OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
November 9, 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 – November 9, 2022

DATE: November 2, 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 November 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/Impact of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators – Appendix B

Action Item – 2023 DUR Board Meeting Dates – Appendix C

Action Item – Vote to Prior Authorize Enjaymo™ (Sutimlimab-jome), Pyrukynd® (Mitapivat), and Zynteglo® (Betibeglogene Autotemcel) and Update the Approval Criteria for the Anemia Medications – Appendix D

Action Item – Vote to Prior Authorize Sotyktu™ (Deucravacitinib), Spevigo® (Spesolimab-sbzo), and Tavneos® (Avacopan) and Update the Approval Criteria for the Targeted Immunomodulator Agents – Appendix E

Action Item – Vote to Prior Authorize Xenpozyme® (Olipudase Alfa-rpcp) – Appendix F

Action Item – Vote to Prior Authorize Besremi® (Ropeginterferon Alfa-2b-njft) and Vonjo™ (Pacritinib) – Appendix G

Action Item – Annual Review of Imcivree™ (Setmelanotide) – Appendix H

Action Item – Annual Review of Lambert-Eaton Myasthenic Syndrome (LEMS) Medications – Appendix I

Action Item – Annual Review of Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications – Appendix J

Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Carvykti™ (Ciltacabtagene Autoleucel) and Tecvayli™ (Teclistamab-cqyv) – Appendix K

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

Annual Review of Atopic Dermatitis Medications and 30-Day Notice to Prior Authorize Adbry™ (Tralokinumab-ldrm) and Cibinqo™ (Abrocitinib) – Appendix M

30-Day Notice to Prior Authorize Skysona® (Elivaldogene Autotemcel) – Appendix N

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – November 9, 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
Ms. Jennifer Boyett –	participating in person
Dr. Megan Hanner –	participating in person
Dr. Lynn Mitchell –	participating in person
Dr. John Muchmore –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person

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

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

Public Comment for Meeting:

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

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. October 12, 2022 DUR Board Meeting Minutes
   B. October 12, 2022 DUR Board Recommendations Memorandum
   C. Correspondence

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

4. **Update on Medication Coverage Authorization Unit/Impact of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators – See Appendix B**
   A. Pharmacy Help Desk Activity for October 2022
   B. Medication Coverage Activity for October 2022
   C. Impact of CFTR Modulators

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

5. **Action Item – 2023 DUR Board Meeting Dates – See Appendix C**
   A. 2023 DUR Board Meeting Dates

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

6. **Action Item – Vote to Prior Authorize Enjaymo™ (Sutimlimab-jome), Pyrukynd® (Mitapivat), and Zynteglo® (Betibeglogene Autotemcel) and Update the Approval Criteria for the Anemia Medications – See Appendix D**
   A. Market News and Updates

B. Product Summaries
C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Sotyktu™ (Deucravacitinib), Spevigo® (Spesolimab-sbzo), and Tavneos® (Avacopan) and Update the Approval Criteria for the Targeted Immunomodulator Agents – See Appendix E**

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

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

8. **Action Item – Vote to Prior Authorize Xenpozyme® (Olipudase Alfa-rpcp) – See Appendix F**

A. Market News and Updates
B. Xenpozyme® (Olipudase Alfa-rpcp) Product Summary
C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Besremi® (Ropeginterferon Alfa-2b-njft) and Vonjo™ (Pacritinib) – See Appendix G**

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

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

10. **Action Item – Annual Review of Imcivree™ (Setmelanotide) – See Appendix H**

A. Current Prior Authorization Criteria
B. Utilization of Imcivree™ (Setmelanotide)
C. Prior Authorization of Imcivree™ (Setmelanotide)
D. Market News and Updates
E. College of Pharmacy Recommendations

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

11. **Action Item – Annual Review of Lambert-Eaton Myasthenic Syndrome (LEMS) Medications – See Appendix I**

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

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

12. Action Item – Annual Review of Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications – See Appendix J

A. Current Prior Authorization Criteria
B. Utilization of VMAT2 Inhibitor Medications
C. Prior Authorization of VMAT2 Inhibitor Medications
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of VMAT2 Inhibitor Medications

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

13. Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Carvykti™ (Ciltacabtagene Autoleucel) and Tecvayli™ (Teclistamab-cqyv) – See Appendix K

A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Multiple Myeloma Medications
D. Prior Authorization of Multiple Myeloma Medications
E. Market News and Updates
F. Product Summaries
G. College of Pharmacy Recommendations
H. Utilization Details of Multiple Myeloma Medications

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

14. Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Tezspire® (Tezepelumab-ekko) – See Appendix L

A. Current Prior Authorization Criteria
B. Utilization of Asthma and COPD Maintenance Medications
C. Prior Authorization of Asthma and COPD Maintenance Medications
D. Market News and Updates
E. Tezspire® (Tezepelumab-ekko) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Asthma and COPD Maintenance Medications
H. Utilization Details of Asthma-Indicated Monoclonal Antibodies

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

15. Annual Review of Atopic Dermatitis (AD) Medications and 30-Day Notice to Prior Authorize Adbry™ (Tralokinumab-ldrm) and Cibinqo™ (Abrocitinib) – See Appendix M

A. Current Prior Authorization Criteria
B. Utilization of AD Medications
C. Prior Authorization of AD Medications
D. Market News and Updates
E. Product Summaries

F. Cost Comparison
G. College of Pharmacy Recommendations
H. Utilization Details of AD Medications

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

16. **30-Day Notice to Prior Authorize Skysona® (Elivaldogene Autotemcel) – See Appendix N**
    A. Introduction
    B. Skysona® (Elivaldogene Autotemcel) Product Summary
    C. College of Pharmacy Recommendations

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

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

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

18. **Future Business* (Upcoming Product and Class Reviews)**
    A. Anticoagulants and Platelet Aggregation Inhibitors
    B. Antidepressants
    C. Crohn's Disease and Ulcerative Colitis (UC) Medications
    D. Skin Cancer Medications
    *Future product and class reviews subject to change.

19. **Adjournment**

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

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING OCTOBER 12, 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	
Laura Tidmore, Pharm.D.	X	
Visiting Pharmacy Student(s): Daisy Nguyen	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
Debra Montgomery, D.O.; Medical Director		X
Traylor Rains; State Medicaid Director		X

Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Interim Chief Medical Officer	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Kara Smith, J.D.; General Counsel		X
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
David Walk, J.D.; General Counsel	X	
Toney Welborn, M.D., MPH, MS; Medical Director		X

OTHERS PRESENT:	
Jason Smith, Gilead	Stacy Sandate, Albireo
Karen Evenson, Albireo	Ann Nelson, Vertex
Collin Verheyden, Vertex	Jordan Kho, Agios
Shawana Crawford, Gilead	Hayley Endicott, Gilead
Frank Alvarado, Johnson & Johnson	David Prather, Novo Nordisk
Marry Moris, SSM Gastroenterology	Rhonda Clark, Indivior
Garth Wright, Genentech	Burl Beasley, OMES
John Omick, Global Blood Therapeutics	Jimmy Dick, Genentech
D.R. McCale, Agios	Robert Greely, Biogen
David Smith, Gilead	John Schillo, Lundbeck
Brian Maves, Pfizer	Sara Gao, AstraZeneca
Gina Heinen, Novo Nordisk	Cheryl Gay, Gene
Andrew Delgado, Bristol Myers Squibb	Ashlee Waring, AstraZeneca
Michelle Bice, Albireo	

PRESENT FOR PUBLIC COMMENT:	
Stacy Sandate, Albireo	Jordan Kho, Agios
Shawana Crawford, Gilead	Mary Morris, SSM Gastroenterology

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

1A: ROLL CALL

Dr. Muchmore called the meeting to order at 4:00pm. Roll call by Dr. Wilcox did not initially establish the presence of a quorum; however, a quorum was established prior to any action items.

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO. 8 STACY SANDATE
2B: AGENDA ITEM NO. 12 JORDAN KHO
2C: AGENDA ITEM NO. 13 SHAWANA CRAWFORD
2D: AGENDA ITEM NO. 13 MARY MORRIS

ACTION: NONE REQUIRED

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

3A: JULY 13, 2022 DUR MINUTES
3B: SEPTEMBER 14, 2022 DUR MINUTES

Materials included in agenda packet; presented by Dr. Muchmore
Dr. Muñoz moved to approve; seconded by Dr. de los Angeles

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/FALL 2022 PIPELINE UPDATE**

4A: PHARMACY HELP DESK ACTIVITY FOR SEPTEMBER 2022
4B: MEDICATION COVERAGE ACTIVITY FOR SEPTEMBER 2022
4C: FALL 2022 PIPELINE UPDATE

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

AGENDA ITEM NO. 5: **APPROVAL OF SEPTEMBER 2022 DUR BOARD RECOMMENDATIONS**

5A: VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE OPHTHALMIC ANTI-INFLAMMATORY PRODUCTS
5B: VOTE TO PRIOR AUTHORIZE RECORLEV® (LEVOKETOCONAZOLE) AND UPDATE THE APPROVAL CRITERIA FOR ISTURISA® (OSILODROSTAT)
5C: VOTE TO PRIOR AUTHORIZE TLANDO® (TESTOSTERONE UNDECANOATE) AND UPDATE THE APPROVAL CRITERIA FOR THE TESTOSTERONE PRODUCTS
5D: VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
5E: VOTE TO PRIOR AUTHORIZE ADLARITY® (DONEPEZIL TRANSDERMAL SYSTEM) AND ADUHELM® (ADUCANUMAB-AVWA)
5F: VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE TOPICAL CORTICOSTEROIDS
5G: VOTE TO PRIOR AUTHORIZE CAMZYOS™ (MAVACAMTEN)
5H: VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) MODULATORS
5I: VOTE TO PRIOR AUTHORIZE ALYMSYS® (BEVACIZUMAB-MALY), LONSURF® (TRIFLURIDINE/TIPIRACIL), AND STIVARGA® (REGORAFENIB) AND UPDATE THE APPROVAL CRITERIA FOR THE COLORECTAL CANCER MEDICATIONS

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

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE AMVUTTRA™ (VUTRISIRAN) AND UPDATE THE APPROVAL CRITERIA FOR AMYLOIDOSIS MEDICATIONS**

6A: MARKET NEWS AND UPDATES
6B: AMVUTTRA™ (VUTRISIRAN) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE HERCEPTIN HYLECTA™ (TRASTUZUMAB/HYALURONIDASE-OYSK) AND UPDATE THE APPROVAL CRITERIA FOR THE BREAST CANCER MEDICATIONS**

7A: MARKET NEWS AND UPDATES
7B: HERCEPTIN HYLECTA™ (TRASTUZUMAB/HYALURONIDASE-OYSK) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Borders
Dr. de los Angeles recommended to update 2.c.iv. in the breast cancer approval criteria for Perjeta® (pertuzumab) to read "used in combination with trastuzumab following adjuvant therapy with *paclitaxel or docetaxel* and carboplatin/

trastuzumab/pertuzumab" to allow prescriber discretion on the choice of taxane therapy.
Dr. de los Angeles moved to approve the amended criteria with the Perjeta® update; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: ANNUAL REVIEW OF BYLVAY® (ODEVIXIBAT) AND LIVMARLI® (MARALIXIBAT)
8A: CURRENT PRIOR AUTHORIZATION CRITERIA
8B: UTILIZATION OF BYLVAY® (ODEVIXIBAT) AND LIVMARLI® (MARALIXIBAT)
8C: PRIOR AUTHORIZATION OF BYLVAY® (ODEVIXIBAT) AND LIVMARLI® (MARALIXIBAT)
8D: MARKET NEWS AND UPDATES
8E: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. de los Angeles
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: ANNUAL REVIEW OF SPINAL MUSCULAR ATROPHY (SMA) MEDICATIONS
9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: UTILIZATION OF SMA MEDICATIONS
9C: PRIOR AUTHORIZATION OF SMA MEDICATIONS
9D: MARKET NEWS AND UPDATES
9E: COLLEGE OF PHARMACY RECOMMENDATIONS
9F: UTILIZATION DETAILS OF SMA MEDICATIONS
Materials included in agenda packet; presented by Dr. Chandler
Dr. Muñoz moved to approve; seconded by Dr. Mitchell
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: ANNUAL REVIEW OF MYELOPROLIFERATIVE NEOPLASM (MPN) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BESREMI® (ROPEGINTERFERON ALFA-2B-NJFT) AND VONJO® (PACRITINIB)
10A: INTRODUCTION
10B: CURRENT PRIOR AUTHORIZATION CRITERIA
10C: UTILIZATION OF MPN MEDICATIONS
10D: PRIOR AUTHORIZATION OF MPN MEDICATIONS
10E: MARKET NEWS AND UPDATES
10F: PRODUCT SUMMARIES
10G: COLLEGE OF PHARMACY RECOMMENDATIONS
10H: UTILIZATION DETAILS OF MPN MEDICATIONS
Materials included in agenda packet; presented by Dr. Borders
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 11: ANNUAL REVIEW OF TARGETED IMMUNOMODULATOR AGENTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE SOTYKTU™ (DEUCRAVACITINIB), SPEVIGO® (SPESOLIMAB-SBZO), AND TAVNEOS® (AVACOPAN)
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF TARGETED IMMUNOMODULATOR AGENTS
11C: PRIOR AUTHORIZATION OF TARGETED IMMUNOMODULATOR AGENTS
11D: MARKET NEWS AND UPDATES
11E: PRODUCT SUMMARIES
11F: COLLEGE OF PHARMACY RECOMMENDATIONS

11G: UTILIZATION DETAILS OF TARGETED IMMUNOMODULATOR AGENTS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 12: ANNUAL REVIEW OF ANEMIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ENJAYMO™ (SUTIMLIMAB-JOME), PYRUKYND® (MITAPIVAT), AND ZYNTEGLO® (BETIBEGLOGENE AUTOTEMCEL)
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF ANEMIA MEDICATIONS
12C: PRIOR AUTHORIZATION OF ANEMIA MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: PRODUCT SUMMARIES
12F: COLLEGE OF PHARMACY RECOMMENDATIONS
12G: UTILIZATION DETAILS OF ANEMIA MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 13: ANNUAL REVIEW OF HEPATITIS C MEDICATIONS
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF HEPATITIS C MEDICATIONS
13C: PRIOR AUTHORIZATION OF HEPATITIS C MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: COLLEGE OF PHARMACY RECOMMENDATIONS
13F: UTILIZATION DETAILS OF HEPATITIS C MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: 30-DAY NOTICE TO PRIOR AUTHORIZE XENPOZYME® (OLIPUDASE ALFA-RPCP)
14A: INTRODUCTION
14B: XENPOZYME® (OLIPUDASE ALFA-RPCP) PRODUCT SUMMARY
14C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 15: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
16A: ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS
16B: ATOPIC DERMATITIS MEDICATIONS
16C: MULTIPLE MYELOMA MEDICATIONS
16D: VESICULAR MONOAMINE TRANSPORTER 2 (VMAT2) INHIBITOR MEDICATIONS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 17: ADJOURNMENT
The meeting was adjourned at 5:47pm.

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

Memorandum

Date: October 13, 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 October 12, 2022

Recommendation 1: Fall 2022 Pipeline Update

NO ACTION REQUIRED.

Recommendation 2A: Vote to Update the Approval Criteria for Ophthalmic Anti-Inflammatory Products

MOTION CARRIED without objection; one Board member abstained.

The College of Pharmacy recommends making Durezol® (difluprednate 0.05%) brand preferred based on net costs (changes are shown in red in the following Tier chart):

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

Ophthalmic Corticosteroids	
Tier-1	**Tier-2**
prednisolone acetate 1% sus (Omnipred®)	
prednisolone acetate 0.12% sus (Pred Mild®)	
prednisolone sodium phosphate 1% sol	

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

Ophthalmic Corticosteroids Tier-2 Approval Criteria:

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

Recommendation 2B: Vote to Prior Authorize Recorlev® (Levoketoconazole) and Update the Approval Criteria for Isturisa® (Osilodrostat)

MOTION CARRIED without objection; one Board member abstained.

The College of Pharmacy recommends the prior authorization of Recorlev® (levoketoconazole) with the following criteria [changes shown in red indicate updates made based on Drug Utilization Review (DUR) Board recommendations and consistent with current treatment guidelines]:

Recorlev® (Levoketoconazole) Approval Criteria:

1. An FDA approved indication for the treatment of adult members with Cushing's disease for whom pituitary or adrenal surgery is not an option or has not been curative; and
2. Member must be 18 years of age or older; and
3. Recorlev® must be prescribed by, or in consultation with, an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
4. Prescriber must document that the member has had an inadequate response to pituitary or adrenal surgery or is not a candidate for pituitary or adrenal surgery; and
5. Prescriber agrees to obtain baseline liver test and electrocardiogram (ECG) prior to initiating treatment; and
6. Prescriber agrees to monitor liver enzymes and bilirubin weekly for at least 6 weeks after initiating treatment, every 2 weeks for the next 6 weeks, monthly for the next 3 months, and then as clinically indicated; and
7. Prescriber must verify that hypokalemia and hypomagnesemia are corrected prior to starting Recorlev®; and

8. Member must not be taking medications that cause QT prolongation associated with ventricular arrhythmias, including torsades de pointes (e.g., dofetilide, dronedarone, methadone, quinidine, ranolazine); and
9. Member must not be taking medications that are sensitive substrates of CYP3A4 and/or P-gp (e.g., digoxin, lovastatin, simvastatin, tacrolimus, triazolam); and
10. If the member is taking medications that are strong CYP3A4 inhibitors (e.g., ritonavir, mifepristone) or strong CYP3A4 inducers (e.g. isoniazid, carbamazepine, rifampicin, phenytoin), the prescriber must verify the medication will be stopped 2 weeks before and during treatment with Recorlev® per package labeling; and
11. For female members, prescriber must verify that the member is not breastfeeding; and
12. A patient-specific, clinically significant reason why the member cannot use ketoconazole tablets and metyrapone capsules must be provided; and
13. Initial authorizations will be for the duration of 3 months. Continued authorization at that time will require the prescriber to provide a recent 24-hour urine free cortisol (UFC) level within the normal range to demonstrate the effectiveness of this medication, and compliance will also be checked at that time. Subsequent approvals will be for the duration of 1 year and will require the prescriber to verify the member is still not a candidate for pituitary or adrenal surgery.

Additionally, the College of Pharmacy recommends updating the approval criteria for Isturisa® based on Drug Utilization Review (DUR) Board recommendations and consistent with current treatment guidelines (updates shown in red):

Isturisa® (Osilodrostat) Approval Criteria:

1. An FDA approved indication for the treatment of adult members with Cushing's disease for whom pituitary or adrenal surgery is not an option or has not been curative;
2. Member must be 18 years of age or older; and
3. Prescriber must document that the member has had an inadequate response to pituitary or adrenal surgery or is not a candidate for pituitary or adrenal surgery; and
4. Prescriber must verify that hypokalemia and hypomagnesemia are corrected prior to starting Isturisa®; and
5. Prescriber must agree to perform and monitor electrocardiogram (ECG) at baseline, 1 week after treatment initiation, and as clinically indicated thereafter; and
6. Prescriber must verify that dose titration will be followed according to package labeling; and
7. If the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin) or strong CYP3A4 and/or CYP2B6 inducers (e.g.,

carbamazepine, rifampin, phenobarbital), the prescriber must verify that the Isturisa® dose will be adjusted according to the package labeling; and

8. For female members, prescriber must verify that the member is not breastfeeding; and
9. Isturisa® must be prescribed by, or in consultation with, an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
10. A patient-specific, clinically significant reason why the member cannot use ketoconazole tablets and metyrapone capsules must be provided; and
11. Initial authorizations will be for the duration of 3 months after which time, compliance and 24-hour urine free cortisol levels within the normal range (to demonstrate the effectiveness of this medication) will be required for continued approval. Subsequent approvals will be for the duration of 1 year and will require the prescriber to verify the member is still not a candidate for pituitary or adrenal surgery.

Recommendation 2C: Vote to Prior Authorize Tlando® (Testosterone Undecanoate) and Update the Approval Criteria for the Testosterone Products

MOTION CARRIED without objection; one Board member abstained.

The College of Pharmacy recommends the following changes to the testosterone products Product Based Prior Authorization (PBPA) category based on new FDA approvals, product discontinuations, net costs, and recommendations from the Drug Utilization Review (DUR) Board (changes shown in red in the following Tier chart and approval criteria):

1. Placement of Tlando® (testosterone undecanoate) into the Special Prior Authorization (PA) Tier; and
2. Moving Androgel® (testosterone topical gel 1% packet and 1.62% packet) from Tier-1 to Tier-2; and
3. Moving Testim® (testosterone topical gel 1% tube) and Vogelxo® (testosterone topical gel 1% packet, 1% pump, and 1% tube) from Tier-2 to Tier-1; and
4. Updating the initial approval criteria for all testosterone products to verify evaluation of the member for a pituitary tumor as the potential cause of low testosterone prior to starting treatment with a testosterone product.

Testosterone Products		
Tier-1	**Tier-2**	**Special PA**
methyltestosterone powder	testosterone enanthate sub-Q auto-injector (Xyosted®)	fluoxymesterone oral tab (Androxy®)
testosterone cypionate IM inj (Depo-Testosterone®)	testosterone nasal gel (Natesto®)	methyltestosterone oral tab/cap (Android®, Methitest®, Testred®)
testosterone enanthate IM inj (Delatestryl®)	testosterone patch (Androderm®)	testosterone buccal tab (Striant®)
testosterone topical gel 1% (Testim®, Vogelxo®)	**testosterone topical gel 1%, 1.62% packet (Androgel®)**	testosterone pellets (Testopel®)
testosterone topical gel **1.62% pump** (Androgel® ~~**1%, 1.62%**~~) – **Brand Preferred**	testosterone topical gel **2% pump** (Fortesta®~~**, Testim®, Vogelxo®**~~)	testosterone undecanoate oral cap (Jatenzo®, **Tlando®)**
	testosterone topical solution (Axiron®)	
	testosterone undecanoate IM inj (Aveed®)	

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)
cap = capsule; IM = intramuscular; inj = injection; PA = prior authorization; sub-Q = subcutaneous; tab = tablet

Initial Approval Criteria for All Testosterone Products:

1. An FDA approved diagnosis of 1 of the following:
   a. Testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchiectomy; or
   b. Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation; or
   c. Delayed puberty; or
   d. Advanced inoperable metastatic mammary cancer in females 1 to 5 years postmenopausal, or premenopausal females with breast cancer benefitting from oophorectomy and have been determined to have a hormone-responsive tumor; and
2. The prescriber must verify the member has been evaluated for the presence of a pituitary tumor as the potential cause of low testosterone and the member will receive appropriate follow-up and/or treatment as necessary; and
3. Must include 2 labs showing pre-medication, morning testosterone (total testosterone) levels <300ng/dL; and
4. Must include 1 lab showing abnormal gonadotropins and/or other information necessary to demonstrate diagnosis; or
5. Testosterone and gonadotropin labs are not required for authorization of testosterone therapy if documentation is provided for established hypothalamic pituitary or gonadal disease, if the pituitary gland or testes has/have been removed, or for postmenopausal females with advanced inoperable metastatic mammary cancer or premenopausal females with breast cancer benefitting from oophorectomy and that have been determined to have a hormone-responsive tumor.

Testosterone Products Tier-2 Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. Member must have a trial of at least 2 Tier-1 products (must include at least 1 injectable and 1 topical formulation) at least 12 weeks in duration; or
3. A patient-specific, clinically significant reason why member cannot use all available Tier-1 products must be provided; or
4. Prior stabilization on a Tier-2 product (within the past 180 days); and
5. Approvals will be for the duration of 1 year; and
6. For Xyosted® [testosterone enanthate subcutaneous (sub-Q) auto-injector]:
    a. Member must be trained by a health care professional on sub-Q administration and storage of Xyosted® sub-Q auto-injector.

Testosterone Products Special Prior Authorization (PA) Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. A patient-specific, clinically significant reason why member cannot use all other available formulations of testosterone must be provided; and
3. Approvals will be for the duration of 1 year.

Recommendation 2D: Vote to Update the Approval Criteria for the Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications

MOTION CARRIED without objection; one Board member abstained.

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

1. Moving hydrocodone/ibuprofen 10/200mg tablet (Ibudone®, Reprexain™) from Tier-1 to Tier-2 of the Short-Acting Opioid Analgesics category based on net cost

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
buprenorphine patch (Butrans®) – **Brand Preferred**	fentanyl patch (Duragesic®)	buprenorphine ER buccal film (Belbuca®)	oxycodone/APAP ER tab (Xartemis® XR)
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER)	tramadol ER cap (ConZip®)
	tramadol ER tab (Ultram ER®, Ryzolt®)	hydromorphone ER tab (Exalgo®)	
		methadone tab and oral soln (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
		morphine ER tab (Arymo™ ER)	
		morphine ER tab (MorphaBond™)	
		oxycodone ER cap (Xtampza® ER)	
		oxycodone/ naltrexone ER cap (Troxyca® ER)	
Short-Acting			
APAP/butalbital/ caff/codeine cap (Fioricet® with Codeine)	**hydrocodone/IBU tab 10/200mg (Ibudone®, Reprexain™)**	benzhydrocodone/ APAP tab (Apadaz®)	levorphanol tab
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	oxymorphone IR tab (Opana®)	dihydrocodeine/ APAP/caff cap (Trezix®)	tramadol 100mg tab
codeine tab	tapentadol IR tab (Nucynta®)	hydrocodone/ APAP oral soln (Zamicet®, Liquicet®)	tramadol oral soln (Qdolo™)

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
codeine/APAP tab (Tylenol® with Codeine)		hydrocodone/ APAP tab (Xodol®)	
dihydrocodeine/ ASA/caff cap (Synalgos-DC®)		oxycodone tab (Oxaydo®)	
hydrocodone/ APAP tab (Norco®)		oxycodone tab (RoxyBond™)	
hydrocodone/IBU tab **5/200mg, 7.5/200mg only** (Vicoprofen®, Ibudone®, Reprexain™)			
hydromorphone tab (Dilaudid®)			
morphine IR tab (MSIR®)			***Oncology Only:***
oxycodone/APAP tab (Percocet®)			fentanyl buccal film (Onsolis®)
oxycodone/ASA tab (Percodan®)			fentanyl buccal tab (Fentora®)
oxycodone IR cap (Oxy IR®)			fentanyl nasal spray (Lazanda®)
oxycodone IR tab (Roxicodone®)			fentanyl SL spray (Subsys®)
tramadol 50mg tab (Ultram®)			fentanyl SL tab (Abstral®)
tramadol/APAP tab (Ultracet®)			fentanyl transmucosal lozenge (Actiq®)

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

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

1. Removal of Bunavail® (buprenorphine/naloxone buccal film) based on product discontinuation

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

1. Generic buprenorphine/naloxone SL tablet is the preferred product. Authorization consideration of ~~Bunavail®,~~ Suboxone® films (brand and generic)~~,~~ and Zubsolv® requires a patient-specific, clinically significant reason why generic buprenorphine/naloxone SL tablets are not appropriate.
2. Subutex® (buprenorphine) 2mg and 8mg SL tablets will only be approved if the member is pregnant or has a documented serious allergy or adverse reaction to naloxone; and
3. Buprenorphine products FDA approved for a diagnosis of opioid abuse/dependence must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and
4. Member must have an FDA approved diagnosis of opioid abuse/dependence; and
5. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
6. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
7. The following limitations will apply:
    a. Suboxone® 2mg/0.5mg and 4mg/1mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    b. Suboxone® 8mg/2mg SL tablets and films: A quantity limit of 60 SL units per 30 days will apply.
    c. Suboxone® 12mg/3mg SL films: A quantity limit of 30 SL films per 30 days will apply.
    d. Subutex® 2mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    e. Subutex® 8mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
    f. Zubsolv® 0.7mg/0.18mg, 1.4mg/0.36mg, and 2.9mg/0.71mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    g. Zubsolv® 5.7mg/1.4mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
    h. Zubsolv® 8.6mg/2.1mg and 11.4mg/2.9mg SL tablets: A quantity limit of 30 SL tablets per 30 days will apply.
    ~~i. Bunavail® 2.1mg/0.3mg buccal films: A quantity limit of 90 buccal films per 30 days will apply.~~
    ~~j. Bunavail® 4.2mg/0.7mg buccal films: A quantity limit of 60 buccal films per 30 days will apply.~~

~~k. Bunavail® 6.3mg/1mg buccal films: A quantity limit of 30 buccal films per 30 days will apply.~~

Recommendation 2E: Vote to Prior Authorize Adlarity® (Donepezil Transdermal System) and Aduhelm® (Aducanumab-avwa)

MOTION CARRIED without objection; one Board member abstained.

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

Alzheimer's Disease Medications Approval Criteria:

1. Special formulation products including oral solutions, transdermal patches, and other convenience formulations require prior authorization with the following approval criteria:
    a. A patient-specific, clinically significant reason why the special formulation is necessary in place of the standard formulation.

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

Aduhelm® (Aducanumab-avwa) Approval Criteria:

1. An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:
    a. Mini-Mental State Exam (MMSE) score between 24 and 30; or
    b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5; or
    c. Montreal Cognitive Assessment (MoCA) score ≥19; or
    d. Quick Dementia Rating System (QDRS) score ≤5; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Aduhelm® must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and
5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Member must not be taking anticoagulant or antiplatelet agents except for aspirin 325mg per day or less; and

7. Member must not have had a stroke or transient ischemic attack (TIA) or unexplained loss of consciousness in the past year; and
8. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
9. Member must not have any pre-treatment localized superficial siderosis, ≥10 brain microhemorrhages, or a brain hemorrhage >1cm within 1 year of treatment initiation as safety with Aduhelm® has not been established in patients with these conditions; and
10. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Aduhelm® and prior to the 7th infusion (1st dose of 10mg/kg) and 12th infusion (6th dose of 10mg/kg); and
11. The prescriber must confirm that the member will be monitored for amyloid-related imaging abnormalities (ARIA) during the first 8 doses of treatment with Aduhelm®, particularly during titration, and also throughout treatment; and
12. If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H); and
13. Aduhelm® must be administered by a health care provider; and
14. Aduhelm® must be shipped via cold chain supply shipping and stored in a refrigerator; and
15. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
16. Initial approvals will be for 6 months. Confirmation that MRI has been completed and is acceptable to the provider prior to 7th infusion is required for continuation; and
17. Subsequent approvals will be for 6 months and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy; and
18. Approval quantities will be dependent on the member's weight and dosing based on the Aduhelm® *Prescribing Information*; and
19. The maximum dose approvable is 10mg/kg per 28 days.

Recommendation 2F: Vote to Update the Approval Criteria for the Topical Corticosteroids

MOTION CARRIED without objection; one Board member abstained.

The College of Pharmacy recommends the following changes to the topical corticosteroids Product Based Prior Authorization (PBPA) Tier chart based on net costs (changes shown in red in the following Tier chart):

1. Ultra-High to High Potency:
    a. Augmented betamethasone 0.05% gel from Tier-1 to Tier-2; and
    b. Augmented betamethasone 0.05% ointment from Tier-2 to Tier-1; and
    c. Betamethasone dipropionate 0.05% cream and ointment from Tier-2 to Tier-1; and
    d. Clobetasol propionate 0.05% lotion from Tier-1 to Tier-2; and
    e. Desoximetasone 0.25% cream and ointment from Tier-3 to Tier-1; and
    f. Fluocinonide 0.1% cream from Tier-2 to Tier-1; and
    g. Halobetasol 0.05% ointment from Tier-2 to Tier-1.
2. Medium-High to Medium Potency:
    a. Betamethasone valerate 0.1% lotion from Tier-1 to Tier-2; and
    b. Desoximetasone 0.05% cream and ointment from Tier-2 to Tier-3.
3. Low Potency:
    a. Alclometasone 0.05% ointment from Tier-2 to Tier-3.
    b. Desonate® (desonide 0.05%) gel from Tier-1 to Tier-3; and
    c. Desonide emollient 0.05% cream and ointment from Tier-3 to Tier-1; and
    d. Fluocinolone 0.01% solution from Tier-2 to Tier-1; and
    e. Fluocinolone 0.01% oil from Tier-3 to Tier-2.

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (**Diprolene®,** Diprolene AF®)	C,~~**G,O**~~	amcinonide 0.1%	C,L	clobetasol propionate 0.05% (Clobex®)	Sh,Spr
betamethasone dipropionate 0.05% (Diprosone®)	**C,O**	augmented betamethasone dipropionate 0.05% (Diprolene®, **Diprolene AF®**)	**G**,L,~~**O**~~	clobetasol propionate 0.05% (Olux®, Olux-E®, Tovet®)	F
~~**clobetasol propionate 0.05% (Clobex®)**~~	~~**L**~~	~~**betamethasone dipropionate 0.05% (Diprosone®)**~~	~~**C,O**~~	clobetasol propionate 0.05% (Impeklo™)	L
clobetasol propionate 0.05% (Temovate®)	C,O,So	**clobetasol propionate 0.05% (Clobex®)**	**L**	desoximetasone 0.25% (Topicort®)	~~**C,O**~~,Spr
desoximetasone 0.25% (Topicort®)	**C,O**	clobetasol propionate 0.05% (Temovate®)	G	diflorasone diacetate 0.05% (Apexicon®)	C,O
fluocinonide 0.05%	C,O,So	desoximetasone 0.05% (Topicort®)	G	diflorasone diacetate 0.05% (Apexicon E®)	C

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
fluocinonide 0.1% (Vanos®)	**C**	fluocinonide 0.05%	G	halobetasol propionate 0.01% (Bryhali®)	L
halobetasol propionate 0.05% (Ultravate®)	C,**O**	~~**fluocinonide 0.1% (Vanos®)**~~	~~**C**~~	halobetasol propionate 0.05% (Lexette®)	F
		flurandrenolide tape 0.05% (Cordran®)	Tape		
		halcinonide 0.1% (Halog®)	C,O,So		
		halobetasol propionate 0.05% (Ultravate®)	L,~~**O**~~		
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	L	betamethasone dipropionate/ calcipotriene 0.064%/ 0.005% (Taclonex®)	O,Spr, Sus	**desoximetasone 0.05% (Topicort LP®)**	**C,O**
betamethasone valerate 0.1% (Beta-Val®)	C,~~**L**~~,O	betamethasone valerate 0.12% (Luxiq®)	F	hydrocortisone valerate 0.2% (Westcort®)	C,O
fluticasone propionate 0.005% (Cutivate®)	O	**betamethasone valerate 0.1% (Beta-Val®)**	**L**		
fluticasone propionate 0.05% (Cutivate®)	C	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (Enstilar®)	F		
mometasone furoate 0.1% (Elocon®)	C,L,O, So	clocortolone pivalate 0.1% (Cloderm®)	C		
triamcinolone acetonide 0.025%	O	~~**desoximetasone 0.05% (Topicort LP®)**~~	~~**C,O**~~		
triamcinolone acetonide 0.1%	C,L,O	fluocinolone acetonide 0.025% (Synalar®)	C,O		
triamcinolone acetonide 0.5%	C,O	fluocinonide emollient 0.05% (Lidex E®)	C		
		flurandrenolide 0.05%	C,LO		
		fluticasone propionate 0.05% (Cutivate®)	L		
		hydrocortisone butyrate 0.1%	C,L,O, So		
		hydrocortisone probutate 0.1% (Pandel®)	C		

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
		prednicarbate 0.1% (Dermatop®)	C,O		
		triamcinolone acetonide 0.147mg/g (Kenalog®)	Spr		
Low Potency					
~~desonide 0.05% (Desonate®)~~	**~~G~~**	alclometasone dipropionate 0.05% (Aclovate®)	C,**~~O~~**	**alclometasone dipropionate 0.05% (Aclovate®)**	**O**
desonide emollient 0.05%	**C,O**	fluocinolone acetonide 0.01% (Synalar®)	C,**~~So~~**	**~~fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®)~~**	**~~Oil~~**
fluocinolone acetonide 0.01% (Capex®)	Sh	**fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®)**	**Oil**	desonide 0.05%	L
fluocinolone acetonide 0.01% (Synalar®)	**So**	hydrocortisone 2.5% (Texacort®)	So	**~~desonide emollient 0.05%~~**	**~~C~~,~~O~~**
hydrocortisone acetate 1%	C,O	hydrocortisone/ pramoxine 1%/1% (Pramosone®)	C,L	**desonide 0.05% (Desonate®)**	**G**
hydrocortisone acetate 2.5%	C,L,O				

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

Topical Corticosteroids Tier-2 Approval Criteria:

1. Documented trials of all Tier-1 topical corticosteroids of similar potency in the past 30 days that did not yield adequate relief; and
2. If Tier-1 trials are completed and do not yield adequate relief, the member must also provide a patient-specific, clinically significant reason for requesting a Tier-2 in the same potency instead of trying a higher potency; and
3. When the same medication is available in Tier-1, a patient-specific, clinically significant reason must be provided for using a special dosage formulation of that medication in Tier-2 (foams, shampoos, sprays, kits, etc.); and
4. Topical corticosteroid kits require tier trials and a patient-specific, clinically significant reason for use of the kit over standard formulations.

Topical Corticosteroids Tier-3 Approval Criteria:

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

Recommendation 2G: Vote to Prior Authorize Camzyos™ (Mavacamten)

MOTION CARRIED without objection; one Board member abstained.

The College of Pharmacy recommends the prior authorization of Camzyos™ (mavacamten) with the following criteria:

Camzyos™ (Mavacamten) Approval Criteria:

1. An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
2. Member must be 18 years of age or older; and
3. Member must have New York Heart Association (NYHA) class II to III heart failure; and
4. Camzyos™ must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and
5. Member must have left ventricular ejection fraction (LVEF) ≥55%; and
6. Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or nondihydropyridine calcium channel blockers; and
7. Member must not be taking concurrent moderate to strong CYP2C19 inhibitors (e.g., proton pump inhibitors, clopidogrel, voriconazole, fluvoxamine), strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir), moderate to strong CYP2C19 inducers (e.g., rifampicin, carbamazepine), or moderate to strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin); and
8. Member must not be taking or planning to take disopyramide, ranolazine, or a combination of a beta blocker and a calcium channel blocker concomitantly with Camzyos™; and

9. Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 4 months after the final dose of Camzyos™; and
10. Prescriber, pharmacy, and member must be enrolled in the Camzyos™ Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
11. 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; and
12. Subsequent approvals will be for the duration of 1 year.

Recommendation 2H: Vote to Update the Approval Criteria for the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators

MOTION CARRIED without objection; one Board member abstained.

The College of Pharmacy recommends updating the current prior authorization criteria for the CFTR modulators to be consistent with clinical practice and recommends updating the age restriction for Orkambi® based on the newly FDA approved age expansion (changes shown in red):

Kalydeco® (Ivacaftor) Approval Criteria:

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

8. Subsequent approvals will be for the duration of 1 year.

Orkambi® (Lumacaftor/Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation in the CF transmembrane conductance regulator *(CFTR)* gene detected by genetic testing; and
2. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene; and
3. Orkambi® will not be approved for members with CF other than those homozygous for the *F508del* mutation; and
4. Member must be 12 months ~~2 years~~ of age or older; and
5. Members using Orkambi® must be supervised by a pulmonary disease specialist; and
6. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Orkambi®, every 3 months during the first year of treatment, and annually thereafter; and
7. Member must not be taking any of the following medications concomitantly with Orkambi®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
8. A quantity limit of 4 tablets per day or 112 tablets per 28 days will apply or a quantity limit of 2 granule packets per day or 56 packets per 28 days will apply; and
9. An age restriction of 12 months ~~2 years~~ to younger than 6 years of age will apply to Orkambi® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
10. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
11. Initial approvals will be for the duration of 6 ~~3~~ months~~, after which time compliance will be required for continued approval~~. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
12. Subsequent approvals will be for the duration of 1 year.

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

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation or who have at least 1 mutation in the CF transmembrane conductance regulator *(CFTR)* gene detected by genetic testing that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence; and
2. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed

by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and
3. Member must be 6 years of age or older; and
4. Members using Symdeko® must be supervised by a pulmonary disease specialist; and
5. If the member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) and experiencing adverse effects associated with Orkambi® use, the prescriber must indicate that information on the prior authorization request; and
6. Prescriber must verify the member has been counseled on proper administration of Symdeko® including taking with a fat-containing food; and
7. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Symdeko®, every 3 months during the first year of treatment, and annually thereafter; and
8. Member must not be taking any of the following medications concomitantly with Symdeko®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
9. A quantity limit of 2 tablets per day or 56 tablets per 28 days will apply; and
10. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
11. Initial approvals will be for the duration of 6 ~~3~~ months~~, after which time compliance will be required for continued approval~~. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events must be provided for members who switched from Orkambi® to Symdeko®; and
12. Subsequent approvals will be for the duration of 1 year.

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

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 *F508del* mutation in the CF transmembrane conductance regulator *(CFTR)* gene or a mutation in the *CFTR* gene that is responsive based on *in vitro* data; and
2. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and
3. Member must be 6 years of age or older; and

4. Members using Trikafta® must be supervised by a pulmonary disease specialist; and
5. If the member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi® or Symdeko® use, the prescriber must indicate that information on the prior authorization request; and
6. Prescriber must verify the member has been counseled on proper administration of Trikafta® including taking with a fat-containing food; and
7. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Trikafta®, every 3 months during the first year of treatment, and annually thereafter; and
8. Prescriber must verify the member does not have severe hepatic impairment; and
9. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the Trikafta® *Prescribing Information*; and
10. Member must not be taking any of the following medications concomitantly with Trikafta®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
11. ~~For members 6 to 11 years of age, the member's recent weight must be provided on the prior authorization request in order to authorize the appropriate dose according to package labeling, as follows:~~
    a. ~~Members 6 to 11 years of age weighing <30kg will be approved for Trikafta® (elexacaftor 50mg/tezacaftor 25mg/ivacaftor 37.5mg and ivacaftor 75mg) upon meeting approval criteria; or~~
    b. ~~Members 6 to 11 years of age weighing ≥30kg and members 12 years of age and older will be approved for Trikafta® (elexacaftor 100mg/tezacaftor 50mg/ivacaftor 75mg and ivacaftor 150mg) upon meeting approval criteria; and~~
12. A quantity limit of 3 tablets per day or 84 tablets per 28 days will apply; and
13. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
14. Initial approvals will be for the duration of 6 ~~3~~ months~~, after which time compliance will be required for continued approval~~. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® or Symdeko® to Trikafta®; and

15. Subsequent approvals will be for the duration of 1 year.

Recommendation 2I: Vote to Prior Authorize Alymsys® (Bevacizumab-maly), Lonsurf® (Trifluridine/Tipiracil), and Stivarga® (Regorafenib) and Update the Approval Criteria for the Colorectal Cancer Medications

MOTION CARRIED without objection; one Board member abstained.

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

Alymsys® (Bevacizumab-maly) and Mvasi® (Bevacizumab-awwb) Approval Criteria:

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

Lonsurf® (Trifluridine/Tipiracil) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of metastatic, recurrent, or unresectable CRC; and
2. Previously treated with a fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
3. Previously treated with an anti-vascular endothelial growth factor (VEGF) therapy; and
    a. If RAS wild-type disease, previously treated with an anti-epidermal growth factor receptor (EGFR) therapy; and
4. Used as monotherapy or in combination with bevacizumab.

Lonsurf® (Trifluridine/Tipiracil) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of metastatic gastric or GEJ adenocarcinoma; and
2. Previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, paclitaxel, docetaxel, or irinotecan; and
3. If human epidermal receptor type 2 (HER2) positive disease, prior treatment should have included HER2 targeted therapy.

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

1. Diagnosis of metastatic, recurrent, or unresectable CRC; and

2. Previous treatment with a fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
3. Previous treatment with an anti-vascular endothelial growth factor (VEGF) therapy; and
    a. If RAS wild-type disease, previously treated with an anti-epidermal growth factor receptor (EGFR) therapy.

Stivarga® (Regorafenib) Approval Criteria [Gastrointestinal Stromal Tumor (GIST) Diagnosis]:

1. Diagnosis of locally advanced unresectable or metastatic GIST; and
2. Previously treated with imatinib and sunitinib.

Stivarga® (Regorafenib) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

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

Additionally, the College of Pharmacy recommends updating the Enhertu® (fam-trastuzumab deruxtecan-nxki), Herceptin® (trastuzumab), Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), Ogivri® (trastuzumab-dkst), Ontruzant® (trastuzumab-dttb), Trazimera® (trastuzumab-qyyp), Keytruda® (pembrolizumab), Opdivo® (nivolumab), Perjeta® (pertuzumab), and Yervoy® (ipilimumab) prior authorization criteria based on FDA approvals, National Comprehensive Cancer Network (NCCN) guideline recommendations, and net costs (changes noted in red):

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

1. Diagnosis of advanced or metastatic disease; and
2. Disease has progressed on prior therapy; and
3. Human epidermal receptor type 2 (HER2) amplified disease; and
4. RAS and BRAF mutation negative; and
5. Used as a single agent.

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

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

5. Authorization of Herceptin® (trastuzumab), Herzuma® (trastuzumab-pkrb), ~~or~~ Kanjinti® (trastuzumab-anns), or Ogivri® (trastuzumab-dkst) will also require a patient-specific, clinically significant reason why the member cannot use ~~Ogivri® (trastuzumab-dkst),~~ Ontruzant® (trastuzumab-dttb)~~,~~ or Trazimera® (trastuzumab-qyyp). Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

1. Diagnosis of unresectable or metastatic CRC; and
2. ~~First-line treatment; and~~
3. 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 [~~Metastatic~~ Colorectal Cancer (~~m~~CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. ~~Disease has progressed on treatment with 5-fluorouracil (5-FU), oxaliplatin, and irinotecan; and~~

3. Tumor is microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR).~~; and~~
~~4. Used as a single agent or in combination with ipilimumab.~~

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

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

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

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

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

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

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

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

Recommendation 3: Vote to Prior Authorize Amvuttra™ (Vutrisiran) and Update the Approval Criteria for the Amyloidosis Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Amvuttra™ (vutrisiran) with criteria similar to Onpattro® (patisiran) as follows (changes shown in red):

Amvuttra™ (Vutrisiran) and Onpattro® (Patisiran) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following:
   a. Tissue (fat pad) biopsy confirming amyloid deposits; ~~and~~ or
   b. Genetic confirmation of transthyretin (TTR) gene mutation (e.g., Val30Met); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. For Onpattro®, prescriber must confirm the member will be pre-medicated with intravenous (IV) corticosteroid, oral acetaminophen, IV histamine-1 (H_1) antagonist, and IV histamine-2 (H_2) antagonist 60 minutes prior to administration to reduce the risk of infusion-related reaction(s); and
9. Amvuttra™ will not be approved for concomitant use with Onpattro® (patisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), or Vyndaqel® (tafamidis meglumine); and
10. Authorization for Amvuttra™ will also require a patient-specific, clinically significant reason why the member cannot use Onpattro®; and
11. Onpattro® will not be approved for concomitant use with Amvuttra™ (vutrisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), or Vyndaqel® (tafamidis meglumine); and
12. For Onpattro®, 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. For Amvuttra™, a quantity limit of 0.5mL per 90 days will apply; and
14. Approvals will be for the duration of 1 year ~~6 months~~. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

The College of Pharmacy also recommends updating the prior authorization criteria for Tegsedi® (inotersen), Vyndamax® (tafamidis), and Vyndaqel® (tafamidis meglumine) as follows (changes shown in red):

Tegsedi® (Inotersen) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy associated with hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following:
   a. Tissue (fat pad) biopsy confirming amyloid deposits; ~~and~~ or
   b. Genetic confirmation of transthyretin (*TTR*) gene mutation (e.g., Val30Met); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Tegsedi® must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must agree to monitor ALT, AST, and total bilirubin prior to initiation of Tegsedi® and every 4 months during treatment; and
7. Prescriber must confirm the first injection of Tegsedi® administered by the member or caregiver will be performed under the guidance of a health care professional; and
8. Prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tegsedi®; and
9. Prescriber must confirm the member has not undergone a liver transplant; and
10. Tegsedi® will not be approved for concomitant use with Amvuttra™ (vutrisiran), Onpattro® (patisiran), Vyndamax® (tafamidis), or Vyndaqel® (tafamidis meglumine); and
11. Prescriber, pharmacy, and member must be enrolled in the Tegsedi® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. Tegsedi® approvals will be for the duration of 1 year ~~6 months~~. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant; and
13. A quantity limit of 4 syringes per 28 days will apply.

Vyndamax® (Tafamidis) and Vyndaqel® (Tafamidis Meglumine) Approval Criteria:

1. An FDA approved indication for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
   a. Genetic confirmation of transthyretin (*TTR*) mutation (e.g., Val122Ile) or wild-type amyloidosis; and
   b. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
   a. Nuclear scintigraphy; or
   b. Endomyocardial biopsy; and
4. Member must have medical history of heart failure (NYHA Class I to III); and
5. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
6. Prescriber must confirm the member has not undergone a liver transplant; and
7. Vyndamax® or Vyndaqel® must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
8. Vyndamax® or Vyndaqel® will not be approved for concomitant use Amvuttra™ (vutrisiran), Onpattro® (patisiran) or Tegsedi® (inotersen); 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 and member has not undergone a liver transplant; and
10. A quantity limit of 1 Vyndamax® capsule or 4 Vyndaqel® capsules per day will apply.

Recommendation 4: Vote to Prior Authorize Herceptin Hylecta™ (Trastuzumab/Hyaluronidase-oysk) and Update the Approval Criteria for the Breast Cancer Medications

MOTION CARRIED by unanimous approval.

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

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
2. Authorization of Herceptin® (trastuzumab), Herceptin Hylecta™ (trastuzumab/hyaluronidase-oysk), Herzuma® (trastuzumab-pkrb), ~~or~~ Kanjinti® (trastuzumab-anns), or Ogivri® (trastuzumab-dkst) will also require a patient-specific, clinically significant reason why the member cannot use ~~Ogivri® (trastuzumab-dkst),~~ Ontruzant® (trastuzumab-dttb)~~,~~ or Trazimera™ (trastuzumab-qyyp). Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic gastric or GEJ adenocarcinoma; and
2. Authorization of Herceptin® (trastuzumab), Herzuma® (trastuzumab-pkrb), ~~or~~ Kanjinti® (trastuzumab-anns), or Ogivri® (trastuzumab-dkst) will also require a patient-specific, clinically significant reason why the member cannot use ~~Ogivri® (trastuzumab-dkst),~~ Ontruzant® (trastuzumab-dttb)~~,~~ or Trazimera™ (trastuzumab-qyyp). Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

The College of Pharmacy also recommends updating the approval criteria for Enhertu® (fam-trastuzumab deruxtecan-nxki), Lynparza® (olaparib), and Verzenio® (abemaciclib) based on recent FDA approvals (changes and new criteria noted in red; only criteria with updates are listed):

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

1. Adult members with unresectable or metastatic disease ~~human epidermal growth factor receptor 2 (HER2)-positive breast cancer~~; and
   a. For human epidermal growth factor receptor 2 (HER2)-positive disease, must meet the following:

i. Member received prior therapy in the metastatic, neoadjuvant, or adjuvant setting and developed disease recurrence during or within 6 months of completing therapy; and
ii. Member has received ≥~~2~~ 1 prior anti-HER2-based regimen~~s in the metastatic setting.~~; or

b. For HER-2 low [immunohistochemistry (IHC) 1+ or IHC 2+/in situ hybridization (ISH)-] disease, must meet the following:
i. Member received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Unresectable or metastatic NSCLC; and
2. Disease is human epidermal growth factor receptor 2 (HER2)-positive; and
3. Member must have received a prior systemic therapy.

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-negative, high-risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy; and
   a. Used in the adjuvant setting; and
   b. Positive test for a germline BRCA-mutation (gBRCAm); and
   c. Maximum treatment duration of 1 year; or
2. Diagnosis of metastatic breast cancer; and
   a. Member must have shown progression on previous chemotherapy ~~in any setting~~; and
   b. Members with hormone receptor positive disease must have failed prior endocrine therapy or are considered to not be a candidate for endocrine therapy.

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

1. Diagnosis of advanced or metastatic breast cancer; and
   a. Hormone receptor positive disease; and
   b. Human epidermal growth factor receptor 2 (HER2)-negative disease; and
      i. Used in 1 of the following settings:
         1. In combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women; or
         2. In combination with fulvestrant with disease progression following endocrine therapy; or
         3. As monotherapy for disease progression following endocrine therapy and prior chemotherapy; or
2. Diagnosis of early-stage breast cancer; and
   a. Hormone receptor positive disease; and

b. HER2-negative disease; and
c. Node-positive disease high risk for recurrence with Ki-67 ≥20%; and
d. Used as adjuvant treatment in combination with endocrine therapy.

Additionally, the College of Pharmacy recommends updating the prior authorization criteria for Ixempra® (ixabepilone) based on National Comprehensive Cancer Network (NCCN) compendium approval (changes noted in red):

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

1. Diagnosis of metastatic or locally advanced breast cancer; and
2. Used in combination with capecitabine; and
   a. After failure of an anthracycline and a taxane unless anthracycline contraindicated; or
3. Used as a single agent; and
   a. Used in 1 of the following settings:
      i. After failure of capecitabine, an anthracycline, and a taxane; or
      ii. In members with no response to preoperative systemic therapy; or
      iii. After at least 1 line of therapy for recurrent unresectable (local or regional) disease; or
      iv. Disease is human epidermal growth factor receptor 2 (HER2)-negative; or
4. Used in combination with trastuzumab; and
   a. Disease is HER2-positive; and
   b. Third-line or subsequent therapy.

Finally, the College of Pharmacy also recommends updating the prior authorization criteria for Perjeta® (pertuzumab) to more closely reflect the FDA approval granted to pertuzumab for this indication, including an update based on the DUR Board's recommendation to allow for the prescriber to choose either paclitaxel or docetaxel for neoadjuvant treatment as shown in 2.c.iv. (changes noted in red):

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

1. Human epidermal growth factor receptor 2 (HER2)-positive; and
2. Used in 1 of the following settings:
   a. Metastatic breast cancer in members who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease; and
      i. Used in combination with trastuzumab and ~~docetaxel~~ chemotherapy; or
   b. Neoadjuvant treatment of members with locally advanced, inflammatory, or early stage breast cancer (either >2cm in diameter or node positive); and

i. Used in combination with trastuzumab and ~~docetaxel or paclitaxel (neoadjuvant treatment may also contain other agents in addition to trastuzumab and docetaxel or paclitaxel~~ chemotherapy; or

c. Adjuvant systemic therapy for members with node positive, HER2-positive tumors or members with high-risk node negative tumors [tumor >1cm; tumor 0.5 to 1cm with histologic or nuclear grade 3; estrogen receptor (ER)/progesterone receptor (PR) negative; or younger than 35 years of age]; and
   i. Used in combination with trastuzumab and chemotherapy ~~paclitaxel following doxorubicin/cyclophosphamide (AC)~~; or
   ii. Used in combination with trastuzumab and docetaxel following doxorubicin/cyclophosphamide (AC); or
   iii. Used in combination with docetaxel/carboplatin/trastuzumab (TCH); or
   iv. Used in combination with trastuzumab following neoadjuvant therapy with paclitaxel or docetaxel and carboplatin/trastuzumab/pertuzumab.

Recommendation 4: Annual Review of Bylvay® (Odevixibat) and Livmarli® (Maralixibat)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Bylvay® (odevixibat) prior authorization criteria with the following changes to be consistent with the Livmarli® (maralixibat) prior authorization criteria (changes shown in red):

Bylvay® (Odevixibat) Approval Criteria:

1. An FDA approved indication for the treatment of pruritus in members with progressive familial intrahepatic cholestasis (PFIC); and
   a. Diagnosis must be confirmed by genetic testing identifying mutations in the *ATP8B1, ABCB11, or ABCB4* genes; and
2. Member must be 3 months of age or older; and
3. Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 ~~3~~ of the following medications, unless contraindicated:
   ~~a. Ursodeoxycholic acid (UDCA); or~~
   b. Cholestyramine; or
   c. Rifampin; or
   d. Sertraline; or

    e. Naltrexone; and
5. Member must have elevated serum bile acid concentration ≥100micromol/L at baseline; and
6. Prescriber must verify member does not have known pathologic variants of the *ABCB11* gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and
7. Members with a history of liver transplantation will generally not be approved for Bylvay®; and
8. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
9. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Bylvay®; and
10. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
11. Initial approvals will be for 40mcg/kg/day for a duration of 3 months. After 3 months of treatment, further approval may be granted at the 40mcg/kg/day dose if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate; or
12. Dose increases to 80mcg/kg/day (for 3 months) and 120mcg/kg/day (for 3 months) may be approved if there is no improvement in pruritus after 3 months of treatment with the lower dose(s). Further approval may be granted if the prescriber documents the member is responding well to treatment at the current dose and is still not a candidate for surgical intervention; and
13. If there is no improvement in pruritus after 3 months of treatment with the maximum 120mcg/kg/day dose, further approval of Bylvay® will not be granted.

Recommendation 5: Annual Review of Spinal Muscular Atrophy (SMA) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for Evrysdi® (risdiplam) based on the recent FDA approved age expansion (changes noted in red):

Evrysdi® (Risdiplam) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA) ~~in members 2 months of age and older~~; and

2. Molecular genetic testing to confirm bi-allelic pathogenic variants in the *survival motor neuron 1* (*SMN1*) gene; and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Evrysdi® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. Prescriber must agree to evaluate member's liver function prior to initiating Evrysdi® and must verify the member does not have severe hepatic impairment (Child-Pugh C); and
6. Pharmacy must confirm Evrysdi® will be constituted to an oral solution by a pharmacist prior to dispensing and must confirm Evrysdi® will be shipped via cold chain supply to adhere to the storage and handling requirements in the Evrysdi® *Prescribing Information*; and
7. Prescriber must confirm the member or caregiver has been counseled on the proper storage of Evrysdi® and has been instructed on how to prepare the prescribed daily dose of Evrysdi® prior to administration of the first dose; and
8. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
9. Female members of reproductive potential must be willing to use effective contraception during treatment with Evrysdi® and for at least 1 month after the last dose; and
10. Prescriber must verify male members of reproductive potential have been counseled on the potential effects on fertility and the potential of compromised male fertility is acceptable; and
11. Member will not be approved for concomitant treatment with Spinraza® (nusinersen); and
12. Member must not have previously received treatment with Zolgensma® (onasemnogene abeparvovec-xioi); and
13. A baseline assessment must be provided using a functionally appropriate exam [e.g., Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), Hammersmith Functional Motor Scale Expanded (HFMSE), Hammersmith Infant Neurological Exam (HINE), Upper Limb Module (ULM) Test]; and
14. Member's recent weight must be provided to ensure accurate dosing in accordance with Evrysdi® *Prescribing Information*; and
15. A quantity limit of 240mL per 36 days will apply.

Recommendation 6: Annual Review of Myeloproliferative Neoplasm (MPN) Medications and 30-Day Notice to Prior Authorize Besremi® (Ropeginterferon Alfa-2b-njft) and Vonjo® (Pacritinib)

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

Recommendation 7: Annual Review of Targeted Immunomodulator Agents and 30-Day Notice to Prior Authorize Sotyktu™ (Deucravacitinib), Spevigo® (Spesolimab-sbzo), and Tavneos® (Avacopan)

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

Recommendation 8: Annual Review of Anemia Medications and 30-Day Notice to Prior Authorize Enjaymo™ (Sutimlimab-jome), Pyrukynd® (Mitapivat), and Zynteglo® (Betibeglogene Autotemcel)

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

Recommendation 9: Annual Review of Hepatitis C Medications

NO ACTION REQUIRED.

Recommendation 10: 30-Day Notice to Prior Authorize Xenpozyme™ (Olipudase Alfa-rpcp)

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

Recommendation 11: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

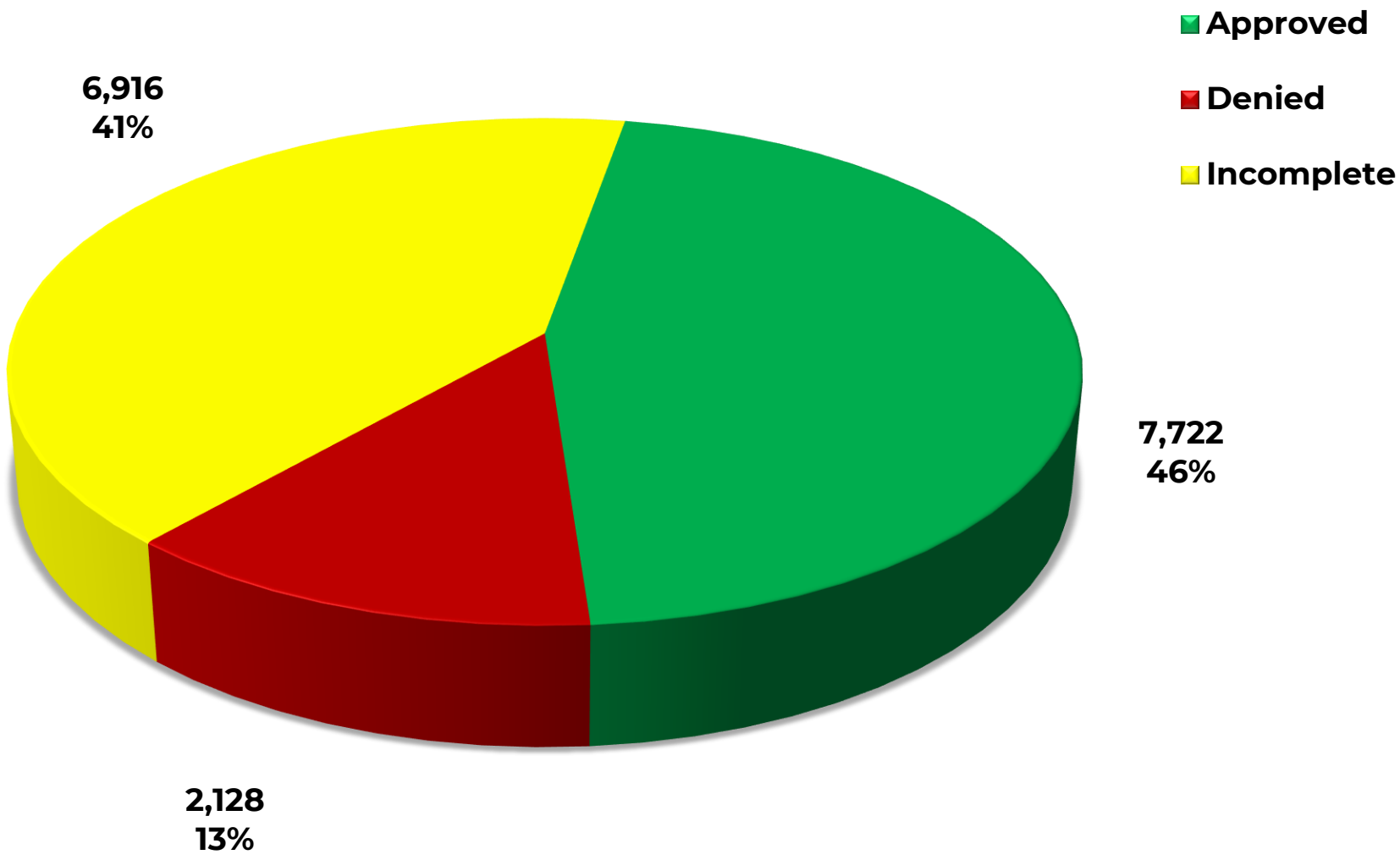
NO ACTION REQUIRED.

Recommendation 12: Future Business

NO ACTION REQUIRED.

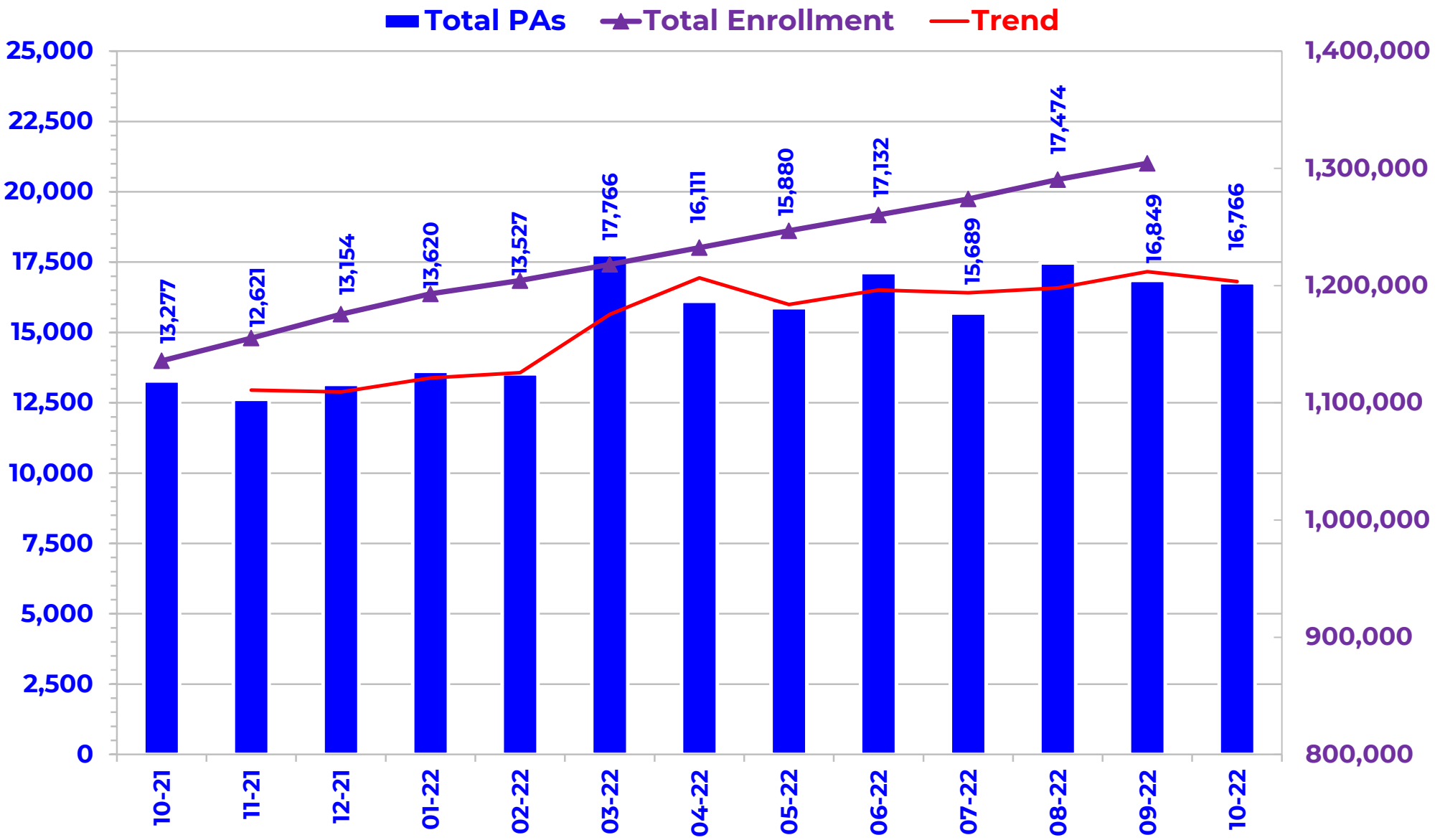
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: OCTOBER 2022



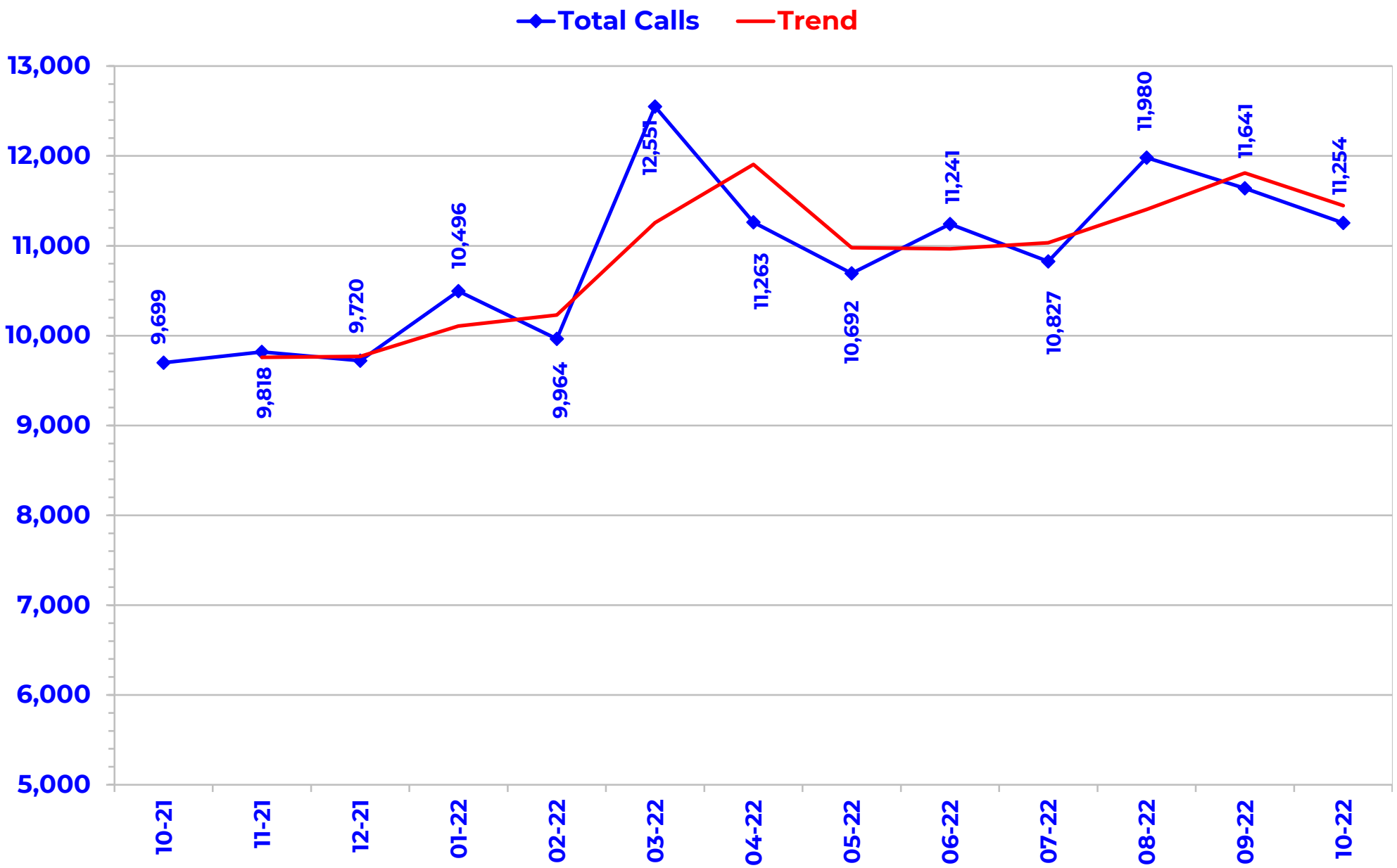
PA totals include approved/denied/incomplete/overrides

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: OCTOBER 2021 – OCTOBER 2022



Prior Authorization Activity

10/1/2022 Through 10/31/2022

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	115	42	5	68	345
Analgesic, Narcotic	374	174	29	171	142
Angiotensin Receptor Antagonist	16	1	3	12	360
Antiasthma	89	30	28	31	285
Antibiotic	62	39	4	19	235
Anticonvulsant	230	93	18	119	302
Antidepressant	364	83	42	239	318
Antidiabetic	1,637	524	382	731	357
Antigout	10	2	1	7	360
Antihemophilic Factor	13	8	0	5	281
Antihistamine	66	19	19	28	345
Antimalarial Agent	146	117	5	24	356
Antimigraine	555	91	165	299	245
Antineoplastic	291	194	15	82	169
Antiobesity	29	2	16	11	239
Antiparasitic	39	13	0	26	14
Antiulcers	41	6	8	27	131
Anxiolytic	31	6	0	25	307
Atypical Antipsychotics	550	220	53	277	352
Benign Prostatic Hypertrophy	15	1	7	7	360
Biologics	370	194	37	139	280
Bladder Control	84	15	24	45	359
Blood Thinners	748	428	19	301	339
Botox	82	52	21	9	346
Buprenorphine Medications	115	42	12	61	86
Calcium Channel Blockers	14	3	2	9	257
Cardiovascular	91	41	15	35	314
Chronic Obstructive Pulmonary Disease	348	76	71	201	328
Constipation/Diarrhea Medications	231	41	71	119	252
Contraceptive	35	16	4	15	323
Corticosteroid	24	3	7	14	145
Dermatological	505	156	145	204	191
Diabetic Supplies	870	290	150	430	243
Endocrine & Metabolic Drugs	89	34	15	40	153
Erythropoietin Stimulating Agents	37	18	5	14	111
Fibric Acid Derivatives	14	1	1	12	360
Fibromyalgia	17	4	2	11	308
Fish Oils	42	6	7	29	359
Gastrointestinal Agents	229	53	30	146	199
Genitourinary Agents	13	2	4	7	183

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Glaucoma	23	3	3	17	158
Growth Hormones	126	89	14	23	158
Hematopoietic Agents	33	11	4	18	239
Hepatitis C	44	22	8	14	6
HFA Rescue Inhalers	1,080	555	9	516	351
Insomnia	121	9	34	78	183
Insulin	271	98	21	152	347
Miscellaneous Antibiotics	22	5	4	13	24
Multiple Sclerosis	83	37	12	34	225
Muscle Relaxant	77	7	15	55	46
Nasal Allergy	64	2	27	35	222
Neurological Agents	189	54	46	89	214
Neuromuscular Agents	11	6	1	4	236
NSAIDs	52	2	15	35	360
Ocular Allergy	26	4	6	16	91
Ophthalmic	12	2	2	8	359
Ophthalmic Anti-infectives	27	18	0	9	39
Ophthalmic Corticosteroid	11	3	1	7	258
Osteoporosis	44	17	7	20	332
Other*	399	102	41	256	287
Otic Antibiotic	21	2	3	16	9
Respiratory Agents	51	37	1	13	304
Statins	55	4	18	33	126
Stimulant	2,024	1,323	100	601	346
Synagis	232	112	61	59	80
Testosterone	202	45	50	107	351
Thyroid	35	11	5	19	341
Topical Antifungal	43	3	13	27	168
Topical Corticosteroids	61	18	21	22	57
Vitamin	125	36	54	35	122
Pharmacotherapy	77	66	2	9	282
Emergency PAs	0	0	0	0	
Total	**14,272**	**5,843**	**2,040**	**6,389**	

* 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	30	16	0	14	249
Compound	12	8	0	4	55
Dosage Change	490	461	0	29	16
High Dose	6	5	0	1	291
IHS-Brand	1	1	0	0	360
Ingredient Duplication	5	4	0	1	96
Lost/Broken Rx	140	131	1	8	21
MAT Override	267	224	2	41	81
NDC vs Age	363	243	40	80	254
NDC vs Sex	5	4	1	0	91
Nursing Home Issue	41	41	0	0	28
Opioid MME Limit	105	37	7	61	114
Opioid Quantity	47	40	0	7	167
Other	85	77	1	7	19
Quantity vs Days Supply	793	509	28	256	254
STBS/STBSM	13	10	2	1	84
Step Therapy Exception	18	8	4	6	327
Stolen	21	18	0	3	17
Third Brand Request	52	42	2	8	16
Overrides Total	**2,494**	**1,879**	**88**	**527**	
Total Regular PAs + Overrides	**16,766**	**7,722**	**2,128**	**6,916**	

Denial Reasons	
Unable to verify required trials.	5,694
Does not meet established criteria.	2,142
Lack required information to process request.	1,229
Other PA Activity	
Duplicate Requests	1,658
Letters	36,353
No Process	8
Changes to existing PAs	1,281
Helpdesk Initiated Prior Authorizations	1,143
PAs Missing Information	1,615

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

Impact of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators

Oklahoma Health Care Authority
November 2022

Introduction[1,2,3]

Cystic fibrosis (CF) is an inherited autosomal recessive disease caused by mutations of the cystic fibrosis transmembrane conductance regulator (CFTR) gene. In order to develop CF, an individual must inherit 2 abnormal CFTR genes (1 from their mother and 1 from their father). A normal CFTR gene encodes CFTR protein that is found in the cells that line various organs, including the lungs and pancreas. The CFTR protein functions as a chloride membrane channel in cells of the exocrine system that produce mucus, sweat, saliva, tears, and digestive enzymes. The protein controls the movement of chloride ions into and out of cells, which also determines the movement of water across cells. Mutations in the CFTR gene lead to the creation of a dysfunctional protein or a shortage or absence of CFTR protein at the cell surface, causing cells to produce mucus that is abnormally thick and sticky. CFTR mutations are generally grouped into 5 different classes based on how they affect the CFTR protein. Disease severity varies depending on the 2 types of CFTR gene mutations the patient inherited.

CF is the most common, life-threatening recessive genetic disorder in Caucasians. Approximately 30,000 people in the United States have CF, and 1,000 new cases are diagnosed each year, with males and females affected equally. More than 75% of individuals with CF are diagnosed by age 2 years, and more than half of the CF population are 18 years of age or older.

CF is progressive and affects multiple organs, with the greatest impact being on the lungs. Abnormal mucus in the lungs decreases clearance of the mucus, which can lead to airway obstruction, inflammation, and infection. Over time, significant lung damage occurs leading to tissue remodeling, progressive deterioration in lung function, and ultimately respiratory failure. Advanced CF lung disease is the most frequent cause of death. Forced expiratory volume in 1 second (FEV1) is the strongest clinical predictor of survival among patients with CF, and it is commonly used to measure disease severity, progression, and therapeutic response.

CF can also cause pancreatic insufficiency when mucus builds up in the pancreatic ducts. This can prevent pancreatic enzymes from reaching the intestines interfering with the breakdown and absorption of food and nutrients, and can then lead to malabsorption resulting in a variety of

nutritional deficiencies in affected individuals, such as failure to thrive. Additionally, due to the effects on the pancreas, patients with CF can also develop cystic fibrosis-related diabetes (CFRD). It is more likely to develop in adulthood, with 20% of adolescents and 40-50% of adults being affected by CFRD. Approximately 21% of SoonerCare members with CF also have a diabetes-related diagnosis.

Patients with CF complete a combination of daily therapies, such as airway clearance, inhaled medications and antibiotics, pancreatic enzyme supplements, individualized fitness plans, and CFTR modulators. There have been numerous advancements in the care of CF patients over the years that have helped increase their quality of life, as well as life expectancy.

CFTR Modulators[4]

CFTR modulators are a class of drugs that act by improving the function of the defective CFTR proteins. How well CFTR modulators work correlates to the specific mutations a patient has in their CFTR genes. Approximately 50% of patients with CF are homozygous for the F508del mutation, and about 90% of patients with CF have at least 1 F508del mutation. However, there are over 2,000 mutations identified in human CFTR alleles. Before prescribing a CFTR modulator therapy, the patient's genotype must be identified through the use of an U.S. Food and Drug Administration (FDA)-approved CF mutation test.

There are currently 4 CFTR modulators that are FDA approved and available on the market:

- Kalydeco® (ivacaftor): Approved in 2012
- Orkambi® (lumacaftor/ivacaftor): Approved in 2015
- Symdeko® (tezacaftor/ivacaftor and ivacaftor): Approved in 2018
- Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor): Approved in 2019

Among these CFTR modulators, there are 2 main types based on their mechanism of action, potentiators and correctors:

- Potentiators hold the protein gate open so chloride can flow through the cell membrane and therefore can help patients with gating and conduction mutations. This includes the medication ivacaftor.
- Correctors help the protein to form the correct shape so that it can move to the cell surface. This is seen in 90% of the CF population with the F508del mutation. This includes the medications lumacaftor, tezacaftor, and elexacaftor.
- Even with correctors, only some of the CFTR protein reaches the cell surface. Additionally, the proteins that do reach the cell surface do not open sufficiently to allow chloride to pass out of the cell. If a corrector is

used in combination with a potentiator to hold the gate on the CFTR protein open, enough chloride can then flow to reduce the symptoms of CF.

CFTR Modulator Impact[5,6,7]

Over time there have been substantial improvements in the survival of patients with CF. The CFTR modulators represent a significant advancement in the treatment of CF and are one of the factors contributing to a longer life expectancy for many patients with CF. From 2007-2011, CF patients were predicted to live to a median age of 38 years. However, with the development and FDA approval of CFTR modulators, from 2017-2021, this life expectancy increased to a median age of 53 years. Along with increased life expectancy, other improvements in patients' health are observed in the United States such as decreased lung transplants (271 in 2016 vs. 52 in 2021), decreases in airway infections with *Pseudomonas aeruginosa* (43% in 2019 vs. 28% in 2021), improvements in lung function, and decreased exacerbations.

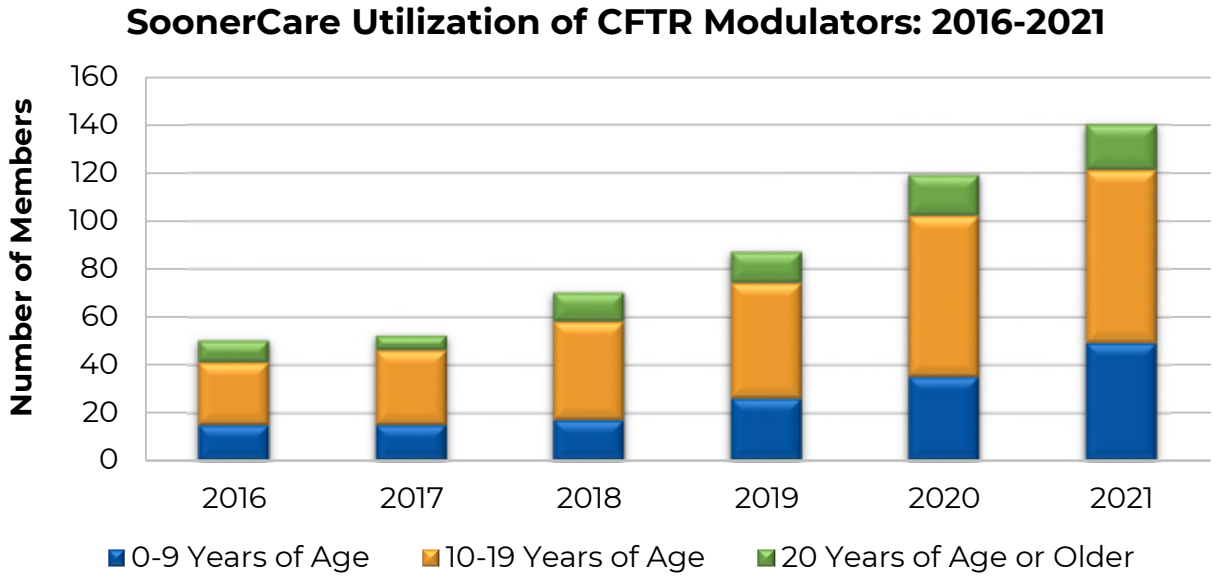
The number of patients with CF who are using CFTR modulator therapies continues to increase. The expanded approval of elexacaftor/tezacaftor/ivacaftor for children with CF from 6 to 11 years of age in June 2021 resulted in approximately 1,500 patients in the United States becoming eligible for treatment. More than 23,000 patients with CF were taking a CFTR modulator by the end of 2021.

SoonerCare Impact

The College of Pharmacy has pulled data from 1/1/2006 to 12/31/2011 (prior to CFTR modulator approval) and 1/1/2016 to 12/31/2021 (after CFTR modulator approval) to assess the impact that CFTR modulators have had on the SoonerCare population. It was found that the average age of death has remained the same, 28.22 vs. 28.19 years of age, respectively. Although this is lower than the national data for life expectancy (median age of 53 years of age), this is likely due to the majority of the SoonerCare population with CF being pediatric members. The recent Oklahoma Medicaid expansion [Healthy Adult Program (HAP)], which became effective July 2021, may impact this data in future years as more adults become or remain eligible for SoonerCare.

In 2016, there were 50 unique SoonerCare members with an average age of 14 years who were utilizing CFTR modulators, with 30% being in the 0-9 years age group, 52% in the 10-19 years age group, and 18% in the ≥20 years age group. The number of members has continued to increase over the years, and by 2021, there were a total of 140 unique members utilizing CFTR modulators with an average age remaining similar at 13 years of age, and with 35% being in the 0-9 years age group, 51% in the 10-19 years age group, and

14% in the ≥20 years age group. The increase in the 0-9 years age group is due to the FDA approved age expansions of CFTR modulators from 2018 to 2021. The following graph shows the SoonerCare utilization of CFTR modulators from 2016 to 2021 by age group.



Since the first approval of CFTR modulators in 2012, utilization in the SoonerCare population has continued to increase, and more members are becoming eligible for CFTR modulator therapy earlier in life. Starting therapy earlier is expected to continue to increase SoonerCare members' quality of life and length of life. The College of Pharmacy will continue to monitor the utilization of the CFTR modulator therapy on the SoonerCare population and assess their impact over time.

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[1] National Organization for Rare Disorders (NORD). Cystic Fibrosis. Available online at: https://rarediseases.org/rare-diseases/cystic-fibrosis/. Last accessed 10/21/2022.
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Appendix C

2023 Drug Utilization Review (DUR) Board Meeting Dates

Oklahoma Health Care Authority
November 2022

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

Appendix D

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

Oklahoma Health Care Authority
November 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:** The FDA approved Oxbryta® (voxelotor) to include use in children 4 to 11 years of age. Voxelotor was previously FDA approved in 2019 for sickle cell disease (SCD) in patients 12 years of age and older. The approved age expansion was based on data from a Phase 2 trial in 45 children that showed 36% of patients had an increase in hemoglobin (Hgb) >1g/dL by week 24. With this new approval, an oral tablet for suspension is now also available. Global Blood Therapeutics is also currently studying voxelotor in patients 9 months of age and older.
- **February 2022:** The FDA approved Enjaymo™ (sutimlimab-jome) to decrease the need for red blood cell (RBC) transfusions due to hemolysis in adults with cold agglutinin disease based on a trial in 24 adults with cold agglutinin disease who had a blood transfusion within the past 6 months. Cold agglutinin disease is an autoimmune disorder characterized by RBC destruction, which leads to anemia and cold-induced circulatory symptoms, such as pain and discoloration of fingers or toes. The disease is called “cold” agglutinin disease because the RBC destruction occurs at cold temperatures. Patients with cold agglutinin disease have anemia symptoms ranging in severity, including fatigue, weakness, shortness of breath, tachycardia, dizziness, and chest pain. Many patients with cold agglutinin disease need RBC transfusions to manage their disease. The disease is rare, affecting about 1 person per million annually and mostly develops in individuals between 40 and 80 years of age.
- **February 2022:** Pyrukynd® (mitapivat) was approved by the FDA for hemolytic anemia in adults with pyruvate kinase (PK) deficiency. PK deficiency is an inherited disorder that causes premature RBC destruction leading to anemia. Patients with PK deficiency have symptoms ranging in severity, including fatigue, unusually pale skin, jaundice, shortness of breath, and tachycardia. Patients can also develop an enlarged spleen, iron overload from repeated blood

transfusions, and gallstones. PK deficiency is rare with approximately 3 to 9 cases per 1 million people; however, it is often misdiagnosed or underdiagnosed.

- **August 2022:** Zynteglo® (betibeglogene autotemcel) was approved by the FDA as the first cell-based gene therapy for the treatment of adult and pediatric patients with beta thalassemia who require regular RBC transfusions. Beta thalassemia is a type of inherited blood disorder that causes a reduction of normal Hgb and RBCs in the blood, through mutations in the beta-globin subunit, leading to insufficient delivery of oxygen in the body. The reduced levels of RBCs can lead to a number of health issues including dizziness, weakness, fatigue, bone abnormalities, and more serious complications. Transfusion-dependent beta thalassemia (TDT), the most severe form of the condition, generally requires life-long RBC transfusions as the standard course of treatment. These regular transfusions can be associated with multiple health complications of their own, including problems in the heart, liver, and other organs due to an excessive build-up of iron in the body. Zynteglo® is a one-time gene therapy product administered as a single dose; each dose of Zynteglo® is a customized treatment created using the patient's own stem cells that are genetically modified to produce functional beta-globin.

Enjaymo™ (Sutimlimab-jome) Product Summary[7]

Indication(s): Enjaymo™ is a classical complement inhibitor indicated to decrease the need for RBC transfusion due to hemolysis in adults with cold agglutinin disease.

How Supplied: 1,100mg/22mL (50mg/mL) single dose vial

Dosing and Administration:

- Weight-based dosing weekly for 2 weeks then every 2 weeks thereafter
  - 39kg to <75kg: 6,500mg by intravenous (IV) infusion
  - ≥75kg: 7,500mg by IV infusion
- Vaccination against encapsulated bacteria should be completed at least 2 weeks prior to treatment.

Mechanism of Action: Sutimlimab-jome is an immunoglobulin G (IgG), subclass 4 (IgG4) monoclonal antibody (mAb) that inhibits the classical complement pathway (CP) and specifically binds to complement protein component 1, s subcomponent (C1s), a serine protease which cleaves C4. Sutimlimab-jome does not inhibit the lectin and alternative pathways. Inhibition of the classical CP at the level of C1s prevents deposition of complement opsonins on the surface of RBCs, resulting in inhibition of hemolysis in patients with cold agglutinin disease.

Contraindication(s):

- Known hypersensitivity to sutimlimab-jome or any of the inactive ingredients

Safety:

- Serious Infections: Enjaymo™ may increase susceptibility to serious infections caused by encapsulated bacteria (e.g., *Neisseria meningitides*, *Streptococcus pneumoniae*, *Haemophilus influenzae*). Patients should be vaccinated against encapsulated bacteria according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations. Patients should be vaccinated at least 2 weeks prior to receiving the first dose of Enjaymo™ or as soon as possible.
- Infusion-Related Reactions: Patients should be monitored for infusion-related reactions and treatment should be interrupted if reaction occurs. Enjaymo™ should be discontinued and appropriate supportive measures should be instituted if signs of hypersensitivity reactions, such as cardiovascular instability or respiratory compromise, occur.
- Risk of Autoimmune Disease: Enjaymo™ may potentially increase the risk for developing autoimmune disease. Patients should be monitored for signs and symptoms and managed medically.
- Recurrent Hemolysis after Enjaymo™ Discontinuation: If treatment with Enjaymo™ is interrupted, patients should be closely monitored for signs and symptoms of recurrent hemolysis [e.g., elevated levels of total bilirubin or lactate dehydrogenase (LDH) accompanied by a decrease in Hgb; reappearance of symptoms such as fatigue, dyspnea, palpitations, or hemoglobinuria]. Consideration should be given to restarting Enjaymo™ if signs and symptoms of hemolysis occur after discontinuation.

Adverse Reactions: The most frequent (incidence ≥10%) adverse reactions in clinical trials were respiratory tract infection, viral infection, diarrhea, dyspepsia, cough, arthralgia, arthritis, and peripheral edema.

Efficacy: The safety and efficacy of Enjaymo™ were studied in a Phase 3 open-label 6-month trial in 24 adult patients with confirmed cold agglutinin disease, recent history of an RBC transfusion within 6 months of study enrollment, Hgb ≤10g/dL, and symptomatic disease.

- Primary Endpoint: The composite primary endpoint was defined as an increase from baseline in Hgb level ≥2g/dL or a Hgb level ≥12g/dL at the treatment assessment time point, no RBC transfusion from week 5 through week 26, and no treatment for cold agglutinin disease (i.e., rituximab with or without cytotoxic agents) beyond what was allowed per protocol.

- Results: Overall, 13 of 24 patients [54.2%; 95% confidence interval (CI): 32.8%, 74.4%] were deemed a responder based on the primary composite endpoint. The results of each of the components of the composite endpoint were also reported: 63% had a Hgb level ≥12g/dL or increase in level ≥2g/dL, 71% of patients did not receive RBC transfusions from week 5 to week 26, and 92% did not receive protocol prohibited cold agglutinin disease medications. Of the 11 patients who did not meet the primary endpoint, 6 showed evidence of a treatment response.

Cost: The Wholesale Acquisition Cost (WAC) of Enjaymo™ is $81.82 per mL, or $1,800.04 per 1,100mg/22mL vial, resulting in an estimated annual cost of $327,607.28 at the maximum recommended dose of 7,500mg every 2 weeks.

Pyrukynd® (Mitapivat) Product Summary[8]

Indication(s): Pyrukynd® is a PK activator indicated for the treatment of hemolytic anemia in adults with PK deficiency.

How Supplied: 5mg, 20mg, and 50mg oral tablets

Dosing and Administration:
- Pyrukynd® tablets should be swallowed whole and may be taken with or without food.
- The recommended starting dose is 5mg orally twice daily with a maximum recommended dose of 50mg twice daily.
- Pyrukynd® should be titrated every 4 weeks based on Hgb levels and transfusion requirements.
- Pyrukynd® should be discontinued if no benefit has been observed by 24 weeks.
- Refer to the *Prescribing Information* for the full recommended titration and maintenance dosing information.

Mechanism of Action: Mitapivat is a PK activator that acts by allosterically binding to the PK tetramer and increasing PK activity. The RBC form of PK (PK-R) is mutated in PK deficiency, which leads to reduced adenosine triphosphate (ATP), shortened RBC lifespan, and chronic hemolysis.

Contraindication(s): None

Safety:
- Acute Hemolysis with Abrupt Treatment Interruption: Abrupt discontinuation of Pyrukynd® should be avoided due to possible acute hemolysis. Pyrukynd® should be gradually tapered to discontinue treatment.
- Pediatric Use: The safety and effectiveness in pediatric patients have not been established.

- Geriatric Use: Studies of Pyrukynd® did not include sufficient numbers of patients 65 years of age and older.
- Hepatic Impairment: Pyrukynd® undergoes extensive hepatic metabolism and should be avoided in patients with moderate-to-severe hepatic impairment.

Adverse Reactions: The most frequent (incidence ≥10%) adverse reactions in clinical trials were decreased estrone (males), increased urate, back pain, decreased estradiol (males), and arthralgia.

Efficacy: Pyrukynd® was studied in 2 trials, ACTIVATE and ACTIVATE-T. ACTIVATE was a randomized, double-blind trial in adults with PK deficiency who were not regularly transfused, defined as having no more than 4 transfusions in the 52-week period prior to treatment and no transfusions in the 3-month period prior to treatment. Of the 80 patients enrolled, 40 were randomized to receive Pyrukynd® up to 50mg twice daily for 12 weeks following a dose titration. ACTIVATE-T was an open-label study in 27 adults with PK deficiency who had a minimum of 6 transfusion episodes in the 52-week period prior to enrollment.

- **ACTIVATE:**
  - Primary Endpoint: Percentage of patients who achieved a Hgb response, defined as ≥1.5g/dL increase in Hgb from baseline sustained at 2 or more assessments during the fixed-dose period without transfusions
  - Results: Pyrukynd® demonstrated a statistically significant increase in Hgb where 40% (N=16) of patients randomized to Pyrukynd® achieved a Hgb response, compared to 0 patients randomized to placebo (2-sided P<0.0001). Of those 16 patients, 15 continued in a long-term extension study and 13 maintained increases in Hgb from baseline without requiring transfusions.
- **ACTIVATE-T:**
  - Primary Endpoint: Reduction in the patient's transfusion burden, defined as ≥33% reduction in the number of RBC units transfused during the fixed-dose period compared with the patient's historical transfusion burden
  - Results: In ACTIVATE-T, 9 (33%) patients who received Pyrukynd® achieved the primary endpoint for a reduction in transfusion burden showing statistical significance. This included 6 patients who did not require any transfusions during the 24-week fixed dose treatment period. All 6 patients who were transfusion-free remained that way in a long-term extension study.

Cost: The WAC of Pyrukynd® is $460 per tablet regardless of strength, resulting in an annual cost of $331,200 at the recommended dosing regimen of 1 tablet twice daily.

Zynteglo® (Betibeglogene Autotemcel) Product Summary[9]

Indication(s): Zynteglo® is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of adult and pediatric patients with beta thalassemia who require regular RBC transfusions.

How Supplied: Zynteglo® is supplied as a cell suspension for IV infusion; a single dose of Zynteglo® contains a minimum of 5 x 10^6 CD34+ cells/kg of body weight, in 1 or more infusion bags.

Dosing and Administration:

- Patients are required to undergo hematopoietic stem cell (HSC) mobilization followed by apheresis to obtain CD34+ cells for Zynteglo® manufacturing. A back-up collection of CD34+ cells is also required.
- Dosing of Zynteglo® is based on the number of CD34+ cells in the infusion bag(s) per kg of body weight.
- The minimum recommended dose is 5 x 10^6 CD34+ cells/kg.
- Full myeloablative conditioning must be administered before infusion of Zynteglo®.
- Patient's identity should be verified to match the unique patient identification information on the Zynteglo® infusion bag(s) prior to infusion.
- Zynteglo® should not be sampled, altered, or irradiated.
- An in-line blood filter or an infusion pump should not be used.
- Each infusion bag of Zynteglo® should be administered via IV infusion over a period of less than 30 minutes.

Mechanism of Action: Zynteglo® adds functional copies of a modified β-globin gene into patients' HSCs through transduction of autologous CD34+ cells with BB305 lentiviral vector (LVV). After Zynteglo® infusion, transduced CD34+ HSCs engraft in the bone marrow and differentiate to produce RBCs containing biologically active βA-T87Q-globin (a modified β-globin protein) that will combine with α-globin to produce functional adult Hgb containing βA-T87Q-globin (HbAT87Q). βA-T87Q-globin can be quantified relative to other globin species in peripheral blood using high-performance liquid chromatography. βA-T87Q-globin expression is designed to correct the β/α-globin imbalance in erythroid cells of patients with beta thalassemia and has the potential to increase functional adult Hgb (HbA) and total Hgb to normal levels and eliminate dependence on regular RBC transfusions.

Contraindication(s): None

Safety:

- Delayed Platelet Engraftment: Delayed platelet engraftment has been observed with Zynteglo® 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 Zynteglo® [defined as failure to achieve 3 consecutive absolute neutrophil counts (ANC) ≥500cells/mcL obtained on different days by day 43 after Zynteglo® infusion]. ANC should be monitored after Zynteglo® infusion, and if neutrophil engraftment does not occur, rescue treatment with the back-up collection of CD34+ cells should be provided.
- Risk of Insertional Oncogenesis: There is a potential risk of LVV-mediated insertional oncogenesis after treatment with Zyntelgo®; patients treated with Zyntelgo® may develop hematologic malignancies and should be monitored lifelong. Patients should be monitored at month 6, month 12, and at least annually for hematologic malignancies for at least 15 years after Zyntelgo® infusion.
- Hypersensitivity Reactions: The dimethyl sulfoxide (DMSO) in Zyntelgo® may cause hypersensitivity reactions, including anaphylaxis. Patients should be monitored for hypersensitivity reactions during the infusion.
- Anti-Retroviral and Hydroxyurea Use: Patients should not take prophylactic human immunodeficiency virus (HIV) anti-retroviral medications or hydroxyurea 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. If a patient requires anti-retrovirals for HIV prophylaxis, a negative test for HIV should be confirmed before beginning mobilization and apheresis of CD34+ cells.
- Iron Chelation: Drug-drug interactions between iron chelating agents and the myeloablative conditioning agent must be considered. Iron chelating agents should be discontinued at least 7 days prior to initiation of conditioning. After Zyntelgo® infusion, iron chelating agents should be avoided for 6 months. If iron chelation is needed, administration of non-myelosuppressive iron chelating agents should be considered, and phlebotomy can be used in lieu of iron chelation, when appropriate.
- Interference with Serology Testing: Patients who have received Zyntelgo® are likely to test positive by polymerase chain reaction (PCR) assays for HIV due to integrated BB305 LVV proviral DNA, resulting in a false-positive test for HIV; therefore, patients who have received Zyntelgo® should not be screened for HIV infection using a PCR-based assay.
- Pregnancy: There is no available data on the administration of Zyntelgo® in pregnant women. The risks associated with myeloablative conditioning should be considered on pregnancy and fertility. No

reproductive and developmental toxicity studies in animals have been conducted with Zyntelgo® to assess whether it can cause fetal harm when administered to a pregnant woman, and it is not known whether Zyntelgo® has the potential to be transferred to the fetus. Therefore, Zyntelgo® should not be administered to women who are pregnant, and pregnancy after Zyntelgo® infusion should be discussed with the treating physician.

- Lactation: There is no information regarding the presence of Zyntelgo® in human milk, the effect on the breastfed infant, and the effects on milk production. Therefore, Zyntelgo® is not recommended for women who are breastfeeding, and breastfeeding after Zyntelgo® infusion should be discussed with the treating physician.
- Females and Males of Reproductive Potential: A negative serum pregnancy test should be confirmed prior to the start of mobilization and should be re-confirmed prior to conditioning procedures and before Zyntelgo® administration. Women of childbearing potential and men capable of fathering a child should use an effective method of contraception [intrauterine device (IUD) or combination of hormonal and barrier contraception] from start of mobilization through at least 6 months after administration of Zyntelgo®. Patients should also be advised of the risks of infertility associated with myeloablative conditioning.
- Pediatric Use: The safety and efficacy of Zyntelgo® have been established in pediatric patients with beta thalassemia requiring regular transfusions. Use of Zyntelgo® is supported by 2 Phase 3 trials that included 27 pediatric patients in the following age groups: 16 children (younger than 12 years) and 11 adolescents (age 12 years to younger than 18 years). The safety and efficacy of Zyntelgo® in children younger than 4 years of age have not been established.
- Geriatric Use: Zyntelgo® has not been studied in patients older than 65 years of age. HSC transplantation must be appropriate for a patient to be treated with Zyntelgo®.
- Patients Seropositive for HIV: Zyntelgo® 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 Zynteglo® manufacturing. Apheresis material from patients with a positive test for HIV will not be accepted for Zynteglo® manufacturing.
- Renal Impairment: Zynteglo® has not been studied in patients with renal impairment. Patients should be assessed for renal impairment (defined as creatinine clearance ≤70mL/min/1.73m^2) to ensure HSC transplantation is appropriate.

- Hepatic Impairment: Zynteglo® has not been studied in patients with hepatic impairment. Patients should be assessed for hepatic impairment to ensure HSC transplantation is appropriate.

Adverse Reactions:

- The most frequent non-laboratory (incidence ≥20%) adverse reactions in clinical trials were mucositis, febrile neutropenia, vomiting, pyrexia, alopecia, epistaxis, abdominal pain, musculoskeletal pain, cough, headache, diarrhea, rash, constipation, nausea, decreased appetite, pigmentation disorder, and pruritus.
- The most frequent grade 3 or 4 laboratory (incidence >50%) adverse reactions in clinical trials were neutropenia, thrombocytopenia, leukopenia, anemia, and lymphopenia.

Efficacy: The safety and efficacy of Zynteglo® were studied in 2 Phase 3 open-label 24-month trials, Northstar-2 and Northstar-3. The trials included a total of 41 patients ranging from 4 to 34 years of age with beta thalassemia requiring regular transfusions, defined as a history of ≥100mL/kg/year of packed RBCs or ≥8 transfusions of RBCs per year in the 2 years preceding enrollment. 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 Zynteglo®.

- Primary Endpoint: The primary endpoint was the proportion of patients who gained transfusion independence defined as Hgb ≥9g/dL without any RBC transfusions for a continuous period of ≥12 months at any time during the study after drug product infusion.
- Results: Between the 2 trials, there was an overall result of transfusion independence in 32 of 36 evaluable patients (89%; 95% CI: 74, 97) who received Zynteglo®. All patients who achieved independence have remained transfusion-free at this time. There is also an ongoing long-term follow-up study to monitor safety and efficacy for those who have received Zynteglo® through 15 years post treatment. Currently, no patients who have received Zynteglo® have developed a hematologic malignancy.

Cost: The WAC of Zynteglo® is $2.8 million per one-time treatment.

Recommendations

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.

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Appendix E

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

Oklahoma Health Care Authority
November 2022

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

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

- **October 2021:** The FDA approved Tavneos® (avacopan) as an adjunctive treatment of adult patients 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. Tavneos® does not eliminate corticosteroid use.
- **December 2021:** The FDA approved Orencia® (abatacept) for a new indication for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adult and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.
- **January 2022:** The FDA approved Rinvoq® (upadacitinib) for a new indication for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. Additionally, the FDA approved a new 30mg strength tablet for use in patients with AD.
- **July 2022:** The FDA approved Benlysta® (belimumab) for an age expansion for patients 5 years of age and older with active lupus nephritis who are receiving standard therapy. Previously, Benlysta® was only FDA approved for use in adults with lupus nephritis.
- **September 2022:** The FDA approved Spevigo® (spesolimab-sbzo) for the treatment of generalized pustular psoriasis (GPP) flares in adults. GPP is a rare autoinflammatory skin disease that is potentially life-threatening. Patients with GPP flares experience widespread eruption of sterile pustules with or without systemic symptoms such as pain, fever, malaise, and fatigue. In severe untreated cases, GPP can result in

death due to septic shock or cardiorespiratory failure. Spevigo® is the first medication to be FDA approved for the treatment of GPP flares.
- **September 2022:** The FDA approved Sotyktu™ (deucravacitinib) for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Sotyktu™ (Deucravacitinib) Product Summary[7,8,9]

Indication(s): Deucravacitinib is a tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- Limitations of Use: Not recommended for use in combination with other potent immunosuppressants

How Supplied: 6mg oral tablet

Dosing and Administration:
- Recommended dose is 6mg orally once daily, with or without food
- Tablets should not be chewed, cut, or crushed

Contraindications:
- Known hypersensitivity to deucravacitinib or any of the excipients in Sotyktu™

Safety:
- Hypersensitivity: Hypersensitivity reactions such as angioedema have been reported in patients receiving deucravacitinib. If a clinically significant hypersensitivity reaction occurs, deucravacitinib should be discontinued and appropriate therapy should be instituted.
- Infections: Deucravacitinib may increase the risk of infections. Serious infections have been reported in patients with psoriasis, including pneumonia and COVID-19. Use of deucravacitinib should be avoided in patients with active or serious infection. In patients with chronic or recurrent infection, previous exposure to tuberculosis (TB), a history of serious or opportunistic infection, or underlying conditions that may predispose them to infection, the risks and benefits of treatment with deucravacitinib should be considered. Patients should be closely monitored for signs and symptoms of infections during and after treatment with deucravacitinib and appropriate antimicrobial therapy should be initiated in patients who develop a new infection during treatment with deucravacitinib. If a patient develops a serious infection, deucravacitinib should be interrupted and should not be resumed until the infection resolves or is adequately treated.
- Viral Reactivation: Herpes virus reactivation was reported in clinical studies with deucravacitinib. The impact of deucravacitinib on chronic viral hepatitis reactivation is unknown. Consider viral hepatitis

screening and monitor for reactivation in accordance with clinical guidelines before and during treatment with deucravacitinib. If signs of reactivation occur, a hepatitis specialist should be consulted. Deucravacitinib is not recommended for use in patients with active hepatitis B (HBV) or hepatitis C (HCV).

- TB: Four patients with latent TB who were treated with deucravacitinib and received appropriate TB prophylaxis did not develop active TB during a mean follow-up of 34 weeks. One patient who did not have latent TB developed active TB after 54 weeks of treatment with deucravacitinib. Patients should be evaluated for latent and active TB infection before beginning treatment with deucravacitinib, and deucravacitinib should not be administered to patients with active TB. Treatment for latent TB should be initiated prior to administering deucravacitinib.
- Malignancy Including Lymphomas: Malignancies, including lymphomas, were observed in clinical studies of deucravacitinib. The benefits and risks of treatment with deucravacitinib should be considered, particularly in patients with a known malignancy (other than successfully treated non-melanoma skin cancer) and patients who develop a malignancy during treatment with deucravacitinib.
- Rhabdomyolysis and Elevated Creatine Phosphokinase (CPK): Cases of rhabdomyolysis were reported in patients treated with deucravacitinib, resulting in interruption or discontinuation of deucravacitinib. There was also an increased incidence of asymptomatic CPK and rhabdomyolysis relative to placebo. Deucravacitinib should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected.
- Laboratory Abnormalities: Treatment with deucravacitinib was associated with increases in triglyceride (TG) levels and liver enzyme elevations. Serum TG should be monitored periodically, and hyperlipidemia should be managed according to clinical guidelines. Liver enzymes should be evaluated at baseline and thereafter in patients with known or suspected liver disease. Deucravacitinib should be interrupted if treatment-related increases in liver enzymes occur and drug-induced liver injury is suspected.
- Immunizations: Consideration for completing all age-appropriate immunizations should be made prior to initiating treatment with deucravacitinib, including herpes zoster vaccination. Live vaccines should be avoided in patients treated with deucravacitinib. The response to live or non-live vaccines has not been evaluated in patients receiving deucravacitinib.
- Potential Risks Related to Janus Kinase (JAK) Inhibition: It is not known whether TYK2 inhibition may be associated with observed or potential adverse reactions of JAK inhibition.

- Pregnancy: The available data on deucravacitinib use during pregnancy are not sufficient to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. In animal studies, no effects on embryo-fetal development were observed in rats and rabbits during organogenesis at doses ≥91 times the maximum recommended human dose (MRHD) of 6mg daily.
- Lactation: There are no data available on the presence of deucravacitinib in human milk, the effects on the breastfed infant, or the effects on milk production. Deucravacitinib is present in rat milk and would likely be present in human milk.
- Pediatric Use: The safety and efficacy of deucravacitinib in pediatric patients have not been established.

Adverse Reactions: The most commonly reported adverse reactions in clinical studies (≥1% and >placebo) include upper respiratory tract infections, increased blood CPK, herpes simplex, mouth ulcers, folliculitis, and acne.

Cost: The Wholesale Acquisition Cost (WAC) of Sotyktu™ is $205.48 per 6mg tablet, resulting in an estimated cost of $6,164.40 per 30 days and $73,972.80 per year based on the recommended dose of 6mg once daily.

Spevigo® (Spesolimab-sbzo) Product Summary[10,11]

Indication(s): Spesolimab is an interleukin-36 (IL-36) receptor antagonist indicated for the treatment of GPP flares in adults.

How Supplied: 450mg/7.5mL solution in a single-dose vial (SDV)

Dosing and Administration:
- Administered as a single 900mg dose [using (2) 450mg/7.5mL SDVs] by intravenous (IV) infusion over 90 minutes
- If GPP flare symptoms persist, a second 900mg dose may be administered 1 week after the initial dose

Contraindications:
- Severe or life-threatening hypersensitivity to spesolimab or to any of the excipients

Safety:
- Infections: Spesolimab may increase the risk of infections. During a 1-week placebo-controlled portion of a Phase 2 study, infections were reported in 14% of patients who received spesolimab vs. 6% of patients who received placebo. In patients with chronic infection or a history of recurrent infections, the potential risks and benefits of treatment should be considered before initiating treatment with spesolimab. Treatment with spesolimab is not recommended in patients with any

clinically significant active infection until the infection resolves or is adequately treated.

- Risk of TB: Patients should be evaluated for TB infection prior to initiation and spesolimab should not be initiated in patients with active TB infection. Treatment of latent TB should be considered prior to initiating treatment with spesolimab for patients with a history of TB in whom an adequate treatment course cannot be confirmed.
- Hypersensitivity and Infusion-Related Reactions: Immediate hypersensitivity reactions, such as anaphylaxis, and delayed hypersensitivity reactions, such as drug reaction with eosinophilia and systemic symptoms (DRESS), may be associated with spesolimab. DRESS has been reported in clinical studies of spesolimab in patients with GPP. Spesolimab should be discontinued immediately, and appropriate treatment should be initiated if a patient develops signs of anaphylaxis or other serious hypersensitivity.
- Vaccinations: The use of live vaccines should be avoided in patients treated with spesolimab. Studies have not been performed in patients treated with spesolimab who have recently received live viral or bacterial vaccines.
- Pregnancy: There are insufficient data available to inform a drug-related risk of adverse pregnancy-related outcomes with spesolimab. Human immunoglobulin G (IgG) is known to cross the placental barrier, and spesolimab may be transmitted from the mother to the developing fetus.
- Lactation: There are no data available on the presence of spesolimab in human milk, the effects on the breastfed infant, or the effects on milk production. Spesolimab is expected to be present in human milk.
- Pediatric Use: The efficacy and safety of spesolimab in pediatric patients have not been established.

Adverse Reactions: The most commonly reported adverse reactions in clinical studies (≥1% and >placebo) include asthenia and fatigue, nausea and vomiting, headache, pruritus and prurigo, infusion site hematoma and bruising, urinary tract infection (UTI), bacteremia, bacteriuria, cellulitis, herpes dermatitis and oral herpes, upper respiratory tract infection, dyspnea, eye edema, and urticaria.

Cost: The WAC of Spevigo® is $3,408.87 per milliliter, resulting in an estimated cost of $51,133.05 for a single 900mg dose or $102,266.10 if a second dose is required for the GPP flare.

Tavneos® (Avacopan) Product Summary[12,13]

Indication(s): Avacopan is a complement 5a receptor (C5aR) antagonist indicated as an adjunctive treatment of adult patients with severe active ANCA-associated vasculitis (GPA or MPA) in combination with standard therapy including corticosteroids. Avacopan does not eliminate corticosteroid use.

How Supplied: 10mg oral capsule

Dosing and Administration:

- The recommended dose is 30mg [(3) 10mg capsules] twice daily with food

Safety:

- Hepatotoxicity: Cases of serious hepatic injury have been observed in patients taking avacopan. In clinical studies, patients receiving avacopan had a higher incidence of transaminase elevations and hepatobiliary events, including serious and life-threatening events. Serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, and total bilirubin should be obtained before starting avacopan, every 4 weeks after starting treatment for the first 6 months, and as clinically indicated thereafter.
- Hypersensitivity Reactions: In clinical studies, 2 cases of angioedema occurred including 1 serious event requiring hospitalization. Avacopan should be discontinued immediately if angioedema occurs and appropriate therapy should be provided; avacopan should not be re-administered unless another cause has been established.
- HBV Reactivation: HBV reactivation, including life-threatening HBV, was observed in clinical studies of avacopan. Patients should be screened for HBV before starting avacopan. For patients with evidence of prior HBV infection, physicians with expertise in managing HBV should be consulted, and HBV antiviral therapy should be considered before and during treatment with avacopan. Patients with evidence of current or prior HBV infection should be monitored for clinical and laboratory signs of hepatitis or HBV reactivation during treatment and for 6 months following treatment with avacopan.
- Serious Infections: Serious and fatal infections have been reported in patients receiving avacopan. The most common serious infections were pneumonia and UTIs. In patients with chronic or recurrent infection, previous exposure to TB, a history of serious or opportunistic infection, who have resided or traveled in areas of endemic TB or endemic mycoses, or with underlying conditions that may predispose them to infection, the risks and benefits of treatment with avacopan should be considered. Patients should be closely monitored for signs and

symptoms of infections during and after treatment with avacopan and appropriate antimicrobial therapy should be initiated in patients who develop a new infection during treatment with avacopan. If a patient develops a serious or opportunistic infection, avacopan should be interrupted and should not be resumed until the infection is controlled.

- Drug Interactions: Avacopan exposure is decreased when co-administered with strong CYP3A4 enzyme inducers (e.g., rifampin); coadministration of avacopan and moderate or strong CYP3A4 inducers should be avoided. Avacopan exposure is increased when co-administered with strong CYP3A4 enzyme inhibitors (e.g., itraconazole); the dose of avacopan should be decreased to 30mg once daily when co-administered with strong CYP3A4 inhibitors. Avacopan is a CYP3A4 inhibitor; dose reduction of sensitive CYP3A4 substrates with a narrow therapeutic window should be considered when co-administered with avacopan, and patients should be closely monitored for adverse reactions.
- Pregnancy: There are no adequate and well-controlled studies with avacopan in pregnant women to inform a drug-associated risk. In animal studies, administration of avacopan to pregnant hamsters and rabbits during the period of organogenesis produced no evidence of fetal harm with exposures up to approximately 5 and 0.6 times, respectively, the exposure at the MRHD of 30mg twice daily. Avacopan caused an increase in the number of abortions in rabbits at an exposure 0.6 times the MRHD.
- Lactation: There are no data available on the effects of avacopan on the breastfed child or on milk production. It is unknown whether avacopan is secreted in human milk. Avacopan was detected in the plasma of undosed hamster pups nursing from drug-treated dams.
- Pediatric Use: The efficacy and safety of avacopan in pediatric patients have not been established.

Adverse Reactions: The most commonly reported adverse reactions in clinical studies (incidence ≥5% and >placebo) include nausea, headache, hypertension, diarrhea, vomiting, rash, fatigue, upper abdominal pain, dizziness, increased blood creatinine, and paresthesia.

Cost: The WAC of Tavneos® is $80.27 per 10mg capsule, resulting in an estimated cost of $14,448.60 per 30 days and $173,383.20 per year based on the recommended dose of 30mg twice daily.

Recommendations

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 aGVHD and Rinvoq® (upadacitinib) for the diagnosis of 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®)±

Targeted Immunomodulator Agents*±		
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**
		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®)π
		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).
πUnique criteria applies for a diagnosis of giant cell arteritis (GCA) and chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome (CRS).
¤Unique 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.

