVALDOGENE AUTOTEMCEL)
16A: INTRODUCTION
16B: SKYSONA® (ELIVALDOGENE AUTOTEMCEL) PRODUCT SUMMARY
16C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

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

AGENDA ITEM NO. 18: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
18A: ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
18B: ANTIDEPRESSANTS
18C: CROHN'S DISEASE AND ULCERATIVE COLITIS (UC) MEDICATIONS
18D: SKIN CANCER MEDICATIONS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: ADJOURNMENT
The meeting was adjourned at 5:56 pm.

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

Memorandum

Date: November 11, 2022

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

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

Subject: DUR Board Recommendations from Meeting on November 9, 2022

Recommendation 1: Impact of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators

NO ACTION REQUIRED.

Recommendation 2: 2023 DUR Board Meeting Dates

MOTION CARRIED by unanimous approval.

DUR Board meetings are held the second Wednesday of every month at 4:00pm at the Oklahoma Health Care Authority:

- January 11, 2023
- February 8, 2023
- March 8, 2023
- April 12, 2023
- May 10, 2023
- June 14, 2023
- July 12, 2023
- August 9, 2023
- September 13, 2023
- October 11, 2023
- November 8, 2023
- December 13, 2023

Recommendation 3: Vote to Prior Authorize Enjaymo™ (Sutimlimab-jome), Pyrukynd® (Mitapivat), and Zynteglo® (Betibeglogene Autotemcel) and Update the Approval Criteria for the Anemia Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Oxbryta® (voxelotor) prior authorization criteria based on the new FDA approved age expansion (changes noted in red):

Oxbryta® (Voxelotor) Approval Criteria:

1. An FDA approved indication for the treatment of sickle cell disease (SCD) in members 4 ~~12~~ years of age and older; and
~~2. Member must have a history of vaso-occlusive crises (VOCs); and~~
3. Member must have baseline hemoglobin ~~≥5.5 to~~ ≤10.5g/dL; and
4. Oxbryta® must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of SCD (or an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating SCD); and
~~5. Member must not be taking concomitant strong CYP3A4 inhibitors (e.g., fluconazole, ketoconazole) or the prescriber must verify the dose of Oxbryta® will be reduced during concomitant use according to package labeling; and~~
6. Member must not be taking concomitant strong or moderate CYP3A4 inducers (e.g., rifampin) or the prescriber must verify the dose of Oxbryta® will be adjusted during concomitant use according to package labeling; and
7. Prescriber must verify that the dose of Oxbryta® will be reduced in accordance with package labeling for members with severe hepatic impairment; and
8. For members younger than 12 years of age, the member's recent weight (kg) must be provided on the prior authorization request to ensure accurate dosing in accordance with Oxbryta® *Prescribing Information*; and
9. Oxbryta® tablets for oral suspension will have an age restriction of 4 to 10 years of age; and
    a. Members older than 10 years of age requesting Oxbryta® tablets for oral suspension will require a patient-specific, clinically significant reason why the member cannot use Oxbryta® oral tablets; and
10. The following quantity limits ~~A quantity limit of 3 tablets per day~~ will apply: ~~; and~~
    a. (3) 500mg tablets per day; and
    b. (5) 300mg tablets for oral suspension per day; and

11. Initial approvals will be for the duration of 6 months. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

The College of Pharmacy also recommends the prior authorization of Enjaymo™ (sutimlimab-jome) with the following criteria:

Enjaymo™ (Sutimlimab-jome) Approval Criteria:

1. An FDA approved diagnosis of primary cold agglutin disease confirmed by the following:
    a. Chronic hemolysis; and
    b. Positive direct antiglobulin (Coombs) test for C3d; and
    c. Cold agglutin titer of ≥64 at 4° Celsius; and
2. Member must have 1 or more symptoms associated with cold agglutinin disease (i.e., symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, a major adverse vascular event); and
3. Member has a history of at least 1 documented red blood cell (RBC) transfusion within 6 months of initiation; and
4. Member has a hemoglobin (Hgb) level ≤10g/dL; and
5. Member has a bilirubin level above the normal reference range; and
6. Enjaymo™ must be prescribed by a hematologist (or an advanced care practitioner with a supervising physician who is a hematologist); and
7. Member has not received rituximab within 3 months of initiation and will not be using rituximab concomitantly with Enjaymo™; and
8. Prescriber must verify the member has been vaccinated against encapsulated bacteria (e.g., *Neisseria meningitides, Streptococcus pneumoniae, Haemophilus influenzae*) at least 2 weeks prior to initiation of treatment; and
9. Enjaymo™ must be administered in a health care setting by a health care provider prepared to manage anaphylaxis; and
10. Prescriber must agree to monitor the member for at least 2 hours following the initial infusion for signs or symptoms of an infusion and/or hypersensitivity reaction and for 1 hour following completion of subsequent infusions; and
11. Prescriber must verify the member has no chronic systemic infections [e.g., hepatitis B, hepatitis C, human immunodeficiency virus (HIV)]; 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. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to therapy, as confirmed by at least 1 of the following:
    a. Member has had an increase in Hgb level ≥2g/dL from baseline; or
    b. Member has had normalization of Hgb level to ≥12g/dL; or
    c. Member has had a decreased number of RBC transfusions since initiation of therapy.

Additionally, the College of Pharmacy recommends the prior authorization of Pyrukynd® (mitapivat) with the following criteria (changes based on discussion at the October 2022 DUR Board meeting are noted in red):

Pyrukynd® (Mitapivat) Approval Criteria:

1. An FDA approved indication of hemolytic anemia in adults with pyruvate kinase (PK) deficiency confirmed by the following:
    a. Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (*PKLR*) gene, with at least 1 missense variant; and
        i. Hemoglobin (Hgb) ≤10g/dL; or
        ii. Member has received ≥6 red blood cell (RBC) transfusions in the past year; and
2. Pyrukynd® must be prescribed by a hematologist (or an advanced care practitioner with a supervising physician who is a hematologist); and
3. Member must not have moderate or severe hepatic impairment; and
4. If Pyrukynd® is to be discontinued, prescriber must verify dose will be tapered gradually according to Pyrukynd® *Prescribing Information* and member will be monitored for signs of acute hemolysis and worsening anemia; and
5. Prescriber must agree to monitor Hgb levels and follow dose titration and maintenance according to Pyrukynd® *Prescribing Information*; and
6. Approvals will be for the duration of 6 ~~3~~ months, after which time the prescriber must provide Hgb levels to support a dose increase or continuation of current dose; and
7. Pyrukynd® should be discontinued in members who do not show evidence of therapeutic benefit (i.e., Hgb increase of ≥1~~.5~~mg/dL from baseline, reduction in number of transfusions, improvement in hemolysis laboratory assessments) by week 24. Members will be granted short term approval to allow for gradual tapering per package labeling.

Further, the College of Pharmacy recommends the prior authorization of Zynteglo® (betibeglogene autotemcel) with the following criteria:

Zynteglo® (Betibeglogene Autotemcel) Approval Criteria:

1. An FDA approved indication for the treatment of adult and pediatric members with beta thalassemia who require regular red blood cell (RBC) transfusions; and
2. Member must be 4 years of age or older; and
3. Member must weigh ≥6kg; and
4. Member must require regular RBC transfusions as demonstrated by the following:
    a. History of ≥100mL/kg/year transfusions of packed RBCs in the last 2 years; or
    b. ≥8 transfusions of packed RBCs per year in the last 2 years; and
5. Zynteglo® must be prescribed by a hematologist with expertise in the treatment of beta thalassemia and the administration of Zynteglo®; and

6. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
7. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
8. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis; and
9. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Zynteglo®); and
10. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Zynteglo® administration; and
11. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Zynteglo®; and
12. Prescriber must verify male and female members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member; and
13. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Zynteglo®; and
14. Member will not be approved for treatment with Reblozyl® (luspatercept-aamt) following Zynteglo® infusion (current authorizations for luspatercept-aamt will be discontinued upon Zynteglo® approval); and
15. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at month 6 and month 12 after treatment with Zynteglo®, then at least annually thereafter for at least 15 years, and with integration site analysis at months 6, 12, and as warranted; and
16. Zynteglo® must be administered at a Zynteglo® qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Zynteglo® dose from receipt to storage to administration; and
17. Approvals will be for 1 dose per member per lifetime.

Finally, the College of Pharmacy recommends the following changes to the Reblozyl® (luspatercept-aamt) prior authorization criteria for beta thalassemia based on FDA approval of Zynteglo® (betibeglogene autotemcel) (changes noted in red):

Reblozyl® (Luspatercept-aamt) Approval Criteria [Beta Thalassemia Diagnosis]:

1. An FDA approved indication for the treatment of adult members with beta thalassemia who require regular red blood cell (RBC) transfusions; and

2. Member must require regular RBC transfusions (no transfusion-free period >35 days during the prior 6 month period); and
3. Member must not have previously received treatment with Zynteglo® (betibeglogene autotemcel); and
4. Reblozyl® must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of beta thalassemia (or an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating beta thalassemia); and
5. Prescriber must verify the member's hemoglobin will be monitored prior to each Reblozyl® administration; and
6. Prescriber must verify Reblozyl® will be administered by a trained health care provider; and
7. A recent (within the last 3 months) weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Approval quantities will be dependent on member's weight and every 3 week dosing in accordance with package labeling; and
9. Initial approvals will be for the duration of 4 months. Further approvals will not be granted if the member does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose of 1.25mg/kg (allows for initial dosing of 6 weeks at 1mg/kg). Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Recommendation 4: Vote to Prior Authorize Sotyktu™ (Deucravacitinib), Spevigo® (Spesolimab-sbzo), and Tavneos® (Avacopan) and Update the Approval Criteria for the Targeted Immunomodulator Agents

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Spevigo® (spesolimab-sbzo) and Tavneos® (avacopan) with the following criteria:

Spevigo® (Spesolimab-sbzo) Approval Criteria:

1. An FDA approved indication for the treatment of generalized pustular psoriasis (GPP) flares (GPP diagnosis should be verifiable in the member's diagnosis history); and
2. Prescriber must verify at least 1 of the following:
   a. Member has experienced >1 flare (relapsing GPP); or
   b. Member has symptoms persisting for >3 months (persistent GPP); and
3. Member must be currently experiencing a moderate-to-severe GPP flare meeting all the following criteria:

   a. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score must be provided and must be ≥3; and
   b. Presence of fresh pustules (new appearance or worsening of pustules); and
   c. GPPPGA pustulation sub-score must be provided and must be ≥2; and
   d. ≥5% of body surface area (BSA) covered with erythema and the presence of pustules; and
4. Member must be 21 years of age or older; and
5. Must be prescribed by a dermatologist or other specialist with expertise in the treatment of GPP (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of GPP); and
6. Prescriber must submit documentation of negative tuberculosis (TB) test or initiation of anti-TB therapy for latent TB prior to initiation of therapy with Spevigo®; and
7. Prescriber must verify the member does not have any clinically significant active infections and the member will be monitored for active infections prior to each dose of Spevigo®; and
8. Approvals will be for 1 dose of Spevigo®. A second dose of Spevigo® may be approved 1 week after the first dose if the prescriber submits documentation that the member has been evaluated and continues to experience GPP flare symptoms; and
9. A quantity limit of 2 doses per year will apply (the safety and efficacy of additional doses of Spevigo® have not been assessed); and
   a. Requests for additional doses of Spevigo® to treat new GPP flares occurring within 1 year (after successful resolution of the previous flare) will be reviewed on a case-by-case basis and will require the prescriber to submit patient-specific, clinically significant information documenting the clinical necessity of additional treatment despite the lack of adequate safety and efficacy data; and
10. Subsequent requests for new GPP flares (after 1 year) will require the member to meet all initial approval criteria, and information regarding the member's response to previous treatment with Spevigo® must be submitted. Members who did not experience resolution of pustules after previous treatment will not be approved for additional use of Spevigo®.

Tavneos® (Avacopan) Approval Criteria:

1. An FDA approved diagnosis as adjunctive treatment of adult members with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis [granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)] in combination with standard therapy including corticosteroids; and
2. Member must be 18 years of age or older; and

3. Tavneos® must be used in combination with standard immunosuppressive therapy including corticosteroids; and
4. Prescriber must agree to monitor liver function tests prior to initiating Tavneos®, every 4 weeks after the start of therapy for the first 6 months of treatment, and as clinically indicated thereafter; and
5. Prescriber must agree to screen the member for hepatitis B virus (HBV) infection prior to initiating treatment with Tavneos®; and
6. Prescriber must verify the member has no active, serious infections, including localized infections and will closely monitor member for the development of signs and symptoms of infection during and after treatment with Tavneos®; and
7. A quantity limit of 180 tablets per 30 days will apply.

Next, the College of Pharmacy recommends additional criteria for Orencia® (abatacept) for the diagnosis of acute graft versus host disease (aGVHD) and Rinvoq® (upadacitinib) for the diagnosis of atopic dermatitis (AD) based on the new FDA approvals for these indications:

Orencia® (Abatacept) Approval Criteria [Acute Graft Versus Host Disease (aGVHD) Prophylaxis in Hematopoietic Stem Cell Transplant (HSCT) Diagnosis]:

1. An FDA approved indication for the prophylaxis of aGVHD in members undergoing HSCT; and
2. Member must be 2 years of age or older; and
3. Member is undergoing HSCT with a matched or 1 allele-mismatched unrelated donor; and
4. Must be used in combination with a calcineurin inhibitor and methotrexate.

Rinvoq® (Upadacitinib) Approval Criteria [Atopic Dermatitis (AD) Diagnosis]:

1. An FDA approved diagnosis of moderate-to-severe AD not adequately controlled with other systemic drug products, including biologics, or when those therapies are not advisable; and
2. Member must be 12 years of age or older; and
3. Member must have a documented trial within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
4. Member must have a documented 16 week trial with Dupixent® (dupilumab) that resulted in inadequate response (or have a contraindication or documented intolerance); and

5. Requested medication must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Rinvoq® will not be approved for use in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, or with other immunosuppressant medications; and
7. Initial approvals will be for the duration of 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
8. The maximum approvable dose for AD is 30mg once daily.

The College of Pharmacy also recommends updating the Benlysta® (belimumab) approval criteria based on the FDA approved age expansion for patients with lupus nephritis with the following changes (shown in red):

Benlysta® (Belimumab) Approval Criteria:

1. The intravenous (IV) formulation will be covered as a medical only benefit while the subcutaneous (sub-Q) formulation will be covered as a pharmacy only benefit; and
2. An FDA approved indication of 1 of the following:
   a. The treatment of members 5 years of age and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) already receiving standard therapy; or
   b. The treatment of members ~~18~~ 5 years of age and older with active lupus nephritis (LN) who are receiving standard therapy; and
3. Documented inadequate response to at least 2 of the following medications appropriate to member's specific disease state:
   a. High-dose oral corticosteroids; or
   b. Methotrexate; or
   c. Azathioprine; or
   d. Mycophenolate; or
   e. Cyclophosphamide; or
   f. Hydroxychloroquine/chloroquine; and
4. Member must not have severe active central nervous system lupus; and
5. Benlysta® will not be approved for concomitant use with biologic therapies; and
6. Benlysta® will not be approved for concomitant use with IV cyclophosphamide (exception for induction treatment with IV cyclophosphamide for members with a diagnosis of LN).

Additionally, the College of Pharmacy recommends the following additions and changes to the Targeted Immunomodulator Agents PBPA Tier chart based on net costs (shown in red in the following Tier chart):

1. Placing Sotyktu™ (deucravacitinib) into Tier-3; and
2. Removing the additional approval criteria for Orencia® ClickJect™.

Targeted Immunomodulator Agents*±		
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**
6-mercaptopurine	adalimumab (Humira®)+	abatacept (Orencia®, Orencia® ClickJect™)≠¤
azathioprine	anakinra (Kineret®)	adalimumab-afzb (Abrilada™)±
hydroxychloroquine	apremilast (Otezla®)ß	adalimumab-atto (Amjevita™)±
leflunomide	etanercept (Enbrel®)	adalimumab-adbm (Cyltezo™)±
mesalamine	rituximab (Rituxan®)~	adalimumab-bwwd (Hadlima™)±
methotrexate		adalimumab-fkjp (Hulio®)±
minocycline		adalimumab-adaz (Hyrimoz™)±
NSAIDs		baricitinib (Olumiant®)
oral corticosteroids		brodalumab (Siliq®)**
sulfasalazine		canakinumab (Ilaris®)¥
		certolizumab pegol (Cimzia®)
		deucravacitinib (Sotyktu™)
		etanercept-szzs (Erelzi®)±
		etanercept-ykro (Eticovo™)±
		golimumab (Simponi®, Simponi Aria®)
		guselkumab (Tremfya®)
		infliximab (Remicade®)±
		infliximab-axxq (Avsola®)±
		infliximab-dyyb (Inflectra®)±
		infliximab-abda (Renflexis®)±
		ixekizumab (Taltz®)
		risankizumab-rzaa (Skyrizi®)
		rituximab-abbs (Truxima®)±
		rituximab-arrx (Riabni™)±
		rituximab-pvvr (Ruxience®)±
		sarilumab (Kevzara®)
		secukinumab (Cosentyx®)
		tildrakizumab-asmn (Ilumya®)
		tocilizumab (Actemra®)¶
		tofacitinib (Xeljanz®, Xeljanz® XR, Xeljanz® oral solution)**
		upadacitinib (Rinvoq®)#
		ustekinumab (Stelara®)
		vedolizumab (Entyvio®)**

DMARDs = disease modifying anti-rheumatic drugs; NSAIDs = nonsteroidal anti-inflammatory drugs
*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Products may be moved to a higher tier based on net cost if the manufacturer chooses not to

participate in supplemental rebates. Appropriate laboratory monitoring must be verified by the prescriber prior to approval.
±Biosimilars or reference products preferred based on lowest net cost product. Authorization of higher net cost biosimilars or reference products requires a patient-specific, clinically significant reason why the member could not use the preferred formulation.
+Unique criteria applies for a diagnosis of hidradenitis suppurativa (HS) and noninfectious intermediate and posterior uveitis and panuveitis.
ß Unique criteria applies for a diagnosis of Behçet's disease (BD).
¥Unique criteria applies for a diagnosis of cryopyrin-associated periodic syndromes (CAPS), tumor necrosis factor receptor-associated periodic syndrome (TRAPS), hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD), familial Mediterranean fever (FMF), systemic juvenile idiopathic arthritis (SJIA), or adult-onset Still's disease (AOSD).
~Unique criteria applies for a diagnosis of pemphigus vulgaris (PV). Unique criteria applies for a diagnosis of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA).
ᵀᵀUnique criteria applies for a diagnosis of giant cell arteritis (GCA) and chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome (CRS).
ᵍUnique criteria applies for acute graft versus host disease (aGVHD) prophylaxis in hematopoietic stem cell transplant (HSCT) recipients.
#Unique criteria applies for a diagnosis of atopic dermatitis (AD).
~~**≠Orencia® ClickJect™ requires a patient-specific, clinically significant reason why the member cannot use the typical pre-filled syringe formulation.**~~
**Unique criteria applies to this medication for approval.

~~**Orencia® ClickJect™ (Abatacept) Approval Criteria:**~~

~~1. Member must meet Tier-3 trial requirements; and~~
~~2. A patient-specific, clinically significant reason why the member cannot use the typical pre-filled syringe formulation must be provided.~~

Lastly, the College of Pharmacy recommends the following changes to the criteria for the Targeted Immunomodulator Agents that have biosimilar product(s) based on net costs (changes noted in red):

Avsola® (Infliximab-axxq) ~~**Inflectra® (Infliximab-dyyb)**~~ **and Remicade® (Infliximab) Approval Criteria:**

1. Member must meet Tier-3 trial requirements; and
2. A patient-specific, clinically significant reason why the member cannot use ~~Avsola® (infliximab-axxq)~~ Inflectra® (infliximab-dyyb) and Renflexis® (infliximab-abda) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Recommendation 5: Vote to Prior Authorize Xenpozyme™ (Olipudase Alfa-rpcp)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Xenpozyme™ (olipudase alfa-rpcp) with the following criteria (changes from the criteria presented at the October 2022 DUR Board meeting are shown in red):

Xenpozyme™ (Olipudase Alfa-rpcp) Approval Criteria:

1. An FDA approved diagnosis of acid sphingomyelinase deficiency (ASMD) type ~~A,~~ B, or A/B confirmed by:
   a. Documented lab results verifying <10% of acid sphingomyelinase (ASM) activity from ~~baseline~~ control; or
   b. Molecular genetic testing confirming a mutation in the *SMPD1* gene; and
2. Documentation of baseline AST and ALT within 1 month prior to treatment initiation or within 72 hours prior to treatment escalation; and
3. Member's weight (kg) and body mass index (BMI) within the last 3 weeks must be provided to ensure accurate weight-based dosing; and
   a. BMI ≤30: The dosage is based on actual body weight (kg); or
   b. BMI >30: The dosage is based on adjusted body weight; and
4. Female members of reproductive potential must have a negative pregnancy test prior to initiation and must agree to use effective contraception during treatment and for 2 weeks after the final dose of Xenpozyme™; and
5. Prescriber must verify ALT and AST will be assessed to manage the risk of elevated transaminases as directed by the Xenpozyme™ *Prescribing Information*; and
6. Xenpozyme™ must be administered by a health care provider prepared to manage anaphylaxis. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Xenpozyme™ will be administered; and
   a. Xenpozyme™ must be shipped via cold chain supply to the health care facility where the member is scheduled to receive treatment; or
   b. Xenpozyme™ must be shipped via cold chain supply to the member's home and administered by a home health care provider prepared to manage anaphylaxis, and the member or member's caregiver must be trained on the proper storage of Xenpozyme™; and
      i. For consideration of home administration by a home health care provider, prescriber must verify member is receiving the maintenance dose and is tolerating the Xenpozyme™ infusion well; and
7. Xenpozyme™ must be prescribed by, or in consultation with, a specialist with expertise in the treatment of lysosomal storage disorders; and
8. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment.

Recommendation 6: Vote to Prior Authorize Besremi® (Ropeginterferon Alfa-2b-njft) and Vonjo® (Pacritinib)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Besremi® (ropeginterferon alfa-2b-njft) and Vonjo® (pacritinib) with the following criteria:

Besremi® (Ropeginterferon Alfa-2b-njft) Approval Criteria [Polycythemia Vera (PV) Diagnosis]:

1. Diagnosis of PV; and
2. Used as a single agent.

Vonjo® (Pacritinib) Approval Criteria [Myelofibrosis (MF) Diagnosis]:

1. Diagnosis of intermediate or high-risk primary or secondary MF; and
2. Platelet count <50 x 10^9/L.

Recommendation 7: Annual Review of Imcivree® (Setmelanotide)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the current Imcivree® (setmelanotide) approval criteria based on the new FDA approved indication for Bardet-Biedl Syndrome (BBS) (changes shown in red):

Imcivree® (Setmelanotide) Approval Criteria:

1. An FDA approved indication of chronic weight management in adult and pediatric members 6 years of age and older with obesity due to 1 of following:
    a. Proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency; or
    b. Bardet-Biedl syndrome (BBS); and
2. For POMC-, PCSK1-, or LEPR-deficiency, diagnosis must be confirmed by molecular genetic testing to confirm variants in the POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance; and
3. For BBS, diagnosis must be confirmed by the following:
    a. Molecular genetic testing to confirm variants in a BBS gene; and
    b. Clinical features of BBS, as follows:
        i. Four primary features (i.e., rod-cone dystrophy, polydactyly, obesity, learning disabilities, hypogonadism in males, renal anomalies); or
        ii. Three of the primary features previously listed in 3.b.i. plus 2 secondary features [i.e., speech disorder/delay,

strabismus/cataracts/astigmatism, brachydactyly/syndactyly, developmental delay, polyuria/polydipsia (nephrogenic diabetes insipidus), ataxia/poor coordination/imbalance, mild spasticity (especially lower limbs), diabetes mellitus, dental crowding/hypodontia/small roots/high arched palate, left ventricular hypertrophy/congenital heart disease, hepatic fibrosis]; and

4. Requests for Imcivree for obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign or other types of obesity not related to POMC, PCSK1, or LEPR deficiency or BBS including obesity associated with other genetic syndromes, or general obesity will not be approved; and
5. Member is currently on a dietician-guided diet and exercise program and has previously failed a dietician-guided diet and exercise program alone; and
6. Member's baseline weight and body mass index (BMI) must be provided; and
7. Baseline BMI must be ≥30kg/m2 for adults or ≥95th percentile on BMI-for-age growth chart assessment for children; and
8. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Imcivree therapy and throughout treatment; and
9. Prescriber must verify member has been counseled on potential sexual adverse reactions and when to seek emergency medical care; and
10. Prescriber must verify member does not have moderate, severe, or end stage renal disease [estimated glomerular filtration rate (eGFR) <60mL/min/1.73m2]; and
11. Prescriber must verify female member is not pregnant or breastfeeding; and
12. Prescriber must confirm member or caregiver has been trained on the proper storage and administration of Imcivree prior to the first dose; and
13. For POMC-, PCSK1-, or LEPR-deficiency, initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; ~~and~~ or
14. For BBS, approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; and
15. A quantity limit of 9mL per 30 days will apply.

Recommendation 8: Annual Review of Lambert-Eaton Myasthenic Syndrome (LEMS) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the LEMS medications prior authorization criteria to be consistent with recent FDA action with the following changes (shown in red):

Firdapse® (Amifampridine) ~~and Ruzurgi® (Amifampridine)~~ Approval Criteria:

1. An FDA approved diagnosis of Lambert-Eaton myasthenic syndrome (LEMS); and
2. LEMS diagnosis must be confirmed by 1 of the following:
   a. A high titer anti-P/Q-type voltage-gated calcium channel (VGCC) antibody assay; or
   b. A confirmatory electrodiagnostic study [e.g., repetitive nerve stimulation (RNS), needle electromyography (EMG), single-fiber electromyography (SFEMG)]; and
3. The requested medication must be prescribed by, or in consultation with, a neurologist or oncologist; and
4. Member must not have a history of seizures or be taking medications that lower the seizure threshold (e.g., bupropion, tramadol, amphetamines, theophylline); and
5. ~~For Firdapse®, a patient-specific, clinically significant reason why the member cannot use Ruzurgi® must be provided; and~~
6. ~~For Firdapse®, a~~ quantity limit of 240 tablets per 30 days will apply~~. For Ruzurgi®, a quantity limit of 300 tablets per 30 days will apply~~; and
7. Initial approvals will be for 6 months. Continued authorization will require the prescriber to indicate that the member is responding well to treatment and continues to require treatment with the requested medication.

Recommendation 9: Annual Review of Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Austedo® (deutetrabenazine) approval criteria to be consistent with package labeling updates (changes shown in red):

Austedo® (Deutetrabenazine) Approval Criteria [Huntington's Disease Diagnosis]:

1. An FDA approved diagnosis of chorea associated with Huntington's disease; and

2. Austedo® must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. A previous trial of Xenazine® (tetrabenazine) or a patient-specific, clinically significant reason why the member cannot use Xenazine® (tetrabenazine) must be provided; and
4. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Austedo® therapy and throughout treatment; and
5. Member must not have hepatic impairment; and
6. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
7. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
8. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with Austedo®; and
9. For members ~~requiring doses of Austedo® above 24mg per day,~~ who are using Austedo® concomitantly with other medications that are known to prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval], the prescriber must agree to monitor the member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures) ~~assess the QTc interval before and after increasing the dose of Austedo® or other medications that are known to prolong the QTc interval~~; and
10. Member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and The daily dose of Austedo® must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion) or if they are a known poor CYP2D6 metabolizer; and
11. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea have decreased, and the member is not showing worsening signs of depression.

Austedo® (Deutetrabenazine) Approval Criteria [Tardive Dyskinesia Diagnosis]:

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
    a. Involuntary athetoid or choreiform movements; and
    b. History of treatment with a dopamine receptor blocking agent (DRBA); and
    c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and

3. Austedo® must be prescribed by a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
~~4. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Austedo® therapy and throughout treatment; and~~
5. Member must not have hepatic impairment; and
6. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
7. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
8. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with Austedo®; and
9. For members ~~requiring doses of Austedo® above 24mg per day,~~ who are using Austedo® concomitantly with other medications that are known to prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval], the prescriber must agree to monitor the member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures) ~~assess the QTc interval before and after increasing the dose of Austedo® or other medications that are known to prolong the QTc interval~~; and
10. Member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and
11. The daily dose of Austedo® must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion) or if they are a known poor CYP2D6 metabolizer; and
12. Female members must not be pregnant or breastfeeding; and
13. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
14. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Recommendation 10: Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Carvykti™ (Ciltacabtagene Autoleucel) and Tecvayli™ (Teclistamab-cqyv)

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

Recommendation 11: Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Tezspire® (Tezepelumab-ekko)

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

Recommendation 12: Annual Review of Atopic Dermatitis (AD) Medications and 30-Day Notice to Prior Authorize Adbry™ (Tralokinumab-ldrm) and Cibinqo™ (Abrocitinib)

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

Recommendation 13: 30-Day Notice to Prior Authorize Skysona® (Elivaldogene Autotemcel)

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

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

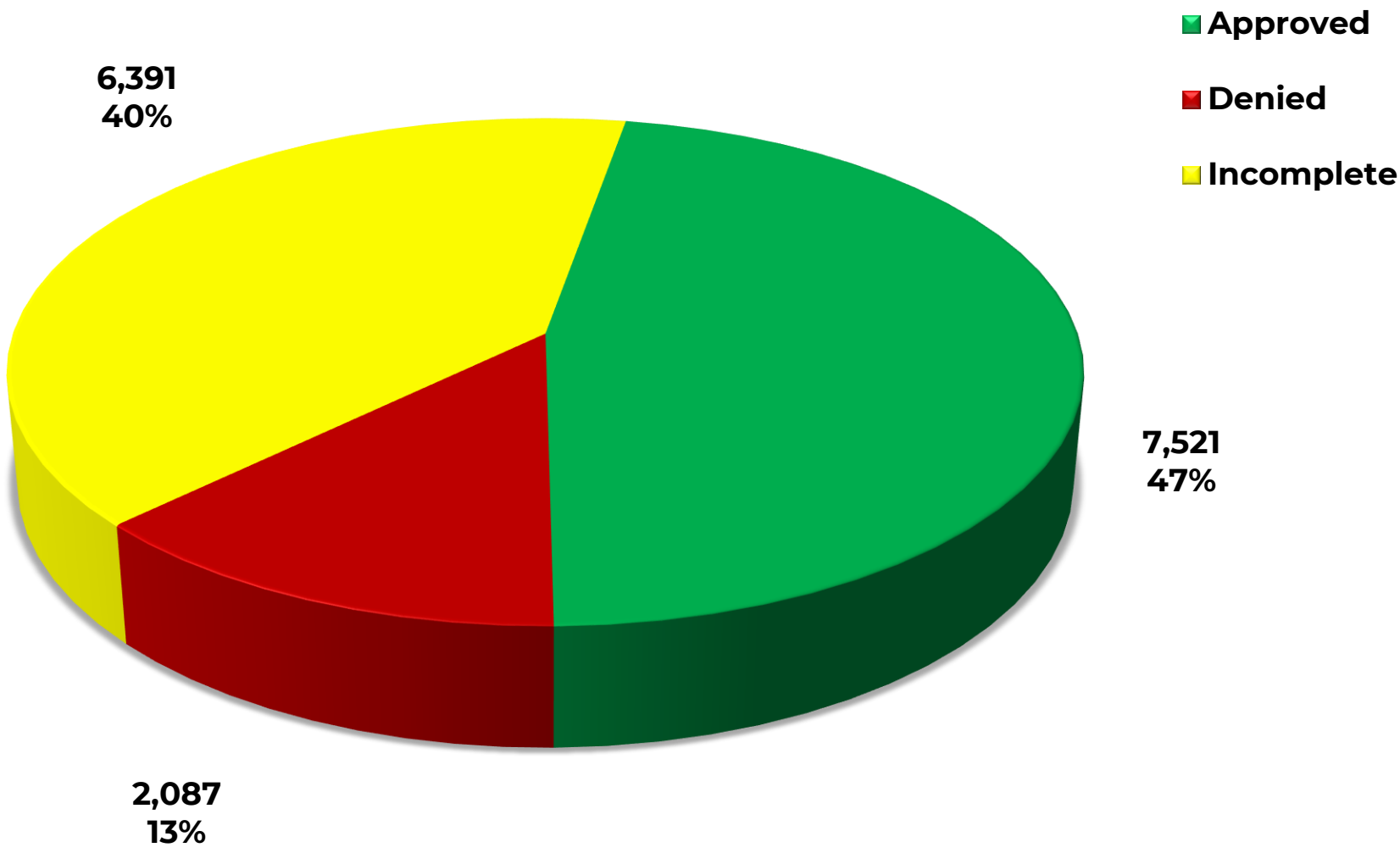
NO ACTION REQUIRED.

