EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel
Meeting June 23, 2026

For the August 2025, November 2025, Addendum to November 2025 held January 16, 2026 and February 2026
DoW Pharmacy and Therapeutics Committee Meetings

The Uniform Formulary Beneficiary Advisory Panel (UFBAP) convened at 10:00 A.M. on June 23, 2026, via teleconference. This is a continuation of the meeting that was started on June 22, 2026. 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 21.

AUGUST 2025 P&T COMMITTEE MEETING

UF DRUG CLASS REVIEWS

I. UF DRUG CLASS REVIEW—ATOPY AGENTS: INTERLEUKIN (IL)-13 AND IL-31 SUBCLASSES

A. Atopy Agents: IL-13 and IL-31 Subclasses—UF Recommendation

- UF
  - dupilumab (Dupixent)
  - lebrikizumab (Ebglyss)
  - nemolizumab (Nemluvio)
  - tralokinumab (Adbry) - *moves from NF to UF*
- NF - none

- Complete Exclusion: none

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

B. Atopy Agents: IL-13 and IL-31—Manual PA Criteria

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

C. Atopy Agents: IL-13 and IL-31 Subclass —UF Recommendation, PA Criteria and Implementation Period of 30 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

II. UF DRUG CLASS REVIEW—DIURETICS MINERALOCORTICOID RECEPTOR ANTAGONISTS SUBCLASS

A. Diuretics: Mineralocorticoid Receptor Antagonists Subclass —UF Recommendation

- UF
  - eplerenone (Inspra, generics)
  - finerenone (Kerendia) - *moves from NF to UF*
  - spironolactone (Aldactone, generics)
  - spironolactone/hydrochlorothiazide (Aldactazide, generics)
  - spironolactone oral suspension (Carospir, generics) - *moves from NF to UF*
- NF: none
- Complete exclusion: none

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

B. Diuretics: Mineralocorticoid Receptor Antagonists Subclass —Manual PA Criteria

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

C. Diuretics: Mineralocorticoid Receptor Antagonists Subclass —UF Recommendation, PA Criteria Removal, and Implementation Period of 60 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

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

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

- UF
  - acoltremon 0.003% (Tryptyr) ophthalmic solution – Ophthalmic Agent
  - atrasentan (Vanrafia) – Nephrology Agent for Immunoglobulin A Nephropathy (IgAN)
  - avutometinib with defactinib (Avmapki Fakzynja Co-pack) – Oncological Agent for low-grade serous ovarian cancer
  - berdazimer 10.3% topical gel (Zelsuvmi) – Anti-Infective Agent for molluscum contagiosum
  - efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) SC injection– Neurological Agent for generalized myasthenia gravis and chronic inflammatory demyelinating polyneuropathy (CIDP)
  - ensartinib (Ensacove) – Oncological Agent for non-small cell lung cancer (NSCLC)
  - fitusiran (Qfitlia) – Antihemophilic Agent
  - insulin aspart-szjj (Merilog vial/pen) – Rapid Acting Insulin
  - nilotinib d- tartrate 50, 150, 200 mg capsules (no brand name) – Oncological Agent for Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)
  - taletrectinib (Ibtrozi) – Oncological Agent for NSCLC

- treprostinil inhalation powder (Yutrepia) – Pulmonary Arterial Hypertension (PAH) Agent

- NF
  - chlorthalidone 12.5 mg tabs (Hemiclor) – Antihypertensive Agent
  - garadacimab-gxii SC injection (Andembry) – Corticosteroids-immune modulator for Hereditary Angioedema (HAE)
  - hydrocortisone 1 mg/ml solution (Khindivi) – Corticosteroids-immune modulator
  - losartan 10 mg/mL oral suspension (Arbli) – Antihypertensive Agent
  - terazosin 1 mg/ml solution (Tezruly) – Benign Prostatic Hyperplasia (BPH) Agent.
  - ustekinumab-srlf (Imuldosa) – Targeted Immunomodulatory Biologics (TIBs) Interleukin (IL)-23s; biosimilar for Stelara
  - ustekinumab (ustekinumab by Janssen) – TIBs IL-23s; unbranded Stelara
- Completely Excluded
  - acetaminophen 325 mg/ibuprofen 97.5 mg tabs (Combogesic) – Pain Agent
  - meloxicam 20 mg/rizatriptan 10 mg (Symbravo) – Pain Agent

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

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

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

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 bisoprolol 2.5 mg tablets, buspirone capsules (Bucapsol), clemastine (Clemasz), diflunisal (Dolobid) 375 mg tablets, flurbiprofen (Lurbipr), and metformin 625 mg IR tabs and implementation period of 60 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

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 Nucala, Rinvoq, Isturisa, Fabhalta, Benlysta, Welireg, and Zoryve and an implementation period of 60 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

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 Doptelet, Eohilia, Lutrate, Myrbetriq, Gemtesa, Zarxio, Zepbound, and Wegovy and an implementation period of 60 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

VII. REMOVAL OF PAs FOR CORLANOR AND IMPLEMENTATION PLAN

Removal of the PAs for ivabradine (Corlanor) and an implementation period of two weeks

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

VIII. UTILIZATION MANAGEMENT—PROSTATE CANCER AGENTS: CYP-17 INHIBITORS ZYTIGA and YONSA AND IMPLEMENTATION PLAN

Removal of the PA for abiraterone acetate 250 mg an implementation period of two weeks; PA updates for abiraterone acetate 500 mg for new and current users and an implementation period of two weeks and PA changes for Yonsa for new and current users and removal of the Tier 1 copay and an implementation period of 120 days.

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

IX. BRAND OVER AUTHORIZED GENERIC AUTHORIZATION FOR UMECLIDINIUM/VILANTEROL (ANORO ELLIPTA) AND IMPLEMENTATION PLAN

Brand over authorized generic PA criteria for Anora Ellipta

UF BAP Comments Mr. DuTeil commented since we are a year behind with the meeting, he has a similar question to the one from yesterday as to whether there is any new information on the generic being re-priced or not, and whether it's been administratively changed already.

CDR Hall answered that we do continually monitor the pricing of these agents, and that currently this is still live with the brand preferred over the authorized generic.

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

NOVEMBER 2025 P&T COMMITTEE MEETING

UF DRUG CLASS REVIEWS

I. METABOLIC DYSFUNCTION AGENTS: INJECTABLE WEIGHT LOSS AGENTS SUBCLASS

A. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—UF Recommendation

- UF
  - semaglutide (Wegovy)
  - tirzepatide (Zepbound)
- NF
  - liraglutide (Saxenda)
- Complete Exclusion: None
- Note that tirzepatide vials (Zepbound vials) will continue to remain designated with complete exclusion status, as this formulation is not available to TRICARE beneficiaries and the manufacturer has limited access to the vials for patient self-pay only.
- Note that as part of the recommendation a trial of generic phentermine or one of the older generic phentermine derivatives is required first for Wegovy, Zepbound and Saxenda.
- There were no changes to the formulary status for phentermine and derivatives, bupropion/naltrexone (Contrave) phentermine/topiramate (Qsymia) or orlistat (Xenical).

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

B. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass — Manual PA Criteria

UF BAP Comments Mr. Wood commented he is a clinical pharmacist who works with three designated providers out of the USFHP. He then stated, as was mentioned, the weight loss GLPs have been very popular. Part of his job is to look at the PAs for these medications, and that 6 out of the 10 PAs that we do are for the GLPs, so 60% of the PAs that are done are for the GLP weight loss medications. He then stated that the P&T Committee has done a great job at controlling these, with the new

information that's been coming out. He also wanted to commend the P&T Committee on the criteria that was changed here about making the patient fail anti-hypertensive medications for uncontrolled hypertension to qualify for a GLP. This was something that prescribers were bypassing to get around using phentermine, which is also a great drug for weight loss. He was happy about this decision.

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

C. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclasses—UF Recommendation, PA Criteria, and Implementation Period of 30 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

II. UF DRUG CLASS REVIEW— METABOLIC DYSFUNCTION AGENTS: INJECTABLE DIABETIC AGENTS SUBCLASS

A. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass Subclass—UF Recommendation

- UF
  - dulaglutide (Trulicity)
  - semaglutide (Ozempic) *moves from NF to UF*
  - tirzepatide (Mounjaro) *moves from NF to UF*
- NF
  - exenatide twice daily (generic Byetta)
  - liraglutide (generic Victoza)
- Complete Exclusion – None

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

B. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass —Manual PA Criteria

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

C. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—UF Recommendation, PA Criteria, and Implementation Period of 60 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

III. UF DRUG CLASS REVIEW—INSULINS: RAPID -ACTING INSULINS (RAI) ANALOGS SUBCLASS

A. Insulins - Rapid Acting Insulins Subclass—UF Recommendation

U-100 Insulins

- UF
  - insulin aspart (Novolog Flexpen and vial)
  - insulin lispro (Humalog Kwikpen and vial)
  - insulin lispro (Humalog Kwikpen unbranded biologic)
  - Insulin lispro Junior (Humalog Kwikpen Junior unbranded biologic)
  - insulin lispro – aabc (Lyumjev Kwikpen and vial)
  - insulin aspart–szjj (Merilog)
- NF
  - insulin lispro Junior Kwikpen branded (Humalog Kwikpen Junior) – moves from UF to NF
  - insulin lispro TEMPO (Humalog TEMPO) – *moves from UF to NF*
  - insulin aspart–xjhz (Kirsty)
  - insulin aspart (Admelog)
  - insulin glulisine (Apidra)
- Complete Exclusion
  - insulin aspart–szjj (Merilog)

- insulin aspart/niacinamide (Fiasp)
- insulin lispro-aabc TEMPO (Lyumjev TEMPO) – *moves from NF to complete exclusion status*

U-200 Insulins

- UF
  - insulin lispro U-200 (Humalog Kwikpen)
- NF
  - insulin lispro-aabc U-200 (Lyumjev Kwikpen) – *moves from UF to NF*
- Complete Exclusion - None

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

B. Insulins - Rapid Acting Insulins Subclass —Manual PA Criteria

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

C. Insulins - Rapid Acting Insulins Subclass —UF Recommendation, PA Criteria and Implementation Period of 90 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

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

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

- UF
  - brensocatib (Brinsupri) – Pulmonary I Agent for non-cystic fibrosis bronchiectasis

- delgocitinib 2% cream (Anzupgo) – Atopy Agent for chronic hand eczema
- dordaviprone (Modeyso) – Oncological Agent for glioma
- gepotidacin (Blujepa) – Antibiotic for urinary tract infections (UTI)
- imlunestrant (Inluriyo) – Oncological Agent for breast cancer
- lecanemab-irmb injection (Leqembi Iqlik) – Alzheimer's Agent
- nalmefene injection (Zurnai) – Alcohol Deterrents-Narcotic Antagonists
- rilzabrutinib (Wayrilz) – Hematological Agents: Platelets, for thrombocytopenia
- sebetralstat (Ekterly) – Hereditary Angioedema (HAE)– Acute treatment
- sepiapterin oral powder (Sephience) – Miscellaneous Metabolic Agents for hyperphenylalaninemia in phenylketonuria
- sitagliptin 25 mg/mL oral solution (Brynovin) – Non-Insulin Diabetes Drugs – Dipeptidyl Peptidase-4 (DPP-4) inhibitor
- sulopenem etzadroxil /probenecid (Orlynvah) – Beta lactam Antibiotic for UTI
- zongertinib (Hernexeos) – Oncological Agents for Non-small Cell Lung Cancer (NSCLC)

- NF
  - dasatinib (Phyrago) – Oncological Agent for Chronic Myelogenous Leukemia and Acute Lymphocytic Leukemia
  - dihydroergotamine mesylate injection (Brekiya) – Migraine Agent
  - donidalorsen injection (Dawnzera) – HAE - prophylaxis Agent
  - gepirone (Exxua) – Antidepressants and Non-Opioid Pain Syndrome Agents
  - metoprolol tartrate 10 mg/mL oral solution (Lopressor) – Beta Blockers and Hydrochlorothiazide Combination Agents
- Completely Excluded:
  - bumetanide nasal spray (Enbumyst) – Diuretics
  - escitalopram 15 mg caps (no brand name) – Antidepressants and Non-Opioid Pain Syndrome Agents
  - nitisinone (Harliku) – Miscellaneous Replacement Enzymes for alkaptonuria-associated urine homogentisic acid

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

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

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

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

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 clemastine (Clemsza), dicyclomine 40 mg tablet, and flurbiprofen (Lurbiro) and an implementation period of 60 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

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

A. Updated PA Criteria for New FDA Approved Indications for Alhemo, Doptelet, Ajovy, Opzelura, Otezla, Zejula, Rybelsus, and Empaveli and an implementation plan of 60 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

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 Nubeqa and Winrevair and an implementation plan of 60 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

VIII. UTILIZATION MANAGEMENT—REMOVAL OF PA FOR IVERMECTIN and IMPLEMENTATION PERIOD

A. Removal of PAs for ivermectin and an implementation plan of two weeks

UF BAP Comments Mr. DuTeil noticed that there were 6 people who voted against this recommendation on the P&T Committee. He asked if our professionals could enlighten us on any observations they might have on this.

CDR Hall answered that the P&T Committee was given two different plans of action, and one involved instead of removing the PA, to add bypasses for specialists and for a drug look back. Some of the providers were in favor of that but overall the Committee did recommend to remove the PA. This explains the mixed vote.

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

IX. UTILIZATION MANAGEMENT—BRAND OVER AUTHORIZED GENERIC ADDITION AND REMOVALS AND IMPLEMENTATION PLAN

A. Brand over authorized generic criteria addition for Tasigna, and the removals for Pradaxa capsules, Vyvanse capsules, and Entresto tablets with an implementation of 60 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

NOVEMBER 2025 ADDENDUM JANUARY 16, 2026 P&T COMMITTEE MEETING

I. TARGETED IMMUNOMODULATORY BIOLOGICS (TIBS): INTERLEUKIN (IL)-23 INHIBITORS—USTEKINUMAB FORMULATIONS FORMULARY STATUS, PA CRITERIA AND IMPLEMENTATION PLAN

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

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

FEBRUARY 2026 P&T COMMITTEE MEETING

UF DRUG CLASS REVIEWS

I. UF DRUG CLASS REVIEW—TARGETED IMMUNOMODULATORY BIOLOGICS (TIBS): INTERLEUKIN-23 (IL-23) INHIBITORS SUBCLASS: USTEKINUMAB AGENTS

A. TIBs: IL-23 Inhibitors: Ustekinumab Agents —UF Recommendation

JNC-Awarded Scenario

- UF and step-preferred
  - JNC-awarded ustekinumab product-moves to UF and step-preferred status
- UF and non-step-preferred
  - ustekinumab-aauz (unbranded Otulfi)
  - ustekinumab-hmny (Starjemza)
  - ustekinumab-srlf (Imuldosa)
- NF and non-step-preferred
  - ustekinumab-aauz (branded Otulfi)
  - ustekinumab-ttwe (Pyzchiva)
  - ustekinumab-aekn (Selarsdi)
  - ustekinumab (unbranded Stelara)
  - ustekinumab-stba (Steqeyma)
  - ustekinumab (Stelara)
  - ustekinumab-auub (Wezlana)
  - ustekinumab-kfce (Yesintek)
- Complete Exclusion: none

UF BAP Comments Mr. Wood wanted to commend the P&T committee for doing this review, since we (USFHP) lost DoD pricing on Stelara. He realized he is not supposed to bring up pricing issues, but stated the Stelara price has increased over $100k annually per patient. Now they are using Otulfi and the price has dropped drastically. So again, a great job and was very excited to see this change.

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

B. TIBs: IL-23 Inhibitors: Ustekinumab Agents—Manual PA Criteria

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

C. TIBs: IL-23 Inhibitors: Ustekinumab Agents —UF Recommendation, PA Criteria and Implementation Period

UF BAP Comments Mr. Wood stated that he was under the impression that this has already started implementing and that the final stage will be July 15th and asked whether that was correct.

Dr. Vonberg replied that there are several parts to this implementation. One thing that is dependent on this meeting and is being presented today is the formulary status of Stelara. That medication is being recommended to be moved from uniform formulary to nonformulary status and that requires your comment prior to the Director review and approval. There are some contracting actions going on with the Joint National Contract that have already started.

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

II. UF DRUG CLASS REVIEW— ONCOLOGICAL AGENTS: MYELOFIBROSIS SUBCLASS

A. Oncological Agents: Myelofibrosis Subclass —UF Recommendation

- UF
  - Inrebic
  - Ojjaara
  - Vonjo
  - Jakafi
- NF none
- Complete exclusion: none

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

B. Oncological Agents: Myelofibrosis Subclass —Manual PA Criteria

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

C. Oncological Agents: Myelofibrosis Subclass —UF Recommendation, PA Criteria Removal, and Implementation Period of 60 weeks

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

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

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

- UF
  - elinzanetant (Lynkuet) – Miscellaneous Gynecological Agent for menopause
  - mitapivat (Aqvesme) – Miscellaneous Metabolic Agents for Alpha or Beta Thalassemia
  - nerandomilast (Jascayd) – Pulmonary I Agents: Idiopathic Pulmonary Fibrosis
  - plozasiran injection (Redemplo) – Antilipidemic 2 Agent for Familial Chylomicronemia Syndrome (FCS)
  - sevabertinib (Hyrnuo) – Lung Cancer: Human Epidermal Growth Factor Receptor 2 (HER2) Agents
  - ziftomenib (Komzifti) – Acute Myelogenous Leukemia (AML)
- NF
  - elamipretide injection (Forzinity) – Miscellaneous Metabolic Agent for Barth Syndrome
  - omidenepag isopropyl 0.002% ophthalmic solution (Omlonti) – Glaucoma Agents
  - paltusotine (Palsonify) – Miscellaneous Endocrine Agent for Acromegaly

- remibrutinib (Rhapsido) – Atopy Agent for Chronic Spontaneous Urticaria
- sibeprenlimab injection (Voyxact) – Miscellaneous Nephrology Agent for Immunoglobulin A (IgA) Nephropathy

- Complete Exclusion
  - celecoxib 10 mg/mL oral suspension (Vyscoxa) – Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
  - clonidine HCl oral solution 0.02 mg/mL (Javadin) – Anti-Hypertensive Agents
  - cyclobenzaprine 2.8 mg SL tab (Tonmya) – Skeletal Muscle Relaxants
  - furosemide 80 mg/mL SC injection (Lasix ONYU) – Diuretics

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

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

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 Complete Exclusion drugs

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

IV. UTILIZATION MANAGEMENT—NEW MANUAL PA AND IMPLEMENTATION PERIOD

A. Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5) for Subvenite and Vraylar, and an implementation period of 60 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

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 Caplyta, Tezspire, Orladeyo, Jaypirca, Revuforj, Zoryve, Simponi, Tremfya and Xeljanz in new users and an implementation period of 60 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

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 Tryngolza, Rexulti, bisoprolol 2.5 mg, Tavneos, Filspari, Onureg, Ninlaro, Ayvakit, Gavreto, Xalkori, Cotellic, Copiktra, Zydelig and adalimumab in new users and an implementation period of 60 days

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

VII. BRAND OVER AUTHORIZED GENERIC AUTHORIZATION FOR CONJUGATED ESTROGEN TABLETS (PREMARIN)

Brand over generic PA criteria for Premarin, and Tier 1 Copay

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

Concur:* 3 *Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA
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 23, 2026

Panel Members Present

- Mr. Jon Ostrowski, Non-Commissioned Officer Association Acting Chair
- Mr. John Du Teil, U.S. Army Warrant Officers Association
- Mr. Bryson Wood, U.S. Family Health Plan

Panel Members Absent

- Dr. Pamela Schweitzer, Commissioned Officers Association of the U.S. Public Health Service, Chair

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)
- 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 25.

- 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 Nguyen introduced herself as the Alternate DFO for the UF BAP and started the meeting by welcoming everyone back. She mentioned that we are on Day 2 of 3 for the UF BAP meeting. She then took roll call (see above). Since Dr. Schweitzer is not present today, Mr.

Ostrowski will be taking on her role as the Chair, and will call for the UF BAP member comments and votes.

Written Comments
Written comments were forwarded to the Panel for their review and consideration. These are included starting on page 188.

1. Abbvie Pharmaceuticals (August 2025 P&T Committee meeting)

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

Chair's Opening Remarks
Mr. Ostrowski stated he was glad to get started and saw that the packet has a lot of information and that it will be a very busy day.

Dr. Vonberg's Opening Remarks
The meeting then proceeded with comments from Dr. Vonberg who thanked the Panel for their involvement today and stated that their voice is critical to this process. He then introduced Dr. Kugler, the P&T Committee Chair, and the FMB members presenting (see 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 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 34. The full meeting information for the August 2025 P&T Committee meeting starts on page 36, the November 2025 P&T Committee meeting starts on page 83, and the Addendum held on January 16, 2026 starts on page 144 and information for the February 2026 P&T Committee meeting starts on page 147.

CAPT Nguyen stated that this time, we are done with the presentations for the morning and we will take a break until 1:00 PM Eastern Time.

The morning session for the August 2025 P&T Committee meeting adjourned at 11:10 AM EDT.

The first afternoon session for the November 2025 and Addendum held on July 16, 2026 P&T Committee meetings re-convened at 1:00 PM EDT

Alternate DFO Remarks

CAPT Nguyen welcomed everyone back for the second portion of Day2 of the UF BAP meeting. She did roll call to ensure all the Panel members were present before reconvening. Three Panel members were present. Similar to the first half of our meeting, Mr. Ostrowski will be acting as the Chair and calling for BAP comments and the vote.

Chair's Remarks

Mr. Ostrowski stated he was looking forward to this afternoon session and that it looks a little long. He did believe that there are three different packets to go over this afternoon. Then he welcomed everyone back and wanted to make it a successful afternoon.

Dr. Vonberg's Remarks

Dr. Vonberg then stated this section will be the Pharmacy and Therapeutics Committee recommendations from the November 2025 meeting which is found under the agenda for the information for the UF BAP meeting for day two in the afternoon.

Closing Remarks

CAPT Nguyen then stated that this was the first part of the second session for the day. There will be another session, and at this time we will go on break and will return back at 3:45 PM Eastern.

The afternoon session for the November 2025 and Addendum held on January 16, 2026 P&T Committee meetings adjourned at 2:51 PM EDT.

The second afternoon session for the February 2026 P&T Committee meeting re-convened at 3:45 PM EDT

Alternate DFO Remarks

CAPT Nguyen welcomed everyone back from the break to finish out the last portion of the day. She then confirmed that all the Panel members were present and noted that Dr. Schweitzer is absent.

Chair's Remarks

Mr. Ostrowski stated he was turning the meeting over to the presenters, as he did not want to take up any more time.

Dr. Vonberg's Remarks

Dr. Vonberg stated that a public comment was received for the Panel for Vraylar. He also had a point of clarification, for the January Addendum to the November 2025 meeting cost effectiveness conclusion, the most cost-effective option for the TRICARE UF step preferred agent is the JNC awardee.

Closing Remarks

Mr. Ostrowski closed the meeting by thanking everyone involved with these reports and presentations, and on behalf of beneficiaries, wanted to thank you. He was so grateful for all the hard work and thoughtfulness that you've put into this. He also stated that the Panel doesn't have a lot of questions because the reports are complete.

Dr. Vonberg thanked the Panel for all their comments and questions today, and that they are very valuable to us. He then made an announcement to remind the Panel regarding the administrative meeting would start tomorrow at 9:30 Eastern time, and that the general session for the May 2026 P&T meeting starts at 10:00 AM. He thanked everyone for all their involvement

CAPT Nguyen thanked the Panel members for their participation and comments and thanked everyone for joining us for day two of three of the UF BAP meetings, and we will talk to you all tomorrow. Thank you.

The second afternoon session for the February 2026 P&T Committee meeting adjourned at 4:55 PM EDT.

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

___Signed/Signature on file

Jon R. Ostrowski
Chairperson, UF BAP

AGENDA

Uniform Formulary Beneficiary Advisory Panel (UF BAP)
For August 2025, November 2025, Addendum to November 2025 (held January 16, 2026) and February 2026 Department of War Pharmacy and Therapeutics Committee Meetings
June 23, 2026 at 10:00 AM Eastern Daylight Time

Day #2 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 – 9:15 AM Eastern Daylight Time

<u>Information from the August 2025 DoW P&T Meeting</u>

- **General session starts at 10:00 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 August 2025 meeting.

- **Drug Class Reviews**
  - *Atopy Agents: Interleukin (IL)-13 and IL-31 Subclasses*
  - *Diuretics: Mineralocorticoid Receptor Antagonists Subclass*
- **Newly Approved Drugs per 32 CFR 199.21(g)(5)**
  - *acetaminophen 325 mg/ibuprofen 97.5 mg tabs (Combogesic) – Pain Agents*
  - *acoltremon 0.003% (Tryptyr) – Ophthalmic Agent*

- *atrasentan (Vanrafia) – Nephrology Agent for immunoglobulin A nephropathy (IgAN)*
- *avutometinib with defactinib (Avmapki Fakzynja Co-pack) – Oncological Agent for low-grade serous ovarian cancer*
- *berdazimer (Zelsuvmi) – Anti-infective Agent for molluscum contagiosum*
- *chlorthalidone 12.5 mg tabs (Hemiclor) – Antihypertensive Agent*
- *efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) – Neurological Agent for generalized myasthenia gravis and chronic inflammatory demyelinating polyneuropathy (CIDP)*
- *ensartinib (Ensacove) – Oncological Agent for non-small cell lung cancer (NSCLC)*
- *fitusiran (Qfitlia) – Antihemophilic Agent*
- *garadacimab-gxii (Andembry) – Corticosteroids-immune modulator for Hereditary Angioedema (HAE)*
- *hydrocortisone 1 mg/ml solution (Khindivi) – Corticosteroids-Immune Modulator*
- *insulin aspart-szjj (Merilog vial/pen) – Rapid Acting Insulin*
- *losartan 10 mg/mL oral suspension (Arbli) – Antihypertensive Agent*
- *meloxicam 20 mg/rizatriptan 10 mg (Symbravo) – Pain Agent*
- *nilotinib tartrate 50, 150, 200 mg capsules (nilotinib tartrate) – Oncological Agent for Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)*
- *taletrectinib (Ibtrozi) – Oncological Agent for (NSCLC)*
- *terazosin 1 mg/ml solution (Tezruly) –Benign prostatic hyperplasia (BPH) Agent*
- *treprostinil inhalation powder (Yutrepia) – Pulmonary arterial Hypertension Agent*
- *ustekinumab-srlf (Imuldosa) – Targeted Immunomodulatory Biologics (TIBs) Interleukin (IL)-23s; biosimilar for Stelara*
- *ustekinumab (ustekinumab by Janssen) – TIBs IL-23s; unbranded Stelara*

➢ **Utilization Management Issues**

- **PA Criteria—Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)**
  - *Antianxiety Agents—buspirone (Bucapsol)*
  - *Antihistamine-1: First Generation and Combos—clemastine (Clemasz)*

        - *Beta Blockers and Hydrochlorothiazide Combinations—bisoprolol 2.5 mg tablets*
        - *Diabetes Non-Insulin: Biguanides—metformin 625 mg IR tablet*
        - *Pain Agents: NSAIDs—diflunisal 375 mg tablets (Dolobid)*
        - *Pain Agents: NSAIDs—flurbiprofen (Lurbipr)*
    - **PA Criteria—Updated PA Criteria for New FDA-Approved Indications**
        - *Atopy—mepolizumab (Nucala)*
        - *Atopy: Oral JAK-1—upadacitinib (Rinvoq)*
        - *Endocrine Agents Miscellaneous—osilodrostat (Isturisa)*
        - *Hematological Agents—iptacopan (Fabhalta)*
        - *Immunosuppressives—belimumab (Benlysta)*
        - *Oncological Agents—belzutifan (Welireg)*
        - *Psoriasis Agents—roflumilast 0.3% foam (Zoryve)*
    - **PA Criteria—Updated PA Criteria for Reasons Other Than New Indications**
        - *Gastrointestinal-1 Agent—budesonide oral suspension (Eohilia)*
        - *Hematological Agents: Platelets—avatrombopag (Doptelet)*
        - *Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists—leuprolide acetate (Lutrate Depot)*
        - *Overactive Bladder Agents: Beta-3 Adrenergic Agonists*
            - *mirabegron (Myrbetriq)*
            - *vibegron (Gemtesa)*
        - *White Blood Cell Stimulants: Filgrastims—filgrastim-sndz (Zarxio)*
        - *Weight Loss Agents—semaglutide (Wegovy) and tirzepatide (Zepbound)*
    - **Removal of PA Criteria**
        - *Cardiovascular Agents Miscellaneous—ivabradine (Corlanor)*
    - **Removal of PA Criteria Prostate Cancer Agents: CYP-17 Inhibitors—abiraterone acetate (Zytiga)**
        - *abiraterone acetate 250 mg and 500 mg (Zytiga, generics)*
        - *abiraterone acetate micronized (Yonsa)*
    - **Brand Over Generic Authorization and Tier 1 Copay**
        - *Pulmonary-2 Agents: umeclidinium/vilanterol inhaler (Anoro Ellipta)*
- **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 12:00 PM – 1:00 PM Eastern Daylight Time**

Information from the November 2025 DoW P&T Meeting

- **General session starts at 1:00 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 November 2025 meeting.

