

EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel Meeting April 6, 2022

For the February 2022 DoD Pharmacy and Therapeutics Committee Meeting

The Uniform Formulary Beneficiary Advisory Panel (UFBAP) convened at 10:00 A.M. EDT on April 6, 2022 via teleconference, due to the ongoing COVID pandemic. The current meeting took place over 1 hour and 45 minutes. The information presented on April 6th included the recommendations from the February 2022 DoD Pharmacy and Therapeutics Committee (P&T) meeting.

The detailed meeting information is found starting on page 7.

UNIFORM FORMULARY (UF) DRUG CLASS REVIEWS

I. UF CLASS REVIEWS—Oncological Agents: Subclasses for the following:

- **Renal Cell Carcinoma (RCC)**
- **Epidermal Growth Factor Receptor (EGFR) + Non-Small Cell Lung Cancer (NSCLC)**
- **Non-Bruton Tyrosine Kinase Inhibitors (Non-BTKIs) for Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**
- **Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors for BRCA+ Cancers (PARPIs)**
- **Janus Kinase Inhibitors for Myelofibrosis (MF)**

A. Oncological Agents —UF Recommendations

- UF: All 23 agents found on page 3
- NF - None
- Tier 4/Not Covered – None

Summary of Panel Questions and Comments

No comments

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

B. Oncological Agents —Manual PA Criteria

Summary of Panel Questions and Comments

No comments.

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

C. Oncological Agents—UF, PA and Implementation Plan upon signing of the minutes

Summary of Panel Questions and Comments

No comments.

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

II. UF CLASS REVIEWS—Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products

A. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —UF Recommendation

- UF
 - Baqsimi
 - Gvoke
 - Zegalogue
- NF – None
- Tier 4/Not Covered - None

Summary of Panel Questions and Comments

No comments.

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

B. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —Baqsimi Tier 1 Status

Summary of Panel Questions and Comments

No comments

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

C. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —UF, Tier 1 Copay and Implementation Plan of 30 days

Summary of Panel Questions and Comments

No comments.

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

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

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF/Tier 4 Recommendation

- **UF:**
 - Scemblix
 - Tavneos
 - Livtencity
 - Eprontia
 - Voxzogo

- **NF:**
 - Qulipta
 - Dhivy
 - Skytrofa
 - Livmarli
 - Besremi
 - Tyrvaya

- **Tier 4/Not Covered:**
 - Elyxyb

Summary of Panel Questions and Comments

Mr. Du Teil asked what the reason was for the one opposing vote for the Tier 4 drug. CDR Raisor responded that the reason was because the P&T member felt that the drug should have been nonformulary instead of Tier 4. Mr. Du Teil asked if this was due to cost? LCDR Elizabeth Hall relayed that there are several other treatments

available for migraine headache including many other NSAIDs that are most cost effective. Input was received from several neurologists who agreed with the Tier 4 recommendation.

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

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria for Scemblix, Norditropin, Qulipta, Besremi, Dhivy, Eprontia, Livmarli, Tavneos, and Voxzogo

Summary of Panel Questions and Comments

Dr. Peloquin asked for Eprontia if the PA affects both new and current users, or just new users? CDR Raisor replied there is an error in the Background document, the PA will apply to new users only.

Dr. Peloquin also had a question on Livmarli, asking if the evaluation for liver transplantation is done in the office, and whether that will increase the cost to the patient. CDR Raisor responded that the criteria was included to ensure there is consideration of liver transplantation prior to prescribing the drug. CDR Raisor also stated that the Committee was aware of the potential of an increased cost for this evaluation to the patient in addition to the drug cost.

Dr. Peloquin also asked for clarification for Livmarli. If the PA expires in 6 months then does the patient have to submit the PA every six months, and whether there was a cap on the renewal period. He also asked what are the actual criteria – does the patient have to show additional improvement every six months? Dr. Lugo responded that the PA requires renewal every 6 months to ensure that the patient is responding and has continued improvement in pruritus symptoms, since the drug does not correct the underlying disease, and only treats symptoms.

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

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF, Tier 4/Not Covered and PA Implementation Plan of two weeks for the UF and NF drugs, and 120 days for the Tier 4 drugs

Summary of Panel Questions and Comments

No comments.

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

IV. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

A. New Manual PA Criteria Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5) for Fenoglide 120 mg tablets, Indocin 50 mg suppositories and Neonatal Plus

Summary of Panel Questions and Comments

No comments.

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

B. New Manual PA Criteria for Testosterone Replacement Therapies: IM testosterone cypionate and testosterone enanthate

Summary of Panel Questions and Comments

No comments.

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

C. New Manual PA Criteria Implementation Plan of 90 days

Summary of Panel Questions and Comments

No comments.

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

V. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA-APPROVED INDICATIONS, AND EXPANDED AGE RANGES

A. Updated PA Criteria for New FDA-Approved Indications and Expanded Age Ranges for Dupixent, Zepatier, Rexulti, Caplyta, Skyrizi, Cosentyx, Xeljanz and Rinvoq ER

Summary of Panel Questions and Comments

No comments.

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

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

Summary of Panel Questions and Comments

No comments.

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

VI. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REMOVAL OF AN INDICATION

A. Updated PA Criteria for removal of indication for Copiktra for follicular lymphoma

Summary of Panel Questions and Comments

No comments.

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

B. Updated PA Criteria for removal of indication for Copiktra for follicular lymphoma implementation plan of 60 days

Summary of Panel Questions and Comments

No comments.

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

VII. REMOVAL OF BRAND OVER GENERIC AUTHORIZATION FOR FLUTICASONE/SALMETEROL DRY POWDER INHALER (ADVAIR DISKUS)

A. Fluticasone/salmeterol dry powder inhaler (Advair Diskus) removal of brand over generic authorization

Summary of Panel Questions and Comments

No comments.

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

Director, DHA:

A handwritten signature in black ink, appearing to be 'D. H. A.', written over a horizontal line.

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

Uniform Formulary Beneficiary Advisory Panel
Virtual Meeting Summary Minutes
April 6, 2022

Panel Members Present

- Mr. Jon Ostrowski, Non-Commissioned Officer Association, Chair
- Dr. Richard Bertin, Ph. D., Commissioned Officer Association of the U.S. Public Health Service
- Dr. Karen Dager, PharmD, Health Net Federal Services
- Mr. John Du Teil, U.S. Army Warrant Officers Association
- Dr. Betsaida Guzman, PharmD, Veterans of Foreign Wars
- Dr. Joseph McKeon, MD, Humana Military
- Dr. Jay Peloquin, Pharm D, Express Scripts
- Dr. Jennifer Soucy, PharmD, U.S. Family Health Plan, Martins Point Services

Acting Designated Federal Officer (Non-Voting): Colonel Paul Hoerner, BSC

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

- Dr. John Kugler, Division Chief, J-6; DoD P&T Committee Chair
- Edward VonBerg, PharmD, BCPS, Chief, Pharmacy Operations Division Formulary Management Branch (POD FMB)
- CDR Scott Raisor, Chief, P&T Section POD FMB
- LCDR Todd Hansen, MC POD FMB
- Maj Angelina Escano, MC POD FMB
- LCDR Giao Phung, MSC POD FMB
- Amy Lugo, PharmD, BCPS POD FMB
- LCDR Elizabeth Hall POD FMB
- Ms. Meghan Gemunder Office of General Counsel

Agenda is found starting on page 16.

- Panel Discussion

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

Opening Remarks

Col Paul Hoerner introduced himself as the Designated Federal Officer (DFO) for the Uniform Formulary (UF) Beneficiary Advisory Panel (BAP). The Panel has convened to comment on the recommendations of the DoD Pharmacy and Therapeutics (P&T) Committee meeting, which occurred on February 9-10, 2022.

Col Hoerner 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 the pharmaceutical agent and establishes the P&T committee to review the formulary on a periodic basis to make additional recommendations regarding the formulary as the committee determines necessary and appropriate.

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

Col Hoerner then outlined the duties of the Uniform Formulary Beneficiary Advisory Panel include the following:

- To review and comment on the recommendations of the P&T Committee concerning the establishment of the UF and subsequent recommended changes. Comments to the Director, DHA, regarding recommended formulary status, pre-authorizations, and the effective dates for changing drugs from "formulary" to "non-formulary" status must be reviewed by the Director before making a final decision.
- To hold quarterly meetings in an open forum. The Panel may not hold meetings except at the call of or with the advance approval of the DFO in consultation with the Chairperson of the Panel.
- To prepare minutes of the proceeding and prepare comments for the Secretary or his designee regarding the Uniform Formulary or changes to the Formulary. The minutes will be available on the website and comments will be prepared by the Director, DHA.

The DFO provided guidance regarding this meeting.

- The role of the BAP is to comment on the UF recommendations made by the P&T Committee at their last meeting. While the Department of Defense appreciates that the 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 BAP.

- The P&T Committee met for approximately 15 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 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 BAP meeting minutes, the DoD P&T Committee meeting minutes, and the Director's decisions will be available on the TRICARE website in approximately four to six weeks.

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

- Due to the travel restriction and guidance regarding COVID-19, this meeting will be conducted in a remote access format.
- 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 and 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 BAP's deliberations. Should a misstatement be made, these individuals may interrupt to ensure the minutes accurately reflect relevant facts, regulations or policy.

Col Hoerner 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 following;

1. Biomarin Pharmaceuticals
2. Mirum Pharmaceuticals
3. ChemoCentryx

Col Hoerner also relayed that there was one public citizen comment that did not pertain to this meeting was not presented since it contained protected health information.

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

Chairman's Opening Remarks

Mr. Ostrowski welcomes all panel members and attendees and stated he was looking forward to the presentations.

Dr. VonBerg's Opening Remarks

The meeting then proceeded with comments from Dr. VonBerg 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*).

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

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

- Dr. VonBerg continued that he wanted to provide a brief summary of what the P&T Committee did at the February meeting: the Committee reviewed some oncology subclasses and the class overdose agents for severe hypoglycemia.
 - For the drug class reviews, all 26 drugs in the classes were recommended for formulary status.
 - One Tier 1 drug was selected in the glucagon drug class. This will have an immediate copay reduction for existing patients and new patients.
- The Committee reviewed a total of 12 newly approved drugs
 - 5 were selected for UF status
 - 6 will be nonformulary
 - And there was 1 drug recommended for Tier 4/not covered status, so far which is not affecting any patients.
- I do have a couple of housekeeping requests:

- Please identify yourself each time you speak, since we are not able to meet in person, and we may not remember everyone's voice.
- For ensuring a smooth process, we ask that BAP members please hold your comments to the designated comment sections

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

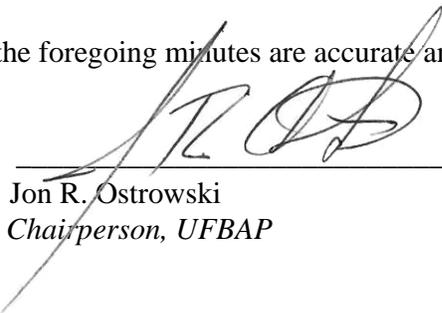
Closing Remarks

Mr. Ostrowski thanked Col Hoerner and the team, thought all the presentations were very good. Aso thanks Maj Fosse for all his efforts with coordinating the meeting. Mr. Ostrowski also thanked his fellow panel members for their dedication today for the meeting.

Col Hoerner closed the meeting by thanking the members of the pubic for their attendance, Mr. Ostrowski for his duties as chair, and the members of the Formulary Management Branch for their presentations. The meeting was closed at 10:45 AM Eastern Daylight Time.

The Meeting Adjourned at 10:45 M EDT.

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



Jon R. Ostrowski
Chairperson, UFBAP

DoD P&T Committee Physician Perspective

Dr. John Kugler's comments on the formulary recommendations followed each individual section and are outlined below.

Drug Class Reviews

Oncological Agents – Five Subclasses: Epidermal Growth Factor Receptor (EGFR) + Non-Small Cell Lung Cancer (NSCLC); Myelofibrosis; Non-Bruton's Tyrosine Kinase Inhibitor (Non-BTKI) for Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL); Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors; Renal Cell Carcinoma

- This is the third oncology class review that we've done in the past 12 months. We took a new approach this time, since the Committee evaluated a total of 23 drugs from five subclasses at once. The clinical and cost review were very detailed and comprehensive.
- The recommendation here is that all the products will be on uniform formulary, so the 5,000 patients that are currently on one of these drugs will continue to pay the Tier 2 copay.
- We will keep the PAs that are currently in place. When the Committee reviewed the current prescribing trends, the utilization appeared to follow the NCCN guidelines, so no new PAs were recommended at this time. Any new updated indications or NCCN guidelines can be handled through the utilization management process that we do at every meeting. However, we will continue to monitor usage, and new PAs can be recommended in the future, if needed.
- Overall, providers will have several drugs to choose from, for their individual patients.

Hypoglycemia Products: Glucagon Agents (Baqsimi nasal spray, Zegalogue, Gvoke and)

- There was no controversy on adding the three new products to the formulary; we won't be requiring a PA or having a preferred product. We did receive feedback from both adult and pediatric endocrinologists for their recommendations.
- The Committee felt that all these products are highly interchangeable. However, there may be some individual patients where a provider would choose one product over another, for example some patients might prefer the nasal spray while others might prefer the injectable products, since they are used to giving themselves insulin injections.
- A Tier 1 copay was recommended for the nasal spray product, Baqsimi. Patients using the Mail Order or Retail Network will pay the generic copay, rather than the branded

(Tier 2 copay) for this drug. The 900 patients currently on this drug will see the copay reduction the next time they get a refill.

- Overall – the Committee recognizes that the newer glucagon preparations (nasal and autoinjectors) offer a significant clinical improvement over the older products, since they are easier to use and don't require mixing like the old emergency kits.

Newly Approved Drugs

- There were a total of 12 new drugs reviewed at this meeting. Five will be designated as UF, with six nonformulary drugs, and one Tier 4 drug.
- We did recommend PA criteria for 10 of the drugs, however, all of the PAs here will apply to new users, so patients who are currently on one of these won't have to go back and fill out the PA.
- There were five drugs that were approved for rare diseases, where very limited numbers of patients have been studied. We did reach out to the appropriate specialists for input on the PA criteria for these drugs. The PA criteria here follow applicable clinical practice guidelines, and also will help ensure the drugs are used for the most appropriate patients.
- The other drugs where PA criteria were recommended were for more common disease states such as migraine headache, dry eye disease, Parkinson's disease, and growth hormone deficiency. The PA criteria follow the general criteria already in place for the other drugs in these classes, or for where there are already step-preferred therapies in the class, or where cost effective generics are available in the same active ingredient.
- The drug recommended for Tier 4 placement is an oral solution of celecoxib (Elyxxb). There are numerous NSAIDs already on the formulary, and several NSAIDs are easily available OTC. Input from neurologists supported Tier 4 status. Currently we don't have any patients on this drug; however, any new patient started on therapy will receive letters letting them know about the formulary change.

Utilization Management – New PA Criteria

- **Indomethacin suppositories; fenoglide; Neonatal plus- Prenatal vitamin**
 - These are examples of a manufacturer bringing older products back to the market, at a significantly increased cost. For the Indocin suppositories, this formulation isn't clinically necessary outside of a hospital setting. For the fenoglide product, there are numerous other cost effective formulations of fenofibrate available. In February, there were about 162 patients receiving the fenoglide formulation, and there are less than 10 patients on the indomethacin suppositories. We will send a letter to the patients currently receiving these drugs to notify them of the new PA requirements.

- For all of these products, if a provider does have a clinically compelling reason, then the PA can be filed.
- **Intramuscular (IM) Testosterone Replacement Therapy testosterone cypionate and testosterone enanthate**
 - For the transdermal testosterone products (like Fortesta and Androderm), there have been PA criteria in place for several years. The PA recommendation here is to have the same requirements for the injectable products. These recommendations were discussed with several MTF endocrinologists.

Utilization Management – Updated PA Criteria – new FDA indications, NCCN guidelines, or expanded age ranges –

Dupixent – children as young as 6 for asthma; Hepatitis C – Zepatier – children as young as 12 yrs; Antipsychotics – Rexulti – children as young as 13 years; Caplyta new bipolar depression indication; TIBs-Skyrizi – psoriatic arthritis; Cosentyx – patients as young as 4 yrs with enthesitis-related arthritis; Xeljanz – ankylosing spondylitis; Rinvoq – psoriatic arthritis

- You will see examples of this section at every BAP meeting. The group does routinely monitor new indications for the drugs where we have PA criteria. The updates for the 8 drugs here expand the numbers of eligible patients, and you can see that several of the drugs today now are approved for children.

Utilization Management - Updated PA Criteria for Removal of an indication

Oncological Agents: Non-Bruton Tyrosine Kinase Inhibitor (Non-BTKI) for Chronic Lymphocytic Leukemia— duvelisib (Copiktra)

- We don't see this situation too often, where the manufacturer is removing an indication. This change will affect new patients. For patients who are currently receiving the drug for this indication, we are leaving the decision up to the provider for their individual patients as to how to handle this change in the package insert.

Removal of Brand Over Generic Requirement for Advair Diskus

- Advair has been the preferred combination inhaler for several years, and currently in order to receive a generic inhaler, a PA has to be completed stating why the patient can't use Advair. The change recommended today is that the PA won't be required in order for a patient to receive the generic inhaler. Providers can still write for Advair, which does not require a PA, and Advair will continue to have a Tier 1 copay.

AGENDA

***Uniform Formulary Beneficiary Advisory Panel (BAP)
For the February 2022 DoD Pharmacy and Therapeutics Committee Meetings
April 6, 2022 at 10:00 AM Eastern Daylight Saving Time***

Virtual Meeting

- **Administrative Meeting: 8:00 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 Tier 4/Not Covered candidates.

