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

TARGETED IMMUNOMODULATORY BIOLOGICS (TIBS): INTERLEUKIN-23 (IL-23) INHIBITORS SUBCLASS: USTEKINUMAB FORMULATIONS

I. TIBs: IL-23 INHIBITORS SUBCLASS: USTEKINUMAB FORMULATIONS

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, and to outline contingency plans if a JNC is not awarded.

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, Medical Necessity (MN) criteria and implementation period for both a scenario if a JNC is awarded, and also if a JNC is not awarded ("contingent scenario").

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, clarification is required 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.
- Additionally, there will be a contingency plan if a JNC is not awarded. For this contingent scenario, a UF step-preferred ustekinumab product will be designated as step-preferred over the other IL-23 subclass agents and all new patients must try this UF step-preferred agent.
- 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 current pricing of all agents, ustekinumab-aauz (Otulfi) is the cost-effective option for the TRICARE UF, if a JNC agent is not awarded.

- 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 <u>new</u> 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.

- Contingent Scenario if a JNC is not awarded:
  - Ustekinumab-aauz (Otulfi) will be designated as the UF step-preferred IL-23 inhibitor, with the formulary status change implemented within two weeks of the signing of the minutes.
  - Ustekinumab products other than ustekinumab-aauz (Otulfi) will be designated as non-step-preferred.
  - The formulary status of the non-step-preferred/completely excluded agents will not change unless reviewed by the DoW P&T Committee and the UF BAP.
  - Step therapy will require trial of ustekinumab-aauz (Otulfi) in all new users of all non-step-preferred IL-23 inhibitors (ustekinumab and non-ustekinumab) and the PAs will be updated to implement this step (as voted on at the November 2024 P&T meeting).
  - Implementation
    - For new users of an IL-23 inhibitor (ustekinumab or non-ustekinumab), implementation of Otulfi as the UF step-preferred product requirement will occur two weeks after the signing of these contingency minutes
    - For current users of a non-step-preferred ustekinumab product, the required trial of Otulfi as the step-preferred agent will be implemented 60 days after the signing of the minutes to allow for updating the PA forms and beneficiary notification with letters (as voted on at the November 2024 P&T meeting).
  - For current users of a non-ustekinumab IL-23 inhibitor (Skyrizi, Tremfya, Ilumya, Omvoh), grandfathering will be allowed.

    COMMITTEE ACTION: USTEKINUMAB FORMULARY STATUS, STEP THERAPY AND PA CRITERIA, MN CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (19 for, 0 against, 0 abstained, 0 absent) the formulary status, step-therapy and PA criteria, MN criteria and implementation plan for the JNC-awarded scenario and the contingent scenario if a JNC is not awarded.

II. Appendices

Appendix A—Table of Medical Necessity Criteria
Appendix B—Table of Prior Authorization Criteria

SUBMITTED BY:

Signed/Signature on file

John P. Kugler, M.D., MPH
DoW 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/Signature on file
Bill A. Soliz
BG, USA
Acting Assistant Director
Health Care Administration and Operations

July 20, 2026
Date

Drug / Drug Class	Medical Necessity (MN) Criteria
JNC Awarded • ustekinumab (Stelara) • ustekinumab (unbranded Stelara) • ustekinumab-aauz (Otulfi) • ustekinumab-ttwe (Pyzchiva) • ustekinumab-auub (Wezlana) • ustekinumab-aekn (Selardsi) • ustekinumab-stba (Steqeyma) • ustekinumab-kfce (Yesintek) **TIBs: IL-23 Inhibitors**	• Patient has experienced ~~or is likely to experience~~ significant adverse effects from formulary agents ~~• No alternative formulary agent: Patient has tried brand Stelara~~ **Formulary alternatives**: adalimumab (Humira), ixekizumab (Taltz), ustekinumab-aauz (Otulfi), **ustekinumab-aauz (unbranded Otulfi), ustekinumab-hmny (Starjemza),** ~~ustekinumab-stba (Steqeyma),~~ **ustekinumab-srlf (Imuldosa)** ~~ustekinumab-auub (Wezlana), ustekinumab (Stelara)~~
JNC Contingency • ustekinumab (Stelara) • ustekinumab (unbranded Stelara) • ustekinumab-ttwe (Pyzchiva) • ustekinumab-auub (Wezlana) • ustekinumab-aekn (Selardsi) • ustekinumab-kfce (Yesintek) **TIBs: IL-23 Inhibitor**	• Patient has experienced ~~or is likely to experience~~ significant adverse effects from formulary agents ~~• No alternative formulary agent: Patient has tried brand Stelara~~ • **Formulary alternatives**: adalimumab (Humira), ixekizumab (Taltz), ustekinumab-aauz (Otulfi), **ustekinumab-aauz (unbranded Otulfi), ustekinumab-hmny (Starjemza),** ustekinumab-stba (Steqeyma), **ustekinumab-srlf (Imuldosa)** ~~ustekinumab-auub (Wezlana), ustekinumab (Stelara)~~

• ustekinumab-stab (Steqeyma) • ustekinumab-auuz (Otulfi) • ustekinumab-auub (Wezlana) • ustekinumab (Stelara) **TIBs: IL-23**	**Updates from the current PA criteria are in bold** Manual PA criteria apply to all new users of ustekinumab-stab (Steqeyma), ustekinumab-auuz (Otulfi), ustekinumab-auub (Wezlana), ustekinumab (Stelara) <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: • **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 • Patients may have used infliximab in lieu of Humira for UC and CD • Coverage is approved for patients 18 years of age or older 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**
• ustekinumab-ttwe (Pyzchiva) • ustekinumab-kfce (Yesintek) • ustekinumab-aekn (Selarsdi) **TIBs: IL-23**	**Updates from the current PA criteria are in bold** Manual PA criteria apply to all new users of ustekinumab-ttwe (Pyzchiva), ustekinumab-kfce (Yesintek), ustekinumab-aekn (Selarsdi) <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: • **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 • **The patient had an inadequate response to Steqeyma, Otulfi, Wezlana, and Stelara OR the patient experienced an adverse reaction to Steqeyma, Otulfi, Wezlana, and Stelara that is not**

	expected to occur with the requested ustekinumab OR the patient has a contraindication to Stequeyma, Otulfi, Wezlana, and Stelara • Patients may have used infliximab in lieu of Humira for UC and CD • Coverage is approved for patients 18 years of age or older 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**
• ustekinumab-ttwe (unbranded) **TIBs: IL-23**	Manual PA criteria apply to all new users of ustekinumab-ttwe (unbranded) <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: • Provider acknowledges that this unbranded ustekinumab ttwe will be completely excluded from the TRICARE Pharmacy benefit 120 days after signing of the DoD P&T Committee meeting minutes by the Director, DHA. • 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 • The provider must write-in trial dates for Humira and the formulary ustekinumab products ▪ Humira Date_____ Duration of therapy _____ ▪ Otulfi Date_____ Duration of therapy _____ ▪ Steqeyma Date_____ Duration of therapy _____ ▪ Wezlana Date_____ Duration of therapy _____ ▪ Stelara Date_____ Duration of therapy _____ • The provider must explain why the patient requires unbranded ustekinumab-ttwe (unbranded) and cannot use on of the other ustekinumab biosimilar products. ▪ Acceptable response: Patient has an allergy to one or more inactive ingredients found in formulary ustekinumab products that is not found in unbanded ustekinumab-ttwe

	Non-FDA approved uses are not approved ~~**PA expires in 120 days, when the complete exclusion status is implemented**~~ **PA does not expire until after implementation of complete exclusion status**