EXECUTIVE SUMMARY
Uniform Formulary Beneficiary Advisory Panel
Meeting January 3, 2024

For the November 2023 DoD Pharmacy and Therapeutics Committee Meeting

The Uniform Formulary Beneficiary Advisory Panel (UF BAP) convened at 10:00 A.M. EDT on January 3, 2024 via teleconference. The current meeting took place over 2 hours and 10 minutes. The information presented included the recommendations from the November 2023 DoD Pharmacy and Therapeutics Committee (P&T) meeting.

The detailed meeting information is found starting on page 10.

UNIFORM FORMULARY (UF) DRUG CLASS REVIEWS

I. UF CLASS REVIEWS—Migraine Agents – CGRP Antagonist Prophylaxis Subclass

A. Migraine Agents – CGRP Antagonist Prophylaxis Subclass—UF Recommendations

Chronic and Episodic Migraine

- UF and step-preferred
  - galcanezumab injection 120 mg (Emgality) – *moves from UF to UF and step-preferred*
- UF and non-step-preferred
  - fremanezumab injections (Ajovy) – *moves from UF to UF and non-step-preferred*
  - erenumab injection (Aimovig) – *moves from UF to UF and non-step-preferred*
- Note that for Ajovy and Aimovig, a trial of Emgality 120 mg is required first in new users.
- NF - none
- Complete exclusion - none

Cluster Headache

- UF
  - galcanezumab injection 100 mg (Emgality)– moves from NF to UF (not part of the step therapy for chronic and episodic migraine)
- NF - none

- Complete exclusion - none

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent:**

B. Migraine Agents – CGRP Antagonist Prophylaxis Subclass—Manual PA Criteria

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

C. Migraine Agents – CGRP Antagonist Prophylaxis Subclass—UF, PA, and Implementation Period

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

II. UF CLASS REVIEWS—Neurological Agents Miscellaneous - Movement Disorders

A. Neurological Agents Miscellaneous - Movement Disorders—UF Recommendations

- UF
  - generic Xenazine
  - Austedo IR
  - Austedo XR
  - Ingrezza
- NF - none
- Complete exclusion - none

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

B. Neurological Agents Miscellaneous—Movement Disorders—Manual Prior Authorization Criteria

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

C. Neurological Agents Miscellaneous—Movement Disorders—UF, PA, and Implementation Period

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

III. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5)

A. Newly Approved Drugs Per 32 CFR 199.21(g)(5)—UF/NF/Complete Exclusion Recommendation

- UF
  - nalmefene nasal spray (Opvee)
  - lotilaner 0.25% ophthalmic solution (Xdemvy)
  - niraparib/abiraterone acetate (Akeega)
  - palvarotene (Sohonos)
  - polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride powder for oral solution with flavor-enhancing packets (Suflave)
  - quizartinib (Vanflyta)

- sodium phenylbutyrate packets for oral suspension (Olpruva)
- nirmatrelvir/ritonavir (Paxlovid)
- molnupiravir (Lagevrio)

- NF
  - adalimumab (Humira) biosimilars–Targeted Immunomodulatory Biologics (TIBs)
    - adalimumab-atto injection (Amjevita)
    - adalimumab-adbm injection (Cyltezo)
    - adalimumab-fkip injection (Hulio)
    - adalimumab-fkip injection (unbranded biologic)
    - adalimumab-aacf injection (Idacio)
    - adalimumab-bwwd injection (Hadlima)
    - adalimumab-aqvh injection (Yusimry)
    - adalimumab-aaty injection (Yuflyma)
    - adalimumab-adaz injection (Hyrimoz)
    - adalimumab-adaz injection (unbranded biologic)
  - albuterol and budesonide metered dose inhaler (Airsupra) – Short-Acting Beta Agonists (SABAs)
  - bexagliflozin (Brenzavvy) – Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors
  - latanoprost 0.005% ophthalmic solution (Iyuzeh) – Glaucoma Agents: Prostaglandin Analogs
  - somatrogon-ghla injection (Ngenla) – Growth Stimulating Agents
- Complete Exclusion
  - colchicine 0.5 mg tabs (Lodoco)

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

B. Newly Approved Drugs Per 32 CFR 199.21(g)(5)—PA Criteria

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

C. Nalmefene Nasal Spray (Opvee) —Tier 1 Copay

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF, PA, Opvee nasal spray Tier 1 copay and Implementation Period

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

IV. RE-EVALUATION OF NONFORMULARY GENERICS—PULMONARY-1 AGENTS AND CONTRACEPTIVES

A. Re-Evaluation of Nonformulary Generics—Pulmonary-1 Agents: ICS/LABAs, and SABAs—Formulary status and Implementation

Summary of Panel Questions and Comments

Dr. Peloquin commended the Formulary Management Branch and DoD P&T Committee on relooking at the nonformulary recommendations. He did ask whether Ventolin HFA has sufficient generic supply, whether Ventolin HFA is staying NF and if the pricing had dropped sufficiently for this product. CDR Phung stated that Ventolin HFA will remain NF, however, generic Proventil HFA will move to UF, and generic ProAir will remain UF.

Dr. Peloquin commented that Retail Network pharmacies sometimes carry different products, and there aren't auto-substitution policies, so patients may run into an issue with a potential nonformulary copay for an acute use drug.

Dr. Peloquin also commented regarding the oral contraceptives that it is the right thing to do to move these to formulary status. He also mentioned that "lesser of logic" has been in place at Retail Network pharmacies for a long time. He asked whether this will positively impact patients using the Mail Order pharmacy? Dr. Trice answered that there will be a benefit to beneficiaries using the Mail Order pharmacy. Dr. Trice stated there is not a lot of usage of these particular products and there are over 100 different oral contraceptive products. The patients who are receiving the products mentioned above will have their copay decreased from the Tier 3 nonformulary copay to the lower Tier 1 generic copay.

Dr. Peloquin then commented that with dynamics of the marketplace, more and more of these types of issue are happening. And he again commended the DoD P&T Committee for including this in the UF BAP information.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

B. Re-Evaluation of Nonformulary Generics—Contraceptives—Formulary Status and Implementation

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

V. UTILIZATION MANAGEMENT—PULMONARY-1 AGENTS—COMBINATIONS WITH INHALED CORTICOSTEROIDS/LONG-ACTING BETA AGONISTS (ICS/LABAs) AND INHALED CORTICOSTEROIDS (ICS)

A. ICS/LABAs—PA, Tier 1 Copay Removal, and Implementation Plan

Summary of Panel Questions and Comments

Dr. Peloquin wanted to clarify that Advair HFA is going off the market, but that the authorized generic by Prasco will remain available. His question concerned the authorized generic and how will it differentiate from other generics, and whether there is a different name for the authorized generic. Also, from the beneficiary standpoint, how will this affect them?

CDR Phung answered that there is not a different brand name for the authorized generic Advair HFA, but that we do know that the product is available from Prasco. CDR Phung also stated that from an adjudication aspect, the flag for the PA will occur at the site of dispensing.

Dr. Peloquin then asked what will happen to the patient at the pharmacy if there is a substitution? He stated if a Retail pharmacy uses the authorized generic as its generic, the PA requirement will occur and there is the potential to cause some beneficiary confusion.

Dr. Peloquin then said he has the same question as to what would happen with the Flovent authorized generic? Will the authorized generic Flovent HFA adjudicate at a pharmacy or will it require a PA? CDR Phung answered that there is not a PA required for the authorized generic Flovent HFA.

Dr. Soucy then asked if Advair HFA has a Tier 2 copay, because from the May 2023 P&T Meeting it should have a Tier 1 copay. CDR Phung answered that the Tier 1 copay for Advair HFA from the May 2023 meeting was not implemented, due to the manufacturer discontinuing it from the market.

Dr. Peloquin recommended that FMB will need to monitor these market changes, because from a pharmacy perspective the authorized generic is indistinguishable from the generics.

FMB note, brand and authorized generics have different national drug codes so they can be distinguished and monitored.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

B. ICS—PA, Tier 1 Copay Removal, Brand over Generic PA removal and Implementation Plan

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

VI. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA-APPROVED INDICATIONS AND IMPLEMENTATION PLAN

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

VII. UTILIZATION MANAGEMENT— UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW INDICATIONS AND IMPLEMENTATION PLAN

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

VIII. BRAND OVER GENERIC PA AUTHORIZATION AND TIER 1 COPAY: PULMONARY-2 AGENTS: LONG-ACTING MUSCARINIC ANTAGONISTS (LAMAs): TIOTROPIUM (SPIRIVA) HANDIHALER AND IMPLEMENTATION PLAN

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

IX. OVER-THE-COUNTER (OTC) DRUG BENEFIT—PROGESTIN-ONLY CONTRACEPTIVES: NORGESTREL TABLETS (OPILL) UF RECOMMENDATION, COPAY, PRESCRIPTION REQUIREMENT AND IMPLEMENTATION PERIOD

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

X. CONSIDERATIONS OF BETTER CARE, HEALTHIER PEOPLE AND SMARTER SPENDING-ANNOVERA AND DEPO-SUBQ PROVERA CONTRACEPTIVES TIER 1 COPAY AND IMPLEMENTATION PERIOD

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

Mr. DuTeil asked if there was a reason given for the abstaining vote? Dr. Kugler said that no reason was given; the P&T Committee members do not have to provide a reason for abstaining.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0**

Director, DHA:

[redacted] The comments outlined above were taken under consideration prior to my final decision.

3/8/24

Uniform Formulary Beneficiary Advisory Panel
Virtual Meeting Summary Minutes
January 3, 2024

Panel Members Present

- Mr. Jon Ostrowski, Non-Commissioned Officer Association, Chair
- Dr. Karen Dager, PharmD, Health Net Federal Services
- Ms. Holly Dailey, the Association of the United States Army
- Mr. John DuTeil, United States Army Warrant Officers Association (USA WOA)
- Dr. Joseph McKeon, MD, Humana Military
- Dr. Jay Peloquin, Pharm D, Express Scripts
- Dr. Jennifer Soucy, PharmD, U.S. Family Health Plan, Martins Point Services

Acting Designated Federal Officer (Non-Voting): COL Paul Carby, MSC

DHA HQ and Pharmacy Operations Division Participants (Non-Voting)

- Dr. John Kugler, Division Chief, J-6; DoD P&T Committee Chair
- Edward VonBerg, PharmD, BCPS, Chief, Pharmacy Operations Division Formulary Management Branch (POD FMB)
- CDR Scott Raisor, Chief, P&T Section POD FMB
- CDR Elizabeth Hall POD FMB
- CDR Giao Phung, POD FMB
- LT Stephani Klimes, POD FMB
- Angela Allerman, PharmD, BCPS, POD FMB
- Shana Trice, PharmD, BCPS, POD FMB
- Ms. Megan Gemunder Office of General Counsel
- CAPT P. Thien Nguyen Acting DFO Alternate

Agenda is found starting on page 16.

- Panel Discussion

The Beneficiary Advisory Panel members will have the opportunity to ask questions to each of the presenters. Upon completion of the presentation and any questions, the Panel will concur or non-concur on the recommendations of the P&T Committee concerning the establishment of the UF and subsequent recommended changes. The Panel will provide comments on their vote as directed by the Panel Chairman. Comments to the Director, DHA, or their designee will be considered before making a final UF decision.

Opening Remarks

COL Carby introduced himself as the Designated Federal Officer (DFO) for the Uniform Formulary (UF) Beneficiary Advisory Panel (BAP) and welcomed everyone to the first Panel meeting of the new year. The Panel has convened to comment on the recommendations of the DoD Pharmacy and Therapeutics (P&T) Committee meeting, which occurred on November 1-2, 2023.

COL Carby then indicated Title 10, United States, (U.S.C.) section 1074g, subsection b requires the Secretary of Defense to establish a DoD Uniform Formulary (UF) of pharmaceutical agents and establishes the P&T committee to review the formulary on a periodic basis to make additional recommendations regarding the formulary as the committee determines necessary and appropriate.