The P&T Committee made recommendations for the following drugs/drug classes during the February 2022 meeting:

- **Drug Class Reviews**

- *Oncological Agents*
 - *Renal Cell Carcinoma (RCC)*
 - *Epidermal Growth Factor Receptor (EGFR) + Non-Small Cell Lung Cancer (NSCLC) subclass*
 - *Non-Bruton Tyrosine Kinase Inhibitors (Non-BTKIs) for Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) subclass*
 - *Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors for BRCA+ Cancers (PARPIs) subclass*
 - *Janus Kinase Inhibitors for Myelofibrosis subclass*
- *Binders-Chelators-Antidotes-Overdose Agent for severe hypoglycemia – Glucagon products*

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

- *asciminib (Scemblix) – Oncologic Agent for chronic myelogenous leukemia (CML) in chronic phase (CP)*
- *atogepant (Qulipta) – Migraine Agent for the preventative treatment of episodic migraine in adults*
- *avacopan (Tavneos) – Hematological Agent for microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA)*

- *carbidopa/levodopa (Dhivy) – Parkinson’s Disease agent*
- *celecoxib oral solution (Elyxyb) –NSAID for acute migraine headache*
- *lonapegsomatropin-tcgd injection (Skytrofa) – Growth Stimulating Agent*
- *marabavir (Livtencity) – Antiviral for CMV infection/disease*
- *maralixibat (Livmarli) – Miscellaneous Metabolic agent for cholestatic pruritus in Alagille syndrome*
- *ropeginterferon alfa-2b-njft injection (Besremi) – Hematological agent for polycythemia vera*
- *topiramate oral solution (Eprontia) – Anticonvulsant-Antimania Agent for epilepsy, migraine headache, and Lennox-Gastaut syndrome*
- *varenicline nasal solution (Tyrvaya) –Dry Eye Disease Agent*
- *vosoritide injection (Voxzogo) – Miscellaneous Growth Stimulating Agent for pediatric achondroplasia*

➤ **Utilization Management Issues**

➤ **Prior Authorization Criteria—New Manual PA Criteria**

- *Antilipidemics-2 – fenofibrate 40 mg and 120 mg (Fenoglide)*
- *NSAIDs – indomethacin 50 mg suppositories (Indocin)*
- *Vitamins: Prenatal – Prenatal Multivitamins (Neonatal Plus)*
- *Androgens-Anabolic Steroids: Intramuscular (IM) Testosterone Replacement Therapy – testosterone cypionate and testosterone enanthate*

➤ **Prior Authorization Criteria—Updated PA Criteria for New FDA-Approved Indications, National Comprehensive Cancer Network Guideline Updates, or Age Ranges**

- *Respiratory Interleukins: dupilumab (Dupixent)*
- *Hepatitis C Agent –Direct Acting Agents: elbasvir/grazoprevir (Zepatier)*
- *Atypical Antipsychotic Agents*
 - *brexpiprazole (Rexulti)*
 - *lumateperone (Caplyta)*
- *Targeted Immunomodulatory Biologics (TIBs)*
 - *risankizumab-rzaa (Skyrizi)*
 - *secukinumab (Cosentyx)*

- *tofacitinib (Xeljanz/Xeljanz XR)*
- *upadacitinib (Rinvoq ER)*

- **Prior Authorization Criteria—Removal of Indication**

- *Oncological Agents: Non-Bruton Tyrosine Kinase Inhibitors (Non-BTKIs) for Chronic Lymphocytic Leukemia – duvelisib (Copiktra)*

- **Removal of Brand Over Generic Authorization**

- *Pulmonary Is: Inhaled Corticosteroid/Long Acting Beta Agonist Inhalers: fluticasone/salmeterol dry powder inhaler (Advair Diskus)*

- **Panel Discussions**

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

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS FROM
THE FEBRUARY 2022 MEETING**

**INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL MEETING APRIL 6, 2022**

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 Tier 4/not covered status, prior authorization (PA), pre-authorizations, and the effective date for a drug's change from formulary to non-formulary (NF) or Tier 4 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—Oncological Agents: Subclasses for the following:

- **Renal Cell Carcinoma (RCC)**
- **Epidermal Growth Factor Receptor (EGFR) + Non-Small Cell Lung Cancer (NSCLC)**
- **Non-Bruton Tyrosine Kinase Inhibitors (Non-BTKIs) for Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**
- **Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors for BRCA+ Cancers (PARPIs)**
- **Janus Kinase Inhibitors for Myelofibrosis (MF)**

P&T Comments

A. Oncological Agents —Relative Clinical Effectiveness Analysis and Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness for five oncology subclasses. The Committee reviewed a distillation of the evidence including attention to guideline recommended use, the strength of those recommendations, the levels of evidence supporting those recommendations, and, where applicable, comparative judgments about the qualitative differences in clinical effectiveness between agents. A safety evaluation of each subclass's agents included comparative quantitative as well as qualitative assessments. There are a total of 23 drugs in the subclasses, with only two products available in generic formulations (everolimus and erlotinib).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

Renal Cell Carcinoma (RCC)

- Nine agents comprise the RCC subclass: axitinib (Inlyta), cabozantinib (Cabometyx), cabozantinib (Cometriq), everolimus (Afinitor, generic), lenvatinib (Lenvima), pazopanib (Votrient), sorafenib (Nexavar), sunitinib (Sutent), and tivozanib (Fotivda).
- Cumulatively, the 9 RCC agents are FDA-approved and/or guideline recommended to treat 14 different disease states including RCC, hepatocellular carcinoma, various forms of thyroid carcinoma, endometrial carcinoma, soft tissue sarcoma, gastrointestinal stromal tumors, pancreatic neuroendocrine tumors, melanoma, non-small cell lung cancer, acute myeloid leukemia, myelofibrosis, cutaneous T-cell lymphoma, bone cancers, and adenoid cystic carcinoma. With the exception of tivozanib (Fotivda) and everolimus (Afinitor) that are used exclusively in RCC, no two agents have perfectly overlapping usage in the exact same disease states.
- Where mutually indicated and/or guideline supported, comparisons can be drawn between agents for a particular disease context in a particular disease state, with some comparisons showing agents are largely qualitatively similar with similar overall clinical effectiveness, strengths of recommendation, and supporting levels of evidence. Meanwhile, other comparisons show a hierarchy of superiority. However, even where such comparisons are possible, it is difficult if not impossible to draw global conclusions about the relative clinical effectiveness of agents because a comparative conclusion among agents for one disease context of a specific disease state may differ from conclusions for another disease context or state.
- A review of safety shows that certain adverse events are class effects associated with mechanism of action, while others are unique to the specific agent. No two agents have identical safety profiles. However, overall the agents have similar tolerability.
- The RCC review concludes that the 9 subclass agents are significantly different from one another, and all the agents are necessary inclusions to the benefit.

Epidermal Growth Factor Receptor-Mutant Non-Small Cell Lung Cancer (EGFR+ NSCLC)

- Five agents comprise the EGFR+ NSCLC subclass: afatinib (Gilotrif), dacomitinib (Vizimpro), erlotinib (Tarceva, generic), gefitinib (Iressa) and osimertinib (Tagrisso).
- The 5 EGFR+ NSCLC agents are FDA-approved and/or guideline recommended to treat NSCLC, and erlotinib is also approved in pancreatic

carcinoma. Osimertinib uniquely can be sequenced with the other EGFR+ NSCLC agents.

- The only disease context where all 5 agents are mutually comparable is frontline therapy for metastatic EGFR+ NSCLC. Osimertinib is the preferred frontline therapy. The remaining four agents have weaker strengths of recommendation supporting their use, with evidence showing qualitatively inferior outcomes relative to osimertinib but relatively equivalent between themselves. Only osimertinib and axitinib are guideline-recommended in the relapsed/refractory setting [and axitinib only in combination with the medical benefit drug cetuximab (Erbix)]. Osimertinib is the only subclass agent recommended in the adjuvant setting.
- A review of safety shows that rate of severe adverse events was similar between all EGFR+ NSCLC agents.
- The EGFR+ NSCLC review concludes that agents are only comparable in the treatment-naïve setting and that osimertinib and erlotinib are not true comparators to the remaining agents because of their alternative usages.

Non-Bruton Tyrosine Kinase Inhibitors for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (non-BTKIs for CLL/SLL)

- Three agents comprise the non-BTKIs for CLL/SLL subclass: duvelisib (Copiktra), idelalisib (Zydelig), and venetoclax (Venclexta).
- The three subclass agents mutually treat CLL/SLL with and without del7p/TP53 mutation. However, their other indications and guideline-supported use in Non-Hodgkin Lymphomas and Acute Myeloid Leukemia (for venetoclax) do not overlap.
- Venetoclax is guideline recommended for CLL/SLL in both the treatment-naïve and relapse-refractory settings. Duvelisib and idelalisib are only used in the relapsed/refractory setting. In the relapsed/refractory setting, venetoclax is the preferred regimen over duvelisib and idelalisib regardless of del17p/TP53 status and patient risk category. While duvelisib and idelalisib have the same strength of recommendation and levels of evidence supporting their use, idelalisib has qualitatively superior overall clinical effectiveness across the disease contexts in which both agents are used.
- A review of safety shows qualitatively and quantitatively unique safety profiles for each agent. Venetoclax has the least number of severe events that resulted in warnings/precautions on the label and has no black box warnings. Duvelisib and idelalisib have a greater number of warnings relative to venetoclax. Duvelisib and idelalisib also have overlapping but non-identical black box warnings.

