EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel
Meeting June 30, 2022

For the May 2022 DoD Pharmacy and Therapeutics Committee Meeting

The Uniform Formulary Beneficiary Advisory Panel (UFBAP) convened at 10:00 A.M. EDT on June 30, 2022 via teleconference. The current meeting took place over 1 hour and 30 minutes. The information presented included the recommendations from the May 2022 DoD Pharmacy and Therapeutics Committee (P&T) meeting.

The detailed meeting information is found starting on page 8.

UNIFORM FORMULARY (UF) DRUG CLASS REVIEWS

I. UF CLASS REVIEWS—Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass

A. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—UF Recommendations

- UF
  - dulaglutide (Trulicity)
- NF
  - semaglutide (Ozempic)
  - exenatide once weekly (Bydureon BCise) - *moves from UF to NF*
  - exenatide twice daily (Byetta)
  - liraglutide (Victoza)
  - lixisenatide (Adlyxin)
  - Note that for Bydureon BCise, Byetta, Victoza and Adlyxin, a trial of both Trulicity and Ozempic are required
- Tier 4/Not Covered - None

Summary of Panel Questions and Comments

Dr. Dager asked why Ozempic was not placed formulary with a lower copay, since it has interchangeability with Trulicity. CDR Raisor responded that both clinical and

cost effectiveness considerations were evaluated when the uniform formulary recommendation was made.

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

B. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—Manual PA Criteria

Summary of Panel Questions and Comments

No comments.

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

C. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass —UF, PA and Implementation Plan 60 days after signing of the minutes

Summary of Panel Questions and Comments

Dr. Peloquin questioned why a 60-day implementation was recommended, instead of 90 days, since about 18,000 patients will be affected. CDR Raisor responded that we have improved communications to patients, and we want to rapidly convert patients to those products that have cardiovascular outcome benefits.

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

II. UF CLASS REVIEWS—Migraine Agents - Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass

A. Migraine Agents - Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass —UF Recommendation

- UF
  - atogepant (Qulipta) – *moves from NF to UF*
  - rimegepant (Nurtec ODT)
  - ubrogepant (Ubrelvy) – *moves from NF to UF*
- NF – None
- Tier 4/Not Covered - None

Summary of Panel Questions and Comments

Dr. Soucy asked if there is any data for concurrent use for an oral CGRP with an injectable CGRP, as she does see patients started on the injectable and wanting an oral used too. Maj Escano responded that the PA does allow use of Nurtec ODT for abortive treatment along with an injectable CGRP for prevention.

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

B. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—Manual Prior Authorization Criteria

Summary of Panel Questions and Comments

No comments.

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

C. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass —UF, PA and Implementation Plan of 30 days

Summary of Panel Questions and Comments

No comments.

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

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

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

- UF:
  - filgrastim-ayow injection (Releuko)
  - mitapivat (Pyrukynd)
  - naloxone 5 mg/0.5 mL injection (Zimhi)
  - pacritinib (Vonjo)
- NF:

- abrocitinib (Cibinqo)
- baclofen oral suspension (Fleqsuvy)
- tenapanor (Ibsrela)
- tralokinumab-ldrm injection (Adbry)

- **Tier 4/Not Covered:**
  - budesonide delayed release (DR) capsules (Tarpeyo)
  - celecoxib/tramadol (Seglentis)
  - glycopyrrolate orally disintegrating tablet (Dartisla ODT)
  - levoketoconazole (Recorlev)
  - torsemide 20 mg, 40 mg and 60 mg tablets (Soaanz)
  - tretinoin 0/1%/benzoyl peroxide 3% topical cream (Twyneo)

Summary of Panel Questions and Comments

No comments

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

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria for Cibinqo, Fleqsuvy, Releuko, Ibsrela, Adbry, Pyrukynd

Summary of Panel Questions and Comments

No comments

- **Concur: 7 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: 7 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 meclizine 25 mg chewable tablet (Antivert), lanreotide 120 mg injection, citalopram 30 mg capsule, and ketoprofen 25 mg capsule

Summary of Panel Questions and Comments

No comments.

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

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

Summary of Panel Questions and Comments

No comments.

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

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

A. Updated PA Criteria for New FDA-Approved Indications for Fintepla, Lynparza, Stelara, and Rinvoq

Summary of Panel Questions and Comments

No comments.

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

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

Summary of Panel Questions and Comments

No comments.

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

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

Updated PA Criteria for removal of indications for Zydelig for relapsed follicular B-cell non-Hodgkin lymphoma (FL) and relapsed small lymphocytic lymphoma (SLL) and implementation plan of 60 days.

Summary of Panel Questions and Comments

No comments.

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

VII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW FDA-APPROVED INDICATIONS

A. Updated PA Criteria for reasons other than new FDA-approved indications for Firdapse, testosterone cypionate IM and testosterone enanthate IM, Oxervate, Omnipod, and Omnipod DASH

Summary of Panel Questions and Comments

No comments.

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

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

Summary of Panel Questions and Comments

No comments.

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

VIII. BRAND OVER GENERIC AUTHORIZATION FOR CYCLOSPORINE 0.05% OPHTHALMIC EMULSION SINGLE DOSE VIALS (RESTASIS), TIER 1 COPAY and IMPLEMENTATION PLAN

Cyclosporine 0.05% ophthalmic emulsion single dose vials (Restasis), Tier 1 copay, and 2 weeks implementation plan

Summary of Panel Questions and Comments

No comments.

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

Director, DHA:

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

Uniform Formulary Beneficiary Advisory Panel
Virtual Meeting Summary Minutes
June 30, 2022

Panel Members Present

- Mr. Jon Ostrowski, Non-Commissioned Officer Association, Chair
- Dr. Karen Dager, PharmD, Health Net Federal Services
- 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
- Ms. Amanda Meyers, Military Officers Association of America (MOAA)
- Mr. Keith Reed, Air Force Sergeants Association

Panel Members Absent

- Dr. Richard Bertin, Ph. D., Commissioned Officer Association of the U.S. Public Health Service
- Ms. Holly Dailey, the Association of the United States Army
- Ms. Catherine Seybold, U.S. Coast Guard Chief Petty Officers Association
- Ms. Patricia Orfini, National Family Member Association

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
- Maj Angelina Escano, MC POD FMB
- LCDR Elizabeth Hall POD FMB
- Angela Allerman, PharmD, BCPS, POD FMB
- Ms. Megan Gemunder Office of General Counsel
- Major Peter Fosse POD, Chief - Patient Safety & Compliance Operations
- Col Paul Carby POD, Pharmacy Market Consultant

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 May 4-5, 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 pharmaceutical agents and establishes the P&T committee to review the formulary on a periodic basis to make additional recommendations regarding the formulary as the committee determines necessary and appropriate.

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

Private Citizen Comments: Written comments were forwarded to the Panel for their review and consideration from the following;

1. Calliditas Therapeutics for budesonide capsules (Tarpeyo)
2. Kala Pharma for loteprednol 0.25% ophthalmic solution (Eysuvis*); note these comments pertain to information presented at the April 6, 2022 BAP meeting, however, the information was submitted late.*

Several submissions were received that contained information that did not fall under the purview of the Panel; these comments were forwarded to the appropriate parties for response.

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

Chairman's Opening Remarks

Mr. Ostrowski welcomed all panel members and attendees 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.

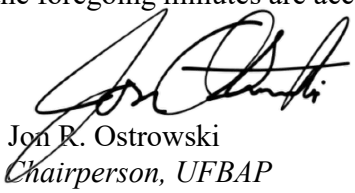
The goal of this presentation is not to provide you with the same in-depth analyses presented to the DoD P&T Committee but a summary of the processes and analyses presented to the DoD P&T Committee.

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 everyone for helping our beneficiaries who use these services, and also thanked the presenters, and Col Hoerner, along with the fellow Panel members.
Col Hoerner closed the meeting by thanking the Panel members for their time, involvement and commitment to improving the health and well-being of our nation's military members and families.

The Meeting Adjourned at 10:30 AM 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

GLP1RAs

- We have reviewed this class four times previously, and currently we have about 90,000 patients on one of these drugs. The recommendation maintains Trulicity on the UF, so there will be no change for 70% of the patients in the class. Any new patient with a Trulicity prescription will only have to try metformin first.
- For Ozempic, which is about 10% of the market share, it will stay nonformulary. However, the PA change for Ozempic is that new patients will only have to try metformin, and won't have to try Trulicity first. There will be no change to patients currently on Ozempic.
- The main change in this class is that Bydureon will move to nonformulary status, plus the PA change will require a trial of both Trulicity and Ozempic in new and current users. This will affect about 15,000 patients who are currently on Bydureon, who will either need to change to Trulicity or Ozempic, or go through the PA again to stay on Bydureon.
- The other three drugs that are currently nonformulary (Victoza, Byetta, and Adlyxin) will stay nonformulary, but all new and current users will also have to go through the PA again, to try Trulicity or Ozempic first. This will affect about 3,500 patients, primarily patients receiving Victoza and Byetta (note that we don't have any patients on Adlyxin).
- Although the recommendations will affect about 18,000 patients, we have done switching with this class before. Also we do think there are several advantages to having patients switch to Trulicity or Ozempic, including that these two drugs have proven benefit in improving cardiovascular outcomes, they are dosed once weekly, and they have devices that are easy to use with small needle sizes.
- The patients who will be affected by the formulary and PA changes will receive letters, and we are also working with ESI to have additional outreach to patients.
- There is one change to the PA to mention. Bydureon and Victoza are the only GLP1RAs approved for use in adolescents, and currently we have about 70 patients younger than age 19 on a GLP1RA. After the May P&T meeting, an article was published in the New England Journal of medicine showing safety and efficacy of Trulicity in adolescents. Based on this trial, we will allow use of Trulicity for adolescents.

Migraine Agents – Oral CGRPs

- This is the first time we are reviewing this drug class, although the three products were previously reviewed as new drugs. The recommendation is that all three drugs will be on the formulary. The Committee did recognize that migraine headache impacts a large number of beneficiaries, including active duty service members.
- The PAs will require the use of guideline-recommended products first. Depending on whether the drug is being used for treatment or prevention of migraine, patients will either have to try an injectable CGRP first, or a triptan. We did receive feedback from neurologists when considering the PA criteria. Also note that the PAs changes will only affect new users- patients who are currently receiving these drugs won't have to go through the PA again.
- The patients who are receiving one of the current nonformulary drugs (Qulipta or Ubrelvy) will see the copay reduction when they get their prescription refilled, after the implementation.