Recommendation 15: Future Business

NO ACTION REQUIRED.

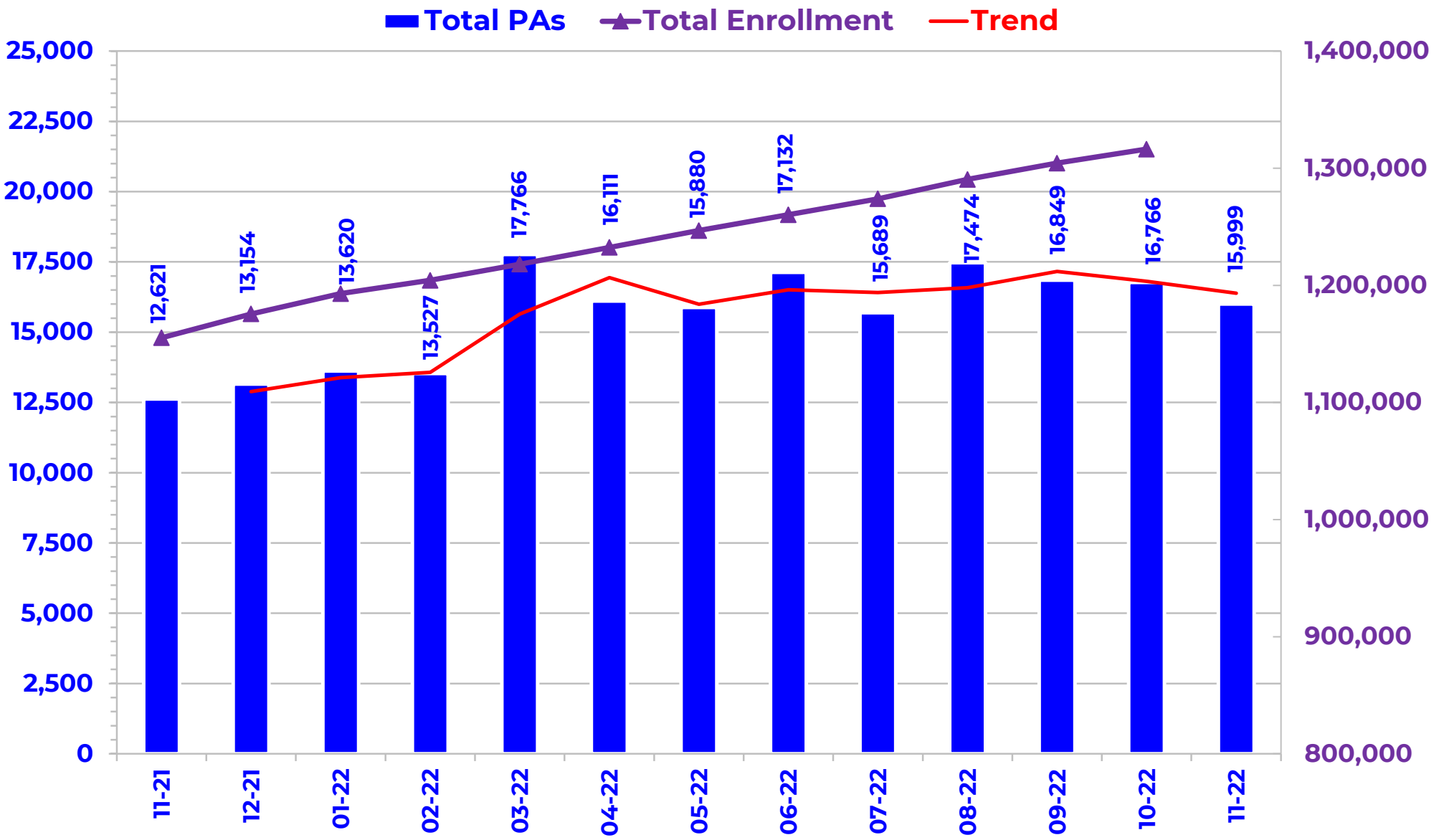
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: NOVEMBER 2022



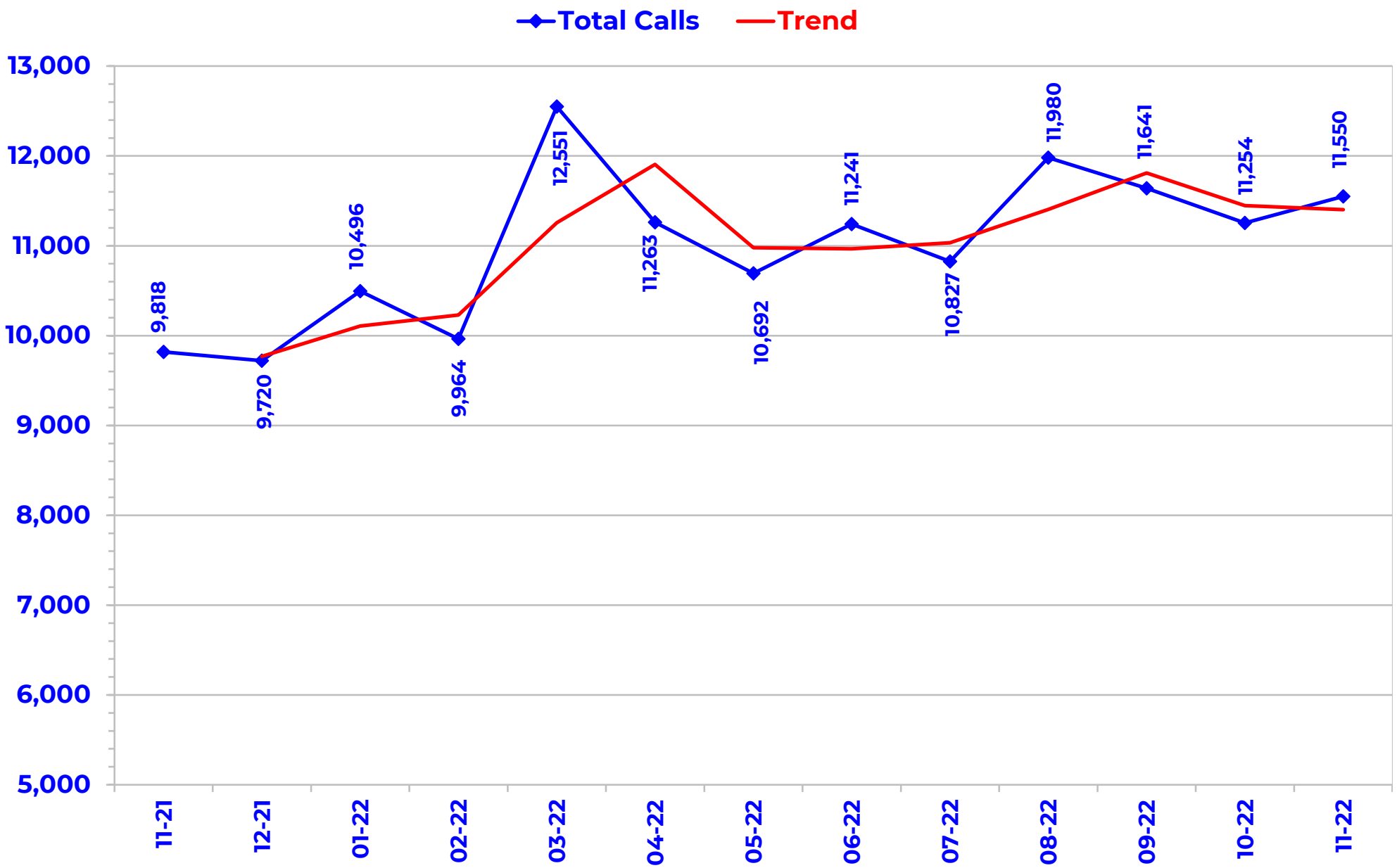
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION (PA) REPORT: NOVEMBER 2021 – NOVEMBER 2022



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: NOVEMBER 2021 – NOVEMBER 2022



Prior Authorization Activity

11/1/2022 Through 11/30/2022

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	91	23	5	63	492
Analgesic - NonNarcotic	13	1	1	11	154
Analgesic, Narcotic	365	160	30	175	139
Antiasthma	92	18	41	33	230
Antibiotic	57	23	10	24	209
Anticonvulsant	239	119	15	105	321
Antidepressant	353	72	63	218	326
Antidiabetic	1,689	521	412	756	356
Antigout	21	7	3	11	332
Antihemophilic Factor	12	11	0	1	285
Antihistamine	49	13	17	19	328
Antimalarial Agent	113	88	1	24	355
Antimigraine	528	96	133	299	241
Antineoplastic	270	196	13	61	166
Antiobesity	20	0	16	4	0
Antiparasitic	46	13	2	31	15
Antiparkinsons	18	1	7	10	361
Antiulcers	48	4	13	31	89
Antiviral	23	9	3	11	76
Anxiolytic	25	7	2	16	262
Atypical Antipsychotics	585	236	67	282	350
Benign Prostatic Hypertrophy	12	1	5	6	360
Biologics	404	218	41	145	286
Bladder Control	94	19	28	47	342
Blood Thinners	736	447	25	264	341
Botox	76	37	31	8	359
Buprenorphine Medications	119	54	14	51	101
Calcium Channel Blockers	14	3	2	9	261
Cardiovascular	98	42	13	43	322
Chronic Obstructive Pulmonary Disease	276	56	61	159	348
Constipation/Diarrhea Medications	243	34	72	137	232
Contraceptive	35	13	6	16	359
Corticosteroid	15	3	4	8	240
Dermatological	482	187	110	185	235
Diabetic Supplies	831	289	131	411	258
Endocrine & Metabolic Drugs	120	51	16	53	216
Erythropoietin Stimulating Agents	23	14	3	6	121
Fibromyalgia	15	2	1	12	191
Fish Oils	33	6	9	18	359

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Gastrointestinal Agents	198	46	37	115	189
Genitourinary Agents	17	3	5	9	277
Glaucoma	19	4	5	10	179
Growth Hormones	89	60	12	17	159
Hematopoietic Agents	41	15	8	18	171
Hepatitis C	27	12	5	10	9
HFA Rescue Inhalers	742	466	5	271	353
Insomnia	133	17	27	89	203
Insulin	299	97	31	171	353
Miscellaneous Antibiotics	26	10	3	13	18
Multiple Sclerosis	144	73	11	60	234
Muscle Relaxant	53	9	11	33	149
Nasal Allergy	42	2	17	23	357
Neurological Agents	209	68	42	99	221
Neuromuscular Agents	13	9	0	4	359
NSAIDs	40	1	8	31	360
Ocular Allergy	22	3	7	12	177
Ophthalmic	14	1	2	11	360
Ophthalmic Anti-infectives	25	9	0	16	14
Ophthalmic Corticosteroid	28	7	2	19	320
Osteoporosis	49	16	15	18	341
Other*	327	86	43	198	287
Otic Antibiotic	27	4	5	18	17
Respiratory Agents	35	24	1	10	323
Statins	63	12	9	42	197
Stimulant	1,989	1,363	85	541	348
Synagis	145	52	43	50	62
Testosterone	167	47	37	83	330
Thyroid	33	13	3	17	293
Topical Antifungal	42	2	8	32	189
Topical Corticosteroids	43	3	25	15	177
Vitamin	143	43	68	32	83
Pharmacotherapy	60	52	0	8	297
Emergency PAs	0	0	0	0	
Total	**13,587**	**5,723**	**2,006**	**5,858**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	25	11	3	11	288
Compound	10	6	0	4	70
Cumulative Early Refill	1	1	0	0	3
Diabetic Supplies	2	2	0	0	358
Dosage Change	478	439	2	37	19
High Dose	8	8	0	0	193
IHS-Brand	1	1	0	0	360
Ingredient Duplication	2	2	0	0	8
Lost/Broken Rx	157	150	3	4	23
MAT Override	313	250	7	56	76
NDC vs Age	357	229	22	106	270
NDC vs Sex	7	5	0	2	97
Nursing Home Issue	32	29	0	3	12
Opioid MME Limit	125	44	6	75	121
Opioid Quantity	42	34	0	8	163
Other	62	53	1	8	19
Quantity vs Days Supply	677	449	30	198	237
STBS/STBSM	20	16	1	3	118
Step Therapy Exception	23	15	1	7	358
Stolen	13	13	0	0	31
Third Brand Request	57	41	5	11	29
Overrides Total	**2,412**	**1,798**	**81**	**533**	
Total Regular PAs + Overrides	**15,999**	**7,521**	**2,087**	**6,391**	

Denial Reasons	
Unable to verify required trials.	5,307
Does not meet established criteria.	2,110
Lack required information to process request.	1,047
Other PA Activity	
Duplicate Requests	1,602
Letters	38,296
No Process	12
Changes to existing PAs	1,307
Helpdesk Initiated Prior Authorizations	1,111
PAs Missing Information	2,291

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

Academic Detailing Program Update

Oklahoma Health Care Authority
December 2022

Background[1,2]

The Academic Detailing (AD) program is an educational initiative combining standards of care with the most current peer-reviewed studies and presenting them in an unbiased, independent, evidence-based manner. AD programs link prescribers with an educator, resulting in improved patient health and cost outcomes. Historically, AD programs that focus specifically on prescribing patterns are shown to reduce inappropriate prescribing to a modest, but significant degree, with a median difference of up to 7%. While not specifically designed to be a tool of cost containment, traditionally AD programs save $2 for every dollar spent.

Since July 2015, under the direction of the Oklahoma Health Care Authority (OHCA), Pharmacy Management Consultants (PMC) has operated an AD program to improve implementation of published guidelines and standards of care. PMC clinical pharmacists, data analysts, and pharmacy graduate students analyze prescription claims data to determine AD topics, identify providers who may benefit from individualized support from an AD pharmacist, and assess outcomes. Continued funding for the PMC-AD program is through a Health Service Initiative (HSI) grant under the Children's Health Insurance Program (CHIP). As such, special care is taken to identify topics with particular relevance to the care of pediatric members. Current and previous areas of focus include treatment of acute and chronic conditions, preventive care, and specialized technical training related to the delivery of pharmacy services.

For each topic, the PMC-AD pharmacist prepares educational materials in consultation with the National Resource Center for Academic Detailing (NaRCAD) and offers the program to providers. Educational materials include the following:

- Clinical treatment guidelines
- Provider resources
- Patient and parent resources
- Diagnostic and treatment tools
- Topic-specific continuing medical education (CME) course listings
- Drug alerts and statements from the U.S. Food and Drug Administration (FDA)
- National quality measures [e.g., Healthcare Effectiveness Data and Information Set (HEDIS)]

- OHCA Product Based Prior Authorization (PBPA) coverage criteria

To date, AD services have been provided to more than 1,050 health care providers and/or their administrative staff. As previously reported, changes in prescribing patterns and associated improvements in health care utilization have led to cost savings to OHCA in the amount of $1,045,872 through December 2021. This amount is inclusive of all federal and supplemental rebates for the analysis periods following AD on the treatment of attention-deficit/hyperactivity disorder (ADHD), use of second generation/atypical antipsychotic medications (SGAs), and treatment of upper respiratory infections (URIs) for pediatric SoonerCare members.

Financial Outcomes: Treatment of Persistent Asthma[3,4,5]

As previously reported at the December 2021 Drug Utilization Review (DUR) Board meeting, Asthma-AD providers increased member use of controller and rescue medications and decreased submissions of asthma-related PAs. Associated health care utilization costs identified during the post-AD analysis are now included below as an annual average per provider during the 5-year Pre-AD period and as a 1-year average per provider during the Post-AD period. Non-drug cost comparisons were assessed by examining non-ambulatory health care service utilization [i.e., hospital and emergency department (ED) visits].

Figure 1: Asthma-AD Comparison of Non-Ambulatory Health Care Utilization

	Hospitalization and ED Visit Costs
Pre-AD	$4,083,760
Post-AD	$2,496,148
% Change*	**-38.88%**
Change*	**-$1,587,612**

*negative indicates improvement
AD = academic detailing; ED = emergency department

Total drug costs were expected to increase as a result of aligning prescribing practices with published guidelines. Drug costs increased by 14% and 21% respectively for rescue medications and controller medications as a result of Asthma-AD.

In the Pre-AD period, 195 prescribers cared for a total of 4,455 members with persistent asthma. Of these total members, 1,584 had an average of 13,453 hospital and ED paid claims per year, with a 5-year average annual cost of **$4,083,760.** In the Post-AD period, 933 of the total members had a total of 3,181 hospital and ED paid claims per year, with a total annual cost of **$2,496,148.** Total hospital and ED annual cost savings of **$1,587,612**, or more than $8,000 per provider, resulted from Asthma-AD. Cost savings are based

on paid claims for SoonerCare members receiving ambulatory care services from detailed prescribers.

Current Topic: Treatment of Diabetes[6,7,8,9]

The American Diabetes Association (ADA) treatment guidelines have been updated annually since 1989 and describe best practices based on comprehensive literature reviews. The International Society for Pediatric and Adolescent Diabetes (ISPAD) and the American College of Obstetrics and Gynecology (ACOG) guidelines are updated much less frequently, but no less rigorously. The most recent ISPAD and ACOG guidelines were published in 2018 and 2019, respectively. Considering the most recent updates, there is agreement across multiple areas impacting the treatment of both type 1 and type 2 pediatric diabetes mellitus (T1DM and T2DM). Guidelines recommend assessing the following as they impact treatment decisions:

- Food security
- Housing stability/homelessness
- Health literacy
- Financial barriers
- Social/community support

Recommendations also address the use of real time continuous glucose monitors (CGMs) and time-specific use of other CGM metrics. Recent changes to the amount and type of physical activity are also included. Lastly, there is additional guidance in the management of new-onset diabetes in youth who are overweight or obese.

Changes and reinforced messaging from these guidelines served as the source material for the fifth AD topic: Pediatric Diabetes – Highs, Lows, and Everything in Between.

Data from SoonerCare paid claims and member diagnoses were used to identify providers who stood to benefit from receiving AD services. Paid claims and diagnosis data for pediatric members were compared across the following criteria, with Diabetes Mellitus-AD (DM-AD) offered to SoonerCare providers meeting 3 or more of the following criteria:

1. Having ≥50% increase in the number of DM claims from 2020 to 2021
2. Having ≥50% increase in the number of claims for any DM medication from 2020 to 2021
3. Having hospital claims for any member with a diagnosis of diabetes during 2020 or 2021
4. Having >100 members in their practice with claims for any DM medication (excluding specialty providers)
5. Having ≥50% more DM claims than their same specialty peers (e.g., general practitioner, physician assistant)

6. Having ≥50% more claims for any DM medication than their same specialty peers (e.g., general practitioner, physician assistant)

DM-AD services were delivered by the PMC-AD pharmacist. Providers in co-practice with identified providers and those who had previously received detailing for other topics were also eligible to receive DM-AD services. In total, 44 providers received DM-AD services. DM prescribing and health care utilization patterns were shared with providers on request. DM-AD was delivered exclusively through phone calls and Zoom meetings due to ongoing social distancing precautions associated with COVID-19 and provider preference.

Results: Treatment of Pediatric Diabetes

Inappropriate Prescribing:

Potentially inappropriate DM treatment has been assessed for all detailed providers meeting criteria as described above. Health care patterns were compared for providers with members having paid claims for both hospital visits and DM medications and/or devices during both the pre- and post-AD periods. Outcomes are reported as a 9-month average and total per provider during the pre-AD period and as a 9-month average and total per provider during the post-AD period. Changes in the health care utilization of members receiving a DM medication or having a DM diagnosis during the post-AD period are represented in Figure 2. Across all detailed providers, health care utilization decreased by nearly 40% for members with DM.

Figure 2: DM-AD Comparison of Health Care Utilization

Detailed Providers	Average Hospital Costs Per Month	Total Hospital Costs
Pre-AD DM Health Care	$56,716.70	$510,450.29
Post-AD DM Health Care	$34,568.07	$311,112.62
% Change*	**-39.05%**	**-39.05%**
Change*	**-$22,148.63**	**-$199,337.67**
Pre-AD All Cause Health Care	$127,428.88	$1,146,859.89
Post-AD All Cause Health Care	$82,072.56	$738,653.04
% Change*	**-35.59%**	**-35.59%**
Change*	**-$45,356.32**	**-$408,206.85**
Non-Detailed Providers		
Pre-AD DM Health Care	$106,477.92	$958,301.30
Post-AD DM Health Care	$123,611.12	$1,112,500.08
% Change*	**16.09%**	**16.09%**
Change*	**$17,133.20**	**$154,198.78**

*negative indicates improvement
AD = academic detailing; DM = diabetes mellitus

Across all parameters, DM-AD providers decreased both DM-specific and all cause hospitalization as a result of DM-AD.

Provider Satisfaction

Provider satisfaction continues to remain very high as measured by post-visit satisfaction surveys. Providers meeting comparison criteria and those in co-practice were given satisfaction surveys in order to determine their acceptance of the program and to predict the likelihood of participation in future AD topics. Participants in the detailing sessions were given an online survey with an anonymous link and survey results are shown in Figure 3. To date, only 9 providers have been excluded due to an unwillingness to participate. Other reasons for exclusion of targeted providers included the following:

- No longer treating the targeted disease or medication class
- Retired, moved out of state, or inactive license
- No longer treating pediatric patients
- No longer treating SoonerCare members

Figure 3: AD Provider Satisfaction	
The information provided was:	**% choosing agree or strongly agree**
Easily understood	95%
Clearly presented	99%
Evidence-based	97%
Based on the information, I intend to:	**% choosing agree or strongly agree**
Make practice changes as a result	83%
Recommend this program to colleagues	88%
Participate in future topics	90%

AD = academic detailing

Academic Meeting Presentation(s)

Since July 2016, the PMC-AD program leaders have been invited to present program outcomes and breakout sessions at the International Conference on Academic Detailing, the Academy of Managed Care Pharmacy (AMCP), and the American Drug Utilization Review Society (ADURS). Additionally, a poster presentation featuring ADHD-AD results was awarded a silver ribbon at the Nexus 2017 meeting of AMCP. The primary PMC-AD pharmacist is also currently 1 of 7 national training facilitators for NaRCAD.

Summary

As a result of AD interventions, the currently available data shows medication costs, PA submissions, inappropriate prescribing, and health care utilization costs have all been reduced substantially. Prescription data has been analyzed using rebated and non-rebated data, pre-and post-detailing

patterns for individual providers, and federal fiscal year and calendar year comparisons. Each analysis shows improvements following delivery of AD services.

Providers report satisfaction with the program and intend to participate in future topics. The AD program is well received by providers. Targeted providers have fulfilled their stated intentions to make practice changes as prompted by the AD sessions. Continued implementation and expansion of the PMC-AD program is expected to increase delivery of evidence-based health care and reduce health care costs to OHCA.

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[7] International Society for Pediatric and Adolescent Diabetes. ISPAD Clinical Practice Consensus Guidelines 2018. Available online at: https://www.ispad.org/page/ISPADGuidelines2018. Last accessed 11/21/2022.
[8] Kelley CE, Weaver A. Diabetes Mellitus: ACOG Clinical Updates in Women's Health Care Primary and Preventive Care Review. *Obstetrics & Gynecology* 2019; 134(5): 1128-1139.
[9] American Diabetes Association. Children and Adolescents: Standards of Medical Care in Diabetes 2021. Available online at: https://diabetesjournals.org/care/article/44/Supplement_1/S180/30606/13-Children-and-Adolescents-Standards-of-Medical. Last accessed 11/29/2022.

Appendix C

SoonerCare Maintenance Drug List

Oklahoma Health Care Authority
December 2022

Introduction[1]

Most adult SoonerCare members have a 6 prescription limit each month; therefore, prescribing for and dispensing 90-day supplies of chronic maintenance medications will help members who are on multiple medications obtain the maintenance medications necessary. Dispensing 90-day supplies of chronic maintenance medications has been shown to increase medication adherence and persistence, compared to dispensing 30-day supplies. Additionally, 90-day supplies will reduce the SoonerCare member's financial burden as they will pay the same copay for a 90-day or 30-day supply.

In November 2019, the Oklahoma Health Care Authority (OHCA) Board voted to update the current policy and rules regarding dispensing limitations. Previously, medications could only be dispensed and reimbursed by SoonerCare up to a 34-day supply or if the quantity did not exceed 100 units. The newly voted OHCA policy and rules state the following regarding dispensing limitations and a maintenance drug list (317:30-5-77.1):

> "Prescription quantities shall be limited to a 34-day supply, except in the following situations:
> 1. The Drug Utilization Review (DUR) Board has recommended a different day supply or quantity limit based on published medical data, including the manufacturer's package insert; or
> 2. The product is included on the Maintenance List of medications which are exempted from this limit and may be dispensed up to a 90-day supply; or
> 3. The manufacturer of the drug recommends a dispensing quantity less than a 34-day supply….".
>
> "The DUR Board shall develop a Maintenance List of medications which are used in general practice on a continuing basis. These drugs shall be made available through the Vendor Drug Program in quantities up to a 90-day supply when approved by the prescriber. The DUR Board shall review the Maintenance List at least annually."

The DUR Board recommended and voted on categories of medications for inclusion on the maintenance drug list in December 2019, and the SoonerCare Maintenance Drug List was implemented in January 2020. The

purpose of this report is to provide the DUR Board with the current maintenance drug list for review, which is to be maintained by the DUR Board. Medications included in the maintenance drug list allow a 90-day supply of medications in the claims processing system without the need for an override. Action by the DUR Board is not required unless the DUR Board recommends changes to the current maintenance drug list.

SoonerCare Maintenance Drug List

The current SoonerCare Maintenance Drug List is available on the OHCA website (https://oklahoma.gov/ohca/providers/types/pharmacy) and includes the following categories of medications:

- Alzheimer's Medications
- Anticonvulsants
- Antidepressants/Anxiolytics
- Antihypertensive Medications
- Antipsychotic Medications
- Anti-Ulcer Medications
- Bladder Control Medications
- Benign Prostatic Hyperplasia (BPH) Medications
- Cardiovascular Medications
- Chronic Obstructive Pulmonary Disease (COPD) Medications
- Diabetes Medications
- Glaucoma Medications
- Hyperlipidemia Medications
- Parkinson's Medications
- Thyroid Medications

Please note that not all medications in each category can be processed for a 90-day supply.

Recommendations

The College of Pharmacy does not recommend any changes to the SoonerCare Maintenance Drug List at this time.

[1] Taitel M, Fensterheim L, Kirkham H, et al. Medication Days' Supply, Adherence, Wastage, and Cost Among Chronic Patients in Medicaid. *MMRR* 2012; 2(3):E1-E13. doi: 10.5600/mmrr.002.03.a04.

Appendix D

Vote to Prior Authorize Skysona® (Elivaldogene Autotemcel)

Oklahoma Health Care Authority
December 2022

Market News and Updates[1,2]

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

- **September 2022:** The FDA granted accelerated approval to Bluebird Bio's Skysona® (elivaldogene autotemcel; formerly known as eli-cel) to slow the progression of neurologic dysfunction in boys 4 to 17 years of age with early, active childhood cerebral adrenoleukodystrophy (CALD). Patients with CALD have a mutation in the *ABCD1* gene which causes a defective adrenoleukodystrophy (ALD) protein. Skysona® is intended to be a one-time gene therapy and is designed to treat the underlying cause of CALD. The therapy uses ex vivo transduction with the Lenti-D lentiviral vector (LVV) to add functional copies of the *ABCD1* gene into a patient's own hematopoietic stem cells (HSCs). The added gene allows patients to produce ALD protein to help break down very long-chain fatty acids (VLCFAs) and slow or possibly prevent further neurological dysfunction.

Skysona® (Elivaldogene Autotemcel) Product Summary[3,4,5,6,7]

Indication: Skysona® is indicated to slow the progression of neurologic dysfunction in boys 4 to 17 years of age with early, active CALD.

- Early, active CALD refers to asymptomatic or mildly symptomatic [neurological function score (NFS) ≤1] boys who have gadolinium enhancement (GdE+) on brain magnetic resonance imaging (MRI) and Loes scores of 0.5 to 9.
- This indication was approved under accelerated approval based on 24-month major functional disabilities (MFDs)-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitation(s) of Use:

- Skysona® does not treat or prevent adrenal insufficiency.
- An immune response to Skysona® may cause rapid loss of efficacy of Skysona® in patients with full deletions of the *ABCD1* gene.
- Skysona® has not been studied in CALD secondary to head trauma.
- Given the risk of hematologic malignancy with Skysona®, and unclear long-term durability of Skysona® and human ALD protein expression,

careful consideration should be given to the timing of treatment for each boy and treatment of boys with isolated pyramidal tract disease as clinical manifestations do not usually occur until adulthood.

Boxed Warning: Hematologic Malignancy

- Hematologic malignancy, including life-threatening cases of myelodysplastic syndrome (MDS), has occurred in patients treated with Skysona®. The cancers appear to be the result of the Skysona® LVV, Lenti-D, integration in proto-oncogenes.
  - Patients should be monitored closely for evidence of malignancy through complete blood counts at least every 6 months and through assessments for evidence for clonal expansion or predominance at least twice in the first year and annually thereafter; bone marrow evaluations should be considered as clinically indicated.

How Supplied: Skysona® is supplied as a cell suspension for intravenous (IV) infusion; a single dose of Skysona® contains a minimum of 5×10^6 CD34+ cells/kg of body weight, suspended in a solution containing 5% dimethyl sulfoxide (DMSO).

Dosing and Administration:

- Patients must undergo HSC mobilization followed by apheresis to obtain CD34+ cells for Skysona® manufacturing. A back-up collection of CD34+ cells is also required.
- Dosing of Skysona® is based on the number of CD34+ cells in the infusion bag(s) per kg of body weight.
- The minimum recommended dose is 5×10^6 CD34+ cells/kg.
- Full myeloablative and lymphodepleting conditioning must be administered before infusion of Skysona®.
- The patient's identity should be verified to match the unique patient identification information on the Skysona® infusion bag(s) prior to infusion.
- Skysona® should not be sampled, altered, or irradiated.
- An in-line blood filter or an infusion pump should not be used.

Mechanism of Action: Skysona® adds functional copies of the *ABCD1* cDNA into patients' HSCs through transduction of autologous CD34+ cells with a Lenti-D LVV. After Skysona® infusion, transduced CD34+ HSCs engraft in the bone marrow and differentiate into various cell types, including monocytes (CD14+) capable of producing functional ALD protein. Functional ALD protein can then participate in the local degradation of VLCFAs, which is believed to slow or possibly prevent further inflammation and demyelination.

Contraindication(s): None

Safety:

- Hematologic Malignancy: MDS, a hematologic malignancy, has developed in patients treated with Skysona® in clinical studies. The cancers appear to be the result of the Skysona® Lenti-D LVV integration in proto-oncogenes. Because of the risk of hematologic malignancy, alternative therapies should be carefully considered prior to the decision to treat a child with Skysona®. Consultation with hematology experts should be considered prior to Skysona® treatment to inform benefit-risk treatment decision and to ensure adequate monitoring for hematologic malignancy. Patients should be closely monitored for evidence of malignancy through complete blood counts at least every 6 months and through assessments for evidence for clonal expansion or predominance at least twice in the first year and annually thereafter; bone marrow evaluations should be considered as clinically indicated.
- Serious Infections: Life-threatening or fatal infections have occurred in patients after Skysona® infusion. Important opportunistic infections that have been diagnosed within the first 3 months after treatment with Skysona® include BK cystitis, cytomegalovirus reactivation, human herpesvirus-6 viremia, candidiasis, and bacteremias. Opportunistic infections after the first 3 months include an atypical mycobacterium vascular device infection, pseudomonas bacteremia, and Epstein-Barr virus reactivations diagnosed as late as 18 months after treatment with Skysona®. Serious infections involving adenovirus include a case of transverse myelitis at 6 months that was attributed to adenovirus and entero/rhinovirus infection, and a fatal adenovirus infection at 21 months in a patient with CALD progression who developed multisystem organ failure. Grade 3 or higher infections occurred in 21% of all patients (12% bacterial, 3% viral, 6% unspecified). The most common Grade 3 or higher infections were vascular device infections (7% of patients) diagnosed as late as 6 months after treatment with Skysona® and bacteremias (6% of patients) diagnosed as late as 8 months after treatment with Skysona®. Febrile neutropenia developed within 2 weeks after Skysona® infusion in 72% of patients. In the event of febrile neutropenia, patients should be evaluated for infection and managed with broad-spectrum antibiotics, fluids, and other supportive care as medically indicated. Patients should be monitored for signs and symptoms of infection before and after Skysona® administration and treated appropriately. Prophylactic antimicrobials should be administered according to best clinical practices and clinical guidelines. Administration of Skysona® should be avoided in patients with active infections.
- Prolonged Cytopenias: Patients may exhibit cytopenias >1 year after treatment with Skysona®. Grade 3 or higher cytopenias on or after day 60 following Skysona® infusion occurred in 47% of patients and

included low platelet count (14%), low neutrophil count (22%), low lymphocyte count (27%), and low hemoglobin (2%). Grade 3 cytopenias persisted beyond day 100 in 15% of patients and included low platelet count (7%), low neutrophil count (9%), and low lymphocyte count (6%). Blood counts should be monitored until normalization, and patients should be assessed for signs and symptoms of bleeding and/or infection prior to and after Skysona® administration.

