EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel
Meeting June 22, 2026

For the February 2025, May 2025 and Addendum to May 2025 held July 10, 2025 DoW Pharmacy and Therapeutics Committee Meetings

The Uniform Formulary Beneficiary Advisory Panel (UFBAP) convened at 10:15 A.M. on June 22, 2026, via teleconference. The Secretary of War has authorized the UF BAP to meet, following a pause on all DoD Advisory Committees that began on March 10, 2025. Prior to this authorization, the committee last convened on December 18, 2024.

The current meeting took place over three days on June 22-24, 2026. The information presented on June 22 (Day #1) included the recommendations from the February 2025 Pharmacy and Therapeutics Committee (P&T) meeting (presented in the morning), May 2025 P&T meeting (presented in the afternoon), and Addendum to the May 2025 P&T meeting held July 10, 2025 (also presented in the afternoon). The information presented on June 23 (Day #2) included the recommendations from August 2025 (presented in the morning) and November 2025, Addendum to November 2025 held January 16,2026 and February 2026 (presented in the afternoon) P&T meetings. The information presented on June 24 (Day #3) included the information presented at the May 2026 P&T meeting.

The detailed meeting information is found starting on page 14.

FEBRUARY 2025 P&T COMMITTEE MEETING

UF DRUG CLASS REVIEWS

I. UF DRUG CLASS REVIEW—SLEEP DISORDERS: WAKEFULNESS PROMOTING SUBCLASS

A. Sleep Disorders: Wakefulness Promoting Subclass—UF Recommendation

- UF generics
  - modafinil (Provigil, generics)
  - armodafinil (Nuvigil, generics)
- UF brands
  - sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)
  - solriamfetol (Sunosi) *moves from NF to UF*
- NF

- sodium oxybate oral solution (Xyrem, authorized generics) *moves from UF to NF*
- sodium oxybate ER packets for oral suspension (Lumryz)
- pitolisant (Wakix)

- Complete Exclusion: none

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

B. Sleep Disorders: Wakefulness Promoting Subclass—Manual PA Criteria

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

C. Sleep Disorders: Wakefulness Promoting Subclass —UF Recommendation, PA Criteria and Implementation Period of 90 days

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

II. UF DRUG CLASS REVIEW—NARCOTIC ANALGESICS AND COMBINATIONS: BUPRENORPHINE AND COMBINATIONS SUBCLASS

A. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass—UF Recommendation

- UF
  - buprenorphine transdermal patch (Butrans, generics)
  - buprenorphine buccal film (Belbuca) *moves from NF to UF*
  - buprenorphine SL tablets (Subutex, generic)
  - buprenorphine/naloxone SL tabs (Zubsolv)
  - buprenorphine/naloxone SL film (Suboxone)
  - buprenorphine/naloxone SL tabs (Suboxone tabs, generic)
- NF: none

- Complete exclusion: none

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

B. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass —Manual PA Criteria Removal for Butrans Patch

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

C. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass —UF Recommendation, PA Criteria Removal, and Implementation Period of two weeks

UF BAP Comments Mr. Ostrowski was concerned if the two-week window had already taken effect and whether we had to worry about people getting the PAs. He commented that it seems to be one of the shortest time frames.

Dr. Allerman replied that the implementation had not yet occurred. Everything is moving to formulary status, and we are removing the prior authorization expanding options for the patients. No letters are needed so we feel we will be able to meet this two-week implementation.

Concur:* 4 *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 Recommendation

- UF
  - acoramidis (Attruby) – Miscellaneous Neurological Agents for transthyretin amyloidosis
  - arimoclomol (Miplyffa) – Miscellaneous Neurological Agents for Niemann-Pick disease
  - crinecerfont (Crenessity) – Miscellaneous Endocrine Agents for congenital adrenal hyperplasia
  - inavolisib (Itovebi) – Oncological Agents: Breast Cancer
  - marstacimab-hncq (Hympavzi) – Antihemophilic Agents

- nilotinib tartrate tablets (Danziten) – Oncological Agents: Chronic Myeloid Leukemia
- olezarsen (Tryngolza) – Antilipidemics-2 for familial chylomicronemia syndrome
- Omnipod 5 Intro G6/Libre 2 Plus Pods and Kits – Insulins: Miscellaneous Insulin Devices; this device was also added to the TRICARE Pharmacy benefit
- revumenib (Revuforj) – Oncological Agents for Acute Leukemia
- ustekinumab-auub (Wezlana) – Targeted Immunomodulatory Biologics: Interleukin-23 (IL-23) inhibitors
- vanzacaftor/tezacaftor/deutivacaftor (Alyftrek) – Cystic Fibrosis Agents

- NF
  - aripiprazole oral film (Opipza) – Antipsychotic Agents: Atypical
  - filgrastim-txid (Nypozi) – White Blood Cell Stimulants: Filgrastim
  - imatinib 80 mg/mL oral solution (Imkeldi) – Oncological Agents: Chronic Myeloid Leukemia
  - minocycline 40 mg ER capsules (Emrosi) – Antibiotics: Tetracyclines
- Completely Excluded: none

UF BAP Comments Mr. Wood stated that he had a question on the Omnipod 5 Intro. He asked why we are limiting the age to 18 years and older because it is FDA approved for much younger ages, and typically kids need these and it is used quite often in kids.

CAPT Raisor responded that at the time of the meeting Omnipod 5 was approved for 18 years and older. He mentioned we do active surveillance to see updated indications for drugs and devices, and that will be something that the Committee can review at a future meeting. Additional clarification provided in the afternoon session.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria for all the new drugs

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

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

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

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

A. Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5) for tramadol 75 mg tablets and implementation period of 60 days

UF BAP Comments There were no questions of comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

V. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA APPROVED INDICATIONS AND IMPLEMENTATION PERIOD

A. Updated Manual PA Criteria and Implementation Period for New FDA Approved Indications for Dupixent, Scemblix, Vtama, Nemluvio, Bimzelx, and Zepbound and implementation period of 60 days

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

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

A. Updated Manual PA Criteria and Implementation plan for reasons other than New FDA Approved Indications for Aqneursa, Vyndaqel, Vyndamax, Wainua and implementation period of two weeks, and for Trintellix, Vyvanse, Rinvoq,

Cibinqo, Braftovi, Restasis, Enbrel, Olumiant, Sotyktu, Xeljanz, Tremfya, Skyrizi OBI, Omvoh, Entyvio, and Zymfentra and implementation period of 60 days

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

VII. REMOVAL OF PAs FOR MIGRAINE AGENTS AND GASTROINTESTIANL-2 AGENTS RETURN OF FROVATRIPTAN TO UF STATUS, AND IMPLEMENTATION PLAN

A. Removal of PAs for frovatriptan, naratriptan, Linzess and Amitiza and implementation period of two weeks

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

MAY 2025 P&T COMMITTEE MEETING

UF DRUG CLASS REVIEWS

I. TARGETED IMMUNOMODULATORY BIOLOGICS (TIBS): INTERLEUKIN (IL)-1, IL-6 AND CYTOTOXIC T-LYMPHOCYTE ASSOCIATED ANTIGEN-4 IMMUNOGLOBULIN (CTLA4-IG) SUBCLASSES

A. TIBS: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—UF Recommendation

- UF and step-preferred
  - IL-6: tocilizumab aazg (Tyenne) *moves from UF non-step-preferred to UF step-preferred*
- UF and non-step-preferred
  - IL-1: anakinra (Kineret) *moves from NF to UF non-step-preferred*
  - IL-6: sarilumab (Kevzara) *moves from NF to UF non-step-preferred*
- NF and non-step-preferred
  - IL-6: tocilizumab (Actemra)
  - CTLA-4Ig: abatacept (Orencia)
  - IL-1: rilonacept (Arcalyst) *moves from UF to NF non-step-preferred*
  - IL-6: satralizumab (Enspryng) *moves from UF to NF (no step required)*
- Complete Exclusion: None
- Note, as part of this recommendation a trial of adalimumab (Humira) and tocilizumab aazg (Tyenne) are required prior to use of the non-step-preferred IL-1, IL-6, CTLA4-Ig products in all new patients, depending on the clinical indications.

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

B. TIBS: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—Manual PA Criteria

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

C. TIBS: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—UF Recommendation, PA Criteria, and Implementation Period of 90 days

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

II. UF DRUG CLASS REVIEW—BREAST CANCER AGENTS: CYCLIN-DEPENDENT KINASE (CDK) INHIBITORS SUBCLASS

A. Breast Cancer Agents: CDK Inhibitors Subclass—UF Recommendation

- UF
  - abemaciclib (Verzenio)
  - palbociclib (Ibrance)
  - ribociclib (Kisqali)
- NF – None
- Complete Exclusion – None

UF BAP Comments Mr. Wood stated he was new to the Panel and if his question was out of line to let him know. He gave some background information that he is a clinical pharmacist and he does look at a lot of prior authorizations, and also the cost of medications. Verzenio, Ibrance and Kisqali are very common PAs that he gets at the USFHP and he is curious as to how the P&T Committee does the cost analysis for medications like these. He knows that the price differences between these drugs are huge, and he is wondering how they are looked at generally for TRICARE.

Dr. VonBerg thanked Mr. Wood for his question and stated that the specifics of the cost analyses are beyond the scope of the UF BAP. But stated we do have expert pharmacoeconomists that do cost analyses, budget impact analyses and look at overall utilization. There are detailed analyses that are done as part of the P&T Committee process. Mr. Wood thanked Dr. VonBerg for his response.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

B. Breast Cancer Agents: CDK Inhibitors Subclass—Manual PA Criteria

UF BAP Comments Dr Schweitzer commented that she appreciated how these PAs were streamlined and that several of the criteria were cut out of the section, to make it easier for the prescriber to complete and turn it around. She acknowledged that there is a lot of work involved with completing, reviewing and approving the PAs, and again said thanks for streamlining the process.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

C. Breast Cancer Agents: CDK Inhibitors Subclass—UF Recommendation, PA Criteria, and Implementation Period of 60 days

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *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 Recommendation

- UF
  - concizumab-mtci (Alhemo) – Antihemophilic Agents
  - diazoxide choline (Vykat XR) – Miscellaneous Metabolic Agent for hyperphagia in Prader-Willi Syndrome
  - hydroxyurea 100 mg/mL oral solution (Xromi) – Oncological Agent for Sickle Cell Anemia
  - letermovir extended release (ER) pellets (Prevymis) – Antiviral for cytomegalovirus (CMV) infection
  - mirdametinib (Gomekli) – Oncological Agent for neurofibromatosis
  - suzetrigine (Journavx) – Pain Agents
  - ustekinumab-auuz (Otulfi) – Targeted Immunomodulatory Biologics (TIBs): Interleukin-23 (IL-23) inhibitors; biosimilar for Stelara
  - ustekinumab-stab (Steqeyma) – TIBs IL-23s; biosimilar for Stelara
  - vimseltinib (Romvimza) – Oncological Agent for tenosynovial giant cell tumor
- NF

- hydrochlorothiazide 10 mg/mL powder for oral suspension (Inzirqo) – Diuretic Agents
- trazodone 10 mg/mL oral solution (Raldesy) – Antidepressants and Non-Opioid Pain Syndrome Agents: Serotonin Antagonist and Reuptake Inhibitor
- ustekinumab-ttwe (Pyzchiva) – TIBs IL-23s; biosimilar for Stelara
- ustekinumab-kfce (Yesintek) – TIBs IL-23s; biosimilar for Stelara
- ustekinumab-aekn (Selarsdi) – TIBs IL-23s; biosimilar for Stelara

- Completely Excluded:
  - benzgalantamine (Zunveyl) – Alzheimer's Agents

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria for all the drugs except Prevymis

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation, PA Criteria, and Implementation Period of two weeks for the UF and NF drugs, and 120 days for the Completely Excluded drugs

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

IV. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PLAN

A. New Manual PA Criteria for Emverm, Korlym and Zyflo and an implementation period of 60 days

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

V. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN

A. Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5) for metformin 750 mg immediate release and tramadol 100 mg immediate release, and an implementation period of 60 days

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

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

A. Updated PA Criteria for New FDA Approved Indications for Imcivree, Odactra, Tremfya, Calquence, Lumakras, and Ozempic and an implementation plan of 60 days

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

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

A. Updated PA Criteria for Reasons other than New FDA Approved Indications for Eucrisa, Uloric, Inrebic, Koselugo, Pomalyst, Qinlock, Rydapt, Tabrecta, Tepmetko, Turalio, Vanflyta, Vivtrakvi, Vizimpro, Xospata, Bylvay, Livmarli and Nuplazid and an implementation plan of 60 days

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

VIII. UTILIZATION MANAGEMENT—REMOVAL OF PAs and IMPLEMENTATION PERIOD

A. Removal of PAs for Tecfidera and Namenda XR and an implementation plan of two weeks

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

IX. UTILIZATION MANAGEMENT—BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR SACUBITRIL/VALSARTAN (ENTRESTO)

A. Brand over generic authorization for Entresto and Tier 1 copay

UF BAP Comments Mr. Wood asked if this recommendation was overturned later on, the requirement to try the brand Entresto first, or if he was misreading something. Since he thought the generic was cheaper.

CAPT Raisor responded that it does appear that the generic is currently required, so this is a change that was reflected later and that we would find the exact date that the change occurred, but that the Panel consider continuing with the vote.

Dr. Schweitzer then noted that the last statement does say that the brand over generic requirement will be removed administratively when it is no longer cost effective. She then responded that we will get the answer clarified, but continue on with the vote.

CDR Hall then clarified that administratively the Entresto brand over generic requirement was pulled in October 2025 and that the generic is required.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

X. UTILIZATION MANAGEMENT—WEIGHT LOSS DRUGS PAs: COMPREHENSIVE LIFESTYLE INTERVENTION AND IMPLEMENTATION

A. Weight loss PAs comprehensive lifestyle intervention and implementation period of 60 days.

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

MAY 2025 ADDENDUM JULY 10 2025 P&T COMMITTEE MEETING

I. TARGETED IMMUNOMODULATORY BIOLOGICS (TIBS): INTERLEUKIN (IL)-23 INHIBITORS—PRIOR AUTHORIZATION CRITERIA AND IMPLEMENTATION PLAN

A. TIBS: IL-23 Inhibitors—Manual PA Criteria and Implementation Plan for the interim virtual meeting

UF BAP Comments There were no questions or comments from the Panel.

Concur:* 4 *Non-Concur: 0 Abstain: 0 Absent: 0

Director, **D**HA/Signed/Signature on file

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

Uniform Formulary Beneficiary Advisory Panel
Virtual Meeting Summary Minutes
June 22, 2026

Panel Members Present

- Dr. Pamela Schweitzer, Commissioned Officers Association of the U.S. Public Health Service, Chair
- Mr. Jon Ostrowski, Non-Commissioned Officer Association
- Mr. John Du Teil, U.S. Army Warrant Officers Association
- Mr. Bryson Wood, U.S. Family Health Plan

Panel Members Absent

- None

Acting Designated Federal Officer (Non-Voting): CAPT P. Thien, Nguyen USPHS

DHA Participants (Non-Voting)

- John Kugler, MD, Division Chief, Clinical Support Division; DoD P&T Committee Chair
- Edward VonBerg, PharmD, BCPS, Chief, Pharmacy Operations Division, Formulary Management Branch (POD FMB)
- CAPT Scott Raisor, Deputy Chief POD FMB
- Angela Allerman, PharmD, BCPS POD FMB
- CDR Elizabeth Hall, PharmD, MPH, BCPS, POD FMB
- Heather Johnson, PharmD, BCCP, BCCP, POD FMB
- Darrilyn Bihm, PharmD, POD FMB
- CPT Ji Yoon Kim, POD FMB
- Helen Feinstein, PharmD, BCPS, POD FMB
- COL James Masterson, PharmD, MPH, Deputy Chief POD
- Ms. Megan Gemunder Office of General Counsel

Agenda is found starting on page 21.

- Panel Discussions

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

Opening Remarks

CAPT Thien Nguyen introduced herself as the Alternate Designated Federal Officer (DFO) for the Uniform Formulary (UF) Beneficiary Advisory Panel (BAP). The Panel has convened to comment on the recommendations of six DoD Pharmacy & Therapeutics Committee meetings plus addendum which occurred on February 5-6, 2025; May 7-8, 2025; August 6-7, 2025; November 5-6, 2025; February 4-5, 2026; and May 6-7, 2026.

CAPT Nguyen then indicated Title 10 United States Code (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 and 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 UF. 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, Defense Health Agency (DHA) before establishing the UF or implementing changes to the UF. The Panel's meetings are conducted in accordance with the Federal Advisory Committee Act (FACA).

CAPT Nguyen then outlined the duties of the Uniform Formulary Beneficiary Advisory Panel including 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 proceedings 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 for the Director, DHA.

CAPT Nguyen then 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 appreciates that the Panel may be interested in the drug classes selected for review or specific pricing data, these topics do not fall under the purview of the BAP.

- The P&T Committee met for approximately 67 hours conducting its reviews of the

drug class recommendations presented today through Wednesday. 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 Panel will receive an abbreviated version of each presentation and its discussion. The materials provided to the Panel are available on the TRICARE website.

- Detailed minutes of this meeting are being prepared. The UF BAP 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.

Ground Rules:

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

- This meeting will be conducted in a remote access format.
- All discussions take place in the open public forum. There is to be NO Committee discussion outside this virtual forum or during breaks.
- Audience participation is limited to private citizens comments received in writing prior to the meeting.
- Participants will be joined in a LISTEN MODE only.
- To ensure that there are disruptions to discussions and as a precaution, please MUTE your phones.

Panel and Presenter Guidance:

- When asking or responding to questions:
    - Panel members are asked to state their name and prior to asking your questions.
    - Presenters or anyone responding to a question are asked to state their name prior to responding.
    - The meeting is being recorded. Please speak clearly.
- When addressing the Panel or responding to questions, please use the microphone.
- 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.

Panel Members
CAPT Nguyen then introduced the individual Panel members (see list above). All four Panel members are present for the 1st day of the meeting.

Written Comments
Written comments were forwarded to the Panel for their review and consideration. These are included starting on page 114.

1. Abbvie Pharmaceuticals (February 2025 P&T Committee meeting)
2. Acadia Pharmaceuticals (May 2025 P&T Committee meeting)

The meeting was then handed over to the Panel Chair, Dr. Schweitzer, for her opening remarks.

Chair's Opening Remarks
Dr. Schweitzer welcomed the Panel members and attendees to this June 22nd meeting and also gave a special welcome to Mr. Wood, who's new to the Panel. She then mentioned we'll be covering several meetings as you saw from the preparation materials. The handouts will be going through the February 2025, May 2025, and the Addendum meeting that was held on July 10th. She then stated she appreciated the Panel's service as a voice of the beneficiaries and their representation of the interest through their respective organizations and associations. Also, the time and commitment required to review these materials and prepare for them and participate in the meetings does not go unnoticed. She did sincerely than the Panel and their dedication to the beneficiaries. She also stated that on behalf of the Panel, she also wanted to recognize and thank tremendously the Pharmacy Operations division and the Formulary Management Branch for their outstanding efforts and support for this year-round work that you do in preparing and managing a benefit.

Dr. Vonberg's Opening Remarks
The meeting then proceeded with comments from Dr. Vonberg the Formulary Management Branch Chief, who thanked the Panel for their involvement today. He also stated that their voice is critical to the process; also doctor and retired Army Colonel John Kugler, the Chairman of the Pharmacy and Therapeutics Committee, will be providing comments after some of the sections to give perspective from the P and T Committee. He then introduced the team speaking today from the Formulary Management Branch. (see list above).

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

The Formulary Management Branch supports the 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 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 P&T Committee, but a summary of the processes and analyses presented to the P&T Committee. The cost-effective analyses will be general in nature since we are unable to disclose the actual costs used in the economic models.

One general comment was received for the February 2025 meeting, regarding implementation of prior authorizations.

He then did have a couple of housekeeping requests,

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

The full presentations then started. The P&T Committee physician perspective was provided by Dr. John Kugler for various sections, and is included starting on page 28. The full meeting information for the February 2025 P&T Committee meeting starts on page 32, the May 2025 P&T Committee meeting starts on page 66, and the Addendum held on July 10, 2025 starts on page 111.

Closing Remarks

CAPT Nguyen stated the morning meeting was concluded, and that the afternoon session would start after lunch at 1:45 PM Eastern Time.

The morning session for the February 2025 P&T Committee meeting Adjourned at 11:35 AM EDT.

The afternoon session for the May 2025 and Addendum held on July 10, 2025 P&T Committee meetings re-convened at 1:45 PM EDT

Alternate DFO Remarks

CAPT Nguyen welcomed everyone back from lunch. She did a roll call of the Panel members. All four Panel members were present.

Chair's Remarks

Dr. Schweitzer welcomed everyone back from lunch. She stated we had a pretty fast pace going through the initial meeting and now we're on to the May 2025 meeting and there's a lot of really good topics that we're going to be discussing here. She then concluded by stating that she appreciated everybody's time and energy and putting all this together, and also for making the information succinct so that the Panel could review and give their recommendations for approval.

Dr. Vonberg's Remarks

Dr. Vonberg then proceeded to state there was one clarification for the February 2025 P&T minutes and therefore for the UF Beneficiary Advisory Panel. The P&T Committee vote did not include any age limits for Omnipod 5. The UF BAP minutes will be corrected for that clarification.