Newly Approved Drugs

Tier 4 drugs – Tarpeyo, Seglentis, Dartisla ODT, Recorlev, Soaanz, Twyneo

- All of the products recommended for Tier 4 placement contain active ingredients that are found in low-cost generic formulations. Based on clinical issues alone, these products are not needed on the formulary. We also solicited feedback from pertinent specialists who agreed with Tier 4 placement. Additionally, we did check whether the VA and commercial health plans covered these drugs, and the majority of the time, these were not covered. Overall, the clinical data and high cost of these drugs supported Tier 4 status. Any patient who has been started on a Tier 4 drug will receive a letter notifying them of the change, and formulary options to consider.

Drugs with PA recommended – Cibinqo, Fleqsuvy, Releuko, Ibsrela, Adbry, Pyrukynd

- There are 6 drugs where a PA is recommended. In general, these PAs match what is already in place for the particular drug class or disease sate, or in the case of the orphan drug for pyruvate deficiency (Pyrukynd), the PA corresponds with the package insert labeling and safety monitoring.

Utilization Management – New PA Criteria

- **New Manual PA Criteria Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)** *(Antivert 25 mg chew tab; Lanreotide 120 mg injection, citalopram 30 mg, ketoprofen 25 mg capsule)*
    - These four drugs fall under a different FDA approval pathway, so they don't qualify as innovators; they were approved using the Abbreviated New Drug Approval pathway (ANDA).

- In general these are older drugs that have been brought back to the market using data that is several decades old. Numerous formulary alternatives are available. Overall, these products have little value clinically or economically.
- The PA criteria will apply to new and current users, and we will mail letters to affected patients. The overall purpose of the PA is intended to shift utilization to more cost effective products.

Utilization Management – Updated PA Criteria – new FDA indications

Fintepla, Lynparza, Stelara, Rinvoq

- This section you will see at every meeting. It's where we give brief summaries on drugs where current PAs are updated for expanded age ranges and indications.
- All the changes will result in an increased number of patients who will qualify for the drug. We do continually check for these types of updates from the package inserts, to ensure our PAs are not outdated.

Utilization Management - Updated PA Criteria for Removal of an indication

Oncological Agents: idelalisib (Zydelig) – removal for Beta cell lymphoma

- The situation here is another oncology drug that was approved on conditional data, and now that the clinical trial has been completed, the results did not allow for continued approval of Zydelig for this particular indication. We had an example of this at the last meeting too.
- When drugs are approved, there is often limited data on efficacy and safety, particularly for oncology drugs and drugs for rare diseases. The PA criteria that we put in place do include criteria that match the FDA-approved indications and monitoring.
- 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.

Updated PA Criteria for Reasons other than new FDA Indications (Firdapse update for Ruzurgi removal from market, testosterone for gender dysphoria, Oxervate, Omnipod DASH)

- All of the examples here show the wide variety of reasons where we update the PAs. We do spend time to ensure our PAs are up to date.

AGENDA

Uniform Formulary Beneficiary Advisory Panel (BAP)
For the May 2022 DoD Pharmacy and Therapeutics Committee Meetings
June 30, 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 May 2022 meeting:

  - **Drug Class Reviews**
    - *Non-Insulin Diabetes Drugs Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass*
    - *Migraine Agents – Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass*
  - **Newly Approved Drugs per 32 CFR 199.21(g)(5)**
    - *abrocitinib (Cibinqo) – Atopy drug class; oral Janus kinase (JAK) inhibitor for atopic dermatitis*
    - *baclofen oral suspension (Fleqsuvy) – Skeletal Muscle Relaxant spasticity associated with multiple sclerosis*
    - *budesonide delayed release (DR) capsules (Tarpeyo) – Miscellaneous nephrology agent; an extended-release formulation of budesonide approved to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN)*
    - *celecoxib/tramadol (Seglentis) – Narcotic Analgesics and Combinations; a fixed-dose combination of celecoxib and tramadol for acute pain*
    - *filgrastim-ayow injection (Releuko) – White Blood Cell Stimulants - filgrastims*
    - *glycopyrrolate orally disintegrating tablet (Dartisla ODT) – Anti-cholinergic/Antispasmodic Agents; another formulation of glycopyrrolate*

approved to reduce the symptoms of peptic ulcer as an adjunct to treatment of peptic ulcer

- *levoketoconazole (Recorlev) – Miscellaneous endocrine agent; a ketoconazole formulation approved to treat Cushing's disease for whom pituitary surgery is not an option or has not been curative*
- *mitapivat (Pyrukynd) – Miscellaneous metabolic agent for pyruvate kinase deficiency*
- *naloxone 5 mg/0.5mL injection (Zimhi) – Narcotic Antagonist*
- *pacritinib (Vonjo) – Oncologic agent for myelofibrosis*
- *tenapanor (Ibsrela) – Gastrointestinal-2 Agent for Constipation-Predominant Irritable Bowel Syndrome (IBS-C)*
- *torsemide 20 mg and 60 mg tablets (Soaanz) – Diuretics; another formulation of torsemide approved to treat patients with heart failure or renal disease with edema who have concerns with excessive urination or hypokalemia*
- *tralokinumab-ldrm injection (Adbry) – Atopy drug class; injectable agent for atopic dermatitis*
- *tretinoin 0.1%/benzoyl peroxide 3% topical cream (Twyneo) – Acne Agent; combination of tretinoin and benzoyl peroxide approved for acne vulgaris in 9 years of age and older*

- **Utilization Management Issues**
  - **Prior Authorization Criteria—New Manual PA Criteria**
    - *Antiemetic/Antivertigo Agents—meclizine 25 mg chewable tablet (Antivert)*
    - *Endocrine Agents Miscellaneous—lanreotide 120 mg injection*
    - *Selective Serotonin Reuptake Inhibitors (SSRIs)—citalopram 30 mg capsule*
    - *Pain Agents: NSAIDs—ketoprofen 25 mg capsule 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**
    - *Anticonvulsants-Antimania Agents—fenfluramine oral solution (Fintepla)*

- *Oncologic Agents: Ovarian Cancer—olaparib (Lynparza)*
- *Targeted Immunomodulatory Biologics (TIBs)*
    - *ustekinumab (Stelara)*
    - *upadacitinib (Rinvoq)*

- **Prior Authorization Criteria—Removal of Indication**
    - *Oncological Agents: idelalisib (Zydelig)*

- **Updated PA Criteria for Reasons other than FDA indications**
    - *Neurological Agents Miscellaneous: amifampridine (Firdapse)*
    - *Androgens-Anabolic Steroids: Intramuscular (IM) Testosterone Replacement Therapy—testosterone cypionate and testosterone enanthate*
    - *Anti-Inflammatory Immunomodulatory Ophthalmic Agents: cenegermin-bkbj ophthalmic solution (Oxervate)*
    - *Miscellaneous Insulin Devices: Omnipod Classic (generation 3), Omnipod DASH (generation 4)*

- **Brand Over Generic Authorization**
    - *Cyclosporine 0.05% ophthalmic emulsion single-dose (Restasis)*

- **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 MAY 2022 MEETING

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL MEETING JUNE 30, 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—NON-INSULIN DIABETES DRUGS: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP1RAs) SUBCLASS

P&T Comments

A. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—Relative Clinical Effectiveness Analysis and Conclusion

Background—The GLP1RAs were most recently reviewed in February 2018 when dulaglutide (Trulicity) replaced albiglutide (Tanzeum) on the formulary, due to market withdrawal. Exenatide once weekly (Bydureon BCise) and Trulicity have been the formulary step-preferred agents since 2018, with the remainder of the products nonformulary and non-step-preferred. This review focused primarily on systematic reviews and meta-analyses of the cardiovascular outcomes trials (CVOTs) with the GLP1As. Oral semaglutide (Rybelsus) was not part of this review, but remains UF.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- Metformin has an established place in therapy and remains first-line in most patients unless there are contraindication for use.

- The previous clinical conclusions from February 2018 remain largely unchanged with regard to GLP1RA effects on glycemic control, lipids, blood pressure, and body weight as well as safety and tolerability in patients with type 2 diabetes (T2DM).

- The GLP1RAs have a comparable range of efficacy across a broad population of patients with T2DM.

- Active comparator studies are available that evaluate the changes in hemoglobin A1c between the once weekly agents, semaglutide (Ozempic), dulaglutide (Trulicity) and exenatide once weekly (Bydureon BCise).

    - Ozempic vs. Bydureon: In the open-label, active comparator SUSTAIN-3 study, Ozempic was statistically and clinically superior to Bydureon BCise in glycemic control, as semaglutide lowered A1c by 1.5% from baseline compared to 0.9% with exenatide. Limitations to the SUSTAIN-3 study include its open label, active comparator design; it was not designed to show superiority.

    - Ozempic vs. Trulicity: In the open-label, active comparator SUSTAIN-7 study, semaglutide (Ozempic) was statistically superior to dulaglutide (Trulicity) in glycemic control, as it reduced A1c by 1.5-1.8% from baseline compared to 1.1-1.4% with dulaglutide. However, the differences in change in A1c between semaglutide and dulaglutide were not considered clinically relevant, as the change in A1c between the two drugs was less than 0.5% in respective treatment arms. Additionally, SUSTAIN-7 did not include the highest doses of dulaglutide (3 mg and 4 mg) which are now available.

- One recent systematic review (Giugliano, 2021) included approximately 60,000 patients with T2DM, where approximately 14,800 patients did not have established CV disease.

    - Overall, the results showed the GLP1RAs have a moderate benefit on major adverse cardiovascular events (MACE), including a reduction in hospitalization from heart failure, all-cause mortality, and the incidence of macroalbuminuria.

    - A greater effect was shown in those patients with known cardiovascular (CV) disease compared to those without.

- Individual clinical trials have shown a neutral or beneficial effect of the GLP1RAs in reducing CV events. The package inserts of Victoza, Ozempic, and Trulicity have an additional indication for CV risk reduction in those with established CV disease or who have multiple CV risk factors.

- Ozempic and Trulicity have warnings regarding diabetic retinopathy in their package inserts. However, studies are not powered to adequately assess this

adverse effect. Additional studies are needed to definitively determine the long term effects of GLP1RAs on diabetic retinopathy.

