

EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel Meeting September 27, 2023

For the August 2023 DoD Pharmacy and Therapeutics Committee Meeting

The Uniform Formulary Beneficiary Advisory Panel (UF BAP) convened at 10:00 A.M. EDT on September 27, 2023 via teleconference. The current meeting took place over 2 hours. The information presented included the recommendations from the August 2023 DoD Pharmacy and Therapeutics Committee (P&T) meeting.

The detailed meeting information is found starting on page 11.

UNIFORM FORMULARY (UF) DRUG CLASS REVIEWS

I. UF CLASS REVIEWS— LUTEINIZING HORMONE-RELEASING HORMONE (LHRH) AGONISTS-ANTAGONISTS—PROSTATE CANCER, ENDOMETRIOSIS AND FIBROIDS, AND CENTRAL PRECOCIOUS PUBERTY SUBCLASSES

A. LHRH Agonists-Antagonists—UF Recommendations

Prostate Cancer Subclass

- UF and step-preferred
 - Eligard SC
 - Firmagon SC
- UF and non-step-preferred
 - Lupron Depot
 - leuprolide acetate depot IM 22.5 mg vial (no brand name)
 - Camcevi
 - Orgovyx
 - Note that as part of this recommendation a trial of Eligard SC is required before Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg, leuprolide acetate (no brand name) 22.5 mg and Camcevi 42 mg.
 - Note that as part of this recommendation a trial of Eligard SC or Firmagon SC is required before Orgovyx tablets.

- NF
 - None
- Complete exclusion
 - None

Endometriosis and Fibroids Subclass

- UF
 - Lupron Depot
 - Oriahnn
 - Myfembree
- NF
 - Orilissa
- Complete exclusion
 - None

Central Precocious Puberty Subclass

- UF
 - Lupron Depot-Ped
 - Fensolvi-Ped
- NF
 - None
- Complete exclusion
 - None

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

• **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

B. LHRH Agonists-Antagonists—Manual PA Criteria

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

C. LHRH Agonists-Antagonists—Tier 1 (generic) Copay for Eligard SC and Fensolvi-Ped SC

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

D. LHRH Agonists-Antagonists—UF, PA, Tier 1 Copay and Implementation Plan of an effective date of 60 days

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

II. UF CLASS REVIEWS—WHITE BLOOD CELL STIMULANTS—FILGRASTIMS AND PEGFILGRASTIMS

A. White Blood Cell Stimulants—UF Recommendations

Filgrastims

- UF and step-preferred
 - Granix
 - Nivestym
 - Zarxio
- NF and non-step-preferred
 - Neupogen
 - Releuko
 - Note that as part of this recommendation a trial of Granix, Nivestym and Zarxio are required before Neupogen or Releuko.
- Complete exclusion

- None

Pegfilgrastims

- UF and step-preferred
 - Fulphila
 - Fylnetra
 - Nyvepria
 - Stimufend
 - Udenyca
 - Ziextenzo
- NF and non-step-preferred
 - Neulasta
 - Neulasta OnPro
 - Note that as part of this recommendation a trial of Udenyca, Fulphila, Ziextenzo, Nyvepria, Fylnetra, and Stimufend is required before Neulasta and Neulasta OnPro.
- Complete exclusion
 - None

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

B. White Blood Cell Stimulants—Manual PA Criteria

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

C. White Blood Cell Stimulants—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: 1**

D. White Blood Cell Stimulants—Safety Net/Rapid Response Program

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1**

E. White Blood Cell Stimulants—UF, PA, Tier 1 Copay, Safety Net/Rapid Response Program and Implementation Plan of 90 days

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 1**

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 Recommendations

- UF
 - atropine sulfate 1% ophthalmic solution
 - Austedo XR
 - Vowst
 - Veozah
 - Joenja
 - Skyclarys

- NF
 - Miebo
 - Lumryz
 - Sogroya
 - Inpefa
 - Zavzpret
- Complete Exclusion
 - Liqrev
 - Cuvrior
 - zolpidem tartrate 7.5 mg capsules

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

B. Newly Approved Drugs Per 32 CFR 199.21(g)(5)—PA Criteria for Austedo XR, Vowst, Veozah, Joenja, Skyclarys, Miebo, Lumryz, Sogroya, Inpefa, Zavzpret, and interim manual PA criteria for Liqrev, Cuvrior and zolpidem 7.5 mg capsules

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

C. Newly Approved Drugs Per 32 CFR 199.21(g)(5)—UF/NF/Complete Exclusion, and PA Implementation Plan of two weeks for the drugs recommended for UF or NF status, and 120 days after signing of the minutes for the drugs recommended for completely excluded

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

IV. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5)

A. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

The P&T Committee recommended new manual PA criteria for Natal PNV tablets.

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

B. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5) Implementation Plan of 60 days

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

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

A. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee evaluated updates to the PA Criteria for Qudexy XR, Trokendi XR, Qulipta, Linzess, Freestyle Libre 2 and 3, Rinvoq, Lynparza, Tafinlar, Mekinist, Ayvakit, and Kevzara due to new FDA-approved indications.

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

B. Updated PA Criteria for New FDA-Approved Indications and Implementation Plan of 60 days

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

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

A. Updated PA Criteria for Reasons other than New Indications for Evrysdi, Tavneos, and Humira

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

B. Updated PA Criteria for Reasons other than New Indications Implementation Plan of 60 days

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

VII. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR DABIGATRAN (PRADAXA) CAPSULES

A. Brand over generic authorization and Tier 1 Copay for Dabigatran (Pradaxa) Capsules

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

B. Brand over generic authorization and Tier 1 Copay for Dabigatran (Pradaxa) Capsules Implementation Plan of 60 days

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

VIII. COMPLETELY EXCLUDED DRUGS: ANNUAL REVIEW AND UF RECOMMENDATION AND IMPLEMENTATION PLAN

The P&T Committee recommended returning baclofen oral granules (Lyvispah) to the formulary, designated as nonformulary (Tier 3 copay), with an implementation date in all points of service of the first Wednesday 2 weeks after signing of the minutes and applying the same prior authorization to Lyvispah as is currently in place for baclofen oral solution (Ozobax) and baclofen oral suspension (Fleqsuvy).

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

IX. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2008 AND IMPLEMENTATION PLAN


The P&T Committee recommended NF status and Pre-Authorization Criteria for Sivextro and Xenleta, with an implementation effective date of two weeks after signing of the minutes for 703 noncompliant NDCs.

Summary of Panel Questions and Comments

There were no questions or comments from the Panel.

- **Concur: 8 Non-Concur: 0 Abstain: 0 Absent: 0**

Director, DHA:

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

Uniform Formulary Beneficiary Advisory Panel
Virtual Meeting Summary Minutes
September 27, 2023

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
- Dr. Joseph McKeon, MD, Humana Military
- Dr. Betsaida Guzman, PharmD, Veterans of Foreign Wars
- Ms. Amanda Meyers, Military Officers Association of America (MOAA)
- Dr. Jennifer Soucy, PharmD, U.S. Family Health Plan, Martins Point Services
- Ms. Patricia Orfini, RN, National Military Family Association

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

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

- Dr. John Kugler, Division Chief, J-6; DoD P&T Committee Chair
- CDR Scott Raisor, Chief, P&T Section POD FMB
- Maj Angelina Escano, MC POD FMB
- CDR Elizabeth Hall POD FMB
- CDR Giao Phung, POD FMB
- LT Stephanie Klimes, POD FMB
- Angela Allerman, PharmD, BCPS, POD FMB
- Shana Trice, PharmD, BCPCS, FMB
- CAPT Phung Nguyen, Alternate DFO UF BAP, POD
- Ms. Megan Gemunder Office of General Counsel

Agenda is found starting on page 17.

- Panel Discussion

The Uniform Formulary Beneficiary Advisory Panel (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 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 Beneficiary Advisory Panel (UF BAP). The Panel has convened to comment on the recommendations of the DoD Pharmacy and Therapeutics (P&T) Committee meeting, which occurred on August 2nd and 3rd, 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 BAP Panel 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 UF BAP 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 UF BAP is to comment on the UF recommendations made by the P&T Committee at their last meeting. While the DoD 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 14 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, however depending on a potential government shutdown the timeline could change.

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.

Written comments were forwarded to the Panel for their review and consideration from the two manufacturers, and are included on pages 62 to 65.

1. Lexicon Pharmaceuticals
2. Sumitomo Pharma America, Inc

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.

CDR Raisor's Opening Remarks

The meeting then proceeded with comments from CDR Raisor, a PHS pharmacist, who thanked the panel for the involvement today and stated that the Panels' voices were critical today. He then introduced the team speaking (*see list above*).

CDR Raisor 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 15. The information starting on page 20 includes the full meeting information.

Closing Remarks

Mr. Ostrowski thanked the Panel members, the presenters, COL Carby and his staff for the presentations, and stated he is looking forward to these changes.

COL Carby closed the meeting by acknowledging the commitment from the Panel members who help improve the pharmacy benefit. He expressed his warmest thanks to everyone who provide our service members, families and veterans with a quality benefit.

The Meeting Adjourned at 11:00 AM EDT.

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

Jon R.
Ostrowski
Jon R. Ostrowski
Chairperson, UFBAP

Digitally signed by Jon R.
Ostrowski
Date: 2023.10.01
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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

Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists—Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty Subclasses

- The class has not previously been reviewed for formulary status, however several of the drugs were individually reviewed as innovators. Three drugs, Camcevi, Orgovyx and Fensolvi, will move from NF to UF status. The one drug that is currently designated as NF (Orlissa) will remain NF.
- For the prostate cancer subclass, there were several updates made to the PAs. New PAs were recommended for Lupron Dept and leuprolide acetate, and changes were made for Camcevi. However, these PAs were simplified, including removing the age requirement and also standardizing the language.
- For Orgovyx, it will move from NF to UF status, along with updates to the PA. Based on feedback from providers and a review of the data, patients will only have to try one product first (either Eligard or Firmagon). Overall, the PA changes will expand access to the drug. The changes only apply to new users, so patients currently receiving Orgovyx will be able to stay on therapy.
- There were no changes to the PAs currently in place for the products used for endometriosis, and PA was not recommended for the precocious puberty drugs.
- There are no PAs required for either Eligard or Firmagon. The Tier 1 copay will apply to Eligard, which will benefit patients who are using the Mail Order or Retail pharmacies, as they will see a decrease in their copay. The Tier 1 copay was also recommended for one of the precocious puberty drugs, Fensolvi.
- One thing to mention is that the formulary recommendations do not affect inpatient or in-clinic use for the injectable products. The recommendations were all unanimous, and there was no controversy.