- **Drug Class Reviews**
  - *Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass*
  - *Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass*
  - *Insulins: Rapid-Acting Insulins Subclass*
- **Newly Approved Drugs per 32 CFR 199.21(g)(5)**
  - *brensocatib (Brinsupri) Pulmonary 1 Agent for Cystic Fibrosis bronchiectasis*
  - *bumetanide nasal spray (Enbumyst) Diuretic*
  - *dasatinib tablets (Phyrago) Oncological Agent for Chronic Myelogenous Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL)*
  - *delgocitinib 2% cream (Anzupgo) – Atopy Agent for chronic hand eczema*
  - *dihydroergotamine mesylate injection (Brekiya) – Migraine Agent*
  - *donidalorsen injection (Dawnzera) – HAE - prophylaxis Agent*
  - *dordaviprone (Modeyso) – Oncological Agent for glioma*
  - *escitalopram 15 mg caps (no brand name) – Antidepressants and Non-*

Opioid Pain Syndrome Agents

- *gepirone (Exxua) – Antidepressants and Non-Opioid Pain Syndrome Agents*
- *gepotidacin (Blujepa) – Antibiotic for urinary tract infections (UTI)*
- *imlunestrant (Inluriyo) – Oncological Agent for breast cancer*
- *lecanemab-irmb injection (Leqembi Iqlik) – Alzheimer's Agents*
- *metoprolol tartrate 10 mg/mL oral solution (Lopressor) – Beta Blockers and Hydrochlorothiazide Combination Agents*
- *nalmefene injection (Zurnai) – Alcohol Deterrents-Narcotic Antagonists*
- *nitisinone (Harliku) – Miscellaneous Replacement Enzymes for alkaptonuria-associated urine homogentisic acid*
- *rilzabrutinib (Wayrilz) – Hematological Agents: Platelets, for thrombocytopenia*
- *sebetralstat (Ekterly) – Hereditary Angioedema (HAE)– Acute treatment*
- *sepiapterin oral powder (Sephience) – Miscellaneous Metabolic Agents for hyperphenylalaninemia in phenylketonuria*
- *sitagliptin 25 mg/mL oral solution (Brynovin) – Non-Inulin Diabetes Drugs – Dipeptidyl Peptidase-4 (DPP-4) inhibitor*
- *sulopenem etzadroxil /probenecid (Orlynvah) – Beta lactam Antibiotic for UTI*
- *zongertinib (Hernexeos) – Lung Cancer: Human Epidermal Growth Factor Receptor 2 (HER2) Agents*

➢ **Utilization Management Issues**

- **PA Criteria— Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)**
  - *Antihistamine-1: First Generation and Combos—clemastine 2.68 mg tablets (Clemsza)*
  - *Anticholinergics-Antispasmodics—dicyclomine 40 mg tablets*
  - *Pain Agents: NSAIDs—flurbiprofen 100 mg tablets (Lurbiro)*
- **PA Criteria—Updated PA Criteria for New FDA-Approved Indications**
  - *Antihemophilic Agents: Non-Factor Agents—concizumab-mtci (Alhemo)*
  - *Hematological Agents—avatrombopag (Doptelet)*
  - *Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Preventive—fremanezumab (Ajovy)*
  - *Atopy—ruxolitinib 1.5% cream (Opzelura)*

- *Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors—apremilast (Otezla)*
- *Oncological Agent: Poly ADP-Ribose Polymerase (PARP) Inhibitors—niraparib (Zejula)*
- *Diabetes Non-Insulin Agents: Oral Glucagon-Like Peptide-1 Receptor Agonists—semaglutide (Rybelsus)*
- *Hematological Agents—pegcetacoplan (Empaveli)*

- **PA Criteria—Updated PA Criteria for Reasons other than New FDA-Approved Indications**
  - *Oncological Agents: Second Generation Antiandrogens—darolutamide (Nubeqa)*
  - *Pulmonary Arterial Hypertension Agents—sotatercept (Winrevair)*
- **Removal of PA Criteria**
  - *Anti-Infectives: Anti-Helminthics—ivermectin (Stromectol, generics)*
- **Brand Over Generic Authorization and Tier 1 Copay**
  - *Additions*
    - *Oncological Agents: Chronic Myelogenous Leukemia—nilotinib (Tasigna)*
  - *Removals*
    - *Anticoagulants: Oral Anticoagulants—dabigatran capsules (Pradaxa)*
    - *Attention Deficit Hyperactivity Disorder (ADHD): Stimulants—lisdexamfetamine capsules (Vyvanse)*
    - *Renin-Angiotensin Antihypertensives: Combinations—sacubitril/valsartan tablets (Entresto)*

➢ **<u>Information from the Addendum to November 2025 DoW P&T Meeting held on January 16, 2026</u>**

- **Therapeutic Class Reviews: Targeted Immunomodulatory Biologics (TIBs): Interleukin (IL-23) Inhibitors – Ustekinumab Formulations Formulary Status, PA Criteria and Implementation Plan**
  - *The DoW P&T Committee held a virtual meeting on January 16, 2026 to determine the formulary status, PA criteria and implementation plan for the ustekinumab formulations.*

➢ **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 3:30 PM – 3:45 PM Eastern Daylight Time**

Information from the February 2026 DoW P&T Meeting

- **General session starts at 3:45 PM 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 2026 meeting.

- **Drug Class Reviews**
  - *Targeted Immunomodulatory Biologics (TIBs): Interleukin (IL-23) Inhibitors Subclass: ustekinumab agents*
  - *Oncological Agents: Myelofibrosis Subclass*
- **Newly Approved Drugs per 32 CFR 199.21(g)(5)**
  - *celecoxib 10 mg/mL oral suspension (Vyscoxa) – Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)*
  - *clonidine HCl oral solution 0.02 mg/mL (Javadin) – Anti-Hypertensive Agents*
  - *cyclobenzaprine 2.8 SL tab (Tonmya) – Skeletal Muscle Relaxants*
  - *elamipretide injection (Forzinity) – Miscellaneous Metabolic Agent for Barth Syndrome*
  - *elinzanetant (Lynkuet) – Miscellaneous Gynecological Agent for Menopause*
  - *furosemide 80 mg/mL SC injection (Lasix ONYU) – Diuretic*
  - *mitapivat (Aqvesme) – Miscellaneous Metabolic Agents for Alpha or Beta Thalassemia*
  - *nerandomilast (Jascayd) – Pulmonary I Agents: Idiopathic Pulmonary Fibrosis*

- *omidenepag isopropyl 0.002% ophthalmic solution (Omlonti) – Glaucoma Agents*
- *paltusotine (Palsonify) – Miscellaneous Endocrine Agent for Acromegaly*
- *plozasiran injection (Redemplo) – Antilipidemic 2 Agent for Familial Chylomicronemia Syndrome*
- *remibrutinib (Rhapsido) – Atopy Agent for Chronic Spontaneous Urticaria*
- *sevabertinib (Hyrnuo) – Lung Cancer: Human Epidermal Growth Factor Receptor 2 (HER2) Agents*
- *sibeprenlimab injection (Voyxact) – Miscellaneous Nephrology Agent for Immunoglobulin A (IgA) Nephropathy*
- *ziftomenib (Komzifti) – Acute Myeloid Leukemia (AML)*

➢ **Utilization Management Issues**

- **PA New Criteria**
  - *Anticonvulsants-Antimania Agents—lamotrigine 10 mg/mL suspension (Subvenite)*
  - *Antipsychotic Agents: Atypical—cariprazine (Vraylar)*
- **PA Criteria—Updated PA Criteria for New FDA-Approved Indications**
  - *Antipsychotic Agents: Atypical—lumateperone (Caplyta)*
  - *Atopy Agents—tezepelumab (Tezspire)*
  - *Corticosteroids-Immune Modulators: Hereditary Angioedema (HAE) Agents—berotralstat (Orladeyo)*
  - *Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKIs)—pirtobrutinib (Jaypirca)*
  - *Oncological Agents—revumenib (Revuforj)*
  - *Psoriasis Agents—roflumilast 0.05% cream (Zoryve)*
  - *TIBs: Tumor Necrosis Factor (TNF) Inhibitors—golimumab (Simponi)*
  - *TIBs: Interleukin 23 (IL-23) inhibitors—guselkumab (Tremfya)*
  - *TIBs: Miscellaneous—tofacitinib (Xeljanz)*
- **PA Criteria—Updated PA Criteria for Reasons Other Than New Indications**
  - *Antilipidemics-2 Agents—olezarsen (Tryngolza)*
  - *Antipsychotic Agents: Atypical—brexpiprazole (Rexulti)*
  - *Beta Blockers and Hydrochlorothiazide Combinations—bisoprolol 2.5 mg*

- *Hematological Agents—avacopan (Tavneos)*
- *Nephrology Agents Miscellaneous —sparsentan (Filspari)*
- *Oncological Agents*
    - *Leukemia and Lymphoma Agents: AML —azacitidine (Onureg)*
    - *Multiple Myeloma—ixazomib (Ninlaro)*
    - *Oncological Agents—avapritinib (Ayvakit)*
    - *Oncological Agents: Lung Cancer—pralsetinib (Gavreto)*
    - *Oncological Agents: Lung Cancer—crizotinib (Xalkori)*
    - *Oncological Agents: Melanoma—cobimetinib (Cotellic)*
    - *Oncological Agents: Non-BTKIs—duvelisib (Copiktra)*
    - *Oncological Agents: Non-BTKIs—idelalisib (Zydelig)*
- *TIBs: TNF inhibitors—adalimumab (Humira and biosimilars)*

- **Brand Over Generic Authorization and Tier 1 Copay**
    - *Menopausal Hormone Therapy: Oral Single Agents—conjugated equine estrogen tablets (Premarin)*

➢ **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 2 June 23, 2026

August 2025

Drug Class Reviews

Atopy Agents: IL-13 and IL-31 Subclasses

- This is another complicated drug class where the drugs have varying FDA indications. All of the drugs have been reviewed previously.
- The PA updates all included the new FDA-approved indications. Recommendations from professional treatment guidelines are also included in the PAs, requiring these therapies first. Automation was added to one of the drugs (Ebglyss) for atopic dermatitis.
- The recommendations here all expand the number of patients eligible for the drugs and all will now be designated as UF.

Mineralocorticoid Receptor Antagonists *(spironolactone, Kerendia, eplerenone)*

- This is example where there is a relatively new entrant to a class where the other products are generics.
- As a result of the formulary decision, Kerendia will move to UF status, so patients will see a reduced copay. The PA changes for Kerendia did include feedback from specialists, and requires use of guideline-directed therapies first.

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Nov 2025

Drug Class Reviews

Weight Loss GLP1s

- The weight loss drugs have been rapidly increasing in utilization since this class was first added to the pharmacy benefit in Nov 2017. Managing the class has been challenging with national shortages and their popularity on social media.
- Both Wegovy and Zepbound will remain as UF. There were several changes made to the PAs, including maintaining the requirement for lifestyle changes, requiring a trial of phentermine first, and annual renewal. Patients who have diabetes will be required to try one of the diabetic GLPs which have the same active ingredients but different brand names. The PA updates are in alignment with clinical practice guidelines.
- There are several products in the pipeline and some recent market entrants. There is room on the formulary for new entrants, if they are clinically and cost effective.

Diabetic GLP1 RAs

- We have reviewed this class several times previously, and the main changes here are that Ozempic and Mounjaro will move to UF status, which expands the

formulary options for providers and patients and reduces the copay. Trulicity will remain UF.

- For the PAs, the previous requirement for Ozempic and Mounjaro to have a trial of Trulicity has been removed. All the products still require a trial of metformin first, which is still in the guidelines.

Rapid-Acting Insulins

- Several biosimilars are now available for the rapid-acting insulins, and this was the main reason for reviewing the class.
- For the formulary changes, there are UF options for both aspart and lispro, including a formulation specific to pediatric patients. Novolog and Humalog, which are used in the vast majority of patients, remain UF.
- Beneficiaries receiving products moving to NF or complete exclusion status will be notified by letter of the changes. We will use auto-substitution at MTF and Mail order for the pediatric product moving to NF status and will also do outreach to pediatric endocrinologists. There are currently less than 20 patients on the insulins that will be completely excluded.

Nov 2025 Addendum for Jan 2026 -*No comments for Dr. Kugler*

Feb 2026

Drug Class Reviews

TIBs – ustekinumabs

- The primary reason this drug class was reviewed was due to the launch of several biosimilars, and the opportunity to participate in a Joint National Contract with the VA. After several delays, the JNC was awarded recently.
- Otulfi will now be UF and step-preferred. Three products will also be UF, but non-step-preferred. Stelara will move to NF and non-step-preferred status. For all the non-step-preferred products, a trial of Otulfi will be required in all new and current patients. We are also allowing specialist bypass for dermatologists and gastroenterologists, eliminating the need for these providers to complete a manual PA. Letters will be sent to patients currently on one of the non-step-preferred products.

Oncological Agents: Myelofibrosis Subclass *(Jakafi, Vonjo, Ojjaara, Inrebic)*

- All four products will remain on the formulary. Feedback was received from several oncologists for the PA updates. The main change here is that Jakafi will now be required first. However, a trial of Jakafi is not required if it does not have the FDA indication, or if the NCCN guidelines have a different primary recommendation, such as for anemia or low platelets.

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

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL MEETING Day #2 AM - 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. UF DRUG CLASS REVIEW—ATOPY AGENTS: Interleukin (IL)-13 and IL-31 Subclasses

P&T Comments

A. Atopy Agents: IL-13 and IL-31 Subclasses—Relative Clinical Effectiveness Conclusion

Background—The IL-13 and IL-31 subclasses include four biologic agents, dupilumab (Dupixent), lebrikizumab (Ebglyss), nemolizumab (Nemluvio) and tralokinumab (Adbry). All four agents are indicated for treatment of moderate to severe atopic dermatitis; additionally, Dupixent and Nemluvio are indicated for treatment of prurigo nodularis. Dupixent also has several additional indications.

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 for atopic dermatitis and prurigo nodularis. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

Atopic Dermatitis

- There are no head-to-head trials comparing Dupixent, Adbry, Ebglyss or Nemluvio.
- Guidelines from the American Academy of Dermatology (AAD) (2023) and the American Academy of Allergy, Asthma & Immunology (2023)

support the use of multiple systemic and biologic treatments to treat moderate to severe atopic dermatitis refractory to topical treatments.

- Both Dupixent and Adbry are recommended in the 2023 AAD guidelines with a high certainty for their evidence for efficacy and that they appear safe. Nemluvio and Ebglyss are not yet included in the guidelines due to their more recent FDA approval in November 2024.
- Topical agents including corticosteroids and calcineurin inhibitors (i.e., tacrolimus and pimecrolimus) are recommended for mild to moderate atopic dermatitis. Topical agents can be used with phototherapy and systemic therapies for maintenance of response or treatment of flares.

- A 2023 network meta-analysis evaluating the four agents along with the oral Janus kinase (JAK) inhibitors in 149 trials with over 28,000 patients concluded the following:
  - Dupixent, Ebglyss, and Adbry are of intermediate effectiveness and have favorable safety profiles.
  - For the Patient Oriented Eczema Measure, Pruritus Numeric Rating Scale, and Dermatology Life Quality Index all four agents were statistically significant when compared to placebo.
  - For the Eczema Area Severity Index, Dupixent, Ebglyss, and Adbry were all statistically significant in relieving symptoms, with Dupixent and Ebglyss also showing clinical significance.
  - In terms of safety, all four agents did not demonstrate a significant increase in frequency of any adverse event. However, Dupixent, Adbry and Ebglyss did show an increased frequency of conjunctivitis, compared with standard care. Dupixent demonstrated a reduced odds of serious adverse events and adverse events leading to discontinuation when compared to placebo.

- Additional literature review included two placebo-controlled trials published in 2024 evaluating Nemluvio and reported statistically significant results for the four rating scales discussed above, with similar outcomes as reported in the 2023 NMA reviewed.

Prurigo Nodularis

- Dupixent and Nemluvio are also approved to treat prurigo nodularis in addition to atopic dermatitis. A 2021 U.S. expert consensus panel recommends Dupixent or Nemluvio for disease refractory to topical treatments, or for patients with more severe presentation. Topical corticosteroids and topical calcineurin inhibitors are recommended for mild disease. Other supported treatments include methotrexate, azathioprine, mycophenolate, and cyclophosphamide.

- An indirect efficacy analysis between Dupixent and Nemluvio is challenging due to varying inclusion criteria among the trials. The Dupixent data includes two randomized trials over 24 weeks allowing continuation of stable topical treatments, while Nemluvio includes 2 randomized trials over 16 weeks excluding use of topicals.
- For the proportion of patients achieving Investigator Global Assessment scores of 0 to1 (clear to near clearance of lesions), the two Dupixent trials and a single Nemluvio trial achieved a statistically significant proportion of responders compared to placebo. For the endpoint of daily quality of life, all the studies showed that treatment with Dupixent and Nemluvio achieved a statistically significant, similar outcome.
    - For the individual prurigo nodularis trials, treatment emergent adverse events occurred in over half of the patients across all trials. A higher proportion of patients had disease flare in the Nemluvio trials compared to those in the Dupixent trials.

Other Factors

- Dupixent carries the most FDA-approved indications (eight). The most recent label updates include bullous pemphigoid in adults and chronic spontaneous urticaria in children down to the age of 12 years. For atopic dermatitis, it is approved for children as young as 6 months of age. The package insert lists more warnings and adverse events compared to other agents in the subclass, including herpes simplex virus infection, conjunctivitis, eosinophilia and arthralgia. It is available in pre-filled syringes and pre-filled pens.
- Adbry and Ebglyss are only indicated for the treatment of atopic dermatitis for adults and children down to 12 years of age. Common adverse events for both include conjunctivitis and herpes simplex virus infection; Adbry can cause eosinophilia. Adbry is available in both an autoinjector and pre-filled syringe, while Ebglyss is supplied as prefilled pens and pre-filled syringes.
- Nemluvio is indicated for atopic dermatitis in adults and children as young as 12 years of age as well as prurigo nodularis for adults. Unique adverse events included in the label include headache, urticaria and myalgia. It offers the longest dosing frequency of up to 8 weeks and is supplied as a pre-filled pen.
- In terms of therapeutic interchangeability, for efficacy for treating atopic dermatitis, Dupixent, Adbry, Ebglyss and Nemluvio have a high degree of therapeutic interchangeability; for safety, there is a moderate degree of therapeutic interchangeability. For prurigo nodularis, Dupixent and Nemluvio have a high degree of

interchangeability for efficacy, and moderate degree of interchangeability for safety.

Overall Conclusion

- For clinical coverage, at least one agent is needed on the formulary to treat atopic dermatitis and prurigo nodularis in order to meet the needs of Military Health System (MHS) beneficiaries.

B. Atopy Agents: IL-13 and IL-31 Subclasses—Relative Cost Effectiveness Conclusion

The P&T Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) designating all four drugs as UF was cost-effective, based on the CMA and BIA.

C. Atopy Agents: IL-13 and IL-31 Subclasses—UF Recommendation

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

- UF
    - dupilumab (Dupixent)
    - lebrikizumab (Ebglyss)
    - nemolizumab (Nemluvio)
    - tralokinumab (Adbry) - *moves from NF to UF*
- NF: None
- Complete Exclusion: None

D. Atopy Agents: IL-13 and IL-31 Subclasses—Manual PA Criteria

Existing PA criteria currently apply to all the drugs. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updated manual PA criteria for new users.

- In general, specialist prescribing is required, and renewal is recommended after one year, documenting improvement in symptoms.
- Guideline-recommend therapies are required first, including topical treatments and phototherapy for atopic dermatitis, and other therapies, depending on indication (e.g., pulmonary inhalers for asthma and chronic obstructive pulmonary disease for

Dupixent; nasal saline irrigation and nasal steroids for nasal polyps).

- The new indications for Dupixent for bullous pemphigoid and chronic spontaneous urticaria were added to the PA.
- For Ebglyss, automated specialist bypass for patients 12 years of age and older when prescribed by a dermatologist, allergist or immunologist was added to bypass the PA. Additionally, an automated drug look back was added for Ebglyss, to allow continuation of coverage by any other prescriber if the patient has received a prescription for Ebglyss in the past 720 days.

The Manual PA criteria are as follows.

1. dupilumab (Dupixent)

Updates from the August 2025 meeting are in bold

Manual PA criteria apply to all new users of Dupixent

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

For all indications

- Non-FDA-approved uses are not approved
- The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair])

Atopic Dermatitis indication

- The patient is at least 6 months of age or older
- The drug is prescribed by a dermatologist, allergist, or immunologist
- The patient has moderate to severe or uncontrolled atopic dermatitis
- The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:
  - Topical Corticosteroids
    - For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
    - For patients 6 months to 17 years of age: any topical corticosteroid

    - For patients 2 years of age and older: topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
    - 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 has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy
- The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair])

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for atopic dermatitis: 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's disease severity has improved and stabilized to warrant continued therapy

Asthma indication

- The patient is 6 years of age or older
- The drug is prescribed by an allergist, immunologist **or** pulmonologist, ~~**or asthma specialist**~~
- The patient has one of the following
    - Moderate to severe asthma with an eosinophilic phenotype, with baseline eosinophils ≥ 150 cells/microliter OR
    - Oral corticosteroid-dependent asthma with at least 1 month of daily oral corticosteroid use within the past 3 months
- For eosinophilic asthma, the patient’s asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following;
    - Hospitalization for asthma in past year OR
    - Two courses oral corticosteroids in past year OR
    - Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids

- For eosinophilic asthma, the patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid:
    - Long-acting beta agonist (LABA e.g., Serevent, Striverdi),
    - Long –acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or
    - Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo)

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for asthma: 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's disease severity has improved and stabilized to warrant continued therapy** ~~the patient has had a positive response to therapy with a decrease in asthma exacerbations, improvements in forced expiratory volume in one second(FEV1) or decrease in oral corticosteroid use~~

Chronic rhinosinusitis with nasal polyposis indication

- The patient is 12 years of age or older
- The drug is prescribed by allergist, immunologist, pulmonologist, or otolaryngologist
- The patient has chronic rhinosinusitis with nasal polyposis defined by all of the following:
- Presence of nasal polyposis is confirmed by imaging or direct visualization AND
- At least two of the following: mucopurulent discharge, nasal obstruction and congestion, decreased or absent sense of smell, or facial pressure and pain
- Dupixent will only be used as add-on therapy to standard treatments, including nasal steroids and nasal saline irrigation
- The symptoms of chronic rhinosinusitis with nasal polyposis must continue to be inadequately controlled despite all of the following treatments:
    - Adequate duration of at least TWO different high-dose intranasal corticosteroids AND
    - Nasal saline irrigation AND

- The patient has a past surgical history or endoscopic surgical intervention or has a contraindication to surgery
- Patients with chronic rhinosinusitis with nasal polyposis must use only the 300 mg strength

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for atopic rhinosinusitis: 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's disease severity has improved and stabilized to warrant continued therapy**
- ~~There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score~~

Eosinophilic Esophagitis (EoE) indication

- The patient is one year of age or older and weighs at least 15 kilograms (approximately 33 lbs)
- The drug is prescribed by or in consultation with a gastroenterologist ~~or allergy/immunology specialist allergist or immunologist~~
- Patient has a documented diagnosis of Eosinophilic Esophagitis (EoE) by endoscopic biopsy
- For EoE, the patient has tried and failed an adequate course of both the following:
  - Proton pump inhibitor (PPI) at up to maximally indicated doses (adults: 20-40 mg twice daily omeprazole equivalent; children: 1-2mg/kg or equivalent), unless contraindicated or clinically significant adverse effects are experienced AND
  - Topical glucocorticoids [e.g., fluticasone (Flovent), budesonide (Pulmicort)] at up to maximally indicated doses, unless contraindicated, or clinically significant adverse effects are experienced, ~~or in children maximal doses cannot be reached due to concerns for growth suppression or adrenal insufficiency~~

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for EoE: 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's disease severity has improved and stabilized to warrant continued therapy**
- ~~For maintenance: patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, c, d, or e):~~
  - ~~Reduced intraepithelial eosinophil count; OR~~
  - ~~Decreased dysphagia/pain upon swallowing; OR~~
  - ~~Reduced frequency/severity of food impaction; OR~~
  - ~~Reduced vomiting/regurgitation; OR~~
  - ~~Improvement in oral aversion/failure to thrive~~
  - ~~For relapse: prior authorization form or chart notes documenting a relapse after treatment was discontinued since last approval~~

Prurigo Nodularis Indication

- Patient is 18 years of age or older
- The drug is prescribed by an allergist, immunologist, or dermatologist
- Patient has a diagnosis of prurigo nodularis
- Patient has 20 or more identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk
- Patient has experienced pruritus for 6 weeks or longer
- Patient’s prurigo nodularis is not medication-induced or secondary to a non-dermatologic condition OR
- The patient has a secondary cause of prurigo nodularis that has been identified and adequately managed
- The patient has a contraindication to, intolerability to, or has failed treatment with one high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream
- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with phototherapy
- **The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair])**

Non-FDA approved uses are not approved

~~Prior authorization does not expire for prurigo nodularis~~ **Prior authorization expires after 12 months**

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

- ~~Prurigo nodularis:~~ **The patient's disease severity has improved and stabilized to warrant continued therapy**

Chronic Obstructive Pulmonary Disease (COPD) indication

- Patient is 18 years of age or older
- Prescribed by a pulmonologist
- Patient has moderate to severe chronic obstructive pulmonary disease (COPD) with both chronic bronchitis and an eosinophilic phenotype (greater than 300 cells/microliter)
- Patient has uncontrolled COPD symptoms despite the use of all of the following: long-acting muscarinic antagonists (e.g., tiotropium bromide); long-acting-beta agonists (e.g., formoterol); inhaled corticosteroid (e.g., budesonide)
- Medication is being requested for add-on maintenance therapy for management of COPD
- **The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair])**

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for COPD: 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's disease severity has improved and stabilized to warrant continued therapy

Chronic Spontaneous Urticaria indication

- **Patient is 12 years of age or older**
- **Prescribed by an allergist, immunologist or dermatologist**
- **Patient has a diagnosis of chronic spontaneous urticaria with symptoms lasting longer than 6 weeks**
- **Patient remains symptomatic despite a trial of at least 4 weeks up to 4 times the standard dosing of a second-generation histamine H-1 antihistamine (i.e., cetirizine, levocetirizine, loratadine, desloratadine, fexofenadine)**

- **The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair])**

Non-FDA approved uses are not approved

Prior authorization expires after 12 months

<u>Renewal criteria for chronic spontaneous urticaria</u>: 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's disease severity has improved and stabilized to warrant continued therapy**

<u>Bullous Pemphigoid indication</u>

- **Patient is 18 years of age or older**
- **Prescribed by a dermatologist, allergist, or immunologist**
- **Patient has a confirmed diagnosis of bullous pemphigoid**
- **Patient has an initial bullous pemphigoid disease area index (BPDAI) score greater than or equal to 24**
- **Patient has an initial Peak Pruritus Numeric Rating Scale score of greater than or equal to 4**
- **The patient has a contraindication to, intolerability to, or has failed treatment with all the following:**
  - **One high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream)**
  - **One oral corticosteroid (e.g., prednisone, prednisolone)**
  - **Two additional adjuncts (e.g., methotrexate, azathioprine, mycophenolate, cyclophosphamide, doxycycline)**

Non-FDA approved uses are not approved

Prior authorization expires after 12 months

<u>Renewal criteria for bullous pemphigoid</u> 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's disease severity has improved and stabilized to warrant continued therapy**

2. lebrikizumab (Ebglyss)

Updates from the August 2025 meeting are in bold and strikethrough

<u>Automated PA criteria:</u> When the patient is 12 years of age and older AND when prescribed by a dermatologist, allergist or immunologist, prior authorization is not required. Once therapy is initiated by a dermatologist, allergist or immunologist, an automated drug lookback will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days OR

Manual PA criteria apply to all new users of Ebglyss if automated criteria are not met

<u>Manual PA Criteria:</u> Ebglyss is approved if all criteria are met:

<u>Atopic Dermatitis indication</u>

- The patient is at least 12 years of age or older
- The patient's weight is 40 kg or greater
- The drug is prescribed by a dermatologist, allergist, or immunologist
- The patient has moderate to severe atopic dermatitis
- The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:
    - Topical Corticosteroids
    - For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
    - For patients 12 to 17 years of age: any topical corticosteroid
    - topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy
- The patient is not currently receiving another immunobiologic **(e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair])**

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for atopic dermatitis: 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's disease severity has improved and stabilized to warrant continued therapy

3. tralokinumab (Adbry)

Manual PA criteria apply to all new users of Adbry

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

Atopic Dermatitis indication

- The patient is 12 years of age or older
- The drug is prescribed by a dermatologist, allergist, or immunologist
- The patient has moderate to severe atopic dermatitis
- The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:
  - Topical Corticosteroids
    - For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
    - For patients 12 to 17 years of age: any topical corticosteroid
  - Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy
- The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair])

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for atopic dermatitis: 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's disease severity has improved and stabilized to warrant continued therapy

4. **nemolizumab (Nemluvio)**

   Updates from the August 2025 meeting are in bold

   Manual PA criteria apply to all new users of Nemluvio

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

   Atopic Dermatitis indication

   - The patient is 12 years of age or older
   - The drug is prescribed by a dermatologist, allergist, or immunologist
   - The patient has moderate to severe atopic dermatitis
   - The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:
     - Topical Corticosteroids
       - For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
       - For patients 12 to 17 years of age: any topical corticosteroid
     - Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
   - The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy
   - **The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair])**

   Non-FDA-approved uses are not approved

   Prior authorization expires after 12 months

   Renewal criteria for atopic dermatitis: 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's disease severity has improved and stabilized to warrant continued therapy

Prurigo Nodularis Indication

- Patient is 18 years of age or older
- The drug is prescribed by an allergist, immunologist, or dermatologist
- Patient has a diagnosis of prurigo nodularis
- Patient has 20 or more identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk
- Patient has experienced pruritus for 6 weeks or longer
- Patient's prurigo nodularis is not medication-induced or secondary to a non-dermatologic condition OR
- The patient has a secondary cause of prurigo nodularis that has been identified and adequately managed
- The patient has a contraindication to, intolerability to, or has failed treatment with one high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream
- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with phototherapy
- The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair])

Non-FDA approved uses are not approved

~~Prior authorization does not expire for prurigo nodularis~~ **Prior authorization expires in 12 months**

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

- ~~Prurigo nodularis:~~ **The patient's disease severity has improved and stabilized to warrant continued therapy**

E. Atopy Agents: IL-13 and IL-31 Subclasses —UF Recommendation, PA Criteria and Implementation Plan

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

III. UF DRUG CLASS REVIEW—ATOPY AGENTS: IL-13 AND IL-31 SUBCLASSES

UF BAP Comments

A. Atopy Agents: IL-13 and IL-31 Subclasses s—UF Recommendation

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

- UF
  - dupilumab (Dupixent)
  - lebrikizumab (Ebglyss)
  - nemolizumab (Nemluvio)
  - tralokinumab (Adbry) - *moves from NF to UF*
- NF: None
- Complete Exclusion: None

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Atopy Agents: IL-13 and IL-31 Subclasses —Manual PA Criteria

The P&T Committee recommended PA criteria in new users of Dupixent, Ebglyss, Adbry and Nemluvio, as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Atopy Agents: IL-13 and IL-31 Subclasses —UF recommendation, PA Criteria, and Implementation Plan

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

UF BAP Comments

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

IV. UF DRUG CLASS REVIEW—DIURETICS MINERALOCORTICOID RECEPTOR ANTAGONISTS SUBCLASS

P&T Comments

A. Diuretics: Mineralocorticoid Receptor Antagonists Subclass—Relative Clinical Effectiveness Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the mineralocorticoid receptor antagonists (MRAs). The subclass is comprised of two generic medications, eplerenone and spironolactone (available in tablets and oral suspension), and branded finerenone (Kerendia). Kerendia was previously reviewed as a new drug in November 2021 and is designated as NF.