Overall Conclusions

- Trulicity and Ozempic have a high degree of therapeutic interchangeability with regard to once weekly administration, cardiovascular benefits, ease of administration, indications, warnings, and adverse reactions.

- Victoza, Adlyxin, Bydureon BCise, and Byetta are less advantageous and have less clinical utility compared to Trulicity and Ozempic, due to such factors as the results of CVOT trials, increased frequency of dosing, or user-friendliness of the device.

B. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—Relative Cost Effectiveness Analysis and Conclusion

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and also conducted a budget impact analysis (BIA). The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- Cost minimization analysis (CMA) results showed that dulaglutide (Trulicity), exenatide (Byetta), exenatide once weekly (Bydureon BCise), liraglutide (Victoza), lixisenatide (Adlyxin), and semaglutide (Ozempic) were all cost effective agents.

- Budget Impact Analysis (BIA) and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating Trulicity as UF, and Byetta, Bydureon BCise, Victoza, Adlyxin, and Ozempic as NF demonstrated significant cost avoidance for the MHS.

C. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—UF Recommendation

The P&T Committee recommended ((15 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
  - dulaglutide (Trulicity)
- NF
  - semaglutide (Ozempic)

- exenatide once weekly (Bydureon BCise) -*moves from UF to NF*
- exenatide twice daily (Byetta)
- liraglutide (Victoza)
- lixisenatide (Adlyxin)
- Note that for Bydureon BCise, Byetta, Victoza and Adlyxin, a trial of both Trulicity and Ozempic are required

- Tier 4/Not Covered
  - None

D. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—Manual PA Criteria

PA criteria have applied to the GLP1RAs for several years, requiring a trial of metformin first, unless the patient has had an adverse event, inadequate response or a contraindication. Currently a trial of dulaglutide (Trulicity) and exenatide once weekly (Bydureon BCise) are required, prior to use of one of the non-step-preferred products.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updated PA criteria for the GLP1RA class. Metformin will still be required in all new users of a GLP1RA, consistent with professional treatment guidelines. For semaglutide (Ozempic), a trial of dulaglutide (Trulicity) will no longer be required in new patients.

All new and current users of Bydureon BCise (which is now moving to NF status), Byetta, Victoza, and Adlyxin will now require a trial of both Trulicity and Ozempic. Children as young as 10 years can receive Victoza or Bydureon BCise without a trial of Trulicity and Ozempic, as these two products are the only GLP1RAs approved for children. *(Note that after the May 2022 meeting a clinical trial evaluating use of Trulicity in adolescents was published; even though Trulicity is not currently approved for use in adolescents, the PA will allow use of Trulicity for children.)*

The Manual PA criteria is as follows:

dulaglutide (Trulicity) and semaglutide (Ozempic)

The only change from the May 2022 meeting is new patients receiving Ozempic do not require a trial of Trulicity first.

All new users of a GLP1RA are required to try metformin before receiving a GLP1RA.

Manual PA criteria—Trulicity or Ozempic are approved (i.e., a trial of metformin is NOT required) if:

- The patient has a confirmed diagnosis of Type 2 diabetes mellitus.
- The patient has experienced any of the following issues on metformin:
    - impaired renal function precluding treatment with metformin
    - history of lactic acidosis
- The patient has had inadequate response to metformin
- The patient has a contraindication to metformin

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

exenatide once weekly (Bydureon BCise), exenatide twice daily (Byetta), liraglutide (Victoza) and lixisenatide (Adlyxin)

Changes from the May 2022 meeting are in bold and strikethrough.

All new users of a GLP1RA are required to try metformin before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin first.

New and current users of Bydureon BCise, Byetta, Victoza, or Adlyxin, must try ~~Bydureon/Bydureon BCise~~ Trulicity ~~and~~ Ozempic first. *(Note that a trial of Bydureon BCise is no longer required)*

Manual PA criteria—Bydureon BCise, Byetta, Victoza, or Adlyxin is approved (i.e., a trial of metformin is NOT required) if:

- The patient has a confirmed diagnosis of Type 2 diabetes mellitus.
- The patient has experienced any of the following issues on metformin:
    - impaired renal function precluding treatment with metformin
    - history of lactic acidosis
- The patient has had inadequate response to metformin
- The patient has a contraindication to metformin

AND

In addition to the above criteria regarding metformin, the following PA criteria would apply specifically to new and current users of Bydureon BCise, Byetta, Victoza, and Adlyxin:

- The patient has had an inadequate response to Trulicity and **Bydureon BCise** Ozempic OR *(Note that a trial of Bydureon BCIse is no longer required)*
- **For Victoza and Bydureon BCise, patient is age 10 years to < 18 years.**

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

E. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—UF, PA and Implementation Period

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday 60-days after signing of the minutes in all points of service.

III. UF DRUG CLASS REVIEWS—NON-INSULIN DIAETES DRUGS: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP1RAs) SUBCLASS

BAP Comments

A. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—UF Recommendations

The P&T Committee recommended the formulary status for the Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass as stated above.

- UF
  - Trulicity
- NF
  - Ozempic
  - Bydureon BCise *moves from UF to NF*

- Byetta
- Victoza
- Adlyxin

- Tier 4/Not Covered
  - None

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—Manual PA Criteria

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

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—UF, PA and Implementation Period

The P&T Committee recommended 1) an effective date of the first Wednesday 60-days after signing of the minutes in all points of service; and 2) DHA send letters to beneficiaries who are affected by the formulary decision.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEWS—Migraine Agents - Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass

P&T Comments

A. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—Relative Clinical Effectiveness Analysis and Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the oral CGRP antagonists. The drugs in the subclass include ubrogepant (Ubrelvy), rimegepant (Nurtec), and atogepant (Qulipta). The CGRP antagonists are available as tablets (Ubrelvy, Qulipta) and as an oral disintegrating tablet (ODT) (Nurtec).

Ubrelvy and Nurtec ODT were reviewed as new drugs during the May 2020 P&T committee meeting, while Qulipta was reviewed in February 2022. The injectable CGRP agents for migraine headache prevention [erenumab (Aimovig), fremanezumab (Ajovy), and galcanezumab (Emgality)] were reviewed for formulary status in February 2019.

The drugs in the subclass differ in their FDA-approved indications. Ubrelvy is approved for the acute treatment of migraine, Qulipta is labeled for prevention of episodic migraine, and Nurtec ODT is approved for both acute treatment of migraine and prevention of episodic migraine.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

Professional Treatment Guidelines

- *Acute treatment:* Medications with established efficacy for acute migraine treatment should be considered prior to initiation of the oral CGRP agents. Specifically, oral CGRP medications may be considered after a trial of two or more oral triptans, or in patients with a contraindication to or intolerability to triptans. These recommendations are based on the 2021 American Headache Society (AHS) consensus statement for integrating new migraine treatments into clinical practice.

- *Preventive treatment*: Medications including antiepileptics (e.g., valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol) and antidepressants (e.g., amitriptyline, nortriptyline), are first-line treatment options for episodic migraine prevention. This is based on the 2012/2015 American Academy of Neurology/American Headache Society migraine prevention guidelines. The 2021 AHS consensus statement for instituting new migraine treatments into clinical practice expands on the use of injectable CGRP antagonists for episodic migraine prevention. However, there is no specific guidance for oral CGRPs, citing the need for additional evidence and data.

Efficacy

- *Acute treatment vs. other therapies*: A 2020 network meta-analysis (NMA) from the Institute for Clinical and Economic Review (ICER) found that the oral CGRP antagonists (Ubrelvy, Nurtec ODT) are less efficacious than triptans when assessing pain freedom at 2 hours post treatment of migraine. A 2020 Cochrane NMA similarly reported that Ubrelvy and Nurtec ODT are less efficacious than

sumatriptan, ibuprofen, diclofenac, and acetylsalicylic acid when assessing pain freedom at 2 hours post treatment of migraine.

- *Preventive treatment vs other therapies*: There are no head-to-head trials comparing Nurtec ODT and Qulipta to other standard migraine preventive treatments, or to their injectable CGRPs counterparts. Of note, the injectable CGRPs (Aimovig, Ajovy, Emgality) are only indicated for prevention of migraine, not acute treatment. Clinical trials demonstrate that the oral CGRP antagonists (Nurtec ODT, Qulipta) decrease monthly migraine days (MMD) by 0.7 to 1.7 days from baseline, compared to placebo. A 2018 ICER NMA found that the injectable CGRP antagonists, decreased MMDs by 1.2 to 1.9 days from baseline, compared to placebo.

- *Oral CGRPs vs. Oral CGRPs:* There are no head-to-head trials between the oral CGRP antagonists for either acute treatment or prevention of migraine headache. The high placebo response rate limits the ability to determine if there are clinically relevant differences in efficacy between Qulipta, Nurtec ODT and Ubrelvy.

Safety

- The oral CGRP agents all have a relatively mild side effect profile. The most frequently reported adverse events for all the products include nausea, nasopharyngitis, urinary tract infection, and upper respiratory tract infection. Constipation and fatigue have been reported with Qulipta.

- There is limited long-term data to understand the risks with chronic CGRP antagonism. CGRP is a known vasodilator; there is a theoretical risk of increased ischemic events with CGRP antagonism. However, the 2021 FDA review for Qulipta states that based on available data, this medication does not require CV restrictions in labeling. The AHS in 2021 states that oral CGRPs (i.e. Nurtec ODT) may have a role in patients with CV contraindications to triptans. Extension studies out to 52 weeks with Ubrelvy report no significant adverse CV outcomes.

Distinguishing Characteristics

- *atogepant (Qulipta)* has multiple strengths available and allows for dosage adjustment in end stage renal disease; however it only carries a single indication (preventive treatment) and has more reported side effects than its competitor, Nurtec ODT.

- *rimegepant (Nurtec ODT)* has dual indications (acute and preventive treatment of migraine). However it only allows for once daily dosing in 24 hours with acute treatment, and must be avoided in patients with renal and hepatic failure. Indirect comparisons suggest Nurtec ODT has fewer reported adverse effects

than Qulipta and Ubrelvy. Nurtec ODT has not been associated with rebound headache for acute migraine treatment.

- *ubrogepant (Ubrelvy)* allows for repeat doses for acute migraine treatment, and dosage adjustment in hepatic failure; however it only carries a single indication for use (acute treatment**).** Ubrelvy has not been associated with rebound headache for acute migraine treatment.