White Blood Cell Stimulants—Filgrastims and Pegfilgrastims

- There are 13 drugs in the class including several biosimilars. The P&T Committee has recognized biosimilars as highly therapeutically interchangeable. Additionally, providers have stated that clinically there is no reason to choose one product over another for either of the two subclasses.
- For the formulary recommendation, there will now be an increased number of step-preferred biosimilars available from both subclasses. This will allow for potential

shortage situations and will provide several options for prescribers to choose from. The step-therapy recommendation will also allow any new market entrants to be placed UF, if they are cost effective.

- The Neulasta Onbody injector (Neulasta Onpro) will move to NF status. The PA criteria do account for patients who are unable to give themselves injections, including those with dexterity issues. Additionally, this product can be applied and programmed in the clinic setting, with the patient sent home wearing the device. The formulary recommendation for outpatient dispensing will not affect this type of clinic use.
- The Committee recommended the Tier1 copay for 3 products in the class (Granix, Nivestym and Stimufend). From a regulatory aspect, biosimilars are not generic, so the only mechanism to have the generic copay apply is with the P&T Committee designating the lower copay.
- Because of the step therapy requirements, and also since these drugs are used in patients undergoing chemotherapy, the class will be part of the Safety Net program at ESI. Patients who submit a prescription but receive a reject and don't have a subsequent prescription fill will receive outreach.

Newly Approved Drugs

- For the new drugs, all the drugs designated as NF fall into classes where we have already done a class review, and PA recommendations are in line with the previous reviews.
- Some of the products that were made NF are in classes where there is an existing clinically and cost effective step-preferred product. Examples of this include for the growth hormone drug and the SGLT-2 inhibitor. The PAs here require use of the step-preferred products first.
- For Inpefa, it is the 5th product on the market that has an SGLT-2 inhibitor as part of its mechanism. It does have an additional mechanism, however there are no head-to-head trials with the other SGLT-2 inhibitors to show that this drug has a better efficacy or safety profile. Heart failure guidelines in the U.S. and Europe recommend an SGLT-2 inhibitor, but do not prefer any one drug over another. Jardiance is the preferred drug for the MHS, it does not require a PA, and has more FDA-approved indications, including a new indication for chronic kidney disease which was granted on September 22nd, 2023.
- For the drugs recommended for complete exclusion, provider input was received which did not find a therapeutic niche for the products. Several other formulary alternatives are available. As we have done in the past for the completely excluded drugs, temporary PA criteria will be in place, to help inform providers of the upcoming formulary change. Patients will be notified by letter of the change.

AGENDA

Uniform Formulary Beneficiary Advisory Panel (UF BAP) For the August 2023 DoD Pharmacy and Therapeutics Committee Meetings September 27, 2023 at 10:00 AM Eastern Daylight Saving Time

Virtual Meeting

- **Administrative Meeting: 9:00 AM – 9:45 AM Eastern Daylight Saving Time
(General session starts at 10:00 AM Eastern Daylight Saving Time)**

- **Roll Call**

- **Therapeutic Class Reviews**

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

The P&T Committee made recommendations for the following drugs/drug classes during the August 2023 meeting:

- **Drug Class Reviews**

- *Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists – Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty subclasses*
- *White Blood Cell Stimulants – Filgrastims and Pegfilgrastims*

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)**

- *atropine sulfate 1% ophthalmic solution – Ophthalmic Miscellaneous: Mydriatics*
- *deutetrabenazine extended-release tabs (Austedo XR) – Neurological Agents Miscellaneous: Movement Disorders*
- *fecal microbiota spores, live-brpk capsules (Vowst) – Gastrointestinal-2 Agents Miscellaneous*
- *fezolinetant (Veozah) – Gynecological Agents Miscellaneous*
- *leniolisib (Joenja) – Immunological Agents Miscellaneous*
- *omaveloxolone (Skyclarys) – Neurological Agents Miscellaneous*
- *perfluorohexyloctane 1.338 g/mL ophthalmic solution (Miebo) – Ophthalmic: Dry Eye Agents*
- *sildenafil 10 mg/mL oral suspension (Liqrev) – Pulmonary Arterial Hypertension (PAH): PDE 5 Inhibitor*
- *sodium oxybate extended-release packets for oral suspension (Lumryz) – Sleep Disorders: Wakefulness Promoting Agents*

- *somapacitan-beco injection (Sogroya) – Growth Stimulating Agents*
- *sotagliflozin (Inpefa) – Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors*
- *trientine tetrahydrochloride tablets (Cuvrior) – Binder-Chelators-Antidotes-Overdose*
- *zavegepant nasal spray (Zavzpret) – Migraine Agents*
- *zolpidem tartrate 7.5 mg capsules – Sleep Disorders: Insomnia*

➤ **Utilization Management Issues**

- **New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)**
 - *Vitamins: Prenatal—Prenatal Multivitamin (Natal PNV)*
- **Prior Authorization Criteria—Updated PA Criteria for New FDA-Approved Indications**
 - *Anticonvulsant and Anti-Mania: topiramate ER capsule sprinkle (Qudexy XR) and topiramate ER capsule (Trokendi XR)*
 - *Migraine Agents: CGRP Antagonists Oral Agents Subclass—atogepant (Qulipta)*
 - *Gastrointestinal-2 Agents: CIC/IBS-C—linaclotide (Linzess)*
 - *CGM: Therapeutic Continuous Glucose Monitoring Systems—Freestyle Libre 2 and 3*
 - *Atopy Agents: Oral Janus Kinase Inhibitor (JAK-1)—upadacitinib (Rinvoq)*
 - *Oncological Agents: Ovarian Cancer—olaparib (Lynparza)*
 - *Oncological Agents—dabrafenib (Tafinlar) and trametinib (Mekinist)*
 - *Oncological Agents—avapritinib (Ayvakit)*
 - *Targeted Immunomodulatory Biologics (TIBs)—sarilumab (Kevzara)*
- **Prior Authorization Criteria—Updated PA Criteria for Reasons Other Than New Indications**
 - *Neurological Agents Miscellaneous—risdiplam (Evrysdi)*
 - *Hematological Agents—avacopan (Tavneos)*
 - *Targeted Immunomodulatory Biologics: Tumor Necrosis Factor Inhibitors—adalimumab (Humira)*

- **Brand Over Generic PA Authorization and Tier 1 Copay**
 - *dabigatran (Pradaxa) Capsules*
- **Completely Excluded Drugs: Annual Review**
- **Drugs Subject to Section 703 National Defense Authorization Act (NDAA) for Fiscal Year 2008**
 - *tidezolid (Sivextro)*
 - *lefamulin (Xenleta)*

➤ **Panel Discussions**

The Uniform Formulary 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.

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

**INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL MEETING SEPTEMBER 27, 2023**

I. UNIFORM FORMULARY REVIEW PROCESS

Under 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 complete exclusion status are received from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director or their designee before making a final decision.

II. UF DRUG CLASS REVIEWS—LUTEINIZING HORMONE-RELEASING HORMONE (LHRH) AGONISTS-ANTAGONISTS—PROSTATE CANCER, ENDOMETRIOSIS AND FIBROIDS, AND CENTRAL PRECOCIOUS PUBERTY SUBCLASSES

P&T Comments

A. Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists—Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty Subclasses—Relative Clinical Effectiveness Conclusion

The P&T Committee evaluated the relative clinical effectiveness of the Luteinizing Hormone-Releasing Hormone (LHRH) Agonist-Antagonists. The class has three subclasses organized by labeled indications: Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty.

There are a total of 12 products in the class, however several contain the same active ingredient, leuprolide acetate. The drugs are administered via intramuscular (IM) injection, subcutaneous (SC) injection, or orally. The IM depot injections have a variety of long-acting formulations, ranging from 1 month to 6 months duration of action.

The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 0 absent) the following:

Prostate Cancer

Products

- The prostate cancer drugs are comprised of LHRH agonists and LHRH antagonists. For the agonists, there are three leuprolide acetate products available in different formulations: Lupron Depot IM, leuprolide acetate IM (no brand name), and Eligard SC. Leuprolide mesylate (Camcevi IM) has a different

salt form. The two LHRH antagonists are degarelix SC (Firmagon) and relugolix tablets (Orgovyx).

Clinical Practice Guidelines

- Current National Comprehensive Cancer Network (NCCN) guidelines for advanced hormone sensitive prostate cancer recommend androgen deprivation therapy (ADT) with either an LHRH agonist, LHRH antagonist, or surgical orchiectomy to achieve castration levels of testosterone (defined as <50 ng/dL). LHRH agonists have an initial testosterone flare prior to reaching castration levels, while LHRH antagonists and surgical orchiectomy as monotherapy have rapid onset of action and avoid the testosterone flare.
- Between the available LHRH antagonists and LHRH agonists, the guidelines do not recommend one product over another. The treatments are considered equivalent in cancer control, although they have not been compared in large randomized controlled trials.

Efficacy

- There are limited direct comparative studies evaluating the effectiveness between leuprolide agents and between leuprolide agents and the LHRH antagonists, oral relugolix (Orgovyx) and SC degarelix (Firmagon). Indirect comparison of efficacy data from the individual pivotal trials reveals similar rates of achieving testosterone castration levels between these products.
 - The LHRH agonists (Lupron Depot, Eligard, and Camcevi) take approximately 3-4 weeks to reach castration levels of testosterone regardless of administration route and salt form, while the LHRH antagonists (Firmagon and Orgovyx) show reduced testosterone levels in as early as 3 days.
 - Orgovyx was compared to leuprolide acetate 22.5 mg in the open-label HERO trial, which was used to obtain FDA approval. Treatment with Orgovyx for 48 weeks maintained testosterone castration levels in 96.7% of men, compared to 88.8% of men who received leuprolide. The FDA review of the HERO trial however, did not accept the non-inferiority comparison of castration rate between Orgovyx and leuprolide, and as such stated no claims of superiority could be made between the two products.
 - Firmagon was compared with leuprolide acetate 7.5 mg in the clinical trial used to gain FDA approval. Treatment with Firmagon resulted in sustained testosterone castration levels in 97.2% of men, compared with 96.4% of men receiving leuprolide.

Safety

- Products in this subclass have similar adverse reactions that are related to the reduced testosterone levels. Commonly reported adverse effects include hot

flashes, injection site reactions, gastrointestinal (GI) symptoms, and testicular atrophy.

- The LHRH agonists (Lupron Depot, Eligard, and Camcevi) carry similar warnings of tumor flare, hyperglycemia, diabetes, and cardiovascular disease.
- The LHRH antagonists (Firmagon and Orgovyx) have similar warnings. In contrast to the LHRH agonists, cardiovascular disease is not listed as a warning with the antagonists.
- There is conflicting evidence, but expert consensus that men with preexisting cardiovascular disease are at an increased risk of cardiovascular toxic effects when treated with androgen deprivation therapy (ADT). There is limited and conflicting data that LHRH antagonists may have a lesser effect on cardiovascular disease compared to LHRH agonists in patients treated with ADT.
 - In the HERO trial, Orgovyx demonstrated reduced major adverse cardiovascular events (MACE) compared to leuprolide. The MACE definition was very broad, and included nonfatal myocardial infarction, nonfatal stroke, and death due to any cause. The FDA reviewers did not agree that the HERO study demonstrated an improved cardiac safety profile with Orgovyx compared to leuprolide.
 - More data is needed to determine the full cardiovascular risk profile of Orgovyx.

Individual Product Characteristics

- LHRH agonists
 - **leuprolide acetate (Lupron Depot 7.5mg, 22.5mg, 30mg, 45mg) leuprolide acetate depot (no brand name), leuprolide acetate (Eligard), leuprolide mesylate (Camcevi)**: There is guideline and expert consensus that clinically, these products are generally considered equivalent. There is no data to suggest differences in efficacy or safety with the different leuprolide salt formulations, leuprolide acetate (Lupron) vs. leuprolide mesylate (Camcevi).
 - **leuprolide acetate (Eligard)** is administered SC, while Lupron Depot, leuprolide acetate depot, and Camcevi are administered IM. Eligard and Camcevi require refrigeration, while the other products are stable at room temperature.
- LHRH antagonists
 - **Relugolix (Orgovyx)** provides convenience to the patient, as it is the only oral product, however data are limited on long-term patient compliance. Orgovyx has a relatively short half-life of 61 hours compared to Firmagon. Military Health System (MHS) provider

feedback supports Orgovyx as an option for short course ADT therapy. The full cardiovascular risk profile remains to be determined.

- **degarelix (Firmagon)** is administered SC and has a much longer half-life of 53 days compared to Orgovyx. There are no studies directly comparing Firmagon with Orgovyx.

Endometriosis and Fibroids

Products

- Injectable leuprolide acetate (Lupron Depot) and three oral tablet formulations of elagolix or relugolix combined with an oral contraceptive (Oriahnn or Myfembree, respectively) or elagolix alone (Orilissa) comprise the endometriosis and fibroid products.

Clinical Practice Guidelines

- *Endometriosis*: The European society of Human Reproduction and Embryology (ESHRE) 2020 updated guidelines for endometriosis recommend offering hormone treatment for endometriosis-related pain. First-line therapies include combined (estrogen and progestin) oral contraceptive tablets, given with or without nonsteroidal anti-inflammatory drugs (NSAIDs). Second-line therapies include progestins, LHRH agonists, LHRH antagonists, and androgens, due to the side effect profiles. No one LHRH agonist product is preferred over another agonist, and likewise no one LHRH antagonist product is preferred over another antagonist.
- *Uterine fibroids*: The 2022 American College of Obstetrics and Gynecology Practice Bulletin for treatment of symptomatic leiomyomas (fibroids) states there is insufficient comparative evidence to guide recommendations on first-line medical management options; treatment should be guided by symptoms. To address symptoms of heavy bleeding, options include LHRH antagonists, levonorgestrel intrauterine devices (e.g., Mirena), combined oral contraceptives and tranexamic acid. To address fibroid size and bleeding symptoms, options include LHRH agonists and selective progesterone receptor modulators (e.g., ulipristal).

Efficacy

- *Endometriosis*: No significant published trials directly comparing available agents for treatment of endometriosis-related pain were found. A 2020 Network Meta Analysis evaluating medication options found that the LHRH analogues, and elagolix were not superior to combined hormonal contraceptives. Additionally similar efficacy was seen between LHRH agonists and elagolix.
- *Fibroids*: There are no trials directly comparing available medical therapies for treatment of symptomatic fibroids. Indirect comparisons of Lupron Depot,

Myfembree, and Oriahnn show that all three drugs met the primary endpoint of achieving a greater than 2 g/dL increase in hemoglobin compared to baseline.

Safety

- Products in this subclass have similar adverse reaction profiles and are mostly related to the hypoestrogenic state. Hot flashes, headaches, mood changes and changes in vaginal bleeding pattern are common side effects with all the products. All products carry the risk of bone mineral density loss. Elevated liver enzymes are listed as a warning for Myfembree, Oriahnn, and Orilissa.
- Myfembree and Oriahnn carry a black box warning for thromboembolic events, due to the estrogen and progesterone components.

Individual Product Characteristics

- LHRH agonists
 - **leuprolide acetate 3.75 mg and 11.25 mg IM (Lupron Depot)** advantages include its long marketing history and that it is the only LHRH agonist indicated for both medical management of endometriosis-related pain and symptomatic fibroids. It should be used with hormonal add-back therapy (e.g., with an estrogen and progestin). Treatment should not exceed 12 months of therapy due to concerns of bone mineral density loss.
- LHRH antagonists
 - **relugolix/estradiol/norethindrone acetate (Myfembree)** is combined with estrogen and progesterone. Advantages include that it is indicated for both treatment of endometriosis-related pain and symptomatic fibroids, and once daily dosing. Disadvantages include the black box warning for thromboembolic disease. Additionally, use is limited to 24 months due to the risk of continued bone mineral density loss which may not be reversible.
 - **elagolix/estradiol/norethindrone acetate (Oriahnn)** is combined with estrogen and progesterone solely indicated for treatment of heavy bleeding associated with fibroids. It carries a black box warning for thromboembolic disease as well as the unique warning of yellow dye. It is dosed twice daily, with the AM dose containing elagolix/estradiol/norethindrone while the PM dose contains only elagolix. Its use is limited to 24 months due to the risk of continued bone mineral density loss which may not be reversible.
 - **elagolix (Orilissa)** is indicated for treatment of endometriosis related pain. It is dosed either daily or twice daily based on

coexisting conditions. Its duration of use is also limited due to coexisting conditions and risk of bone mineral density loss.

Central Precocious Puberty

Products

- This subclass is composed of two leuprolide acetate products; one is administered IM (Lupron Depot Ped), and one is administered SC (Fensolvi).

Guidelines

- The American Academy of Pediatrics recommends LHRH agonists to treat Central Precocious Puberty. Guidelines do not prefer one product over, although it is common to start a patient on a 1- or 3-month depot formulation.

Efficacy

- No significant published trials were found that directly compare Lupron Depot Ped with Fensolvi. These products are considered similarly efficacious, based on indirect comparison of the clinical trial endpoints used to gain FDA approval.

Safety

- Products in this subclass have similar adverse reactions and commonly include injection site reactions and pain. Fensolvi alone carries the adverse reaction of bronchospasm.

Individual Product Characteristics

- **leuprolide acetate (Lupron Depot Ped)** is an LHRH agonist available in multiple strengths, with dosing for 1-month, 3-months, and 6-months. The 6-month formulation was recently approved in April 2023. It is approved for children as young as 1 year.
- **leuprolide acetate (Fensolvi)** is administered SC and is available in one strength for a 6-month injection. It requires healthcare provider administration. FDA approval is in children down to the age of 2 years.

Overall Clinical Conclusion

- In order to meet the needs of MHS patients, a variety of agents are required to treat all indications of advanced prostate cancer, endometriosis, fibroids, and central precocious puberty.

B. Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists—Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty Subclasses—Relative Cost-Effectiveness Conclusion

A cost minimization analysis (CMA), budget impact analysis (BIA) and sensitivity analysis were performed. The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that within the Prostate Cancer subclass, leuprolide acetate SC (Eligard) is the most cost-effective agent; within the Endometriosis and Fibroids subclass, relugolix/estradiol/norethindrone (Myfembree) is the most cost-effective agent and within the Central Precocious Puberty subclass, leuprolide acetate (Fensolvi-Ped) is the most cost-effective agent.
- Budget Impact Analysis (BIA) was performed to evaluate the potential impact of designating the LHRH agents as UF, NF, or completely excluded from the formulary. BIA results showed that designating agents in accordance with the formulary recommendation listed below demonstrated significant cost avoidance to the MHS.

C. Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists—Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty Subclasses—UF Recommendation

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following. Note that the formulary recommendations do not apply to inpatient, or in-clinic uses.

Prostate Cancer Subclass

- UF and step-preferred
 - leuprolide acetate SC 7.5 mg (1 month), 22.5 mg (3 month), 30 mg (4 month), 45 mg (6 month) (Eligard)
 - degarelix SC 80 mg, 120 mg (Firmagon)
- UF and non-step-preferred
 - leuprolide acetate IM 7.5 mg (1 month), 22.5 mg (3 month), 30 mg (4 month), 45 mg (6 month) (Lupron Depot)
 - leuprolide acetate depot IM 22.5 mg vial (no brand name)
 - leuprolide mesylate IM 42 mg (6 month) (Camcevi) – *moves from NF to UF*
 - relugolix tabs 120 mg (Orgovyx) – *moves from NF to UF*
 - Note that as part of this recommendation a trial of Eligard SC is required before Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg, leuprolide acetate (no brand name) 22.5 mg and Camcevi 42 mg
 - Note that as part of this recommendation a trial of Eligard SC or Firmagon SC is required before Orgovyx tablets.
- NF
 - None
- Complete exclusion

- None

Endometriosis and Fibroids Subclass

- UF
 - leuprolide acetate IM 3.7 mg (1 month), 11.25 mg (3 month) (Lupron Depot)
 - elagolix/estradiol/norethindrone 300 mg/1 mg/0.5 mg tabs (Oriahnn)
 - relugolix/estradiol/norethindrone 40 mg/1 mg/0.5 mg tabs (Myfembree)
- NF
 - elagolix 150 mg, 200 mg tabs (Orilissa)
- Complete exclusion
 - None

Central Precocious Puberty Subclass

- UF
 - leuprolide acetate IM 7.5 mg (1 month) 11.25 mg (1 month), 15 mg (3 month), 30 mg (4 month), 45 mg (6 month) (Lupron Depot-Ped)
 - leuprolide acetate SQ 45 mg (6 month) (Fensolvi-Ped) – *moves from NF to UF*
- NF
 - None
- Complete exclusion
 - None

D. Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists—Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty Subclasses—Manual PA Criteria

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following PA criteria for new users.

Prostate Cancer Subclass: Eligard and Firmagon do not require PA. New PA criteria were recommended for Lupron Depot formulations used for prostate cancer (7.5 mg, 22.5 mg, 30 mg, and 45 mg) and leuprolide acetate IM in new users, requiring a trial of Eligard first, unless the patient has tried and failed or cannot tolerate Eligard. The current PA criteria for Camcevi was updated, to require Eligard first, unless the patient had tried and failed or has a contraindication to Eligard.

For Orgovyx tablets, the current PA criteria were updated to require a trial of Eligard or Firmagon in new users. Orgovyx will also be allowed in patients receiving short-term androgen deprivation therapy (ADT). Additionally, patients with significant cardiovascular risk can receive Orgovyx.

Endometriosis and Fibroids Subclass: No changes were made to the current PA criteria for Oriahnn, Myfembree or Orilissa; PA is not required for Lupron Depot IM 3.7 mg and 11.25 mg. The current PA criteria can be found on the TRICARE Formulary Search Tool.

Central Precocious Puberty Subclass: PA criteria is not required for Lupron Depot-Ped or Fensolvi-Ped SC.

The Manual PA criteria is as follows:

1. leuprolide acetate (Lupron Depot) IM 7.5 mg (1 month), 22.5 mg (3 month), 30 mg (4 month), 45 mg (6 month) and leuprolide acetate IM 22.5 mg vial (no brand name)

Manual PA criteria apply to all new users of Lupron Depot and leuprolide acetate (no brand name)

Manual PA criteria: Coverage is approved if all criteria are met:

- Provider is aware leuprolide acetate SC (Eligard) is the preferred leuprolide product and does not require PA
- Patient has tried and failed or has not been able to tolerate Eligard

PA does not expire

2. leuprolide mesylate SC 42 mg (6 month) injection (Camcevi Kit)

Updates from the August 2023 meeting are in **bold and strikethrough**

Manual PA criteria apply to all new users of Camcevi.

Manual PA criteria: Coverage is approved if all criteria are met:

- ~~Patient is 18 years of age or older~~
- ~~Drug is prescribed by or in consultation with an oncologist or urologist~~
- ~~Patient has a diagnosis of advanced prostate cancer~~
- The provider is aware that **leuprolide acetate SC (Eligard)** is the preferred leuprolide product and does not require a PA
- Patient has tried and failed or has not been able to tolerate Eligard **Patient has intolerability to, or has failed alternative formulary leuprolide injections (i.e., Lupron Depot, Eligard)**

~~Non-FDA approved uses are NOT approved~~

PA does not expire

3. relugolix tablets (Orgovyx)

Updates from the August 2023 meeting are in **bold and strikethrough**

Manual PA criteria apply to all new users of Orgovyx

Manual PA criteria: Coverage is approved if all criteria are met:

- The provider is aware and acknowledges that ~~leuprolide acetate IM (Lupron Depot)~~, **leuprolide acetate SC (Eligard)**, and **degarelix SC (Firmagon)** are available to DoD beneficiaries without requiring prior authorization
- Patient is 18 years of age or older
- Orgovyx is prescribed by or in consultation with an oncologist or urologist
- Patient has a diagnosis of advanced prostate cancer
- Patient has tried and failed **or is unable to use injectable leuprolide formulation (i.e., subcutaneous injection or implant)-leuprolide acetate SC (Eligard) or degarelix SC (Firmagon) OR**
- **The patient has significant cardiovascular risk factors as determined by their oncologist OR**
- **The patient is prescribed short-term androgen deprivation therapy (ADT)**

Non-FDA approved uses are NOT approved including cancers other than prostate cancer, and in women for endometrial thinning, endometriosis, and uterine leiomyomata (fibroids)

PA does not expire

E. Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonist—Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty Subclasses—Tier 1 Copay for SC Eligard and SC Fensolvi-ped

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) lowering the current Tier 2 copay to the Tier 1 (generic) copay for Eligard and Fensolvi-Ped, per 32 CFR 199.21(e)(3)(iii). Having Eligard and Fensolvi-Ped at the Tier 1 copay will provide a greater incentive for beneficiaries to use the most cost-effective prostate cancer and central precocious puberty drugs in the purchased care points of service.

F. Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonist—Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty Subclasses—UF, PA, Tier 1 Copay, and Implementation Period

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service.

X. UF DRUG CLASS REVIEWS—LUTEINIZING HORMONE-RELEASING HORMONE (LHRH) AGONISTS-ANTAGONISTS—PROSTATE CANCER, ENDOMETRIOSIS AND FIBROIDS, AND CENTRAL PRECOCIOUS PUBERTY SUBCLASSES

BAP Comments

A. Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists—Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty Subclasses—UF Recommendation

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

Prostate Cancer Subclass

- UF and step-preferred
 - Eligard SC
 - Firmagon SC
- UF and non-step-preferred
 - Lupron Depot
 - leuprolide acetate depot IM 22.5 mg vial (no brand name)
 - Camcevi – *moves from NF to UF*
 - Orgovyx – *moves from NF to UF*
 - Note that as part of this recommendation a trial of Eligard SC is required before Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg, leuprolide acetate (no brand name) 22.5 mg and Camcevi 42 mg
 - Note that as part of this recommendation a trial of Eligard SC or Firmagon SC is required before Orgovyx tablets.
- NF
 - None
- Complete exclusion
 - None

Endometriosis and Fibroids Subclass

- UF
 - Lupron Depot
 - Oriahnn
 - Myfembree

- NF
 - Orilissa
- Complete exclusion
 - None

Central Precocious Puberty Subclass

- UF
 - Lupron Depot-Ped
 - Fensolvi-Ped – *moves from NF to UF*
- NF
 - None
- Complete exclusion
 - None

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists—Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty Subclasses—Manual PA Criteria

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

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists—Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty Subclasses — Tier 1 (generic) Copay for Eligard SC and Fensolvi-Ped SC

The P&T Committee recommended lowering the current Tier 2 copay to the Tier 1 (generic) copay for Eligard and Fensolvi-Ped, as discussed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

D. Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists—Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty Subclasses—UF, PA, Tier 1 Copay and Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday 30 days after signing of the minutes in all points of service.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XI. UF DRUG CLASS REVIEWS—WHITE BLOOD CELL STIMULANTS—FILGRASTIMS AND PEGFILGRASTIMS

P&T Comments

A. White Blood Cell Stimulants—Filgrastims and Pegfilgrastims—Relative Clinical Effectiveness Analysis and Conclusion

The P&T Committee evaluated the relative clinical effectiveness of the White Blood Cell Stimulants (WBC) drug class, which is comprised of the filgrastims and pegfilgrastims. The class was last reviewed for formulary status at the August 2020 P&T Committee meeting, since then four new entrants were reviewed as newly approved drugs.

The drugs in the WBC stimulants class include the original products and several biosimilars. The FDA definition of a biosimilar is a biological product that is approved based on data demonstrating it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product.

The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- The clinical conclusions from the August 2020 class review remain unchanged.
- There are now five FDA-approved filgrastims (Neupogen, Zarxio, Granix, Nivestym, and Releuko) and seven pegfilgrastims (Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, Fylnetra, and Stimufend). Both the filgrastim and pegfilgrastim subclasses are made up of a reference biologic (Neupogen, Neulasta) and multiple biosimilars.

Efficacy

- Per the definition of biosimilars, there are no clinically meaningful differences between the reference drug product and biosimilar, allowing for a high degree of therapeutic interchangeability. The 2023 NCCN Hematopoietic Growth Factors guidelines state that an FDA-approved biosimilar is an appropriate substitute for filgrastim and pegfilgrastim.

Safety

- Bone pain and pain in the extremities are commonly reported adverse reactions which are more commonly seen with the pegfilgrastims compared to the filgrastims.
- The filgrastim and pegfilgrastim products have a low potential for immunogenicity.

Other Factors

- All drugs in the subclasses are available as syringes; in addition, Neupogen, Granix, Nivestym, and Releuko are available as vials, and Udenyca is available as an auto-injector. Neulasta is the only product available as an on-body injector (OnPro device).
- Patients with a latex allergy cannot use syringes made with rubber (Neupogen, Zarxio, Neulasta, Neulasta OnPro, Ziextenzo, and Stimufend).

Individual Product Characteristics

Filgrastims

- **filgrastim (Neupogen)** is the reference biologic for the filgrastims. Advantages include availability in both a syringe and vial, and approval for both SC and IV administration. One disadvantage is that the syringe (but not the vial) contains latex, which is a concern in patients with latex allergy.
- **tbo-filgrastim (Granix)** is a follow-on biologic to Neupogen, which means it was approved via a different pathway than the biosimilars. Granix is available in both syringes and vials, which do not contain latex. Both formulations are only approved for SC administration.
- **filgrastim-sndz (Zarxio)** disadvantages include that it is only available in a syringe, which contains latex, and that volumes smaller than 0.3 mL cannot be accurately measured due to limitations of the measuring units in the syringe.
- **filgrastim-aafi (Nivestym)** advantages include availability in both a syringe and vial, that it does not contain latex and can be administered by both SC and IV routes.
- **filgrastim-ayow (Releuko)** advantages include availability in both a syringe and vial, that it does not contain latex and can be administered by both SC and IV routes.

Pegfilgrastims

- **pegfilgrastim (Neulasta)** is the reference biologic for the pegfilgrastims. In addition to the syringe, it also comes in an on-body injector (Neulasta OnPro) which allows for delayed administration 27 hours after application. This provides a

convenience for patients who cannot self-inject at home. Both formulations contain latex.

- **pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), and pegfilgrastim-apgf (Nyvepria)** are available as syringes that do not contain latex.
- **pegfilgrastim-cbqv (Udenyca)** does not contain latex and is available in a syringe and an auto-injector.
- **pegfilgrastim-bmez (Ziextenzo) and pegfilgrastim-fpgk (Stimufend)** have latex in the syringe.

Overall Clinical Conclusion

- According to FDA guidance, providers can interchange biosimilars at the time of prescribing, but the FDA requires further data for substitution by other than the prescriber (e.g., a pharmacist cannot substitute products at the pharmacy window). However, overall, there is a very high degree of interchangeability within the filgrastims subclass, and within the pegfilgrastims subclass.
- The overall choice for prescribing a particular filgrastim or pegfilgrastim should be based on the patient's chemotherapy regimen (e.g., cycle frequency and the risk for causing febrile neutropenia), convenience, and cost.

B. White Blood Cell Stimulants—Filgrastims and Pegfilgrastims—Relative Cost-Effectiveness Analysis and Conclusion

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

Filgrastims

- CMA results showed that tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), filgrastim-sndz (Zarxio), filgrastim (Neupogen), and filgrastim-ayow (Releuko) 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 filgrastims in accordance with the formulary recommendation below demonstrated significant cost avoidance to the MHS.

Pegfilgrastims

- CMA results showed that pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim (Neulasta and Neulasta OnPro), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo) 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 pegfilgrastims in accordance with the formulary recommendation below demonstrated significant cost avoidance to the MHS.

C. White Blood Cell Stimulants—Filgrastims and Pegfilgrastims—UF Recommendation

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following. Note that the formulary recommendations do not apply to inpatient, or in-clinic uses.