[1] ChemoCentryx, Inc. ChemoCentryx Announces FDA Approval of Tavneos® (Avacopan) in ANCA-Associated Vasculitis. Available online at: https://www.biospace.com/article/releases/chemocentryx-announces-fda-approval-of-tavneos-avacopan-in-anca-associated-vasculitis/. Issued 10/08/2021. Last accessed 10/26/2022.
[2] Bristol Myers Squibb. U.S. Food and Drug Administration Approves Orencia® (Abatacept) in Combination with a Calcineurin Inhibitor and Methotrexate for the Prevention of Acute Graft Versus Host Disease (aGvHD). Available online at: https://news.bms.com/news/details/2021/U.S.-Food-and-Drug-Administration-Approves-Orencia-abatacept-in-Combination-with-a-Calcineurin-Inhibitor-and-Methotrexate-for-the-Prevention-of-Acute-Graft-Versus-Host-Disease-aGvHD/default.aspx. Issued 12/15/2021. Last accessed 10/26/2022.
[3] AbbVie. U.S. FDA Approves Rinvoq® (Upadacitinib) to Treat Adults and Children 12 Years and Older with Refractory, Moderate to Severe Atopic Dermatitis. Available online at: https://news.abbvie.com/news/press-releases/us-fda-approves-rinvoq-upadacitinib-to-treat-adults-and-children-12-years-and-older-with-refractory-moderate-to-severe-atopic-dermatitis.htm. Issued 01/14/2022. Last accessed 10/26/2022.
[4] GlaxoSmithKline. GSK Announces US FDA Approval of Benlysta® (Belimumab) for Pediatric Patients with Active Lupus Nephritis. Available online at: https://us.gsk.com/en-us/media/press-releases/gsk-announces-us-fda-approval-of-benlysta-belimumab-for-pediatric-patients-with-active-lupus-nephritis/. Issued 07/27/2022. Last accessed 10/26/2022.
[5] Boehringer Ingelheim. FDA Approves the First Treatment Option for Generalized Pustular Psoriasis Flares in Adults. Available online at: https://www.boehringer-ingelheim.us/press-release/fda-approves-first-treatment-option-generalized-pustular-psoriasis-flares-adults. Issued 09/01/2022. Last accessed 10/26/2022.
[6] Bristol Myers Squibb. U.S. Food and Drug Administration Approves Sotyktu™ (Deucravacitinib), Oral Treatment for Adults with Moderate-to-Severe Plaque Psoriasis. Available online at: https://news.bms.com/news/details/2022/U.S.-Food-and-Drug-Administration-Approves-Sotyktu-deucravacitinib-Oral-Treatment-for-Adults-with-Moderate-to-Severe-Plaque-Psoriasis/default.aspx. Issued 09/09/2022. Last accessed 10/26/2022.
[7] Sotyktu™ (Deucravacitinib) Prescribing Information. Bristol Myers Squibb Company. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214958s000lbl.pdf. Last revised 09/2022. Last accessed 10/26/2022.
[8] Armstrong AW, Gooderham M, Warren RB, et. Al. Deucravacitinib Versus Placebo and Apremilast in Moderate to Severe Plaque Psoriasis: Efficacy and Safety Results from the 52-Week, Randomized, Double-Blinded, Placebo-Controlled Phase 3 POETYK PSO-1 Trial. *J Am Acad Dermatol* 2022; doi: https://doi.org/10.1016/j.jaad.2022.07.002.
[9] Strober B, Thaçi D, Sofen H, et. al. Deucravacitinib Versus Placebo and Apremilast in Moderate to Severe Plaque Psoriasis: Efficacy and Safety Results from the 52-Week, Randomized, Double-Blinded, Phase 3 POETYK PSO-2 Trial. *J Am Acad Dermatol* 2022; doi: https://doi.org/10.1016/j.jaad.2022.08.061.
[10] Spevigo® (Spesolimab-sbzo) Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761244s000lbl.pdf. Last revised 09/2022. Last accessed 10/26/2022.
[11] Bachelez H, Eng Choon S, Marrakchi S, et al. Trial of Spesolimab for Generalized Pustular Psoriasis. *N Engl J Med* 2021; 385:2431-2440.
[12] Tavneos® (Avacopan) Prescribing Information. ChemoCentrx, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214487s000lbl.pdf. Last revised 10/2021. Last accessed 10/26/2022.
[13] Jayne DRW, Merkel PA, Schall TJ, et al. Avacopan for the Treatment of ANCA-Associated Vasculitis. *N Engl J Med* 2021; 384(7):599-609.

Appendix F

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

Oklahoma Health Care Authority
November 2022

Market News and Updates[1,2]

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

- **August 2022:** The FDA approved Xenpozyme™ (olipudase alfa-rpcp) for intravenous (IV) infusion in pediatric and adult patients with acid sphingomyelinase deficiency (ASMD). ASMD is a rare genetic disease that causes premature death in pediatric and adult patients. It is caused by a mutation in the sphingomyelin phosphodiesterase-1 (*SMPD1*) gene and is inherited in an autosomal recessive manner. Patients with ASMD lack the enzyme, acid sphingomyelinase (ASM), needed to break down sphingomyelin; sphingomyelin is a complex lipid that accumulates in the liver, spleen, lung, and brain.

Xenpozyme™ (Olipudase Alfa-rpcp) Product Summary[3]

Indication(s): Hydrolytic lysosomal sphingomyelin-specific enzyme indicated for the treatment of non-central nervous system (CNS) manifestations of ASMD in adult and pediatric patients

Boxed Warning: Severe Hypersensitivity Reactions

- Xenpozyme™ can cause hypersensitivity reactions, including anaphylaxis.
  - Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available during Xenpozyme™ administration.
- If a severe hypersensitivity reaction occurs, Xenpozyme™ should be discontinued.
- In patients with a severe hypersensitivity reaction, a desensitization procedure to Xenpozyme™ may be considered.

How Supplied: 20mg lyophilized powder in a single-dose vial (SDV) for reconstitution

Dosing and Administration:

- Prior to initiating treatment, pregnancy status should be verified in females of reproductive potential and baseline transaminase levels should be obtained

- Pretreatment with antihistamines, antipyretics, and/or corticosteroids should be considered
- Recommended starting dose:
  - Adults: 0.1mg/kg administered as an IV infusion
  - Pediatrics: 0.03mg/kg administered as an IV infusion
- Recommended maintenance dosage for all patients is 3mg/kg via IV infusion
- Refer to the full *Prescribing Information* for the recommended titration and maintenance dosing algorithm

Mechanism of Action: Xenpozyme™ provides an exogenous source ASM. The deficiency of ASM causes an accumulation of sphingomyelin in various tissues. Xenpozyme™ is not expected to cross the blood-brain barrier or modulate the CNS manifestations of ASMD.

Contraindication(s): None

Adverse Reactions:
- The most common (>7%) adverse reactions in adult patients include headache, cough, diarrhea, hypotension, ocular hyperemia, erythema, asthenia, pharyngitis, dyspnea, urticaria, papule, myalgia, throat irritation, and abnormal C-reactive protein.
- The most common (≥13%) adverse reactions in pediatric patients include pyrexia, cough, diarrhea, rhinitis, abdominal pain, vomiting, headache, urticaria, nausea, rash, arthralgia, pruritus, fatigue, pharyngitis, increased C-reactive protein, hypotension, anaphylactic reaction, hypersensitivity, and infusion site swelling.

Efficacy:
- The approval of Xenpozyme™ was based on data from the ASCEND and ASCEND-Peds clinical trials, which showed clinically relevant improvement in lung function, platelet count, and reduction of spleen and liver volumes with use of Xenpozyme™.
- **ASCEND** was a multicenter, randomized, double-blinded, placebo-controlled, repeat dose Phase 2/3 trial in adult patients with ASMD type B and type A/B. Patients were randomized to receive either Xenpozyme™ or placebo as an IV infusion once every 2 weeks for 52 weeks. All patients were started on 0.1mg/kg of Xenpozyme™ or placebo and titrated up to the 3mg/kg maintenance dose. It was dosed as follows: 0.1mg/kg (day 1, week 0), 0.3mg/kg (weeks 2 and 4), 0.6mg/kg (weeks 6 and 8), 1mg/kg (week 10), 2mg/kg (week 12), and then a maintenance dose of 3mg/kg (week 14 onwards).
  - Primary Endpoint: The primary efficacy endpoints included assessment of percent predicted diffusion capacity of the lungs for

carbon monoxide (DLco), spleen volume, liver volume, and platelet count.
    - Results: A greater proportion of patients showed improvement in the primary endpoint at week 52 compared to placebo. There was an increase of 21% in mean percent change in percent predicted DLco in Xenpozyme™-treated patients compared to placebo [95% confidence interval (CI): 10.6, 31.2; P=0.0003] and a 39% reduction in spleen volume (95% CI: -47.6, -31.2; P<0.0001). Additionally, there was a decrease in mean liver volume (95% CI: -33.4, -16.1; P<0.0001) and an increase in mean platelet count (95% CI: 1.8, 29.4; P=0.0280) at 52 weeks with Xenpozyme™-treatment compared to placebo.
- **ASCEND-Peds** was a multicenter, open-label, repeated-dose trial of Xenpozyme™ given IV once every 2 weeks for 64 weeks in pediatric patients younger than 18 years of age with a diagnosis of ASMD type B and A/B. Xenpozyme™ was dosed as follows: 0.03mg/kg (day 1, week 0), 0.1mg/kg (weeks 2), 0.3mg/kg (weeks 4 and 6), 0.6mg/kg (weeks 8 and 10), 1mg/kg (week 12), 2mg/kg (week 14), and then a maintenance dose of 3mg/kg (week 16 onwards).
    - Primary Endpoint: The primary endpoints were related to organomegaly, pulmonary and liver functions, and linear growth which were all evaluated at week 52.
    - Results: Treatment with Xenpozyme™ resulted in improvements in mean percent change in percent predicted DLco (95% CI: -12.5, 104.3), spleen volume (95% CI: -55.5, -37.9), liver volumes (95% CI: -44.1, -32.0), platelet counts (95% CI: 8.5, 66.7), and linear growth progressions (95% CI: 0.2, 0.8) at week 52 as compared to baseline.

Cost: The Wholesale Acquisition Cost (WAC) of Xenpozyme™ is $7,142 per 20mg SDV, resulting in an estimated cost of $157,124 per month and $2,042,612 per year, based on the maximum recommended maintenance dose of 3mg/kg every 2 weeks for an adult member weighing 70kg.

Recommendations

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.

[1] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for Acid Sphingomyelinase Deficiency, a Rare Genetic Disease. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-acid-sphingomyelinase-deficiency-rare-genetic-disease. Issued 08/31/2022. Last accessed 10/17/2022.

[2] National Organization for Rare Disorders. Acid Sphingomyelinase Deficiency. Available online at: https://rarediseases.org/rare-diseases/acid-sphingomyelinase-deficiency. Last revised 10/18/2019. Last accessed 10/17/2022.

[3] Xenpozyme™ (Olipudase Alfa-rpcp) Prescribing Information. Sanofi. Available online at: https://products.sanofi.us/xenpozyme/xenpozyme.pdf. Last revised 08/2022. Last accessed 10/17/2022.

Appendix G

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

Oklahoma Health Care Authority
November 2022

Market News and Updates[1,2]

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

- **November 2021:** The FDA approved Besremi® (ropeginterferon alfa-2b-njft) injection for the treatment of adults with polycythemia vera (PV). Besremi® can be used regardless of treatment history, and it is the first interferon therapy specifically approved for PV.
- **February 2022:** The FDA approved Vonjo® (pacritinib) for the treatment of adults with intermediate or high-risk primary or secondary [post-PV or post-essential thrombocythemia (ET)] myelofibrosis (MF) with a platelet count below 50 x 10^9/L. Vonjo® is a novel oral kinase inhibitor with specificity for Janus kinase 2 (JAK2) and interleukin-1 receptor-associated kinase 1 (IRAK1), without inhibiting JAK1.

Product Summaries[3,4]

Besremi® (Ropeginterferon Alfa-2b-njft):

- **Therapeutic Class:** Type I interferon
- **Indication(s):** Interferon alfa-2b indicated for the treatment of adults with PV
- **How Supplied:** 500mcg/mL solution in a single-dose prefilled syringe
- **Dose:**
  - Starting dose: 100mcg by subcutaneous (sub-Q) injection every 2 weeks or 50mcg if receiving hydroxyurea
  - Subsequent dosing: Dose may be increased by 50mcg every 2 weeks (up to a maximum of 500mcg) until hematological parameters are stabilized
- **Cost:** The Wholesale Acquisition Cost (WAC) is $7,288 per mL, resulting in a cost per month of $14,576 and an annual cost of $189,488 based on the maximum recommended dosing of 500mcg every 2 weeks.

Vonjo® (Pacritinib):

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):** Treatment of adults with intermediate or high-risk primary or secondary (post-PV or post-ET) MF with a platelet count below 50 x 10^9/L.
- **How Supplied:** 100mg oral capsules

- **Dose:** 200mg [(2) 100mg capsules] twice daily
- **Cost:** The WAC is $178.58 per capsule, resulting in a cost per month of $21,429.60 and an annual cost of $257,155.20 based on the recommended dosing of 200mg twice daily.

Recommendations

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.

[1] U.S. Food and Drug Administration (FDA). FDA Approves Treatment for Rare Blood Disease. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-treatment-rare-blood-disease. Issued 11/12/2021. Last accessed 10/11/2022.
[2] CTI BioPharma. CTI BioPharma Announces FDA Accelerated Approval of Vonjo® (Pacritinib) for the Treatment of Adult Patients with Myelofibrosis and Thrombocytopenia. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/cti-biopharma-announces-fda-accelerated-approval-of-vonjo-pacritinib-for-the-treatment-of-adult-patients-with-myelofibrosis-and-thrombocytopenia-301492159.html. Issued 02/28/2022. Last accessed 10/11/2022.
[3] Besremi® (Ropeginterferon Alfa-2b-njft) Prescribing Information. PharmaEssentia. Available online at: https://us.pharmaessentia.com/wp-content/uploads/2021/11/BESREMi-USPI-November-2021-1.pdf. Last revised 11/2021. Last accessed 10/11/2022.
[4] Vonjo® (Pacritinib) Prescribing Information. CTI BioPharma. Available online at: https://www.ctibiopharma.com/VONJO_USPI.pdf. Last revised 02/2022. Last accessed 10/11/2022.

Appendix H

Fiscal Year 2022 Annual Review of Imcivree® (Setmelanotide)

Oklahoma Health Care Authority
November 2022

Current Prior Authorization Criteria

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 proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency; and
2. 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. 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, obesity associated with other genetic syndromes, or general obesity will not be approved; and
4. Member's baseline weight and body mass index (BMI) must be provided; and
5. Baseline BMI must be ≥30kg/m^2 for adults or ≥95th percentile on BMI-for-age growth chart assessment for children; and
6. 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
7. Prescriber must verify member has been counseled on potential sexual adverse reactions and when to seek emergency medical care; and
8. Prescriber must verify member does not have moderate, severe, or end stage renal disease [estimated glomerular filtration rate (eGFR) <60mL/min/1.73m^2]; and
9. Prescriber must verify female member is not pregnant or breastfeeding; and
10. Prescriber must confirm member or caregiver has been trained on the proper storage and administration of Imcivree® prior to the first dose; and
11. 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
12. A quantity limit of 9mL per 30 days will apply.

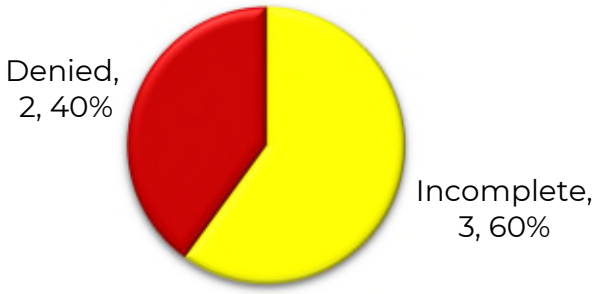
Utilization of Imcivree® (Setmelanotide): Fiscal Year 2022

There was no SoonerCare utilization of Imcivree® (setmelanotide) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of Imcivree® (Setmelanotide)

There were 5 prior authorization requests submitted for Imcivree® (setmelanotide) 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):

- Imcivree® (setmelanotide): July 2034

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

- **June 2022:** The FDA approved a supplemental New Drug Application (sNDA) for Imcivree® (setmelanotide), a melanocortin-4 receptor (MC4R) agonist, for patients with Bardet-Biedl syndrome (BBS). Imcivree® was originally approved by the FDA in November 2020 for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency. Imcivree® is not indicated for the treatment of patients with 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 and general (polygenic) obesity. The FDA approval of Imcivree® for BBS was based on data from a pivotal Phase 3 clinical trial, which was the largest and longest interventional clinical trial in BBS. In the clinical trial, Imcivree® delivered early, significant, and sustained weight reduction. The trial

met its primary endpoint and all key secondary endpoints, with statistically significant reductions in weight and hunger at 52 weeks of therapy. As presented in the label, trial results in patients 6 years of age and older with obesity due to BBS who were treated with Imcivree® (N=31) included the following:

- Mean percent change in body mass index (BMI) was -7.9% without requirements for diet and exercise; and
- Placebo-adjusted change in BMI was -4.5% in a 14-week double-blind placebo-controlled stage (Imcivree®: N=22, -4.6% change in BMI; placebo: N=22, -0.1% change in BMI); and
- Statistically significant mean change in hunger score was -2.1 at 52 weeks in patients 12 years of age and older who were able to self-report their hunger (N=14).

In clinical trials, Imcivree® was generally well-tolerated. Disturbance in sexual arousal, depression and suicidal ideation, increased skin pigmentation and darkening of pre-existing nevi, and benzyl alcohol toxicity in neonates and low birth-weight infants may occur. The most common adverse reactions were skin hyperpigmentation, injection site reactions, and nausea. BBS is a rare genetic disease that affects approximately 1,500 to 2,500 people in the United States. People living with BBS may experience insatiable hunger, also known as hyperphagia, and severe obesity beginning early in life. BBS may also be associated with cognitive impairment, polydactyly, renal dysfunction, hypogonadism, and visual impairment.

Recommendations

The College of Pharmacy recommends updating the current Imcivree® (setmelanotide) approval criteria based on the new FDA approved indication for 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 ≥1 of the following:
   a. Molecular genetic testing to confirm variants in a BBS gene; or

b. Four of the following primary features:
    i. Rod-cone dystrophy, polydactyly, obesity, learning disabilities, hypogonadism in males, or renal anomalies; or
c. Three of the primary features previously listed in 3.b.i. plus 2 secondary features including:
    i. 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, or 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.

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[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 10/2022. Last accessed 10/19/2022.

[2] Rhythm Pharmaceuticals. Rhythm Pharmaceuticals Announces FDA Approval of Imcivree® (Setmelanotide) for Use in Patients with Bardet-Biedl Syndrome. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2022/06/16/2464337/0/en/Rhythm-Pharmaceuticals-Announces-FDA-Approval-of-IMCIVREE-setmelanotide-for-Use-in-Patients-with-Bardet-Biedl-Syndrome.html. Issued 06/16/2022. Last accessed 10/23/2022.

Appendix I

Fiscal Year 2022 Annual Review of Lambert-Eaton Myasthenic Syndrome (LEMS) Medications

Oklahoma Health Care Authority
November 2022

Current Prior Authorization Criteria

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.

Utilization of LEMS 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	1	12	$118,684.95	$9,890.41	$329.68	1,470	360
2022	1	15	$396,643.95	$26,442.93	$986.68	2,010	402
% Change	**0.00%**	**25.00%**	**234.20%**	**167.40%**	**199.30%**	**36.70%**	**11.70%**
Change	**0**	**3**	**$277,959.00**	**$16,552.52**	**$657.00**	**540**	**42**

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 LEMS Medications

- There was 1 unique member utilizing Firdapse® (amifampridine) during fiscal year 2022. However, due to the limited number of members utilizing LEMS medications, detailed demographic information could not be provided.
- There was no SoonerCare utilization of Ruzurgi® (amifampridine) during fiscal year 2022.

Top Prescriber Specialties of LEMS Medications by Number of Claims

- There were 15 paid claims for Firdapse® (amifampridine) during fiscal year 2022, all of which were prescribed by a neurologist.

Prior Authorization of LEMS Medications

There was 1 prior authorization request submitted and approved for Firdapse® (amifampridine) during fiscal year 2022. There were no prior authorization requests submitted for Ruzurgi® (amifampridine) during fiscal year 2022.

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

Anticipated Patent and/or Exclusivity Expiration(s):

- Firdapse® (amifampridine): February 2037

News:

- **February 2022:** In September 2021, a United States appeals court ruled the U.S. Food and Drug Administration (FDA) should not have approved Ruzurgi® for the treatment of pediatric patients with LEMS because its approval violates the 7-year exclusivity period awarded to Firdapse® under the Orphan Drug Act. As a result, the FDA converted its prior approval of Ruzurgi® from a final approval to a tentative approval. Therefore, Ruzurgi® may not be legally marketed until final approval is obtained from the FDA.
- **July 2022:** Catalyst Pharmaceuticals, the manufacturer of Firdapse®, announced the settlement of its patent infringement litigation with Jacobus Pharmaceuticals, the former manufacturer of Ruzurgi®. With this settlement, Catalyst has acquired certain portions of Jacobus' intellectual property rights, including the rights to develop and commercialize Ruzurgi® in the United States.
- **September 2022:** The FDA approved a supplemental New Drug Application (sNDA) for Firdapse® for the treatment of patients 6 years of age and older with LEMS. Previously, Firdapse® was only FDA approved for the treatment of adults with LEMS. With this age expansion, Firdapse® can now be used by pediatric patients who may have been previously treated, or eligible for treatment, with Ruzurgi®.

Recommendations

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~~ 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.

Utilization Details of LEMS Medications: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AMIFAMPRIDINE PRODUCTS						
FIRDAPSE TAB 10MG	15	1	$396,643.95	$26,442.93	15	100%
TOTAL	**15**	**1***	**$396,643.95**	**$26,442.93**	**15**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
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.cf. Last revised 10/2022. Last accessed 10/19/2022.
[2] U.S. FDA. Conversion to NDA Tentative Approval. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209321Orig1s000TA_ltr.pdf. Issued 02/01/2022. Last accessed 10/19/2022.
[3] Catalyst Pharmaceuticals, Inc. Catalyst Pharmaceuticals Announces Settlement of U.S. Patent Litigation and Resolution of Litigation Challenging Ruzurgi® Approval with Jacobus Pharmaceutical. Available online at: https://ir.catalystpharma.com/news-releases/news-release-details/catalyst-pharmaceuticals-announces-settlement-us-patent. Issued 07/12/2022. Last accessed 10/19/2022.
[4] Catalyst Pharmaceuticals, Inc. Catalyst Pharmaceuticals Announces FDA Approval of Supplemental New Drug Application for Firdapse® Expanding Patient Population to Include Pediatric Patients. *Globe Newswire*. Available online at: https://www.globenewswire.com/en/news-release/2022/09/29/2525448/13009/en/Catalyst-Pharmaceuticals-Announces-FDA-Approval-of-Supplemental-New-Drug-Application-for-FIRDAPSE-Expanding-Patient-Population-to-Include-Pediatric-Patients.html. Issued 09/29/2022. Last accessed 10/19/2022.

Appendix J

Fiscal Year 2022 Annual Review of Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications

Oklahoma Health Care Authority
November 2022

Current Prior Authorization Criteria

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 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. 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 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.

Ingrezza® (Valbenazine) Approval Criteria:

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. Ingrezza® 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. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine); and
5. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); and
6. Member must not be taking strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and
7. Member must not be taking monoamine oxidase inhibitors (MAOIs); and
8. Member must not be taking other vesicular monoamine transporter 2 (VMAT2) inhibitors (e.g., tetrabenazine, deutetrabenazine); and
9. The daily dose of Ingrezza® must not exceed 40mg per day for members with moderate or severe hepatic impairment (Child-Pugh score 7 to 15); and
10. Member must not have congenital long QT syndrome or a history of arrhythmias associated with a prolonged QT interval; and
11. Female members must not be pregnant or breastfeeding; and
12. Prescriber must agree to monitor digoxin concentration when co-administering Ingrezza® with digoxin; and

13. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
14. A quantity limit of 1 capsule per day will apply; and
15. 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.

Xenazine® (Tetrabenazine) Approval Criteria:

1. Diagnosis of 1 of the following:
    a. Chorea associated with Huntington's disease; or
    b. Tardive dyskinesia; or
    c. Tourette syndrome; and
2. Xenazine® must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Xenazine® therapy and throughout treatment; and
4. Member must not have hepatic impairment; and
5. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
6. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
7. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., deutetrabenazine, valbenazine) concurrently with Xenazine®; and
8. Member must not be taking medications that are known to prolong the QTc interval concomitantly with Xenazine® [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]; and
9. Members who require doses of tetrabenazine greater than 50mg per day must be tested and genotyped to determine if they are poor metabolizers (PMs), intermediate metabolizers (IMs), or extensive metabolizers (EMs) by their ability to express the drug metabolizing enzyme, CYP2D6. The following dose limits will apply based on the member's metabolizer status:
    a. Extensive and Intermediate CYP2D6 Metabolizers: 100mg divided daily; or
    b. Poor CYP2D6 Metabolizers: 50mg divided daily; and

10. The daily dose of Xenazine® must not exceed 50mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion); 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, tardive dyskinesia, or Tourette syndrome have decreased, and the member is not showing worsening signs of depression.

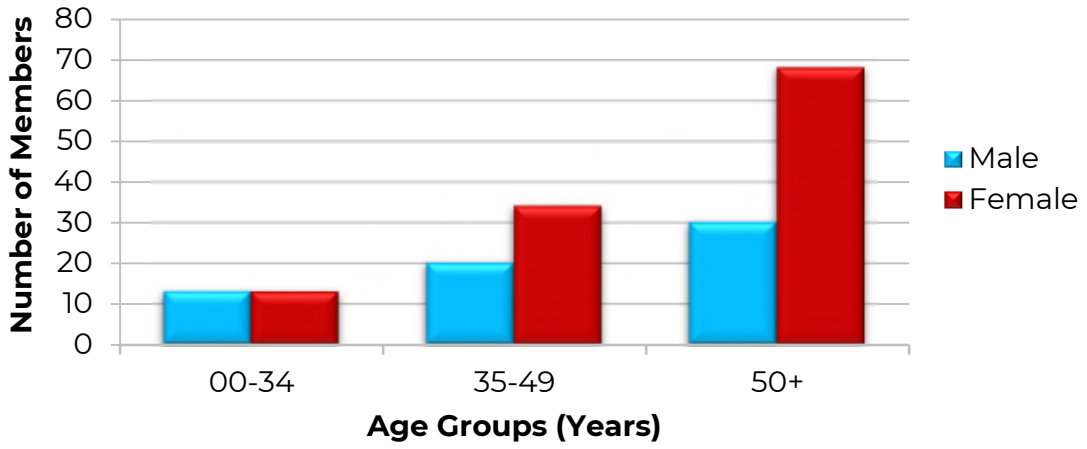
Utilization of VMAT2 Inhibitor Medications: Fiscal Year 2022

Comparison of Fiscal Years

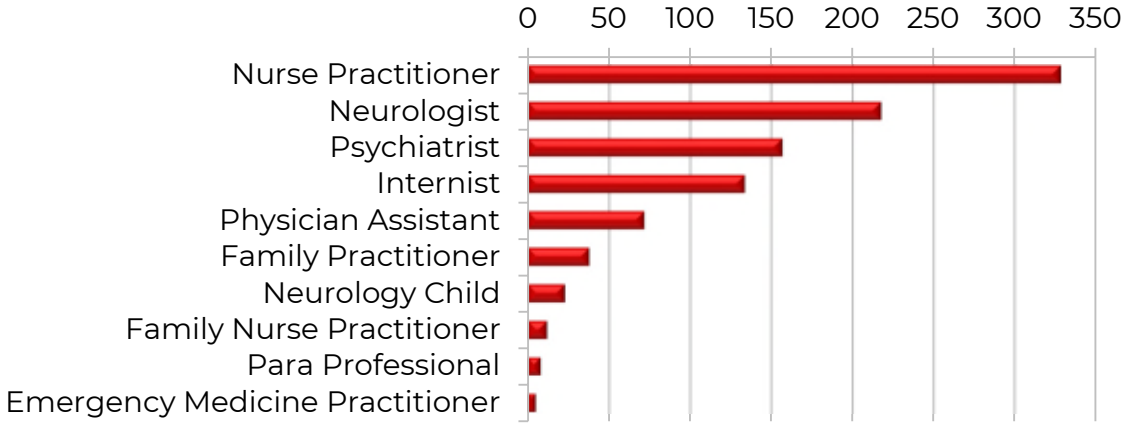
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	123	865	$5,936,007.35	$6,862.44	$230.04	43,670	25,804
2022	178	996	$7,210,806.56	$7,239.77	$242.67	53,109	29,715
% Change	**44.7%**	**15.1%**	**21.5%**	**5.5%**	**5.5%**	**21.6%**	**15.2%**
Change	**55**	**131**	**$1,274,779.21**	**$377.33**	**$12.63**	**9439**	**3911**

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 VMAT2 Inhibitor Medications



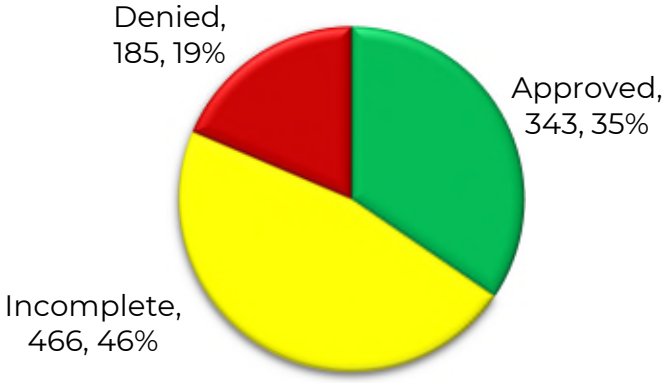
Top Prescriber Specialties of VMAT2 Inhibitor Medications by Number of Claims



Prior Authorization of VMAT2 Inhibitor Medications

There were 994 prior authorization requests submitted for VMAT2 inhibitor 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[1,2,3,4,5]

Anticipated Patent Expiration(s):

- Austedo® (deutetrabenazine): September 2038
- Ingrezza® (valbenazine): August 2039

News:

- **February 2022:** The package labeling for Austedo® was updated based on long-term efficacy and safety of deutetrabenazine in 3-year, single-arm, open-label extension study in adult patients with tardive dyskinesia (TD) that was associated with sustained improvements in the Abnormal Involuntary Movement Scale (AIMS) score, with a

favorable safety and tolerability profile. A separate assessment of suicidality was conducted using the Columbia-Suicide Severity Rating Scale (C-SSRS). At screening, 24% patients reported suicidal ideation prior to study, 18% reported suicidal behavior, and 3% reported self-injurious behavior with suicidal intent; at any time post-baseline, 7% patients displayed suicidal ideation, <1% patients displayed suicidal behavior, and no patients displayed self-injurious behavior without suicidal intent. There were no new safety signals identified over the course of the study, including no signals for increased suicide, torsade de pointes/QT prolongation, parkinsonism, or depression. The *Boxed Warning* for depression and suicidality in the package labeling for Austedo® was removed for patients with TD based on these findings and was updated to be specific to patients with Huntington's disease.