In addition, 10 U.S.C. Section 1074g, subsection c, also requires the Secretary to establish a UF Beneficiary Advisory Panel (BAP) to review and comment on the development of the Uniform Formulary. The Panel includes members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries. The Panel's comments must be considered by the Director of the Defense Health Agency (DHA) before establishing the UF or implementing changes to the UF. The Panel's meetings are conducted in accordance with the Federal Advisory Committee Act (FACA).

COL Carby then outlined the duties of the Uniform Formulary Beneficiary Advisory Panel include the following:

- To review and comment on the recommendations of the P&T Committee concerning the establishment of the UF and to subsequently recommend changes. Comments to the Director, DHA, regarding recommended formulary status, and the effective dates for changing drugs from "formulary" to "non-formulary" status must be reviewed by the Director before making a final decision.

- To hold quarterly meetings in an open forum. The Panel may not hold meetings except at the call of or with the advance approval of the DFO in consultation with the Chairperson of the Panel.

- To prepare minutes of the proceeding and prepare comments for the Secretary or his designee regarding the Uniform Formulary or changes to the Formulary. The minutes will be available on the website and comments will be prepared by the Director, DHA.

The DFO provided guidance regarding this meeting.

- The role of the BAP is to comment on the UF recommendations made by the P&T Committee at their last meeting. While the Department of Defense appreciates that the UF BAP may be interested in the drug classes selected for review, drugs recommended for the basic core formulary (BCF) or specific pricing date, these topics do not fall under the purview of the UF BAP.

- The P&T Committee met for approximately 16 hours conducting its reviews of the drug class recommendations that will be presented today. Since this meeting is considerably shorter, the Panel will not receive the same extensive information that is presented to the P&T Committee members. However, the UF BAP will receive an abbreviated version of each presentation and its discussion. The materials provided to the Panel are available on the TRICARE website.

- Detailed minutes of this meeting are being prepared. The UF BAP meeting minutes, the DoD P&T Committee meeting minutes, and the Director's decisions will be available on the TRICARE website in approximately four to six weeks.

The DFO provided a few ground rules for conduct during the virtual meeting:

- Audience participation is limited to private citizen comments received in writing prior to the meeting.

- Participants will be joined in a LISTEN MODE only.

- To ensure that there are not disruptions to discussion and as a precaution, please mute your phones.

Panel and Presenter Guidance

- When asking or responding to questions:
    - Panel members are asked to state their name prior to asking your questions.
    - Presenters or anyone responding to a question are asked to state their name prior to responding.
    - The meeting is being recorded. Please speak clearly.
- Members of the Formulary Management Branch and the P&T Committee are available to answer questions related to the UF BAP's deliberations. Should a misstatement be made, these individuals may interrupt to ensure the minutes accurately reflect relevant facts, regulations, or policy.

COL Carby introduced the individual Panel members (see list above) and noted house-keeping considerations.

Private Citizen Comments: No private citizen submissions were received.

The meeting was handed over to the Panel Chair Mr. Ostrowski for his opening remarks.

Chairman's Opening Remarks
Mr. Ostrowski welcomed all panel members and attendees participating today.

Dr. VonBerg's Opening Remarks
The meeting then proceeded with comments from Dr. VonBerg, a pharmacist and retired Navy Captain who thanked the panel for the involvement today. He then introduced the team speaking *(see list above)*.

Dr. VonBerg then continued with his opening remarks, stating that the DoD Formulary Management Branch supports the DoD P&T Committee by conducting the relative clinical effectiveness analyses and relative cost effectiveness analyses of the drugs and drug classes under review and consideration by the DoD P&T Committee for the Uniform Formulary.

The goal of this presentation is not to provide you with the same in-depth analyses presented to the DoD P&T Committee, but a summary of the processes and analyses presented to the DoD P&T Committee.

The full presentations then started. Following some of the sections the DoD P&T Committee physician perspective was provided by Dr. John Kugler, and is included starting on page 13. The information starting on page 19 includes the full meeting information.

Closing Remarks
Mr. Ostrowski wished everyone a happy new year again. He also stated he is looking forward to working on the panel for coming year.

Dr. VonBerg thanked the P&T Committee and BAP members for the continuing reviews and updates to the benefit, especially in streamlining coverage for multiple medications.

COL Carby closed the meeting by thanking the Panel members for their time, involvement, and stated that he expresses warmest appreciation for continued commitment to the TRICARE pharmacy benefit.

The Meeting Adjourned at 1210 PM EDT.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

[redacted]

Jon R. Ostrowski
Chairperson, UFBAP

DoD P&T Committee Physician Perspective

Dr. John Kugler's comments on the formulary recommendations followed selected individual sections and are outlined below:

Drug Class Reviews

Migraine Agents – Calcitonin Gene-Related Peptide (CGRP) Antagonist Prophylaxis Subclass

This is the second time that the drug class has been reviewed. The main change here is that one product, Emgality 120 mg, will be preferred, however, all three drugs will remain UF. The current PA for Emgality will be removed, which will encourage providers to use the preferred product. New patients will be required to try Emgality, unless they have a contraindication, therapeutic failure or an adverse reaction. Patients currently receiving Aimovig or Ajovy will be able to remain on therapy, since the step-therapy will apply only to new users.

The P&T Committee members felt that any of the three products could be preferred clinically. The two opposed votes were in favor of designating at least one of the medications NF, due to cost-effectiveness, but the majority of the members were in favor of the recommendation.

Neurological Agents Miscellaneous - Movement Disorders

This class review was previously reviewed, and now there are overlapping FDA-indications for Austedo and Ingrezza. The two diseases are not that common, and there are only about 1,100 patients receiving a movement disorder drug in the MHS.

All the drugs will remain on the formulary. PA criteria have been in place for a while, and we did streamline some of the safety questions, to reduce the number of questions on the PA form.

Overall, all the votes were unanimous, and there was no controversy with this drug class.

New Drugs

The nine Humira biosimilars are recommended for NF status, as they are currently not cost-effective compared to brand Humira. The P&T Committee reviews all biosimilars as new drugs and will complete relative clinical and relative cost analyses to make the formulary recommendation. The PA criteria here will allow the biosimilar if there is an individual patient issue where the brand Humira can't be used, such as an allergy to an inactive ingredient. This situation would only occur in rare cases.

Lodoco was the one drug recommended to be completely excluded from the formulary. It contains colchicine in a dosage of 0.5 mg, which has historically been used in Australia and New Zealand. The colchicine 0.6 mg dosage has been used in North America for decades for both gout and off-label for cardiovascular indications. We are not aware of published cost-effectiveness data evaluating the 0.5 mg Lodoco

formulation. Feedback from MHS cardiologists supported using the generic 0.6 mg off-label for cardiovascular uses, and completely excluding the Lodoco 0.5 mg product. The VA also concluded that Lodoco was not clinically needed and will not be adding this drug to their formulary. Additionally, ESI has excluded it from their civilian health plans.

The Tier 1 copay was recommended for two drugs, the COVID drug Paxlovid, and the opioid-reversal agent Opvee. Patients filling prescriptions for these branded drugs at the Mail Order and Retail pharmacies will pay the generic copay instead of the Tier 2 copay.

There were several orphan drugs reviewed at this meeting. For these drugs used for rare conditions, we do reach out to the specialists for feedback on the PA criteria. We will also look at PA criteria from other health care plans, and the VA, if available. As new information becomes available, we will update the PAs.

Nonformulary Generics – Symbicort, Proventil HFA and contraceptives

This is a continuing project where we check current pricing for nonformulary products that now have generic equivalents available. Any new pertinent clinical information is summarized for the P&T Committee members. We update any existing manual PAs or step therapy, if needed, as part of the process.

For Symbicort, we have received several provider requests to move this product to formulary status, based on clinical practice guidelines. The generic pricing is now cost effective, so Symbicort will be designated UF. We had previously updated the PA criteria to account for the new guidelines, and now we will remove the PA requirements completely.

For the Proventil inhaler and the contraceptive agents, the generic prices are now cost effective compared to the previous branded products, and these products will now be UF.

AGENDA

Uniform Formulary Beneficiary Advisory Panel (UF BAP)
For the November 2023 Department of Defense Pharmacy and Therapeutics Committee Meeting
January 3, 2024 at 10:00 AM Eastern Standard Time

Virtual Meeting

- **General session starts at 10:00 AM Eastern Standard Time (Administrative meeting preceding)**
- **Roll Call**
- **Therapeutic Class Reviews**

  Members of the Defense Health Agency (DHA) Pharmacy Operations Division (POD) Formulary Management Branch (FMB) will present relative clinical and cost-effective analyses along with the Department of Defense (DoD) Pharmacy & Therapeutics Committee (P&T) recommendations for the Uniform Formulary (UF) and any recommended complete exclusion candidates.

  The DoD P&T Committee made recommendations for the following drugs/drug classes during the November 2023 meeting.

- **Drug Class Reviews**
  - *Migraine Agents–Calcitonin Gene-Related Peptide (CGRP) Antagonist Prophylaxis Subclass*
  - *Neurological Agents Miscellaneous–Movement Disorders*

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)**
  - *adalimumab (Humira) biosimilars–Targeted Immunomodulatory Biologics (TIBs)*
    - *adalimumab-aacf injection (Idacio)*
    - *adalimumab-aaty injection (Yuflyma)*
    - *adalimumab-adaz injection (Hyrimoz)*
    - *adalimumab-adaz injection (unbranded biologic)*
    - *adalimumab-adbm injection (Cyltezo)*
    - *adalimumab-aqvh injection (Yusimry)*
    - *adalimumab-bwwd injection (Hadlima)*
    - *adalimumab-fkip injection (Hulio)*
    - *adalimumab-fkip injection (unbranded biologic)*

- *albuterol and budesonide metered dose inhaler (Airsupra) – Short-Acting Beta Agonists (SABAs)*
- *bexagliflozin (Brenzavvy) – Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors*
- *colchicine 0.5 mg tabs (Lodoco) – Cardiovascular Agents Miscellaneous*
- *latanoprost 0.005% ophthalmic solution (Iyuzeh) – Glaucoma Agents: Prostaglandin Analogs*
- *lotilaner 0.25% ophthalmic solution (Xdemvy) – Ophthalmic Anti-infectives*
- *molnupiravir (Lagevrio) Emergency Use Authorization – Antivirals for Coronavirus Disease (COVID-19)*
- *nalmefene nasal spray (Opvee) – Alcohol Deterrents-Narcotic Antagonists*
- *niraparib/abiraterone acetate (Akeega) – Oncological Agents*
- *nirmatrelvir/ritonavir (Paxlovid) – Antivirals for Coronavirus Disease COVID-19*
- *palvarotene (Sohonos) – Skeletal Muscle Relaxants and Combination*
- *polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride powder for oral solution with flavor-enhancing packets (Suflave) – Laxatives-Cathartics-Stool Softeners: Bowel Preparations*
- *quizartinib (Vanflyta) – Oncological Agent for Acute Myelogenous Leukemia (AML)*
- *sodium phenylbutyrate packets for oral suspension (Olpruva) – Gastrointestinal (GI) - 2 Agents*
- *somatrogon-ghla injection (Ngenla) – Growth Stimulating Agents*

➢ **Re-evaluation of Nonformulary Generics**

- *Pulmonary-1 Agents*
  - *Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs)*
    - *budesonide/formoterol hydrofluoroalkane inhaler (Symbicort HFA)*
  - *Short-Acting Beta Agonists and Combinations*
    - *albuterol HFA 90 mcg (6.7 gram) inhaler (Proventil HFA)*
- *Contraceptives*

➢ **Utilization Management Pulmonary-1 Agents: PA Criteria and Tier 1 Copay Removal**

- *ICS/LABAs*
  - *fluticasone/salmeterol (Advair Diskus, Advair HFA)*

        - *mometasone/formoterol (Dulera)*
        - *fluticasone/vilanterol (Breo Ellipta)*
        - *fluticasone/salmeterol respiclick (AirDuo Respiclick)*
    - *ICS*
        - *fluticasone (Flovent HFA)*
        - *fluticasone (Flovent Diskus)*