He next stated that the UF BAP did receive one written comment regarding Nuplazid.

Closing Remarks

Dr. Schweitzer closed by saying thank you so much to everyone involved in this. She realized the complexity of all these drugs and just how much work it takes to just review every single one and all the criteria and to stay current. She also stated how impressed she is with all the work that was put into preparing all this. She also gave a big thank you to everybody on the Panel because there was a lot of detail to go through and read, and also stated you guys were wonderful, you know, staying with it the whole time. So, thank you so much.

Dr. Vonberg mentioned the only thing he had to say was to echo the thanks to the Panel members, to our designated Federal Officer and the members of the Formulary Management Branch. And of course, to the members of the public who are attending the Beneficiary Advisory Panel meeting. He concluded by stating the general session starts at 10:00 AM Eastern Time tomorrow, so we'll see you again and have an opportunity to go through three more P&T Committee meetings.

CAPT Nguyen thanked Dr Vonberg and the FMB team for the information presented today. She said a thank you to the Panel members for their attendance and input and thanked everyone for joining us for day one of three of the UF BAP meeting, and we will see you virtually tomorrow at 1000 Eastern.

The afternoon session for the May 2025 and Addendum held on July 10, 2025 P&T Committee meetings Adjourned at 3:28 PM EDT.

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

Pamela Schweitzer, PharmD
Signed/Signature on file
Chairperson, UF BAP

AGENDA

Uniform Formulary Beneficiary Advisory Panel (UF BAP)
For February 2025, May 2025 and Addendum to May 2025 (held July 10, 2025) Department of War Pharmacy and Therapeutics Committee Meetings
June 22, 2026 at 10:15 AM Eastern Daylight Time

Day #1 Meeting

The UF BAP meetings occurring on June 22-24, 2026, will include information presented at the DoW Pharmacy and Therapeutics (P&T) Committee meetings from February 2025, May 2025, Addendum to May 2025 held July 10, 2025, August 2025, November 2025, Addendum to November 2025 held January 16, 2026, February 2026 and May 2026. The information presented on June 22 (Day #1) will include the recommendations from the February 2025 (presented in the morning) and May 2025 and the July 10 Addendum (presented in the afternoon) P&T meetings. The information presented on June 23 (Day #2) will include the recommendations from August 2025 (presented in the morning) and November 2025, Addendum to November 2025 held January 16,2026 and February 2026 (presented in the afternoon) P&T meetings. The information presented on June 24(Day #3) will include the information presented at the May 2026 P&T meeting.

Administrative Meeting 9:00 AM - 10:00 AM Eastern Daylight Time

Information from the February 2025 DoW P&T Meeting

- **General session starts at 10:15 AM Eastern Daylight Time**
- **Roll Call**
- **Therapeutic Class Reviews**

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

  The DoW P&T Committee made recommendations for the following drugs/drug classes during the February 2025 meeting.

- **Drug Class Reviews**
  - *Sleep Disorders Class: Wakefulness Promoting Agents Subclass*
  - *Narcotic Analgesics and Combinations Class: Buprenorphine and Combinations Subclass*
- **Newly Approved Drugs per 32 CFR 199.21(g)(5)**
  - *acoramidis (Attruby)—Miscellaneous Neurological Agents for Transthyretin Amyloidosis*
  - *arimoclomol (Miplyffa)—Miscellaneous Neurological Agents for Niemann-*

Pick Disease

- *aripiprazole oral film (Opipza)—Atypical Antipsychotic Agents*
- *crinecerfont (Crenessity)—Miscellaneous Endocrine Agents for Congenital Adrenal Hyperplasia*
- *filgrastim-txid (Nypozi)—White Blood Cell Stimulants: Filgrastims*
- *imatinib oral solution (Imkeldi)—Oncological Agents: Chronic Myeloid Leukemia*
- *inavolisib (Itovebi)—Oncological Agents: Breast Cancer*
- *marstacimab-hncq (Hympavzi)—Antihemophilic Factors*
- *minocycline 40 mg extended-release capsules (Emrosi)—Antibiotics: Tetracyclines*
- *nilotinib tartrate tablets (Danziten)—Oncological Agents: Chronic Myeloid Leukemia*
- *olezarsen (Tryngolza)—Antilipidemic-2 Agents for familial chylomicronemia syndrome*
- *Omnipod 5 Intro G6/Libre 2 Plus pods and kits automated insulin delivery system: Insulins: Miscellaneous Insulin Devices*
- *revumenib (Revuforj)—Oncological Agents for Acute Leukemia*
- *ustekinumab-aaub (Wezlana)—Targeted Immunomodulatory Biologics (TIBs): Interleukin-23 (IL-23) inhibitors*
- *vanzacaftor/tezacaftor/deutivacaftor (Alyftrek)—Cystic Fibrosis Agents*

➢ **Utilization Management Issues**

- **PA Criteria—Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)**
  - *Narcotic Analgesics and Combinations: tramadol 75 mg tablets*
- **PA Criteria—Updated PA Criteria for New FDA-Approved Indications**
  - *Atopy Agents—dupilumab (Dupixent)*
  - *Oncological Agents—asciminib (Scemblix)*
  - *Psoriasis Agents—tapinarof 1% cream (Vtama)*
  - *TIBs: Miscellaneous Interleukins—nemolizumab (Nemluvio)*
  - *TIBs: IL-17 inhibitors—bimekizumab (Bimzelx)*
  - *Weight Loss Agents—tirzepatide (Zepbound)*
- **PA Criteria—Updated PA Criteria for Reasons Other Than New Indications**

- *Antidepressants and Non-Opioid Pain Syndrome Agents: Selective Serotonin Reuptake Inhibitors—vortioxetine (Trintellix)*
- *Attention Deficit Hyperactivity Disorder Agents: Stimulants—lisdexamfetamine (Vyvanse)*
- *Atopy Agents: Oral Janus Kinase-1 (JAK-1) Inhibitors—abrocitinib (Cibinqo) and upadacitinib (Rinvoq)*
- *Miscellaneous Neurological Agents: Niemann-Pick Disease—levacetylleucine (Aqneursa)*
- *Miscellaneous Neurological Agents: Transthyretin amyloidosis—tafamidis (Vyndaqel), tafamidis meglumine (Vyndamax) and eplontersen (Wainua)*
- *Oncological Agents—encorafenib (Braftovi)*
- *Ophthalmic: Dry Eye Agents—cyclosporine 0.05% ophthalmic emulsion unit dose (Restasis, generic unit dose)*
- *TIBs: Tumor necrosis factor (TNF) inhibitors—etanercept (Enbrel)*
- *TIBs: Miscellaneous—baricitinib (Olumiant), deucravacitinib (Sotyktu) and tofacitinib (Xeljanz)*
- *TIBs: Updates for Inflammatory Bowel Disease*
  - *ustekinumab (Stelara)*
  - *guselkumab (Tremfya)*
  - *risankizumab on-body injector (Skyrizi OBI)*
  - *mirikizumab (Omvoh)*
  - *vedolizumab (Entyvio*
  - *infliximab (Zymfentra)*

- **Removal of PA Criteria**
  - *Migraine Agents: Triptans—frovatriptan and naratriptan; return of frovatriptan to UF status*
  - *Gastrointestinal-2 Agents for Constipation-Predominant Irritable Bowel Syndrome—linaclotide (Linzess) and lubriprostone (Amitiza)*

➢ **Panel Discussions**

The UF BAP members will have the opportunity to ask questions to each of the presenters. Upon completion of the presentation and any questions, the Panel will concur or non-concur on the recommendations of the DoW 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.

- **Break for Lunch 12:45 PM – 1:45 PM Eastern Daylight Time**

Information from the May 2025 DoW P&T Meeting

- **General session starts at 1:45 PM Eastern Daylight Time**
- **Roll Call**
- **Therapeutic Class Reviews**

  Members of the DHA POD FMB will present relative clinical and cost-effectiveness analyses along with the DoW P&T Committee recommendations for the UF and any recommended complete exclusion candidates.

  The DoW P&T Committee made recommendations for the following drugs/drug classes during the May 2025 meeting.

- **Drug Class Reviews**
  - *Targeted Immunomodulatory Biologics (TIBs): Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses*
  - *Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors Subclass*
- **Newly Approved Drugs per 32 CFR 199.21(g)(5)**
  - *benzgalantamine (Zunveyl) – Alzheimer's Agents*
  - *concizumab-mtci (Alhemo) – Antihemophilic Agents*
  - *diazoxide choline (Vykat XR) – Miscellaneous Metabolic Agent for hyperphagia in Prader-Willi Syndrome*
  - *hydrochlorothiazide 10 mg/mL powder for oral suspension (Inzirqo) – Diuretic Agents*
  - *hydroxyurea 100 mg/mL oral solution (Xromi) – Oncological Agent for Sickle Cell Anemia*
  - *letermovir extended release (ER) pellets (Prevymis) – Antiviral for cytomegalovirus (CMV) infection*
  - *mirdametinib (Gomekli) – Oncological Agent for neurofibromatosis*
  - *suzetrigine (Journavx) – Pain Agents*
  - *trazodone 10 mg/mL oral solution (Raldesy) – Antidepressants and Non-Opioid Pain Syndrome Agents: Serotonin Antagonist and Reuptake Inhibitor*
  - *ustekinumab-auuz (Otulfi) – Targeted Immunomodulatory Biologics (TIBs): Interleukin-23 (IL-23) inhibitors; biosimilar for Stelara*
  - *ustekinumab-stab (Steqeyma) – TIBs IL-23s; biosimilar for Stelara*

- *ustekinumab-ttwe (Pyzchiva) – TIBs IL-23s; biosimilar for Stelara*
- *ustekinumab-kfce (Yesintek) – TIBs IL-23s; biosimilar for Stelara*
- *ustekinumab-aekn (Selardsi) – TIBs IL-23s; biosimilar for Stelara*
- *vimseltinib (Romvimza) – Oncological Agent for tenosynovial giant cell tumor*

➢ **Utilization Management Issues**

- **PA Criteria—New Manual PA Criteria**
  - *Anti-infectives: Anthelmintics—mebendazole (Emverm)*
  - *Endocrine Agents Miscellaneous: Antihyperglycemic-Glucocorticoid* **Receptor Blocker—mifepristone (Korlym)**
  - *Leukotriene Modifying Agents—zileuton (Zyflo), zileuton ER generic*
- **PA Criteria—Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)**
  - *Diabetes Non-Insulin: Biguanides—metformin 750 mg IR tablet*
  - *Narcotic Analgesics and Combinations—tramadol 100 mg immediate release (IR) tablet*
- **PA Criteria—Updated PA Criteria for New FDA-Approved Indications**
  - *Miscellaneous Metabolic Agents: setmelanotide (Imcivree)*
  - *Miscellaneous Immunological Agents: Oral Agents—house dust mite allergen extract (Odactra)*
  - *TIBs: IL-23s—guselkumab (Tremfya)*
  - *Leukemia and Lymphoma Agents: BTK Inhibitors—acalabrutinib (Calquence)*
  - *Oncological Agents: Lung Cancer—sotorasib (Lumakras)*
  - *Diabetes Non-Insulin: Glucagon-Like Peptide 1-ReceptorAgonits—semaglutide (Ozempic)*
- **PA Criteria—Updated PA Criteria for Reasons other than New FDA-Approved Indications**
  - *Corticosteroids-Immune Modulators: Atopic Dermatitis—crisaborole (Eucrisa)*
  - *Antigout Agents—febuxostat (Uloric)*
  - *Oncological Agents*
    - *fedratinib (Inrebic)*
    - *selumetinib (Koselugo)*
    - *pomalidomide (Pomalyst)*

- *ripretinib (Qinlock*
- *midostaurin (Rydapt)*
- *capmatinib (Tabrecta)*
- *tepotinib (Tepmetko)*
- *pexidartinib (Turalio)*
- *quizartinib (Vanflyta)*
- *larotrectinib (Vitrakvi)*
- *dacomitinib (Vizimpro)*
- *gilteritinib (Xospata)*

▪ *Miscellaneous Metabolic Agents*

- *odevixibat (Bylvay)*
- *maralixibat (Livmarli)*

▪ *Antipsychotic Agents for Parkinson's Psychosis—pimavanserin (Nuplazid)*

- **Removal of PA Criteria**
  - *Multiple Sclerosis Agents: Methyl Fumarate—dimethyl fumarate (Tecfidera)*
  - *Alzheimer's Agents—memantine ER (Namenda XR)*
- **Brand Over Generic Authorization and Tier 1 Copay**
  - *Renin-Angiotensin Antihypertensives: Combinations: sacubitril/valsartan (Entresto)*
- **Weight Loss Drugs PA Criteria: Comprehensive Lifestyle Intervention**

<u>Information from the Addendum to the May 2025 DoW P&T Meeting held on July 10, 2025</u>

- Prior Authorizations: Targeted Immunomodulatory Biologics (TIBs): Interleukin (IL-23) Inhibitors Prior Authorization Criteria and Implementation Plan
  - *The DoW P&T Committee held a virtual meeting on July 10, 2025 as an addendum to the May 2025 P&T Committee meeting, to update the PA criteria and implementation plan for the IL-23 Inhibitors.*

➢ **Panel Discussions**

The UF BAP members will have the opportunity to ask questions to each of the presenters. Upon completion of the presentation and any questions, the Panel will concur or non-concur on the recommendations of the DoW 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.

- **Adjournment**

P&T Committee Physician Comments

Day 1 June 22

Feb 2025

Drug Class Reviews

Wakefulness Promoting Drugs *(Sunosi, Xyrem, Wakix, modafinil, armodafinil, Xywav)*

- We previously reviewed the wakefulness promoting drug class in 2020. The reason for doing another look is due to updated clinical practice guidelines, new drugs in the class, generic entrants, and changes in indications.
- The main change to the formulary status is that Sunosi will now be on the formulary and the original Xyrem formulation will now be NF. The other drugs that are currently NF will stay NF. Anytime there are drugs that will move to NF status, beneficiaries will be notified by letter.
- We did reach out to MTF providers, who stated that prescribing of these drugs should be limited to specialists, and that annual follow-up was recommended. These factors were taken into account when the PA criteria were updated.
- PAs are currently in place for all the drugs. For Sunosi, automated specialist bypass will now apply, so no PA will be required if the prescription is written by a neurologist, psychiatrist, sleep medicine specialist, pulmonologist, or cardiologist. This update will help streamline the process for these providers.

Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass *(Butrans patch, Belbuca, Subutex, Suboxone)*

- This review focused on the buprenorphine subclass, due to updates in the clinical practice guidelines.
- All the products will now be on the formulary. We will also be removing the PA for the Butrans patch, since none of the other products currently have a PA. Overall, these changes will provide more options to treat pain and manage opioid use disorder.
- We do continually monitor all of the narcotic analgesics and look for any changes in clinical evidence and utilization patterns, to determine whether any formulary actions are needed.

<u>Newly Approved Drugs</u>

- There were a total of 15 new drugs reviewed, with 11 drugs that will go to UF status. The 4 drugs recommended for NF status all contain active ingredients that are found in other formulations that are UF. There were no recommendations for Complete Exclusion where TRICARE does not cost-share and the patient would pay the full price at retail.
- Prior authorization will apply to all 15 drugs, which will only apply to new patients. We do obtain input from providers when drafting PA criteria to ensure the most

appropriate use is reflected in the criteria. Additionally, if there is existing PA criteria for other drugs in a particular class, then the new drug will often have similar criteria. This is often seen with the oncology drugs for example, or drugs where we have existing step therapy.

- We will also add Miplyffa, Opipza, Nypozi, Imkeldi and Wezlana to the Rapid Response or Safety Net program managed by the TRICARE pharmacy contractor. The program identifies beneficiaries who have not received a prescription fill after the initial reject and notifies the prescriber.

Utilization Management

New Manual PA Criteria Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5) *(tramadol 75 mg)*

- The drugs that you heard about for this section are older drugs that have been brought back to the market using data that is several years old. Numerous formulary alternatives are available. Overall, these products have little value clinically or economically.
- FDA approval was through the Abbreviated New Drug Approval pathway (ANDA), therefore they don't qualify as innovators and we can't designate them with completely excluded status without a subsequent class review.
- The PA criteria will apply to new and current users. The overall purpose of the PA is intended to shift utilization to more cost-effective products.

Updated PA criteria for new FDA-approved indications *(Dupixent, Scemblix, Vtama, Nemluvio, Bimzelx, Zepbound)*

- You will see this section at every meeting. It's where we give brief summaries on drugs where current PAs are updated for pediatric use and new indications.
- All the changes will result in an increased number of patients who will qualify for the drug. We continually monitor the FDA website to ensure that the most recent package insert changes are evaluated by the Committee and appropriate changes are reflected in the PA criteria.

Updated PA Criteria for Reasons other than new FDA Indications *(Trintellix, Vyvanse, Rinvoq, Cibinqo, plus several other drugs)*

- All of the examples here show the wide variety of reasons that we use to update the PAs. This is another section that you will see at every meeting.
- These PA updates will apply to new patients, so patients who have already been approved for one of these drugs won't have to go through the PA process again.
- For three of the drugs, Trintellix, Vyvanse, and Restasis, automation was added to the PA to either look for previous drug history or specialist prescribing.

Automating some of the criteria still ensures appropriate patient selection while eliminating the need for providers to submit a paper PA.

- For the oncology drugs, we have been simplifying the PAs and removing some extraneous questions relating to safety, plus standardizing the wording to allow appropriate off-label use that is included in the main cancer network guidelines. You'll see several examples of this today and tomorrow. You'll also see several examples where the TIBs PAs have also been standardized.

Removal of PAs *(migraine drugs, GI drugs – Linzess and Amitiza)*

- In addition to adding new PAs, the Committee does routinely monitor utilization, pricing, and the strength of clinical data when deciding if a PA should be removed. For the migraine and GI drugs mentioned, removing the PA requirement will streamline the prescribing process for these medications.

May 2025

Drug Class Reviews

TIBs - IL-1, IL-6 and CTLA4-Ig Subclasses *(Arcalyst, Tyenne, Actemra, Kevzara, Orencia)*

- This is a very involved drug class with several complicated disease states. The clinical review was extensive, and several specialists were consulted for their expertise regarding the place in therapy for these drugs, formulary status, and PA criteria, including allowances for off-label use supported by the evidence.

- One of the main recommendations for this class is that the biosimilar Tyenne will now be step-preferred over the originator Actemra. The P&T Committee has previously endorsed the use of biosimilars and considers them therapeutically interchangeable with the reference drug. Automation was also added to the Tyenne PA to look back for Humira and Actemra, which should help with implementation.

- Letters will be mailed to the patients affected by the change to NF status for two of the drugs, Arcalyst and Enspryng. We will also mail letters to the patients currently receiving Actemra, as they will now be required to try the biosimilar first. In cases where there are adverse events or an inadequate response, Actemra will be allowed for continuation of therapy.

Breast Cancer Agents: Cyclin Dependent (CDK) Inhibitors Subclass *(Ibrance, Verzenio, Kisqali)*

- This is the second time that we've reviewed this oncology subclass. The clinical review looked at individual published trials, along with recommendations from several oncology guidelines. Provider feedback was also obtained for the PA criteria updates.

- For the formulary recommendation, all three drugs will remain designated as UF. This provides the optimal situation for providers and patients, since these products will be available to beneficiaries at the Tier 2 copay. Additionally, several updates were made to streamline the PA criteria.

Newly Approved Drugs

- A total of 15 new drugs were reviewed, with 9 designated as UF, 5 recommended for NF, and two drugs recommended for Complete Exclusion status. The drugs that will not be UF all contain active ingredients found in other formulations that are on the formulary.
- For the Alzheimer's drug recommended for Complete Exclusion status, two sets of letters will be mailed to the patients notifying them of the change. Additionally, the PA criteria does state that the product will be excluded. Currently there are 11 patients on this therapy.
- Five of the new drugs were biosimilars for Stelara. There will be extensive discussion of the biosimilars throughout this meeting. The discussion from the February 2026 P&T Committee meeting will have the final formulary recommendations for these products.

No comments on the Utilization Management sections for the default PAs, new indications or new PAs.

Entresto Brand Over Generic and Tier 1 copay

- This is an example of where we continue to monitor pricing and availability of generics. Here we will be preferring the branded product and lowering the copay to the tier one generic amount. Patients will notice this copay reduction the next time they fill their prescription.

No comments on the Weight Loss Comprehensive lifestyle intervention

May 2025 Addendum from July 2025 *No comments*

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
FROM THE FEBRUARY 2025 MEETING

INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL MEETING DAY #1 AM – refer to the posted Agenda for meeting dates and times https://health.mil/About-MHS/Federal-Advisory-Committees/BAP

I. UNIFORM FORMULARY REVIEW PROCESS

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

II. UF DRUG CLASS REVIEW—SLEEP DISORDERS: WAKEFULNESS PROMOTING SUBCLASS

P&T Comments

A. Sleep Disorders: Wakefulness Promoting Subclass—Relative Clinical Effectiveness Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the Wakefulness Promoting Agents. The subclass was previously reviewed for formulary status in August 2020. Drugs in this subclass include modafinil (Provigil, generics), armodafinil (Nuvigil, generics), sodium oxybate oral solution (Xyrem, authorized generics), sodium oxybate calcium/magnesium/potassium oral solution (Xywav), sodium oxybate extended release (ER) packets for oral suspension, (Lumryz), solriamfetol (Sunosi), and pitolisant (Wakix). The drugs in the class vary in their FDA-approved indications, which include excessive daytime sleepiness due to shift work sleep disorder, obstructive sleep apnea, narcolepsy, cataplexy associated with narcolepsy, and idiopathic hypersomnia.