Overall Conclusions

- In terms of efficacy, there is a high degree of interchangeability between the oral CGRP antagonists when compared across the same clinical indication. In terms of safety, there is a moderate degree of therapeutic interchangeability, as each medication carries a few unique adverse events. However, the side effects are mild and the oral agents are considered well tolerated.

- In order to meet the needs of MHS beneficiaries, at least one oral CGRP agent is required for treatment of each indication, acute migraine treatment, and episodic migraine prevention.

B. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—Relative Cost Effectiveness Analysis and Conclusion

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that atogepant (Qulipta) was the most cost-effective oral CGRP antagonist, followed by rimegepant (Nurtec ODT), and then ubrogepant (Ubrelvy).

- BIA was performed to evaluate the potential impact of designating the three oral CGRP agents as UF, NF, or Tier 4 on the formulary. BIA results found that designating Ubrelvy, Nurtec ODT, and Qulipta as UF demonstrated significant cost avoidance for the Military Health System (MHS).

C. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—UF Recommendation

The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
    - atogepant (Qulipta) *moves from NF to UF*

- rimegepant (Nurtec ODT)
- ubrogepant (Ubrelvy) *moves from NF to UF*

- NF
  - None
- Tier 4/Not Covered
  - None

D. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—Manual Prior Authorization Criteria

PA criteria were originally recommended when the individual oral CGRP medications were first evaluated as new drugs. The current PA criteria require a trial of first-line medications for both acute and preventive indications. For Ubrelvy, currently a trial of Nurtec ODT is required.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) minor updates to the current manual PA criteria in new users. The PA criteria and updates reflect the recommendations from the 2021 AHS Consensus Statement regarding candidates for a CGRP and assessment of response. For episodic migraine prevention, a trial of two standard therapies (antiepileptics, beta blockers, or antidepressants) as well as one injectable CGRP agent (Aimovig, Ajovy, or Emgality) will continue to be required first, before an oral CGRP agent. Additionally, for acute migraine treatment, a trial of two triptans are still required. Consultation with or evaluation by a neurologist is also still required for the oral CGRP agents.

For Ubrelvy and Nurtec ODT, the exclusion for patients with underling cardiovascular disease has been removed. Additionally, a trial of Nurtec ODT is no longer required in new patients receiving Ubrelvy. There were no changes made to the PA criteria for Qulipta (the CV exclusion was previously removed at the February 2022 meeting).

The PA Criteria are as follows:

1. atogepant (Qulipta)

There were no changes made at the May 2022 meeting

Manual PA criteria apply to all new users of Qulipta.

- Patient is 18 years of age or older
- Medication is prescribed by or in consultation with 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 after 6 months.

Renewal Criteria: (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply:

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

- Reduction of ≥ 30% when baseline score is > 20

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

2. rimegepant (Nurtec ODT)

Updates from the May 2022 meeting are in bold and strikethrough.

Manual PA criteria apply to all new users of rimegepant (Nurtec ODT).

- The patient is 18 years of age or older
- Medication is prescribed by or in consultation with neurologist
- Concurrent use with any other small molecule CGRP targeted medication (i.e., Ubrelvy or another "gepant") is not allowed
- ~~**Not approved for patients who have clinically significant or unstable cardiovascular disease**~~

For Acute Treatment

- Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications
  - sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax)

For Prevention of Episodic Migraine

- The patient has episodic migraine as defined by one of the following:
  - Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR
  - Patient has episodic migraine at a rate of at least 8 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.
PA expires after 6 months.

Renewal Criteria: (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply:

Acute Treatment

- Patient has a documented positive clinical response to therapy

Preventive Treatment

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

3. **ubrogepant (Ubrelvy)**

Updates from the May 2022 Meeting are in strikethrough.

Manual PA criteria apply to all new users of ubrogepant (Ubrelvy).

- The patient is 18 years of age or older
- Medication is prescribed by or in consultation with neurologist
- Concurrent use with any other small molecule CGRP targeted medication (i.e., Nurtec ODT or another "gepant") is not allowed
- ~~Not approved for patients who have clinically significant or unstable cardiovascular disease~~
- Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications
- sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax)
- ~~Patient has had a contraindication to, intolerability to, or has failed a 2-month trial of Nurtec ODT~~

Non-FDA-approved uses are not approved.
PA expires after 6 months

Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if the following criteria is met (Note that initial TRICARE PA approval is required for renewal):

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

E. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—UF, PA, and Implementation Period

The P&T Committee recommended (15 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.

V. UF DRUG CLASS REVIEWS—Migraine Agents - Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass

BAP Comments

A. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
  - Qulipta *moves from NF to UF*
  - Nurtec ODT
  - Ubrelvy *moves from NF to UF*
- NF
  - None
- Tier 4/Not Covered
  - None

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—Manual Prior Authorization

The P&T Committee recommended minor updates to the current manual PA criteria in new users as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—UF, PA, and Implementation Period

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

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: 15 for, 0 opposed, 0 abstained, 1 absent; and Group 2: 16 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 Recommendations

Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
  - filgrastim-ayow injection (Releuko) – White Blood Cell Stimulants - filgrastims. Note that as part of this recommendation Releuko will be designated as non-step-preferred.
  - mitapivat (Pyrukynd) – Miscellaneous metabolic agent for pyruvate kinase deficiency
  - naloxone 5 mg/0.5mL injection (Zimhi) – Narcotic Antagonist
  - pacritinib (Vonjo) – Oncologic agent for myelofibrosis
- NF
  - abrocitinib (Cibinqo) – Atopy drug class; oral Janus kinase (JAK) inhibitor for atopic dermatitis
  - baclofen oral suspension (Fleqsuvy) – Skeletal Muscle Relaxant for spasticity associated with multiple sclerosis
  - tenapanor (Ibsrela) – Gastrointestinal-2 Agent for Constipation-Predominant Irritable Bowel Syndrome (IBS-C)
  - tralokinumab-ldrm injection (Adbry) – Atopy drug class; injectable agent for atopic dermatitis
- Tier 4/Not Covered

The drugs listed below were recommended for Tier 4 status, as they provide little to no additional clinical effectiveness relative to similar agents in their respective drug classes, and the needs of TRICARE beneficiaries are met by available alternative agents.

- budesonide delayed release (DR) capsules (Tarpeyo) – Miscellaneous nephrology agent; an extended-release formulation of budesonide approved to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN)
    - Alternatives include prednisone, methylprednisolone, and budesonide DR capsules (Entocort EC, generics).
- celecoxib/tramadol (Seglentis) – Narcotic Analgesics and Combinations; a fixed-dose combination of celecoxib and tramadol for acute pain
    - Alternatives include tramadol and celecoxib individual components, or tramadol with other NSAIDs
- glycopyrrolate orally disintegrating tablet (Dartisla ODT) – Anti-cholinergic/Antispasmodic Agents; another formulation of glycopyrrolate approved to reduce the symptoms of peptic ulcer as an adjunct to treatment of peptic ulcer
    - Alternatives include glycopyrrolate tablets, glycopyrrolate oral solution (Cuvposa), omeprazole or other PPIs, and famotidine or other H-2 blockers.
- levoketoconazole (Recorlev) – Miscellaneous endocrine agent; a ketoconazole formulation approved to treat Cushing's disease for whom pituitary surgery is not an option or has not been curative
    - Alternatives include ketoconazole (generic), osilodrostat (Isturisa), metyrapone, mitotane, and pasireotide SQ (Signifor LAR injection, available under the medical benefit).
- torsemide 20 mg, 40 mg and 60 mg tablets (Soaanz) – Diuretics; another formulation of torsemide approved to treat patients with heart failure or renal disease with edema who have concerns with excessive urination or hypokalemia
    - Alternatives include torsemide tablets (generic), bumetanide, furosemide, and ethacrynic acid.
- tretinoin 0.1%/benzoyl peroxide 3% topical cream (Twyneo) – Acne Agent; combination of tretinoin and benzoyl peroxide approved for acne vulgaris in 9 years of age and older

- Alternatives include the individual components of tretinoin and benzoyl peroxide, Epiduo, and Epiduo Forte

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

The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- Releuko will be non-step-preferred, requiring a trial of both Granix and Nivestym prior to use. The same manual PA criteria that currently applies to the non-step-preferred filgrastims, Neupogen and Zarxio, will apply to new users of Releuko.

- Applying manual PA criteria to new users of Adbry and Cibinqo, requiring a trial of topical corticosteroids and topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus), similar to the requirements for other products approved for atopic dermatitis, including Dupixent, Opzelura cream and Rinvoq (see Utilization Management section).

- Applying manual PA criteria to new users of Fleqsuvy, similar to the current PA for baclofen oral solution (Ozobax).

- Applying manual PA criteria to new users of Ibsrela, similar to the current PA for prucalopride (Motegrity).

- Applying manual PA criteria to new users of Pyrukynd, consistent with the FDA indications and monitoring requirements.

The PA Criteria is as follows:

1. abrocitinib (Cibinqo)

Manual PA criteria apply to all new users of abrocitinib (Cibinqo).

- Patient is 18 years of age or older

- Medication is prescribed by an allergist, dermatologist, or immunologist

- Drug is used to treat moderate to severe atopic dermatitis

- Patient failed, has a contraindication, or intolerability to one medication in EACH of the following two categories:

- Topical Corticosteroids: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) AND

- Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)

- Patient is unable to access, has a contraindication to, or intolerability to UVB phototherapy
- Patient has had a negative TB test in the last 12 months (or is adequately managed)
- Patient has no history of venous thromboembolism (VTE)
- Provider is aware of the boxed FDA warnings
- Patient does not have neutropenia (ANC < 1000)
- Patient does not have lymphocytopenia (ALC < 500)
- Patient does not have anemia (Hgb < 8 mg/dL)
- Patient is not taking a concomitant JAK inhibitors (e.g., Rinvoq, Xeljanz), immunosuppressants (e.g., Dupixent), or biologic immunomodulators (e.g., Humira)

Non-FDA-approved uses are not approved.

PA expires in 1 year.

Renewal criteria: (Note that initial TRICARE PA approval is required for renewal). The PA will be approved indefinitely if the patient's disease severity has improved and stabilized to warrant continued therapy

2. baclofen oral suspension (Fleqsuvy)

Manual PA criteria apply to all new users of baclofen oral suspension (Fleqsuvy).

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

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

3. filgrastim-ayow injection (Releuko)

Manual PA criteria apply to all new users of filgrastim (Neupogen), **filgrastim-ayow (Releuko)**, and filgrastim-sndz (Zarxio).

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

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

4. tenapanor (Ibsrela)

Manual PA criteria apply to all new users of Ibsrela.

- Patient is 18 years of age or older
- Patient has diagnosis of IBS-C
- Patient has had documented symptoms for ≥ 3 months
- Patient has tried and failed all formulary agents including Linzess, Amitiza, and Trulance
- Patient does not have GI obstruction
- Patient has documentation of failure of an increase in dietary fiber/dietary modification
- Patient has tried at least 2 standard laxative classes or has an intolerance or FDA-labeled contraindication to at least 2 standard laxative classes defined as:

- osmotic laxative (e.g., lactulose, sorbitol, magnesium [Mg] citrate, Mg hydroxide, glycerin rectal suppositories)
- bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids;
- stool softener (e.g., docusate)
- stimulant laxative (e.g., bisacodyl, sennosides)

- Patient is not taking any of these agents concomitantly (Amitiza, Linzess, Trulance, Zelnorm, Motegrity, Symproic, Relistor, or Movantik)

Non-FDA-approved uses are not approved including opioid-induced constipation (OIC), chronic idiopathic constipation (CIC), and hyperphosphatemia.

Prior authorization expires in 1 year.

Renewal criteria: (Initial TRICARE PA approval required for renewal) Coverage will be approved for an additional year if both of the following applies:

- Patient has had improvement in constipation symptoms
- Patient is not taking any of these agents concomitantly Amitiza, Linzess, Trulance, Motegrity, Zelnorm, Symproic, Relistor, or Movantik

5. tralokinumab-ldrm injection (Adbry)

Manual PA criteria apply to all new users of Adbry.

- Patient is 18 years of age or older
- The drug is prescribed by a dermatologist, allergist, or immunologist
- The patient has moderate to severe atopic dermatitis
- The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:
    - Topical Corticosteroids: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) AND

- Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy

Non-FDA-approved uses are not approved.

PA expires in 1 year

Renewal criteria: (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely if the following applies:

- The patient's disease severity has improved and stabilized to warrant continued therapy.

6. mitapivat (Pyrukynd)

Manual PA criteria apply to all new users of Pyrukynd.

- Patient is 18 years of age or older
- Patient has a documented diagnosis of hemolytic anemia due to pyruvate kinase (PK) deficiency
- Patient has a documented presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, at least one of which is a missense variant
- Patient has a hemoglobin less than or equal to 10 g/dL
- Patient and provider are aware that abrupt discontinuation may lead to acute hemolysis

Non-FDA-approved uses are not approved including patients who were homozygous for the c.1436G>A (p.R479H) variant or had 2 non-missense variants (without the presence of another missense variant) in the PKLR gene.

Prior authorization expires in 6 months.

Renewal criteria: (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely if the following applies:

- Patient has experienced a ≥ 1.5 g/dL sustained increase in Hgb from baseline after 24 weeks of therapy.
- Patient must demonstrate significant improvement in pruritus symptoms.

D. 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: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 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 stated above:

- UF
  - Releuko
  - Pyrukynd
  - Zimhi
  - Vonjo
- NF
  - Cibinqo
  - Fleqsuvy

- Ibsrela
- Adbry

- Tier 4/Not Covered
  - Tarpeyo
  - Seglentis
  - Dartisla ODT
  - Recorlev
  - Soaanz
  - Twyneo

BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

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

BAP Comments

Concur: 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

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

BAP Comments

Concur: Non-Concur: Abstain: Absent:

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

P&T Comments

A. Utilization Management--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 within the Newly Approved Drug process. These drugs all have numerous cost-effective formulary alternatives available 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 medications first.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for citalopram 30 mg capsule, lanreotide 120 mg injection, ketoprofen 25 mg capsule, and meclizine 25 mg chewable tablet (Antivert) in new and current users, due to the significant cost differences compared with numerous available alternative agents.

1) **Antiemetic/Antivertigo Agents—meclizine 25 mg chewable tablet (Antivert)—**Meclizine is an older antiemetic widely available in 12.5 mg and 25 mg tablets in prescription and over-the-counter (OTC) formulations. A new 25 mg chewable tablet has come to market manufactured by a single company which requires a prescription prior to dispensing.

   Manual PA criteria:

   - Provider is aware and acknowledges that meclizine 25 mg tablet is available to DoD beneficiaries without the need of prior authorization, and is encouraged to consider changing the prescription to the preferred meclizine 25 mg tablet
   - The provider must explain why the patient requires meclizine 25 mg chewable tablet (Antivert) and cannot take the cost-effective meclizine 25 mg tablet (fill-in blank)

   Non-FDA-approved uses are not approved.

   Prior authorization does not expire.

2) **Endocrine Agents Miscellaneous—lanreotide 120 mg injection**

Lanreotide 120 mg injection is a new Somatuline Depot formulation only available in this one dosage strength. Somatuline Depot is more cost-effective than the lanreotide 120 mg injection made by a sole manufacturer.

Manual PA criteria:

- Provider acknowledges that this drug has been identified as having cost-effective alternatives and Somatuline Depot is available without prior authorization.
- Provider must explain why the patient cannot use the 120 mg Somatuline Depot brand.

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

3) Selective Serotonin Reuptake Inhibitors (SSRIs)—citalopram 30 mg capsule

Citalopram 30 mg capsules are manufactured by a single company and are markedly not cost-effective relative to other generic SSRIs. All other formulations of citalopram and various other SSRIs are included on the TRICARE pharmacy benefit and do not require prior authorization criteria.

Manual PA criteria:

- Provider acknowledges other strengths of citalopram and other formulary SSRIs are available without prior authorization.
- Provider must explain why the patient cannot take a combination of lower strengths to achieve the desired dose.

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

4) Pain Agents: NSAIDs—ketoprofen 25 mg capsule

Ketoprofen 25 mg capsule is manufactured by a single company, which requires a prescription prior to dispensing. Numerous cost-effective ketoprofen formulations are available without prior authorization in addition to other formulary cost-effective NSAIDs.

Manual PA criteria:

- Provider acknowledges that other strengths of ketoprofen and other formulary NSAIDs are available without the need of prior authorization.

- The provider must explain why the patient requires ketoprofen 25 mg capsule and cannot take the cost-effective generic ketoprofen or other formulary NSAIDs (fill-in blank)

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

B. Utilization Management--New Manual PA Criteria Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an implementation plan of the first Wednesday 60 days after signing of the minutes for the manual PA criteria for citalopram 30 mg capsule, lanreotide 120 mg injection, ketoprofen 25 mg capsule, and meclizine 25 mg chewable tablet (Antivert). DHA will send letters to affected patients.

IX. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

BAP Comments

A. Utilization Management--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 citalopram capsule, lanreotide injection, ketoprofen capsule, and meclizine chewable tablet (Antivert), as listed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Utilization Management--New Manual PA Criteria Implementation Plan

The P&T Committee recommended PAs criteria for citalopram capsule, lanreotide injection, ketoprofen capsule, and meclizine chewable tablet (Antivert) become effective the first Wednesday 60 days after signing of the minutes, and DHQ will send letters.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

A. Utilization Management—Updated Manual PA Criteria for New FDA-Approved Indications The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications. The updated PA criteria outlined below will apply to new users. The most current PA criteria is found on the TRICARE Formulary Search Tool at: **www.esrx.com/tform.**

1. **Anticonvulsants-Antimania Agents—fenfluramine oral solution (Fintepla).** The manual PA criteria were updated to expand use for Lennox-Gastaut syndrome.
2. **Oncologic Agents: Ovarian Cancer—olaparib (Lynparza)—**The manual PA criteria were updated to expand use for adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm, (HER2)-negative, high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy.
3. **Targeted Immunomodulatory Biologics (TIBs)**
   a) **ustekinumab (Stelara) -** The manual PA criteria were updated to expand use for moderate to severe ulcerative colitis (UC). Patients must first try adalimumab (Humira) before use of Stelara for UC. Alternatively, the medical benefit drug infliximab (Remicade) may be used first in lieu of Humira.
   b) **upadacitinib (Rinvoq) -** The manual PA criteria were updated for Rinvoq to expand use for atopic dermatitis (AD) and moderately to severely active ulcerative colitis (UC). For AD, patients must first try a high potency topical corticosteroid and a topical calcineurin inhibitor similar to other agents approved for AD. For UC, patients must first try adalimumab (Humira) before use of Rinvoq. Additionally, other non-biologics (e.g., azathioprine, sulfasalazine) are well established therapies for UC, and are more cost effective than Rinvoq.

B. Utilization Management—Updated Manual PA Criteria Implementation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an implementation date of the first Wednesday 60 days after signing of the minutes for Lynparza, Fintepla, Stelara, and Rinvoq in new users.

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

BAP Comments

A. Utilization Management—Updated Manual PA Criteria for New FDA-Approved Indications The P&T Committee recommended updates to the PA criteria for Lynparza, Fintepla, Stelara, and Rinvoq in new users drugs, as stated above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Utilization Management—Updated Manual PA Criteria Implementation Plan The implementation will be effective the first Wednesday 60 days after signing of the minutes for the updates to the drugs stated above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REMOVAL of INDICATIONS AND IMPLEMENTATION PLAN

P&T Comments

Oncological Agents: idelalisib (Zydelig)—Zydelig was reviewed as a newly approved drug in November 2019. PA criteria was implemented at that time. Recently the FDA determined that two previously-approved indications were no longer merited, including relapsed follicular B-cell non-Hodgkin lymphoma (FL) and relapsed small lymphocytic lymphoma (SLL). The indication of chronic lymphocytic leukemia (CLL) will remain.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) to remove the FL and SLL indications for new users but will allow current users to consult their provider as to whether continued treatment is clinically appropriate. The other FDA-approved indication for CLL for Zydelig is not affected and will remain on the PA. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

XIII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REMOVAL of INDICATIONS AND IMPLEMENTATION PLAN

BAP Comments

The P&T Committee recommended updates to the PA for Zydelig to remove the indications of FL and SLL, with an implementation plan of 60 days, as stated above,

BAP Comments

Concur: Non-Concur: Abstain: Absent

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

P&T Comments

A. Utilization Management—Updated PA Criteria for Reasons other than new FDA Indications

a) Neurological Agents Miscellaneous: amifampridine (Firdapse)—Manual PA criteria for Firdapse for treating Lambert-Eaton myasthenic syndrome (LEMS) were first recommended in May 2019. Ruzurgi is another amifampridine formulation approved for ALS. In May 2019, manual PA criteria for Firdapse required a trial of the cost-effective amifampridine agent Ruzurgi first in new patients. The FDA deemed Ruzurgi's license in pediatric patients as no longer valid in February 2022 therefore the manual PA criteria for Firdapse was updated to allow use for LEMS without a trial of Ruzurgi.

b) Androgens-Anabolic Steroids: Intramuscular (IM) Testosterone Replacement Therapy—testosterone cypionate and testosterone enanthate—PA criteria were recommended for the injectable testosterone products at the February 2022 meeting. Based on current policies and guidelines for treating gender dysphoria, the Committee recommended removal of the requirement of 3 months of real life experience (RLE) and/or 3 months of psychotherapy prior to PA approval.

c) Anti-Inflammatory Immunomodulatory Ophthalmic Agents: cenegermin-bkbj ophthalmic solution (Oxervate)—Oxervate was reviewed as a new drug in February 2019 and is FDA-approved to treat neurotrophic keratitis. Manual PA criteria currently allow for an indefinite duration of use. PA Criteria were updated to expire after 6 months to ensure an appropriate duration of therapy, consistent with the product labeling for Oxervate.

d) Miscellaneous Insulin Devices: Omnipod, Omnipod DASH—Manual PA criteria were recommended for Omnipod Classic (generation 3) and Omnipod DASH (generation 4) in November 2021. These devices may be used for up to 72 hours but could be changed every 48 hours. The renewal PA criteria were updated to remove the previously listed limit for duration of use.

B. Utilization Management—Updated PA Criteria for Reasons other than new FDA Indications Implementation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to the PA for Firdapse, IM testosterone products, Oxervate and the Omnipod products. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

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

BAP Comments

A. Utilization Management—Updated PA Criteria for Reasons other than new FDA Indications

The P&T Committee recommended manual PA criteria for Firdapse, IM testosterone products, Oxervate and the Omnipod products as stated above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Utilization Management--Updated PA Criteria for Reasons other than new FDA Indications Implementation Plan

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

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XVI. BRAND OVER GENERIC AUTHORIZATION FOR CYCLOSPORINE 0.05% OPHTHALMIC EMULSION SINGLE DOSE VIALS (RESTASIS), TIER 1 COPAY and IMPLEMENTATION PLAN

P&T Comments

Background—The Ophthalmic Immunomodulatory Agents subclass was reviewed in February 2018. This class includes cyclosporine 0.05% ophthalmic emulsion (Restasis) and lifitegrast 5% ophthalmic solution (Xiidra). Since then, generic formulations of Restasis have come to market however these generics are less cost-effective compared to brand Restasis at the MTFs and Mail Order.

Brand Restasis will now be required prior to receiving generic cyclosporine 0.05% ophthalmic emulsion at the MTFs and Mail Order. This brand over generic PA will not

apply at the retail point of service. Additionally, the requirement only applies to the Restasis single dose formulation, and not the multi-dose formulation. The Tier 1 copay for brand Restasis single dose is also recommended.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) requiring brand Restasis over generic cyclosporine 0.05% ophthalmic emulsion in all new and current users at MTF and mail, based on cost effectiveness. The prescriber will provide patient-specific justification as to why brand Restasis cannot be used. The Tier 1 (generic) copayment will also apply to brand Restasis. The effective date will be two weeks after signing of the minutes at MTF and mail. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

The authority for the Tier 1 copayment is codified in 32 CFR 199.21(j)(3): When a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the P&T Committee may also designate that the drug be cost-shared at the generic rate.

XVII. BRAND OVER GENERIC AUTHORIZATION FOR CYCLOSPORINE 0.05% OPHTHALMIC EMULSION SINGLE DOSE VIALS (RESTASIS), TIER 1 COPAY and IMPLEMENTATION PLAN

BAP Comments

The P&T Committee recommended brand over generic authorization for Brand Restasis and the Tier 1 copay, with a 2 week implementation, as stated above.

BAP Comments

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

XVIII. INFORMATIONAL ITEM—BENEFICIARY IMPACT (MAY 2022 DoD P&T COMMITTEE MEETING)

Table of Implementation Status of UF Recommendations/Decisions Summary and Affected Unique Utilizers

Date	DoD PEC Drug Class	Type of Action	UF Medications	Nonformulary Medications	Implement Date	Notes and Unique Users Affected
May 2022	**Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RA) Subclass**	UF Class Review Class previously reviewed Nov 2010 Nov 2012 Aug 2015 Feb 2018	▪ dulaglutide (Trulicity)	▪ exenatide once weekly Bydureon BCise) – *moves from UF to NF* ▪ exenatide twice daily (Byetta) ▪ liraglutide (Victoza) ▪ lixisenatide (Adlyxin) ▪ semaglutide (Ozempic) – *trial of Trulicity no longer required*	60 days	▪ Metformin required first in new users of any GLP1RA unless a contraindicated ▪ Ozempic remains NF; a trial of Trulicity is no longer required for new users. ▪ Manual PA criteria required for all new and current users of Bydureon BCise, Byetta, Victoza, and Adlyxin. Must try Trulicity and Ozempic first. ▪ No patients currently receiving Adlyxin <u>Unique Users Affected</u> Affected by NF status: 15,275 Affected by PA: Mail 10,354 MTF 7,439 <u>Retail 928</u> Total 18,721
May 2022	**Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass**	UF Class review Class not previously reviewed; drugs individually reviewed as innovators	<u>UF</u> ▪ atogepant (Qulipta) - *moves from NF to UF* ▪ rimegepant (Nurtec ODT) ▪ ubrogepant (Ubrelvy) - *moves from NF to UF*	▪ None	30 days	▪ PA criteria in place since 2020; only minor updates made. ▪ For episodic migraine prevention (Nurtec ODT, Qulipta) a trial of an injectable CGRP is required first, and other preventive treatments ▪ For acute treatment of migraine headache (Nurtec ODT, Ubrelvy), a trial of two oral triptans is required first. ▪ For Ubrelvy a trial of Nurtec ODT is no longer required in new patients. ▪ Unique Users Affected – N/A (no NF drugs)

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

Drug	Total
budesonide delayed release (DR) capsules (Tarpeyo)	4
celecoxib/tramadol (Seglentis)	10
glycopyrrolate orally disintegrating tablet (Dartisla ODT)	2
levoketoconazole (Recorlev)	Zero
torsemide 20 mg and 60 mg tablets (Soaanz)	37
tretinoin 0.1%/benzoyl peroxide 3% topical cream (Twyneo)	39

Drugs with New Prior Authorization Criteria—Unique Utilizers Affected

Drug	MTF	Mail Order	Retail	Total
meclizine 25 mg chewable tablets (Antivert)	0	0	3	3
lanreotide 120 mg injection	0	0	3	3
citalopram 30 mg capsules	0	0	2	2
ketoprofen 25 mg capsules	0	0	28	28

From: Warren Brooks
To: DHA NCR J-6 Mailbox BAPREQUESTS
Subject: [URL Verdict: Suspect][Non-DoD Source] Calliditas Therapeutics Written Comments
Date: Friday, June 24, 2022 9:10:12 AM
Attachments: image001.png
Tricare Written Comments_Calliditas Therapeutics.pdf
Prof Barratt letter.pdf

To the Designated Federal Officer,
Please find attached the written comments from Calliditas Therapeutics and a letter from Professor Jonathan Barratt, for the upcoming Uniform Formulary Beneficiary Advisory Panel Meeting on June 30, 2022.

Thank you!

-Warren Brooks, PhD

Med vänliga hälsningar/Best Regards

Warren P. Brooks, PhD
VP of Medical Affairs

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Professor Jonathan Barratt PhD FRCP
The Mayer Professor of Renal Medicine and
Honorary Consultant Nephrologist

6th April 2022

Dear colleagues

I have been asked to provide clarification on the treatment approach to IgA nephropathy included in the 2021 KDIGO Clinical Practice Guidelines (*KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. Kidney Int. 2021 Oct;100(4S):S1-S276. doi: 10.1016/j.kint.2021.05.021 PMID: 34556256*). I chaired the evidence review and writing group for the IgAN section of these guidelines. The IgAN guideline is quite clear that we do not recommend the use of systemic glucocorticoids (prednisone, prednisolone, and methylprednisolone), as first line therapy in all patients with IgAN who remain at high risk of progression despite optimised supportive care. We clearly state an individualised decision needs to be made between the treating physician and patient on the risk to benefit of systemic glucocorticoids as clinical benefit of systemic glucocorticoids in IgAN is not established and the toxicity associated with this treatment is well documented. We also acknowledge that following evaluation of the risk to benefit many patients and physicians will conclude that systemic glucocorticoids are not an appropriate treatment choice. We also identify patient groups where systemic glucocorticoids are contraindicated. Furthermore, we highlight in our research recommendations that a priority for future treatment of IgAN is the introduction of therapies that minimise or avoid the need to use systemic glucocorticoids for any patient with IgAN. We absolutely do not say that when such new therapies are approved and available that they should only be considered after a trial of systemic glucocorticoids, which in many cases would be an inappropriate treatment choice. As already stated, new approved therapies should be used to avoid the use of systemic glucocorticoids and their associated toxicity.

Yours sincerely

Professor Jonathan Barratt

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January 17, 2022

Beneficiary Advisory Panel (BAP), Pharmacy Division, Defense Health Agency
c/o Col. Paul Hoerner, USAF
Deputy Chief, Pharmacy Operations Division
7700 Arlington Blvd.
Falls Church, VA 22402

Dear Col. Hoerner and Members of the DoD Beneficiary Advisory Panel,

Pursuant to 41 CFR 102-3.140, Kala is providing this written statement to the Uniform Formulary Beneficiary Advisory panel in response to the proposed Department of Defense Pharmacy and Therapeutics Committee recommendations for EYSUVIS® (loteprednol etabonate 0.25% ophthalmic solution) which will be reviewed at the January 25th BAP meeting.