- **Utilization Management Issues**
    - *PA Criteria—Updated PA Criteria for New FDA-Approved Indications*
        - *Targeted Immunomodulatory Biologics (TIBs): adalimumab-atto injection biosimilar (Amjevita)*
        - *Metabolic Agents Miscellaneous: odevixibat (Bylvay) and maralixibat (Livmarli)*
        - *Oncological Agents: dabrafenib (Tafinlar) and trametinib (Mekinist)*
        - *Oncological Agents: Breast Cancer: talazoparib (Talzenna)*
    - *PA Criteria—Updated PA Criteria for Reasons Other Than New Indications*
        - *Atypical Antipsychotics: brexpiprazole (Rexulti)*
        - *Phosphodiesterase-5 (PDE-5) Inhibitors: tadalafil (generic Cialis)*
        - *Skeletal Muscle Relaxants and Combinations: baclofen oral solution (Ozobax), baclofen oral suspension (Fleqsuvy), baclofen oral granules (Lyvispah)*
        - *Gastrointestinal-2 Agents: Chronic Idiopathic Constipation/Constipation-predominant Irritable Bowel Syndrome: linaclotide (Linzess) and lubriprostone (Amitiza)*

- **Brand Over Generic PA Authorization and Tier 1 copay**
    - *Pulmonary-2 Agents: Long-Acting Muscarinic Antagonists – tiotropium handihaler (Spiriva Handihaler)*
- **Over-the-Counter (OTC) Formulary Addition**
    - *Progestin-Only Contraceptives: norgestrel tablets (Opill)*
- **Considerations of Better Care, Healthier People and Smarter Spending**
    - *Contraceptives Tier 1 Copay*
        - *segesterone acetate/ethinyl estradiol vaginal ring (Annovera)*
        - *medroxyprogesterone acetate (Depo-subq Provera)*

- **Panel Discussions**

  The UF BAP members will have the opportunity to ask questions to each of the presenters. Upon completion of the presentation and any questions, the Panel will concur or non-concur on the recommendations of the DoD P&T Committee concerning the establishment of the UF and subsequent recommended changes. The Panel will provide comments on their vote as directed by the Panel Chairman. Comments to the Director, DHA, or their designee will be considered before making a final UF decision.

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS FROM THE NOVEMBER 2023 MEETING

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL MEETING JANUARY 3, 2024

I. UNIFORM FORMULARY REVIEW PROCESS

In accordance with 10 United States Code § 1074g, as implemented by 32 Code of Federal Regulations 199.21, the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, Defense Health Agency (DHA) or their designee, on formulary or complete exclusion status, prior authorizations (PAs), pre-authorizations, and the effective date for a drug's change from formulary to nonformulary (NF) or to complete exclusion status are received from the Uniform Formulary Beneficiary Advisory Panel (UF BAP), which must be reviewed by the Director or their designee before making a final decision.

II. UF DRUG CLASS REVIEWS—MIGRAINE AGENTS – CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONIST PROPHYLAXIS SUBCLASS

P&T Comments

A. Migraine Agents – Calcitonin Gene-Related Peptide (CGRP) Antagonist Prophylaxis Subclass—Relative Clinical Effectiveness Conclusion

The P&T Committee evaluated the relative clinical effectiveness of the injectable CGRP antagonists. The drugs in the subclass include erenumab (Aimovig), fremanezumab (Ajovy), and galcanezumab (Emgality). The products are administered once monthly for prevention of episodic and chronic migraine. Emgality has an additional formulation approved for treating cluster headache. The class was previously reviewed for formulary placement in February 2019.

The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

CGRP antagonists vs. oral preventive therapies

- The 2021 American Headache Society consensus statement encourages use of oral medications including antiepileptics (e.g., valproate, topiramate), beta- blockers (e.g., metoprolol, propranolol) and antidepressants (e.g., amitriptyline, nortriptyline) as first-line treatment options for migraine headache prevention. Injectable CGRP antagonists are recommended after trials of two different oral preventive medications administered at target therapeutic doses for a minimum of 8 weeks.

- There was no new data to change the conclusion from a 2018 network

meta- analysis that the evidence is inadequate to distinguish the net health benefit

between treatment with the CGRP inhibitors versus oral preventive therapies (e.g., amitriptyline, topiramate, or propranolol).

CGRP antagonist vs. CGRP antagonist

- Although there are still no published head-to-head trials comparing erenumab, fremanezumab, or galcanezumab, there does not appear to be clinically relevant differences in efficacy, based on indirect comparisons from network-meta-analyses for episodic and chronic migraine.
- The 2018 network meta-analysis evaluated the reduction in monthly migraine days for preventive treatment and concluded the three injectable CGRP medications had similar effectiveness and are more effective than the oral CGRPs *(Note that the oral CGRPs Qulipta, Nurtec ODT and Ubrelvy were not included in this class review.)*

Safety

- The CGRP antagonists have a relatively mild side effect profile, with injection site reactions the most commonly reported adverse event. Injection site reactions occurred at an incidence of 5.6% with Aimovig, 18%-23% with Emgality, and 45% with Ajovy.
- A 2023 network meta-analysis concluded the following:
  - Compared to Emgality, treatment with Ajovy has a higher odds ratio for serious adverse effects and treatment-emergent adverse effects. No significant differences were noted in serious adverse events between injectable CGRP treatments and placebo.
  - Ajovy and Emgality showed greater odds of injection site erythema, induration, and pruritus, while Aimovig and Ajovy had higher odds of injection site pain. Ajovy also showed higher odds of diarrhea, and Aimovig had greater odds of constipation, compared to placebo.
  - Overall, the meta-analysis concluded that monoclonal antibodies targeting the calcitonin gene-related peptide pathway are a safe and well-tolerated option for migraine prevention.
- There is limited long term efficacy and safety with chronic use. The five-year extension studies for Aimovig report no significant cardiovascular concerns.

Individual Product Characteristics

- **erenumab (Aimovig)** is available in two dosages, 70 mg and 140 mg. It is unclear whether the two doses differ in efficacy or safety. Advantages include publication of a five-year efficacy and safety extension study, fewer reported adverse effects, and availability of both a prefilled syringe and autoinjector, however the prefilled syringe contains latex. Aimovig is stable at room temperature for up to 7 days.
- **fremanezumab (Ajovy**) is the only CGRP inhibitor approved for quarterly dosing in addition to monthly dosing, however administration of three pens

at the same time is required. Ajovy is available in both a prefilled syringe and autoinjector. Disadvantages include the high rate of injection site reactions, and stability at room temperature for only one day.

- **galcanezumab (Emgality)** requires a loading dose, administered as two pens at the same time, however it has a faster onset of action compared to the other drugs. One other advantage is stability at room temperature for up to 7 days. It is the only injectable CGRP with an additional indication for acute cluster headache. Emgality has a higher rate of injection site irritation than Aimovig.

Overall Clinical Conclusion

- Overall, there was no new data to substantially change the clinical effectiveness conclusion from the February 2019 class review.
- There is a high degree of interchangeability between the CGRP antagonists. However, there remains uncertainty regarding the long-term efficacy and safety of this drug class.
- At least one injectable CGRP inhibitor is required on the formulary to meet the needs of the majority of Military Health System (MHS) beneficiaries with chronic or episodic migraine headache.

B. Migraine Agents – CGRP Antagonist Prophylaxis Subclass—Relative Cost-Effectiveness Conclusion

The P&T Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that erenumab (Aimovig), fremanezumab (Ajovy), and galcanezumab (Emgality) were all cost effective.
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating the injectable CGRP agents in accordance with the formulary recommendation below demonstrated significant cost avoidance to the MHS.

C. Migraine Agents – CGRP Antagonist Prophylaxis Subclass—UF Recommendation

The P&T Committee recommended (18 for, 2 opposed, 0 abstained, 0 absent) the following for the CGRP Antagonist Prophylaxis agents, as outlined below, based on clinical and cost-effectiveness.

Chronic and Episodic Migraine

- UF and step-preferred
  - galcanezumab injection 120 mg (Emgality) – *moves from UF to UF and step- preferred*

- UF and non-step-preferred
  - fremanezumab injection (Ajovy) – *moves from UF to UF and non-step-preferred*
  - erenumab injection (Aimovig) – *moves from UF to UF and non-step-preferred*
- Note that for Ajovy and Aimovig, a trial of Emgality 120 mg is required first in new users.
- NF - none
- Complete Exclusion - none

Cluster Headache

- UF
  - galcanezumab injection 100 mg (Emgality) – *moves from NF to UF (not part of the step therapy for chronic and episodic migraine)*
- NF - none
- Complete exclusion - none

D. Migraine Agents – CGRP Antagonist Prophylaxis Subclass—Manual PA Criteria

Current PA criteria require a trial of standard oral preventive therapies for migraine headache first (antiepileptic medications, beta blockers, or antidepressants), consistent with the American Headache Society Consensus Statement.

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the current manual PA criteria. The PA for Emgality 120 mg was removed, based on cost effectiveness. The PAs for Aimovig and Ajovy were updated to require a trial of Emgality 120 mg (the new step-preferred agent) in new users, unless the patient has a contraindication, adverse event, or therapeutic failure with Emgality 120 mg. Only new users will be affected by the step-therapy requirements. No changes were recommended for the existing PA criteria for the Emgality 100 mg formulation for cluster headache.

The Manual PA criteria is as follows:

1. erenumab (Aimovig), fremanezumab (Ajovy)

Changes from the November 2023 meeting are in BOLD and strikethrough.

Manual PA criteria applies to all new users of Aimovig and Ajovy

- **Provider acknowledges that Emgality 120 mg is the DoD's preferred injectable CGRP inhibitor and is available without a PA.**

- **Patient has tried and failed Emgality 120 mg OR**
- **Patient has experienced an adverse reaction to Emgality 120 mg that is not expected to occur with Aimovig or Ajovy OR**
- **Patient has a contraindication to Emgality 120 mg**
- Patient is 18 years of age or older
- Patient is not pregnant
- The drug is prescribed by or in consultation with a neurologist
- The patient also meets one of the following:
  - Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR
  - Patient has episodic migraines at a rate a migraine diagnosis with of at least 8 migraine days per month for 3 months OR
  - Patient has a diagnosis of chronic migraine
- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes:
  - Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate
  - Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol
  - Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine
- Concurrent use with other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality) is not allowed

Non-FDA-approved uses are NOT approved

PA expires after 6 months

Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if one of the following apply:

- The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR
- The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:
  - Migraine Disability Assessment (MIDAS)
    - Reduction of ≥ 5 points when baseline score is 11–20
    - Reduction of ≥ 30% when baseline score is > 20

- Headache Impact Test (HIT-6)
  - Reduction of ≥ 5 points
- Migraine Physical Functional Impact Diary (MPFID)
  - Reduction of ≥ 5 points

2. galcanezumab 100 mg injection (Emgality)

Changes from the November 2023 meeting are in BOLD and strikethrough.

Note that this PA applies to the Emgality 100 mg cluster headache formulation. **The Emgality 120 mg migraine prophylaxis formulation is available without a PA**. ~~**The Emgality 120 mg migraine prophylaxis indication PA criteria is on a separate form.**~~

Manual PA criteria apply to all new users of Emgality at a dosage of 300 mg/month for episodic cluster headaches.

- Patient is 18 years of age or older
- Patient is not pregnant
- The drug must be prescribed by or in consultation with a neurologist
- Patient has a diagnosis of episodic cluster headaches
- Patient has a contraindication to, intolerability to, or has failed an adequate trial of verapamil, topiramate, or lithium
- Concurrent use with other CGRP inhibitors (e.g., Aimovig, Emgality 120 mg, Ajovy) is not allowed

Non-FDA-approved uses, including for migraine prophylaxis, chronic cluster headache, medication overuse headache, etc., are not approved

PA expires after 6 months

Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if there is a clinically appropriate reduction in weekly attacks (≥ 50% reduction in weekly cluster headache attack frequency) during an episode as reported by the patient.