Relative Clinical Effectiveness Conclusion—The current review focused on evidence from updated professional clinical practice guidelines and network meta-analyses with systematic reviews. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

Clinical Practice Guidelines

- *Narcolepsy*: The 2021 American Academy of Sleep Medicine (AASM) Guideline for Treatment of Central Disorders of Hypersomnolence lists a variety of agents which may be considered for treating excessive daytime sleepiness (EDS) or cataplexy in patients with narcolepsy. Modafinil, Wakix, sodium oxybate and Sunosi are listed as a "strong" strength of recommendation for EDS associated with narcolepsy, with Wakix and sodium oxybate listed as a "strong" strength of recommendation for cataplexy. Armodafinil and dextroamphetamines are listed as "conditional" for EDS associated with narcolepsy.
- *Obstructive Sleep Apnea (OSA)*: The 2024 French Sleep Research and Medicine Society Guideline for Assessment and Management of Residual Sleepiness in OSA recommends comprehensive medical assessment and management before consideration of pharmacotherapy. Individual drug selection should be based on clinical judgement and managed by appropriate specialists.

Efficacy

- *Narcolepsy* A network meta-analysis and systematic review concludes that Sunosi, Xyrem, Xywav, Wakix, and modafinil result in statistically significant and clinically meaningful reductions in Epworth Sleepiness Scale (ESS) Scores compared to placebo. Additionally, Wakix and Xyrem were found to significantly reduce cataplexy rate when compared to placebo.
- *OSA*: A network meta-analysis and systematic review concludes that Sunosi, Wakix, armodafinil and modafinil treatment result in statistically significant and clinically meaningful reductions in ESS Scores versus placebo. The results were listed as "high certainty" for Sunosi, and "moderate certainty" for armodafinil, modafinil and Wakix
- For all indications, the data is limited by the lack of head-to-head trials and low adherence to pharmacological treatments. Non-pharmacologic measures are also recommended (e.g., sleep hygiene, continuous positive air pressure for OSA). Additionally, the Wakefulness Promoting drugs only treat the disease symptoms and do not alter the underlying disease course.

Safety

- *Narcolepsy*: A network meta-analysis and systematic review demonstrated a statistically significant increase in neurologic adverse events for armodafinil and Sunosi; gastrointestinal events for armodafinil, Sunosi, and Xyrem; and psychiatric events for Sunosi, when compared to placebo. Notably, treatment withdrawal due to adverse events was significantly increased for Xyrem. None of the agents resulted in a significantly increased risk for serious adverse events compared to placebo.

- *OSA*: A network meta-analysis and systematic review demonstrated an increased risk for discontinuation due to adverse effects for armodafinil and modafinil vs. placebo (high certainty) in patients treated for excessive daytime sleepiness and OSA.

Other Factors

- *armodafinil (Nuvigil, generics) and modafinil (Provigil, generics)* are both indicated for adults with EDS due to narcolepsy, shift work disorder or OSA and are available in generic formulations. Unique safety issues include serious rashes and anaphylaxis. They are both C-IV scheduled products (low potential for abuse). Generic formulations are available.
- *pitolisant (Wakix)* does not provide compelling clinical advantages other than it is not a controlled substance. It is approved for patients as young as 6 years of age with EDS associated with narcolepsy and for adults with cataplexy. Unique safety concerns include QT interval prolongation.
- *sodium oxybate*: There are three formulations of sodium oxybate, Xyrem, Xywav, and Lumryz. All the products carry a warning for central nervous system depression, respiratory depression and risk of abuse, misuse and diversion; are subject to risk evaluation and mitigation strategies (REMS) requirements; and are controlled substances and labeled as schedule C-III drug (moderate potential for abuse). The sodium oxybate products can only be dispensed by certified pharmacies. All three products are approved for treating EDS or cataplexy associated with narcolepsy in adults and children as young as 7 years of age.
    - *sodium oxybate oral solution (Xyrem)* is the original formulation and is now available in an authorized generic formulation. Dosing is administered at bedtime, with a second dose given 2.5 to 4 hours later.
    - *sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)* is the only drug in the subclass approved for adults with idiopathic hypersomnia; for this indication the dosing is once or twice nightly. Xywav contains less sodium than the original Xyrem formulation. There is a lack of robust data regarding this reduced sodium content, thereby limiting definitive conclusions for cardiovascular outcomes for narcolepsy patients.
    - *sodium oxybate ER packets for oral suspension (Lumryz)* is dosed once daily at bedtime.
- *solriamfetol (Sunosi)* is a C-IV scheduled product indicated for adults with EDS associated with narcolepsy or OSA. Safety concerns include hypertension and tachycardia.

Overall Conclusions

- For narcolepsy and excessive daytime sleepiness, there is a high degree of interchangeability between all the products. For narcolepsy with cataplexy, Wakix and the sodium oxybate formulations (Xyrem, Xywav, and Lumryz) have a moderate degree of therapeutic interchangeability and for sleepiness with OSA, modafinil, armodafinil and Sunosi have a moderate degree of therapeutic interchangeability.
- In order to meet the needs of Military Health System (MHS) beneficiaries, at least one agent is required for the treatment of each clinical indication.

B. Sleep Disorders: Wakefulness Promoting Subclass—Relative Cost Effectiveness Conclusion

The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that Sunosi was the most cost-effective branded Wakefulness Promoting agent.
- BIA results showed that designating the Wakefulness Promoting Agents with the formulary status below generated significant cost avoidance for the MHS.

C. Sleep Disorders: Wakefulness Promoting Subclass—UF Recommendation

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent), the following.

- UF generics
  - modafinil (Provigil, generics)
  - armodafinil (Nuvigil, generics)
- UF brands
  - sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)
  - solriamfetol (Sunosi) *moves from NF to UF*
- NF
  - sodium oxybate oral solution (Xyrem and authorized generics) *moves from UF to NF*
  - sodium oxybate ER packets for oral suspension (Lumryz)
  - pitolisant (Wakix)
- Complete Exclusion: none

D. Sleep Disorders: Wakefulness Promoting Subclass—Manual PA Criteria

PA criteria are not required for armodafinil or modafinil. PA criteria for the branded products have been in place since the original review and require the following: management by the appropriate specialist, confirmation of the diagnosis by objective testing, use of generic products first when clinically appropriate, and ruling out of other causes for sleep disorders. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria in new users, as outlined below.

- For the indication of EDS associated with narcolepsy in adults, a trial of stimulants (e.g., methylphenidate, dextroamphetamine) and armodafinil or modafinil is required first. For children, a trial of armodafinil or modafinil is not required, due to the limited evidence and lack of FDA-approval.
- For cataplexy associated with narcolepsy, a trial of stimulants is required, but armodafinil or modafinil is not required, due to limited evidence.
- For OSA, a trial of generic armodafinil or modafinil is required first.
- For Sunosi, an automated specialist bypass and age edit will apply. For manual PA criteria, if the patient is an adult and the provider is a neurologist, psychiatrist, sleep medicine specialist, pulmonologist, or cardiologist, then PA is not required.
- For Xywav, language now specifies that treatment for cataplexy does not require a trial of modafinil or armodafinil.
    - For Xyrem, Lumryz, and Wakix, for EDS due to narcolepsy in adults, a trial of stimulants, armodafinil or modafinil, Sunosi and Xywav are required first, based on clinical and cost effectiveness. For cataplexy, the requirement for a trial of modafinil or armodafinil and Sunosi does not apply.

The Manual PA criteria is as follows.

1. **pitolisant (Wakix)**

   Changes from the February 2025 meeting are in bold

   PA criteria apply to all new users

   Manual PA Criteria:

   - Provider acknowledges that PA is not required for modafinil or armodafinil
   - Prescribed by a neurologist, psychiatrist, or sleep medicine specialist
   - Prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy

- Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing
- Patient is 18 years of age or older:
  - The patient has history of failure, contraindication, or intolerance to all of the following:
    - modafinil or armodafinil
      - **Treatment for cataplexy does not require trial of modafinil or armodafinil**
    - stimulant-based therapy (amphetamine-based therapy or methylphenidate)
    - **sodium oxybate (Xywav)**
    - **solriamfetol (Sunosi)**
      - **Treatment for cataplexy does not require trial of Sunosi**
- Patient is 6 years of age or older:
  - The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate)

- Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)
- The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic, a benzodiazepine, or a sedative hypnotic

Non-FDA approved uses are not approved

Prior Authorization expires after 1 year

A new PA must be submitted annually

2. sodium oxybate ER packets for oral suspension (Lumryz) and sodium oxybate oral solution (Xyrem brand)

Changes from the February 2025 meeting are in bold

PA criteria apply to all new users

Manual PA Criteria:

- **Provider acknowledges that PA is not required for modafinil or armodafinil**
- Prescribed by a neurologist, psychiatrist, or sleep medicine specialist
- Prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy

- Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing
- Patient is 18 years of age or older:
  - The patient has history of failure, contraindication, or intolerance to all of the following:
    - **modafinil or armodafinil**
      - **Treatment for cataplexy does not require trial of modafinil or armodafinil**
    - stimulant-based therapy (amphetamine-based therapy or methylphenidate)
    - **sodium oxybate (Xywav)**
    - **solriamfetol (Sunosi)**
      - **Treatment for cataplexy does not require trial of Sunosi**
- Patient is 7 years of age or older:
  - The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate)

- Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)
- The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic, a benzodiazepine, or a sedative hypnotic

Non-FDA approved uses are not approved

Prior Authorization expires after 1 year

A new PA must be submitted annually

3. sodium oxybate oral solution (Xyrem authorized generic)

Changes from the February 2025 meeting are in bold

PA criteria apply to all new users

Manual PA Criteria:

- Provider will include a patient-specific justification as to why the Xyrem brand cannot be used in this patient: _____ (fill in the blank)
  - Acceptable reasons include a patient has had an adverse reaction not expected to occur with the generic

- **Provider acknowledges that PA is not required for modafinil or armodafinil**
- Prescribed by a neurologist, psychiatrist, or sleep medicine specialist
- Prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy
  - Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing
  - Patient is 18 years of age or older:
    - The patient has history of failure, contraindication, or intolerance to all of the following:
      - **modafinil or armodafinil**
        - **Treatment for cataplexy does not require trial of modafinil or armodafinil**
      - stimulant-based therapy (amphetamine-based therapy or methylphenidate)
      - **sodium oxybate (Xywav)**
      - **solriamfetol (Sunosi)**
        - **Treatment for cataplexy does not require trial of Sunosi**
  - Patient is 7 years of age or older:
    - The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate)
- Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)
- The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic, a benzodiazepine, or a sedative hypnotic

Non-FDA approved uses are not approved

Prior Authorization expires after 1 year

A new PA must be submitted annually

4. sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)

Changes from the February 2025 meeting are in bold

PA criteria apply to all new users

Manual PA Criteria:

- **Provider acknowledges that PA is not required for modafinil or armodafinil**
- Prescribed by a neurologist, psychiatrist, or sleep medicine specialist
- Prescribed for the treatment of idiopathic hypersomnia OR
- Prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy
  - Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing
  - Patient is 18 years of age or older:
    - The patient has history of failure, contraindication, or intolerance to all of the following:
      - **modafinil or armodafinil**
        - **Treatment for cataplexy does not require trial of modafinil or armodafinil**
      - stimulant-based therapy (amphetamine-based therapy or methylphenidate)
  - Patient is 7 years of age or older:
    - The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate)
- Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)
- The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic, a benzodiazepine, or a sedative hypnotic

Non-FDA approved uses are not approved

Prior Authorization expires after 1 year

A new PA must be submitted annually

5. **solriamfetol (Sunosi)**

   Changes from the February 2025 meeting are in bold

   PA criteria apply to all new users

   <u>Automated PA Criteria</u>: When the patient is 18 years of age or older, and when prescribed by a neurologist, psychiatrist, sleep medicine specialist, pulmonologist or cardiologist, prior authorization is not required.

Manual PA Criteria: If automated criteria are not met, then Sunosi is approved if:

- Provider acknowledges that PA is not required for modafinil or armodafinil
- Patient is 18 years of age or older
- Sunosi is prescribed for either:
  - Excessive daytime sleepiness associated with narcolepsy
    - Prescribed by a neurologist, psychiatrist, or sleep medicine specialist
    - Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing
    - Other causes of sleepiness have been ruled out or treated including but not limited to obstructive sleep apnea
    - The patient must have tried and failed, had a contraindication to, or had an inadequate response to modafinil or armodafinil
    - The patient must have tried and failed, had a contraindication to, or had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate)
  - Excessive daytime sleepiness associated with obstructive sleep apnea:
    - Prescribed by a specialist who treats patients with obstructive sleep apnea (e.g., pulmonologist, cardiologist, sleep medicine)
    - Patient's underlying airway obstruction has been treated with continuous positive airway pressure (CPAP) for at least one month prior to initiation, and the patient demonstrated adherence to therapy during this time, and the patient will continue treatment for underlying airway obstruction (CPAP or similar) throughout duration of therapy
    - The patient must have tried and failed, had a contraindication to, or had an inadequate response to modafinil or armodafinil
- The patient is not concurrently taking a central nervous system depressants, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic

Non-FDA-approved uses are not approved

Prior authorization expires in 1 year

A new PA must be submitted annually

E. Sleep Disorders: Wakefulness Promoting Subclass—UF Recommendation, PA Criteria and Implementation Plan

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday 90 days after signing of the minutes, and 2) that DHA will send letters to beneficiaries receiving sodium oxybate (Xyrem) and authorized generics who will be affected by the formulary status change and PA.

III. UF DRUG CLASS REVIEW—SLEEP DISORDERS: WAKEFULNESS PROMOTING SUBCLASS

UF BAP Comments

A. Sleep Disorders: Wakefulness Promoting Subclass—UF Recommendation

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

- UF generics
  - modafinil (Provigil, generics)
  - armodafinil (Nuvigil, generics)
- UF brands
  - sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)
  - solriamfetol (Sunosi) *moves from NF to UF*
- NF
  - sodium oxybate oral solution (Xyrem, authorized generics) *moves from UF to NF*
  - sodium oxybate ER packets for oral suspension (Lumryz)
  - pitolisant (Wakix)
- Complete Exclusion: none

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Sleep Disorders: Wakefulness Promoting Subclass—Manual PA Criteria

The P&T Committee recommended PA criteria in new users as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Sleep Disorders: Wakefulness Promoting Subclass —UF Recommendation, PA Criteria and Implementation Plan

The P&T Committee recommended for the Wakefulness Promoting Agents an effective date of the first Wednesday 90 days after signing of the minutes in all points of service and that DHA send letters to the patients affected by the formulary change for Xyrem.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEW—NARCOTIC ANALGESICS AND COMBINATIONS: BUPRENORPHINE AND COMBINATIONS SUBCLASS

P&T Comments

A. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass—Relative Clinical Effectiveness Conclusion

The Narcotic Analgesics and Combinations include older generic opioids and abuse-deterrent products, along with two subclasses, the Transmucosal Immediate Release Fentanyl Products and the Buprenorphine and Combinations subclasses. The Narcotic Analgesics are routinely monitored to ensure alignment with clinical practice guidelines, emerging clinical evidence and Military Health System (MHS) utilization trends.

- Older generic opioids and abuse-deterrent formulations: New entries to the market are routinely evaluated for formulary status as part of the newly approved drugs program pursuant to 32 CFR 199.21(g)(5). Numerous clinically and cost effective opioid options are available on the formulary that do not require PA, overall utilization has decreased and an updated full class review of opioid agents is not warranted.
- Transmucosal Immediate Release Fentanyl products: There are no compelling clinical advancements or updated guidelines to warrant a full review since the original subclass review in 2015.
- Buprenorphine and Combinations: Joint clinical practice guidelines from the DoD and U. S. Department of Veteran's Affairs (VA) were recently updated and increasing MHS spend has been noted for the subclass. As a result, the current review focused on the Buprenorphine and Combinations Subclass. The drugs in the subclass include various formulations of buprenorphine, which are FDA-approved for managing severe and persistent pain, and combinations of buprenorphine with naloxone, which are approved for managing opioid use disorder.

Relative Clinical Effectiveness Conclusion—The clinical review focused on clinical practice guidelines, systematic reviews, differences in FDA-labeling, and safety profiles. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following

Clinical Practice Guidelines:

Chronic Pain: The 2022 DoD/VA guidelines for the use of opioids in the management of chronic pain assigned buprenorphine as a "weak for" recommendation, due to limitations in the available body of evidence, but superior safety profile over traditional opioids.

The 2024 updated guidance continues to recommend non-opioid medications in combination with non-pharmacologic interventions as the preferred treatment for chronic pain. Many non-opioid options are available to TRICARE beneficiaries and are regularly added to the UF through the new drug program. Buprenorphine was acknowledged to retain many of the same risks associated with use of full agonist opioids yet demonstrates less risk of respiratory depression. However, the guidelines further state when treatment with opioids is indicated, buprenorphine may be preferred over full agonist opioids due to a unique mechanism of action and safety profile.

Opioid Use Disorder: The 2022 Centers for Disease Control clinical practice guideline for prescribing opioids for pain specifically mentions buprenorphine for opioid use disorder. Overall, evidenced-based treatment should be used. Buprenorphine can also be considered due to reduced overdosage risk compared to the risks seen with full agonist opioids.

Efficacy

Chronic Pain

There are no head-to-head data comparing the buprenorphine formulations approved for chronic persistent pain. Based on indirect evidence, the buprenorphine patch (Butrans) and sublingual (SL) film (Belbuca) both demonstrate comparable efficacy in moderate-to-severe chronic pain.

A 2018 network meta-analysis and systematic review assessed the effectiveness and tolerability of buprenorphine for pain in adults and children with cancer. The conclusion was that there was insufficient evidence to designate buprenorphine as a valid first-line choice alongside standard therapies including morphine, oxycodone and fentanyl. Buprenorphine could be considered a fourth-line option.

Another 2023 meta-analysis and systematic review from the International Anesthesia Research Society compared the analgesic efficacy of buprenorphine to a control group for treating chronic noncancer pain. Both the transdermal and buccal administration routes produced statistically significant reductions in

pain and can be considered as an alternative to traditional analgesics for non-cancer pain.

Opioid Use Disorder

When used for opioid use disorder, buprenorphine reduces withdrawal symptoms and opioid cravings.

Safety

Chronic Pain: The labeling for all the buprenorphine agents carries similar safety warnings and adverse effect profiles.

buprenorphine vs. other narcotic analgesics: Buprenorphine has an analgesic ceiling effect, reducing the risk of respiratory depression and overdose. Additionally, there is a lower risk of misuse and dependence compared to full opioid agonists.

buprenorphine products: Both the Butrans patch and Belbuca buccal film have similar adverse effects and contain the same warnings seen with other opioids, including nausea, constipation, addiction, abuse, misuse, life-threatening respiratory depression, and risks with concurrent use with other central nervous system depressants.

Opioid Use Disorder: For opioid use disorder, buprenorphine/naloxone combinations when compared to methadone are safer overall and safer in overdose, are more accessible, and require less frequent dosing. However, the ceiling effect may limit efficacy in some cases.

Individual Product Characteristics

Chronic Pain

buprenorphine transdermal system (Butrans, generics): The patch requires once weekly application. Butrans is labeled for patients previously taking up to80 oral morphine milligram equivalents daily. Advantages include the long duration of action. Disadvantages include the low bioavailability (15% with Butrans vs. 45% to 65% with Belbuca), risk of application-site pruritus and QTc interval prolongation at doses greater than 20 mcg/hour, which limits use in patients with unstable cardiac disease. It is contraindicated in patients with severe liver impairment.

buprenorphine buccal film (Belbuca): The buccal film has a 12-hour dosing frequency. Labeling includes patients previously taking less than 160 oral morphine milligram equivalents daily. Advantages include the high bioavailability via mucosal absorption and lower risk of QTc interval prolongation (risk is increased with doses above 900 mcg/hour). Disadvantages include adverse dental effects, including dental caries. The restriction regarding avoidance of eating, drinking and oral hygiene for 60 minutes following application may limit use.

Opioid Use Disorder

buprenorphine/naloxone formulations: The combinations with naloxone include SL tablets and an oral film. Compared with the generic Suboxone SL tabs, the branded Zubsolv SL tabs are available in more dosage strengths (6 dosages vs. 5 with Suboxone), have a higher bioavailability, reported better taste, and shorter dissolution time. For opioid use disorder, target maintenance doses can exceed 24 mg buprenorphine daily.

buprenorphine SL tabs (Subutex, generics): This generic oral buprenorphine formulation is available in 2 mg and 8 mg SL tablets.

Overall Conclusions

In terms of efficacy and safety for chronic pain treatment, there is a moderate to high degree of therapeutic interchangeability within the buprenorphine agents indicated for pain, with differences primarily based on dosing flexibility, administration routes, adverse event profiles and formulation-specific risks.