- **May 2022:** The package labeling for Austedo® was updated based on a study published which found that deutetrabenazine did not have a clinically relevant effect on QT prolongation at the maximum recommended doses in either cytochrome P450 2D6 extensive/ intermediate metabolizers (EMs) or poor metabolizers (PM). The study included healthy adults 18 to 50 years of age with a body mass index (BMI) between 20-30kg/m^2. The study excluded subjects with clinically significant abnormalities in a 12-lead electrocardiogram (ECG) or any cardiac conduction abnormality. Escalating deutetrabenazine doses were administered to EMs and PMs to determine the pharmacokinetic exposure of the parent drug and active metabolites and collect ECGs for evaluation of the effect using concentration-QTc (C-QTc) modeling. Participants received placebo or single doses of deutetrabenazine 24mg, 48mg, or 72mg. Adverse events increased with high exposure in the PM group receiving 48 and 72mg. No subjects discontinued due to cardiac related events and no clinically relevant ECG findings were reported.

Recommendations

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.

Utilization Details of VMAT2 Inhibitor Medications: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	COST/ MEMBER	% COST
VALBENAZINE PRODUCTS						
INGREZZA CAP 80MG	345	67	$2,493,306.00	$7,226.97	$37,213.52	34.58%
INGREZZA CAP 60MG	26	7	$189,578.28	$7,291.47	$27,082.61	2.63%
INGREZZA CAP 40MG	127	46	$829,795.63	$6,533.82	$18,039.03	11.51%
INGREZZA CAP 40-80MG	5	5	$35,902.05	$7,180.41	$7,180.41	0.50%
SUBTOTAL	**503**	**125**	**$3,548,581.96**	**$7,054.83**	**$28,388.66**	**49.22%**
DEUTETRABENAZINE PRODUCTS						
AUSTEDO TAB 12MG	228	47	$1,812,835.76	$7,951.03	$38,570.97	25.14%
AUSTEDO TAB 9MG	136	34	$870,748.80	$6,402.56	$25,610.23	12.08%
AUSTEDO TAB 6MG	58	22	$260,684.15	$4,494.55	$11,849.28	3.62%
SUBTOTAL	**422**	**103**	**$2,944,268.71**	**$6,979.94**	**$28,585.13**	**40.84%**
TETRABENAZINE PRODUCTS						
XENAZINE TAB 25MG	18	2	$557,154.09	$30,953.01	$278,577.0	7.73%
TETRABENAZINE TAB 25MG	24	6	$32,851.81	$1,368.83	$5,475.30	0.46%
XENAZINE TAB 12.5MG	10	1	$119,659.46	$11,965.95	$119,659.46	1.66%
TETRABENAZINE TAB 12.5MG	19	4	$8,290.53	$115.15	$2,072.63	0.11%
SUBTOTAL	**72**	**13**	**$717,955.89**	**$9,971.61**	**$55,229.38**	**10.00%**
TOTAL	**996**	**178***	**$7,210,806.56**	**$7,239.77**	**$40,510.15**	**100%**

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

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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 10/2022. Last accessed 10/17/2022.

[2] Austedo® (Deutetrabenazine) Prescribing Information. Teva Pharmaceuticals. Available online at: https://www.austedo.com/globalassets/austedo/prescribing-information.pdf. Last revised 05/2022. Last accessed 10/17/2022.

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Appendix K

Fiscal Year 2022 Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Carvykti™ (Ciltacabtagene Autoleucel) and Tecvayli™ (Teclistamab-cqyv)

Oklahoma Health Care Authority
November 2022

Introduction[1,2]

Multiple myeloma is characterized by a malignant proliferation of plasma cells that accumulate in the bone marrow eventually causing destruction and marrow failure. Multiple myeloma overall is a rare cancer (1.8% of all cancers) and is diagnosed at a median age of 69 years. With the currently available treatment options, multiple myeloma is considered a non-curable malignancy. Early disease is often highly susceptible to chemotherapy agents and prolonged responses are attained; however, relapse is anticipated in all patients.

There has been significant growth and changes in newer agents to treat multiple myeloma in recent years. Several new classes or new generations of older drugs have been added to the standard of care for multiple myeloma. These agents include immunotherapy options [i.e., chimeric antigen receptor (CAR) T-cell therapy, bi-specific T-cell engager (BiTE) therapy], immunomodulatory drugs, monoclonal antibodies, histone deacetylase inhibitors, and proteasome inhibitors (PIs).

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

Current Prior Authorization Criteria

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.

Blenrep (Belantamab Mafodotin-blmf) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM) in adults; and
2. Member has received ≥4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor (PI), and an immunomodulatory agent; and
3. Prescriber must verify the member will receive eye exams, including visual acuity and slit lamp ophthalmic examinations, with each cycle (every 3 weeks).

Darzalex® (Daratumumab) and Darzalex Faspro® (Daratumumab/ Hyaluronidase-fihj) Approval Criteria [Light Chain Amyloidosis Diagnosis]:

1. Relapsed/refractory light chain amyloidosis as a single agent; or
2. Newly diagnosed light chain amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone.

Darzalex® (Daratumumab) and Darzalex Faspro® (Daratumumab/ Hyaluronidase-fihj) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of multiple myeloma; and
2. Used in 1 of the following settings:
a. In combination with lenalidomide and dexamethasone as primary therapy in members who are ineligible for autologous stem cell transplant (ASCT) or in members who have received at least 1 prior therapy; or
b. In combination with bortezomib, melphalan, and prednisone as primary therapy in members who are ineligible for ASCT; or

c. In combination with bortezomib, thalidomide, and dexamethasone or bortezomib, lenalidomide, and dexamethasone as primary therapy in members who are eligible for ASCT; or
d. After at least 1 prior therapy, in combination with 1 of the following:
    i. Dexamethasone and bortezomib; or
    ii. Carfilzomib and dexamethasone; or
    iii. Dexamethasone and lenalidomide; or
    iv. Cyclophosphamide, bortezomib, and dexamethasone; or
    v. Pomalidomide and dexamethasone* [*previous therapy for this combination must include lenalidomide and a protease inhibitor (PI)]; or
    vi. Selinexor and dexamethasone; or
e. In combination with lenalidomide and dexamethasone for members who are ineligible for ASCT or with cyclophosphamide, bortezomib, and dexamethasone as primary therapy or for disease relapse after 6 months following primary induction therapy with the same regimen; or
f. As a single-agent in members who have received ≥3 prior therapies, including a PI and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.

Empliciti® (Elotuzumab) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of previously treated multiple myeloma with relapsed or progressive disease; and
2. Used in combination with 1 of the following regimens:
    a. Lenalidomide and dexamethasone in members who have received 1 to 3 prior therapies; or
    b. Bortezomib and dexamethasone; or
    c. Pomalidomide and dexamethasone in members who have received ≥2 prior therapies, including an immunomodulatory agent and a proteasome inhibitor (PI).

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).

Hemady® (Dexamethasone 20mg Tablet) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of multiple myeloma; and

2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use dexamethasone 4mg tablets to achieve the required dose in place of Hemady® must be provided.

Ninlaro® (Ixazomib) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of symptomatic multiple myeloma; and
2. Used in 1 of the following settings:
    a. As primary therapy; or
    b. Following disease relapse after 6 months following primary induction therapy with the same regimen, used in combination with 1 of the following regimens:
        i. Lenalidomide and dexamethasone; or
        ii. Cyclophosphamide and dexamethasone for transplant candidates only; or
        iii. Pomalidomide and dexamethasone if member has failed ≥2 prior therapies and demonstrated disease progression within 60 days; or
    c. As a single-agent for the maintenance treatment of disease.

Sarclisa® (Isatuximab-irfc) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and
2. Used in 1 of the following settings:
    a. Used in combination with pomalidomide and dexamethasone after ≥2 prior therapies [previous treatment must have included lenalidomide and a proteasome inhibitor (PI)]; or
    b. Used in combination with carfilzomib and dexamethasone after 1 to 3 prior therapies.

Xpovio® (Selinexor) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. Diagnosis of relapsed/refractory DLBCL, not otherwise specified, including DLBCL arising from follicular lymphoma; and
2. Member has received ≥2 prior lines of systemic therapy.

Xpovio® (Selinexor) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and
2. Used in 1 of the following settings:
    a. In combination with dexamethasone in members who have received ≥4 prior therapies including refractory disease to ≥2 proteasome inhibitors (PIs), ≥2 immunomodulatory agents, and an anti-CD38 monoclonal antibody; or
    b. Used in combination with bortezomib and dexamethasone in members who have failed at least 1 prior therapy.

Utilization of Multiple Myeloma Medications: 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	3	14	$148,100.74	$10,578.62	$377.81	42	392
2022	1	10	$111,739.10	$11,173.91	$399.07	30	280
% Change	**-66.70%**	**-28.60%**	**-24.60%**	**5.60%**	**5.60%**	**-28.60%**	**-28.60%**
Change	**-2**	**-4**	**-$36,361.64**	**$595.29**	**$21.26**	**-12**	**-112**

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

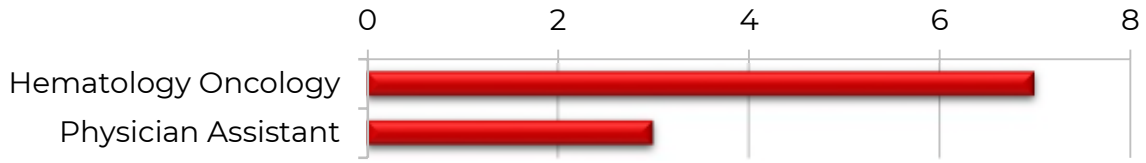
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	5	11	$64,398.66	$5,854.42	2.2
2022	12	91	$997,396.00	$10,960.40	7.58
% Change	**140.00%**	**727.27%**	**1,448.78%**	**87.22%**	**244.55%**
Change	**7**	**80**	**$932,997.34**	**$5,105.98**	**5.38**

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 Multiple Myeloma Medications

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

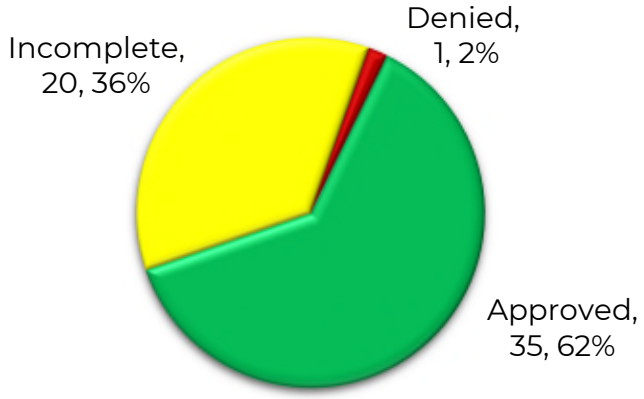
Top Prescriber Specialties of Multiple Myeloma Medications by Number of Claims



Prior Authorization of Multiple Myeloma Medications

There were 56 prior authorization requests submitted for the multiple myeloma 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[3,4,5,6,7]

Anticipated Patent Expiration(s):

- Ninlaro® (ixazomib): November 2029
- Xpovio® (selinexor): August 2035
- Hemady® (dexamethasone): December 2037

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 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, immunomodulatory drug, and 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 NDA approval for Farydak® (panobinostat) 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[8]

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[9]

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 at least 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 chimeric antigen receptor (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.

Utilization Details of Multiple Myeloma Medications: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
NINLARO CAP 3MG	10	1	$111,739.10	10	$11,173.91
TOTAL	**10**	**1***	**$111,739.10**	**10**	**$11,173.91**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
J9144 DARATUMUMAB/ HYALURONIDASE INJ	82	10	$940,500.00	8.2	$11,469.51
J9145 DARATUMUMAB INJ	9	2	$56,896.00	4.5	$6,321.78
TOTAL	**91**	**12**	**$997,396.00**	**7.58**	**$10,960.40**

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

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[9] 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 11/02/2022.

Appendix L

Fiscal Year 2022 Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Tezspire® (Tezepelumab-ekko)

Oklahoma Health Care Authority
November 2022

Current Prior Authorization Criteria: Asthma and COPD Maintenance Medications

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.

AirDuo® Digihaler® (Fluticasone Propionate/Salmeterol Inhalation Powder) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be 12 years of age or older; and

3. A patient-specific, clinically significant reason why the member requires AirDuo® Digihaler® over AirDuo RespiClick® and all preferred Tier-1 inhaled corticosteroid (ICS) and long-acting beta$_2$-agonist (ICS/LABA) products (Advair®, Dulera®, and Symbicort®) must be provided; and
4. Failure of Advair®, Dulera®, and Symbicort® or a reason why Advair®, Dulera®, and Symbicort® are not appropriate for the member must be provided; and
5. Member must have used an ICS for at least 1 month immediately prior; and
6. Member must be considered uncontrolled by provider [required rescue medication >2 days a week (not for prevention of exercise induced bronchospasms) and/or needed oral systemic corticosteroids]; or
7. A clinical situation warranting initiation with combination therapy due to severity of asthma; and
8. Prescriber agrees to closely monitor member adherence; and
9. Member should be capable and willing to use the Companion Mobile App and to follow the Instructions for Use, and member must ensure the Digihaler® Companion Mobile App is compatible with their specific smartphone; and
10. Member's phone camera must be functional and able to scan the inhaler QR code and register the AirDuo® Digihaler® inhaler; and
11. Approvals will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and member compliance >80% with prescribed maintenance therapy must be provided. In addition, a patient-specific, clinically significant reason why the member cannot transition to Tier-1 medications must be provided. Tier structure rules continue to apply.

AirDuo RespiClick® (Fluticasone Propionate/Salmeterol) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be at or above the minimum age indicated; and
3. Failure of Advair®, Dulera®, and Symbicort® or a reason why Advair®, Dulera®, and Symbicort® are not appropriate for the member must be provided; and
4. Member must have used an inhaled corticosteroid for at least 1 month immediately prior; and
5. Member must be considered uncontrolled by provider [required rescue medication >2 days a week (not for prevention of exercise induced bronchospasms) and/or needed oral systemic corticosteroids]; or
6. A clinical situation warranting initiation with combination therapy due to severity of asthma.

ArmonAir® Digihaler® (Fluticasone Propionate Inhalation Powder) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be 12 years of age or older; and
3. A patient-specific, clinically significant reason why Flovent® (fluticasone propionate) and other preferred monotherapy inhaled corticosteroids (ICS) are not appropriate for the member must be provided; and
4. The prescriber agrees to closely monitor member adherence; and
5. The member should be capable and willing to use the Companion Mobile App and to follow the Instructions for Use, and member must ensure the Digihaler® Companion Mobile App is compatible with their specific smartphone; and
6. The member's phone camera must be functional and able to scan the inhaler QR code and register the ArmonAir® Digihaler® inhaler; and
7. Approvals will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and member compliance >80% with prescribed maintenance therapy must be provided. In addition, a patient-specific, clinically significant reason why the member cannot transition to Tier-1 medications must be provided. Tier structure rules continue to apply.

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.

Asmanex® HFA (Mometasone Furoate) 50mcg and QVAR® RediHaler® (Beclomethasone Dipropionate) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be at the age indicated for the requested product:
    a. Asmanex® HFA 50mcg: Member must be between 5 and 11 years of age; or
    b. QVAR® RediHaler®: Member must be 4 years of age or older; and
3. A trial of all available Tier-1 inhaled corticosteroids or a patient-specific, clinically significant reason why they are not appropriate for the member must be provided.

Breo® Ellipta® (Fluticasone Furoate/Vilanterol) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD) or chronic bronchitis and/or emphysema associated with COPD; and
    a. For a diagnosis of COPD or chronic bronchitis and/or emphysema associated with COPD, trials of Advair® and Symbicort®, consisting

of at least 30 days each within the last 90 days that did not adequately control COPD symptoms; or

2. An FDA approved diagnosis of asthma in members 18 years of age and older; and
    a. For a diagnosis of asthma, trials of Advair®, Dulera®, and Symbicort® consisting of at least 30 days each within the last 120 days that did not adequately control asthma symptoms.

Dulera® (Mometasone Furoate/Formoterol) 50mcg/5mcg Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be between 5 and 11 years of age; and
3. Failure of Advair® and Symbicort® or a reason why Advair® and Symbicort® are not appropriate for the member must be provided; and
4. Member must have used an inhaled corticosteroid (ICS) for at least 1 month immediately prior; and
5. Member must be considered uncontrolled by provider [required rescue medication >2 days a week (not for prevention of exercise induced bronchospasms) and/or needed oral systemic corticosteroids]; or
6. A clinical situation warranting initiation with combination therapy due to severity of asthma.

Wixela Inhub® (Fluticasone/Salmeterol Inhalation Powder) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the brand formulation (Advair® Diskus®) or other generic formulations (fluticasone/salmeterol) must be provided (brand formulation and other generics are preferred and do not require prior authorization).

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®)

Long-Acting Beta$_2$ Agonists (LABA) and Long-Acting Muscarinic Antagonists (LAMA)	
Tier-1	**Tier-2**
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).

Long-Acting Beta$_2$ Agonist (LABA) and Long-Acting Muscarinic Antagonist (LAMA) Tier-2 Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD), chronic bronchitis, or emphysema; and
2. Member must be 18 years of age or older; and
3. A 4-week trial of at least 1 LABA and a 4-week trial of 1 LAMA within the past 90 days; or
4. A documented adverse effect, drug interaction, or contraindication to all available Tier-1 products; or
5. A clinical exception may apply for members who are unable to effectively use hand-actuated devices, such as Spiriva® HandiHaler®, or who are stable on nebulized therapy.

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

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
2. Member must be 18 years of age or older; 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.

Breztri Aerosphere® (Budesonide/Glycopyrrolate/Formoterol) and Trelegy Ellipta® (Fluticasone Furoate/Umeclidinium/Vilanterol) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and

3. A 4-week trial of at least 1 long-acting beta$_2$ agonist (LABA) and a 4-week trial of 1 long-acting muscarinic antagonist (LAMA) within the past 90 days used concomitantly with an inhaled corticosteroid (ICS); and
4. A patient-specific, clinically significant reason why the member requires the triple combination therapy in place of the individual components or use of a LABA/ICS combination with a LAMA must be provided.

Daliresp® (Roflumilast) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD) with history of chronic bronchitis; and
2. Forced expiratory volume (FEV) ≤50% of predicted; and
3. Member is inadequately controlled on long-acting bronchodilator therapy (must have 3 or more claims for long-acting bronchodilators in the previous 6 months).

Current Prior Authorization Criteria: Asthma-Indicated Monoclonal Antibodies

Cinqair® (Reslizumab) Approval Criteria:

1. An FDA approved indication of add-on maintenance treatment of members with severe asthma with an eosinophilic phenotype; and
2. Member must be 18 years of age or older; and
3. Member must have a blood eosinophil count ≥400cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose 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
6. 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
7. Cinqair® must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
8. Cinqair® 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

9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
10. Member's weight should be provided on prior authorization requests. Weights should have been taken within the last 4 weeks to provide accurate weight-based dosing.

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 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.

Dupixent® (Dupilumab Injection) Approval Criteria [Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment in adult members with inadequately controlled CRSwNP; and
2. Member must be 18 years of age or older; and
3. Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and
4. Member must meet 1 of the following:
    a. Member has required prior sino-nasal surgery; or

    b. Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and
5. Dupixent® must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
6. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/ congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
7. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
8. Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
9. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
10. 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; and
11. 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
12. A quantity limit of 2 syringes every 28 days will apply.

Dupixent® (Dupilumab Injection) Approval Criteria [Eosinophilic Phenotype Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with moderate-to-severe eosinophilic phenotype asthma or oral corticosteroid-dependent asthma; and
2. Member must be 6 years of age or older; and
3. Member must have a blood eosinophil count of ≥150cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose 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
6. 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
7. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
8. Dupixent® 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
9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
10. Quantities approved must not exceed FDA recommended dosing requirements.

Fasenra® (Benralizumab Injection) Approval Criteria:

1. An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and
2. Member must be 12 years of age or older; and
3. Member must have a blood eosinophil count of ≥150cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose 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
6. 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
7. For authorization of Fasenra® prefilled syringe, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Fasenra® prefilled autoinjector pen, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Fasenra®; and

9. Fasenra® 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
10. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
11. A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 56 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment in adult members with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and
2. Member must be 18 years of age or older; and
3. Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and
4. Member must meet 1 of the following:
    a. Member has required prior sino-nasal surgery; or
    b. Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and
5. Nucala must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or be an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
6. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
7. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
8. Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
9. For authorization of Nucala vial, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
10. For authorization of Nucala prefilled autoinjector or prefilled syringe, prescriber must verify the member or caregiver has been trained by a

health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
11. Requests for concurrent use of Nucala with other biologic medications will be reviewed on a case-by-case basis and will require patient specific information to support the concurrent use; and
12. Initial approvals will be for the duration of 6months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
13. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Eosinophilic Granulomatosis with Polyangiitis (EGPA) Diagnosis]:

1. An FDA approved diagnosis of EGPA; and
2. Member meets 1 of the following:
    a. Member must have a past history of at least 1 confirmed EGPA relapse [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of immunosuppressive therapy, or hospitalization] within the past 12 months; or
    b. Member must have refractory disease within the last 6 months following induction of a standard treatment regimen administered compliantly for at least 3 months; and
3. Diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) will not be approved; and
4. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent ≥7.5mg/day) for a minimum of 4 weeks duration; and
5. Nucala must be prescribed by an allergist, pulmonologist, pulmonary specialist, or rheumatologist or the member must have been evaluated by an allergist, pulmonologist, pulmonary specialist, or rheumatologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, pulmonary specialist, or rheumatologist); and
6. For authorization of Nucala vial, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
7. For authorization of Nucala prefilled autoinjector or prefilled syringe, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
8. A quantity limit of 3 vials, prefilled autoinjectors, or prefilled syringes per 28 days will apply; and

9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant and prescriber must verify the member is responding to Nucala as demonstrated by a Birmingham Vasculitis Activity Score (BVAS) of 0 (zero), fewer EGPA relapses from baseline, or a decrease in daily OCS dosing from baseline.

Nucala (Mepolizumab Injection) Approval Criteria [Eosinophilic Phenotype Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and
2. Member must be 6 years of age or older; and
3. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose 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
6. 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
7. For authorization of Nucala vial, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Nucala prefilled autoinjector or prefilled syringe, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
9. Nucala 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
10. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
11. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Hypereosinophilic Syndrome (HES) Diagnosis]:

1. An FDA approved diagnosis of HES for ≥6 months without an identifiable non-hematologic secondary cause; and
2. Member must be 12 years of age or older; and
3. Member must have a past history of at least 2 confirmed HES flares [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of cytotoxic or immunosuppressive therapy, or hospitalization] within the past 12 months; and
4. Member must have a baseline blood eosinophil count of ≥1,000 cells/mcL in the last 4 weeks prior to initiating Nucala; and
5. Diagnosis of FIP1L1-PDGFRα kinase-positive HES will not be approved; and
6. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent ≥10mg/day) for a minimum of 4 weeks duration or member is unable to tolerate corticosteroid therapy due to significant side effects from corticosteroid therapy; and
7. Nucala must be prescribed by a hematologist or a specialist with expertise in treatment of HES (or an advanced care practitioner with a supervising physician who is a hematologist or a specialist with expertise in treatment of HES); and
8. For authorization of Nucala vial, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
9. For authorization of Nucala prefilled autoinjector or prefilled syringe, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
10. A quantity limit of 3 vials, prefilled autoinjectors, or prefilled syringes per 28 days will apply; and
11. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant and prescriber must verify the member is responding to Nucala as demonstrated by fewer HES flares from baseline or a decrease in daily OCS dosing from baseline.

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

1. 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 1 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 medium-to-high dose inhaled corticosteroids (ICS) (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose) for at minimum the past 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 health care setting by a health care 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 12 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 12 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 12 months after which time compliance will be evaluated for continued approval.

Xolair® (Omalizumab Injection) Approval Criteria [Chronic Idiopathic Urticaria (CIU) Diagnosis]:

1. An FDA approved diagnosis of CIU; and
2. Member must be 12 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. Other potential causes of urticaria must be ruled out; and
5. Member must have an Urticaria Activity Score (UAS) ≥16; and
6. Prescriber must be an allergist, immunologist, or dermatologist (or an advanced care practitioner with a supervising physician that is an allergist, immunologist, or dermatologist); and
7. A trial of a second generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and
8. Initial dosing will only be approved for 150mg every 4 weeks. If the member has inadequate results at this dose, then the dose may be increased to 300mg every 4 weeks; and
9. Initial approvals will be for the duration of 3 months at which time compliance will be evaluated for continued approval.

Xolair® (Omalizumab Injection) Approval Criteria [Nasal Polyps Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of nasal polyps in adult members with inadequate response to nasal corticosteroids; and
2. Member must be 18 years of age or older; and
3. Member must have a trial of intranasal corticosteroids for at minimum the past 4 weeks; and
4. Prescriber must verify member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
5. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/ congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
6. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
7. Member must have a pretreatment serum IgE level between 30 and 1,500 IU/mL; and
8. Member's weight must be between 31kg and 150kg; and
9. Prescribed Xolair® dose must be an FDA approved regimen per Xolair® *Prescribing Information*; and
10. Xolair® must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
11. Xolair® must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
12. 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.

Utilization of Asthma and COPD Maintenance Medications: Fiscal Year 2022

Comparison of Fiscal Years: Asthma and COPD Maintenance Medications (Pharmacy Claims)

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	28,296	95,747	$30,696,786.68	$320.60	$9.17	2,536,659	3,348,535
2022	38,514	120,506	$39,852,755.99	$330.71	$9.37	3,349,683	4,252,457
% Change	**36.1%**	**25.9%**	**29.8%**	**3.2%**	**2.2%**	**32.1%**	**27.0%**
Change	**10,218**	**24,759**	**$9,155,969.31**	**$10.11**	**$0.20**	**813,024**	**903,922**

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
Please note, the above utilization data does not include asthma-indicated monoclonal antibodies.