E. Migraine Agents – CGRP Antagonist Prophylaxis Subclass—UF, PA, and Implementation Period

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30 days after the signing of the minutes in all points of service, with the exception that the current PA for Emgality 120 mg will be removed 2 weeks after signing of the minutes.

III. UF DRUG CLASS REVIEWS—MIGRAINE AGENTS –CGRP ANTAGONIST PROPHYLAXIS SUBCLASS

UF BAP Comments

A. Migraine Agents – CGRP Antagonist Prophylaxis Subclass—UF Recommendation

The P&T Committee recommended formulary status as discussed above.

Chronic and Episodic Migraine

- UF and step-preferred
  - Emgality 120 mg – *moves from UF to UF and step-preferred*
- UF and non-step-preferred
  - Ajovy – *moves from UF to UF and non-step-preferred*
  - Aimovig – *moves from UF to UF and non-step-preferred*
- NF - none
- Complete Exclusion - none

Cluster Headache

- UF
  - Emgality 100 mg – *moves from NF to UF*
- NF - none
- Complete Exclusion - none

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Migraine Agents –CGRP Antagonist Prophylaxis Subclass—Manual PA Criteria

The P&T Committee recommended manual PA criteria as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Migraine Agents – CGRP Antagonist Prophylaxis Subclass—UF, PA, and Implementation Period

The P&T Committee recommended an effective date of the first Wednesday 30 days after signing of the minutes in all points of service and removing the PA for Emgality 120 mg two weeks after signing of the minutes.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

IV. UF DRUG CLASS REVIEWS—NEUROLOGICAL AGENTS MISCELLANEOUS - MOVEMENT DISORDERS

P&T Comments

A. Neurological Agents Miscellaneous - Movement Disorders—Relative Clinical Effectiveness Analysis and Conclusion

The P&T Committee evaluated the relative clinical effectiveness of the Movement Disorder subclass, which includes the vesicular monoamine transporter type 2 (VMAT2) inhibitors. The drugs evaluated were tetrabenazine (Xenazine, generics), deutetrabenazine immediate release and extended release (Austedo IR and XR), and valbenazine (Ingrezza). All four drugs are approved for treating Huntington's disease chorea. Deutetrabenazine and valbenazine are also approved for tardive dyskinesia, while tetrabenazine is used off-label for this indication. The class was last reviewed for formulary status in November 2018; since then, there are now overlapping indications for deutetrabenazine and valbenazine.

The clinical review focused on available published trials, clinical practice guidelines, meta-analyses, and systematic reviews.

The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

Guidelines

- *Huntington's disease chorea*: Professional clinical practice guidelines from the 2019 International Guideline for Treatment of Huntington's Disease from the European Huntington's Disease Network recommend considering treatment when the disorder causes patient distress or discomfort. Tetrabenazine is mentioned as a first-line treatment option, with deutetrabenazine considered as an alternative to tetrabenazine. Austedo XR and Ingrezza were recently FDA-approved for Huntington's disease chorea in 2023 and are not mentioned in this publication.
- *Tardive dyskinesia*: The 2019 Canadian Journal of Psychiatry treatment recommendations for tardive dyskinesia state that all antipsychotic mediations are

associated with risk. Recommendations include considering switching from a first-generation antipsychotic to a second-generation (atypical) antipsychotic. For the VMAT2 inhibitors, recommendations are specified for valbenazine and deutetrabenazine (Evidence I+, Grade A), and tetrabenazine (Evidence I-, Grade B).

Efficacy

- There are currently no head-to-head trials comparing Xenazine, Austedo, or Ingrezza for tardive dyskinesia or Huntington's disease chorea.
- *Huntington's disease chorea:* An indirect efficacy analysis of individual placebo-controlled clinical trials of Xenazine, Austedo IR, and Ingrezza was reviewed. Each trial demonstrated statistically significant and similar magnitude of reductions in Unified Huntington's Disease Rating Scale (UHDRS) Total Chorea Scores when the individual drugs were compared to placebo. Of note, Austedo XR was approved via the FDA 505(b)(2) pathway using pharmacokinetic date from the Austedo IR FDA application, and there was no new clinical trial data available for review.
- *Tardive dyskinesia*: A 2020 Journal of Clinical Psychiatry network meta-analysis evaluating data for Xenazine, Austedo IR, and Ingrezza suggested that VMAT2 inhibitors may be effective for tardive dyskinesia treatment. An additional 2017 network meta-analysis concluded Ingrezza and Austedo IR were promising but inconclusive, based on improvement in Abnormal Involuntary Movement Scale (AIMS) scores. Additionally, the network meta-analysis suggested a possible benefit for Xenazine for treating tardive dyskinesia symptoms but overall was rated as insufficient.

Safety

- In terms of safety, all agents carry similar warnings, including a black box warning for increased risk of depression and suicidal ideation in patients with Huntington's disease. Multiple contraindications are listed for tetrabenazine (generic Xenazine) and Austedo, whereas Ingrezza only lists a contraindication for hypersensitivity. Overall, more sedation and extra-pyramidal symptoms are reported with tetrabenazine (generic Xenazine), while the rates of dry mouth and diarrhea are higher with Austedo IR and XR, and urticaria and rash are more common with Ingrezza.

Individual Product Characteristics

- **tetrabenazine (generic Xenazine):** Advantages include generic availability and long history of use. Although tetrabenazine does not carry a tardive dyskinesia indication, off-label use is widely accepted. Disadvantages include the lack of data regarding special populations, such as dosing adjustments for geriatric patients and those with renal failure, and the need for genotyping to identify possible drug interactions with CYPD26 metabolic variants. Multiple daily dosing is also required.
- **deutetrabenazine (Austedo IR and Austedo XR):** Both formulations are indicated for treating tardive dyskinesia, in addition to Huntington's disease chorea. Austedo IR uniquely requires administration with food and multiple daily dosing.

Advantages of Austedo XR include once daily administration, however there is insufficient evidence at this time to determine what the average daily dosage requirement will be in terms of numbers of tablets required. Data regarding dosage adjustments in special populations is not available.

- **valbenazine (Ingrezza):** Advantages of Ingrezza include FDA-approval for both Huntington's disease chorea and tardive dyskinesia, once daily dosing, and no requirement for dosage adjustment in geriatric patients or patients with renal failure.

Clinical Coverage

- At least one VMAT2 inhibitor is required on the formulary to meet the needs of the majority of MHS beneficiaries with either Huntington's disease chorea or tardive dyskinesia.

B. Neurological Agents Miscellaneous—Movement Disorders—Relative Cost-Effectiveness Analysis and Conclusion

A CMA, BIA, and sensitivity analysis were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that within the Movement Disorder subclass, the generic formulation of tetrabenazine (Xenazine) is the most cost-effective agent.
- BIA was performed to evaluate the potential impact of designating the Movement Disorder subclass agents as UF, NF, or completely excluded from the formulary. BIA results showed that designating all agents as UF offered cost avoidance to the MHS.

C. Neurological Agents Miscellaneous—Movement Disorders—UF Recommendation

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
  - tetrabenazine (generic Xenazine)
  - deutetrabenazine IR (Austedo IR)
  - deutetrabenazine ER (Austedo XR)
  - valbenazine (Ingrezza)
- NF - none
- Complete Exclusion - none

D. Neurological Agents Miscellaneous—Movement Disorders—Manual PA Criteria

Manual PA criteria have been in place for both Austedo and Ingrezza for several years, and for Austedo XR since the new drug review in August 2023. PA is not required for tetrabenazine. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) minor updates to manual PA criteria for Austedo IR/XR and Ingrezza, in new users, primarily focusing on streamlining the safety monitoring requirements. For Huntington's disease chorea, the PA will still require a trial of generic tetrabenazine first, based on cost-effectiveness. There were no changes to the criteria for tardive dyskinesia.

The Manual PA criteria is as follows:

deutetrabenazine immediate release (Austedo), deutetrabenazine extended-release (Austedo XR), valbenazine (Ingrezza)

Changes from the November 2023 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Austedo IR, Austedo XR **and Ingrezza**

Manual PA Criteria: Coverage is approved for initial therapy for one year if all criteria are met:

- ~~**Patient does not have congenital or acquired long QT syndrome or arrhythmias associated with QT prolongation**~~
- ~~**Patient does not have severe hepatic impairment**~~
- ~~**Patient is not taking any of the following: MAOI within the past 14 days, reserpine, CYP3A4 inducers, or another VMAT2 inhibitor (e.g., tetrabenazine, deutetrabenazine [Austedo, Austedo XR], valbenazine [Ingrezza])**~~
- **Patient is 18 years of age or older**
- **Provider acknowledges the FDA safety alerts, boxed warnings, precautions, and drug interactions**

Huntington's Disease Chorea

- The drug is prescribed by or in consultation with a neurologist
- Patient has a diagnosis of chorea associated with Huntington's Disease
- Patient does not have suicidal ideation
- Patient does not have depression or is being adequately treated for depression
- Patient has had an adequate trial of tetrabenazine for 12 weeks and has experienced treatment failure or experienced an adverse event that is not expected to occur with Austedo IR, **Austedo XR or Ingrezza**

Tardive Dyskinesia

- ~~**The patient is 18 years of age or older**~~
- The drug is prescribed by or in consultation with a neurologist or psychiatrist
- Patient does not have suicidal ideation
- Patient does not have depression or is being adequately treated for depression
- Patient has moderate to severe tardive dyskinesia causing functional impairment along with schizophrenia, schizoaffective disorder, or a mood disorder
- Provider has considered a dose reduction, tapering, or discontinuation of the dopamine receptor blocking agent suspected of causing the symptoms

Non-FDA-approved uses are NOT approved (e.g., Tourette's, dystonia)

PA expires in one year

Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all criteria are met:

- Huntington's Disease Chorea:
  - Patient has demonstrated improvement in symptoms based on clinician assessment
  - Patient is being monitored for depression and suicidal ideation
- Tardive Dyskinesia:
  - Patient has demonstrated improvement in symptoms based on an improvement of at least 2 on the Abnormal Involuntary Movement Scale (AIMS)
  - Patient is being monitored for depression and suicidal ideation

E. Neurological Agents Miscellaneous—Movement Disorders—UF and PA Implementation Period

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after the signing of the minutes in all points of service.

V. UF DRUG CLASS REVIEWS—NEUROLOGICAL AGENTS MISCELLANEOUS—MOVEMENT DISORDERS

UF BAP Comments

A. Neurological Agents Miscellaneous—Movement Disorders—UF Recommendation

The P&T Committee recommended the following.

- UF
  - generic Xenazine
  - Austedo IR
  - Austedo XR
  - Ingrezza
- NF - none

- Complete Exclusion - none

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

B. Neurological Agents Miscellaneous—Movement Disorders—Manual Prior Authorization Criteria

The P&T Committee recommended Manual PA criteria as outlined above.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

C. Neurological Agents Miscellaneous—Movement Disorders—UF, PA, and Implementation Period

The P&T Committee recommended the implementation plan of an effective date of the first Wednesday 30 days after the signing of the minutes as described above.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

VI. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5)

P&T Comments

The products were divided into three groups when presented at the P&T Committee meeting. The generic names are provided below. Group 1 included the Humira biosimilars, Brenzavvy, Lodoco, Iyuzeh, Akeega, Suflave, Vanflyta, and Olpruva; Group 2 was comprised of Xdemvy, Ngenla, Opvee nasal, Sohonos, and Airsupra inhaler; and Group 3 included the coronavirus disease (COVID-19) drugs, Paxlovid and Lagevrio. Paxlovid was granted formal

FDA approval in May 2023, while Lagevrio is available under an Emergency Use Authorization (EUA).[1]

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions

The P&T Committee agreed (Group 1: 20 for, 0 opposed, 0 abstained, 0 absent; Group 2: 19 for, 0 opposed, 0 abstained, 1 absent; and Group 3: 19 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5).