In order to meet the needs of Military Health System (MHS) beneficiaries, multiple dosage formulations are preferred.

B. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass—Relative Cost Effectiveness Analysis and Conclusion

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

CMA results showed that generic Butrans was more cost effective than Belbuca, and generic buprenorphine agents for opioid use disorder were more cost effective than Zubsolv.

BIA results found that designating Belbuca as UF resulted in increased spend, especially considering the recent price increase.

C. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass—UF Recommendation

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

- UF
  - buprenorphine transdermal patch (Butrans, generics)
  - buprenorphine buccal film (Belbuca) *moves from NF to UF*
  - buprenorphine SL tablets (Subutex, generic)
  - buprenorphine/naloxone SL tabs (Zubsolv)
  - buprenorphine/naloxone SL film (Suboxone)
  - buprenorphine/naloxone SL tabs (Suboxone tabs, generic)
- NF: none
- Complete exclusion: none

D. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass—Manual PA Criteria

PA criteria currently apply to the Butrans patch since it was reviewed as a new drug in August 2011 due to concerns regarding respiratory depression at high doses. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) removing the Butrans patch PA, as the other buprenorphine formulations do not have a PA, and to maintain alignment with clinical practice guidelines for chronic pain.

E. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass —UF Recommendation, PA Criteria Removal, and Implementation Period

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

V. UF DRUG CLASS REVIEW—NARCOTIC ANALGESICS AND COMBINATIONS: BUPRENORPHINE AND COMBINATIONS SUBCLASS

UF BAP Comments

A. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass—UF Recommendation

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

- UF
  - buprenorphine transdermal patch (Butrans, generics)
  - buprenorphine buccal film (Belbuca) *moves from NF to UF*
  - buprenorphine SL tablets (Subutex, generic)
  - buprenorphine/naloxone SL tabs (Zubsolv)
  - buprenorphine/naloxone SL film (Suboxone)
  - buprenorphine/naloxone SL tabs (Suboxone tabs, generic)
- NF: none
- Complete exclusion: none

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass —Manual PA Criteria Removal

The P&T Committee recommended removing the manual PA criteria for Butrans patch, as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass —UF Recommendation, PA Criteria Removal, and Implementation Period

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

UF 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

The P&T Committee agreed (19 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).

Addition of new medical devices to the TRICARE pharmacy benefit is also reviewed in this section. Medical devices are primarily covered by the TRICARE medical benefit, and any additions to the TRICARE pharmacy benefit are not meant to replace this pathway for procuring medical devices. The Committee identified one medical device for review at this meeting, Omnipod 5 Intro G6/Libre 2 Plus.

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

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

- UF
    - acoramidis (Attruby) – Miscellaneous Neurological Agents for transthyretin amyloidosis
    - arimoclomol (Miplyffa) – Miscellaneous Neurological Agents for Niemann-Pick disease
    - crinecerfont (Crenessity) – Miscellaneous Endocrine Agents for congenital adrenal hyperplasia
    - inavolisib (Itovebi) – Oncological Agents: Breast Cancer
    - marstacimab-hncq (Hympavzi) – Antihemophilic Agents
    - nilotinib tartrate tablets (Danziten) – Oncological Agents: Chronic Myeloid Leukemia
    - olezarsen (Tryngolza) – Antilipidemics-2 for familial chylomicronemia syndrome
    - Omnipod 5 Intro G6/Libre 2 Plus Pods and Kits – Insulins: Miscellaneous Insulin Devices; this device was also added to the TRICARE Pharmacy benefit
    - revumenib (Revuforj) – Oncological Agents for Acute Leukemia
    - ustekinumab-auub (Wezlana) – Targeted Immunomodulatory Biologics: Interleukin-23 (IL-23) inhibitors
    - vanzacaftor/tezacaftor/deutivacaftor (Alyftrek) – Cystic Fibrosis Agents
- NF
    - aripiprazole oral film (Opipza) – Antipsychotic Agents: Atypical
    - filgrastim-txid (Nypozi) – White Blood Cell Stimulants: Filgrastim
    - imatinib 80 mg/mL oral solution (Imkeldi) – Oncological Agents: Chronic Myeloid Leukemia
    - minocycline 40 mg ER capsules (Emrosi) – Antibiotics: Tetracyclines
- Completely Excluded: none

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

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

- Applying manual PA criteria to new users of Wezlana, the biosimilar to Stelara, similar to what is required for all non-step-preferred Interleukin-23 inhibitors. A trial of adalimumab (Humira) and ixekizumab (Taltz) will be required first.

- Applying manual PA criteria to new users of Omnipod 5 Intro G6/Libre2 Plus pods and kits, similar to what is required for the Omnipod 5 G6/G7 pods and kits. Note that corresponding updates were also made to the Omnipod 5 G6/G7 PA criteria (see page 32).
- Applying manual PA criteria to Nypozi, similar to what is in place for the other non-step-preferred filgrastims. New patients receiving Nypozi or one of the other non-step-preferred filgrastims (Releuko and Neupogen) will be required to have a trial of Granix, Nivestym and Zarxio first.
- Applying manual PA criteria to new users of the oncology drugs Danziten, Imkeldi, Itovebi, and Revuforj.
- Applying manual PA criteria to new users of Alyftrek, Crenessity, Hympavzi, Opipza, and Tryngolza.
- Applying manual PA criteria to new users of Emrosi, requiring a trial of generic minocycline and other products for rosacea first, similar to what is required for other non-step-preferred minocycline products.
- Applying manual PA criteria to new users of Attruby. Accordingly, updates were made to the other drugs used for transthyretin amyloidosis (Vyndaqel, Vyndamax and Wainua); (see the utilization management section on page 32.)
- Applying manual PA criteria to new users of Miplyffa; updates were also made to the Aqneursa PA, the other drug approved for Niemann-Pick disease, to allow concomitant use with Miplyffa; (see the utilization management section on page 32.)

The Manual PA criteria are as follows:

1. **acoramidis (Attruby)**
   Manual PA criteria apply to all new users of the Attruby

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

   - The patient is 18 years of age or older
   - The requested medication is prescribed by or in consultation with a specialist who manages transthyretin amyloidosis (for example, cardiologist, geneticist, or neurologist)
   - Patient has a diagnosis of transthyretin-mediated amyloidosis
   - The patient is not receiving concurrent treatment with tafamidis (Vyndaqel, Vyndamax), (inotersen) Tegsedi, (patisiran) Onpattro, or vutrisiran Amvuttra)

   Non-FDA approved uses are not approved, including ATTR-polyneuropathy

   PA does not expire

2. arimoclomol (Miplyffa)

Manual PA criteria apply to all new users of Miplyffa

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

- Patient is 2 years of age or older
- Prescribed by a physician who specializes in the treatment of Niemann-Pick disease type C
- Patient has a genetically confirmed diagnosis of Niemann-Pick disease type C
- Patient is able to walk independently or with assistance
- Patient has one or more neurologic symptoms (e.g., loss of motor function, difficulty swallowing, and speech and cognitive impairment)
- Patient has tried and failed or experienced an adverse reaction or has a contraindication to levacetylleucine (Aqneursa)
- Patient will use the requested medication with miglustat

Non-FDA approved uses are not approved

PA does not expire

3. aripiprazole oral film (Opipza)

Manual PA criteria apply to all new users of Opipza

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

1. Opipza is prescribed by a neurologist, psychiatrist, or developmental pediatrician
2. The provider must explain why the patient requires Opipza and cannot take the generic formulary alternatives: aripiprazole ODT and oral solution (fill-in blank)
    - Acceptable responses include
        - The patient has had an adverse reaction to an excipient in aripiprazole ODT and oral solution that would not be likely to occur with Opipza oral film OR
        - The patient has documented oral aversion (e.g., due to developmental delay, sensory aversion) requiring an alternative formulation for treatment

Non-FDA-approved uses are not approved

Prior Authorization does not expire

4. crinecerfont (Crenessity)

Manual PA criteria apply to all new users of Crenessity

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

- Patient is 4 years of age or older
- The drug is prescribed by an endocrinologist, urologist, or a physician who specializes in the treatment of adrenal hyperplasia
- Patient has a diagnosis of 21-hydroxylase deficiency Congenital Adrenal Hyperplasia (CAH)
- Patient will take Crenessity in combination with systemic glucocorticoids

Non-FDA approved uses are not approved

PA does not expire

5. filgrastim-txid (Nypozi)

Manual PA criteria apply to all new users of Nypozi

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

- Provider acknowledges that tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), and filgrastim-sndz (Zarxio) are the TRICARE preferred filgrastims and are available without a prior authorization. Please consider changing the prescription to a formulary preferred medication. Note: Granix and Nivestym are available at the generic (Tier 1) copay at the Mail Order and Retail pharmacies
- Prescribed by or in consultation with a hematologist or oncologist

3. Patient experienced an inadequate treatment response or intolerance to tbo-filgrastim (Granix) and is expected to respond to filgrastim (Neupogen) or filgrastim-ayow (Releuko) or filgrastim-txid (Nypozi)
4. Patient experienced an inadequate treatment response or intolerance to filgrastim-aafi (Nivestym) and is expected to respond to filgrastim (Neupogen) or filgrastim-ayow (Releuko) or filgrastim-txid (Nypozi)
5. Patient experienced an inadequate treatment response or intolerance to filgrastim-sndz (Zarxio) and is expected to respond to filgrastim (Neupogen) or filgrastim-ayow (Releuko) or filgrastim-txid (Nypozi)

PA does not expire

6. imatinib 80 mg/mL oral solution (Imkeldi)

Manual PA criteria apply to all new users of Imkeldi

Age edit: PA is not required for patients 6 years or age or younger

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

- Patient is 12 years of age or older
- Provider acknowledges that generic imatinib tablets can be dissolved in water or juice and are available to TRICARE beneficiaries without requiring prior authorization
- Prescribed by an oncologist
- Patient has had an adverse reaction to an excipient in imatinib tablets that would not be likely to occur with Imkeldi OR
- Patient has tried and failed treatment with dissolving imatinib tablets in liquid

Non-FDA approved uses are not approved

PA does not expire

7. inavolisib (Itovebi)

Manual PA criteria apply to all new users of Itovebi

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

- Patient is 18 years of age or older
- Prescribed by or in consultation with an oncologist
- Patient has locally advanced or metastatic hormone receptor (HR)-positive disease
- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease
- Patient has PIK3CA-mutated breast cancer as detected by an FDA approved test
- Patient has disease recurrence on or after completing adjuvant endocrine therapy
- Medication will be used in combination with Ibrance (palbociclib capsules and tablets) and fulvestrant injection
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guidelines version and page number _____.

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

PA does not expire

8. marstacimab-hncq (Hympavzi)

Manual PA criteria apply to all new users of Hympavzi

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

Patient is 12 years of age or older

- The drug is prescribed by or in consultation with a hematologist
- Patient has moderate to severe hemophilia A without factor VIII inhibitors or hemophilia B without factor IX inhibitors
- Patient is not concurrently receiving Factor VIII or IX therapy unless for the treatment of breakthrough bleeding

Non-FDA approved uses are not approved

PA does not expire

9. minocycline 40 mg ER caps (Emrosi)

Manual PA criteria apply to all new users of Emrosi

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

- Provider acknowledges that minocycline immediate release (IR), metronidazole gel and cream, and azelaic acid 15% gel are available to DoD beneficiaries without the need of prior authorization. The provider is encouraged to change the prescription to one of these preferred agents
- Patient is 18 years of age or older
- Prescribed by or in consultation with a dermatologist
- Patient has inflammatory lesions (papulopustular) of rosacea
- Patient has tried and failed or has a contraindication to an oral minocycline or doxycycline product
- Patient has tried and failed or has a contraindication to topical ivermectin
- Patient has tried and failed or has a contraindication to one of the following medications for rosacea: topical azelaic acid, topical metronidazole, isotretinoin, or topical minocycline
- Prescriber will provide the name and date of trial for the three above-mentioned drugs below:
  - Drug name: _____ Date of Trial and Failure: _____ Contraindication: _____
  - Drug name: _____ Date of Trial and Failure: _____ Contraindication: _____
  - Drug name: _____ Date of Trial and Failure: _____ Contraindication: _____

Non-FDA approved uses are not approved

PA does not expire

10. nilotinib tartrate tablets (Danziten)

Manual PA criteria apply to all new users of Danziten

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

- Provider acknowledges PA is not required for Tasigna
- Patient is 18 years of age or older
- Prescribed by or in consultation with a hematologist or oncologist
- Patient has a diagnosis of:
  - Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase OR
  - Chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib
- Patient has tried Tasigna and had an adverse reaction not expected to occur with Danziten, OR
- Patient cannot avoid food 2 hours before and one hour after taking Tasigna
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guidelines version and page number _____.

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

PA does not expire

11. olezarsen (Tryngolza)

Manual PA criteria apply to all new users of Tryngolza

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

- Patient is 18 years of age or older
- Prescribed by cardiologist, an endocrinologist, or an internal medicine physician experienced in treating disorders related to severe hypertriglyceridemia
- Patient has undergone genetic testing to confirm the diagnosis of familial chylomicronemia syndrome
- Patient has fasting triglyceride level of 880 mg/dL or greater
- Patient will adhere to a low fat-diet (less than or equal to 20 g fat per day) while receiving Tryngolza

Non-FDA approved uses are not approved

PA does not expire

12. Omnipod 5 Intro G6/Libre2 Plus pods and kits

Manual PA criteria apply to all new users of Omnipod 5 Intro G6/Libre 2 Plus Pods and Kits

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

- The Omnipod 5 device is being used to monitor diabetes mellitus
- Provider acknowledges that a current approved TRICARE PA for Omnipod 3 or Omnipod 4 does not grant automatic approval for Omnipod 5. New PA is required.
- Omnipod 5 is prescribed by or in consultation with an endocrinologist
- Patient is receiving multiple daily injections of insulin
- Patient has completed a comprehensive diabetes education program (to include teaching patient and caregiver how to administer insulin via syringe)
- Patient has demonstrated willingness and ability to play an active role in diabetes self-management

Non-FDA approved uses are not approved

PA expires in 1 year

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

- Patient has been successful with therapy as shown by an increase in blood glucose time in range or improved A1c
- Patient has experienced a decrease in hypoglycemic episodes

13. revumenib (Revuforj)

Manual PA criteria apply to all new users of Revuforj

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

- The drug is prescribed by or in consultation with an oncologist
- Patient has relapsed or refractory acute leukemia
- Disease is positive for lysine methyltransferase 2A (KMT2A) gene translocation
- The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guidelines version and page number _____.

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

PA does not expire

14. vanzacaftor/tezacaftor/deutivacaftor (Alyftrek)
Manual PA criteria apply to all new users of Alyftrek

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

- Patient is 6 years of age or older
- Prescribed by or in consultation with a pulmonologist
- Patient has diagnosis of cystic fibrosis
- Patient has at least one F508del mutation or another responsive mutation to Alyftrek in the CFTR gene and if the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one indicated mutation

Non-FDA approved uses are not approved

PA does not expire

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

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent an effective date of the following:

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

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

UF BAP Comments

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

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

- UF
  - Attruby
  - Miplyffa
  - Crenessity
  - Itovebi
  - Hympavzi
  - Danziten
  - Tryngolza

        - Omnipod 5 Intro G6/Libre 2 Plus Pods and Kits
        - Revuforj
        - Wezlana
        - Alyftrek
    - NF
        - Opipza
        - Nypozi
        - Imkeldi
        - Emrosi
    - Complete Exclusion - none

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

The P&T Committee recommended implementation period of two weeks for the drugs recommended for UF and NF status, as discussed above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN

P&T Comments

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

Manual PA criteria were recommended for one recently marketed drug produced by a sole manufacturer which contain active ingredients that are widely available in low-cost generic formulations. 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. Numerous cost-effective formulary alternatives are available that do not require prior authorization.

- **Narcotic Analgesics and Combinations—tramadol 75 mg tablet—**There are other tramadol formulations available, including scored tramadol 50 mg tablets, that are more cost-effective than this 75 mg formulation made by a sole manufacturer.

The Manual PA criteria are as follows:

1. tramadol 75 mg tablets

Manual PA criteria apply to all new users of tramadol 75 mg tablets

Manual PA criteria: tramadol 75 mg tablets are approved if all criteria are met:

- Provider is aware and acknowledges that tramadol 50 mg tablets are available to DoD beneficiaries without the need of prior authorization. Providers are encouraged to consider changing the prescription to the preferred tramadol 50 mg.
- Provider must explain why the patient requires tramadol 75 mg and cannot take the cost-effective generic tramadol 50 mg formulations (fill-in the blank)

a. Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available tramadol 50 mg tablets

Non-FDA-approved uses are not approved

Prior authorization does not expire

B. New PA Criteria for Drugs Not Subject to 32 CFR 199.21(G)(5) and Implementation Plan

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for tramadol 75 mg tablets in new and current users, due to the significant cost differences compared with other available alternative agents. The new PA will become effective the first Wednesday 60 days after the signing of the minutes

IX. UTILIZATION MANAGEMENT— NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended manual PA for tramadol 75 mg tablets as stated above and an effective date the first Wednesday 60 days after signing of the minutes

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

A. Updated PA Criteria for New FDA Approved Indications

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users.

a) **Atopy—dupilumab (Dupixent)—**The manual PA criteria were updated to allow for Dupixent use in patients with chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype after a trial of triple therapy with traditional inhalers approved for COPD.

b) **Oncological Agents—asciminib (Scemblix)—**The manual PA criteria were expanded to include newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Additionally, other updates were done to include the standard wording found in the other oncology PAs, including updating the National Comprehensive Cancer Network (NCCN) guidelines question and removing warnings and precautions language.

c) **Psoriasis Agents—tapinarof 1% cream (Vtama)—**The manual PA criteria were updated to allow for treatment of atopic dermatitis in patients 2 years of age or older.

d) **TIBs: Miscellaneous Interleukins—nemolizumab-ilto (Nemluvio)—**The manual PA criteria were updated to allow for treatment of atopic dermatitis in patients 12 years of age or older.

e) **TIBs: IL-17s—bimekizumab-bkzx (Bimzelx)—**Bimzelx received a new indication for hidradenitis suppurativa in adults. The manual PA criteria were updated and require a trial of Humira and Cosentyx first.

f) **Weight Loss Agents—tirzepatide (Zepbound)—**Zepbound is now indicated for moderate to severe obstructive sleep apnea in adults with obesity. The manual PA criteria were updated. A trial of phentermine will not be required for this new indication, due to the increased risk of cardiovascular events. Patients are required to have a body mass index of at least 30 and have a documented diagnosis of sleep apnea.

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

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Scemblix, Vtama, Nemluvio, Bimzelx, Zepbound, and Dupixent in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

XI. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEW FDA APPROVED INDICATIONS AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Dupixent, Scemblix, Vtama, Nemluvio, Bimzelx and Zepbound in new users and an implementation effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

A. Updated PA Criteria for Reasons other than New FDA Approved Indications

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs, due to reasons other than new FDA-approved indications. The updated PA criteria outlined below will apply to new users.

a) **Antidepressants and Non-Opioid Pain Syndrome Agents: Selective Serotonin Reuptake Inhibitors—vortioxetine (Trintellix)—**An automated drug lookback was added to the Trintellix PA allowing approval if a patient has tried two formulary antidepressants in the past 720 days.

b) **Attention Deficit Hyperactivity Disorder (ADHD): Stimulants—lisdexamfetamine capsule, chew tab (Vyvanse)—**An automated drug look back was added, allowing approval of the Vyvanse PA if a patient has had a trial of at least one amphetamine and one methylphenidate product within the past 720 days.

c) **Atopy: Oral Janus Kinase-1 (JAK-1) Inhibitors**

- **upadacitinib (Rinvoq)—**At the November 2024 P&T meeting, ixekizumab (Taltz) was selected as the step-preferred IL-17 inhibitor. The PA criteria for Rinvoq previously required a secukinumab (Cosentyx) trial first. The PA criteria was updated to replace Cosentyx with the step-preferred IL-17 Taltz. The PA was also modified with the other TIBs standardization edits (e.g., removing the monitoring and safety questions).
- **abrocitinib (Cibinqo)—**The Cibinqo PA was standardized and the exception to allow for concomitant use with apremilast (Otezla) was removed, as Cibinqo and Otezla do not have overlapping indications.

d) **Neurologic Agents: Miscellaneous drugs for Niemann-Pick disease—** levacetylleucine (Aqneursa)—The Aqneursa PA was updated to allow for concomitant use with arimoclomol (Miplyffa); (see new drug section on page 19).

e) **Neurologic Agents: Miscellaneous drugs for transthyretin amyloidosis—tafamidis (Vyndaqel), tafamidis meglumine (Vyndamax) and eplontersen (Wainua)—**The manual PA criteria for Vyndaqel, Vyndamax and Wainua were updated due to the recent approval of acoramidis (Attruby), (see new drugs section on page 19). The PAs were updated to expand the list of other amyloidosis drugs where concomitant use is prohibited.

f) **Oncological Agents—encorafenib (Braftovi)—**The Braftovi PA was updated as part of the continuing process for oncology PA standardization, to include removing monitoring and safety criteria, and standardizing wording for NCCN guideline updates.

g) **Ophthalmic: Dry Eye Agents—cyclosporine 0.05% ophthalmic emulsion unit dose (Restasis, generic unit dose**)—The Restasis PA was updated to add an automated specialist bypass for optometrists and ophthalmologists. Clinical criteria will still apply.

h) **TIBs: Tumor necrosis factor (TNF) inhibitors—etanercept (Enbrel)—**The Enbrel PA and MN criteria were updated to require a trial of ixekizumab (Taltz)

in addition to adalimumab (Humira) first, based on the recommendations made at the November 2024 IL-17 class review. The Taltz step therapy requirement will not apply to adult patients with rheumatoid arthritis or pediatric patients with juvenile idiopathic arthritis or juvenile psoriatic arthritis.