Filgrastims

- UF and step-preferred
 - tbo-filgrastim vial and syringe (Granix)
 - filgrastim-aafi vial and syringe (Nivestym)
 - filgrastim-sndz syringe (Zarxio)-*moves from UF and non-step-preferred to UF step-preferred*
- NF and non-step-preferred
 - filgrastim syringe and vial (Neupogen)-*moves from UF and non-step-preferred to NF and non-step-preferred*
 - filgrastim-ayow syringe and vial (Releuko)-*moves from UF and non-step-preferred to NF and non-step-preferred*
 - Note that as part of this recommendation a trial of Granix, Nivestym and Zarxio are required before Neupogen or Releuko.
- Complete exclusion
 - None

Pegfilgrastims

- UF and step-preferred
 - pegfilgrastim-jmdb syringe (Fulphila)
 - pegfilgrastim-pbbk syringe (Fylnetra)-*moves from UF and non-step-preferred to UF step-preferred*
 - pegfilgrastim-apgf syringe (Nyvepria)
 - pegfilgrastim-fpgk syringe (Stimufend)-*moves from UF and non-step-preferred to UF step-preferred*
 - pegfilgrastim-cbqv syringe and auto-injector (Udenyca)
 - pegfilgrastim-bmez syringe (Ziextenzo)-*moves from UF and non-step-preferred to UF step-preferred*

- NF and non-step-preferred
 - pegfilgrastim syringe (Neulasta)-*moves from UF non-step-preferred to NF non-step-preferred*
 - pegfilgrastim on-body injector (Neulasta OnPro)-*moves from UF non-step-preferred to NF non-step-preferred*
 - Note that as part of this recommendation a trial of Udenyca, Fulphila, Ziextenzo, Nyvepria, Flyneta, and Stimufend is required before Neulasta and Neulasta OnPro.
- Complete exclusion
 - None

D. White Blood Cell Stimulants—Filgrastims and Pegfilgrastims—Manual PA Criteria

PA criteria has been in place for the non-step-preferred products since the original class review in 2020.

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for the non-step-preferred WBC stimulants, requiring the step-preferred products first, unless the patient has had an inadequate response or could not tolerate the preferred WBC stimulants. For new users of Neupogen and Releuko, a trial of Granix, Nivestym, and Zarxio is required. New users of Neulasta, Neulasta OnPro, are required to try Fulphila, Flyneta, Nyvepria, and Stimufend, Udenyca, and Ziextenzo first. Patients requiring a pegfilgrastim who cannot self-inject will be able to receive Neulasta OnPro. Note that as part of changes in the step-preferred drugs, the existing PAs for Zarxio, Flyneta, Stimufend and Ziextenzo.

The Manual PA criteria is as follows:

1. filgrastim (Neupogen) and filgrastim-avow (Releuko)

Manual PA criteria apply to all new users of filgrastim (Neupogen) and filgrastim-avow (Releuko)

Note that Granix and Nivestym are available at the Tier 1 copay at the Mail Order and Retail Network pharmacies.

Manual PA Criteria: Coverage will be approved if:

- Provider acknowledges that tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), and filgrastim-sndz (Zarxio) are the preferred filgrastims and are available without a PA
- Drug is prescribed by or in consultation with a hematologist/oncologist
- Patient has experienced an inadequate treatment response or intolerance to tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), and filgrastim-sndz

(Zarxio) and is expected to respond to filgrastim (Neupogen) or filgrastim-ayow (Releuko)

PA does not expire

2. pegfilgrastim (Neulasta) and pegfilgrastim (Neulasta OnPro)

Manual PA criteria apply to all new users of pegfilgrastim (Neulasta) and pegfilgrastim (Neulasta OnPro)

Note that Stimufend is available at the Tier 1 copay at the Mail Order and Retail Network pharmacies.

Manual PA criteria: Coverage is approved if all criteria are met:

- Provider acknowledges that pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo) are the preferred pegfilgrastims and are available without a PA
- Drug is prescribed by or in consultation with a hematologist/oncologist
- Patient requires use of an on-body injector (Neulasta OnPro) because the patient/caregiver cannot self-inject and/or cannot reasonably attend multiple visits to the clinic for administration OR
- Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo) and is expected to respond to pegfilgrastim (Neulasta)

PA does not expire

E. White Blood Cell Stimulants—Filgrastims and Pegfilgrastims—Tier 1 Copay

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) lowering the current Tier 2 copay to the Tier 1 (generic) copay for Nivestym (both syringe and vial) and Stimufend, maintaining the Tier 1 copay for Granix (both syringe and vial) and moving Nyvepria and Udenyca (both syringe and auto-injector) back to the Tier 2 copay, per 32 CFR 199.21(e)(3)(iii). Having Granix, Nivestym, and Stimufend available at the Tier 1 copay will provide a greater incentive for beneficiaries to use the most cost-effective WBC stimulant for the filgrastims and pegfilgrastims, in the purchased care points of service.

F. White Blood Cell Stimulants—Filgrastims and Pegfilgrastims—Safety Net/Rapid Response Program

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) adding the non-step-preferred filgrastims (Neupogen and Releuko) and pegfilgrastims (Neulasta and Neulasta Onpro) to the Safety Net/Rapid Response Program managed by ESI. The program targets beneficiaries who have not received a prescription fill for either a step-preferred or non-step-preferred drug, after the initial reject.

G. White Blood Cell Stimulants—Filgrastims and Pegfilgrastims—UF, PA, Tier 1 Copay and Rapid Response Program Implementation

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday 90 days after signing of the minutes in all points of service; 2) DHA send letters to patients affected by the NF, non-step-preferred recommendation (Neupogen, Releuko, Neulasta, Neulasta OnPro), and 3) DHA send letters to those patients affected by the products returning to Tier 2 status from Tier 1 status (Udenyca syringe and auto-injector and Nyvepria).

XII. UF DRUG CLASS REVIEWS—WHITE BLOOD CELL STIMULANTS—FILGRASTIMS AND PEGFILGRASTIMS

BAP Comments

A. White Blood Cell Stimulants—Filgrastims and Pegfilgrastims—UF Recommendation

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following.

Filgrastims

- UF and step-preferred
 - Granix
 - Nivestym
 - Zarxio
- NF and non-step-preferred
 - Neupogen
 - Releuko
 - Note that as part of this recommendation a trial of Granix, Nivestym and Zarxio are required before Neupogen or Releuko.
- Complete exclusion
 - None

Pegfilgrastims

- UF and step-preferred

- Fulphila
- Fylnetra
- Nyvepria
- Stimufend
- Udenyca
- Ziextenzo
- NF and non-step-preferred
 - Neulasta
 - Neulasta OnPro
 - Note that as part of this recommendation a trial of Udenyca, Fulphila, Ziextenzo, Nyvepria, Fylnetra, and Stimufend is required before Neulasta and Neulasta OnPro
- Complete exclusion
 - None

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. White Blood Cell Stimulants—Filgrastims and Pegfilgrastims—Manual Prior Authorization Criteria

The P&T Committee recommended Manual PA criteria for filgrastims and pegfilgrastims as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. White Blood Cell Stimulants—Filgrastims and Pegfilgrastims—Tier 1 Cost-Share

The P&T Committee recommended the Tier 1 (generic) Copay for Nivestym,

Stimufend, and Granix, and the Tier 2 Copay for Nyvepria and Udenyca

BAP Comments

Concur: Non-Concur: Abstain: Absent:

D. White Blood Cell Stimulants—Filgrastims and Pegfilgrastims—Safety Net/Rapid Response Program

The P&T Committee adding Neupogen, Releuko, Neulasta and Neulasta Onpro to the Safety Net/Rapid Response Program managed by ESI.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

E. White Blood Cell Stimulants—Filgrastims and Pegfilgrastims—UF, PA, Tier 1 Copay, Safety Net/Rapid Response Program and Implementation Period

The P&T Committee recommended the implementation plan of 60 days for all the drugs as described above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

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

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

- UF
 - atropine sulfate 1% ophthalmic solution – Ophthalmic Miscellaneous: Mydriatics
 - deutetrabenazine extended-release tabs (Austedo XR) – Neurological Agents Miscellaneous: Movement Disorders
 - fecal microbiota spores, live-brpk capsules (Vowst) – Gastrointestinal-2 Agents Miscellaneous
 - fezolinetant (Veozah) – Gynecological Agents Miscellaneous
 - leniolisib (Joenja) – Immunological Agents Miscellaneous
 - omaveloxolone (Skyclarys) – Neurological Agents Miscellaneous
- NF
 - perfluorohexyloctane 1.338 g/mL ophthalmic solution (Miebo) – Ophthalmic: Dry Eye Agents
 - sodium oxybate extended-release packets for oral suspension (Lumryz) – Sleep Disorders: Wakefulness Promoting Agents
 - somapacitan-beco injection (Sogroya) – Growth Stimulating Agents
 - sotagliflozin (Inpefa) – Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors
 - zavegepant nasal spray (Zavzpret) – Migraine Agents
- Complete Exclusion
 - sildenafil 10 mg/mL oral suspension (Liqrev)– Pulmonary Arterial Hypertension (PAH): PDE 5 Inhibitor
 - Liqrev was recommended for complete exclusion as it has little to no clinical benefit relative to other PDE-5 inhibitors for PAH, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include sildenafil tablets, sildenafil 10 mg/mL oral suspension (generic Revatio), and tadalafil oral suspension (Tadliq).
 - trientine tetrahydrochloride tablets (Cuvrior) – Binder-Chelators-Antidotes-Overdose
 - Cuvrior was recommended for complete exclusion as it has little to no clinical benefit relative to other chelators for Wilson’s disease, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include trientine hydrochloride capsules and penicillamine.

- zolpidem tartrate 7.5 mg capsules–Sleep Disorders: Insomnia
 - Zolpidem tartrate 7.5 mg capsules were recommended for complete exclusion as they have little to no clinical benefit relative to other insomnia drugs, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include zolpidem IR 5 mg and 10 mg tabs, zolpidem ER 6.5 and 12.5 mg tabs, and zaleplon.

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

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

- Applying manual PA criteria to new users of Austedo XR, Joenja, Lumryz, Miebo, Skyclarys, Sogroya, Veozah, Vowst, and Zavzpret.
- Applying manual PA criteria to Inpefa, similar to what is in place for the other non-step-preferred SGLT2 Inhibitors. New patients receiving Inpefa or one of the other non-step-preferred SGLT2 Inhibitors (Farxiga, Invokana, Steglatro) will be required to have a trial of Jardiance first.
- Applying interim manual PA criteria for Liqrev, Cuvrior, and zolpidem tartrate 7.5 mg capsules prior to the complete exclusion implementation, in order to minimize the impact on beneficiaries.

The Manual PA criteria is as follows:

1. deutetrabenazine extended-release tabs (Austedo XR)

Manual PA criteria apply to all new users of Austedo XR

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: monoamine oxidase inhibitors (MAOIs) within the past 14 days, reserpine, CYP3A4 inducers, or another VMAT2 inhibitor (e.g., tetrabenazine, valbenazine)

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 XR.