- The non-BTKIs for CLL/SLL review concludes that mechanism of action categorizes the agents by usage, guideline support, and safety profiles. Agents are only comparable in the relapsed/refractory context of CLL/SLL and such a comparison shows a clear hierarchy of overall clinical effectiveness with venetoclax superior to idelalisib and both venetoclax and idelalisib superior to duvelisib.

Poly (Adenosine Diphosphate-Ribose) Polymerase Inhibitors for BRCA+ Cancers (PARPI)

- Four agents comprise the PARPI subclass: niraparib (Zejula), olaparib (Lynparza), rucaparib (Rubraca), and talazoparib (Talzenna).
- The four PARPI agents have overlapping but non-identical FDA-approved indications: olaparib is approved for ovarian cancer, breast cancer, pancreatic cancer, and prostate cancer. Niraparib is only indicated for ovarian cancer. Rucaparib is indicated for ovarian cancer and prostate cancer. Talazoparib is indicated only for breast cancer.
- Where mutually indicated and/or guideline supported, comparisons can be drawn between agents, showing that the PARPI products are largely qualitatively similar with similar overall clinical effectiveness, strengths of recommendation, and supporting levels of evidence. However, the absence of evidence supporting the use of certain agents in particular disease states limits the ability to draw comparative conclusions of global efficacy across the various disease states. Rather only indirect comparisons can be drawn using olaparib as a reference point.
- The PARPI products show statistically significant differences in rates of severe adverse events, with olaparib and talazoparib showing lower rates than niraparib and rucaparib. No statistically significant difference is observed between olaparib and talazoparib, nor between niraparib and rucaparib.
- The PARPI review concludes that the products are not broadly comparable because of the difference in approved indications, but where mutually used, the agents have qualitatively similar overall clinical effectiveness. However, olaparib and talazoparib demonstrate quantitative superior safety in terms of reduced rates of severe adverse events.

Janus Kinase Inhibitors for Myelofibrosis (MF)

- Only two agents comprise the MF subclass: fedratinib (Inrebic) and ruxolitinib (Jakafi).

- Ruxolitinib is used in a variety of hematopoietic disorders including myelofibrosis, polycythemia vera, essential thrombocythemia, and graft vs. host disease. Fedratinib is only indicated and guideline supported for treating myelofibrosis.
- Ruxolitinib and fedratinib have overlapping but non-identical guideline supported use in myelofibrosis; only ruxolitinib is recommended in low-risk patients. The comparative conclusion between the two agents depends on the disease context. For example, in high-risk non-transplant candidates with treatment-naïve disease, ruxolitinib has superior overall qualitative clinical effectiveness. However, in the relapsed/refractory setting, fedratinib shows qualitatively superior efficacy. Another difference is that in the relapsed/refractory setting, fedratinib can be used in ruxolitinib refractory disease (but not vice-a-versa; ruxolitinib was not tested in fedratinib-refractory disease).
- Ruxolitinib and fedratinib have significantly different rates of adverse events with fedratinib showing greater rates of hematologic and gastrointestinal adverse events. Fedratinib also uniquely increases the risk of Wernicke’s encephalopathy due to an indirect thiamine deficiency from malnutrition related to its poor gastrointestinal tolerability.
- The MF review concludes that fedratinib and ruxolitinib are not true comparators given the difference in usage, context of use within the same disease state, and clinically significant difference in adverse event profiles.

Overall Conclusions

- Comparative clinical statements between members within all five subclasses are confounded by differences between agents based on usage, guidelines, and safety profiles.
- Where agents are comparable, comparisons are often limited to either a subset of agents, a subset of disease states and/or disease contexts, or a combination of the two.

B. Oncological Agents—Relative Cost Effectiveness Analysis and Conclusion

Relative Cost-Effectiveness Analysis and Conclusion— The Committee reviewed the solicited bids and also conducted a budget impact analysis (BIA). The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- BIA was performed to evaluate the projected spend and cost avoidance after considering the solicited bids. BIA results showed that designating all of the 23 drugs in the 5 subclasses as UF demonstrated the greatest cost avoidance for the MHS.

C. Oncological Agents —UF/Tier 4/Not Covered Recommendation

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
 - Renal Cell Carcinoma (RCC)
 - axitinib (Inlyta)
 - cabozantinib (Cabometyx)
 - cabozantinib (Cometriq)
 - everolimus (Afinitor tab and disperz tab; generic)
 - lenvatinib (Lenvima)
 - pazopanib (Votrient)
 - sorafenib (Nexavar)
 - sunitinib (Sutent)
 - tivozanib (Fotivda)
 - Epidermal Growth Factor Receptor (EGFR) plus Non-Small Cell Lung Cancer (NSCLC)
 - afatinib (Gilotrif)
 - dacomitinib (Vizimpro)
 - erlotinib (Tarceva; generic)
 - gefitinib (Iressa)
 - osimertinib (Tagrisso)
 - Non-Bruton Tyrosine Kinase Inhibitor (Non-BTKIs) for Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)
 - duvelisib (Copiktra)
 - idelalisib (Zydelig)
 - venetoclax (Venclexta)
 - Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors
 - olaparib (Lynparza)
 - niraparib (Zejula)

- rucaparib (Rubraca)
- talazoparib (Talzenna)
- JAK Kinase inhibitors for Myelofibrosis
 - ruxolitinib (Jakafi)
 - fedratinib (Inrebic)
- NF
 - None
- Tier 4/Not Covered
 - None

D. Oncological Agents —Manual PA Criteria

PA criteria currently apply to 10 drugs. Newer products that have been reviewed as innovators generally have PA criteria. PAs are in place based on NCCN guideline recommendations suggesting step therapy (e.g., RCC – Fotivda) or for safety issues or poor tolerability (e.g., Myelofibrosis: Inrebic; EGFR+NCSLC: Vizimpro). PAs are in place for all the drugs in the class for the PARPIs and the non-BTKIs for CLL/SL subclass.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) to maintain the current PAs for the drugs listed below. The most current PA criteria is found on the TRICARE Formulary Search Tool at: <https://www.express-scripts.com/frontend/open-enrollment/tricare/fst/#/>.

- RCC: Fotivda
- EGFR+NCLC: Vizimpro
- Non-BTKIs for CLL/SL: Copiktra, Zydelig, Venclexta
 - For Copiktra, refer to the Utilization Management section on pp. 31-32 for the removal of the indication for relapsed or refractory follicular zone lymphoma
- PARPIs: Lynparza, Zejula, Rubraca, Talzenna
- Myelofibrosis: Inrebic

E. Oncological Agents —UF, PA and Implementation Period

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) an effective date upon signing of the minutes in all points of service.

III. UF DRUG CLASS REVIEWS-Oncological Agents

BAP Comments

D. Oncological Agents —UF Recommendations

The P&T Committee recommended the formulary status for the Oncological Agents in the five subclasses as discussed above.

- UF: All 23 agents
- NF - None
- Tier 4/Not Covered - None

BAP Comments

a. Concur: Non-Concur: Abstain: Absent:

E. Oncological Agents —Manual PA Criteria

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

BAP Comments

b. Concur: Non-Concur: Abstain: Absent:

F. Oncological Agents—UF, PA and Implementation Plan

The P&T Committee recommended the implementation plan upon signing of the minutes in all points of service.