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation

The P&T Committee recommended Group 1: 20 for, 0 opposed, 0 abstained, 0 absent; Group 2: 18 for, 0 opposed, 0 abstained, 2 absent; and Group 3: 19 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
  - nalmefene nasal spray (Opvee) – Alcohol Deterrents-Narcotic Antagonists
  - lotilaner 0.25% ophthalmic solution (Xdemvy) – Ophthalmic Anti-infectives
  - niraparib/abiraterone acetate (Akeega) – Oncological Agents
  - palvarotene (Sohonos) –Skeletal Muscle Relaxants and Combination
  - polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride powder for oral solution with flavor-enhancing packets (Suflave) – Laxatives-Cathartics-Stool Softeners: Bowel Preparations
  - quizartinib (Vanflyta) – Oncological Agent for Acute Myelogenous Leukemia (AML)
  - sodium phenylbutyrate packets for oral suspension (Olpruva) – Gastrointestinal-(GI) 2 Agents
  - nirmatrelvir/ritonavir (Paxlovid) – Antivirals for Coronavirus Disease (COVID-19)
  - molnupiravir (Lagevrio) Emergency Use Authorization – Antivirals for COVID-19
- NF
  - adalimumab (Humira) biosimilars–Targeted Immunomodulatory Biologics (TIBs)
    - adalimumab-adbm injection (Cyltezo)
    - adalimumab-fkip injection (Hulio)

[1] Based on the FDA EUA status, this drug is technically not subject to 32 CFR 199.21(g)(5) and EUA drugs, in general, are not subject to automatic addition to the UF.

        - adalimumab-fkip injection (unbranded biologic)
        - adalimumab-aacf injection (Idacio)
        - adalimumab-bwwd injection (Hadlima)
        - adalimumab-aqvh injection (Yusimry)
        - adalimumab-aaty injection (Yuflyma)
        - adalimumab-adaz injection (Hyrimoz)
        - adalimumab-adaz injection (unbranded biologic)
    - albuterol and budesonide metered dose inhaler (Airsupra) – Short-Acting Beta Agonists (SABAs)
    - bexagliflozin (Brenzavvy) – Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors
    - latanoprost 0.005% ophthalmic solution (Iyuzeh) – Glaucoma Agents: Prostaglandin Analogs
    - somatrogon-ghla injection (Ngenla) – Growth Stimulating Agents
- Complete Exclusion
    - colchicine 0.5 mg tabs (Lodoco) – Cardiovascular Agents Miscellaneous
        - Lodoco was recommended for complete exclusion as it has little to no clinical benefit relative to other colchicine formulations when used for cardiovascular risk prevention, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include colchicine 0.6 mg tablets (generic Colcrys) and 0.6 mg capsules (generic Mitigare).

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended Group 1: 20 for, 0 opposed, 0 abstained, 0 absent; and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent) the following PA criteria:

- Applying manual PA criteria to new users of Akeega, Iyuzeh, Sohonos, and Vanflyta.
- Applying manual PA criteria to new and current users of Xdemvy.
- Applying manual PA criteria to new users of the Humira biosimilars, similar to what is in place for the first Humira biosimilar, Amjevita. A trial of the Humira branded product is required first as per the February 2023 P&T Committee meeting minutes.
- Applying manual PA criteria to Brenzavvy, similar to what is in place for the other non-step-preferred SGLT2 Inhibitors. New patients receiving Brenzavvy or one of the other non-step-preferred SGLT2 Inhibitors (Farxiga, Invokana, Steglatro, or Inpefa) will require a trial of Jardiance first.
- Applying manual PA criteria to Ngenla, similar to what is in place for the other non-step-preferred growth stimulating agents. A trial of Norditropin, the step-preferred product is required first.

- Applying interim manual PA criteria for colchicine 0.5 mg tabs (Lodoco) prior to implementation of complete exclusion status, in order to minimize the impact on beneficiaries.

The Manual PA criteria is as follows:

1. **adalimumab-adbm injection (Cyltezo), adalimumab-fkip injection (Hulio), adalimumab-fkip injection unbranded biologic, adalimumab-aacf injection(Idacio), adalimumab-bwwd injection (Hadlima), adalimumab-aqvh injection (Yusimry), adalimumab-aaty injection (Yuflyma), adalimumab- adaz injection (Hyrimoz), adalimumab-adaz injection unbranded biologic**

   Updates from November 2023 are in bold

   Manual PA criteria apply to all new and current users of the Humira biosimilar

   - The provider acknowledges that the originator adalimumab (Humira) is the preferred product over biosimilar adalimumab formulations
   - The provider must provide patient specific justification as to why the originator Humira product cannot be used in this patient
     - Acceptable responses include that the patient has an allergy to an inactive ingredient found in the originator Humira that is not in the Humira biosimilar
   - If the patient is younger than 18 years of age, coverage is provided for moderate to severe polyarticular juvenile idiopathic arthritis or moderate to severe Crohn's disease
     - If the indication is moderate to severe polyarticular juvenile idiopathic arthritis, patient must be 2 years of age or older
     - If the indication is moderate to severe Crohn’s disease patient must be 6 years of age or older
   - If the patient is 18 years of age or older coverage is provided for moderately to severely active rheumatoid arthritis, moderate to severe Crohn’s disease, moderate to severe chronic plaque psoriasis where patient is candidate for systemic or phototherapy or when other systemic therapies are medically less appropriate, psoriatic arthritis, ankylosing spondylitis, moderate to severe ulcerative colitis, **non-infectious uveitis, intermediate uveitis, posterior uveitis and panuveitis**, and hidradenitis suppurativa
     - If the indication is moderate to severe chronic plaque psoriasis OR moderate to severe Crohn’s disease OR moderate to severe ulcerative colitis then patient must have had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine, cyclosporine], acitretin, or phototherapy), etc. unless they have fistulizing Crohn’s disease

    - If the indication is ankylosing spondylitis has patient must have had inadequate response to at least two NSAIDs over a period of at least 2 months
- Patient has not had worsening congestive heart failure (CHF) and new onset CHF has not been reported with TNF blockers, including Humira
- Patient had evidence of negative TB test in the past 12 months (or TB is adequately managed)
- Patient is not receiving other targeted immunomodulatory biologics with Humira, including but not limited to the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER)

Non-FDA-approved uses are NOT approved, with the exception **that if an indication is approved for Humira, it is approved for a biosimilar**

PA does not expire

2. bexagliflozin (Brenzavvy)

Manual PA criteria apply to all new users of Brenzavvy

- The patient is 18 years of age or older
- Provider is aware and acknowledges that empagliflozin (Jardiance) and empagliflozin/metformin (Synjardy, Synjardy XR) are DoD's preferred SGLT2 inhibitors, and that PA is not required for these drugs
- Brenzavvy is prescribed to improve glycemic control in patients with Type 2 Diabetes Mellitus
- Patient has experienced an inadequate response to metformin OR
- Patient has experienced a significant adverse effect to metformin OR
- Patient has a contraindication to metformin OR
- Patient has experienced significant adverse reactions to empagliflozin (Jardiance) or empagliflozin/metformin (Synjardy, Synjardy XR) OR
- Patient has a contraindication to empagliflozin (Jardiance) or empagliflozin/metformin (Synjardy, Synjardy XR)

Non-FDA-approved uses are not approved, including type 1 Diabetes Mellitus

PA does not expire

3. **colchicine 0.5 mg tabs (Lodoco)**

Interim Manual PA criteria apply to all users of Lodoco

- Provider acknowledges that Lodoco will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of these meeting minutes by the Director, DHA
- Provider acknowledges that other formulations of colchicine are available to TRICARE beneficiaries and do not require prior authorization including colchicine 0.6 mg tablets (generic Colcrys) and colchicine 0.6 mg capsules (generic Mitigare)
- Patient is 18 years of age or older
- Prescription is written by or in consultation with a cardiologist
- Patient has had a previous myocardial infarction or a history of an acute coronary syndrome, angina, history of stroke or transient ischemic attack, coronary artery disease, peripheral arterial disease or has undergone a coronary or other arterial revascularization procedure in the past.
- Patient is on guideline-directed standard therapies for the secondary prevention of cardiovascular events
- Patient has a creatinine clearance greater than or equal to 50 mL/min
- Patient does not have severe liver disease or pre-existing blood dyscrasias

Non-FDA-approved uses are NOT approved, including for gout, pericarditis, primary biliary cirrhosis, or periodic fever syndrome (must use the generic 0.6 mg formulations instead)

PA does not expire (until complete exclusion status implementation)

4. **latanoprost 0.005% ophthalmic solution (Iyuzeh)**

Manual PA criteria apply to all new users of Iyuzeh

- Iyuzeh is prescribed by an ophthalmologist or an optometrist
- Patient has a diagnosis of ocular hypertension or open-angle glaucoma
- Patient has had a trial of appropriate duration with two different formulary options, from any of the following glaucoma drug classes, in combination or separately:
  - prostaglandin analogs (e.g., Lumigan, Travatan, Xalatan)
  - beta blockers (e.g., Timoptic)
  - alpha2-adrenergic agonists (e.g., Alphagan P)
  - topical carbonic anhydrase inhibitors (e.g., Azopt, Trusopt, Cosopt)
- Patient has failed to reach intraocular target goals using medications from standard therapy classes (standard therapy classes include prostaglandin

analogs, beta blockers, alpha2-adrenergic agonists, topical carbonic anhydrase inhibitors)
- Patient is currently taking latanoprost and requires a preservative-free formulation due to experiencing adverse events OR
- Patient is on three or more different ocular medications that contain preservatives and accumulation of preservatives is a concern

Non-FDA-approved uses are NOT approved

PA does not expire

5. niraparib and abiraterone acetate tabs (Akeega)

Manual PA criteria apply to all new users of Akeega

- Patient is 18 years of age or older
- Akeega is prescribed by or in consultation with hematologist/oncologist or urologist
- Patient has deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC)
- Patient is using Akeega concurrently with a gonadotropin – releasing hormone (GnRH) analog (e.g., leuprolide, Eligard, Triptorelin, Goserelin) or has had a bilateral orchiectomy
- Akeega will be used in combination with prednisone

OR

- The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, the provider must list the diagnosis.

AND

- Males with female partners will use effective contraception during treatment and for 4 months after the last dose
- Provider is aware of the warnings, screening and monitoring precautions for Akeega.

Other non-FDA-approved uses are NOT approved except as noted

above PA does not expire

6. lotilaner 0.25% ophthalmic solution (Xdemvy)

Manual PA criteria apply to all new and current users of Xdemvy

- The patient is 18 years of age or older
- The drug is prescribed by an ophthalmologist or optometrist

- Patient has a diagnosis of Demodex blepharitis confirmed by the presence of Demodex mites on microscopic examination
- Patient has Demodex infestation with at least 10 eyelashes with collarettes
- Patient tried and failed an adequate treatment course with topical tea tree oil
- Patient will continue to practice good eyelid hygiene including eye lid wipes (e.g., Ocusoft)

Non-FDA-approved uses are NOT approved, including for dry eye disease or meibomian gland dysfunction

PA expires in 6 months; provider must fill out a new PA

7. palovarotene caps (Sohonos)

Manual PA criteria apply to all new users of Sohonos

- Female patients are 8 years of age and older
- Male patients are 10 years of age and older
- The drug is prescribed by a provider who specializes in the treatment of Fibrodysplasia Ossificans Progressiva
- Patient has a diagnosis of Fibrodysplasia Ossificans Progressiva confirmed with a genetic test
- Female patients of childbearing age are not pregnant as confirmed by (-) HCG prior to the first dose and then periodically during treatment
- Female patients of childbearing potential have been counseled to use effective contraception 1 month prior to treatment, during treatment and for 1 month after the cessation of therapy
- Pediatric patients with open epiphyseal plates will undergo assessments of skeletal maturity and linear growth prior to the first dose and every 6 to 12 months thereafter until reaching skeletal maturity or final adult height
- Provider is aware of the warnings, screening and monitoring precautions for Sohonos

Non-FDA-approved uses are not approved

PA expires in 1 year

Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all criteria are met:

- The patient has had a positive response to therapy
- The risks of continued therapy do not outweigh the benefits

8. quizartinib tab (Vanflyta)

Manual PA criteria apply to all new users of Vanflyta

- Patient is 18 years of age or older
- The drug is prescribed by or in consultation with a hematologist/oncologist
- Patient has newly diagnosed acute myeloid leukemia (AML) that is tyrosine kinase 3 (FLT3) internal tandem duplication (ITD)-positive as detected by an FDA-approved test
- The provider is aware of all warnings, monitoring and screening precautions for Vanflyta
- Provider is certified to prescribe Vanflyta per REMS requirements

OR

- The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, the provider must list the diagnosis.