In terms of FDA-approved indications, eplerenone and spironolactone are both indicated for treating hypertension, and all three drugs are approved for heart failure. Finerenone is also approved for treating type 2 diabetic chronic kidney disease (CKD). Spironolactone has several additional indications including edema due to nephrotic syndrome or cirrhosis, and primary hyperaldosteronism. The clinical review focused on the place in therapy for type 2 diabetic CKD and heart failure.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 1 absent) the following:

Efficacy for Type 2 diabetic CKD

- In patients with type 2 diabetes receiving therapy with angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs), finerenone is approved to reduce the composite endpoint of decline in estimated glomerular filtration rate (eGFR) end-stage kidney disease, cardiovascular (CV) death, non-fatal myocardial infarction and heart failure hospitalization, based on the FIDELIO and FIGARO studies.
    - Limitations to the results include the low use (4%) of current guideline-accepted background therapy with sodium-glucose transportor-2 (SGLT-2) inhibitors. Additionally, in the FIDELIO study, the results were driven by the reduction in eGFR; no difference was noted in progression to end-stage kidney disease or the other individual components of the composite endpoint.
- Studies with eplerenone and spironolactone report that both drugs reduce proteinuria, but do not reduce adverse renal outcomes (e.g., progression to

end-stage kidney disease). There was a significantly increased risk of hyperkalemia. Overall, the long-term effects of eplerenone and spironolactone on renal outcomes, mortality and safety for type 2 diabetic CKD remain to be established.

- Finerenone is now included in several clinical practice guidelines to slow the progression of CKD in patients with Type 2 diabetes. However, ACE inhibitors or ARBs remain the mainstay of therapy as first-line treatment. Guidelines also state the SGLT-2 inhibitors are preferred and more-established therapies, before adding finerenone. Guidelines reviewed included, but were not limited to, the following: 2024 American Diabetes Association, 2024 Kidney Disease Improving Global Outcomes, 2025 VA/DoD, and the 2023 United Kingdom National Institute for Clinical Effectiveness.

Efficacy for heart failure

- In July 2025, finerenone received approval for patients with heart failure and preserved ejection fraction (HFpEF) based on the FINEARTS trial. Treatment with finerenone resulted in a 16% risk reduction in the composite of worsening heart failure event and CV death. No significant difference was noted for the individual endpoints of mortality or kidney outcomes. The results were driven by a reduction in heart failure events. As with CKD, the study is limited by low background use of SGLT-2 inhibitors.
- Spironolactone showed a 30% reduction in all-cause death in patients with heart failure and reduced ejection fraction (HFrEF) in the landmark RALES study. Reduced mortality (20% risk reduction) was seen for HFpEF in the TOPCAT study, when the results were limited to North America.
- Eplerenone showed a 15% reduction in all-cause death in patients with heart failure after myocardial infarction (EPHESUS).
- For HFpEF, SGLT-2 inhibitors remain the mainstay of therapy, based on results from several large trials. Other drug classes, including diuretics, eplerenone or spironolactone, sacubitril/valsartan or ARBs are added, based on individual patient clinical presentation (2023 American College of Cardiology.) Finerenone is not specifically mentioned in the guidelines.
- For HFrEF, spironolactone and eplerenone hold a Class I recommendation (strong evidence) for patients with New York Heart Association (NYHA) class II-IV heart failure (2023 American College of Cardiology.)

Safety

- Adverse events associated with all three MRAs include hyperkalemia, hypotension, and hyponatremia.

- Finerenone has different receptor affinity than spironolactone, which may account for some differences in the adverse event profile. Lack of head-to-head trials and study design run-in criteria complicates ability to determine if the hyperkalemia risk with finerenone is favorable or unfavorable compared to eplerenone or spironolactone.
- Gynecomastia does not appear to be an issue with eplerenone or finerenone.

Other Factors

- MHS providers requested UF placement of finerenone, due to inclusion in national guidelines for T2DM and CKD but acknowledged other guideline-recommended therapies should be used first.

Clinical Coverage

- In order to meet the needs of MHS patients, finerenone should be included on the formulary, despite limitations in clinical trial data.
- Spironolactone oral suspension is required for the pediatric population for edema and heart failure.

B. Diuretics: Mineralocorticoid Receptor Antagonists Subclass—Relative Cost Effectiveness Analysis and Conclusion

CMA and BIA were performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 1 absent) that designating finerenone as UF rather than NF would be cost effective.

C. Diuretics: Mineralocorticoid Receptor Antagonists Subclass—UF Recommendation

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

- UF
  - eplerenone (Inspra, generics)
  - finerenone (Kerendia) - *moves from NF to UF*
  - spironolactone (Aldactone, generics)
  - spironolactone/hydrochlorothiazide (Aldactazide, generics)
  - spironolactone oral suspension (Carospir, generics) - *moves from NF to UF*
- NF – None
- Complete Exclusion – None

D. Diuretics: Mineralocorticoid Receptor Antagonists Subclass—Manual PA Criteria

PA criteria currently apply to Kerendia and for spironolactone oral suspension. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) revising the PA criteria for Kerendia in new users to incorporate feedback from MHS providers for the CKD indication, to modify the safety questions, and to add the new indication for HFpEF based on the inclusion and exclusion criteria from the FINEARTS trial. Other guideline-directed therapies are required first, based on clinical practice guidelines. No changes were recommended for the PA for spironolactone suspension.

The Manual PA criteria are as follows:

1. finerenone (Kerendia)

Updates from the August 2025 meeting are in bold and ~~strikethrough~~.

Manual PA criteria apply to all new users of Kerendia

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

- The patient is 18 years of age and older

For Type 2 Diabetes Mellitus and Chronic Kidney Disease

- Kerendia is prescribed by or in consultation with a nephrologist
- The patient has a diagnosis of type 2 diabetes mellitus (T2DM)
- The patient has documented diabetic kidney disease with albuminuria, defined as ~~one of the following~~
  - An estimated glomerular filtration rate (eGFR) of 25-75 AND urinary albumin-to-creatinine ratio of ≥ 30 mg/g OR
  - ~~eGFR 25-60 with albuminuria > 30mg/g plus diabetic retinopathy~~
- Patient has been taking max-dose ACE inhibitor or ARB ~~for at least 4 weeks~~ **or has a contraindication to ACE inhibitor or ARB or is unable to tolerate ACE or ARB**
- Patient **is maintained on a** ~~has tried DoDs preferred~~ sodium-glucose-co-transporter 2 (SGLT-2) inhibitor [**e.g., empagliflozin (Jardiance) note that-empagliflozin is DoD's preferred SGLT2 inhibitor and does not require PA or dapagliflozin] or has a contraindication to or is unable to tolerate an SGLT2 inhibitor**
- The patient is receiving other appropriate background therapy for diabetes and chronic kidney disease

- **Patient's potassium is less than 5 mEq/mL at initiation of therapy**
- **Provider agrees to discontinue Kerendia if the patient begins renal replacement therapy**
- ~~Patient does not have uncontrolled hypertension (>170/110 mmHg) at initiation of Kerendia therapy~~
- ~~Patient does not have renal artery stenosis~~
- ~~Patient is not concomitantly taking CYP3A4 inhibitors (e.g., ketoconazole, diltiazem, verapamil, clarithromycin, erythromycin, etc) or inducers (e.g., rifampicin, phenobarbital, phenytoin, etc)~~
- ~~Women of child-bearing potential must have a negative pregnancy test, and have received counseling for using 2 forms of contraception~~

For Heart Failure with Preserved Ejection Fraction (HFpEF)

- **Prescribed by or in consultation with a cardiologist**
- **Patient has a documented diagnosis of chronic heart failure (New York Heart Association (NYHA) class II-IV) with a left ventricular ejection fraction (LVEF) greater than 40% and with continued heart failure symptoms**
- **Patient is maintained on an SGLT2 inhibitor [e.g., empagliflozin (Jardiance) note that-empagliflozin is DoD's preferred SGLT2 inhibitor and does not require PA or dapagliflozin] or has a contraindication to or is unable to tolerate an SGLT2 inhibitor**
- **Patient is maintained on other guideline-directed therapy for heart failure**
- **Patient's potassium is less than 5 mEq/mL at initiation of therapy**

Non-FDA approved uses are not approved, including in patients undergoing renal transplant
Prior authorization does not expire

2. spironolactone oral suspension (Carospir, generic)

Manual PA criteria apply to all new users

Manual PA Criteria: spironolactone oral suspension is approved if all of the following criteria are met:

Age Edit: PA does not apply to children 12 year of age and younger

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

- The patient has heart failure, hypertension or edema from cirrhosis
- The provider must write in why the patient requires CaroSpir and cannot take an aldosterone blocker / potassium-sparing 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

Prior Authorization does not expire

E. Diuretics: Mineralocorticoid Receptor Antagonists Subclass—UF, PA, and Implementation Period

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 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—DIURETICS MINERALOCORTICOID RECEPTOR ANTAGONISTS SUBCLASS

UF BAP Comments

A. Diuretics: Mineralocorticoid Receptor Antagonists Subclass —UF Recommendation

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

- UF
  - eplerenone (Inspra, generics)
  - finerenone (Kerendia) - *moves from NF to UF*
  - spironolactone (Aldactone, generics)
  - spironolactone/hydrochlorothiazide (Aldactazide, generics)
  - spironolactone oral suspension (Carospir, generics) - *moves from NF to UF*
- NF – None
- Complete Exclusion – None

UF BAP Comments

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

B. Diuretics: Mineralocorticoid Receptor Antagonists Subclass —Manual PA Criteria

The P&T Committee recommended updated manual PA criteria for Kerendia, as detailed above.

UF BAP Comments

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

C. Diuretics: Mineralocorticoid Receptor Antagonists 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

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).

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
  - acoltremon 0.003% (Tryptyr) ophthalmic solution – Ophthalmic Agent

- atrasentan (Vanrafia) – Nephrology Agent for Immunoglobulin A Nephropathy (IgAN)
- avutometinib with defactinib (Avmapki Fakzynja Co-pack) – Oncological Agent for low-grade serous ovarian cancer
- berdazimer 10.3% topical gel (Zelsuvmi) – Anti-Infective Agent for molluscum contagiosum
- efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) SC injection– Neurological Agent for generalized myasthenia gravis and chronic inflammatory demyelinating polyneuropathy (CIDP)
- ensartinib (Ensacove) – Oncological Agent for non-small cell lung cancer (NSCLC)
- fitusiran (Qfitlia) – Antihemophilic Agent
- insulin aspart-szjj (Merilog vial/pen) – Rapid Acting Insulin
- nilotinib d- tartrate 50, 150, 200 mg capsules (no brand name) – Oncological Agent for Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)
- taletrectinib (Ibtrozi) – Oncological Agent for NSCLC
- treprostinil inhalation powder (Yutrepia) – Pulmonary Arterial Hypertension (PAH) Agent

- NF
  - chlorthalidone 12.5 mg tabs (Hemiclor) – Antihypertensive Agent
  - garadacimab-gxii SC injection (Andembry) – Corticosteroids-immune modulator for Hereditary Angioedema (HAE)
  - hydrocortisone 1 mg/ml solution (Khindivi) – Corticosteroids-immune modulator
  - losartan 10 mg/mL oral suspension (Arbli) – Antihypertensive Agent
  - terazosin 1 mg/ml solution (Tezruly) – Benign Prostatic Hyperplasia (BPH) Agent Note the manufacturer discontinued Tezruly in February 2026. If Tezruly is returned to the market, the NF status will apply, along with the PA criteria.
  - ustekinumab-srlf (Imuldosa) – Targeted Immunomodulatory Biologics (TIBs) Interleukin (IL)-23s; biosimilar for Stelara
  - ustekinumab (ustekinumab by Janssen) – TIBs IL-23s; unbranded Stelara
- Completely Excluded
  - acetaminophen 325 mg/ibuprofen 97.5 mg tabs (Combogesic) – Pain Agent

- Combogesic was recommended for complete exclusion status as it has little to no clinical benefit relative to administering acetaminophen and ibuprofen separately, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include acetaminophen 325 mg and ibuprofen 200 mg.

- meloxicam 20 mg/rizatriptan 10 mg (Symbravo) – Pain Agent
  - Symbravo was recommended for complete exclusion status as it has little to no clinical benefit relative to administering meloxicam and rizatriptan separately, and the needs of TRICARE beneficiaries are met by alternative agents. Alternatives include meloxicam, rizatriptan and sumatriptan/naproxen (Treximet).

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 the NF ustekinumab products ustekinumab (unbranded Stelara by Janssen) and ustekinumab-slrf (Imuldosa), 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.
- Applying manual PA criteria to new users of Qfitlia, similar to the PA requirements for other hemophilia agents.
- Applying manual PA criteria to new users of Andembry, Arbli, Avmapki Fakzynja, Ensacove, Ibtrozi, Khindivi, nilotinib d-tartrate 50, 150, 200 mg capsules, Tezruly, Tryptyr, Vanrafia, Vyvgart Hytrulo, Yutrepia, and Zelsuvmi.
- Applying manual PA criteria to new and current users of Combogesic and Symbravo, until implementation of complete exclusion status.

The Manual PA criteria are as follows:

3. acetaminophen 325 mg/ibuprofen 97.5 mg tabs (Combogesic)
Manual PA criteria apply to all new users of Combogesic

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

- Provider acknowledges that Combogesic 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

- Provider acknowledges that other formulations of acetaminophen and ibuprofen are available to TRICARE beneficiaries and do not require prior authorization
- The patient is 18 years of age or older
- The patient is being treated for short-term mild to moderate acute pain
- Provider must document why the patient cannot take formulary alternatives or OTC products
    - Acceptable responses include the patient has tried all the listed agents including acetaminophen 325 mg tablet, acetaminophen 500 mg tablet, acetaminophen 160 mg/5ml solution/suspension, ibuprofen 200 mg tablet, ibuprofen 800 mg tablet, ibuprofen 100 mg/5ml solution/suspension

Non FDA-approved uses are not approved

PA does not expire until implementation of Complete Exclusion status

4. acoltremon 0.003% ophthalmic solution (Tryptyr)

Manual PA criteria apply to all new users of Tryptyr

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 an ophthalmologist or optometrist
- The patient has signs and symptoms of dry eye disease as supported by both of the criteria below:
    - Positive symptomology screening for dry eye disease from an appropriate measure
    - At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test)
- Patient must have tried and failed the following:
    - At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube])
    - Followed by at least 1 month of a different ocular lubricant that is nonpreserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol)
    - 3-month trial of cyclosporine 0.05% (Restasis, generics)

Non-FDA approved uses are not approved

PA does not expire

5. atrasentan (Vanrafia)

Manual PA criteria apply to all new users of Vanrafia

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 a nephrologist
- The patient has a diagnosis of biopsy-verified primary immunoglobulin A nephropathy (IgAN) without cellular crescents in more than 25% of sampled glomeruli
- Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/gram
- Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m2
- Patient is not currently receiving dialysis or has not undergone kidney transplant
- Patient has not received immunosuppressants, including corticosteroids, in the past 2 weeks and is not expected to need immunosuppressants in the next 6 months
- Patient has continued to have proteinuria despite maximal ACE-inhibitor or ARB therapy and is at high risk for disease progression
- The patient's baseline liver aminotransferase (AST and ALT) levels are not elevated to greater than 3 times the upper limit of normal
- If patient is a female of child-bearing age, the patient must be tested for pregnancy before, during and 1 month after treatment discontinuation
- If patient can become pregnant, they will use effective contraception before starting treatment, during and for 1 month after treatment discontinuation

Non-FDA approved uses are not approved, including IgAN due to systemic lupus erythematosus, liver cirrhosis, Henoch-Schonlein purpura, or pulmonary arterial hypertension, or focal segmental glomerulosclerosis (FSGS)

PA expires in 9 months

Renewal criteria: Coverage will be approved indefinitely if all the following apply

- Patient has had a response to Vanrafia defined by:
  - reduction in urine protein-to-creatinine ratio (UPCR) from baseline OR
  - reduction in proteinuria from baseline AND

- Patient's eGFR rate ≥ 30 mL/min/1.73 m2

6. avutometinib / defactinib (Avmapki Fakzynja Co-pack)
Manual PA criteria apply to all new users of Avmapki Fakzynja Co-pack

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 a hematologist or oncologist
- Patient has recurrent low-grade serous ovarian cancer
- The cancer has a KRAS mutation
- Patient has tried at least one systemic therapy
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: 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. berdazimer 10.3% topical gel (Zelsuvmi)
Manual PA criteria apply to all new users of Zelsuvmi

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

- Patient is 2 years of age or older
- Prescribed by a dermatologist
- Patient has a diagnosis of molluscum contagiosum which fulfills all the following criteria:
  - Treatment is not solely due to cosmetic concern
  - The lesions must be symptomatic (e.g. painful, itchy)
- A single lesion will be treated with Zelsuvmi for no more than 12 weeks
- Provider must explain why this agent is required and cannot be treated with ALL the following: cryotherapy, AND curettage, AND two additional topical agents
  - Acceptable responses include the following: Patient has contraindication to, intolerability to, or has failed treatment with cryotherapy, AND curettage, AND two additional topical treatments (e.g. salicylic acid, cantharidin (Ycanth))

Non-FDA approved uses are not approved

Initial PA expires in 3 months

Renewal Criteria: No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA

8. chlorthalidone 12.5 mg tabs (Hemiclor)

Manual PA criteria apply to all new users of chlorthalidone 12.5 mg tablets (Hemiclor)

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

- Provider acknowledges that generic chlorthalidone 25 mg and 50 mg tablets can be split or crushed and are available to TRICARE beneficiaries and do not require prior authorization
- The patient is 18 years of age or older
- Patient has hypertension or edema from congestive heart failure, hepatic cirrhosis, or renal disease
- Provider must write in why the patient requires Hemiclor and cannot take a loop diuretic and a thiazide diuretic in a tablet formulation
    - Acceptable responses: patient has tried and failed chlorthalidone 25 mg and 50 mg tablets or hydrochlorothiazide 25 mg tablets

Non-FDA approved uses are not approved

PA does not expire

9. efgartigimod alfa-fcab injection (Vyvgart Hytrulo)

Manual PA criteria apply to all new users of Vyvgart Hytrulo

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

- The patient is 18 years of age or older
- Prescribed by a neurologist
- Patient is being treated for chronic inflammatory demyelinating polyneuropathy OR
- Patient is being treated for generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AchR) antibody positive
- For patients being treated for generalized myasthenia gravis:

- Patient had insufficient response or intolerance to pyridostigmine AND
- Patient had insufficient response or intolerance to glucocorticoid sparing therapy such as azathioprine, mycophenolate, cyclosporine, or tacrolimus

- Patient is not receiving concomitant neonatal Fc receptor antagonists or other C5 inhibitors with Vyvgart Hytrulo including but not limited to the following: efgartigimod injection for intravenous use (Vyvgart), eculizumab (Soliris), ravulizumab (Ultomiris), rozanolixizumab (Rystiggo), or zilucoplan (Zilbrysq)

Non-FDA approved uses are not approved

PA expires in 6 months

Renewal criteria: Note that initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely if the following applies:

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

10. ensartinib (Ensacove)

Manual PA criteria apply to all new users of Ensacove

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 a hematologist or oncologist
- Patient has locally advanced or metastatic non-small cell lung cancer (NSCLC)
- Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected by an FDA-approved test
- 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

11. fitusiran injection (Qfitlia)

Manual PA criteria apply to all new users of Qfitlia

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 or without factor VIII inhibitors or hemophilia B with or without factor IX inhibitors
- Patient is not concurrently receiving factor VIII or factor IX therapy after initial transition period unless for the treatment of breakthrough bleeding
- For patients with hemophilia A, patient has had an inadequate response, intolerance, or contraindication to emicizumab-kxwh (Hemlibra)

Non-FDA approved uses are not approved

PA does not expire

12. garadacimab injection (Andembry)

Manual PA criteria apply to all new users of Andembry

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

- Patient is 12 years of age or older
- Andembry is prescribed for prophylaxis to prevent attacks of hereditary angioedema (HAE)
- Prescribed by an allergist, immunologist, rheumatologist, or HAE specialist
- The patient must have monthly HAE attacks or a history of severe attacks that require prophylaxis treatment (i.e., two or more HAE attacks/month, or laryngeal attacks, etc.)
- The patient is not currently receiving another drug for HAE prophylaxis (e.g., Orladeyo, Takhzyro, Cinryze or Haegarda will not be used concomitantly)
- The patient has had an inadequate response, adverse reaction, or contraindication to all of the following:
  - One C1-inhibitor (e.g., Cinryze, Haegarda, Berinert, Ruconest)
  - One Kallikrein inhibitor (e.g., Takhzyro, Orladeyo)

Non-FDA approved uses are not approved

PA does not expire

13. hydrocortisone 1mg/mL oral solution (Khindivi)
Manual PA criteria apply to all new users of Khindivi

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

- Patients is at least 5 years of age
- Patient is not older than 18 years of age
- Provider acknowledges that the following products are available without a prior authorization: 5 mg generic hydrocortisone tablets, hydrocortisone 100 mg act-O-vials, and prednisone Intensol oral solution. Please consider changing the prescription to one of these agents
- Patient is using Khindivi as replacement therapy for adrenocortical insufficiency
- Provider acknowledges that the patient's dosing regimen requires small doses of hydrocortisone and cannot accurately split the dose using 5 mg hydrocortisone tablets
- Provider must explain why this agent is required and patient cannot take generic hydrocortisone tablets, Alkindi Sprinkle, hydrocortisone 100 mg act-O-vials, and prednisone Intensol oral solution. Blank write in _____
    - Acceptable response: patient requires a g-tube

Non-FDA approved uses are not approved

PA does not expire

14. losartan 10 mg/mL oral suspension (Arbli)
Manual PA criteria apply to all new users of Arbli

Automated PA Criteria: Age edit – PA not required if patient is 12 years of age and younger

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

- Provider must write in why the patient requires Arbli oral suspension and cannot take losartan tablets
    - Acceptable responses: Patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience

Non-FDA approved uses are not approved

PA does not expire

15. meloxicam 20 mg/rizatriptan10 mg tabs (Symbravo)
Manual PA criteria apply to all new users of Symbravo

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

- Provider acknowledges that Symbravo will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T Committee meeting minutes by the Director, DHA
- Provider acknowledges that other formulations of triptans are available to TRICARE beneficiaries and do not require prior authorization including eletriptan, sumatriptan, rizatriptan
- Patient is 18 years of age or older
- Patient is being treated for acute treatment of migraine with or without aura
- Provider must document why the patient cannot use rizatriptan tablet and meloxicam tablet.
    - Acceptable responses include the patient has had an adverse reaction to an excipient in rizatriptan tablet and/or meloxicam tablet that would not be likely to occur with Symbravo

Non-FDA approved uses are not approved

PA does not expire until after implementation of complete exclusion status

16. nilotinib d-tartrate 50 mg, 150 mg and 200 mg caps (no brand name)
Manual PA criteria apply to all new users of nilotinib

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

- Provider acknowledges Prior Authorization is not required for Tasigna capsules. Please consider changing the prescription to Tasigna.
- Prescribed by or in consultation with a hematologist or oncologist
- Patient is 18 years of age or older
- Patient has a diagnosis of either:
    - 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

- The patient has tried nilotinib tartrate tablet (Danziten) and had an adverse reaction to an excipient that would not be likely to occur with nilotinib tartrate capsule
- 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

17. taletrectinib (Ibtrozi)
Manual PA criteria apply to all new users of Ibtrozi

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 a hematologist or oncologist
- Patient has locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)
- 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

18. terazosin 1 mg/mL oral solution (Tezruly)
Manual PA criteria apply to all new users of Tezruly

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

- Provider must explain why the patient requires Tezruly and cannot take terazosin tablets
    - Acceptable responses include the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia) and not due to convenience

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

PA does not expire

19. treprostinil inhalation powder (Yutrepia)
Manual PA criteria apply to all new users of vimseltinib (Yutrepia)

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

- Prescribed by or in consultation with a cardiologist or pulmonologist
- Patient has WHO Group 1 pulmonary arterial hypertension (PAH) OR WHO Group 3 pulmonary hypertension with interstitial lung disease (PH-ILD)
- Patients with WHO Group 1 PAH have had a right heart catheterization
- Documentation was provided to confirm that patient had the procedure and confirmed diagnosis of WHO Group 1 PAH

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.
- 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

- acoltremon 0.003% (Tryptyr) ophthalmic solution – Ophthalmic Agent
- atrasentan (Vanrafia) – Nephrology Agent for Immunoglobulin A Nephropathy (IgAN)
- avutometinib with defactinib (Avmapki Fakzynja Co-pack) – Oncological Agent for low-grade serous ovarian cancer
- berdazimer 10.3% topical gel (Zelsuvmi) – Anti-Infective Agent for molluscum contagiosum
- efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) SC injection– Neurological Agent for generalized myasthenia gravis and chronic inflammatory demyelinating polyneuropathy (CIDP)
- ensartinib (Ensacove) – Oncological Agent for non-small cell lung cancer (NSCLC)
- fitusiran (Qfitlia) – Antihemophilic Agent
- insulin aspart-szjj (Merilog vial/pen) – Rapid Acting Insulin
- nilotinib d- tartrate 50, 150, 200 mg capsules (no brand name) – Oncological Agent for Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)
- taletrectinib (Ibtrozi) – Oncological Agent for (NSCLC)
- treprostinil inhalation powder (Yutrepia) – Pulmonary Arterial Hypertension Agent

- NF
  - chlorthalidone 12.5 mg tabs (Hemiclor) – Antihypertensive Agent
  - garadacimab-gxii SC injection (Andembry) – Corticosteroids-immune modulator for Hereditary Angioedema (HAE)
  - hydrocortisone 1 mg/ml solution (Khindivi) – Corticosteroids-immune modulator
  - losartan 10 mg/mL oral suspension (Arbli) – Antihypertensive Agent
  - terazosin 1 mg/ml solution (Tezruly) – Benign Prostatic Hyperplasia (BPH) Agent
  - ustekinumab-srlf (Imuldosa) – Targeted Immunomodulatory Biologics (TIBs) Interleukin (IL)-23s; biosimilar for Stelara

- ustekinumab (ustekinumab by Janssen) – TIBs IL-23s; unbranded Stelara

- Completely Excluded
  - acetaminophen 325 mg/ibuprofen 97.5 mg tabs (Combogesic) – Pain Agent
  - meloxicam 20 mg/rizatriptan 10 mg (Symbravo) – Pain Agent

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 PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5)

P&T Comments

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

Manual PA criteria were recommended for six 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.

Beta Blockers and Hydrochlorothiazide Combinations—bisoprolol 2.5 mg tablets (no brand name)—There are other bisoprolol formulations available, including bisoprolol 5 mg tablets (scored), that are more cost-effective than this 2.5 mg strength.

Antianxiety Agents—buspirone capsules (Bucapsol)—These buspirone capsules are less cost-effective than currently available buspirone tablets. Buspirone tablets are available in the same strengths or can be split to achieve the same strengths as these buspirone capsules

Antihistamine-1: First Generation and Combos—clemastine 2.68 mg tablets (Clemasz)—This clemastine tablet is less cost-effective than other clemastine tablets that are available in the same strength.

Pain Agents: NSAIDs—diflunisal 375 mg tablet (Dolobid)—Numerous other more cost-effective generic NSAIDs are available.

Pain Agents: NSAIDs—flurbiprofen (Lurbipr)—There are other flurbiprofen 100 mg tablets formulations and other NSAIDs that are more cost-effective than this product.

Diabetes Non-Insulin: Biguanides—metformin 625 mg immediate release (IR) tablet—Numerous other more cost-effective generic metformin IR and extended release (ER) tablets are available.

The Manual PA criteria are as follows:

1. **bisoprolol 2.5 mg tablets**

   The PA criteria are as follows:

   Manual PA criteria apply to all new users of bisoprolol 2.5 mg tabs

   Manual PA criteria: bisoprolol 2.5 mg tablets are approved if all criteria are met:

   - Provider acknowledges other formulations of bisoprolol tablets are available without prior authorization.
   - Provider must explain why the patient requires bisoprolol 2.5 mg tablet and cannot take the cost-effective generic bisoprolol 5 mg 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 bisoprolol formulations

   Non-FDA approved uses are not approved

PA does not expire

2. buspirone capsules (Bucapsol)

Manual PA criteria apply to all new users of Bucapsol

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

- Provider acknowledges other formulations of buspirone tablets are available without prior authorization.
- Provider must explain why the patient requires Bucapsol capsules and cannot take the cost-effective buspirone tablets 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 buspirone formulations

Non-FDA approved uses are not approved

PA does not expire

3. clemastine 2.68 mg tablets (Clemasz)

Manual PA criteria apply to all new users of Clemasz

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

- Provider acknowledges other formulations of clemastine are available without prior authorization.
- Provider must explain why the patient requires Clemasz and cannot take the cost-effective clemastine 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 clemastine formulations

Non-FDA approved uses are not approved

PA does not expire

4. diflunisal 375 mg tablets (Dolobid)

Manual PA criteria apply to all new users of Dolobid

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

- Provider acknowledges other formulations of diflunisal are available without prior authorization.

- Provider must explain why the patient requires diflunisal 375 mg tablets and cannot take the cost-effective generic diflunisal 250 mg or 500 mg 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 buspirone formulations

Non-FDA approved uses are not approved

PA does not expire

5. flurbiprofen (Lurbipr)

Manual PA criteria apply to all new users of Lurbipr

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

- Provider acknowledges other formulations of flurbiprofen are available without prior authorization.
- Provider must explain why the patient requires Lurbipr and cannot take the cost-effective flurbiprofen 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 buspirone formulations

Non-FDA approved uses are not approved

PA does not expire

6. metformin 625 mg IR tablet

Manual PA criteria apply to all new t users of metformin 625 mg IR tablet

Manual PA criteria: metformin 625 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 625 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

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

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for bisoprolol 2.5 mg tablets, buspirone capsules (Bucapsol), clemastine (Clemasz), diflunisal (Dolobid) 375 mg tablets, flurbiprofen (Lurbipr), and metformin 625 mg IR tabs in new 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)

UF BAP Comments

The P&T Committee recommended manual PA for bisoprolol 2.5 mg tabs, Clemasz, Dolobid 375 mg tablets, Lurbipr and metformin 625 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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

X. 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 (18 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) **Atopy—mepolizumab (Nucala)—**Nucala is now indicated for the treatment of COPD. The manual PA criteria were updated to allow for this new indication with PA criteria mirroring the COPD criteria for other biologics, requiring use of traditional oral inhalers first.

b) **Atopy: Oral JAK-1—upadacitinib (Rinvoq)—**The manual PA criteria were updated to allow for the new giant cell arteritis indication. Specialists supported requiring a trial of glucocorticoids and tocilizumab first, for this indication.

c) **Endocrine Agents Miscellaneous—osilodrostat (Isturisa)**—The manual PA criteria were updated to reflect minor changes in the FDA label and to remove the warnings and precautions language as this drug is restricted to specialists.

d) **Hematological Agents—iptacopan (Fabhalta)—**The manual PA was updated to include the new indication of Complement 3 Glomerulopathy (C3G). In addition, the PA for IgAN was updated to require a trial of Vanrafia or Filspari.

e) **Immunosuppressives—belimumab (Benlysta)—**Benlysta is now indicated in children as young as 5 years old with lupus nephritis. The PA criteria were updated accordingly.

f) **Oncological Agents—belzutifan (Welireg)**—Welireg received a new indication for locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma. Additionally, the FDA revised the renal cell carcinoma indication to clarify use for a clear cell component. The manual PA was updated to reflect these changes.

g) **Psoriasis Agents—roflumilast 0.3% foam (Zoryve)—**The manual PA criteria were updated to include the new indication for plaque psoriasis with the PA mirroring standard plaque psoriasis criteria.

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

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) implementation for the new PA criteria for Nucala, Rinvoq, Isturisa, Fabhalta, Benlysta, Welireg, and Zoryve in new users will be effective the first Wednesday 60 days after the signing of the minutes.

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

UF BAP Comments

A. Updated PA Criteria for New FDA Approved Indications and Implementation Plan

The P&T Committee recommended updates to the PA criteria due for Nucala, Rinvoq, Isturisa, Fabhalta, Benlysta, Welireg, and Zoryve 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:

XII. 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 (18 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) **GI-1 Agent—budesonide oral suspension (Eohilia)**—The Eohilia PA was modified to allow use by general surgeons due to MTF provider feedback.

b) **Hematological Agents: Platelets—avatrombopag (Doptelet)**—The manual PA criteria were updated based on MTF provider feedback, expanding the specialists to allow hematologist and oncologist prescribing in addition to gastroenterologists, regardless of indication.

c) **Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists—leuprolide acetate (Lutrate Depot) 22.5 mg**—Lutrate Depot is a new formulation similar to other leuprolide products (Lupron Depot, Eligard). It is less cost-effective than the preferred leuprolide (Eligard), so new PA criteria will apply, requiring a trial of Eligard first, similar to Lupron Depot.

d) **Overactive Bladder (OAB) Agents): Beta-3 Adrenergic Agonists—mirabegron tablets (Myrbetriq) and vibegron (Gemtesa)—**

Myrbetriq and Gemtesa are beta-3 agonists used to treat OAB. Currently, both drugs are UF with a PA requiring a trial of generic anticholinergics. Efficacy is similar between anticholinergics and beta-3 agonists. PA automation was added to both PAs, to include specialist bypass for Myrbetriq tablets and an automated lookback for anticholinergics for both Myrbetriq and Gemtesa.

e) **White Blood Cell Stimulants: Filgrastims—filgrastim-sndz (Zarxio)—**Zarxio was moved from step-preferred to non-step-preferred status on the filgrastim PA. This change was due to Zarxio no longer being cost-effective and due to a high degree of therapeutic interchangeability in this biosimilar class.

f) **Weight Loss Agents—semaglutide (Wegovy) and tirzepatide (Zepbound)—**The definition of uncontrolled hypertension was clarified on the Wegovy and Zepbound PAs, based on provider feedback and hypertension professional treatment guidelines. Patients are considered to have uncontrolled hypertension if they do not meet individual blood pressure goal on two or more antihypertensive drugs.

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

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Doptelet, Eohilia, Lutrate, Myrbetriq, Gemtesa, Zarxio, Zepbound, and Wegovy in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

XIII. 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 Doptelet, Eohilia, Lutrate, Myrbetriq, Gemtesa, Zarxio, Zepbound, and Wegovy 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:

XIV. UTILIZATION MANAGEMENT—REMOVAL OF PA AND IMPLEMENTATION PERIOD

P&T Comments

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) removing the PA for one drug with implementation effective the first Wednesday 2 weeks after signing of the minutes.

a) **Cardiovascular Agents Miscellaneous—ivabradine (Corlanor)—**Currently, ivabradine (Corlanor) tablets are UF, with cost effective generic formulations now available. There is stable utilization of the drug and a low risk of inappropriate use. The PA will be removed for ivabradine (Corlanor) tablets

XV. UTILIZATION MANAGEMENT—REMOVAL OF PA and IMPLEMENTATION PERIOD

UF BAP Comments

The P&T Committee recommended removing the manual PA criteria for Corlanor tablets as outlined above, with implementation effective two weeks after signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XVI. UTILIZATION MANAGEMENT—PROSTATE CANCER AGENTS: CYP-17 INHIBITORS ZYTIGA and YOSA AND IMPLEMENTATION PLAN

P&T Comments

Abiraterone acetate 250 mg and 500 mg tablets (Zytiga) are available in generic formulations and require administration on an empty stomach. Abiraterone acetate micronized (Yonsa) is only available as a branded agent and is taken without regard to meals. Provider feedback and prostate cancer guidelines suggest that there is a high degree of therapeutic interchangeability between these two products. Yonsa has a tier 1 copay from when the class was last reviewed in February 2019. PA criteria apply to all three abiraterone formulations. At the August 2024 meeting, the PA for Zytiga and generic formulations were given automated PA specialist bypass and drug lookback criteria to allow PA approval if the prescriber is an oncologist, hematologist or urologist and continuation by a non-specialist.

Generic Zytiga 250 mg is now the most cost effective abiraterone formulation, compared with the generic Zytiga 500 mg strength and Yonsa. The following changes were recommended (18 for, 0 opposed, 0 abstained, 1 absent):

- abiraterone acetate 250 mg (Zytiga and generic)
  - Remove PA
  - Effective date of the first Wednesday 2 weeks after signing of the minutes
- abiraterone acetate 500 mg Zytiga and generic)
  - Remove automated specialist bypass and the automated drug lookback
  - Require a trial of abiraterone acetate 250 mg in new and current users
  - Send letters to current users
  - Effective date of the first Wednesday 120 days after signing of the minutes
- abiraterone acetate micronized (Yonsa)
  - Remove Tier 1 copay
  - Require a trial of generic abiraterone 250 mg in new and current users
  - Send letters to current users
  - Effective date of the first Wednesday 120 days after signing of the minutes

XVII. UTILIZATION MANAGEMENT—PROSTATE CANCER AGENTS: CYP-17 INHIBITORS ZYTIGA and YOSA AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended the changes to the abiraterone products as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XVIII. BRAND OVER AUTHORIZED GENERIC AUTHORIZATION FOR UMECLIDINIUM/VILANTEROL (ANORO ELLIPTA) AND IMPLEMENTATION PERIOD

P&T Comments

Pulmonary-2 Agents: Chronic Obstructive Pulmonary Disease— Umeclidinium /vilanterol (Anoro Ellipta) inhaler is designated as UF without a PA. An authorized generic has entered the market; however, this product is less cost-effective compared to the branded agent. Therefore, the branded Anoro Ellipta inhaler will continue to be dispensed at all three points of service, and the authorized generic will only be available with prior authorization. The brand Anoro Ellipta will continue to have the Tier 2 copay, as the authorized generic umeclidinium/vilanterol has a Tier 2 copay.

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) requiring brand Anoro Ellipta inhalers over the authorized generic in new and current users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. The effective date will be the first Wednesday 60 days after signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

XIX. BRAND OVER AUTHORIZED GENERIC AUTHORIZATION FOR UMECLIDINIUM/VILANTEROL (ANORO ELLIPTA) AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended brand over authorized generic criteria for Anora Ellipta as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL MEETING Day #2 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. UF DRUG CLASS REVIEW—METABOLIC DYSFUNCTION AGENTS: INJECTABLE WEIGHT LOSS AGENTS Subclass

P&T Comments

A. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—Relative Clinical Effectiveness Conclusion

Background The last drug class review was in May 2024 and included both older oral weight loss medications (e.g., phentermine, phentermine/topiramate, bupropion/naltrexone and orlistat) and the injectable glucagon-like peptide-1 receptor agonists (GLP-1RAs). The drug class encompassing these GLP-1RAs is now termed the Metabolic Dysfunction Agents, to more accurately reflect the physiologic properties of these drugs.

The class is divided into subclasses including the Injectable Weight Loss agents (discussed here), the Injectable Diabetes agents (discussed in the next section). The drugs in the subclass include injectable liraglutide (Saxenda), semaglutide (Wegovy) and tirzepatide (Zepbound). Semaglutide, tirzepatide and liraglutide are also FDA-approved under distinct brand names for diabetes (Ozempic, Mounjaro, and Victoza, respectively).

Information regarding the regulatory controls for coverage of weight loss treatments is not within scope of the P&T Committee and is found at *https://newsroom.tricare.mil/News/TRICARE-News/Article/4266447/tricare-coverage-of-weight-loss-medications-what-to-know*.

Relative Clinical Effectiveness Conclusion—The clinical review focused on new information available since the last class review in May 2024, including updated clinical practice guidelines, meta-analyses, systematic reviews and published real-word evidence. The review also analyzed the literature for differences in the class with respect to weight loss, reduction in major adverse cardiovascular events, obstructive sleep apnea, and metabolic dysfunction-associated steatohepatitis. In accordance with the regulatory information above, evaluations for the treatment benefit for conditions other than weight loss considered whether weight loss was a sole or major component, not incidental, to treatment with the agent.

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

Clinical Practice Guidelines for Weight Loss

- When national and international weight loss guidelines were reviewed, there were no significant updates from the previous clinical conclusion from 2017 that comprehensive lifestyle intervention remains the foundation for obesity management.
- The 2025 American Diabetes Association (ADA) guideline recommends setting weight management goals with incorporation of nutrition, behavior, physical activity and an evidence-based weight management program, along with additional consideration for weight loss pharmacotherapy or surgery.

Weight Loss

- Liraglutide (Saxenda), semaglutide (Wegovy) and tirzepatide (Zepbound) are all indicated for weight loss.
- The 2025 American Diabetes Association (ADA) guidelines state that a relatively small degree of weight loss of approximately 3% to 7% of baseline weight improves glycemia and other intermediate cardiovascular (CV) risk factors.
    - The 2025 ADA guidelines categorize the efficacy for weight loss as very high with semaglutide and tirzepatide, and as high with liraglutide.
- Individual placebo-controlled trials report that tirzepatide treatment results in greater weight loss than with liraglutide or semaglutide.

- A 2025 Annals of Internal Medicine network meta-analysis in over 15,000 patients without diabetes from 26 randomized controlled trials reported the greatest weight loss was demonstrated with semaglutide (Wegovy) and tirzepatide (Zepbound). The rates of severe adverse events (e.g. gastrointestinal [GI] or biliary disorders or pancreatitis) remained low. The most common adverse events were GI in nature and were mostly mild to moderate, with some evidence of a dose-response relationship.
- The 2025 Institute for Clinical and Economic Review (ICER) concluded semaglutide and tirzepatide when added on to lifestyle modifications resulted in substantial weight loss and improved cardiometabolic risk factors, which was rated as high certainty of a substantial net health benefit. When tirzepatide was compared with subcutaneous (SC) semaglutide, tirzepatide demonstrated greater weight loss and potentially improved GI tolerability, which was rated as moderate certainty of a small or substantial net health benefit.
- One head-to-head study (SURMOUNT-5) found tirzepatide treatment was superior to semaglutide for both body weight reduction at 72 weeks and change in waist circumference. The study results are limited by the open-label study design, small patient sample and manufacturer sponsorship.
- Real-world evidence from a retrospective cohort review (2025 Advanced Therapeutics) supports that there is less of a difference between semaglutide and tirzepatide with regard to weight loss, as patients receiving semaglutide achieved 14.1% weight loss compared to 16.5% with tirzepatide.
- A review of the evidence demonstrates that patients are more likely to reach maximal doses with semaglutide rather than tirzepatide. However, achievement of maximal dosages is not required to have meaningful weight loss.
- GI adverse effects are the most commonly reported side effect with all three agents. Indirect data suggests that tirzepatide may have improved GI tolerability over liraglutide or semaglutide.
- Although the magnitude of weight loss differs among the agents, particularly that liraglutide is less effective than semaglutide or tirzepatide, there is strong evidence that the weight loss benefits with the GLP-1RAs are a class effect. The drugs mechanistically all reduce appetite and promote weight loss.

Major Adverse Cardiovascular Events (MACE)

- Clinical practice guidelines from the ADA and American College of Cardiology (ACC) suggest that sustained weight loss above 10% of baseline weight confers benefits, including disease-modifying effects and possible remission of type 2 diabetes mellitus (T2DM), and may improve long-term CV outcomes and mortality.
- Semaglutide (Wegovy) is the only weight loss GLP-1RA also indicated to reduce the risk of MACE in adults with established CV disease and either obesity or overweight, based on the SELECT trial, which was conducted in over 17,000 patients with no history of diabetes.
    - Semaglutide was associated with a statistically significant 20% reduction in MACE (a composite of CV death, nonfatal myocardial infarction or non-fatal stroke), compared with placebo, after a mean follow-up of 40 months. The mean weight loss with semaglutide was approximately 9% in the trial.
    - Safety data reported a statistically significantly higher rate of GI adverse events leading to discontinuation with semaglutide compared to placebo. Reported adverse events of special interest (e.g. pancreatitis, gallbladder disease) remained equally low in both treatment arms.
- There is currently no data with tirzepatide to show MACE benefits. The ongoing SURMOUNT-MMO trial is investigating CV outcomes with tirzepatide in obese patients without diabetes who have atherosclerotic disease, with results expected in 2027.
- The 2025 ICER report concluded that there is substantial uncertainty regarding whether semaglutide or tirzepatide has greater CV benefit in overweight patients without diabetes.
- While weight loss contributes to the CV benefit, there is uncertainty as to size of the CV benefit independent of weight loss. More data is needed. Weight loss is not incidental to CV benefits.

Obstructive Sleep Apnea (OSA)

- Tirzepatide (Zepbound) is the only weight loss GLP1-RA also indicated for treatment of moderate to severe obstructive sleep apnea (OSA) in adults with obesity.
- Guidelines for OSA recommend positive airway pressure (PAP) therapy as first line in treatment of OSA. (2025 VA/DoD; 2019 American Academy of Sleep Medicine [AASM]).

- The 2024 Australian guidelines report that weight loss of 10% from baseline is expected to result in a clinically meaningful reduction in apnea-hypopnea index.
- Data supporting tirzepatide use for OSA is from the SURMOUNT-OSA trials. Adults with obesity and moderate to severe OSA received Zepbound or placebo, with the change from baseline in the apnea-hypopnea index (AHI) evaluated as the primary outcome. After 52 weeks, Zepbound treatment led to a statistically significantly greater AHI reduction when compared to placebo.
    - The trial also showed a positive correlation between improvement in OSA symptoms and weight reduction. The average body mass index (BMI) of randomized patients was 39, while the lowest BMI was 30. The average weight loss with tirzepatide was 17.5% to 19.6%.
- There is limited clinical trial data with liraglutide showing a reduction in AHI compared to placebo and treatment with PAP.
- The 2024 AASM guidelines state that tirzepatide is only effective for cases of sleep apnea that are related to obesity.
- Overall, there is moderate evidence of a class effect for the GLP1-RAs for improving OSA.
- There is strong evidence that improvement in OSA from the GLP1-RAs is driven by weight loss, and the weight loss is not incidental to GLP1-RA treatment.

Metabolic dysfunction–associated steatohepatitis (MASH)

- Clinical practice guidelines suggest that a 5-10% reduction in body weight will improve markers of liver steatosis and fibrosis.
- Semaglutide (Wegovy) is the only weight loss GLP1-RA also indicated for the treatment of MASH in adults with moderate to advanced liver fibrosis. FDA-approval was via an accelerated approval pathway, and verification of clinical benefit is ongoing.
    - The ESSENCE trial evaluated semaglutide against placebo in patients with MASH. The primary outcomes included resolution of steatohepatitis and improvement in liver fibrosis. The trial found that after 72 weeks, treatment with semaglutide demonstrated statistically significantly higher rates of steatohepatitis resolution, as well as liver fibrosis reduction, when compared to placebo. Of note, a subgroup analysis by baseline BMI demonstrated that for those with BMI

lower than 27, there was no difference in improvement in liver fibrosis when compared to placebo. Patients with weight loss greater than 10% from baseline showed the highest histologic response.

- Data is available with tirzepatide from the SYNERGY-NASH study and with liraglutide from the LEAN trial, however these are smaller studies and neither drug is currently indicated for MASH.
- Overall, it is uncertain whether there is a class effect with the GLP1-RAs for MASH with respect to reduction of liver fibrosis. However, GLP1-RAs as a class improve steatosis and liver enzymes.
- There is strong evidence that the benefit of GLP1-RAs in MASH is driven or driven at least partially by weight loss, and weight loss is not incidental to GLP1-RA treatment/MASH improvement.

Safety

- There was no significant new data to change the previous May 2024 conclusions that the three agents have minor differences in their individual safety profiles.
- The GLP1-RAs share the same precautions, warnings, and adverse events. GI adverse events are most commonly reported and include nausea and vomiting.
- *Individual Product Characteristics*
- Liraglutide (Saxenda) is available as a prefilled pen and is given once daily. It is approved for pediatric patients as young as 12 years of age. Generic formulations of liraglutide are now marketed.
- Semaglutide (Wegovy) is available as a prefilled pen-injector, given once weekly. It carries the largest number of indications within this subclass (weight loss, MACE, and MASH). It is approved for pediatric patients as young as 12 years of age for weight loss. Wegovy currently is the only agent in the class to reduce MACE in obese patients who do not have diabetes. The dosing for weight loss differs than Ozempic formulation approved for treating T2DM.
- Tirzepatide (Zepbound) is available as a prefilled pen and is administered once weekly. It is approved for both weight loss and OSA in adults. The dosing formulation for weight loss is the same as the formulation for T2DM (Mounjaro).

Overall Clinical Conclusion

- In terms of efficacy

        - Weight loss: semaglutide and tirzepatide have a high degree of therapeutic interchangeability; liraglutide is less effective.
        - MACE/OSA/MASH, there is a moderate to low degree of therapeutic interchangeability, as only one drug is approved for these individual indications. [MACE (Wegovy); OSA (Zepbound); MASH (Wegovy)].
- In terms of safety, all three drugs have a high degree of therapeutic interchangeability.
- For clinical coverage, at least one injectable Metabolic Dysfunction-Weight Loss Agent is required in order to meet the majority of needs of DoD beneficiaries.

B. Metabolic Dysfunction Agents: Injectable Weight Loss Agents 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 (19 for, 0 opposed, 0 abstained, 1 absent):

- CMA results showed that semaglutide (Wegovy) and tirzepatide (Zepbound) were cost effective relative to liraglutide (Saxenda, generic) under any formulary scenario.
- The BIA demonstrated that selecting both semaglutide (Wegovy) and tirzepatide (Zepbound) as UF without a step therapy requirement was more cost effective than selecting either semaglutide (Wegovy) or tirzepatide (Zepbound) as the sole UF step-preferred agent.
- A sensitivity analysis confirmed that the UF no step scenario resulted in more cost avoidance under any realistic assumption of switching to a given step-preferred agent.
- Placement of both agents as UF without a step therapy requirement offers beneficiaries UF copays and allows for future entrants into this class to be designated as UF, if warranted.
- While continued increases in utilization and cost are anticipated in this drug class, manufacturer bids are expected to result in substantial cost avoidance relative to current pricing (lower cost per patient treated).

C. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—UF Recommendation

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

- UF
  - semaglutide (Wegovy)
  - tirzepatide (Zepbound)
- NF
  - liraglutide (Saxenda)
- Complete Exclusion: Note that tirzepatide vials (Zepbound vials) will continue to remain designated with complete exclusion status, as this formulation is not available to TRICARE beneficiaries and the manufacturer has limited access to the vials for patient self-pay only.
- Note that as part of the recommendation a trial of generic phentermine or one of the older generic phentermine derivatives is required first for Wegovy, Zepbound and Saxenda. (See the PA section below.)
- There were no changes to the formulary status for phentermine and derivatives, bupropion/naltrexone (Contrave) phentermine/topiramate (Qsymia) or orlistat (Xenical).

D. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—Manual PA Criteria

PA for the weight loss drugs has applied since the initial formulary review in 2017, with several subsequent updates. Updates made to the weight loss drug PAs are summarized below. Implementation of some of these changes is delayed, due to the BAP pause.

- Feb 2025: Zepbound new indication to treat moderate to severe OSA in adults with obesity
- May 2025: Definition of comprehensive lifestyle intervention expanded to include exercise
- August 2025: Uncontrolled hypertension definition for phentermine updated
- Revised PAs in accordance with 32 CFR 199.17(f)(3) were implemented on August 31, 2025

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria as discussed below in new users, while renewal criteria will apply to both new and current users.

- Ongoing lifestyle modification remains a requirement prior to use of pharmacotherapy, based on clinical practice guidelines. PAs will explicitly require diet, exercise and behavioral components that are provider-led and documented in the medical record.
- A trial of generic phentermine, benzphetamine, diethylpropion immediate release/sustained release (IR/SR) or phendimetrazine IR/SR will remain.
- Patients with T2DM will be required to use a GLP1-RA specifically indicated for diabetes management [e.g., dulaglutide (Trulicity), liraglutide (Victoza), semaglutide (Ozempic) or tirzepatide (Mounjaro)].
- For the nonformulary drug Saxenda, the requirement for a trial of phentermine, phentermine/topiramate (Qsymia), bupropion/naltrexone (Contrave), Wegovy and Zepbound remains.
- Continuation of GLP1-RA therapy will be allowed for patients who have successfully lost weight with phentermine, but who require additional pharmacotherapy to reach a lower weight loss goal.
- PA will expire annually, with yearly renewal required.
- The Saxenda PA will have the BMI categories added, in order to align with the Wegovy and Zepbound PAs.

The Manual PA criteria are as follows.

1. **semaglutide (Wegovy) and tirzepatide (Zepbound)**

   Updates from the November 2025 meeting are in bold and ~~strikethrough~~

   Manual PA criteria apply to all new users of Wegovy and Zepbound

   Manual PA Criteria: Coverage for Wegovy or Zepbound is approved if:

   - **If the diagnosis is Diabetes Mellitus and the patient meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, please consider these alternatives.**
   - The provider has verified and documented in the medical record that the patient engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health modification for at least 6 months, has failed to achieve the desired weight loss and will remain engaged throughout course of therapy. Medical record documentation will be made available to TRICARE for audit, if requested.

- The provider will document the major condition and comorbidities treated selecting all that apply:
  - Obesity
  - Diabetes or impaired glucose tolerance
  - Obstructive sleep apnea
  - Osteoarthritis
  - Metabolic syndrome
  - Dyslipidemia
  - Hypertension
  - Metabolic dysfunction-associated steatohepatitis (MASH)
  - Established cardiovascular disease with a history of stroke
  - Established cardiovascular disease with a history of myocardial infarction
  - Established cardiovascular disease with a history of peripheral artery disease

<u>For Wegovy and Zepbound for adults for obesity</u>

- Patient is 18 years of age or older
- Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity for those with risk factors in addition to obesity
- The provider will document the BMI
  - For BMI less than 27, coverage is not approved
  - For BMI ranging between 27 and 29 with a comorbidity
  - For BMI ranging between 30 to 34
  - For BMI ranging between 35 to 39
  - For BMI greater than or equal to 40
- Patient has tried 3 months of generic phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR and had an inadequate response
  - Phentermine: Date_____ Duration of therapy _____ OR
- **Patient has achieved greater than equal to 5 percent weight loss from baseline while on phentermine, benzphetamine, diethylpropion IR/SR or phendimetrazine IR/SR but BMI**

and central adiposity remain high, and further reduction is needed to attain optimal outcomes

- The patient has a contraindication to generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke, ~~**uncontrolled hypertension**~~ **or a patient not meeting blood pressure goal on 2 or more antihypertensives)** OR *(changes from the August 2025 meeting)*
- The patient has experienced an adverse reaction to phentermine benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR that is not expected to occur with Wegovy or Zepbound

For Wegovy for adolescents (note that Zepbound is not currently FDA-approved for adolescents) for obesity

- Patient is 12 years of age or older and younger than 18 years of age
- Patient has a BMI greater than or equal to 95th percentile standardized for age

For Zepbound for moderate to severe obstructive sleep apnea (OSA) in adults with obesity

- Patient is 18 years of age or older
- Patient has moderate to severe OSA (documented apnea-hypopnea index greater than 15 events per hour) and a BMI greater than 30

For all patients

- Concomitant use of this medication with another GLP1-RA is not allowed (e.g., **exenatide ~~Bydureon~~**, Trulicity, ~~**Byetta**~~, ~~**Adlyxin**~~, Victoza, **liraglutide**, Soliqua, Xultophy)
- The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2
- Patient is not pregnant

Non-FDA approved uses are not approved including diabetes mellitus

PA expires in 12 months for initial therapy; annual renewal required

Renewal PA Criteria: Note that initial TRICARE PA approval is required for renewal. Wegovy and Zepbound will be approved for an additional 12 months if the following are met. Renewal criteria will apply to all users when the prescription is up for renewal.

- The provider will document the BMI for renewal:

- BMI less than 27
- BMI ranging between 27 and 29
- BMI ranging between 30 to 34
- BMI ranging between 35 to 39
- BMI greater than or equal to 40

For Obesity

- The provider continues to verify and will maintain documentation in the medical record that the patient is currently engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health modification. Medical record documentation will be made available to TRICARE for audit, if requested.
- For Wegovy: for patients older than 12 years of age and younger than 18 years of age, the patient has lost greater than or equal to 4% of baseline body weight since starting medication with full dosage titration
- For Wegovy and Zepbound: for patients older than 18 years of age, the patient has lost greater than or equal to 5% of baseline body weight since starting medication
- The patient is not pregnant
- **The patient does not have a history of or a family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2**

For OSA

- The patient has shown improvement in OSA symptoms based on the improvement of apnea hypopnea index

2. liraglutide (Saxenda)

Updates from the November 2025 meeting are in bold and ~~strikethrough~~

Manual PA criteria apply to all new users of Saxenda

Manual PA Criteria: Coverage for Saxenda is approved if:

- **If the diagnosis is Diabetes Mellitus and the patient meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, please consider these alternatives.**
- The provider has verified and documented in the medical record that the patient engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health

modification for at least 6 months, has failed to achieve the desired weight loss and will remain engaged throughout course of therapy. Medical record documentation will be made available to TRICARE for audit, if requested.

- **The provider will document the major condition and comorbidities treated selecting all that apply:**
  - **Obesity**
  - **Diabetes or impaired glucose tolerance**
  - **Obstructive sleep apnea**
  - **Osteoarthritis**
  - **Metabolic syndrome**
  - **Dyslipidemia**
  - **Hypertension**
  - **Metabolic dysfunction-associated steatohepatitis (MASH)**
  - **Established cardiovascular disease with a history of stroke**
  - **Established cardiovascular disease with a history of myocardial infarction**
  - **Established cardiovascular disease with a history of peripheral artery disease**

Adults

- Patient is 18 years of age or older
- Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity for those with risk factors in addition to obesity.
- **The provider will document the BMI**
  - **For BMI less than 27, coverage is not approved**
  - **For BMI ranging between 27 and 29 with a comorbidity**
  - **For BMI ranging between 30to 34**
  - **For BMI ranging between 35 to 39**
  - **For BMI greater than or equal to 40**
- Patient has tried and failed all of the following (generic phentermine [or benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR], Qsymia, and Contrave) or has

experienced an adverse reaction or has a contraindication to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug)

- phentermine, benzphetamine, diethylpropion (IR/SR), or phendimetrazine (IR/SR: Date_____ _____
  Duration of therapy _____
  CI _____ OR

- **Patient has achieved greater than equal to 5 percent weight loss from baseline while on phentermine, benzphetamine, diethylpropion IR/SR or phendimetrazine IR/SR but BMI and central adiposity remain high, and further reduction is needed to attain optimal outcomes**
  - **Note that for phentermine, contraindications include, arrhythmias, coronary artery disease, heart failure, stroke, ~~uncontrolled hypertension~~ or a patient not meeting blood pressure goal on 2 or more antihypertensives)** *(changes from the August 2025 meeting)*

- Qsymia (or one of its individual generic components phentermine or topiramate): Date_____ Duration of therapy _____
  CI _____
- Contrave (or one of its individual generic components bupropion or naltrexone): Date _____ Duration of therapy _____
  CI _____
- Wegovy: Date _____ Duration of therapy _____
  CI _____
- Zepbound: Date _____ Duration of therapy _____
  CI _____

Adolescents

- Patient is 12 years of age or older and younger than 18 years of age with BMI greater than or equal to 95th percentile standardized for age
- Patient has tried and failed Qsymia or its individual generic components OR

- Patient has a contraindication or has had an adverse reaction to Qsymia or its individual generic components (Note: provider must include the date of use and duration of therapy or contraindication to the drug) and Wegovy
- – Qsymia (or one of its individual generic components, phentermine or topiramate):Date_____ Duration of therapy _____
  CI _____
- – Wegovy: Date _____ Duration of therapy _____
  CI _____

For all patients

- Concomitant use of this medication with another GLP1-RA is not allowed (e.g., **exenatide ~~Bydureon~~**, Trulicity, **~~Byetta~~**, **~~Adlyxin~~**, Victoza, **liraglutide**, Soliqua, Xultophy)
- The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2
- Patient is not pregnant

Non-FDA approved uses are not approved including diabetes mellitus

PA expires in 12 months for initial therapy; annual renewal required

Renewal PA Criteria: Note that initial TRICARE PA approval is required for renewal. Wegovy and Zepbound will be approved for an additional 12 months if the following are met. Renewal criteria will apply to all users when the prescription is up for renewal.

- **The provider will document the BMI for renewal:**
  - **BMI less than 27**
  - **BMI ranging between 27 and 29**
  - **BMI ranging between 30 to 34**
  - **BMI ranging between 35 to 39**
  - **BMI greater than or equal to 40**
- **The provider continues to verify and will maintain documentation in the medical record that the patient is currently engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health**

modification. Medical record documentation will be made available to TRICARE for audit, if requested.

- Patient is older than 12 years of age and younger than 18 years of age: the patient has lost greater than or equal to 4% of baseline body weight since starting medication
- Patient is older than 18 years of age: the patient has lost greater than or equal to 5% of baseline body weight since starting medication
- The patient is not pregnant
- **The patient does not have a history of or a family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2**

E. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—UF recommendation, PA and Implementation Plan

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

III. UF DRUG CLASS REVIEW—METABOLIC DYSFUNCTION AGENTS: INJECTABLE WEIGHT LOSS AGENTS SUBCLASS

UF BAP Comments

A. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—UF Recommendation

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

- UF
  - semaglutide (Wegovy)
  - tirzepatide (Zepbound)
- NF
  - liraglutide (Saxenda)

- Complete Exclusion: Note that tirzepatide vials (Zepbound vials) will continue to remain designated with complete exclusion status, as this formulation is not available to TRICARE beneficiaries and the manufacturer has limited access to the vials for patient self-pay only.
- Note that as part of the recommendation a trial of generic phentermine or one of the older generic phentermine derivatives is required first for Wegovy, Zepbound and Saxenda.

- There were no changes to the formulary status for phentermine and derivatives, bupropion/naltrexone (Contrave) phentermine/topiramate (Qsymia) or orlistat (Xenical).

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—Manual PA Criteria

The P&T Committee recommended PA criteria in new users of Wegovy, Zepbound and Saxenda, with renewal criteria applying to new and current users, as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—UF Recommendation, PA Criteria, and Implementation Plan

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEW—METABOLIC DYSFUNCTION AGENTS: INJECTABLE DIABETIC AGENTS SUBCLASS

P&T Comments

A. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—Clinical Effectiveness Conclusion

Background—The drugs in the subclass class include exenatide (Byetta, Bydureon B-Cise), liraglutide (Victoza), lixisenatide (Adlyxin), dulaglutide (Trulicity), semaglutide (Ozempic) and tirzepatide (Mounjaro). The class was last reviewed in May 2022 as the "Non-Insulin Diabetes Drugs: GLP1-RA" class. At that time, dulaglutide was placed UF, with all other agents designated as NF. Since the last class review, exenatide once weekly (Bydureon BCise), lixisenatide, and branded exenatide twice daily (Byetta) were discontinued from the market, with generic exenatide twice daily and generic liraglutide now available. Additionally, in August 2022, tirzepatide (Mounjaro) was reviewed as an innovator drug and designated NF. Liraglutide, semaglutide and tirzepatide are also available under the brand names of Saxenda, Wegovy and Zepbound, respectively for weight loss. Of note, the fixed dose combination GLP1-RA/insulin products (Soliqua, Xultophy) and oral semaglutide (Rybelsus) are categorized in different classes and are not reviewed here. Oral Rybelsus was not reviewed here but remains designated as UF.

The clinical effectiveness review focused on the primary literature, systematic reviews and meta-analyses, guidelines and specialist (endocrinologist, cardiologist) feedback regarding use of these agents.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

T2DM and Glycemic Control

- All agents within the subclass are approved for glycemic control.
- The 2025 ADA Pharmacologic Approaches to Glycemic Treatment guideline recommends individualized hemoglobin A1C (HbA1C) or glycemic goals with an aim to avoid symptomatic hypoglycemia, although a HbA1C goal of less than 7% is appropriate for the majority of non-pregnant adults. Metformin or other agents (including combination therapy) can be considered to achieve glycemic treatment goals. Metformin continues to have an established place in therapy as it is effective, safe, inexpensive, available in a variety of oral formulations, is weight neutral, and does not cause hypoglycemia.
    - Dulaglutide (high-dose), semaglutide, tirzepatide and insulin were categorized as having very high efficacy for glucose lowering. The other GLP1-RAs (exenatide, liraglutide and lixisenatide) have high glucose-lowering efficacy.

- A 2025 network meta-analysis from the Journal of Diabetes, Obesity, and Metabolism compared efficacy and tolerability of the injectable diabetic drugs. All agents demonstrated clinically meaningful reductions of HbA1c to less than 7%, with a general trend towards greater efficacy with newer agents (e.g., dulaglutide, semaglutide and tirzepatide). Safety concerns predominantly included GI adverse events with a greater trend for discontinuation reflected with higher doses.

T2DM and MACE Reduction

- Liraglutide (based on the LEADER trial), dulaglutide (based on the REWIND trial), and semaglutide (based on the SUSTAIN-6 trial) are approved for reducing MACE outcomes in patients with T2DM.
- The 2025 ADA Cardiovascular Disease and Risk Management guideline recommends that adults with T2DM and atherosclerotic CV disease (ASCVD) or multiple risk factors for ASCVD should consider use of a GLP1-RA (dulaglutide, semaglutide, liraglutide) or a sodium–glucose cotransporter-2 (SGLT2) inhibitor (empagliflozin, dapagliflozin, canagliflozin) with proven CV benefit, irrespective of background metformin use or HbA1C level. However, the guideline notes that most individuals enrolled in relevant trials were receiving metformin at baseline as glucose-lowering therapy.
- A 2025 network meta-analysis from the Journal of the American College of Cardiology (JACC) reviewed CV effects and tolerability of the GLP1-RAs. The results for liraglutide and semaglutide SC demonstrated a statistically significant reduction in the incidence rate ratio for T2DM and MACE outcomes; dulaglutide was not statistically significant in this review. However, in the REWIND trial, dulaglutide did demonstrate a statistically significant reduction in the hazard ratio for composite MACE outcomes.
- Overall, the JACC meta-analysis safety review concluded that the GLP1-RAs are generally well tolerated, although associated with an increase in GI and gallbladder events, and showed no increased risk of severe complications such as pancreatitis.

T2DM and Chronic Kidney Disease (CKD)

- Semaglutide is the sole GLP1-RA approved for adult patients with T2DM and CKD. Ozempic received FDA approval for CKD based on the FLOW trial, which was terminated early for

benefit. The endpoint was a reduction in the composite of estimated glomerular filtration rate (eGFR) decline, end stage renal disease (ESRD), and CV death.

- The 2025 ADA Chronic Kidney Disease and Risk Management guideline recommends either an SGLT-2 inhibitor, metformin, or a GLP1-RA in patients with T2DM. The 2024 Kidney Disease: Improving Global Outcomes (KDIGO) guideline for CKD states that a GLP1-RA may be considered in patients with T2DM for those unable to achieve glycemic control on metformin and SGLT2 inhibitor treatment.
- A 2025 network meta-analysis from the Cochrane group reviewed GLP1-RAs for CKD and diabetes; tirzepatide was not included in the analysis. The conclusion found that evidence for GLP1-RAs in CKD and diabetes is limited and had little or no effect on kidney failure or composite kidney outcomes. Additionally, adverse events were inconsistently reported. However, many of the trials primarily analyzed CV outcomes data, and not renal endpoints. The semaglutide FLOW study included a dedicated renal population with T2DM and CKD; the agent reached statistically significant reduction for composite major kidney disease events, mean annual rate of change in eGFR, major CV events, and all-cause death when compared to placebo.

Safety

- GI events including nausea, vomiting, diarrhea and constipation are most commonly reported. All the agents except exenatide include a black box warning for thyroid tumor risk, and avoidance in those with Multiple Endocrine Neoplasia syndrome type 2.

Individual Product Characteristics

- Exenatide is only available as a generic product and is administered twice daily. (The once-weekly Bydureon BCise formulation is currently discontinued from the market). Exenatide's warning and adverse event profile uniquely lists drug-induced thrombocytopenia, headache, asthenia, and dizziness. It is not recommended for use in ESRD.
- Liraglutide (Victoza) is available in both branded and generic formulations and is administered once daily. The label does not include a warning for retinopathy, in contrast to the labeling for

dulaglutide, semaglutide and tirzepatide. It has not been studied for use in ESRD but is approved to reduce MACE.

- Dulaglutide (Trulicity) is brand-only and is given once weekly. Advantages include that dosage adjustment is not required for renal impairment and the FDA indication to reduce MACE.
- Semaglutide (Ozempic) is brand-only and is given once weekly; of note, the dosing for diabetes is different than that for weight loss treatment. Semaglutide currently includes the largest number of indications amongst agents within the class – glycemic control, MACE and CKD. It does not require dose adjustment for renal or hepatic impairment.
- Tirzepatide (Mounjaro) is brand-only and is given once weekly. It does not require dose adjustment for renal or hepatic impairment. Dosing is similar for diabetic patients and for weight loss. One disadvantage is the limited number of FDA-approved indications (glycemic control); however, studies are ongoing for reduction of MACE events in patients with T2DM (SURPASS-CVOT trial) as well as T2DM and CKD (TREASURE trial). *Note that following the meeting, on December 17, 2025, the results of the SURPASS-CVOT were published. Tirzepatide was noninferior to dulaglutide for MACE outcomes in patients with T2DM and CV disease.*

Overall Conclusions

- In terms of efficacy for glycemic control, there is a high degree of therapeutic interchangeability for all the drugs in the subclass.
- In terms of efficacy for MACE reduction, dulaglutide, liraglutide and semaglutide have a high degree of therapeutic interchangeability.
- In terms of efficacy for CKD outcomes, there is a low degree of therapeutic interchangeability, as semaglutide in the sole drug approved for this indication.
- In terms of safety: for all reviewed indications, all agents have a high degree of therapeutic interchangeability.

B. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—Relative Cost Effectiveness Analysis and Conclusion

CMA and BIA were performed. The P&T Committee reviewed the solicited bids from manufacturers and CMA and BIA were performed.

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

- The two generically available products—exenatide (generic Byetta) and liraglutide (generic Victoza)—were not substantially lower in cost overall and showed markedly low utilization, consistent with clinical disadvantages relative to the other agents.
- CMA results showed that of the three most-used agents, dulaglutide (Trulicity) was the most cost-effective agent if selected either as a sole UF step-preferred agent or as one of three agents selected as UF with no step therapy requirement, followed by tirzepatide (Mounjaro) and semaglutide (Ozempic).
- The BIA demonstrated that selecting all three agents UF without a step therapy requirement was more cost effective than selecting any one of the three as the sole UF step-preferred product.
- A sensitivity analysis confirmed that the UF no step scenario resulted in more cost avoidance under any realistic assumption of switching to a given step-preferred agent.
- Placement of all three agents as UF without a step therapy offers beneficiaries UF copays and allows for future entrants into this class to be placed UF if warranted.
- While continued increases in utilization and cost are anticipated in this drug class, manufacturer bids are expected to result in substantial cost avoidance relative to current pricing (lower cost per patient treated)

C. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—UF Recommendation

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

- UF
  - dulaglutide (Trulicity)
  - semaglutide (Ozempic) *moves from NF to UF*
  - tirzepatide (Mounjaro) *moves from NF to UF*
- NF
  - exenatide twice daily (generic Byetta)
  - liraglutide (generic Victoza)
- Complete Exclusion – None

- Note that if generic or branded formulations of lixisenatide (Adlyxin), exenatide once weekly (Bydureon BCise) or Victoza return to the market they will be designated as NF.

D. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—Manual PA Criteria

PA criteria apply to all agents within the class, requiring a trial of metformin first. Additionally, exenatide and liraglutide require a trial of both Trulicity and Ozempic. Trulicity currently has an automated look back allowing coverage if the patient has received any diabetic drug in the past 720 days.

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) updated PA criteria for the subclass for new users. An initial trial of metformin is still required first. For exenatide and liraglutide, Trulicity, Ozempic and now Mounjaro are required first. The automated lookback for any diabetic drug will remain for dulaglutide.

The Manual PA criteria are as follows:

1. dulaglutide (Trulicity)

Updates from the November 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Trulicity

Automated PA criteria: The patient has filled a prescription for metformin or any diabetic drug at any MHS Pharmacy point of service (MTFs, retail pharmacies or TRICARE mail order pharmacy) during the previous 720 days.

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

~~Patients currently taking a GLP1RA must have had a trial of metformin first~~.

~~Manual PA criteria:~~ **Manual PA criteria apply to all new uses of Trulicity** if automated criteria are not met, Trulicity is approved ~~(i.e., a trial of metformin is NOT required)~~ if

- The patient has a confirmed diagnosis of Type 2 diabetes mellitus
- The patient has had inadequate response to metformin (alone or in combination) OR
- The patient has experienced any of the following issues on metformin:
  - ~~impaired renal function precluding treatment with metformin OR~~

- history of lactic acidosis OR
- The patient has a contraindication to metformin **(e.g., impaired renal function)**

Non-FDA approved uses are not approved**, including use for weight loss in patients who do not have diabetes**
Prior authorization does not expire

2. semaglutide (Ozempic) and tirzepatide (Mounjaro)

Updates from the November 2025 meeting are in bold and strikethrough
Manual PA criteria apply to all new users of Ozempic and Mounjaro

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

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

- ~~Provider acknowledges that Trulicity is available to TRICARE beneficiaries at a lower copay than Ozempic or Mounjaro. Trulicity also has an indication to reduce the risk of major adverse cardiovascular events in adults with Type 2 diabetes mellitus (T2DM) who have established cardiovascular disease or multiple cardiovascular risk factors, Mounjaro does not have this indication.~~
- The patient has a confirmed diagnosis of Type 2 diabetes mellitus
- The patient has had inadequate response to metformin (alone or in combination) OR
- The patient has experienced any of the following issues on metformin:
  - Acceptable responses: patient cannot swallow tablets due to some documented medical condition – dysphagia, etc., and not due to convenience
  - ~~impaired renal function precluding treatment with metformin OR~~
  - history of lactic acidosis OR
- The patient has a contraindication to **metformin (e.g., impaired renal function)**

Non-FDA approved uses are not approved**, including use for weight loss in patients who do not have diabetes**
Prior authorization does not expire

3. **exenatide twice daily (generic Byetta) and liraglutide (generic Victoza)**

Updates from the November 2025 meeting are in bold and ~~strikethrough~~
Manual PA criteria apply to all new users of exenatide or liraglutide

Manual PA Criteria: ~~Bydureon BCise, Byetta, Victoza, or Adlyxin~~ **Coverage** is approved ~~(i.e., a trial of metformin and Trulicity and Ozempic is NOT required)~~ if

- ~~Provider acknowledges that Trulicity is available to TRICARE beneficiaries at a lower copay than Ozempic or Mounjaro. Trulicity also has an indication to reduce the risk of major adverse cardiovascular events in adults with Type 2 diabetes mellitus (T2DM) who have established cardiovascular disease or multiple cardiovascular risk factors. Adlixyn, Byetta, and Bydureon B-Cise do not have this indication.~~
- The patient has a confirmed diagnosis of Type 2 diabetes mellitus
- The patient has had inadequate response to metformin (alone or in combination) OR
- The patient has experienced any of the following issues on metformin:
  - ~~impaired renal function precluding treatment with metformin OR~~
  - history of lactic acidosis OR
- The patient has a contraindication to **metformin (e.g., impaired renal function)**
- The patient has had **an adverse reaction,** inadequate **response or has a contraindication to all of the following**: Trulicity, Ozempic **and Mounjaro**

Non-FDA approved uses are not approved**, including use for weight loss in patients who do not have diabetes**
PA does not expire

E. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—UF recommendation, PA, and Implementation Period

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 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——METABOLIC DYSFUNCTION AGENTS: INJECTABLE DIABETIC AGENTS SUBCLASS

UF BAP Comments

A. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—UF Recommendation

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

- UF
  - dulaglutide (Trulicity)
  - semaglutide (Ozempic) - *moves from NF to UF*
  - tirzepatide (Mounjaro) *moves from NF to UF*
- NF
  - exenatide twice daily (generic Byetta)
  - liraglutide (generic Victoza)
- Complete Exclusion – None
- Note that if generic or branded formulations of lixisenatide (Adlyxin), exenatide once weekly (Bydureon BCise) or Victoza return to the market they will be designated as NF.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—Manual PA Criteria

The P&T Committee recommended updated manual PA criteria for Trulicity, Ozempic, Mounjaro, generic Byetta and generic Victoza as detailed above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Metabolic Dysfunction Agents: Injectable Diabetic Agents 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. UF DRUG CLASS REVIEW—INSULINS: RAPID -ACTING INSULINS (RAIS) ANALOGS SUBCLASS

P&T Comments

A. Insulins: RAIs Subclass—Clinical Effectiveness Conclusion

Background— The Rapid Acting Insulin (RAI) subclass was last reviewed at the November 2024 DoD P&T Committee meeting, in preparation for a Joint National Contract (JNC) with the Department of Veterans Affairs (VA). A JNC solicitation was not awarded due to manufacturer-projected supply fluctuations and market changes.

The RAIs class is comprised of insulin lispro (Humalog), insulin aspart (Novolog), insulin glulisine (Apidra) and biosimilars and unbranded biologics, which are identical to the originator product. Two new insulin biosimilar formulations have entered the market since the last review, insulin aspart-szjj (Merilog) and insulin aspart-xjhz (Kirsty). The clinical analysis focused on professional treatment guidelines and new information published since November 2024.

The DoD P&T Committee concluded in November 2022 and reaffirmed at the August 2024 meeting ("Process for Evaluating Biosimilars and Biologics") that by FDA approval and definition, biosimilars are equally safe and efficacious, which provides strong competition within products for drug classes with biosimilars. Switching between biosimilar agents and the reference product has not demonstrated clinically meaningful differences in outcomes. Indications may be extrapolated between reference products and biosimilars.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 0 absent) the following:

Efficacy and Safety

- The clinical conclusions from the 2024 class review remain unchanged, finding no clinically relevant differences between

insulin aspart and insulin lispro in ability to lower HbA1c or cause hypoglycemia.

- A review of several professional guidelines confirmed that one RAI is not recommended over another.
- Although there are subtle differences between RAIs in pharmacokinetic profiles in terms of onset and duration of action, there are no clinically relevant differences between the products in outcomes including glycemic control or hypoglycemia.
- A 2025 Expert Consensus Review funded by the manufacturer of insulin lispro-aabc (Lyumjev) and insulin aspart/niacinamide (Fiasp) failed to prove compelling benefits of these two products compared to other RAIs. Lyumjev and Fiasp were possibly beneficial in certain populations and have a quicker onset of action; however, the clinical evidence does not show sustained effectiveness or superior outcomes. This was not a systematic review.

Individual Product Characteristics

- *Insulin aspart (Novolog)* is the originator aspart product and is available in pens, vials, and cartridges; it is approved in children down to two years of age. Novolog has a long history of use in the MHS.
- *Insulin lispro (Humalog)* is the originator lispro product and is available in pens, vials, and cartridges. It is approved in children as young as three years of age. Available products include a U-200 formulation and Junior Kwikpen for half-unit dosing in the pediatric space. U-200 insulin formulations are sometimes used in patients with highly elevated HbA1c levels who require more than 60 units of insulin in multiple daily doses.

- An unbranded biologic insulin lispro formulation is available, which also includes a Junior Kwik pen that is the identical product as the originator Humalog Junior Kwik pen and from the same manufacturer.
    - *Insulin lispro (Admelog)* is a "follow-on" lispro product approved via the FDA 505(b)(2) pathway using data from Humalog (prior to the establishment of the biosimilar pathway) in 2017. It does not display clinical superiority over Humalog based on previous P&T Committee drug class reviews.
    - *Insulin glulisine (Apidra)* demonstrated more adverse events when used in insulin pumps along with higher rates of documented hypoglycemia compared to the other RAIs.

- *Insulin lispro-aabc (Lyumjev)* is available in two strengths. The U-100 formulation is compatible with insulin pumps; the U-200 formulation is available for patients requiring larger doses but is not compatible with pumps.
- *Insulin aspart niacinamide (Fiasp)* is an insulin aspart formulation containing niacinamide, a form of vitamin B3. There is no data to show that Fiasp is superior to other rapid-acting insulins, and it has been completely excluded from the formulary since November 2019.
- *The new biosimilars insulin aspart-szjj (Merilog) and insulin aspart-xjhz (Kirsty)* do not provide a compelling clinical advantage over existing agents. Merilog is not approved for use in insulin pumps and Kirsty is non-Trade Agreement Act compliant.
- *TEMPO formulations* are available for two lispro formulations – Humalog and Lyumjev. The TEMPO pens are identical to the Kwik Pens, however when the TEMPO Smart Button is attached, it can transmit data via Bluetooth to a smart phone application. The TEMPO system also includes a phone app, glucometer, and TEMPO Smart Button; these components are not part of the TRICARE pharmacy benefit.

Therapeutic Interchangeability and Clinical Coverage

- Overall, there is a high degree of interchangeability among the RAIs.
- One RAI is needed on the formulary to meet the needs of the majority of DoD beneficiaries. A "Junior" formulation should remain on formulary to provide small doses for pediatric patients. Additionally, an RAI compatible with insulin pumps is required.
- Due to a history of national shortages, consideration of an additional RAI on the formulary is necessary to meet healthcare demand.

B. Insulins: RAIs Subclass—Relative Cost Effectiveness Analysis and Conclusion

CMA and BIA were performed. The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- The cost analysis for the RAIs included the influence of shortages and termination of pricing agreements on current pricing.

- CMA results showed U-100 and U-200 rapid acting insulins recommended for UF were more cost-effective than those recommended for NF, as outlined below. Those recommended for complete exclusion were not cost-effective.
- BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as UF, NF or completely excluded from the formulary. BIA results showed that the below UF, NF and completely excluded recommendations demonstrated the greatest cost avoidance for the MHS.

C. Insulins: RAIs Subclass—UF Recommendation

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

U-100 Insulins

- UF
  - insulin aspart (Novolog Flexpen and vial)
  - insulin lispro (Humalog Kwikpen and vial)
  - insulin lispro (Humalog Kwikpen unbranded biologic)
  - Insulin lispro Junior (Humalog Kwikpen Junior unbranded biologic)
  - insulin lispro – aabc (Lyumjev Kwikpen and vial)
  - insulin aspart–szjj (Merilog)
- NF
  - insulin lispro Junior Kwikpen branded (Humalog Kwikpen Junior) – *moves from UF to NF*
  - insulin lispro TEMPO (Humalog TEMPO) – *moves from UF to NF*
  - insulin aspart–xjhz (Kirsty)
  - insulin aspart (Admelog)
  - insulin glulisine (Apidra)
- Complete Exclusion
  - insulin aspart/niacinamide (Fiasp)
  - insulin lispro-aabc TEMPO (Lyumjev TEMPO) – *moves from NF to complete exclusion status*

U-200 Insulins

- UF
  - insulin lispro U-200 (Humalog Kwikpen)
- NF
  - insulin lispro-aabc U-200 (Lyumjev Kwikpen) – *moves from UF to NF*
- Complete Exclusion - None

D. Insulins: RAIs Subclass—Manual PA Criteria

PA currently applies to Apidra, Admelog and the Lyumjev TEMPO and Humalog TEMPO pens. The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the PAs as outlined below, in new users.

- PA is not required for the branded insulin lispro Humalog Junior Kwik pen, intended for pediatric patients.
- PA will apply to the RAIs recommended for NF status (with the exception of branded Humalog Junior), as these products currently have or are expected to have low utilization in the MHS. PA will only apply to new users of Apidra, Admelog, Kirsty, Humalog TEMPO, Lyumjev TEMPO pens, and Lyumjev U-200.
- For Apidra and Admelog, the current automated lookback will be removed, however patients are still required to try Novolog, Humalog or unbranded biologic insulin lispro.
- For Kirsty and the Humalog TEMPO pen, a trial of Novolog, Humalog and insulin lispro unbranded biologic will be required in new users.
- The PA currently in place for Lyumjev TEMPO pen will remain until implementation of the complete exclusion status.
- For the Lyumjev U-200 product, a trial of Humalog U-200 is required first in new users.

The Manual PA criteria are as follows:

1. **insulin glulisine (Apidra)**
   insulin lispro (Admelog)
   insulin aspart-xjhz (Kirsty)
   insulin lispro TEMPO (Humalog TEMPO)

   Updates from the November 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Apidra Admelog, Kirsty and Humalog TEMPO

~~Automated PA Criteria: The patient has filled a prescription for insulin aspart (Novolog) and insulin lispro (Humalog or authorized generic lispro) at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days~~

Manual PA criteria: ~~if automated criteria are not met,~~ Apidra, Admelog, **Kirsty or Humalog TEMPO** are approved if all criteria are met:

- Provider acknowledges that Novolog, Humalog ~~and the authorized generic~~ insulin lispro **unbranded biologic, insulin lispro-aabc (Lyumjev) and insulin aspart szjj (Merilog) do not require prior authorization.** ~~are the DoD's preferred rapid-acting insulins. If the prescription is for Novolog, Humalog or the authorized generic insulin lispro, prior authorization is not required.~~
- The patient has diabetes AND
  - The patient has tried and failed insulin aspart (Novolog) AND
  - The patient has tried and failed insulin lispro (Humalog) or authorized generic unbranded biologic insulin lispro)

  OR
- The patient is using an insulin pump/continuous subcutaneous insulin infusion (CSII) and is stabilized on insulin glulisine (Apidra) or insulin lispro (Admelog). **Note this does not apply to insulin aspart-xjhz (Kirsty) or Humalog TEMPO.**

Non-FDA-approved uses are not approved

PA does not expire

2. **insulin lispro-aabc U-200 (Lyumjev U-200)**
   Manual PA criteria apply to all new users of Lyumjev U-200

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

   - Provider acknowledges that Humalog U-200 does not require prior authorization.
   - The patient has diabetes AND
   - The patient has tried and failed Humalog U-200
   -

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

3. **Lyumjev TEMPO**
   Manual PA criteria apply to all new users of Lyumjev TEMPO Pen

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

   - Provider acknowledges that Lyumjev TEMPO pen 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
   - Provider acknowledges that Novolog, Humalog, insulin lispro unbranded biologic, insulin lispro-aabc (Lyumjev) and insulin aspart szjj (Merilog) do not require prior authorization
   - The patient has diabetes AND
     - The patient has tried and failed insulin aspart (Novolog) AND
     - The patient has tried and failed insulin lispro (Humalog) or authorized generic unbranded biologic insulin lispro)

   Non FDA-approved uses are not approved

   PA does not expire until implementation of Complete Exclusion status

E. Insulins: RAIs Subclass—UF recommendation, PA, and Implementation Period

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday 90 days after signing of the minutes in all points of service, and 2) DHA send letters to patients affected by the recommendation for NF status for branded Humalog Kwikpen Junior, Humalog TEMPO pen and Lyumjev U-200 pen; and 3) DHA send letters at 60 and 30 days prior to implementation for the patients affected by the recommendation for Complete Exclusion status for Lyumjev TEMPO pen.

VII. UF DRUG CLASS REVIEW—RAPID -ACTING INSULINS (RAIS) ANALOGS S SUBCLASS

UF BAP Comments

A. Insulins: RAIs Subclass—UF Recommendation

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

U-100 Insulins

- UF
  - insulin aspart (Novolog Flexpen and vial)
  - insulin lispro (Humalog Kwikpen and vial)
  - insulin lispro (Humalog Kwikpen unbranded biologic)
  - Insulin lispro Junior (Humalog Kwikpen Junior unbranded biologic)
  - insulin lispro – aabc (Lyumjev Kwikpen and vial)
  - insulin aspart–szjj (Merilog)
- NF
  - insulin lispro Junior Kwikpen branded (Humalog Kwikpen Junior) – *moves from UF to NF*
  - insulin lispro TEMPO (Humalog TEMPO) – *moves from UF to NF*
  - insulin aspart–xjhz (Kirsty)
  - insulin aspart (Admelog)
  - insulin glulisine (Apidra)
- Complete Exclusion
  - insulin aspart/niacinamide (Fiasp)
  - insulin lispro-aabc TEMPO (Lyumjev TEMPO) – *moves from NF to complete exclusion status*

U-200 Insulins

- UF
  - insulin lispro U-200 (Humalog Kwikpen)
- NF
  - insulin lispro-aabc U-200 (Lyumjev Kwikpen) – *moves from UF to NF*
- Complete Exclusion - None

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Insulins: RAIs Subclass—Manual PA Criteria

The P&T Committee recommended updated manual PA criteria for Apidra, Admelog, Kirsty, Humalog TEMPO, Lyumjev TEMPO, and Lyumjev U-200 as detailed above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Insulins: RAIs Subclass—UF Recommendation, PA Criteria, and Implementation Period

The P&T Committee recommended 1) an effective date of the first Wednesday 90 days after signing of the minutes in all points of service, and 2) DHA send letters to patients affected by the recommendation for NF status for branded Humalog Kwikpen Junior, Humalog TEMPO pen and Lyumjev U-200 pen; and 3) DHA send letters at 60 and 30 days prior to implementation for the patients affected by the recommendation for Complete Exclusion status for Lyumjev TEMPO pen.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions— The P&T Committee agreed (20 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5).