BAP Comments

c. Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEWS—Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products

P&T Comments

A. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —Relative Clinical Effectiveness Analysis and Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the agents used for treating severe hypoglycemia in diabetic patients. The drugs in the class all contain glucagon as the active ingredient. There are three new branded products marketed, glucagon nasal (Baqsimi), glucagon subcutaneous (SC) injection (Gvoke), and dasiglucagon SC injection (Zegalogue). The drugs were individually reviewed as innovators. Baqsimi and Gvoke were reviewed and made UF in November 2019 and Zegalogue was reviewed and made UF in August 2021.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Professional treatment guidelines from the American Diabetes Association and Diabetes Canada recommend using glucagon to treat severe hypoglycemia events. Diabetic patients at increased risk for hypoglycemia should have access to a glucagon product. However, the guidelines do not give a preference for any one agent over another.
- Older formulations of glucagon (e.g., Glucagon emergency kit, GlucaGen Hypokit) have been available for several years in intramuscular (IM) formulations that require reconstitution prior to administration.
- The three ready-to-use formulations offer significant advantages over existing agents in emergency situations due to their ease of use. Gvoke and Zegalogue are available as SC injections that don't require reconstitution, while Baqsimi is administered nasally.
- Specific clinical considerations for the products are as follows:
 - *Zegalogue* is available in a prefilled syringe and autoinjector, and is approved in patients as young as 6 years of age. It has an approximately 3 minute slower onset of action compared to glucagon IM. Common adverse events include injection site reactions. Disadvantages include that *Zegalogue* should not be used in patients with latex allergy, as the grey cap contains latex. Once removed from the refrigerator, *Zegalogue* has a shelf life of 12 months at room temperature, compared to 2 years at room temperature with Baqsimi and Gvoke.
 - *Baqsimi* nasal spray advantages include it is the only non-injectable glucagon formulation, and is easy for both patient and caregiver administration. Its onset of action is approximately 3 minutes slower compared to glucagon IM. It is approved for patients as young as 4 years of age. Unique adverse events with Baqsimi include localized upper respiratory tract irritation due to the nasal administration route.
 - *Gvoke* advantages include FDA-approval in children as young as 2 years of age. The available formulations include a prefilled syringe and autoinjector for SC use. The onset of action is approximately 4 minutes slower compared to glucagon IM. The adverse event profile is similar to *Zegalogue*.

- Overall, there is a high degree of therapeutic interchangeability between the newer products, with treatment success approaching 100%.
- The P&T Committee recognizes that the newer glucagon preparations (nasal and autoinjectors) offer a significant advantages in terms of ease of administration.

B. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —Relative Cost Effectiveness Analysis and Conclusion

Relative Cost-Effectiveness Analysis and Conclusion—Cost Minimization Analysis (CMA) and BIA were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that Baqsimi, Gvoke and Zegalogue were all cost effective agents.
- BIA was performed to evaluate the potential impact of designating the three newer glucagon agent as UF, NF, or Tier 4 on the formulary. BIA results showed that designating all the products as UF demonstrated the greatest cost avoidance for the MHS.

C. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —UF Recommendation The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
 - glucagon nasal (Baqsimi)
 - glucagon prefilled syringe, autoinjector, and kit (Gvoke, Gvoke Hypopen, Gvoke PFS)
 - dasiglucagon prefilled syringe and autoinjector (Zegalogue)
- NF
 - None
- Tier 4/Not Covered
 - None

Note that the older IM product (Glucagon emergency kit, GlucaGen Hypokit, GluGen Diagnostic) will remain on the formulary

D. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —Baqsimi Tier 1 Status

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) lowering the current Tier 2 cost-share for Baqsimi to the generic Tier 1 cost-share.

The authority for this recommendation is codified in 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020 which states “in implementing this rule, the Committee will not only evaluate drugs for exclusion from coverage, but will also include identifying branded drugs that may be moved to Tier 1 status with a lower copayment for beneficiaries. The intent of identifying agents in this manner as well as the new exclusion authority is to yield improved health, smarter spending, and better patient outcomes.” Lowering the cost-share for Baqsimi will provide a greater incentive for beneficiaries to use the most cost-effective glucagon in the purchased care points of service.

E. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —UF, Tier 1 Copay and Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service (POS).

V. UF DRUG CLASS REVIEWS-Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products

BAP Comments

A. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —UF Recommendation

The P&T Committee recommended the formulary status for the glucagon products as discussed above:

- UF
 - Baqsimi
 - Gvoke
 - Zegalogue
- NF – None
- Tier 4/Not Covered - None

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —Baqsimi Tier 1 Status

The P&T Committee recommended lowering the current Tier 2 cost-share for Baqsimi to the generic Tier 1 cost-share as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —UF, 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:

VI. 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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—
The P&T Committee agreed (Group 1 and Group 2: 17 for, 0 opposed, 0 abstained, 0 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/Tier 4/Not Covered Recommendation

The P&T Committee recommended for group 1: (16 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 0 abstained, 0 absent); and for celecoxib oral solution (Elyxyb): (15 for, 1 opposed, 0 abstained, 1 absent)the following:

- UF:
 - asciminib (Scemblix) – Oncological Agent for chronic myelogenous leukemia (CML)
 - avacopan (Tavneos) – Hematological Agent for microscopic polyangiitis and granulomatosis with polyangiitis
 - marabavir (Livtency) – Antiviral for CMV infection/disease
 - topiramate oral solution (Eprontia) – Anticonvulsant-Antimania Agent for Epilepsy, migraine headache, and Lennox-Gastaut syndrome
 - vosoritide injection (Voxzogo) – Miscellaneous Growth Stimulating Agent for pediatric achondroplasia

- NF:
 - atogepant (Qulipta) – Migraine agent for acute treatment of migraines
 - carbidopa/levodopa IR scored tab (Dhivy) – a scored immediate-release tablet formulation of carbidopa and levodopa for Parkinson’s disease
 - lonapegsomatropin-tcgd injection (Skytrofa) – Growth stimulating Agent
 - maralixibat (Livmarli) – Miscellaneous Metabolic Agent for treatment of cholestatic pruritus in Alagille syndrome
 - ropeginterferon alfa-2b-njft injection (Besremi) – Hematological Agent for polycythemia vera
 - varenicline nasal solution (Tyrvaya) –Dry Eye Disease agent
- Tier 4 (Not covered):
 - celecoxib oral solution (Elyxyb) – NSAIDs: another formulation of celecoxib as an oral solution approved for acute treatment of migraines
 - Elyxyb was recommended for Tier 4/Not Covered status as it has little to no clinical benefit relative to NSAIDs, and the needs of TRICARE beneficiaries are met by available alternative agents. Formulary alternatives include ibuprofen, naproxen, diclofenac, and numerous other NSAIDs or combo products.

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

The P&T Committee recommended for group 1: (16 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Oncologic drugs: Applying manual PA criteria to new users of Scemblix.
- Growth Stimulating Agents: Applying manual PA criteria to new users of Skytrofa, similar to other products in the class. A trial of Norditropin, the step-preferred product is required first.
- Migraine Agents: Applying manual PA criteria to new users of Qulipta, similar to the other oral migraine agents.
- Applying manual PA criteria to new users of Besremi, Dhivy, Eprontia, Livmarli, Tavneos, Tyrvaya, and Voxzogo.

Full PA Criteria for the Newly Approved Drugs per 32 CFR 199.21(g)(5) is as follows

1. **asciminib (Scemblix)**

Manual PA criteria apply to all new users of Scemblix

- Patient is 18 years of age and older
- Scemblix is prescribed by or in consultation with a hematologist/oncologist
- The patient has Philadelphia chromosome-positive CML (Ph+ CML) in chronic phase (CP) and was previously treated with two or more tyrosine kinase inhibitors
- The provider will monitor for myelosuppression, pancreatitis, hypertension, hypersensitivity, and cardiovascular toxicity
- Female patients of childbearing age are not pregnant confirmed by (-) HCG
- Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment
- Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy.
- The diagnosis IS NOT listed above, but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so the provider must list the diagnosis

Non-FDA-approved uses are not approved except as noted above.

Prior authorization does not expire.

2. **avacopan (Tavneos)**

Manual PA criteria apply to all new users of Tavneos

- Patient is 18 years of age or older
- Tavneos is prescribed by or in consultation with a rheumatologist
- Patient has a documented diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's) and microscopic polyangiitis (MPA)
- Patient meets one of the following criteria (either a or b):
 - a. Positive ELISA test for anti-proteinase-3 (PR-3)
 - b. Positive ELISA test for anti-myeloperoxidase (MPO)

- Patient has documentation of baseline Birmingham vasculitis activity score (BVAS), with at least one of the following criteria (at least a, b, or c):
 - c. At least 1 major item (i.e. gangrene, scleritis/episcleritis, hearing loss, massive hemoptysis/alveolar hemorrhage, respiratory failure, ischemic abdominal pain, rise/fall in serum creatinine, meningitis, CVA);
 - d. At least 3 non-major items;
 - e. At least 2 renal items of proteinuria and hematuria
- Patient has experienced or has a high probability to experience significant adverse effect from prednisone
- Tavneos is prescribed in combination with cyclophosphamide or rituximab, unless clinically significant adverse effects are experienced or both cyclophosphamide or rituximab are contraindicated

Non-FDA-approved uses are not approved, including Immunoglobulin A nephropathy, Hidradenitis suppurativa, acne inversa, and C3 Glomerulopathy (C3G).

Prior authorization expires after 6 months. Tavneos will be approved indefinitely if the following criteria are met:

- Patient has responded positively to therapy as evidenced by at least a 50% reduction in BVAS from baseline or remission (BVAS of zero) AND
- If request is for a dose increase, new dose does not exceed 60 mg (2 tabs) per day

3. atogepant (Qulipta)

Manual PA criteria apply to all new users of Qulipta.

- Patient is 18 years of age or older
- Qulipta is prescribed by or in consultation with a neurologist
- Concurrent use with any small molecule CGRP targeted medication (i.e., Ubrelvy, Nurtec ODT or another gepant) is not allowed
- Patient has Episodic Migraine as defined by the following:
 - 4 to 7 migraine days per month for 3 months AND has at least moderate disability shown by Migraine Disability

Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR

- 8 to 14 migraine days per month for 3 months
- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes:
 - Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate
 - Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol
 - Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine
- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE of the following CGRP injectable agents
 - erenumab-aooe (Aimovig)
 - fremanezumab-vfrm (Ajovy)
 - galcanezumab-gnlm (Emgality)

Non-FDA approved uses are not approved

Prior authorization expires in 6 months.

Qulipta will be approved indefinitely if one of the following criteria are met:

- The patient has had a reduction in mean monthly headache days of $\geq 50\%$ relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR
- The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:
 - Migraine Disability Assessment (MIDAS)
 - Reduction of ≥ 5 points when baseline score is 11–20
 - Reduction of $\geq 30\%$ when baseline score is > 20
 - Headache Impact Test (HIT-6) - Reduction of ≥ 5 points
 - Migraine Physical Functional Impact Diary (MPFID)
Reduction of ≥ 5 points

4. carbidopa/levodopa IR scored tab (Dhivy)

Manual PA criteria apply to all new users of Dhivy

- Provider acknowledges that generic immediate-release carbidopa/levodopa is available without a PA (e.g. generic Sinemet)
- The patient has tried and failed a generic immediate-release formulation of carbidopa/levodopa OR
- The patient cannot achieve the required dose with generic immediate-release carbidopa/levodopa (e.g. generic Sinemet)

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

5. lonapegsomatropin-tcgd injection (Skytrofa)

Manual PA criteria apply to all new users of Skytrofa

The provider acknowledges that Norditropin is the DoD's preferred somatropin agent

- Patient is a pediatric patient at least one year of age and older who weights at least 11.5 kg
- Skytrofa is being used for the indication of growth failure due to an inadequate secretion of endogenous growth hormone (GH) in pediatric patients
- Skytrofa is prescribed by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment
- Patient has one or more of the following:
 - Patient has a contraindication to Norditropin OR
 - Patient has experienced an adverse reaction(s) to Norditropin, Omnitrope, AND Zomacton not expected with Skytrofa
 - Note that patient preference for a particular device is insufficient grounds for approval of an NF agent

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.

6. maralixibat (Livmarli)

Manual PA criteria apply to all new users of Livmarli.

- Patient is 1 year of age or older
- Patient has diagnosed Alagille syndrome with severe refractory pruritus
- The prescription is written by a pediatric gastroenterologist, or pediatric hepatology transplant specialist
- Patient has been evaluated for possible orthotopic liver transplant (OLT)
- Patient has previously tried and failed all of the following:
 - ursodiol
 - cholestyramine
 - rifampin
 - naltrexone
 - At least one antihistamine (e.g. Atarax, Benadryl, etc.)

Non-FDA-approved uses such as non-alcoholic steatohepatitis (NASH), non-alcoholic fatty liver disease (NAFLD), progressive familial intrahepatic cholestasis (PFIC), biliary atresia and other cholestatic disease are not approved.

Prior authorization expires after 6 months. Livmarli will be approved for an additional 6 months if the following criteria are met:

- Patient must demonstrate significant improvement in pruritus symptoms.

7. ropeginterferon alfa-2b-njft injection (Besremi)

Manual PA criteria apply to all new users of Besemri.

- Provider acknowledges that another pegylated interferon (Pegasys) is available at the formulary copay and without requiring prior authorization
- Patient is 18 years of age or older
- Drug is prescribed by or in consultation with a hematologist/oncologist
- Patient has a confirmed diagnosis of polycythemia vera (PV)

- Patient is high-risk (age >60 years and/or prior history of thrombosis)
- Patient is currently taking aspirin 81-100mg daily and is undergoing regular phlebotomy (to maintain hematocrit < 45%)
- Patient must try and fail or be intolerant or resistant to (showing phlebotomy-dependence and/or progressive splenomegaly) hydroxyurea OR
- The patient has a contraindication to hydroxyurea (e.g., pregnancy)

Non-FDA-approved uses are not approved including myeloproliferative neoplasms, essential thrombocythemia (ET), or adult T-cell leukemia (ATL).

Prior authorization does expires after 1 year. Besremi will be approved for an additional year if the following criteria are met:

- Patient has a documented improvement in symptoms.

8. topiramate oral solution (Eprontia)

Manual PA criteria apply to all new users of Eprontia.

- PA does not apply to patients less than 12 years of age (age edit)
- Eprontia is prescribed by or in consultation with an adult or pediatric neurologist
- Patient has a diagnosis of one of the following:
 - For epilepsy monotherapy: Partial onset seizure or primary generalized tonic-clonic seizures in patients 2 years of age or older
 - For epilepsy adjunctive therapy: Partial onset seizure or primary / generalized tonic-clonic seizures or seizures associated with Lennox Gastaut syndrome in patients 2 years of age or older
 - For Migraine: preventive treatment in patients 12 years of age or older
- Patient requires a liquid formulation due to swallowing difficulty or has a feeding tube and cannot use topiramate (sprinkles)

Non-FDA-approved uses are not approved.
Prior authorization does not expire

9. varenicline nasal solution (Tyrvaya)

Manual PA criteria apply to all new users of Tryvaya

- Patient is 18 years of age or older
- Tyrvaya is prescribed by an ophthalmologist or optometrist
- Patient has a diagnosis of dry eye disease as supported by both of the criteria below:
 - Positive symptomology screening for dry eye disease from an appropriate measure
 - At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test)
- Patient must try and fail the following:
 - At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube])
 - Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol)
- If the patient has moderate to severe Dry Eye Disease
 - Patient has tried and failed an adequate course (at least 6 weeks) of treatment of lifitegrast (Xiidra) or cyclosporine treatment (Restasis)

Non-FDA-approved uses are NOT approved

Prior authorization expires after 1 year. Tyrvaya will be approved indefinitely if the following criteria are met:

- The drug is prescribed by an ophthalmologist or optometrist.
- The patient must have documented improvement in ocular discomfort.
- The patient must have documented improvement in signs of dry eye disease.

10. vosoritide injection (Voxzogo)

Manual PA criteria apply to all new users of Voxzogo

- Patient is 5 years of age or older

- Voxzogo is prescribed by or in consultation with a pediatric endocrinologist
- Patient has a documented diagnosis of achondroplasia with open epiphyses
- Patient/Caregiver and provider acknowledge that Voxzogo was FDA approved in an accelerated fashion and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials
- Patient/Caregiver and provider acknowledge that a clinical benefit with Voxzogo has not been proven
- Patient/Caregiver have been instructed on how to properly use, store, and administer Voxzogo
- Provider agrees to monitor growth and adjust dose according to body weight
- Provider agrees to permanently discontinue Voxzogo upon closure of epiphyses

Non-FDA-approved uses are not approved.

Prior Authorization expires after 1 year; provider must fill out a new PA.

G. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF, Tier 4/Not Covered, and PA Implementation Plan

The P&T Committee recommended for group 1: (16 for, 0 opposed, 0 abstained, 1 absent); for group 2: (17 for, 0 opposed, 0 abstained, 0 absent); and for celecoxib oral solution (Elyxyb): (15 for, 1 opposed, 0 abstained, 1 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 Tier 4 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 Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation.

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

BAP Comments

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF/Tier 4 Recommendation

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

- **UF:**
 - Scemblix
 - Tavneos
 - Livtencity
 - Eprontia
 - Voxzogo

- **NF:**
 - Qulipta
 - Dhivy
 - Skytrofa
 - Livmarli
 - Besremi
 - Tyrvaya

- **Tier 4/Not Covered:**
 - Elyxyb

BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

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

BAP Comments

Concur: Non-Concur: Abstain: Absent:

E. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF, Tier 4/Not Covered and PA Implementation Plan

The P&T Committee recommended the following implementation plans as described above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

P&T Comments

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

Manual PA criteria were recommended for several recently marketed drugs which contain active ingredients that are widely available in low-cost generic formulations. These products are usually produced by a single manufacturer. Due to the pathway used to gain FDA approval, these products do not meet the criteria for innovators and cannot be reviewed for formulary status. These drugs all have numerous cost effective formulary alternatives that do not require prior authorization. For the products listed below, PA criteria is recommended in new and current users, requiring a trial of cost effective generic formulary medication first.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for Neonatal Plus (regardless of the woman's age), Fenoglide, and Indocin suppositories in new and current users, due to the significant cost differences compared with numerous available alternative agents. The criteria are as follows:

- 1) Anti lipidemics-2: Fenofibrates – fenofibrate 120 mg (Fenoglide)—**
Fenoglide is a new fenofibrate formulation available in a 120 mg strength. There are several formulations of fibric acid derivatives currently available, including gemfibrozil (Lopid, generics), generic fenofibrate micronized/nonmicronized formulations (including Lofibra), and fenofibrate nanocrystallized (Tricor). Fenoglide is made by a sole manufacturer and is not cost-effective relative to other fibric acid derivatives.