Other non-FDA-approved uses are not approved except as noted above

PA does not expire

9. somatrogon-ghla injection (Ngenla)

Manual PA criteria apply to all new users of Ngenla

- Provider acknowledges that Norditropin is the Department of Defense's preferred somatropin agent.
- Patient is a pediatric patient between the ages of 3 to 17 years of age
- Ngenla is being used for the indication of growth failure due to an inadequate secretion of endogenous growth hormone (GH) in pediatric patients
- Ngenla is prescribed by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment
- Patient has a contraindication to Norditropin OR
- Patient has experienced an adverse reaction(s) to Norditropin, Omnitrope, AND Zomacton not expected with Ngenla AND
- Patient requires a less than daily dosing regimen due to needle intolerance or aversion

Non-FDA-approved uses are not approved, including Idiopathic Short Stature, normal aging process, obesity, and depression

Coverage is not approved for concomitant use of multiple somatropin agents

PA expires in 1 year; provider must fill out a new PA

D. Nalmefene Nasal Spray (Opvee) —Tier 1 Copay

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) applying the Tier 1 (generic) copay for Opvee nasal spray per 32 CFR 199.21(e)(3)(iii). Other narcotic antagonists (i.e., naloxone) are also available at the Tier 1 copay. Availability of Opvee at the Tier 1 copay will provide a greater incentive for beneficiaries to use a cost-effective narcotic reversal agent in the private sector points of service.

E. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF, PA, Opvee nasal spray Tier 1 copay and Implementation Period

The P&T Committee recommended (Group 1: 20 for, 0 opposed, 0 abstained, 0 absent; Group 2: 19 for, 0 opposed, 0 abstained, 1 absent; and Group 3: 19 for, 0 opposed, 0 abstained, 1 absent) an effective date of the following:

- **New Drugs Recommended for UF or NF Status and Opvee nasal spray Tier 1 copay:** an effective date of the first Wednesday two weeks after signing of the minutes.
- **New Drugs Recommended for Complete Exclusion Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in all points of service, and 2) DHA send letters to beneficiaries who are affected by the complete exclusion recommendation at 30 days and 60 days prior to implementation.
- **New COVID-19 drugs Paxlovid and Lagevrio:** an effective date of no later than two weeks after signing of the minutes.

Addendum to the UF recommendation – COVID Therapeutics

***Tier 1 Copay for Paxlovid*:** After the P&T Committee meeting, updated information was received regarding Paxlovid pricing for DoD. The new information was presented to the DoD P&T Committee members via electronic means. An electronic vote was obtained to recommend a Tier 1 copay for Paxlovid.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) applying the Tier 1 copay for Paxlovid, with implementation occurring no later than 2 weeks after signing of the minutes.

VII. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5)

UF BAP Comments

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation

The P&T Committee recommended the formulary status for the newly approved drugs as discussed above.

- UF
  - Opvee
  - Xdemvy
  - Akeega
  - Sohonos
  - Suflave
  - Vanflyta
  - Olpruva
  - Paxlovid
  - Lagevrio
- NF
  - adalimumab (Humira) biosimilars–Targeted Immunomodulatory Biologics (TIBs)
    - Cyltezo
    - Hulio
    - unbranded biologic for Hulio
    - Idacio
    - Hadlima
    - Yusimry
    - Yuflyma
    - Hyrimoz
    - unbranded biologic for Hyrimoz
  - Airsupra
  - Brenzavvy
  - Iyuzeh
  - Ngenla
- Complete Exclusion
  - Lodoco

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended the PA criteria for new drugs as stated previously.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—Opvee Nasal Spray Tier 1 Copay

The P&T recommended a Tier 1 copay for Opvee nasal spray, as stated previously.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF, PA, Opvee Tier 1 Copay, Paxlovid Tier 1 Copay, and Implementation Period

The P&T Committee recommended and effective date of the first Wednesday two weeks after the signing of the minutes for UF or NF status and the Tier 1 copay for Opvee nasal spray; 120 days after signing of the minutes for completely excluded status and an effective date of no later than two weeks after signing of the minutes for new COVID-19 drugs and Tier 1 copay for Paxlovid as outlined above.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

VIII. RE-EVALUATION OF NONFORMULARY GENERICS—PULMONARY-1 AGENTS AND CONTRACEPTIVES

P&T Comments

The DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs now available in generic formulations requires reassessment.

A. Re-Evaluation of Nonformulary Generics—Pulmonary-1 Agents: Short-Acting Beta Agonists (SABAs) and Combinations (Inhaled Corticosteroids/Long-Acting Beta Agonists – ICS/LABAs) Subclasses

The P&T Committee reviewed current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per 30-day equivalent prescriptions for two NF Pulmonary-1 Agents, Symbicort and Proventil HFA.

1) **Pulmonary-1 Agents: Combinations Subclass: budesonide/formoterol hydrofluoroalkane inhaler (Symbicort HFA)—**At the February 2014 P&T Committee meeting, Symbicort was designated as NF, non-step-preferred, with PA requiring a trial of fluticasone/salmeterol (Advair) first. Subsequently the Symbicort manual PA criteria were updated in November 2019 to allow for acute use as a rescue therapy, based on clinical practice guidelines from the Global Initiative for Asthma (GINA) supporting ICS-formoterol over SABAs. The criteria were updated again in February 2021 to allow for intermittent and daily therapy, known as maintenance and reliever therapy or "MART", based on the U.S. National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC) focused update to the Asthma Management Guidelines. Feedback from MTF providers supports moving Symbicort to UF status to expand beneficiary access to guideline-recommended MART treatment.

   Generic formulations of Symbicort are now available, including the product labeled as Breyna and an authorized generic from Prasco. The cost of generic budesonide/formoterol HFA was compared to ICS/LABA formulary alternatives, including Advair Diskus, Advair HFA, and generic fluticasone/salmeterol diskus. The P&T Committee concluded that the weighted average cost per 30-day equivalent prescriptions for generic budesonide/formoterol HFA inhalers is within the range of other formulary options.

2) **Pulmonary-1 Agents: SABAs: albuterol HFA 90 mcg (6.7 gram) inhaler (Proventil HFA)**—The ProAir formulation (18 gram) of albuterol HFA inhaler was designated UF at the November 2013 P&T meeting, with other albuterol HFA inhalers designated as NF, including Proventil (6.7 gram) and Ventolin (8.5 gram). Step therapy does not apply to the class, since SABAs are used acutely for asthma and COPD symptoms.

   Brand ProAir HFA has been discontinued from the market. There is now significant generic penetration into the SABA market basket, with availability of generic formulations for ProAir HFA, Proventil HFA and Ventolin HFA. The costs for the albuterol HFA inhalers and respective generics were evaluated. The P&T Committee concluded that the cost of generic Proventil HFA has decreased substantially and is

now similar to generic ProAir HFA. Moving Proventil to UF status will allow another rescue option for patients.

B. Re-Evaluation of Nonformulary Generics—Pulmonary-1 Agents—Formulary Status and Implementation

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following, effective the first Wednesday 30 days after the signing of the minutes.

1) Pulmonary-1 Agents: Combinations: budesonide/formoterol HFA

- Returning generic Symbicort HFA to UF status
- Removing the budesonide/formoterol HFA PA criteria

2) Pulmonary-1 Agents: SABAs: albuterol HFA 90 mcg (6.7 gram), (Proventil HFA)

- Returning generic Proventil HFA to UF status

C. Re-Evaluation of Nonformulary Generics—Contraceptives

The P&T Committee reviewed current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per 28-day cycle, for the NF contraceptive products.

After comparison to similar agents on the UF, the P&T Committee agreed that seven products, including two chewable tablet formulations and two extended cycle products, should return to UF status. The P&T Committee noted that the two extended cycle products, which are packaged as 84 tablets containing active ingredients followed by 7 placebo tablets, are considered 3-month supply products. An 84-day supply of active drug would require the payment of 3 copays at retail. However, under existing "lesser-of" logic in place for retail network pharmacies for generic medications, patients pay the lesser of standard copays or the cost of the medication, sometimes resulting in total copayments for a 90-day supply that are less than the 30-day supply amount. Generic versions of these products have now dropped in cost below standard generic/Tier 1 copays. Patients would pay the standard generic/Tier 1 copay for a 3-month supply at mail order.

D. Re-Evaluation of Nonformulary Generics—Contraceptives—Formulary Status and Implementation

The P&T Committee recommended (19 for, 0 opposed, 1 abstained, 0 absent) returning the following generically available contraceptives products to UF status, effective the first Wednesday 2 weeks after the signing of the minutes.

- norethindrone 1 mg/ethinyl estradiol 20 mcg/iron (chew tab) (e.g., Charlotte 24 Fe, Finzala, Mibelas 24 Fe) – Generic Code Number (GCN) 34725
- norethindrone 1 mg/ethinyl estradiol 20 mcg/iron (e.g., Aurovela 24 Fe, Blisovi 24 Fe, Hailey 24 Fe, Junel Fe 24, Larin 24 Fe, Microgestin 24 Fe, Tarina 24 Fe) – GCN 26629

- norethindrone 0.8mg/ethinyl estradiol 25 mcg (chew tab) (e.g., Kaitlib Fe, Layolis Fe) – GCN 29719
- norethindrone 0.4mg/ethinyl estradiol 35 mcg (e.g., Balziva, Briellyn, Philith, Vyfemla) – GCN 11470
- norethindrone 0.4mg/ethinyl estradiol 35 mcg/iron (chew tab) (e.g., Wymzya Fe) – GCN 97167
- levonorgestrel 0.15 mg/ethinyl estradiol 30 mcg 3-month dose pack (e.g., Amethia, Ashlyna, Camrese, Daysee, Jaimiess, Simpesse) – GCN 27096
- levonorgestrel 0.1 mg/ethinyl estradiol 20 mcg 3-month dose pack (e.g., Camrese Lo, Lojaimiess) – GCN 18167

IX. RE-EVALUATION OF NONFORMULARY GENERICS—PULMONARY-1 AGENTS AND CONTRACEPTIVES

UF BAP Comments

A. Re-Evaluation of Nonformulary Generics—Pulmonary-1 Agents: ICS/LABAs, and SABAs—Formulary status and Implementation

The P&T Committee recommended returning generic Symbicort and generic Proventil HFA to UF status, and removing the PA for generic Symbicort, with implementation occurring 30 days after signing of the minutes, as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Re-Evaluation of Nonformulary Generics——Contraceptives—Formulary Status and Implementation

The P&T Committee recommended returning the seven contraceptives to UF status and an effective date of the Wednesday 2 weeks after the signing of the minutes as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

X. UTILIZATION MANAGEMENT—PULMONARY-1 AGENTS—COMBINATIONS WITH INHALED CORTICOSTEROIDS/LONG-ACTING BETA AGONISTS (ICS/LABAs) AND INHALED CORTICOSTEROIDS (ICS)

P&T Comments

A. Pulmonary-1 Agents—ICS/LABAs

Background: Brand fluticasone/salmeterol (Advair Diskus and Advair HFA) have been the step-preferred ICS/LABA combination inhalers since the February 2014 drug class review. A generic formulation of fluticasone/salmeterol diskus (Wixela) was launched in January 2019. A trial of fluticasone/salmeterol is required before the NF non-step-preferred products, [budesonide/formoterol (Symbicort), mometasone/formoterol (Dulera), fluticasone/vilanterol (Breo Ellipta) and fluticasone /salmeterol respiclick (AirDuo Respiclick)] in patients 12 years of age and older. The generic (Tier 1 copay) applies to Advair Diskus, while Advair HFA has a Tier 2 copay. Authorized generic formulations of Advair HFA, Advair Diskus, Breo Ellipta and Symbicort are available; additionally, Advair Diskus and Symbicort also have multiple "traditional" generics.