EYSUVIS was approved by the FDA on October 27, 2020. EYSUVIS® 0.25% mg is a corticosteroid indicated for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease. In the largest clinical trial program in dry eye disease to date (n= 2871), EYSUVIS® was shown to rapidly (as early as day 2) and significantly improve both signs and symptoms of dry eye disease. **EYSUVIS® is the only corticosteroid (or any) medication with this short-term dry eye indication.**

EYSUVIS® was specifically formulated for the short-term treatment of dry eye disease. Using Kala's proprietary AMPPLIFY® technology, particles of loteprednol 200 to 400 microns are coated with a mucus penetrating surface coating that allows the lowest effective dose of loteprednol, 0.25% to penetrate the mucous surface of the eye and deposit medication on the affected corneal tissue. As a result of increased penetration 3-4 times that of traditionally applied ophthalmic solutions and the medication is more evenly distributed on the corneal surface. This allows EYSUVIS® to deliver a smaller and more effective amount of medication directly to the impacted tissue safely and with quick symptom relief.

The Final Rule, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: TRICARE Pharmacy Benefits Program, published on 27 July 2015 in the Federal Register, Vol. 80, No. 143, pages 44269 – 44274, with an effective date of 26 August 2015, clarifies the process for formulary placement of Food and Drug Administration (FDA) newly approved innovator drugs (i.e., "newly approved drugs"), giving the Pharmacy and Therapeutics (P&T) Committee up to 120 days to recommend tier placement on the uniform formulary.

In accordance with the above, EYSUVIS® was reviewed by the DoD Pharmacy and Therapeutics Committee Meeting February 3-4, 2021. Prior to the meeting and up until May 21, 2021, EYSUVIS® was available to TRICARE members in a non-formulary position with a prescribing provider only required to submit a general prior authorization for "Newly Approved Innovator Drugs".

On May 21, 2021 and without notice or BAP review, new and specific prior authorization criteria was applied to EYSUVIS®. On reviewing the information made public almost 8 months later on January 13, 2022, announcing the upcoming January 25th BAP meeting on the Health.Mil BAP Committee website- specifically "Background Information February 2021 P&T Committee Recommendations" it appears that this new prior authorization criteria were based on the P&T committee's initial evaluation. The prior authorization criteria implemented by DoD on May 21st is inconsistent with the standard of care for dry eye disease, promotes off-label usage and increases patient/prescriber risks. Kala feels strongly that EYSUVIS® was inappropriately restricted.

The current prior authorization allows access to EYSUVIS® therapy only after a patient fails to achieve relief after two trials of non-indicated, non-approved corticosteroid therapies. In addition, the prior authorization specifically states that non- FDA uses of EYSUVIS® are not approved which appears to contradict the endorsement of non-indicated non-approved corticosteroid therapies described as available first line therapies. As shown by the two attached letters from **THE AMERICAN OPTOMETRIC ASSOCIATION (AOA)** and **AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY (ASCRS)**, eye care professionals are reluctant to prescribe off label corticosteroids to their patients in all but the most controlled situations and strongly feel that EYSUVIS® provides an appropriate indicated step in the treatment paradigm before a patient advances to life-long chronic therapies. Concerns related to the use of non-indicated steroid therapies include damage from increased intraocular pressure and associated damage to the eye to include glaucoma, optic nerve damage and potential blindness at the dosages available. As noted in the attached letter from **Lisa Nijm, MD, JD**, practitioner and Assistant Clinical Professor at the University of Illinois, physician liability is also a significant issue relative to potential eye damage and the use of non-indicated and non-approved corticosteroid therapy.

Prior to the FDA approval of EYSUVIS®, the only alternatives available to eye care professionals treating dry eye patients not satisfied with OTC drops and lubricants where the approved chronic dry eye therapies- cyclosporines (Restasis®, Cequa®) and lifitegrast (Xiidra®) which can take from six weeks to three months to provide relief. EYSUVIS® was shown to provide relief in as little as two days. Patients suffering from dry eye seek immediate relief- chronic medications that don't provide that relief waste the patient's and the DoD's time and money.

In addition, research shows that approximately 40% of patients seeking treatment for dry eye suffer from episodic exacerbations of their symptoms (dry eye flares) and would benefit from an acute therapy v. chronic therapy. EYSUVIS® is the only indicated product for the acute, up to two weeks treatment of dry eye patients only experiencing dry eye flares.

While patient instructions for the appropriate use of the chronic medications recommend continuous monthly use for an indefinite period of time, commercial claims data suggests that actual compliance is less than 12 prescriptions per year. Possible reasons for lack of adherence include time to action (mentioned above) and side effects (typically eye irritation on initiation of therapy). Kala's EYSUVIS® launch-to-date data suggests that an EYSUVIS® patient will use 1.2 Rxs/year. Reduced utilization along with Kala's enhanced discount to the DoD will contribute to reduced costs and better patient care in this therapeutic category.

In summary:

- EYSUVIS® is the first and only FDA approved corticosteroid indicated for the short- term (up to two weeks) treatment of the signs and symptoms of dry eye disease.
- EYSUVIS® is uniquely formulated with Kala's proprietary AMPPLIFY mucous penetrating technology designed to allow the lowest clinically effective dose of loteprednol to enhance ocular surface tissue distribution and penetration.
- EYSUVIS® demonstrated rapid onset of symptom relief- as soon as two days.
- Most (~40%) patients with dry eye experience dry eye flares alone and not consistent, continuous symptoms.
- Artificial tears and chronic therapies may not be well suited for the treatment of dry eye flares.
- In clinical rials, the incidence of treatment related adverse events and the intraocular pressure (IOP) profile were comparable between the EYSUVIS® and vehicle arms.
- Prolonged use of non-indicated and non-approved corticosteroids may result in glaucoma with damage to the optic nerve, as well as defects in visual acuity and fields of vision. Corticosteroids should be used with extreme caution in the presence of glaucoma. Renewal of medication orders should be made by a physician only after examination of the patient and evaluation of IOP.
- The most common adverse drug reaction following the use of EYSUVIS® for two weeks was installation site pain which was reported in 5% of patients.
- EYSUVIS® may lead to significant cost savings and better outcomes for DoD patients as a replacement for chronic therapies.

In closing, Kala respectfully requests that the members of the Beneficiary Advisory Panel:

- Align DoD dry eye therapy treatment with the standard of care practiced by the members of the AOA and ASCRS by reviewing the current prior authorization criteria for EYSUVIS® and removing restrictions requiring the use of non-indicated and non-approved therapies that are not aligned with the standard of care, and,
- Place EYSUVIS® in the Tier 2 (Brand Name) TRICARE formulary tier to allow TRICARE patients and their providers affordable access to appropriate dry eye therapy.

Removing these restrictions will allow eye care providers treating our war fighters and their families suffering from the debilitating effects of dry eye disease access to an FDA approved safe, effective and appropriate treatment option.

Respectfully,

Kim Brazzell, PhD
Head of R&D and Chief Medical Officer
Kala Pharmaceuticals, Inc.

Attached: Letters from Lisa Nijm, MD, JD, Assistant Clinical Professor, University of Illinois; the American Optometric Association (AOA); the American Society of Cataract and Refractive Surgery (ASCRS)

WARRENVILLE
EYECARE & LASIK

Lisa M. Nijm, MD, JD
Cornea, Cataract and LASIK Surgeon
[redacted]

January 17, 2022

Beneficiary Advisory Panel (BAP), Pharmacy Division, Defense Health Agency
c/o Col. Paul Hoerner, USAF
Deputy Chief, Pharmacy Operations Division
7700 Arlington Blvd.
Falls Church, VA 22402

Dear Col. Hoerner and Member of the Beneficiary Advisory Panel,

My name is Dr. Lisa Nijm, I am a board-certified ophthalmologist and corneal specialist at Warrenville Eyecare and LASIK, a licensed attorney and an assistant clinical professor of ophthalmology at the University of Illinois Eye and Ear Infirmary in Chicago. I also serve as the CEO of Women in Ophthalmology and the Chief Medical Editor of a leading educational website on Dry Eye/Ocular Surface Disease Continuing Medical Education for eye care professionals (OSDCME.com).

I am writing to you on behalf of the large population of dry eye patients whom I care for. Dry eye is a terrible disease that affects the daily activities of my patients to a great extent. Most patients describe typical symptoms of burning, aching, soreness, redness and feeling that there is constant "sand in my eyes." To understand the impact of dry eye syndrome in "real-world" terms, one only needs to look at its utility score. Utility scores quantify how many years a patient would give up from the end of their lives in exchange for avoiding a certain illness. *Studies have shown that utility scores for moderate to severe dry eye are comparable to that of angina and dialysis* (Schiffman RM, Walt JG, Jacobsen G, et al. Utility assessment among patients with dry eye disease. Ophthalmology 2003; 110:1412–1419. Buchholz P, Steeds CS, Stern LS, et al. Utility assessment to measure the impact of dry eye disease. Ocul Surf 2006; 4:155–161). *Further, untreated dry eye is associated with a high prevalence of sleep disorders, mood disorders, depression, and anxiety* (Ayaki M, Kawashima M, Negishi K, Tsubota K. High prevalence of sleep and mood disorders in dry eye patients: survey of 1,000 eye clinic visitors. Neuropsychiatr Dis Treat 2015; 11:889–894. Kitazawa M, Sakamoto C, Yoshimura M, et al. The relationship of dry eye disease with depression and anxiety: a naturalistic observational study. Transl Vis Sci Technol 2018; 7:35. Zheng Y, Wu X, Lin X, Lin H. The prevalence of depression and depressive symptoms among eye disease patients: a systematic review and meta-analysis. Sci Rep 2017; 7:464-53. Ayaki M, Tsubota K, Kawashima

M, et al. Sleep disorders are a prevalent and serious comorbidity in dry eye. Invest Ophthalmol Vis Sci 2018; 59:DES143–DES150).

Up until recently, even though we knew it was crucial to break the vicious inflammatory cycle of dry eye with anti-inflammatory therapy, there was no on-label steroid that was available for that purpose. **EYSUVIS changed that. EYSUVIS is the first and only FDA on label product approved for the short-term treatment of dry eye.** Many of my dry eye patients have acute episodes of dry eye triggered by various causes (computer use, wind, allergies, etc..) and when those flares occur, they need immediate relief to continue functioning. EYSUVIS is the ONLY medication I have that I can safely prescribe for my patients that are suffering from an acute flare up.