Other changes were made to standardize the PA, consistent with the PA criteria in place for other TIBs. Examples of these standardization edits across the TIBs class include removing monitoring and safety questions, adding a trial of NSAIDs for axial spondyloarthritis, and editing the non-biologic systemic therapy step. Additionally, the current automated PA criteria for Enbrel were removed.

i) TIBs: Miscellaneous

- **baricitinib (Olumiant)—**Similar to the Cibinqo PA, the Olumiant PA wording was standardized and the exception to allow for concomitant use with Otezla was removed. Additionally, the automated PA criteria currently in place were removed.
- **deucravacitinib (Sotyktu)—**The Sotyktu PA and MN criteria were updated to require a trial of Taltz in addition to Humira and Cosentyx before Sotyktu. Other TIBs standardization edits were also made.
- **tofacitinib (Xeljanz)—**The Xeljanz PA wording was standardized and the automated PA criteria currently in place were removed. In addition, the PA criteria that mentioned dosing requirements were removed as this is not found in other PAs within the class.

j) TIBs—ustekinumab (Stelara), guselkumab (Tremfya), risankizumab on-body injector (Skyrizi OBI), mirikizumab (Omvoh), vedolizumab (Entyvio), and infliximab (Zymfentra): Updates for Inflammatory Bowel Disease PA Criteria—Recent guideline updates for inflammatory bowel disease (IBD) prompted a review of the TIBs used for ulcerative colitis (UC) and Crohn's Disease (CD). Similar to existing guidelines for CD, the American Gastroenterological Association's (AGA) 2024 UC guidelines now recommend early biologic use and recommend against requiring monotherapy with non-biologic step-up therapy. Humira is listed as a lower efficacy medication for UC for both biologic therapy-naïve and biologic therapy-experienced patients. Intravenous (IV) infliximab (Remicade – available under the TRICARE Medical benefit) is listed as a highly effective medication for UC and for all special populations of CD.

Based on the AGA guideline update, the following changes were recommended for Stelara, Tremfya, Skyrizi OBI, and Omvoh: the non-biologic requirement for the UC indication was removed and a trial of IV infliximab is allowed in lieu of Humira for UC and CD. Additionally, the PA criteria for Omvoh were updated to allow for the new FDA indication for CD. The Entyvio and Zymfentra PAs were updated to add an automated specialist bypass for gastroenterologists, and to remove the requirements to try Humira or infliximab first. As with the other IBD agents, the requirement of non-biologic therapy for UC was removed.

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

The P&T Committee recommended (19 for, 0 opposed, 0 abstained and 0 absent) updated manual PA criteria for Trintellix, Vyvanse, Rinvoq, Cibinqo, Aqneursa, Vyndaqel, Vyndamax, Wainua, Braftovi, Restasis, Enbrel, Olumiant, Sotyktu, Xeljanz, Stelara, Tremfya, Skyrizi OBI, Omvoh, Entyvio, and Zymfentra in new users.

- Implementation for Aqneursa, Vyndaqel, Vyndamax, and Wainua will be effective the first Wednesday 2 weeks after signing of the minutes, along with the PA criteria implementation for the other drugs in their respective classes.
- Implementation for Enbrel, Sotyktu, Rinvoq, Cibinqo, Olumiant, Xeljanz, Stelara, Tremfya, Skyrizi OBI, Omvoh, Entyvio, and Zymfentra will be effective the first Wednesday 30 days after signing of the minutes.
- Implementation for Braftovi, Restasis, Vyvanse and Trintellix will be effective the first Wednesday 60 days after signing of the minutes.

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

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Trintellix, Vyvanse, Rinvoq, Cibinqo, Aqneursa, Vyndaqel, Vyndamax, Wainua, Braftovi, Restasis, Enbrel, Olumiant, Sotyktu, Xeljanz, Stelara, Tremfya, Skyrizi OBI, Omvoh, Entyvio, and Zymfentra, with the implementation effective at two weeks, 30-days or 60-days after signing of the minutes as outlined above.

UF BAP Comments

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

XIV. REMOVAL OF PAs—MIGRAINE AGENTS AND GASTROINTESTINAL-2 AGENTS, RETURN OF FROVA TO UF STATUS, AND IMPLEMENTATION PLAN

P&T Comments

A. Migraine Agents—frovatriptan (Frova, generics) and naratriptan (Amerge, generics)

Both frovatriptan (designated as NF) and naratriptan (designated as UF) require PA. They are available as generics, have relatively low utilization and cost, and a high PA

approval rate. The PAs for frovatriptan and naratriptan will be removed, and frovatriptan will move to UF status.

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) removing the PA criteria for frovatriptan and naratriptan, and moving frovatriptan from NF to UF status. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

B. Gastrointestinal-2 Agents: Chronic Idiopathic Constipation: Constipation-predominant Irritable Bowel Syndrome (CIC/IBS-C)—linaclotide (Linzess) and lubriprostone (Amitiza)

Currently, both Linzess and Amitiza are designated as UF requiring PA. They account for a high PA volume, and several commercial plans do not require a PA for these drugs. A review of the clinical and cost data supports removing the PAs for these two drugs.

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) removing the PA criteria for Linzess, and Amitiza. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

XV. REMOVAL OF PAs for MIGRAINE AGENTS AND GASTROINTESTIANL-2 AGENTS RETURN OF FROVATRIPTAN TO UF STATUS, AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended removing the PA criteria for frovatriptan, naratriptan, Linzess, and Amitiza. Additionally, frovatriptan will move from NF to UF status. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

UF BAP Comments

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

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
FROM THE MAY 2025 MEETING

INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL MEETING DAY #1 PM – refer to the posted Agenda for meetings dates and times at https://health.mil/About-MHS/Federal-Advisory-Committees/BAP

I. UNIFORM FORMULARY REVIEW PROCESS

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

II. TARGETED IMMUNOMODULATORY BIOLOGICS (TIBS): INTERLEUKIN (IL)-1, IL-6 AND CYTOTOXIC T-LYMPHOCYTE ASSOCIATED ANTIGEN-4 IMMUNOGLOBULIN (CTLA4-IG) SUBCLASSES

P&T Comments

A. Targeted Immunomodulatory Biologics (TIBs): Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—Relative Clinical Effectiveness Conclusion

Background—The Targeted Immunomodulatory Biologics (TIBs) class is comprised of several subclasses, including the tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab [Humira]), non-TNF inhibitors, and miscellaneous interleukin subclasses. The entire TIBs class was last reviewed at the August 2014 P&T Committee meeting and branded adalimumab (Humira) is currently step-preferred for most indications. Since the original review, 18 new drugs with multiple new mechanisms of action have entered the market. These newer agents have strong clinical evidence in specific disease states. Two subclasses were reviewed at the November 2024 meeting, the interleukin (IL)-17s, and the IL-23s.

Biosimilar entrants have now entered the market for the originator tocilizumab (Actemra) formulation and are on the horizon for abatacept (Orencia). The advent of biosimilars is expected to reshape treatment. Therefore, to address the growing complexity of the TIBs class, additional subclasses were created,

the Interleukin-1 inhibitors (IL-1), Interleukin-6 inhibitors (IL-6), and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig).

The drugs in the subclasses include the following:

- IL-1: anakinra (Kineret), rilonacept (Arcalyst)
- IL-6: tocilizumab (Actemra), tocilizumab-aazg (Tyenne, a biosimilar for Actemra), sarilumab (Kevzara), satralizumab (Enspryng)
- CTLA4-Ig: abatacept (Orencia)

Relative Clinical Effectiveness Conclusion—The clinical review focused on clinical practice guidelines, meta-analyses and systematic reviews, differences in FDA-labeling, use in pediatrics, and safety profiles. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

Interleukin-1 Agents

- **anakinra (Kineret)** is indicated for rheumatoid arthritis (RA), cryopyrin-associated periodic syndromes (CAPS), neonatal-onset multisystem inflammatory disease (NOMID), and deficiency of interleukin-1 receptor antagonist (DIRA). There is substantial supporting evidence for off-label utilization for systemic juvenile idiopathic arthritis (sJIA), Adult-Onset Still's Disease (AOSD), familial cold auto-inflammatory syndrome (FCAS), Muckle-Wells Syndrome (MWS), and recurrent pericarditis (RP). Despite carrying the FDA approval, anakinra is not recommended by contemporary guidelines for use in RA. Limitations include frequent dosing intervals, requiring daily injections.
- **rilonacept (Arcalyst)** is indicated for CAPS, DIRA, FCAS, MWS, and RP. Most indications are approved for patients aged 12 and older, with the exception of DIRA which is indicated for use in infants weighing 10 kilograms (kg) or more. Limitations include lack of approval for more common disease states, including RA or JIA.

Interleukin-6 Agents

- **tocilizumab (Actemra, and the biosimilar Tyenne)** is FDA indicated for RA, pJIA, sJIA, giant cell arteritis (GCA), and systemic sclerosis-associated interstitial lung disease (SSc-ILD), which are available as part of the TRICARE pharmacy benefit. Indications available as IV infusions under the medical benefit include treatment of cytokine release syndrome (CRS) and hospitalized patients with COVID-19 (C19). There is substantial off-label evidence for AOSD, neuromyelitis optica spectrum disorder (NMOSD), and polymyalgia rheumatica (PMR). Advantages include evidence to support use in young children, while limitations include multiple uses without formal FDA-approved labeling. Biosimilars are considered identical to the

reference product for efficacy and safety, based on the conclusions from the August 2024 DoD P&T Committee meeting minutes' "Process for Evaluating Biosimilars and Biologics" section.

- *Biosimilars:* There are currently three FDA-approved biosimilars to the reference tocilizumab (Actemra). These include Tofidence, Tyenne, and Avtozma. Tofidence infusion is available under the TRICARE medical benefit. Tyenne has both a subcutaneous (SC) injection (available under the TRICARE pharmacy benefit) and a vial for infusion (available under the TRICARE medical benefit.) Avtozma is FDA-approved but had not launched at the time of the meeting and was not reviewed for formulary status. *(Refer to the November 2022 and August 2024 DoD P&T Committee meeting minutes for the "Process for Evaluating Biosimilars and Biologics").*

- **sarilumab (Kevzara)** is indicated for RA, pJIA in patients two years of age or older and weighing at least 63 kg and is the only FDA-approved therapy for PMR.
- **satralizumab (Enspryng)** is indicated for treatment of neuromyelitis optica spectrum disorder in adult patients who are aquaporin-4 immunoglobulin G (AQP4-IgG) positive. Advantages include that it is the only FDA-approved outpatient medication for this indication. Disadvantages include approval for adults only and lack of approval or data in AQP4-IgG negative disease.

Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin Agents

- **abatacept (Orencia)** is indicated for RA, pJIA, and psoriatic arthritis (PsA) under the pharmacy benefit and under the medical benefit as an IV infusion for graft versus host disease (GVHD). Advantages include approval for use in pediatrics as young as two years old as well as the risk of causing less immunosuppression than the other TIBs. Disadvantages include a relatively lower level of efficacy per rheumatoid arthritis and psoriatic arthritis guidelines. Orencia additionally carries risk for unique side effects including cytomegalovirus (CMV) and Epstein-Barr virus (EBV), which was primarily seen in the studies for GVHD.
    - *Biosimilars:* Based on patent expiration, abatacept (Orencia) will likely have the next biosimilar within this subclass.

Rheumatoid Arthritis (IL-1s, IL-6s, and CTLA4-Ig)

- After failure of a TNF inhibitor, use of the tocilizumab and sarilumab (Kevzara) are equally recommended in professional treatment guidelines. Abatacept (Orencia) is also recommended after failure of other agents or in patients at very high risk of infections.

- Although anakinra (Kineret) is FDA-approved for rheumatoid arthritis, it is not mentioned or recommended in the RA guidelines from the United States, Europe or France.

Polyarticular Juvenile Idiopathic Arthritis (IL-6, CTLA4-Ig)

- American College of Rheumatology (ACR) guidelines recommend non-biologics including non-steroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, and methotrexate as first-line therapy. A biologic can be considered after failure of a non-biologic disease modifying antirheumatic drug (DMARD). These guidelines indicate a TNF inhibitor is the most commonly used biologic in children, and that all agents approved at the time of publication were equally recommended, including both tocilizumab and Orencia.

Systemic Juvenile Idiopathic Arthritis, Adult-Onset Still's Disease (IL-1, IL-6)

- Literature within the space of systemic juvenile idiopathic arthritis (sJIA) and Adult-Onset Still's Disease (AOSD) is rapidly evolving. Newly published joint guidelines from Europe have combined these two, previously considered distinct, disease states into one disease called Still's Disease. These new guidelines recommend for patients without macrophage activation syndrome (MAS) early treatment with either anakinra (Kineret) or tocilizumab is clinically appropriate. For patients with MAS, the European guidelines indicate treatment with an IL-1 is preferred due to the amount of clinical experience by the guideline committee, specifically in those patients aged 16 years or older.
- Tocilizumab is FDA-approved for treating sJIA, while anakinra (Kineret) is approved by the European Medicines Agency (EMA) for treating Adult-Onset Still's Disease. Based on the published literature and guidelines, it is unclear whether therapy with anakinra or tocilizumab is more safe or efficacious than the other at this time.

Psoriatic Arthritis (CTLA4-Ig)

- Various guidelines for psoriatic arthritis recommend TNF-inhibitors, IL-23 inhibitors (e.g., Tremfya, Skyrizi) and IL-17 inhibitors (e.g., Taltz) as first-line. Contemporary guidelines list abatacept (Orencia) as an option only after failure of one or more other targeted therapies due to limited efficacy.

Neuromyelitis optica spectrum disorder (IL-6)

- Satralizumab (Enspryng) is the only FDA-approved pharmacy benefit drug approved for treating adult patients with AQP4-IgG positive NMOSD. Additionally, tocilizumab has substantial evidence for efficacy and safety in treating AQP4-IgG positive and negative NMOSD, despite lack of formal FDA-approval.

- A systematic review from 2021 concluded that both tocilizumab and satralizumab (Enspryng) were effective at decreasing the annualized relapse rate in NMOSD. Additionally, tocilizumab, but not Enspryng, significantly improved both pain and fatigue compared to placebo. Adverse events were similar between the two agents.

Polymyalgia Rheumatica (IL-6)

- Guidelines for polymyalgia rheumatica (PMR) are outdated. The British Society of Rheumatology is currently working on an update with an anticipated 2025 release. The scoping document states both tocilizumab and sarilumab (Kevzara) have data in new-onset and refractory PMR. Sarilumab (Kevzara) is the only FDA-approved biologic pharmacy benefit drug for treating patients with PMR.
- Tocilizumab is FDA-approved for treating giant cell arteritis (GCA), which is a condition closely related to PMR.

Recurrent Pericarditis (IL-1)

- Rilonacept (Arcalyst) is the only FDA-approved biologic pharmacy benefit item indicated to treat patients older than 12 with recurrent pericarditis. The 2015 guidelines from the European Society of Cardiology (ESC) recommend the standard of care including NSAIDs, colchicine, and corticosteroids. The ESC guidelines also recommend anakinra (Kineret) as a category IIB level of evidence. It is unknown when the guidelines will be updated to include Arcalyst.
- One published study from the Journal of the American Heart Association 2021 continues to recommend either anakinra (Kineret) or rilonacept (Arcalyst) for the treatment of colchicine-refractory recurrent pericarditis, based on their demonstrated effectiveness in decreasing pericarditis recurrence and increasing time to recurrence.

Safety

- Published clinical practice guidelines do not make a distinction among individual IL-1, IL-6, or CTLA4-Ig agents in terms of safety, with the distinction of abatacept (Orencia) as potentially preferred if the patient has a history of non-tuberculosis mycobacterium infection.
- Noted adverse events for all the products include hypersensitivity risk, increased risk of infections including tuberculosis, injection site reactions, and warnings against concurrent use of live vaccines. IL-6 agents all carry the additional risk for hepatotoxicity and gastrointestinal perforation. Unique safety concerns were discussed with the individual product summaries.
- A review of the package inserts, guidelines, and other published literature of the adverse events with IL-1, IL-6, and CTLA4-Ig found the following:

- The most common adverse drug reactions across all therapies included injection site reactions, infections, nasopharyngitis or upper respiratory tract infection, and headaches.
- Overall, agents within this subclass appear well-tolerated with acceptable safety profiles.

Other Factors

- Special populations:
  - The agents are generally considered safe during the pregnancy planning phase but are discontinued once pregnancy is confirmed. There is no compelling evidence that one IL-1, IL-6, or CTLA4-Ig should be preferred over another during pregnancy. TNF inhibitors are also considered safe and effective in pregnancy.
  - All agents are approved for use in the pediatric patient population with the exception of satralizumab (Enspryng), based on FDA-labeling.
- Provider opinion:
  - Military Health System (MHS) rheumatologists voiced that a TNF inhibitor should remain first-line for RA and pJIA, while subsequent therapy with an IL-6, CTLA4-Ig, or a JAK inhibitor is appropriate based on patient characteristics. Pediatric providers are more likely to utilize tocilizumab for pJIA rather than sarilumab (Kevzara), due to the minimum weight requirement with Kevzara. Providers did note that SC administration of abatacept (Orencia) is less effective than other choices.
  - For the treatment of psoriatic arthritis, providers were in agreement that abatacept was less effective than drugs with other mechanisms of action. Providers were supportive of the requirement to utilize an IL-17 prior to use of a CTLA4-Ig for treatment of psoriatic arthritis.
  - For treatment of Still's Disease, encompassing both systemic JIA and AOSD, rheumatologists were highly supportive of increasing access to both the IL-1 anakinra (Kineret) and the IL-6 tocilizumab as first-line agents. The providers agreed that a step requirement was not appropriate due to the multitude of patient factors, including those currently stabilized on therapy.
  - Ophthalmologists and neuroimmunologists relayed opinions on using tocilizumab and satralizumab (Enspryng) for NMOSD and MOGAD. While feedback was mixed on the use of tocilizumab in adults, for the pediatric population

there was full support for utilizing tocilizumab as the preferred outpatient therapy for NMOSD as it is useful in both AQP4-Ig positive and negative disease, as well as MOGAD. Since Enspryng is the only FDA-approved agent for this condition, a step requirement was not recommended.

- MHS rheumatologists were supportive of increasing options for evidence-based treatment of polymyalgia rheumatica. At this time, only sarilumab (Kevzara) carries the FDA-approved labeling for this condition, however other agents, including tocilizumab are used off-label, therefore a step requirement was not recommended.
- For treatment of recurrent pericarditis, providers were in agreement with increasing access to multiple treatment options. Rilonacept (Arcalyst) is the only FDA-approved biologic treatment, however older guidelines and current treatment algorithms recommend therapy with either anakinra (Kineret) or rilonacept (Arcalyst). Due to off label utilization of anakinra, a step requirement was not recommended.

Overall Conclusion

- Based on FDA indication and published guidelines it is reasonable to continue to require a trial of Humira first for many rheumatologic diseases including rheumatoid arthritis and polyarticular juvenile idiopathic arthritis, consistent with the previous class review in 2014.
- Biosimilars are interchangeable to the reference product. Market launch of tocilizumab biosimilars in 2024 provides an opportunity for contracting initiatives with other Federal agencies via a Joint National Contract. Abatacept (Orencia) is the next biosimilar expected to enter the market.
- Within the subclass, when the agents are compared to one another, there are not compelling differences in efficacy and safety. Individual patients may show variability in response to different agents.
- Provider feedback overwhelmingly supported increasing accessibility to several agents, including optimizing PA pathways to allow off-label indications for which these medications are considered standard of care.
- For clinical coverage, at least one IL-1, IL-6, and CTLA4-Ig agent is needed on the formulary to cover each indication of RA, pJIA, and Still's Disease (sJIA, AOSD) to meet the needs of MHS beneficiaries. Additional options should be considered to provide more choices for providers based on individual patient characteristics.

B. TIBs: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—Relative Cost Effectiveness Conclusion

The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

Interleukin-1s, Interleukin-6s, Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin

- CMA results showed that the formulary placement of tocilizumab (Tyenne) as UF and step-preferred was cost-effective.
- BIA and sensitivity results showed cost avoidance by designating Tyenne as step-preferred and all the other IL-1s, IL-6s, and CTLA4-Ig as non-step-preferred.

