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

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

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—PRIOR AUTHORIZATION CRITERIA AND IMPLEMENTATION PLAN

P&T Comments

A. TIBs: IL-23 Inhibitors—Background

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

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

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

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

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

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

- The general Manual PA criteria are as follows:
  - The JNC-awarded ustekinumab will be UF and step-preferred. Automated specialist bypass for gastroenterologists and dermatologists, and automated lookback for adalimumab (Humira) and other ustekinumabs will be added.
  - The UF non-step-preferred ustekinumab products will require a trial of the JNC-awarded ustekinumab first.
  - The NF non-step-preferred ustekinumab products will require a trial of the JNC-awarded ustekinumab and UF non-step-preferred ustekinumab products first.
  - The completely excluded ustekinumab products will have interim PA criteria apply, requiring a trial of the JNC- awarded ustekinumab and UF non-step-preferred ustekinumab products first.
- Implementation Plan
  - For the JNC-awarded ustekinumab step-preferred product, an implementation within two weeks of the JNC effective date.
  - For the UF and NF non-step-preferred products, UF formulary status will be effective 60 days after the effective date.

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

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

UF BAP Comments

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

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent: