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

Addendum Excerpt May 1, 2026
Therapeutic Substitution for Ustekinumab (Stelara and biosimilars)

I. THERAPEUTIC SUBSTITUTION AT MILITARY TREATMENT FACILITIES (MTFs) AND APPLICATION TO USTEKINUMAB

A virtual Pharmacy and Therapeutics Committee (P&T) meeting was held on July 10th, 2025, to recommend therapeutic substitution for ustekinumab, and 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.

Background: The principles of therapeutic interchange were discussed at the May 2025 P&T Committee meeting, including how the direct care network could optimize current utilization management activities through formal recommendations for MTF providers to MTF pharmacies. Additional discussion and recommendations are warranted, due to opportunities to participate in JNCs with other Federal partners and to maximize implementation of P&T Committee formulary changes in drug classes, especially those with biosimilars.

Therapeutic substitution is defined as switching from one drug to another within the same therapeutic class or from different classes that have an expected similar pharmacological outcome.

To ensure high quality, effective operation of the TRICARE Pharmacy benefit and to optimize drug selection and maximize cost avoidance, standardized therapeutic substitution programs will be utilized at the MTFs, as directed by the DoD P&T Committee. Therapeutic substitution will only apply to orders/prescriptions written by MTF providers and filled/dispensed at an MTF pharmacy.

At the virtual meeting, the P&T Committee was further briefed on the benefits of therapeutic substitution from both a local MTF and Military Health System (MHS) perspective. A recommended procedure for therapeutic substitution, along with specific recommendations for ustekinumab (Stelara originator) were discussed. Providers and pharmacies are notified when the P&T Committee meeting minutes are approved prior to implementation. When a therapeutic substitution occurs, if the original prescription is written for the non-preferred medication, the patient is notified, with subsequent dispensing of the preferred product. This process will occur automatically at the MTF pharmacy, without additional administrative burden for the provider or patient. Benefits include providing an efficient and effective process for maximizing use of cost-effective pharmaceuticals recommended by the DoD P&T Committee and reducing duplicative

work for each individual MTF to develop local therapeutic substitution programs or contacting providers on every prescription that needs to be changed.

Therapeutic Substitution for ustekinumab: 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.
    - *ustekinumab:* The IL-23 subclass was reviewed at the November 2024 DoD P&T Committee meeting. The JNC ustekinumab biosimilar (pending selection) was chosen as the UF step-preferred IL-23 agent. 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 for new and current users, with beneficiary notification for the non-step-preferred affected users.

Conclusion

- Ustekinumab biosimilars are equally safe and efficacious to their respective biosimilar and reference products. Any new market entrants will be added to the UF only after DoD P&T Committee review.
- Therapeutic substitution for medications filled at MTF pharmacies written by MTF providers will improve efficiency and facilitate cost avoidance by increasing patient movement to the DoD P&T Committee preferred products, while maintaining clinically appropriate care.
- The DoD P&T Committee will ensure appropriate implementation through DHA Pharmacy Operations Division actions, including:
    - Determining clinically appropriate and cost-effective care.
    - Notifying MTF providers and MTF pharmacies prior to implementation.

- Collaborating with the Department of Veteran's Affairs as necessary regarding monitoring, implementation and follow-up (e.g., patient safety reports).

COMMITTEE ACTION: RECOMMENDATION ON THERAPEUTIC SUBSTITUTION—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) with implementing therapeutic substitution for new and current users to the step-preferred ustekinumab (i.e., JNC selected product), contingent on the Director, DHA granting authority. Implementation timeline specifics will be detailed when the JNC award is known and will include notification of current patients.

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

☐ concurs with the recommendations, except for the following:

\\Signed

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