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

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

- UF
  - brensocatib (Brinsupri) – Pulmonary I Agent for non-cystic fibrosis bronchiectasis
  - delgocitinib 2% cream (Anzupgo) – Atopy Agent for chronic hand eczema
  - dordaviprone (Modeyso) – Oncological Agent for glioma
  - gepotidacin (Blujepa) – Antibiotic for urinary tract infections (UTI)
  - imlunestrant (Inluriyo) – Oncological Agent for breast cancer
  - lecanemab-irmb injection (Leqembi Iqlik) – Alzheimer's Agent
  - nalmefene injection (Zurnai) – Alcohol Deterrents-Narcotic Antagonists
  - rilzabrutinib (Wayrilz) – Hematological Agents: Platelets, for thrombocytopenia
  - sebetralstat (Ekterly) – Hereditary Angioedema (HAE)– Acute treatment
  - sepiapterin oral powder (Sephience) – Miscellaneous Metabolic Agents for hyperphenylalaninemia in phenylketonuria
  - sitagliptin 25 mg/mL oral solution (Brynovin) – Non-Inulin Diabetes Drugs – Dipeptidyl Peptidase-4 (DPP-4) inhibitor
  - sulopenem etzadroxil /probenecid (Orlynvah) – Beta lactam Antibiotic for UTI
  - zongertinib (Hernexeos) – Oncological Agents for Non-small Cell Lung Cancer (NSCLC)
- NF
  - dasatinib (Phyrago) – Oncological Agent for Chronic Myelogenous Leukemia and Acute Lymphocytic Leukemia
  - dihydroergotamine mesylate injection (Brekiya) – Migraine Agent

- donidalorsen injection (Dawnzera) – HAE - prophylaxis Agent
- gepirone (Exxua) – Antidepressants and Non-Opioid Pain Syndrome Agents
- metoprolol tartrate 10 mg/mL oral solution (Lopressor) – Beta Blockers and Hydrochlorothiazide Combination Agents

- Complete Exclusion
  - bumetanide nasal spray (Enbumyst) – Diuretics
    - Enbumyst was recommended for complete exclusion status as it has little to no clinical benefit relative to the other loop diuretics, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include bumetanide tablets, furosemide tablets, and torsemide tablets.
  - escitalopram 15 mg caps (no brand name) – Antidepressants and Non-Opioid Pain Syndrome Agents
    - Escitalopram 15 mg capsules were recommended for complete exclusion status as it has little to no clinical benefit relative to the other selective serotonin reuptake inhibitors (SSRIs), and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include other selective serotonin reuptake inhibitors SSRIs, including citalopram, escitalopram, sertraline, and fluoxetine tablets and oral solutions.
  - nitisinone (Harliku) – Miscellaneous Replacement Enzymes for alkaptonuria-associated urine homogentisic acid
    - Harliku was recommended for complete exclusion status as it has little to no clinical benefit relative to the other nitisinone formulations, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include other nitisinone products such as Orfadin and generic Nityr.

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

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

- Applying manual PA criteria to new users of Brinsupri, requiring specialist prescribing and a trial of azithromycin.
- Applying manual PA criteria to new users of Orlynvah, and Blujepa, requiring culture-proven bacterial UTI, and contraindications to or antibiotic resistance to standard UTI antimicrobials. Automated specialist bypass was added to allow PA approval if the prescriber is a urologist, urogynecologist or infectious disease specialist.
- Applying manual PA criteria to new users of Leqembi, requiring specialist prescribing and medical documentation that the patient has completed 18 months of initial treatment with intravenous lecanemab-irmb (Leqembi).
- Applying manual PA criteria to new users of Exxua, requiring a trial of three formulary antidepressants first.
- Applying manual PA criteria to new users of Anzupgo, requiring a trial of topical corticosteroids, and topical calcineurin inhibitors, consistent with the PA criteria for other products used to treat eczema.
- Applying manual PA criteria to the hematology/oncology drugs Modeyso, Inluriyo, Wayrilz, Hernexeos, and Phyrago.
- Applying manual PA criteria to new and current users of Brekiya, requiring a trial of two triptans and nasal dihydroergotamine spray first.
- Applying manual PA criteria to new users of Ekterly, Brynovin, Dawnzera, Sephience and Lopressor oral solution.
- Applying manual PA criteria to new and current users of Enbumyst nasal spray, escitalopram 15 mg capsules and Harliku until implementation of complete exclusion status.

The Manual PA criteria are as follows:

1. **brensocatib (Brinsupri)**

   Manual PA criteria apply to all new users of brensocatib (Brinsupri)

   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 pulmonologist, infectious disease specialist, or rheumatologist
   - Patient has clinical bronchiectasis confirmed by chest CT scan

- For adults – the patient had at least 2 exacerbations in the past 12 months requiring an antibiotic prescription, urgent care or emergency room visit or hospitalization
- For pediatric patients – the patient had at least 1 exacerbation in the past 12 months requiring an antibiotic prescription, urgent care or emergency room visit or hospitalization
- The respiratory symptoms being treated with brensocatib are not primarily due to asthma or COPD
- Patient does not have cystic fibrosis
- Patient does not require oxygen for more than 12 hours per day
- Patient is not currently smoking
- The patient has had an inadequate response, adverse reaction, or contraindication to azithromycin

Non-FDA approved uses are not approved

PA does not expire

2. bumetanide nasal spray (Enbumyst)

Manual PA criteria apply to all new and current users of bumetanide nasal spray (Enbumyst)

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

- Provider acknowledges that Enbumyst will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the DoD P&T meeting minutes by the Director, DHA
- Provider acknowledges that other loop diuretics are available to TRICARE beneficiaries, including bumetanide tablets, furosemide tablets, and torsemide and do not require prior authorization
- Patient is 18 years of age or older
- Patient has edema associated with congestive heart failure, hepatic and renal disease, including nephrotic syndrome
- Patient is experiencing an increase in signs and symptoms of fluid overload
- Patient has failed a trial of two oral loop diuretics including
  - furosemide
  - bumetanide
  - torsemide

- ethacrynic acid

- Patient does not have rhinitis, nasal congestion, or nasal structural abnormalities
- Patient is stable and does not require emergency care or hospitalization for heart failure, acute pulmonary edema or other condition that could result in hospitalization

Non-FDA approved uses are not approved

PA does not expire until after implementation of complete exclusion status

3. dasatinib (Phyrago)

Manual PA criteria apply to all new users of dasatinib (Phyrago)

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

- Phyrago tablets are prescribed by or in consultation with a hematologist/oncologist
- The patient has one of the following diagnoses:
  - Adults 18 years of age or older with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase
  - Adults 18 years of age or older with Ph+ CML who no longer benefit from, or did not tolerate, other treatment, including imatinib
  - Adults 18 years of age or older with Ph+ acute lymphoblastic leukemia (Ph+ ALL) who no longer benefit from, or did not tolerate, other treatment
  - Pediatric patients 1 year of age and older with Ph+ CML in chronic phase.
  - Pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy.
- Patient is receiving concurrent H2 blockers (e.g., famotidine, ranitidine, cimetidine) or Proton Pump Inhibitors (PPIs) (e.g., omeprazole esomeprazole, rabeprazole, lansoprazole).
  - The provider must document the reason why the patient requires long-term concurrent H2 blockers or proton pump inhibitors. _____ OR
  - The patient has been referred to GI for additional work up (e.g., endoscopy)
- 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 expires yearly

Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for an additional year if all the criteria are met:

- The patient has a documented reason to remain on concurrent H2 blockers of PPIs

4. delgocitinib 2% cream (Anzupgo)

Manual PA criteria apply to all new users of delgocitinib (Anzupgo)

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

- Patient is 18 years of age or older
- Patient has moderate to severe chronic hand eczema
- Prescribed by a dermatologist, allergist, or immunologist
- The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:
  - High potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
  - Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
- The patient is not using other immuno-biologics (e.g., Humira, Stelara etc.), other JAK inhibitors (e.g., Xeljanz, Olumiant, Rinvoq), or potent immunosuppressants such as azathioprine or cyclosporine

Non-FDA-approved uses are not approved.

Prior authorization 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:

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

5. dihydroergotamine mesylate injection (Brekiya)

Manual PA criteria apply to all new and current users of dihydroergotamine mesylate subcutaneous injection (Brekiya)

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

- Patient is 18 years or older
- Patient is using Brekiya for the following indications
  - acute treatment of migraines with or without aura OR
  - cluster headaches
- Medication is prescribed by or in consultation with a neurologist
- Patient has a contraindication to, intolerability to, or has failed a trial of ALL the following:
  - Two different triptans (one must be either nasal or injectable): sumatriptan, rizatriptan, zolmitriptan, eletriptan
  - Nasal dihydroergotamine spray

Non-FDA approved uses are not approved

PA does not expire

6. donidalorsen injection (Dawnzera)

Manual PA criteria apply to all new users of donidalorsen (Dawnzera)

Manual PA criteria: Coverage is approved if all apply:

- Patient is 12 years of age or older
- The patient has a diagnosis of hereditary angioedema
- Prescribed by an allergist, immunologist, rheumatologist, or HAE specialist
- Medication is prescribed for prophylaxis to prevent attacks of hereditary angioedema
- The patient must have monthly HAE attacks or a history of severe attacks that require prophylaxis treatment (i.e., greater than or equal to 2 HAE attacks/month, or laryngeal attacks)
- The patient is not currently receiving another drug for HAE prophylaxis (e.g., Orladeyo, Takhzyro, Cinryze or Haegarda will not be used concomitantly)
- The patient has had an inadequate response, adverse reaction, or contraindication to all the following:

- One C1-inhibitor (e.g., Cinryze, Haegarda, Berinert, Ruconest)
- One Kallikrein inhibitor (e.g., Takhzyro, Orladeyo)

Non-FDA-approved uses not approved

Prior Authorization does not expire

7. dordaviprone (Modeyso)

Manual PA criteria apply to all new users of dordaviprone (Modeyso)

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

- Patient is one year of age or older
- Prescribed by a hematologist or oncologist
- Patient has diagnosis of diffuse midline glioma (DMG)
- Patient has a histone 3 (H3) K27M mutation
- Patient has progressive disease
- Patient has received at least one prior therapy. Note: Examples of prior therapy include radiation, temozolomide, procarbazine, lomustine, or vincristine.
- 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 as noted above

PA does not expire

8. escitalopram oxalate 15 mg capsules (no brand name)

Manual PA criteria apply to all new and current users of escitalopram oxalate 15 mg capsules

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

- Provider acknowledges that escitalopram oxalate 15 mg capsules will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the DoD P&T meeting minutes by the Director, DHA

- Provider acknowledges that other escitalopram formulations are available to TRICARE beneficiaries and do not require prior authorization
- Patient has major depressive disorder and is 12 years of age or older and younger than 65 years of age
- Patient has generalized anxiety disorder and is younger than 65 years of age
- Provider must document why the patient cannot take formulary alternatives (blank write in)
    - Acceptable responses include that the patient has tried and failed escitalopram 5 mg tablets, escitalopram 10 mg tablets, and escitalopram 20 mg tablets

Non-FDA approved uses are not approved

PA does not expire until after implementation of complete exclusion status

9. gepirone (Exxua)

Manual PA criteria apply to all new users of gepirone (Exxua)

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

- Patient is 18 years of age or older
- Provider acknowledges that patient and provider have discussed that non-pharmacologic interventions (i.e., cognitive behavioral therapy (CBT), sleep hygiene) are encouraged to be used in conjunction with this medication.
- Provider has complied with the safety and monitoring criteria (i.e., EKG to monitor for QT prolongation)
- Patient is being treated for major depressive disorder and:
    - The patient has a contraindication to, intolerability to, or has failed a trial of THREE formulary antidepressant medications. For example,
        - SSRIs (selective serotonin reuptake inhibitors, for example, citalopram, escitalopram, fluoxetine, paroxetine, sertraline)
        - SNRIs (serotonin/norepinephrine reuptake inhibitors, for example, amitriptyline, desipramine, imipramine, nortriptyline)
        - mirtazapine
        - bupropion

- trazodone immediate release
- nefazodone and
- monoamine oxidase inhibitors
- Note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated doses

Non-FDA approved uses are not approved

PA expires does not expire

10. gepotidacin (Blujepa)

Manual PA criteria apply to all new users of gepotidacin (Blujepa)

Automated PA Criteria: When prescribed by a urologist, urogynecologist, or infectious disease provider specialist to a patient 12 years or age or older, prior authorization is not required OR

Manual PA criteria: If automated criteria are not met, coverage is approved if all criteria are met:

- Patient is 12 years of age or older
- Patient weighs 40 kilograms or more
- Patient has an uncomplicated urinary tract infection (uUTI) (i.e., afebrile, infection that is limited to the bladder, and non-catheter associated infection)
- Patient has a urine culture indicating the organism is *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus,* or *Enterococcus faecalis*
- Patient has a contraindication to or has culture proven resistance to ALL alternative oral antibiotic treatment options (i.e. nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin, fluoroquinolones, penicillins, and cephalosporins)

Non-FDA approved uses are not approved

PA expires after each course of therapy. PA renewal is not allowed; no refills allowed; each course of therapy requires a new PA

11. imlunestrant (Inluriyo)

Manual PA criteria apply to all new users of imlunestrant (Inluriyo)

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 a diagnosis of ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer
- Patient must have disease progression following at least one prior line of endocrine therapy (e.g., letrozole, fulvestrant)
- 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

12. lecanemab-irmb injection (Leqembi Iqlik)

Manual PA criteria apply to all new users of lecanemab-irmb (Leqembi IQLIK)

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

- Medication is being prescribed by a neurologist, psychiatrist, or specialist in geriatric medicine
- Patient has a diagnosis of Alzheimer's disease
- Patient is being treated for mild cognitive impairment or mild dementia
- Patient has completed 18 months of intravenous lecanemab (Leqembi) treatment and achieved maintenance dosing
    - Prescriber must submit medical documentation to confirm completion of 18 months of initial treatment with intravenous lecanemab (Leqembi)

Non-FDA approved uses are not approved

Prior authorization does not expire

13. metoprolol tartrate 10 mg/mL oral solution (Lopressor)

Manual PA criteria apply to all new users of metoprolol tartrate oral solution (Lopressor)

Age edit: PA not required for patients 12 years of age and younger

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

- Patient has hypertension or angina
- Provider must write in why the patient requires Lopressor oral solution and cannot crush metoprolol tablets
    - Acceptable responses: Patient requires a liquid formulation due to documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis) and not due to convenience

Non-FDA-approved uses are not approved

PA does not expire

14. nitisinone (Harliku)

Manual PA criteria apply to all new and current users of nitisinone (Harliku)

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

- Provider acknowledges that Harliku will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the DoD P&T meeting minutes by the Director, DHA
- Provider acknowledges that other formulations of nitisinone are available to TRICARE beneficiaries and do not require prior authorization
- Patient is 18 years of age or older
- Patient has a diagnosis of alkaptonuria (AKU)
- The provider must document why the patient cannot take formulary alternatives, including generic nitisinone 2 mg capsules (blank write-in)
    - Acceptable responses include that the patient has experienced a serious allergic reaction (i.e., hives, anaphylaxis) to an excipient in nitisinone 2 mg capsules

Non-FDA approved uses are not approved

PA does not expire until after implementation of complete exclusion status

15. rilzabrutinib (Wayrilz)

Manual PA criteria apply to all new users of rilzabrutinib (Wayrilz)

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

- Patient is 18 years of age or older
- Medication is prescribed by a hematologist or oncologist
- Patient has had primary Immune Thrombocytopenic Purpura (ITP) for at least 3 months
- Patient had two platelet counts of less than 30×10^9/L at least 5 days apart
- Patient has documented intolerance, insufficient response, or any contraindication to all the following: corticosteroids, IVIG, and a thrombopoietin receptor agonist (eltrombopag or and avatrombopag)

Non-FDA approved uses are not approved

PA does not expire

16. sebetralstat (Ekterly)

Manual PA criteria apply to all new users of sebetralstat (Ekterly)

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

- Patient is 12 years of age or older
- Prescribed by an allergist, immunologist, rheumatologist, OR in consultation with an HAE specialist
- Patient has a diagnosis of hereditary angioedema (HAE)
- Ekterly will be used for the acute treatment of HAE attacks
- Patient is not currently receiving another drug for the acute treatment of HAE attacks
- The patient has had an inadequate response, adverse reaction, or contraindication to generic icatibant

Non-FDA approved uses are not approved.

PA does not expire

17. sepiapterin oral powder (Sephience)

Manual PA criteria apply to all new users of Sephience

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

- Patient is 1 month of age or older
- Prescribed by or in consultation with a metabolic disease specialist

- Patient has a diagnosis of phenylketonuria with hyperphenylalaninemia
- Patient has uncontrolled blood phenylalanine concentrations >360 micromol/L while on at least one existing treatment modality (e.g., restriction of dietary phenylalanine)
- Patient is not receiving concomitant pharmacologic treatment for PKU (e.g., sapropterin, pegvaliase)
- Requested medication must be used in conjunction with a phenylalanine restricted diet
- Patient has had an inadequate response, adverse reaction, or contraindication to generic sapropterin up to maximally tolerated dose

Non-FDA-approved uses are not approved

PA expires in 6 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:

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

18. sitagliptin 25 mg/mL oral solution (Brynovin)

Manual PA criteria apply to all new users of sitagliptin oral solution (Brynovin)

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

- Provider acknowledges that Januvia and its combination products are DoD's preferred dipeptidyl peptidase-4 inhibitors and are available to TRICARE beneficiaries without requiring prior authorization.
- Patient is 18 years or older
- Patient has Type 2 Diabetes Mellitus (T2DM)
- Provider must explain why the patient requires Brynovin oral solution and cannot take Januvia tablets
    - Acceptable responses: Patient needs a liquid formulation due to documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis) and not due to convenience

Non-FDA approved uses are not approved

PA does not expire

19. sulopenem etzadroxil/probenecid (Orlynvah)

Manual PA criteria apply to all new users of sulopenem etzadroxil and probenecid (Orlynvah)

Automated PA Criteria: When prescribed by a urologist, urogynecologist, or infectious disease provider specialist to a patient 18 years of age or older, prior authorization is not required.
OR

Manual PA criteria: If automated criteria are not met, coverage is approved if all criteria are met:

- The provider acknowledges that all generic antibiotics for the treatment of UTI do not require prior authorization
- Patient is 18 years of age or older
- Patient has a diagnosis of uncomplicated urinary tract infection (i.e., afebrile, infection that is limited to the bladder, and non-catheter associated infection)
- Patient has a culture proven infection from the Enterobacterales family (e.g. *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis*). Note: This drug does not cover Pseudomonas aeruginosa
- Patient has a contraindication to or has culture proven resistance to all alternative oral antibacterial treatment options (i.e., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin, fluoroquinolone, or beta-lactam)

Non-FDA approved uses are not approved

PA expires after each course of therapy. PA renewal is not allowed; no refills allowed; each course of therapy requires a new PA

20. zongertinib (Hernexeos)

Manual PA criteria apply to all new users of zongertinib (Hernexeos)

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 a diagnosis of unresectable or metastatic NSCLC with confirmed HER2 (ERBB2) tyrosine kinase domain activating mutations
- Patient has received prior systemic therapy

- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: 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, and Implementation Period

The P&T Committee recommended (20 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.
- **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.

VIII. 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
  - brensocatib (Brinsupri) – Pulmonary I Agent for non-cystic fibrosis bronchiectasis
  - delgocitinib 2% cream (Anzupgo) – Atopy Agent for chronic hand eczema
  - dordaviprone (Modeyso) – Oncological Agent for glioma
  - gepotidacin (Blujepa) – Antibiotic for urinary tract infections (UTI)
  - imlunestrant (Inluriyo) – Oncological Agent for breast cancer

    - lecanemab-irmb injection (Leqembi Iqlik) – Alzheimer's Agent
    - nalmefene injection (Zurnai) – Alcohol Deterrents-Narcotic Antagonists
    - rilzabrutinib (Wayrilz) – Hematological Agents: Platelets, for thrombocytopenia
    - sebetralstat (Ekterly) – Hereditary Angioedema (HAE)– Acute treatment
    - sepiapterin oral powder (Sephience) – Miscellaneous Metabolic Agents for hyperphenylalaninemia in phenylketonuria
    - sitagliptin 25 mg/mL oral solution (Brynovin) – Non-Inulin Diabetes Drugs – Dipeptidyl Peptidase-4 (DPP-4) inhibitor
    - sulopenem etzadroxil /probenecid (Orlynvah) – Beta lactam Antibiotic for UTI
    - zongertinib (Hernexeos) – Oncological Agents for Non-small Cell Lung Cancer (NSCLC)
- NF
    - dasatinib (Phyrago) – Oncological Agent for Chronic Myelogenous Leukemia and Acute Lymphocytic Leukemia
    - dihydroergotamine mesylate injection (Brekiya) – Migraine Agent
    - donidalorsen injection (Dawnzera) – HAE - prophylaxis Agent
    - gepirone (Exxua) – Antidepressants and Non-Opioid Pain Syndrome Agents
    - metoprolol tartrate 10 mg/mL oral solution (Lopressor) – Beta Blockers and Hydrochlorothiazide Combination Agents
- Completely Excluded
    - bumetanide nasal spray (Enbumyst) – Diuretics
    - escitalopram 15 mg caps (no brand name) – Antidepressants and Non-Opioid Pain Syndrome Agents
    - nitisinone (Harliku) – Miscellaneous Replacement Enzymes for alkaptonuria-associated urine homogentisic acid

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:

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

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 three 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.

a) **Antihistamine-1: First Generation and Combos—clemastine 2.68 mg tablets (Clemasza)—**This clemastine tablet is less cost-effective than other clemastine tablets that are available in the same strength.

b) **Anticholinergics Antispasmodics—dicyclomine 40 mg tablets—** This dicyclomine tablet formulation is less cost-effective than currently available dicyclomine tablets and capsules. The 40 mg dose can be achieved using other available formulations.

c) **Pain Agents: NSAIDs—flurbiprofen 100 mg tablets (Lurbiro)—** There are other flurbiprofen 100 mg tablets formulations and other NSAIDs that are more cost-effective than this product.

The Manual PA criteria are as follows:

1. **clemastine 2.68 mg tablets (Clemasza)**

   Manual PA criteria apply to all new users of Clemasza

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

   - Provider acknowledges other formulations of clemastine are available without prior authorization.
   - Provider must explain why the patient requires Clemasza and cannot take the cost-effective clemastine 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 clemastine formulations

   Non-FDA approved uses are not approved

   PA does not expire

2. **dicyclomine 40 mg tablet**

   The PA criteria are as follows:

   Manual PA criteria apply to all new users of dicyclomine 40 mg tabs

   Manual PA criteria: dicyclomine 40 mg tablets are approved if all criteria are met:

   - Provider acknowledges other formulations of dicyclomine are available without prior authorization.
   - Provider must explain why the patient requires dicyclomine 40 mg tablet sand cannot take the cost-effective generic dicyclomine 10 mg or 20 mg 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 bisoprolol formulations

Non-FDA approved uses are not approved

PA does not expire

3. flurbiprofen (Lurbiro)

Manual PA criteria apply to all new users of Lurbiro

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

- Provider acknowledges other formulations of flurbiprofen are available without prior authorization.
- Provider must explain why the patient requires Lurbiro and cannot take the cost-effective flurbiprofen 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 buspirone formulations

Non-FDA approved uses are not approved

PA 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 (20 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for clemastine (Clemsza), dicyclomine 40 mg tablet, and flurbiprofen (Lurbiro) in new 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.

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

UF BAP Comments

The P&T Committee recommended manual PA for clemastine (Clemsza), dicyclomine 40 mg tablet, and flurbiprofen (Lurbiro) 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:

XI. 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 (20 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users.

a) **Antihemophilic Agents: Non-Factor Agents—concizumab-mtci (Alhemo)—**The PA for Alhemo was updated to allow for the new indication for hemophilia A or B without inhibitors. Previously, Alhemo was only indicated in hemophilia A or B with inhibitors.

b) **Hematological Agents: Platelets—avatrombopag (Doptelet)**—Doptelet received an expanded age indication for thrombocytopenia in pediatric patients one year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. The Doptelet manual PA criteria were updated to remove a minimum age for ITP.

c) **Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Preventative—fremanezumab (Ajovy)—**The manual PA was updated to allow for an expanded age indication for episodic migraine prevention to include pediatric patients 6-17 years old and weighing greater than or equal to 45kg.

d) **Atopy—ruxolitinib 1.5% cream (Opzelura)**—Opzelura is now indicated in children as young as 2 years old with atopic dermatitis. The PA criteria were updated accordingly.

e) **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors—apremilast (Otezla)—**The manual PA for Otezla was updated to allow for an expanded age indication for psoriatic arthritis to include pediatric patients 6-17 years old.

f) **Oncological Agents: Poly ADP-Ribose Polymerase (PARP) Inhibitors—niraparib (Zejula)**—The FDA narrowed Zejula's

indication for first-line maintenance treatment of advanced ovarian cancer to those with homologous recombination deficiency (HRD)-positive tumors only. Additional edits were made to the Zejula PA to align with ongoing oncology standardization efforts. For more information on oncology standardization, please refer to the November 2024 P&T meeting minutes.

g) **Diabetes Non-Insulin: Oral GLP-1RAs—semaglutide (Rybelsus)—**Rybelsus is now indicated to reduce the risk of MACE in type 2 diabetic adults. The current PA states that Rybelsus has not been proven for MACE. This line will be removed due to this new indication and supporting data.

h) **Hematological Agents—pegcetacoplan (Empaveli)—**The manual PA criteria for Empaveli were updated to allow for treatment of complement 3 glomerulopathy (C3G) and immune-complex membranoproliferative glomerulonephritis (IC-MPGN). The PA criteria are based on the VALIANT study.

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

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) implementation for the updates to the PA criteria for Alhemo, Doptelet, Ajovy, Opzelura, Otezla, Zejula, Rybelsus, and Empaveli in new users 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 Alhemo, Doptelet, Ajovy, Opzelura, Otezla, Zejula, Rybelsus, and Empaveli 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:

XII. 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 (20 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for two drugs. The updated PA criteria outlined below will apply to new users.

a) **Oncological Agents: 2nd Generation Antiandrogens—darolutamide (Nubeqa)**—The Nubeqa PA was updated based on provider feedback and National Comprehensive Cancer Network (NCCN) guideline updates. The PA now aligns with NCCN guidelines on Nubeqa use with docetaxel and on high vs. low volume metastases.

b) **Pulmonary Arterial Hypertension Agents—sotatercept (Winrevair)—**The manual PA was updated to remove the current diuretic requirement. In the STELLAR trial used to gain FDA approval, not all the participants were receiving diuretics. The P&T Committee also reviewed an analysis of background medications for patient dispensed Winrevair.

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

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

XIII. 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 Nubeqa and Winrevair 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:***

XIV. UTILIZATION MANAGEMENT—REMOVAL OF PA AND IMPLEMENTATION PERIOD

P&T Comments

The P&T Committee recommended (12 for, 6 opposed, 2 abstained, 0 absent) removing the PA for one drug with implementation effective the first Wednesday 2 weeks after signing of the minutes.

Anti-infectives: Anti-Helminthics—ivermectin (Stromectol, generics)—In 2021, PA criteria were added to ivermectin due to increased utilization during the COVID-19 pandemic. MTF providers are now requesting easier access to ivermectin to treat scabies. The PA will be removed for ivermectin.

XV. UTILIZATION MANAGEMENT—REMOVAL OF PA and IMPLEMENTATION PERIOD

UF BAP Comments

The P&T Committee recommended removing the PA criteria for ivermectin as outlined above, with implementation effective the first Wednesday two weeks after signing of the minutes.

UF BAP Comments

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

XVI. BRAND OVER AUTHORIZED GENERIC AUTHORIZATIONS ADDITIONS AND REMOVALS AND IMPLEMENTATION PLAN

P&T Comments

Additions

- **Oncological Agents: Chronic Myelogenous Leukemia—nilotinib (Tasigna)** is designated as UF without a PA. A generic is now marketed, however, this product is less cost-effective compared to the branded agent. Therefore, the branded Tasigna capsules will continue to be dispensed at all three points of service, and the generic will only be available with PA. Accordingly, the Tier 1 (generic) copay for brand Tasigna is recommended.

Removals

- **Anticoagulants: Oral Anticoagulants—dabigatran capsules (Pradaxa)** were recommended for brand over generic status at the August 2023 P&T meeting. Generic dabigatran capsules are now more cost effective than the branded agent. The brand over generic criteria for the Pradaxa capsules will be removed, and the Tier 2 copay will apply.
- **Attention Deficit Hyperactivity Disorder (ADHD) Agents: Stimulants—lisdexamfetamine capsules (Vyvanse)** At the May 2024 P&T meeting, brand over generic criteria was recommended for lisdexamfetamine (Vyvanse) capsules and chewable tablets in all new users at all points of service. Lisdexamfetamine capsules are now more cost-effective than the brand; however, the Vyvanse chewable tablets remain more cost-effective than the generic. The brand over generic criteria and Tier 1 copay for Vyvanse capsules will be removed and Vyvanse capsules will have a Tier 2 copay. There are no changes to the brand over generic preference and Tier 1 copay for the Vyvanse chewable tablets.
- **Renin-Angiotensin Antihypertensives: Combinations—sacubitril/valsartan tablets (Entresto)** were recommended for brand over generic criteria at the May 2025 P&T meeting. At this time, generic sacubitril/valsartan is more cost effective than Entresto, and the brand over generic preference will be removed and the Tier 2 copay will apply for Entresto.