- Delayed Platelet Engraftment: Delayed platelet engraftment has been observed with Skysona® treatment; bleeding risk is increased prior to platelet engraftment and may continue after engraftment in patients with prolonged thrombocytopenia. Platelet counts should be monitored until platelet engraftment and recovery are achieved. Patients should also be monitored for thrombocytopenia and bleeding.
- Risk of Neutrophil Engraftment Failure: There is a potential risk of neutrophil engraftment failure after treatment with Skysona® [defined as failure to achieve 3 consecutive absolute neutrophil counts (ANC) ≥500cells/mcL obtained on different days by day 43 after Skysona® infusion]. ANC should be monitored after Skysona® infusion, and if neutrophil engraftment does not occur, rescue treatment with the back-up collection of CD34+ cells should be provided.
- Hypersensitivity Reactions: The DMSO in Skysona® may cause hypersensitivity reactions, including potentially life-threatening anaphylaxis requiring immediate intervention.
- Anti-Retroviral Use: Patients should not take anti-retroviral medications prior to mobilization (for at least 1 month prior to mobilization or for the expected duration for elimination of the medications) and until all cycles of apheresis are completed. Anti-retroviral medications may interfere with manufacturing of the apheresed cells. If a patient requires anti-retroviral medications for human immunodeficiency virus (HIV) prophylaxis, mobilization and apheresis of CD34+ cells should be delayed until HIV infection is adequately ruled out.
- Laboratory Test Interference: Skysona® affects polymerase chain reaction (PCR) assays for HIV due to LVV provirus insertion. A PCR-based assay should not be used to screen for HIV infection in patients treated with Skysona® as a false-positive test result is likely.
- Vaccines: The safety and effectiveness of vaccination during or following Skysona® treatment have not been studied. Vaccination is not recommended during the 6 weeks preceding the start of myeloablative conditioning and until hematological recovery following treatment with Skysona®. Where feasible, consider administering childhood vaccinations prior to myeloablative conditioning for Skysona®.
- Pregnancy: There are no available data with Skysona® administration in pregnant women. Consider the risks associated with mobilization and conditioning agents on pregnancy and fertility. No animal reproductive

and developmental toxicity studies have been conducted to assess whether Skysona® can cause fetal harm when administered to a pregnant woman. No nonclinical germline transmission studies have been conducted with Skysona®.

- Lactation: There is no information regarding the presence of Skysona® in human milk, the effect on the breastfed infant, or the effects on milk production.
- Females and Males of Reproductive Potential: The *Prescribing Information* of the mobilization and conditioning agents should be consulted for information on the need for effective contraception. There are insufficient exposure data to provide a precise recommendation on duration of contraception following treatment with Skysona®. Males capable of fathering a child and their female partners of childbearing potential should use an effective method of contraception (intra-uterine device or combination of hormonal and barrier contraception) from start of mobilization through at least 6 months after administration of Skysona®.
- Infertility: There are no data on the effects of Skysona® on fertility. Data are available on the risk of infertility with myeloablative conditioning. Patients should be advised of the option to cryopreserve semen before treatment if appropriate.
- Pediatric Use: The safety and efficacy of Skysona® in children younger than 4 years of age have not been established.
- Patients with a Full *ABCD1* Gene Deletion: In the only patient in the Skysona® clinical studies who had a full *ABCD1* deletion, disease progression occurred. The patient experienced radiologic disease progression in the setting of declining peripheral blood vector copy number, suggesting loss of product efficacy which may have been immune mediated. The patient was subsequently treated with allogeneic HSC transplant.
- Renal Impairment: Skysona® has not been studied in patients with renal impairment. Patients should be assessed for renal impairment to ensure HSC transplantation is appropriate.
- Hepatic Impairment: Skysona® has not been studied in patients with hepatic impairment. Patients should be assessed for hepatic impairment to ensure HSC transplantation is appropriate.
- Patients Seropositive for HIV: Skysona® has not been studied in patients with HIV-1, HIV-2, or human T-lymphotrophic virus 1 or 2 (HTLV-1 or HTLV-2). A negative serology test for HIV is necessary to ensure acceptance of apheresis material for Skysona® manufacturing. Apheresis material from patients with a positive test for HIV will not be accepted for Skysona® manufacturing.

Adverse Reactions:

- The most frequent non-laboratory adverse reactions (incidence ≥20%) in clinical trials were mucositis, nausea, vomiting, febrile neutropenia, alopecia, decreased appetite, abdominal pain, constipation, pyrexia, diarrhea, headache, and rash.
- The most frequent grade 3 or 4 laboratory abnormalities (incidence ≥40%) adverse reactions in clinical trials were leukopenia, lymphopenia, thrombocytopenia, neutropenia, anemia, and hypokalemia.

Efficacy:

- The safety and efficacy of Skysona® were assessed in (2) 24-month, open-label, single-arm studies, Phase 2/3 Starbeam (ALD-102) and the Phase 3 ALD-104, in patients with early, active CALD as defined by Loes score between 0.5 and 9 (inclusive) and GdE+ on MRI, as well as a NFS of ≤1, indicating limited changes in neurologic function. A total of 67 patients were enrolled in both studies. All patients were administered granulocyte colony stimulating factor (G-CSF) and plerixafor to mobilize HSCs prior to apheresis. All patients also received full myeloablative conditioning with busulfan prior to treatment with Skysona®.
- The efficacy of Skysona® was compared to an external untreated natural history control. Data for the natural history population in the retrospective natural history study (ALD-101) was collected from existing medical records for patients with CALD. The natural history population had early, active disease at diagnosis, though gadolinium status was defined by either having a GdE+ MRI during the study or unknown GdE+ status and a clinical course that suggested active disease.
    - Primary Endpoints: Percentage of patients who are alive and have none of the 6 MFDs at month 24
    - Results: In the studies, patients who received Skysona® had an estimated 72% likelihood of MFD-free survival at 24 months from onset of symptoms, whereas untreated patients from a natural history study had an estimated 43% likelihood of MFD-free survival.
- As a condition of the accelerated approval, Bluebird Bio will provide confirmatory long-term clinical data to the FDA, including results of the ongoing long-term follow-up study (LTF-304), which is following patients treated in clinical trials for 15 years, and data from commercially treated patients.

Cost: The Wholesale Acquisition Cost (WAC) of Skysona® is $3 million per one-time treatment.

Recommendations

The College of Pharmacy recommends the prior authorization of Skysona® (elivaldogene autotemcel) with the following criteria:

Skysona® (Elivaldogene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of early, active cerebral adrenoleukodystrophy (CALD) in male members 4 to 17 years of age; and
2. Diagnosis must be confirmed by all of the following:
    a. Molecular genetic testing confirming a mutation in the *ABCD1* gene; and
        i. Members must not have a full deletion of the *ABCD1* gene; and
    b. Lab results indicating elevated very long-chain fatty acids (VLCFAs); and
    c. Active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating the following:
        i. Loes score between 0.5 and 9 on the 34-point scale; and
        ii. Gadolinium enhancement (GdE+) on MRI of demyelinating lesions; and
    d. Neurological Function Score (NFS) of ≤1; and
3. Skysona® must be prescribed by a neurologist, endocrinologist, or hematologist/oncologist with expertise in the treatment of CALD and the administration of Skysona®; and
4. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
5. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
6. Member must not be taking statins, Lorenzo's oil, or dietary regimens used to lower VLCFA levels; and
7. Member must not have an immediate family member with known or suspected familial cancer syndrome (FCS); and
8. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to the package labeling; and
9. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Skysona®); and
10. Members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Skysona®; and
11. Prescriber must verify members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member or member's caregiver; and
12. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Skysona®; and

13. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at month 6 and month 12 after treatment with Skysona®, then at least annually thereafter for at least 15 years, and with integration site analysis at months 6, 12, and as warranted; and
14. Skysona® must be administered at a Skysona® qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Skysona® dose from receipt to storage to administration; and
15. Approvals will be for 1 dose per member per lifetime.

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[1] U.S. Food and Drug Administration (FDA). Skysona. Available online at: https://www.fda.gov/vaccines-blood-biologics/skysona. Last revised 10/24/2022. Last accessed 11/11/2022.
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[3] Skysona® (Elivaldogene Autotemcel) Prescribing information. Bluebird Bio, Inc. Available online at: https://www.fda.gov/media/161640/download. Last revised 09/2022. Last accessed 11/11/2022.
[4] Eichler F, Duncan C, Musolino PL, et al. Hematopoietic Stem-cell Gene Therapy for Cerebral Adrenoleukodystrophy. *N Engl J Med* 2017; 377(17):1630-1638. doi:10.1056/NEJMoa1700554.
[5] A Study of the Efficacy and Safety of Hematopoietic Stem Cells Transduced with Lenti-D Lentiviral Vector for the Treatment of Cerebral Adrenoleukodystrophy (CALD). *Clinicaltrials.gov*. Available online at: https://clinicaltrials.gov/ct2/show/NCT01896102. Last revised 04/25/2022. Last accessed 11/11/2022.
[6] A Clinical Study to Assess the Efficacy and Safety of Gene Therapy for the Treatment of Cerebral Adrenoleukodystrophy (CALD). *Clinicaltrials.gov*. Available online at: https://clinicaltrials.gov/ct2/show/NCT03852498. Last revised 04/04/2022. Last accessed 11/11/2022.
[7] Observational Study to Evaluate Allogeneic HSCT Outcomes for Cerebral Adrenoleukodystrophy (CALD). *Clinicaltrials.gov*. Available online at: https://clinicaltrials.gov/ct2/show/NCT02204904. Last revised 05/21/2020. Last accessed 11/11/2022.

Appendix E

Vote to Prior Authorize Tezspire® (Tezepelumab-ekko) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications

Oklahoma Health Care Authority
December 2022

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

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

- **December 2021:** AstraZeneca and Amgen's Tezspire® (tezepelumab-ekko) was approved for add-on maintenance treatment of adult and pediatric patients 12 years of age and older with severe asthma. Tezspire® is a first-in-class biologic for severe asthma that acts at the top of the inflammatory cascade by targeting thymic stromal lymphopoietin (TSLP), an epithelial cytokine, and is the only biologic approved for severe asthma with no phenotype or biomarker limitations within its approved label. The approval was following Priority Review by the FDA and based on results from the PATHFINDER clinical trial program. The application included results from the pivotal NAVIGATOR Phase 3 trial in which Tezspire® demonstrated superiority across every primary and key secondary endpoint in patients with severe asthma, compared to placebo, when added to standard therapy.
- **May 2022:** Dupixent® (dupilumab) was granted FDA approval to treat eosinophilic esophagitis (EoE) in adults and pediatric patients 12 years of age and older weighing at least 40kg, making it the first FDA approved medication for this diagnosis. EoE is a chronic inflammatory disorder in which eosinophils are found in the tissue of the esophagus leading to inflammation that causes symptoms such as difficulty swallowing, difficulty eating, and food getting stuck in the esophagus. The safety and efficacy of Dupixent® were studied in a randomized, double-blind, placebo-controlled trial that included (2) 24-week treatment periods (Part A and Part B) that were conducted independently in separate groups of patients. In Part A and Part B, patients received either placebo or Dupixent® 300mg every week. The 2 primary measurements of efficacy were the proportion of patients who achieved ≤6 eosinophils per high-power field (eos/hpf) in the esophagus and the change in the patient-reported Dysphagia Symptom Questionnaire (DSQ) score from baseline to week 24. The DSQ is a questionnaire designed to measure difficulty swallowing

associated with EoE, with total scores ranging from 0 to 84; higher DSQ scores indicate worse symptoms. In Part A, 60% of patients who received Dupixent® achieved the pre-determined level of reduced eosinophils in the esophagus compared to 5% of patients who received placebo [difference: 57.0; 95% confidence interval (CI): 40.9, 73.1]. Those who received Dupixent® experienced an average improvement of 22 points in their DSQ score compared to 10 points in patients who received placebo (difference: -12.3; 95% CI: -19.1, -5.5). In Part B, 59% of patients who received Dupixent® achieved the pre-determined level of reduced eosinophils in the esophagus compared to 6% who received placebo (difference: 53.5; 95% CI: 41.2, 65.8). Additionally, those who received Dupixent® experienced an average improvement of 24 points in their DSQ score compared to 14 points in patients who received placebo (difference: -9.9; 95% CI: -14.8, -5.0). Assessments incorporating the perspectives from patients with EoE supported that the DSQ score improvement in patients who received Dupixent® in the clinical trial was representative of clinically meaningful improvement in dysphagia.

- **September 2022:** Dupixent® (dupilumab) was approved as the first FDA approved treatment for adults with prurigo nodularis (PN). PN is a rare chronic inflammatory skin disease that affects about 87,000 adults per year and is defined by the presence of chronic pruritis and nodular lesions. PN can arise without an identifiable cause or as a secondary manifestation of another condition. The main findings in PN are the presence of lesions or pruritis that lasts at least 6 weeks and a history of scratching or picking at the skin. The itching can become very intense causing patients to scratch themselves to the point of bleeding or pain and thereby causing new lesions to appear. Current treatment options are limited and prior to the approval of Dupixent®, there were no FDA approved treatments. The safety and efficacy of Dupixent® were studied in 2 Phase 3 randomized, double-blind trials and assessed its effects on pruritis improvement and its effect on lesions. The trials included 311 adults with a Worst Itch-Numeric Rating Scale (WI-NRS) ≥7 and who had ≥20 lesions in total. The primary endpoints were patients who had a ≥4-point reduction in WI-NRS from baseline and achieved clear or almost clear skin on the Investigator's Global Assessment for Prurigo Nodularis-Stage (IGA PN-S) scale at week 24. In study 1, 60% of those receiving Dupixent® compared to 18% receiving placebo experienced a ≥4-point reduction in WI-NRS from baseline at 24 weeks (difference: 29.6%; 95% CI: 16.4, 42.8). In study 2, 58% of patients receiving Dupixent® versus 20% receiving placebo achieved the ≥4-point reduction in WI-NRS (difference: 25.5%; 95% CI: 13.1, 37.9). In addition, 48% and 45% of patients receiving Dupixent® in study 1 and study 2, respectively, achieved clear or almost clear skin at 24 weeks on the IGA PN-S scale, compared with 18% and 16% of patients receiving placebo.

Tezspire® (Tezepelumab-ekko) Product Summary[7]

Indication(s): Tezepelumab-ekko is a TSLP blocker, human monoclonal antibody indicated for the add-on maintenance treatment of adult and pediatric patients 12 years of age and older with severe asthma.

Limitation(s) of Use:

- Not indicated for acute bronchospasm or status asthmaticus

How Supplied: 210mg/1.91mL solution in a single-dose glass vial or pre-filled syringe

Dosing and Administration: The recommended dose is 210mg administered subcutaneously (sub-Q) once every 4 weeks.

Mechanism of Action: Tezepelumab-ekko is a TSLP blocker, human monoclonal antibody that binds to human TSLP with a dissociation constant of 15.8pM and blocks its interaction with the heterodimeric TSLP receptor. TSLP is a cytokine mainly derived from epithelial cells and occupies an upstream position in the asthma inflammatory cascade. Airway inflammation is an important component in the pathogenesis of asthma. Multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes, ILC2 cells) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) are involved in airway inflammation. Blocking TSLP with tezepelumab-ekko reduces biomarkers and cytokines associated with inflammation including blood eosinophils, airway submucosal eosinophils, immunoglobulin E (IgE), fractional exhaled nitric oxide (FeNO), IL-5, and IL-13; however, the mechanism of action of tezepelumab-ekko in asthma has not been definitively established.

Contraindication(s): Known hypersensitivity to tezepelumab-ekko or excipients

Safety:

- Hypersensitivity Reactions: Hypersensitivity reactions (e.g., rash, allergic conjunctivitis) can occur after administration of Tezspire®. These reactions can occur within hours of administration, but in some instances have a delayed onset (i.e., days). Appropriate treatment should be initiated as clinically indicated in the event of a hypersensitivity reaction, and the benefits and risks for the individual patient should be considered to determine whether to continue or discontinue treatment with Tezspire®.
- Acute Asthma Symptoms or Deteriorating Disease: Tezspire® should not be used to treat acute asthma symptoms or acute exacerbations. Tezspire® should not be initiated to treat acute bronchospasm or status asthmaticus. Patients should seek medical advice if their asthma

remains uncontrolled or worsens after initiation of treatment with Tezspire®.

- Risk Associated with Abrupt Reduction in Corticosteroid Dosage: Systemic or inhaled corticosteroids should not be discontinued abruptly upon initiation of therapy with Tezspire®. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.
- Parasitic (Helminth) Infection: TSLP may be involved in the immunological response to some helminth infections. Patients with known helminth infections were excluded from participation in clinical trials. It is unknown if Tezspire® will influence a patient's response against helminth infections. Patients with pre-existing helminth infections should be treated before initiating therapy with Tezspire®. If patients become infected while receiving treatment with Tezspire® and do not respond to anti-helminth treatment, treatment with Tezspire® should be discontinued until the infection resolves.
- Vaccination: The concomitant use of Tezspire® and live attenuated vaccines has not been evaluated. The use of live attenuated vaccines should be avoided in patients receiving Tezspire®.

Adverse Reactions: The most common adverse reactions (incidence ≥3% and more frequently than in placebo) in clinical studies were pharyngitis, arthralgia, and back pain.

Efficacy: Tezspire® was evaluated in 2 randomized, double-blind placebo-controlled clinical trials, PATHWAY and NAVIGATOR. The 2 trials enrolled 1,609 patients 12 years of age and older with severe asthma. PATHWAY was a 52-week dose-ranging exacerbation trial that enrolled 550 adult patients with severe asthma who received treatment with Tezspire® 70mg sub-Q every 4 weeks, Tezspire® 210mg sub-Q every 4 weeks, Tezspire® 280mg sub-Q every 2 weeks, or placebo sub-Q. Patients were required to have a history of 2 or more asthma exacerbations requiring oral or injectable corticosteroid treatment or 1 asthma exacerbation resulting in hospitalization in the past 12 months. NAVIGATOR was a 52-week exacerbation trial that enrolled 1,061 adult and pediatric patients 12 years of age and older with severe asthma who received treatment with Tezspire® 210mg sub-Q every 4 weeks or placebo sub-Q every 4 weeks. Patients were required to have a history of 2 or more asthma exacerbations requiring oral or injectable corticosteroid treatment or resulting in hospitalization in the past 12 months. In both trials, patients were required to have an Asthma Control Questionnaire 6 (ACQ-6) score of 1.5 or more at screening and reduced lung function at baseline. Patients were

required to have been on regular treatment with medium- or high-dose inhaled corticosteroids (ICS) and at least 1 additional asthma controller, with or without oral corticosteroids (OCS) for ≥6 months in PATHWAY and ≥3 months in NAVIGATOR. Patients continued background asthma therapy throughout the duration of the trials. In both trials, patients were enrolled without requiring a minimum baseline level of blood eosinophils or FeNO.

- Primary Endpoint: The primary endpoint for PATHWAY and NAVIGATOR was the rate of clinically significant asthma exacerbations measured over 52 weeks. Clinically significant asthma exacerbations were defined as worsening of asthma requiring the use of or increase in oral or injectable corticosteroids for at least 3 days or a single depo-injection of corticosteroids and/or emergency department visits requiring use of oral or injectable corticosteroids and/or hospitalization.
- Results: In both PATHWAY and NAVIGATOR, patients receiving Tezspire® had significant reductions in the annualized rate of asthma exacerbations compared to placebo, 71% and 56%, respectively [(rate ratio: 0.29; 95% CI: 0.16, 0.51) and (rate ratio: 0.44; 95% CI: 0.37, 0.53)]. There were also fewer exacerbations requiring emergency room visits and/or hospitalization in patients treated with Tezspire® compared with placebo.

Cost: The Wholesale Acquisition Cost (WAC) of Tezspire® is $1,902.09 per mL or $3,633 per 210mg/1.91mL vial or syringe. This results in an estimated annual cost of $47,229 at the recommended dose of 210mg every 4 weeks.

Recommendations

The College of Pharmacy recommends the prior authorization of Tezspire® (tezepelumab-ekko) with the following criteria:

Tezspire® (Tezepelumab-ekko) Approval Criteria:

1. An FDA approved diagnosis of add-on maintenance treatment for severe asthma; and
2. Member must be 12 years of age or older; and
3. Member must have experienced ≥2 asthma exacerbations requiring oral or injectable corticosteroids or that resulted in hospitalization in the last 12 months; and
4. Member must have failed a medium-to-high dose inhaled corticosteroid (ICS) used compliantly for at least the past 12 months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
5. Member must have failed at least 1 other asthma controller medication used in addition to the medium to high dose ICS compliantly for at least the past 3 months; and

6. Tezspire® must be administered by a health care provider prepared to manage anaphylaxis; and
7. Tezspire® must be prescribed by an allergist, pulmonologist, or pulmonary specialist, or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
8. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
9. A quantity limit of 1.91mL (1 single-dose glass vial or single-dose pre-filled syringe) per 28 days will apply.

Next, the College of Pharmacy recommends the addition of prior authorization criteria for Dupixent® (dupilumab) for a diagnosis of EoE or PN based on the new FDA approved indications:

Dupixent® (Dupilumab) Approval Criteria [Eosinophilic Esophagitis (EoE) Diagnosis]:

1. An FDA approved diagnosis of EoE; and
2. Member must be 12 years of age or older and weigh ≥40kg; and
3. Dupixent® must be prescribed by a gastroenterologist, allergist, or immunologist, or the member must have been evaluated by a gastroenterologist, allergist, or immunologist within the last 12 months (or be an advanced care practitioner with a supervising physician who is a gastroenterologist, allergist, or immunologist); and
4. Member must have 2 or more episodes of dysphagia per week; and
5. Member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf); and
6. Member must have documented trials for a minimum of 8 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
    a. 1 high-dose proton pump inhibitor; and
    b. 1 swallowed inhaled respiratory corticosteroid (e.g., budesonide); and
7. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
9. A quantity limit of 8mL (4 syringes) every 28 days will apply.

Dupixent® (Dupilumab) Approval Criteria [Prurigo Nodularis (PN) Diagnosis]:

1. An FDA approved diagnosis of PN for at least 3 months; and
2. Member must have a Worst-Itch Numeric Rating Scale (WI-NRS) score of ≥7; and
3. Member must have ≥20 PN lesions; and
4. Member must be 18 years of age or older; and
5. Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Prescriber must verify that all other causes of pruritis have been ruled out; and
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
    b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
8. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Additionally, the College of Pharmacy recommends updating the Xolair® (omalizumab) prior authorization criteria with the following changes to be consistent with the criteria for the other asthma-indicated monoclonal antibodies (changes shown in red):

Xolair® (Omalizumab) Approval Criteria [Asthma Diagnosis]:

1. Member must have a diagnosis of severe persistent asthma [as per National Asthma Education and Prevention Program (NAEPP) guidelines]; and
2. Member must be between 6 and 75 years of age; and
3. Member must have a positive skin test to at least one perennial aeroallergen. Positive perennial aeroallergens must be listed on the prior authorization request; and
4. Member must have a pretreatment serum IgE level between 30 and 1,300 IU/mL (depending on member age); and

5. Member's weight must be between 20kg and 150kg; and
6. Member must have been on high-dose inhaled corticosteroids (ICS) for at minimum the past 12 ~~3~~ months; and
7. Prescribed Xolair® dose must be an FDA approved regimen per Xolair® prescribing information; and
8. Xolair® must be administered in a healthcare setting by a healthcare professional prepared to manage anaphylaxis; and
9. Xolair® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last twelve months (or be an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
10. Member must have been in the emergency room (ER) or hospitalized, due to an asthma exacerbation, twice in the past twelve months (date of visits must be listed on the prior authorization request), or member must have been determined to be dependent on systemic corticosteroids to prevent serious exacerbations; and
11. Initial approvals will be for the duration of 6 ~~12~~ months after which time compliance will be evaluated for continued approval.

Finally, the College of Pharmacy recommends the following changes to the Asthma and COPD Maintenance Medications Product Based Prior Authorization (PBPA) category based on product discontinuations (changes noted in red in the following Tier chart and approval criteria; only criteria with changes are listed):

1. Removal of Aerospan® (flunisolide)
2. Removal of ArmonAir® RespiClick® (fluticasone propionate)
3. Removal of Utibron® Neohaler® (indacaterol/glycopyrrolate)
4. Removal of Arcapta® Neohaler® (indacaterol inhalation powder)
5. Removal of Seebri® Neohaler® (glycopyrrolate inhalation powder)

Inhaled Corticosteroids (ICS) and Combination Products	
Tier-1	**Tier-2***
budesonide (Pulmicort Flexhaler®)	beclomethasone dipropionate (QVAR® RediHaler®)
budesonide/formoterol (Symbicort®) – **Brand Preferred**	fluticasone furoate (Arnuity® Ellipta®)
ciclesonide (Alvesco®)	fluticasone furoate/vilanterol (Breo® Ellipta®)
~~**flunisolide (Aerospan®)**~~	fluticasone propionate (ArmonAir® Digihaler®)
fluticasone propionate (Flovent®)	~~**fluticasone propionate (ArmonAir® RespiClick®)**~~
fluticasone propionate/salmeterol (Advair®)α	fluticasone propionate/salmeterol (AirDuo® Digihaler®)

mometasone furoate (Asmanex®)¥	fluticasone propionate/salmeterol (AirDuo RespiClick®)
mometasone furoate/formoterol (Dulera®)◊	mometasone furoate 50mcg (Asmanex® HFA)
	mometasone furoate/formoterol 50mcg/5mcg (Dulera®)

Tier-1 products indicated for the member's age are covered with no prior authorization required.
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria applies to each Tier-2 product.
αDoes not include Wixela Inhub®; authorization of Wixela Inhub® requires a reason why the member cannot use the brand formulation (Advair®) or other generic formulations of fluticasone propionate/ salmeterol.
¥Includes all strengths and formulations other than Asmanex® HFA 50mcg.
◊ Includes all strengths other than Dulera® 50mcg/5mcg.

Anoro® Ellipta® (Umeclidinium/Vilanterol), Bevespi Aerosphere® (Glycopyrrolate/Formoterol Fumarate), Duaklir® Pressair® (Aclidinium Bromide/Formoterol Fumarate), and Stiolto® Respimat® (Tiotropium/ Olodaterol)~~, and Utibron® Neohaler® (Indacaterol/Glycopyrrolate)~~ Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
3. A patient-specific, clinically significant reason why the member cannot use Tier-1 long-acting beta$_2$ agonist (LABA) and long-acting muscarinic antagonist (LAMA) individual components must be provided.

Arnuity® Ellipta® (Fluticasone Furoate) ~~and ArmonAir® RespiClick® (Fluticasone Propionate)~~ Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be at or above the minimum age indicated, and
3. A patient-specific, clinically significant reason why Flovent® (fluticasone propionate) is not appropriate for the member must be provided.

Long-Acting Beta$_2$ Agonists (LABA) and Long-Acting Muscarinic Antagonists (LAMA)	
Tier-1	**Tier-2**
Long-Acting Beta$_2$ Agonists* (LABA)	
salmeterol inhalation powder (Serevent®)	arformoterol nebulizer solution (Brovana®)
	formoterol nebulizer solution (Perforomist®)
	~~indacaterol inhalation powder (Arcapta® Neohaler®)~~
	olodaterol inhalation spray (Striverdi® Respimat®)

Long-Acting Muscarinic Antagonists (LAMA)	
tiotropium inhalation powder (Spiriva® HandiHaler®)	aclidinium inhalation powder (Tudorza® PressAir®)
tiotropium soft mist inhaler (Spiriva® Respimat®)	~~**glycopyrrolate inhalation powder (Seebri® Neohaler)**~~
	glycopyrrolate inhalation solution (Lonhala® Magnair®)
	revefenacin inhalation solution (Yupelri®)
	umeclidinium inhalation powder (Incruse® Ellipta®)

*Tier-1 combination products that contain a long-acting beta$_2$ agonist (LABA) qualify for the LABA trial requirement.
Tier-1 medications do not require prior authorization.
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

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Appendix F

Vote to Prior Authorize Adbry™ (Tralokinumab-ldrm) and Cibinqo™ (Abrocitinib) and Update the Approval Criteria for the Atopic Dermatitis (AD) Medications

Oklahoma Health Care Authority
December 2022

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

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

- **December 2021:** The FDA approved Adbry™ (tralokinumab-ldrm) for the treatment of moderate-to-severe AD in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry™ can be used with or without topical corticosteroids (TCS). Tralokinumab is the first medication for AD that specifically targets interleukin (IL)-13 and is given by subcutaneous (sub-Q) administration.
- **January 2022:** The FDA approved Cibinqo™ (abrocitinib), an oral Janus kinase (JAK) inhibitor, for the treatment of adults with refractory, moderate-to-severe AD whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.
- **January 2022:** The FDA approved Rinvoq® (upadacitinib) for a new indication for the treatment of adult and pediatric patients 12 years of age and older with refractory, moderate-to-severe AD whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable. Additionally, the FDA approved a new 30mg strength tablet for use in patients with AD.
- **June 2022:** The FDA approved Dupixent® (dupilumab) for an age expansion down to 6 months of age for patients with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent® can be used with or without TCS. Previously, Dupixent® was approved for this same indication in patients 6 years of age and older. The new approval is based on data from a Phase 3 randomized, double-blind, placebo-controlled study in 162 children from 6 months to 5 years of age with uncontrolled moderate-to-severe AD. All patients also received concurrent treatment with low-potency TCS. The study met all primary and secondary endpoints, showing Dupixent® use in this age range was effective, with a similar safety profile as seen in older patients.

- **July 2022:** The FDA approved Opzelura™ (ruxolitinib 1.5% cream) for a new indication for the treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older. Ruxolitinib is a topical JAK inhibitor and is the first medication to be FDA approved for the treatment of vitiligo. The approval was based on data from the Phase 3 TRuE-V1 and TRuE-V2 studies which enrolled more than 600 patients 12 years of age and older with nonsegmental vitiligo. Patients received treatment for up to 52 weeks, and the results of the study showed treatment with Opzelura™ resulted in significant improvements in facial and total body repigmentation at week 24 compared to vehicle cream, with additional benefits in repigmentation seen at week 52.

Adbry™ (Tralokinumab-ldrm) Product Summary[6]

Indication(s): Adbry™ (tralokinumab-ldrm) is an IL-13 antagonist indicated for the treatment of moderate-to-severe AD in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry™ can be used with or without TCS.

How Supplied: 150mg/mL solution in a single-dose prefilled syringe

Dosing and Administration:
- Recommended initial dose is 600mg [(4) 150mg injections] followed by 300mg [(2) 150mg injections] every other week
- After 16 weeks of treatment, for patients weighing <100kg who achieve clear or almost clear skin, a dosage of 300mg every 4 weeks may be considered
- Adbry™ is to be administered by sub-Q injection into the thigh or abdomen or into the upper arm if administered by a caregiver
- Each 150mg injection should be administered at a different injection site within the same body area, and body areas should be rotated for subsequent injections

Mechanism of Action: Tralokinumab is a human monoclonal antibody that binds specifically to IL-13 and prevents its interaction with the IL-13 receptor. IL-13 is a naturally occurring cytokine involved in the Type 2 immune response. Tralokinumab therefore inhibits IL-13 induced release of proinflammatory cytokines, chemokines, and immunoglobulin E (IgE).

Contraindication(s): Known hypersensitivity to tralokinumab or any excipients in Adbry™

Adverse Reactions: The most common adverse reactions in Phase 3 studies (occurring in ≥1% of patients treated with tralokinumab or tralokinumab + TCS and at a greater incidence than placebo) were upper respiratory tract infections, conjunctivitis, injection site reactions, and eosinophilia.

Cibinqo™ (Abrocitinib) Product Summary[7]

Indication(s): Cibinqo™ (abrocitinib) is a JAK inhibitor indicated for the treatment of adults with refractory, moderate-to-severe AD whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

Limitations of Use:

- Cibinqo™ is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

How Supplied: 50mg, 150mg, and 200mg oral tablets

Dosing and Administration:

- Recommended dosage is 100mg once daily
- After 12 weeks of treatment, a dosage of 200mg once daily may be considered for patients with inadequate response
- Should be discontinued if inadequate response is seen with the 200mg dose
- Lower doses recommended in patients with moderate renal impairment [estimated glomerular filtration rate (eGFR) 30-59mL/min], in patients who are CYP2C19 poor metabolizers, and with concurrent use of strong CYP2C19 inhibitors (e.g., fluconazole, fluvoxamine)

Mechanism of Action: Abrocitinib is a JAK inhibitor that reversibly inhibits JAK1 to a much greater extent than JAK2, JAK3, or tyrosine kinase 2 (TYK2). The relevance of specific JAK enzyme inhibition to therapeutic effectiveness is not currently known.

Contraindication(s):

- Patients taking antiplatelet therapies, except for low-dose aspirin (≤81mg daily), during the first 3 months of treatment

Adverse Reactions: The most common adverse reactions in clinical studies (occurring in ≥1% of patients treated with abrocitinib and at a greater incidence than with placebo) were nasopharyngitis, nausea, headache, herpes simplex, increased blood creatinine phosphokinase, dizziness, urinary tract infection, fatigue, acne, vomiting, impetigo, oropharyngeal pain, hypertension, influenza, gastroenteritis, contact dermatitis, upper abdominal pain, abdominal discomfort, herpes zoster, and thrombocytopenia.

Cost Comparison

Product	Cost Per Unit*	Cost Per Month⁺	Cost Per Year†
Adbry™ (tralokinumab-ldrm) 150mg/1mL syringe	**$837.20**	**$3,348.80**	**$45,208.80**
Cibinqo™ (abrocitinib) 200mg tablet	**$163.80**	**$4,914.00**	**$58,968.00**
Dupixent® (dupilumab) 300mg/2mL pen	$818.62	$3,274.48	$44,205.48
Rinvoq® (upadacitinib) 30mg tablet	$189.04	$5,671.20	$68,054.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC)
*Unit = tablet or mL
⁺Cost per month based on the maximum FDA approved maintenance dosing for each product
†Cost per year based on the maximum FDA approved dosing for each product, including recommended loading doses if applicable

Recommendations

The College of Pharmacy recommends the following changes and additions to the AD medications approval criteria (changes and additions shown in red):

1. The prior authorization of Adbry™ (tralokinumab-ldrm); and
2. The prior authorization of Cibinqo™ (abrocitinib) with criteria similar to Rinvoq® (upadacitinib) for AD; and
3. Updating the prior authorization criteria for Dupixent® (dupilumab) for AD based on the recent FDA approved age expansion; and
4. The addition of prior authorization criteria for Opzelura™ (ruxolitinib 1.5% cream) for a diagnosis of vitiligo based on the new FDA approved indication.

Adbry™ (Tralokinumab-ldrm Injection) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are not advisable; and
2. Member must be 18 years of age or older; and
3. Member must have a documented trial within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
4. Adbry™ must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and

5. Requests for concurrent use of Adbry™ with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Adbry™ has not been studied in combination with other biologic therapies); and
6. Initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Cibinqo™ (Abrocitinib) and Rinvoq® (Upadacitinib) Approval Criteria [Atopic Dermatitis (AD) Diagnosis]:

1. An FDA approved diagnosis of moderate-to-severe AD not adequately controlled with other systemic drug products, including biologics, or when those therapies are not advisable; and
2. For Cibinqo™, member must be 18 years of age or older; and
3. For Rinvoq®, member must be 12 years of age or older; and
4. Member must have a documented trial within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
5. Member must have a documented 16-week trial with Adbry™ (tralokinumab-ldrm) or Dupixent® (dupilumab) that resulted in inadequate response (or have a contraindication or documented intolerance); and
6. Requested medication must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
7. For Cibinqo™, prescriber must verify the member will not use antiplatelet therapies (e.g., clopidogrel, prasugrel, ticagrelor) concurrently with Cibinqo™, except for low-dose aspirin, during the first 3 months of treatment; and
8. Cibinqo™ and Rinvoq® will not be approved for use in combination with other Janus kinas (JAK) inhibitors, biologic immunomodulators, or with other immunosuppressant medications; and
9. Initial approvals will be for the duration of 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and

10. For Rinvoq®, the maximum approvable dose for AD is 30mg once daily.

Dupixent® (Dupilumab Injection) Approval Criteria [Atopic Dermatitis Diagnosis]:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies; and
2. Member must be 6 ~~years~~ months of age or older; and
3. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
4. Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
5. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
6. Initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Opzelura™ (Ruxolitinib 1.5% Cream) Approval Criteria [Nonsegmental Vitiligo Diagnosis]:

1. An FDA approved indication of nonsegmental vitiligo; and
2. The member's body surface area (BSA) involvement must be provided and must be ≤10%; and
3. Member must be 12 to 20 years of age; and
4. Member must have documented trials within the last 6 months for a minimum of 12 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (used continuously or intermittently); and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
5. Concurrent use with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants (e.g., azathioprine, cyclosporine) will not generally be approved; and

6. Prescriber must verify female members are not breastfeeding; and
7. If the member is pregnant or becomes pregnant, prescriber must verify member has been counseled on potential risks of this medication and will report the exposure to the Opzelura™ pregnancy registry; and
8. Initial approvals will be for a duration of 24 weeks of treatment; and
9. Reauthorization for an additional 28 weeks of treatment (to complete 1 year of treatment) may be considered if the prescriber documents both of the following:
    a. The member had a positive response to and tolerated previous treatment with Opzelura™; and
    b. The member has been evaluated by the prescriber and continues to require treatment with Opzelura™; and
10. Further approval beyond 1 year of treatment will require patient-specific, clinically significant information to support the member's need for additional treatment.

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Appendix G

Vote to Prior Authorize Carvykti™ (Ciltacabtagene Autoleucel) and Tecvayli™ (Teclistamab-cqyv) and Update the Approval Criteria for the Multiple Myeloma Medications

Oklahoma Health Care Authority
December 2022

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

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

- **February 2022:** The FDA approved Carvykti™ (ciltacabtagene autoleucel) for the treatment of adult patients with relapsed or refractory multiple myeloma after 4 or more prior lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
- **October 2022:** The FDA approved Tecvayli™ (teclistamab-cqyv) for the treatment of adult patients with relapsed or refractory multiple myeloma, who previously received 4 or more prior lines of therapy, including a PI, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. Tecvayli™ is a first-in-class, bispecific T-cell engager antibody that is administered as a subcutaneous (sub-Q) treatment. This indication was approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

News:

- **November 2021:** Based on discussions with the FDA, Secura Bio requested the withdrawal of the New Drug Application (NDA) approval for Farydak® (1panobinostat) oral capsules. Farydak® received accelerated approval in February 2015 for use in combination with bortezomib and dexamethasone to treat patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent. The accelerated approval was based on progression-free survival and, consistent with FDA regulations, required further adequate and well-controlled clinical studies to verify and describe the product's clinical benefit. In its withdrawal submission, Secura Bio noted that it was not feasible for the company to complete the required post-approval clinical studies. As of March 24, 2022, the FDA withdrew the NDA approval for Farydak® 10mg, 15mg, and 20mg oral capsules.

Carvykti™ (Ciltacabtagene Autoleucel) Product Summary[5]

Therapeutic Class: B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy

Indication(s): Treatment of adult patients with relapsed or refractory multiple myeloma after 4 or more prior lines of therapy, including a PI, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

How Supplied: Cell suspension of 0.5-1.0 x 10^6 chimeric antigen receptor (CAR)-positive viable T-cells per kg body weight in 1 infusion bag for intravenous (IV) infusion

Dosing and Administration:

- Dosing is based on the number of CAR-positive viable T-cells
- Recommended dose range is 0.5-1.0 x 10^6 CAR-positive viable T-cells per kg of body weight, with a maximum dose of 1 x 10^8 CAR-positive viable T-cells per single-dose infusion

Cost: The wholesale acquisition cost (WAC) for Carvykti™ is $465,000 per one-time treatment.

Tecvayli™ (Teclistamab-cqyv) Product Summary[6]

Therapeutic Class: Bispecific BCMA-directed CD3 T-cell engager

Indication(s): Treatment of adult patients with relapsed or refractory multiple myeloma after at least 4 prior lines of therapy, including a PI, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

How Supplied:

- 30mg/3mL (10mg/mL) preservative-free solution in a single-dose vial (SDV)
- 153mg/1.7mL (90mg/mL) preservative-free solution in an SDV

Dosing and Administration:

- Tecvayli™ is for sub-Q injection only
- The recommended dosage of Tecvayli™ is step-up doses of 0.06mg/kg and 0.3mg/kg followed by 1.5mg/kg once weekly; refer to the Tecvayli™ *Prescribing Information* for the complete dosing schedule

Cost: The WAC for the 30mg/3mL SDV is $1,770 and $9,027 for the 153mg/1.7mL SDV. For an 80kg adult, the annual cost including step-up dosing is $364,620.

Recommendations

The College of Pharmacy recommends the prior authorization of Carvykti™ (ciltacabtagene autoleucel) and Tecvayli™ (teclistamab-cqyv) with the following criteria:

Carvykti™ (Ciltacabtagene Autoleucel) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM):
    a. Member has received ≥4 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody; and
        i. Induction with or without autologous hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen; and
        ii. Member must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and
    b. Member must have measurable disease, including at least 1 of the following:
        i. Serum M-protein ≥0.5g/dL; or
        ii. Urine M-protein ≥200mg/24hr; or
        iii. Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or
        iv. Bone marrow plasma cells >30% of total bone marrow cells; and
    c. Member must not have any central nervous system involvement with multiple myeloma; and
2. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements; and
3. Approvals will be for 1 dose per member per lifetime.

Tecvayli™ (Teclistamab-cqyv) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Member has received ≥4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody; and
3. Health care facilities must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements.

The College of Pharmacy also recommends the removal of the Farydak® (panobinostat) approval criteria based on the withdrawal of the NDA approval by the FDA:

~~**Farydak® (Panobinostat) Approval Criteria [Multiple Myeloma Diagnosis]:**~~

~~1. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and~~
~~2. Used in combination with bortezomib and dexamethasone after 1 or more lines of therapy; or~~
~~3. Used in combination with carfilzomib or dexamethasone and lenalidomide after 2 or more lines of therapy (including bortezomib and an immunomodulatory agent).~~

Finally, the College of Pharmacy recommends updating the Abecma® (idecabtagene vicleucel) criteria to be consistent with the other CAR T-cell therapies (changes shown in red):

Abecma® (Idecabtagene Vicleucel) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM):
    a. Member has received ≥4 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor (PI), and an anti-CD38 monoclonal antibody; and
        i. Induction with or without autologous hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen; and
        ii. Must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and
    b. Member must have measurable disease, including at least 1 of the following:
        i. Serum M-protein ≥0.5g/dL; or
        ii. Urine M-protein ≥200mg/24hr; or
        iii. Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or
        iv. Bone marrow plasma cells >30% of total bone marrow cells; and
    c. Member must not have any central nervous system involvement with multiple myeloma; and
2. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements; and
3. Approvals will be for 1 dose per member per lifetime.

[1] U.S. Food and Drug Administration (FDA). Hematology/Oncology (Cancer) Approvals & Safety Notifications. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/oncology-cancer-hematologic-malignancies-approval-notifications. Last revised 11/08/2022. Last accessed 11/10/2022.

[2] Janssen Pharmaceutical. U.S. FDA Approves Tecvayli™ (Teclistamab-cqyv), the First Bispecific T-cell Engager Antibody for the Treatment of Patients with Relapsed or Refractory Multiple Myeloma. *Johnson & Johnson Innovation*. Available online at: https://www.jnj.com/u-s-fda-approves-tecvayli-teclistamab-cqyv-the-first-bispecific-t-cell-engager-antibody-for-the-treatment-of-patients-with-relapsed-or-refractory-multiple-myeloma. Issued 10/25/2022. Last accessed 11/10/2022.

[3] Secura Bio, Inc. Secura Bio Announces U.S. Withdrawal of Farydak® (Panobinostat) NDA. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/secura-bio-announces-us-withdrawal-of-farydak--panobinostat-nda-301434428.html. Issued 11/30/2021. Last accessed 11/10/2022.

[4] Secura Bio, Inc. Withdrawal of Approval of New Drug Application for Farydak® (Panobinostat) Capsules, 10 Milligrams, 15 Milligrams, and 20 Milligrams. *Federal Register*. Available online at: https://www.federalregister.gov/documents/2022/03/24/2022-06182/secura-bio-inc-withdrawal-of-approval-of-new-drug-application-for-farydak-panobinostat-capsules-10#:~:text=SUMMARY%3A,%2C%20Las%20Vegas%2C%20NV%2089134. Issued 03/18/2022. Last accessed 11/10/2022.

[5] Carvykti™ (Ciltacabtagene Autoleucel) Prescribing Information. Janssen Biotech. Available online at: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/CARVYKTI-pi.pdf. Last revised 03/2022. Last accessed 11/10/2022.

[6] Tecvayli™ (Teclistamab-cqyv) Prescribing Information. Janssen Biotech. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761291s000lbl.pdf. Last revised 10/2022. Last accessed 11/10/2022.

Appendix H

Fiscal Year 2022 Annual Review of Anticoagulants and Platelet Aggregation Inhibitors

Oklahoma Health Care Authority
December 2022

Current Prior Authorization Criteria

Aggrenox® (Aspirin/Dipyridamole Extended-Release) Approval Criteria:

1. An FDA approved indication for the prophylaxis of recurrent thromboembolic stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use immediate-release dipyridamole and over-the-counter (OTC) aspirin in place of Aggrenox® must be provided; and
4. A quantity limit of 60 capsules for a 30-day supply will apply.

Brilinta® (Ticagrelor) Approval Criteria:

1. The first 365 days of therapy with Brilinta 90mg twice daily does not require prior authorization.
2. After the first 365 days, a patient-specific, clinically significant reason for continuing the 90mg twice daily dosage will need to be provided or the member should be switched to the 60mg twice daily dosage.
3. Approvals will be for the duration of one year.

Eliquis® (Apixaban) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Non-valvular atrial fibrillation; or
    b. Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) and for the reduction in the risk of recurrent DVT and PE following initial therapy; or
    c. PE or DVT prophylaxis in members who have had hip or knee replacement surgery.

Pradaxa® (Dabigatran) Approval Criteria:

1. Pradaxa® (dabigatran) capsules require the following:
    a. An FDA approved indication of 1 of the following:
        i. Non-valvular atrial fibrillation; or
        ii. Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) after treatment with a parenteral anticoagulant for 5 to 10 days; or
        iii. To reduce the risk of recurrent DVT or PE in members who have been previously treated; or

iv. For the prophylaxis of DVT and PE in members who have undergone hip replacement surgery; or
v. For the treatment of venous thromboembolic events (VTE) in pediatric members 8 to 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days; or
vi. To reduce the risk of recurrent VTE in pediatric members 8 to 18 years of age who have been previously treated.

2. Pradaxa® (dabigatran) oral pellets require the following:
   a. An FDA approved indication of 1 of the following:
      i. Treatment of VTE in members who have been treated with a parenteral anticoagulant for at least 5 days; or
      ii. To reduce the risk of recurrent VTE in members who have been previously treated; and
   b. Member must be 3 months of age or older; and
   c. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used.

Savaysa® (Edoxaban) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. To reduce the risk of stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation (NVAF); or
   b. For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) following 5 to 10 days of initial therapy with a parenteral anticoagulant; and
2. Requests for therapy for the treatment of DVT and PE must verify that the member has undergone 5 to 10 days of initial therapy with a parenteral anticoagulant; and
3. Members with NVAF must not have a creatinine clearance (CrCl) >95mL/min due to increased risk of ischemic stroke compared to warfarin at the highest dose studied (60mg); and
4. A quantity limit of 30 tablets per 30 days will apply.

Xarelto® (Rivaroxaban) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Non-valvular atrial fibrillation (NVAF); or
   b. Treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), or to reduce the risk of recurrent DVT and PE; or
   c. Prophylaxis of DVT, which may lead to PE in members undergoing knee or hip replacement surgery; or
   d. In combination with aspirin, to reduce the risk of major cardiovascular (CV) events [CV death, myocardial infarction (MI), and stroke] in members with chronic coronary artery disease (CAD) or peripheral artery disease (PAD); or

e. Prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding; and

2. For Xarelto® (rivaroxaban) 15mg and 20mg:
   a. Treatment of NVAF, DVT, or PE; or
   b. Prophylaxis of recurrent DVT or PE; or
3. For Xarelto® (rivaroxaban) 10mg:
   a. One prescription for up to 39 days of therapy is allowed without prior authorization every 6 months to allow for DVT prophylaxis in members following hip or knee replacement surgery or for prophylaxis of VTE in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding; or
   b. Secondary prophylaxis of recurrent DVT or PE; or
4. For Xarelto® (rivaroxaban) 2.5mg:
   a. Must be used in combination with aspirin 75 to 100mg to reduce the risk of major CV events in members with chronic CAD or PAD.

Zontivity® (Vorapaxar) Approval Criteria:

1. An FDA approved indication for the reduction of thrombotic cardiovascular events in members with 1 of the following:
   a. History of myocardial infarction (MI); or
   b. Peripheral arterial disease (PAD); and
2. Zontivity® must be used in combination with aspirin and/or clopidogrel (not monotherapy); and
3. Zontivity® will not be approved for members with history of transient ischemic attack (TIA), stroke, or intracranial hemorrhage (ICH) or with active pathological bleeding; and
4. A quantity limit of 30 tablets per 30 days will apply

Utilization of Anticoagulants and Platelet Aggregation Inhibitors: Fiscal Year 2022

Comparison of Fiscal Years: Anticoagulants

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	2,851	14,484	$5,839,338.77	$403.16	$10.56	845,167	553,156
2022	4,626	19,728	$9,499,901.59	$481.54	$11.81	1,262,208	804,499
% Change	**62.3%**	**36.2%**	**62.7%**	**19.4%**	**11.8%**	**49.3%**	**45.4%**
Change	**1,775**	**5,244**	**$3,660,562.82**	**$78.38**	**$1.25**	**417,041**	**251,343**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

- The anticoagulants are influenced by federal and supplemental rebates. These rebates are collected after reimbursement for the

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

- Aggregate drug rebates collected during fiscal year 2022 for the anticoagulants: $9,168,196.07[Δ]

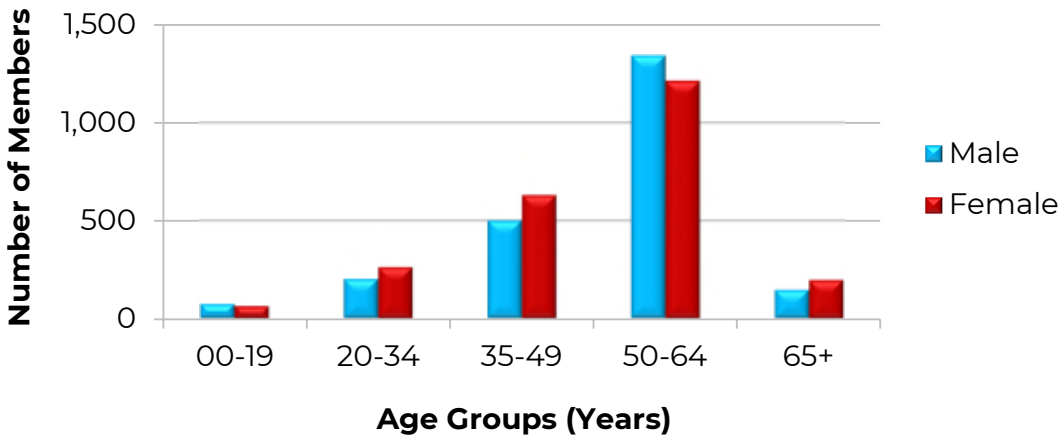
Comparison of Fiscal Years: Platelet Aggregation Inhibitors

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	2,939	11,669	$791,141.62	$67.80	$1.33	644,070	594,848
2022	5,158	18,032	$1,305,108.41	$72.38	$1.40	1,013,809	934,703
% Change	**75.5%**	**54.5%**	**65.0%**	**6.8%**	**5.3%**	**57.4%**	**57.1%**
Change	**2,219**	**6,363**	**$513,966.79**	**$4.58**	**$0.07**	**369,739**	**339,855**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

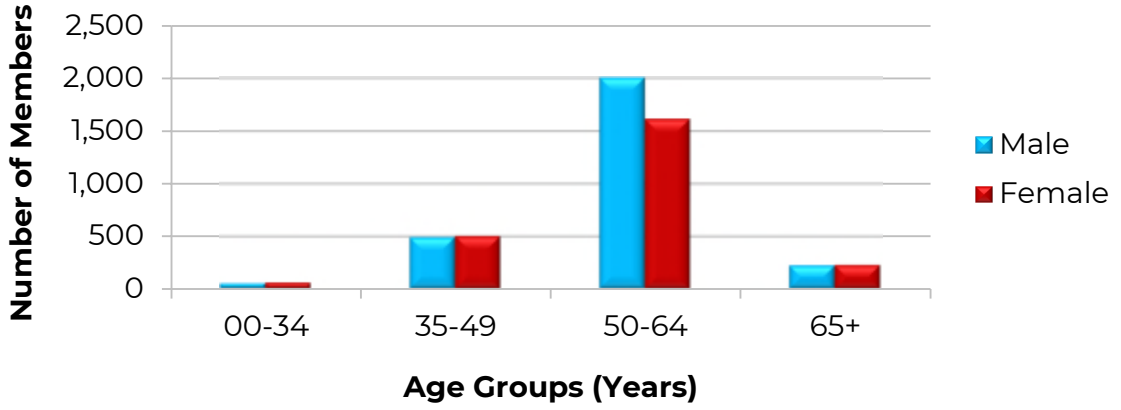
- The platelet aggregation inhibitors are influenced by federal and supplemental rebates. These rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.
  - Aggregate drug rebates collected during fiscal year 2022 for the platelet aggregation inhibitors: $919,326.02[Δ]

Demographics of Members Utilizing Anticoagulants

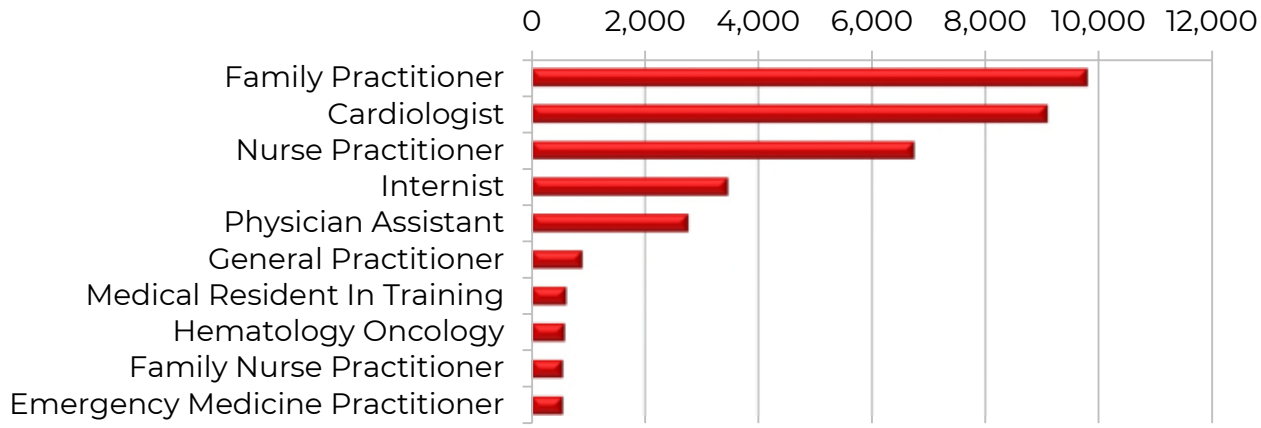


[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Demographics of Members Utilizing Platelet Aggregation Inhibitors



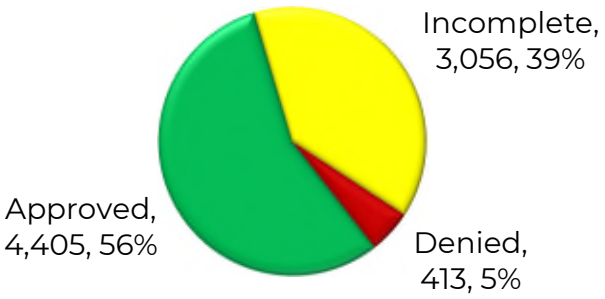
Top Prescriber Specialties of Anticoagulants and Platelet Aggregation Inhibitors by Number of Claims



Prior Authorization of Anticoagulants and Platelet Aggregation Inhibitors

There were 7,874 prior authorization requests submitted for anticoagulants and platelet aggregation inhibitors during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Xarelto® (rivaroxaban oral suspension): August 2024
- Pradaxa® (dabigatran pellets): March 2026
- Zontivity® (vorapaxar): December 2027
- Savaysa® (edoxaban): March 2028
- Eliquis® (apixaban): February 2031
- Pradaxa® (dabigatran capsules): July 2031
- Brilinta® (ticagrelor): January 2036
- Xarelto® (rivaroxaban tablets): January 2039

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

- **December 2021:** The FDA approved 2 pediatric indications for Xarelto® (rivaroxaban): (1) the treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in patients from birth to younger than 18 years of age after at least 5 days of initial parenteral anticoagulation and (2) thromboprophylaxis in children 2 years of age and older with congenital heart disease who have undergone the Fontan procedure. Along with these new indications, a new oral suspension formulation was also approved. Xarelto® is the only direct oral anticoagulant (DOAC) FDA approved for primary prevention of thrombus development in pediatric patients following the Fontan procedure and the only DOAC in the United States to offer an oral suspension formulation for flexible, body weight-adjusted dosing options for pediatric patients. The approval of Xarelto® for these new indications was based on 2 separate studies, EINSTEIN-Jr and UNIVERSE.
    - **EINSTEIN-Jr** was a randomized, multicenter, active-controlled, open-label Phase 3 study that evaluated the use of Xarelto® in 500 children, from birth to 17 years of age, who were previously diagnosed with acute VTE and had started parenteral anticoagulation therapy. Patients were randomized 2:1 to receive either an open-label, body weight-adjusted dose of Xarelto® to approximate a 20mg adult dose or standard anticoagulation therapy such as unfractionated heparin, low molecular weight heparin, fondaparinux, or a vitamin K antagonist for 3 months. The primary efficacy endpoint was symptomatic recurrence of VTE, and by the end of the study, 1.2% (4 of 335 children) of those on Xarelto® versus 3% (5 of 165 children) in the standard of care group had signs and symptoms of recurrent VTE [hazard ratio (HR): 0.40; 95% confidence interval (CI): 0.11, 1.41]. Complete resolution of thrombus on repeat imaging without recurrent VTE occurred in 128 of 335 children (38.2%; 95% CI: 33.0%, 43.5%) in the Xarelto® group and 43 of 165 children (26.1%; 95% CI: 19.8%, 33.0%) in the standard of care

group. The study could not be powered to independently show non-inferiority for efficacy of rivaroxaban in comparison to standard therapy in children; therefore, interpretation of the results relies in part on extrapolation of data obtained with rivaroxaban in adults.

- **UNIVERSE** was a prospective, open-label, active-controlled, multicenter, 2-part study, designed to evaluate the single- and multiple-dose pharmacokinetic properties of Xarelto® (part A) and to evaluate the safety and efficacy of Xarelto® when used for thromboprophylaxis for 12 months compared with aspirin (part B) in children 2 to 8 years of age with single ventricle physiology who had the Fontan procedure. Patients in part B were randomized 2:1 to receive either body weight-adjusted doses of Xarelto® (exposures to match a 10mg daily dose in adults) or aspirin (approximately 5mg/kg). The median time between the Fontan procedure and the first dose of Xarelto® was 4 days (range: 2-61) in part A and 34 days (range: 2-124) in part B. In comparison, the median time to initiating aspirin was 24 days (range: 2-117). The primary efficacy endpoint was occurrence of any thrombotic event. In part A, 1 of 12 patients (8.3%) had a thrombotic event, which was a VTE. In part B, 1 of 64 patients (1.6%) on Xarelto® versus 3 of 34 patients (8.8%) on aspirin had a thrombotic event (risk difference: -7.3%; 95% CI: -21.7%, 1.1%). The 1 patient in the Xarelto® group developed a pulmonary embolism, and in the aspirin group, 1 patient had an ischemic stroke and 2 had a VTE. Although the study was not powered for efficacy outcomes and did not reach statistical significance, the study showed a trend toward a favorable risk/benefit profile for rivaroxaban in this clinical scenario.

Pipeline:

- **Abelacimab:** Anthos Therapeutics' abelacimab is a novel, highly selective, fully human monoclonal antibody designed to induce effective hemostasis-sparing anticoagulation through Factor XI inhibition. Abelacimab targets the active domain of Factor XI, demonstrating dual inhibitory activity against both Factor XI and its activated form, Factor XIa. It can be given by intravenous (IV) infusion to achieve rapid inhibition and can then be used subcutaneously (sub-Q) to maintain nearly complete inhibition in a chronic setting. Abelacimab was granted Fast Track designation by the FDA for the treatment of thrombosis associated with cancer in July 2022 and for the prevention of stroke and systemic embolism in patients with atrial fibrillation in September 2022.

Recommendations

The College of Pharmacy recommends the following changes to the Xarelto® (rivaroxaban) approval criteria based on the new FDA approved indications and formulation (changes noted in red):

Xarelto® (Rivaroxaban) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Non-valvular atrial fibrillation (NVAF); or
    b. Treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), or to reduce the risk of recurrent DVT and PE; or
    c. Prophylaxis of DVT, which may lead to PE in members undergoing knee or hip replacement surgery; or
    d. In combination with aspirin, to reduce the risk of major cardiovascular (CV) events [CV death, myocardial infarction (MI), and stroke] in members with chronic coronary artery disease (CAD) or peripheral artery disease (PAD); or
    e. Prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding; or
    f. Treatment of VTE and the reduction in the risk of recurrent VTE in pediatric members from birth to younger than 18 years of age after at least 5 days of initial parenteral anticoagulant treatment; or
    g. Thromboprophylaxis in pediatric members 2 years of age and older with congenital heart disease who have undergone the Fontan procedure; and

~~2. For Xarelto® (rivaroxaban) 15mg and 20mg:~~
~~a. Treatment of NVAF, DVT, or PE; or~~
~~b. Prophylaxis of recurrent DVT or PE; or~~

~~3. For Xarelto® (rivaroxaban) 10mg:~~
~~a. One prescription for up to 39 days of therapy is allowed without prior authorization every 6 months to allow for DVT prophylaxis in members following hip or knee replacement surgery or for prophylaxis of VTE in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding; or~~
~~b. Secondary prophylaxis of recurrent DVT or PE; or~~

~~4. For Xarelto® (rivaroxaban) 2.5mg:~~
~~a. Must be used in combination with aspirin 75 to 100mg to reduce the risk of major CV events in members with chronic CAD or PAD.~~

5. Approvals will be based on the recommended dosing per package labeling based on the member's diagnosis, age, and recent weight, if applicable. The member's recent weight must be provided on the prior authorization request for all pediatric members; and
6. For Xarelto® (rivaroxaban) 1mg/mL oral suspension, a patient-specific, clinically significant reason why the member requires the oral

suspension and cannot use the oral tablet formulation, even when tablets are crushed, must be provided.

Additionally, the College of Pharmacy recommends the following changes to the Savaysa® (edoxaban) approval criteria based on net costs in comparison to other available DOACs (changes noted in red):

Savaysa® (Edoxaban) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. To reduce the risk of stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation (NVAF); or
   b. For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) following 5 to 10 days of initial therapy with a parenteral anticoagulant; and
2. Requests for therapy for the treatment of DVT and PE must verify that the member has undergone 5 to 10 days of initial therapy with a parenteral anticoagulant; and
3. Members with NVAF must not have a creatinine clearance (CrCl) >95mL/min due to increased risk of ischemic stroke compared to warfarin at the highest dose studied (60mg); and
4. A patient-specific, clinically significant reason why the member cannot use Eliquis® (apixaban), Pradaxa® (dabigatran), and Xarelto® (rivaroxaban) must be provided; and
5. A quantity limit of 30 tablets per 30 days will apply.

Utilization Details of Anticoagulants: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
APIXABAN PRODUCTS						
ELIQUIS TAB 5MG	8,970	2,363	$5,968,078.38	$665.34	3.8	62.82%
ELIQUIS TAB 2.5MG	947	256	$574,673.46	$606.84	3.7	6.05%
ELIQUIS ST P TAB 5MG	26	26	$16,214.61	$623.64	1	0.17%
SUBTOTAL	**9,943**	**2,645**	**$6,558,966.45**	**$659.66**	**3.76**	**69.04%**
RIVAROXABAN PRODUCTS						
XARELTO TAB 20MG	2,633	683	$1,935,210.05	$734.98	3.86	20.37%
XARELTO TAB 10MG	705	335	$401,313.23	$569.24	2.1	4.22%
XARELTO TAB 2.5MG	372	103	$252,396.83	$678.49	3.61	2.66%
XARELTO TAB 15MG	289	95	$171,881.40	$594.75	3.04	1.81%
XARELTO SUS 1MG/ML	25	9	$19,037.19	$761.49	2.78	0.20%
XARELTO STAR TAB	14	14	$11,825.86	$844.70	1	0.12%
SUBTOTAL	**4,038**	**1,239**	**$2,791,664.56**	**$691.35**	**3.26**	**29.38%**
WARFARIN PRODUCTS						
WARFARIN TAB 5MG	1,761	498	$20,855.46	$11.84	3.54	0.22%
WARFARIN TAB 1MG	718	205	$8,517.99	$11.86	3.5	0.09%
WARFARIN TAB 4MG	629	166	$7,089.71	$11.27	3.79	0.07%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
WARFARIN TAB 3MG	566	146	$6,918.87	$12.22	3.88	0.07%
WARFARIN TAB 6MG	449	117	$5,687.28	$12.67	3.84	0.06%
WARFARIN TAB 2MG	386	119	$4,768.41	$12.35	3.24	0.05%
WARFARIN TAB 7.5MG	367	119	$4,581.64	$12.48	3.08	0.05%
WARFARIN TAB 10MG	341	111	$4,008.04	$11.75	3.07	0.04%
WARFARIN TAB 2.5MG	307	107	$3,923.03	$12.78	2.87	0.04%
JANTOVEN TAB 5MG	34	13	$548.23	$16.12	2.62	0.01%
JANTOVEN TAB 1MG	21	4	$296.18	$14.10	5.25	0.00%
JANTOVEN TAB 6MG	17	5	$229.83	$13.52	3.4	0.00%
JANTOVEN TAB 2MG	6	3	$82.54	$13.76	2	0.00%
JANTOVEN TAB 3MG	3	3	$49.16	$16.39	1	0.00%
JANTOVEN TAB 2.5MG	3	2	$49.37	$16.46	1.5	0.00%
JANTOVEN TAB 7.5MG	2	2	$36.65	$18.33	1	0.00%
JANTOVEN TAB 4MG	1	1	$14.57	$14.57	1	0.00%
SUBTOTAL	**5,611**	**1,621**	**$67,656.96**	**$12.06**	**3.46**	**0.70%**
DABIGATRAN PRODUCTS						
PRADAXA CAP 150MG	104	20	$66,116.01	$635.73	5.2	0.70%
PRADAXA CAP 75MG	10	2	$4,776.75	$477.68	5	0.05%
SUBTOTAL	**114**	**22**	**$70,892.76**	**$621.87**	**5.18**	**0.75%**
EDOXABAN PRODUCTS						
SAVAYSA TAB 30MG	13	2	$6,542.07	$503.24	6.5	0.07%
SAVAYSA TAB 60MG	9	1	$4,178.79	$464.31	9	0.04%
SUBTOTAL	**22**	**3**	**$10,720.86**	**$487.31**	**7.33**	**0.11%**
TOTAL	**19,728**	**4,626***	**$9,499,901.59**	**$481.54**	**4.26**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; STAR = starter; ST P = starter pack; SUS = suspension; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Utilization Details of Platelet Aggregation Inhibitors: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	COST/ MEMBER	% COST
CLOPIDOGREL PRODUCTS						
CLOPIDOGREL TAB 75MG	14,013	4,476	$176,869.92	$12.62	3.13	13.55%
CLOPIDOGREL TAB 300MG	2	2	$41.38	$20.69	1	0.00%
SUBTOTAL	**14,015**	**4,478**	**$176,911.30**	**$12.62**	**3.13**	**13.55%**
TICAGRELOR PRODUCTS						
BRILINTA TAB 90MG	2,478	568	$996,053.52	$401.96	4.36	76.32%
BRILINTA TAB 60MG	257	50	$104,465.16	$406.48	5.14	8.00%
SUBTOTAL	**2,735**	**618**	**$1,100,518.68**	**$402.38**	**4.43**	**84.32%**
PRASUGREL PRODUCTS						
PRASUGREL TAB 10MG	1,215	223	$24,947.20	$20.53	5.45	1.91%
PRASUGREL TAB 5MG	47	10	$1,006.17	$21.41	4.7	0.08%
SUBTOTAL	**1,262**	**233**	**$25,953.37**	**$20.57**	**5.42**	**1.99%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	COST/ MEMBER	% COST
ASPIRIN/DIPYRIDAMOLE PRODUCTS						
ASA/DIPYRIDA CAP 25-200MG	18	2	$1,035.74	$57.54	9	0.08%
SUBTOTAL	**18**	**2**	**$1,035.74**	**$57.54**	**9**	**0.08%**
VORAPAXAR PRODUCTS						
ZONTIVITY TAB 2.08MG	2	1	$689.32	$344.66	2	0.05%
SUBTOTAL	**2**	**1**	**$689.32**	**$344.66**	**2**	**0.05%**
TOTAL	**18,302**	**5,158***	**$1,305,108.41**	**$72.38**	**3.5**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ASA = aspirin; CAP = capsule; DIPYRIDA = dipyridamole; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

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Appendix I

Fiscal Year 2022 Annual Review of Crohn's Disease (CD) and Ulcerative Colitis (UC) Medications

Oklahoma Health Care Authority
December 2022

Current Prior Authorization Criteria

Apriso® (Mesalamine Extended-Release Capsule) Quantity Limit Approval Criteria:

1. A quantity limit of 120 capsules per 30 days will apply.

Asacol® HD (Mesalamine Delayed-Release Tablet) Approval Criteria:

1. An FDA approved indication for the treatment of moderately active ulcerative colitis (UC); and
2. A patient-specific, clinically significant reason the member cannot use other available mesalamine products that do not require prior authorization must be provided; and
3. Approvals will be for the duration of 6 weeks in accordance with manufacturer recommended duration of therapy; and
4. A quantity limit of 180 tablets per 30 days will apply.

Canasa® (Mesalamine Suppository) Quantity Limit Approval Criteria:

1. A quantity limit of 30 suppositories per 30 days will apply.
2. The first 6 weeks of treatment do not require prior authorization.
3. After 6 weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason member needs a longer duration of treatment.

Colazal® (Balsalazide Capsule) Quantity Limit Approval Criteria:

1. A quantity limit of 270 capsules per 30 days will apply.
2. The first 12 weeks of treatment do not require prior authorization.
3. After 12 weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason member needs a longer duration of treatment.
4. An age restriction of 5 years and older will apply.

Delzicol® (Mesalamine Delayed-Release Capsule) Quantity Limit Approval Criteria:

1. A quantity limit of 180 capsules per 30 days will apply.

Dipentum® (Olsalazine Capsule) Quantity Limit Approval Criteria:

1. A quantity limit of 120 capsules per 30 days will apply.

Lialda® (Mesalamine Delayed-Release Capsule) Quantity Limit Approval Criteria:

1. A quantity limit of 60 capsules per 30 days will apply.
2. For quantity limit requests for >2 capsules per day:
    a. An FDA approved indication for the induction of remission in members with active, mild-to-moderate ulcerative colitis (UC); and
    b. A patient-specific, clinically significant reason the member cannot use other available mesalamine products that are indicated to induce remission that do not require prior authorization must be provided; and
    c. Approvals will be for the duration of 8 weeks in accordance with manufacturer recommended duration of therapy; and
    d. A maximum approval of 120 capsules per 30 days will apply.

Ortikos® (Budesonide Extended-Release Capsule) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. For the treatment of mild-to-moderate active Crohn's disease (CD) involving the ileum and/or the ascending colon, in members 8 years of age or older; or
    b. For the maintenance of clinical remission of mild-to-moderate CD involving the ileum and/or the ascending colon for up to 3 months duration in adult members; and
2. Member must have previous failure of Entocort® EC (budesonide controlled ileal-release enteric coated capsule) within the last 3 months at recommended dosing and a reason for trial failure with Entocort® EC must be provided; or
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use other oral corticosteroids, including Entocort® EC, that are available without prior authorization must be provided; and
4. Dosing regimen and duration of therapy must be in accordance with the Ortikos® *Prescribing Information*; and
5. Approval length will be based on the manufacturer maximum recommended duration of therapy; and
6. A quantity limit of 30 capsules per 30 days will apply.

Pentasa® (Mesalamine Extended-Release Capsule) Quantity Limit Approval Criteria:

1. A quantity limit of 480 capsules per 30 days will apply for the 250mg strength and a quantity limit of 240 capsules per 30 days will apply for the 500mg strength.
2. The first 8 weeks of treatment do not require prior authorization.
3. After 8 weeks of treatment:

a. Provider must document a patient-specific, clinically significant reason the member needs a longer duration of treatment.

Rowasa® (Mesalamine Rectal Suspension Enema) Approval Criteria:

1. The first 3 weeks of treatment do not require prior authorization.
2. An FDA approved indication for the treatment of active, mild-to-moderate, distal ulcerative colitis (UC), proctosigmoiditis, or proctitis; and
3. A patient-specific, clinically significant reason the member cannot use mesalamine suppositories (Canasa®) which do not require prior authorization must be provided; and
4. Provider documentation that member is still having active symptoms after 3 weeks of treatment; and
5. Approvals will be for the duration of 6 weeks in accordance with manufacturer recommended duration of therapy; and
6. A quantity limit of 30 enemas (1,800mL) per 30 days will apply.

Uceris® (Budesonide Extended-Release Tablet) Approval Criteria:

1. An FDA approved indication of induction of remission in members with active, mild-to-moderate ulcerative colitis (UC); and
2. Previous failure of at least 2 of the following (or a contraindication to all preferred medications):
   a. Oral aminosalicylates; or
   b. Topical mesalamine; or
   c. Topical corticosteroids; and
3. A patient-specific, clinically significant reason why the member cannot use other oral corticosteroids available without prior authorization must be provided; and
4. Approvals will be for the duration of 8 weeks in accordance with manufacturer maximum recommended duration of therapy; and
5. A quantity limit of 30 tablets per 30 days will apply.

Uceris® (Budesonide Rectal Foam) Approval Criteria:

1. An FDA approved indication of induction of remission in members with active, mild-to-moderate, distal ulcerative colitis (UC) extending up to 40cm from the anal verge; and
2. A patient-specific, clinically significant reason why the member cannot use oral aminosalicylates, topical mesalamine, or other topical (rectally administered) corticosteroids available without prior authorization must be provided; and
3. Approvals will be for the duration of 6 weeks in accordance with manufacturer recommended duration of therapy; and
4. A quantity limit of 133.6 grams per 42 days will apply.

The following medications do not require prior authorization: Colazal® (balsalazide) capsules, Cortenema® (hydrocortisone) enemas, Apriso® (mesalamine) extended-release (ER) capsules, Canasa® (mesalamine) suppositories, Delzicol® (mesalamine) delayed-release (DR) capsules, Lialda® (mesalamine) DR capsules, Pentasa® (mesalamine) ER capsules, Rowasa® (mesalamine) rectal suspension enemas, Dipentum® (olsalazine) capsules, sulfasalazine 500mg tablets, and sulfasalazine DR 500mg tablets.

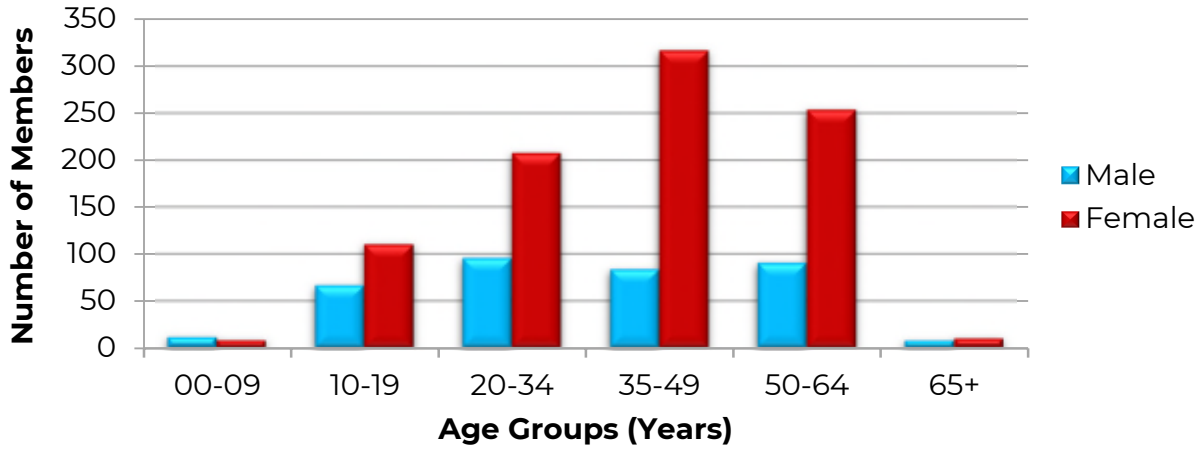
Utilization of CD and UC Medications: Fiscal Year 2022

Comparison of Fiscal Years

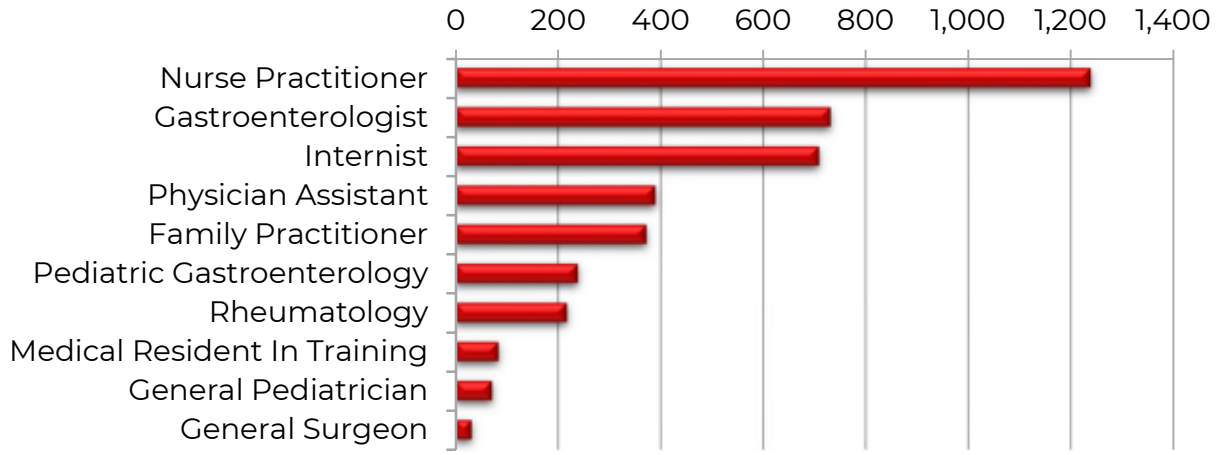
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	760	2,752	$411,106.40	$149.38	$4.93	317,558	83,461
2022	1,256	4,161	$509,458.91	$122.44	$4.06	459,510	125,604
% Change	**65.30%**	**51.20%**	**23.90%**	**-18.00%**	**-17.60%**	**44.70%**	**50.50%**
Change	**496**	**1,409**	**$98,352.51**	**-$26.94**	**-$0.87**	**141,952**	**42,143**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing CD and UC Medications



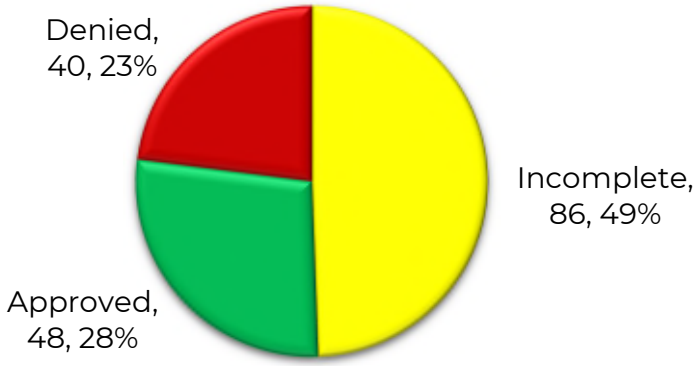
Top Prescriber Specialties of CD and UC Medications by Number of Claims



Prior Authorization of CD and UC Medications

There were 174 prior authorization requests submitted for CD and UC medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Colazal® (balsalazide capsule): February 2027
- Canasa® (mesalamine suppository): June 2028
- Apriso® [mesalamine extended-release (ER) tablet]: May 2030
- Uceris® (budesonide ER tablet): September 2031
- Ortikos® (budesonide ER capsule): September 2036

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

- **May 2022:** The FDA approved the first generic formulation of Pentasa® (mesalamine ER 500mg capsule) for the induction of remission and treatment of adult patients with mildly-to-moderately active UC. With this approval, Sun Pharma received 180 days of generic exclusivity for their generic product.

Recommendations

The College of Pharmacy recommends the prior authorization of generic Pentasa® based on net cost and recommends updating the prior authorization criteria for Pentasa® with the following changes (shown in red):

Pentasa® (Mesalamine Extended-Release Capsule) ~~Quantity Limit~~ Approval Criteria:

1. Brand name Pentasa® does not require prior authorization for the first 8 weeks of treatment. Approval of the generic formulation requires a patient-specific, clinically significant reason the member cannot use the brand formulation (Pentasa®) and all other mesalamine products that do not require prior authorization; and
2. A quantity limit of 480 capsules per 30 days will apply for the 250mg strength and a quantity limit of 240 capsules per 30 days will apply for the 500mg strength; and
3. ~~The first 8 weeks of treatment do not require prior authorization.~~
4. After 8 weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason the member needs a longer duration of treatment.

The following medications do not require prior authorization: Colazal® (balsalazide) capsules, Cortenema® (hydrocortisone) enemas, Apriso® (mesalamine) extended-release (ER) capsules, Canasa® (mesalamine) suppositories, Delzicol® (mesalamine) delayed-release (DR) capsules, Lialda® (mesalamine) DR capsules, brand name Pentasa® (mesalamine) ER capsules, Rowasa® (mesalamine) rectal suspension enemas, Dipentum® (olsalazine) capsules, sulfasalazine 500mg tablets, and sulfasalazine DR 500mg tablets.

Utilization Details of CD and UC Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SULFASALAZINE PRODUCTS						
SULFASALAZINE TAB 500MG	2,056	687	$48,060.66	$23.38	2.99	9.43%
SULFASALAZINE TAB 500MG DR	376	153	$12,389.13	$32.95	2.46	2.43%
SULFASALAZINE POW	8	2	$1,024.42	$128.05	4	0.20%
SUBTOTAL	**2,440**	**842**	**$61,474.21**	**$25.19**	**2.9**	**12.07%**
MESALAMINE PRODUCTS						
MESALAMINE TAB 1.2GM	630	149	$185,739.97	$294.83	4.23	36.46%
MESALAMINE CAP 0.375GM	157	33	$34,395.70	$219.08	4.76	6.75%
MESALAMINE SUP 1000MG	132	76	$13,440.15	$101.82	1.74	2.64%
PENTASA CAP 250MG ER	87	20	$49,777.91	$572.16	4.35	9.77%
PENTASA CAP 500MG ER	82	26	$78,150.01	$953.05	3.15	15.34%
MESALAMINE CAP 400MG DR	53	19	$16,155.95	$304.83	2.79	3.17%
MESALAMINE ENE 4GM	24	15	$4,788.07	$199.50	1.6	0.94%
MESALAMINE TAB 800MG DR	16	12	$11,060.62	$691.29	1.33	2.17%
MESALAMINE CAP 500MG ER	6	6	$6,088.18	$1,014.70	1	1.20%
APRISO CAP 0.375GM	4	3	$1,908.67	$477.17	1.33	0.37%
DELZICOL CAP 400MG	3	2	$1,823.74	$607.91	1.5	0.36%
SUBTOTAL	**1,194**	**361**	**$403,328.97**	**$337.80**	**3.31**	**79.17%**
BUDESONIDE PRODUCTS						
BUDESONIDE CAP 3MG DR	458	178	$31,434.26	$68.63	2.57	6.17%
BUDESONIDE TAB ER 9MG	8	5	$7,651.69	$956.46	1.6	1.50%
SUBTOTAL	**466**	**183**	**$39,085.95**	**$83.88**	**2.55**	**7.67%**
BALSALAZIDE PRODUCTS						
BALSALAZIDE CAP 750MG	54	16	$4,224.15	$78.23	3.38	0.83%
SUBTOTAL	**54**	**16**	**$4,224.15**	**$78.23**	**3.38**	**0.83%**
HYDROCORTISONE PRODUCTS						
HYDROCORTISONE ENE 100MG	7	6	$1,345.63	$192.23	1.17	0.26%
SUBTOTAL	**7**	**6**	**$1,345.63**	**$192.23**	**1.17**	**0.26%**
TOTAL	**4,161**	**1,256***	**$509,458.91**	**$122.44**	**3.31**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DR = delayed-release; ENE = enema; ER = extended-release; POW = powder; SUP = suppository; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 11/2022. Last accessed 11/02/2022.
[2] Pentasa® (Mesalamine) – First-time Generic. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/new-generics/newgenerics_pentasa_2022-0524.pdf. Issued 05/17/2022. Last accessed 11/07/2022.

Appendix J

Fiscal Year 2022 Annual Review of Skin Cancer Medications and 30-Day Notice to Prior Authorize Kimmtrak® (Tebentafusp-tebn) and Opdualag™ (Nivolumab/Relatlimab-rmbw)

Oklahoma Health Care Authority
December 2022

Introduction[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16]

Skin cancers are commonly divided into 2 different types: non-melanoma skin cancer (NMSC) and melanoma skin cancer. In general, NMSC are far more common than melanomas but result in lower mortality. Basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) are the most common forms of NMSC. BCC is the most common cancer diagnosed in the United States, occurring in over 2 million people annually, and the incidence of BCC continues to increase. More people are diagnosed with BCC than all other cancers combined. The incidence of SCC is approximately half that of BCC. Because NMSC rarely metastasizes, treatment is largely focused on localized therapies including different surgical approaches and topical agents. Systemic therapy is reserved for the select number of advanced and metastatic cases.

According to the National Cancer Institute, in 2022, an estimated 99,780 new cases of melanoma skin cancer will be diagnosed in the United States, and an estimated 7,650 deaths will occur from the disease. The average lifetime risk of developing melanoma in the United States is 1 in 40 for women and 1 in 27 for men. While the incidence of melanoma is far lower than NMSC, melanomas behave much more aggressively and have high rates of metastases leading to poor survival outcomes in advanced cases. Survival rates vary based on the clinical stage of the disease at diagnosis, with 5-year survival ranging from 15 to 60% in patients with distant and local metastases, respectively. Traditional cytotoxic chemotherapy has failed to provide successful treatment outcomes in this patient population and has a very small role in treating patients with melanoma. Surgery, immunotherapy, molecularly targeted agents, and radiation are the cornerstones to the treatment of melanoma.

Over the past 10 years, drug developers have focused on agents that target various immune checkpoints, specifically cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) and the programmed death 1/programmed death ligand 1 (PD-1/PD-L1) pathway, which result in a tumor-specific immune response in a subset of patients. Additionally, the development of molecularly targeted

therapy began after it was found that activating *BRAF* mutations occur in half of all melanomas. *BRAF* mutations lead to activation of the mitogen-activated protein kinase (MAPK) pathway and promote tumor development. Research in these areas has led to U.S. Food and Drug Administration (FDA) approval of multiple new agents in the last 5 years. The National Comprehensive Cancer Network (NCCN) guidelines for melanoma treatment recommend all of these agents as first-line therapy, some as monotherapy and others in combination. Use of these agents has also expanded into the adjuvant setting. Development of these new drugs has produced an increase in response rates and modest improvements in survival in some melanoma cases. The cost associated with treating skin cancer, approximately $8.1 billion, increased 5 times faster than treatments for any other cancer between 2002 and 2011.

Current Prior Authorization Criteria

Bavencio® (Avelumab) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. Diagnosis of metastatic MCC; and
2. Member must be 12 years of age or older.

Bavencio® (Avelumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC; and
2. Used as first-line treatment; and
3. Used in combination with axitinib.

Bavencio® (Avelumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and
2. Disease has progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy; or
3. Used as maintenance therapy for members not progressing on a first-line platinum-containing regimen.

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

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

Braftovi® (Encorafenib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
3. Used in combination with binimetinib.

Cotellic® (Cobimetinib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Cobimetinib is not indicated for wild-type *BRAF* melanoma; and
3. Member meets 1 of the following:
    a. Used as first-line therapy in combination with vemurafenib; or
    b. Used as second-line therapy or subsequent therapy with vemurafenib.

Erivedge® (Vismodegib) Approval Criteria [Basal Cell Carcinoma (BCC) Diagnosis]:

1. Diagnosis of locally advanced BCC that has either:
    a. Recurred following surgery or radiation therapy; or
    b. Surgery or radiation is contraindicated; or
2. Diagnosis of metastatic BCC.

Imlygic® (Talimogene Laherparepvec) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable cutaneous, subcutaneous, or nodal lesions that are recurrent after initial surgery; and
    a. Not indicated in members with visceral metastases; and
2. Member is not immunocompromised or pregnant.

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

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

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

1. Diagnosis of recurrent or metastatic cervical cancer; and
2. Tumor must express programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1)]; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
    a. Disease progression on or after chemotherapy; or

b. As first-line therapy in combination with chemotherapy, with or without bevacizumab.

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

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

Keytruda® (Pembrolizumab) Approval Criteria [Cutaneous Squamous Cell Carcinoma (cSCC) Diagnosis]:

1. Diagnosis of recurrent or metastatic disease; and
2. Not curable by radiation or surgery.

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

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

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

1. Diagnosis of locally advanced, recurrent, or metastatic esophageal or GEJ carcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
4. For first-line therapy:
    a. In combination with platinum- and fluoropyrimidine-based chemotherapy; or
5. For second-line or greater therapy:
    a. Following disease progression after 1 or more prior lines of systemic therapy; and
    b. Tumor must be squamous cell histology; and
    c. Used as a single agent; and
    d. Tumor expresses programmed death ligand 1 (PD-L1) [combined positive score (CPS ≥10).

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

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

Keytruda® (Pembrolizumab) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Used in first-line or recurrent setting; and
2. Squamous cell histology; and
3. If used in the recurrent setting, member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of relapsed or progressive HCC; and
2. Member must have been previously treated with sorafenib; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

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

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

Keytruda® (Pembrolizumab) Approval Criteria [Melanoma Diagnosis]:

1. Member meets 1 of the following:
    a. Adjuvant treatment of members with melanoma with involvement of lymph node(s) following complete resection; or

   b. Diagnosis of unresectable or metastatic melanoma; and
2. Used as a single agent; and
3. Member meets 1 of the following:
   a. Used as first-line therapy; or
   b. Used as second-line therapy or subsequent therapy for disease progression if not previously used; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
5. For adjuvant treatment of melanoma, approvals will be for a maximum duration of 1 year.

Keytruda® (Pembrolizumab) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. Diagnosis of recurrent, locally advanced, or metastatic MCC; and
2. No history of prior systemic chemotherapy; and
3. Used as a single agent; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) Approval Criteria [Metastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. Tumor proportion scores for programmed death ligand 1 (PD-L1) expression as follows:
   a. As a single agent, first-line: ≥1%; or
   b. First-line in combination: No expression required; or
   c. As a single agent, second-line: ≥1%; and
4. Member meets 1 of the following:
   a. Previously untreated, metastatic squamous NSCLC in combination with carboplatin and either paclitaxel or nab-paclitaxel; or
   b. Previously untreated, metastatic non-squamous NSCLC in combination with pemetrexed and carboplatin; or
   c. New diagnosis as first-line therapy (member has not received chemotherapy to treat disease) if:
      i. Tumor does not express sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) translocations; or
   d. Used as a single agent for disease progression on or after platinum-containing chemotherapy (i.e., cisplatin, carboplatin):
      i. Members with EGFR-mutation-positive tumors should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not*

apply if tumors do not have these mutations (*examples of drugs for EGFR-mutation-positive tumors: osimertinib, erlotinib, afatinib, or gefitinib);* and

ii. Members with ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations (examples of drugs for ALK-mutation-positive tumors: crizotinib, ceritinib, or alectinib).*

Keytruda® (Pembrolizumab) Approval Criteria [Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumor (Tissue/Site-Agnostic) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)]; and
2. MSI-H or dMMR solid tumors that have progressed following prior treatment with no satisfactory alternative treatment options.

Keytruda® (Pembrolizumab) Approval Criteria [Nonmetastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of stage 3 NSCLC; and
2. Ineligible for surgery or definitive chemoradiation; and
3. Tumor proportion scores for programmed death ligand 1 (PD-L1) expression ≥1%; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

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

1. 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.

Keytruda® (Pembrolizumab) Approval Criteria [Primary Mediastinal Large B-cell Lymphoma (PMBCL) Diagnosis]:

1. Diagnosis of PMBCL; and
2. Member must have refractory disease or relapsed after 2 or more prior lines of therapy; and
3. Authorizations will not be granted for members who require urgent cytoreduction; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of new or recurrent stage 4 clear-cell RCC; and
    a. Member has not received previous systemic therapy for advanced disease; and
    b. Must be used in combination with axitinib or lenvatinib; and
    c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; or
2. Diagnosis of RCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.

Keytruda® (Pembrolizumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of metastatic SCLC; and
2. Progressed on or following a platinum-based regimen and at least 1 other regimen; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) Approval Criteria [Tumor Mutational Burden-High (TMB-H) Solid Tumors Diagnosis]:

1. Diagnosis of unresectable or metastatic TMB-H [≥10 mutations/megabase (mut/Mb)] solid tumors; and
2. Used following disease progression after prior treatment; and
3. No satisfactory alternative treatment options.

Keytruda® (Pembrolizumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Member must have 1 of the following:
    a. Locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy; or
    b. Within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; or
    c. Frontline for members with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy; and
        i. Cisplatin ineligibility is defined as:
            1. Baseline creatinine clearance of <60mL/min; or
            2. ECOG performance status of 2; or
            3. Class III heart failure; or
            4. Grade 2 or greater peripheral neuropathy; or
            5. Grade 2 or greater hearing loss; and

2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)].

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

1. Diagnosis of locally advanced or metastatic BCC; and
2. Member has previously been treated with a hedgehog pathway inhibitor (HHI); or
3. Treatment with a HHI is not appropriate for the member.

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Cutaneous Squamous Cell Carcinoma (cSCC) Diagnosis]:

1. Diagnosis of metastatic or locally advanced cSCC; and
2. Member is ineligible for curative surgery or radiation; and
3. Member has not received prior immunotherapy agent(s) [e.g., Keytruda® (pembrolizumab), Opdivo® (nivolumab), Yervoy® (ipilimumab)].

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

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

Mekinist® (Trametinib) Approval Criteria [Anaplastic Thyroid Cancer (ATC) Diagnosis]:

1. Diagnosis of ATC; and
2. Locally advanced or metastatic disease; and
3. *BRAF* V600E mutation; and
4. No satisfactory locoregional treatment options.

Mekinist® (Trametinib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Trametinib is not indicated for wild-type *BRAF* melanoma; and
3. Must meet 1 of the following:
    a. Used as first-line therapy in combination with dabrafenib; or
    b. Used as second-line or subsequent therapy with dabrafenib; or
    c. Used as second-line therapy or subsequent therapy as a single agent if:
        i. Member was intolerant to prior *BRAF* inhibitor therapy (i.e., dabrafenib, vemurafenib); and

ii. No evidence of disease progression on prior *BRAF* inhibitor therapy (i.e., dabrafenib, vemurafenib).

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

1. Diagnosis of refractory or metastatic NSCLC; and
2. *BRAF* V600E or V600K mutation; and
    a. Trametinib is not indicated for wild-type *BRAF* NSCLC; and
3. Used in combination with dabrafenib.

Mekinist® (Trametinib) Approval Criteria [Serous Ovarian Cancer Diagnosis]:

1. Diagnosis of persistent disease or recurrent low-grade serous carcinoma; and
2. Meets 1 of the following:
    a. Immediate treatment for serially rising CA-125 in members who previously received chemotherapy; or
    b. Progression on primary, maintenance, or recurrence therapy; or
    c. Stable or persistent disease (if not on maintenance therapy); or
    d. Complete remission and relapse after completing chemotherapy.

Mektovi® (Binimetinib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
3. Used in combination with encorafenib.

Odomzo® (Sonidegib) Approval Criteria [Basal Cell Carcinoma (BCC) Diagnosis]:

1. Diagnosis of locally advanced BCC that has either:
    a. Recurred following surgery or radiation therapy; or
    b. Surgery or radiation is contraindicated; or
2. Diagnosis of metastatic BCC.

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

1. Member has had complete resection of melanoma; and
2. Diagnosis of stage 3 melanoma following complete resection; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Used as a single agent; and
5. Dose as follows:
    a. Single agent: 240mg every 2 weeks or 480mg every 4 weeks; and
    b. Maximum duration of 1 year.

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

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

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

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

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

1. Diagnosis of advanced or metastatic disease; and
2. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy.

Opdivo® (Nivolumab) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic head and neck cancer; and
2. Squamous cell histology; and
3. Member has received prior platinum-containing regimen (i.e., cisplatin, carboplatin); and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
5. Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.

Opdivo® (Nivolumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Member must have unresectable disease and is not a transplant candidate; or
2. Metastatic disease or extensive liver tumor burden; and
3. Must meet 1 of the following:
    a. If used as first-line therapy, must be used as single agent; and
        i. Ineligible for tyrosine kinase inhibitors or anti-angiogenic agents; or
    b. If used as second-line or greater therapy, may be used as single agent or in combination with ipilimumab; and
        i. Must not have failed other checkpoint inhibitors.

Opdivo® (Nivolumab) Approval Criteria [Hodgkin Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory classical Hodgkin lymphoma; and
    a. Exception: Lymphocyte-predominant Hodgkin lymphoma; and
2. Used as a single agent; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)].

Opdivo® (Nivolumab) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of malignant pleural mesothelioma that cannot be surgically removed; and
2. Used as first-line therapy; and
3. Used in combination with ipilimumab.

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

1. Diagnosis of NSCLC; and
2. For first-line therapy for recurrent, advanced, or metastatic disease, meeting the following:
    a. Used in combination with Yervoy® (ipilimumab) and 2 cycles of platinum-doublet chemotherapy; and
    b. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
    c. Expresses programmed death ligand 1 (PD-L1) ≥1%; or
3. For first-line therapy for resectable disease (>4cm or node positive), meeting the following:
    a. Used in the neoadjuvant setting in combination with platinum-doublet chemotherapy for up to 3 treatment cycles; or
4. For second-line therapy for metastatic disease, meeting the following:
    a. Tumor histology is 1 of the following:
        i. Adenocarcinoma; or
        ii. Squamous cell; or
        iii. Large cell; and

b. Disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin); and
c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
d. Used as a single agent; and
e. Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.

Opdivo® (Nivolumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
2. Used in 1 of the following settings:
    a. For nivolumab monotherapy:
        i. Diagnosis of relapsed or surgically unresectable stage 4 disease; and
        ii. Failed prior therapy with 1 of the following medications:
            1. Sunitinib; or
            2. Sorafenib; or
            3. Pazopanib; or
            4. Axitinib; or
    b. For nivolumab use in combination with ipilimumab:
        i. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; or
    c. For nivolumab use in combination with cabozantinib:
        i. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with advanced RCC; and
        ii. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years; and
3. Dose as follows:
    a. Single agent: 240mg every 2 weeks or 480mg every 4 weeks; or
    b. In combination with ipilimumab: nivolumab 3mg/kg followed by ipilimumab 1mg/kg on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240mg every 2 weeks or 480mg every 4 weeks thereafter; or
    c. In combination with cabozantinib: cabozantinib 40mg once daily with nivolumab 240mg every 2 weeks or 480mg every 4 weeks; nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.

Opdivo® (Nivolumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Must meet 1 of the following criteria:

    a. Disease relapsed within 6 months of initial chemotherapy; or
    b. Disease is progressive on initial chemotherapy; and
2. Used as a single agent or in combination with ipilimumab; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)].

Opdivo® (Nivolumab) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. Used as a single agent or in combination with ipilimumab:
    a. As first-line therapy for untreated melanoma; or
    b. As second-line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy; and
        i. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
3. Dose as follows:
    a. Single agent: 240mg every 2 weeks or 480mg every 4 weeks; or
    b. In combination with ipilimumab: nivolumab 1mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 240mg every 2 weeks or 480mg every 4 weeks.

Opdivo® (Nivolumab) Approval Criteria [Urothelial Bladder Cancer Diagnosis]:

1. Diagnosis of urothelial carcinoma; and
    a. Member has undergone radical resection; and
    b. Disease is at high risk of recurrence; or
2. Diagnosis of metastatic or unresectable locally advanced disease; and
    a. Used as second-line or greater therapy; and
    b. Previous failure of a platinum-containing regimen; and
    c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)].

Tafinlar® (Dabrafenib) Approval Criteria [Anaplastic Thyroid Cancer (ATC) Diagnosis]:

1. Diagnosis of ATC; and
2. Locally advanced or metastatic disease; and
3. *BRAF* V600E mutation; and
4. No satisfactory locoregional treatment options.

Tafinlar® (Dabrafenib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Dabrafenib is not indicated for wild-type *BRAF* melanoma; and
3. Used as a single agent or in combination with trametinib; and

4. Must meet 1 of the following:
    a. Used as first-line therapy; or
    b. Used as second-line or subsequent therapy.

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

1. Diagnosis of refractory or metastatic NSCLC; and
2. *BRAF* V600E or V600K mutation; and
    a. Not indicated for wild-type BRAF NSCLC; and
3. Used as a single agent or in combination with trametinib.

Tecentriq® (Atezolizumab) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600 mutation-positive; and
3. Used in combination with cobimetinib and vemurafenib.

Approval criteria for Tecentriq® (atezolizumab) for indications other than skin cancer diagnoses can be found in the May 2022 DUR Board packet. Atezolizumab approval criteria are reviewed annually with the lung cancer medications.

Yervoy® (Ipilimumab) Approval Criteria [Adjuvant Treatment of Melanoma Diagnosis]:

1. Member has had complete resection of melanoma with lymphadenectomy; and
2. Member has stage 3 disease with regional nodes of >1mm and no in-transit metastasis; and
3. Used as a single agent; and
4. Maximum dose of 10mg/kg will apply.

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

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

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

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

Yervoy® (Ipilimumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Member must have unresectable disease and is not a transplant candidate; or
2. Metastatic disease or extensive liver tumor burden; and
3. Used as second-line or greater therapy; and
4. Used in combination with nivolumab; and
5. Must not have failed other checkpoint inhibitors.

Yervoy® (Ipilimumab) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of malignant pleural mesothelioma that cannot be surgically removed; and
2. Used as first-line therapy; and
3. Used in combination with nivolumab.

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

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
    a. Used for first-line therapy and must meet the following:
        i. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
        ii. Used in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy; and
        iii. Expresses programmed death ligand 1 (PD-L1) $\geq$1%.

Yervoy® (Ipilimumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; and
2. Used in combination with nivolumab; and
3. Member has not failed previous programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Dose as follows: nivolumab 3mg/kg followed by ipilimumab 1mg/kg on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240mg every 2 weeks or 480mg every 4 weeks.

Yervoy® (Ipilimumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of SCLC; and
2. Must meet 1 of the following criteria:
    a. Disease relapsed within 6 months of initial chemotherapy; or
    b. Disease is progressive on initial chemotherapy; and
3. Used in combination with nivolumab.

Yervoy® (Ipilimumab) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. Used in combination with nivolumab as:
    a. First-line therapy; or
    b. Second-line or subsequent therapy for disease progression if nivolumab was not previously used; or
3. Used as a single agent for 1 of the following:
    a. First-line therapy as a single course of 4 treatments; or
    b. Second-line or subsequent lines of therapy as a single course of 4 treatments; or
    c. Retreatment, consisting of a 4-dose limit, for a member who had:
        i. No significant systemic toxicity during prior ipilimumab therapy; and
        ii. Whose disease progressed after being stable >6 months following completion of a prior course of ipilimumab; and
        iii. For whom no intervening therapy has been administered; and
4. Maximum dose of 3mg/kg will apply.

Zelboraf® (Vemurafenib) Approval Criteria [Erdheim-Chester Disease (ECD) Diagnosis]:

1. Diagnosis of ECD; and
2. *BRAF* V600E or V600K mutation; and
3. Used as a single agent.

Zelboraf® (Vemurafenib) Approval Criteria [Hairy-Cell Leukemia Diagnosis]:

1. Diagnosis of hairy-cell leukemia; and
2. Used as a single agent; and
3. Disease progression following failure of purine analog therapy (i.e., pentostatin, cladribine).

Zelboraf® (Vemurafenib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Vemurafenib is not indicated for wild-type *BRAF* melanoma; and
3. Must meet 1 of the following:
    a. Used as first-line therapy; or
    b. Used as second-line or subsequent therapy; and
4. Used as a single agent or in combination with cobimetinib.

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

1. Diagnosis of refractory or metastatic NSCLC; and

2. *BRAF* V600E or V600K mutation; and
    a. Vemurafenib is not indicated for wild-type *BRAF* NSCLC; and
3. Used as a single agent.

Utilization of Skin Cancer Medications: Fiscal Year 2022

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

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	13	58	$416,088.90	$7,173.95	$245.77	3,990	1,693
2022	27	183	$1,668,536.09	$9,117.68	$317.63	11,925	5,253
% Change	**107.70%**	**215.50%**	**301.00%**	**27.10%**	**29.20%**	**198.90%**	**210.30%**
Change	**14**	**125**	**$1,252,447.19**	**$1,943.73**	**$71.86**	**7,935**	**3,560**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	187	845	$9,985,447.24	$11,817.10	4.52
2022	362	1,436	$17,626,196.85	$12,274.51	3.97
% Change	**93.58%**	**69.94%**	**76.52%**	**3.87%**	**-12.17%**
Change	**175**	**591**	**$7,640,749.61**	**$457.41**	**-0.55**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

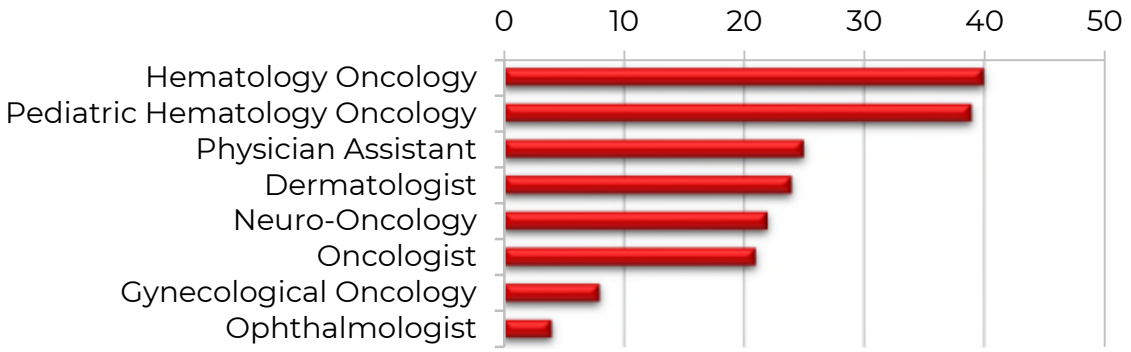
- Aggregate drug rebates collected during fiscal year 2022 for skin cancer medications: $475,045.39.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Skin Cancer Medications: Pharmacy Claims

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

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

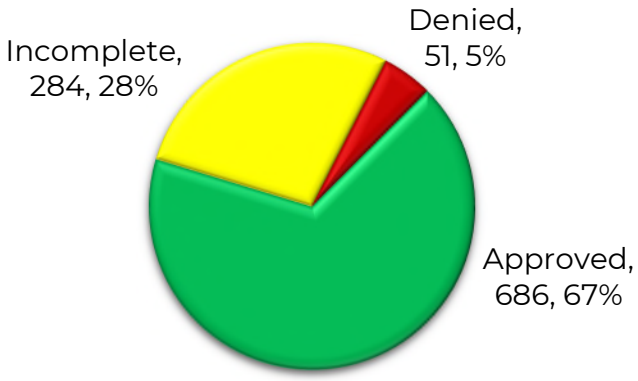
Top Prescriber Specialties of Skin Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Skin Cancer Medications

There were 1,021 prior authorization requests submitted for skin cancer medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[17,18]

Anticipated Patent Expiration(s):

- Erivedge® (vismodegib): December 2028
- Zelboraf® (vemurafenib): June 2032
- Braftovi® (encorafenib): August 2033
- Mekinist® (trametinib dimethyl sulfoxide): August 2033
- Tafinlar® (dabrafenib mesylate): August 2033
- Mektovi® (binimetinib): October 2033
- Odomzo® (sonidegib phosphate): March 2036
- Cotellic® (cobimetinib fumarate): December 2036

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

- **December 2021:** The FDA approved Keytruda® (pembrolizumab) for the adjuvant treatment of adult and pediatric patients 12 years of age and older with stage 2B or 2C melanoma following complete resection.
- **January 2022:** The FDA approved Kimmtrak® (tebentafusp-tebn), a bispecific gp100 peptide-human leukocyte antigen (HLA)-directed cluster of differentiation 3 (CD3) T cell engager, for HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.
- **March 2022:** The FDA approved Opdualag™ (nivolumab/relatlimab-rmbw) for adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma. Opdualag™ is a fixed-dose combination of the lymphocyte activation gene-3 (LAG-3)-blocking antibody (relatlimab-rmbw) and a PD-1 blocking antibody (nivolumab).
- **June 2022:** The FDA granted accelerated approval to Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib) for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with *BRAF* V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.
- **November 2022:** The FDA approved Libtayo® (cemiplimab-rwlc) in combination with platinum-based chemotherapy for adult patients with advanced non-small cell lung cancer (NSCLC) with no epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS1 aberrations.

Kimmtrak® (Tebentafusp-tebn) Product Summary[19]

- **Therapeutic Class:** Bispecific gp100 peptide-HLA-directed CD3 T cell engager
- **Indication(s):** Treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma
- **How Supplied:** 100mcg/0.5mL solution in a single-dose vial (SDV) for intravenous (IV) infusion
- **Dose:** 20mcg on day 1, 30mcg on day 8, 68mcg on day 15, and 68mcg once every week thereafter
- **Cost:** The Wholesale Acquisition Cost (WAC) is $37,520 per mL, resulting in a cost per dose of $18,760 and an annual cost of $994,280 based on the recommended dosing.

Opdualag™ (Nivolumab/Relatlimab-rmbw) Product Summary[20]

- **Therapeutic Class:** Combination PD-1 blocking antibody and a LAG-3 blocking antibody
- **Indication(s):** Treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma

- **How Supplied:** 240mg of nivolumab and 80mg of relatlimab-rmbw per 20mL (12mg/4mg/mL) in a SDV for IV infusion
- **Dose:**
  - Adult patients and pediatric patients 12 years of age or older who weigh at least 40kg: 480mg nivolumab/160mg relatlimab-rmbw every 4 weeks
- **Cost:** The WAC is $684.71 per mL, resulting in a cost per dose of $27,388.40 and an annual cost of $356,049.20 based on the recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Kimmtrak® (tebentafusp-tebn) and Opdualag™ (nivolumab/relatlimab-rmbw) with the following criteria (shown in red):

Kimmtrak® (Tebentafusp-tebn) Approval Criteria [Uveal Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic uveal melanoma; and
2. Positive expression of HLA-A*02:01 genotype.

Opdualag™ (Nivolumab/Relatlimab-rmbw) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. Member must be 12 years of age or older; and
3. As first-line therapy; and
4. Member has not previously failed programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab), Opdivo® (nivolumab)].

The College of Pharmacy also recommends updating the approval criteria for Keytruda® (pembrolizumab), Libtayo® (cemiplimab-rwlc), Mekinist® (trametinib), and Tafinlar® (dabrafenib) based on recent FDA approvals (updates shown in red):

Keytruda® (Pembrolizumab) Approval Criteria [Melanoma Diagnosis]:

1. Member meets 1 of the following:
   a. ~~Adjuvant treatment of members with melanoma with involvement of lymph node(s) following complete resection; or~~
   b. Adjuvant treatment of adult and pediatric members 12 years or older with stage 2B, 2C, or 3 melanoma following complete resection; or
   c. Diagnosis of unresectable or metastatic melanoma; and
2. Used as a single-agent; and
3. Member meets 1 of the following:
   a. Used as first-line therapy; or

b. Used as second-line therapy or subsequent therapy for disease progression if not previously used; and

4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo (nivolumab)]; and
5. For adjuvant treatment of melanoma, approvals will be for a maximum duration of 1 year.

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

1. Diagnosis of advanced, unresectable, or metastatic NSCLC; and
2. Used in the first-line setting; and
3. No epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS1 mutations; and
4. Used in 1 of the following settings:
   a. Used as a single agent; and
      i. High programmed death ligand 1 (PD-L1) expression [tumor proportion score (TPS) ≥50%]; or
   b. Used in combination with platinum-based chemotherapy; and
      i. No requirement for PD-L1 expression.

Mekinist® (Trametinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
4. Used in combination with dabrafenib.

Tafinlar® (Dabrafenib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
4. Used in combination with trametinib.

Utilization Details of Skin Cancer Medications: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
DABRAFENIB PRODUCTS						
TAFINLAR CAP 75MG	52	8	$396,030.60	6.5	$7,615.97	23.74%
TAFINLAR CAP 50MG	14	2	$84,181.25	7	$6,012.95	5.05%
SUBTOTAL	**66**	**10**	**$480,211.85**	**6.6**	**$7,275.94**	**28.79%**
VISMODEGIB PRODUCTS						
ERIVEDGE CAP 150MG	43	11	$469,139.55	3.91	$10,910.22	28.12%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
SUBTOTAL	**43**	**11**	**$469,139.55**	**3.91**	**$10,910.22**	**28.12%**
TRAMETINIB PRODUCTS						
MEKINIST TAB 2MG	28	6	$365,612.32	4.67	$13,057.58	21.91%
SUBTOTAL	**28**	**6**	**$365,612.32**	**4.67**	**$13,057.58**	**21.91%**
COBIMETINIB PRODUCTS						
COTELLIC TAB 20MG	18	3	$113,997.35	6	$246.75	6.83%
SUBTOTAL	**18**	**3**	**$113,997.35**	**6**	**$246.75**	**6.83%**
VEMURAFENIB PRODUCTS						
ZELBORAF TAB 240MG	18	3	$107,862.10	6	$5,992.34	6.46%
SUBTOTAL	**18**	**3**	**$107,862.10**	**6**	**$5,992.34**	**6.46%**
ENCORAFENIB PRODUCTS						
BRAFTOVI CAP 75MG	7	3	$92,998.63	2.33	$13,285.52	5.57%
SUBTOTAL	**7**	**3**	**$92,998.63**	**2.33**	**$13,285.52**	**5.57%**
BINIMETINIB PRODUCTS						
MEKTOVI TAB 15MG	3	2	$38,714.29	1.5	$12,904.76	2.32%
SUBTOTAL	**3**	**2**	**$38,714.29**	**1.5**	**$12,904.76**	**2.32%**
TOTAL	**183**	**27***	**$1,668,536.09**	**6.78**	**$9,117.68**	**100.00%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
J9271 PEMBROLIZUMAB INJ	835	203	$10,656,236.00	4.11	$12,761.96
J9299 NIVOLUMAB INJ	305	74	$3,460,406.61	4.12	$11,345.60
J9022 ATEZOLIZUMAB INJ	242	62	$2,598,492.72	3.9	$10,737.57
J9228 IPILIMUMAB INJ	44	21	$794,456.32	2.1	$18,055.83
J9023 AVELUMAB INJ	8	1	$97,271.20	8	$12,158.90
J9119 CEMIPLIMAB-RWLC INJ	2	1	$19,334.00	2	$9,667.00
TOTAL	**1,436**	**362**	**$17,626,196.85**	**3.97**	**$12,274.51**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

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Appendix K

Fiscal Year 2022 Annual Review of Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon) and 30-Day Notice to Prior Authorize Vyvgart® (Efgartigimod Alfa-fcab)

Oklahoma Health Care Authority
December 2022

Current Prior Authorization Criteria

Empaveli® (Pegcetacoplan) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Must have an established diagnosis of PNH via international classification of disease (ICD) coding in member's medical claims history; and
3. An age restriction of 18 years and older will apply; and
4. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Empaveli®; and
5. Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For members switching from Soliris® to Empaveli®, prescriber must verify the member will continue the current dose of Soliris® for 4 weeks before switching to Empaveli® as monotherapy; and
7. For members switching from Ultomiris® to Empaveli®, prescriber must verify that Empaveli® will be initiated no more than 4 weeks after the last dose of Ultomiris®.

Enspryng® (Satralizumab-mwge) Approval Criteria:

1. An FDA approved indication of neuromyelitis optica spectrum disorder (NMOSD) in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤6.5; and

5. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
6. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
7. Prescriber must verify liver function tests have been assessed prior to initiation of treatment with Enspryng® and levels are acceptable to prescriber; and
8. Prescriber must agree to counsel the member to monitor for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
9. Prescriber must agree to monitor neutrophil counts 4 to 8 weeks after initiation of therapy and thereafter as clinically appropriate; and
10. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
11. Member and/or caregiver must be trained by a health care professional on subcutaneous administration and storage of Enspryng®; and
12. A quantity limit override for the loading dose will be approved upon meeting the Enspryng® approval criteria. A quantity limit of 1 syringe per 28 days will apply for the maintenance dose, according to the package labeling; and
13. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Soliris® (Eculizumab) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) or Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. Member must have an established diagnosis of aHUS or PNH via international classification of disease (ICD) coding in member's medical claims history; and
2. An age restriction of 18 years and older will apply; and
3. For members younger than 18 years of age, approval can be granted with a documented diagnosis of aHUS.

Soliris® (Eculizumab) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
3. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
4. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
5. Member must meet 1 of the following:

    a. Failed treatment over 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; or
    b. Failed at least 1 IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIg); and
6. Initial approvals will be for the duration of 6 months at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Soliris® (Eculizumab) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have a history of at least 2 NMOSD attacks in last 12 months or 3 attacks in the last 24 months, with at least 1 attack in the past 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤7; and
5. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:

1. Member must have a documented diagnosis of aHUS.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. Member must have an established diagnosis of PNH via international classification of disease (ICD) coding in member's medical claims history; and
2. An age restriction of 18 years and older will apply.

Uplizna® (Inebilizumab-cdon) Approval Criteria:

1. An FDA approved indication of neuromyelitis optica spectrum disorder (NMOSD) in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months, or at least 2 attacks in the prior 24 months, requiring rescue therapy; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤8; and

5. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
6. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
7. Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
8. Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and
9. Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and
10. The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and
11. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and
12. Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and
13. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
14. A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and
15. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Utilization of Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon): Fiscal Year 2022

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	5	100	$2,373,069.81	$23,730.70	$1,734.70	22,746	1,368
2022	4	42	$1,368,017.73	$32,571.85	$1,252.76	5,137	1,092
% Change	**-20.0%**	**-58.0%**	**-42.4%**	**37.3%**	**-27.8%**	**-77.4%**	**-20.2%**
Change	**-1**	**-58**	**-$1,005,052.08**	**$8,841.15**	**-481.94**	**-17,609**	**-276**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022= 07/01/2021 to 06/30/2022

Comparison of Fiscal Years: Medical Claims

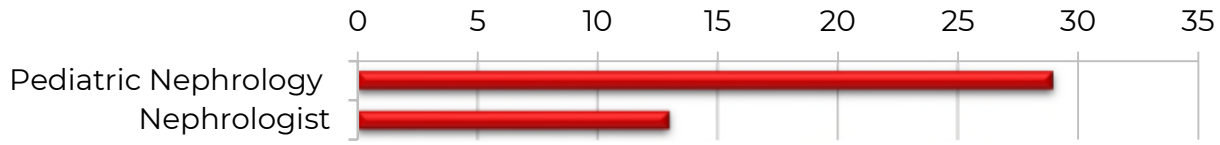
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2021	4	14	$776,477.40	$55,462.67	3,510
2022	5	17	$933,019.50	$54,883.50	4,140
% Change	**25%**	**21.43%**	**20.16%**	**-1.04%**	**17.95%**
Change	**1**	**3**	**$156,542.10**	**-$579.17**	**630**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022= 07/01/2021 to 06/30/2022

Demographics of Members Utilizing Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon): Pharmacy Claims

- Due to the limited number of members utilizing Empaveli®, Enspryng®, Soliris®, Ultomiris®, and Uplizna® during fiscal year 2022, detailed demographic information could not be provided.

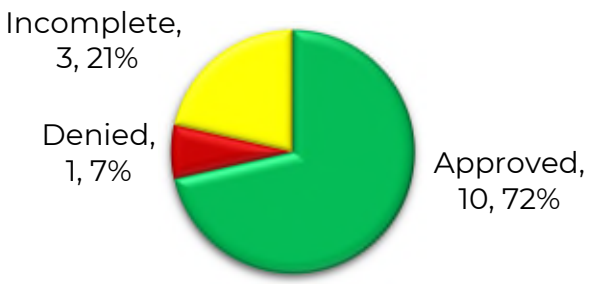
Top Prescriber Specialties of Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon) by Number of Claims: Pharmacy Claims



Prior Authorization of Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon)

There were 14 prior authorization requests submitted for Empaveli® Enspryng®, Soliris®, Ultomiris®, and Uplizna® during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



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

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

- **December 2021:** The FDA approved Vyvgart® (efgartigimod alfa-fcab) for the treatment of generalized myasthenia gravis (gMG) in adults who test positive for the anti-acetylcholine receptor (AChR) antibody. In gMG, the immune system produces AChR antibodies that interfere with communication between nerves and muscles, resulting in muscle weakness. Vyvgart® is the first approval of a new class of medications. It is an antibody fragment that binds to the neonatal Fc receptor (FcRn), preventing FcRn from recycling immunoglobulin G (IgG) back into the blood. The medication causes a reduction in overall levels of IgG, including the abnormal AChR antibodies that are present in gMG.
- **April 2022:** The FDA approved Ultomiris® (ravulizumab-cwvz) for the treatment of adult patients with gMG who are AChR antibody positive. Ultomiris® is the first and only long-acting C5 complement inhibitor approved for the treatment of gMG. Ultomiris® is a humanized monoclonal antibody that specifically binds with high affinity to the human terminal complement protein C5, preventing disruption of neuromuscular transmission, presumably by inhibiting membrane attack complex-mediated destruction of the neuromuscular junction. Ultomiris® was engineered to maintain therapeutic serum concentrations over an 8-week dosing interval. The approval for gMG was based on positive results from the CHAMPION-MG Phase 3, randomized, double-blind, placebo-controlled study in which Ultomiris® was superior to placebo. In total, 175 patients were enrolled. Ultomiris® significantly increased the magnitude of mean changes from baseline to week 26 versus placebo in the Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) (−3.1 vs. −1.4; P<0.001) and Quantitative Myasthenia Gravis (QMG) (−2.8 vs. −0.8; P<0.001) total scores. Improvements in both measures occurred within 1 week of Ultomiris® initiation and were sustained through week 26. QMG total scores improved by ≥5 points in a significantly greater proportion of Ultomiris® treated patients compared to those receiving placebo (30.0% vs. 11.3%; P=0.005). No notable differences in adverse events were observed. The most common adverse reactions in patients receiving Ultomiris® were upper respiratory tract infection and diarrhea.

Pipeline:

- **Efgartigimod SC (ARGX-113 SC)**: A subcutaneous (sub-Q) formulation of efgartigimod is being studied in the Phase 3 randomized, open-label, parallel-group ADAPTsc study in comparison to intravenous (IV) Vyvgart® for 12 weeks. The ADAPTsc study met its primary endpoint and showed that efgartigimod SC was noninferior to Vyvgart® on total IgG

reduction at day 29. Efgartigimod SC has a Prescription Drug User Fee Act (PDUFA) target action date of March 20, 2023.

- **Rozanolixizumab (UCB7665)**: Rozanolixizumab is a sub-Q infused monoclonal antibody targeting the FcRn. It is being studied in a Phase 3 randomized, double-blind, placebo-controlled study in adults with gMG, Myasthenia Gravis Foundation of America (MGFA) class II to IVa, MG-ADL score ≥3, and a QMG score ≥11. The study met its primary endpoint, demonstrating a statistically significant and clinically meaningful change from baseline in the MG-ADL total score at day 43.
- **Zilucoplan (RA101495):** Zilucoplan is a sub-Q self-administered C5 complement inhibitor that targets the key elements of the underlying pathophysiology of gMG. In the Phase 3, placebo-controlled, 12-week RAISE study, in which 174 adult patients with AChR-positive gMG were randomized to receive daily, sub-Q, self-administered doses of zilucoplan or placebo, the study met its primary endpoint with zilucoplan demonstrating a placebo-corrected mean improvement of 2.09 points in the MG-ADL score at week 12 (P <0.001). The FDA has accepted the New Drug Application (NDA) for zilucoplan, and a response is expected in late 2023.

Vyvgart® (Efgartigimod Alfa-fcab) Product Summary[9,10]

Indication(s): Vyvgart® (efgartigimod alfa-fcab) is a neonatal FcRn blocker indicated for the treatment of gMG in adult patients who are AChR antibody positive.

How Supplied: 400mg in 20mL (20mg/mL) solution single-dose vial (SDV) for IV infusion

Dosing and Administration:

- The need to administer age-appropriate vaccines should be evaluated according to immunization guidelines before initiation of a new treatment cycle with Vyvgart®.
- The recommended dosage is 10mg/kg administered as an IV infusion over 1 hour via a 0.2 micron in-line filter once weekly for 4 weeks.
- In patients weighing ≥120kg, the recommended dose is 1,200mg per infusion.
- Subsequent treatment cycles should be administered based on clinical evaluation; the safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.

Mechanism of Action: Efgartigimod alfa-fcab is a human IgG1 antibody fragment that binds to the FcRn, resulting in the reduction of circulating IgG.

Warnings and Precautions:

- Infections: Vyvgart® may increase the risk of infection. The most common infections observed were urinary tract infections and respiratory infections. A higher frequency of patients who received Vyvgart® versus placebo were observed to have below normal levels of white blood cell counts, lymphocyte counts, and neutrophil counts. Most infections and hematologic abnormalities were mild to moderate in severity. Administration of Vyvgart® should be delayed in patients with an active infection until the infection is resolved. During treatment with Vyvgart®, patients should be monitored for clinical signs and symptoms of infections. If serious infection occurs, appropriate treatment should be administered and withholding Vyvgart® until the infection has resolved should be considered.
- Immunization: Administration of vaccines during Vyvgart® treatment has not been studied. The safety of immunization with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because Vyvgart® causes a reduction in IgG levels, patients should not receive live-attenuated or live vaccines during treatment with Vyvgart®. The need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with Vyvgart® should be considered.
- Hypersensitivity Reactions: Angioedema, dyspnea, and rash have occurred. Patients should be monitored during administration and for 1 hour after for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs during administration, therapy should be discontinued, and appropriate supportive measures should be used, if needed.
- Drug Interactions: Concomitant use of Vyvgart® with medications that bind to the human FcRn (e.g., immunoglobulin products, monoclonal antibodies, antibody derivates containing the human Fc domain of the IgG subclass) may lower systemic exposures and reduce effectiveness of such medications. Patients should be monitored closely for reduced effectiveness of medications that bind to the human FcRn. When concomitant long-term use of such medications is essential for patient care, discontinuing Vyvgart® and using alternative therapies should be considered.

Contraindication(s): None

Adverse Reactions: The most common adverse reactions (≥10%) occurring in patients with gMG treated with Vyvgart® were respiratory tract infection, headache, and urinary tract infection.

Efficacy: The safety and efficacy of Vyvgart® were established in a 26-week, multicenter, randomized, double-blind, placebo-controlled study. A total of

167 patients were enrolled in the study and met the following criteria at screening:

- MGFA clinical classification class II to IV; and
- MG-ADL total score ≥5; and
- On stable dose of gMG therapy prior to screening [i.e., acetylcholinesterase (AChE) inhibitors, corticosteroids, or non-steroidal immunosuppressive therapies (NSISTs), either in combination or alone]; and
- IgG level ≥6g/L.

Patients were randomized to receive either Vyvgart® (n=84) or placebo (n=83). The median MG-ADL total score was 9, and the median QMG total score was 16. Most patients (n=65 for Vyvgart®; n=64 for placebo) were positive for AChR antibodies.

- Primary Endpoint: Comparison of the percentage of MG-ADL responders (≥2-point MG-ADL improvement sustained for ≥4 weeks) during the first treatment cycle between treatment groups in the AChR antibody positive population
- Secondary Endpoint: Comparison of the percentage of QMG responders (≥3-point QMG improvement sustained for ≥4 weeks) during the first treatment cycle between both treatment groups in the AChR antibody positive population
- Results: For both endpoints, a statistically significant difference favoring Vyvgart® was observed. The MG-ADL responder rate, during the first treatment cycle, was 67.7% in the Vyvgart®-treated group vs. 29.7% in the placebo-treated group (P<0.0001). The QMG responder rate, during the first treatment cycle, was 63.1% in the Vyvgart®-treated group vs. 14.1% in the placebo-treated group (P<0.0001).

Cost: The Wholesale Acquisition Cost (WAC) of Vyvgart® is $5,950 per 400mg/20mL SDV, resulting in an estimated annual cost of $333,200 based on the recommended dose for an 80kg patient of 800mg once weekly for 4 weeks with subsequent cycles not being dosed sooner than 50 days from the start of the previous treatment cycle.

Cost Comparison: gMG Therapies

Medication	Cost for First Year	Cost Per Year for Maintenance
Vyvgart® (efgartigimod alfa-fcab)⁺	**$333,200**	**$333,200**
Ultomiris® (ravulizumab-cwvz)*	$550,744	$493,108
Soliris® (eculizumab)	$704,484	$678,392

Costs do not reflect rebated prices or net costs.
Cost of therapy calculated based on wholesale acquisition cost (WAC).
⁺Costs based on recommended dose for patients weighing 80kg.
*Costs based on recommended dosing for patients weighing 60kg to <100kg with gMG.

Recommendations

The College of Pharmacy recommends the prior authorization of Vyvgart® (efgartigimod alfa-fcab) with the following criteria:

Vyvgart® (Efgartigimod Alfa-fcab) Approval Criteria:

1. An FDA approved diagnosis of generalized myasthenia gravis (gMG); and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥5; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapy (IST); and
7. Vyvgart® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Next, the College of Pharmacy recommends the addition of prior authorization criteria for Ultomiris® for a diagnosis of gMG based on the new FDA approved indication:

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV; and
5. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapy (IST); and
7. Ultomiris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and

9. Prescriber must verify member is currently vaccinated against *Neisseria meningitidis*, unless the risks of delaying Ultomiris® treatment outweigh the risks of developing a meningococcal infection; and
10. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Additionally, the College of Pharmacy recommends updating the current prior authorization criteria for the following medications to be consistent with clinical practice (changes shown in red):

Empaveli® (Pegcetacoplan) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. ~~Must have an established diagnosis of PNH via international classification of disease (ICD) coding in member's medical claims history; and~~
3. An age restriction of 18 years and older will apply; and
4. Empaveli® must be prescribed by, or in consultation with, a gastroenterologist, hematologist, geneticist, or a specialist with expertise in the treatment of PNH; and
5. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Empaveli®; and
6. Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
7. For members switching from Soliris® to Empaveli®, prescriber must verify the member will continue the current dose of Soliris® for 4 weeks before switching to Empaveli® as monotherapy; and
8. For members switching from Ultomiris® to Empaveli®, prescriber must verify that Empaveli® will be initiated no more than 4 weeks after the last dose of Ultomiris®.

Enspryng® (Satralizumab-mwge) Approval Criteria:

1. An FDA approved indication of neuromyelitis optica spectrum disorder (NMOSD) in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤6.5; and

5. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
6. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
7. Enspryng® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
8. Prescriber must verify liver function tests have been assessed prior to initiation of treatment with Enspryng® and levels are acceptable to prescriber; and
9. Prescriber must agree to counsel the member to monitor for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
10. Prescriber must agree to monitor neutrophil counts 4 to 8 weeks after initiation of therapy and thereafter as clinically appropriate; and
11. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
12. Member and/or caregiver must be trained by a health care professional on subcutaneous administration and storage of Enspryng®; and
13. A quantity limit override for the loading dose will be approved upon meeting the Enspryng® approval criteria. A quantity limit of 1 syringe per 28 days will apply for the maintenance dose, according to the package labeling; and
14. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Soliris® (Eculizumab) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS)]:

1. Member must have an FDA approved diagnosis of aHUS; and
2. ~~Member must have an established diagnosis of aHUS or PNH via international classification of disease (ICD) coding in member's medical claims history; and~~
3. ~~For members younger than 18 years of age, approval can be granted with a documented diagnosis of aHUS; and~~
4. Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS.

Soliris® (Eculizumab) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. Member must have an FDA approved diagnosis of PNH; and

~~2. Member must have an established diagnosis of aHUS or PNH via international classification of disease (ICD) coding in member's medical claims history; and~~
3. An age restriction of 18 years and older will apply; and
4. Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or a specialist with expertise in the treatment of PNH.

Soliris® (Eculizumab) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
3. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
4. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
5. Member must meet 1 of the following:
    a. Failed treatment over 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; or
    b. Failed at least 1 IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIg); and
6. Soliris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
7. Initial approvals will be for the duration of 6 months at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Soliris® (Eculizumab) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have a history of at least 2 NMOSD attacks in last 12 months or 3 attacks in the last 24 months, with at least 1 attack in the past 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤7; and
5. Soliris® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and

6. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:

1. Member must have ~~a documented~~ an FDA approved diagnosis of aHUS; and
2. Ultomiris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. Member must have an ~~established~~ FDA approved diagnosis of PNH ~~via international classification of disease (ICD) coding in member's medical claims history~~; and
2. An age restriction of 18 years and older will apply; and
3. Ultomiris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or a specialist with expertise in the treatment of PNH.

Uplizna® (Inebilizumab-cdon) Approval Criteria:

1. An FDA approved indication of neuromyelitis optica spectrum disorder (NMOSD) in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months, or at least 2 attacks in the prior 24 months, requiring rescue therapy; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤8; and
5. Uplizna® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
7. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
8. Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
9. Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and

10. Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and
11. The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and
13. Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and
14. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
15. A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and
16. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Utilization Details of Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon): Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SOLIRIS INJ 10MG/ML	28	3	$541,738.53	$19,347.80	9.33
ULTOMIRIS INJ 300MG/30ML	12	2	$685,367.86	$57,113.99	6
ULTOMIRIS INJ 1,100MG/11ML	2	1	$140,911.34	$70,455.67	2
TOTAL	**42**	**4***	**$1,368,017.73**	**$32,571.85**	**10.5**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SOLIRIS INJ 10MG/ML (J1300)	5	1	$102,871.80	$20,574.36	5
ULTOMIRIS INJ 300/30ML (J1303)	12	4	$830,147.70	$69,178.98	3
TOTAL	**17⁺**	**5***	**$933,019.50**	**$54,883.50**	**3.4**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

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Appendix L

Fiscal Year 2022 Annual Review of Antidepressants and 30-Day Notice to Prior Authorize Auvelity™ (Dextromethorphan/Bupropion) and Venlafaxine 112.5mg Extended-Release (ER) Tablet

Oklahoma Health Care Authority
December 2022

Current Prior Authorization Criteria

Antidepressants*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram (Celexa®)			citalopram 30mg caps
escitalopram (Lexapro®)			citalopram 20mg/10mL soln (UDC)
fluoxetine caps (Prozac®)			escitalopram 10mg/10mL soln (UDC)
fluvoxamine (Luvox®)			fluoxetine 20mg/5mL soln (UDC)
paroxetine (Paxil®)			fluoxetine tabs
sertraline (Zoloft®)			fluoxetine DR (Prozac® Weekly™)
			fluvoxamine CR (Luvox CR®)
			paroxetine CR (Paxil CR®)
			paroxetine (Pexeva®)
			sertraline 150mg & 200mg caps
Dual-Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, XL®)	desvenlafaxine (Pristiq®)	desvenlafaxine (Khedezla®)	bupropion ER (Aplenzin®)
duloxetine (Cymbalta®)		levomilnacipran (Fetzima®)	bupropion ER (Forfivo XL®)

Antidepressants*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
mirtazapine (Remeron®, Remeron SolTab®)		nefazodone (Serzone®)	duloxetine (Drizalma Sprinkle™)
trazodone 50mg, 100mg, & 150mg tabs (Desyrel®)		vilazodone (Viibryd®)	duloxetine 40mg (Irenka™)
venlafaxine (Effexor®, Effexor XR® caps)			trazodone 300mg tabs (Desyrel®)
			venlafaxine ER tabs (Effexor XR® tabs)
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	isocarboxazid (Marplan®)
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
		vortioxetine (Trintellix®)	esketamine nasal spray (Spravato®)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
caps = capsules; CR = controlled-release; DR = delayed-release; ER = extended-release; PA = prior authorization; soln = solution; tabs = tablets; UDC = unit dose cups

Antidepressants Tier-2 Approval Criteria:

1. Member must have a documented, recent (within 6 months) trial of 2 Tier-1 medications at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response. Tier-1 selection must include at least 1 medication from the SSRI category; or
2. Prior stabilization on the Tier-2 medication documented within the last 100 days. A past history of success on the Tier-2 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by Tier-1 medications or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Antidepressants Tier-3 Approval Criteria:

1. Member must have a documented, recent (within 6 months) trial with 2 Tier-1 medications (Tier 1 selection must include at least 1 medication from the SSRI category) and a trial of a Tier-2 medication at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response; or

2. Prior stabilization on the Tier-3 medication documented within the last 100 days. A past history of success on the Tier-3 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by a lowered tiered medication or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Antidepressants Special Prior Authorization (PA) Approval Criteria:

1. Use of any Special PA medication will require a patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 medications; or
2. A petition may be submitted for consideration whenever a unique patient-specific situation exists; and
3. Tier structure rules still apply.
4. **Citalopram Capsule Approval Criteria:**
    a. An FDA approved indication of major depressive disorder (MDD) in adults; and
    b. Member must have initiated treatment with citalopram tablets for dose titration up to the 30mg dose; and
    c. A patient-specific, clinically significant reason why the member cannot use citalopram tablets, which are available without a prior authorization, in place of the capsule formulation must be provided; and
    d. Citalopram capsules will not be approved for members 60 years of age or older; and
    e. A quantity limit of 30 capsules per 30 days will apply.
5. **Citalopram 20mg/10mL Solution, Escitalopram 10mg/10mL Solution, and Fluoxetine 20mg/5mL Solution Unit Dose Cup (UDC) Approval Criteria:**
    a. An FDA approved indication; and
    b. A patient-specific, clinically significant reason why the member cannot use the bulk medication must be provided.
6. **Desyrel® (Trazodone 300mg Tablet) Approval Criteria:**
    a. A patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 products including 2 trazodone 150mg tablets or 3 trazodone 100mg tablets to achieve a 300mg dose must be provided.
7. **Drizalma Sprinkle™ (Duloxetine Capsule) Approval Criteria [Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]:**
    a. An FDA approved diagnosis of diabetic peripheral neuropathy or chronic musculoskeletal pain; and

b. A patient-specific, clinically significant reason why the member cannot use generic duloxetine 20mg, 30mg, or 60mg capsules, which are available without prior authorization, in place of Drizalma Sprinkle™ must be provided; and
c. A quantity limit of 30 capsules per 30 days will apply.

8. **Fluoxetine Tablet Approval Criteria:**
   a. Fluoxetine capsules are available without a prior authorization. The tablet formulation will require prior authorization and a patient-specific, clinically significant reason why the tablet formulation is required in place of the capsule formulation.
9. **Irenka™ (Duloxetine 40mg Capsule) Approval Criteria [Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]:**
   a. An FDA approved diagnosis of diabetic peripheral neuropathy or chronic musculoskeletal pain; and
   b. A patient-specific, clinically significant reason why the member cannot use 2 duloxetine 20mg capsules in place of Irenka™ 40mg capsules must be provided; and
   c. A quantity limit of 30 capsules per 30 days will apply; and
10. **Marplan® (Isocarboxazid) Approval Criteria:**
    a. A patient-specific, clinically significant reason why the member cannot use any of the Tier-3 monoamine oxidase inhibitors (MAOIs) or other cost-effective, lower tiered alternatives in place of Marplan® must be provided.
11. **Sertaline Capsule Approval Criteria:**
    a. An FDA approved indication of major depressive disorder (MDD) in adults or obsessive-compulsive disorder (OCD) in adults and pediatric patients 6 years of age and older; and
    b. Member must have initiated treatment with sertraline tablets for dose titration up to the 150mg or 200mg dose; and
    c. A patient-specific, clinically significant reason why the member cannot use sertraline tablets, which are available without a prior authorization, in place of the capsule formulation must be provided; and
    d. A quantity limit of 30 capsules per 30 days will apply.

Approval Criteria for Atypical Antipsychotics as Adjunctive Treatment of Major Depressive Disorder (MDD):*

1. For Rexulti® (brexpiprazole) or Symbyax® (olanzapine/fluoxetine), a diagnosis of MDD requires current use of an antidepressant and requires previous trials with at least 2 other antidepressants from both categories (an SSRI and a dual-acting antidepressant) and a trial of aripiprazole tablets that did not yield adequate response; and
2. Tier structure rules still apply.

*Rexulti® (brexpiprazole) and Symbyax® (olanzapine/fluoxetine) are reviewed annually with the atypical antipsychotic medications. A full review of these medications can be found in the June 2022 Drug Utilization Review (DUR) Board packet.

Spravato® (Esketamine Nasal Spray) Approval Criteria [Depressive Symptoms in Adults with Major Depressive Disorder (MDD) with Acute Suicidal Ideation or Behavior Diagnosis]:

1. An FDA approved indication of depressive symptoms in adults with MDD with acute suicidal ideation or behavior; and
2. Member must be 18 years of age or older; and
3. Spravato® must be used in conjunction with an oral antidepressant; and
4. Prescriber must agree that member will be monitored by a health care provider for at least 2 hours after each administration; and
5. Prescriber must agree that member's blood pressure will be monitored prior to and after administration of Spravato® in accordance with the Spravato® *Prescribing Information*; and
6. Member must not have any contraindications to therapy [i.e., aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation; intracerebral hemorrhage; hypersensitivity to esketamine, ketamine, or any of the excipients]; and
7. Member must not have severe hepatic impairment (Child Pugh C); and
8. Prescriber must verify that female member is not currently pregnant and will use effective contraception while receiving treatment with Spravato®; and
9. Prescriber must verify female member is not breastfeeding; and
10. Pharmacy and health care setting must be certified in the Spravato® Risk Evaluation and Mitigation Strategy (REMS) program; and
11. Member must be enrolled in the Spravato® REMS program; and
12. Spravato® must be administered under the direct observation of a health care provider in a REMS certified health care setting; and
13. For initial approval, the number of doses the member received while hospitalized, if applicable, and the dates of these doses must be provided to allow authorization of the appropriate quantity for the initial 4 weeks of treatment; and
14. For continued authorization, prescriber must verify member demonstrated an adequate response during the initial 4 weeks of treatment, verify member is using Spravato® in combination with an oral antidepressant, and provide patient-specific, clinically significant information to support continued use of Spravato®; and
15. A quantity limit of 8 kits per 28 days will apply.

Spravato® (Esketamine Nasal Spray) Approval Criteria [Treatment-Resistant Depression Diagnosis]:

1. An FDA approved indication of treatment-resistant depression in adults; and
2. Member must be 18 years of age or older; and
3. Spravato® must be used in conjunction with an oral antidepressant; and
4. Member must have had an inadequate response to at least 2 different antidepressants from different classes at least 4 weeks in duration each and titrated to recommended dosing during the current depressive episode, unless contraindicated or clinically significant adverse effects; and
5. Prescriber must agree that member will be monitored by a health care provider for at least 2 hours after each administration; and
6. Prescriber must agree that member's blood pressure will be monitored prior to and after administration of Spravato® in accordance with the Spravato® *Prescribing Information*; and
7. Member must not have any contraindications to therapy [e.g., aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation; intracerebral hemorrhage; hypersensitivity to esketamine, ketamine, or any of the excipients]; and
8. Member must not have severe hepatic impairment (Child Pugh C); and
9. Prescriber must verify that female member is not currently pregnant and will use effective contraception while receiving treatment with Spravato®; and
10. Prescriber must verify female member is not breastfeeding; and
11. Pharmacy and health care setting must be certified in the Spravato® Risk Evaluation and Mitigation Strategy (REMS) program; and
12. Member must be enrolled in the Spravato® REMS program; and
13. Spravato® must be administered under the direct observation of a health care provider in a REMS certified health care setting; and
14. Initial approvals will be for the duration of the induction phase. For continued authorization, prescriber must verify member demonstrated an adequate response during the induction phase and verify member is using Spravato® in combination with an oral antidepressant; and
15. A quantity limit of 4 kits per 28 days will apply for maintenance dosing.

Utilization of Antidepressants: Fiscal Year 2022

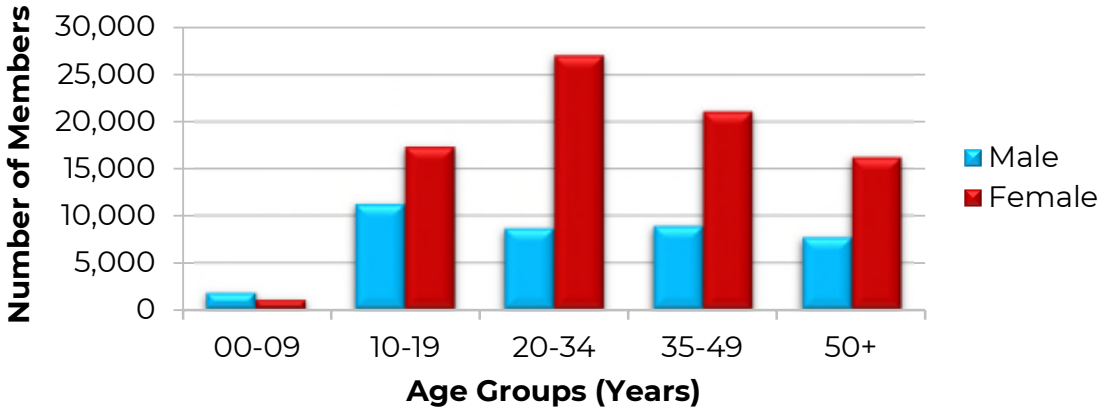
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	77,107	423,114	$7,188,461.98	$16.99	$0.45	18,333,691	15,853,396
2022	119,876	612,837	$10,349,951.94	$16.89	$0.43	27,659,629	23,931,353
% Change	**55.5%**	**44.8%**	**44.0%**	**-0.6%**	**-4.4%**	**50.9%**	**51.0%**
Change	**42,769**	**189,723**	**$3,161,489.96**	**-$0.10**	**-$0.02**	**9,325,938**	**8,077,957**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

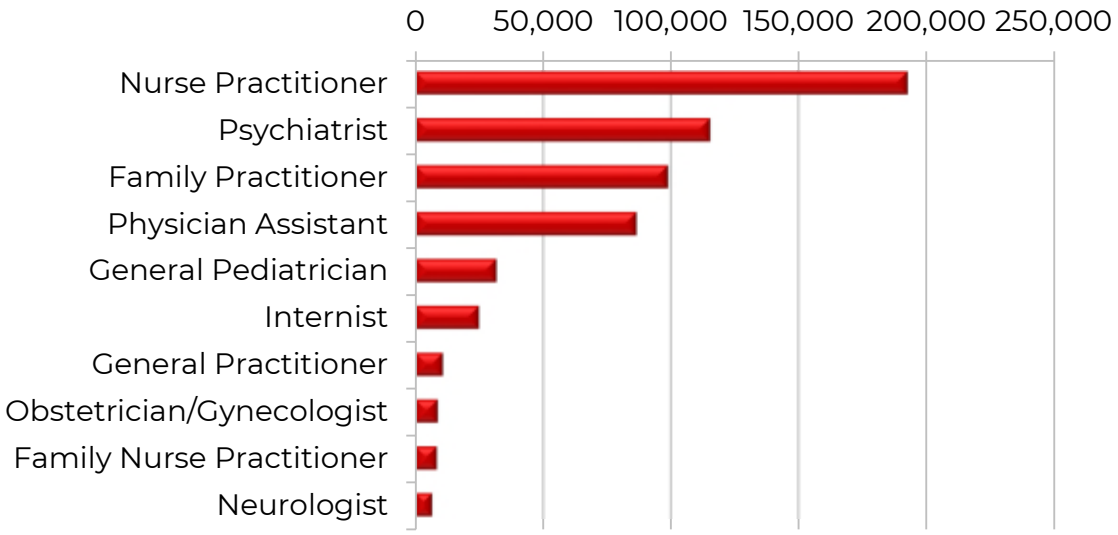
- There were no SoonerCare paid medical claims for antidepressants in fiscal year 2022 (07/01/2021 to 06/30/2022).
- The antidepressants are influenced by federal rebates. These rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.
    - Aggregate drug rebates collected during fiscal year 2022 for antidepressants: $1,905,338.67[Δ]

Demographics of Members Utilizing Antidepressants



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

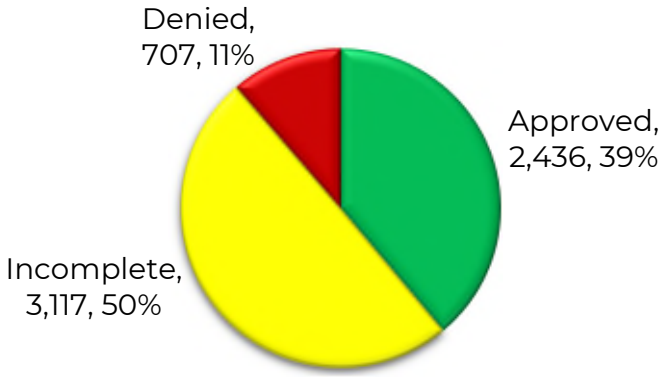
Top Prescriber Specialties of Antidepressants by Number of Claims



Prior Authorization of Antidepressants

There were 6,260 prior authorization requests submitted for antidepressants during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Pexeva® (paroxetine tablets): May 2025
- Aplenzin® [bupropion extended-release (ER) tablets]: June 2026
- Forfivo XL® (bupropion ER tablets): June 2027
- Trintellix® (vortioxetine tablets): March 2032
- Fetzima® (levomilnacipran ER capsules): May 2032
- Spravato® (esketamine nasal spray): September 2035
- Drizalma Sprinkle™ [duloxetine delayed-release (DR) capsules]: April 2037
- Auvelity™ (dextromethorphan/bupropion ER tablets): January 2040

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

- **June 2022:** The FDA approved a New Drug Application (NDA) for a new tablet formulation of ER venlafaxine for the indications of major depressive disorder (MDD) or generalized anxiety disorder (GAD) in adults. The new formulation is available as venlafaxine besylate 112.5mg ER tablets. Venlafaxine besylate ER tablets are not recommended for initial dosage, titration, or doses below 112.5mg once daily; however, venlafaxine besylate ER tablets can be initiated at a dose of 112.5mg once daily in patients who have received at least 75mg of another venlafaxine ER product for at least 4 days. The maximum recommended dose of venlafaxine besylate ER is 225mg once daily. The efficacy of venlafaxine besylate ER tablets for the treatment of MDD and GAD in adults was based upon adequate and well-controlled studies of venlafaxine ER capsules. Effexor XR® (venlafaxine hydrochloride ER) is available generically and is supplied as ER tablets in 4 strengths, 37.5mg, 75mg, 150mg, and 225mg and as ER capsules in 3 strengths, 37.5mg, 75mg, and 150mg.
- **August 2022:** The FDA approved Auvelity™ (dextromethorphan hydrobromide/bupropion hydrochloride) ER tablets for the treatment of MDD in adults. It is the first and only N-methyl D-aspartate (NMDA) receptor antagonist approved for the treatment of MDD. The efficacy of Auvelity™ in the treatment of MDD was demonstrated in the GEMINI placebo-controlled study and confirmatory evidence which included the ASCEND study comparing Auvelity™ to bupropion sustained-release (SR) tablets.

Pipeline:

- **Psilocybin:** A phase 2 study is underway to evaluate the use of psilocybin for MDD. Data suggests that psilocybin may have behavioral effects relevant to the treatment of depression, and it may have possible antidepressant properties. To test this, patients with MDD were randomized in a 1:1 ratio to receive a 25mg oral dose of psilocybin or a single 100mg dose of niacin, which will serve as an active placebo. The purpose of the study is to assess the differences between groups in changes in depressive symptoms from baseline to day 43 post dose. In October 2022, the Phase 3 design was presented to the FDA and is expected to start following the completion of the Phase 2 study. The Phase 2 study is expected to be completed in December 2022.
- **Zuranolone:** Sage Therapeutics and Biogen announced additional data from the Phase 3 SKYLARK study of zuranolone in adult women with postpartum depression (PPD). Zuranolone (SAGE-217/BIIB125) is a once-daily, 14-day, investigational drug in development for treatment of MDD and PPD. If approved, it would be the first oral medication specifically for PPD. The SKYLARK study achieved primary and all key secondary

endpoints, with participants demonstrating rapid and significant improvements in depressive symptoms as early as day 3 and sustained through day 45. Women with PPD were treated with zuranolone 50mg and showed a significant and clinically meaningful improvement in depressive symptoms at day 15 compared to placebo. Sage and Biogen plan to submit an NDA to the FDA in the first half of 2023.

Auvelity™ (Dextromethorphan/Bupropion) Product Summary[6]

Indication(s): Auvelity™ is a combination of dextromethorphan, an NMDA receptor antagonist and sigma-1 receptor agonist, and bupropion, an aminoketone and CYP450 2D6 inhibitor, indicated for the treatment of MDD in adults.

Boxed Warning: Risk for Suicidal Thoughts and Behaviors

- Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. All antidepressant-treated patients should be closely monitored for clinical worsening and emergence of suicidal thoughts and behaviors.
- Auvelity™ is not approved for use in pediatric patients.

How Supplied: 45mg/105mg dextromethorphan/bupropion ER tablets

Dosing and Administration:

- Prior to initiating treatment and during treatment with Auvelity™:
  - Blood pressure should be assessed and monitored periodically during treatment.
  - Patients should be screened for a personal or family history of bipolar disorder, mania, or hypomania.
  - Patients should be screened to determine if they are receiving any other medications that contain bupropion or dextromethorphan.
- The recommended starting dose is 1 tablet once daily in the morning. After 3 days, the dose should be increased to the maximum recommended dosage of 1 tablet twice daily, separated by at least 9 hours. Patients should not exceed 2 doses within the same day.
- Tablets should be swallowed whole and should not be crushed, divided, or chewed.
- For moderate renal impairment or CYP2D6 poor metabolizers, the recommended dose is 1 tablet by mouth once daily in the morning.

Mechanism of Action:

- Dextromethorphan is a noncompetitive antagonist of the NMDA receptor and a sigma-1 receptor agonist.

- Bupropion increases plasma levels of dextromethorphan by competitively inhibiting cytochrome P450 2D6, which catalyzes a major biotransformation pathway for dextromethorphan.

Contraindication(s):

- Seizure disorder
- Current or prior diagnosis of bulimia or anorexia nervosa
- Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs
- Concomitant use of monoamine oxidase inhibitors (MAOIs) or within 14 days of discontinuing an MAOI
- Known hypersensitivity to bupropion, dextromethorphan, or other components of Auvelity™

Safety:

- Seizures: Bupropion, a component of Auvelity™, can cause seizures. The risk of seizures with bupropion is dose-related. Because the risk of seizures with bupropion is dose-related patients should be screened for other bupropion-containing products prior to initiating Auvelity™. If concomitant use of Auvelity™ with other bupropion-containing products is clinically warranted, patients should be informed of the risk of seizures. Auvelity™ should be discontinued and treatment with Auvelity™ should not be restarted if a patient experiences a seizure.
- Increased Blood Pressure and Hypertension: Bupropion can cause elevated blood pressure and hypertension. The risk of hypertension is increased if Auvelity™ is used concomitantly with MAOIs or other drugs that increase the dopaminergic or noradrenergic activity. Blood pressure should be assessed prior to initiating treatment and should be periodically monitored during treatment with Auvelity™.
- Activation of Mania or Hypomania: Antidepressant treatment can precipitate a manic, mixed, or hypomanic manic episode. The risk appears to be increased in patients with bipolar disorder or who have risk factors for bipolar disorder. Prior to initiating Auvelity™, patients should be screened for a history of bipolar disorder and the presence of risk factors for bipolar disorder.
- Psychosis and Other Neuropsychiatric Reactions: Depressed patients treated with bupropion have had a variety of neuropsychiatric signs and symptoms, including delusions, hallucinations, psychosis, concentration disturbance, paranoia, and confusion. Dextromethorphan overdose can cause toxic psychosis, stupor, coma, and hyperexcitability. The risks of neuropsychiatric reactions are dose-related. Patients should be screened for use of other bupropion- or dextromethorphan-containing products prior to initiating Auvelity™. If concomitant use of Auvelity™ with other bupropion- or dextromethorphan-containing products is clinically warranted, patients

should be monitored for neuropsychiatric reactions and should be instructed to contact a health care provider if such reactions occur.

- Angle-Closure Glaucoma: The pupillary dilation that occurs following the use of many antidepressant drugs including bupropion may trigger an angle closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy. Use of antidepressants, including Auvelity™, should be avoided in patients with untreated anatomically narrow angles.
- Dizziness: Auvelity™ may cause dizziness. Precautions should be taken to reduce the risk of falls, particularly in patients with motor impairment affecting gait or those with a history of falls. Patients should be cautioned about operating hazardous machinery, including motor vehicles, until they are reasonably certain that Auvelity™ therapy does not affect them adversely.
- Serotonin Syndrome: Concomitant use of Auvelity™ with selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants may cause serotonin syndrome, a potentially life-threatening condition with changes including altered mental status, hypertension, restlessness, myoclonus, hyperthermia, hyperreflexia, diaphoresis, shivering, and tremor. Patients should be screened for use of other dextromethorphan-containing products prior to initiating Auvelity™. If concomitant use of Auvelity™ with other serotonergic drugs is clinically warranted, patients should be informed of the increased risk of serotonin syndrome and should be monitored for symptoms. If symptoms of serotonin syndrome occur, Auvelity™ and/or concomitant serotonergic drug should be discontinued immediately and supportive symptomatic treatment should be initiated.
- Embryo-fetal Toxicity: Based on animal studies, Auvelity™ may cause fetal harm when administered during pregnancy. In developmental toxicity studies in rats and rabbits, when a combination of dextromethorphan/quinidine was given to pregnant animals, fetal malformations (rabbits) and embryo lethality were demonstrated in offspring. The separate effect of dextromethorphan on developmental toxicity at the recommended clinical dose is unclear. Treatment with Auvelity™ should be discontinued in pregnant females, and the patient should be advised about the potential risk to the fetus. Alternative treatment should be used for females who are planning to become pregnant.

Adverse Reactions:

- Most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) in clinical studies were dizziness, headache, diarrhea, somnolence, dry mouth, sexual dysfunction, and hyperhidrosis.

Efficacy: The efficacy of Auvelity™ for treatment of MDD in adults was demonstrated in a placebo-controlled clinical study known as GEMINI and confirmatory evidence from the ASCEND study which compared Auvelity™ to bupropion SR tablets.

- In the **GEMINI study**, adult patients who met the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria for MDD were randomized to receive Auvelity™ (N=156) or placebo (N=162) twice daily for 6 weeks. The primary outcome was the change from baseline to week 6 in the total score of the Montgomery-Asberg Depression Rating Scale (MADRS). MADRS is a clinician-rated scale used to assess the severity of depressive symptoms. Scores range from 0 to 60, with higher scores indicating more severe depression. Auvelity™ was statistically significantly superior to placebo in improvements of depressive symptoms. The mean baseline MADRS total score was 33.6 [standard deviation (SD): 4.4] in the Auvelity™ group and 33.2 (SD: 4.4) in the placebo group. At week 6, the least-squares (LS) mean change from baseline in the MADRS total score was -15.9 [standard error (SE): 0.9] in the Auvelity™ group compared to -12.1 (0.9) in the placebo group [LS mean difference: -3.9; 95% confidence interval (CI): -6.4, -1.4].
- In the **ASCEND study**, patients with MDD were randomized to receive Auvelity™ or bupropion SR 105mg tablets twice daily for 6 weeks. The primary outcome calculated by assessing the change from baseline in the total MADRS score at each on-site visit from week 1 to 6 and then taking the average of those scores. The results showed treatment with Auvelity™ compared to bupropion demonstrated an average decrease of MADRS points of 13.7 versus 8.8 with bupropion, which showed that dextromethorphan contributes to the antidepressant properties of Auvelity™.

Cost: The wholesale acquisition cost (WAC) of Auvelity™ is $17.47 per tablet, resulting in an estimated monthly cost of $1,048.20 and annual cost of $12,578.40 based on the recommended dose of 1 tablet twice a day.

Cost Comparison: Venlafaxine ER Products

Product	Cost Per Unit	Cost Per 30 Days
Venlafaxine besylate ER tab 112.5mg	**$6.17**	**$185.10**
Venlafaxine HCl ER cap 75mg	$0.11	$3.30
Venlafaxine HCl ER tab 75mg	$3.17	$95.10
Venlafaxine HCl ER cap 150mg	$0.14	$4.20
Venlafaxine HCl ER tab 150mg	$3.45	$103.50
Venlafaxine HCl ER tab 225mg	$13.24	$397.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based once daily dosing of each strength.
Unit = capsule or tablet
cap = capsule; ER = extended release; HCl = hydrochloride; tab = tablet

Recommendations

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

1. Prior authorization of Auvelity™ (dextromethorphan/bupropion) and placement in the Special PA Tier; and
2. Prior authorization of venlafaxine 112.5mg ER tablet and placement in the Special PA Tier.