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: 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

2. fecal microbiota spores, live -brpk capsules (Vowst)

Manual PA criteria apply to all new users of fecal microbiota spores, live-brpk (Vowst)

Manual PA criteria: Coverage is approved if all criteria are met:

- Patient is 18 years of age or older

- Patient has had 3 or more episodes of *Clostridioides difficile* infection within the last 12 months that is refractory to standard antibiotic therapy
- Patient's current episode of *Clostridioides difficile* infection must be controlled following 10 to 21 days of antibiotic therapy
- Patient had a positive stool test for *Clostridioides difficile* within 30 days
- Patient will start therapy within 2 to 4 days following completion of an antibiotic course for *Clostridioides difficile* treatment
- Patient will undergo bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution on the day before the first dose of Vowst

Non-FDA approved uses are NOT approved

PA expires after each fill (new PA required for each treatment course)

3. fezolinetant (Veoza)

Manual PA criteria apply to all new users of fezolinetant (Veoza)

Manual PA criteria: Coverage is approved if all criteria are met:

- Patient has moderate to severe vasomotor symptoms due to menopause
- Patient has a contraindication to menopausal hormone therapy (estrogens with or without progestins) OR
- Patient has an intolerance to menopausal hormone therapy OR
- Based on individual patient characteristics and risk factors, the provider has determined that the patient is not a candidate for menopausal hormone therapy
- Patient has tried and failed or had an adverse reaction to at least one of the following non-hormonal treatments for vasomotor symptoms
 - an SSRI (i.e., paroxetine, escitalopram, or citalopram)
 - an SNRI (i.e., venlafaxine, desvenlafaxine, or duloxetine)
 - gabapentin
- Patient does not have severe renal impairment (eGFR of 15 to 30 mL/min/1.73m²) or end-stage renal disease (eGFR less than 15 mL/min/1.73m²)
- Patient does not have cirrhosis

- Provider acknowledges that patient’s baseline hepatic function will be evaluated via bloodwork prior to therapy, at 3 months, at 6 months, at 9 months and when symptoms suggest hepatic injury

Non-FDA approved uses are NOT approved
PA expires after 6 months

Renewal Criteria: Coverage will be approved indefinitely if the following applies:

- Patient has had a positive response to therapy as noted by a decrease in the number of moderate to severe hot flashes

4. leniolisib phosphate (Joenja)

Manual PA criteria apply to all new users of leniolisib (Joenja)

Manual PA criteria: Coverage is approved if all criteria are met:

- Patient is 12 years of age or older and weighs 45 kg or greater
- Medication is prescribed by a specialist who treats patients with primary immune deficiencies
- Patient has a genetically confirmed diagnosis of phosphoinositide 3-kinase delta (PI3K) mutation with a variant in PIK3CD and/or PIK3R1 genes
- Patient has at least one clinical finding or manifestation consistent with activated phosphoinositide 3-kinase delta syndrome (APDS)

Non-FDA approved uses are NOT approved
PA does not expire

5. omaveloxolone (Skyclarys)

Manual PA criteria apply to all new users of omaveloxolone (Skyclarys)

Manual PA criteria: Coverage is approved if all criteria are met:

- Patient is 16 years of age or older
- Medication is prescribed by a neurologist
- Patient has genetic testing confirming the diagnosis of Friedreich’s Ataxia
- Provider is aware of the warnings, screening and monitoring precautions for Skyclarys.

Non-FDA approved uses are NOT approved

PA does not expire

6. perfluorohexyloctane 1.338 g/mL ophthalmic solution (Miebo)

Manual PA criteria apply to all new users of perfluorohexyloctane (Miebo)

Manual PA criteria: Coverage is approved if all criteria are met:

- Medication is prescribed by an ophthalmologist or optometrist
- Patient is 18 years of age or older
- Patient has a diagnosis of dry eye disease
- Patient had positive symptomology screening for dry eye disease from an appropriate measure
- Patient has at least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test)
- Patient has had at least 1 month of one ocular lubricant used at optimal dosing and frequency
- Patient has had at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency
- Patient has had at least a 3-month trial of cyclosporine (Restasis) or cyclosporine (Cequa) or lifitegrast (Xiidra)

Non-FDA approved uses are NOT approved

PA does not expire

7. sodium oxybate extended-release packets for oral suspension (Lumryz)

Manual PA criteria apply to all new users of sodium oxybate (Lumryz)

Manual PA criteria: Coverage is approved if all criteria are met:

- Patient is 18 years of age or older
- Lumryz is prescribed by a neurologist, psychiatrist, or sleep medicine specialist
- Lumryz is prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy
- Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing
- The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic, a benzodiazepine, or a sedative hypnotic

- The patient has history of failure, contraindication, or intolerance of both of the following
 - modafinil or armodafinil AND
 - stimulant-based therapy (amphetamine-based therapy or methylphenidate)
- Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)

Coverage is NOT provided for the treatment of other conditions not listed above or any non-FDA-approved use, including fibromyalgia, insomnia, and excessive sleepiness not associated with narcolepsy

Prior Authorization expires after 1 year

Renewal PA criteria: Renewal not allowed; provider must fill out a new PA.

8. somapacitan-beco injection (Sogroya)

Manual PA criteria apply to all new users of Sogroya

Manual PA criteria: Sogroya is approved if all criteria are met:

- Provider acknowledges that Norditropin is the Department of Defense's preferred somatotropin agent

Pediatric patients

- Patient is a pediatric patient between the ages of 2.5 to 17 years of age
- Sogroya is being used for the indication of growth failure due to an inadequate secretion of endogenous growth hormone (GH) in pediatric patients
- Sogroya is prescribed by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment

Adult patients

- Sogroya is being used for adult growth hormone deficiency as a result of pituitary disease, hypothalamic disease, trauma, surgery, or radiation therapy that was acquired as an adult or diagnosed during childhood
- The prescription was written by or in consultation with an appropriate specialty (endocrinologist, infectious disease specialist, general surgeon, or gastroenterologist)

All patients

- Patient has a contraindication to Norditropin OR
- Patient has experienced an adverse reaction(s) to Norditropin, Omnitrope, AND Zomacton not expected with Sogroya

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 not approved for concomitant use of multiple somatropin agents

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

9. sotagliflozin (Inpefa)

Manual PA criteria apply to all new users of Inpefa.

Manual PA Criteria: Inpefa will be approved if all criteria are met:

- The patient is 18 years of age or older
- Provider is aware and acknowledges that empagliflozin (Jardiance), empagliflozin/metformin (Synjardy, Synjardy XR) and empagliflozin/linagliptin (Glyxambi) are DoD's preferred SGLT2 inhibitor, and that PA is not required for empagliflozin
- Inpefa is prescribed to reduce the risk of cardiovascular death, hospitalization for heart failure and urgent heart failure visits in patients heart failure, type 2 diabetes, chronic kidney disease and other cardiovascular risk factors.
- Patient has experienced significant adverse reactions or has a contraindication to empagliflozin
- Prescription is written by or in consultation with a cardiologist
- Patient is receiving appropriate guideline-directed medical therapy including the following: angiotensin-converting enzyme inhibitor (ACEI), angiotensin II receptor blocker (ARB), or angiotensin receptor neprilysin inhibitor (ARNI); beta blocker; and aldosterone antagonist, unless contraindicated or if the patient has experienced adverse effects or could not tolerate these therapies

Non-FDA-approved uses are not approved, including type 1 diabetes mellitus
PA does not expire

10. zavegepant nasal spray (Zavzpret)

Manual PA criteria apply to all new users of Zavzpret.

Manual PA criteria: Zavzpret is approved if all criteria are met:

- The patient is 18 years of age or older
- Medication is prescribed by or in consultation with neurologist
- Concurrent use with any other small molecule CGRP targeted medication (i.e., Nurtec ODT or Ubrelvy) is not allowed
- Patient has a diagnosis of acute treatment of migraine headache AND
- Patient has a contraindication to, intolerance to, or has failed a trial of BOTH of the following medications
 - sumatriptan (Imitrex) nasal spray AND
 - Nurtec ODT or Ubrelvy tabs

Non-FDA-approved uses are not approved

PA expires after 6 months

Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if the following criteria is met:

- Acute Treatment: Patient has a documented positive clinical response to therapy

11. sildenafil 10 mg/mL oral suspension (Liqrev)

Interim Manual PA criteria apply to all users of sildenafil 10 mg/mL oral suspension (Liqrev)

Manual PA criteria: Coverage is approved if all criteria are met:

- Provider acknowledges that Liqrev will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the August 2023 DoD P&T Committee meeting minutes by the Director, DHA
- Provider acknowledges that generic sildenafil 10 mg/mL oral suspension (generic Revatio) is available to TRICARE beneficiaries
- Patient has diagnosis of WHO group 1 pulmonary arterial hypertension (PAH)
- Prescriber is cardiologist or pulmonologist
- Patient had a right heart catheterization

- Patient has documentation that patient had right heart catheterization that results confirm diagnosis of WHO Group 1 pulmonary arterial hypertension (PAH)
- Patient is not receiving other PDE-5 inhibitors, nitrates, or riociguat concomitantly
- Patient requires a liquid formulation due to swallowing difficulty

Non-FDA approved uses are NOT approved

PA does not expire (until complete exclusion status implementation)

12. trientine tetrahydrochloride tabs (Cuvrior)

Interim Manual PA criteria apply to all users of Cuvrior tabs

Manual PA criteria: Coverage is approved if all criteria are met:

- Provider acknowledges Cuvrior will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the August 2023 DoD P&T Committee meeting minutes by the Director, DHA
- Provider acknowledges that generic trientine hydrochloride capsules are available without prior authorization
- Patient has tried and failed generic trientine hydrochloride capsules
- The provider must document why the patient cannot use generic trientine hydrochloride capsules
 - Acceptable responses include that the patient has a contraindication/intolerance to an inactive ingredient in the generic trientine hydrochloride capsules

Non-FDA approved uses are NOT approved

PA does not expire (until complete exclusion status implementation)

13. zolpidem 7.5 mg capsules (no brand name)

Interim Manual PA criteria apply to all users of zolpidem 7.5 mg capsules

Manual PA criteria: Coverage is approved if all criteria are met:

- Provider acknowledges zolpidem 7.5 mg capsules will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the August 2023 DoD P&T Committee meeting minutes by the Director, DHA
- Provider acknowledges that generic zolpidem IR 5 mg and 10 mg tabs, zolpidem ER 6.25 mg and 12.5 mg tabs, zaleplon 5 mg and 10 mg caps; and eszopiclone 1 mg, 2 mg and 3 mg tabs are available without requiring PA. Please consider changing the prescription to one of these other products.