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) requiring brand Tasigna capsules over the generic in new and current users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. Brand Tasigna will be available at a Tier 1 copay. In addition, the brand over generic criteria for Pradaxa capsules, Vyvanse capsules, and Entresto tablets will be removed and the branded agents will return to a Tier 2 copay. The effective date will be the first Wednesday 60 days after signing of the minutes. The "brand over generic" requirement for Tasigna will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

XVII. BRAND OVER AUTHORIZED GENERIC AUTHORIZATION AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended the addition of brand over authorized generic criteria for Tasigna, and the removals for Pradaxa capsules, Vyvanse capsules, and Entresto tablets as outlined above, with an implementation of the first Wednesday 60 days after signing of the minutes.

UF BAP Comments

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

DEPARTMENT OF WAR
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
VIRTUAL MEETING HELD JANUARY 16, 2026

INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL MEETING Day #2 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 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.

II. TARGETED IMMUNOMODULATORY BIOLOGICS (TIBS): INTERLEUKIN (IL)-23 INHIBITORS—USTEKINUMAB FORMULATIONS FORMULARY STATUS, PA CRITERIA AND IMPLEMENTATION PLAN

P&T Comments

TIBs: IL-23 Inhibitors

Background: A virtual P&T Committee meeting was held on January 16, 2026, to further discuss and clarify the processes for implementing the anticipated upcoming ustekinumab Joint National Contract (JNC), as originally outlined in the November 2024 P&T Committee meeting minutes.

Following the virtual meeting held July 10, 2025 (Addendum to the May 2025 P&T Committee minutes), the JNC for ustekinumab was delayed. A new JNC opportunity is now available in collaboration with the Department of Veteran's Affairs (VA). JNC selection determines the sole step-preferred product on the TRICARE Uniform Formulary (UF). Other agents not selected will occupy a non-step-preferred status.

The purpose of this meeting is to clarify the process to implement the recommended formulary status, step-therapy and Prior Authorization (PA) criteria, and implementation period if a JNC is awarded.

The recommendations from this virtual meeting replace the recommendations from the Addendum to the May 2025 P&T Committee meeting, held virtually on July 10, 2025.

- For several years, branded ustekinumab (Stelara) has been designated as UF, non-step-preferred, requiring a trial of adalimumab (Humira) first. Note that at the time of the November 2024 P&T Committee meeting, ustekinumab biosimilars had not yet entered the market. Market entrance of ustekinumab biosimilars first occurred in January 2025 and these biosimilars were subsequently reviewed as new drugs at the February 2025, May 2025 and August 2025 quarterly P&T Committee meetings.
- In collaboration, the DoW and VA are soliciting for a JNC for ustekinumab. At the November 2024 P&T Committee meeting, the JNC-awarded ustekinumab product was selected as UF, step-preferred. Stelara was recommended for UF non-step-preferred placement at the meeting.
- After the November 2024 P&T Committee meeting, the expected JNC was delayed and the UF step-preferred position remained open for future selection. The second solicitation is ongoing, with an award date expected later in 2026.
- If a JNC is awarded, the committee reaffirms that the JNC-selected ustekinumab product will be step-preferred over the other IL-23 inhibitor subclass agents and that all new patients must try the JNC-selected ustekinumab product.
- Other formulary management actions of these classes and the PA changes will be reviewed at the February 2026 P&T meeting.

Relative Clinical Effectiveness: Previous clinical conclusions for biosimilar products support that FDA approved biosimilar products, whether officially designated as interchangeable or not, are equally safe and efficacious when compared to the reference product.

Relative Cost Effectiveness Conclusion: Based on JNC, the JNC awardee is the most cost-effective option for the TRICARE UF formulary.

The Committee recommended (19 for, 0 against, 0 abstained, 0 absent) the following for the JNC-awarded scenario for the formulary status, PA criteria, and implementation period.

- JNC-awarded scenario:
  - The JNC-awarded ustekinumab product will be UF and step-preferred.
  - The non-selected agents will be designated non-step-preferred.
  - The formulary status of the non-step-preferred/completely excluded agents will not change unless reviewed by the P&T Committee and the UF BAP.

- Step therapy will require a trial of the JNC-awarded step-preferred product in all new users for all non-step-preferred IL-23 inhibitor agents (ustekinumab and non-ustekinumab products) and the PAs will be updated to implement this step as voted on at the November 2024 P&T meeting.
  - The non-ustekinumab products are guselkumab (Tremfya), mirikizumab (Omvoh), risankizumab (Skyrizi), and tildrakizumab (Ilumya).
- Implementation
  - For new users prescribed an IL-23 inhibitor (ustekinumab or non-ustekinumab), implementation of the JNC step-preferred requirement will occur on the JNC award date or no later than 2 weeks following the JNC award date.
  - For current users of a non-step-preferred ustekinumab product, the required trial of the JNC step-preferred agent will be implemented 30 days after the JNC effective date, to allow for updating the PA forms and notifying affected beneficiaries with letters.
- For current users of a non-ustekinumab IL-23 inhibitor (Skyrizi, Tremfya, Ilumya, Omvoh), patients will be grandfathered, and not subject to the requirement to try the JNC-awarded ustekinumab.

III. TIBS: IL-23 INHIBITORS—USTEKINUMAB FORMULATIONS FORMULARY STATUS, PA CRITERIA AND IMPLEMENTATION PLAN

UF BAP Comments

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

The P&T Committee recommended the PA criteria and the implementation plan for the IL-23 inhibitors as outlined above.

UF BAP Comments

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

DEPARTMENT OF WAR
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS FROM THE FEBRUARY 2026 MEETING

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL MEETING Day #2 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. UF DRUG CLASS REVIEW—TARGETED IMMUNOMODULATORY BIOLOGICS (TIBS): INTERLEUKIN-23 (IL-23) INHIBITORS SUBCLASS: USTEKINUMAB AGENTS

P&T Comments

A. TIBs: IL-23 Inhibitors: Ustekinumab Agents—Relative Clinical Effectiveness Conclusion

Background— The IL-23 inhibitor subclass review for formulary status was completed in November 2024. New ustekinumab biosimilar products were reviewed as innovator drugs in February, May, and August 2025, however implementation is delayed due to the UF BAP pause. Two products, ustekinumab-aauz (unbranded Otulfi) and ustekinumab-hmny (Starjemza) are reviewed here as part of this subclass review. Previous P&T Committee conclusions regarding biosimilars are found in the August 2024 and November 2022 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 P&T Committee will consider all approved biosimilars as highly interchangeable to the reference product for both efficacy and safety.
- The IL-23 inhibitor subclass, which included the originator ustekinumab (Stelara), was reviewed at the November 2024 P&T Committee meeting. At the February, May and August 2025 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 step-preferred ustekinumab will be required before use of the other UF non-step-preferred and NF non-step-preferred products once selected.
- In joint federal collaboration with the VA, DoW elected to participate in a Joint National Contract (JNC) for ustekinumab. The JNC ustekinumab biosimilar (pending selection) was chosen as the Uniform Formulary (UF) step-preferred IL-23 agent during the November 2024 subclass review. The expected 2025 solicitation was postponed until 2026, with an expected award date in March 2026.
- At this meeting, formulary recommendations are made for the formulary status, step-therapy and Prior Authorization (PA) criteria, and implementation period for JNC.
- The ustekinumab products evaluated include ustekinumab (Stelara), ustekinumab (unbranded Stelara), ustekinumab-auub (Wezlana), ustekinumab-kfce (Yesintek), ustekinumab-ttwe (Pyzchiva), ustekinumab-stba (Steqeyma), ustekinumab-aekn (Selarsdi), ustekinumab-aauz (Otulfi), ustekinumab-aauz (unbranded Otulfi), ustekinumab-hmny (Starjemza), and ustekinumab-srlf (Imuldosa). These products are all equally safe and efficacious. Private label products that are not intended for TRICARE patients are excluded from the TRICARE pharmacy benefit, as outlined in the November 2025 P&T Committee meeting minutes.

Relative Clinical Effectiveness Conclusion— The clinical review focused on the similarity and interchangeability of the available ustekinumab products. Additional discussion occurred for the evidence supporting ustekinumab in the pediatric population.

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

Special Populations

- The FDA is currently evaluating the literature for expanded ages and indications for pediatric patients. Supplemental Biologic License Applications have been submitted for the indications of ulcerative colitis and Crohn's disease in patients aged two and older.

- Ustekinumab is currently approved by the European Medicines Association for use in pediatric patients with plaque psoriasis and Crohn's disease with no age limitations.
- Use of ustekinumab in pediatric patients for psoriatic arthritis, plaque psoriasis, ulcerative colitis, and Crohn's disease is supported by clinical evidence.

Other Factors

- Trade Agreements Act (TAA) Compliance: Two agents, ustekinumab-hmny (Starjemza) and ustekinumab-kfce (Yesintek) are not TAA compliant and are therefore not available for purchase for the MTF or TMOP points of service. These products are available in the retail ~~network~~ pharmacies.
- Latex Content: All products are latex-free, with the exception of ustekinumab (Stelara and unbranded Stelara) and ustekinumab-hmny (Starjemza).
- Formulations: All products are available in both 45 mg/0.5mL and 90 mg/mL prefilled syringes or prefilled pens. A 45mg/0.5mL single dose vial is available for all the products except ustekinumab-stba (Steqeyma).
- FDA Interchangeability: Ustekinumab-srlf (Imuldosa) is the only ustekinumab biosimilar that does not have FDA-labeled interchangeable status. As per the previous conclusions regarding biosimilars summarized above, for purposes of the TRICARE Pharmacy benefit, all biosimilars are interchangeable to one another and the reference product.

Overall Clinical Conclusion

- In terms of relative clinical effectiveness and safety, all ustekinumab products are interchangeable with each other.
- Only one ustekinumab product is needed to meet the needs of MHS beneficiaries.
- A trial of the ustekinumab product that will be selected for UF and step-preferred status will be required in all new and current users of the non-step-preferred products (e.g., "no grandfathering").
- Due to clinical literature supporting use in children, ustekinumab may be used to treat pediatric patients with diseases including plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease, regardless of FDA-labeling.

B. TIBs: IL-23 Inhibitors: Ustekinumab Agents—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 (19 for, 0 opposed, 0 abstained, 0 absent):

- CMA results showed that the formulary placement of a JNC-awarded ustekinumab product as the UF step-preferred agent would be cost effective.
- The BIA demonstrated that a JNC-awarded ustekinumab product will generate cost avoidance.

C. TIBs: IL-23 Inhibitors: Ustekinumab Agents——UF Recommendation

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

Per the November 2024 IL-23 inhibitor subclass review recommendations:

- The JNC-awarded ustekinumab product will move to the UF step-preferred position

Per the virtual meeting held on January 16, 2026 recommendations:

- Reaffirms the JNC-awarded ustekinumab product will move to the UF step-preferred position.
- Reaffirms implementation of the step therapy requiring a trial of the JNC-awarded ustekinumab product for all non-step-preferred IL-23 agents.

Per this meeting:

- Reaffirms the JNC-awarded ustekinumab product will move to the UF step-preferred position as stated above.
- Defines which products are designated as UF and non-step-preferred and which are designated as NF and non-step-preferred.

Note that the previous formulary recommendations for the ustekinumab biosimilars when they were reviewed as newly approved drugs at the February, May, and August 2025 P&T Committee meetings were not implemented, due to the UF BAP Pause. Accordingly, the formulary recommendations below supersede any previous formulary recommendations.

JNC-Awarded Scenario

- UF and step-preferred
  - JNC-awarded ustekinumab product-moves to UF and step-preferred status
- UF and non-step-preferred
  - ustekinumab-aauz (unbranded Otulfi)
  - ustekinumab-hmny (Starjemza)
  - ustekinumab-srlf (Imuldosa) *moves from NF non-step-preferred to UF non-step-preferred (August 2025 meeting)*
- NF
  - ustekinumab-aauz (branded Otulfi) *moves from UF non-step-preferred to NF non-step-preferred (recommended from the May 2025 meeting)*
  - ustekinumab-ttwe (Pyzchiva)
  - ustekinumab-aekn (Selarsdi)
  - ustekinumab (unbranded Stelara)
  - ustekinumab-stba (Steqeyma) *moves from UF non-step-preferred to NF non-step-preferred (recommended from the May 2025 meeting)*
  - ustekinumab (Stelara) *moves from UF non-step-preferred to NF non-step-preferred (November 2024 meeting)*
  - ustekinumab-auub (Wezlana) *moves from UF non-step-preferred to NF non-step preferred (recommended from the February 2025 meeting)*
  - ustekinumab-kfce (Yesintek)
- Complete Exclusion: None
- Note as part of the step therapy recommendation, a trial of the JNC selected product is required first in all new and current users of another ustekinumab product.
- As per the November 2025 P&T Committee meeting, any private label ustekinumab biosimilars are not part of the TRICARE Pharmacy benefit.

D. TIBs: IL-23 Inhibitors: Ustekinumab Agents——Manual PA Criteria

At the November 2024 P&T Committee meeting, several updates were made to the PA criteria for the IL-23 inhibitors. Additional updates recommended in subsequent P&T Committee meetings are summarized

below, although implementation for some of these changes is delayed, due to the UF BAP pause.

- February 2025: Updated the requirement for previous use of Humira to allow previous use of Humira or infliximab; and removed the requirement for failure of non-biologic therapy for ulcerative colitis.
- February, May, August 2025: Ustekinumab biosimilar products were reviewed as innovator drugs, with PAs added.

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria as discussed below in new and current users.

- For the UF step-preferred ustekinumab product, if the prescribing physician specialist is identified as a dermatologist or gastroenterologist during adjudication, no PA will be required ("automated specialist bypass.") An automated drug-lookback will apply for adalimumab (Humira) and ustekinumab (Stelara) to allow for PA approval if the patient has received either of these two drugs in the last 720 days. The current age restrictions will be removed, allowing utilization in patients of any age for the treatment of plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease.
- For the UF non-step-preferred agents, a trial of the UF step-preferred agent will be required in all new and current users. No changes will be made to automation or age restrictions.
- For the NF non-step-preferred agents, a trial of all UF agents will be required in all new and current users. No change will be made to the automation or age restrictions.

The Manual PA criteria are as follows

1. UF Step-Preferred ustekinumab JNC-awardee ustekinumab

Automated PA Criteria: When prescribed by a dermatologist or gastroenterologist a prior authorization is not required. Once therapy is initiated by a dermatologist or gastroenterologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days.

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

Manual PA criteria apply to all **new** users of **JNC awarded ustekinumab product**

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

- The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira
- Patients may have used infliximab in lieu of Humira for UC and CD
- Coverage is approved for patients with:
  - Active psoriatic arthritis
  - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
  - Moderately to severely active Crohn's Disease (CD)
  - Moderately to severely active ulcerative colitis (UC)
- The criteria below apply to all patients unless noted:
  - Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g. sulfasalazine, mesalamine) corticosteroids, or immunosuppressants (e.g. azathioprine). (Note: Does not apply to CD, UC)
  - **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, S1P, JAK inhibitors**

Non-FDA approved uses are not approved

PA does not expire

2. UF non-step-preferred ustekinumab

- **ustekinumab-aauz (unbranded Otulfi)**
- **ustekinumab-hmny (Starjemza)**
- **ustekinumab-srlf (Imuldosa)**

Updates from the February 2026 meeting are in bold

Manual PA criteria apply to all **new and current** users of **ustekinumab-aauz (unbranded Otulfi), ustekinumab-hmny (Starjemza) and ustekinumab-srlf (Imuldosa)**

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

- **The provider acknowledges that the JNC awarded ustekinumab product is TRICARE's preferred ustekinumab product**
- The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira AND
- **Please provide patient-specific justification as to why the step-preferred JNC awarded ustekinumab product cannot be used in this patient._____**
  - **Acceptable reasons include: the patient has an allergy to an inactive ingredient found in the step-preferred product that is not in the non-step-preferred product**
- Patients may have used infliximab in lieu of Humira for UC and CD
- Coverage is approved for patients with:
  - Active psoriatic arthritis
  - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
  - Moderately to severely active Crohn's Disease (CD)
  - Moderately to severely active ulcerative colitis (UC)
- Coverage is approved for patients ages 6 to 17 years of age with:
  - Active psoriatic arthritis
  - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- The criteria below apply to all patients unless noted:
  - Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g. sulfasalazine, mesalamine) corticosteroids, or immunosuppressants (e.g. azathioprine). (Note: Does not apply to CD, UC)
  - 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, S1P, JAK inhibitors

Non-FDA approved uses are not approved

PA does not expire

3. **NF non-step-preferred**
    - **ustekinumab-ttwe (Pyzchiva)**
    - **ustekinumab-aekn (Selarsdi)**
    - **ustekinumab (Stelara)**
    - **ustekinumab (unbranded Stelara)**
    - **ustekinumab-stba (Steqeyma)**
    - **ustekinumab-auub (Wezlana)**
    - **ustekinumab-kfce (Yesintek)**

Updates from the February 2026 meeting are in bold and Strikethrough

Manual PA criteria apply to all **new and current** users of **ustekinumab-ttwe (Pyzchiva), ustekinumab-aekn (Selarsdi), ustekinumab (Stelara), ustekinumab (unbranded Stelara), ustekinumab-stba (Steqeyma), ustekinumab-auub (Wezlana), ustekinumab-kfce (Yesintek)**

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

- ~~The provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira~~
- The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira AND
- **Please provide a patient-specific justification as to why the step-preferred JNC awarded ustekinumab product and the UF non-step-preferred products unbranded Otulfi, Starjemza, Imuldosa cannot be used in this patient**
    - **Acceptable reasons include: the patient has an allergy to an inactive ingredient found in the step-preferred product that is not in the NF non-step-preferred product**
- Patients may have used infliximab in lieu of Humira for UC and CD
- Coverage is approved for patients with:

- Active psoriatic arthritis
- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Moderately to severely active Crohn's Disease (CD)
- Moderately to severely active ulcerative colitis (UC)

- Coverage is approved for patients ages 6 to 17 years of age with:
  - Active psoriatic arthritis
  - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- The criteria below apply to all patients unless noted:
  - Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g. sulfasalazine, mesalamine) corticosteroids, or immunosuppressants (e.g. azathioprine). (Note: Does not apply to CD, UC)
  - 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, S1P, JAK inhibitors

Non-FDA approved uses are not approved

PA does not expire

E. TIBs: IL-23 Inhibitors: Ustekinumab Agents—UF recommendation, PA and Implementation Plan

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

- The JNC-awarded ustekinumab product will be designated UF and step-preferred no later than two weeks after the JNC award date, as recommended at the November 2024 P&T Committee meeting.
- Step therapy will require trial of the JNC preferred product in all new users for all non-step-preferred IL-23 inhibitors (ustekinumab, risankizumab, guselkumab, tildrakizumab, mirikizumab), and the PAs will be updated to implement this step

therapy requirement two weeks after the JNC award date, as voted on at the November 2024 P&T meeting.

- The formulary status of the non-step-preferred agents will not change unless reviewed by the UF BAP and Director's signature.
- The formulary status of the ustekinumab products not selected by the JNC will have their formulary status change the first Wednesday 30 days after the date the P&T Committee meeting minutes are signed.
  - For current users of a non-step-preferred ustekinumab product, the required trial of the JNC step-preferred agent will be implemented the first Wednesday 30 days after the JNC effective date. There will be no-grandfathering between ustekinumab products. New and current users of a non-step-preferred ustekinumab product will be subject to the step at this implementation.
  - This timeline allows time to update the PA forms and for DHA to mail letters to beneficiaries affected by the NF copay change and PA step therapy requirements.
- For current users of a non-ustekinumab IL-23 inhibitor (Skyrizi, Tremfya, Ilumya, Omvoh), grandfathering will be allowed and only new patients will be affected

III. UF DRUG CLASS REVIEW—TIBS: IL-23 INHIBITORS SUBCLASS: USTEKINUMAB AGENTS

UF BAP Comments

A. TIBs: IL-23 Inhibitors: Ustekinumab Agents—UF Recommendation

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

- UF and step-preferred
  - JNC awarded ustekinumab product
- UF and non-step-preferred
  - unbranded Otulfi
  - Starjemza
  - Imuldosa
- NF
  - Pyzchiva
  - Selarsdi

    - unbranded Stelara
    - Steqeyma
    - Stelara
    - Wezlana
    - Yesintek
- Complete Exclusion: None
- Note as part of the step therapy recommendation, a trial of the JNC selected product is required first in all new and current users of another ustekinumab product.
- As per the November 2025 P&T Committee meeting, any private label ustekinumab biosimilars are not part of the TRICARE Pharmacy benefit.

UF BAP Comments

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

B. TIBs: IL-23 Inhibitors: Ustekinumab Agents—Manual PA Criteria

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

UF BAP Comments

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

C. TIBs: IL-23 Inhibitors: Ustekinumab Agents—UF Recommendation, PA Criteria, and Implementation Plan

The P&T Committee recommended the effective dates, timelines and beneficiary communication, as outlined above.

UF BAP Comments

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

IV. UF DRUG CLASS REVIEW—ONCOLOGICAL AGENTS: MYELOFIBROSIS SUBCLASS

P&T Comments

A. Oncological Agents: Myelofibrosis Subclass—Clinical Effectiveness Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the janus kinase (JAK) inhibitors in the myelofibrosis subclass. Two drugs, ruxolitinib (Jakafi) and fedratinib (Inrebic) were part of the original drug class review at the February 2022 P&T Committee meeting. Since then, two additional agents, pacritinib (Vonjo) and momelotinib (Ojjaara), were reviewed during new drug presentations at the May 2022 and February 2024 meetings, respectively.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

Efficacy

- All four agents are FDA-approved for the treatment of myelofibrosis.
- A 2024 network meta-analysis for the JAK inhibitors supported continued first-line use of Jakafi for efficacy in spleen reduction volume (SVR) and total symptoms score reduction (TSSR).
    - Ojjaara was identified as a significant alternative option for SVR and TSSR.
- There are no high-quality head-to-head trials available directly comparing one JAK inhibitor with another to demonstrate superiority of any agent.
- No benefits in overall survival have been seen with the newer agents (Inrebic, Vonjo and Ojjaara) when compared to Jakafi.

Professional Treatment Guidelines

- The National Comprehensive Cancer Network (NCCN) guidelines recommend all four agents, ruxolitinib (Jakafi), fedratinib (Inrebic), pacritinib (Vonjo), and momelotinib (Ojjaara), for treating myelofibrosis.
    - Jakafi and Inrebic have a Category 1 recommendation for higher risk patients in non-transplant candidates with platelets above 50 x 10^9/L.
    - Vonjo has a Category 1 recommendation for higher-risk myelofibrosis in non-transplant candidates with low platelet counts (<50 x 10^9/L).

- Ojjaara has a Category 1 recommendation for patients with myelofibrosis-associated anemia with ongoing symptomatic splenomegaly and/or constitutional symptoms.

Safety

- The safety profiles of the agents overlap, with anemia and gastrointestinal (GI) toxicity the most commonly reported class-related adverse events.
- Inrebic carries a unique Black Box Warning for Wernicke's encephalopathy and has the highest rate of Grade 3-4 anemia (43%) based on the JAKARTA trials when indirectly compared to the individual clinical trial data with the other drugs.
- Vonjo showed a significantly higher rate of other serious adverse events (47%) in the PERSIST-2 clinical trial. It has a significantly decreased risk Grade 3-4 anemia when compared to ruxolitinib (Jakafi).
- Ojjaara demonstrated a decreased risk of Grade 3-4 anemia (5.6%) when compared to Jakafi (23.1%), in the SIMPLIFY-1 trial.
- When compared to Jakafi, Ojjaara and Vonjo did not show a reduced risk of thrombocytopenia.

Individual Product Characteristics

- Jakafi remains the standard first-line JAK inhibitor for myelofibrosis due to its mature efficacy and safety data and its long-standing NCCN Category 1 recommendation. It has additional indications for treating polycythemia vera, essential thrombocytopenia and graft versus host disease. Dose titration guidelines and NCCN recommendations are available to manage patients with thrombocytopenia and anemia. Provider feedback also indicated that ruxolitinib (Jakafi) is an appropriate first-line treatment choice.
- Vonjo is an option for patients with low platelets.
- Ojjaara is preferred for patients with anemia and has been shown noninferior for efficacy when compared to Jakafi.
- Inrebic is a reasonable alternative for patients who have failed prior JAK inhibitor therapy (refractory disease) but has a black box warning for Wernicke's encephalopathy.

Overall Conclusions

- In terms of clinical effectiveness for myelofibrosis, all four products are highly therapeutically interchangeable.
- In terms of safety, there is a moderate degree of therapeutic interchangeability among the four products
- To meet the needs of the beneficiaries, all four products should remain on the formulary.

B. Oncological Agents: Myelofibrosis Subclass—Relative Cost Effectiveness Analysis and Conclusion

CMA and BIA were performed. The P&T Committee reviewed the solicited bids from manufacturers and CMA and BIA were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- Jakafi was the most cost-effective JAK inhibitor, while Ojjaara was the least cost-effective agent.
- A BIA was performed to evaluate the potential impact of designating selected agents as formulary or non-formulary. BIA results showed that designating all agents as UF was the most cost-effective course of action for the Military Health System (MHS).

C. Oncological Agents: Myelofibrosis Subclass—UF Recommendation

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

- UF
  - fedratinib (Inrebic)
  - momelotinib (Ojjaara)
  - pacritinib (Vonjo)
  - ruxolitinib (Jakafi)
- NF– None
- Complete Exclusion – None

D. Oncological Agents: Myelofibrosis Subclass—Manual PA Criteria

PA criteria currently apply only to Inrebic and Ojjaara. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for the myelofibrosis drugs as outlined below

- PA is not required for Jakafi, due to its long marketing history for efficacy and safety, provider feedback and low risk of

inappropriate use. A trial of Jakafi is now required first in all new users of Inrebic, Vonjo, and Ojjaara

- The current Inrebic PA now includes the Jakafi step preference.
- For Ojjaara, a trial of Jakafi is not required for patients with anemia who have been considered for treatment with Jakafi and erythropoietin-stimulating agents (e.g., Epoetin).
- New PA criteria for Vonjo in new users includes the Jakafi step, however a trial of Jakafi is not required in patients with thrombocytopenia.

The Manual PA criteria are as follows:

1. **fedratinib (Inrebic)**

   Updates from the February 2026 meeting are in bold and strikethrough

   Manual PA criteria apply to all new users of Inrebic

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

   - Patient is 18 years of age or older
   - The drug is prescribed by or in consultation with a hematologist/oncologist
   - **Provider is aware that ruxolitinib (Jakafi) is the preferred agent for myelofibrosis and that it is available without a PA**
   - **Patient has tried and progressed on ruxolitinib (Jakafi) or had an inadequate response to, experienced an adverse reaction to, or has a contraindication to ruxolitinib (Jakafi) that is not expected to occur with fedratinib**
   - Fedratinib will be used for intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis
   - 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. **Note that the presence of the NCCN recommendation does not allow a trial of fedratinib without first trying ruxolitinib if ruxolitinib is also recommended. To facilitate approval, please list the diagnosis, guideline version, and page number: _____.**

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

   Prior authorization does not expire

2. **momelotinib (Ojjaara)**

   Updates from the February 2026 meeting are in bold and strikethrough

   Manual PA criteria apply to all new users of Ojjaara

   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 hematologist/oncologist
   - **Provider is aware that ruxolitinib (Jakafi) is the preferred agent for myelofibrosis and that it is available without a PA**
   - **Patient has tried and progressed on ruxolitinib (Jakafi) or had an inadequate response to, experienced an adverse reaction to, or has a contraindication to ruxolitinib (Jakafi) that is not expected to occur with momelotinib**
   - Patient has diagnosis of intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis
   - ~~Provider is aware of the warnings, screenings, and monitoring precautions of Ojjaara~~
   - ~~If female of reproductive potential patient is not pregnant and not planning to become pregnant~~
   - ~~If female of reproductive potential patient will avoid breast feeding for at least 1 week after discontinuation~~
   - **A trial of Jakafi is not required if the patient has anemia with a Hg<8 g/dL and has been considered for Jakafi and erythropoiesis stimulating agents (e.g., Procrit, Epogen, Aranesp)**
   - 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**. Note that the presence of the NCCN recommendation does not allow a trial of momelotinib without first trying ruxolitinib if ruxolitinib is also recommended**. To facilitate approval, please list the diagnosis, guideline version, and page number: _____.

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

   Prior authorization does not expire

3. **pacritinib (Vonjo)**

New criteria from the February 2026 meeting

Manual PA criteria apply to all new users of Vonjo

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 hematologist/oncologist
- Provider is aware that ruxolitinib (Jakafi) is the preferred agent for myelofibrosis and that it is available without a PA
- Patient has tried and progressed on ruxolitinib (Jakafi) or had an inadequate response to, experienced an adverse reaction to, or has a contraindication to ruxolitinib (Jakafi) that is not expected to occur with Vonjo OR
- A trial of Jakafi is not required if Vonjo will be used for intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 109 /L.

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

PA does not expire

E. Oncological Agents: Myelofibrosis Subclass——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 first Wednesday 60 days after signing of the minutes in all points of service.