- The asthma and COPD maintenance medications 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 asthma and COPD maintenance medications: $39,081,795.37[Δ]

Comparison of Fiscal Years: Asthma-Indicated Monoclonal Antibodies (Pharmacy Claims)

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	282	2,032	$6,177,109.05	$3,039.92	$106.04	6,371	58,251
2022	509	3,302	$10,456,790.86	$3,166.81	$109.32	10,799	95,656
% Change	**80.5%**	**62.5%**	**69.3%**	**4.2%**	**3.1%**	**69.5%**	**64.2%**
Change	**227**	**1,270**	**$4,279,681.81**	**$126.89**	**$3.28**	**4,428**	**37,405**

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
Please note, the above utilization data includes Xolair®, Nucala, Dupixent® used for all diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

- The asthma-indicated monoclonal antibody medications 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 asthma-indicated monoclonal antibodies: $1,904,020.68[Δ]

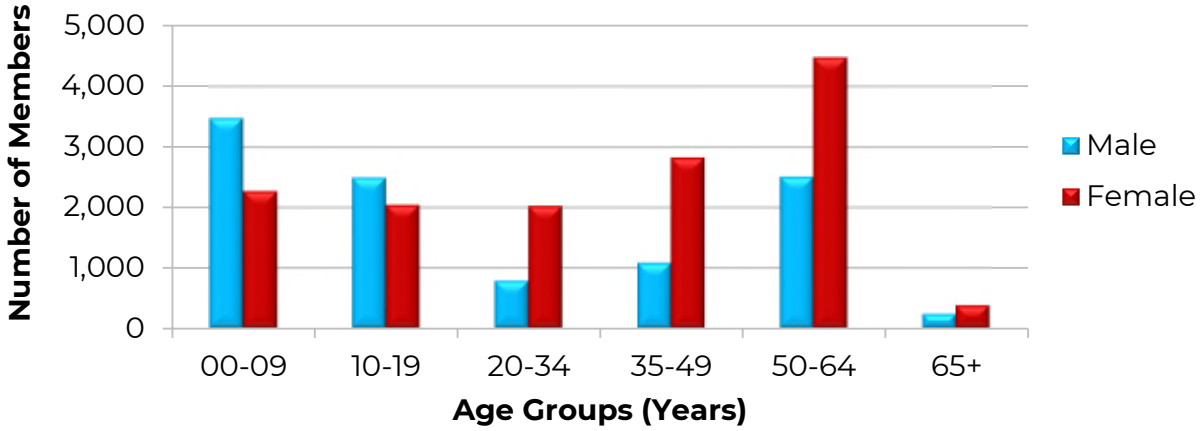
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Comparison of Fiscal Years: Asthma-Indicated Monoclonal Antibodies (Medical Claims)

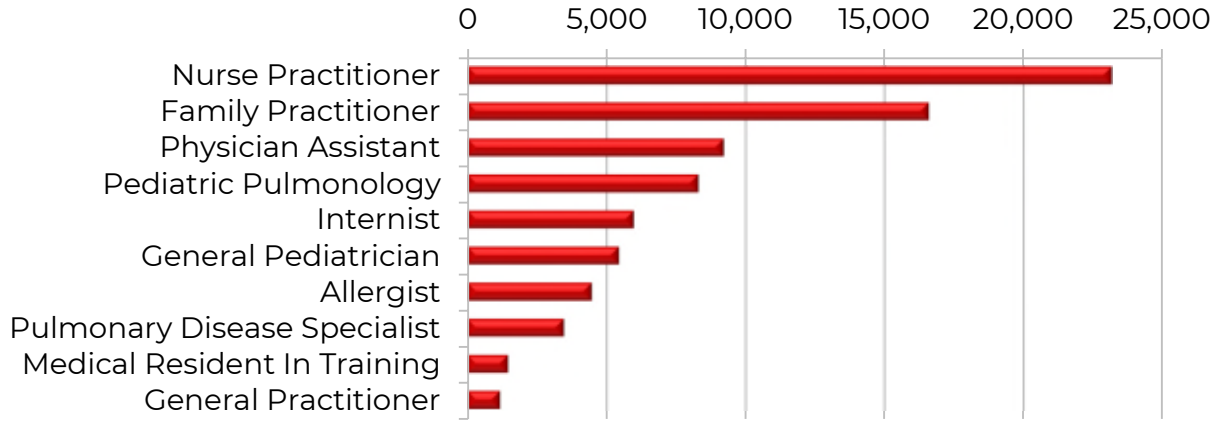
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	21	211	$524,919.41	$2,487.77	10.05
2022	33	290	$699,901.60	$2,413.45	8.79
% Change	**57.1%**	**37.4%**	**33.3%**	**-2.99%**	**-12.5%**
Change	**12**	**79**	**$174,982.19**	**-$74.32**	**-1.26**

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
Please note, the above utilization data includes Xolair® and Nucala used for all diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

Demographics of Members Utilizing Asthma and COPD Maintenance Medications

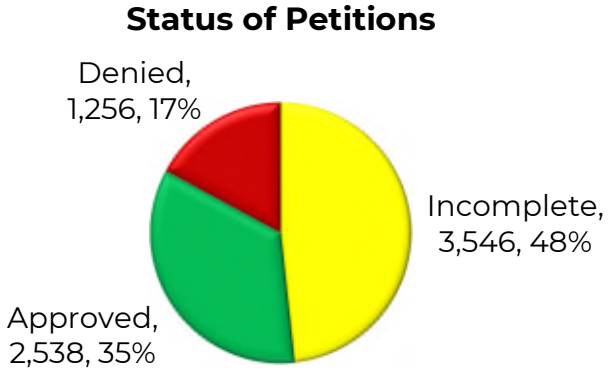


Top Prescriber Specialties of Asthma and COPD Maintenance Medications by Number of Claims



Prior Authorization of Asthma and COPD Maintenance Medications

There were 7,340 prior authorization requests submitted for asthma and COPD maintenance medications during fiscal year 2022. Of those prior authorization requests, 1,798 were submitted for monoclonal antibody medications. The following chart shows the status of the submitted petitions for fiscal year 2022.



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

Anticipated Patent and/or Exclusivity Expiration(s):

- Dulera® (mometasone/formoterol inhalation aerosol): February 2023; exclusivity expiration
- Daliresp® (roflumilast oral tablet): March 2024
- Tudorza® Pressair® (aclidinium inhalation powder): March 2029
- Duaklir® Pressair® (aclidinium/formoterol inhalation powder): March 2029
- Symbicort® (budesonide/formoterol inhalation aerosol): October 2029
- Spiriva® HandiHaler® (tiotropium inhalation powder): April 2030
- Striverdi® Respimat® (olodaterol inhalation spray): October 2030
- Stiolto® Respimat® (tiotropium/olodaterol inhalation spray): October 2030
- Breo® Ellipta® (fluticasone furoate/vilanterol inhalation powder): October 2030
- Incruse® Ellipta® (umeclidinium inhalation powder): October 2030
- Arnuity® Ellipta® (fluticasone furoate inhalation powder): October 2030
- Anoro® Ellipta® (umeclidinium/vilanterol inhalation powder): November 2030
- Trelegy® Ellipta® (fluticasone furoate/umeclidinium/vilanterol inhalation powder): November 2030
- Bevespi Aerosphere® (glycopyrrolate/formoterol inhalation aerosol): March 2031

- Breztri Aerosphere® (budesonide/glycopyrrolate/formoterol aerosol): March 2031
- Spiriva® Respimat® (tiotropium soft mist inhaler): April 2031
- QVAR® RediHaler® (beclomethasone inhalation aerosol): January 2032
- AirDuo RespiClick® (fluticasone propionate/salmeterol inhalation powder): April 2035
- AirDuo® Digihaler® (fluticasone propionate/salmeterol inhalation powder): June 2039
- ArmonAir® Digihaler® (fluticasone propionate inhalation powder): June 2039

New U.S. Food and Drug Administration (FDA) Approval(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.
- **January 2022:** The FDA approved an age expansion for Nucala (mepolizumab) 40mg prefilled syringe to include use in pediatric patients 6 to 11 years of age with severe eosinophilic asthma. Previously, this age range could only receive the solution that was mixed and then administered by a health care provider. The approval of the prefilled syringe will allow at-home administration, if appropriate as determined by the patient's health care provider. If at-home administration with the prefilled syringe is appropriate, the patient's caregiver will need to be counseled regarding proper administration of Nucala and monitoring for allergic reactions.
- **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% 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.

Pipeline:

- **Depemokimab:** Depemokimab, a long-acting anti-interleukin 5 (IL-5) monoclonal antibody, is currently being studied for multiple indications including severe asthma with an eosinophilic phenotype, chronic rhinosinusitis with nasal polyps, hypereosinophilic syndrome, and eosinophilic granulomatosis with polyangiitis. Depemokimab is currently in Phase 3 trials for severe asthma and completion is expected in 2023, with an FDA submission anticipated in 2024.

Tezspire® (Tezepelumab-ekko) Product Summary[10]

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.

Limitations 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, ILC2cells) 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 a pulmonologist or pulmonary specialist, or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a 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. One high-dose proton pump inhibitor; and
    b. One 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. One medium potency to very-high potency Tier-1 topical corticosteroid; and
    b. One 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.
[α]Does 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).

Utilization Details of Asthma and COPD Maintenance Medications: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ICS/LABA COMBINATION PRODUCTS					
TIER-1 UTILIZATION					
SYMBICORT AER 160/4.5MCG	14,396	4,754	$5,957,878.94	$413.86	3.03
ADVAIR HFA AER 115/21MCG	7,584	2,472	$2,998,418.29	$395.36	3.07
FLUTIC/SALME AER 250/50MCG	5,377	2,275	$865,459.65	$160.96	2.36
SYMBICORT AER 80/4.5MCG	5,250	2,155	$1,788,172.19	$340.60	2.44
ADVAIR DISKUS AER 250/50MCG	4,803	1,903	$2,048,331.16	$426.47	2.52
DULERA AER 200/5MCG	2,764	849	$924,818.85	$334.59	3.26
ADVAIR HFA AER 230/21MCG	2,243	709	$1,227,917.99	$547.44	3.16
ADVAIR HFA AER 45/21MCG	2,236	783	$713,797.75	$319.23	2.86
DULERA AER 100/5MCG	2,069	681	$674,238.58	$325.88	3.04
FLUTIC/SALME AER 100/50MCG	1,845	778	$224,141.48	$121.49	2.37
ADVAIR DISKUS AER 500/50MCG	1,764	634	$1,018,539.03	$577.40	2.78
FLUTIC/SALME AER 500/50MCG	1,740	585	$437,203.03	$251.27	2.97
ADVAIR DISKUS AER 100/50MCG	1,462	674	$474,372.34	$324.47	2.17
BUDES/FORMOT AER 160/4.5MCG	5	3	$525.44	$105.09	1.67
BUDES/FORMOT AER 80/4.5MCG	3	2	$296.60	$98.87	1.50
TIER-1 SUBTOTAL	**53,541**	**19,257**	**$19,354,111.32**	**$361.48**	**2.78**
TIER-2 UTILIZATION					
BREO ELLIPTA INH 100/25MCG	154	35	$63,246.88	$410.69	4.40
DULERA AER 50/5MCG	40	25	$12,772.25	$319.31	1.60
FLUTIC/VILAN INH 100/25MCG	4	4	$1,285.14	$321.29	1.00
TIER-2 SUBTOTAL	**198**	**64**	**$77,304.27**	**$390.43**	**3.09**
ICS/LABA TOTAL	**53,739**	**19,321**	**$19,431,415.59**	**$361.59**	**2.78**
INDIVIDUAL COMPONENT LAMA PRODUCTS					
TIER-1 UTILIZATION					
SPIRIVA CAP HANDIHLER 18MCG	5,980	1,888	$3,972,324.24	$664.27	3.17
SPIRIVA SPR 2.5MCG	4,584	1,400	$2,155,916.86	$470.31	3.27
SPIRIVA AER 1.25MCG	2,445	765	$1,122,510.31	$459.10	3.20
TIER-1 SUBTOTAL	**13,009**	**4,053**	**$7,250,751.41**	**$557.36**	**3.21**
TIER-2 UTILIZATION					
INCRUSE ELLIPTA INH 62.5MCG	64	15	$25,393.34	$396.77	4.27
YUPELRI SOL 175MCG/3ML	45	18	$65,132.20	$1,447.38	2.50
TUDORZA PRES AER 400MCG/ACT	31	5	$18,555.32	$598.56	6.20
LONHALA MAGNAIR SOL 25MCG	26	5	$30,917.08	$1,189.12	5.20
TIER-2 SUBTOTAL	**166**	**43**	**$139,997.94**	**$843.36**	**3.86**
LAMA TOTAL	**13,175**	**4,096**	**$7,390,749.35**	**$560.97**	**3.22**
INDIVIDUAL COMPONENT ICS PRODUCTS					
TIER-1 UTILIZATION					

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
FLOVENT HFA AER 110MCG	18,353	8,065	$4,940,128.50	$269.17	2.28
FLOVENT HFA AER 44MCG	17,922	7,963	$3,646,838.65	$203.48	2.25
BUDESONIDE SUS 0.5MG/2ML	3,563	1,735	$239,009.75	$67.08	2.05
BUDESONIDE SUS 0.25MG/2ML	3,050	1,942	$221,424.47	$72.60	1.57
FLOVENT HFA AER 220MCG	2,359	1,166	$1,021,945.80	$433.21	2.02
PULMICORT INH 90MCG	994	532	$211,457.74	$212.73	1.87
PULMICORT INH 180MCG	844	543	$224,023.21	$265.43	1.55
ASMANEX HFA AER 100MCG	753	269	$148,403.13	$197.08	2.80
FLOVENT DISKUS AER 100MCG	527	250	$125,176.15	$237.53	2.11
FLOVENT DISKUS AER 50MCG	347	153	$69,898.15	$201.44	2.27
ALVESCO AER 80MCG	317	145	$88,678.52	$279.74	2.19
BUDESONIDE SUS 1MG/2ML	295	123	$109,032.92	$369.60	2.40
FLUTICAS HFA AER 110MCG	261	261	$50,181.55	$192.27	1.00
FLUTICAS HFA AER 44MCG	256	253	$37,191.96	$145.28	1.01
FLOVENT DISKUS AER 250MCG	249	86	$80,531.73	$323.42	2.90
ASMANEX HFA AER 200MCG	208	110	$49,368.64	$237.35	1.89
ALVESCO AER 160MCG	169	68	$46,054.89	$272.51	2.49
ASMANEX 60 AER 220MCG	167	63	$43,702.19	$261.69	2.65
ASMANEX 30 AER 220MCG	114	44	$23,454.85	$205.74	2.59
ASMANEX 30 AER 110MCG	59	19	$11,357.51	$192.50	3.11
ASMANEX 120 AER 220MCG	47	30	$16,449.02	$349.98	1.57
FLUTICAS HFA AER 220MCG	46	46	$15,138.24	$329.09	1.00
ASMANEX 14 AER 220MCG	2	2	$170.37	$85.19	1.00
TIER-1 SUBTOTAL	**50,902**	**23,868**	**$11,419,617.94**	**$224.35**	**2.13**
TIER-2 UTILIZATION					
ARNUITY ELPT INH 100MCG	7	3	$1,698.82	$242.69	2.33
QVAR REDIHALER AER 80MCG	39	10	$11,396.50	$292.22	3.90
QVAR REDIHALER AER 40MCG	22	6	$4,837.23	$219.87	3.67
TIER-2 SUBTOTAL	**68**	**19**	**$17,932.55**	**$263.71**	**3.58**
ICS TOTAL	**50,970**	**23,887**	**$11,437,550.49**	**$224.40**	**2.13**
INDIVIDUAL COMPONENT LABA PRODUCTS					
TIER-1 UTILIZATION					
SEREVENT DISKUS AER 50MCG	772	328	$380,937.31	$493.44	2.35
TIER-1 SUBTOTAL	**772**	**328**	**$380,937.31**	**$493.44**	**2.35**
TIER-2 UTILIZATION					
ARFORMOTEROL NEB 15MCG/2ML	80	27	$49,867.94	$623.35	2.96
FORMOTEROL NEB 20MCG/2ML	42	21	$41,803.42	$995.32	2.00
BROVANA NEB 15MCG	30	9	$32,549.55	$1,084.99	3.33
PERFOROMIST NEB 20MCG	4	3	$5,918.65	$1,479.66	1.33
TIER-2 SUBTOTAL	**156**	**60**	**$130,139.56**	**$834.23**	**2.60**
LABA TOTAL	**928**	**388**	**$511,076.87**	**$550.73**	**2.39**
LABA/LAMA/ICS COMBINATION PRODUCTS					
TRELEGY AER 100-62.5-25MCG	855	197	$648,906.92	$758.96	4.34

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BREZTRI AEROSPHERE 160-9-4.8MCG	175	51	$116,641.48	$666.52	3.43
SUBTOTAL	**1,030**	**248**	**$765,548.40**	**$743.25**	**4.15**
LABA/LAMA COMBINATION PRODUCTS					
ANORO ELLIPTA AER 62.5-25MCG	324	76	$168,681.15	$520.62	4.26
STIOLTO AER 2.5-2.5MCG	87	22	$45,425.78	$522.14	3.95
BEVESPI AER 9-4.8MCG	39	9	$20,098.63	$515.35	4.33
SUBTOTAL	**450**	**107**	**$234,205.56**	**$520.46**	**4.21**
PDE4 ENZYME INHIBITOR PRODUCTS					
DALIRESP TAB 500MCG	156	32	$60,252.37	$386.23	4.88
DALIRESP TAB 250MCG	58	14	$21,957.36	$378.58	4.14
SUBTOTAL	**214**	**46**	**$82,209.73**	**$384.16**	**4.65**
TOTAL	**120,506**	**38,514***	**$39,852,755.99**	**$330.71**	**2.51**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = actuation; AER = aerosol; BUDES = budesonide; CAP = capsule; FLUTIC = fluticasone; FORMOT = formoterol; HFA = hydrofluoroalkane; ICS = inhaled corticosteroid; INH = inhaler; LABA = long-acting beta$_2$ agonist; LAMA = long-acting muscarinic antagonist; NEB = nebulizer; PDE4 = phosphodiesterase-4; PRES = Pressair; SALME = salmeterol; SOL = solution; SPR = spray; TAB = tablet; VILAN = vilanterol
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Utilization Details of Asthma-Indicated Monoclonal Antibodies: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
DUPILUMAB PRODUCTS					
DUPIXENT INJ 300MG/2ML	1,144	191	$3,649,957.52	$3,190.52	5.99
DUPIXENT PEN INJ 300MG/2ML	904	168	$2,893,634.38	$3,200.92	5.38
DUPIXENT INJ 200MG/1.14ML	761	108	$2,419,792.70	$3,179.75	7.05
DUPIXENT PEN INJ 200MG	54	16	$181,562.12	$3,362.26	3.38
DUPIXENT INJ 100MG/0.67ML	1	1	$3,396.24	$3,396.24	1.00
SUBTOTAL	**2,864**	**484**	**$9,148,342.96**	**$3,194.25**	**5.92**
OMALIZUMAB PRODUCTS					
XOLAIR INJ 150MG/ML	146	25	$439,528.91	$3,010.47	5.84
XOLAIR INJ 75MG/0.5ML	84	13	$96,180.71	$1,145.01	6.46
XOLAIR SOL 150MG	18	3	$19,342.25	$1,074.57	6.00
SUBTOTAL	**248**	**41**	**$555,051.87**	**$2,238.11**	**6.05**
MEPOLIZUMAB PRODUCTS					
NUCALA INJ 100MG	81	14	$258,919.60	$3,196.54	5.79
NUCALA INJ 100MG/ML	34	6	$110,386.05	$3,246.65	5.67
NUCALA INJ 100MG/ML	3	1	$9,998.25	$3,332.75	3.00
SUBTOTAL	**118**	**21**	**$379,303.90**	**$3,214.44**	**5.62**
BENRALIZUMAB PRODUCTS					
FASENRA PEN INJ 30MG/ML	36	10	$190,288.99	$5,285.81	3.60

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
FASENRA INJ 30MG/ML	35	9	$180,158.73	$5,147.39	3.89
SUBTOTAL	**71**	**19**	**$370,447.72**	**$5,217.57**	**3.74**
TEZEPELUMAB-EKKO PRODUCTS					
TEZSPIRE SOL 210MG/1.91ML	1	1	$3,644.41	$3,644.41	1
SUBTOTAL	**1**	**1**	**$3,644.41**	**$3,644.41**	**1**
TOTAL	**3,302**	**509***	**$10,456,790.86**	**$3,166.81**	**6.49**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; SOL = solution
Fiscal Year 2022 = 07/01/2021 to 06/30/2022
Please note: The above utilization data includes all FDA-approved diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
OMALIZUMAB INJ (J2357)	266	28	$597,295.20	$2,245.47	9.5
BENRALIZUMAB (J0517)	14	4	$71,135.40	$5,081.10	3.5
MEPOLIZUMAB INJ (J2812)	10	1	$31,471.00	$31,471.10	10
TOTAL	**290⁺**	**33***	**$699,901.60**	**$2,413.45**	**8.79**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Total number of unduplicated claims.
INJ = injection
Fiscal Year 2022 = 07/01/2021 to 06/30/2022
Please note: The above medical utilization data for omalizumab (J2357) and mepolizumab (J2182) includes all FDA-approved diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

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[9] GlaxoSmithKline plc. Pipeline. Available online at: https://www.gsk.com/en-gb/innovation/pipeline/. Last revised 07/27/2022. Last accessed 10/21/2022.
[10] Tezspire® (Tezepelumab-ekko). Prescribing Information. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761224s000lbl.pdf. Last revised 12/2021. Last accessed 10/21/2022.

Appendix M

Fiscal Year 2022 Annual Review of Atopic Dermatitis (AD) Medications and 30-Day Notice to Prior Authorize Adbry™ (Tralokinumab-ldrm) and Cibinqo™ (Abrocitinib)

Oklahoma Health Care Authority
November 2022

Current Prior Authorization Criteria

Approval criteria for Dupixent® (dupilumab injection) for indications other than AD can be found in the Fiscal Year 2022 Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications report, which is also being presented at the November 2022 Drug Utilization Review (DUR) Board meeting. Dupixent® is reviewed annually with the asthma and COPD maintenance medications.

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 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.

Elidel® (Pimecrolimus Cream) and Protopic® (Tacrolimus Ointment) Approval Criteria:

1. The first 90 days of a 12-month period will be covered without prior authorization; and
2. After the initial period, authorization may be granted with documentation of 1 trial with a Tier-1 topical corticosteroid at least 6 weeks in duration within the past 90 days; and
3. Therapy will be approved only once each 90-day period to ensure appropriate short-term and intermittent utilization as advised by the FDA; and
4. Quantities will be limited to 30 grams for use on the face, neck, and groin, and 100 grams for all other areas; and
5. Authorizations will be restricted to those members who are not immunocompromised; and
6. Members must meet all of the following criteria:
    a. An FDA approved indication:
        i. Elidel®: Short-term and intermittent treatment for mild-to-moderate atopic dermatitis (eczema); or
        ii. Protopic®: Short-term and intermittent treatment for moderate-to-severe atopic dermatitis (eczema); and
    b. Age restrictions:
        i. Elidel® 1% is restricted to 2 years of age and older; and
        ii. Protopic® 0.03% is restricted to 2 years of age and older; and
        iii. Protopic® 0.1% is restricted to 15 years of age and older; or
7. Clinical exceptions for the trial requirement may be considered for the following:
    a. Documented adverse effect, drug interaction, or contraindication to Tier-1 topical corticosteroids; or
    b. Atopic dermatitis of the face or groin where prescriber does not want to use topical corticosteroids; or
8. Clinical exceptions for the age restrictions (for members younger than the FDA approved age) may be considered for the following:
    a. Prescribed by a dermatologist.

Eucrisa® (Crisaborole Ointment) Approval Criteria:

1. An FDA approved indication for treatment of mild-to-moderate atopic dermatitis (eczema); and
2. Member must be at least 3 months 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 a topical corticosteroid (or have a contraindication or documented intolerance); and
4. A quantity limit of 1 tube per 30 days will apply; and

5. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
6. Clinical exceptions for the trial requirement may be considered for the following:
    a. Documented adverse effect, drug interaction, or contraindication to topical corticosteroids; or
    b. Atopic dermatitis of the face or groin where prescriber does not want to use topical corticosteroids; or
7. Clinical exceptions for the age restriction (for members younger than the FDA approved age) may be considered for the following:
    a. Prescribed by a dermatologist.

Opzelura™ (Ruxolitinib 1.5% Cream) Approval Criteria:

1. An FDA approved indication for short-term and non-continuous treatment of mild-to-moderate atopic dermatitis; and
2. Member must be 12 years of age or older; and
3. Member must not be immunocompromised; and
4. Member must have a body surface area (BSA) involvement ≤20%; and
5. Member must have documented trials within the last 6 months for a minimum of 2 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 (TCS); and
    b. 1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
    c. Eucrisa® (crisaborole); and
6. Concurrent use with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants (e.g., azathioprine, cyclosporine) will not generally be approved; and
7. Prescriber must verify female members are not breastfeeding; and
8. 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
9. Approvals will be for a maximum duration of 8 weeks of treatment; and
10. Reauthorization may be considered if member has a recent TCS, TCI, or Eucrisa® trial (or a contraindication or documented intolerance); and
    a. Additionally, the prescriber must document the member had a positive response to and tolerated previous treatment with Opzelura™; and
11. Subsequent approvals will only be considered once each 90-day period to ensure appropriate short-term and non-continuous utilization.

Prudoxin® and Zonalon® (Doxepin Cream) Approval Criteria:

1. An FDA approved indication for the short-term (up to 8 days) management of moderate pruritus in members with atopic dermatitis or lichen simplex chronicus; and
2. Requests for longer use than 8 days will not generally be approved. Chronic use beyond 8 days may result in higher systemic levels and should be avoided.

Approval criteria for Rinvoq® (upadacitinib) for indications other than AD can be found in the Fiscal Year 2022 Annual Review of Targeted Immunomodulator Agents in the October 2022 DUR Board packet. Rinvoq® is reviewed annually with the targeted immunomodulator agents. The following Rinvoq® approval criteria for a diagnosis of AD will be voted on with the updates for the targeted immunomodulator agents at the November 2022 DUR Board meeting.

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.

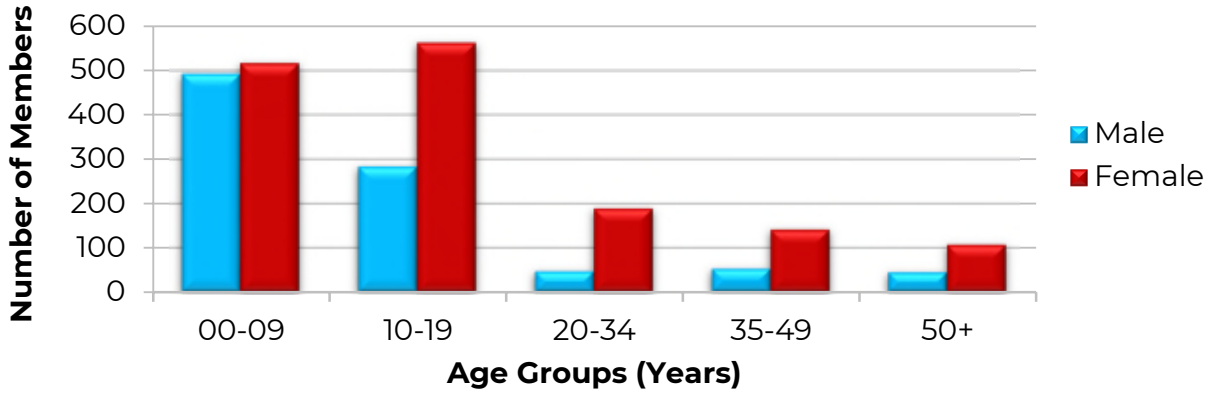
Utilization of AD Medications: Fiscal Year 2022

Comparison of Fiscal Years

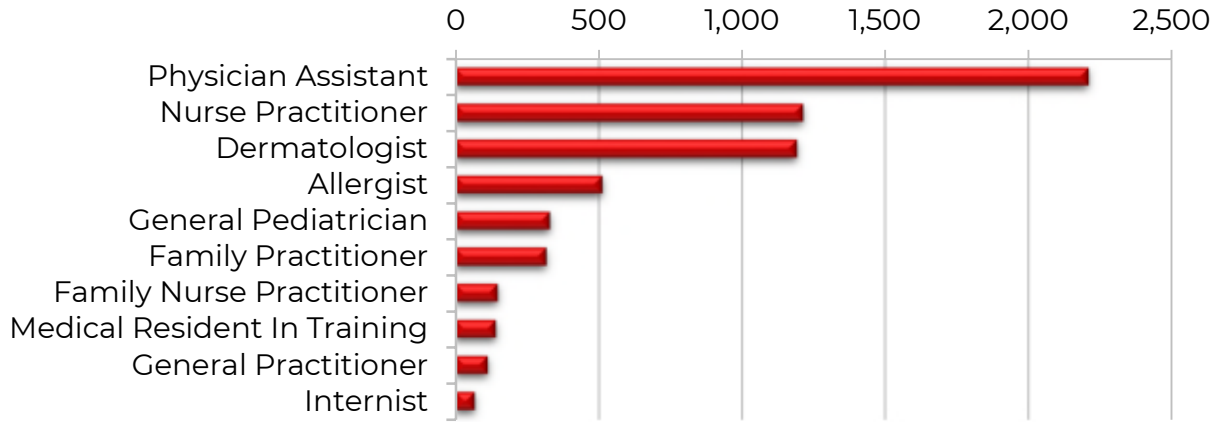
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	1,904	4,788	$6,255,685.45	$1,306.53	$43.50	181,748	143,802
2022	2,431	6,428	$10,370,958.78	$1,613.40	$53.42	203,430	194,152
% Change	**27.70%**	**34.30%**	**65.80%**	**23.50%**	**22.80%**	**11.90%**	**35.00%**
Change	**527**	**1,640**	**$4,115,273.33**	**$306.87**	**$9.92**	**21,682**	**50,350**

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
Utilization data includes Dupixent® used for all diagnoses and does not differentiate between AD diagnoses and other diagnoses, for which use may be appropriate.

Demographics of Members Utilizing AD Medications

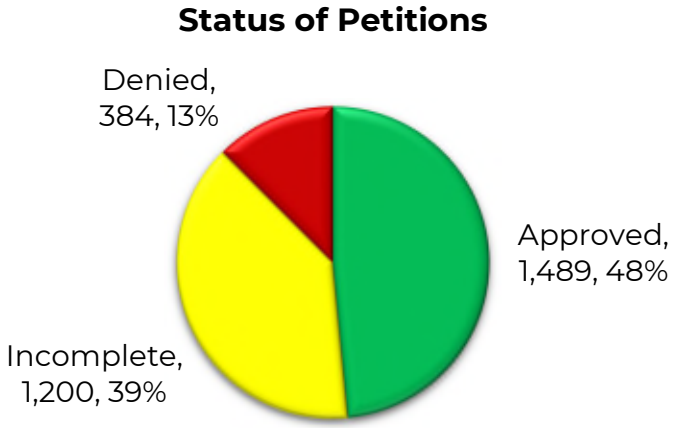


Top Prescriber Specialties of AD Medications by Number of Claims



Prior Authorization of AD Medications

There were 3,073 prior authorization requests submitted for AD medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



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

Anticipated Patent Expiration(s):

- Eucrisa® (crisaborole): July 2030
- Opzelura™ (ruxolitinib): May 2031
- Cibinqo™ (abrocitinib): February 2034
- Rinvoq® (upadacitinib): October 2036

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.