- The provider must provide a clinical rationale to document why the patient cannot take any of the drugs listed above, including zolpidem IR 5 mg and 10 mg tabs or zolpidem ER 6.25 mg or 12.5 mg tabs
 - Acceptable responses include that the patient has tried and failed ALL of the following: zolpidem IR 5 mg and 10 mg tabs; zolpidem ER 6.25 mg and 12.5 mg tabs; zaleplon 5 mg and 10 mg caps; and eszopiclone 1 mg, 2 mg and 3 mg tabs

Non-FDA approved uses are NOT approved

No refills allowed; new prescription is required for each fill until complete exclusion status implementation.

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF and PA Implementation Period

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

- **New Drugs Recommended for UF or NF Status:** an effective date of the first Wednesday two weeks after signing of the minutes in all points of service.
- **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.

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

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
 - atropine sulfate 1% ophthalmic solution
 - Austedo XR
 - Vowst
 - Veozah
 - Joenja
 - Skyclarys

- NF
 - Miebo
 - Lumryz
 - Sogroya
 - Inpefa
 - Zavzpret
- Complete exclusion
 - Liqrev
 - Cuvrior
 - zolpidem tartrate 7.5 mg capsules

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.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF, PA, and Implementation Period

The P&T Committee recommended the implementation plan of two weeks for the drugs recommended for UF or NF status, and 120 days after signing of the minutes for the drugs recommended for completely excluded status, as described above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XV. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5)

P&T Comments

A. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

Manual PA criteria was recommended for one recently marketed drug which contains active ingredients that are widely available in low-cost generic formulations. Due to the pathway used to gain FDA approval, this product does not meet the criteria for an innovator. For the product listed below, PA criteria is recommended in new and current users, requiring a trial of all cost-effective generic formulary medications first.

Vitamins: Prenatal— Natal PNV tablets—Natal PNV is a prenatal dietary supplement manufactured by a single company. The primary ingredients of Natal PNV are similar to those found in other prenatal vitamins which require manual PA and are very expensive. Several cost-effective prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than the age of 45 and do not require prior authorization criteria.

The Manual PA criteria is as follows:

Manual PA criteria applies to new and current users of prenatal MVI (Natal PNV).

Manual PA Criteria: Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, Neonatal Complete, Neonatal Plus, or Natal PNV is approved if all criteria are met:

- The provider is aware and acknowledges that Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, or Prenatal Plus DHA are the preferred products over Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, Neonatal Complete, Neonatal Plus, and Natal PNV. The preferred vitamins listed above are covered without a PA for women who are under the age of 45 years and planning to become pregnant or who are pregnant. Please consider changing the prescription to one of these agents.
- The provider must explain why the patient requires Natal PNV and cannot take one of the cost-effective formulary alternatives (fill-in blank)

Non-FDA-approved uses are NOT approved

Prior Authorization does not expire

B. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5) Implementation Period

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for Natal PNV tablets in new and current users, due to the significant cost differences compared with numerous available alternative agents. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients.

XVI. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5)

BAP Comments

A. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)b

The P&T Committee recommended manual PA criteria for Natal PNV tablets as stated above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5) Implementation Plan

The P&T Committee recommended the new PAs will become effective the first Wednesday 60 days after the signing of the minutes.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XVII. 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 (20 for, 0 opposed, 0 abstained, 0 absent) 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.

- a) **Anticonvulsant and Anti-Mania: topiramate ER capsule sprinkle (Qudexy XR) and topiramate ER capsule (Trokendi XR)**—For Qudexy XR, the manual PA criteria were updated for patients with partial-onset or primary generalized tonic clonic (GTC) seizures to include children 2 years of age and older. For Trokendi XR, the manual PA criteria were updated for patients with partial-onset or primary GTC seizures to include children 6 years of age and older. The PAs for both Qudexy XR and Trokendi XR were also updated to align with other topiramate PAs, including that a requirement for the medication to be prescribed by or in consultation with a neurologist was added.

- b) **Migraine Agents: CGRP Antagonists Oral Agents Subclass—atogepant (Qulipta)**—The manual PA criteria were updated for Qulipta to allow for the new indication for the preventative treatment of migraine in adults to include chronic migraine. Previously, Qulipta was only indicated for the preventive treatment of episodic migraine.
- c) **Gastrointestinal-2 Agents: CIC/IBS-C—linaclotide (Linzess)**—The manual PA criteria were updated to reflect the new expanded indication in children as young as 6 years old with functional constipation. The PA requires pediatric patients to try or have an intolerance to at least two other agents for constipation before Linzess.
- d) **Continuous Glucose Monitoring Systems (CGMs): Therapeutic CGMs Freestyle Libre 2 and 3**—Manual PA criteria were updated for an expanded age indication. Freestyle Libre 2 and 3 systems are now indicated for use in children 2 years of age and older.
- e) **Atopy Agents: Oral Janus Kinase Inhibitor (JAK-1)—upadacitinib (Rinvoq)**—The manual PA criteria were updated to include the new indication for adults with moderately to severely active Crohn’s disease. A trial of adalimumab (Humira) is required before Rinvoq.
- f) **Oncological Agents: Ovarian Cancer—olaparib (Lynparza)**—The manual PA criteria were updated to include the new indication for use in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer.
- g) **Oncological Agents—dabrafenib (Tafinlar) and trametinib (Mekinist)**—The manual PA criteria were updated for Tafinlar and Mekinist to allow for use in pediatric patients 1 year of age or older with low-grade glioma with a BRAF V600E mutation and who require systemic therapy.
- h) **Oncological Agents—avapritinib (Ayvakit)**—Manual PA criteria were updated to allow for a new indication for indolent systemic mastocytosis.
- i) **Targeted Immunomodulatory Biologics (TIBs)—sarilumab (Kevzara)**—The manual PA criteria were updated to allow for a new indication for polymyalgia rheumatica in adults. The new PA criteria for this indication require that the prescription be written by or in consultation with a rheumatologist, and that the patient has tried glucocorticoids first unless the patient is not a candidate for them.

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 Qudexy XR, Trokendi XR, Qulipta, Linzess, Freestyle Libre 2 and 3, Rinvoq, Lynparza, Tafinlar, Mekinist, Ayvakit, and Kevzara in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

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

BAP Comments

A. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee evaluated updates to the PA Criteria for several drugs, due to FDA as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Updated Manual PA Criteria for New FDA-Approved Indication Implementation Plan

The P&T Committee recommended an effective date of 60 days after signing of the minutes for the drugs discussed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XIX. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW INDICATIONS AND IMPLEMENTATION PERIOD

P&T Comments

A. Updated PA Criteria for Reasons other than New Indications

- a) **Neurological Agents Miscellaneous—risdiplam (Evrysdi)**—The Evrysdi PA was last reviewed at the February 2021 meeting. At that time, Evrysdi had not been studied in patients with hepatic impairment. Since then, studies have been conducted in patients with mild and moderate hepatic impairment. The P&T Committee recommended changing the existing PA criteria to allow for Evrysdi use in patients with hepatic impairment.
- b) **Hematological Agents—avacopan (Tavneos)**—Tavneos was reviewed as an innovator drug at the February 2022 meeting for formulary status and PA criteria. The Tavneos PA required documentation of the Birmingham Vasculitis Activity

Score (BVAS). Provider feedback supported removal of the BVAS requirement, as it is not commonly performed in clinical practice.

- c) **Targeted Immunomodulatory Biologics: Tumor Necrosis Factor Inhibitors—adalimumab (Humira)**—The Humira PA in its current form required pediatric patients with non-fistulizing Crohn’s disease to have an inadequate response to a non-biologic systemic therapy before they could try Humira. Based on provider feedback and a review of the available literature, the P&T committee recommended removing the requirement for pediatric Crohn’s disease patients to try non-biologic systemic therapy before Humira.

B. Updated Manual PA Criteria and Implementation Period for Reasons other than New Indications

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) criteria updates to the manual PA criteria for Evrysdi, Tavneos, and Humira. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

XX. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW INDICATIONS AND IMPLEMENTATION PERIOD

BAP Comments

A. Updated PA Criteria for Reasons other than New Indications

The P&T Committee recommended PA revisions as listed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Updated Manual PA Criteria and Implementation Period for Reasons other than New Indications

The P&T Committee recommended PA implementation of 60 days as listed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XXI. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR DABIGATRAN (PRADAXA) CAPSULES AND IMPLEMENTATION PERIOD

P&T Comments

Dabigatran (Pradaxa) capsules are 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, the branded Pradaxa capsules will continue to be dispensed at all three points of service, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy). The Tier 1 copay for brand Pradaxa dose is recommended, and generic dabigatran capsules will be added to the Safety Net/Rapid Response program. Note that the Tier 1 copay does not apply to Pradaxa pellets for oral suspension, which was designated as NF when reviewed as a new drug at the May 2023 DoD P&T Committee meeting.

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) requiring brand Pradaxa capsules over the generic in all new and current users at all points of service, based on cost-effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. The Tier 1 (generic) copayment will apply to brand Pradaxa capsules, and dabigatran capsules will be added to the Safety Net/Rapid Response program. The effective date will be no later than 60 days after the signing of the minutes at MTF and mail. The “brand over generic” requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

XXII. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR DABIGATRAN (PRADAXA) CAPSULES AND IMPLEMENTATION PERIOD

BAP Comments

The P&T Committee recommended brand over generic authorization and Tier 1 copay for Dabigatran (Pradaxa) capsules, with an implementation period of 60 days as stated above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XXIII. COMPLETELY EXCLUDED DRUGS: ANNUAL REVIEW AND UF RECOMMENDATION

P&T Comments

The P&T Committee reviewed all drugs completely excluded from the pharmacy benefits program under 32 CFR 199.21(e)(3), which allows the Committee to recommend 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.” This specifically includes “a complete or partial exclusion from the pharmacy benefits program of any pharmaceutical agent the Director determines provides very little or no clinical effectiveness relative to similar agents to covered beneficiaries and DoD.” Drugs designated as completely excluded are not available at the MTFs or Mail Order points of service, and beneficiaries are required to pay the full out-of-pocket cost at retail network pharmacies. The Committee plans to review completely excluded drugs on an annual basis.

The P&T Committee reviewed all the completely excluded drugs and found no new clinical data, guidelines, or indications for any of the completely excluded drugs that would change the previous conclusion that the drug offers little or no clinical effectiveness relative to similar agents. The Committee also found that with one exception (baclofen oral granules discussed below), all the completely excluded drugs remain substantially more costly than similar agents.