Guidelines now recommend use of ICS-formoterol as both maintenance and reliever therapy ("MART") for asthma symptom control; MART therapy does not apply to ICS combinations containing salmeterol.

Current step-therapy PA criteria were reviewed for the ICS/LABA combinations, due to the updated clinical practice guidelines, impending changes in availability for brand Advair HFA and Advair Diskus on December 31, 2023 (authorized generics by Prasco will remain available), and upcoming termination of current pricing agreements in January 2024.

The P&T Committee evaluated utilization trends and pricing for the ICS/LABA combinations. With the termination of current pricing agreements, Advair Diskus brand and Advair HFA brand will be less cost-effective, relative to other formulations.

B. Pulmonary-1 Agents—(ICS/LABAs—PA Criteria, Tier 1 Copay Removal, and Implementation

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following, effective the first Wednesday 30 days after the signing of the minutes. There are no changes in the UF status for the ICS/LABA combinations, with the exception of Symbicort, which will move from NF to UF as noted in the NF Generic section.

- *Advair Diskus brand:*
  - Remove the Tier 1 copay and return to the Tier 2 copay
  - Will remain UF
  - Note that PA will not be required for generic fluticasone/salmeterol diskus (e.g., Wixela and other generics).
- *Advair HFA brand and fluticasone/salmeterol HFA generics*
  - Will remain UF

- New PA criteria requiring a trial of the more cost-effective generic fluticasone/salmeterol diskus (e.g., Wixela and other generics) in new users older than 12 years of age. Providers will also acknowledge that PA is not required for Symbicort.

- *Dulera, Breo Ellipta, AirDuo Respiclick*
  - Update the PA criteria for Dulera, Breo Ellipta and AirDuo Respiclick requiring a trial of the more cost-effective generic fluticasone/salmeterol diskus (e.g., Wixela and other generics, rather than brand Advair Diskus or brand Advair HFA) in new users older than 12 years of age. The current automated step for the Advair Diskus/HFA lookback will be removed. Providers will also acknowledge that PA is not required for Symbicort.
  - Will remain NF
- *budesonide/formoterol (Symbicort and generics)* -will move from NF to UF, and the PA will be removed.

The Manual PA criteria is as follows:

1. fluticasone/salmeterol HFA(Advair HFA) and authorized generic fluticasone/salmeterol HFA

Manual PA criteria apply to all new users of fluticasone/salmeterol HFA (Advair DHFA) and authorized generic fluticasone/salmeterol HFA 12 years of age and older

PA is not required in patients younger than 12 years of age

Manual PA Criteria: Advair HFA is approved if:

- Provider acknowledges that generic fluticasone/salmeterol diskus (e.g., Wixela and other generics) and generic budesonide/formoterol (Symbicort) are available without requiring prior authorization and the provider should consider writing for generic fluticasone/salmeterol diskus or generic budesonide/formoterol instead.
- Provider acknowledges that if the patient requires an hydrofluoroalkane (HFA) inhaler that generic budesonide/formoterol (Symbicort) is an HFA inhaler, and the provider should consider writing for generic budesonide/formoterol instead
- Patient has experienced significant adverse effects from generic fluticasone/salmeterol diskus that is not expected to occur with brand Advair HFA
- Patient has had an inadequate response to generic fluticasone/salmeterol diskus

- Patient previously responded to Advair HFA and changing to fluticasone/salmeterol diskus would incur unacceptable risk

Non-FDA-approved uses are NOT approved

PA does not expire

2. mometasone/formoterol (Dulera), fluticasone/vilanterol (Breo Ellipta)

Changes from the November 2023 meeting are in bold and strikethrough. The previous automated step therapy has been removed

Manual PA criteria apply to all new users of Dulera or Breo Ellipta 12 years of age and older

PA is not required in patients younger than 12 years of age

Manual PA Criteria: Dulera or Breo Ellipta is approved if:

- **Provider acknowledges that generic fluticasone/salmeterol diskus (e.g., Wixela) and budesonide/formoterol (Symbicort) are available without requiring prior authorization and the provider should consider writing for generic fluticasone/salmeterol diskus or generic budesonide/formoterol instead.**
- Use of **generic budesonide/formoterol (Symbicort) and generic fluticasone/salmeterol diskus (e.g., Wixela)** ~~formulary agents (Advair Diskus and Advair HFA) is~~ are contraindicated
- Patient has experienced significant adverse effects from **generic budesonide/formoterol (Symbicort) and generic fluticasone/salmeterol diskus (e.g., Wixela)** ~~Advair~~ that is not expected to occur with **Dulera or Breo Ellipta** ~~the nonformulary ICS/LABA medication~~
- ~~Formulary agents (Advair Diskus and Advair HFA)~~ Use of **generic budesonide/formoterol (Symbicort) and generic fluticasone/salmeterol diskus (e.g., Wixela)** have resulted or are like to result in therapeutic failure
- Patient previously responded to **Dulera or Breo Ellipta**~~nonformulary agent~~ and changing to generic budesonide/formoterol (Symbicort) and **generic fluticasone/salmeterol diskus (e.g., Wixela)** ~~a formulary agent (Advair Diskus and Advair HFA)~~ would incur unacceptable risk
- The patient has asthma and requires rescue therapy or intermittent and daily ICS-LABA therapy with an ICS-formoterol combination **and generic budesonide/formoterol is not an option. Note that this does not apply to Breo Ellipta**

Non-FDA-approved uses are NOT approved

PA does not expire

3. fluticasone/salmeterol respiclick (AirDuo Respiclick)

Changes from the November 2023 meeting are in bold and strikethrough. The previous automated step therapy has been removed

Manual PA criteria apply to all new users of AirDuo Respiclick 12 years of age and older

PA is not required in patients younger than 12 years of age

Manual PA Criteria: AirDuo Respiclick is approved if:

- **Provider acknowledges that generic fluticasone/salmeterol diskus (e.g., Wixela) and generic budesonide/formoterol (Symbicort) are available without requiring prior authorization and the provider should consider writing for generic fluticasone/salmeterol diskus or generic budesonide/formoterol instead.**
- ~~Is the patient 12 years of age or older?~~
- The patient has a diagnosis of asthma
- The patient requires salmeterol as the long-acting beta agonist (LABA) and requires a lower salmeterol dose than found in AirDuo vs. **generic fluticasone/salmeterol diskus (e.g., Wixela)** Advair Diskus or Advair HFA.
- The patient requires fluticasone/salmeterol and cannot manipulate the generic fluticasone/salmeterol diskus (e.g., Wixela) Advair Diskus or Advair HFA metered dose inhaler devices.

Non-FDA-approved uses are NOT approved, **including for chronic obstructive pulmonary disease (COPD)**

PA does not expire

C. Pulmonary-1 Agents: Inhaled Corticosteroids (ICS)—PA Criteria, Tier 1 Copay Removal, and Implementation

Background: Both of the fluticasone formulations, Flovent Diskus and Flovent HFA, are the step-preferred ICS agents, dating back to the May 2014 class review. An authorized generic fluticasone HFA formulation entered the market in August 2022, and a brand over generic requirement for a trial of brand Flovent HFA or Flovent Diskus was required before dispensing of the generic fluticasone HFA. The generic (Tier 1) copay applies to both Flovent HFA and Flovent Diskus.

Current PA criteria, utilization trends, and costs were evaluated for the ICS inhalers, due to upcoming market withdrawal of branded Flovent HFA and Flovent Diskus on December 31, 2023, with subsequent termination of current pricing agreements in January 2024. As a result, brand Flovent Diskus, brand Flovent HFA and authorized generic fluticasone HFA will not be cost effective.

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following, effective the first Wednesday 30 days after the signing of the minutes

- Flovent HFA
  - Remove Tier 1 copay and return to the Tier 2 copay
  - Will remain UF
  - Remove brand over generic preference for Flovent HFA (remove the current PA for generic fluticasone HFA requiring a trial of Flovent HFA first).
- Flovent Diskus
  - Remove Tier 1 copay and return to Tier 2 copay
  - Will remain UF
- Note that there are no changes to the PA for the NF, non-step-preferred ICS, as the subclass will be reviewed at an upcoming meeting.

XI. UTILIZATION MANAGEMENT—PULMONARY-1 AGENTS UTILIZATION MANAGEMENT—ICS/LABA AND ICS

UF BAP Comments

A. ICS/LABAs—PA, Tier 1 Copay Removal, and Implementation Plan

The P&T Committee recommended removing the Tier 1 copay for Advair Diskus; new PA criteria for Advair Diskus brand and generic inhalers; updated PAs for Dulera, Breo Ellipta and AirDuo Respiclick in new users; and an implementation plan of 30 days after signing of the minutes, as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. ICS—PA, Tier 1 Copay Removal, Brand over Generic PA removal and Implementation Plan

The P&T Committee recommended removing the Tier 1 copay for Flovent Diskus and Flovent HFA and removing the brand over generic preference for Flovent HFA, with an implementation plan of 30 days after signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA-APPROVED INDICATIONS

P&T Comments

A. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee recommended updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users.

1) **Targeted Immunomodulatory Biologics (TIBs)**: **Tumor Necrosis Factor (TNF) Inhibitors Agents—adalimumab-atto (Amjevita)**—Amjevita is now indicated for the treatment of uveitis in adults, including non-infectious intermediate, posterior, and panuveitis. The manual PA criteria were updated to allow for this indication, with the criteria matching what is currently in place for Humira.
2) **Metabolic Agents-Miscellaneous**
   - **odevixibat (Bylvay)—**Bylvay has a new indication for cholestatic pruritis in patients 12 months of age and older with Alagille syndrome. The manual PA criteria were updated to allow for this new indication without an age limitation.
   - **maralixibat (Livmarli)—**The manual PA criteria were updated to reflect the new expanded age indication in children as young as 3 months old with cholestatic pruritus from Alagille syndrome.
3) **Oncological Agents—dabrafenib (Tafinlar) and trametinib (Mekinist)—**The manual PA criteria were updated to allow for use in pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.
4) **Oncological Agents: Breast Cancer—talazoparib (Talzenna)—**The manual PA criteria were updated to allow for Talzenna use in combination with Xtandi for the treatment of homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) in adults. In addition, the PA was updated to include conception and breastfeeding warnings similar to what is in place for other oncology agents.

B. Updated Manual PA Criteria and Implementation Period for New FDA-Approved Indications

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Amjevita, Bylvay, Livmarli, Mekinist, Tafinlar, and Talzenna in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

XIII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA-APPROVED INDICATIONS AND IMPLEMENTATION PLAN

UF BAP Comments

Updated PA Criteria for New FDA-Approved Indications and Implementation Plan

The P&T Committee recommended updates to the manual PA criteria for Amjevita, Bylvay, Livmarli, Mekinist, Tafinlar, and Talzenna in new users with an implementation date the first Wednesday 60 days after the signing of the minutes as stated above.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

XIV. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW INDICATIONS

P&T Comments

A. Updated PA Criteria for Reasons other than New Indications

1) **Antipsychotics: Atypical— brexpiprazole (Rexulti)**—Earlier this year, Rexulti received a new indication for treatment of agitation associated with dementia due to Alzheimer's disease. It was previously approved for schizophrenia and as adjunctive therapy to antidepressants in major depressive disorder. Updated manual PA criteria were recommended for the new agitation indication based on provider feedback.
   The new PA criteria will require specialist prescribing, ruling out other causes of agitation, and trial and failure of non-pharmacologic methods first. The manual PA criteria for the other indications will remain unchanged.