Manual PA criteria applies to new and current users of fenofibrate 120 mg tablets (Fenoglide)

- The provider is aware and acknowledges that other formulations of fenofibrate, including Tricor, Trilipix and Lofibra are available to DoD beneficiaries without the need of prior authorization
- The provider must explain why the patient t cannot take one generic fenofibrate 134 mg capsule or two fenofibrate 54 mg tablets or another formulation of fenofibrate (*fill-in blank*)

Non-FDA approved uses are NOT approved.

Prior Authorization does not expire.

2) Pain Agents: NSAIDs—indomethacin 50 mg suppositories (Indocin):

The indomethacin suppositories are markedly not cost-effective. All other formulations of indomethacin (suspension and capsules) and various other NSAIDs (generic meloxicam, ibuprofen suspension, diclofenac potassium, and naproxen) are included on the TRICARE pharmacy benefit and do not require prior authorization criteria. OTC NSAIDs are also widely available.

Manual PA criteria applies to new and current users of indomethacin suppositories

- The provider acknowledges that several other indomethacin formulations, including generic indomethacin suspension and capsules are available to TRICARE beneficiaries without requiring prior authorization
- The provider acknowledges that several other NSAIDs are available to TRICARE beneficiaries without requiring prior authorization including generic meloxicam, ibuprofen suspension, diclofenac potassium, and naproxen
- The provider must explain why the patient requires Indocin suppositories and cannot take generic indomethacin suspension, indomethacin capsules, or other formulary NSAIDs (*fill-in blank*)

Non-FDA-approved uses are NOT approved.

Prior authorization does not expire.

3) Vitamins: Prenatal—prenatal MVI (Neonatal Plus): Neonatal Plus is a prenatal dietary supplement manufactured by a single company which requires a prescription prior to dispensing. The primary ingredients of Neonatal Plus are similar to that found in Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, and Neonatal Complete, 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.

Manual PA criteria applies to new and current users of prenatal Neonatal Plus

- The provider 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, and Neonatal Complete and 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 Neonatal Complete 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—Androgens-Anabolic Steroids:
Intramuscular (IM) Testosterone Replacement Therapy testosterone cypionate and testosterone enanthate:**

The Testosterone Replacement Therapy (TRT) class was reviewed for formulary placement in August 2012, with PA criteria required for the gel and topical formulations. The IM injectable products were not included in the 2012 review, due to low utilization and cost at that time. They remain Uniform Formulary “by default” (since not previously reviewed) with no Prior Authorization requirements. A DHA provider workgroup requested that the DoD P&T Committee evaluate the need for a PA for the injectable testosterone formulations.

There has been a notable increase in utilization of the injectable products, while use of the topicals has declined across all age groups. Several commercial health plans have PAs in place for the injectable TRT formulations.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) placing PA criteria for testosterone cypionate and testosterone enanthate IM in new users, to ensure appropriate clinical use. The Committee also recommended updating the existing PA criteria for the topicals and all other brand and generic TRT formulations (e.g., Fortesta, Androgel, Testim Xyosted etc.), to ensure that the provider has investigated the etiology of low testosterone levels, as several clinical conditions (e.g., untreated DM) can lower testosterone levels. This criteria will not apply when the TRTs are used for the indication of gender dysphoria.

The PA criteria is as follows, with updates shown in bold also applying to the current PA criteria for the topical products.

Manual PA criteria applies to new users of testosterone cypionate or testosterone enanthate IM injections.

- Coverage approved for male patients if:
 - Patient is over the age of 17 years AND
 - Patient has diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL AND
 - **Provider has investigated the etiology of the low testosterone levels and acknowledges that testosterone therapy is clinically appropriate and needed AND**
 - The patient does not have prostate cancer AND
 - The patient is experiencing symptoms usually associated with hypogonadism

OR

- Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if:
 - Patient has diagnosis of gender dysphoria made by a TRICARE authorized mental health provider according to most current edition of the DSM
 - Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2 AND
 - Patient has no signs of breast cancer AND
 - For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding AND
 - Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g. unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment) AND
 - Patient has a documented minimum of three months of real-life experience (RLE) and/or three months of continuous psychotherapy addressing gender transition as an intervention for gender dysphoria

Non-FDA approved uses are NOT approved.

Not approved for concomitant use with other testosterone products.

Prior Authorization does not expire.

C New Manual PA Criteria Implementation Plan

The P&T Committee recommended the following implementation periods:

- The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) the manual PA criteria for Fenoglide, Indocin suppositories, and Neonatal Plus (regardless of the woman’s age), become effective the first Wednesday 90 days after the signing of the minutes, and DHA will send letters to affected patients.
- The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the new PA criteria for IM testosterone cypionate and testosterone enanthate will become effective the first Wednesday 90 days after the signing of the minutes.

IX. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

BAP Comments

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

The P&T Committee recommended new manual PA criteria for the 3 products listed above that contain active ingredients that are widely available in cost effective generic formulations: Fenoglide 120 mg tablets, Indocin 50 mg suppositories and Neonatal Plus, as listed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. New Manual PA Criteria for Testosterone Replacement Therapies: IM testosterone cypionate and testosterone enanthate

The P&T Committee recommended new manual PA criteria for IM testosterone cypionate and testosterone enanthate as listed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

D. New Manual PA Criteria Implementation Plan

The P&T Committee recommended the new PA criteria for Fenoglide, Indocin suppositories Neonatal plus and IM testosterone cypionate and testosterone

enanthate become effective the first Wednesday 90 days after signing of the minutes.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

X. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA-APPROVED INDICATIONS, AND EXPANDED AGE RANGES

P&T Comments

A. Updated PA Criteria for New FDA-Approved Indications and Expanded Age Ranges

The P&T Committee recommended (17 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.

Note that since these types of updates expand the patient population eligible for the drug, only a summary of the PA criteria is provided here; the current full PA criteria can be found on the TRICARE Formulary Search Tool at <https://www.express-scripts.com/frontend/open-enrollment/tricare/fst/#/>.

- 1.) **Respiratory Interleukins—dupilumab (Dupixent)**—The manual PA criteria were updated to expand use in children as young as 6 years of age for add-on maintenance therapy for moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.
- 2.) **Hepatitis C Agents: Direct Acting Agents—elbasvir/grazoprevir (Zepatier)**—The manual PA criteria were updated for Zepatier, allowing use in children as young as 12 years of age or weighing 30 kg or more for chronic hepatitis C virus (HCV) genotype 1 or 4 infection.
- 3.) **Atypical Antipsychotic Agents**
 - **brexpiprazole (Rexulti)**—The manual PA criteria were updated to allow use in children as young as 13 years of age for schizophrenia (Rexulti was previously only approved for adults)
 - **lumateperone (Caplyta)**—Includes the new indication for depressive episodes associated with bipolar disorder I or II in adults, as monotherapy or as adjunct to lithium or valproate.
- 4.) **Targeted Immunomodulatory Biologics (TIBs)**

- **risankizumab-rzaa (Skyrizi)**—Includes the new indication for active PsA in adults.
- **secukinumab (Cosentyx)**—Includes the new indication for active enthesitis-related arthritis (ERA) in patients 4 years of age and older. The manual PA criteria were also updated allowing use in children as young as 2 years of age for PsA. Note that for the ERA indication a trial of a non-biologic (e.g., methotrexate, sulfasalazine, mesalamine steroids or azathioprine) is not required.
- **tofacitinib (Xeljanz/Xeljanz XR)**—Includes the new indication for active ankylosing spondylitis in adults who have had an inadequate response or intolerance to 1 or more tumor necrosis factor (TNF) blockers. Note that for the ankylosing spondylitis indication, a trial of a non-biologic (e.g., methotrexate, sulfasalazine, mesalamine steroids or azathioprine) is not required. The PA update also includes the new safety warnings for the drug class.
- **upadacitinib (Rinvoq ER)**—Includes the new indication for active psoriatic arthritis (PsA) in adults who have had an inadequate response or intolerance to one or more TNF blockers.

B. Updated PA Criteria for New FDA-Approved Indications and Expanded Age Ranges - Implementation plan:

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) implementation of the first Wednesday 60 days after signing of the minutes for the updated PAs discussed above.