- **baclofen oral granules (Lyvispah) – Skeletal Muscle Relaxants:** After substantial wholesale acquisition cost (WAC) reductions by the manufacture, Lyvispah is now similar in price to baclofen oral solution (Ozobax) and baclofen oral suspension (Fleqsuvy), both of which are designated as nonformulary.
- **dexlansoprazole (Dexilant, generics)- Proton Pump Inhibitors (PPIs):** The Committee also reviewed post-implementation pharmacy claims rejection rates and cost data for dexlansoprazole, noting that generic versions of the drug remain up to 2 orders of magnitude more costly compared to formulary proton pump inhibitors (PPIs).

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- Returning baclofen oral granules (Lyvispah) to the formulary, designated as nonformulary (Tier 3 copay), with an implementation date in all points of service of the first Wednesday 2 weeks after signing of the minutes.
- Applying the same prior authorization to Lyvispah as is currently in place for baclofen oral solution (Ozobax) and baclofen oral suspension (Fleqsuvy).

The manual PA criteria is as follows:

Manual PA criteria apply to all new users of baclofen oral granules (Lyvispah)

Manual PA criteria: baclofen oral granules are approved if all criteria are met:

- Baclofen will be used for spasticity
- Patient requires baclofen and cannot use the tablet formulation due to some documented medical condition – dysphagia, systemic sclerosis, etc. and not due to convenience

Non-FDA-approved uses are not approved

Prior authorization does not expire

XXIV. COMPLETELY EXCLUDED DRUGS: ANNUAL REVIEW AND UF RECOMMENDATION

BAP Comments

The P&T Committee recommended returning baclofen oral granules (Lyvispah) to the formulary, designated as nonformulary (Tier 3 copay), with an implementation date in all points of service of the first Wednesday 2 weeks after signing of the minutes and applying the same prior authorization to Lyvispah as is currently in place for baclofen oral solution (Ozobax) and baclofen oral suspension (Fleqsuvy), as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XXV. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2008 AND IMPLEMENTATION PERIOD

P&T Comments

The P&T Committee reviewed two drugs from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs were not in compliance with FY08 NDAA, Section 703, permanently codified at 10 USC 1074g(f). If a drug is not compliant, it will be designated NF on the UF and will be restricted to the TRICARE Mail Order Pharmacy, requiring pre-authorization prior to use in the retail point of service (POS) and medical necessity at MTFs. These NF drugs will be exempt from movement to the Mail Order POS due to the potential for acute use; and will remain available at the Retail POS with pre-authorization.

A. Drugs designated NF

The P&T Committee recommended (19 for, 0 opposed, 1 abstained, 0 absent) that the Section 703 non-compliant national drug code numbers (NDCs) of the following products be designated NF on the UF:

- Nabriva Therapeutics, Inc.: tidezolid (Sivextro) (New Drug Application; NDC 72000-0310-06, 72000-0310-30) 200 mg tabs
- Nabriva Therapeutics, Inc.: lefamulin (Xenleta) (New Drug Application; NDC 72000-0110-10, 72000-0110-30) 600 mg tabs

B. Pre-Authorization Criteria

The P&T Committee recommended (19 for, 0 opposed, 1 abstained, 0 absent) the following pre-authorization criteria for the Section 703 non-compliant NDCs:

1. Use of the formulary alternatives are contraindicated.
2. Obtaining the product by home delivery would be detrimental to the patient.

These pre-authorization criteria do not apply to any other POS other than retail network pharmacies.

C. Implementation Period

The P&T Committee recommended (19 for, 0 opposed, 1 abstained, 0 absent) an effective date of two weeks after signing of the minutes for the non-compliant NDCs. Letters are not needed since these are acute use medications used to treat infections, and existing patients are unlikely to be continuing therapy once the implementation period has occurred.

XXVI. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2008 AND IMPLEMENTATION PERIOD

BAP Comments

The P&T Committee recommended Drugs designated NF and Pre-Authorization Criteria as outlined above, with an implementation effective date of two weeks after signing of the minutes for 703 noncompliant NDCs.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

[Redacted]

From: [Redacted] Michael [Redacted]
Sent: Tuesday, September 19, 2023 12:27 PM
To: DHA NCR J-6 Mailbox BAPREQUESTS
Subject: [Non-DoD Source] August 2023 DoD P&T Recommendations: Response Requested

Dear Sir or Madam,

Following the careful review of the DEPARTMENT OF DEFENSE PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS FROM THE AUGUST 2023 MEETING, INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL MEETING SEPTEMBER 27, 2023, we found medically incorrect information in the meeting minutes document regarding Inpefa. Given that fact, I'm respectfully requesting the statement be deleted from those meeting minutes as described below.

The medically incorrect information is referenced on page 30 of the final statement under Inpefa that starts on page 29 under, item number 9. The statement "Non-FDA-approved uses are not approved, including Type 1 Diabetes Mellitus, Heart Failure with preserved ejection fraction, or acute decompensated heart failure PA does not expire." Since this is inconsistent with the FDA approved label, we are requesting the entire statement be removed from the minutes prior to the Beneficiary Advisory Panel scheduled for September 27, 2023.

I can be reached at [Redacted] or at [Redacted] and would be happy to discuss this matter live at your convenience.

Sincerely,
Mike Lucy

Michael L [Redacted]
Executive Director, Head of
Market Access



[Redacted]
Bridgewater, NJ [Redacted]
[Redacted]
[Redacted]

The contents of this communication, including any attachments, may be confidential, privileged or otherwise protected from disclosure. They are intended solely for the use of the individual or entity to whom they are addressed. If you are not the intended recipient, please do not read, copy, use or disclose the contents of this communication. Please notify the sender immediately and delete the communication in its entirety.



From: Myovant Medical Information [REDACTED]
Sent: Thursday, September 21, 2023 2:10 PM
To: DHA NCR J-6 Mailbox BAPREQUESTS
Cc: P [REDACTED], Janis
Subject: [Non-DoD Source] Orgovyx: Written Comment to PA Criteria Recommendations
Attachments: DoD Orgovyx Prior Authorization Criteria Wrtn Comments.pdf; Orgovyx_Prescribing Information_March2023.pdf

Dear UF BAP Designated Federal Officer,

Please find attached the Orgovyx® (relugolix) Written Comments to the PA Criteria Recommendations and the most recent USPI. Thank you for the opportunity to submit this response for consideration during the General Meeting on Wednesday, September 27, 2023. Additionally, could the UF BAP Designated Federal Officer kindly acknowledge receipt of this email?

Thank you,

Medical Information
Sumitomo Pharma America, Inc.

**DoD Orgovyx Prostate Cancer
Prior Authorization Criteria Written Comments**

Sumitomo Pharma America, Inc. (SMPA) is providing this document in response to the initial recommendations for Orgovyx® (relugolix) Prior Authorization (PA) criteria. The information enclosed is a summary of the best available clinical data related to the initial PA criteria. Some of the data included in this response may be outside the FDA-approved prescribing information for the referenced product. SMPA does not intend to offer an opinion regarding the clinical relevance of these data or the advisability of administering any drug in a manner inconsistent with its approved labeling. Please refer to the enclosed Full Prescribing Information for complete information.

General Comments:

- Consider removing "Patient has tried and failed leuprolide acetate SC (Eligard) or degarelix SC (Firmagon)" from PA criteria.

Reasoning:

Orgovyx is the first and only orally active androgen deprivation therapy (ADT); it is a gonadotropin-releasing hormone (GnRH) antagonist that is given once daily.¹ The primary evidence of efficacy and safety comes from the pivotal phase 3 trial in men with advanced prostate cancer requiring at least 1 year of continuous ADT (HERO, NCT03085095)² with supportive data from the phase 2 study in men with localized intermediate-risk prostate cancer requiring 6 months of neoadjuvant/adjuvant ADT with external beam radiation therapy (EBRT) (C27003, NCT02135445).³

- **Route of administration**

Orgovyx is the first and only orally available ADT. Currently, all other FDA-approved ADTs for advanced prostate cancer are only available as injectable or implantable formulations, including a GnRH receptor antagonist (degarelix) and the luteinizing hormone releasing hormone (LHRH) agonists (i.e., leuprolide acetate [subcutaneous (SC), intramuscular (IM)], leuprolide mesylate [SC], goserelin acetate [SC], and triptorelin pamoate [IM]). While LHRH agonists are generally well tolerated, their use is often limited by their route of administration, initial testosterone surge, prolonged testosterone recovery after discontinuation, and increased risk of cardiovascular events. Degarelix dosing is also limited to injections in the office every 28 days.⁴ Incidence of injection-site reactions for current LHRH agonists and GnRH antagonists vary from 3 to 44%.⁴⁻⁶

Injectable ADT is usually administered by a health care professional whereas Orgovyx is self-administered. Potential benefits of oral administration include decreased health care provider time (treatment administration, patient education on self-administration), avoidance of injection preparation, avoidance of injection site reactions, reduction in the number of office visits for ADT administration especially in the setting of the emergence of telehealth, and increased patient satisfaction with the convenience of the oral route of administration.

The BAP background document highlights that Orgovyx provides convenience to the patient but that data are limited on long-term compliance. Efficacy, safety, and pharmacokinetic information from two phase I studies, two phase II studies, and the phase III safety and efficacy study (HERO) were used to develop a population pharmacokinetic (PopPK) model and a semi-mechanistic population pharmacokinetic/pharmacodynamic (PopPK/PD) model that characterizes relugolix exposure and its relationship to testosterone concentrations. Simulations using the PopPK/PD model predicts that 97.3% and 85.5% of the patients remain at castration levels (<50 ng/dL) upon temporary interruption of treatment for 7 days and 14 days, respectively.⁷

Background

HERO is a multinational, randomized, open-label, phase 3 study to evaluate the efficacy and safety of Orgovyx in men with androgen-sensitive advanced prostate cancer who required at least one year of continuous ADT. Patients enrolled in the study were randomized 2:1 to receive either Orgovyx (120 mg once daily after a single oral loading dose of 360 mg) or leuprolide acetate (22.5 mg [or 11.25 mg in

Japan and Taiwan per local guidelines, and is not recommended for this indication in the United States] by injection every 3 months) for 48 weeks.²

Study C27003 was a phase 2, randomized, open-label, parallel group study evaluating the safety and efficacy of Orgovyx in men with intermediate-risk prostate cancer who required 6 months of neoadjuvant/adjuvant ADT in conjunction with EBRT. Patients enrolled in the study were randomized 3:2 to receive 24 weeks of either Orgovyx (loading dose of 320 mg on Day 1 followed by 120 mg daily thereafter) or degarelix subcutaneous depot injection (loading dose of 240 mg on Day 1 followed by 80 mg every 4 weeks).³ The overall AE profile was similar between Orgovyx and degarelix except for findings of increased alanine aminotransferase (13%) and injection site erythema (11%) in the degarelix group compared to 0% for both alanine aminotransferase and injection site erythema in the Orgovyx group.³

References

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