C. TIBS: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—UF Recommendation

The P&T Committee recommended for the IL-1, IL-6s, and CTLA4-Igs (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF and step-preferred
  - IL-6: tocilizumab-aazg (Tyenne) *moves from UF non-step-preferred to UF step-preferred*
- UF and non-step-preferred
  - IL-1: anakinra (Kineret) *moves from NF non-step-preferred to UF non-step-preferred*
  - IL-6: sarilumab (Kevzara) *moves from NF non-step-preferred to UF non-step-preferred*
- NF and non-step-preferred
  - IL-6: tocilizumab (Actemra)
  - CTLA-4Ig: abatacept (Orencia)
  - IL-1: rilonacept (Arcalyst) *moves from UF no step to NF non-step-preferred*
  - IL-6: satralizumab (Enspryng) *moves from UF no step to NF (no step required)*
- Complete Exclusion: None
- Note, as part of this recommendation, a trial of adalimumab (Humira) and tocilizumab aazg (Tyenne) are required prior to use of the non-step-preferred IL-1, IL-6, CTLA4-Ig products in all new patients, depending on the clinical indication.

- Enspryng is not subject to the step therapy requirements for its indication of NMOSD.

D. TIBs: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig)—Manual PA Criteria

Existing PA criteria currently apply to all the drugs. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) updated manual and step therapy PA criteria for the IL-1, IL-6 and CTLA4-Ig products as outlined below.

- *General Changes*:
  - Updating the step therapy requirements as outlined in the formulary recommendation and adding new indications as necessary.
  - Streamlining the list of medications that should not be used concurrently by drug classes rather than individual agents (new medications, biosimilars).
- *IL-1s:* Current PA criteria for the IL-1s require a trial of Humira first for all overlapping indications. The recommended PA changes for the IL-1s include the following:
  - For Kineret, which is now the UF non-step-preferred IL-1, clarifying that a trial of Tyenne and Humira are both required for rheumatoid arthritis only, unless the patient has had an inadequate response, contraindication or adverse reaction to Humira and Tyenne. Neither Humira nor Tyenne will be required prior to Kineret for non-RA indications. The indications for recurrent pericarditis and chronic infantile neurological cutaneous and articular (CINCA) disease will be added.
  - For Arcalyst, a trial of Kineret is now required first for treatment of deficiency of interleukin receptor 1 antagonist (DIRA). Rheumatologists will also be able to prescribe Arcalyst for recurrent pericarditis, in addition to cardiologists. Kineret is not required prior to use of Arcalyst for recurrent pericarditis.
- *IL-6s*: For the IL-6 agents, currently Humira is required first for all overlapping indications. The recommended PA changes include the following:
  - For Tyenne, which is now UF step-preferred, an automated drug lookback for utilization of either Humira or Actemra will be added. New indications for Still's Disease, polymyalgia rheumatica (PMR), neuromyelitis optica spectrum disorder (NMOSD), and myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) were added to the PA form.
  - For Actemra, which is the NF non-step-preferred tocilizumab product, all new and current users will be required to move to Tyenne. The current automated Humira lookback will be removed. A trial of Tyenne will be required for all indications, and a trial of Humira will be required for

appropriate indications. All new and current users of Actemra and the other tocilizumab biosimilars (when they are marketed) will require a trial of Tyenne first.

- For Kevzara, which moves to UF non-step-preferred status, a trial of Tyenne will be added for the conditions of RA and pJIA; the Humira step requirement will remain.
- Enspryng will not be subject to step-therapy requirements as there are currently no overlapping FDA-approved indications with either Humira or Tyenne. Any future indications that may overlap with Humira or Tyenne will require step-therapy. Documentation will now be required to demonstrate aquaporin-4 immunoglobulin G (AQP4-IgG) positivity.

- *CTLA4-Igs*: For the CTLA4-Ig agents, currently Humira is required first for all indications. The recommended PA changes include the following:
  - Orencia will maintain the requirement for a trial of Humira first. A Tyenne step will be added for rheumatoid arthritis and pJIA. A trial of the IL-17 ixekizumab (Taltz) will be added for adult psoriatic arthritis. The automated drug lookback for Humira will be removed. The PA changes will apply to new users.
  - Biosimilars for the CTLA4-Ig Orencia are expected to launch in 2026. This will allow formulary addition of a cost effective abatacept product in a future review.

The Manual PA criteria are as follows.

1. abatacept (Orencia)

Updates from the May 2025 meeting are in bold and strikethrough.

Manual PA criteria apply to all new users of abatacept (Orencia).

~~Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND~~

Manual PA Criteria: ~~If automated criteria are not met,~~ Orencia is approved if all criteria are met:

- **Provider acknowledges the Department of Defense's preferred IL-1, IL-6, CTLA4-Ig is Tyenne. The patient must have tried Tyenne AND**
  - **The patient has had an inadequate response to Tyenne OR**
  - **The patient experienced an adverse reaction to Tyenne that is not expected to occur with the requested agent OR**
  - **The patient has a contraindication to Tyenne**

    - **A trial of Tyenne is not required for adult or pediatric psoriatic arthritis**
- **Humira is the Department of Defense's preferred targeted biologic agent.** The patient must have tried Humira AND:
    - The patient had an inadequate response to Humira OR
    - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
    - The patient has a contraindication to Humira
- **The patient must have tried Taltz AND:**
    - **The patient had an inadequate response to Taltz OR**
    - **The patient experienced an adverse reaction to Taltz that is not expected to occur with the requested agent OR**
    - **The patient has a contraindication to Taltz**
    - **A trial of Taltz is not required for adult or pediatric psoriatic arthritis**
- Coverage approved for patients 18 years of age or older with one of the following diagnoses/indications:
    - Moderate to severely active rheumatoid arthritis
    - Active psoriatic arthritis
- ~~Patient has had an inadequate response to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine], etc.)~~
- Coverage approved for patients 2 to 17 years of age with one of the following diagnoses/indications:
    - Moderately to severely active polyarticular juvenile idiopathic arthritis
    - Active psoriatic arthritis. Note that a trial of non-biologic systemic therapy and Humira is required
- ~~Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~
- ~~May not be used concomitantly with other TIBs agents~~
- **Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors, C5 inhibitors, or rituximab**

Non-FDA approved uses are not approved

Prior Authorization does not expire

2. anakinra (Kineret)

Updates from the May 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of anakinra (Kineret).

Manual PA Criteria: Kineret is approved if all criteria are met:

- **Provider acknowledges the Department of Defense requires a trial of Humira. The patient must have tried Humira AND**
  - **The patient has had an inadequate response to Humira OR**
  - **The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR**
  - **The patient has a contraindication to Humira**
- **Provider acknowledges the Department of Defense's preferred IL-1, IL-6, CTLA4-Ig is Tyenne. The patient must have tried Tyenne AND**
  - **The patient has had an inadequate response to Tyenne OR**
  - **The patient experienced an adverse reaction to Tyenne that is not expected to occur with the requested agent OR**
  - **The patient has a contraindication to Tyenne AND**
- Patient is 18 years of age or older with:
  - ~~Adult-Onset Still's Disease (AOSD) with active systemic features of moderate to high disease activity (Trial of Humira not required) OR~~
  - Moderate to severe active rheumatoid arthritis ~~AND~~
    - ~~Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications~~
    - ~~The patient has a contraindication to Humira (adalimumab), an inadequate response to Humira, OR an adverse reaction to Humira that is not expected to occur with the requested agent~~
    - ~~The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])~~
- **Patients 12 years of age or older with**
  - **Recurrent pericarditis**

- **Prescription has been written by or in consultation with a cardiologist or rheumatologist AND**
- **Patient has a contraindication to colchicine and at least ONE of the following drug classes**
  - **aspirin**
  - **NSAIDs OR**
- **Patient has tried and failed a treatment course of at least 6 months with colchicine and at least ONE of the following drug classes**
  - **aspirin**
  - **NSAIDs**
  - **corticosteroids**

- ~~Pediatrics~~ **Patients** (all ages) with:
  - Neonatal-Onset Multisystem Inflammatory Disease (NOMID) ~~a subset of cryopyrin associated periodic syndrome (Trial of Humira not required)~~
  - **Chronic Infantile Neurological Cutaneous and Articular (CINCA) disease**
  - **Cryopyrin-Associated Periodic Syndrome (CAPS)**. ~~(Trial of Humira not required)~~
  - Systemic Juvenile Idiopathic Arthritis (sJIA) ~~(Trial of Humira not required).~~
  - ~~Adult-Onset~~ Still's Disease with active systemic features of moderate to high disease activity
  - Deficiency of Interleukin-1 Receptor Antagonist (DIRA~~) (Trial of Humira not required).~~
- Coverage is NOT provided for concomitant use with other TIBs including, but not limited to the following: ~~adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab-rzaa (Skyrizi), or upadacitinib (Rinvoq ER)~~ **TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors**

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

Prior authorization does not expire

3. rilonacept (Arcalyst)

Updates from the May 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of rilonacept (Arcalyst)

Manual PA Criteria: Arcalyst is approved if all criteria are met:

- Patient **is 12 years of age or older with** one of the following diagnoses:
  - Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS)
    - ~~Patient is 12 years of age of older~~
  - Recurrent pericarditis
    - ~~Patient is 12 years of age of older~~
    - Prescription is **written by or in consultation with a cardiologist or rheumatologist**
    - Patient has a contraindication to colchicine and at least ONE of the following drug classes: aspirin, NSAIDs OR
    - Patient has tried and failed a treatment course of at least 6 months with colchicine and at least ONE of the following drug classes: aspirin, NSAIDs, corticosteroids
- **Patients of all ages with**
  - Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
    - The patient weighs at least 10 kg (22 pounds)
    - **Patient has had an inadequate response to anakinra OR**
    - **Patient has experienced an adverse reaction to anakinra that is not expected to occur with the requested agent OR**
    - **Patient has a contraindication to anakinra**
- ~~The patient is not concurrently receiving a TNF-inhibitor (e.g., Humira, Enbrel, Cimzia, and Simponi) due to the increased risk of serious infections.~~
- **Coverage is not provided for concomitant use with other TIBs including, but not limited to: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors**

Non-FDA approved uses are not approved, including rheumatoid arthritis, neonatal-onset multisystemic inflammatory disease (NOMID), cardiovascular disease other than pericarditis (MI, acute coronary

syndrome, atherosclerosis, heart failure, and Kawasaki disease), and gout.

Prior authorization does not expire

4. sarilumab (Kevzara)

Updates from the May 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Kevzara

Manual PA Criteria: Kevzara is approved if all criteria are met:

- Kevzara is prescribed by or in consultation with a rheumatologist
- Provider acknowledges ~~Humira~~ **Tyenne** is the Department of Defense's preferred ~~targeted biologic agent~~ **IL-1, IL-6, CTLA4-Ig agent.** The patient must have tried Humira AND:
  - The patient had an inadequate response to ~~Humira~~ **Tyenne** OR
  - The patient experienced an adverse reaction to ~~Humira~~ **Tyenne** that is not expected to occur with the requested agent OR
  - The patient has a contraindication to ~~Humira~~ **Tyenne**
  - **Note that a trial of Tyenne is not required for Polymyalgia Rheumatica**
- The patient requires a trial of Humira.
  - The patient has had an inadequate response to Humira OR
  - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
  - The patient has a contraindication to Humira
  - **Note that a trial of Humira is not required for Polymyalgia Rheumatica**
- Patient has a diagnosis of:
  - Moderately to severely active rheumatoid arthritis OR ~~AND~~
    - ~~Had inadequate response or intolerance to one or more disease-modifying antirheumatic drug (DMARD)~~
  - Active polyarticular juvenile idiopathic arthritis (pJIA) and weighs 63 kg or more OR ~~AND~~
    - ~~Had inadequate response or intolerance to one or more disease-modifying antirheumatic drug (DMARD)~~
  - Polymyalgia Rheumatica (PMR) (Trial of **Tyenne and** Humira is not required) AND
    - Patient has tried and/or failed ONE systemic corticosteroid; OR

- The patient is not a candidate for corticosteroid therapy

- ~~Patient will not be receiving other targeted immunomodulatory biologics with Kevzara, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kineret, Olumiant, Orencia, Otezla, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, Xeljanz or Xeljanz XR~~
- **Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors**

Non-FDA approved uses are not approved

~~PA for non-PMR indications approved indefinitely.~~

PA does not expire for indications other than Polymyalgia Rheumatica

For Polymyalgia Rheumatica, PA expires after 12 months.

- **Renewal Criteria: (initial TRICARE PA approval is required for renewal). Coverage will be approved indefinitely for continuation of therapy if the following criteria are met:**
  - **The patient has had a positive response to therapy**

5. satralizumab (Enspryng)

Updates from May 2025 are in bold and ~~strikethrough~~

Manual PA is required for all new users of Enspryng.

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

- The patient is 18 years of age or older
- The drug is prescribed by or in consultation with a neurologist
- The patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
- **Provider acknowledges the Department of Defense's preferred IL-1, IL-6, CTLA4-Ig product is tocilizumab-aazg (Tyenne). Tyenne is available for the treatment of aquaporin-4 (AQP4) seropositive or seronegative NMOSD**
- Patient has aquaporin-4 (AQP4) antibody positive NMOSD; documentation must be submitted
- Patient has clinical evidence of at least 2 documented relapses (including first attack) in the last 2 years prior to screening, at least one of which has occurred in the 12 months prior to screening

- ~~Patient has laboratory evidence of HBV negative and TB negative~~
- ~~Patient and provider are enrolled in the REMS program~~
- **Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors, C5 inhibitors, or rituximab**

Non-FDA approved uses are not approved

PA does not expire

6. tocilizumab-aazg (Tyenne)

Updates from the May 2025 meeting are in bold and strikethrough

<u>Automated PA Criteria</u>: The patient has filled a prescription for adalimumab (Humira) or tocilizumab (Actemra) at any MHS pharmacy point of service (MTFs, retail pharmacies, or mail order) during the previous 180 days. AND

Manual PA criteria apply to all new users of tocilizumab-aazg (Tyenne), **if automated criteria are not met**

<u>Manual PA criteria</u>: If automated criteria are not met, coverage is approved if all criteria are met:

- Provider acknowledges the Department of Defense's preferred targeted immune biologic is Humira. The patient must have tried Humira AND
  - The patient has had an inadequate response to Humira OR
  - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
  - The patient has a contraindication to Humira AND
- Patient has moderate to severely active RA ~~then has patient has inadequate response to at least 1 or more DMARDs~~ OR
- Patient has active polyarticular Juvenile Idiopathic Arthritis (pJIA) OR
- Patient has a diagnosis for which adalimumab is not approved including
  - Giant cell arteritis **(GCA)**
  - Systemic sclerosis-associated lung disease **(SSc-ILD)**
  - Systemic Juvenile Idiopathic Arthritis (sJIA)
  - **Still's Disease with active systemic features of moderate- to high- disease activity**

- **Polymyalgia Rheumatica (PMR) AND**
  - **Patient has tried and failed ONE systemic corticosteroid OR**
  - **Patient is not a candidate for corticosteroid therapy**
- **Neuromyelitis Optica Spectrum Disorder (NMOSD), aquaporin-4 (AQP4) seropositive or seronegative**
- **Myelin oligodendrocyte glycoprotein antibody associated disease (MOGAD**)
- ~~If "other" diagnosis, please provide appropriate literature-based support documentation for the indication and utilization~~

- Patient is not receiving other targeted immunomodulatory biologics with Tyenne

Non-FDA approved uses are not approved, **except as noted above**

PA does not expire

7. tocilizumab (Actemra)

Updates from the May 2025 meeting are in bold and strikethrough.

Manual PA criteria apply to all new **and current** users of tocilizumab (Actemra)

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

- Provider acknowledges the Department of Defense~~'s preferred targeted immune biologic is~~ **requires a trial of** Humira. The patient must have tried Humira AND
  - The patient has had an inadequate response to Humira OR
  - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
  - The patient has a contraindication to Humira AND
- Provider acknowledges the Department of Defense's preferred ~~tocilizumab~~ **IL-1, IL-6, CTLA4-Ig product** is Tyenne. The patient must have tried Tyenne AND
  - The patient has had an inadequate response to Tyenne OR
  - The patient experienced an adverse reaction to Tyenne that is not expected to occur with the requested agent OR
  - The patient has a contraindication to Tyenne AND
- Patient has tried Humira **and has a diagnosis of**
  - Moderate to severely active RA ~~then has patient has inadequate response to at least 1 or more DMARDs for example:~~

~~methotrexate, aminosalicylates [for example, sulfasalazine, mesalamine], corticosteroids, immunosuppressants [for example, azathioprine)~~

- Active polyarticular Juvenile Idiopathic Arthritis (pJIA)

- ~~•~~ Patient has not tried Humira and has a diagnosis for which adalimumab is not approved:~~ AND is greater than 18 years of age:~~
  - Giant cell arteritis
  - Systemic sclerosis-associated lung disease
  - Systemic Juvenile Idiopathic Arthritis (sJIA)
  - ~~If "other" diagnosis, please provide appropriate literature-based support documentation for the indication and utilization~~
- Patient is not receiving other targeted immunomodulatory biologics with ~~tocilizumab~~ the requested agent, included but not limited to the following: **TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors, rituximab**

Non-FDA approved uses are not approved~~, except as noted above~~

PA does not expire

E. TIBS: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—UF, PA and Implementation Plan

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following 1) an effective date of the first Wednesday 90 days after signing of the minutes, and 2) that DHA will send letters to beneficiaries receiving Enspryng and Arcalyst who will be affected by the formulary status change and to beneficiaries receiving Actemra due to the PA changes affecting both new and current users.

III. UF DRUG CLASS REVIEW—TIBS: INTERLEUKIN (IL)-1, IL-6 AND CYTOTOXIC T-LYMPHOCYTE ASSOCIATED ANTIGEN-4 IMMUNOGLOBULIN (CTLA4-IG) SUBCLASSES

UF BAP Comments

A. TIBS: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—UF Recommendation

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

- UF and step-preferred
  - IL-6: tocilizumab aazg (Tyenne) *moves from UF non-step-preferred to UF step-preferred*

- UF and non-step-preferred
  - IL-1: anakinra (Kineret) *moves from NF to UF non-step-preferred*
  - IL-6: sarilumab (Kevzara) *moves from NF to UF non-step-preferred*
- NF and non-step-preferred
  - IL-6: tocilizumab (Actemra)
  - CTLA-4Ig: abatacept (Orencia)
  - IL-1: rilonacept (Arcalyst) *moves from UF to NF non-step-preferred*
  - IL-6: satralizumab (Enspryng) *moves from UF to NF (no step required)*
- Complete Exclusion: None
- Note, as part of this recommendation a trial of adalimumab (Humira) and tocilizumab aazg (Tyenne) are required prior to use of the non-step-preferred IL-1, IL-6, CTLA4-Ig products in all new patients, depending on the clinical indications.

UF BAP Comments

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

B. TIBS: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—Manual PA Criteria

The P&T Committee recommended PA criteria in new users of Tyenne, Kineret, Arcalyst, Kevzara, Enspryng and Orencia, and in new and current users of Actemra as outlined above.

UF BAP Comments

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

C. TIBS: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—UF Recommendation, PA Criteria, and Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday 90 days after signing of the minutes in all points of service and that DHA will send letters to beneficiaries receiving Enspryng and Arcalyst who will be affected by the formulary status change and to beneficiaries receiving Actemra due to the PA changes affecting both new and current users.

UF BAP Comments

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

IV. UF DRUG CLASS REVIEW—BREAST CANCER AGENTS: CYCLIN-DEPENDENT KINASE (CDK) INHIBITORS SUBCLASS

P&T Comments

A. Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors—Subclass Relative Clinical Effectiveness Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the CDK inhibitor subclass used for advanced or metastatic hormone receptor-positive (HR(+)), human epidermal growth factor receptor 2-negative (HER2(-)) breast cancer. The drugs in the class include abemaciclib (Verzenio), palbociclib (Ibrance), and ribociclib (Kisqali). The drugs were last reviewed for formulary status in February 2021. Updates to clinical practice guidelines and FDA-approved indications were reviewed.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 1 abstained, 0 absent) the following:

Efficacy

- A comprehensive review of the evidence shows that each CDK inhibitor offers a statistically and clinically significant advantage in median progression free survival and objective response rate (ORR) relative to the respective controls used in the individual clinical trials.
- Abemaciclib (Verzenio) and ribociclib (Kisqali) both provide a statistically and clinically significant advantage in invasive disease-free survival (iDFS), relative to the respective controls used in the individual clinical trials for early breast cancer treatment. This is a new indication for both agents that was not present in the prior class review.
- There are no high-quality head-to-head trials available directly comparing one CDK inhibitor with another.

Professional Treatment Guidelines

- The National Comprehensive Cancer Network (NCCN) and European Society for Medical Oncology (ESMO) guidelines recommend abemaciclib (Verzenio), palbociclib (Ibrance), and ribociclib (Kisqali) in the treatment of advanced or metastatic HR(+)/HER2(-) breast cancer as preferred first-line, second-line, or subsequent therapy. In the NCCN Guidelines, all agents carry a Category 1 recommendation in specific settings.
- Abemaciclib (Verzenio) and ribociclib (Kisqali) are now also recommended in the setting of early breast cancer. Both agents carry the same level of recommendations in this setting by the NCCN and ESMO Guidelines.
- Other guidelines (e.g., American Society of Clinical Oncology, European Society for Medical Oncology) are in agreement with one another and make no distinction in the choice of a particular agent. Each CDK inhibitor has the same preference and strength of recommendation.