Pipeline:

- **Lebrikizumab:** Eli Lilly is conducting Phase 3 studies of lebrikizumab for the treatment of moderate-to-severe AD. Lebrikizumab is an investigational monoclonal antibody designed to bind IL-13 with high affinity, resulting in inhibition of signaling pathways thought to be responsible for multiple aspects of the pathophysiology of AD, including skin barrier dysfunction, itching, skin thickening, and infection. In June 2022, Lilly announced positive topline results demonstrating the efficacy and safety of lebrikizumab at 1 year from the Phase 3 ADvocate 1 and ADvocate 2 studies, which had previously showed positive efficacy and safety results at 16 weeks during the double-blinded, placebo-controlled portion of the studies. Lilly plans to submit a Biologics License Application (BLA) to the FDA for lebrikizumab in the second half of 2022.

Adbry™ (Tralokinumab-ldrm) Product Summary[8]

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™

Safety:

- Hypersensitivity: Hypersensitivity reactions including anaphylaxis and angioedema have been reported with use of tralokinumab. Tralokinumab should be discontinued immediately if a serious hypersensitivity reaction occurs, and appropriate therapy should be initiated.
- Conjunctivitis and Keratitis: Conjunctivitis and keratitis occurred more frequently in AD patients who received tralokinumab, with conjunctivitis being the most frequently reported eye disorder. Most patients who experienced these adverse effects recovered or were recovering during the treatment period. Patients should be advised to report new onset or worsening eye symptoms to their health care provider.
- Parasitic (Helminth) Infections: Patients with known helminth infections were excluded from participation in clinical studies of tralokinumab. It is not known if tralokinumab will influence the

immune response against helminth infections by inhibiting IL-13 signaling.

- Risk of Infection with Live Vaccines: Tralokinumab may alter a patient's immunity and increase the risk of infection following administration of live vaccines. All age-appropriate vaccinations should be completed prior to initiating therapy with tralokinumab, and live vaccines should be avoided. Limited data are available regarding coadministration of tralokinumab with non-live vaccines.
- Eosinophil Counts: Patients treated with tralokinumab had greater mean initial increase from baseline in eosinophil count compared to patients who received placebo. The mean increase from baseline to week 4 was 190 cells/mcL, and this declined to baseline level with continued treatment. Eosinophilia (>5,000 cells/mcL) was reported in 1.2% of patients who received tralokinumab vs. 0.3% of patients who received placebo during the initial 16-week treatment period.
- Pregnancy: There is limited data from the use of tralokinumab in pregnant women to inform a drug-associated risk of adverse developmental outcomes. Human immunoglobulin G (IgG) antibodies are known to cross the placental barrier; therefore, tralokinumab may be transmitted from the mother to the fetus. In an animal developmental study in monkeys, no adverse developmental effects were observed in offspring born after intravenous (IV) administration of tralokinumab during organogenesis through parturition at doses up to 10 times the maximum recommended human dose (MRHD).
- Lactation: There are no data available on the presence of tralokinumab in human milk, the effects on the breastfed child, or the effects of the drug on milk production. Maternal IgG is present in breast milk. The effects of local gastrointestinal exposure and limited systemic exposure to tralokinumab on the breastfed infant are unknown. The development and health benefits of breastfeeding, the mother's clinical need for tralokinumab, and any potential adverse effects on the breastfed child should be considered.
- Pediatric Use: The safety and efficacy of tralokinumab have not been established in pediatric patients.
- Geriatric Use: In 5 different studies in patients with AD, a total of 77 of the 1,605 patients were 65 years of age or older. Studies did not include a sufficient number of patients 65 years of age or older to determine whether they respond differently from younger patients.

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.

Efficacy: The efficacy of tralokinumab for the treatment of AD was assessed in 3 Phase 3 studies (ECZTRA 1, ECZTRA 2, and ECZTRA 3) which were randomized, double-blind, placebo-controlled studies in 1,934 patients 18 years of age and older with moderate-to-severe AD who were not adequately controlled with topical medications. ECZTRA 1 and ECZTRA 2 were monotherapy trials which compared tralokinumab monotherapy to placebo. ECZTRA 3 compared combination therapy with tralokinumab plus TCS to patients who received placebo plus TCS.

- Inclusion Criteria: Patients were required to have moderate-to-severe AD, defined as an Investigator's Global Assessment (IGA) score of ≥3, Eczema Area and Severity Index (EASI) score ≥16, and body surface area (BSA) involvement ≥10%.
- Primary Endpoint: The co-primary efficacy endpoints in all 3 studies were the proportion of patients achieving an IGA response, defined as an IGA score of 0 (clear) or 1 (almost clear) at week 16, and the proportion of patients achieving at least 75% improvement in the EASI score (EASI-75) at week 16.
- Results: In all 3 studies, the co-primary efficacy endpoints were met with tralokinumab achieving statistically higher responses relative to placebo. In ECZTRA 1 and ECZTRA 2 respectively, IGA response was achieved in 16% and 21% of patients who received tralokinumab and 7% and 9% of patients who received placebo. EASI-75 was achieved in 25% and 33% of patients who received tralokinumab and 13% and 10% of patients who received placebo. In ECZTRA 3 in patients receiving concurrent treatment with TCS, IGA response was achieved in 38% of patients who received tralokinumab and 27% of patients who received placebo. EASI-75 was achieved in 56% of patients who received tralokinumab and 37% of patients who received placebo.

Cibinqo™ (Abrocitinib) Product Summary[9]

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.

Boxed Warning: Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events (MACE), and Thrombosis (see the *Safety* section of this report for additional details)

- **Serious Infections:** Patients treated with abrocitinib may be at increased risk for developing serious infections that may lead to hospitalization or death. Use of abrocitinib should be avoided in patients with active, serious infection, including localized infections.
- **Mortality:** Higher rate of all-cause mortality, including sudden cardiovascular (CV) death, was observed in patients 50 years of age and older with at least 1 CV risk factor treated with a different oral JAK inhibitor for rheumatoid arthritis (RA). Abrocitinib is not approved for use in RA.
- **Malignancies:** Malignancies were reported in patients treated with abrocitinib. Lymphoma and other malignancies have been observed in patients treated with JAK inhibitors for inflammatory conditions.
- **MACE:** MACE was reported in patients treated with abrocitinib. A higher rate of MACE [including CV death, myocardial infarction (MI), and stroke] was observed in patients treated with another JAK inhibitor for RA.
- **Thrombosis:** Deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients treated with abrocitinib. Thrombosis, including DVT, PE, and arterial thrombosis, has been reported in patients treated with JAK inhibitors for inflammatory conditions. Many of these adverse reactions were serious and some resulted in death.

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

Safety:

- Serious Infections: The most frequent serious infections reported in clinical studies of abrocitinib for AD were herpes simplex, herpes zoster, and pneumonia. In patients receiving JAK inhibitors for inflammatory conditions, serious infections leading to hospitalization or death, including tuberculosis (TB) and bacterial, invasive fungal, viral, and other opportunistic infections have occurred. Use of abrocitinib should be avoided in patients with active, serious infection, including localized infections. The risks and benefits of abrocitinib should be considered in patients with chronic or recurrent infection, with previous exposure to TB, with history of a serious or an opportunistic infection, who previously resided or traveled in areas with endemic TB or endemic mycoses, or with underlying conditions that may predispose them to infection. Patients should be closely monitored for signs and symptoms of infection during and after treatment with abrocitinib. If a serious or opportunistic infection develops, treatment with abrocitinib should be discontinued and appropriate antimicrobial treatment should be initiated.
- Mortality: In clinical studies of another JAK inhibitor used for RA in patients 50 years of age and older with at least 1 CV risk factor, a higher rate of all-cause mortality, including sudden CV death, was observed. The benefits and risks should be considered for the individual patient before initiating treatment with abrocitinib. Abrocitinib is not FDA approved for use in RA.
- Malignancy and Lymphoproliferative Disorders: In clinical studies of abrocitinib for AD, malignancies, including non-melanoma skin cancer, were observed. Periodic skin examinations should be performed during treatment with abrocitinib for patients at increased risk for skin cancer. The benefits and risks for the individual patients should be considered prior to initiating treatment with abrocitinib, particularly for patients with a known malignancy, patients who develop a malignancy when on treatment, and patients who are current or past smokers.
- MACE: MACE was reported in clinical studies of abrocitinib for AD. In clinical studies of another JAK inhibitor in RA, MACE (defined as CV death, non-fatal MI, and non-fatal stroke) was observed. The benefits and risks should be considered for the individual patient before initiating or continuing treatment with abrocitinib, particularly in patients who are current or past smokers and in patients with other CV risk factors. Patients should be informed about the symptoms of serious CV events and the steps to take if these symptoms occur.

Abrocitinib should be discontinued in patients who have experienced an MI or stroke.

- Thrombosis: DVT and PE were observed in patients receiving abrocitinib for AD. In patients treated with oral JAK inhibitors for inflammatory conditions, thrombosis, including DVT, PE, and arterial thrombosis, has been observed. Many of these were serious and some resulted in death. Abrocitinib should be avoided in patients at increased risk of thrombosis. If symptoms of thrombosis occur, abrocitinib should be discontinued and patients should be evaluated appropriately.
- Laboratory Abnormalities: Treatment with abrocitinib was associated with an increased incidence of thrombocytopenia and lymphopenia. A complete blood count (CBC) should be performed prior to initiation, at 4 weeks after initiation, and 4 weeks after a dose increase with abrocitinib. Discontinuation of abrocitinib is recommended for certain laboratory abnormalities. Additionally, dose-dependent increases in lipid parameters were reported in patients treated with abrocitinib. Lipid parameters should be assessed approximately 4 weeks after initiation and patients should be managed according to clinical guidelines for hyperlipidemia.
- Immunizations: All age-appropriate vaccinations should be completed prior to initiating treatment with abrocitinib, including prophylactic herpes zoster vaccination. Live vaccines should be avoided immediately prior to, during, and immediately after abrocitinib treatment.
- Drug Interactions: Coadministration of abrocitinib with antiplatelet drugs may increase the risk of bleeding with thrombocytopenia. Antiplatelet drugs, except low-dose aspirin, are contraindicated during the first 3 months of treatment with abrocitinib.
- Pregnancy: Available data from pregnancies reported during clinical studies of abrocitinib are not sufficient to establish a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In animal studies, oral administration of abrocitinib during organogenesis at exposures 14 or 5 times the MRHD resulted in maternal dystocia and skeletal variations in rats and no adverse effects in rabbits. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to abrocitinib during pregnancy. Pregnant patients exposed to abrocitinib and their health care providers should report the exposure to the pregnancy registry.
- Lactation: There are no data available on the presence of abrocitinib in human milk, the effects on the breastfed child, or the effects of the drug on milk production. Abrocitinib was secreted in the milk of lactating rats and would likely be present in human milk as well. Because of the serious adverse event findings in adults, including the risk of serious infections, malignancy, and thrombocytopenia, women

should not breastfeed during treatment with abrocitinib and for 1 day after the last dose.

- Females and Males of Reproductive Potential: Based on findings in rats, oral administration of abrocitinib may impair female fertility. Impaired fertility in female rats was reversible 1 month after cessation of abrocitinib treatment.
- Pediatric Use: The safety and efficacy of abrocitinib have not been established in pediatric patients.
- Geriatric Use: Clinical studies of abrocitinib did not include sufficient numbers of patients 65 years of age and older to determine if they respond differently than younger adult patients.
- Renal Impairment: Abrocitinib is not recommended in patients with severe renal impairment (eGFR <30mL/min) and end-stage renal disease (ESRD) including those on renal replacement. A dosage adjustment is recommended in patients with moderate renal impairment (eGFR 30-59mL/min).
- Hepatic Impairment: Abrocitinib should be avoided in patients with severe hepatic impairment (Child Pugh C). Dosage adjustment is not required in patients with mild (Child Pugh A) or moderate (Child Pugh B) hepatic impairment.
- CYP2C19 Poor Metabolizers: The area under the curve (AUC) of abrocitinib is increased in patients who are CYP2C19 poor metabolizers due to reduced metabolic clearance. Dosage reduction of abrocitinib is recommended in patients who are known or suspected CYP2C19 poor metabolizers.

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.

Efficacy: The efficacy of abrocitinib for the treatment of AD was assessed in 3 Phase 3 studies (Trial-AD-1, Trial-AD-2, and Trial-AD-3) which were randomized, double-blind, placebo-controlled studies in 1,615 patients with moderate-to-severe AD. Trial-AD-1 and Trial-AD-2 were monotherapy trials which compared abrocitinib monotherapy to placebo. Trial-AD-3 compared combination therapy with abrocitinib plus TCS to patients who received placebo plus TCS. Additionally, some patients in Trial-AD-3 received dupilumab plus TCS.

- Inclusion Criteria: Patients were required to have moderate-to-severe AD, defined as an IGA score of ≥3, EASI score ≥16, BSA involvement ≥10%, and Peak Pruritus Numeral Rating Scale (PP-NRS) ≥4 at baseline.
- Primary Endpoint: The co-primary efficacy endpoints in all 3 studies were the proportion of patients achieving an IGA response, defined as an IGA score of 0 (clear) or 1 (almost clear) at week 12 with at least a 2-point improvement from baseline, and the proportion of patients achieving EASI-75 at week 12.
- Results: In all 3 studies, the co-primary efficacy endpoints were met with both strengths of abrocitinib achieving statistically higher responses relative to placebo. In Trial-AD-1 and Trial-AD-2 respectively, IGA response was achieved in 44% and 38% of patients who received abrocitinib 200mg, 24% and 28% of patients who received abrocitinib 100mg, and 8% and 9% of patients who received placebo. EASI-75 was achieved in 62% and 61% of patients who received abrocitinib 200mg, 40% and 44% of patients who received abrocitinib 100mg, and 12% and 10% of patients who received placebo. In Trial-AD-3 in patients receiving concurrent treatment with TCS, IGA response was achieved in 47% of patients who received abrocitinib 200mg, 36% of patients who received abrocitinib 100mg, and 14% of patients who received placebo. EASI-75 was achieved in 68% of patients who received abrocitinib 200mg, 58% of patients who received abrocitinib 100mg, and 27% of patients who received placebo.

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 prior authorization 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 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.

Utilization Details of AD Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TOPICAL PRODUCTS						
EUCRISA OIN 2%	1,290	673	$881,909.01	$683.65	1.92	8.50%
PIMECROLIMUS CRE 1%	974	734	$191,597.28	$196.71	1.33	1.85%
TACROLIMUS OIN 0.03%	749	536	$86,725.51	$115.79	1.4	0.84%
TACROLIMUS OIN 0.1%	549	414	$58,442.21	$106.45	1.33	0.56%
ELIDEL CRE 1%	1	1	$585.60	$585.60	1	0.01%
SUBTOTAL	**3,563**	**2,358**	**$1,219,259.61**	**$342.20**	**1.51**	**11.76%**
INJECTABLE PRODUCTS						
DUPIXENT SYR INJ 300MG/2ML	1,144	191	$3,649,957.52	$3,190.52	5.99	35.19%
DUPIXENT PEN INJ 300MG/2ML	904	168	$2,893,634.38	$3,200.92	5.38	27.90%
DUPIXENT SYR INJ 200MG/1.14ML	761	108	$2,419,792.70	$3,179.75	7.05	23.33%
DUPIXENT PEN INJ 200MG/1.14ML	54	16	$181,562.12	$3,362.26	3.38	1.75%
DUPIXENT SYR INJ 100MG/0.67ML	1	1	$3,396.24	$3,396.24	1	0.03%
ADBRY INJ 150MG/ML	1	1	$3,356.21	$3,356.21	1	0.03%
SUBTOTAL	**2,865**	**485**	**$9,151,699.17**	**$3,194.31**	**5.91**	**88.24%**
TOTAL	**6,428**	**2,431***	**$10,370,958.78**	**$1,613.40**	**2.64**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CRE = cream; INJ = injection; OIN = ointment; SYR = syringe
Utilization data includes Dupixent® used for all diagnoses and does not differentiate between AD diagnoses and other diagnoses, for which use may be appropriate.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

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Appendix N

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

Oklahoma Health Care Authority
November 2022

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

Adrenoleukodystrophy (ALD) is a rare genetic disorder caused by a mutation in the *ABCD1* gene located in the X-chromosome that leads to the progressive loss of white matter in the nervous system and the degradation of adrenal glands. ALD is an X-linked recessive disorder, therefore males develop more serious complications than females, while some females will have no symptoms at all.

The mutation in the *ABCD1* gene causes a defective ALD protein. ALD protein is a transporter protein; it helps to transport fat molecules called very long-chain fatty acids (VLCFAs) into structures called peroxisomes where the VLCFAs are then broken down. Because there is a deficiency of ALD protein, VLCFAs are not transported into the peroxisomes to ultimately be broken down. This causes a buildup of VLCFAs in the tissues, specifically in the myelin of nerve cells and the adrenal cortex. Research suggests that the abnormal accumulation of VLCFAs in the brain initiates an inflammatory response by the immune system that leads to damage of the myelin leading to the neurological symptoms of ALD.

The signs and symptoms of ALD can vary widely, even among members of the same family. Some individuals have serious complications in infancy or childhood while others develop symptoms as adults. The diagnosis of ALD can be established based on clinical findings, elevated VLCFAs, and confirmed via genetic testing. There are different forms of ALD including adrenomyeloneuropathy (AMN), childhood cerebral ALD (CALD), adult CALD, and Addison's-only ALD. CALD is the most severe and neurodegenerative form of ALD. The overall prevalence of ALD is approximately 1 in 17,000 newborns. CALD develops in approximately 40% of affected boys and a smaller number of adult men.

Boys with CALD typically present with neurologic symptoms between 3 and 10 years of age. After an initial period of normal development, symptoms typically include behavioral problems, such as attention-deficit/hyperactivity disorder (ADHD) and learning disabilities. Progressive symptoms include diminished visual acuity, hearing loss, gait instability, weakness and stiffness of limbs, and seizures. Within 2 to 3 years, symptoms progress to a loss of

most neurologic function and total disability, with death occurring by the second decade of life.

There are 4 measures of disease severity used for CALD:

- The Loes score measures the extent of disease severity on magnetic resonance imaging (MRI). The score ranges from 0 to 35, with higher scores indicating more severe disease. A Loes score of less than 0.5 is considered normal.
- Gadolinium enhancement (GdE+) on an MRI of demyelinating lesions is associated with an increased probability of progression and higher 5-year mortality.
- The neurological function score (NFS) is a 25-point composite scale that assesses functional disabilities in 15 domains. It is the most used clinical evaluation tool for CALD patient evaluation. A score of 0 indicates absence of clinical signs of cerebral disease and a higher score corresponds to increasing severity of functional deficiencies.
- Major functional disabilities (MFDs) are a subset of the NFS that are considered largely irreversible clinical neurological changes in CALD. The 6 MFDs include loss of communication, cortical blindness, requirement of tube feeding, total incontinence, wheelchair dependence, and complete loss of voluntary movement.

Allogeneic hematopoietic stem cell transplantation (HSCT) is the treatment of choice for early-stage CALD, meaning patients have no or mild signs and symptoms of the disease. Observational studies have reported 5- and 8-year survival rates of 56%, with 5-year survival rates as high as 92% among patients treated at very early stages of the illness. Risks of HSCT treatment are higher among matched unrelated donors and unmatched donors, as well as when patients are older and have more advanced disease. Bluebird Bio, the manufacturer of Skysona®, has reported that 70% of CALD patients do not have a matched sibling donor.

With newborn screening, some patients can be diagnosed with CALD before symptoms occur. If the results of the newborn screening are positive for CALD, patients can be monitored before the onset of symptoms, increasing the likelihood of undergoing HSCT in time to stabilize the disease. Early diagnosis is imperative, as untreated CALD is life-threatening and HSCT offers little clinical benefit for patients with late-stage disease. In February 2016, the U.S. Department of Health and Human Services recommended that screening for CALD be a part of the routine newborn screening; Oklahoma's newborn screening panel includes CALD screening. Besides HSCT, no other disease-modifying treatments exist for CALD. Symptomatic and supportive treatments for CALD include physical therapy, psychological support, and special education.

In September 2022, the U.S. Food and Drug Administration (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 CALD. 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 VLCFAs and slow or possibly prevent further inflammation and demyelination.

Skysona® (Elivaldogene Autotemcel) Product Summary[9,10,11,12,13]

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 (NFS ≤1) boys who have gadolinium enhancement on brain MRI and Loes scores of 0.5-9.
- This indication was approved under accelerated approval based on 24-month MFD-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitations 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 x 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 x 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, and the effects on milk production.
- Females and Males of Reproductive Potential: Consult the *Prescribing Information* of the mobilization and conditioning agents 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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Appendix O

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

FDA NEWS RELEASE

For Immediate Release: October 17, 2022

FDA Awards 19 Grants and 2 Contracts Related to Rare Diseases, Including Amyotrophic Lateral Sclerosis (ALS)

The FDA announced it has awarded 19 new grants and 2 new contracts totaling more than $38 million in funding over the next 4 years to support clinical trials, natural history studies, and regulatory science tools related to rare diseases. These grants and contracts, which were funded by the FDA's Orphan Products Grants Program, aim to advance the development of medical products to treat rare diseases. Several awards support the Accelerating Access to Critical Therapies for Amyotrophic Lateral Sclerosis (ACT for ALS) Act which recently established the FDA Rare Neurodegenerative Disease Grant Program to promote medical product development for rare neurodegenerative diseases such as ALS.

The FDA received 33 clinical trial grant applications and awarded more than $25 million spread over the next 4 years to 11 clinical trials that support product development for rare disease treatments. Seven of the awards fund studies of rare cancers, mostly targeting cancers of the brain and peripheral nerves.

The FDA received 43 natural history grant applications and funded 8 new grants totaling more than $11 million spread over the next 4 years for natural history studies that support innovative research to inform medical product development. Several studies seek to characterize certain subgroups within a disease, identify novel clinical outcome measures and biomarkers, which have the potential to improve the current standard of care and inform future drug development, including gene therapies.

The Rare Neurodegenerative Disease Grant Program was established specifically for ALS and neurodegenerative conditions upon enactment of the ACT for ALS Act in December 2021. The Act requires that the FDA award grants and contracts to public and private entities to cover costs of research on, and development of interventions intended to prevent, diagnose, mitigate, treat, or cure ALS and other rare neurodegenerative diseases in adults and children. Three of the natural history studies awarded by the FDA are related to rare neurodegenerative diseases including for ALS, Myotonic Dystrophy Type 1, and Ataxia-Telangiectasia.

Additionally, the FDA funded 2 contracts related to rare neurodegenerative diseases. One contract, co-funded by National Institutes of Health (NIH) and the FDA, will study whether a physical assessment of ALS patients, typically done in a health care professional's office, can be done remotely at home to minimize the burden on patients. This can ultimately lead to lower clinical trial costs and enable decentralized trials, where appropriate, improving access to trials for patients in rural areas and lower-resource health care settings.

The second contract is a landscape analysis of patient preference information (PPI) studies focused on brain-computer interface (BCI) devices. The FDA is specifically interested in BCI devices that communicate with the brain and provide patients, who are no longer able to speak or move, with the ability to interact with their families and health care professionals. The contract will review the literature to determine what is already

known about BCI devices and PPI studies in ALS. In total, through collaborative efforts, the FDA and its partners were able to support nearly $6 million in research and science to advance the mission of the ACT for ALS Act.

FDA NEWS RELEASE

For Immediate Release: October 12, 2022

Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose in Younger Age Groups

The FDA amended the emergency use authorizations (EUAs) of the Moderna COVID-19 vaccine, bivalent and the Pfizer-BioNTech COVID-19 vaccine, bivalent to authorize their use as a single booster dose in younger age groups. The Moderna COVID-19 vaccine, bivalent is authorized for administration at least 2 months following completion of primary or booster vaccination in children as young as 6 years of age. The Pfizer-BioNTech COVID-19 vaccine, bivalent is authorized for administration at least 2 months following completion of primary or booster vaccination in children as young as 5 years of age.

These bivalent COVID-19 vaccines include a messenger ribonucleic acid (mRNA) component of the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component in common between the omicron variant BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the omicron variant. The mRNA in these vaccines is a specific piece of genetic material that instructs cells in the body to make the distinctive “spike” protein of the original virus strain and the omicron variant lineages BA.4 and BA.5. The spike proteins of BA.4 and BA.5 are identical.

With this authorization, the monovalent Pfizer-BioNTech COVID-19 vaccine is no longer authorized as a booster dose for individuals 5 through 11 years of age. Both the Moderna COVID-19 vaccine and Pfizer-BioNTech COVID-19 vaccine continue to be authorized for primary series administration in individuals 6 months of age and older.

For each of the bivalent COVID-19 vaccines authorized, the FDA relied on immune response and safety data that it had previously evaluated from a clinical study in adults of a booster dose of a bivalent COVID-19 vaccine that contained a component of the original strain of SARS-CoV-2 and a component of omicron lineage BA.1. The FDA considers such data as relevant and supportive of vaccines containing a component of the omicron variant BA.4 and BA.5 lineages. In addition, the FDA has evaluated and considered immune response and safety data from clinical studies of the monovalent mRNA COVID-19 vaccines, including as a booster dose in pediatric age groups. These data and real-world experience with the monovalent mRNA COVID-19 vaccines, which have been administered to millions of people, including young children, support the EUA of the bivalent COVID-19 vaccines in younger age groups.

FDA NEWS RELEASE

For Immediate Release: October 07, 2022

FDA Approves Vaccine for Use During Third Trimester of Pregnancy to Prevent Whooping Cough in Infants Younger Than Two Months of Age

The FDA approved Boostrix® [tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed (Tdap)] for immunization during the third trimester of pregnancy to prevent pertussis, commonly known as whooping cough, in infants younger than 2 months of age.

Most serious pertussis cases, hospitalizations, and deaths occur in infants younger than 2 months of age who are too young to be protected by the childhood pertussis vaccine series. According to the Centers for Disease Control and Prevention (CDC), 4.2% of the total cases of pertussis reported in the United States in 2021 were in infants younger than 6 months of age and approximately 31% required hospitalization. When the Boostrix® vaccine is given during pregnancy, it boosts antibodies in the mother, which are transferred to the developing baby.

Boostrix® was initially approved by the FDA in 2005 as a single dose for booster immunization against tetanus, diphtheria, and pertussis in individuals 10 through 18 years of age. Subsequently, the FDA also approved Boostrix® to include use in individuals 19 years of age and older and to include use of an additional dose 9 years or more after the initial dose of a Tdap vaccine. The FDA's approval of Boostrix® has always included its use during pregnancy to protect the vaccinated individual. This recent approval is specific to use in pregnancy to prevent pertussis in infants younger than 2 months of age. Since 2012, the CDC has recommended the use of Tdap vaccines during the third trimester of each pregnancy.

The determination of effectiveness of Boostrix® administered during the third trimester to prevent pertussis among infants younger than 2 months of age was based on a re-analysis of the Boostrix®-relevant data from an observational case-control study of Tdap vaccine effectiveness. The FDA found these real-world data as providing real-world evidence to support this approval. In this re-analysis, data from 108 cases of pertussis in infants younger than 2 months of age (including 4 cases whose mothers received Boostrix® during the third trimester) and 183 control infants who did not have pertussis (including 18 whose mothers received Boostrix® during the third trimester) resulted in a preliminary estimate of Boostrix® as 78% effective in preventing pertussis among infants younger than 2 months of age, when administered during the third trimester of pregnancy. This preliminary estimate of effectiveness was updated using data from published observational studies. These statistical analyses provided estimates of effectiveness that are consistent with the preliminary estimate of 78%.

The safety of Boostrix® administered during the third trimester of pregnancy was assessed in a randomized, placebo-controlled study with a non-United States formulation of Boostrix®. The FDA considers the safety data with the non-United States formulation relevant because it contains the same components as the United States formulation of Boostrix®, except that the non-United States formulation contains more aluminum per dose. The study included approximately 680 pregnant individuals of whom about 340 received the non-United States formulation of Boostrix® and of whom about 340 received saline placebo. After childbirth, the placebo recipients were then vaccinated with the non-United States formulation of Boostrix®. The rates of reported side effects following receipt of the non- United States formulation of Boostrix® administered during pregnancy were consistent with the rates following receipt of the non-United States formulation of Boostrix® administered to study participants after childbirth. The study did not identify any vaccine-related adverse effects on pregnancy or on the fetus/newborn.

Current Drug Shortages Index (as of October 26, 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***
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***
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***
Iohexol Injection	***Currently in Shortage***
Iomeprol injection	***Currently in Shortage***
Iopromide (Ultravist) Injection	***Currently in Shortage***
Isoniazid Injection	***Currently in Shortage***
IV Fat Emulsion	***Currently in Shortage***
Ketamine Injection	***Currently in Shortage***
Ketoprofen Capsules	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Lyophilized Powder for Injection	***Currently in Shortage***
Leuprolide Acetate Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***

Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine	***Currently in Shortage***
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***
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***
Vandetanib Tablets	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***
Verteporfin (Visudyne) Injection	***Currently in Shortage***