2) **Phosphodiesterase-5 (PDE-5) Inhibitors—tadalafil**—The PDE-5 inhibitors for erectile dysfunction were last reviewed in November 2019. Since the review, generic sildenafil and generic tadalafil prices have dropped precipitously. MTF providers requested a re-review of the current tadalafil PA criteria. TRICARE policy precludes eliminating the PDE-5 inhibitor PA, as treatment of organic impotency is a covered benefit subject to all applicable provisions of 32 CFR 199.4, but impotence solely due to psychological or psychiatric reasons is not covered.

   The current tadalafil manual PA requires a trial of sildenafil first, unless the patient has failed therapy, experienced an adverse event or has a contraindication to sildenafil. Tadalafil also is approved for benign prostatic hyperplasia (BPH) which requires use of an alpha blocker (alfuzosin or tamsulosin) first. Upon review of clinical and cost data, the following three edits were recommended: adding an age

and gender edit, to allow men 40 years and older to bypass the PA; removing the sildenafil step preference; and removing the BPH step requiring a trial of tamsulosin or alfuzosin.

3) **Skeletal Muscle Relaxants and Combinations—baclofen oral solution (Ozobax), baclofen oral suspension (Fleqsuvy), and baclofen oral granules (Lyvispah)—** Ozobax, Fleqsuvy, and Lyvispah are all alternate oral baclofen dosage formulations and are designated as NF. Current PA criteria restricts use to the sole FDA- approved indication for treatment of spasticity. An MTF oncologist requested allowing use for oncology patients experiencing hiccups as a side effect to their chemotherapy regimens. The PA was updated accordingly.

4) **Gastrointestinal-2 Agents: Chronic Idiopathic Constipation/Constipation-predominant Irritable Bowel Syndrome (CIC/IBS-C)—linaclotide (Linzess) and lubriprostone (Amitiza)—**The CIC/IBS-C class was last reviewed in November 2018. At that time, Linzess and Amitiza were designated as UF, and the PAs for both drugs required a trial of standard laxatives first. Annual PA resubmission was also required. At the May 2021 P&T meeting, PA criteria were updated for Amitiza requiring new users to try Linzess first. The PAs for both Linzess and Amitiza were re-reviewed due to changes in commercial practice and analysis of PA submission rates by Military Health System providers. Based on a review of available clinical and cost data, the Linzess and Amitiza PAs will now expire after the first year and then afterwards will be approved indefinitely, if renewal criteria are met. In addition, the requirement for a trial of Linzess first before Amitiza was removed.

B. Updated Manual PA Criteria and Implementation Period

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) criteria updates to the manual PA criteria for Rexulti, tadalafil, Ozobax, Fleqsuvy, Lyvispah, Linzess, and Amitiza. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

XV. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW INDICATIONS AND IMPLEMENTATION PLAN

UF BAP Comments

Updated PA Criteria for Reasons other than New FDA-Approved Indications and Implementation Plan

The P&T Committee recommended criteria updates to the manual PA criteria for Rexulti, tadalafil, Ozobax, Fleqsuvy, Lyvispah, Linzess, and Amitiza with an implementation date effective the first Wednesday 60 days after signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XVI. BRAND OVER GENERIC PA AUTHORIZATION AND TIER 1 COPAY: PULMANARY-2 AGENTS: LONG-ACTING MUSCARINIC ANTAGONISTS (LAMAs): TIOTROPIUM (SPIRIVA) HANDIHALER

P&T Comments

A. Tiotropium (Spiriva) HandiHaler

Tiotropium dry powder inhaler (Spiriva) HandiHaler was reviewed for formulary status in February 2013 and designated as UF. AB-rated generic versions have entered the market; however, these generic products are less cost-effective compared to the branded agent. Therefore, dispensing of the branded Spiriva Handihaler will continue at all three points of service and the generic will only be available with PA (i.e., the reverse of the current brand to generic policy). The prescriber will provide patient specific justification as to why the brand cannot be used. The Tier 1 (generic) copayment will apply to brand Spiriva HandiHaler.

The Manual PA criteria is as follows:

generic tiotropium dry powder HandiHaler

Manual PA criteria apply to all new users of generic tiotropium dry powder HandiHaler.

Manual PA criteria: generic tiotropium dry powder HandiHaler is approved if all the following criteria are met:

- The provider acknowledges that Spiriva Respimat is the Department of Defense's preferred long-acting muscarinic antagonist and does not require prior authorization and is available at the lowest (generic) copay.
- The provider must document a patient-specific reason as to why the patient requires Spiriva Handihaler and cannot use the Spiriva Respimat device. (blank write-in)
  - Acceptable responses include that the patient cannot activate and prime the Respimat device.
- In order to receive the generic tiotropium dry powder HandiHaler the provider must document why the patient requires the generic and not the brand Spiriva Handihaler (blank write-in).
  - Acceptable responses include that the patient has had an adverse reaction to an excipient in brand Spiriva HandiHaler that would not be likely to occur with the generic tiotropium HandiHaler.

Non-FDA-approved uses are NOT approved

PA does not expire

B. Brand Over Generic Requirement, PA Criteria, Tier 1 Copay, and Implementation Period

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) requiring brand Spiriva HandiHaler over the generic in all new users at all points of service, based on cost effectiveness.

The effective date will be no later than 30 days after the signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics. Additionally, Spiriva HandiHaler will be added to the rapid response ("safety net") program, which is included in the new TRICARE Pharmacy, 5th Generation (TPharm5) contract.

XVII. BRAND OVER GENERIC PA AUTHORIZATION AND TIER 1 COPAY: PULMONARY-2 AGENTS: LONG-ACTING MUSCARINIC ANTAGONISTS (LAMAs): TIOTROPIUM (SPIRIVA) HANDIHALER AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended requiring brand Spiriva HandiHaler over the generic in all new users at all points of service based on cost effectiveness with an effective no later than 30 days after the signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XVIII. OVER-THE-COUNTER (OTC) DRUG BENEFIT—PROGESTIN-ONLY CONTRACEPTIVES: NORGESTREL TABLETS (OPILL)

P&T Comments

In accordance with 10 U.S.C. 1074g(a)(2)(F), implemented by 32 CFR 199.21(h)(5), an OTC drug may be included on the UF upon the recommendation of the P&T Committee and approval of the Director, DHA, based on a finding that it is cost-effective and clinically effective, as compared with other drugs in the same therapeutic class of pharmaceutical agents. OTC drugs placed on the UF, in general, will be treated the same as generic drugs on the UF for purposes of availability in the MTF pharmacies, retail pharmacies, and the Mail Order pharmacy program and other requirements. However, upon the recommendation of the P&T Committee and approval of the Director, DHA, the requirement for the prescription may

be waived for a particular OTC drug for certain emergency care treatment situations. In addition, a special retail pharmacy copayment may be established under 32 CFR 199.21(i)(2)(xii) for OTC drugs specifically used in certain emergency care treatment situations.

A. Progestin-Only Contraceptive—OTC Opill:

The P&T Committee evaluated the clinical and cost-effectiveness of the first OTC oral contraceptive, norgestrel 0.075 mg (Opill), for UF addition. Norgestrel 0.075 mg (Ovrette) was previously a legend drug but was pulled from the market in 2005 for business reasons, not due to efficacy or safety concerns. Opill was FDA-approved in July 2023 for OTC use, with commercial launch planned for early 2024.

Opill is a progestin-only contraceptive pill (POP). Other POPs include norethindrone 0.35 mg which is UF and drospirenone 4 mg (Slynd) which is NF. POPs require strict adherence and administration at the same time each day for maximal efficacy. Opill has similar efficacy to other prescription oral contraceptives and greater efficacy than other OTC contraceptives (e.g., condoms and spermicides.) POPs have fewer contraindications than combined oral contraceptives which contain estrogen. POPs can be safely used in a wider population including women who have just given birth, are breastfeeding, or have a history of, or risk factors for venous thromboembolism.

Retail pricing for Opill was not available at the time of the P&T Committee review as the product was not yet commercially launched. A cost-analysis of other contraceptive agents including other POPs was presented. Price bands were established for Opill to define cost effectiveness and to determine formulary placement when pricing is released.

B. Progestin-Only Contraceptive—OTC Opill—UF Recommendation, Copay, Prescription Requirement, and Implementation Period

The P&T Committee recommended (18 for, 0 opposed, 2 abstained, 0 absent) the following:

- Adding OTC norgestrel 0.075 mg tablets (Opill) to the UF, contingent on retail pricing cost effectiveness. If Opill pricing is not cost effective, then the formulary recommendation will be brought back to the DoD P&T Committee for further consideration at a later date.
- A copay is required pursuant to 10 USC 1074g(a)(6)(A) and 32 CFR 199.21(h)(5)(ii).
- A prescription is required pursuant to 32 CFR 199.21(h)(5)(ii).
- Implementation plan of two weeks after signing of the minutes or, if OTC Opill has not launched when the minutes are signed, implementation will occur two weeks after market launch of OTC Opill at all points of service.

MHS provider feedback and opinions voiced by P&T Committee members were in support of waiving the copay and prescription requirement for Opill. In contrast to naloxone and the emergency contraceptive Plan B, Opill is not considered an emergency treatment, and the copay and prescription requirement cannot be waived.

Notably, over half of U.S. states allow pharmacist prescribing of contraceptives, which is a potential option for MHS beneficiaries to obtain Opill.

The P&T Committee recognizes the continued challenges with variations in standards of practice and prescribing rules that are solely under the control of the individual U.S. states. MTF healthcare professionals should work with their local credentialing/privileging authority for any questions they have.

XIX. OVER-THE-COUNTER (OTC) DRUG BENEFIT—PROGESTIN-ONLY CONTRACEPTIVES: NORGESTREL TABLETS (OPILL) UF RECOMMENDATION, COPAY, PRESCRIPTION REQUIREMENT AND IMPLEMENTATION PERIOD

UF BAP Comments

The P&T Committee recommended adding OTC norgestrel 0.075 mg tablets (Opill) to the UF, contingent on retail pricing cost effectiveness, with an implementation plan of two weeks after signing of the minutes or two weeks after market launch of OTC Opill at all points of service as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XX. CONSIDERATIONS OF BETTER CARE, HEALTHIER PEOPLE AND SMARTER SPENDING

P&T Comments

In accordance with 10 U.S.C. 1074g(a)(10), as implemented in 32 CFR 199.21(e)(3)(i), the P&T Committee may recommend, and the Director may, after considering the comments and recommendations of the Beneficiary Advisory Panel, approve special uniform formulary actions to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending.

A. Contraceptives

- Segesterone acetate/ethinyl estradiol vaginal ring (Annovera) was reviewed as an innovator in November 2019. It is the second contraceptive vaginal ring in the U.S. and can be used for up to one year. Annovera is currently available as UF with a Tier 2 copay. It is cost-effective compared to other alternate dose formulations.
- Medroxyprogesterone acetate (Depo-subq Provera) is a SC contraceptive injection administered every 3 months. Depo-subq Provera is currently available as UF with a

Tier 2 copay. Depo-subq Provera is cost-effective and is similar in price to Depo-Provera which is available at a Tier 1 copay.

B. Tier 1 Copay and Implementation Period

The P&T Committee recommended (19 for, 0 opposed, 1 abstained, 0 absent) the following updates to the Tier 1. Implementation will be effective the first Wednesday 30 days after the signing of the minutes.

- Applying the Tier 1 copay at Mail/Retail for Annovera and Depo-subq Provera

XXI. CONSIDERATIONS OF BETTER CARE, HEALTHIER PEOPLE AND SMARTER SPENDING

UF BAP Comments

The P&T Committee recommended applying the Tier 1 copay to Annovera and Depo-subq Provera, as outlined above, with an implementation effective the first Wednesday 30 days after the signing of the minutes.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***