XI. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA-APPROVED INDICATIONS AND EXPANDED AGE RANGES

BAP Comments

A. Updated PA Criteria for New FDA-Approved Indications and Expanded Age Ranges:

The P&T Committee recommended updates to the PA criteria for Dupixent, Zepatier, Rexulti, Caplyta, Skyrizi, Cosentyx, Xeljanz and Rinvoq ER as discussed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Updated PA Criteria for New FDA-Approved Indications and Expanded Age Ranges - Implementation Plan

The updated PA criteria for the drugs discussed above will become effective the first Wednesday 60 days after the signing of the minutes.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REMOVAL OF AN INDICATION

P&T Comments

A. Updated PA Criteria for Removal of an indication

Oncological Agents: Non-Bruton Tyrosine Kinase Inhibitor (Non-BTKIs) for Chronic Lymphocytic Leukemia— duvelisib (Copiktra)

In December 2021, the manufacturer of Copiktra voluntarily withdrew the indication for Copiktra in patients with relapsed or refractory follicular lymphoma following at least 2 previous systemic therapies. The manufacturer determined this indication was no longer merited, based on the current treatment landscape for follicular lymphoma in the U.S. and the logistics, cost, and timing of the post-marketing requirements for the drug. This indication was originally approved by the FDA in September 2018 via accelerated pathway and was contingent upon the manufacturer completing confirmatory trials to receive full approval.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) removing the follicular lymphoma indication for new users; current users will be able to consult their provider as to whether continued treatment is clinically appropriate. The other FDA-approved indications for Copiktra are not affected and will remain on the PA (e.g., relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), marginal zone lymphoma (MZL),

B. Updated PA Criteria for Safety Information Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an implementation of the first Wednesday 60 days after signing of the minutes for Copiktra.

XIII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REMOVAL OF AN INDICATION

BAP Comments

C. Updated PA Criteria for Safety Information

The P&T Committee recommended updates to the PA criteria for Copiktra as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

D. Updated PA Criteria for Safety - Implementation Plan

The updated PA criteria for Copiktra will become effective the first Wednesday 60 days after the signing of the minutes as discussed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XIV. REMOVAL OF BRAND OVER GENERIC AUTHORIZATION FOR FLUTICASONE/SALMETEROL DRY POWDER INHALER (ADVAIR DISKUS)

P&T Comments

A. Fluticasone/salmeterol dry powder inhaler (Advair Diskus) removal of brand over generic authorization

Brand over generic PA requirements and a Tier 1 (generic) co-payment have applied to fluticasone/salmeterol dry powder inhaler (Advair Diskus DPI) since May 2019, due to cost effectiveness compared to AB-rated generics (e.g. Wixela). The branded agent, Advair Diskus is no longer the most cost effective inhaled corticosteroid/long-acting beta agonist (LABA/ICS) dry powder inhaler at the MTF and Mail Order points of service. Generic prices of fluticasone/salmeterol DPI will continually be monitored.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) removing the Advair Diskus brand over generic PA requirement. As a result, the current PA criteria for the generic fluticasone/salmeterol DPI will be removed. The branded Advair Diskus will remain available at the Tier 1 (generic) co-payment at the Mail Order and the Retail network pharmacies, until further direction from the P&T Committee.

**XV. REMOVAL OF BRAND OVER GENERIC AUTHORIZATION FOR
FLUTICASONE/SALMETEROL DRY POWDER INHALER (ADVAIR DISKUS)**

BAP Comments

**A. Fluticasone/salmeterol dry powder inhaler (Advair Diskus) removal of
brand over generic authorization**

The P&T Committee recommended removing the Advair Diskus brand over generic authorization, as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XIV. INFORMATIONAL ITEM—BENEFICIARY IMPACT (FEBRUARY 2022 DoD P&T COMMITTEE MEETING)

Table of Newly Approved New Drugs Designated Tier 4—Unique Utilizers Affected

Drug	Total
celecoxib oral solution (Elyxyb)	0

Drugs with New Prior Authorization Criteria—Unique Utilizers Affected

Drug	MTF	Mail Order	Retail	Total
Fenofibrate 120 mg tablets	22	90	50	162
Indomethacin suppositories	0	3	6	9
prenatal vitamin Neonatal Plus	0	0	0	0

Biomarin Pharmaceuticals

From: Becky Hanson

Sent: Tuesday, April 5, 2022 10:52 AM

To: DHA NCR J-6 Mailbox BAPREQUESTS <dha.ncr.j-6.mbx.baprequests@mail.mil>

Subject: [Non-DoD Source] Written Comment Regarding Voxzogo

To Whom it May Concern,

I am writing in regards to the proposed policy for Voxzogo (vosoritide injection). I would like to request the following changes:

- Current language in question 3: Voxzogo is prescribed by or in consultation with a pediatric endocrinologist
 - Please consider changing to “Voxzogo is prescribed by or in consultation with a pediatric endocrinologist, geneticist, or other specialist with experience in treating achondroplasia patients”. In our clinical trials, 12 principle investigators were geneticists, 5 were orthopedists, and 6 were pediatric endocrinologists. Thus, many achondroplasia patients are currently seen by these specialists, and they are well positioned to monitor patients being treated with Voxzogo.
- Current language in question 5: Patient/Caregiver and provider acknowledge that a clinical benefit with Voxzogo has not been proven
 - Please consider changing to “Does the patient/caregiver and provider acknowledge Voxzogo was approved based on an increase in linear growth which was determined by FDA to be likely to predict clinical benefit but that clinical benefit is being researched and has not yet been proven” When answering a yes or no question we want to ensure that the intent is clear for the provider.

Thank you for your consideration. If there are any questions, please do not hesitate to reach out.

Kind Regards,

Becky Hanson

Becky Hanson, PharmD

Senior Director, Managed Markets



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Beneficiary Advisory Panel Members,

With the release of the Pharmacy and Therapeutics Committee recommendations for Livmarli (Maralixibat) Oral Solution, we seek to provide comments to PA criteria 4 and 5 which are misaligned with how patients with Alagille's Syndrome are traditionally treated.

PA Criteria 4 Recommendation: "Patient has been evaluated for possible orthotopic liver transplant (OLT)"

- **Response:** From the observations of several Tricare physicians, who have prescribed Livmarli, this OLT evaluation is not the standard for newly diagnosed Alagille Syndrome patients one year of age or older. This is especially true if liver function is mildly impaired. OLT Evaluation is usually performed when a patient has signs and symptoms of advanced liver disease, failure to thrive, along with severe pruritus. Severe pruritus alone is usually not a reason for an OLT referral. This recommendation is an outlier as less than 1% of lives in Commercial or Medicaid insurance plans require an OLT evaluation as part of their prior authorization policy for Livmarli (Maralixibat) Oral Solution.

PA Criteria 5 Recommendation: Patient has previously tried and failed all of the following:

- ursodiol
 - cholestyramine
 - rifampin
 - naltrexone
 - At least one antihistamine (e.g. Atarax, Benadryl, etc.)
- **Response:** The 5 medications recommended by the P&T Committee are not approved by the FDA for use in the treatment of cholestatic pruritus in patients with Alagille Syndrome. Not only are they not indicated to treat cholestatic pruritus, but efficacy is also poorly understood based on current data in this patient population. In the ICONIC trial, 94% of patients utilized concomitant medications (most commonly ursodiol and rifampin). These patients showed poor pruritus control as shown by mean ItchRO(obs) scores of 2.9 (mean score is before the initiation of Livmarli). The scale for ItchRo(obs) ranges from 0 (no pruritus) to 4 (severe pruritus).

As a result of poor pruritus control, 86% of lives within Commercial and Medicaid insurance plans require the trial and failure of **one or fewer** medications (predominantly Ursodiol) before Livmarli (Maralixibat) Oral Solution can be considered for usage.

On behalf of Alagille Syndrome patients and their families, we ask each of the BAP members to consider voting for the removal of the OLT evaluation requirement (criteria 4), and adjust the previous therapies tried and failed in these patients to one (criteria 5).

We recognize that the P&T recommendations were published on April 4th in preparation for the April 6th meeting. As a result, we were not able to provide these comments 5 days in advance of the BAP session. Respectfully, we ask each BAP member to consider these comments before taking a vote on the final Prior Authorization criteria for Livmarli (Maralixibat) Oral Solution.

Sincerely,

Mirum Pharmaceuticals

ChemoCentryx Pharmaceuticals

From: Kathy Blecha >

Sent: Tuesday, April 5, 2022 10:52 AM

To: DHA NCR J-6 Mailbox BAPREQUESTS <dha.ncr.j-6.mbx.baprequests@mail.mil>

Subject: [Non-DoD Source] Written Comment Regarding Tavneos

I am a new Account Director for ChemoCentryx. I understand per the Federal Register that our newly approved molecule will be reviewed by BAP at the April 6 meeting.

I missed the cutoff date to submit information for consideration. The agenda states it must be submitted 5 days prior to the meeting and the Federal Register notice says 1 day— my sincere apologies I missed the cutoff.

I just saw something in the meeting background document that I wanted to alert you about. It's regarding the criteria for one of the newly approved drugs being reviewed:

TAVNEOS® (avacopan)

Respectfully, think perhaps there may be an error in the proposed criteria on bullet point 5 where the criteria says (at least a, b, or c): where it references BVAS score. It may need to be c, d, or e? BVAS scores are used in clinical trials, but not typically used by provider specialists in clinical practice. Many specialists at facilities or as contracted providers in the community will not know how to use a BVAS score.

I will be sure to follow up with XXX who is in charge of Industry Relations and ask for guidance related to any requests for clinical information.

Have a great meeting tomorrow. I'm excited to listen in and learn!

Respectfully,
Kathy

Kathy Blecha, National Account Director
ChemoCentryx