Safety

- There is no one clearly superior CDK inhibitor in terms of safety or tolerability.
- The safety profiles of the CDK inhibitors overlap, however, there are unique adverse events associated with each agent. Hematologic adverse events (e.g., neutropenia, anemia, and thrombocytopenia) are considered class effects.
    - Palbociclib (Ibrance) has the highest rate of thrombocytopenia.
    - Abemaciclib (Verzenio) has a higher relative risk for diarrhea and unique warnings for venous thromboembolism (VTE).
    - Ribociclib (Kisqali) has a higher relative risk for QT interval prolongation.

Overall Clinical Conclusion

- Treatment choice in HR(+)/HER2(-) advanced or metastatic breast cancer depends on several factors, including the safety profile of the individual CDK inhibitor, comorbidities, and disease burden.

B. Breast Cancer Agents: CDK Inhibitors Subclass—Relative Cost Effectiveness Analysis and Conclusion

CMA and BIA were performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that ribociclib, abemaciclib and palbociclib were all cost-effective.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating all CDK inhibitors as UF demonstrated significant cost avoidance for the MHS.

C. Breast Cancer Agents: CDK Inhibitors Subclass—UF Recommendation

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

- UF
  - abemaciclib (Verzenio)
  - palbociclib (Ibrance)
  - ribociclib (Kisqali)
- NF – none
- Complete Exclusion – none

D. Breast Cancer Agents: CDK Inhibitors Subclass—Manual PA Criteria

Manual PA currently apply to all three CDK inhibitors. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) streamlining the criteria by removing questions on detailed indication criteria, removing the safety and monitoring questions, and standardizing the verbiage for updates to NCCN criteria, consistent with the actions taken for other oncology drug PA criteria.

The Manual PA criteria are as follows.

1. abemaciclib (Verzenio)

Updates from the May 2025 meeting are in bold and strikethrough.

Manual PA criteria apply to all new users of Verzenio.

Manual PA Criteria: Verzenio is approved if all of the following criteria are met:

- Drug is prescribed by or in consultation with an oncologist
- ~~The patient is not currently taking another cyclin-dependent kinase inhibitor~~
- ~~For Verzenio only, the patient has hormone receptor~~ ~~HR(+)/HER2(-), node(+) early~~ breast cancer ~~at high risk of recurrence as determined by an FDA-approved test.~~
- The patient has advanced or metastatic ~~hormone receptor~~ (HR(+))/(HER2(-)) breast cancer

- ~~If the patient is female, the patient meets one of the following criteria:~~
  - ~~Verzenio will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR~~
  - ~~Verzenio will be as first-line or later-line endocrine therapy in combination with fulvestrant; OR~~
  - ~~Verzenio will be used as monotherapy following metastatic progression on chemotherapy~~
- ~~If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation.~~
- ~~Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease~~
- ~~Provider is aware and has informed the patient of the risk of venous thromboembolism, diarrhea, and hepatotoxicity~~
- ~~Female patients of childbearing age are not pregnant confirmed by (-) HCG~~
- ~~Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment~~
- ~~Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only~~
- ~~Male patients have been informed of the risk of infertility~~
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, the provider must list the diagnosis:_____.~~ **To facilitate approval please list the diagnosis, guidelines version and page number**.

  _____

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

Prior authorization does not expire

2. palbociclib (Ibrance)

Updates from the May 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Ibrance

Manual PA Criteria: Ibrance is approved if all of the following criteria are met:

- Drug is prescribed by or in consultation with an oncologist
- ~~The patient is not currently taking another cyclin-dependent kinase inhibitor~~
- The patient has ~~advanced or metastatic~~ ~~hormone receptor~~ ~~(~~HR(+)~~)~~/HER2(-) breast cancer
- ~~If the patient is female, the patient meets one of the following criteria:~~
  - ~~Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR~~
  - ~~Ibrance will be as first-line or later-line endocrine therapy in combination with fulvestrant~~
- ~~If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation.~~
- ~~Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease~~
- ~~For Ibrance only: provider is aware and has informed the patient of the risk of pulmonary embolism~~
- ~~Female patients of childbearing age are not pregnant confirmed by (-) HCG~~
- ~~Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment~~
- ~~Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only~~
- ~~Male patients have been informed of the risk of infertility~~
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, the provider must list the diagnosis:_____.~~ **To facilitate approval please list the diagnosis, guidelines version and page number**_____.

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

Prior authorization does not expire

~~3.~~ **ribociclib (Kisqali)**

Updates from the May 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Kisqali

Manual PA Criteria: Kisqali is approved if all of the following criteria are met:

- Drug is prescribed by or in consultation with an oncologist
- ~~The patient is not currently taking another cyclin-dependent kinase inhibitor~~
- The patient has ~~advanced or metastatic hormone receptor (~~HR(+)~~)~~HER2(-) breast cancer
- ~~If the patient is female, the patient meets one of the following criteria:~~
- ~~Kisqali will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR~~
- ~~Kisqali will be as first-line or later-line endocrine therapy in combination with fulvestrant; OR~~
- ~~If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation.~~
- ~~Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease~~
- ~~For Kisqali: provider is aware and has informed the patient of the risk of QT prolongation and hepatobiliary toxicity~~
- ~~Female patients of childbearing age are not pregnant confirmed by (-) HCG~~
- ~~Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment~~
- ~~Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only~~
- ~~Male patients have been informed of the risk of infertility~~
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, the provider must list the~~

~~diagnosis:_____~~. **To facilitate approval please list the diagnosis, guidelines version and page number_____.**

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

Prior authorization does not expire

E. Breast Cancer Agents: CDK Inhibitors Subclass—UF Recommendation, PA Criteria, and Implementation Period

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service.

V. UF DRUG CLASS REVIEW—BREAST CANCER AGENTS: CYCLIN-DEPENDENT KINASE (CDK) INHIBITORS SUBCLASS

UF BAP Comments

A. Breast Cancer Agents: CDK Inhibitors Subclass—UF Recommendation

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

- UF
  - abemaciclib (Verzenio)
  - palbociclib (Ibrance)
  - ribociclib (Kisqali)
- NF – None
- Complete Exclusion – None

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Breast Cancer Agents: CDK Inhibitors Subclass—Manual PA Criteria

The P&T Committee recommended streamlining the Manual PA Criteria as detailed above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Breast Cancer Agents: CDK Inhibitors Subclass—UF Recommendation, PA Criteria, and Implementation Period

The P&T Committee recommended an effective date the first Wednesday 60 days after signing of the minutes in all points of service.

UF 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

The products were divided into two groups when presented at the DoD P&T Committee meeting. The generic names are included below. Group 1 included Zunveyl, Alhemo, Inzirqo, Xromi, Prevymis, Gomekli, Raldesy, and five ustekinumab biosimilars (Steqeyma, Otulfi, Pyzchiva, Yesintek, and Selarsdi). Group 2 included Journavx, Vykat extended release (XR) and Romvimza.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 16 for, 0 opposed, 1 abstained, and 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5).

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

The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
  - concizumab-mtci (Alhemo) – Antihemophilic Agents
  - diazoxide choline (Vykat XR) – Miscellaneous Metabolic Agent for hyperphagia in Prader-Willi Syndrome
  - hydroxyurea 100 mg/mL oral solution (Xromi) – Oncological Agent for Sickle Cell Anemia
  - letermovir extended release (ER) pellets (Prevymis) – Antiviral for cytomegalovirus (CMV) infection
  - mirdametinib (Gomekli) – Oncological Agent for neurofibromatosis
  - suzetrigine (Journavx) – Pain Agents

        - ustekinumab-auuz (Otulfi) – Targeted Immunomodulatory Biologics (TIBs): Interleukin-23 (IL-23) inhibitors; biosimilar for Stelara
        - ustekinumab-stab (Steqeyma) – TIBs IL-23s; biosimilar for Stelara
        - vimseltinib (Romvimza) – Oncological Agent for tenosynovial giant cell tumor
    - NF
        - hydrochlorothiazide 10 mg/mL powder for oral suspension (Inzirqo) – Diuretic Agents
        - trazodone 10 mg/mL oral solution (Raldesy) – Antidepressants and Non-Opioid Pain Syndrome Agents: Serotonin Antagonist and Reuptake Inhibitor
        - ustekinumab-ttwe (Pyzchiva) – TIBs IL-23s; biosimilar for Stelara
        - ustekinumab-kfce (Yesintek) – TIBs IL-23s; biosimilar for Stelara
        - ustekinumab-aekn (Selarsdi) – TIBs IL-23s; biosimilar for Stelara
    - Completely Excluded:
        - benzgalantamine (Zunveyl) – Alzheimer's Agents
            - Zunveyl was recommended for complete exclusion status as it has little to no clinical benefit relative to the other Alzheimer's Agents, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include galantamine, galantamine ER and donepezil.

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

The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 for, 0 opposed, 0 abstained, 1 absent) the following PA criteria:

- Applying manual PA criteria to new users of the UF ustekinumab products Otulfi and Steqeyma, similar to what is required for all non-step-preferred Interleukin-23 inhibitors, where a trial of adalimumab (Humira) will be required first. These products are non-step-preferred.
    - For the NF ustekinumab products Pyzchiva, Yesintek, and Selarsdi, the PA will also apply to new users and require a trial of Humira, plus a trial of all the UF ustekinumab products. These products are non-step-preferred.
- Applying manual PA criteria to new users of Alhemo, similar to the PA requirements for other hemophilia agents.
- Applying temporary manual PA criteria to new users of Zunveyl, until implementation of complete exclusion status.

- Applying manual PA criteria to new users of Vykat XR, Xromi, Gomekli, Inzirqo, Raldesy, and Romvimza.

The Manual PA criteria are as follows:

1. **benzgalantamine (Zunveyl)**

   Manual PA criteria apply to all new users of Zunveyl

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

   - Provider acknowledges that Zunveyl will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the DoD P&T Committee meeting minutes by the Director, DHA
   - The patient is 18 years of age or older
   - The medication is being prescribed by a neurologist, psychiatrist, or specialist in geriatric medicine
   - The patient is being treated for mild or moderate dementia of the Alzheimer's type
   - Provider must document why the patient cannot use galantamine immediate release and galantamine extended release and donepezil products. (blank write-in)
     - Acceptable responses include the patient has had an adverse reaction t galantamine immediate release and galantamine extended-release products that are not likely to occur with benzgalantamine (Zunveyl) or
     - The patient has had an inadequate response, experienced an adverse effect, or has a contraindication to donepezil

   Non-FDA approved uses are not approved

   PA does not expire until implementation of Complete Exclusion status

2. **concizumab-mtci (Alhemo)**

   Manual PA criteria apply to all new users of Alhemo

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

   - Patient is 12 years of age or older
   - Prescribed by or in consultation with a hematologist
   - Patient has hemophilia A with factor VIII inhibitors or hemophilia B with factor IX inhibitors
   - Patient is not concurrently receiving factor VIII or factor IX therapy unless for the treatment of breakthrough bleeding

   Non-FDA approved uses are not approved

PA does not expire

3. diazoxide choline (Vykat XR)

Manual PA criteria apply to all new users of diazoxide choline (Vykat XR)

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

- Patient is 4 years of age or older
- Prescribed by a physician who specializes in the treatment of Prader-Willi Syndrome
- Patient has a diagnosis of Prader-Willi Syndrome confirmed by genetic testing
- Patient is being treated for hyperphagia
- Patient weighs between 20 kg and 135 kg

Non-FDA approved uses are not approved

Initial PA expires in 6 months

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

- The patient's hyperphagia has improved and stabilized to warrant continued therapy
- Medication continues to be prescribed by a physician who specializes in the treatment of Prader-Willi Syndrome

4. hydrochlorothiazide 10 mg/mL oral suspension (Inzirqo)

Manual PA criteria apply to all new users of hydrochlorothiazide suspension (Inzirqo) who are over 12 years of age

PA does not apply to patients 12 years of age and younger (age edit)

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

- Patient has hypertension or edema from congestive heart failure, hepatic cirrhosis, or renal disease
- Provider must write in why the patient requires Inzirqo and cannot take a loop diuretic and a thiazide diuretic in a tablet formulation
    - Acceptable responses: patient cannot swallow tablets due to some documented medical condition – dysphagia, etc., and not due to convenience

Non-FDA approved uses are not approved

PA does not expire

5. hydroxyurea 100 mg/mL oral solution (Xromi)

Manual PA criteria apply to all new users of hydroxyurea oral solution (Xromi) who are 18 years of age and older

PA does not apply to patients younger than 18 years of age (age edit)

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

- Patient has sickle cell anemia with recurrent moderate to severe painful crises
- Patient is not using Xromi for malignancy, including chronic myelocytic leukemia or other cancers
- The provider must explain why the patient cannot use the preferred products generic hydroxyurea or Siklos dispersed in water
    - Acceptable responses include the patient has swallowing difficulties, not just for convenience AND patient has sickle cell disease

Non-FDA approved uses are not approved

PA expires after 12 months

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

- Patient continues to have swallowing difficulties that preclude the use of hydroxyurea capsules AND Siklos tablets dispersed in water

6. mirdametinib (Gomekli)

Manual PA criteria apply to all new users of mirdametinib

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

- Patient is 2 years of age or older
- Prescribed by or in consultation with a hematologist or oncologist
- Patient has a diagnosis of neurofibromatosis type 1 (NF1) with symptomatic, inoperable plexiform neurofibromas
- Patient has tried and had an inadequate response, adverse effect, or has a contraindication to selumetinib (Koselugo)
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number _____.

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

PA does not expire

7. trazodone 10 mg/mL oral solution (Raldesy)

Manual PA criteria apply to all new users of trazodone oral solution (Raldesy)

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

- Patient has major depressive disorder (MDD)
- Provider must explain why the patient requires Raldesy and cannot take trazodone tablets
    - Acceptable responses include the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia) and not due to convenience

Non-FDA approved uses are not approved

PA does not expire

8. vimseltinib (Romvimza)

Manual PA criteria apply to all new users of vimseltinib (Romvimza)

Manual PA criteria:

Coverage is approved if all criteria are met:

- Patient is 18 years of age or older
- Prescribed by or in consultation with a hematologist or oncologist
- Patient has symptomatic tenosynovial giant cell tumor
- Tumor is not amenable to treatment with surgery
- Patient has tried and had an inadequate response to pexidartinib (Turalio) OR
- Patient has tried and had an adverse effect to pexidartinib (Turalio) OR
- Patient has a contraindication to use of pexidartinib (Turalio)
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number _____.

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

PA does not expire

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

The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the following:

- **New Drugs Recommended for UF and NF Status:** An effective date of the first Wednesday two weeks after signing of the minutes in all points of service.
- **New Drugs Recommended for Complete Exclusion Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in all points of service; and 2) DHA will send letters to beneficiaries who are affected by the complete exclusion status at 30 days and 60 days prior to implementation.

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

UF BAP Comments

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

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

- UF
  - concizumab-mtci (Alhemo) – Antihemophilic Agents
  - diazoxide choline (Vykat XR) – Miscellaneous Metabolic Agent for hyperphagia in Prader-Willi Syndrome
  - hydroxyurea 100 mg/mL oral solution (Xromi) – Oncological Agent for Sickle Cell Anemia
  - mirdametinib (Gomekli) – Oncological Agent for neurofibromatosis
  - letermovir extended release (ER) pellets (Prevymis) – Antiviral for cytomegalovirus (CMV) infection
  - suzetrigine (Journavx) – Pain Agents
  - vimseltinib (Romvimza) – Oncological Agent for tenosynovial giant cell tumor
- NF
  - hydrochlorothiazide 10 mg/mL powder for oral suspension (Inzirqo) – Diuretic Agents
  - trazodone 10 mg/mL oral solution (Raldesy) – Antidepressants And Non-Opioid Pain Syndrome Agents: Serotonin Antagonist and Reuptake Inhibitor
- Completely Excluded:

- benzgalantamine (Zunveyl) – Alzheimer's Agents

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

The P&T Committee recommended implementation periods as noted above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PLAN

P&T Comments

A. New Manual PA Criteria

1) **Anti infectives: Antihelmintics—mebendazole (Emverm)—**Emverm is indicated to treat a variety of parasitic worm infections. The price of Emverm has increased exponentially in recent years and some commercial health plans require a PA for Emverm. MTF providers support the addition of a PA restricting use to parasitic indications and requiring a step of over-the-counter (OTC) pyrantel pamoate, ivermectin, or albendazole. Off-label uses for indications other than parasitic infections will not be allowed.

The PA criteria are as follows:

mebendazole (Emverm)

Manual PA criteria apply to all new users of Emverm

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

- Patient has a diagnosis of pinworm (*Enterobius vermicularis)*, hookworm (*Ancylostoma duodenale* or *Necator americanus*), roundworm (*Ascaris lumbricoides*), or whipworm (Trichuris trichiura) OR
- Medication is prescribed by an infectious disease specialist for another parasitic infection AND
- For all indications, patient has a failure, contraindication, or intolerance to at least one of the following: OTC pyrantel pamoate, ivermectin, or albendazole

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

PA expires in one month. A new PA is required for each course of therapy

2.) **Miscellaneous Endocrine Agents: Antihyperglycemic-Glucocorticoid Receptor Blocker—mifepristone (Korlym)—**Korlym is indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Korlym is more costly than other alternatives used to treat Cushing's syndrome. A manual PA was recommended for Korlym to restrict use to its FDA-approved indication in new and current users, to require prescribing by an endocrinologist, and a trial of at least one other agent for Cushing's syndrome in new users. MTF providers supported establishment of PA criteria.

mifepristone (Korlym)

The PA criteria are as follows:

The following manual PA criteria apply to all new users of Korlym

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

- Patient is 18 years of age or older
- Prescription is written by an endocrinologist
- Patient has a diagnosis of endogenous Cushing's syndrome AND
- Patient has a diagnosis of type 2 diabetes mellitus or glucose intolerance AND
- Patient has failed surgery or is not a candidate for surgery
- Patient has tried and failed one of the following for the treatment of endogenous Cushing's syndrome: ketoconazole tablets, metyrapone capsules, mitotane, pasireotide, osilodrostat, or cabergoline

Non-FDA-approved uses are not approved including type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome

PA expires in 1 year

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

- Patient has had a positive clinical response while on Korlym

The following manual PA criteria apply to all **current** users of Korlym

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

- Patient has a diagnosis of endogenous Cushing's syndrome AND
- Patient has a diagnosis of type 2 diabetes mellitus or glucose intolerance AND
- Patient has failed surgery or is not a candidate for surgery

Non-FDA-approved uses are not approved including type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome.

PA expires in 1 year

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

- Patient has had a positive clinical response while on Korlym

3.) **Leukotriene Modifying Agents—zileuton (Zyflo), zileuton ER generic—**Zileuton is indicated to treat asthma and is less cost-effective than other agents in the class. Hepatic monitoring is required for zileuton due to liver function test elevations. A manual PA affecting new and current users was recommended requiring a trial of montelukast (generic Singulair) and zafirlukast (generic Accolate) first, due to safety concerns. Zyflo will be added to the Rapid Response/Safety Net program, which will provide additional outreach to beneficiaries who have not received a prescription after an initial PA reject.

zileuton (Zyflo), zileuton ER generic

The PA criteria are as follows:

Manual PA criteria apply to all new and current users

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

- Patient is being treated for asthma
- Patient is 12 years of age or older
- Patient has a contraindication to, intolerability to, or has failed treatment with both of the following:
  - montelukast AND
  - zafirlukast

Non-FDA-approved uses are not approved

PA expires in 1 year

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

- The patient has had a positive response to therapy, as defined by one of the following:
  - a decrease in asthma exacerbations
  - improvements in forced expiratory volume in one second (FEV1)
  - decrease in oral corticosteroid use

B. New Manual PA Criteria and Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Emverm in new users and for Korlym, and zileuton in new and current users. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients currently receiving Korlym, zileuton IR and zileuton ER.

IX. UTILIZATION MANAGEMENT— NEW MANUAL PA CRITERIA AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended manual PA criteria for Emverm, Korlym and zileuton, as outlined above. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients currently receiving Korlym, zileuton IR and zileuton ER.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

X. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN

P&T Comments

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

Manual PA criteria were recommended for two recently marketed drugs produced by a sole manufacturer which contain active ingredients that are widely available in low-cost generic formulations. 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. Numerous cost-effective formulary alternatives are available that do not require prior authorization.

Diabetes Non-Insulin: Biguanides—metformin 750 mg IR tablet—Numerous other more cost-effective generic metformin IR and ER tablets are available.

Narcotic Analgesics and Combinations—tramadol 100 mg immediate release (IR) tablet—There are other tramadol formulations available, including tramadol 50 mg tablets, that are more cost-effective than this 100 mg strength.

The Manual PA criteria are as follows:

1. **metformin 750 mg IR tablet**

   Manual PA criteria apply to all new and current users of metformin 750 mg IR tablet.

   Manual PA criteria: metformin 750 mg IR Tablet is approved if all criteria are met:

   - Provider acknowledges other formulations of metformin are available without prior authorization.
   - Provider must explain why the patient requires metformin 750 mg IR Tablet and cannot take the cost-effective generic metformin formulations
     - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available metformin formulations

   Non-FDA approved uses are not approved

   Prior authorization does not expire

2. **tramadol 100 mg immediate release (IR) tablet**

   Manual PA criteria apply to all new and current users of tramadol 100 mg tablets

   Manual PA criteria: tramadol 100 mg tablets are approved are approved if all criteria are met:

   - Provider is aware and acknowledges that tramadol 50 mg tablets are available to DoD beneficiaries without the need of prior authorization. Providers are encouraged to consider changing the prescription to the preferred tramadol 50 mg.
   - Provider must explain why the patient requires tramadol 100 mg tablets and cannot take the cost-effective generic tramadol 50 mg formulations (fill-in the blank)

- Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available tramadol 50 mg tablets

Non-FDA approved uses are not approved

Prior authorization does not expire

B. New PA Criteria for Drugs Not Subject to 32 CFR 199.21(G)(5) and Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for metformin 750 mg and tramadol 100 mg tablets in new and current users, due to the significant cost differences compared with other available alternative agents. The new PA will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients.

XI. UTILIZATION MANAGEMENT— NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended manual PA for metformin 750 mg IR tabs and tramadol 100 mg tablets as stated above; and an effective date the first Wednesday 60 days after signing of the minutes and DHA will send letters to the affected beneficiaries.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

A. Updated PA Criteria for New FDA Approved Indications

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users.

a) **Miscellaneous Metabolic Agents—setmelanotide (Imcivree**)—The manual PA criteria were expanded to include children two years of age and older with certain syndromic or monogenic forms of obesity.

b) **Miscellaneous Immunological Agents: Oral Agents—house dust mite allergen extract (Odactra)**—The manual PA criteria were expanded to include children ages 5 to 11 years of age.

c) **TIBs**: **IL-23 Inhibitor—guselkumab (Tremfya)—**Tremfya is now indicated for the treatment of Crohn's disease in adults. The manual PA criteria were updated to allow for this new indication with PA criteria mirroring the ulcerative colitis criteria for this drug.

d) **Leukemia and Lymphoma Agents: BTK Inhibitors—acalabrutinib (Calquence)—**The manual PA criteria were updated to allow for treatment of a subset of previously untreated mantel cell lymphoma patients

e) **Oncological Agents: Lung Cancer —sotorasib (Lumakras)—**Lumakras received a new indication for KRAS G12C-mutated metastatic colorectal cancer. The manual PA form was updated to include this indication and require coadministration with panitumumab in patients who have received prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy based on the FDA label. Additionally, edits were made to match the recent changes in other oncology PAs as part of the ongoing oncology standardization process.

f) **Diabetes Non-Insulin: Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RAs)—semaglutide (Ozempic)—**Semaglutide under the trade name Ozempic is now indicated to reduce the risk of sustained decline in estimated glomerular filtration rate (eGFR), end-stage kidney disease, and cardiovascular death in adults with chronic kidney disease and type 2 diabetes. Current treatment guidelines recommend a renin angiotensin system inhibitor (ACE inhibitor or angiotensin receptor blocker) and sodium-glucose co-transporter 2 (SGLT-2) inhibitor. The Ozempic PA criteria were updated to require use of the cost effective guideline-recommended therapies first.

B. Updated PA Criteria for New FDA Approved Indications Implementation Plan

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) implementation for the new PA criteria for Imcivree, Odactra, Tremfya, Calquence, Lumakras, and Ozempic in new users will be effective the first Wednesday 60 days after the signing of the minutes.

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

UF BAP Comments

Updated PA Criteria for New FDA Approved Indications and Implementation Plan

The P&T Committee recommended updates to the PA criteria due for Imcivree, Odactra, Tremfya, Calquence, Lumakras, and Ozempic in new users, due to FDA-approved indications and expanded age ranges. Implementation for the new PA criteria will be effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

A. Updated PA Criteria for Reasons other than New FDA Approved Indications

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria for several drugs. The updated PA criteria outlined below will apply to new users.

a) **Corticosteroids-Immune Modulators: Atopic Dermatitis—crisaborole (Eucrisa)—**An age edit was added allowing patients two years of age and younger to bypass the PA as other non-steroid treatments are only approved for children older than age two.

b) **Antigout Agents: Chronic—febuxostat (Uloric)**—An automated lookback for allopurinol 300 mg was added to the Uloric PA. Patients with a prescription claim for allopurinol in the past 180 days will bypass the Uloric PA. In addition, the safety questions were removed.

c) **Oncological Agents—fedratinib (Inrebic), selumetinib (Koselugo), pomalidomide (Pomalyst), ripretinib (Qinlock), midostaurin (Rydapt), capmatinib (Tabrecta), tepotinib (Tepmetko), pexidartinib (Turalio), quizartinib (Vanflyta), larotrectinib (Vitrakvi), dacomitinib (Vizimpro), and gilteritinib (Xospata)**— Updates were made as part of the continuing process for oncology PA standardization, to include removing monitoring and safety criteria, and standardizing wording for National Cancer Care Network (NCCN) guideline updates. For more details on oncology PA standardization, please refer to the November 2024 meeting minutes. Additionally, the PA for Pomalyst was updated to add the Kaposi Sarcoma indication.

d) **Metabolic Agents Miscellaneous—odevixibat (Bylvay) and maralixibat (Livmarli)**—Bylvay and Livmarli are FDA-approved to treat pruritus due to progressive familial intrahepatic cholestasis or Alagille syndrome. The drugs

treat the pruritic symptoms, but do not change the underlying disease course. Both drugs were reviewed as innovators and were designated as NF with a PA requiring a trial of five other generic, well-established agents first. Bylvay and Livmarli are not yet included in professional treatment guidelines. Based on a review of MHS prescription claims, the PA will expand the options to the six drugs included in the current treatment guidelines, but only require a trial of three products first, prior to Bylvay or Livmarli. Other updates included standardizing the new nomenclature for non-alcoholic fatty liver disease (NAFLD), now known as metabolic dysfunction-associated steatotic liver disease (MASLD).

e.) **Antipsychotic Agents: Parkinson's Psychosis—pimavanserin (Nuplazid)—** Nuplazid will now require a trial of clozapine first, unless the patient has a contraindication, intolerability to, or has failed treatment with clozapine. The reasons for the clozapine step are due to removal of the previous clozapine Risk Evaluation and Mitigation System (REMS) program, network meta-analysis data supporting its use before Nuplazid, and provider feedback supporting using Nuplazid as a later-line agent. Additionally, clozapine is more cost-effective than Nuplazid.

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

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Eucrisa, Uloric, Inrebic, Koselugo, Pomalyst, Qinlock, Rydapt, Tabrecta, Tepmetko, Turalio, Vanflyta, Vitrakvi, Vizimpro, Xospata, Bylvay, Livmarli, and Nuplazid in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

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

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Eucrisa, Uloric, Inrebic, Koselugo, Pomalyst, Qinlock, Rydapt, Tabrecta, Tepmetko, Turalio, Vanflyta, Vitrakvi, Vizimpro, Xospata, Bylvay, Livmarli, and Nuplazid in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

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

XVI. UTILIZATION MANAGEMENT—REMOVAL OF PAs and IMPLEMENTATION PERIOD

P&T Comments

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing the PA for two drugs, with implementation effective the first Wednesday 2 weeks after signing of the minutes.

a) **Multiple Sclerosis Agents: Methyl Fumarate—dimethyl fumarate (Tecfidera)—**Tecfidera is designated as UF. Generic formulations of Tecfidera are now available and dimethyl fumarate is the most cost-effective methyl fumarate agent. The Tecfidera PA will be removed for these reasons.

b) **Alzheimer's Agents—memantine ER (Namenda XR)—**Currently, memantine IR (Namenda) is designated as UF while memantine ER (Namenda XR) is designated as NF with a PA. Namenda XR is administered once daily and is available as a generic. Due to clinical and cost considerations, the PA will be removed for Namenda XR, but Namenda XR will remain as NF.

XVII. UTILIZATION MANAGEMENT—REMOVAL OF PAs and IMPLEMENTATION PERIOD

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Tecfidera and Namenda XR as outlined above, with implementation effective two weeks after signing of the minutes.

UF BAP Comments

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

XVIII. UTILIZATION MANAGEMENT—BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR SACUBITRIL/VALSARTAN (ENTRESTO)

P&T Comments

Renin-Angiotensin Antihypertensives: Combinations—Sacubitril/valsartan (Entresto) tablets are designated as UF without a PA. AB-rated generic versions have entered the market; however, these generic products are less cost-effective compared to the branded agent. Therefore, the branded Entresto tablets will continue to be dispensed at all three points of service, and the generics will only be available with prior authorization. The Tier 1 copay for brand Entresto is recommended.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) requiring brand Entresto tablets over the generics in new users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. The Tier 1 (generic) copayment will apply to brand Entresto tablets. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics

XIX. UTILIZATION MANAGEMENT—BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR SACUBITRIL/VALSARTAN (ENTRESTO)

UF BAP Comments

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

UF BAP Comments

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

XX. UTILIZATION MANAGEMENT—WEIGHT LOSS DRUGS PAs: COMPREHENSIVE LIFESTYLE INTERVENTION AND IMPLEMENTATION

P&T Comments

The current PA criteria for the weight loss drugs was reviewed. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) adding to the PA criteria that the patient has had verifiable participation in a comprehensive lifestyle intervention that targets all three aspects of weight management: diet, physical activity, and behavioral changes on both treatment initiation and annual renewal. Implementation will occur the first Wednesday 60 days after signing of the minutes in all three points of service.

XXI. UTILIZATION MANAGEMENT—WEIGHT LOSS DRUGS PAs: COMPREHENSIVE LIFESTYLE INTERVENTION AND IMPLEMENTATION

UF BAP Comments

The P&T Committee recommended adding to the PA criteria that the patient has had verifiable participation in a comprehensive lifestyle intervention that targets all three aspects of weight management: diet, physical activity, and behavioral changes on both initiation and annual renewal. Implementation will occur the first Wednesday 60 days after signing of the minutes in all three points of service.

UF BAP Comments

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

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
ADDENDUM TO THE MAY 2025 MEETING HELD JULY 10, 2025

INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL MEETING Day #1 PM – refer to the posted Agenda for meetings dates and times at https://health.mil/About-MHS/Federal-Advisory-Committees/BAP

XXII. UNIFORM FORMULARY REVIEW PROCESS

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

XXIII. TARGETED IMMUNOMODULATORY BIOLOGICS (TIBS): INTERLEUKIN (IL)-23 INHIBITORS—PRIOR AUTHORIZATION CRITERIA AND IMPLEMENTATION PLAN

P&T Comments

A. TIBs: IL-23 Inhibitors—Background

A virtual meeting was held on July 10th, 2025 to clarify processes for implementing the anticipated upcoming ustekinumab Joint National Contract (JNC) with other Federal partners, as originally outlined in the November 2024 DoD P&T Committee meeting minutes. In anticipation of the ustekinumab JNC selection, updates to the Prior Authorization (PA) criteria and implementation period are required.

Previous DoD P&T Committee conclusions regarding biosimilars are found in the November 2022 and August 2024 DoD P&T Committee meeting minutes. In summary:

- FDA approved biosimilar products, whether officially designated as interchangeable or not, are equally safe and efficacious when compared to the reference product.
- Similar to the U.S. FDA, European Medicines Agency, and the United Kingdom Medicines and Healthcare Regulatory Agency guidance, the DoD P&T

Committee will consider all approved biosimilars as highly interchangeable to the reference product for both efficacy and safety.

- The evidence supports the statement that biosimilars, including but not limited to adalimumab, etanercept, certolizumab, golimumab, tocilizumab, ustekinumab and infliximab are equivalent to the originator product and respective biosimilars for efficacy and safety and may be interchanged based on cost effectiveness.
- The IL-23 subclass was reviewed at the November 2024 DoD P&T Committee meeting. JNC ustekinumab biosimilar (pending selection) was chosen as the UF step-preferred IL-23 agent. Stelara was recommended for UF non-step-preferred placement at the meeting. At the February 2025 and May 2025 DoD P&T Committee meetings, newly approved ustekinumab biosimilars were reviewed for formulary placement and considered therapeutically equivalent to the reference product and each other. A trial of the JNC-selected ustekinumab biosimilar will be required before use of the other UF non-step-preferred and NF non-step-preferred products.
- In collaboration, the DoD and the Department of Veteran's Affairs (VA) are soliciting for a Joint National Contract (JNC) for ustekinumab. Bids for the JNC solicitation are anticipated in late July 2025, with an anticipated award date of late September 2025, and subsequent effective date of late 2025.

B. TIBs: IL-23 Inhibitors Manual PA Criteria and Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) updated manual PA criteria for the ustekinumab products, and the implementation plan as outlined below:

- The general Manual PA criteria are as follows:
  - The JNC-awarded ustekinumab will be UF and step-preferred. Automated specialist bypass for gastroenterologists and dermatologists, and automated lookback for adalimumab (Humira) and other ustekinumabs will be added.
  - The UF non-step-preferred ustekinumab products will require a trial of the JNC-awarded ustekinumab first.
  - The NF non-step-preferred ustekinumab products will require a trial of the JNC-awarded ustekinumab and UF non-step-preferred ustekinumab products first.
  - The completely excluded ustekinumab products will have interim PA criteria apply, requiring a trial of the JNC- awarded ustekinumab and UF non-step-preferred ustekinumab products first.
- Implementation Plan
  - For the JNC-awarded ustekinumab step-preferred product, an implementation within two weeks of the JNC effective date.

- For the UF and NF non-step-preferred products, UF formulary status will be effective 60 days after the effective date.
- For the UF and NF non-step-preferred products, the PA update will be effective 90 days after the effective date.

XXIV. TARGETED IMMUNOMODULATORY BIOLOGICS (TIBS): INTERLEUKIN (IL)-23 INHIBITORS—PRIOR AUTHORIZATION CRITERIA AND IMPLEMENTATION PLAN

UF BAP Comments

TIBS: IL-23 Inhibitors—Manual PA Criteria and Implementation Plan

The P&T Committee recommended the general PA criteria and the implementation plan for the ustekinumab products, as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

-----Original Message-----

From: Cuccaro, Dominic

Sent: Sunday, June 7, 2026 5:00 AM

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

Subject: BAP Question

Hello-

Can you please confirm the date and time in 2026 that the BAP has already met to review the Feb 2026 P&T Committee meeting minutes?

It is my understanding that the BAP has yet to be conveyed in 2026 as of June however the Feb 2026 Prior Authorizations and recommendations are already actively being implemented in the ESI system. For example June 3 PA updates of IL-23 drug class is complete. Has BAP reviewed these changes?

Can you please explain?

Thank you

Dom Cuccaro

National Director

Federal

Abbvie

Dear Designated Federal Officer,

We would like to share with you some important information regarding the proposed change to the NUPLAZID® (pimavanserin) prior authorization criteria. We kindly ask that you continue to allow NUPLAZID® (pimavanserin) to be available to patients with hallucinations and delusions associated with Parkinson's disease (PD) psychosis without requiring clozapine step therapy, as the change would be inconsistent with evidence-based care for the following reasons:

American Geriatrics Society 2023 updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults

The AGS Beers Criteria recommendation is to avoid use of antipsychotics in older adults, except for FDA-approved indications.[1]

- AGS Beers Criteria supports use of pimavanserin in older adults for the FDA-approved indication for the treatment of hallucinations and delusions associated with PD psychosis.
- AGS Beers Criteria does not support use of other antipsychotics for the treatment of PD psychosis in older adults as they are not FDA-approved for this indication.

NUPLAZID Prescribing Information

NUPLAZID is the first and only FDA-approved product for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.[2,3] The NUPLAZID Boxed WARNING language is as follows: "Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. NUPLAZID is not approved for the treatment of patients with dementia who experience psychosis unless their hallucinations and delusions are related to Parkinson's disease."[2] Clinical trials supporting the efficacy and safety of NUPLAZID included PD patients (with or without dementia) experiencing hallucinations and delusions related to Parkinson's disease.

Clozapine Prescribing Information

Clozapine is not FDA-approved for PD psychosis, and has Boxed WARNINGs for severe neutropenia, orthostatic hypotension, bradycardia, and syncope; seizures; myocarditis, pericarditis, and cardiomyopathy; in addition to increased mortality in elderly patients with dementia-related psychosis, which is described in the label as follows: "Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. CLOZARIL is not approved for use in patients with dementia-related psychosis."

Though the Risk Evaluation and Mitigation Strategy (REMS) program has been removed, treatment with clozapine still maintains the same absolute neutrophil count (ANC) monitoring recommendations.[4] As discussed in the literature, the REMS removal creates a confusing transition for prescribers, patients, families, and pharmacies as there may be mismatches between the FDA recommendations for lifetime monitoring and data suggesting a relaxation in monitoring after the period of highest neutropenia risk.[5]

International Parkinson and Movement Disorder Society (MDS)-commissioned review

In the 2019 update on treatments for nonmotor symptoms of PD, the MDS committee recognized the efficacy of both NUPLAZID and clozapine as clinically useful interventions for the treatment of PD psychosis, but highlighted the need for specialized monitoring with clozapine.[6]

Real World Evidence – Fall and Fracture Findings

Layton et al. compared the risk of falls and fractures among patients with PD psychosis treated with pimavanserin vs. other atypical antipsychotics in a retrospective claims analysis of US Medicare patients. The comparator antipsychotic arm included patients receiving quetiapine (79%), risperidone (12%), olanzapine (6%), aripiprazole (3%), and clozapine and brexpiprazole (<1% each). Patients who initiated comparator antipsychotics (n=216) were matched 2:1 to patients who initiated pimavanserin (n=108) using propensity scoring. Incidence rate estimates for composite falls/fractures in matched treatment groups were 18.7 events per 100 person-years (95% CI 8.1-36.9) for patients who initiated pimavanserin and 26.4 events per 100 person-years (95% CI, 16.3-40.3) for patients who initiated comparator antipsychotic treatment. Limitations of this study include the potential for missing or misclassified study variables characteristic of claims data, that claims data may lack the granularity to determine the etiology of all fracture events or differentiate accidental

falls/fractures from those with external causes, and potential residual imbalances even after propensity score matching.[7]

In closing, the use of step therapy with clozapine prior to NUPLAZID is not consistent with the prescribing information or current scientific evidence, including the 2023 AGS Beers Criteria which recognizes NUPLAZID as the only FDA-approved therapy indicated for the treatment of hallucinations and delusions associated with PD psychosis. Acadia respectfully requests that the supporting evidence be considered to ensure patients are able to obtain this therapy without delay. If the panel requires any additional materials or supporting publications, please reach out to the contact information enclosed below. Thank you for your time.

Please see below for NUPLAZID's Indication and Important Safety Information.

Indication
NUPLAZID is indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

Important Safety Information
WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
- NUPLAZID is not approved for the treatment of patients with dementia who experience psychosis unless their hallucinations and delusions are related to Parkinson's disease.

Contraindication: NUPLAZID is contraindicated in patients with a history of a hypersensitivity reaction to pimavanserin or any of its components. Rash, urticaria, and reactions consistent with angioedema (e.g., tongue swelling, circumoral edema, throat tightness, and dyspnea) have been reported.

Warnings and Precautions: QT Interval Prolongation

- NUPLAZID prolongs the QT interval. The use of NUPLAZID should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval (e.g., Class 1A antiarrhythmics, Class 3 antiarrhythmics, certain antipsychotics or antibiotics).
- NUPLAZID should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and presence of congenital prolongation of the QT interval.

Adverse Reactions: The adverse reactions (≥2% for NUPLAZID and greater than placebo) were peripheral edema (7% vs 2%), nausea (7% vs 4%), confusional state (6% vs 3%), hallucination (5% vs 3%), constipation (4% vs 3%), and gait disturbance (2% vs <1%).

Drug Interactions:

- Coadministration with strong CYP3A4 inhibitors increases NUPLAZID exposure. Reduce NUPLAZID dose to 10 mg taken orally as one tablet once daily.
- Coadministration with strong or moderate CYP3A4 inducers reduces NUPLAZID exposure. Avoid concomitant use of strong or moderate CYP3A4 inducers with NUPLAZID.

Dosage and Administration
Recommended dose: 34 mg capsule taken orally once daily, without titration, with or without food.
NUPLAZID is available as 34 mg capsules and 10 mg tablets.
Please read the full Prescribing Information.

Best Regards,
Ben Skoog, PharmD.

Ben Skoog, Pharm.D.
HEOR Director, Field
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References

1. American Geriatrics Society 2023 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults. *J Am Geriatr Soc.* 2023;71(7):2052-2081.
2. NUPLAZID® (pimavanserin) [package insert]. San Diego, CA. Acadia Pharmaceuticals Inc. [Link]
3. FDA approves first drug to treat hallucinations and delusions associated with Parkinson's disease [press release]. US Food and Drug Administration. 29 April 2016.
4. CLOZARIL® (clozapine) [package insert]. Rosemont, PA. HLS Therapeutics.
5. Meyer JM, Rubio JM. Clozapine Monitoring in the Post-REMS World: Some Guidance for Clinicians. *J Clin Psychiatry.* 2025;86(2).
6. Seppi K, Ray Chaudhuri K, Coelho M, et al. Update on treatments for nonmotor symptoms of Parkinson's disease-an evidence-based medicine review. *Mov Disord.* 2019;34(2):180-198.
7. Layton JB, Forns J, Turner ME, et al. Falls and Fractures in Patients with Parkinson's Disease-Related Psychosis Treated with Pimavanserin vs Atypical Antipsychotics: A Cohort Study. *Drugs Real World Outcomes.* 2022;9(1):9-22.