Antidepressants*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram (Celexa®)			citalopram 30mg caps
escitalopram (Lexapro®)			citalopram 20mg/10mL soln (UDC)
fluoxetine caps (Prozac®)			escitalopram 10mg/10mL soln (UDC)
fluvoxamine (Luvox®)			fluoxetine 20mg/5mL soln (UDC)
paroxetine (Paxil®)			fluoxetine tabs
sertraline (Zoloft®)			fluoxetine DR (Prozac® Weekly™)
			fluvoxamine CR (Luvox CR®)
			paroxetine CR (Paxil CR®)
			paroxetine (Pexeva®)
			sertraline 150mg & 200mg
Dual-Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, XL®)	desvenlafaxine (Pristiq®)	desvenlafaxine (Khedezla®)	bupropion ER (Aplenzin®)
duloxetine (Cymbalta®)		levomilnacipran (Fetzima®)	bupropion ER (Forfivo XL®)
mirtazapine (Remeron®, Remeron SolTab®)		nefazodone (Serzone®)	duloxetine (Drizalma Sprinkle™)
trazodone 50mg, 100mg, & 150mg tabs (Desyrel®)		vilazodone (Viibryd®)	duloxetine 40mg (Irenka™)

Antidepressants*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
venlafaxine (Effexor®, Effexor XR® caps)			trazodone 300mg tabs (Desyrel®)
			venlafaxine 112.5mg ER tab
			venlafaxine ER tabs (Effexor XR® tabs)
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	isocarboxazid (Marplan®)
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
		vortioxetine (Trintellix®)	**dextromethorphan/ bupropion (Auvelity™)**
			esketamine nasal spray (Spravato®)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
caps = capsules; CR = controlled-release; DR = delayed-release; ER = extended-release; PA = prior authorization; soln = solution; tabs = tablets; UDC = unit dose cups

Antidepressants Special Prior Authorization (PA) Approval Criteria:

1. Use of any Special PA medication will require a patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 medications; or
2. A petition may be submitted for consideration whenever a unique patient-specific situation exists; and
3. Tier structure rules still apply.
4. **Auvelity™ (Dextromethorphan/Bupropion) Approval Criteria:**
   a. An FDA approved indication of major depressive disorder; and
   b. Member must be 18 years of age or older; and
   c. Prescriber must agree that member's blood pressure will be assessed prior to treatment initiation and monitored periodically during treatment; and
   d. Prescriber must agree to screen members for history of bipolar disorder, mania, or hypomania; and
   e. Member must not be taking any other medications containing bupropion or dextromethorphan; and
   f. Member must not have any contraindications to therapy (i.e., seizure disorder; current or prior diagnosis of bulimia or anorexia nervosa; abrupt discontinuation of alcohol, benzodiazepines,

barbiturates, and antiepileptic drugs; concomitant use of a monoamine-oxidase inhibitor (MAOI) or within 14 days of discontinuing an MAOI; known hypersensitivity to bupropion, dextromethorphan, or other components of Auvelity™); and
   g. Member must not have severe hepatic or renal impairment; and
   h. The maximum approvable dose is 1 tablet once daily if the member has moderate renal impairment, is taking a strong CYP2D6 inhibitor (e.g., paroxetine, fluoxetine, quinidine, bupropion), or is a known poor CYP2D6 metabolizer; and
   i. Prescribers must verify that female members are not currently pregnant and will use effective contraception while receiving treatment with Auvelity™; and
   j. A quantity limit of 60 tablets per 30 days will apply.
5. **Citalopram Capsule Approval Criteria**
   a. An FDA approved indication of major depressive disorder (MDD) in adults; and
   b. Member must have initiated treatment with citalopram tablets for dose titration up to the 30mg dose; and
   c. A patient-specific, clinically significant reason why the member cannot use citalopram tablets, which are available without a prior authorization, in place of the capsule formulation must be provided; and
   d. Citalopram capsules will not be approved for members 60 years of age or older; and
   e. A quantity limit of 30 capsules per 30 days will apply.
6. **Citalopram 20mg/10mL Solution, Escitalopram 10mg/10mL Solution, and Fluoxetine 20mg/5mL Solution Unit Dose Cup (UDC) Approval Criteria:**
   a. An FDA approved indication; and
   b. A patient-specific, clinically significant reason why the member cannot use the bulk medication must be provided.
7. **Desyrel® (Trazodone 300mg Tablet) Approval Criteria:**
   a. A patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 products including 2 trazodone 150mg tablets or 3 trazodone 100mg tablets to achieve a 300mg dose must be provided.
8. **Drizalma Sprinkle™ (Duloxetine Capsule) Approval Criteria [Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]:**
   a. An FDA approved diagnosis of diabetic peripheral neuropathy or chronic musculoskeletal pain; and
   b. A patient-specific, clinically significant reason why the member cannot use generic duloxetine 20mg, 30mg, or 60mg capsules,

which are available without prior authorization, in place of Drizalma Sprinkle™ must be provided; and
    c. A quantity limit of 30 capsules per 30 days will apply.
9. **Fluoxetine Tablet Approval Criteria:**
    a. Fluoxetine capsules are available without a prior authorization. The tablet formulation will require prior authorization and a patient-specific, clinically significant reason why the tablet formulation is required in place of the capsule formulation.
10. **Irenka™ (Duloxetine 40mg Capsule) Approval Criteria [Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]:**
    a. An FDA approved diagnosis of diabetic peripheral neuropathy or chronic musculoskeletal pain; and
    b. A patient-specific, clinically significant reason why the member cannot use 2 duloxetine 20mg capsules in place of Irenka™ 40mg capsules must be provided; and
    c. A quantity limit of 30 capsules per 30 days will apply; and
11. **Marplan® (Isocarboxazid) Approval Criteria:**
    a. A patient-specific, clinically significant reason why the member cannot use any of the Tier-3 monoamine oxidase inhibitors (MAOIs) or other cost-effective, lower tiered alternatives in place of Marplan® must be provided.
12. **Sertraline Capsule Approval Criteria:**
    a. An FDA approved indication of major depressive disorder (MDD) in adults or obsessive-compulsive disorder (OCD) in adults and pediatric patients 6 years of age and older; and
    b. Member must have initiated treatment with sertraline tablets for dose titration up to the 150mg or 200mg dose; and
    c. A patient-specific, clinically significant reason why the member cannot use sertraline tablets, which are available without a prior authorization, in place of the capsule formulation must be provided; and
    d. A quantity limit of 30 capsules per 30 days will apply.
13. **Venlafaxine 112.5mg Extended-Release (ER) Tablet Approval Criteria:**
    a. An FDA approved indication of major depressive disorder (MDD) or generalized anxiety disorder (GAD); and
    b. Member must be 18 years of age or older; and
    c. Member must have received at least 75mg of venlafaxine ER capsules for at least 4 days; and
    d. A patient-specific, clinically significant reason why the member cannot use venlafaxine ER capsules must be provided; and
    e. A quantity limit of 30 tablets per 30 days will apply.

Utilization Details of Antidepressants: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 MEDICATIONS						
SERTRALINE PRODUCTS						
SERTRALINE TAB 50MG	44,714	16,819	$546,422.60	$12.22	2.66	5.28%
SERTRALINE TAB 100MG	43,478	11,328	$548,827.38	$12.62	3.84	5.30%
SERTRALINE TAB 25MG	22,596	9,222	$278,001.61	$12.30	2.45	2.69%
SERTRALINE 20MG/ML	939	261	$45,724.63	$48.69	3.59	0.44%
ZOLOFT TAB 100MG	2	1	$2,183.45	$1,091.73	2	0.02%
SUBTOTAL	**111,729**	**37,631**	**$1,421,159.67**	**$121.17**	**2.97**	**13.73%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 50MG	43,388	14,175	$457,029.07	$10.53	3.06	4.42%
TRAZODONE TAB 100MG	33,848	9,451	$399,640.40	$11.81	3.58	3.86%
TRAZODONE TAB 150MG	18,146	4,571	$258,760.55	$14.26	3.97	2.50%
SUBTOTAL	**95,382**	**28,197**	**$1,115,430.02**	**$11.69**	**3.38**	**10.78%**
FLUOXETINE PRODUCTS						
FLUOXETINE CAP 20MG	41,439	13,967	$437,164.23	$10.55	2.97	4.22%
FLUOXETINE CAP 40MG	22,310	6,336	$266,336.01	$11.93	3.52	2.57%
FLUOXETINE CAP 10MG	20,307	7,873	$244,299.15	$12.03	2.58	2.36%
PROZAC CAP 20MG	13	2	$20,740.52	$1,595.42	6.5	0.20%
PROZAC CAP 40MG	11	1	$10,878.22	$988.93	11	0.11%
SUBTOTAL	**84,080**	**28,179**	**$979,418.13**	**$11.65**	**2.98**	**9.46%**
ESCITALOPRAM PRODUCTS						
ESCITALOPRAM TAB 10MG	35,802	13,887	$439,898.00	$12.29	2.58	4.25%
ESCITALOPRAM TAB 20MG	30,519	8,481	$411,038.23	$13.47	3.59	3.97%
ESCITALOPRAM TAB 5MG	6,986	3,141	$86,745.58	$12.42	2.22	0.84%
ESCITALOPRAM 5MG/5ML	330	79	$36,537.13	$110.72	4.18	0.44%
SUBTOTAL	**73,637**	**25,588**	**$974,218.94**	**$13.23**	**2.88**	**9.5%**
BUPROPION PRODUCTS						
BUPROPION TAB 150MG XL	23,477	9,066	$396,302.85	$16.88	2.59	3.83%
BUPROPION TAB 300MG XL	16,909	4,939	$298,274.43	$17.64	3.42	2.88%
BUPROPION TAB 150MG SR	11,425	4,018	$185,263.18	$16.22	2.84	0.84%
BUPROPION TAB 100MG SR	4,527	1,710	$66,050.99	$14.59	2.65	0.64%
BUPROPION TAB 200MG SR	2,460	678	$41,920.16	$17.04	3.63	0.41%
BUPROPION TAB 75MG	2,453	949	$38,000.42	$15.49	2.58	0.37%
BUPROPION TAB 100MG	1,770	598	$30,484.59	$17.22	2.96	0.29%
WELLBUTRIN TAB XL 150MG	17	3	$54,878.65	$3,228.16	5.67	0.53%
SUBTOTAL	**63,038**	**21,961**	**$1,111,175.27**	**$17.63**	**2.87**	**9.79%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 60MG	26,732	7,395	$445,277.35	$16.66	3.61	4.30%
DULOXETINE CAP 30MG	19,136	7,451	$290,027.35	$15.16	2.57	2.80%
DULOXETINE CAP 20MG	4,464	1,858	$71,359.64	$15.99	2.4	0.69%
CYMBALTA CAP 60MG	11	2	$3,464.13	$314.92	5.5	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**50,343**	**16,706**	**$810,128.47**	**$16.09**	**3.01**	**7.82%**
CITALOPRAM PRODUCTS						
CITALOPRAM TAB 20MG	17,512	6,414	$169,934.87	$9.70	2.73	1.64%
CITALOPRAM TAB 40MG	10,737	3,110	$108,796.56	$10.13	3.45	1.05%
CITALOPRAM TAB 10MG	8,505	3,432	$84,235.16	$9.90	2.48	0.81%
CITALOPRAM 10MG/5ML	199	79	$11,148.87	$56.02	2.52	0.11%
SUBTOTAL	**36,953**	**13,035**	**$374,115.46**	**$10.12**	**2.83**	**3.61%**
MIRTAZAPINE PRODUCTS						
MIRTAZAPINE TAB 15MG	16,362	5,390	$198,438.66	$12.13	3.04	1.92%
MIRTAZAPINE TAB 30MG	8,743	2,587	$116,586.30	$13.33	3.38	1.12%
MIRTAZAPINE TAB 45MG	3,030	734	$42,731.28	$14.10	4.13	0.41%
MIRTAZAPINE TAB 7.5MG	2,541	920	$85,403.92	$33.61	2.76	0.83%
MIRTAZAPINE 15MG ODT	327	119	$9,566.60	$29.26	2.75	0.09%
MIRTAZAPINE 30MG ODT	171	49	$5,006.14	$29.28	3.49	0.05%
MIRTAZAPINE 45MG ODT	115	34	$3,962.24	$34.45	3.38	0.04%
SUBTOTAL	**31,289**	**9,833**	**$461,695.14**	**$14.76**	**3.18**	**4.46%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE CAP 150MG ER	13,014	3,227	$220,800.58	$16.97	4.03	2.13%
VENLAFAXINE CAP 75MG ER	11,251	4,042	$168,021.72	$14.93	2.78	1.62%
VENLAFAXINE CAP 37.5MG ER	5,800	2,802	$82,166.05	$14.67	2.07	0.79%
VENLAFAXINE TAB 75MG	2,049	650	$31,250.04	$15.25	3.15	0.30%
VENLAFAXINE TAB 37.5MG	982	437	$13,336.23	$13.58	2.25	0.13%
VENLAFAXINE TAB 100MG	650	177	$10,719.39	$16.49	3.67	0.10%
VENLAFAXINE TAB 50MG	291	108	$4,715.39	$16.20	2.69	0.05%
VENLAFAXINE TAB 25MG	190	88	$3,030.03	$15.95	2.16	0.03%
EFFEXOR XR CAP 75MG	8	1	$3,858.45	$482.31	8	0.04%
EFFEXOR XR CAP 150MG	4	2	$5,201.70	$1300.43	2	0.05%
SUBTOTAL	**34,239**	**11,536**	**$543,099.58**	**$15.86**	**2.97**	**5.24%**
PAROXETINE PRODUCTS						
PAROXETINE TAB 20MG	6,417	2,425	$70,800.46	$11.03	2.65	0.68%
PAROXETINE TAB 40MG	4,503	1,193	$65,440.64	$14.53	3.77	0.63%
PAROXETINE TAB 10MG	3,452	1,506	$44,234.51	$12.81	2.29	0.43%
PAROXETINE TAB 30MG	2,002	622	$26,373.76	$13.17	3.22	0.25%
PAROXETINE 10MG/5ML	42	11	$17,450.04	$415.48	3.82	0.17%
PAXIL 10MG/5ML	41	9	$12,052.04	$293.95	4.56	0.12%
SUBTOTAL	**16,457**	**5,766**	**$236,351.45**	**$14.36**	**2.85**	**2.28%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE TAB 100MG	1,790	357	$49,345.87	$27.57	5.01	0.48%
FLUVOXAMINE TAB 50MG	1,717	472	$38,810.73	$22.60	3.64	0.37%
FLUVOXAMINE TAB 25MG	610	181	$12,106.86	$19.85	3.37	0.12%
SUBTOTAL	**4,117**	**1,010**	**$100,263.46**	**$24.35**	**4.08**	**0.97%**
TIER-1 SUBTOTAL	**601,264**	**118,909***	**$8,126,052.69**	**$13.52**	**5.06**	**78.51%**
TIER-2 MEDICATIONS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE TAB 50MG ER	2,066	640	$65,563.18	$31.73	3.23	0.63%
DESVENLAFAXINE TAB 100MG ER	1,839	429	$61,057.46	$33.20	4.29	0.59%
DESVENLAFAXINE TAB 25MG ER	571	234	$18,202.59	$31.88	2.44	0.18%
PRISTIQ TAB 100MG	5	1	$4,567.66	$913.53	5	0.04%
SUBTOTAL	**4,481**	**1,304**	**$149,390.89**	**$33.33**	**3.44**	**1.44%**
TIER-2 SUBTOTAL	**4,481**	**1,016***	**$149,390.89**	**$33.33**	**3.44**	**1.44%**
TIER-3 MEDICATIONS						
VORTIOXETINE PRODUCTS						
TRINTELLIX TAB 20MG	1,612	274	$650,936.29	$403.80	5.88	6.29%
TRINTELLIX TAB 10MG	952	269	$397,319.76	$417.35	3.54	3.84%
TRINTELLIX TAB 5MG	209	66	$85,076.11	$407.06	3.17	0.82%
SUBTOTAL	**2,773**	**609**	**$1,133,332.16**	**$408.70**	**4.55**	**10.95%**
VILAZODONE PRODUCTS						
VIIBRYD TAB 40MG	951	168	$281,736.83	$296.25	5.66	2.72%
VIIBRYD TAB 20MG	475	121	$143,145.50	$301.36	3.93	1.38%
VIIBRYD TAB 10MG	82	35	$26,873.93	$327.73	2.34	0.26%
VILAZODONE TAB 40MG	21	21	$3,877.68	$184.65	1	0.04%
VILAZODONE TAB 20MG	16	16	$3,567.57	$222.97	1	0.03%
VILAZODONE TAB 10MG	2	2	$510.66	$255.33	1	0.00%
SUBTOTAL	**1,547**	**363**	**$459,712.17**	**$297.16**	**4.26**	**4.43%**
LEVOMILNACIPRAN PRODUCTS						
FETZIMA CAP 120MG	79	10	$34,286.70	$434.01	7.9	0.33%
FETZIMA CAP 80MG	42	8	$18,179.77	$432.85	5.25	0.18%
FETZIMA CAP 40MG	4	3	$1,734.86	$433.72	1.33	0.02%
FETZIMA CAP TITRATION	2	2	$822.44	$411.22	1	0.01%
SUBTOTAL	**127**	**23**	**$55,023.77**	**$433.26**	**5.52**	**0.54%**
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE TAB 50MG ER	50	22	$7,029.64	$140.59	2.27	0.07%
DESVENLAFAXINE TAB 100MG ER	13	9	$3,546.97	$272.84	1.44	0.03%
SUBTOTAL	**63**	**31**	**$10,574.61**	**$167.85**	**2.03**	**0.1%**
TRANYLCYPROMINE PRODUCTS						
TRANYLCYPROMINE TAB 10MG	6	1	$1,026.12	$171.02	6	0.01%
SUBTOTAL	**6**	**1**	**$1,026.12**	**$171.02**	**6**	**0.01%**
TIER-3 SUBTOTAL	**4,516**	**808***	**$1,659,670.83**	**$367.51**	**4**	**16.04%**
SPECIAL PRIOR AUTHORIZATION (PA) MEDICATIONS						
FLUOXETINE PRODUCTS						
FLUOXETINE SOL 20MG/5ML	1,650	376	$94,098.96	$57.03	4.39	0.91%
FLUOXETINE TAB 10MG	292	95	$4,685.62	$17.88	3.07	0.05%
FLUOXETINE TAB 20MG	111	28	$2,540.02	$22.88	3.96	0.02%
FLUOXETINE CAP 90MG DR	46	5	$7,365.36	$160.12	9.2	0.07 %
FLUOXETINE TAB 60MG	13	4	$367.31	$28.25	3.25	0.00%
SUBTOTAL	**2,112**	**508**	**$109,057.27**	**$51.63**	**4.15**	**2.08%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PAROXETINE PRODUCTS						
PAROXETINE TAB 25MG ER	114	17	$5,250.34	$46.06	6.71	0.05%
PAROXETINE TAB 37.5MG ER	70	11	$2,764.15	$39.49	6.36	0.03%
PAROXETINE TAB 12.5MG ER	30	7	$1,227.92	$40.93	4.29	0.01%
SUBTOTAL	**214**	**35**	**$9,242.41**	**$43.19**	**6.11**	**0.09%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE CAP 150MG ER	105	13	$28,555.19	$271.95	8.08	0.28%
FLUVOXAMINE CAP 100MG ER	20	5	$4,725.92	$236.30	4	0.05%
SUBTOTAL	**125**	**18**	**$33,281.11**	**$508.25**	**12.08**	**0.33%**
ESKETAMINE PRODUCTS						
SPRAVATO 84MG DOSE	66	12	$232,830.09	$3,527.73	5.5	2.25%
SPRAVATO 56MG DOSE	9	5	$23,656.84	$2,628.54	1.8	0.23%
SUBTOTAL	**75**	**17**	**$256,486.93**	**$6,156.27**	**7.3**	**2.48%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 40MG	24	4	$3,485.61	$145.23	6	0.03%
DRIZALMA CAP 20MG DR	1	1	$386.99	$386.99	1	0.00%
SUBTOTAL	**25**	**5**	**$3,872.60**	**$154.90**	**5**	**0.03%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE TAB 225MG ER	18	3	$1,902.79	$105.71	6	0.02%
VENLAFAXINE TAB 75MG ER	5	2	$707.93	$141.56	2.5	0.01%
SUBTOTAL	**23**	**5**	**$2,610.72**	**$113.51**	**4.6**	**0.03%**
BUPROPION PRODUCTS						
BUPROPION TAB 450MG XL	1	1	$128.08	$128.08	1	0.00%
SUBTOTAL	**1**	**1**	**$128.08**	**$128.08**	**1**	**0.00%**
SERTRALINE PRODUCTS						
SERTRALINE CAP 150MG	1	1	$158.41	$158.41	1	0.00%
SUBTOTAL	**1**	**1**	**$158.41**	**$158.41**	**1**	**0.00%**
SPECIAL PA SUBTOTAL	**2,576**	**589***	**$414,837.53**	**$161.04**	**4.37**	**4.01%**
TOTAL	**612,837**	**119,876***	**$10,349,951.94**	**$16.89**	**5.11**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DR = delayed-release; ER = extended-release; ODT = orally disintegrating tablet; SR = sustained-release; TAB = tablet; XL = extended-release
Fiscal Year 2021 = 07/01/2021 to 06/30/2022

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[2] Venlafaxine Extended-Release Tablets Prescribing Information. Norwich Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215429s000lbl.pdf. Last revised 06/2022. Last accessed 11/16/2022.
[3] Axsome Therapeutics, Inc. Axsome Therapeutics Announces FDA Approval of Auvelity™, the First and Only Oral NMDA Receptor Antagonist for the Treatment of Major Depressive Disorder in Adults. Available online at: https://www.globenewswire.com/news-release/2022/08/19/2501453/33090/en/Axsome-Therapeutics-Announces-FDA-Approval-of-AUVELITY-the-First-and-Only-Oral-NMDA-Receptor-Antagonist-for-the-Treatment-of-Major-Depressive-Disorder-in-Adults.html. Issued 08/19/2022. Last accessed 11/21/2022.
[4] Sage Therapeutics, Biogen Report Further Analyses from Zuranolone Trial in Postpartum Depression. *Nasdaq*. Available online at: https://www.nasdaq.com/articles/sage-therapeutics-biogen-report-further-analyses-from-zuranolone-trial-in-postpartum. Issued 10/17/2022. Last accessed 11/21/2022.
[5] A Study of Psilocybin for Major Depressive Disorder (MDD). *ClinicalTrials.gov.* Available online at: https://clinicaltrials.gov/ct2/show/NCT03866174. Last revised 07/19/2022. Last accessed 11/21/2022.
[6] Auvelity™ (Dextromethorphan/Bupropion) Extended-Release Tablets Prescribing Information. Axsome Therapeutics, Inc. Available online at: https://www.axsome.com/auvelity-prescribing-information.pdf. Last revised 10/2022. Last accessed 11/18/2022.

Appendix M

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: November 22, 2022

FDA Approves First Gene Therapy to Treat Adults with Hemophilia B

The U.S. FDA approved Hemgenix (etranacogene dezaparvovec), an adeno-associated virus vector-based gene therapy for the treatment of adults with Hemophilia B (congenital Factor IX deficiency) who currently use Factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.

Hemophilia B is a genetic bleeding disorder resulting from missing or insufficient levels of blood clotting Factor IX, a protein needed to produce blood clots to stop bleeding. Symptoms can include prolonged or heavy bleeding after an injury, surgery, or dental procedure; in severe cases, bleeding episodes can occur spontaneously without a clear cause. Prolonged bleeding episodes can lead to serious complications, such as bleeding into joints, muscles or internal organs, including the brain.

Most individuals who have Hemophilia B and experience symptoms are men. The prevalence of Hemophilia B in the population is about one in 40,000; Hemophilia B represents about 15% of patients with hemophilia. Many women carriers of the disease have no symptoms. However, an estimated 10-25% of women carriers have mild symptoms; in rare cases, women may have moderate or severe symptoms.

Treatment typically involves replacing the missing or deficient clotting factor to improve the body's ability to stop bleeding and promote healing. Patients with severe Hemophilia B typically require a routine treatment regimen of intravenous (IV) infusions of Factor IX replacement products to maintain sufficient levels of clotting factor to prevent bleeding episodes.

Hemgenix is a one-time gene therapy product given as a single dose by IV infusion. Hemgenix consists of a viral vector carrying a gene for clotting Factor IX. The gene is expressed in the liver to produce Factor IX protein, to increase blood levels of Factor IX and thereby limit bleeding episodes.

The safety and effectiveness of Hemgenix were evaluated in two studies of 57 adult men 18 to 75 years of age with severe or moderately severe Hemophilia B. Effectiveness was established based on decreases in the men's annualized bleeding rate (ABR). In one study, which had 54 participants, the subjects had increases in Factor IX activity levels, a decreased need for routine Factor IX replacement prophylaxis, and a 54% reduction in ABR compared to baseline.

The most common adverse reactions associated with Hemgenix included liver enzyme elevations, headache, mild infusion-related reactions, and flu-like symptoms. Patients should be monitored for adverse infusion reactions and liver enzyme elevations (transaminitis) in their blood.

This application received Priority Review, Orphan and Breakthrough Therapy designations. The FDA granted approval of Hemgenix to CSL Behring LLC.

FDA NEWS RELEASE

For Immediate Release: November 17, 2022

FDA Approves First Drug that Can Delay Onset of Type 1 Diabetes (T1DM)

The FDA approved Tzield (teplizumab-mzwv) injection to delay the onset of stage 3 T1DM in adults and pediatric patients 8 years and older who currently have stage 2 T1DM.

T1DM occurs when the immune system attacks and destroys the cells that make insulin. Tzield binds to certain immune system cells and delays progression to stage 3 T1DM. Tzield may deactivate the immune cells that attack insulin-producing cells, while increasing the proportion of cells that help moderate the immune response. Tzield is administered by intravenous infusion once daily for 14 consecutive days.

Tzield's safety and efficacy were evaluated in a randomized, double-blind, event-driven, placebo-controlled trial with 76 patients with stage 2 T1DM. In the trial, patients randomly received Tzield or a placebo once daily via intravenous infusion for 14 days. The primary measure of efficacy was the time from randomization to development of stage 3 T1DM diagnosis. The trial results showed that over a median follow-up of 51 months, 45% of the 44 patients who received Tzield were later diagnosed with stage 3 T1DM, compared to 72% of the 32 patients who received a placebo. The mid-range time from randomization to stage 3 T1DM diagnosis was 50 months for the patients who received Tzield and 25 months for those who received a placebo. This represents a statistically significant delay in the development of stage 3 T1DM.

The most common side effects of Tzield include decreased levels of certain white blood cells, rash, and headache. The use of Tzield comes with warnings and precautions, including premedicating and monitoring for symptoms of Cytokine Release Syndrome; risk of serious infections; decreased levels of a type of white blood cell called lymphocytes; risk of hypersensitivity reactions; the need to administer all age-appropriate vaccinations prior to starting Tzield; as well as avoiding concurrent use of live, inactivated and mRNA vaccines with Tzield.

Tzield received Priority Review and Breakthrough Therapy designations for this indication. The FDA granted the approval of Tzield to Provention Bio.

FDA NEWS RELEASE

For Immediate Release: November 15, 2022

FDA Announces Preliminary Assessment that Certain Naloxone Products Have the Potential to be Safe and Effective for Over-the-Counter (OTC) Use

The FDA issued a Federal Register notice, *Safety and Effectiveness of Certain Naloxone Hydrochloride Drug Products for Nonprescription Use*, that may help facilitate the development and approval of certain nonprescription naloxone drug products, including through the switch of certain naloxone drug products from prescription status to nonprescription status. Naloxone is a medicine that can help reduce opioid overdose deaths and when administered timely, usually within minutes of the first signs of an opioid overdose, can counter the overdose effects.

The Federal Register notice includes a preliminary assessment that certain naloxone drug products – up to 4mg nasal spray and up to 2mg autoinjector for intramuscular (IM) or subcutaneous (Sub-Q) use – may be approvable as safe and effective for nonprescription use. This preliminary assessment is intended to facilitate development and approval of nonprescription naloxone products; however, it is not a final determination that certain naloxone drug products are safe and effective for

nonprescription use, and it does not mandate an immediately effective switch to nonprescription/OTC availability for naloxone.

To make its final determination, the FDA needs additional data, such as product-specific data on the nonprescription user interface design, including packaging and labeling. These data would usually be submitted to the agency in an application for a proposed nonprescription naloxone product.

By issuing this notice, the FDA is making application holders of certain prescription naloxone drug products aware of the preliminary assessment and the possibility that the agency may make a conclusive determination, through approval of a nonprescription naloxone drug product, that such products are safe and effective for use without a prescription.

The notice does not cover all naloxone products, as more data are needed on the safety and efficacy for nonprescription use of higher dose naloxone products and naloxone supplied in other presentations (including vials, ampules, or syringes without integrated needles) before a preliminary assessment with respect to those products can be reached. The notice requests comments from the public on whether there is data to support safe and effective nonprescription use of higher dose naloxone products and on potential consequences of a switch from prescription to nonprescription status.

Over the last several years, the FDA has taken a number of steps to improve access to naloxone products. In September, the agency issued an immediately in effect guidance to clarify that certain Drug Supply Chain Security Act requirements do not apply to distribution of naloxone to harm reduction programs during the Opioid Public Health Emergency. Additional efforts include development of a model Drug Facts Label, which is required for OTC drug products, with easy-to-understand pictograms on how to use the drug to encourage manufacturers to pursue approval of OTC naloxone products; requiring drug manufacturers for all opioid pain relievers and medicines to treat opioid use disorder to add new recommendations about naloxone to their prescribing information; and extending the shelf life of naloxone nasal spray from 24 months to 36 months.

The FDA continues to make progress implementing the new *FDA Overdose Prevention Framework* – our vision to undertake impactful, creative actions to prevent drug overdoses and reduce deaths. The agency remains focused on responding to all facets of substance use, misuse, substance use disorders, overdose, and death in the U.S. through the four priorities of the framework, including: supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing; encouraging harm reduction through innovation and education; advancing development of evidence-based treatments for substance use disorders; and protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks.

Current Drug Shortages Index (as of November 29, 2022):

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

Albuterol Sulfate Inhalational Solution	***Currently in Shortage***
Alprostadil (Muse) Suppository	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acids	***Currently in Shortage***

Amoxapine Tablets	***Currently in Shortage***
Amoxicillin Oral Powder for Suspension	***Currently in Shortage***
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine for Injection	***Currently in Shortage***
Azithromycin (Azasite) Ophthalmic Solution 1%	***Currently in Shortage***
Bacteriostatic 0.9% Sodium Chloride Injection	***Currently in Shortage***
Bacteriostatic Water for Injection	***Currently in Shortage***
Belatacept (Nulojix) Lyophilized Powder for Injection	***Currently in Shortage***
Belladonna and Opium Suppositories	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride and Epinephrine Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Calcium Disodium Versenate Injection	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Cefazolin Injection	***Currently in Shortage***
Cefixime Oral Capsules	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Collagenase Ointment	***Currently in Shortage***
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container	***Currently in Shortage***
Conjugated Estrogens/Bazedoxifene (Duavee) Tablet, Film Coated	***Currently in Shortage***
Cyclopentolate Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***
Desmopressin Acetate Nasal Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Injection	***Currently in Shortage***
Dextrose 10% Injection	***Currently in Shortage***
Dextrose 25% Injection	***Currently in Shortage***
Dextrose 5% Injection	***Currently in Shortage***
Dextrose 50% Injection	***Currently in Shortage***
Diazepam Rectal Gel	***Currently in Shortage***
Diflunisal Tablets	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Disopyramide Phosphate (Norpace) Capsules	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***

Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Injection, 0.1 mg/mL	***Currently in Shortage***
Epinephrine Injection, Auto-Injector	***Currently in Shortage***
Erythromycin Ophthalmic Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Floxuridine for Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Fluorescein Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsules	***Currently in Shortage***
Fluvoxamine ER Capsules	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Guanfacine Hydrochloride Tablets	***Currently in Shortage***
Heparin Sodium and Sodium Chloride 0.9% Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert	***Currently in Shortage***
Ibutilide Fumarate Injection	***Currently in Shortage***
Indigotindisulfonate Sodium Injection	***Currently in Shortage***
Iomeprol injection	***Currently in Shortage***
Isoniazid Injection	***Currently in Shortage***
IV Fat Emulsion	***Currently in Shortage***
Ketamine Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Lyophilized Powder for Injection	***Currently in Shortage***
Leuprolide Acetate Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine	***Currently in Shortage***
Lithium Oral Solution	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***
Mepivacaine Hydrochloride Injection	***Currently in Shortage***
Methyldopa Tablets	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***

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