V. UF DRUG CLASS REVIEW—ONCOLOGICAL AGENTS: MYELOFIBROSIS SUBCLASS

UF BAP Comments

A. Oncological Agents: Myelofibrosis Subclass—UF Recommendation

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

- UF
  - Inrebic
  - Ojjaara
  - Vonjo
  - Jakafi
- NF
- Complete Exclusion – None

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Oncological Agents: Myelofibrosis Subclass—Manual PA Criteria

The P&T Committee recommended updated manual PA criteria for Inrebic, Vonjo and Ojjaara, as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Oncological Agents: Myelofibrosis 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

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

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

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

- UF
  - elinzanetant (Lynkuet) – Miscellaneous Gynecological Agent for menopause
  - mitapivat (Aqvesme) – Miscellaneous Metabolic Agents for Alpha or Beta Thalassemia
  - nerandomilast (Jascayd) – Pulmonary I Agents: Idiopathic Pulmonary Fibrosis
  - plozasiran injection (Redemplo) – Antilipidemic 2 Agent for Familial Chylomicronemia Syndrome (FCS)
  - sevabertinib (Hyrnuo) – Lung Cancer: Human Epidermal Growth Factor Receptor 2 (HER2) Agents
  - ziftomenib (Komzifti) – Acute Myelogenous Leukemia (AML)
- NF
  - elamipretide injection (Forzinity) – Miscellaneous Metabolic Agent for Barth Syndrome
  - omidenepag isopropyl 0.002% ophthalmic solution (Omlonti) – Glaucoma Agents
  - paltusotine (Palsonify) – Miscellaneous Endocrine Agent for Acromegaly
  - remibrutinib (Rhapsido) – Atopy Agent for Chronic Spontaneous Urticaria
  - sibeprenlimab injection (Voyxact) – Miscellaneous Nephrology Agent for Immunoglobulin A (IgA) Nephropathy
- Complete Exclusion
  - celecoxib 10 mg/mL oral suspension (Vyscoxa) – Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
    - Vyscoxa oral suspension was recommended for complete exclusion status as it has little to no clinical benefit relative to the other NSAIDs, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include celecoxib capsules, naproxen oral suspension and meloxicam oral suspension.

- clonidine HCl oral solution 0.02 mg/mL (Javadin) – Anti-Hypertensive Agents
    - Javadin was recommended for complete exclusion status as it has little to no clinical benefit relative to other clonidine formulations, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include clonidine tablets and clonidine transdermal systems.
- cyclobenzaprine 2.8 mg SL tab (Tonmya) – Skeletal Muscle Relaxants
    - Tonmya was recommended for complete exclusion status as it has little to no clinical benefit relative to other cyclobenzaprine formulations, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include cyclobenzaprine tablets, pregabalin caps, and duloxetine caps.
- furosemide 80 mg/mL SC injection (Lasix ONYU) – Diuretics
    - Lasix ONYOU was recommended for complete exclusion status as it has little to no clinical benefit relative to the other loop diuretics, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include furosemide tablets, bumetanide tablets, and torsemide tablets.

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

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) for all the drugs except Jascayd, and for Jascayd (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- Applying manual PA criteria to new users of Redemplo. Note that updates were also made to the PA for olezarsen (Tryngolza), the other drug approved for FCS, to require a trial of Redemplo first,
- Applying temporary PA criteria to new and current users of the Vyscoxa, Javadin, Lasix ONYU, and Tonmya, until implementation of the recommended Compete Exclusion status.
- Applying manual PA criteria to new users of Lynkuet, requiring a trial of other non-hormonal drugs first.
- Applying manual PA criteria to new users of Forzinity. FDA accelerated approval was based on an intermediate clinical

endpoint and continued approval may be contingent on confirmatory trials. As a result, manual PA criteria will require specialist prescribing with required renewal criteria for clinical reassessment of ongoing treatment response.

- Applying manual criteria to new users of Rhapsido, requiring specialist prescribing, and a trial of second-generation antihistamines, Xolair and Dupixent first.
- Applying manual PA criteria to new users of the oncology drugs and specialty drugs Aqvesme, Jascayd, Palsonify, Hyrnuo, Voyxact, and Komzifti.
- Applying manual PA criteria to new users of Omlonti, requiring a trial of generic latanoprost first.

The Manual PA criteria are as follows:

1. **celecoxib 10 mg/mL oral suspension (Vyscoxa)**

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

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

   - Provider acknowledges that Vyscoxa will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T meeting minutes by the Director, DHA
   - Provider acknowledges that other celecoxib formulations are available to TRICARE beneficiaries, including celecoxib capsules and do not require prior authorization
   - Provider must document why the patient cannot take celecoxib capsules
     - Acceptable responses include: the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to an excipient in celecoxib capsules.

   Non-FDA approved uses are not approved

   PA does not expire until after implementation of complete exclusion status

2. **clonidine HCl 0.02 mg/mL oral solution (Javadin)**

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

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

   - Provider acknowledges that Javadin will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T meeting minutes by the Director, DHA

- Provider acknowledges that other clonidine formulations are available to TRICARE beneficiaries, including clonidine tablets and clonidine transdermal system and do not require prior authorization
- Patient is 18 years of age or older
- Patient has hypertension
- Provider must document why the patient cannot take clonidine tablets and clonidine transdermal system
    - Acceptable responses include: the patient cannot swallow tablets due to documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience, and has had significant skin irritation with clonidine transdermal system

Non-FDA approved uses are not approved

PA does not expire until after implementation of complete exclusion status

3. cyclobenzaprine 2.8 mg SL tabs (Tonmya)

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

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

- Provider acknowledges that Tonmya will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T meeting minutes by the Director, DHA
- Provider acknowledges that other cyclobenzaprine formulations are available to TRICARE beneficiaries, including generic cyclobenzaprine tablets and do not require prior authorization
- Patient is 18 years of age or older
- Patient has a diagnosis of fibromyalgia based on American College of Rheumatology (ACR) diagnostic criteria
- Patient has had a trial and failed or had intolerance to one or more generic medications used to treat fibromyalgia, such as cyclobenzaprine, pregabalin, and duloxetine
- Provider must document why the patient is unable to use cyclobenzaprine tablets
    - Acceptable responses include: the patient cannot swallow tablets due to documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not

due to convenience, and has had significant skin irritation with clonidine transdermal system

Non-FDA approved uses are not approved

PA expires in 6 months. A new PA must be submitted until implementation of complete exclusion status

4. elamipretide injection (Forzinity)

Manual PA criteria apply to all new users of Forzinity

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

- Patient is 12 years of age or older
- Patient weighs at least 30 kg
- Medication is prescribed by a physician with expertise in mitochondrial medicine or genetic disorders
- Patient has genetically confirmed Barth syndrome
- Patient is ambulatory, yet impaired as assessed by the 6-minute walk test
- Patient must not have any of the following: undergoing a pubertal growth spurt, uncontrolled hypertension, history of heart transplant, implantation of cardiac defibrillator, receiving chemotherapeutic or immunosuppressant agents, or prior radiation therapy to the chest
- Provider acknowledges FDA-accelerated approval is based on improvement in knee extensor muscle strength and continued FDA approval may be contingent upon verification of clinical benefit in confirmatory trials

Non-FDA approved uses are not approved

PA expires in 6 months. Provider must fill out a new PA form

5. elinzanetant (Lynkuet)

Manual PA criteria apply to all new users of Lynkuet

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

- Patient has moderate to severe vasomotor symptoms due to menopause
- Patient has a contraindication to menopausal hormone therapy (estrogens with or without progestins) OR
- Patient has an intolerance to menopausal hormone therapy OR

- Based on individual patient characteristics and risk factors, the provider has determined that the patient is not a candidate for menopausal hormone therapy
- Patient has tried and failed or had an adverse reaction to at least one of the following non-hormonal treatments for vasomotor symptoms: an SSRI (for example, paroxetine, escitalopram, or citalopram), an SNRI (for example, venlafaxine, desvenlafaxine, or duloxetine), OR gabapentin

Non-FDA approved uses are not approved

PA expires in 6 months.

Renewal criteria: Note initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely if the following applies:

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

6. furosemide 80 mg/mL SC injection (Lasix ONYOU)

Manual PA criteria apply to all new and current users of Lasix ONYOU

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

- Provider acknowledges that Lasix ONYOU will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T meeting minutes by the Director, DHA
- Provider acknowledges that other loop diuretics are available to TRICARE beneficiaries, including bumetanide tablets, furosemide tablets, and torsemide tablets and do not require prior authorization
- Patient is 18 years of age or older
- Patient has edema associated with congestive heart failure, hepatic and renal disease, including nephrotic syndrome
- Patient is experiencing an increase in signs and symptoms of fluid overload
- Patient has failed a trial of two oral loop diuretics including
  - furosemide
  - bumetanide
  - torsemide
  - ethacrynic acid

- Patient is stable and does not require emergency care or hospitalization for heart failure, acute pulmonary edema or other condition that could result in hospitalization

Non-FDA approved uses are not approved

PA does not expire until after implementation of complete exclusion status

7. mitapivat (Aqvesme)

Manual PA criteria apply to all new users of Aqvesme

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

- Patient is 18 years of age or older
- Medication is prescribed by or in consultation with a hematologist or oncologist
- Patient has a diagnosis of anemia associated with transfusion dependent or non-transfusion dependent alpha-thalassemia or beta-thalassemia

Off-label uses are not approved unless supporting documentation is provided

PA expires in 6 months

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

- Patient had a positive response to therapy as noted by a decrease in the number of RBC units transfused or an increase in hemoglobin

8. nerandomilast (Jascayd)

Manual PA criteria apply to all new users of Jascayd

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

- Provider acknowledges pirfenidone (Esbriet generic) is the Department of Defense's preferred drug for Idiopathic Pulmonary Fibrosis (IPF)
- Patient is 18 years of age or older
- Prescribed by a pulmonologist
- Patient is non-smoking
- Patient has documented diagnosis of idiopathic pulmonary fibrosis (IPF) AND
    - Patient requires add-on therapy with nerandomilast (Jascayd) and:

- Patient tried and failed pirfenidone (Esbriet generic) due to progression of disease as defined as greater than 10% decline of forced vital capacity (FVC) OR
- Patient tried and failed nintedanib (Ofev) due to progression of disease as defined as greater than 10% decline of forced vital capacity (FVC)

OR

- Patient requires monotherapy with nerandomilast (Jascayd) and:
  - Patient tried and failed pirfenidone (Esbriet generic) due to experiencing intolerable adverse effects (e.g., rash, photosensitivity; GI adverse events) or is taking a drug that will interact with pirfenidone (Esbriet generic) OR
  - Patient tried and failed nintedanib (Ofev) due to experiencing intolerable adverse effects (e.g., rash, photosensitivity; GI adverse events) or is taking a drug that will interact with nintedanib (Ofev)

- Patient is not receiving triple therapy with nerandomilast (Jascayd), pirfenidone (Esbriet, generics), and nintedanib (Ofev)

Non-FDA approved uses are not approved; usage for progressive pulmonary fibrosis is not approved at this time

PA expires in 12 months

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

- Prescribed by a pulmonologist
- Patient has shown clinical benefit with therapy

9. omidenepag isopropyl 0.002% ophthalmic solution (Omlonti)

Manual PA criteria apply to all new users of Omlonti

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

- Patient is 18 years of age or older
- Patient has elevated intraocular pressure (IOP) due to open-angle glaucoma or ocular hypertension
- Patient has tried and failed or had an adverse reaction or contraindication to generic latanoprost 0.005%

Non-FDA-approved uses are not approved.

PA does not expire.

10. paltusotine (Palsonify)

Manual PA criteria apply to all new users of Palsonify

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

- Patient is 18 years or older
- Prescribed by or in consultation with an endocrinologist
- Patient has a diagnosis of acromegaly
- The patient has had inadequate response to surgery or is not a candidate for surgery
- The patient has had an inadequate response to, intolerability to, or has a contraindication to one injectable somatostatin analog (for example, octreotide, lanreotide, pasireotide)

Non-FDA approved uses are not approved

PA does not expire

11. plozasiran (Redemplo)

Manual PA criteria apply to all new users of Redemplo

Manual PA criteria: Coverage is approved if all apply:

- Patient is 18 years of age or older
- Prescribed by cardiologist, an endocrinologist, or an internal medicine physician experienced in disorders related to severe hypertriglyceridemia
- Patient has undergone genetic testing to confirm the diagnosis of familial chylomicronemia syndrome OR
- Patient has evidence of symptomatic persistent chylomicronemia with recurrent pancreatitis
- Patient has a 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 Redemplo

Non-FDA-approved uses not approved

Prior Authorization does not expire

12. remibrutinib (Rhapsido)

Manual PA criteria apply to all new users of Rhapsido

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

- Patient is 18 years of age or older
- Prescribed by an allergist, immunologist or dermatologist
- Patient has chronic spontaneous urticaria with symptoms lasting greater than 6 weeks
- The patient remains symptomatic despite trial of at least 4 weeks with recommended second generation H1 antihistamine (e.g., cetirizine, levocetirizine, loratadine, desloratadine, fexofenadine)
- The patient has had an inadequate response to, intolerability to, or has a contraindication to both Xolair and Dupixent

Non-FDA approved uses are not approved

PA expires in 12 months

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

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

13. sevabertinib (Hyrnuo)

Manual PA criteria apply to all new users of Hyrnuo

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 locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC)
- Patient's tumor has human epidermal growth factor receptor 2 (HER2) (ERBB2) tyrosine kinase domain activating mutations
- Patient has received prior systemic therapy
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: 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

14. sibeprenlimab injection (Voyxact)

Manual PA criteria apply to all new users of Voyxact

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

- Patient is 18 years of age or older
- Prescribed by a nephrologist
- Patient has biopsy verified primary immunoglobulin A nephropathy (IgAN) without cellular crescents in more than 25% of sampled glomeruli
- Patient have an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73m2
- Patient has urinary protein excretion greater than or equal to 1.0 g/day or urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.75
- Patient continues to have proteinuria despite maximal Angiotensin-Converting Enzyme (ACE) inhibitor or Angiotensin II receptor blockers (ARB) therapy and an SGLT-2 inhibitor (for example, empagliflozin, dapagliflozin) and is at high risk for disease progression
- Patient will not use Voyxact concomitantly with Filspari or Vanrafia or Fabhalta

Non-FDA approved uses are not approved

PA expires in 9 months

Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely if the following applies

- The patient experienced a reduction in urine protein-to-creatinine ratio (UPCR) from baseline or reduction in proteinuria from baseline

15. ziftomenib (Komzifti)

Manual PA criteria apply to all new users of Komzifti

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 relapsed or refractory acute myeloid leukemia
- Patient has a susceptible NPM1-mutation with no satisfactory alternative treatment options

- Patient does not have concomitant 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, 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, and Implementation Period

The P&T Committee recommended (18 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
  - elinzanetant (Lynkuet) – Miscellaneous Gynecological Agent for menopause
  - mitapivat (Aqvesme) – Miscellaneous Metabolic Agents for Alpha or Beta Thalassemia
  - nerandomilast (Jascayd) – Pulmonary I Agents: Idiopathic Pulmonary Fibrosis
  - plozasiran injection (Redemplo) – Antilipidemic 2 Agent for Familial Chylomicronemia Syndrome (FCS)

- sevabertinib (Hyrnuo) – Lung Cancer: Human Epidermal Growth Factor Receptor 2 (HER2) Agents
- ziftomenib (Komzifti) – Acute Myelogenous Leukemia (AML)

- NF
  - elamipretide injection (Forzinity) – Miscellaneous Metabolic Agent for Barth Syndrome
  - omidenepag isopropyl 0.002% ophthalmic solution (Omlonti) – Glaucoma Agents
  - paltusotine (Palsonify) – Miscellaneous Endocrine Agent for Acromegaly
  - remibrutinib (Rhapsido) – Atopy Agent for Chronic Spontaneous Urticaria
  - sibeprenlimab injection (Voyxact) – Miscellaneous Nephrology Agent for Immunoglobulin A (IgA) Nephropathy
- Complete Exclusion
  - celecoxib 10 mg/mL oral suspension (Vyscoxa) – Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
  - clonidine HCl oral solution 0.02 mg/mL (Javadin) – Anti-Hypertensive Agents
  - cyclobenzaprine 2.8 SL tab (Tonmya) – Skeletal Muscle Relaxants
  - furosemide 80 mg/mL SC injection (Lasix ONYU) – Diuretics

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. Manual PA Criteria

a) Anticonvulsants-Antimania Agents—lamotrigine 10 mg/mL oral suspension (Subvenite)— This suspension formulation of lamotrigine is less cost-effective than lamotrigine tablets. The addition of a PA, similar to the existing PA for topiramate oral solution (Eprontia), was recommended to encourage use of the lamotrigine tablet formulation. An automated age edit will allow patients younger than 12 years of age to bypass the PA. Additionally, both Subvenite suspension and Eprontia oral solution will be added to the Rapid Response/Safety Net Program managed by the TPharm5 pharmacy contractor.

b) Antipsychotic Agents: Atypical—cariprazine (Vraylar)— Vraylar is currently designated as NF without a PA. Based upon a review of guidelines, provider feedback and cost, PA criteria were recommended for Vraylar. The PA criteria were modeled off existing PA criteria for other nonformulary psychiatric medications and include the FDA-approved indication, requiring , prescribing by or in consultation with a specialist, and requiring a trial of other generic agents first.

The PA criteria are as follows:

The Manual PA criteria are as follows:

1. lamotrigine 10 mg/mL suspension (Subvenite)

Manual PA criteria apply to all new users of Subvenite

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

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

- Drug is prescribed by or in consultation with an adult or pediatric neurologist or psychiatrist
- Patient requires a liquid formulation due to swallowing difficulty or has a feeding tube

PA does not expire

2. cariprazine (Vraylar)

Manual PA criteria apply to all new users of Vraylar

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

- Drug is prescribed by or in consultation with a psychiatrist
- Major Depressive Disorder
  - Patient is 18 years of age or older
  - Patient has had treatment failure of at least two other formulary antidepressants, for example:
    - SSRI (e.g. citalopram, escitalopram, fluoxetine)
    - SNRl (e.g. venlafaxine IR, venlafaxine ER, desvenlafaxine succinate ER)
    - TCA (e.g. amitriptyline, desipramine, imipramine, nortriptyline)
    - mirtazapine
    - bupropion
    - trazodone immediate-release
    - nefazodone
    - MAOI
  - Patient has had an inadequate response, intolerance to, or contraindication to aripiprazole
  - Patient has concurrent use of an antidepressant

- Schizophrenia
  - Patient is 13 years of age or older
  - Patient has tried and failed at least two formulary atypical antipsychotics (e.g., risperidone, aripiprazole, lurasidone, quetiapine)
- Manic or mixed episodes associated with Bipolar I
  - Patient is 10 years of age or older

- Patient has tried and failed at least two formulary atypical antipsychotics

- Depressive episodes associated with Bipolar I
  - Patient is 18 years of age or older
  - Patient has tried and failed at least two formulary atypical antipsychotics (e.g., risperidone, aripiprazole, lurasidone, quetiapine)

Non-FDA approved uses are not approved

PA does not expire

B. New PA Criteria and Implementation Plan

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

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

UF BAP Comments

The P&T Committee recommended manual PA for Subvenite and Vraylar, 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:

X. 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 (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) **Antipsychotic Agents: Atypical—lumateperone (Caplyta)—**The manual PA criteria for Caplyta were updated to include its use as adjunctive therapy for major depressive disorder in adults. The PA criteria were modeled off existing PA criteria for other nonformulary psychiatric medications and include FDA-approved indication, requiring prescribing by or in consultation with a specialist, and requiring a trial of other generic agents first, similar to what was done with Vraylar above.

b) **Atopy—tezepelumab (Tezspire)—**Tezspire is now indicated for add-on maintenance therapy in patients 12 years of age and older for inadequately controlled chronic rhinosinusitis with nasal polyps. The PA was updated mirroring Dupixent's criteria for this indication.

c) **Corticosteroids-Immune Modulators: Hereditary Angioedema (HAE) Agents berotralstat (Orladeyo)—**The manual PA criteria were updated to expand use in pediatric patients 2 to 11 years of age for HAE prophylaxis.

d) **Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKIs)—pirtobrutinib (Jaypirca)—**The manual PA criteria for Jaypirca were updated to allow use for relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) in patients who have previously been treated with a covalent BTK inhibitor.

e) **Oncological Agents—revumenib (Revuforj)—**The manual PA criteria for Revuforj were updated to allow for the treatment of relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 mutation.

f) **Psoriasis Agents—roflumilast 0.05% cream (Zoryve)—**The manual PA for Zoryve was updated to allow for the expanded age indication for atopic dermatitis to include pediatric patients 2 to 5 years of age.

g) **TIBs: Tumor Necrosis Factor Inhibitors (TNFs)—golimumab (Simponi)—**Simponi received an expanded indication to include pediatric patients weighing 15 kg or more with ulcerative colitis. The updated PA criteria for this pediatric indication mirror the existing requirements for adults with ulcerative colitis.

h) **TIBs: Interleukin 23 (IL-23) inhibitors—guselkumab (Tremfya)—**The PA criteria for Tremfya were updated to allow for use in pediatric patients 6 years of age and older weighing 40 kg or more with moderate-to-severe plaque psoriasis or active psoriatic arthritis. A trial of adalimumab and a non-biologic systemic therapy will be required for both indications.

i) **TIBs: Miscellaneous—tofacitinib (Xeljanz)—**Xeljanz is now indicated in psoriatic arthritis patients 2 years and older. The manual PA was updated to include this expanded age indication and also

incorporate the TIBs PA standardization updates, which included removing the automated lookback for Humira and removal of safety monitoring information.

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

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) implementation for updates to the manual PA criteria for Caplyta, Tezspire, Orladeyo, Jaypirca, Revuforj, Zoryve, Simponi, Tremfya and Xeljanz in new users. Implementation of the PA criteria updates will be effective the first Wednesday 60 days after the signing of the minutes.

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

UF BAP Comments

A. Updated PA Criteria for New FDA Approved Indications and Implementation Plan

The P&T Committee recommended updates to the PA criteria for Caplyta, Tezspire, Orladeyo, Jaypirca, Revuforj, Zoryve, Simponi, Tremfya and Xeljanz in new users. Implementation of the PA criteria updates will be 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 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. The updated PA criteria outlined below will apply to new users.

a) **Antilipidemic 2 Agents: olezarsen (Tryngolza)—**The manual PA criteria for Tryngolza was updated to require a trial of Redemplo

first, in new users, due to cost effectiveness. Refer to the new drug section on page 17.

b) **Antipsychotic Agents: Atypical—brexpiprazole (Rexulti)—**The Rexulti PA was updated to require prescribing by or in consultation with a psychiatrist for the major depressive disorder and schizophrenia indications, plus require a trial of two generic antidepressants. Additionally, the Alzheimer's disease indication was updated to allow prescribing by or in consultation with a neurologist, psychiatrist, or specialist in geriatric medicine. Rexulti will be added to the Rapid Response/Safety Net program.

c) **Beta Blockers and Hydrochlorothiazide Combinations—bisoprolol 2.5 mg tablet—**At the August 2025 P&T meeting, the P&T Committee recommended PA criteria for bisoprolol 2.5 mg tablets. Other bisoprolol formulations, including generic bisoprolol 5 mg tablets (scored), are more cost-effective than the 2.5 mg strength. A provider requested access to this lower strength for patients who require very low dose titration for heart failure or post myocardial infarction. In these instances, splitting the 2.5 mg tablet to attain even smaller doses may be desirable. As a result, this rationale will be added to the acceptable write-in PA criteria for approval.

d) **Hematological Agents—avacopan (Tavneos)—**The Tavneos manual PA was updated to allow for nephrologist prescribing, based on MTF feedback.

e) **Nephrology Agents Miscellaneous—sparsentan (Filspari)—**The Filspari PA criteria were updated to lower the baseline qualifying urine-protein creatinine ratio from at least 1.5 g/grams to at least 1.0 g/grams, based on a recent update to the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines.

f) **Oncological Agents—**Efforts to standardize and streamline the PAs for oncology drugs are ongoing. Edits were made to the PA criteria for nine oncology drugs. As part of this standardization effort, the following actions were taken: editing the NCCN guideline question to cite specific guideline version and page number to ease approvals for new indications, updating indications to more closely match FDA label language, and removing lengthy clinical monitoring and counseling questions based on provider feedback. Other required updates identified at this time are detailed below.

   - **Leukemia and Lymphoma Agents: Acute Myeloid Leukemia (AML)—azacitidine (Onureg)—**The PA was updated to include t-cell lymphoma indications that are in the NCCN guidelines and in other commercial health plan PAs.

- **Multiple Myeloma—ixazomib (Ninlaro)—**The PA was updated for the indications and limitations of use language, to better align with FDA labeling for Ninlaro.
- **Oncological Agents—avapritinib (Ayvakit)—**The PA was updated to allow allergists to write for Ayvakit. This update was based on MTF oncologist feedback that stated that allergist prescribing for mastocytosis is appropriate.
- **Oncological Agents: Lung Cancer—pralsetinib (Gavreto)—**The PA was updated to include an FDA-approved thyroid cancer indication that was not on the current PA.
- **Oncological Agents: Lung Cancer—crizotinib (Xalkori)—** The PA was updated for oncology standardization only.
- **Oncological Agents: Melanoma—cobimetinib (Cotellic)—** The Cotellic PA did not have the NCCN question that is present in all other oncology PAs; therefore, this question was added.
- **Oncological Agents: Non-BTKIs—duvelisib (Copiktra)—** The marginal zone lymphoma indication was removed, and limitations of use language was added to the PA. This aligns the Copiktra PA with current FDA labeling.
- **Oncological Agents: Non-BTKIs—idelalisib (Zydelig)—** The indications for small lymphocytic lymphoma and follicular lymphoma were withdrawn by the manufacturer and were removed from the PA.

g) TIBs: TNFs—adalimumab (Humira, biosimilars)—An MTF provider requested that the adalimumab PA be updated to allow use for refractory sarcoidosis and to allow prescribing by pulmonologists. These updates were made along with TIBs standardization updates

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, 0 absent) updates to the manual PA criteria for Tryngolza, Rexulti, bisoprolol 2.5 mg, Tavneos, Filspari, Onureg, Ninlaro, Ayvakit, Gavreto, Xalkori, Cotellic, Copiktra, Zydelig and adalimumab in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes

XIII. 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 the new drugs listed above 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:

XIV. BRAND OVER GENERIC AUTHORIZATIONS AND TIER 1 COPAY AND IMPLEMENTATION PLAN: MENOPAUSAL HORMONE THERAPY: ORAL SINGLE AGENTS—CONJUGATED ESTROGEN TABLETS (PREMARIN)

P&T Comments

Menopausal Hormone Therapy: Oral Single Agents—conjugated estrogen tablets (Premarin): Premarin tablets are designated as UF with a PA required for certain populations (e.g., males). A generic formulation is now marketed; however, this product is less cost-effective compared to the branded agent. Therefore, the branded Premarin tablets will continue to be dispensed at all three points of service, and the generic will only be available with prior authorization. Accordingly, the Tier 1 (generic) copay for brand Premarin tablets is recommended.

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) requiring brand Premarin tablets over the generic in new and current users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. Brand Premarin will be available at a Tier 1 copay. The effective date will be no later than the first Wednesday 60 days after signing of the minutes. The "brand over generic" requirement for Premarin tablets will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

XV. BRAND OVER GENERIC AUTHORIZATIONS AND TIER 1 COPAY AND IMPLEMENTATION PLAN: MENOPAUSAL HORMONE THERAPY: ORAL SINGLE AGENTS—CONJUGATED ESTROGEN TABLETS (PREMARIN

UF BAP Comments

The P&T Committee recommended the addition of brand over generic criteria for Premarin tablets, as outlined above, with an implementation of the first Wednesday 60 days after signing of the minutes.

UF BAP Comments

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

From: Hornig, Amy
Sent: Wednesday, June 17, 2026 2:05 PM
To: DHA NCR J-6 Mailbox BAPREQUESTS <dha.ncr.j-6.mbx.baprequests@health.mil>
Subject: Request for Inclusion of a 180-720 Day Look-Back Period in the Vraylar Prior Authorization

Dear BAP Members and Designated Federal Officer,

I am writing to respectfully urge support for including a 180–720 day look-back period in the prior authorization requirements for Vraylar® (cariprazine).

For more than 12 years, Vraylar® (cariprazine) was available for Tricare patients without a prior authorization requirement. The proposed requirement for patients to step through two atypical antipsychotics before access may create avoidable barriers for individuals living with schizophrenia, bipolar disorder, and other serious mental health conditions. These patients often have a high burden of illness and may be at increased risk for treatment disruption, nonadherence, and gaps in care when access is delayed.[1,2]

A defined look-back period would balance appropriate utilization management with timely access by allowing prescribers to use existing medical record history instead of repeating workups or therapies. It would also help speed approvals, reduce administrative burden, and limit avoidable appeals and delays for patients. From a clinical perspective, this matters. In serious mental illness, even short interruptions in treatment can have meaningful consequences for stability, functioning, and relapse risk.[1] Patients who are already established on clinically appropriate therapy should not face unnecessary barriers that could lead to disruption or relapse.[3,4]

A 180–720 day look-back window offers a practical, evidence-informed solution that supports both responsible formulary management and patient-centered access. I would respectfully ask the BAP to consider this modification to help reduce avoidable barriers and better protect continuity of care for this vulnerable population.

Thank you for your consideration!

Best regards,

Amy

References:

1. Velligan, D. I., Weiden, P. J., Sajatovic, M., Scott, J. A., Carpenter, D., Ross, R., Docherty, J. P., & Expert Consensus Panel on Adherence Problems in Serious Mental Illness. (2009). The expert consensus guideline series: Adherence problems in patients

with serious and persistent mental illness. The Journal of Clinical Psychiatry, 70(Suppl 4), 1–46.

2. Higashi, K., Medic, G., Littlewood, K. J., Diez, T., Granström, O., & De Hert, M. (2013). Medication adherence in schizophrenia: Factors influencing adherence and consequences of nonadherence, a systematic literature review. Therapeutic Advances in Psychopharmacology, 3(4), 200–218.

3. Ainslie M, Brunette MF, Capozzoli M. Treatment Interruptions and Telemedicine Utilization in Serious Mental Illness: Retrospective Longitudinal Claims Analysis. *JMIR mental health*. 2022;9(3):e33092. doi:10.2196/33092

4. Ghanean, H., Nojomi, M., & Jacobsson, L. (2019). Insight and medication adherence in schizophrenia and bipolar disorder: A systematic review. BMC Psychiatry, 19, 1–12.

For additional information, please review Vraylar® (cariprazine) full prescribing information at www.rxabbvie.com or contact AbbVie Medical Information at 1-800-633-9110.

AMY HORNIG, PharmD, MBA

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