Other medications that are used to treat chronic causes of dry eye work well in certain patients but do NOTHING to care for these patients with acute flares. In fact, in my experience, if patients are experiencing an acute flare, often times a chronic medication such as Restasis or Xiidra cannot even be prescribed until the flare has calmed down because it causes too much irritation and burning. Many patients will fill a prescription for Xiidra, for example, but then quickly discontinue because they are not able to tolerate the medication and return to the office for another visit seeking relief. That doesn't occur with EYSUVIS. EYSUVIS is an entirely different medication that has advanced drug delivery technology which allows for improvement in symptoms with a well-tolerated, comfortable formulation.

I have shared with my colleagues through OSDCME and as an invited speaker at several national meetings how impressed I have been with the quick relief my patients have experienced with EYSUVIS. I have had mild to moderate cases resolve in a few days and even severe cases have shown great improvement in a week. As I mentioned earlier, this is of great importance to me in treating patients as I know of the costly co-morbidities associated with untreated or undertreated dry eye disease.

As a licensed attorney, I would be remiss if I did not mention the medicolegal risks as well. Off label use of medication is fraught with risk of litigation. In fact, this is why many optometrists and even some ophthalmologists have not frequently utilized steroids to care for dry eye patients in the past. These off label steroids have not been studied in dry eye patients and open everyone involved to risk of litigation should the intraocular pressure rise. Indeed, steroid induced glaucoma can cause irreversible blindness and is a well-known reason for malpractice suits. Now that EYSUVIS is available and is the only FDA approved steroid for the short term treatment of dry eye disease with data showing its safety and efficacy, it is prudent to give access to the medication to mitigate any legal risks involved in treatment. Certain off label steroids like prednisolone are very potent and may produce additional risks to the eye.

We all strive to deliver the highest quality patient care and I know that is of the utmost importance at DoD. I also understand the need to provide a formulary that is medically appropriate and cost effective. To this end, I strongly believe EYSUVIS is an ideal choice as short term therapy will be economically favorable vs. maintenance treatments such as Restasis or Xiidra (less doses per year). Indeed, for those TriCare patients that have mild to moderate forms of dry eye, they may not even need to be on a chronic treatment, but they may be placed on that because there is no other FDA approved medication on the formulary for treatment of dry eye! Further, the ability to rapidly relieve symptoms with EYSUVIS will likely lead to a reduction of co-morbidities related to dry eye which will translate to less additional prescriptions for conditions such as worsening depression, anxiety, and sleep disorders.

In summary, I believe EYSUVIS is a valuable, necessary product to have available on formulary as it provides great relief to TriCare patients and helps physicians and DoD deliver the highest quality of care. **EYSUVIS is the only FDA approved on-label treatment for the short term relief of dry eye signs and symptoms. I urge you to include this on your formulary for the benefit of our TriCare patients suffering from dry eye disease.**

Should you need any additional information, please do not hesitate to contact me. I would welcome the opportunity to speak with your clinical team. Thank you for your time and attention to this important matter.

Sincerely,

Lisa Nijm, MD, JD

Founder & Medical Director

[redacted]

AMERICAN OPTOMETRIC ASSOCIATION

January 16, 2022

Beneficiary Advisory Panel (BAP), Pharmacy Division, Defense Health Agency
c/o Col. Paul Hoerner, USAF
Deputy Chief, Pharmacy Operations Division
7700 Arlington Blvd.
Falls Church, VA 22402

Dear Col. Hoerner and Members of the DoD Beneficiary Advisory Panel,

The American Optometric Association (AOA) represents more than 44,000 Doctors of Optometry, optometric professionals, and optometry students. Doctor of Optometry take a leading role in patient care with respect to eye health and vision care, as well as general health and wellbeing. As primary health care providers, Doctor of Optometry have extensive, ongoing training to examine, diagnose, treat, and manage ocular disorders, diseases, and injuries. They also play an important role in the management of systemic diseases with ocular manifestations including diabetes, hypertension, cardiovascular disease, autoimmune diseases, and neurologic disease. The AOA serves the needs of the public and health professionals through the provision of evidence-based clinical practice guidelines that promote prevention, identification, treatment, and management strategies for eye and vision conditions/diseases to improve the nation's health.

We believe patients need greater flexibility when it comes to access to ophthalmic medications. Some health plans restrict formulary coverage for certain ophthalmic medications. In some cases, access to a pharmaceutical is limited or patients are forced to pay higher copayments because of the way that plans have structured their formularies. From the patient perspective, this means that a patient may not have access to a needed prescription drug or may be forced to pay more simply because of how a plan may have categorized medications on their formulary. We believe the clinical judgement of the clinician must always be respected and that patients should have access to a range of effective pharmaceuticals.

Access to a range of interventions is critical, especially for conditions that are chronic. Dry eye disease (DED) is often a serious condition that significantly impairs quality of life and can result in permanent ocular surface damage if untreated. With increased electronic device use throughout the pandemic, doctors of optometry are noting an increase in patients reporting signs and symptoms of DED. To ensure that doctors and patients have access to proven pharmaceuticals for DED we believe that EYSUVIS® (loteprednol etabonate ophthalmic suspension) 0.25% should be added to your formulary without restriction. Most dry eye patients initiate treatment with over-the-counter artificial tears, which at best provide a temporary, palliative effect. The vast majority (~90%) of dry eye patients experience episodic acute inflammation (also known as dry eye flares) triggered by a multitude of environmental and behavior stimuli. EYSUVIS is currently the only Food and Drug Administration (FDA) approved on-label corticosteroid for the short-term treatment of dry eye disease. The inclusion of EYSUVIS on the formulary is important for both prescribers and patients. We believe it is in the best interest to all to provide unrestricted access to an on-label corticosteroid dry eye treatment rather than limit access to only off-label products that have not been thoroughly tested for the disease and that could lead to litigation risks for prescribers.

There are an estimated 17.2 million diagnosed dry eye patients under the care of an eye care professional in the United States. Dry eye disease results in approximately $55 billion in direct and indirect costs in the United States each year, of which approximately $3.8 billion are direct medical costs. Indirect costs relate to comorbidities caused by untreated dry eye, such as a high prevalence of sleep disorders, mood disorders, depression, and anxiety. The utility score for patients with dry eye disease is very telling. Utility scores quantify how many years a patient would give up from the end of their lives in exchange for avoiding a

certain illness. Concerningly, studies have shown that utility scores for moderate to severe dry eye are comparable to that of angina and dialysis.[1]

AOA strongly supports the inclusion of EYSUVIS on your formulary as it is the only on label FDA-approved therapy for the short-term treatment of the signs and symptoms of dry eye disease, including dry eye flares. The unrestricted addition of this intervention will ensure that there are no barriers for physicians to ensure patients have access to the pharmaceuticals that best meet patients' unique needs. If you have any additional questions or concerns, please contact Kara Webb, Chief Strategy Officer at kcwebb@aoa.org.

Thank you for your time and attention to this important matter.

Sincerely,

Robert C. Layman OD

Robert Layman, O.D.
President, American Optometric Association (AOA)

[1] Schiffman RM, Walt JG, Jacobsen G, et al. Utility assessment among patients with dry eye disease. Ophthalmology 2003; 110:1412–1419. Buchholz P, Steeds CS, Stern LS, et al. Utility assessment to measure the impact of dry eye disease. Ocul Surf 2006; 4:155–161.

ASCRS
FOR SURGEONS. FOR YOU.

January 17, 2022

Beneficiary Advisory Panel (BAP)
c/o Col. Paul Hoerner, USAF
Deputy Chief, Pharmacy Operations Division
7700 Arlington Blvd.
Falls Church, VA 22402

Members of the DoD Beneficiary Advisory Panel,

On behalf of the American Society of Cataract and Refractive Surgery (ASCRS), a medical specialty society representing nearly 7,000 ophthalmologists in the United States and abroad who share an interest in cataract and refractive surgical care, we are writing to urge you to include EYSUVIS® (loteprednol etabonate ophthalmic suspension) 0.25% on your plan's formulary, as it's the only FDA-approved product approved for short term treatment of dry eye disease and is the only corticosteroid approved for dry eye therapy.

Dry eye disease is a chronic, episodic, progressive disease affecting the tears and ocular surface. It significantly impacts the daily activities of patients and can lead to permanent damage of the ocular surface. Most patients describe symptoms of discomfort, burning, redness and vision impairment. Over 80% of dry eye disease patients experience acute, episodic exacerbations of their symptoms, often referred to as dry eye flares, which occur at various times throughout the year and cause significant discomfort and disability. A dry eye flare is defined as a rapid onset, inflammation-driven response to a variety of triggers that typically cannot be adequately managed with the patient's ongoing therapy. These flares can be triggered by numerous factors, such as environmental stimuli (e.g. allergens, pollution, wind and low humidity), intense visual activity (e.g. television, computer or hand-held device use) contact lens wear, smoking, and sleep deprivation. Many dry eye patients only experience episodic flares rather than persistent symptoms, and EYSUVIS® is, in our Cornea Clinical Committee's opinion, the best therapy for those particular patients.

Approximately 90% of dry eye patients begin treatment with OTC artificial tears, which are palliative and do not treat the underlying inflammation associated with the disease. Many patients seek treatment from eyecare professionals after failure with artificial tears, and some are prescribed a chronic prescription dry eye therapy. Unfortunately, the current FDA-approved chronic medications have a slow onset of action of several weeks to several months. As such, they are not clinically suited for patients who require short-term treatment of dry eye disease and rapid relief of symptoms. Only 10-15% of diagnosed patients suffer from persistent symptoms and are prescribed daily treatment with chronic dry eye medications. Even when treated with long-term prescription therapy, most of these patients still suffer from dry eye flares. EYSUVIS®, the only product specifically approved by The FDA for short-term treatment, safely and effectively treats these episodic flares of dry eye, utilizing a short course of rapid-acting, potent, low-risk topical steroid eye drops. In addition to chronic dry eye therapies, our patients need an on-label FDA-approved short-term treatment. EYSUVIS® is currently the only product that meets those criteria.

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ASCRS urges you to ensure eyecare professionals and patients have access to EYSUVIS® 0.25% by including this medication in your formulary. Doing so will guarantee dry eye patients who present episodic flares will have a path to secure an FDA-approved, on-label steroid to treat their condition.

Thank you for your time and attention to this important matter. If you have any questions or would like additional information, please contact Angela Nichols, Director of Clinical Education at ASCRS at [redacted]

Sincerely,

Richard S. Hoffman, MD
ASCRS President